Pharmaceutical Consumption: Prescribing the Conditions to the Branding of "Life"

by

Mary Elizabeth Bryne

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Abstract

This thesis explores the various roles at play in the production of the pharmaceutical market in Canada. This thesis investigates the intersection between Canadian health policy and intellectual property through an examination of recent case law, which depict normative understandings of the way in which Canadian bodies govern and are governed by the consumption of prescription medications. The work of John Gagnon and Erving Goffman inspired the theatrical landscape from which this examination unfolds. Additionally, Alan Hunt, Gary Wickham, Francois Ewald, Ben Golder and Peter Fitzpatrick's interpretation of Foucault's work on governmentality, bio-power and bio-politics form the theoretical backdrop for this project.

Through a critical analysis of the intersection of health policy and intellectual property, examined through the concept of the performative stage, we are able to unpack and examine the various roles and relationships present in the consumption of pharmaceuticals. This examination offers a critical lens into the growing pharmaceutical market in Canada, including governmental efforts in an ongoing attempt to control the "push to prescribe."

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Table of Contents

Introduction:

Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care)

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Pharmaceutical companies and medical associations today thrive on the invention of disease, to the point whereby illness and "selling sickness" has become an industrial product. [1] Through this practice of selling sickness, these various companies and associations transform normal everyday life processes into medical problems, resulting in the medicalization of life. This medicalization transcends all markets and borders. This thesis will examine the intersection of law, in its attempt to control the evolving pharmaceutical market in the province of Ontario, and health policy. Important shifts in the interpretation of the law have occurred, resulting in a new area of research and development.

The idea for this thesis originated from an examination of the medicalization of society, however wishing to ascertain a meaningful understanding of a legal issue closer to home, I began to examine the interplay between governmental jurisdictional authority and the pharmaceutical industry in Canada, and more specifically the province of Ontario. The evolution of law, in its attempt to regulate the pharmaceutical industry, is portrayed in the recent court decision of the Ontario Superior Court of Justice (Divisional Court) ruling of *Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care).*[2] Through an examination of case law this thesis inquiries into how the interplay between provincial and

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[1] Blech, J. *Inventing Disease and Pushing Pills: Pharmaceutical Companies and Medicalisation of Normal Life,* (London: Routledge Press, 2006), at introduction.
[2] Shoppers Drug Mart Inc. v. Ontario, 2011 ONSC 615, (CanLII).

federal jurisdictional authority impacts on the pharmaceutical (generic v. brand name drugs) industry in Canada? This thesis argues that the interpretation of the law in respect to this recent Shopper's Drug Mart court decision creates space for an unfair market advantage over the alternative brand name pharmaceutical competitor, who must adhere to Canadian law and practice, therefore creating preferential treatment to Shoppers Drug Mart and Katz Group Canada Inc. This thesis is deeply rooted in constitutional law, examining the interplay between provincial and federal regulation of pharmaceuticals. This thesis examines the intersection of intellectual property and health policy in Canada by using the narratives of the *Competition Act*[3] and recent case law. This thesis will be explained by drawing an illustrative parallel narrative of a theatrical performance, in order to facilitate a tangible understanding of the material. Primarily, for a performance or narrative to be enacted it is best to set the scene. The literary review enacted in chapters one and two will serve as a contextual outline upon which the play exists. This enactment of dramaturgy is necessary in order to provide the reader with a general knowledge of the literary resources and history, for the performance to take place.

Chapter One explores the *Constitution Act, 1982*[4] arguing that the interplay of jurisdictional authority between provincial and federal legislation plays an imperative role when examining the intersection of health policy and intellectual property. Chapter one explains that under constitutional law, matters concerning the health of Canadians does not exclusively fall under one level of government. However, law dealing with any aspect of health may fall within the federal or provincial jurisdiction, "depending on the

[3] *Competition Act*, R.C.S. 1985, c. C-34), at 1.
[4] *Constitution Act, 1982* (UK), 30 & 31 Vict. C3, reprinted in RCS 1985, Appll No. 5.

purpose and effect of the law."[5] This chapter explores the roles of each jurisdiction and the regulations, which impact health policy, and more specifically pharmaceutical consumption in Canada.

Chapter Two will briefly, define and explain branding and trademarks in the historical context of a global economy. This chapter provides a framework illustrating how intellectual property came into fruition. Furthermore the discussion will briefly explain the evolution of pharmaceuticals in America. The chapter will conclude with an explanation of the regulatory process of generic pharmaceuticals in Canada.

Chapter Three entitled, "Role Call: Depiction of Characters in Connection to Competition, Policy and Regulation of Pharmaceuticals in Canada," explores the three major stakeholders (actors) in connection to *Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care)* [6] and their implications on competition, policy, and the regulation of pharmaceuticals in Canada. This chapter highlights the work of Erving Goffman and John Gagnon, using performativity of the self, and social adherence to script-like narratives, in order to best illustrate and facilitate discussion of this material by drawing a connection to the theatrical stage. This chapter explores the main stakeholders and their adherence to, or diverging roles in Canadian health policy and intellectual property.

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[5] Hogg, Peter. W. *Constitutional Law of Canada: 2011 Student Edition* (Toronto: Carlswell, 2011), at 32-33.
[6] Supra, see note 2.

Chapter Four will discuss the theoretical framework used in order to provide an understanding will be Foucault's concept of governmentality. This theoretical lens is ideal for an exploration of constitutional law, regarding questions of jurisdictional authority because it will give us the tools to examine the various mechanisms of control, which manipulate and create our current health system. Foucault's lens allows one to interrogate the law, asking *who* or *what* is being governed? *Why* should they be governed? *How* should they be governed? *To what ends* should they be governed? These questions are integral to the examination of *Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care)* because we see the interplay of the government in their attempt at control- incompleteness (failure)-attempt at control, through the imposition of legislation which imposed regulations of pharmaceuticals, which has been ruled as *ultra-vires,* meaning beyond the scope of what the legislation was originally set out to impose (failure).

Foucault's lens allows one to pose questions concerning how we use such "instruments of law" which act as various regulations that have developed and expanded in an era of bio-power. Governmentality can be described as "the dramatic expansion in the scope of government, featuring an increase in the number and size of the governmental calculation mechanisms."[7] Foucault's theoretical framework of governmentality is suitable for the examination of the various governmental acts imposed in a regulatory manner governing the consumption of pharmaceuticals. It is these "mechanisms" which will be explored in order to argue the very nature of the February 3rd, Ontario Superior Court ruling infringes

[7] Hunt, Alan & Gary Wickham. *Foucault and Law: Towards a Sociology of Law as Governance* (London: Pluto Press 1994), at 76.

upon the very rights it seeks to protect. Such rights include commercial freedoms and rights to trade. Governmentality will be used as a lens to explore the various parent statutes or "technologies of power" imposed by the Ontario Government and their interaction with branding and pharmaceuticals. Utilizing the lens of Foucault, this thesis will examine the distinction between prohibition and regulation involving the language used within the various conditions imposed by law. This chapter highlights three primary competing interpretations of Foucault's concepts of governmentality, medicalization and bio-power in order to develop a proper theoretical landscape for this project. It is important to examine these various interpretations, reframing Foucault's concepts so they may resonate with modernity.

This qualitative research will be conducted through a discourse analysis of five selected recent case law in comparison with the primary case of *Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care)* in order to examine the way in which the *Ontario Drug Benefit Act (ODBA)*[8], *the Drug Interchangeability and Dispensing Fee Act (DIDFA)*[9] and the *Competition Act* are used. Qualitative discourse analysis is suitable for a comparative examination of case law because it allows one to formulate an understanding of why, how and in what way Canadian legislation is formed. Discourse analysis is an approach to the inspection of language that examines the patterns of language across various texts as well as the social and cultural contexts in which the texts

[8] *Ontario Drug Benefit Act* (ODBA) was enacted by Bill 54, S.O 1986, c.27.
[9] *Drug Interchangeability and Dispensing Fee Act* (DIDFA), was originally entitled the *Prescription Cost Regulation Act*, and was enacted by Bill 55, S.O. 1986, c. 28.

occur.[10] The power of law rests within the interpretation of legal precedence, which will later impact future law. The following questions will foster this investigation:

- How does the generic pharmaceutical policy of Canada, reflective in the Shoppers Drug Mart v. Minister of Health and Long Term Care infringe upon the very rights it is imposed to protect, as outlined in the Competition Act? What is the nature of the relationship between intellectual property and health care policy?
- Does current public health policy concerning pharmaceuticals create a gap for Shoppers Drug Mart? If yes, how so?
- To what ends do current regulations impinge upon the stakeholder Shoppers Drug Mart?
- How does selected case law frame brand name and generic pharmaceuticals in relation to the Competition Act?
- Does Shoppers Drug Mart play a direct role in direct-to consumer advertising in Canada and how does this impose upon the regulations of the Competition Act?

The various "tools of discovery" which will be used include both primary and secondary resources. The primary sources will include case law, "*Shopper Drug Mart v. Ontario (Minister of Health and Long Term Care),* [11] *Canadian Generic Pharmaceutical Association v. Minister of Health and The Attorney General of Canada and Canada's Research-Based Pharmaceutical Companies,* [12] *Apotex Inc., v. Executive Officer for the Ontario Public Drug Programs and Attorney General of Ontario,*[13] *Pharmascience Inc. v. Ontario (Minister of Health and Long Term Care),*[14] *Apotex v. AstraZeneca Canada Inc., Minister of Health and Attorney General of Canada (2006)* Indexed as *AstraZeneca Canada Inc. v. Canada (Minister of Health)(2006) SCC 49* [15] Also, government

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[10] Paltridge, Brian, *Discourse Analysis: An Introduction* (New York: Continuum, 2006), at 1
[11] Supra, see note 2.
[12] *Canadian Generic Pharmaceutical Association v. Minister of Health and The Attorney General of Canada,*(2009) FC 725(CanLII), at 1.
[13] *Apotex Inc. v. Executive Officer for the Ontario Drug Programs and Attorney General of Ontario* (2009) ONSC (CanLII), at 1
[14] *Pharmascience Inc., et al. v. Minister of Health and Long Term Care et. al.,* (2007)ONSC (CanLII) 50601., at 1.
[15] *AstraZeneca Canada Inc. v. Minister of Health and Attorney General of Canada* (2006) SCC 49, at 2.

documents issued by the Department of Justice and the Department of Health Canada such as the Guidance Document: Drugs and Health Products, *Competition Act*, *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act.*

Chapter Five will provide a brief abstract of each of the five-selected case studies. This will be beneficial in order to conceptualize and situate the language under investigation by performing a discourse analysis. Each case will be briefly outlined discussing the parties involved (actors), the issue at hand (story depiction), pertinent reference to legislation (scripts), as well as a brief discussion of judicial interpretation of legislation.

Chapter Six will provide a discourse analysis, depicting the prominent themes in language and practice, which make up current Canadian legal opinions concerning the intersection of health policy and intellectual property. The patterns in language that, have emerged are the prominent scripts of the ongoing narrative in the enactment of health policy today. Furthermore, these themes will be analyzed using Foucault's concepts of governmentality, bio-power and bio-politics to further explore these thematic narratives, prior to responding to my primary thesis question and subsidiary questions.

Description of Plot:
Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care)

Recent changes in legislation in the province of Ontario have resulted in an expansion of the roles which a pharmacist plays. [16] This examination of the expansion of pharmaceutical duties plays an integral role in this thesis because Shoppers Drug Mart

[16] Supra, see note 2, at 6-7.

plays a part in every medical role from producer, distributer, prescriber, and consumer, thereby creating points of contention concerning issues of ethics and legality. Paradoxically, the province, in accordance with these various new provisions, which give pharmacists additional authority to perform alternative duties, also in attempts to regulate pharmaceutical consumption, imposed various restrictions, which adversely affected Shoppers Drug Mart's ability to market their "Life" brand range of generic drugs. Shoppers Drug Mart took the Government of Ontario to court over this matter, which judgment is described as follows.

The Superior Court ruled in favor of Katz Group Canada Inc. and Shoppers Drug Mart, holding that private label generic prohibitions contained in the regulations outlined by the *Ontario Drug and Benefit Act (ODBA)* and the *Drug Interchangeability and Dispensing Fee Act (DIDFA)* were *"ultra vires and of no force and effect."*[17] In short the applications challenged the validity of the regulations made under the ODBA and DIDFA.

The applicants sought judicial review of the regulations on pharmaceuticals because both companies "own or control companies that manufacture generic drugs, or plan to do so."[18] The applicants seek to use their own, private label generic drugs, rather than purchasing those generic drugs from third parties. Private label generic drugs are identical to other generic drugs, and identical in formula to the brand-name drug.[19]

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[17] Supra, see note 2, at 2.
[18] "Ontario Superior Court Strikes Down Prohibition of "Private Label" Generic Drugs,"(Ogilvy Renault LLP 2011).
[19] Ibid.

The application was brought to the attention of judicial review because in Spring 2010, the Ontario Government adopted regulations, which prevented private label pharmaceutical products from being designated "interchangeable or reimbursable" under the Ontario Public Drug Programs.[20] These regulations were imposed in order to prevent the private label generic drug companies from selling their products in either the private or the public pharmaceutical markets in Ontario. [21] The Ontario Government trimmed the profit margins of Shoppers Drug Mart and other pharmaceutical companies in 2010, by capping the price of generic drugs at 25% of the equivalent brand name pharmaceuticals.[22] This was a 50% cut in profits, accompanied by a ban on professional allowances paid to the pharmacists by generic drug companies.[23]

The court ruled, " 'controlling the profitability' of corporations that manufactures and sells drugs is "not a legitimate object or purpose of the ODBA or DIDFA, and therefore the regulations do not fall within the object and purpose of the enabling statutes and were held to be *ultra vires* on this basis." [24] The court also ruled that the regulations and prohibitions on private label generic drugs significantly interfered with the commercial freedom of the applicant's right to trade and profit, which was beyond the scope of the enabling legislation enacted by the Ontario Government.[25] The court ruling enables Shoppers Drug Mart to sell their "Life" Brand, a discounted drug in place of more

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[20] Supra, see note 2, at 6-8.
[21] Ibid.
[22] Ibid.
[23] Ferguson, Rob. "Ontario Court Ruling Backs Private-Label Generic Drugs" (thestar.com 2011).
[24] Supra, see note 16.
[25] Supra, see note 2, at 2.

expensive name brand products.[26] In Ontario, the legislation is organized in such a way that pharmacists and doctors make prescription drugs available to the public at lower prices.[27]

History of Shoppers Drug Mart

The Shoppers Drug Mart Corporation (Shoppers) is the licensor of full-service retail drug stores, operating under the name Shoppers Drug Mart® (Pharmaprix® in Québec).[28] Shoppers Drug Mart was founded in 1962 by Toronto pharmacist Murray Koffler. The Company has grown to a network of more than 1,181 Shoppers Drug Mart/Pharmaprix stores across Canada.[29] In 2009, Shoppers grossed approximately $10 billion in sales; the Company is the leader in Canada's retail drug store marketplace and is the number one provider of pharmacy products and services in Canada.[30] Shoppers is a franchised business. In order to own and operate a Shoppers Drug Mart, you must be a Pharmacist licensed to practice in Canada. "Pharmacists are employed by Associate-Owners who are directly involved in the profession of Pharmacy."[31]

Shoppers owns Sanis Health Inc., which is deemed a generic drug manufacturer.[32] Sanis is a licensed manufacturer regulated by Health Canada and it provides generic drugs under its own label to Shoppers Drug Mart pharmacies.[33] Sanis does not fabricate the

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[26] Ibid, at 17.
[27] Ibid.
[28] "About Us" Shoppers Drug Mart (2011).
[29] Ibid.
[30] Ibid.
[31] "Franshise FAQ" Shoppers Drug Mart (2011).
[32] Supra, see note 2, at 7.
[33] Ibid.

pharmaceuticals itself; another company under contract fabricates the drugs for Sanis.[34] These drugs supplied by Sanis, owned and operated by Shoppers Drug Mart are considered to be private label drugs.[35]

The issue at hand here is the fact that Shopper Drug Mart through corporate ownership of pharmacies and pharmaceutical manufacturers has created an upper hand in the pharmaceutical market in Canada because they are able to keep the accumulated profit within their own corporation, which would otherwise be shared by the arms-length manufacturers. This thesis argues that the legislation creates an otherwise unfair competitive advantage for Shoppers because brand name pharmaceutical companies must adhere to by Canadian law and practice. There is a conflict of interests in that pharmacists (franchise owners) will have to choose between drugs created and sold by their own store versus similar drugs made by other companies (Big Pharma/Competitors).[36]

Ontario Drug Benefit Act (ODBA)

"The Ontario Drug Benefit Act governs conditions under which Ontario will pay pharmacists for prescription drugs provided to eligible persons (primarily seniors and persons on social assistance). The ODBA creates the position of Executive Officer, whose responsibilities include deciding which drugs will be listed as benefits under the ODBA and as interchangeable under the DIDFA. The ODBA also provides for the creation and maintenance of a "Formulary" containing a list of all drug products for

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[34] Ibid.
[35] Ibid.
[36] Supra, see note 23.

which Ontario will provide reimbursement and the price Ontario will pay for those drugs" (CanLII 2011).

Drug Interchangeability and Dispensing Fee Act (DIDFA)

"A generic prescription drug cannot be sold to the public unless it has been deemed "interchangeable" within the relevant brand-name drug by the Executive Officer of the Ministry of Health and Long Term Care ("the Ministry").[37] Once the interchangeability designation is made, a pharmacist is required to dispense the lower cost interchangeable generic version of the drug to a patient, unless the prescribing physician has specified that no substitutions can be made or the patient agrees to pay the incremental costs of the higher priced brand-name drug.[38] The provision is meant to benefit the public by making the lower cost generic drugs available as the norm, subject to the right of the doctor and/or patient to select the more expensive brand-name drug if they choose.[39] The DIDFA also regulates the pricing of interchangeable generic drugs and the dispensing fees that may be charged by pharmacies."[40]

In Canada, the approval of a prescription drug by Health Canada is required before the drug is issued anywhere in Canada.[41] This requirement applies to all drugs both generic version and brand-name. "A generic drug that is not designated as interchangeable under the DIDFA cannot be substituted for a brand-name drug, and is thereby effectively barred

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[37] Supra, see note 2, at 3.
[38] Supra, see note 9, at s. 5.
[39] Ibid.
[40] Ibid.
[41] Supra, see note 2, at 3.

from the "private" market.[42] A generic drug that is not listed on the Formulary is excluded from the coverage under the ODBA, and is thereby effectively removed from the "public" market.[43]

Competition Act

The purpose of the Competition Act is to assure the maintenance and encouragement of competition in Canada in order to promote efficiency and adaptability of the Canadian economy.[44] The Act endeavors to "expand opportunities for Canadian participation in world markets while at the same time recognizing the role of foreign competition in Canada."[45] This falls within federal jurisdictional authority, whereby the federal government utilizes such an act to ensure that "small and medium-sized enterprises have an equitable opportunity to participate in the Canadian economy and in order to provide consumers with competitive prices and product choices."[46] This thesis utilizes the Competition Act, focusing on federal government's role in assuring the trade between generic and name brand pharmaceuticals, while adhering to the regulations of patent protection and health policy. The interplay between generic and name brand pharmaceuticals continues to be an ongoing debate with the increased consumption of pharmaceuticals. This thesis will focus on Section 78, focusing on "Abuse of a Dominant Position" and Section 79, "Prohibition where Abuse of Dominant Position." These sections will demonstrate Shoppers Drug Mart's competitive advantage over the

[42] Supra, see note 9, at s. 1-3.
[43] Supra, see note 2, at 5.
[44] See note 3, at s.1.1
[45] Ibid.
[46] Ibid.

pharmaceutical market in Canada, such an advantage, which is paradoxically supported by recent changes in legislation on health policy.

"Law is a form of knowledge, and therefore a form of power. That power derives, in part, from law's ability to impose its definition of events onto everyday life."[47] This thesis explores the various interpretations of law, and those definitions, which inevitably form the way in which pharmaceutical consumption is understood in Canadian health policy. The following chapter will explore the *Constitution Act* of *1982*, creating the scene for this theatrical enactment, casting light on the ongoing dialogue between provincial and federal authority, in their endeavor to impose prohibitions, regulations and definitions on pharmaceuticals in Canada.

[47] Balfour, G. & Elizabeth Comack *The Power to Criminalize: Violence, Inequality and the Law* (Canada: Fernwood Press 2004), at 32.

Chapter One:

Creation of the Setting: Constitutional Law

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When dealing with matters concerning the health of Canadians it is important to note that the regulatory powers of control are not exclusively assigned to one particular level of government.[1] The *Constitution Act of 1982* under section 91 and 92 outlines the provincial and federal legislative powers concerning jurisdictional authority in matters of health.[2] This chapter will outline the provincial and federal powers over health in Canada and the creation of accessibility to health care, more specifically of pharmaceuticals in Canada. Furthermore, it will discuss the regulations outlined in the *Canada Health Act.* This chapter highlights the importance of framing this thesis within the confines of a constitutional argument.

1.1 - Provincial Health Jurisdiction

Provincial Legislative powers are outlined in the *Constitution Act, 1982,* under s. 92 (16), which bestow upon the provinces the power to make laws concerning "all matters of merely local or private nature in the province."[3] Additionally, this section is the source of provincial authority over some matters of public health, like defining the requirements for medical assessments, for example. Section 92(13) outlines power over "property and civil rights in the province" which covers contract, tort and property law, which also relates to provincial power over health.[4] These provincial mechanisms of control enable provinces

[1] Hogg, Peter, W. *Constitutional Law: 2011 Student Edition* (Toronto: Carlswell, 2011), at 32-1.
[2] Ibid, at 32-1.
[3] Ibid, at 32-2.
[4] *Constitution Act, 1982* (UK), 30 & 31 Vict. C3, s. 91(13), reprinted RSC 1985, App II, No. 5.

to regulate business in the province (except those which fall under federal jurisdiction).[5] Provincial legislation has the right imposed under section 92, to regulate business such as Shoppers Drug Mart. Additionally, this section permits provinces to impose regulations over the insurance industry, which includes the public provisions of health insurance and furthermore the regulation of private provisions of health insurance.[6]

All matters concerning professions, including health care professions are also regulated under section 92(13). Furthermore, it covers the field of labor relations and labor standards (excluding those industries which fall under federal authority), including employment-related health benefits and occupational health and safety services. Additionally, provincial authority regulates food and drug standards, as well as the regulation and preparations thereof. Section 92 (7) authorizes the province to make laws in relation to "the establishment, maintenance, and management for hospitals, asylums, charities, and eleemosynary institutions in and for the province, other than marine hospitals"[7] (which falls under federal jurisdiction). Under s. 92(6) the province has authority in the "Establishment, Maintenance, and Management of Public Reformatory Prisons in and for the Province," including matters of health.[8] Although the federal government imposes a national standard, all services aforementioned above, which fall under provincial jurisdictional authority, may vary province to province.

[5] Supra, see note 1, at 32-2.
[6] Supra, see note 1, at 32-2.
[7] Supra, see note 4, at s.92 (7).
[8] Ibid, at s. 92(6).

2.2 - Federal Health Jurisdiction

Federal Legislative powers over health concerns with parliament's power "over the peace, order, and good government of Canada, which is outlined under section 91 of the *Constitution Act, 1982.*[9] The "peace, order, and good government" power extends to public health concerning matters which include the totality of the population, "either under the national concern branch of power, or under the emergency branch of power."[10] The later "emergency branch of power," was created by the Privy Council who declared this branch as a source of authority to deal with "epidemic of pestilence."[11] This federal preoccupation with matters concerning the general well-being of the population is deeply rooted in Foucault's concept of medicalization and governmentality, which will further be addressed in chapter four.

While provinces have the authority to impose regulations, which control most industries and their labor and insurance relations, however there are sets of industries, which are controlled by the federal government. Such industries include banking, transportation and communications sector, "including ships, railways, airlines, telephone systems and radio and television stations."[12] In this particular sector, employment-related health benefits and occupational health and safety come within federal jurisdiction.

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[9] Supra, see note 1, at 32-2.
[10] Ibid.
[11] Ibid.
[12] Ibid, at 32-3.

Additionally, the federal government has regulatory authority over classes of people who fall under the "care" of the state. These classes include: veterans (s.91 (7)), aboriginal peoples (s. 91(24)), those individuals in penitentiaries (s. 91(28)), and immigrants (s. 91(25)); and (concurrently with the provinces) has the authority over their health care).[13] This regulation over particular classes or populations of individuals will also be discussed in chapter four.

Inherent in the examination of pharmaceuticals and health policy is the regulation and power over patents. This is outlined in s. 92(22) entitled "Patents of Invention and Discovery" of the *Constitution Act, 1982,* falling under federal jurisdiction.[14] This section obviously outlines provisions of pharmaceutical patents, which extend compulsory licensing of the manufacturer of patented drugs. [15] This mechanism of control is imposed in order to protect Canadian citizens, improving accessibility to pharmaceuticals and ensuring lowest cost for consumer, while maintaining a competitive market. [16] Likewise, this associates with the federal duty to Regulate Trade and Commerce, outlined under s. 91(2). This power must be exercised in a manner, which balances accessibility and availability of pharmaceutical products to ensure the health of the population, while at the same time ensuring a competitive market among competing brand name and generic pharmaceutical companies.

[13] Supra, see note 4, at s. 91(7)(24)(25)(28).
[14] Ibid, at 92(22).
[15] Supra, see note 1, at 32-3.
[16] Ibid.

The federal government has judicial authority to impose conditions on federal grants, which are allocated to the provinces, including conditions that come within provincial jurisdiction.[17] The federal government has a larger budget, which exercises authority through parliament, creating conditions, which may fall under provincial authority. "Parliament has used this power to impose national standards on provincial health care insurance plans as a condition of federal cash contributions to the provinces."[18] These conditions imposed by the federal government are enacted through the Canada Health Act, executed to ensure uniformity of health care to Canadians.[19]

The Canada Health Act is a mechanism of control, imposed by the federal government. It recognizes that matters of health care services to individuals fall within the jurisdictional authority of the provinces.[20] In exercise of its power over the provision of health care allotted to individual citizens, each provincial legislature has enacted health insurance plans, which govern the delivery of hospital and physician services, including some other medical services, as outlined under s. 92(7) and s. 92(13).[21] Each province establishes a publicly funded insurance system for health care services. All provincial residents, who have paid for health care services through taxes or premiums are entitled to receive those services free of charge.[22] Physicians, hospitals and medical providers are paid directly from the government.[23] However, not all medical services are covered by provincial

[17] Ibid.
[18] Supra, see note 1, at 32-3-4.
[19] Ibid, at 32-4.
[20] Ibid.
[21] Ibid.
[22] Ibid.
[23] Ibid.

governments; restrictions on health care services are described under each provincial health care policy under "insured services."[24]

The Canada Health Act is a provision imposed by the federal government to ensure the uniformity of health care. Through various mechanisms of control provinces must adhere to a national standard regarding insurance plans and health care services.[25] The government of Canada contributes to the cost of each province's health care, imposing conditions, which are enacted through the Canada Health Act. The Federal conditions stipulate that each provincial plan must adhere to five criteria: "(1) public administration; (2) comprehensiveness; (3) universality; (4) portability and (5) accessibility."[26] It is important to note that the Canada Health Act does not directly impose regulations on the delivery of health care in the provinces; this would be "an unconstitutional intrusion on provincial authority."[27] However the Act simply stipulates the terms under which the federal government allocates funding to each province. The Act only applies to federal spending, not provincial, and therefore does not regulate the delivery of health care in each province; it is only an exercise of parliamentary spending power.[28]

This very "unconstitutional intrusion" is imperative in the examination of jurisdictional authority because through the investigation of roles of jurisdictional authority, one is able to critically examine what acts are deemed to be "unconstitutional intrusions." This thesis explores the "*ulta v. intra vires*" argument, investigating the jurisdictional authority in the

[24] Ibid.
[25] Ibid.
[26] Ibid.
[27] Ibid.
[28] Ibid.

intersection of health policy and intellectual property. Which jurisdiction has the "right," will further be explored in chapter five in the presentation, exploration and analysis of recent case law concerning this topic.

1.3 – "Universality" of Canadian Health Care

The Universality of the Canadian health care system originated with the "shared cost program," which included both the federal and provincial governments each allocating funding at 50% of the cost for provincial insurance plans.[29] However this changed with Medicare.[30] Medicare as a national program began in 1968, reflecting Canadian's welfare state model of the time. In order to limit the growth of federal spending, and provide provinces with an increase control over their individual health care, Parliament modified Medicare in 1977. These new provisions focused on a formula for federal contributions, which are now based on Gross National Product and the population, rather than growth of individual provincial expenditures on health care.[31]

The "universality" of Canadian health policy lies in the Health Act under s. 10, which states that all "residents" of the province must be covered under the provincial health plan. This provision is also extended to non-citizens (permanent residents) as well as to Canadian citizens.[32] This section also permits each province to enact "reasonable

[29] Supra, see note 1, at 32-5
[30] Ibid.
[31] Ibid.
[32] Ibid.

residency requirements as a qualification for the receipt of publicly provided social services."[33] Additionally stipulated in the Health Act,

> all provincial health care insurance plans must be "comprehensive" In nature, in that the provincial plans must cover all "insured health services", which means all "medically necessary" hospital services, all "medically required" physician services and all "medically or dentally required" surgical-dental procedures, which are to be performed in hospital.[34]

Criticism of the Act, stipulates that it neglects to define crucial phrases such as what is deemed to be "medically necessary" or "medically required." Additionally, provincial statutes neglect to define these terms, leaving them open to interpretation.[35] Each province is responsible for determining which services are deemed necessary, and only those become listed under "insured services" that are covered by each individual provincial plan.[36]

This creates various interpretations and provincial divide, calling into question the "universality" of Canadian Health Care. This thesis highlights the discrepancy in the "universality" of Canadian health care in respect to provincial and federal policy concerning pharmaceuticals. For example, the province of Ontario allots increased duties for pharmacists, which are not allocated in the majority of provinces and territories in Canada. This differing provincial legislation creates a space, whereby Shoppers Drug Mart's pharmacists' duties are extended, creating an unfair advantage over their brand name competitors. This unfair advantage exists not only over pharmaceutical providers in the United States, but those from other provinces with stricter legislative requirements

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[33] Ibid.
[34] Ibid, at 32-7.
[35] Ibid.
[36] Ibid.

and regulations of pharmaceuticals. This thesis will further explore the federal duties required under s. 91(2) through the Regulation of Trade and Commerce, and additionally, the *Competition Act*, in chapter three.

"The *Canada Health Act* does not require that prescriptions drugs or non-surgical dental services be covered, and the provincial plans mostly do not cover these costs."[37] Also, excluded from the Act are services of non-physicians, which are mostly not included in provincial plans either. Such medical services include the services of pharmacists. These services are added to the cost of drug dispensing in each province, which will be discussed in chapter three.

This lack of public funding of prescription drugs, dental and other non-physician services causes most Canadians to take out alternative private health insurance, which fill in the gaps of public coverage.[38] This necessity to take out alternative coverage further strengthens my argument calling into question the "universality" of Canadian Health Care. It is through the examination of these gaps in policy that we may dissect the intersection of provincial and federal jurisdiction concerning matters in health policy between generic and name brand pharmaceuticals.

The "in-between" nature of a *vires* argument or the "gap" is a great space from which to explore the nature of health policy, whereby the acknowledgement of the gaps or possibility of a gap creates a space for the interpretation of law, an exploration of either

[37] Ibid.
[38] Ibid.

side of the argument. This thesis examines the gap or space created by new legislation and how the mechanism of control imposed by both levels of government in fact creates a space which gives generic pharmaceutical companies like Shoppers Drug Mart, an unfair competitive advantage.

This chapter has situated this thesis within a "vires" argument, therefore calling upon the framework of Constitution Act, 1982 to outline the necessary regulatory jurisdiction of the provincial and federal governments in regards to health care. Pharmaceutical consumption and the medicalization of society is a growing market, which both levels of government, in accordance with their respective duties outlined in sections 91 and 92 of the *Constitution Act*, attempt to control for the health of individual citizens and the overall wellbeing of the population. In summation, this chapter highlighted that the majority of health matters concerning individual citizens are handled by provincial jurisdiction, and each provincial health plan varies based on their interpretation of the *Health Act.* Provincial jurisdiction also regulates food and drug standards, and insurance and health care services. Comparatively, federal jurisdiction exercises control over the health and wellbeing of the population, ensuring the "peace, order and good government" of the nation.[39] Federal jurisdiction controls power over patents, including pharmaceutical patents, while maintaining a balance of competition of trade and commerce. The federal government imposes mechanisms of control through the Canada Health Act, which stipulates particular conditions for the federal allocation of provincial funding in matters of health. Finally, this chapter concluded with a discussion of the "universality" of Canadian health care, declaring the gaps created in legislation, produces an unfair market

[39] Supra, see note 1, at 32-2.

advantage for Shoppers Drug Mart to market their "Life" brand generic pharmaceutical, which goes against federal jurisdiction of adherence to fair trade and commerce, calling upon the *Competition Act*.

The following chapter will firstly define and explain trademark and branding, moving into a discussion of the history, social value and business enterprise of branding, which exists today. This will further establish an important basis from which to explore Shoppers Drug Mart's "Life" brand. Moreover, the discussion will include the process of acquiring pharmaceutical patents, as well as the history of pills and their regulation in Canada.

Chapter Two:

Trademark and Branding

Chapter Two: Trademark and Branding

"We live in a culture in which medical pharmaceuticals are ubiquitous and widely accepted."[1] The prescribing of these products takes place within particular social, cultural and political environments. This chapter examines how pharmaceuticals come to exist in Canada, understanding the context of the pharmaceutical industry is essential to an informed opinion on Canadian health policy and the way in which pharmaceuticals come to exist.[2] This chapter creates the setting, developing a historical account from which to set the performance. This chapter will firstly, define and explain branding in the historical context of a global economy. Further, the discussion will briefly explain the evolution of pharmaceuticals in America. The discussion will then move into the Canadian context, to an explanation of the regulatory process of generic pharmaceuticals in Canada.

2.1 - What is a Trademark?

A trademark has been described as a "mark" that serves to distinguish the wares and/or services of one person or organization in the marketplace from the wares and/or services of others."[3] The key to this concept of a trademark is "distinctiveness," that is, does this mark distinguish your wares and/ or services from other those wares and or/services of your competitors.[4] Is the consumer,

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[1] Ford, A.R. & D. Saibil. (eds) *The Push to Prescribe: Women and Canadian Drug Policy* (Toronto: Women's Press, 2009) at 15.
[2] Ibid.
[3] Hughes, R.T. *Trade-marks Act & Commentary. 2009/2010 Edition* (Canada: LexisNexis, 2009) at 3.
[4] Ibid.

depending on your "mark," capable of distinguishing your product and/ or services from your competitors?[5]

A "mark" may take several forms, usually it is a work or symbol or a combination of both. Sometimes a whole phrase, sound, color or smell may be considered as a trademark.[6] Physical things like shape of an article, or something applied to an article or its packaging can be considered as a trademark.[7] For example, some multi-colored pharmaceutical capsules, such as Viagra's "little blue pill" may be considered as a mark. In the case of Shopper's Drug Mart, the "Life" brand is a red horizontally shaped oval with the word "Life" in bold white letters, with the word "BRAND" in smaller caps underneath it. This mark holds particular meaning in the pharmaceuticals market, which leads the conversation to the topic of branding.

What is a Brand?

Over the past fifty years the primary use of the word "brand" has changed to be used and understood within the commercial market. The word "brand" irrespective of how it is used today has historically been understood as "the way in which an impression is formed."[8]

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[5] Ibid.
[6] Ibid
[7] Ibid.
[8] Clifton, R. & J. Simmons. *The Economist: Brands and Branding* (Princeton New Jersey: Bloomberg Press, 2004) at 14.

History of Branding

The word brand originates from the Old Norse *brandr*, meaning to burn. Early humans claimed ownership of their livestock, by burning various symbols on their animals. With the development of trade, these various brands were used to distinguish between the animals of one farmer to another. [9] The farmers found that the brands of quality cattle were highly sought after. This marked the utility of brands as a guide to choice, which remains in practice today.[10]

Some of the earliest manufactured goods in "mass" production were clay pots, the remains originating from the Mediterranean region, particularly Rome and Greece.[11] There is considerable evidence from these remains of the use of symbols and markings, branding various potters' marks. Pots were identified with various symbols from thumb and fingerprints, crosses, stars and fish.[12] These visual forms of branding were the first forms of symbols from which to identify goods. Principles of commercial law originated in Ancient Rome, where the origin and title of potter's marks, were imitated by inferior potters, who copied the marks by well-known potters. This practice of unlawful imitation of marks continues to take place today, even in modern and developed systems of law.[13]

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[9] Cohen, J.C., P. Illingworth & U. Schuklenk (eds).*The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing* (London: Pluto Press, 2006) at 153.
[10] Ibid.
[11] Ibid.
[12] Ibid.
[13] Supra, see note 8, at 15.

Branding continued throughout the 17th and 18th centuries, with various manufactures of fine porcelain, furniture and tapestries, which used branding to identify the quality and origin of a product.[14] Also at this time laws originated in order to regulate the marking of gold and silver, this form of branding marked the prestige of products, increasing consumer confidence in the product.[15]

The industrial revolution with its improvements in manufacturing and communication, allowed the western world to participate in mass marketing and consumption of goods. Many of today's best known consumer brands date from this period in time, such as Sunlight Soap, Quaker Oats, and Coca-Cola.[16] With the introduction of these various brands came early trademark legislation. The government imposed this legislation in order to protect the brand and trademarks of these various companies.[17]

The periods following the Second World War and the Cold War marked the real expansion of brands. Propelled by the collapse of communism, the arrival of the Internet and mass communications through broadcasting lead to the convergence of a global economy, powered by consumption.[18] The competition of brands and brand power mark the cultural understanding of everyday life.[19]

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[14] Ibid.
[15] Ibid.
[16] Ibid.
[17] Ibid.
[18] Supra, see note 8, at 16.
[19] Ibid.

Elements of Branding

The visual impression of a brand may be a combination of the following: name, letters, numbers, symbol, signature, shape, slogan, color, or typeface.[20] Although all of the aforementioned elements make up a brand, one of the most important elements to a brand is the name. All elements can change over time, however the brand name should remain a constant.[21]

In developed countries consumers have an array of choice between the selections of various brands. This diversity of choice puts pressure on individuals trying to make or sell their products or services in a method, which differentiates their product, or services, thereby securing a competitive edge.[22]

Much of the competition between brands in the 21st century today is concerned with building equity for products whose characteristics; pricing, distribution and availability are quite similar in nature.[23] Take the competition between generic drugs and name brand pharmaceuticals, like Shopper's "Life" brand for instance. Generic drugs consist of the same chemical compounds as those drugs owned by brand name manufacturers. The manner in which those drugs are manufactured, distributed and readily made available is the heart of the issue for this thesis.

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[20] Ibid.
[21] Supra, see note 8, at 17.
[22] Ibid.
[23] Supra, see note 8, at 18

The Social Value of Brands

The rise of globalization and the consumer society is frequently blamed for brands negative attributes and rarely praised for its various social contributions such as generating wealth which finances and sustains social progress. [24] Long-term improvements to health, education, living standards and opportunities depend on the process of wealth accumulation, and although wealth creation is a process often associated with "capitalism" alone, the connection between capitalism, consumers and brands is rarely made explicit.[25]

It may be argued that the power of branding in society today is ever growing in nature reflecting a wide-range of forces at our disposal for positive social change. Clifton, Simmons et al. describe the social benefits to brands as the "seven social wins" explaining that brands foster customer loyalty, employment and wealth creation. Secondly, brands spur innovation, assuring large returns for companies, which make investments to improve production and services. Thirdly, brands create a reliable mechanism for consumer protection. Fourth, brands create pressure to ensure corporate social responsibility. Fifth, brands provide a platform upon which to create corporate social leadership. Sixth, brands play a progressive social role through the creation of various opportunities for non-for-profit-organizations. Lastly, brands create a sense of social cohesion, both nationally and globally, empowering shared participation in aspirational and democratic narratives.[26]

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[24] Ibid, at 48.
[25] Ibid.
[26] Ibid, at 49.

Branding as Business

The value of owning a strong brand to businesses and corporations is incontestable. Strong Brands promise to attract loyal consumers who will return and continue to use the particular brands over a continual period of time. The benefit of owning a brand becomes easier over time as the company develops. The stronger the product, the stronger the brand, the greater the confidence the consumer has and will likely continue to use the product or service.[27] This consumer confidence and brand loyalty additionally contributes to the brand company's ability to manage pricing power.

Shoppers Drug Mart generic pharmaceuticals depend on this very principle as a strategy of business. Shoppers Drug Mart depends on the marketing ability of larger pharmaceutical companies to market their brand name product before the patent expiry date through direct-to-consumer advertising, which is less regulated in the United States than in Canada. After the brand name company's patent expiry date lapses, Shoppers may produce and distribute their generic version of the originator drug. This method of business means little risk for Shoppers Drug Mart with high rewards.

Shoppers Drug Mart's innovative "Life" brand is marketed through its effectiveness, functionality and convenience. In order to prosper as a business, Shoppers understands that it must offer its consumers these various benefits,

[27] Ibid.

creating a sense of community, value and trust in the local pharmacy (social cohesion).[28]

2.3 - Pharmaceutical Patents

The purpose of patents and other forms of exclusivity is to delay the introduction of competing products, generally referred to as 'generic drugs.'[29] A generic drug is defined as "one having the same ingredients as an earlier-approved drug, often called the 'originator' or 'reference' drug, and the applicant for a marketing authorization for a generic drug needs only to show that its product produces the same effects in patients as the originator drug and has no additional side effects."[30]

Generic pharmaceuticals must consult the original data from the originator's product in order to prove their drug produces the same effects in patients as the originator drug with no additional side effects.[31] The generic applicant would need the consent of the originator marketing authorization holder. Consent, by "originator" companies is not often given voluntarily.[32]

In order for a pharmaceutical company to obtain a marketing authorization, it must prove itself with the regulatory health authorities. This is successfully obtained by a large amount of pre-clinical and clinical trials on the drugs in order to generate data

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[28] Ibid.
[29] Grubb, P.W. & P.R. Thomsen.(eds) *Patents for Chemicals, Pharmaceuticals, and Biotechnology: Fundamentals of Global Law, Practice, and Strategy*, 5th ed.(New York: Oxford University Press 2010) at 267.
[30] Ibid, at 268.
[31] Ibid.
[32] Ibid.

on the drugs performance.[33] The data collected during the drug trials is principally the property of the sponsor of the testing and investigation, who have the right to prevent any third part from using the drug data.

Grubb and Thomsen assert that it is within the public interest that the data generated from drug trials be used by generic drug applicants who refer to these tests to provide evidence that their generic products are equally as safe and effective as the reference product.[34] Policy considerations has led to a concept which states that submitted data should be protected by patents for a limited period of time, before being referred to by a third party. This particular concept is called 'regulatory data exclusivity.'[35]

This regulatory data exclusivity has a duration, which includes the acceptance of the actual grant of marketing authorization and generally lasts a period of ten years.[36] This regulation is imposed in order to challenge the accessibility of a drug.[37] Generic applicants are free to submit their application for marketing authorization after the period of authorization for the reference drug expires. A generic drug is able to submit an application at the earliest after eight years, however it will not be authorized until the date of expiry of the ten-year period.[38]

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[33] Ibid.
[34] Ibid.
[35] Ibid.
[36] Supra, see note 9, at 153.
[37] Ibid.
[38] Supra, See note 29, at 296.

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, is one of the treaties enforced by the World Trade Organization (WTO), has set a twenty year patent life for all products, including pharmaceuticals.[39] Once the low-cost generic competitors appear, brand name products will lose the bulk of the market share since they are unable to keep up with generic pricing. [40] Therefore, brand-name pharmaceutical companies are keen to maximize the patent life of their products because patent protection provides them with legal authorization to restrict competition from generic manufacturers during the protection period.

2.4 - History of Pills

In the Victorian times people relied on patent medicines to remedy all manners of illnesses and as there was no scientific basis on which to judge the effectiveness of pharmaceuticals.[41] Many individuals and groups, who created these medications, thrived by promoting their products on the strength of testimonials and heavy advertising.[42]

The prohibition movement of the early twentieth century marked the shift in the way in which North American culture understood medicine.[43] The prohibition of alcohol, opiates, cocaine and marijuana paralleled the increased use of "patent

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[39] Ibid, at 19.
[40] Ibid.
[41] Newton, D. *Trademarked: A History of Well-Known Brands from Aertex to Wright's Coal Tar* (United Kingdom: Sutton Publishing, 2008) at 273.
[42] Ibid.
[43] DeGrandpre, R. *The Cult of Pharmacology: How America Became the World's Most Troubled Drug Culture* (London: Duke University Press Durham, 2006) at 139.

medications" which reflected the advent of prescription medications. [44] New synthesized artificial substitutes emerged, replacing organic methods to treat discomfort.

Here we see how the use of legislation and social discourse in the prohibition movement created a gap for preferential treatment for the pharmaceutical industry whereby prohibited drugs such as opiates, cocaine and marijuana, which are mood-altering substances, have been replaced by artificial pharmaceuticals. [45] New legislation gave preferential treatment to the pharmaceutical industry while creating an illegal market for "illicit drugs.[46] This is what Degrandpre refers to as the "differential prohibition" which he explains reflects the prohibition of the drugs which "socially fell from grace" and the capacity of the pharmaceutical industry to manufacture new drugs which eventually reinforced the same prohibitions that at one time seriously threatened the drug market.[47] The pharmaceutical industry in cooperation with medical practioners has continued to grow enveloping discourses and practices, which deliver "safer and more effective" forms of treatment.[48]

Since the Second World War, there has been much scientific advancement resulting in the growth of prescription medications.[49] Names of patent remedies of earlier times reflected the maker and the organic ingredients used, such as "Beecham's

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[44] Ibid.
[45] Ibid, at 138.
[46] Ibid.
[47] Ibid.
[48] Ibid, at 139.
[49] Supra, see note 9, at 273.

Milk of Magnesia" and "Eno's Fruit Salt."[50] Many of the prescription medications such as antibiotics reflect trademarks of scientific names today, which speak to the shift in weight of testimonials to scientific evidence.[51] Many of the name brand pharmaceutical companies have emerged from individuals who were the early makers of patent remedies, whose popular elixirs, tonics and medical potions paved the way for pharmaceutical advancement.[52]

Thomas Beecham, born in Curbridge Oxfordshire, Great Britain in 1820, was one of the first to apply for a trademark for his pills in 1876.[53] Beecham's Pill Manufactory was a leader in antibiotics, and the first to discover Amoxicillin.[54] This groundbreaking company eventually merged with the American drug company Smith Kline to become SmithKline Beecham, pioneers in the evolution of pharmaceuticals. [55] GlaxoSmithKline still exists today, grossing over $500 million annually through successful drugs such as Paxil, Zyloric and Septrin.[56]

2.5 - Regulation in Canada

Canada has one of the most rigorous drug approval systems in the world, along with one of the best safety records.[57] At the center of debate in much of the Canadian drug industry is the controversy over how the pharmaceutical industry co-

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[50] Ibid.
[51] Ibid.
[52] Supra ,see note 29, at 239.
[53] Supra, see note 41 at 277.
[54] Supra, see note 41, at 273.
[55] Supra, see note 41, at 279.
[56] Ibid.
[57] Supra, see note 1, at 18.

funds Health Canada's drug approval process.[58] Many critics state that this particular arrangement has led to an advantageous situation for the pharmaceutical industry.[59]

The pharmaceutical approval process in Canada falls under the responsibility of the Health Products and Food Branch (HPFB), which falls under Health Canada, and therefore federal jurisdiction.[60] The HPFB's Therapeutic Products Directorate manages the prescription drug-approval process. Biologics-blood products, vaccines, and drugs derived from biotechnology, are managed by a separate dictatorate, the Biologics and Genetic Therapies Directorate.[61]

To have a drug approved for market in Canada, the pharmaceutical manufacturer must test it on cells and tissues, on animals, and finally, on people in order to ensure the drug is acceptably safe and effective.[62] The manufacturer must submit to the regulator basic chemistry, laboratory data, animal studies, and manufacturing information, as well as the results from the clinical trials. The results of all drug trials must be submitted, regardless of their outcome to the HPFB or the BGT.[63] The information provided to Health Canada by drug companies is considered to be the property to those drug companies, and therefore kept secret from the Canadian public.[64] Researchers and media who seek information about the drug approval

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[58] Ibid.
[59] Ibid.
[60] Ibid.
[61] Supra, see note 41, at 120.
[62] Ibid, at 121.
[63] Ibid.
[64] Ibid.

process in Canada must submit an "Access to Information (ATI) request to Health Canada.[65] Much more information regarding the drug approval process is publicly available in the United States. Canadians who seek information on a drug, approved in both Canada and the United States can log onto the FDA website, and find a wide range of information.[66] This leads one to question the transparency of the drug approval process in Canada, especially concerning generic drugs.

Given the global public attributes of pharmaceuticals, there is strong role for law to play in regulating the conditions under which medications are developed administered, and allocated. [67] Drug regulation in Canada is empowered by the government at both the provincial and federal levels. The Canadian federal government imposes price controls on pharmaceuticals through legislation, such as Drug Interchangeability and Dispensing Fee Act.[68] Price control policies enhance the government's ability to provide affordable medicines to their population, however this action sometimes undermines the pharmaceutical company's patent protection, as well as obstructing the various pharmaceutical firms ability to recover their research investments (data exclusivity).[69]

Drug regulatory agencies are public servants, entrusted with the responsibility of maximizing safety and effectiveness of drugs. [70] These agencies must be

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[65] Ibid.
[66] Supra, see note 43, at 131.
[67] Supra, see note 9 at 78.
[68] Supra, see note 9, at 38.
[69] Ibid.
[70] Supra, see note 43, at 137.

accountable to the public and the scientific community must be able to ensure, through access to information that the agencies are acting in the best interest of the public.[71]

The best way to describe the relationship between generic and brand name pharmaceuticals in respect to intellectual property is through the discourses of the economy. The United States Trade officials frequently use the rhetoric of "free riding" and "piracy" when discussing intellectual property rights in relation to pharmaceuticals.[72] The term "free rider," is when developed countries use their power to negotiate price discounts on patented pharmaceuticals.[73] In contrast, developing nations usually lack sufficient market power as a purchaser and are often unable to negotiate discounts for their low-middle class populations.[74] In this case, governments and their patients may resort to unlicensed generic drugs and compulsory licensing, which is labeled as "piracy." Free riding is not limited to tangible good and services. With intangible property, such as knowledge, free riding is in many ways, easier than with tangible goods.[75] Intellectual Property laws obstruct misappropriation (or free riding) by creating temporary legal barriers such as patents and copyrights.[76]

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[71] Ibid.
[72] Supra, see note 9, at 164.
[73] Ibid.
[74] Ibid.
[75] Ibid.
[76] Ibid, at 165.

Pharmaceutical knowledge is an intangible item. Knowledge may be shared with an infinite number of people, without suffering from exhaustion or congestion.[77] "In economic terms, it is generally *non-rivalrous.*"[78] A rivalrous item can be explained as anything that can suffer from exhaustion or congestion. Congestion occurs in times of high demand, when too many people attempt to simultaneously use a product or service.[79] For example, ten thousand people cannot share one bathroom at the same time. Exhaustion occurs when multiple individuals use a product to the point at which the resource is degraded. [80] An example of this would be a depleted local fishing hole.[81]

Intangible property such as patents, copyrights and trademarks are more likely to be exposed to appropriation or theft, because they are not visible.[82] The physical theft of stealing someone's bicycle is easy to identify, whereas using patent or trade secrets without permission may be harder to discover. Pharmaceutical knowledge is very easy to copy. For example, for years India produced unlicensed generic drugs, which were under patent protection outside of India.[83]

In our market-based economy, property rights are the primary solution to ongoing rivalry. Ownership acquired though the process of intellectual property, entrusts

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[77] Ibid, at 166.
[78] Ibid, at 154.
[79] Ibid.
[80] Ibid.
[81] Ibid.
[82] Ibid, at 165.
[83] Ibid.

one person to be in control of the property's use, controlling the congestion and exhaustion of the property. This ownership includes the right to exclude others. [84]

Globalized legal and moral culture of westernized and developed nations generally respects private property. If someone takes property without the permission of the owner, society often morally excludes that person, labeling him or her as a thief.[85] In summation this chapter illustrated the basic concepts of branding and trademark, additionally, providing an historical account of branding, discussing the various elements thereof, including both the social and economic value of branding. Furthermore, this chapter illustrated the patent process, the history of pills and regulation in Canada. Imperative to the discussion was to illustrate that brands, in the mass market of consumption, have ensured consumer choice.[86] The evolution of mechanisms imposed by government; in attempt to regulate such "choices" of drugs in the market are evident throughout history, from Ancient Rome, the prohibition movement, and the creation of inclusionary and exclusionary legislation. The evolution of language however remains constant, this ongoing narrative engrained in the consumption of pharmaceuticals is the government's "duty to care" for the population, ensuring the "well-being, safety and effectiveness" of all pharmaceuticals.

The various narratives and scripts which came to light in the previous chapters will be further developed in Chapter Three, which will encompass a presentation of all

[84] Ibid.
[85] Ibid.
[86] Supra, see note 9, at 135.

stakeholders (characters) involved in the interplay between intellectual property and health policy in Canada. Chapter Three, entitled "Role Call: Depiction of Characters in Connection to Competition, Policy and Regulation of Pharmaceuticals in Canada," depicts these various narratives, illustrating the adherence or divergence from the script demonstrating a historical account of the repetitive nature of attempts to control and inevitable failures of government in the ongoing dialogue between jurisdictional authority.

Chapter Three:

Role Call: Depiction of Characters in Connection to Competition, Policy and Regulation of Pharmaceuticals in Canada.

Chapter Three:
Role Call: Depiction of Characters in Connection to Competition, Policy and Regulation of Pharmaceuticals in Canada.

This chapter examines the three major stakeholders (actors) in connection to Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care)[1] and their implications on competition, policy, and the regulation of pharmaceuticals in Canada. In order to extrapolate a concrete understanding of the material I make reference to Erving Goffman's work, in *The Presentation of Self in Everyday Life*, where I intend to facilitate discussion by way of explaining a theatrical performance. The chapter will commence with an explanation of Erving Goffman's work in connection to this thesis, in hopes to explore the intricate workings and details of intellectual property and health policy. The discussion will also draw upon John Gagnon's work, *An Interpretation of Desire: Essays in the Study of Sexuality,* where he explores sexual scripts. This thesis will primarily use Gagnon's argument that individuals in society adhere to a script-like structure in their everyday practice. By using these illustrative materials I am able to draw attention to the intricate underpinnings of socio-legal study in connection to black letter law.

3.1 – Theatrical Illustrations

Erving Goffman argues that there is an ongoing performance by individuals in society.[2] Individuals play a part, which they expect observers to take seriously. Observers are asked to take these roles of characters seriously, by way of accepting the various attributes the character possesses, the tasks the character performs in their role, as well as

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[1] Shoppers Drug Mart Inc. v. Ontario, 2011 ONSC 615(CanLII).
[2] Goffman, Erving. *The Presentation of the Self in Everyday Life* (New York: Doubleday Anchor Books & Company, 1959), at 17.

the consequences implicitly claimed for it.[3] In line with this notion of performance, Goffman states, "there is a popular view that the individual offers his performance and puts on his show for the benefit of the people."[4] This notion will be convenient in consideration of the various actors adherence to social scripts. Health policy is inevitably paved with good intentions or "for the benefit of the people."[5] The way in which society perceives itself can be explained through the theatrical gaze, Goffman quotes Robert Ezra Park:

> It is probably no mere historical accident that the word person, in its first meaning, is a mask. It is rather a recognition of the fact that everyone is always and everywhere, more or less consciously, playing a role... it is in these roles that we know each other; it is in these roles that we known ourselves."[6]

The above quote, articulates how we as members of society create our foundation of knowledge by way of constantly playing a role. Citizens of society play many roles in our daily lives, sporting many masks. For example, a mother assumes many roles such as caregiver, teacher, nurse, seamstress, chef, psychologist, cheerleader, dry cleaner, cab driver etc. These adaptive social roles are based on individual context and cultural assimilation.[7] Our daily roles are ritualistic performance whereby actors incorporate cultural values of society into their behavior.[8] Goffman argues that our daily performances are "socialized, molded and modified" to fit social expectations of what is deemed to be the "norm" of the time.[9] We are all both the performers and the audience,

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[3] Ibid.
[4] Ibid.
[5] Ibid.
[6] Supra, see note 2 at 19.
[7] Ibid, at 35.
[8] Ibid, at 35.
[9] Ibid.

whereby we all assume particular roles in society, one of which as the audience, as observers.[10]

Like Erving Goffman, John Gagnon speaks to a similar narrative, urging the use of sexual scripts. Gagnon argues there is a form of cultural script, which is enacted in the public domain. Our attempt to understand and locate ourselves within society is achieved through the creation of social scripts.[11] These scripts are determined by individual context. Our social experiences are based on the context of our time. Gagnon depicts the changes that occurred in sexual life dating back from World War I and World War II, discussing the evolution of relationships and the social acceptance of various forms of expression, intricately intertwined with the dating scene.[12] He uses various forms of expression of sexuality articulated through dance, music, and pop media to highlight the transformation of ideologies surrounding sexuality and the body.[13] Social acceptance of these differing perspectives on sexuality continues to create tension within the scripted framework of the sexual experience today. Our mediated worldliness continues to be experienced through a similar narrative of our past, for example, the emergence of the "good girl," Marsha Brady depiction or the "bad boy," Danny Zuko continue to be traditional narratives popular in media during the 60s and 70s.[14]

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[10] Ibid.
[11] Gagnon, John H. *An Interpretation of Desire: Essays in the Study of Sexuality* (Chicago: The University of Chicago Press 2004), at 108.
[12] Ibid,
[13] Ibid.
[14] Ibid.

Inherent in Gagnon's discussion is the idea of when we interpret concrete role enactments, for example when people are thought to be engaging in sequences of action, these interactions are thought to be scripted in terms of who the person is, what is to be done, when and where their action is to take place, and why they are acting in that particular manner.[15] Gagnon explains that everyday actors, particularly those aware of popular understandings of social conduct, self-consciously "self script" or near script their own interactions as they negotiate their daily lives.[16] A great example of this would be how people often self-script human interactions by running through various scenarios for an important meeting, presentation or interview. An alternative example of the way in which we script ourselves is through social networking. People often tweet or post their daily itinerary for the world to see for various reasons from organization to social affirmation of daily activities.

By using Goffman and Gagnon's work on performative actions and scripting I intend to illustrate my argument. Through the adoption of theatrical conventions the intricate world of intellectual property is articulated through establishing techniques, practices and devices unique to the theatre.

For the purpose of clarity I call to the stage an ensemble of actors, characterized by various interpretations of the roles of the judiciary, the government, brand name and generic pharmaceutical manufacturers. The performance is collaborative in nature, whereby the actors and directors work together in order to develop the script/play. These

[15] Ibid, at 119.
[16] Ibid.

actors exchange an ongoing dialogue based on their own adherence, deviation and interpretation of scripts. An examination of the intersection of intellectual property and health policy introduces several actors, all vying for the spotlight at center stage. For years the Canadian stage has been set by the growing demand for clarity and understanding of the pharmaceutical market, this ongoing dialogue is one in which lay Canadians could easily characterize as the "typical song and dance" of government melodrama, characterized by a growing concern of a country in crisis, fearful of illness and plagued by discourses of risk. This thesis will clarify the gap created by legislation, health policy and intellectual property, by drawing parallels to the theatre, I hope to explain the endless monologue, which is often articulated through an unknown and exclusionary language.

This chapter will cast a spotlight to the interactive role of pharmaceutical policy in Canada, focusing the discussion based on government and its attempt at control, ensuing the role of actor and director. Furthermore, the conversation will then move onward to Shoppers Drug Mart (actor) and their role in generic production and distribution of pharmaceuticals. This chapter will further examine brand name pharmaceutical companies (homogenous actor) and their stake in the ongoing competition in the pharmaceutical market in Canada. The discussion will then conclude with an exploration of direct-to-consumer advertising of pharmaceuticals in Canada and the legal ramifications or alternative plot, which ensues.

3.2 - The Role of Government

The interactions between the provincial and federal government, the pharmaceutical industry and consumers have shaped the competitive landscape of prescription drugs in Canada.[17] Pharmaceutical consumption has increased steadily over the last decade, and is now one of the fastest growing expenditures in Canadian health care.[18] The cost of pharmaceuticals is therefore a field, which the Canadian government continues to monitor in its attempt to regulate and control this particular field of competition. Here we see the government assuming the role of director, attempting to control and oversee the entire process of staging the production of Canadian health care.

According to the Canadian Institute for Health Information (CIHI), spending on prescription drugs in Canada was estimated at roughly $25.4 billion dollars in 2009.[19] This section will examine the interplay between provincial and federal jurisdictions concerning the regulation of pharmaceutical and health policy. This ongoing dialogue is divided between two often-opposing positions in the fight for control. This argument is deeply rooted in questions of constitutional law, exploring the question of jurisdiction between provincial and federal authority. The government of Canada plays a strong role in regulating the conditions under which prescription pharmaceuticals are developed, administered and allocated.[20] This section will conclude with a discussion of Canada's "near universal" health care system in connection to the welfare model.

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[17] Anis, Aslam. H. " Pharmaceutical Policies in Canada: Another Example of Federal-Provincial Discord" in Canadian Medical Association Journal 2000;162 (4):523-6.
[18] Ibid.
[19] Health Council of Canada "Generic Drug Pricing and Access in Canada: What are the Implications?"(A Commissioned Discussion Paper by SECOR Consulting: 2010), at 7.
[20] Cohen, J.C., P. Illingworth & U. Schuklenk (eds)*The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing* (London: Pluto Press, 2006),at 70.

Pharmaceutical policy in Canada is implemented both at the provincial and federal levels of jurisdiction. For the purposes of this paper all legislation including health policy may be interpreted as the main script of the performance, comprising of dialogue and directions for each scene. The role of the federal government is responsible for intellectual property rights of manufactures (regarding matters of patents), the initial approval of labeling of prescription drugs and finally ensuring the overall market of competitiveness between combines.[21] The role of the provincial government carries the responsibility of jurisdiction over funding of all health care services, which include pharmaceuticals.[22]

Provincial Jurisdiction

Prescription medication is not universally covered in Canada, therefore for the purpose of this thesis I refer to our "universal system of health care" as " near universal." The evolution of "near universal" health care in Canada has similarly impacted on all provinces across Canada except for one exception, the regulation of prescription pharmaceuticals. Outpatient prescription medication, that is all medication accessed outside hospitals in Canada is determined by individual provincial legislatures, and therefore varies by province.[23]

In each province, pharmaceutical coverage is regulated through different techniques and mechanisms of power and control. Provincial and territorial drug insurance covers a larger proportion of the population than federal, covering approximately nine million

[21] Supra, see note 17, at 523.
[22] Ibid.
[23] Ibid, at 525.

Canadians, including those who require social assistance.[24] Each provincial drug plan sets specific price and other price containment guidelines such as the "Ontario Drug Benefit Act" which determines price points for prescription medication. This legislation also controls drug product substitution laws and alternative regulations on insurance and funding.

Provincial regulation on prescription medications provides two services. Provincial jurisdiction aims to promote drug substitution, whereby more expensive drugs are substituted by the cheaper generic version. This means that provinces mandate pharmacists and pharmaceutical distributers by law to distribute cheaper pharmaceuticals to "the economic benefit of the patient."[25] Substitution of cheaper generic products is often accomplished through implementing product and price selection rules. Regulations on product selection involve the switching of brand name pharmaceutical products to generic pharmaceuticals. Regulation on price selection involves choosing the least costly generic drug available.[26] Provincial healthcare is mandated to provide all health services to the benefit of its citizens, this notion parallels to the performative attribute of the theatre whereby the final product, the performance, is to benefit the audience, which is to provide entertainment.

Secondly, provincial legislation presides over decisions regarding what new drugs are permitted in provincial drug formularies.[27] Provincial and territorial drug plans may use

[24] Supra, see note 19, at 11.
[25] Supra, see note 17, at 525.
[26] Ibid.
[27] Ibid.

specific reimbursement lists, or formularies, to specify which brand name and generic drugs are covered.[28] Here we see an inclusionary/exclusionary tactic of control whereby the provincial and territorial government imposes regulations on prescription drug consumption, likely in favor of generic drugs. For each drug listed on a formulary, there are sets of policies, which outline the appropriate price. The formularies regulate the price of the drug charged by the pharmacy, covered by the insurance providers (private/public).[29] To facilitate these regulations, the majority of provincial legislation exempt physicians and pharmacists from any form of a legal liability associated with switching generic pharmaceuticals from the original brand name drug.[30]

Provincial legislation enacts structural components, which reflect normalizing mechanisms of control. This is a form of performativity whereby the provincial government presents an idealized structure, depicting a normalized practice, which must be followed. Goffman speaks on the idea of stratified idealization, whereby there is a presentation of the ideal or proper performance, outlined in legislation, accompanied by an attempt to adhere to or aspire to adhere to these actions which result in favorable outcomes.[31]

Alternative structural components include reimbursements for drug-dispensing fees, which are services that include checking for prescription errors, filling the prescription

[28] Supra, see note 19, at 12.
[29] Ibid.
[30] Supra, see note 17 at 525.
[31] Supra, see note 11, at 36.

and providing information on the appropriate usage and side effects of the medication.[32] Additional charges in the province of Ontario are charged for the "MedsCheck," which is a program that reviews medication use of patients who suffer from chronic conditions, using more than three prescription medications daily.[33] This service is provided in the form of medical counseling.

In addition to the existing reimbursement framework, afforded by provincial and territorial governments, manufacturers supply pharmacies with additional economic incentives to sell their product in the form of rebates.[34] For years rebates have been a source of revenue for pharmacies. However, the government of Ontario tried to retain their control over pharmaceutical companies by implementing Bill 102, known as the Transparent Drug System for Patients Act.[35] Bill 102 replaced rebates with "professional allowances," which were capped at 20% of the drug's invoice price. [36] "Professional allowances" were to be used by pharmacies for services provided which would directly relate to patient-related care, not to the benefit of the pharmacists. [37] In addition to capping manufacturers' rebates, the province also reduced payment to pharmacies for generic drugs from 63% to 50% of the equivalent brand name drug price. [38] Note, this was only for public insurance plans, not private, which in turn, created a large gap in the price of prescription pharmaceuticals between private and public insurance plans. This act seriously inhibited the economic return for pharmaceutical companies across

[32] Supra, see note 19, at 13.
[33] Ibid.
[34] Ibid, at 14.
[35] *Transparent Drug System for Patents Act,* 2006, S.O. 2006,c.
[36] Supra, see note 19, at 14.
[37] Ibid.
[38] Ibid, at 19.

Ontario.[39] Further action was imposed by the legislation under examination, which was the Ontario Drug Reform of 2010, which amended the *ODBA* and the *DIDFA*. This legislation directly targeted "professional allowances," hoping to completely eliminate these incentives by 2014.

Inherent in this examination of intellectual property and health policy, is an examination of the implications each jurisdiction has on legislation, and the possible outcomes, which ensue. This is an inherent ideology prevalent within discourses and narratives of healthcare in Canada, reflecting homogenous equality and access to treatment. These performative narratives are rooted in idealization of our healthcare model.

Federal Jurisdiction

The federal jurisdiction of the regulation of drugs is imposed to approve of all drugs in Canada. The Patented Medicines Prices Review Board of Canada was established in 1987 under the Patent Act.[40] It is a federal agency with quasi-judicial powers, which enforce and regulate the introduction of new pharmaceuticals and their price point. This board imposes guidelines, which require the voluntary compliance of the pharmaceutical industry.[41] The mandate of this agency is based on the protection of "healthy" competition between pharmaceutical companies within Canada. Criticism of this federal agency is rooted in the federal price regulations of new drugs. The prices of existing drugs are not as effectively monitored; therefore prices can be increased over time.[42] The

[39] Ibid.
[40] *The Patent Act,* R.S.C., 1985, c. P-4.
[41] Supra, see note 17, at 524.
[42] Ibid.

federal government provides insurance for roughly one million Canadians, which include First Nations and Inuit Peoples, veterans, members of the military, the RCMP, prisoners doing time in the federal correctional facilities, and refugees.[43]

There is an ongoing dialogue between the provincial and federal government. Each jurisdiction has a similar mandate to improve the health and welfare of Canadians, however tension is created whereby each jurisdiction must adhere to their individual "duties," very few of which overlap. This is where gaps are created in legislation or the script, leaving room for improvisation and interpretation. These gaps create an unfair advantage for those actors wishing to take the spotlight.

"Near Universal" Health Care Policy and the Welfare State

All Canadians share a stake in the ongoing debate of the regulation between generic and brand name pharmaceuticals in Canada. In a time of economic crisis, a growing aging population and the massive increase of drug utilization,[44] it is important to examine the government's role in health policy and concern for the welfare of its population.

Medicalization is a great lens through which to examine the institutionalization of social welfare.[45] Holmqvist argues that medicalization is represented in various processes such as examination, documentation, training and development, and testing, imposed as

[43] Supra, see note 19, at 3.
[44] Ibid.
[45] Holmqvist, Mikael. *The Institutionalization of Social Welfare: A Study of Medicalizing Management.* (New York: Routledge, 2008), at 133.

methods of control over the population.[46] Medical management is a conditioned phenomenon, driven by standards and classifications of human subjects. The medical model manages human conduct through diagnosis, classification, rehabilitation, treatment, and therapy, which become the very mechanisms for its institutionalization.[47] The evolution of the institutionalization of medicine directly correlates with the actions of the welfare state, under its goal to "take care" of the population. This is a repetitive narrative, evident throughout this thesis. The public health movement, which developed in the late nineteenth century imposed a new rationale for the surveillance of bodies in the interests of gathering information to better serve the health interests of the population.[48]

The late twentieth century continued on with concerns for public health, focusing attention on the control of bodies. However, this infatuation with control over the body shifted from concern over infectious diseases to discourses of responsibility and maintenance of personal health.[49] This directly correlated to Gagnon's discussion on the adaptation of the script. This shift in discourse reflects a shift in the social script and a shift in the routine structure of our daily lives. When the social context changes, in this case ideologies surrounding health, so too does the way in which we understand proper hygiene, disease, and healthy lifestyle choices, reflected in population management. These discourses inevitably turn into social tropes, normalizing particular forms of action.

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[46] Ibid, at 135.
[47] Ibid, at 111.
[48] Lupton, Deborah. *Medicine as Culture: Illness, Disease and the Body in Western Societies* (London: SAGE Publications 1994), at 31.
[49] Ibid.

Public health in Canada is based on a constant tension between individual freedom of choice, regarding their health concerns, pitted against the rights of society to control individuals' bodies in the name of health.[50] For public health in Canada the utilitarian perspective rules, whereby the good of the state and the population's health takes precedence over individual concerns.[51] This too is evident within the jurisdictional structure of our system, whereby federal priorities trump provincial priorities.

3.3 - The Role of Shoppers Drug Mart

The Katz Group (Rexall) and Shoppers Drug Mart are the two largest pharmaceutical groups in Canada, with over 1,100 and 800 stores dispersed all over Canada. According to the Health Council of Canada, pharmacy density in the province of Ontario is roughly equal to the average sample of European countries; however almost double that of the United States.[52] In recent years, retail pharmaceutical chains, like Shoppers Drug Mart franchises, have come to dominate the Canadian market, overpowering many non-chain and local pharmacies. Exercising considerable purchasing power, they have come to economically benefit from substantial rebates from manufacturers.[53]

The balance of power of pharmaceutical development and distribution has shifted in favor of the pharmacy sector and the generic drug market.[54] Generic pharmaceuticals play an important role in the containment of the massive drug expenditures in Canada, as well

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[50] Ibid, at 32.
[51] Ibid,
[52] Ibid.
[52] Ibid,
[53] Ibid, at 9.
[54] Ibid, at 5.

as playing a primary role in enhancing the accessibility to lower income segments of the population, who may not be able to afford the more expensive brand name drugs.[55] "Pricing of generic pharmaceuticals is primarily driven by provincial and territorial drug plans."[56] "These provincial and territorial drug plans have traditionally reimbursed generic drugs by paying a percentage of the price of the brand name drug or by paying a price quoted by a generic manufacturer."[57] Most drug plans also allow for pharmacist mark-up and dispensing fee.[58]

The role of pharmacists has expanded with the increase in demand for prescription pharmaceuticals.[59] Their role has expanded allowing them to provide services beyond drug dispensing such as, giving blood tests, diabetes care, and vaccinations and including some prescribing privileges.[60] In 2009, Ontario passed legislation which permits pharmacists to "extend, adapt, and adjust prescription medications, and to dispense medications remotely."[61]

Generic pharmaceuticals account for roughly 54% of all prescriptions in Canada, however this only represents 24% of prescription drug sales, in terms of total value.[62] The generic drug manufacturing industry in Canada employs approximately 12,000 Canadians, the majority of these jobs directly relate to the manufacturing of pharmaceuticals. Unlike their brand name competitors to the south, the majority of

[55] Ibid, at 4.
[56] Supra, see note 19, at 4.
[57] Ibid.
[58] Ibid, at 9.
[59] Ibid, at 5.
[60] Ibid.
[61] Ibid, at 25.
[62] Ibid, at 4.

generic drugs produced in Canada are also sold in Canada, therefore directly impacting our economy.[63]

In 2010, the Ontario government amended provisions of two interconnected pieces of legislation, the *Ontario Drug and Benefit Act (ODBA)* and the *Drug Interchangeability and Dispensing Fee Act (DIDFA).* These provisions govern the conditions under which pharmacies are able to produce and sell their own generic brand of pharmaceuticals. This form of legislation acts a primary script, depicting acceptable dialogue and action within the particular framework of health. The objective of the script is the very nature by which the goal or intention to preserve the health and well being of the Canadian population is outlined. The legislation prohibits the purchase of pharmaceuticals from "arms-length" third party distributers. These regulations are based on the government's concern that pharmacies would select their own private label drug in preference to their competitors, and the pharmacies would therefore retain profits without benefiting the consumers. This new policy of 2010 directly restricted Shoppers Drug Mart's ability to retain high profits, therefore this case was brought before the Ontario Division Court.

3.4 – The Role of Brand Name Pharmaceutical Companies

The history of federal drug regulation in Canada is marked by attempts at control and failure. These attempts to regulate have further created continued tension between both provincial and federal government as well as between brand name pharmaceutical companies and their generic competitors. Brand name pharmaceutical companies, which

[63] Supra, see note 19, at 20.

hold the original patent rights, oppose many of the pharmaceutical regulations imposed by the Canadian government in the last 25 years.[64]

As mentioned in the previous chapter, brand name pharmaceutical companies conduct expensive drug testing and adhere to the requirements imposed by Canadian and American governments, in order for the proper development of the pharmaceuticals.[65] Brand name companies enjoy the benefits of patent protection, which is a limited period of time in which their particular drug holds market exclusivity.[66] This time is precious for originator drug companies to recover the costly expenditures on development and research.[67]

Manufacturers of patented medications also known as "originator drugs" strongly oppose the compulsory licensing provisions of the Canadian Patent Act.[68] Bill C-22 led to the creation of the Patented Medicines Prices Review Board to regulate drug prices. Alternatively, Bill C-22 states that patent-holding pharmaceutical companies are guaranteed a ten-year exclusivity period whereby generic equivalents cannot be produced nor distributed in the market. In 1993, Bill C-91 further amended pharmaceutical regulation, completely abolishing compulsory licensing and extended Canadian drug patent law to twenty years before generic competition was allowed. In other words, the legislation protected brand name manufacturers.

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[64] Supra, see note 17, at 524.
[65] Supra, see note 19, at 4.
[66] Ibid.
[67] Ibid.
[68] Supra, see note 40.

3.5 - Direct-to-Consumer Advertising of Pharmaceuticals (DTCA)

To what extent should direct-to-consumer advertisements of pharmaceuticals be regulated and how, is an ongoing debate in Canadian health policy. The restriction on advertising in Canada is linked to the restriction on sales which directly connects to the rules and regulations outlined in the Competition Act, which is under examination in this thesis. Weighing the pros and cons of DTCA in Canada is extensively discussed by many of the actors mentioned above. This section will firstly define and explain direct-to-consumer advertising in Canada. Secondly, I will then discuss the main opponents to the argument for DTCA.

DTCA in Canada is particularly controversial because it goes against our Canadian platform on "near universal" health care, which reflects the values and narratives of the welfare state. Accepting DTCA of pharmaceuticals in Canada means that we as Canadians would accept the commercialization of healthcare, inevitably excluding those members of the population who cannot afford to pay for health care. This ideology of fully marketed pharmaceuticals creates a moral dilemma. However, one must ask doesn't this combination of healthcare with the commercialization and commodification of pharmaceuticals already exist in Canada? How do our current system's regulations of DTCA impose restrictions on generic and brand name pharmaceutical companies and what are the implications? And like most Canadian legislation, does this current model have any teeth?

"The responsibility for interpreting and enforcing drug-advertising regulations lies within the jurisdiction of Health Canada."[69] This is a very important role as the interpretation of legislation reflects cultural standards and narratives of health. Direct-to-consumer advertising is defined under the *Food and Drug Act,*[70] which is part of the *Criminal Code.* Health Canada is a federal department responsible for the enforcement of the *Food and Drug Act,* however this job is delegated through three primary organizations: the Code of Marketing Practices Committee of RxetD, the Advertising Standards Canada (ASC) and the Pharmaceutical Advertising Advisory Board (PAAB).[71]

Recently, important shifts in the interpretation of the law have resulted in an increased volume of direct-to-consumer advertisements in Canada.[72] This shift in cultural practice has resulted in a changing dialogue when it comes to the way in which we communicate discourses of health promotion. Additionally, Canadian exposure to DTCA has increased exponentially in the past 15 years.[73] Direct-to-consumer advertising is in principle, illegal in Canada, as in most industrialized countries.[74] The Canadian *Food and Drug Act* was imposed in 1985 and describes the regulations of pharmaceuticals.[75] Amendments to the act have adapted over time with the growing pharmaceutical industry.[76] The *Food and Drug Act* states that "No person shall advertise any food, drug, cosmetic or device to the general public as treatment, preventive or cure of any of the diseases, disorders or

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[69] Regis, Catherine. "Direct-to-Consumer Advertising of Prescription Drugs in Canada: Beyond Good or Evil." Vol.14 No. 2(Health Law Review), at 28.
[70] The Food and Drug Act, R.S.C., 1985, c. F-27.
[71] Mintzes, Barbara.PhD. "Direct-to-Consumer Advertising of Prescription Drugs in Canada: What Are the Implications,"(Toronto: Health Council of Canada, 2006), at 9.
[72] Supra, see note 69, at 9.
[73] Ibid, at 1.
[74] Supra, see note 69, at 1.
[75] Supra, see note 70.
[76] Ibid.

abnormal physical states [...]"[77] According to Regis, the *Food and Drug Act* defines advertisement of pharmaceuticals as "a representation by any means whatsoever for the purpose of directly or indirectly promoting the sale or disposal of any food, drug, cosmetic or device."[78] This Act's definition is not limited to paid communication or any specific form of media. [79] Section 9 (1) of the *Food and Drug Act*, states that "No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its composition, merit or safety."[80]

The intent of government on the prohibition of DTCA was "to protect the purchasing consumer against injury to health and against deception." [81] This reoccurring, routine narrative of the protection of society also occurs through the regulation of DTCA. DTCA is allowed to target non-prescription medications; however the scope of this thesis primarily focuses on an examination of prescription medication.

The status of DTCA under Canadian law is riddled with various interpretations of the regulations. This interpretation of narrative creates tension among actors, whereby there is a diversion from script, resulting in a change in performance. Under Canadian law, DTCA of pharmaceuticals is permissible if it is within the form of either "disease oriented" or "help-seeking" advertisements or "reminder" advertisements. "Disease

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[77] Supra, see note 69, at 28.
[78] Ibid.
[79] Supra, see note 70, at 7.
[80] Ibid.
[81] Rochon Ford, Anne & Diane Saibil. *The Push to Prescribe: Women & Canadian Drug Policy* (Toronto: Women's Press 2009), at 19.

oriented" or "help-seeking" advertisements describe the condition for which the drug treats, however does not disclose the name of the drug.[82] These forms of advertisements suggest to consumers to ask their doctor about an unspecified treatment.[83] Within this category of "disease oriented" or "help-seeking" advertisements, no risk information is required. [84] "Reminder" advertisements state the name of the drug, the price, and the quantity of the drug without stating what condition the drug is meant to treat.[85] No risk information is required from this form of drug advertisement.[86]

The type of advertisement that is not permitted in Canada, under the *Food and Drug Act*, however is used in the United States, is called "product claim" advertising which links the name of the drug with the specific condition that it claims to treat.[87] This form of advertisement must include information on the risk and side effects of the medication enforced by U.S Law.[88] This form of advertising is also known as "disease awareness" campaigns, "which constantly urge you to see your doctor for practically everything."[89] We see here, a particular form of language, which is developed by healthcare system. The language of "care" carries with it notions of risk and welfare, "reminder," "disease" and "help-seeking" carry with it a fundamental need for "help" from the state.

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[82] Supra, see note 69, at 29.
[83] Supra, see note 70, at 1.
[84] Ibid.
[85] Supra, see note 69, at 29.
[86] Supra, see note 70, at 1.
[87] Supra, see note 69, at 29.
[88] Supra, see note 70, at 1.
[89] Moynihan, Ray, & Alan Cassels. *Selling Sickness: How the World's Biggest Pharmaceutical Companies are Turning us all into Patients* (Toronto: Douglas and McIntyre Publishing: Greystone Books 2006), at ix.

In Canada pharmaceutical companies are mainly limited to aiming their advertisements directly to health professionals.[90] These health care professionals vary from physicians; home care workers, and pharmacists. Healthcare professionals are considered "learned intermediaries" who take on the responsibility of educating the public to make informed choices when it comes to prescription medication.[91] For instance, the physician is responsible for making an informed decision when prescribing medications to patients and also for educating patients on the adverse effects of the medication that they prescribed.[92]

There are many arguments, which support and denounce DTCA in Canada. Supporters of direct-to-consumer advertising claim benefits to public health.[93] There is an ongoing dialogue, between actors who support or condemn not only the message of DTCA but also the manner or the medium in which it is delivered. DTCA educates the population; through mass media individuals are prompted to take charge thus, giving consumers autonomy over their personal health.[94] Supporters claim that DTCA informs the public, leading to earlier diagnosis and care of serious disease and illness.[95] DTCA also prompts individuals to abide by government funded health initiatives, creating a "social climate" for order and compliance in taking prescribed medication, therefore inevitably protecting the population of the state.[96]

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[90] Supra, see note 69, at 5.
[91] Ibid.
[92] Ibid, at 5.
[93] Supra, see note 70, at 1.
[94] Ibid.
[95] Ibid.
[96] Ibid.

Alternatively, critics of DTCA argue, that advertising of drugs increases unnecessary patient demand for medicines through hyper self-diagnosis, resulting in fear and anxiety among the population.[97] Inevitably these practices result in an increased demand for medications, therefore increasing drug costs.[98] Additionally, because drug companies are allowed to target physicians directly, this therefore creates an unfair advantage when consumers ask specifically for the product advertised, the physician will likely prescribe the specific drug creating an ambivalent diagnosis.[99] Furthermore, opponents of DTCA argue that DTCA targets the vulnerability of people who are seriously ill, who actually require prescription medication for their complex and serious health problems, which cannot easily be self-diagnosed or managed.[100]

When examining the various roles of health care it is evident that Shoppers Drug Mart sits in a very lucrative position, capable of playing all actors, the creators, consumers, and distributers of their own product. Shoppers attempts to play the role of a protagonist, pharmacists are within a position of trust in the community. This is due in part by provincially imposed policy; physicians are often cut out of the picture. The majority of Canadian provincial policies state that pharmacists must issue the cheapest drug to the consumer. Therefore, by replacing the name brand drugs with the cheaper generic brand, Shoppers has an advantage over their competitors. This thesis argues that Shoppers Drug Mart participates in DTCA of pharmaceuticals with their own generic product, relying on the "originator" name brand American pharmaceutical companies to market their own

[97] Supra, see note 69 at 27.
[98] Ibid.
[99] Ibid.
[100] Supra, see note 81, at 18.

products, based on the knowledge of pending patent loss. Evidently, due to the increased commodification of prescription pharmaceuticals the United States spent more than $4 billion dollars on DTCA in 2004.[101] In light of patent loss, Shoppers therefore is able to create a generic version of said medication and rely on the simple slogan of "try our "Life" brand, it's the same product as *'insert "Big Pharma" name brand here,'* but cheaper." Shoppers does not have to pay the millions of dollars on marketing their drug, when they can simply rely on the "originator" drug to market their product for them. The authors of the systemic review of research on DTCA found that "fully branded product ads were found to stimulate sales of similar drugs as well as the specific brand."[102]

Shoppers may directly participate in "product claim" form of advertising straightforwardly between pharmacist (owner, producer, distributer) and patient (consumer). This illegal act is backed by the provincial government, which imposes regulations stating that pharmacists by law must issue the cheaper drug, to the benefit of the patient. This practice is known as interchangeability laws, whereby laws permit, but not require pharmacists to change products.[103] This thesis explores this gap in legislation, arguing that provincial and federal policy creates a systemic advantage for Shoppers Drug Mart, which negates the policy set out in the *Competition Act.*

Canadian rules and regulations concerning DTCA are undermined by loopholes in DTCA of pharmaceuticals through American advertisements, which reach Canadians through

[101] Supra, see note 69, at 1.
[102] Ibid, at 23.
[103] Supra, see note 17, at 13.

television, magazines, and the Internet.[104] These mediated narratives depict particular ideas surrounding healthcare. In the United States, the pharmaceutical industry spends more than 3 billion dollars a year in direct-to-consumer advertising.[105] This pushing of pills, also pushes the boundaries of legislation, inevitably transcending our borders and impacting the way in which we as Canadians are informed of "important health matters" [106] In the United States, DTCA spending is highly concentrated, accounting for almost 40% of annual marketing budget, spent on ten medicines.[107] According to Mintzes, the largest amount of advertising is spent on the top five drugs, which target chronic or intermittent term use, therefore targeting a relatively healthy part of the population.[108] Merck, one of the world's largest pharmaceutical companies' Chief executive once stated his distress in the pharmaceutical markets' limitation of being restricted to sick people, stating that it had long been his dream to make drugs for healthy people, therefore providing Merck with a larger target population, allowing them to "sell to everyone."[109] This reflects inclusionary discourse whereby narratives of health are targeting the entire population.

DTCA pharmaceutical campaigns are the most intensive within the first few years of distribution, when less is known about the medication's side effects or long-term benefits.[110] Intensive DTCA results in rapid widespread exposure to the population. This

[104] Supra, see note 19, at 28.
[105] Supra, see note 81, at 101.
[106] Ibid, at 103.
[107] Supra see note 48, at 26.
[108] Ibid.
[109] Supra, see note 89, at xi.
[110] Supra, see note 69, at 26.

widespread knowledge of pharmaceuticals transcends borders, resulting in Canadian exposure to the selling of sickness.[111]

Further loopholes in Canadian legislation and policy creates a gap, favoring generic pharmaceutical companies, like Shoppers Drug Mart. *The Food and Drug Act* Inspectorate has a variety of measures available if a pharmaceutical company were to breach the regulations imposed by health Canada. Such measures include

> "fines, injunctions, prosecution, and imprisonment, forfeiture, public warning and advisory, letter to trade and regulated parties, regulatory stop-sale, search and seizure, seizure and detention, suspension or cancellation of marketing authorization/ product licenses or establishment of licenses, or warning letters.[112]

However, according to Mintzes, there has been no enforcement of DTCA violations since 1978.[113] This undermines public confidence in health policy in Canada, for what is the point of having rules and regulations if they are not taken seriously? Health Canada provides little public information on criteria or methods used to investigate breaches in DTCA of pharmaceuticals in Canada.[114]

It is unfair to state that Canadian Health policy has taken their cue from our neighbors to the south, concerning DTCA.[115] According to Mintzes, although Canadian law prohibits DTCA and the United States does not, it is unjust to state that we as Canadians hold stricter policy and enforcement when it comes to DTCA and the regulation of drugs.[116]

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[111] Ibid.
[112] Supra, see note 69, at 10.
[113] Ibid.
[114] Ibid, at 12.
[115] Ibid, at 16.
[116] Ibid.

Some branded reminder ads presented by Health Canada would be considered illegal in the United States. Additionally, the FDA in the United States presents more pharmaceutical information relating to drug trials and the restrictions and limitations of marketing pharmaceuticals[117]

DTCA highlights the shift in health care policy in Canada. Those who support DTCA reflect the shift in ideology, marking the neo-conservative notion of self-autonomy and empowerment, whereby the consumer (patient) takes control of their own health care, seeking to educate, self-diagnose and self-medicate (with a little help from their family doctor). Regulation of DTCA in Canada marks the government's ongoing attempt to regulate and control the knowledge surrounding pharmaceuticals in Canada, reflecting the welfare model. As Canadian policy continues to shift towards allowing DTCA as we have with "Disease oriented"/"help-seeking" and "reminder" advertisements, it is important to critically examine the implications and infringements within current alternative legislation, such as the *Competition Act*.

3.6 - Competition

Currently, both regulatory and financial incentives in Canada encourage the use of generic drugs.[118] Being that the government plays multiple roles in regulations, price setting and purchasing they must ensure that all stakeholders involved in pharmaceutical access are treated fairly, keeping in mind their duty to abide by the *Competition Act.*[119] The *Competition Act* is imposed to "provide the general regulation of trade and

[117] Ibid.
[118] Supra, see note 19, at 5.
[119] Ibid.

commerce in respect to conspiracies, trade practices and mergers affecting competition."[120] The federal government role is to "ensure an appropriate balance is maintained between protecting intellectual property rights and facilitating a competitive supply of pharmaceutical products for Canadian consumers."[121] The Competition Bureau believes that Canadians deserve a health system that is "safe and effective," but also delivers the maximum possible health benefits to Canadians.[122]

In order to further substantiate this argument, it is necessary to draw reference to Sections 78 and 79 of the *Competition Act*. By using section 78(1)(a), I argue that the legislation imposed by the government of Canada, regarding the price controls and the provincial government's regulations concerning the mandatory issuance of the cheapest product, creates an unfair market advantage for Shoppers Drug Mart which, "impedes and prevents the competitor's ability to enter into, or prevent their further participation in the pharmaceutical market."[123] Furthermore, I argue using section 79(1), which states

> "Prohibition where Abuse of Dominant Position," where on application by the Commissioner, the Tribunal finds that...
> (a) one or more persons substantially, or completely control, throughout Canada or any area thereof, a class or species of business...
> (b) the practice has had, is having or is likely to have an effect of preventing or lessening competition substantially in a market.

In Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care), the final ruling found that the government of Ontario interfered with Shoppers Drug Mart's right

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[120] *Competition Act,* R.C.S., 1985, c. c-34.
[121] Weil, Tim "Competition Bureau Responds to Complaint over Alleged Misuse of Canada's Drug Patent Rules" (Ottawa: Competition Bureau 2010).
[122] " Benefiting from Generic Drug Competition in Canada: The Way Forward" (Ottawa: Competition Bureau 2008).
[123] Supra, see note 20, at 78(1)(a).

to property and commercial freedoms that were not expressly authorized within the parent statutes (*ODBA* and the *DIDFA*).[124]

In October 2007, the Competition Bureau released a Generic Drug Sector Study, which found that strong competition exists amongst generic competitors in Canada, however the benefits of this competition are not reaching the Canadian public in the form of lower prices. This thesis argues that due to Shoppers Drug Mart's ability to circulate their financial benefits between their manufacturer (creator), Sanis (producer) and Shoppers Pharmacies (distributer), these benefits rarely are passed onto to public. Over the next few years, several blockbuster brand name pharmaceuticals are scheduled to come off patent protection, thereby making the generic drug market in Canada even bigger.[125]

"The agglomeration of retail pharmacies into franchises, chains, and banner groups has shifted the balance of power in respect to pharmaceutical competition in Canada."[126] These pharmacies have the power to drive their drug-acquisition costs further down by demanding deeper rebates from the manufacturers.[127] The cost is further decreased if these pharmaceutical companies own "arm's length" third party manufacturing companies, at which point the profits remain within the same company. Shoppers Drug Mart owns Sanis Health, therefore keeping the profits within the same company.

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[124] Supra, see note 1, at 2.
[125] Ibid.
[126] Ibid, at 4.
[127] Ibid.

Additionally, the Patented Medicines Prices Review Board (PMPRB) regulates patented brand name prices. One of the mechanisms of control of this board is to impose limits on the prices of patented drugs in Canada. However, no such price regulations are imposed on generic brand pharmaceutical, making Canadian generics ranked highest priced in the industrialized world.[128] The Health Council of Canada reports that Canadian pharmacies profit more on generic drugs than brand name pharmaceuticals because the pharmacy has financial incentive, in the form of "rebates" backed by the government to provide generic substitution.[129]

Additional studies of the Competition Bureau of Canada published in 2008, found that Canadian tax payers, consumers, and businesses could save up to $800 million a year if changes were made to the way in which generic drugs were regulated and paid for by the government of Canada.[130]

This chapter examined the three major stakeholders (actors) in connection to *Shoppers Drug Mart v. Minister of Health and Long Term Care* (2011) and their implications for competition, policy, and the regulation of pharmaceuticals in Canada. This chapter explored pharmaceutical policy in Canada, focusing the discussion based on government and its attempt at control. The argument was illustrated by calling upon Goffman and Gangon's work by using a theatrical performance reference. Legislation and routinized narratives of health are evident within this chapter. I discussed Shoppers Drug Mart's role in generic production and distribution of pharmaceuticals. This chapter then examined

[128] Supra, see note 19, at 8.
[129] Ibid, at 12.
[130] Ibid, at 2.

brand name pharmaceutical companies and their stake in the ongoing competition in the pharmaceutical market in Canada. The discussion then concluded with an exploration of Direct-to-consumer advertsising of pharmaceuticals in Canada and the legal ramifications that ensue. This analysis of the various actors involved in connection to DTCA and competition problematizes current issues, highlighting the necessity for an ongoing critical gaze at the intersection of health policy and intellectual property. This chapter serves to create an understanding of the primary actors involved as well as a basic knowledge of the valuable terms and concepts used to substantiate this thesis.

The following chapter will elucidate the theoretical framework, encompassing three varying interpretations from Alan Hunt and Gary Wickham, Francois Ewald, and finally, Ben Golder and Peter Fitzpatrick, illustrating Foucault's work on governmentality, bio-power and bio-politics. It is important to shift between competing discourses and popular academic thought not only to situate Foucault's concept of law in modernity, but also to provide a framework upon which to critically interpret the intersection of intellectual property and health policy in Canada. Furthermore, this chapter will explain the methodological framework upon which this project has been executed.

Chapter Four:

Theatrical Conventions:
Methodological and Theoretical Framework

Chapter Four: Theatrical Conventions: Methodological and Theoretical Framework

The previous chapters have provided a foundation upon which I move forward with my argument. This chapter follows with a methodological and theoretical outline, which depicts the purpose of this project, how it will be executed and upon which theoretical basis the argument will be established. This chapter illustrates the theatrical conventions of this thesis by way of an explanation of the established techniques, practices and devices, which are unique to each theatrical performance.[1] These theatrical conventions will form the methodological and theoretical framework for this project. By way of Foucault, this thesis examines the connection between social science research and black letter law. Foucault's concepts challenge us to rethink the relationship between power, control and dominance surrounding the questions of "rights" to the body and health. Foucault's concepts will further be addressed at the second half of this chapter.

4.1 - Methodology

What is in Question?

- How does the generic pharmaceutical policy of Canada, reflective in the *Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care)* infringe upon the very rights it is in place to protect, as outlined in the *Competition Act*? What is the nature of the relationship between intellectual property and health care policy?
- Does current public health policy concerning pharmaceuticals create a gap for Shoppers Drug Mart? If yes, how so?

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[1] "Theatre Vocabulary" Sparked : Spark in Education (2011).

- To what ends do current regulations impinge upon the stakeholder Shoppers Drug Mart?
- How does selected case law frame brand name and generic pharmaceuticals in relation to the Competition Act?
- Does Shoppers Drug Mart play a direct role in direct-to consumer advertising in Canada and how does this impose upon the regulations of the Competition Act?

This qualitative form of social research is unobtrusive in that it is a method of studying social behavior or phenomenon without affecting it.[2] Content analysis is appropriate for this thesis because I am examining "who says what, to whom, why, how, and with what effect?"[3] The complexity of this examination lies in the interpretation of performing a discourse analysis.

4.2 - Analysis

I chose to perform a qualitative analysis because judicial interpretation itself is based on examination and observation, imposed in order to discover meanings and patterns of relationships.[4] Qualitative analysis of case law through a discourse analysis will be purposeful especially through an examination of the historical accounts of regulation of legislation in connection to health policy and intellectual property. Performing a discourse analysis of policy and legal material using a social research method is very appropriate when examining human communications because discourse is at the center of

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[2] Babbie, Earl & Lucia Benaquisto. *Fundamentals of Social Research*. (Canada: Thomson Nelson, 2002), at 283.
[3] Ibid, at 287-288.
[4] Ibid, at 283.

human understanding. The way, in which we understand and interpret words and phrases are central to the study of law because legal interpretation is solely based on a temporal context. This exploration of re-occurring language will formulate themes, which will help to respond to the primary thesis question and alternative sub questions.

4.3 - Discourse Analysis

A discourse analysis will explore the textual legal interpretations in order to seek gaps in the legislation. Discourse analysis is an approach to the analysis of language that examines patterns of language across texts as well as the social and cultural contexts in which the texts occur.[5] The view of discourse as a social construction of reality works under the notion that texts are communicable units, which are embedded in social and cultural practice.[6] This similar narrative parallels John Gagnon's discussion relating to how sexual scripts and narratives of everyday life are formed from individual interpretations of cultural understandings.[7] Discourse is both shaped by the world as well as shaping the world.[8] Brian Paltridge explains the multidimensional use of discourse stating,

> Discourse is shaped by language as well as shaping language. It is shaped by the people who use the language as well as shaping the language that people use. Discourse is shaped, as well, by the discourse that has preceded it as well that which might follow it. Discourse is also shaped by the medium in which it occurs as well as it shapes the possibilities for that medium.[9]

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5 Paltridge, Brian 2006, Discourse Analysis: An Introduction (New York: Continuum), at 1.
6 Ibid.
7 Gagnon, John H. An Interpretation of Desire: Essays in the Study of Sexuality (Chicago: The University of Chicago Press 2004), at 108.
8 Supra, see note 5, at 9.
9 Ibid.

In the case of this thesis, the medium is law. Legal case law is open to the rules of interpretation. Pierre Cote defines interpretation as a way "to interpret an enactment is to determine its meaning and effect [...], to interpret an enactment is to clarify its obscurities, [and...] "to seek the intention of the legislator."[10] The language of law is an empty vessel, often meaningless until applied within the everyday context. [11] My discourse analysis focuses on two major roles the courts play in respect to decisions on the regulation of pharmaceuticals in Canada. Through the use of five Canadian cases, this thesis will examine the traditional common law role of interpretation of discourse based on past precedent. Interpretation of statutes, the second role of courts analyzed within the thesis, will focus on an examination surrounding the manner of judicial interpretation of presiding statutes such as health policy.

To facilitate this analysis, it is necessary to define the methods of interpretations judges utilize. The modern principle regarding statutory interpretation requires that the words of the legislation be read "in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament."[12] Often judicial review seeks a literal rule whereby if statutes are clear, then they are not subject to judicial interpretation.[13] However this is not often the case with evolving health policy in Canada. There are four methods of judicial interpretation, which will play a vital role in my discourse analysis. Through the literal method a judge

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[10] Stuart,D.,Delisle, R.J & S. Coughlan. *Learning Canadian Criminal Law. 11th ed.* (Toronto: Thomson Reuters 2009), at 11.
[11] Ibid
[12] Ibid.
[13] Ibid, at 27.

interprets a statute by focusing on the textual approach, stressing, "what the law says, is what the legislator meant to say." This is method is often referenced as the "Golden Rule" of literal construction, whereby the construction of a statute "should be interpreted in a manner consistent with the plain meaning of its terms."[14] The contextual approach and logical method is based on the assumption that legislator is rational. In the case of interpretation, this means that judges should take the law at face value, recognizing the primacy of constitutional authority. The teleological method primarily focuses on the question surrounding parliamentary intent in the enactment of the legislation.[15] This is clarified under the s. 12 of the *Interpretation Act,* which states, "Every enactment is deemed remedial, and shall be given fair, large and liberal construction and interpretation as best ensures the attainment of its objects."[16] Finally, the fourth method is a historical interpretation. This refers to the factual or legal consideration, which the legislature is assumed to have been aware of at the time of the enactment. It also refers to the preparatory documents of the law and parliamentary history.[17] To examine law based on a historical context one must examine the general historical information, history of the enactment itself (predecessors, previous governmental policy and or discussions) and finally, the parliamentary history of the enactment.[18]

4.4 - Purpose and Relevance

This thesis will examine the intersection of law concerning health policy and intellectual property of the pharmaceutical industry. New areas of research and development have

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[14] Ibid.
[15] Supra, see note 10.
[16] Watt, D. & M. Fuerst. *The 2012 Annotated Tremeear's Criminal Code: Student Edition* (Toronto: Carswell 2012), at 2181.
[17] Supra see note 10.
[18] Ibid.

forced legislation and judicial interpretation to evolve, changing the way in which we understand health policy and the consumption of pharmaceuticals. This makes the law reactionary as Hunt and Wickham show through their concept of the government's ongoing attempt to control the population.

Laws surrounding intellectual property in health policy are a growing area of law and regulation within Canada. My research uses the theatrical conceptions of Gagnon and Goffman to provide a framework for a Foucaultian analysis of the shifts and changes in government's role in the regulation of health. In regulating health, the government exercise mechanisms of control that regulate the actions of individuals and the public in relation to production, distribution, and consumption of pharmaceuticals.

4.5 - Constraints of Project

Some analytical constraints, which may emerge will likely be due in part to the selected methodological approach of discourse analysis. To ensure consistency through my analysis, I have chosen to use the same methods of interpretation judges currently employ. This does mean that my interpretation may not be as critical because I am not going beyond and employing a further socio-legal perspective. Additionally, all statistics mentioned in this thesis were provided from governmental and non-governmental agencies, which provide statistical data pertinent to this examination of health care policy in Canada and more specifically the province of Ontario. Therefore, this analysis is dependent on existing statistical data. The disadvantage of performing a content analysis

is inherently limited by nature of the availability of sources. This raises issues of reliability and bias due to the fact that I have not collected my own information.

Further constraints of this project encompass issues surrounding the scope in relation to the selected theoretical framework of Foucault. I acknowledge Foucault did not write on current health policy in Canada; however I have chosen to use his work on governmentality and bio-politics to provide a lens through which to examine governmental regulation of health policy. The selected scope of this project may also be problematic, as Foucault's concepts focus on a multi-dimensional power structure, not just a top down structure.

4.6 - Theoretical Framework

Foucault's ideological shifts, from position to position parallel the outline of this theoretical framework. This thesis will highlight Alan Hunt and Gary Wickham's position from their book *Foucault and Law: Towards a Sociology of Law and Governance.* This section will examine terms and concepts of relevance to this thesis, in connection to Hunt and Wickham's "expulsion thesis."[19] This perspective helps frame the discussion through concepts of regulation and social control, the backbone to the analysis of Canadian health policy. The discussion will then move into the second section, which explores Francois Ewald's position on Foucault and Law. This thesis specifically extracts Ewald's interpretation based on his article, "Norms, Discipline and the Law." This second section will discuss Ewald's interpretation of Foucault and law, culminating in his

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[19] Hunt, Alan & Gary Wickham, *Foucault and Law: Towards a Sociology of Governance.* (Colorado: Pluto Press, 1994).

concept of "social law."[20] This section will highlight the interplay between Hunt and Wickham's "sociology of law" and Ewald's "social law". This is relevant to this thesis because it further extrapolates the interplay between sociology and the law. The third and final comparative section will elucidate Ben Golder and Peter Fitzpatrick's interpretation of Foucault and Law from their work, *Foucault's Law.* In highlighting Golder and Fitzpatrick's differing interpretation of Foucault and law, we are able to critically analyze and interpret the concepts and material selected in order to examine intellectual property law. To them, law exists in the form of regulation.[21] Intellectual property law functions through regulation of the production, distribution and consumption of pharmaceuticals. In addition to the three selected works, this thesis will draw upon and critically engage with a range of Foucaultian texts such as *Discipline and Punish, Governmentality* and *Power/Knowledge.* First, in order to explore the intersection between Canadian health policy and intellectual property law, it is important to unpack Foucault's work on governmentality and bio-politics This section will summarize the key themes to Foucault's 'governmentality' literature dealing with Foucault's own analysis and then work of others who further developed his ideas.

4.7 - Governmentality

Governmentality can be described as the "art of governing."[22] Governmentality is the dramatic expansion in the scope of government, featuring an increase in the number and size of governmental mechanisms, which began in the mid eighteenth century onward,

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[20] Ewald, Francois. 1991. 'Norms, Discipline, and the Law' 30 Representation 138-161, reprinted in Robert Post (ed.) Special Issue: *Law and Order of Culture* (Berkely: University of California Press),at 139.
[21] Golder & Fitzpatrick. *Foucault's Law* (New York: Routledge-Cavendish, 2009), at 36-37.
[22] Foucault, Michel. 1977. *Discipline and Punish: The Birth of the Prison.* Translated by Alan Sheridan. (New York: Vintage Books), at 87.

and continues today.[23] In "Security, Territory, and Population," Foucault summarized government as "an activity that undertakes to conduct individuals throughout their lives by placing them under the authority of a guide responsible for what they do and for what happens to them."[24] With governmentality comes the emergence of reason of the state; and the emergence of the human sciences as a new mechanism of calculation in the protection of the population."[25] Foucault suggested that the reason of state has in fact displaced earlier forms of governing whose principles were based on traditional virtues such as "wisdom, justice, liberality, respect for the divine laws and human customs," or common abilities, like that of "prudence, thoughtful decisions, as well as, taking care to surround oneself with the best advisor."[26] This gave way to the art of governing, which assigned priority to strengthening the state, and power structures that sought to intervene and manage the habits and activities of its subjects to achieve an end.[27] Western states in particular have become progressively 'governmentalized.'[28] What Foucault means by this is that state authorities have increasingly understood their task as a matter of controlling individuals and populations, civil society and economic life, in such a way as to increase the over-all well-being, security and prosperity of society.[29] This can be explained best as

> Governments came to be a means for ends in relation to population concerns: how to guarantee the health, wealth, happiness, longevity, and so on, of the population; a whole series of strategies, which elsewhere

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[23] Connell, E. & Alan Hunt, "The HPV Vaccination Campaign: A Project of Moral Regulation in an Era of Bio-politics."(Canadian Journal of Sociology 35(1) 2010), at 76.

[24] Rose, Nikolas, Pat O'Malley and Maria Valverde "Governmentality" 2 Annual Review of Law and Social Science 83-104 (2006), at 1.

[25] Supra, see note 23, at 76.

[26] Supra, see note 24, at 1.

[27] Supra, see note 24, at 2.

[28] Supra, see note 24, at 12.

[29] Garland, David. 1997. *'Governmentality' and the Problem of Crime: Foucault, Criminology, Sociology.* Vol. 1(2): 173-214.(London Thousand Oaks and New Delhi: Sage Publications), at 178.

> Foucault has termed bio-power or bio-politics, which sought practical answers to practical questions.[30]

Foucault states "government in modernity is in a constant pursuit of perfection and intensification of the processes which it directs; and the instruments of government, instead of being law, now come to be a range of multiform tactics."[31]

Inherent in the power of governmentality is the use of discourse and its effects on society. Discourse structures the possibility of what is included and excluded in society. "Discourse authorizes some to speak, some views to be taken seriously, while others are marginalized, derided, excluded and even prohibited. [32] Governance structures the normative of discourse and discourse is central to truth seeking. The conception of truth helps us to understand the discursive elements of society, helping us to interpret the relationship between ideas and practices.[33]

> Truth operates through the exclusion, marginalization and even prohibition of other competing truths; indeed it is itself a 'prodigious machinery designed to exclude.' Truth is not separated from power, rather it is one of the most important vehicles and expressions of power; power is exercised through the production and dissemination of truth.[34]

It is important to identify techniques of truth and power for this thesis because it will provide a framework for an account of the transformation of medical knowledge and practice and the emergence of a systemic regularization of "modern medicine." Medical discourse and knowledge continues to evolve as practices, institutions and knowledge

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[30] Supra, see note 23, at 76.
[31] Rabinow, Paul (ed.) 1984. *The Foucault Reader* (New York, Pantheon Books), at 95
[32] Supra, see note 19, at 11.
[33] Ibid.
[34] Ibid.

change.[35] An examination of discourse and medical knowledge allows us to interrogate the "truth" seeking techniques and mechanisms of control inherent in our modern medical system today, forcing one to question *how* these truths are produced and maintained.

'Government,' according to Foucault, did not refer only to political structures of the management of states; rather it examines the way in which the conduct of individuals or states may be directed.[36] 'Governmentality' can be explained as the expansion of scope of government, featuring an increase in the calculation mechanisms of government.[37]

Hunt and Wickham describe the action of governing as "to structure the possible field of action of others."[38] One of the ways in which to "structure the field of action of others" is through governmental regulation of the population. Through targeting the population, governments are able to target each individual as part of a general population.[39] This gave rise to a new political economy, which sought to promote the flow of government between individual, family and state through the concept of population.[40] This type of population management gave rise to a series of technologies both social and scientific. In order to obtain a precise knowledge of the population, statistical analysis came to the fore, suddenly knowledge circulated concerning birth rate, mortality, longevity, heath,

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[35] Ibid.
[36] Ibid, at 25.
[37] Ibid, at 76.
[38] Ibid, at 25
[39] Ibid, at 77.
[40] Ibid.

illness, suicide etc.[41] These statistical discourses push the medical community today, driven by notion of "risk."[42]

This development of new knowledge created an inherent resistance because politics and law are perpetually behind social and scientific development. Resistance, according to Hunt and Wickham, is a technical component of governance and is part of the social mechanism, which drives the ongoing cycle of attempt and failure.[43] Foucault, according to Hunt and Wickham, insists that 'government' is "not a matter of imposing laws on men, but rather of disposing things, that is to say to employ tactics rather than laws, and if need be to use the laws themselves as tactics."[44] This Foucaultian tool concerning the government as tactics can also be used to explore the position of brand name pharmaceutical companies, who employ these tactics or patent controls in order to protect intellectual property. These tactics of control are employed as an exclusionary method of knowledge, imposing a scientific hierarchy of knowledge between the brand name manufacturers and the generic manufacturers.

Hunt and Wickham suggest that in order to perform an analysis of power relations, one must proceed by firstly, identifying the various powers at work, and then performing an evaluation of the results of the various powers.[45] These results give rise to domination

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[41] Supra, see note 24, at 6.
[42] Supra, see note 19, at 77.
[43] Ibid, at 53.
[44] Ibid, at 52.
[45] Ibid, at 12.

and subordination or inclusion and exclusion.[46] Foucault extrapolates that cumulative increased observation of the population gave birth to various techniques of record keeping, writing of reports, monitoring and inspection, which all form important techniques of governing the modern world.[47] This advance in disciplinary techniques gave rise to 'regulation' as a distinctive technique of government.[48] This concept is imperative to the study of health policy and intellectual property law because we must interrogate each individual interpretation of law and policy to understand the perspectives of the various actors involved.

Hunt and Wickham criticize Foucault for ignoring the fact that in modernity, state law is always involved with exercising control or exempting control from different forms of disciplinary regulation.[49] Hunt and Wickham further assert a more adequate account of regulation is based on a social aspect. It involves an ongoing process of expansion and contradiction of various sites of regulation imposed by norms and discourse, resulting in the jurdification of social life. Here we see the constant cycle, encompassing 'attempt at control-incompleteness (failure) – attempt at control'. There is an ongoing process of regulation in an attempt to control pharmaceuticals, followed by failure or public disapproval, which in turn triggers another attempt at control. For Hunt and Wickham, this process far exceeds that of black letter law itself. Instead it is an ongoing negotiation between the various actors involved in the regulation of pharmaceuticals, whether that be policy analysts, scientists, medical practioners, or community members who select to

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[46] Ibid, at 15.
[47] Ibid, at 21.
[48] Ibid, at 22.
[49] Ibid, at 65

purchase generic brands. Hunt and Wickham's interpretation of Foucault allow one to explore how law is articulated through the discipline of the evolution of pharmaceuticals under the gaze of both the medical and governmental community. Hunt and Wickham note that law in modernity increasingly functions as a social "norm."[50] Francois Ewald's further expands on Foucault's thesis concerning the 'normativisation of law.'[51]

Francois Ewald's exploration and interpretation of Foucault's work in his article entitled, "Norms, Discipline, and the Law," resulted in his notion of "social law," which can be explained as "the term for the legal protection that typify the Welfare State."[52] Ewald argues the emergence and development of principles of social law are not confined to labor and social security law.[53] The advent of the welfare state is a new type of legal system, based not on universal principles, but rather the use of the law as a political instrument.[54] Resource allocation and access to political processes are indeed the central focus of the welfare model. Ewald's concept of social law highlights Foucault's mechanisms of power, whereby techniques and technologies of power are pivotal in society's pursuit of community and a normative state.[55] Inherent value is placed in finding a balance of judgment in the social law model, where all actions are judged based on social norms of acceptance. Here we see the interplay of law and the social, in that law is based on social normality, enshrined in customs, and habits of a particular group, at a particular moment in time. Ewald's "social law" interpretation of Foucault brings to the

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[50] Ibid, at 68.
[51] Ibid, at 66.
[52] Supra, see note 21, at 37.
[53] Ibid.
[54] Ibid, at 38.
[55] Ibid.

fore social law and space. His argument highlights the fact the "legal regulation should not be examined in isolation but though its complex interconnection with regulatory techniques."[56] This examination of law through the social intersects with Hunt and Wickham's concept of the sociology of law.

Ewald highlight's the importance of distinguishing the terms *norm* and *discipline.* He explains that *disciplines* are concerned with the body and it's training, while the *norm* is a measurement and a means of producing a common standard.[57] The *norm* is to be distinguished from the rule; norms identify general standards, not in the sense of 'principles' or meta-rules, but rather as a set of criteria.[58] Ewald suggests that according to Foucault, the normalization of various disciplines and the shift from discipline as constraint towards discipline as a regulatory mechanism, are indeed symptomatic of modernity as a normative age. This new formation of a disciplinary society is founded on a new kind of social space, which constantly reflects negotiation, fluidity and flexibility of an entirely self-contained and homogenous population.[59] Ewald wishes to expand on Foucault's social analysis of modernity in order to examine the transformation of techniques and mechanisms of discipline based on standards of normalization in connection to the law.[60] Ewald's expansion on Foucault's normalization thesis allows us to investigate what standards of normalization are imposed on the pharmaceutical industry in Canada. An example for the province of Ontario would be the *Ontario Drug*

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[56]Supra, see note 19, at 67.
[57] Supra, see note 20, at 141.
[58] Supra, see note 19, at 66.
[59] Supra, see note 20, at 141.
[60] Ibid, at 159.

and Benefit Act and the *Drug Interchangeability and Dispensing Fee Act*, not to mention the norms and standards imposed by Health Canada.

Practices of normalization are imposed to regulate human conduct. No social object can escape normalization, and society would be inconceivable without it. According to Ewald, norms and standardization have always played an essential role in social development of the population.[61] Inherent to this thesis, normalization is deeply rooted in the scientific and technological aspects of human bio and medical advancement. [62] A new language of the expert emerged, taking on an institutional existence and the creation of official medical norms and standards.[63] These standards of normalization are inherent within the requirements of pharmaceuticals in Canada.

Ewald's exploration of the welfare state will be important to the examination of parent statutes imposed by the government to ensure the health and well being of the population. Ewald's exploration of the social law, and norms created through the discourses of the medical experts will help to provide a framework upon which to adopt Foucault's adaptation to public health policy in Canada based on the welfare model.

Foucault's project, according to Ewald's interpretation, was neither to denounce the imminent disappearance of law, nor to criticize bio-power in the name of law.[64] Ewald argues along the lines of Hunt and Wickham stating that Foucault was concerned less

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[61] Ibid, at 150.
[62] Ibid.
[63] Ibid.
[64] Ibid, at 159.

with the place of law in the exercise of power. Ewald highlights Foucault's passage at the end of *The History of Sexuality*, stating, "we have entered a phase of juridical regression in comparison with the pre-seventeenth-century societies we are acquainted with."[65] Power does not necessarily function through law. Ewald argues the instead, law serves as a form of camouflage over the mechanisms of power. Ewald's analysis of power and the law begs one to question how we make sense of instruments of law and legal regulations of pharmaceuticals in an era of bio-power? I believe Ewald's interpretation of this Foucaultian concept would be weighted in favor of generic pharmaceuticals with no legal regulation imposed by the government.

Golder and Fitzpatrick's account of *Foucault and Law*, lies within the ideology that law is in fact present within Foucaultian accounts of power, governmentality and technology.[66] In Western Societies since the Middle Ages the exercise of power has always been formulated in terms of the law.[67] The authors' argument is based on the fact that Foucault did indeed include law in his conception of power. Law and modernity is important to the examination of health policy and intellectual property because we are able to examine their interpretation of law and how new techniques and technologies have controlled society and the evocation of the law.

Golder and Fitzpatrick's main argument concerning the law is that Foucault seems to want to circumscribe the role of law as a particular form of power, rooted in a negative

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[65] Ibid, at 158.
[66] Supra, see note 21.
[67] Ibid, at 17.

context, functioning within a restricted juridico-discursive economy.[68] Law according to Golder and Fitzpatrick's interpretation does not allow, but in fact prohibits.[69] It is essentially, indeed excessively, repressive in its mode of interpretation. Golder and Fitzpatrick argue that although law is purely negative and seemingly inherently limited, the law is fading in importance with the advent of modernity.[70] The discussion of bio-politics will further this ongoing dialogue on the techniques and mechanisms of controlling society.

4.8 - Bio-Politics

Bio-politics can be described as when the state controls, regulates and surveys the conduct of bodies on an individual and group level in order to maintain social stability.[71] Post-structuralist theorists like Deborah Lupton, would argue "the body is conceived as a collection of practices, or 'body techniques,' which represent and regulate bodies in time and space."[72] She further explains that bodies are shaped by social relationships, both facilitated and limited by historical, cultural, and political factors of society.[73] Bio-politics is an excellent lens through which to examine health policy and intellectual property law because it investigates "the way in which states undertake surveillance and control of bodies, and how in turn individuals come to self-regulate and discipline their

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[68] Ibid, at 15-16.
[69] Ibid.
[70] Ibid, at 17.
[71] Lupton, Deborah. *Medicine as Culture: Illness, Disease and the Body in Western Societies* (London: Sage Publications 1994), at 22.
[72] Ibid.
[73] Ibid.

bodily deportment."[74] Bio-politics will be used as a tool to investigate the methods of control, the government deploys in attempt to control the consumption of pharmaceuticals, aiding in the health of the Canadian population.

For Foucault, the body is the ultimate site of political and ideological control, surveillance and regulation.[75] Since the 18th century onward, "the body has been the focal point for the exercise of disciplinary power."[76] State apparatuses such as medicine, the education system and the law, are imposed to control the body and its behaviors. [77] These various apparatuses define the limits of behavior in everyday life, recording activities through constant manipulation and surveillance and then punishing those bodies that deviate from the norm. These apparatuses of society keep the population in check, enabling productive and politically and economically useful citizens. Lupton explains that Foucault viewed medicine as a major institution of power playing an inclusionary or exclusionary role in society "by labeling bodies as deviant or normal as hygiene or unhygienic, as controlled or needful of control." [78] These very inclusionary and exclusionary tactics are paramount in the intersection of public health policy and intellectual property in that there is a question of accessibility to medication. Also, there is constant debate surrounding the power and control dynamic between federal and provincial governments and pharmaceutical companies like Shoppers Drug Mart.

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[74] Ibid
[75] Ibid, at 23.
[76] Ibid.
[77] Ibid
[78] Ibid.

Bio-politics reflective of a welfare state involves regulatory rather than legislative or disciplinary initiatives to control the health and wellbeing of the masses.[79] The great public health projects of the mid-19th century were not directed at the conduct of individual members of society, but focused on conditions that affected the health and general way of life of populations.[80] Contemporary forms of bio-political projects differ from those of the 19th century, whereby expertise took the form of medical experts functioning under the authorization of the state. Central to Golder and Fitzpatrick's description of Foucault's interpretation of law was the use of disciplinary power whereby subjects in modernity became *docile* through mechanisms and techniques of power, which included subtle repetition of forms of graduated exercise and daily routine.[81] Central to this idea was the move away from physical violence of sovereign power, to the individual empowerment of the population, working for the benefit of the whole. The constitution of the modern subject was achieved through new and different techniques of power, which included "special distributions, normalizing judgments, constant surveillance and examinations (with small penalties and forced exercises)."[82]

Bio-politics is rooted in the constant state of truth seeking and the hierarchy of knowledge. For example, Foucault stated that rational forms of knowledge (law, medicine, social sciences, etc.) extend the normative power of the knowledge so that each

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[79] Supra, see note 23, at 65.
[80] Ibid.
[81] Supra, see note 21, at 19.
[82] Supra, see note 71, at 23.

step towards advancing the health of populations also empowers and expands the institutional mechanisms of control. [83]

Bio-politics is a perfect framework upon which to examine the Canadian government's attempt to control pharmaceuticals through implications of legislation, and health policy because Foucault's concept challenges us to disturb present understandings of medical health policy by examining the past. Foucault argues that the modern state has been preoccupied with controlling bodies *en masse* in unison with the development of the birth of the medical clinic, the increased demand for individual medical care and the concern with the protection of the population.[84] Foucault argued that new discourses emerged from the mid-18th century onward, which problematized disease as an economic and political problem for societies as a whole, therefore requiring a response in the form of collective control methods. [85] Foucault explains the priority of state health of the population as a general objective and policy stating,

> health and sickness, as characteristics of a group, a population, are problematized in the eighteenth century through the initiatives of multiple social instances, in relation to which the state itself plays various different roles. On occasion, it intervenes directly: a policy of free distribution of medicines was pursued in France on varying scale from Louis XIV to Louis XVI.[86]

Here we see the intersection of the social and the state in regards to policy and law concerning health. The above example illustrates health as a priority of the state, whereby the state intervenes directly, controlling the distributions of medicines.

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[83] Supra, see note 23, at 67.
[84] Supra, see note 31, at 274-275.
[85] Supra, see note 71, at 30.
[86] Supra, see note 31, at 274.

Governmental intervention, management and control are achieved through the administration of regulations on pharmaceuticals. These practices are quintessential to the modern forms of power expressed in current health policy and intellectual property. These tactics and techniques of legislation and law create a homogenization of a norm. Society is no longer to necessarily target individuals who transgress a pre-given law but rather target individuals who neglect to attain the societal standard, contributing to society as a positive and productive member. Golder and Fitzpatrick explain that law forms a primary aspect of governmental control over health in connection to the disciplinary mechanisms of society.[87] They use governmental policies as an example defining them as "regulations concerned with order at the level of populations and their individual components are informed by the regularities and interests depicted by the human sciences."[88] Golder and Fitzpatrick argue the importance of tracing law's narrative from the rule of sovereignty when law was "blunt and vicious" to modernity whereby the law is used as an instrumental tool of tactical administration.[89] Golder and Fitzpatrick help us to examine how the law remains part of the regulation of pharmaceuticals in Canada.

Moreover there is a connection between Hunt and Wickham's interpretation and Golder and Fitzpatrick's interpretation of Foucault and that is the ongoing practice of the

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[87] Supra, see note 21, at 34.
[88] Ibid.
[89] Ibid.

mechanisms of power, "doomed to repeat itself."[90] This assimilates with Hunt and Wickham's concept that governance is an ongoing cycle with attempt at control-incompleteness (failure)-attempt at control. We see that in both instances, constant tactics are being deployed. All theorists would also agree in the interpretation of Foucault's stance on the regression of law, that with modernity came the 'phase of juridico regression' characterized by the importance of the norm. The point in contention here is the placement or existence of the law. Where these theorists differ is that Golder and Fitzpatrick highlight Foucault's discussion of power in the legal sense, whereas Hunt and Wickham argue that Foucault excludes consideration of the law's constitutive concepts.

When we combine the various interpretations of governmentality, bio-power and bio-politics we are able to create an understanding of Foucault's work in connection an ongoing issue in Canadian health policy today. This framework will be the backbone to the discourse of pertinent case law, concerning the way in which generic pharmaceuticals of Shoppers Drug Mart goes against the *Competition Act* of Canada. Foucault helps us to stir the pot, making us question, who or what is be governed? Why should they be governed? How should they be governed? To what ends should they be governed? These questions are integral to the examination of *Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care)* because we see the interplay of the government in their attempt at control-incompleteness (failure)-attempt at control.[91] The imposition of legislation (attempt at control) imposed regulations on pharmaceuticals, which was ruled to be *ultra-vires,* meaning beyond the scope of what the legislation was originally set to

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[90] Ibid, at 16.
[91] Supra, see note 19, at 121.

impose (failure). This current case is in the appeal stage, and will likely continue the cycle of contention for years to come in Canadian Health reform.

In summation this chapter has provided the reader with the theatrical conventions necessary to formulate an understanding of this theatrical performance. The first half of this chapter discussed the methodological framework, offering an account of the purpose, qualitative methodology, through discourse analysis, relevance and constraints of this project. The methodological framework further stipulated the why, how and in what way this thesis will be executed, rooted in the theoretical analysis of Foucault, which was further explained in the second portion of this chapter.

The aim of the second portion of this chapter was illustrate how Foucault is an excellent lens through which to examine the ongoing governance of formal knowledge in the regulations of pharmaceuticals. Hunt and Wickham provided their 'expulsion thesis' to examine the sociology of law, showing the ongoing cycle of governance in the attempt at control-incompleteness (failure)-attempt at control.[92] What is imperative to this discussion on the perpetuity of governance is the fact that the failures of governance are just as important as the attempts at control, it is through the evolution that we learn. Through reading various interpretations of Foucault, which question the role of law in modernity, we are able to formulate a critical framework for the analysis of health policy and law.

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[92] Supra, see note 19, at 121.

The following chapter will provide an abstract of the five-selected cases under investigation. Each case will be briefly outlined discussing the parties involved (actors), the issue at hand (story depiction), pertinent reference to legislation (scripts), as well as a brief discussion of judicial interpretation of legislation. Finally, this chapter will conclude with a discourse analysis, depicting the prominent themes in language and practice, which make up current Canadian legal opinions concerning the intersection of health policy and intellectual property. These themes will then be compared and analyzed based on the theatrical conceptions outlined in this chapter regarding the established techniques, practices and devices outlined in Foucault's theoretical framework on governmentality, bio-politics and bio-power.

Chapter Five:

Performative Provisions for the Pushing of Pills

Chapter Five:
Performative Provisions for the Pushing of Pills

This chapter will outline a description of the various scripts under investigation. First, this chapter will present an explanation of the primary case law under examination *Shoppers Drug Mart Inc. v. Ontario*,[1] which will set the scene for a critical analysis of the four-selected cases under investigation. Each case will be briefly outlined discussing the parties involved (actors), the issue at hand (story depiction), pertinent reference to legislation (scripts), as well as a brief discussion of judicial interpretation of legislation. A discourse analysis will conceptualize and situate the language under investigation.

This selection of case law was designed to select pertinent parallel arguments reflecting a dispute between a generic pharmaceutical company and the government of Canada, presented at either the provincial or federal level. The selected case law will be examined based on Hunt and Wickham's Foucaultian theory of attempt to control and failure, in connection with bio-politics and bio-power. The case law under examination will provide basic themes of language, which will form the primary basis of analysis, which will be discussed in the following chapter.

For the interpretations of legislation, the meaning of the words is discerned by examining the words in their particular context.[2] "The true ambiguities in a statute exist only where the meaning remains unclear after a full contextual analysis."[3] The first step in an

[1] Shoppers Drug Mart Inc. v. Ontario, 2011 ONSC 615, (CanLII), at 2.
[2] Ibid, at 23.
[3] Ibid.

analysis of law is to determine the "pith and substance" or the character of the law. When looking into the "pith and substance of the law" the court must reference ss. 91 and 92, to inquire, "What is the "matter" with the law? [4] Furthermore, there are two aspects of the law, which must be examined: the purpose of the enacting body, and the legal effect of the law. [5]

"The second step is to classify that essential character by examining the *Constitution Act, 1982*, in order to determine whether the law comes within the jurisdiction of the enacting government."[6] Based on the examined case law, it is necessary to see whether the law is within the scope of government (intra vires) or beyond the scope of government (ultra vires).

5.1 - Shoppers Drug Mart Inc. v. Ontario (Minister of Health and Long Term Care)

The applicant Shoppers Drug Mart challenged the validity of the regulations concerning the sale of prescription drugs in the province of Ontario. This case was heard in the Ontario Superior Court. These new rules imposed in 2010, banned "private label" generic drugs from being sold on the same basis as other generic drugs.[7] As previously discussed, a private label drug is identical to other generic drugs, and identical in formula to the name brand originator drug, for which it seeks to be interchangeable.[8] The difference between private label generic drugs and other generic drugs is the nature of ownership or control of the company which manufacturers it. The applicant, Shoppers Drug Mart owns

[4] Ibid, at 27.
[5] Ibid.
[6] Ibid.
[7] Ibid.
[8] ibid.

Sanis, a company that manufactures generic drugs. The issue at hand is that new legislation imposed by the Ontario provincial government prohibits Shoppers Drug Mart's ability to substitute their private label generic drugs for brand name drugs. However there is an ongoing inter-play between two varying discourses, the provincial and the federal government, both in attempts to control and regulate pharmaceuticals in Canada.

This particular case outlines several pieces of pertinent legislation and case law by which pharmaceutical conduct in Canada must adhere. The provincial legislation of Ontario, imposes controls on the sale of prescription medication through two separate, yet interconnected pieces of legislation, the Ontario Drug Benefit Act (ODBA)[9] and the Drug Interchangeability and Dispensing Fee Act (DIDFA).[10]

The court made reference to *Apotex Inc. v. Ontario (Minister of Health) 2004*,[11] discussing the purpose of the DIDFA and ODBA, explaining the Court of Appeal held that

> the purpose of the system is to allow pharmacists to be able to supply a prescribed drug in the cheapest form possible, both to persons who pay for the drugs themselves and to those who qualify to have the government pay for their drugs.[12]

The court drew attention to this pertinent case law in order to clarify the purpose for the two pieces of legislation, which is to make prescription medications accessible to the

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[9] *Ontario Drug Benefit Act* (ODBA) was enacted by Bill 54, S.O 1986, c.27.
[10] *Drug Interchangeability and Dispensing Fee Act* (DIDFA), was originally entitled the *Prescription Cost Regulation Act*, and was enacted by Bill 55, S.O. 1986, c. 28.
[11] *Apotex Inc. v. Ontario* (Minister of Health) (2004), 73 O.R. (3rd) 1. (C.A.)
[12] Supra, see note 1, at 3.

public at a lower cost.[13] Additionally, the court stated that under both acts, the Lieutenant Governor in council is given the regulation-making authority.[14] These provisions are outlined in the DIDFA, found in s. 14(1), which states,

> 14.(1) The Lieutenant Governor in Council may make regulations,
> (a) prescribing the conditions to be met by products or by manufacturers of the products in order to be designated as interchangeable with other products;
> (b) prescribing conditions to be met for a product to continue to be designates as interchangeable;[15]

The ODBA follows a similar narrative concerning the regulation-making powers, which are outlined in s. 18(1):

> 18.(1) The Lieutenant Governor in Council may make regulations,
> (0.a) defining any word or expression used in this Act but not defined in this Act;
> ...
> (b) prescribing conditions to be met for a drug product to be designated as a listed drug product;
> (b.1) prescribing conditions to be met for a listed drug product to continue to be designated as a listed drug product;
> ....
> (m) respecting any matter considered necessary or advisable to carry out the intent and purposes of this Act.[16]

This reference to previous changes in legislation and the consequences thereof, by calling up previous price controls imposed by the prior changes to the *DIDFA* and *ODBA*, which occurred in 2006.[17] This is relevant to current changes imposed by the Ontario government because we can see a pattern of attempts to control. Providing a history of

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[13] Ibid.
[14] Ibid, at 4.
[15] Ibid.
[16] Ibid.
[17] Ibid.

the province of Ontario's attempts to regulate and control the pharmaceutical market provides us with information to establish a critical analysis.

Prior to 2006, the *DIDFA* stipulated that pharmacies must charge the lowest price for the drug, which was outlined in the drug inventory. [18] Additionally, prior to 2006, price controls were fixed under the *ODBA*, which would pay generic drugs based on the "70/90 rule."[19] This rule stated that the first generic drug to apply for listing in the drug formulary, after the original patent expiry date, would be priced at 70% of the originator or brand name drug.[20] The following drug would be listed at 90% of the price of the first generic drug listed. Logically, this would result in the originator drug dropping its price in order to remain competitive.[21] Prior to 2006, the generic pharmaceuticals were listed at 63% of the competitor brand name pharmaceutical. These price controls were challenged by *Apotex Inc. v. Ontario (Minister of Health)(2004),* however the court ruled that it was within the jurisdiction *(intra vires)* of the province of Ontario to impose these conditions.[22]

After 2006, further amendments were made to the *ODBA* and the *DIDFA*. Ontario greatly reduced the price they would pay for generic pharmaceuticals from 63% to 50% of the originator name brand drug. Additionally, dispensing fees were raised, however drug

[18] Ibid.
[19] Ibid.
[20] Ibid, at 5.
[21] Ibid.
[22] Ibid.

mark ups were reduced from 10% to 8%.[23] In 2006, Ontario banned rebates, but imposed "professional allowances" which were to be applied to patient care.[24]

The Amendments of 2010 came into force on July 1, 2010 and are expected to apply into fruition by April 1, 2013.[25] The new amendments will eliminate the "professional allowances" introduced by the 2006 amendments. Additionally, the prices the Ontario government would pay for generic drugs were reduced to 25% of the originator or name brand drug. Furthermore, $100 million was allocated for the increase in pharmaceutical development and professional services. [26] A fee schedule for professional services will be created in order to monitor this new development.[27] This parallels the government's allocation of additional pharmaceutical duties aforementioned in chapter two.

The court called upon the Supreme Court of Canada's decision of the *United Taxi Drivers' Fellowship of Southern Alberta v. Calgary (city),* in order to establish a standard of review.[28] In *United Taxi Drivers' Fellowship of Southern Alberta v. Calgary (city),* the court established that whenever there is a question of regulation which is held to be beyond the scope of government or *ultra vires,* that its enabling statute "will always be reviewed on a standard of correctness."[29] The court ruled that when the regulatory measures of statutes are called into question they must always be examined by an ultra

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[23] Ibid.
[24] Ibid.
[25] Ibid, at 6.
[26] Ibid, at 6.
[27] Ibid, at 6.
[28] *United Taxi Drivers' Fellowship v. Calgary (city),* (2004) 1 S.C.R. 485, at para 5.
[29] Ibid, at para 5.

vires analysis, which "involved some degree of deference to matters of government policy."[30]

The court's investigation into the pith and substance of the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act* was based on a contextual and liberal interpretation that is consistent with the intention of parliament.[31] The contextual approach requires that the language of an Act "be read in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of parliament."[32] This form of interpretation resulted in the final ruling that the regulations imposed by the Ontario government,

> 1.) fell outside the regulation-making authority which empowered action on behalf of the parent statute, in particular because the regulations were set out to prohibit rather than regulate.
> 2.) The new prohibitions do not fall within the purpose of the parent statute, which inevitably results in ...
> 3) an interference with property and commercial rights to trade, that is not expressly authorized by the parent statute. In short, the prohibitions set out to target private label generic pharmaceuticals (Shoppers Drug Mart private label generics) was *ultra vires,* and of no force and effect, meaning beyond the scope of provincial legislation. [33]

If we refer back to the production/performative stage, the provincial government imposed a script which the Superior Court ruled deviates from the original intended purpose of the act. This deviation of script results in a tension whereby the actor (Shoppers Drug Mart) is able to "ad lib," resulting in financial gains for their company.

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[30] Supra see note 1, at 8.
[31] Ibid, at 5.
[32] Ibid, at 8.
[33] Ibid, at 9.

5.2 - Canadian Generic Pharmaceutical Association v. Minister of Health and The Attorney General of Canada and Canada's Research-Based Pharmaceutical Companies, 2009[FEDERAL COURT]

The Canadian Generic Pharmaceutical Association (Apotex) sought judicial review, calling into question the 2006 amendments, which enacted section C.08.004.2 (the Data Protection Regulation) of the *Food and Drug Regulations*, C.R.C, c.870 (the FDA Regulations)(the Act). This dispute was between the Canadian Pharmaceutical Association, the Minister of Health and the Attorney General of Canada, which was heard in federal Court. "The applicant declared that the *Data Protection Regulations* were beyond the scope (*ultra vires*) and were without legal force and effect and other related remedies"[34]

This case raises the question of *ultra vires*, interrogating the jurisdictional authority in the matter of pharmaceuticals. Constitutional law is at the heart of this *ultra vires* argument, calling into question the authority of the federal government. This case is positioned within the confines of federal jurisdiction which has particular obligations to implementing data protection provisions, evident in the *North American Free-trade Agreement* (NAFTA) and the agreement of *Trade-Related Aspects of Intellectual Property Rights* (TRIPS), which were outlined in chapter three.[35] Additionally, the federal Government is responsible for regulation of competition.

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[34] *Canadian Generic Pharmaceutical Association v. Minister of Health and The Attorney General of Canada,* (2009) FC 725(CanLII), at 1.
[35] Ibid, at 4.

The issue at hand is whether "the parliament of Canada has the constitutional authority to enact subsection 30(3) of the *Food and Drug Act* and the Data Protection Regulation, additionally whether the Governor in Council may enact the Data Protection Regulation form."[36] The substantive issues addressed by the court included:

1. Is the *Data Protection Regulation intra vires* the federal legislative powers pursuant to subsection 91(27) of the *Constitution Act, 1982*?
2. In subsection 30(3) of the *Food and Drug Act* and the *Data Protection Regulation intra vires* the federal legislative powers as being enacted to the international trade agreements NAFTA and TRIPS under:
    a) the general regulation of trade and commerce branch of subsection 91(2);
    Or
    b) The national concern branch of the peace, order, and good government power (POGG).
3. Is the Data Protection Regulation invalid:
    a) For not being rationally connected to the grant of authority in subsection 30(3) of the *Food and Drug Act*; or
    b) Because the enabling provision, subsection 30(3), is an impermissible sub-delegation by parliament of international treaty implementation responsibility.[37]

Section 08.004.1 of the *Food and Drug Act* regulations is described in the Regulatory Impact Assessment Statement (RIAS) as a data protection provision. The Governor in Council who has the authority to impose regulations, enacted this amendment pursuant of subsection 30(3) of the *Food and Drug Act*, which states.

> Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations as the Governor in Council deems necessary for the purpose of implementing, in relation to drugs, Article 1711 of the North American Free Trade Agreement or paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the WTO Agreement.[38]

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[36] Ibid, at 4.
[37] Ibid, at 19.
[38] Food and Drugs Act (R.S.C., 1985, c. F-27).

Pertinent reference to authority included *Bayer v. Canada (Attorney General),(1998) F. C. J. No. 1560* which sought judicial review for the first version of c. 08.004.1 of the *Food and Drug Act* calling for a protection period for innovator drugs from competition by generic manufacturers. This case stated the Regulatory Impact Assessment Statement (data protection provision) was introduced to ensure Canada's compliance with NAFTA.[39] Here we see evidence of federal jurisdiction enacting provision which support data protection of originator pharmaceuticals, while keeping in mind the many alternative Acts and agreements such as NAFTA, TRIPS, the *Competition Act* and the welfare of Canadian health. Alternatively, this case in itself performed a discourse analysis, examining the definition of what constitutes a "new drug" interpreting the provisions and regulations outlined in the Act.

Furthermore, the judge ruled that the regulations imposed on how a new generic drug came into the market in Canada was so regulated in nature that it performs a routinized sequence of events: first, filing of an "Abbreviated New Drug Submission (ANDS), second, an examination of previous information filed by the originator drug company, i.e. their " New Drug Submission"(NDS), and third, reliance on information by the Minister on the issuance of a "Notice of Compliance"(NOC) for the (ANDS) generic drug.[40] This routinization of medical science reflects adherence to a script like structure, evident in Goffman and Gagnon's work, as well as the work of Foucault. The court ruled that it is within federal jurisdiction to preside over matters concerning *Data Protection*

[39] Supra, see note 35, at 16.
[40] Ibid, at 17.

Regulations Subsection 30(3), and regulation of Trade and Commerce, subsection 91(2) of the *Constitution Act, 1982.*

Additional authority through case law was referenced using *RJR-MacDonald Inc. v. Canada (Attorney General)(1995)* 3 S.C.R. 199, at para 32 citing

> ... it is important to emphasize once again the plenary nature of the criminal law power. In the Margarine Reference, supra, at pp. 49-50, Rand J. made it clear that the protection of "health" is one of the "ordinary ends" served by criminal law, and the criminal law power may validly be used to safeguard the public from any "injurious or undesirable effect." The scope of the federal power to create criminal legislation with respect to health matters is broad, and is circumscribed only by the requirements that the legislation must contain a prohibition accompanied by a penal sanction and must be directed at a legitimate public health evil. If a given piece of federal legislation contains these features, and if that legislation is not otherwise a "colorable" intrusion upon provincial jurisdiction, then it is valid as criminal law.[41]

RJM-MacDonald is pertinent authority in the examination of a *vires* argument because when calling into question the jurisdictional authority of federal legislation one must question the intended purpose or intent of the legislation when originally imposed. The final line making reference to "legislation is not otherwise a "colorable" intrusion upon provincial jurisdiction..." is of great importance because colorable legislation can be explained as legislation that is passed off as being within the scope of government authority (*intra vires*), however, is beyond the scope of government within its effects (*ultra vires*).[42] Likewise, colorable legislation can be described as "when the effects of

[41] Supra, see note 35 at 28.
[42] Stuart,D.,Delisle, R.J & S. Coughlan. Learning Canadian Criminal Law. 11th ed. (Toronto: Thomson Reuters 2009), at 11.

the law diverge substantially from the stated aim."[43] The prohibition aforementioned above in this case pertains to section C. 08.002 of the *Food and Drug Act,* which imposes restrictions on the sale of new drugs unless specific conditions are achieved.[44]

The court ruled that the Standard of Review by the joint application of the Canadian Generic Pharmaceutical Association (CGPA) and *Apotex Inc.* were based on an *ultra vires* argument and therefore warranted the standard of review of correctness, substantiating their argument based on

> *Dunsmuir v. New Brunswick,* (2008) SCC 9, at para 58
> *Nanaimo (city) v. Rascal Trucking Ltd., (2000)* 1. S.C.R. 342
> *Westcoast Energry Inc v. Canada (National Energy Board, (1998) 1* S.C.R. 322.[45]

Judicial interpretation of this case was based on a contextual approach, whereby Canada submits that the *Data Protection Regulation* must be considered in the context of the entire drug regulation process, which was established by parliament in order to protect public safety.[46] Canada found that protecting public health and safety is a valid exercise within the jurisdictional authority of the federal government, under subsection 91(27) of the *Constitution Act, 1982.*[47]

The court ruled that the *Data Protection Regulation* was *ultra vires* because the pith and substance of the regulations were directed at the balancing of commercial considerations between brand name innovator pharmaceutical companies and generic pharmaceutical

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[43] Supra, see note 2, at 27.
[44] Supra, see note 35, at 28.
[45] Ibid, at 20.
[46] Ibid, at 27.
[47] Ibid, at 28.

companies from the agreements of international trade.[48] Additionally the court ruled, that the *Data Protection Regulation* has a national economic dimension due to Canada's obligations pursuant to international trade and commerce, and is a matter, which the provinces cannot address legislatively, individually, or collectively, as it is beyond provincial scope (*ultra vires).*[49] The court ruled that the requirements imposed by the Canadian government to introduce a new drug to the Canadian market are consistent with the requirements in the NAFTA and the TRIPS agreements.[50]

This case examined the various roles and duties of the federal government, relating to various scripts and narratives taking part on both the national and international stage. The duty of the federal government not only to attempt to impose regulations through direction, but also to pose as an actor on the world stage, with adherence NAFTA and TRIPS agreements.

5.3 - Apotex Inc., v. Executive Officer for the Ontario Public Drug Programs and Attorney General of Ontario, (2009) [PROVINCIAL COURT]

The applicant sought judicial review for the pricing of generic drugs listed under the Ontario Drug Benefit Act. This matter was heard in the Superior Court of Justice in Ontario, between Apotex Inc. and the Executive Officer of the Ontario Public Drug Programs and Attorney General of Ontario.[51] The issue raised pertained to the refusal by the Executive Officer ("E.O.") of the Ontario Public Drug Programs to increase the

[48] Ibid, at 60.
[49] Ibid.
[50] Ibid.
[51] Apotex Inc. v. Executive Officer for the Ontario Drug Programs and Attorney General of Ontario (2009) ONSC (CanLII), at 1

reimbursement pricing of three generic antibiotic drugs, as listed in the Formulary maintained under the *ODBA*.[52]

The applicant, Apotex Inc., requested judicial review regarding the amendments made to the *ODBA* concerning the January 2008 Decision, stating that the decisions were "unlawful, arbitrary, unreasonable, discriminatory and unfair."[53] Furthermore, Apotex sought a mandatory order requiring the E.O. to list its products on the Formulary at the prices granted to its competitor Novopharm. Additionally, the applicant sought a mandatory order by the court that the request of price increase of January 2009 Decision of the E.O. be over turned.[54] It is evident that this issue raises question concerning authority of the E.O. and competition, concerning the regulation of price controls.

"The Executive Officer (E.O.) is appointed by the Lieutenant Governor in Council pursuant to section 1.1(1) of the *ODBA*."[55] The E.O. is responsible for the administration of the Ontario Public Drug Programs. [56] These programs involve the interaction and applications of complementary legislation to provide drugs at a responsible cost to the public, ensuring accessibility.[57]

This matter started in 2007, when the generic manufacturer Apotex, was concerned over the increased price in drug production. [58] Apotex advised the E.O. it would be increasing

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[52] Ibid, at 1.
[53] Ibid, at 2.
[54] Ibid.
[55] Ibid.
[56] Ibid.
[57] Ibid.
[58] Ibid, at 4.

their prices on three generic antibiotic products, and if their application for price increase was denied, the applicants would have to remove their products from the drug formulary.[59] Apotex, along with five other companies that manufacture the antibiotics in question, requested that their drugs be delisted from the formulary due to the increase cost in production, at the same time.[60] The E.O. argued that no company had the authority to increase their price unless they were subject to the single price source exemption. The drug manufacturers were not content with the legislative changes of 2008, because of the price reduction, the province of Ontario limited the price generic manufacturers could charge for drugs listed in the Ontario Drug Formulary.[61]

The E.O. sought advice from the medical community, as a result of the inquiries, she ruled that the "removal of these drugs from the Formulary would pose significant health and safety concerns for drug benefit customers, as these antibiotics are more effective than others listed on the Formulary for treating certain medical conditions." The E.O. exercised her authority pursuant to section 19 of the ODBA which, provides:

> In deciding whether or not to designate a drug product as a listed drug product or to remove such a designation, the Executive Officer may consider anything he or she considers advisable in the public interest, including, without limiting the generality of the foregoing, the drug benefit price of the drug product or other drug products or the price charged to operators of pharmacies for the drug product or other drug products.[62]

The above quote highlights a script-like narrative of the welfare state, rooted in notions of healthcare for the good of the population. We see that the E.O.'s decision was dependent

[59] Ibid.
[60] Ibid, at 6.
[61] Ibid, at 4.
[62] Ibid, at 6.

on consultation from important "specialists" within the medical community. This relates to Foucault's discussion on the power of knowledge and the knowledge of the medicalized "specialist."

The strategy the E.O. used for responding to this issue was ensuring that the last generic manufacturer (Novopharm) who requested to be removed from the drug Formulary could meet the required supply of pharmaceuticals for the drug benefit program.[63] The E.O. then removed the other five generic drug manufacturers who requested to be delisted, thereby enacting the "single source exemption rule." The E.O. then negotiated an increased price for the drugs in question with the remaining manufacturer. [64] These actions raised controversy for Apotex, arguing that their drug be relisted on the Formulary at the same price as its competitor Novopharm. The court noted that Apotex asked to be removed from the formulary and asked to be reinstated after the E.O.'s actions gave Novopharm the competitive advantage.[65] Hence, as previously mentioned Apotex called into question the action of the E.O. based on the 2008 Decisions which were "unlawful, arbitrary, unreasonable, discriminatory and unfair."[66]

In 2006, the Ontario Government passed a series of amendments to the ODBA and the DIDFA. Included in these new provisions was the *Transparent Drug System for Patients Act,* 2006, S.O. c. 14. These new amendments reflected the government's attempt to

[63] Ibid, at 7.
[64] Ibid.
[65] Ibid.
[66] Ibid, at 2.

control the cost of generic pharmaceuticals.[67] Two exceptions were enacted by the Amendments of 2006, concerning generic price controls to the "50% rule." The first exemption includes those generic drugs that are the only originator equivalent on the market. [68]The price of this drug may be negotiated with the E.O. to exceed the 50% rule, due to high demand. This is known as the "single source pricing exemption."[69] The second exemption is when the price of a generic drug and the originator drug have the same drug benefit price on the drug Formulary, the generic manufacturer can negotiate price with the E.O. [70] This second exemption is known as the "historic pricing exemption."[71]

Due to the amendments to the Ontario Drug Formulary on January 15, 2008 ("the 2008 decisions"), new provisions were imposed which allowed generic manufacturers to apply for price variations due to an increased cost of raw materials necessary to produce their product.[72] Accordingly, Apotex applied for a price increase for three generic antibiotic medications in December 2008. The E.O. responded January 19, 2009, by granting a modest increase in price, not the amount requested by Apotex. Apotex argued that "jurisprudence provides that legislation and regulations cannot be interpreted to provide an absurd result," further continuing that, "if the regulations, in fact, mandates an absurd result, then you have a duty to seek an immediate amendment."[73] The three generic drugs in question were subject to exemption on the grounds that they fell into the second

[67] Ibid, at 3.
[68] Ibid.
[69] Ibid.
[70] Ibid.
[71] Ibid.
[72] Ibid, at 1.
[73] Ibid, at 5.

category, whereby the prices of the originator drugs were not listed on the Formulary. Pertinent case law used as authority in this case was *Apotex Inc. v. Ontario (Public Drug Programs)(2008),* 241 O.C.A 47 (Div. Ct.). This case was used to establish Apotex unsuccessful history of challenging aspects of the Ontario Health Legislation.[74]

The court ruled that the appropriate standard of review for this case was the application of reasonableness.[75] The application for a standard of review was based on the E.O.'s interpretation and application of legislation. For this purpose the court called up *Dunsmuir v. New Brunswick, (2008),* 1 S.C.R. 190, at para. 62 to "establish whether the appropriate standard has already been judicially determined for the particular category of question."[76] An example of a category of question when it comes to a *vires* argument would be the application of "correctness standard." Furthermore, *Dunsmuir* found that as long as the interpretation of legislation is reasonable, the court should not interfere.[77]

D*unsmuir* provides that the "standard of correctness" be applied to general questions of law, "that [are] both of central importance to the legal system as a whole and outside the adjudicator's specialized area of expertise."[78] This contrasts to the "standard of reasonableness," which is applicable for specific questions to a particular statutory or administrative regime, which involves "a discrete and special administrative regime in which the decision maker has special expertise."[79] This "standard of reasonableness" is

[74] Ibid, at 3.
[75] Ibid, at 7.
[76] Ibid, at 8.
[77] Ibid.
[78] Ibid.
[79] Ibid.

applicable in this particular case because Apotex has called into question the authority and actions of a particular person of authority, in this case the Executive Officer of the Ontario Drug Programs.

The judicial interpretation relied upon a grammatical/literal approach whereby the language of the *ODBA* and the *DIDFA* were interpreted in their ordinary sense, read within their context and in light of the intent of parliament (legislative purpose).[80] The ruling fell within the purpose and intended legal effect of parliament. The court ruled that the interpretation of the E.O. was within the "range of possible, acceptable outcomes which are defensible in respect of the facts and the law."[81]

The court ruled that it was reasonable for the E.O. to interpret the "single source pricing exemption" under section 12(1)(6.1) of the *ODBA* to read "the last listed" of a "drug product of its type" to allow for a "single source pricing exemption" to apply to drugs which are already listed on the Formulary.[82] Furthermore, the court ruled that it was not within the E.O.'s role to secure immediate legislative changes in response to the demands of drug manufacturers, but to ensure the administration of legislation is followed in light of its intended purposes.[83]

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[80] Ibid, at 12.
[81] Ibid.
[82] Ibid, at 14.
[83] Ibid.

5.4 - Pharmascience Inc. v. Ontario (Minister of Health and Long Term Care), (2007) [PROVINCIAL COURT]

The applicants consisted of a group of seven generic manufacturers: Pharmascience Inc., Ratiopharm Inc., Cobalt Pharmaceuticals Inc., Ranbaxy Pharmaceuticals Canada Inc., Sandoz Canada Inc., Genpharm Inc., and Novopharm Limited (the applicants), who sought judicial review at the Ontario Superior Court of Justice against the Minister of Health and Long Term Care, Executive Officer of the Ontario Public Drug Programs, Lieutenant Governor in Council and Attorney General of Canada (the Ministry).[84]

The applicants sought judicial review of the Ministry's decision pertaining to the designation of Apotex Inc. version of Lisinopril, as a benefit under the *ODBA*. The applicant's argument was based on the interpretation of the *ODBA* and the *DIDFA*. The applicants argument was rooted in section 12(1)(e) of the *ODBA* which outline the necessary regulations of pharmaceuticals in issue:

> 1) A strength form of a drug shall not be designated as a listed product unless the manufacturer of the drug product submits to the Executive Officer...
>
> e.) evidence that the manufacturer is able to supply the product at the proposed drug benefit price in a quantity sufficient to meet the anticipated demand for the product.

Simply put, the issue at hand was that the applicants believed that Apotex could not have met the required supply pre-condition outlined in the *ODBA*, at the date of its application for its product to be designated on October 3rd, 2007.[85] Apotex was bound by an

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[84] *Pharmascience Inc., et al. v. Minister of Health and Long Term Care et. al.,* (2007)ONSC (CanLII) 50601., at 1.
[85] Ibid, at 4.

injunction, which regulated the generic manufacturers' ability to have the product in hand, or have the capability of making the product until the patent expiration date of the originator drug, which was dated for October 16th, 2007.[86] If Apotex did have access to the product or have the product on hand by October 3rd 2007, then the company breached the aforementioned injunction, imposed by the federal Court.[87] Here is another case where we see the difference between jurisdictional authorities, transcending the border from provincial legislation, concerning matters of federal legislation.

The applicants argued that the E.O. "failed to adhere to the plain meaning of the legislation that mandated compliance on a *present* as opposed to a *prospective* basis"[88] Furthermore, the applicants argued that the E.O. and staff failed to comply with their own protocol on "transparency," and "the duty of fairness."[89] The applicants argued the there is a judicially pronounced "duty of fairness" which results in a consistent manner of treatment, which was ignored in this particular case.[90] Apotex had many chances to adhere to the guidelines and standards imposed by the industry, yet the judiciary ignored these actions. These regulatory embodiments pertain to the requirements of health policy, such examples include the issuance of information, time lines, and adherence to applications for filing.[91] Therefore, the applicants argued that "the Ministry did not hold Apotex to the same standard to which they believed they were subjected both by operation of statute and the practice, acted manifestly unfairly, preferentially and

[86] Ibid.
[87] Ibid.
[88] Ibid, at 5.
[89] Ibid.
[90] Ibid.
[91] Ibid.

unlawfully."[92] This question of unfairness directly relates to matters concerning competition.

Pertinent reference to authority included previous case law concerning Apotex Inc. calling upon *Apotex Inc. v. Ontario (Minister of Health and Long Term Care)(2006)* O.J. no. 5141, substantiating the judicial claim that economic loss, although extensive should not be the necessary drive to find a verdict.[93] Furthermore, the applicants argument called upon, *Mt Sinai Hospital Centre v. Quebec (Minister of Health and Social Services)(2000), 200 D.L.R (4th) 193 and McLachlin CJC in Baker v. Canada (Minister of Citizenship and Immigration)(1999) S.C.J. No. 39 at 40,* to substantiate the applicants claim that a change in the ministerial position, gives rise to the principle and consequences of "legitimate expectation."[94] This term explains that the Ministry is responsible to follow past practices, unless notice is given to all those affected that the rules and regulations of the DIDFA or the ODBA have been changed.[95] This is important to the applicant's argument because they claimed that if they (generic manufacturers) had known that the requirements changed based on the "prospective assurance and representations," then each of them would have applied to have their own products designated as a benefit on the Ontario drug Formulary.[96] This argument was based on the preferential treatment allotted to Apotex.

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[92] Ibid.
[93] Ibid, at 2.
[94] Ibid, at 6.
[95] Ibid.
[96] Ibid.

Furthermore, additional pertinent authority highlighted in *Kerr v. Danier Leather (2005),* 77 O.R (3r) 321 at para 81 et seq. This instructive case law was used to examine the question of time period concerning Apotex Inc.'s ability to produce the pharmaceuticals. The judge ruled that

> the time period that is relevant to the issue of supply is not necessarily the date of the application, but, the date when the pharmacies are actually called upon to fill the prescriptions with the designated product, which is some four weeks, at least, down the road.

The method of interpretation was based on a contextual analysis of the factual information on hand paired with a literal interpretation of text.[97] The judge ruled that the interpretation of the words ".. is able to supply the product..." " ... to meet the anticipated demand for the product....." was interpreted correctly.[98] The court ruled that the interpretation called into play in this case did not concern questions of fact, necessary to call upon the expertise of the E.O.[99] This was a matter of statutory interpretation, which engages a correctness standard.[100] The final ruling on this case was that Apotex was not given preferential treatment, but participated in an ongoing dialogue with the Ministry, which was deemed "business as usual."[101] The issue at hand was that applicants were disgruntled not by the application process *per se,* but from the fact the Apotex had a pre-existing NOC for a product and because it never lost its designation as an interchangeable product in the *DIDFA.*[102] The judge ruled that Apotex was the only generic manufacturer who could apply for designation by the October Formulary date,

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[97] Ibid, at 7.
[98] Ibid, at 8.
[99] Ibid, at 7.
[100] Ibid.
[101] Ibid, at 11.
[102] Ibid, at 12.

and therefore saw no unforeseen reason to inhibit the process. Additionally, the judge ruled that the Ministry, abided by its mandate to "insure that the public drug system met the needs of Ontarians, as patients, consumers, and taxpayers, was obliged to ensure that an interchangeable ACE inhibitor was available as soon as was practically possible."[103] This language particularly speaks to the role of government and their actions, which are "mandated" or scripted for the betterment of the population.

5.5 - Apotex v. AstraZeneca Canada Inc., Minister of Health and Attorney General of Canada (2006) Indexed as AstraZeneca Canada Inc. v. Canada (Minister of Health)(2006) SCC 49.

This matter arose in the Supreme Court of Canada between the appellant *Apotex Inc. v. AstraZeneca Canada Inc. and the Minister of Health.* This matter fell within the federal jurisdiction of Canada. AstraZeneca Canada is an innovator drug company for which Apotex Inc. applied for the "bioequivalent" generic product to treat acidic stomach conditions.[104]

The issue at hand was the innovator company (AstraZeneca) continued to list new patents, which were associated with a drug even though the original drug had been withdrawn from the market.[105] In 1989 the respondent AstraZeneca obtained a NOC from the Minister of Health, enabling it to market its drug Omeprazole.[106] It was marketed in Canada as *Losec 20* from 1989 to 1996, when the company had removed it from the

[103] Ibid.
[104] *AstraZeneca Canada Inc. v. Minister of Health and Attorney General of Canada* (2006) SCC 49, at 2.
[105] Ibid, at 5.
[106] Ibid, at 3.

market to replace it with another drug. The patent for *Losec 20* expired in 1999.[107] Since then the innovator company, AstraZeneca obtained and registered two patents associated with *Losec 20*, however did not incorporate this new technology into any of their products. The appellant, Apotex Inc., filed for an ANDS (Abbreviated New Drug Submission) for a NOC of its generic version of Omeprazole, comparing their product to AstraZeneca's 1989 version of *Losec 20*. [108]The Minister determined that Apotex was not required to address the "after-issue" patents and issued the company an NOC in 2004. AstraZeneca applied for judicial review of this decision, whereby the decision of the judge was upheld, for Apotex to keep their NOC.[109] However, this matter further was discussed in the federal Court of Appeal, whereby the decision was overturned resulting in Apotex losing their NOC.[110]

This case highlights the various procedural and legislative mechanisms of control, which may be imposed on generic manufacturers to impede competition. This case explains that under the *Patent Medicines (Notice of Compliance) Regulations* ("NOC Regulations"), a generic manufacturer that is not prepared to await the expiry date of patents, must challenge their validity or applicability to its proposed product.[111] Through a Notice of Allegation an innovator pharmaceutical company may apply for an order prohibiting the issuance of a NOC to the generic company, based on the "relevance, validity, and applicability of the listed patents."[112] This application triggers a 24-month "statutory

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[107] Ibid.
[108] Ibid.
[109] Ibid.
[110] Ibid.
[111] *Patented Medicines* (Notice of Compliance) Regulations, SOR/93-133, ss. 3(3),4,5,6,7,8
[112] Supra, see note 105, at 3.

freeze" on the issuance of a NOC to a generic pharmaceutical. This process of statutory freeze can be used as a strategic game enabling further monopolization of a product. This ensures that the generic "copy-cat" will not be available to market. This process may result in "ever-greening" product indefinitely. AstraZeneca's interpretation of the NOC Regulations, would trigger an indefinite series of 24-month statutory freezes.[113] This interpretation however was rejected. The scope of protection to which the innovator drug company is entitled is predicted under the *Patent Act*, which refers to drugs, which are added to patents afterwards.[114] This regulation states that the "patentee must link the submission to the patent list to which it relates, which further ensures that the Minister is capable of identifying patents relevant to the "early working" drug by the generic manufacturer in attempt to "copy-cat" the originator.[115]

NOC Regulations lie in the intersection of two regulatory regimes. First, the law governing the approval of new drugs falls within the federal jurisdiction, mandated to ensure the safety of the population. Under the federal legislation lies the *Food and Drug Act,* and *Food and Drug Regulations*, which are mandated to "bring safe and effective medicines to market to advance the nation's health."[116] The secondary and overlapping mechanism, still existing under federal jurisdiction is the *Patent Act.* This regulatory system, in exchange for full disclosure to the public of an invention of a medication, protects the exclusive rights to the innovator drug for a period of 20 years. These two

[113] Ibid, at 4.
[114] Ibid.
[115] Ibid.
[116] Ibid, at 7.

regulatory regimes were kept separate until 1993, however jurisdictional authority today is overlapping, blurring the lines of regulation and prohibition.[117]

Federal jurisdiction is concerned with issues of patent protection and all statutes which fall under federal jurisdiction. Parliament must find this balance between allocating patent privileges to the originator (brand name) pharmaceutical companies and ensuring that the monopolization of patents does not occur, giving space for generic pharmaceuticals, thereby opening up access to affordable health care for the population.[118] It is evident that there is an ongoing dialogue, constantly challenging the pith and substance of health policy. There is an ongoing exploration further delving into the purpose and legal effect of current legislation.

This case highlighted the attempts to control and the failures of government through the implementation of *Bill-91*, in 1993, which was introduced to apply an exemption from owner's patent rights. [119] This permitted generic manufacturers to work on a "copy-cat" drug within the 20-year period (the "early working exception"). This enabled generic manufacturers to work on a drug, in order to obtain a NOC, which would enable them to market their drug as soon as the originator drug's patent expired. [120]This allowed for "stock piling" of generics towards the end of the 20-year expiration dates, allowing for lawful entry into the Canadian market. This exception, however, was overruled once parliament realized it was being abused. This realization enabled parliament to create

[117] Ibid, at 12.
[118] Ibid.
[119] Ibid.
[120] Ibid.

exceptions with implementation of a summary procedure, which was designed to protect originator (name brand) pharmaceutical, as outlined in section 55.2 of the *Patent Act.*[121]

Pertinent selected case law calling upon authority included *Eli Lilly Canada Inc. v. Canada (Minister of Health)(2003)* 3F.C. 140,2003 FCA 24 which called into question that a patent list is submitted in respect of a drug, not of any particular submission.[122] Based on this fact, whereby a patent list focuses on a particular drug, an innovator company could continue "ever-greening" their product indefinitely by marginally changing their product, thereby triggering a statutory freeze for the generic manufacturer.[123] This case examined how legislation can be pitted against each other to inhibit competition, by monopolizing patents. This raises issues in contention with the Competition Act, thereby triggering federal jurisdictional authority.

Additionally, the court called upon *Bell ExpressVu Limited Partnership v. Rex (*2002) 2 S.C.R. 559,2002 SCC42, at para 29, to substantiate in matters concerning the ambiguity of text, " one must consider the 'entire context' of a provision before one can determine if it is reasonably capable of multiple interpretations."[124] This ruling thereby proposes a contextual analysis.

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[121] Ibid.
[122] Ibid, at 18.
[123] Ibid.
[124] Ibid, at 22.

The court ruled that the conflicting interpretations of the N*OC Regulations* was a statutory issue, therefore the standard of review on the point in issue was correctness.[125] Both the contextual and grammatical/literal approach was taken in the interpretation of this case, whereby words were transcribed in their ordinary sense with "the scheme of the Act, the object of the Act, and the intention of parliament"[126]

The judge ruled that Apotex did not claim bioequivalence or take advantage of the early working exception with respect to the technology incorporated in the two "after-issued patents," therefore the *NOC Regulations* concerning a statutory freeze should not apply in this case. [127] Furthermore, The judge ruled that "in matters of drug approval, bioequivalence requires proof, not conjecture. If Apotex claims bioequivalence with *Losec 20* it is important to be precise about what generation of *Losec 20* is the comparator drug."[128] In this case Apotex wished to "copy-cat" the 1989 version. Parliament's stated purpose in authorizing *NOC Regulations* was to permit "early working" of the patented invention. As Apotex did not attempt to use the technology of the two new drugs, which were offsets of the original drug omeprazole, Apotex should not lose their NOC for the 1989 "copy-cat" version of
Omeprazole.[129]

Furthermore, the judge ruled that previous decisions by the federal Court of Appeal to impose the statutory freeze, inevitably undermines the achievement for the balance of

[125] Ibid, at 19.
[126] Ibid, at 20.
[127] Ibid, at 4.
[128] Ibid, at 21.
[129] Ibid, at 25.

structure imposed by parliament between the objectives of *the Food and Drug Act* (making safe and effective drugs accessible to Canadian population) and the *Patent Act* (protecting the rights to patents).

In summation this chapter has presented abstracts of each of the case law under investigation. Each case outlined the parties involved (actors), the issue at hand (story depiction), pertinent reference to legislation (scripts), as well as a brief discussion of judicial interpretation of legislation. These cases have provided basic themes in language, which will further be explored through a discourse analysis in the following chapter.

The following chapter will provide a discourse analysis, which will conceptualize and situate the language under investigation based on three themes, which emerged concerning the "duties of government". These thematic narratives will be examined using the lens of Foucault. Foucault's theories of governmentality, bio-power and bio-politics form the theoretical landscape from which these repetitive narratives will be investigated. Additionally, the following chapter will respond to the thesis question and sub questions under investigation, culminating in the final analysis of health policy and intellectual property for this thesis. These prominent scripts are the backbone upon which current health policy is performed on both the national and international stage.

Chapter Six:

Analysis

Chapter Six: Analysis

Now that the case law has been properly outlined discussing the parties involved (actors), the issue at hand (story depiction), pertinent reference to legislation (scripts), it is time to move into a discourse analysis. The analysis will conceptualize and situate the language under investigation. The patterns in language, which have emerged, are the prominent scripts of the ongoing narrative in the enactment of health policy today.

The re-occurring themes in language, evident by the repetitive narrative of legal discourse will be highlighted in order to examine the intersection of health policy between the various roles of government and intellectual property, by examining name brand and generic pharmaceuticals. The root of this thesis is based on the performative roles of governmental authority. Three themes, which emerged concerning governmental roles, included the duty to protect the health and safety of the population, duty to protect competition and finally the duty of government to adhere to the duties of state. In what follows the discussion will analyze and examine the prominent themes in relation to the five-selected case law. This chapter will now break down what each individual attribute of the rulings previously discussed, dissecting the language of a discourse analysis, adopted through the lens of Foucault.

6.1 - Duty of Government to Care

The first duty of government is of care, ensuring the health and safety of the Canadian population. This section will argue the following narratives are reflective of essentialist and homogenous language a kin to the welfare state. On November 7, 1985 the Minister of Health, the Honorable Murray Elston introduced two bills into the House, stating the new bills "will ensure sound management of the Ontario drug benefit plan, protect all consumers of prescription drugs in Ontario, and re-establish public confidence in our retail drug industry..."[1] These two bills were the ODBA and the DIDFA, which were challenged in *Shopper Drug Mart v. Ontario (Minister of Health and Long Term Care).* The province of Ontario imposes regulations on pharmaceuticals through the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act,* which is "meant to benefit the public by making lower cost generic drugs available as the norm." [2]

Furthermore, the court outlined the purpose of the ODBA, explaining the underlying principles recognized under Section 0.1

1. The public drug system aims to meet the needs of Ontarians, as patients, consumers and tax payers.
2. The public drug system aims to involve consumers and patients in a meaningful way.
3. The public drug system aims to operate transparently to the extent possible for all persons with an interest in the system, including, without being limited to, patients, health care practioners, consumers, manufacturers, wholesalers and pharmacies.
4. The public drug system aims to consistently achieve value for money and ensure the best use of resources at every level of the system.

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[1] Shoppers Drug Mart Inc. v. Ontario, 2011 ONSC 615, (CanLII), at 17
[2] Supra, see note 1, at 3.

In *Canadian Generic Pharmaceutical Association v. Minister of Health and The Attorney General of Canada and Canada's Research-Based Pharmaceutical Companies, 2009,* the complainant challenged the provisions of *Data Protection Regulations*, raising the question *"is the Data Protection Regulation intra vires the federal legislation powers pursuant to section 91(27) of the Constitution Act, 1867?"* The court ruled that the protection of public health and safety is a valid exercise of the federal government's criminal law power. Furthermore, "the essence of the regulatory drug scheme in the FDA Regulations is the prohibition of all drugs except for drugs that are proven to be safe and effective."[3] Furthermore, narratives rooted in the health, safety of the public were evident throughout this case, highlighting the *Margarine Reference* which argued that the protection of "health" is one of the "ordinary ends" served by criminal law, and the criminal law power may validly be used to safeguard the public from any "injurious or undesirable effect." [4] Moreover, that judicial interpretation of drug regulations must be considered within the full context of the process, which was established by parliament in order to protect public safety.[5]

In *Apotex Inc., v. Executive Officer for the Ontario Public Drug Programs and Attorney General of Ontario, (2009),* the complainant challenged the validity of a decision by the Executive Officer concerning the listing and pricing of generic

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[3] *Canadian Generic Pharmaceutical Association v. Minister of Health and The Attorney General of Canada*,(2009) FC 725(CanLII), at 26.
[4] Ibid, at 28.
[5] Ibid, at 27.

pharmaceuticals on the Drug Formulary. This case adhered to the script of health and welfare of the population referencing section 19 of the *ODBA*,

> In deciding whether or not to designate a drug product as a listed drug product or to remove such a designation, the executive officer may consider anything he or she considers advisable in the public interest [...][6]

Furthermore, the notion of "expert opinion" is present in the appointment of the Executive Officer to be the regulation making authority of the *ODBA* and the *DIDFA*. This involves the interpretation of regulations and provisions, which impact the way in which pharmaceutical policy is carried out.[7]

In *Pharmascience Inc. v. Ontario (Minister of Health and Long Term Care), (2007),* the narratives of health benefits were rooted in accessibility of medication.[8] The complainants pharmascience et. al. argued Apotex could not have been able to meet the supply pre-condition, at the date of its application for its product to have been designated under the ODBA.[9] The applicants used section 12 (1)(e) of the ODBA, which stipulates that

> (1)...a drug shall not be designated as a listed product unless the manufacturer of the drug product submits...
> (e)Evidence that the manufacturer is able to supple the product at the proposed dosage drug benefit price in a quantity sufficient to meet the anticipated demand for the product.)[10]

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[6] *Apotex Inc., v. Executive Officer for the Ontario Public Drug Programs and Attorney General of Ontario* (2009) ONSC(CanLII), at 6.
[7] Ibid.
[8] *Pharmascience Inc., et al. v. Minister of Health and Long Term Care et. al.,* (2007)ONSC (CanLII), at 4.
[9] Supra, see note 8, at 4.
[10] Supra, see note 8, at 4.

In AstraZeneca Canada Inc. v. Canada (Minister of Health)(2006), narratives of heath emerged in the objective of the Food and Drug Regulations, arguing that their purpose "is to encourage bringing safe and effective medicines to market to advance that nations' health."[11]

Government's concern for the well-being and health of the population is deeply rooted within the narratives and interpretation of health policy. These scripts reflect that of Foucault's theory on governmentality whereby concern for the health of the population is inherent in the success of state.[12] The repetitive thematic narrative of "government's duty of care" is rooted in governmentality because it focuses on the "dramatic expansion of scope of governmental mechanisms," which are imposed to ensure the health and wellbeing of the population.[13] These governmental mechanisms of control are expressed through the implementation of legislation both at the provincial and federal level. Legislation acts as an authoritative guide or script depicting a norm, which establishes an inherent social structure.[14] The repetitive discourses in health policy can be connected to Hunt and Wickham's discussion on the systemic regularization of "modern medicine," whereby similar repetitive language creates a social understanding of an expected norm of the

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[11] *AstraZeneca Canada Inc. v. Minister of Health and Attorney General of Canada* (2006) SCC 49, at 12

[12] Connell, E. & Alan Hunt, "The HPV Vaccination Campaign: A Project of Moral Regulation in an Era of Bio-politics."(Canadian Journal of Sociology 35(1) 2010), at 76.

[13] Foucault, Michel. 1977. *Discipline and Punish: The Birth of the Prison.* Translated by Alan Sheridan. (New York: Vintage Books), at 87.

[14] Rose, Nikolas, Pat O'Malley & Mariana Valverde "Governmentality" (University of Sydney Australia 2009), at 1.

Canadian health care system. [15] Furthermore, Ewald's interpretation of normalization suggests, norms, which are created in society, impose particular criteria, which regulate human conduct. [16]

Medical knowledge today is based on an inherent discourse of risk. [17] Lupton furthers this argument by stating, Western medicine is directed towards controlling the body, keeping it from subsiding into chaos or disorder, threatened by illness and disease.[18] It is evident based on repetitive discourse above that the government assumes a paternalistic role of authority, taking care of the health of the population. Thus, governmental concern of the welfare of the population is linked welfare to the state.[19] Bio-politics is a great lens through which to examine state intervention, through the regulation of pharmaceuticals. Bio-politics can also be used in the examination of the welfare state, which involves regulatory forms of legislation in order to control the masses in connection to the population, reflective of federal government jurisdiction, or individual health, reflective of the provincial government jurisdiction.[20]

It is easy to relate the mass expansion of pharmaceuticals consumption with the advancement of human sciences. Legislation is constantly evolving in attempt to

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[15]Hunt, Alan & Gary Wickham, *Foucault and Law: Towards a Sociology of Governance.* (Colorado: Pluto Press, 1994), at 11.
[16] Ewald, Francois. 1991. 'Norms, Discipline, and the Law' 30 Representation 138-161, reprinted in Robert Post (ed.) Special Issue: *Law and Order of Culture* (Berkeley: University of California Press),at 150.
[17] Supra, see note 15, at 77.
[18] Lupton, Deborah. *Medicine as Culture: Illness, Disease and the Body in Western Societies* (London: Sage Publications 1994), at 87
[19] Supra, see note 15 at 87.
[20] Supra, see note 12, at 65.

keep up with advancements in prescription pharmaceuticals. This relates to Hunt and Wickham's theory of "attempt to control and failure" as medicine and "ways of knowing" are in constant evolution. There is an ongoing negotiation amongst actors involved in the regulation of health policy and intellectual property in Canada, in attempt to keep up with the technological advancements in science. This ongoing narrative reflects the perpetuity of legislation, in an ongoing cycle of advancement, continually changing, modifying its tactics of control. According to Lupton,

> medical knowledge is regarded not as an incremental progression towards a more refined and better knowledge, but as a series of relative construction which are dependent upon socio-historical settings in which they occur and are constantly renegotiated.[21]

Lupton argues that medical knowledge, like pharmaceutical advancements for example, are constantly evolving, and changing in both time and space, therefore socially and contextually dependent.[22]

6.2 – Duty of Government to Ensure Competition

It is evident that legislation and the various statutes of health policy impose restrictions that create an environment for pharmaceutical competition between generic and brand name pharmaceuticals. The second duty of government is to ensure competition. Competition was a prominent re-occurring theme within the narratives of the selected case law. Especially regarding matters of ensuring "fair" competition as a standard, which must be upheld by governmental authority. All

[21] Supra, see note 15, at 11
[22] Supra, see note 18, at 12.

cases were brought to judicial review due to the fact that legislation or interpretation of legislation inhibited the pharmaceutical companies ability to engage competitively in the Canadian market.

The issue of competition is definitely raised in *Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care)* whereby, the regulations imposed by the *ODBA* and the *DIDFA* prohibit the "*private label*" generic drug of Shoppers to be sold in the province of Ontario.[23] The government regulates the consumption of pharmaceuticals through the impositions of conditions.[24] Furthermore the case stated,

> it is interesting to note that most, if not all, cases involving the distinction between prohibition and regulation involve language that on its face appears to impose conditions, but which in effect constitutes a prohibition. The language in this case however, it is prohibitory on its face.[25]

Furthermore, the court ruled that the regulations concerning private label products

> (1)fell outside the regulation-making authority which empowered action on behalf of the parent statute, in particular because the regulations were set out to prohibit rather than regulate.
> [...] which inevitably results in
> (3) an interference with property and commercial rights to trade, that is not expressly authorized by the parent statute. In short the prohibitions set out to target private label generic pharmaceuticals.[26]

These regulations were found to be prohibitive in nature, which were found to infringe upon the commercial rights to trade, and inevitably the ability prohibited Shoppers from competing in the generic market in Canada.[27]

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[23] Supra, see note 1, at 2.
[24] Supra, see note 1, at 11.
[25] Supra, see note 1, at 11.
[26] Supra, see note 1, at 9.

Likewise, in *Canadian Generic Pharmaceutical Association v. Minister of Health and The Attorney General of Canada and Canada's Research-Based Pharmaceutical Companies, 2009,* the narrative of Competition was prominent in the dialogue between Canadian generic pharmaceutical companies and the Minister of Health et. al. The court ruled that the "regulation of trade and commerce falls within federal jurisdictional authority."[28] Furthermore, it is within the federal jurisdiction to endeavor to "achieve a greater balance between the need for innovative drugs and the need for competition in the marketplace."[29] Moreover, the court ruled the

> *Data Protection Regulations* rounds outs the valid federal drug regulatory scheme, has a national economic dimension because of Canada's obligations pursuant to international trade agreements NAFTA and TRIPS, and is a matter which the provinces cannot address legislatively, individually, or collectively.[30]

In *Apotex Inc., v. Executive Officer for the Ontario Public Drug Programs and Attorney General of Ontario (2009),* narratives of competition were inherent in the ongoing discourse between applicants who sought judicial review of the Executive Officer's decision to grant competitive pricing to their competitor Novopharm.[31] Furthermore, the application argued that the interpretation of the *ODBA* and the *DIDFA* by the Executive Officer resulted in preferential pricing.

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[27] Supra, see note 1, at 23.
[28] Supra, see note 3, at 4.
[29] Supra, see note 3, at 18.
[30] Supra, see note 3, at 61.
[31] Supra, see note 4, at 2.

In *Pharmascience Inc. v. Ontario (Minister of Health and Long Term Care), (2007),* the complainants sought judicial review concerning the accepted application of Apotex's generic drug. The complainants argued that Apotex refused to adhere to the regulations imposed by the conditions outlined in the *DIDFA* and *ODBA.* Additionally, the manner in which the legislation was interpreted gave preferential treatment to Apotex, thereby affording a competitive market advantage.[32] The judge was called upon to determine

> (a) whether Apotex was given an unfair advantage in being able to correct any perceived deficiencies subsequent to the submission date; and
> (b) whether the Applications were prejudiced by this conduct or by the interpretation of the Regulations of which they say they were unaware.[33]

Finally, *AstraZeneca Canada Inc. v. Minister of Health and Attorney General of Canada (2006)* also reflected the narrative of competition. This case dealt with the innovator drug companies' ability to impose mechanisms of control, which prevented the generic drugs form acquiring a NOC.[34] The NOC Regulations provide an innovator drug company like Astra Zeneca with the power to "freeze" for the purpose of assuring patent compliance, furthering their competitive market advantage.[35] Astrazeneca's interpretation of NOC Regulations would result in a process called "Evergreening." Utilized as a commercial strategy this process

> triggers an indefinite series of 24-month statutory freezes, even though such subsequently listed patents are not the subject of "early working" by the generic manufacturer, and from which (as in the

[32] Supra, see note 8, at 5.
[33] Supra, see note 8, at 10.
[34] Supra, see note 11, at 7.
[35] Supra, see note 11, at 7.

> circumstances here) the generic manufacturer derives no advantage.[36]

Also, this case recognized the importance of legislative mechanisms such as the *Patent Act*, reflecting "Parliament's intention to strengthen the protection of patent owners' [rights] against generic competitors within the 20-year patent period."[37]

Furthermore, the court ruled,

> By imposing the 24-month delay called for by the NOC Regulations, the decision of the Federal Court of Appeal undermines [the] achievement of the balance struck by Parliament between the objectives of the FDA and regulations thereunder making safe and effective drugs available to the public) and the Patent Act and its regulations (preventing abuse of the "early working" exceptions to patent infringement).[38]

The duty of government to ensure competition can be analyzed through the lens of Foucault, based on the inclusionary and exclusionary tactics of control, which either enable or disable competition amongst generic and brand name drugs in Canada. These tactics of control or mechanisms can be explored through the implementation of legislation such as the *ODBA*, the *DIDFA*, the *Patent Act,* the *Competition Act*, and the *Food and Drug Act* for example. Also, tactics may be examined from brand name and generic pharmaceutical manufacturers who employ various tactics as commercial strategies of control. This directly relates to Hunt and Wickham's discussion on utilizing "laws themselves as tactics."[39] Ewald would agree with this notion, stating that technologies and tactics of control further empower society in pursuit of a norm. [40] These tactics of control are employed as an exclusionary

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[36] Supra, see note 11, at 19.
[37] Supra, see note 11, at 13.
[38] Supra, see note 11, at 25.
[39] Supra, see note 14, at 52.
[40] Golder & Fitzpatrick. *Foucault's Law* (New York: Routledge-Cavendish, 2009), at 38.

method of knowledge, imposing a scientific hierarchy of knowledge between the brand name manufacturers, generic manufacturers and the government. Further empowerment is also obtained through the adherence to the structural mechanisms of filing of reports, monitoring, inspection, surveillance etc., which are inherently rooted in the ongoing process of pharmaceutical consumption, in connection to intellectual property.

These inclusionary and exclusionary tactics are embedded in Bio-politics, which is rooted in the constant state of truth seeking and the hierarchy of knowledge. For example, Foucault stated that rational forms of knowledge (law, medicine, social sciences, etc.) extend the normative power of the knowledge so that each step towards advancing the health of populations also empowers and expands the institutional mechanisms of control. [41] This also relates to the knowledge, which circulates amongst pharmaceutical manufacturers. Intellectual property rights protect this commodity of medical knowledge, which also can be a mechanism of control.

6.3 – Duty of Government to Adhere to Duties of State

The third duty of government is to adhere to the duties of state. The government plays a dual role, playing both the actor and the director; therefore there is an obligation to adhere to the script. There are many rehearsals before a drug is presented to the public. Likewise, there is a duty imposed on government to not only enact but also abide by those very mechanisms of power, which it creates. The

[41] Supra, see note 12, at 67.

duty to of adherence, through the exploration of the "pith and substance" of each enactment is explored. The forms of legislation, which are enacted by government, are to be carried out in a manner, which is impartial and fair to all parties involved.

In *Shoppers Drug Mart Inc. v. Ontario, (The Minister of Health and Long Term Care)(2011),* the duty and adherence to the roles of government in accordance to the provisions imposed by the "parent statutes" are highlighted in the ongoing dialogue between the provincial duties of the legislation and the federal duties of legislation. The examination of the pith and substance of enabling statutes and the application of those principles therein, were at the heart of the investigation of the *ODBA* and the *DIDFA.* Moreover, the legislative provisions imposed by government create the health system, which is enacted in a routinized structure of conditions.

"The general principle underlying each concept is that executive regulation of power must be exercised in conformity with the legislative authority providing for it and any regulations that not conform have been enacted without jurisdiction."[42] Further discourse relating to the systemic nature of health care in Canada is "The approval of a prescription drug by health Canada is required before that drug can be sold anywhere in the country."[43] There is a constant dialogue referring to the various necessary requirements of the regulation process, which must be accomplished in order for a drug to be accepted in the Canadian market. Often the

[42] Supra, see note 1, at 2.
[43] Supra, see note 1, at 2.

discourse within the legislation further empowers or enables these mechanisms to extend their regulatory-making authority, as expressed by the ruling which states "[...] based on the regulation-making power in s. 18(1)(m) of the ODBA, which authorizes the making of regulations "respecting any matter considered necessary or advisable to carry out the intent and purpose of the Act."[44]

Likewise, in *Canadian Generic Pharmaceutical Association v. Minister of Health and The Attorney General of Canada and Canada's Research-Based Pharmaceutical Companies, 2009,* the necessity and adherence to script is engrained in what the ruling judge depicted as a "routinized sequence of events." [45] This is evident within the explanation of the drug approval process, generally, an originator drug company obtains approval of a new drug by submitting to health Canada

> NDS (New Drug Submission).... Which includes extensive data establishing the safety and efficiency of a new drug. If proven satisfactory by the Minister of Health and his officials, the innovator drug company obtains a NOC (Notice of Compliance)... [46]

Additionally, following this cycle a

> generic manufacturer... who seeks to market a generic version of a drug, previously approved by the Minister of Health,...may submit an...ANDS (Abbreviated New Drugs Submission)... when the generic drug's safety and efficiency is proven, the generic drug manufacturer also obtains a NOC (Notice of Compliance) for its generic product.[47]

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[44] Supra, see note 1, at 13.
[45] Supra, see note 3, at 17.
[46] Supra, see note 3, at 5.
[47] Supra, see note 3, at 5.

Similarly, in *Apotex Inc., v. Executive Officer for the Ontario Public Drug Programs and Attorney General of Ontario, (2009),* the role and decisions of the Executive Officer were challenged. The duty of government as a regulation making authority was explored in the examination of the interpretation of the ODBA and the DIDFA, stating that,

> Jurisprudence provides that legislation and regulations cannot be interpreted to provide an absurd result ... Alternatively, if the regulations, in fact, mandates an absurd result, that you [the regulation making authority] have the duty to seek an immediate amendment.[48]

Furthermore, this case highlighted routinized mechanisms which are to be expected stating, "The law is clear that it is not necessary to engage in a standard of review analysis when the allegation is a denial of natural justice or procedural fairness."[49] This idea of "procedural fairness" is rooted in a narrative of an expected adherence to a particular script.

Also, in *Pharmascience Inc. v. Ontario (Minister of Health and Long Term Care), (2007),* narrative deeply rooted in the necessity of adherence to script by the government are presented in the applicants position stating that the E.O. was incorrect in the interpretation of the ODBA, ..."in failing to follow or adhere to the plain meaning of the legislation that mandated compliance on a present as opposed to a prospective basis."[50] Furthermore, the applicants argued that the E.O. "failed to adhere to its own protocol of transparency, if not the stated and judicially

[48] Supra, see note 4, at 5.
[49] Supra, see note 4, at 8.
[50] Supra, see note 8, at 5.

pronounced duty of fairness..." [51] The applicants argued that there are inconsistencies within the system, and that system "is obliged to impose the same...limits... therein specified on all manufacturers" Furthermore, " The Applicants assert that the Ministry did not hold Apotex to the same standard to which they believed they were subjected both by operation of stature and by practice, acted manifestly unfairly, preferentially and unlawful."[52] It is evident that the system's routinized structure imposed by government creates a standard of fairness, in which all actors involved are to be treated equally.

There is an ongoing dialogue between and amongst actors is understood in a particular language of intellectual property law and health policy. The judge ruled that this "dialogue routinely occurs between members of the association [pharmaceutical manufacturers] and the Ministry as part of the process."[53]

Finally, in *AstraZeneca Canada Inc. v. Minister of Health and Attorney General of Canada (2006),* the necessity to abide by the script was evident in the dialogue between the Federal government's role in finding the balance between protecting patent rights through the Patent Act and NOC Regulations and ensuring access to prescription medications. This case highlights the overlap between legislative regulations, which create a tension within the system of drug regulations. Under the NOC Regulations, there is an intersection of two regulatory systems within sometimes-conflicting objectives

[51] Ibid.
[52] Supra, see note 8, at 5.
[53] Supra, see note 8, at 10.

> First, the law governing approval of new drugs, which seeks to ensure the safety and efficiency of new medications before they can be put on the market. The governing rules are set out in *the Food and Drugs Act*, R.S.C 1985, c. F-27, and the *Food and Drugs Regulations*, C.R.C. 1978, c. 870..... The achievement of this objective is tempered by a second and to some extent overlapping regulatory system created by the Patent Act, R.S.C. 1985, c. P-4[...][54]

Furthermore, parliament is expected to balance the international, federal and provincial duties of government,. This is achieved through various outsourcing of legislative duties, which further imposes limitations on actions concerning health policy in Canada. These various mechanisms of control relate directly to Foucault's discussion on bio-power, which will now be discussed in connection to this discourse analysis.

Inherent in the analysis of the "duty of governmental adherence" is the importance of a created norm. Adherence to these norms, create the basic script of the performance. This theme can be analyzed through the lens of Foucault because it is through the creation of a norm that we define the limits of behavior. This section is deeply rooted in Foucault's theory on bio-politics whereby the stability of the system is maintained through various practices, which regulate the conduct of actions, within the contextual framework of health policy. Adherence to these routinized structures further perpetuates the system, encouraging contribution of an ongoing dialogue between actors. These mechanisms of control homogenize health policy enabling further regulation of pharmaceuticals.

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[54] Supra, see note 11, at 12.

This duty of governmental adherence to the norm, relates to Golder and Fitzpatrick's discussion on how the mechanisms of power are "doomed to repeat itself,"[55] furthermore on Hunt and Wickham's discussion of "attempts to control and failures" [56] because with the evolution of pharmaceuticals, comes the development of new normative standards, further perpetuating this cycle. What is important is the binding of social cohesion in relation to health.

The three prominent narratives of "duties of government," concerning the duty of care, competition and adherence to the script, create the inherent legal fiction upon which we explore the interaction of Canadian health policy and intellectual property. Each of the selected case law has stressed the importance of adherence to these scripts, in order for the enactment of the consumption of pharmaceuticals to take the national and international stage.

Response to Investigative Questions

The following questions act as tools in which I use to interrogate this material, examined through the lens of Foucault.

Q: How does the generic pharmaceutical policy of Canada, reflective in the *Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care)* infringe upon the very rights it is in place to protect, as outlined in the

[55] Supra, see note 40, at 16
[56] Supra, see note 15, at 121.

Competition Act? What is the nature of the relationship between intellectual property and health care policy?

A: In *Shoppers Drug Mart v. Ontario (Minister of Health and Long Term Care),* the judge ruled that the changes to the *ODBA* and the *DIDFA* resulted in prohibitions of Shoppers Drug Mart's private label product from entering the Canadian pharmaceutical market.[57] The judge ruled that these prohibitions were *ultra vires* in their effect, meaning they were beyond the scope of the intended purpose of the legislation. [58] Additionally the court ruled that the government interfered with Shoppers' right to trade and commerce.[59] This thesis argues that the Canadian government allows for the "Abuse of a Dominant Position" and "Prohibition of Dominant Position" in favor of Shoppers Drug Mart, under section 78 and 79 of the *Competition Act.*[60] With the allowance of private label products from Shoppers Drug Mart it greatly impacts brand name companies ability to compete, significantly impacting their "right to trade and commerce."

The nature of the relationship between health policy and intellectual property in Canada can be explained as overlapping. This thesis has demonstrated that there are no clear-cut, black and white narratives, however the interpretation of the scripts is contextually dependent. The federal government must balance all of its required duties, caring for the population's health at the federal and provincial level, encouraging and maintaining trade, commerce and

[57] Supra, see note 1, at 6.
[58] Supra, see note 1, at 2.
[59] Supra, see note 1, at 2.
[60] *Competition Act,* R.C.S., 1995 c. c-34, at s. 78-79

competition, while protecting intellectual property rights of pharmaceuticals. Finally, there is a duty of obligatory adherence to the systemic structures, which perpetuates this performance of pharmaceutical consumption. The adherence to the scripts of regulations further perpetuates the ongoing narratives of consumption.

Q: Does current public health policy concerning pharmaceuticals create a gap for Shoppers Drug Mart? If yes, how so?

- A: This thesis argues that the 2010 amendments to the *ODBA and the DIDFA*, in connection to the *Patent Act,* create a gap which gives preferential treatment to Shoppers Drug Mart, allowing them to monopolize the Canadian the generic market.

The balance of power has dramatically shifted in favor of the generic drug industry. By allowing Shoppers Drug Mart's private label products, Shoppers plays multiple roles of manufacturers, producers, prescribers, and distributers.[61] Furthermore, with the expansion of pharmacists' roles they now can perpetuate scripts counsel and perform minor medical roles (checking blood pressure, taking blood etc.).[62] Additionally, in order to "promote accessibility and low drug costs," the province of Ontario imposed regulations concerning the mandatory issuance of the cheapest product. This

[61] Health Council of Canada "Generic Drug Pricing and Access in Canada: What are the Implications?" (A Commissioned Discussion Paper by SECOR Consulting: 2010), at 5.
[62] Ibid, at 4.

thesis argues that the legislation "impedes and prevents the competitor's ability to enter into, or prevent further participation in the pharmaceutical market."[63] This is due to the fact name brand pharmaceuticals must adhere to the scripts of intellectual property and health policy in Canada, while Shoppers "Life" brand generic is exempt. The production, drug testing, marketing and distribution of the pharmaceutical process is costly and time exhaustive, therefore once patent expiry date of brand name pharmaceuticals lapses, there is no space for competition within the national pharmaceutical market in the province of Ontario between generic and brand name pharmaceuticals.

Q: To what ends do current regulations impinge upon the stakeholder Shoppers Drug Mart?

- A: The decision of *Shopper Drug Mart v. Ontario (Minister of Health and Long Term Care)*, ruled in favor of Shoppers Drug Mart and KATZ Group Canada Inc., presiding that the *ODBA* and the *DIDFA* regulations were prohibitory in nature, ranging beyond the scope of the provincial legislation.[64] If the regulations were held to be within the scope of the regulation-making powers of the parent statutes (*ODBA* and *DIDFA*) then the regulations would significantly impinge upon the stakeholders. However, for the moment this is not the case. This matter has moved to the

[63] Supra see note 60, at s. 79.
[64] Supra, see note 1, at 23.

Court of Appeal of Ontario and will be further examined in light of the Competition Act.

Q: **How does selected case law frame brand name and generic pharmaceuticals in relation to the Competition Act?**

- A: The selected case law frames brand name and generic pharmaceuticals in a thematic narrative, which is rooted in the Competition Act. All cases were brought to the attention of judicial review because the legislation or the interpretation of the legislation by the E.O., infringed upon either the generic or name brand pharmaceutical companies' ability to engage in a fair and competitive market, which is a federal jurisdictional responsibility, outline in the Competition Act.

Q: **Does Shoppers Drug Mart play a direct role in direct-to-consumer advertising in Canada and how does this impose upon the regulations of the Competition Act?**

- A: This thesis argues that although there is no collaborative data or proof of Shoppers Drug Mart's engagement in direct-to-consumer advertising in Canada, it is a requirement of their success. Shoppers is dependent upon the American brand name pharmaceutical companies' ability to market their product before patent expiry date, so when Shoppers distributes their

product, they can rely on consumer knowledge of the originator drug. This knowledge is obtained through advertisements in American broadcasts and the Internet, which escape Canadian Broadcast Standards. The narratives of "try our "Life" brand, it is the same drug, but cheaper," is also supported in legislation, whereby the cheaper prescribed medication must be allocated to the consumer anyway. This further infringes upon section 78 and 79 of the *Competition Act* because generic pharmaceuticals impede competition between brand name pharmaceutical companies once patents have expired.

Shoppers Drug Mart's success is rooted in "Life" brand's effectiveness, functionality, convenience and affordability for community consumers. In effective, their brand loyalty is deeply rooted in these narratives, which enforces Shoppers Drug Mart's role of protagonist. Community members alike strongly identify with this character due to brand loyalty, and their friendly neighborhood pharmacist, rather than identifying with big pharmaceutical companies or the government, both often playing the role of the antagonist.

Conclusion

Conclusion

By framing health policy and intellectual property within the narrative of the performative stage, thematic scripts arise. Through Goffman and Gagnon's work on performativity and societal scripts, as a tool for conceptualization of this subject, I have discovered the characterization and development of the actors and their role in this legal fiction, which has emerged in health policy and intellectual property.

I have approached this work based on the assumption that all actors are rational and in a constant state of reformation. Health policy and intellectual property are the backbone of pharmaceutical consumption in Canada, constantly in search of a state of perfection. I chose Foucault's theories on governmentality, bio-power and bio-politics as a platform upon which to make my own interpretations of the selected case law and current legal practice. Most importantly, Foucaultian theory is central to this analysis based on Hunt and Wickham's interpretation of Foucault's work, of "attempt at control and failures (incompleteness)."[1] This particular theory works as the moral of the story, whereby all research and case law reflect the historical development of the government's attempt to control pharmaceutical consumption through the imposition of various mechanisms and tactics of control (legislation) and the inevitable failure or incompleteness which ensues, due to the prohibitive or regulatory nature of the very same mechanisms. This cycle is ongoing due to the constant state of evolution of the medical science industry. This ongoing dialogue or an exchange of narrative reflects the reactive role of government, perpetually changing its mechanisms of control, one step forward, and two steps back.

[1] Hunt, Alan & Gary Wickham, *Foucault and Law: Towards a Sociology of Governance.* (Colorado: Pluto Press, 1994), at 121.

Furthermore, I shall now rehearse the previous chapters, highlighting their role in this performance.

Chapter One presented the *Constitution Act of 1982*, as a main narrative which highlights the interplay between provincial and federal legislative powers outlined in sections 91 and 92. This chapter created the setting of the performance, situating this narrative within the *Constitution Act, 1982*. The division of power between provincial and federal legislature is central in the examination of a *vires* argument concerning health policy and intellectual property. This chapter outlined the requirements of both the provincial and federal governments as, greatly impacting pharmaceutical consumption in Canada. This act explained how the majority of health matters concerning individual citizens are handled by provincial jurisdiction, while health matters regarding the general health and well-being of the population are handled through the federal government. Through the examination of the *Constitution Act, 1982* the narratives of "peace, order and good government" emerge.[2] Furthermore, the act concluded with a discussion of the near "universality" of the Canadian health care system, arguing that a legislative gap between provincial health care plans produces an unfair competitive market advantage. The *Constitution Act, 1982*, highlights the dramatic structure of the literary and legislative style in which these various narratives of health policy and roles of government emerge. These discourses are repetitive in nature, reflective of similar narratives, which have evolved in Canadian legal interpretation and understanding.

[2] Competition Act, R.C.S. 1985, c. C-34, at 32-2

Chapter Two explored how the pharmaceutical market in Canada developed through a particular social, cultural and political environment. This chapter emphasized the importance of examining pharmaceutical development based on a contextual approach. This chapter highlighted the evolution and history of branding and trademarks. Furthermore, I examined how the pharmaceutical industry came to be in Canada in order to develop an understanding of the context of the pharmaceutical market. Additionally, this chapter presented the evolution of pharmaceuticals in America, highlighting the regulatory process of pharmaceutical consumption. An important extraction from this act is drawing the connection between brands and consumption. Imperative to this discussion was the fact that the evolution of brands has ensured consumer choice, thereby creating a market for competition.[3] Additionally, we see the historical evolution of various mechanisms of control, imposed by government, in attempts to regulate such "choices" of drugs. This evolution dates back to Ancient Rome, the prohibition movement, and the creation of inclusionary and exclusionary legislation. The narrative of "duty to care" for the population, ensuring the "well-being, safety, and effectiveness" of all pharmaceuticals is engrained within the long-standing narratives of Canadian health policy.

Chapter Three presented the main actors of the performance and their roles in connection to competition, policy and intellectual property of pharmaceuticals in Canada. Additionally, this chapter highlighted Erving Goffman and John Gagnon's work regarding performativity of the self, and social adherence to script-like narratives, which works as the framework of this thesis. This chapter explored the stakeholders and their

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[3] Cohen, J.C., P. Illingworth & U. Schuklenk(eds). *The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing* (London: Pluto Press, 2006), at 135

adherence to, or diverging roles in the pharmaceutical consumption in Canada. The ensemble of actors under investigation, work together, to produce the pharmaceutical market. Shoppers Drug Mart inherently plays the role of the protagonist and is the main character. The audience most strongly identifies with this character because of their brand loyalty to their "Life" product. This friendly neighborhood pharmacy is easy to connect with as opposed to a big pharmaceutical company or the government, both roles which often carry a negative connotation within social discourse. The government, at both the provincial and federal levels, often plays the role of the antagonist, often opposing the generic or brand name companies' goals. Big Pharma may also be viewed as the protagonist, often seeking various strategies, which prolong patent protection. Brand name pharmaceutical companies are often critiqued for excluding members of society who are socially, economically, and geographically disadvantaged.

Chapter Four explored the methodological and theoretical tools used in this thesis. This chapter explored the theoretical conventions of the theatrical performance of pharmaceuticals. By way of exploring the techniques, practices and devices (methodology) in connection to Foucault's theoretical framework, I establish this unique exploration of health policy and intellectual property. This thesis was explored through an unobtrusive qualitative form of analysis. Through discourse analysis of recent case law I was able to examine who said what, to whom, why, how, and with what effect. Discourse is at the heart of human understanding and interpretation. I was able to explore the social, cultural, contextual patterns of text evident within legal language. This exploration of language, in search of reoccurring themes helped me to respond to my questions of

analysis, disclosed in the final act. I called upon Brian Paltridge's quote to draw a connection to my subject

> Discourse is shaped by language as well as shaping language. It is shaped by people who use the language, as well as shaping the language that people use. Discourse is shaped, as well, by the discourse that has preceded it as well that which might follow it. Discourse is also shaped by the medium in which it occurs as well as it shapes the possibilities for that medium.[4]

The thematic narratives of health policy and intellectual property are reflective of Canadian understanding and values. The repetitive narratives of health policy and intellectual property are both shaped by language and language shaping. This language is that of "expert" medical and scientific knowledge. The language of health policy and intellectual property is shaped based on passed precedents and future medical advancement. It is shaped by various social and cultural understandings, imposed by various mediums and messages as well as shaping those mediums and messages. I use this example to highlight the "up-down" power relationship of pharmaceutical consumption, whereby it's dynamic power structure may be directed by various actors from various positions on the national stage. From this platform I called upon Foucault's theoretical concepts to facilitate analysis.

For my theoretical framework I cast the spotlight on Alan Hunt and Gary Wickham, Francois Ewald, and finally Golder and Fitzpatrick's interpretation of Foucault's work on governmentality, bio-power and bio-politics. These topics further highlighted the use of discourse and its effects on society as a powerful tool of governmentality. Furthermore, this act addressed the "art of governing" the masses in respect to health of the population

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[4] Paltridge, Brian, *Discourse Analysis: An Introduction* (New York: Continuum 2006), at 9.

through governmentality, bio-power and bio-politics. The discussion highlighted techniques, tactics mechanisms of control and surveillance evident within health care policy. Most importantly, this act highlighted the moral of the story, encompassing Hunt and Wickham's perpetual cycle of "government's attempt at control-incompleteness (failure)-attempt at control," in connection to current health policy and intellectual property.[5] This chapter highlighted the perpetuity of governance, in connection to ongoing attempts at control and failures, whereby the failures of governance are just as important as the attempts at control, because it is through this evolutionary process we learn.

Chapter Five explored the legal fiction of health policy and intellectual property, which are deeply rooted within narratives that must be individually interpreted based on the literal and contextual approach. This chapter set the scene, describing the scripts (case law) under investigation, parties involved (actors), issues at hand (story depiction) and pertinent reference to authority (legislation). This act explored the pith and substance of each script, asking, "What is the matter with law?" This chapter played an essential role in the classification of the character of health policy and intellectual property law. This act noted the importance of contextual interpretation, discussing the nature of "colorable legislation," explaining that the intended purpose of legislation is often very different than its inevitable consequences.[6] Furthermore, this act also highlighted the *vires* argument, as each script explored the jurisdictional and regulation making authority in connection to health policy and intellectual property. Moreover, this chapter also

[5] Supra, see note 1, at 121.
[6] Canadian Generic Pharmaceutical Association v. Minister of Health and The Attorney General of Canada,(2009) FC 725(CanLII), at 28.

highlighted a legal history of attempt at control and failures within the interplay of generic and brand name prescription medications.

Chapter Six depicted the analysis of the theatrical performance. Three major themes emerged by performing a discourse analysis of selected case law. The themes, which emerged are imperative in the examination of a *vires* argument concerning jurisdictional authority, between provincial and federal duties of government. These duties relate to the regulation of health of the population, the regulation of competition and the adherence to the very systemic structures it imposes. These themes were then examined based on Foucault's theoretical concepts. The regulation of health policy and intellectual property is a complex interaction of regulatory techniques and technologies reflective in Canadian social, cultural and political understanding. These thematic narratives are based on normative language, which create a legal fiction upon which one can explore this topic further.

Future exploration of this topic would include a comparative examination of the intersection of generic and brand name pharmaceuticals between Canada and the United States. This examination would be broader in scope, comparing case law within the last five years, which would cover recent health policy developments. Additionally, I would use American and Canadian Hansards in order to examine the various narratives of health policy in both Countries. It is important for future examination because American and Canadian pharmaceuticals play an inter-dependent role within the market of consumption. I would call upon Foucault's theoretical conventions of governmentality,

bio-power and bio-politics to examine further attempts at control and failures. I would also mix in Actor Network Theory, calling upon the various actors and their role in the prescribing the conditions of consumption. This topic of exploration highlights the gaps in legislation, which problematizes current understandings of "rights" in the consumption of pharmaceuticals and health care.

This thesis has contributed to further academic discussion concerning the way in which we view health policy and intellectual property of pharmaceuticals. By way of the performative stage, this thesis portrayed a way in which one may examine the various actors involved in the performance of consumption. Through an adaptation of socio-legal perspective, I performed a discourse analysis of five recent cases, which reflect current legal opinion and understanding in the matter of health policy. This thesis highlighted the importance of adopting a literal and contextual interpretation of law, examining each case individually. Additionally, this thesis examined current case law based on the theoretical interpretation of Foucault's work on governmentality, bio-power and bio-politics, which presented that law in the regulatory sense is present in the governing acts of pharmaceutical consumption.

The performative nature of pharmaceutical consumption relating to issues of health policy and intellectual property is ongoing. There are substantive issues to be raised concerning the methods of regulation and their effects and possible infringements upon additional legislation, which already exists. This thesis argued that the Ontario government's 2010 amendments to the Ontario Drug Benefit Act and the Drug

Interchangeability and dispensing fee act created a gap which gives preferential treatment to Shoppers Drug Mart, allowing the monopolization of the Canadian generic prescription drug market. This thesis contends that recent policy developments create a space which gives rise to anti-competitive consumption of generic pharmaceuticals. The Canadian government must balance its duty to care for the health and well-being of the population, while adhering to the alternative obligations imposed by the Competition Act and TRIPS agreements. This thesis highlighted the tension created between provincial and federal jurisdiction, highlighting the *vires* argument. When dealing with a *vires* argument one must firstly examine the roles and jurisdictional authority of the provincial and federal government, roles which are not black and white in nature, but overlap. Because of the gap, which is often created by this legislation it is imperative that the interpretation of legislation takes a literal and contextual approach in the examination of current health policy concerning the interplay between generic and brand name pharmaceuticals.

Appendix

Case Law Chart

Case Law	Issue	Legislation	Relevant Authority	Standard of Review	Judicial Interpretation	Ruling
Shopper Drug Mart, 2011	Constitutional Law (*ultra*)Vires Argument →PLP prohibitions Generic v. Brand Name Health Competition	*ODBA* *DIDFA* *Competition Act*	**Apotex Inc. v. Ontario (Minister of Health) 2004* **United Taxi Drivers' Fellowship of Southern Alberta v. Calgary (city),(2004)*	Correctness	Logical Literal/ Contextual	Won
Canadian Generic Pharmaceutical Association, 2009	Constitutional Law (*intra*)Vires Argument → Data protection regulations. Competition	*ODBA* *DIDFA* *FDA Regulations* *TRIPS* *NAFTA* *Competition Act* *Constitution Act, 1982*	**Bayer v. Canada (Attorney General),(1998).* **RJR-MacDonald Inc. v. Canada (Attorney General)(1995)* *Margarine Reference **Dunsmuir v. New Brunswick,* (2008). * *Nanaimo (city) v. Rascal Trucking Ltd., (2000).* **Westcoast Energy Inc v. Canada (National Energy Board, (1998).*	Correctness	Contextual	Lost
Apotex Inc, 2009	Person of Authority	*ODBA* *DIDFA*	**Apotex Inc. v. Ontario (Public Drug*	Reasonableness	Grammatical/Literal	Lost

	→ Challenged authority of EO in execution of Price Controls Competition	*Transparent Drug System for Patients Act, 2006,(Under ODBA)*	*Programs)(2008). *Dunsmuir v. New Brunswick(2008).*	Balance of Probabilities	Contextual	
Pharamscience Inc., 2007	Person of Authority →Challenged the authority of the EO re. designation of Apotex's generic drug under the ODBA. →Inconsistent treatment Competition	*ODBA DIDFA*	**Apotex Inc. v. Ontario (Minister of Health and Long Term Care)(2006) *Mt Sinai Hospital Centre v. Quebec (Minister of Health and Social Services)(2000) *McLachlin CJC in Baker v. Canada (Minister of Citizenship and Immigration)(1999). *Kerr v. Danier Leather (2005)*	Reasonableness	Teleological Approach- Contextual Grammatical/Literal	Lost
Apotex Inc.,2006	Constitutional Law →generic vs. innovator drug Competition Copycat drugs Evergreening	*Patent Medicines (Notice of Compliance) Regulations FDA Regulations Bill-91, in 1993 The Patent Act The Competition*	**Eli Lilly Canada Inc. v. Canada (Minister of Health)(2003). *Bell ExpressVu Limited Partnership v. Rex* (2002).	Correctness	Contextual Grammatical/Literal	Lost

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