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Pharmaceutical Direct-to-Consumer Advertising: Analyses of Policy Stakeholders and Supreme Court of Canada Interveners

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Abstract

Background: Pharmaceutical direct-to-consumer advertising (DTCA) is a controversial form of advertising that markets prescription pharmaceuticals to patients and consumers. The positions, power, interests and influence of pharmaceutical DTCA stakeholders shape Canadian DTCA policies; however, no focused analysis of DTCA stakeholders has occurred.

Methods: This study involved a two-pronged stakeholder analysis: First was a broad analysis of pharmaceutical DTCA stakeholders using Canadian publicly available documents and websites. The second analyzed interveners on pharmaceutical litigation at the Supreme Court of Canada, and the comparisons to a leading tobacco advertising case, *RJR-MacDonald v Canada (A.G)* and a pharmaceutical DTCA case *CanWest Media Works Inc. v Canada (A.G)*.

Results: There is a broad range of pharmaceutical DTCA stakeholders, with varying positions, power, interests and influence. Positions on DTCA policy ranged from supporting less regulation to maintaining current regulations. Stakeholders are often networked with each other through participation in self-regulatory groups or membership in associations; pharmaceutical industry stakeholders were most highly networked. All interveners identified in the second analysis are stakeholders identified in the first analysis. Pharmaceutical litigation interveners were either brand or generic pharmaceutical industry stakeholders. Public policy stakeholders were notably absent in pharmaceutical case litigation despite their participation in *RJR-MacDonald* and *CanWest*. **Conclusion:** Future pharmaceutical DTCA policy may be shaped by ‘high’ power stakeholders who favour maintaining the current regulations. Those same ‘high’ power stakeholders can be found participating in pharmaceutical litigation at the Supreme Court. Indications are that pharmaceutical industry stakeholders would be accepted to participate in Supreme Court pharmaceutical advertising litigation while public health stakeholders might apply as a coalition to participate.

Keywords: Pharmaceutical Direct-to-Consumer Advertising, Stakeholders, Intervenors, Policy Analysis, Legal Analysis

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Chapter 1 : Introduction

1.1 Introduction

Pharmaceutical direct-to-consumer advertising is explained as “an effort (usually via popular media) made by a pharmaceutical company to sell its prescription products directly to patients” (Ventola, 2011, p.669). Pharmaceutical direct-to-consumer advertising, commonly abbreviated as ‘pharmaceutical DTCA,’ is a controversial form of advertising that markets prescription pharmaceuticals to patients and consumers through a number of different mediums (television, radio, print, internet, etc.) Pharmaceutical DTCA has become an increasingly prevalent practice in Canada; spending on pharmaceutical DTCA has increased from \$1.2 billion to \$4.5 billion, and continues to prompt discussion and argument (Ventola, 2011). Harker (2007) summarized the debate surrounding pharmaceutical advertising by stating that pharmaceutical advertising is “a controversial issue as it operates at the nexus of population healthcare and ‘for profit’ enterprise” (p. 76). This study identified the stakeholders operating at this nexus and analyzed their influence, power, and position on future pharmaceutical DTCA policy.

1.2 Pharmaceutical Direct-to-Consumer Advertising

In 2015, drug expenditure was the second largest category of health spending, accounting for 15.7% of total Canadian health expenditure, or \$946 per person, and constituting an increase in spending of 0.7% over the previous year (Canadian Institute for Health Information, 2015). The Canadian Institute for Health Information cites increased drug utilization as a major driver of prescription drug spending, which experienced average annual expenditure growth of 10.1% from 1998 to 2007 (CIHI, 2011), and identifies pharmaceutical DTCA as one factor that may influence drug use and expenditure (CIHI, 2012). A number of studies have made similar arguments, suggesting an association between drug costs and pharmaceutical DTCA, typically citing advertising by pharmaceutical companies to consumers through mediums such as television and print, and consequent increased pressure from patients on physicians to prescribe drugs (Wilkes, 2000; Kravitz, 2005; Law, 2009). This increased pressure on physicians to prescribe pharmaceuticals may be a factor driving increased drug use and expenditures

(CIHI, 2012). Concerns about pharmaceutical DTCA have led to calls from prominent health groups such as the Canadian Medical Association (CMA) and Canadian Pharmacists Association (CPhA), for increased regulation (CMA, 2002; CPhA, 2009). In Canada and abroad, pharmaceutical DTCA regulation continues to be a point of debate (Auton, 2006; Frosh, 2010).

The policy positions on pharmaceutical DTCA exist on a continuum ranging from completely prohibiting pharmaceutical DTCA to unregulated pharmaceutical DTCA; both positions can be found in the literature but most academics and stakeholders hold views somewhere in between the two extremes. The position to further regulate and restrict DTCA practices argues that pharmaceutical DTCA is driving patients to request unnecessary treatment, negatively impacts physician-patient relationships, and increases costs on the healthcare system. The argument that pharmaceutical DTCA should be deregulated maintains that less restricted dissemination of health information would better inform patients about the existence of health conditions and treatments, possibly leading to consultations with physicians that might contribute to reducing under diagnosis and under treatment amongst the public. The proliferation of pharmaceutical DTCA has been found to be financially advantageous to drug producers and manufacturers (Liu & Gupta, 2011; Roberts, 2011). Intrinsic to all positions is a set of stakeholders who are invested in the regulatory status of pharmaceutical DTCA and who thus may choose to play a role in future policy and legal proceedings involving pharmaceutical DTCA.

1.3 Policy and Stakeholders

Public policy, the focus of this research, is “a course of action or inaction chosen by public authorities to address a given problem or interrelated set of problems” (Pal, 2010, p.2). Policy is typically developed in a non-linear process, but often aligns with key stages: problem identification, policy formulation, policy implementation, and policy evaluation. Health policy is a subset of public policy, defined by Buse et al. (2012) as “assumed to embrace courses of action (and inaction) that affect the set of institutions, organizations, services and funding arrangements of the health and health care system” (p.4). It includes policy made in the public sector (by governments) and as well as policies in the private sector (Buse et al, 2012, p.4). All stages of the policy process are

entirely dependent on actors who are participants and have a stake or interest in the policy processes that affect policy, including individuals, organizations, and governments (Buse et al, 2012, p.4). These actors are often referred to as stakeholders.

Pharmaceutical advertising policy is an outcome of the legislative process in Canada: a function of policy-making at the federal level (as will be explained further in Chapter 3). Pharmaceutical policy development often involves stakeholders such as healthcare providers, pharmaceutical companies, media companies, and health-associated organizations, some of whom may make contributions to the relevant federal legislation while it is being considered in either the House of Commons or the Senate. These stakeholders should have their policymaking intentions and means understood to better understand how pharmaceutical advertising policy may develop.

Under the Canadian system of government, while Canada's executives (its cabinets are subordinate to its legislatures, a characteristic of all "responsible governments" of the post-1830s British model). The courts are independent of Canada's legislatures (including the federal Parliament) and executives, and can rule both legislation and regulations invalid if they find fundamental legal tenets have been violated by the legislatures or executives involved (for instance, by violating provisions of the Canadian Charter of Rights and Freedoms). A Charter case is the type of court intervention that occurred in Canada's leading case of tobacco DCTA and which may well, for reasons to be explored in this thesis, can also occur in the context of pharmaceutical DTCA. The presence of interveners, a type of stakeholder, in litigation is a relatively new phenomenon in Canada (Kearney & Merrill, 2000) – traditionally only the parties to litigation (those who bring the litigation and those who defend against it) have been able to appear in Canadian courts or make submissions to court. That Canadian courts will now, on occasion, accept interveners into their processes gives those who intervene another means of influencing policy. As will be described in this thesis, when a court gives a stakeholder standing as an intervener it is both evidence of recognition of stakeholder status in a given policy area and also an opportunity for that intervener to influence a completely different aspect of law-making than is available through the democratic channels that culminate in legislation and regulation.

Thus, two stakeholder analyses are completed in this study to better understand DTCA stakeholders and how they may impact DTCA policy: those who attempt to influence the democratic processes of law-making and those who attempt to influence judicial decision-making. Neither stakeholder group has been well studied in any context in Canada.

1.4 Relevance to Health Information Sciences

The World Health Organization states that health information systems provide the underpinnings for decision-making and have four key functions: data generation, compilation, analysis and synthesis, and communication use (WHO, 2008). At Western University, the goal of health information science is partly described as to:

Understand the existing and emerging sources of recorded health information in its many forms; understand, through examination of relevant research, the need of particular health user groups (e.g., health policy makers, health professionals, health vendors, patients, advocates and members of the public) (Western University, 2017).

This policy analysis relies on a series of stakeholder analyses to identify stakeholders who could play an important role in shaping Canadian pharmaceutical DTCA policy. The intended result of this project is identification of a set of stakeholders who are positioned to influence not only legislative and regulatory policy outcomes but also legal proceedings that themselves could change legislative and regulatory outcomes. Generating and compiling data on pharmaceutical DTCA policy stakeholders, and then analyzing that data in order to communicate stakeholder position, power, interests, and influence for the purposes of informing government and private organization policymaker's health and healthcare decision making situates this project firmly in the domain of the Health Information Sciences.

1.5 Research Gap

Although there is research on DTCA, healthcare stakeholders, and interveners at the Supreme Court, at this time there is a lack of literature which addresses the specific

stakeholders in Canadian pharmaceutical DTCA, and how those stakeholders are positioned and functioning in the policy and legal settings.

1.6 Problem Statement

As concerns continue amidst increasing costs of drugs and the potential role of DTCA on consumers and health providers, pharmaceutical DTCA policy continues to be a focus of stakeholders including pharmaceutical companies, health groups, and government. Identifying Canadian pharmaceutical DTCA stakeholders, and their positions, power, interests, and influence, and then situating those stakeholders in terms of their potential ability to influence legislative or regulatory policy or to play roles as future legal intervenors in the Supreme Court provides analysis of two complementary but different avenues through which a policy change in pharmaceutical DTCA can be achieved. This study employed stakeholder analysis and examined the current pharmaceutical advertising environment. It also analyzed the key Supreme Court of Canada decision which involved healthcare advocates and addressed key constitutional limitations on tobacco DCTA regulation (*RJR-MacDonald v Canada* [1995] 3 SCR 199, hereinafter “*RJR-MacDonald*”) as a prelude to examining current pharmaceutical legal proceedings which may key indicators of how the Supreme Court would treat a pharmaceutical DTCA case should it come before the Court. The two analyses, taken together, identify stakeholders positioned to influence pharmaceutical DTCA policy in Canada.

1.7 Research Questions

Stakeholder analysis methods used in conjunction with content analysis methods were used to interpret primary and secondary documents. The primary and secondary documents were retrieved from publicly available websites and a small set of primary documents were retrieved from the Supreme Court of Canada archives. These methods and documents were used to answer the following research questions:

1. Given that there is a literature gap on Canadian pharmaceutical DTCA stakeholders, what can be learned about these stakeholders? This overall question leads to a number of subsidiary questions:

- Who are the direct-to-consumer pharmaceutical advertising stakeholders in the Canadian policy environment, and what are their interests, positions, power, and influence?
- what is the potential for these stakeholders to shape future DTCA policy?

This first set of questions is explored in Chapter 2.

2. Given the relatively recent rise of interveners in the Supreme Court process in Canada and the presence of interveners in the landmark advertising case in the Supreme Court of Canada, *RJR-MacDonald*, are the stakeholders identified in Research Question #1 found as interveners in current pharmaceutical related Supreme Court litigation?
 - If so, which and to what extent?
 - For those interveners found in answer to Research Question 1 and also found present in Supreme Court of Canada litigation, do the interests, positions, influence, and power parallel those found in the broader policy environment of Research Question 1?

This second set of questions is explored in Chapter 3. Chapter 4 will discuss the stakeholder and intervener findings from Chapter 2 and Chapter 3 respectively.

1.8 Format

This thesis has begun with this introductory chapter briefly outlining the concepts of pharmaceutical DTCA, policy, stakeholders, and interveners. Problem statements, relevance to Health Information Science, and the research questions explored in the next two chapters have been explained.

Chapter 2 explores the positions, power, interests and influence of Canadian pharmaceutical DTCA stakeholders and answers Research Question #1. Chapter 3 answers Research Question #2 by reviewing and analyzing recent pharmaceutical court cases decided by the Supreme Court of Canada and involving interveners at the Supreme

Court. The final chapter discusses these two investigations and draws conclusions drawn by examining and comparing the two sets of findings from Chapters 2 and 3.

1.9 References

- Auton, F. (2006). Direct-To-Consumer-Advertising (DTCA) of pharmaceuticals: AN updated review of the literature and debate since 2003. *Institute of Economic Affairs*, 24–32. doi: 10.1111/j.1468-0270.2006.00646.x
- Buse, K., Mays, N., Walt, G. (2012). *Making Health Policy* (2nd ed.). UK: McGraw-Hill Education.
- Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act*, 1982, Schedule B to the *Canada Act 1982 (UK)*, 1982, c 11.
- Canadian Institute for Health Information. (2015). *National Health Expenditure Trends, 1975 to 2015*. Ottawa. Retrieved from:
https://secure.cihi.ca/free_products/nhex_trends_narrative_report_2015_en.pdf
- Canadian Institute for Health Information. (2012). *Prescribed Drug Spending in Canada, 2012: A Focus on Public Drug Programs*. Ottawa. Retrieved from:
https://secure.cihi.ca/free_products/Prescribed_Drug_Spending_in_Canada_EN.pdf
- Canadian Institute for Health Information. (2011). *Health Care Cost Drivers: The Facts*. Ottawa. Retrieved from
https://secure.cihi.ca/free_products/health_care_cost_drivers_the_facts_en.pdf
- Canadian Medical Association. (2002). *Direct-to-consumer advertising (DTCA)*. Retrieved from: https://www.cma.ca/Assets/assets_library/document/en/advocacy/CMA_advertising_PD03-01e.pdf#search=advertising
- Canadian Pharmacists Association. (2009). *CPhA position state on direct-to-consumer advertising (DTCA)*. Retrieved from: <http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/PPDirectToConsumerAdvertising.pdf>

- Frosch, D. L., Grande, D., Tarn, D. M., & Kravitz, R. L. (2010). A decade of controversy: Balancing policy with evidence in the regulation of prescription Drug advertising. *American Journal of Public Health, 100*(1), 24–32.
<http://doi.org/10.2105/AJPH.2008.153767>
- Harker, M., & Harker, D. (2007). Direct-to-consumer-advertising of prescription medicines. *Leadership in Health Services, 20*(2), 76–84.
<http://doi.org/10.1108/17511870710745411>
- Kearney, J. D., & Merrill, T. W. (2000). The influence of amicus curiae briefs on the Supreme Court. *University of Pennsylvania Law Review, 148*(3), 743-855.
- Liu, Q., & Gupta, S. (2011). The impact of direct-to-consumer advertising of prescription drugs on physician visits and drug requests: Empirical findings and public policy implications. *International Journal of Research in Marketing, 28*(3), 205–217.
<http://doi.org/10.1016/j.ijresmar.2011.04.001>
- Law, M. (2009). Costs and consequences of direct-to-consumer advertising for clopidogrel in Medicaid. *Arch Intern Med, 169*(21). Retrieved from:
<https://www.ncbi.nlm.nih.gov/pubmed/19933958>
- Pal, L. A. (2005). *Beyond policy analysis: Public issue management in turbulent times*. Toronto, ON: Nelson.
- RJR-MacDonald v Canada*, [1995] 3 Supreme Court Reports 199.
- Roberts, C. (2011). *Addressing the health system impacts of domestic and international direct-to-consumer advertising in Canada* (Master's Major Research Project). Retrieved from: [file:///Users/tomeldik/Downloads/etd6581_CRoberts%20\(7\).pdf](file:///Users/tomeldik/Downloads/etd6581_CRoberts%20(7).pdf)
- Western University. (2017). *Master of health information science: goals & objectives*. Retrieved from:
http://www.fims.uwo.ca/programs/graduate_programs/master_of_health_information_science/goals_objectives.html

Wilkes, M. S., Bell, R. a., & Kravitz, R. L. (2000). Direct-to-consumer prescription drug advertising: Trends, impact, and implications. *Health Affairs, 19*(2), 110–128.
<http://doi.org/10.1377/hlthaff.19.2.110>

World Health Organization. (2008). *Health information systems*. Retrieved from:
http://www.who.int/healthinfo/statistics/toolkit_hss/EN_PDF_Toolkit_HSS_InformationSystems.pdf

Ventola, C. (2011). Direct-to-consumer pharmaceutical advertising: therapeutic or toxic? *Pharmacy and Therapeutics, 36*(10), 669–84.

2 Chapter Two: Analysis of Policy Stakeholders

2.1 Introduction

A report by the Canadian Institute for Health Information (CIHI) found that prescription drug expenditures were the second largest category of drug spending as a proportion of the national gross domestic product (GDP), accounting for 15.7% of total Canadian health expenditures; a share of health spending that has been increasing since the 1980s and is now only behind hospital spending in health expenditures (CIHI, 2015). CIHI identified increased drug utilization as a major contributor and driver of the increase in prescription drug expenditures, and names direct-to-consumer advertising (DTCA) as a potential catalyst for increased prescription drug utilization (CIHI, 2015; CIHI, 2012; Law, 2008). Supporting the claim that DTCA contributes to increased drug utilization is a cross-sectional study by Mintzes et al (2002) that found that patient requests for prescription pharmaceuticals are a driver of physician prescribing behaviours. Kravitz et al. (2005) similarly found that DTCA could increase prescription drug utilization, but added that it could mitigate underuse and promote overuse of drugs for major depression and adjustment disorders.

Pharmaceutical DTCA is defined as “an effort (usually via popular media) made by a pharmaceutical company to promote its prescription products directly to patients” (Ventola, 2011, p.669). Canadian spending on DTCA has risen sharply since 1999, from \$2 million in 1999 to \$22 million in 2006. American spending on DTCA increased from \$340 [US] million in 1995 to \$4.5 [US] billion in 2009; which is notable because American advertising likely affects Canadian pharmaceutical drug utilization (Law et al., 2008; Mintzes, 2009; Pharma Marketing, 2010; Ventola, 2011). The reach of American pharmaceutical DTCA into Canada has contributed to a discussion and debate surrounding the effects, benefits, and detriments of the practice. Harker (2007) summarized the debate surrounding pharmaceutical advertising by stating that pharmaceutical advertising is “a controversial issue as it operates at the nexus of population healthcare and “for profit” enterprise” (p. 76).

There is a potential for harm in misdiagnosis by patients, over-prescription, and misinformation about prescription pharmaceuticals; all concerns prompted by the introduction of DTCA (Health Council of Canada, 2006). The pharmaceutical industry is largely located in the private sector, where the primary developers and manufacturers of prescription drugs are found. These companies are incentivized by profit to proliferate the sale of these drugs to make a return on investment and further the financial standing of their corporations. Pharmaceutical DTCA has both the potential to spread essential health information about drugs and diseases that may benefit populations who may not otherwise receive this information, but also the risk of advertising campaigns incentivized by profit that contribute to misdiagnosis, over-prescription, and misinformation about certain drugs and diseases (Health Council of Canada, 2006).

In Canada, and internationally, there are two predominant perspectives on the effects of pharmaceutical DTCA. The first perspective suggests that there is a relationship between pharmaceutical advertising and increased pressure on physicians to prescribe drugs from patients who have been influenced by television, print, or electronic advertisements, a relationship which has resulted in a broad increase in prescription drug utilization (CIHI, 2012; Wilkes et al., 2000; Law, 2009; Wilkes et al., 2000;). Mintzes (2002) identified a perceived change in the prescribing behaviour in the physician-patient relationship with the introduction of DTCA: ‘Patients’ requests for medicines are a powerful driver of prescribing decisions. In most cases physicians prescribed requested medicines but were often ambivalent about the choice of treatment’ (Mintzes, 2002, p.279). This perceived change in prescribing behaviour and the physician-patient relationship has prompted concern among prominent health groups who have taken a stance against the practice, often articulated as a policy statement expressing support for increased regulation of pharmaceutical DTCA. The second perspective on the effects of pharmaceutical DTCA is that the pharmaceutical advertisements serve as a vehicle for communicating health information about health ailments and their remedies to potential patients. These advertisements may be encouraging patients to seek out their physicians for consultation, thereby addressing issues such as under-diagnosis and under-treatment of the patient population. This perspective suggests that the deregulation and proliferation

of DTCA should be advantageous to both patients and the pharmaceutical companies that manufacture and develop the drugs (Liu & Gupta, 2011; Roberts, 2011).

The positions to further regulate and to deregulate pharmaceutical DTCA are located along a spectrum of regulation, ranging from completely unregulated to completely prohibited DTCA. Canada's current pharmaceutical DTCA regulations are best interpreted as being closer to complete prohibition than they are to completely unregulated DTCA (Gardner, 2003); this spectrum of regulation and positions informs the study going forward. The positions to further regulate pharmaceutical DTCA and the positions to reduce regulation are supported and advanced by sets of stakeholders, individuals, and groups who have an interest in policy, who are invested in the regulatory status of DTCA and may choose to assume a role in future policy or legal developments involving pharmaceutical DTCA. Stakeholders may have a role in pharmaceutical DTCA policy, may particularly influence any legislative or regulatory developments, and are important to understand in the broader context of developing policy for DTCA.

The aim of this aspect of the study was to identify Canadian pharmaceutical advertising stakeholders, their positions, power, interests, and influence to influence future Canadian pharmaceutical DTCA policy, either through legislative or regulatory change or through influence upon judicial outcomes in legal proceedings.

2.2 Background

2.2.1 Stakeholders and Stakeholder Analysis

Stakeholder theory (Freeman, 1984) is used as the framework and lens through which this policy analysis was conducted. All stages of the policy process are dependent on stakeholders, who are described by Freeman as those that "can affect or be affected by the achievement of the organizations perspectives" (Freeman, 1984, p.46). Adapted to a policy context, it is more appropriate to use the description posited by Buse, Mays, and Walt (2012), who defined policy stakeholders as "those individuals and groups with an interest in an issue or policy, those who might be affected by a policy and those who may play a role in relation to make or implementing a policy" (p.4). Stakeholders can be individuals, groups, organizations, or governments. On the topic of stakeholders, Guba

and Lincoln add that "...interest may be measured in terms of money, status, power, face, opportunity or other coin, and may be large or small, as construed by the groups in question" (Guba and Lincoln, 1989, p.52).

Policy and stakeholders can often be referred to as operating within a policy network, defined as "inter-dependent organizations involved in an area of policy that exchange resources and bargain to varying degrees to attain their specific goals" (Buse et al., 2012, p. 106). A more focused policy network, focusing on a single issue, are often referred to as an 'issue network' (Buse et al., 2012). Within these networks there are competing individuals and organizations, who may themselves form smaller networks and communities to advance policy objectives.

Stakeholders can be organized into a number of categories, and one means of doing this is to organize them according to their interests. Stakeholders organized according to their interests can be divided into "sectional" groups and "cause" groups. Sectional groups are "groups whose main goal is to protect and enhance the interests of their members and/or of the section of society they proclaim to stand for" (Buse et al., 2012, p. 111): an example of sectional stakeholder groups in pharmaceutical DTCA policy are unions (e.g Canadian Autoworkers Union) or the Canadian Generic Pharmaceutical Association, whose focus is, in-part, to represent the views of their respective members. Cause groups are described as "groups whose main goal is to promote a particular issue or cause and whose membership is open to anyone who supports the cause without necessarily having anything to gain personally if the case is successful" (Buse et al, 2012, p. 111). The Canadian Health Coalition is one example of a cause group stakeholder because it is a public advocacy organization dedicated to the preservation and improvement of public healthcare in Canada, which includes advocating in a number of DTCA policy areas (Canadian Health Coalition, 2016).

Another common categorization of interest groups is that of 'insider' and 'outsider' groups. Insider groups are those groups which are well connected within government, considered legitimate by policymakers, and will often be able to consult policymakers or advance their policy agendas (Buse et al., 2012). Outsider groups are

described as the contrasting set of groups to the insider groups, are often seen as illegitimate groups by policymakers, and either reject the processes of government or have been unable to gain legitimacy (Buse et al., 2012). Insider and outsider groups will have varying levels of public policy influence; typically, insider groups will have more influence than an outsider group. Understanding which stakeholders have insider or outsider status contributes to our understanding of the pharmaceutical DTCA policy landscape. An insider group, BIOTECanada, is a member of the Pharmaceutical Advertising Advisory Board, a self-regulatory pre-clearance DTCA group, and so has more potential to influence change to the policy landscape than the Consumer Association of Canada, which was identified in this study only as a witness on the Standing Committee on Health report (2004) but may be interested in pharmaceutical DTCA policy nonetheless.

2.2.2 Pharmaceutical DTCA Legal Regulation

Health Canada, the federal Ministry of Health, is mandated with regulating pharmaceutical DTCA and enforcing pharmaceutical advertising legislation: the *Food and Drugs Act* (RSC 1985, c F-27), originally enacted in 1920 (and most recently consolidated in 1985), is the Canadian federal statute that governs pharmaceutical advertising in Canada. Alongside the Act are the *Food and Drug Regulations* (CRC, c 870), which Health Canada describes as: "...regulations [which], where applicable, set the standards for composition, strength, potency, purity, quality, or other property, or the other property of the article of food or drug to which they refer" (Health Canada, 2007, p.1). Together, these set out the policies for pharmaceutical DTCA in Canada.

Specifically, Section 9(1) of the *Food and Drugs Act* prohibits false, misleading, deceptive, or erroneous advertising of products. Section 20(1) states that "no person shall label, package, treat, process, sell, or advertise in a manner that is false, misleading or deceptive, intended use, quantity, character, value, composition, merit or safety". Section 3(1) prohibits consumer-directed advertisements for health products that make claims to treat, prevent, or cure any diseases listed in Schedule A to the Act. The *Food and Drug Regulations* contain sections C.01.044 and C.08.002(1). Section C.01.044 prohibits consumer directed prescription advertising beyond the drug's name, price, and quantity.

Section C.08.002 (1) prohibits the advertising of new drugs that have not been approved for sale by Health Canada. Canada's legislation and regulations on pharmaceutical DTCA frame the policy discussion around it, as different stakeholders adopt various policy positions that may be intended to alter the current legislation and regulations.

In the absence of specific pharmaceutical DTCA definitions and categorization of advertisements in the relevant Canadian legislation and regulations, the U.S Food and Drug Administration (US FDA) provides information that may be relevant to understanding different types of pharmaceutical DTCA. The US FDA recognizes three types of pharmaceutical DTCA: 1) product claim advertisements, which are the only type of ad to feature both the name of the drug and explain its benefits and risks; 2) reminder advertisements, which provide the name of the drug, but not the uses, benefits, or risks of the drug; and 3) help-seeking advertisements (sometimes referred to as disease-oriented ads) which describe a disease or condition but do not recommend or suggest a specific drug treatment (FDA, 2015).

Health Canada's policy on pharmaceutical DTCA, in accordance with its *Food and Drugs Act* and the *Food and Drug Regulations*, does not have a permitted category for the first category of advertisements above, those that feature both the name of pharmaceutical and the use of said drug: such ads are prohibited in Canada (Health Council of Canada, 2006). The second and third types of ads, reminder advertisements (as defined by the US FDA) and help-seeking announcements are permitted in Canada (Health Council of Canada, 2006). Help seeking announcements, as defined by Health Canada, cannot mention a specific drug, cannot imply that a drug is a sole treatment for any disease or ailment, can make no mention of a drug manufacturer, and can be considered an advertising if other factors indicate that the purpose of the announcement is to promote sale or disposal of a drug (Health Canada, 2005)

Although Health Canada is the federally mandated regulator of pharmaceutical advertising in Canada, industry body stakeholders, such as the Pharmaceutical Advertising Advisory Board (PAAB) and Advertising Standards Canada (ASC), have become prominent in the Canadian pharmaceutical DTCA regulatory environment. In particular, PAAB provides pre-clearance services to assist advertisers in meeting federal

regulatory standards and ASC provides regulatory advice on the compliance of promotional messages (Vakratsas & Kolsarici, 2014). However, as Health Canada is the only legally recognized regulator, all complaints about pharmaceutical advertisements are handled by Health Canada.

2.2.3 Policy Context for Direct-to-Consumer Advertising

A 2004 report by the House of Commons Standing Committee on Health (“the Standing Committee”) explored the role of prescription drugs in the health care system in terms of the potential of those drugs to improve the lives of Canadians and reviewed the costs of those drugs on the healthcare system. One area of focus of the report was pharmaceutical DTCA (Standing Committee on Health, 2004). The committee’s mandate is described as follows by the Federal Government: “The House of Commons Standing Committee on Health ... is empowered to study and report on all matters relating to the mandate, management, and operation of Health Canada.” (HESA Standing Committee on Health Mandate, 2015, p.1)

In its 2004 report, the Standing Committee expressed concern about both the rising costs of health expenditures (of which drug expenditures are a sizeable share), and the evidence that suggests a relationship exists between DTCA and growing costs. The Standing Committee agreed with the original rationale for prohibition of pharmaceutical DTCA and rebuffed calls for legislative changes to allow wider public advertising of prescription drugs. In regards to the DTCA pre-clearance services offered by the PAAB and Advertising Standards Canada, the Standing Committee was concerned with the voluntary approach to pre-clearance of prescription drug advertisements. PAAB’s process of reviewing advertisements prior to submission of advertisements to Health Canada, and Health Canada’s evident dependence on these agencies for regulatory oversight, was described as a “feeble mechanism”, and the Standing Committee found that Health Canada has disregarded its responsibility to enforce existing regulations (Standing Committee on Health, 2004).

The Standing Committee’s recommendations included the following:

1. Health Canada immediately enforce the current prohibition on all industry sponsored advertisements on drugs to the public;
2. Health Canada ensure the provision of independent, unbiased and publicly financed information on prescription drugs to Canada;
3. Health Canada should dedicate specific resources to Health Products and Food Branch Inspectorate for vigorous enforcement of the DTCA regulations on prescription drugs include active surveillance of all relevant media, identification of potential infractions, appropriate corrective action, and production of annual public reports; and
4. Health Canada should ensure that all DTCA complaints about prescription drugs received by Advertising Standards Canada or the Pharmaceutical Advertising Advisory Board are forwarded to Health Canada for investigation and action (Standing Committee on Health, 2004, p. 14).

Following upon this 2004 report, the now defunct Health Council of Canada, a federal council that was mandated to monitor the progress of health care renewal in Canada (Health Council of Canada, 2006), again examined the issue of pharmaceutical DTCA in 2006. Its report, titled: “What are the Public Health Implications? Direct-to-Consumer Advertising of Prescription Drugs in Canada” (Health Council of Canada, 2006), described the legislative and regulatory state of pharmaceutical DTCA in Canada, United States and New Zealand, summarized research evidence examining the effects of DTCA, looking at pharmaceutical DTCA policy developments in countries where the practice was prohibited, proposed legislative changes in Canada to introduce some pharmaceutical DTCA into the country, and made a number of recommendations in that light (Health Council of Canada, 2006). The Health Council of Canada report elaborated on recommendations in the Standing Committee report (Health Council of Canada, 2006; Standing Committee on Health, 2004). The recommendations from the Health Council of Canada report included [recommendations are paraphrased]:

1. Independent, publicly financed, information and education on drugs and other medical treatments;
2. Better enforcement of regulations governing both physician-oriented drug promotion and DTCA;
3. Given the lack of justification for allowing reminder advertising from public health perspective, clause C.01.033 of the *Food and Drugs Act* should be repealed;
4. Canada's approach to cross-border television broadcasting should be reviewed (Health Council of Canada, 2006).

Despite the policy recommendations that were made by the Standing Committee on Health (2004) and the Health Council of Canada (2006), the regulations on pharmaceutical advertising have not been changed (Health Council of Canada, 2006; Standing Committee on Health, 2004). The lack of change to pharmaceutical DTCA regulation by the Government of Canada has been described as a “stalemate...in initiatives for legislative change” (Mintzes et al, 2005, p.326). The authors are referring to the absence of new DTCA which uses the recommendations from the reports, which mainly call for improved enforcement on the current regulations and legislation, and that Health Canada's interpretation of the *Food and Drugs Act* by Health Canada in 1996 and 2000 softened the restrictions on pharmaceutical DTCA (Health Canada 1996; Canada, 2000) instead of increasing regulation.

The Standing Committee Report (2004) also addressed post-market surveillance and clinical trials, the importance of attracting a wide range of stakeholders in the pharmaceutical, pharmaceutical advertising sector, and health sectors as witnesses before the Standing Committee or inviting them to submit policy briefs to the Standing Committee with intentions of contributing to and informing the report with respect to their positions and interests. It is important to identify and understand these stakeholders, and the policy networks they operate in, to better understand the broader pharmaceutical

advertising policy environment as they shape the policy discussions and debates regarding pharmaceutical DTCA.

2.3 Literature Review

To establish an understanding of the current state of the research pertaining to Canadian pharmaceutical advertising policy and stakeholders, a literature search was conducted. CINAHL, PubMed, Scopus, Google Scholar, and Western's Library Catalogue were all accessed in a database search for research that addressed Canadian pharmaceutical advertising policy and stakeholders that was published between 2000 and 2016 in English. Search terms used in each database included "Canada" or "Canadian" combined with "direct-to-consumer advertising", "DTCA", or "pharmaceutical advertising", and "stakeholder" or "stakeholders". A search with all three main search terms combined (Canadian, DTCA, and stakeholders) yielded no results. The use of "Canada" (and Canadian) with "DTCA" (and Pharmaceutical Advertising" search terms was next used, titles and abstracts were reviewed to determine if they included content on Canadian DTCA appropriate for this review. This search produced 38 works on Canadian DTCA. Of the 38 works, 35 were peer reviewed journal articles, two were journal published commentaries on DTCA, and one was a graduate major research project.

A search using only "pharmaceutical advertising" and "stakeholders" search terms produced one study: "Marketing and societal welfare: A multiple stakeholder approach" (Matear & Dacin, 2010). Although the study is relevant to DTCA and stakeholders, the authors do not focus on Canada or policy. However, the study provides insight on the relationship and scope of business strategy, societal welfare, and consumer behaviour in relation to DTCA (Matear & Dacin, 2010), and broadly describes groups of stakeholders in the DTCA environment. The study is a secondary literature review of 86 published works pertaining to DTCA, stakeholder theory, societal welfare, consumer behavior, or business strategy; which intersects with this project, with our shared interests in DTCA and stakeholders. The study aimed to "help identify the nature, scope and domain of the business strategy-consumer behaviour-societal welfare link, and ways to explore the trade-offs between individuals and societal gain" (Matear & Dacin, 2010, p.1173) while using stakeholder theory as a lens to examine DTCA. The authors briefly

described pharmaceutical DTCA, the link between DTCA and societal welfare (including a summary and list of arguments for and against DTCA), and identified groups of stakeholders involved in pharmaceutical advertising: consumers, physicians, insurance companies and formularies, pharmacists, and the government.

Matear & Dacin (2010) identified stakeholder groups but did not engage in any search for specific stakeholders or seek to understand the stakeholder groups outside of their interests in DTCA through the perspective of societal welfare, business strategy or consumer behaviour. The study did not name many specific stakeholders within each broad grouping, or explore specific stakeholder position, power, interests, and influence, or the nuances between stakeholders in each grouping. The authors do not acknowledge that stakeholders of similar type (or within the same grouping) are not homogenous in their positions, power, interests, and influence, and this study does not provide sufficient granularity to understand the differences between stakeholder groups or between the constituents of each stakeholder groups – necessitating further research.

Once the literature search was broadened to include all Canadian works on pharmaceutical DTCA, and not just those specific to DTCA stakeholders (this was necessary to broaden the search, as no Canadian DTCA literature involving policy stakeholders is currently available), one master's research project was identified: *Addressing the health system impacts of domestic and international DTCA in Canada* (Roberts, 2011). Roberts' problem statement is that DTCA has negative impacts on health and increases inappropriate use of the healthcare system, which echoes concerns with DTCA expressed in other literature (Roberts, 2011), and the study addressed four research questions:

What range of impacts does DTCA have on the health system in British Columbia?; What strategy is British Columbia employing with the goal of addressing the negative impacts of DTCA on the health care system? If the province employs any strategy, how effective is it at addressing the negative impacts of DTCA? What strategies have been employed in other jurisdictions to address negative impacts of DTCA on their health system? (Roberts, 2011, p. 4).

Roberts (2011) conducted a thematic content analysis of government documents, case studies, ministry interviews, and expert interviews. Roberts' analysis produced a number of themes and the identification of a number of regulatory loopholes and flaws. Four policy options are evaluated: 1) funding a working group on DTCA in Canada; 2) improving public discourse on DTCA; 3) using financial penalties to encourage DTCA compliance; 4) relieving pressure on the health care system through education. To discuss possible policy options, Roberts introduces a criterion of 'Stakeholder Acceptability' for four policy options, where Roberts hypothesizes whether certain stakeholder groups would be accepting or rejecting of the policy recommendation. After analyzing the policy options, Roberts (2011) suggests two policy recommendations: funding a working group on pharmaceutical DTCA in Canada, and relieving pressure on the healthcare system through education on pharmaceutical DTCA.

The literature review suggested an absence of research investigating the role of stakeholders on Canadian pharmaceutical advertising policy. This study sought to address this gap.

2.4 Research Aim

The aim of this study was to identify and conduct an analysis of the stakeholders relevant to DTCA in terms of their positions, power, interest, and ability to influence or affect future pharmaceutical policy and legal proceedings that pertain to pharmaceutical advertising – and thus to better understand pharmaceutical DTCA policymaking.

2.5 Methods

2.5.1 Study Design

This study is guided by a stakeholder analysis approach (Brugha, 2000; Varvasovszky, 2000). Stakeholder analysis is described as: “one of a number of different but closely related policy research or strategic tools now found in the health policy literature.” It is said that “the usefulness of the tool, along with other-nonlinear policy analysis approaches, is that stakeholder analysis highlights the importance of actors and interest groups in the policy making process” (Brugha, 2000, p.243). Stakeholder analysis

is a versatile tool used to describe stakeholders, and is a method that is commonly used in policy circles. Understanding the role of stakeholders in Canadian pharmaceutical DTCA policy informs our broader understanding of how and why certain DTCA policies exist, what the pharmaceutical DTCA policy positions are, and how pharmaceutical DTCA may continue to evolve.

Varvasovszky (2000) states that a stakeholder analysis is “a tool or set of tools for generating knowledge about actors – individuals and organizations – so as to understand their behavior, intentions, interrelations and interests; and for assessing the influence and resources they bring to bear on decision-making or implementation processes” (p.338) and describes how one might conduct a stakeholder analysis. A stakeholder analysis is a snapshot of a context that is always changing and there are limits to the data that can be accessed about stakeholders. Some considerations must be made for the validity and of the analysis, mainly, the researcher must recognize that public stakeholder positions, or those collected in an interview, may change over time. Also, the position of a single member of an organization may not always represent the position of the organization as a whole. (Varvasovszky, 2000).

This stakeholder analysis is purposefully broad and does not focus on any one interest group but rather on a range of interest groups (Wu et al, 2013). The stakeholder analysis focused on describing the position, power, interest, and influence of stakeholders relative to Canadian pharmaceutical DTCA policy. Researchers should also be aware of their biases during the research process (Varvasovszky, 2000). Buse, Mays, & Walt (2012) suggest that a stakeholder analysis should identify policy stakeholders, their political resources, and understand their positions and interests.

2.5.2 Data Collection

Both primary and secondary documents were accessed and analyzed for this study: 1) primary documents, in the form of policy documents and websites that describe each stakeholder’s position, power, interests, and influence; and 2) secondary documents in the form of government documents and reports which address DTCA policy that met the inclusion criteria. Inclusion criteria were 1) documents and websites that listed

Canadian pharmaceutical advertising stakeholders, 2) were written in English, 3) were published in the years between 2000 and 2015, and 4) were publicly available.

Identifying Canadian pharmaceutical DTCA stakeholders meant first identifying documents that were relevant to pharmaceutical advertising. Collecting documents that met the inclusion criteria involved database searches (CINAHL, PubMed, Scopus, Google Scholar, and Western's Library Catalogue) and a Google search engine search with the search terms "DTCA" or "Pharmaceutical Advertising" and "Canada" or "Canadian", and from the year 2000 onwards.

The website of the Commission on the Future of Health Care in Canada ("Romanow Commission"), a federal government commission mandated in 2002 to review Canada's Medicare and recommend policies and measures to improve the system and long term sustainability including pharmaceutical policies (Commission on the Future of Health Care in Canada, 2002), was accessed. A number of submissions by stakeholders were made to the Romanow Commission, submissions were either requested by the Commission, or received in an "open" call. Documents were screened for pharmaceutical advertising content by using the text search feature available on all pdf viewers, Microsoft Word, and web browsers. The terms: "DTCA", "pharmaceutical", "advertising", "pharma", "advert", and "direct" were used to find pharmaceutical advertising content in the documents. If the document included content that pertained to pharmaceutical advertising then it met the inclusion criteria, and the individual or organization that produced and submitted the document was recorded in Microsoft Excel. The relevant text was then excerpted and organized in a Microsoft Excel document for coding. A total of 10 documents were identified, and 10 excerpts were included in this analysis. A google search for the website of stakeholders identified in the documents produced 10 websites, from which the constituent members of each stakeholder organization found in the Romanow Commission submissions were also identified, totaling 63 constituent organizations. 'Constituent organizations' are the individuals or organizations which constitute or form the member base of each association or organization identified, and are stakeholders themselves.

The Health Canada main website page search bar was searched to identify pharmaceutical advertising documents. Entering “DTCA” or “Pharmaceutical Advertising” produced a publicly available list of complainants, those who had submitted a formal complaint about a breach in pharmaceutical advertising law was identified. The individuals or organizations that submitted the complaint, the law that was breached, and the category of the complaint, and the details of the complaint were recorded in an Excel spreadsheet for analysis. This data was collected to gather insights about the individuals and organizations who express interests in DTCA regulations and policy. Two policy documents by the Food and Drugs branch of Health Canada interpret the Food and Drugs Act and Regulations on behalf of the Federal Government were also identified (Health Canada 1996; Health Canada 2000).

The Pharmaceutical Advertising Advisory Board (PAAB), a pre-clearance regulatory agency composed of high-interest stakeholders, website was accessed and its 16 constituent members identified (many of whom are themselves associations or coalitions comprised of several organizational members). The webpages of those constituent members were also accessed to find position papers or pages on pharmaceutical advertising, and the members that make up the organizations in PAAB. As can be seen in Table 2.1, the websites of 12 constituent members, and one LinkedIn profile (The Association of Medical Advertising Agencies does not have a website and LinkedIn is the only online resource with a description of the organization) were reviewed for position papers, and eight position papers were identified and downloaded.

Table 2.1: Data Collection of Documents Relevant to Pharmaceutical DTCA Policy Stakeholders

Source	Number of Documents	Number of Stakeholders identified	Number of Websites Found	Number of Constituent Stakeholders* Identified
Romanow Commission	10	10	10	63
Pharmaceutical Advertising Advisory Board	1	13	12	375
Standing Committee Report	1	1	13	127
Health Canada – Health Product Advertising Complain	1	1	1	56

Note: * Constituent Stakeholders are members of other organizations or associations, and may belong to multiple organizations associations.

The House of Commons Standing Committee on Health included a list of 127 associations and individuals who contributed to its report, *Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs Report* (Standing Committee on Health, 2004). Factoring in the report's significant focus on pharmaceutical advertising, those participants in the Standing Committee consultations were informing decision-making (and the potential policy-making, should recommendations be implemented) on pharmaceutical DTCA policy. These stakeholders were likely to have a position on pharmaceutical DTCA policy, have interests that concern pharmaceutical DTCA, and may continue to attempt to influence future pharmaceutical DTCA policymaking. It was important to include these stakeholders in the study to better understand their role in pharmaceutical DTCA policymaking. The website of each association or individual was accessed (if available) and searched for references, pharmaceutical DTCA policy documents or, in lieu of a position document, the website was searched for references to pharmaceutical DTCA. Similar stakeholders were grouped into different categories along with available information on each stakeholder. Following the collection of the stakeholder webpages, policy documents, and government documents, the analysis of each document began. Stakeholders from each document were first identified. The ensuing analytic process consisted of coding text for stakeholder power, position, interests, and influence.

2.6 Data Analysis

2.6.1 Coding

Excerpts of text and stakeholder names found in the documents and website texts were organized in Excel files for analysis in terms of position, power, interests, and influence. The stakeholders identified in the documents were coded for positions, power, interests, and influence using specific criteria and coding definitions. Stakeholders were then categorized by position, power, interests, and influence.

2.6.2 Criteria & Coding Definitions

Qualitative and quantitative content analysis of all documents was conducted to identify the position, power, interests, and influence of each stakeholder. Vaismoradi et al. describe the purpose of a content analysis as “to describe the characteristics of the document’s content by examining who says what, to whom, and with what effect” (Vaismoradi, Turunen, & Bondas, 2013, p. 399). The analytic process of qualitative content analysis is considered a “description and interpretation, both inductive, and emphasizing context, integration of manifest and latent contents, drawing thematic map, non-linear analysis process, no peer checking” (Vaismoradi, Turunen, & Bondas, 2013, p. 399). The qualitative analysis was used to situate pharmaceutical DTCA stakeholders in terms of position, power, interests, and influence by interpreting the text collected from policy documents and websites with context to pharmaceutical DTCA and policy; keeping in mind that the source of the document or website, the context in which that specific document was drafted, and the stakeholders involved has an impact on the interpretation of that text.

This analysis makes use of quantitative counts, where specific words in a document may be counted to the examine position, power, interests, and influence. The quantitative content analysis was used for a number of purposes, including: grouping and counting stakeholders to understand the size, power, and influence of a stakeholder, the number of stakeholders with certain positions, power, interests, and influence, the

number of stakeholders who are part of different associations, and the size of different groupings of stakeholders (White & Marsh, 2006).

2.6.3 Code Definitions

Details of the codes and definitions – position, power, interests, and influences – applied to this analysis are presented in this section. Table 2.2 provides a summary of the codes and definitions (See Appendix A for examples and excerpts).

Table 2.2: Codes and Definitions

Variable	Definition	Question	Codes and Definitions
Position	stakeholder's stance on DTCA; choosing to either favour more restrictive regulation, less restrictive regulation, or maintain the currently regulatory scheme	What is the policy stance of the stakeholder?	Less regulated DTCA – policy statement or policy involvement in favour of less regulated DTCA.
			More regulated DTCA – policy statement or involvement in favour of more regulated DTCA.
			Maintain current regulation – policy statement or involvement in favour of maintaining the current regulations.
		What is the strength of that position?	Low - A weak policy statement with respect to their position or that the position had to be inferred, and that there was few or no policymaking involvement to advance their position.
			Medium - strength suggests either a strong statement on DTCA policy or policymaking involvement to advance their position.
			High – a strong statement on DTCA policy and policymaking actions that further their position.
Power	The quantity of resources that a stakeholder has within his or her organization or area and the ability to mobilize those resources	How many resources does the stakeholder command?	Low – very little financial resources or organizational capital
			Medium – Some financial resources or organizational capital
			High – significant and obvious amounts of financial resources or organizational capital
Interests	What an actor or group stands to gain or lose	What are the interests of the stakeholder?	Loss - stakeholder losses in a financial or influential capacity as a result of the current regulations

Variable	Definition	Question	Codes and Definitions
	from a policy change		Neutral - stakeholder does not gain or lose in a financial or influential capacity as a result of regulations Benefit - stakeholder benefits in a financial or influential capacity as a result of the current regulations
Influence	influence is the measure a stakeholder's perceived ability to impact regulatory and legal events regarding DTCA, and the stakeholder's desire to do so	How much is the stakeholder ready to initiate changes in more or less restrictive DTCA regulation?	Low - readiness infers that the stakeholder has participated few or no policymaking functions Medium - readiness infers the stakeholder participated in some of the policymaking functions. High - stakeholder participated in most or all policymaking functions.
		How much is the stakeholder able to assert their position on a national level?	Little to none - low amount of policymaking participation and low or medium resources Medium - some policymaking function participation and low, medium, or high resources Greatly - high policymaking function participation and high resources

2.6.4 Position

In the context of stakeholder analysis, 'position' is defined as "whether the stakeholder supports, opposes, or is neutral about the policy" (Schmeer, 1999, p.8). Contextualized for this analysis, position refers to a stakeholder's stance on pharmaceutical DTCA regulation; choosing to favour more restrictive regulation, less restrictive regulation, or maintain the currently regulatory scheme. Varvasovszky (1998) adds that the strength of the stakeholder's position can and should be measured and analyzed; this study adapts Varvasovszky's work to employ three categories of strength with which to label stakeholders: low, medium, and high. To assess the strength of a stakeholder's position, Varvasovszky adds "the strength of support or opposition is assessed according to the level of resources committed to the actor's policy position" (Varvasovszky, 1998, p.1820). Stakeholders found to be participating in numerous policymaking activities or venues, or showing evidence of using resources to influence pharmaceutical DTCA policymaking, were coded as "high, medium, or low" in strength

of position with respect to other stakeholders' allocation of resources towards furthering their positions.

The stakeholder's position on pharmaceutical DTCA regulation was coded as 1) Less Regulated DTCA (in favour of less restrictive DTCA regulation), 2) More Regulated DTCA (in favour of more restrictive DTCA regulation), or 3) Maintaining the currently regulatory scheme. The strength of each stakeholder's position on pharmaceutical DTCA regulation was coded as high, medium, or low strength. Analyzing a stakeholder's position as less regulated DTCA, more regulated DTCA, or maintain regulations was completed by a conducting a textual analysis of each stakeholder's public stance on pharmaceutical DTCA regulation as published in the collected documents or on the stakeholder's website. If a stakeholder had no public stance, then their position was inferred from the stance of their constituent members (if available) or their policy-related involvement. The strength of the stakeholder's position was determined both by the perceived (subjectively by the researcher) strength of the stakeholder's position statement (as evidenced by the language used by the stakeholder in the policy statement) and by the actions taken by the stakeholder to advance its position (e.g. involvement in different pharmaceutical DTCA policymaking events). 'High' strength suggested a strong statement on pharmaceutical DTCA policy and policymaking actions that further that stakeholder's position. 'Medium' strength suggested either a strong statement on pharmaceutical DTCA policy or policymaking involvement to advance its position. 'Low' strength means that there was a weak policy statement with respect to its position or that the position had to be inferred, and that there were few or no examples of policymaking involvement to advance its position.

2.6.5 Power

Power is defined as "the quantity of resources that a stakeholder has within his or her organization or area and the ability to mobilize those resources" (Schmeer, 1999, p. 17?). Buse and colleagues (2012) explain that power is typically understood as operating in a relational sense, where one subject has influence or control over another. For this project, power will be analyzed by assessing the amount of financial or organizational resources at a given stakeholder's disposal which can be used to exert influence on the

policy agenda or other stakeholders. Different pharmaceutical DTCA stakeholders will have varying amounts of power, and that will shape the DTCA policymaking agenda as each attempts to use that power to further its position on and interests in pharmaceutical DTCA. Understanding the relative power of these stakeholders is important to analyzing the stakeholder landscape for policy.

To measure the power of stakeholders in the pharmaceutical DTCA environment, power was defined as the amount of resources at the stakeholder's disposal in total by way of publicly available documents regarding finances or financial status) and compared to other pharmaceutical DTCA stakeholders, and if an association has constituent members. The number of members was factored into coding as "organization capital", as can be determined from the analysis of document text, website text, or the constituent composition of the organization. A stakeholder's organizational capital is dependent not just on the number of constituent members but also the perceived size and power of those members. 'Low' implies that this stakeholder does not wield many financial resources or much organizational capital that can be applied to influence policy. 'Medium' implies that the analysis determined that the stakeholders had some financial resources or organizational capital with which to influence policy. 'Large' implies that the organization had a significant and obvious amount of financial resources or organizational capital that could be applied to influence pharmaceutical DTCA policy.

2.6.6 Interests

Identifying the interests of a stakeholder is instrumental in triangulating its influence. Interests are "what an actor or group stands to gain or lose from a policy change" (Buse et al., 2012, p. 213). Interests are distinct from position, as interests are derived only the potential for benefit or loss incurred from a policy, not the stance of the stakeholder in question on that specific policy.

The interests of the stakeholder were identified in this study through answering one question, "what are the interests of the stakeholder" relative to pharmaceutical DTCA policy. The codes used for this criteria were: benefit, neutral, and loss. 'Benefit' means that the stakeholder benefits in a financial or influential capacity as a result of the current

pharmaceutical DTCA regulations. 'Neutral' means that the stakeholder does not gain or lose in financial or influential capacity as a result of the current regulations. 'Loss' means that the stakeholder loses in a financial or influential capacity as a result of the current regulations.

2.6.7 Influence

Stakeholder influence is considered to be the extent to which the views of a particular stakeholder are reflected in initiatives for change, in agenda setting, in the drafting of regulations and legislation, and in the major national forums (Varvasovsky, 1998). For the purposes of this project, influence was the expression of a stakeholder's position within the context of its interests, and through the application of its power. More succinctly, influence is the measure of a stakeholder's perceived ability to impact regulatory and legal events regarding pharmaceutical DTCA, and the stakeholder's desire to do so. Adapted definitions from Varvasovsky were used in this study (Varvasovsky, 1998, p. 1821). Adapting Varvasovsky's approach to Canadian pharmaceutical advertising policy, the criteria for measuring pharmaceutical advertising were: how much is the stakeholder ready to initiate changes toward more or less restrictive DTCA regulation; how much is the stakeholder able to assert its position on the national level; how much power does the stakeholder have on the outcome of a policy debate.

Influence was measured by coding for two questions: How much is the stakeholder ready to initiate changes to more or less restrictive DTCA regulation (high, medium, or low readiness); how much is the stakeholder able to assert its position on the national level (high, medium, or little to none); how much a stakeholder was ready to initiate change to more or less restrictive pharmaceutical DTCA regulation was measured by the amount of participation in pharmaceutical DTCA regulatory functions (whether that be PAAB, the Standing Committee, the Romanow Commission, or Health Canada advertising complaints). 'Policy-making functions' in this study refers to any event, report, commission, meeting, or similar policymaking event in which a stakeholder could participate. 'Low' readiness indicates that the stakeholder has participated few or no policymaking functions. 'Medium' readiness indicates the stakeholder participated in

some of the policymaking functions. ‘High’ readiness indicates that the stakeholder participated in most or all policymaking functions.

How much a stakeholder is able to assert its position on the national level is coded by how many policymaking functions it is participating in and the number of resources at its disposal. ‘Little to none’ indicates a low amount of policymaking participation and low or medium resources. ‘Medium’ indicates some policymaking function participation and medium, low, or high resources. ‘Greatly’ indicates high policymaking function participation and high resources.

2.6.8 Thematic Groupings

In addition to coding documents as described in the previous section, some stakeholders were analyzed thematically. The Standing Committee report included 127 witnesses - both individuals and groups - who expressed interest in pharmaceutical policy. These witnesses were considered stakeholders, however, the Report covers a number of issues pertaining to pharmaceutical policy other than DTCA. The lack of information on witnesses’ intentions for involvement and the lack of evidence about which policy issues they were involved in means they could not be coded for position, power, interests, or influence. Instead, these witnesses represent the broad range of stakeholders that could potentially be involved in pharmaceutical DTCA; these stakeholders were thematically grouped to represent the different groupings, or “networks”, that *could* be involved in pharmaceutical DTCA. Thematic grouping was achieved by reviewing the ‘about’ page (or website equivalent) of each organization’s website for the organization’s mandate and purpose.

2.7 Results

The results of the analysis are presented as follows. A thematic grouping of the stakeholders identified in the Standing Committee Report is described (Table 2.3) followed by findings of the organizations represented more than once by the Pharmaceutical Advertising Advisory Board (Table 2.4). Shared constituent members from associations found in the Romanow Commission Submissions and PAAB are displayed in Figure 2.1. The positions of stakeholders found in the Romanow

Commission Report and PAAB, and the strength of those positions are displayed in Figure 2.2 (additional details can be found in Appendices B and C), followed by the analysis of the power of those same stakeholders (Table 2.6), their interests (Table 2.7), and their influence on pharmaceutical DTCA policy (Tables 2.8 & 2.9).

The 127 individuals and organizations listed in *Opening the Medicine Cabinet: Standing Committee Report on Health (2004)*, were organized into 15 different “networks” of stakeholders (see again Table 2.3). The members of each network do not necessarily have the same positions, power, interests, and influence, but are similar types of organizations; they are the same in having in such common characteristics as similar mandate, similar functions, or similar purpose. For example, the Canadian Centre for Policy Alternatives and the Fraser Institute are both policy think tanks but hold to different political views and may have different positions on policy issues; they perform a similar function but would not be coded into the same network. These thematic groupings represent the various policy networks that are interested in the broader pharmaceutical policy environment, and within these networks are stakeholders with a specific interest in pharmaceutical DTCA policy.

The analysis identified a broad range of stakeholders with an interest in pharmaceutical policy and that may be interested specifically in pharmaceutical DTCA, providing key insight on the types and number of stakeholders that may be involved in pharmaceutical DTCA. Different thematic groupings of stakeholders have varying types and numbers of organizations. For example, ‘Health Interested Organizations’ is the largest grouping with 34 members. Universities/Academic Units, Unions, Research Groups and Think Tanks, Pharmacists, Other Health Industry, and Government all have between nine and fourteen members, suggesting considerable interest from a wide spectrum of different stakeholders and groups.

Table 2.3: Thematic Grouping of Stakeholders into Networks by Stakeholder Type from the Standing Committee on Health Report

Network	Stakeholders	Number of Stakeholders in Network Type
Universities/Academic Units	Centre for Health Services & Policy Research, University of British Columbia; Faculty of Pharmaceutical Sciences; University of British Columbia; University of British Columbia Therapeutics Initiative; Health Law Institute (University of Alberta); University of Ottawa; Centre for Emotions and Health, Dalhousie University; Dalhousie University; University of New Brunswick Faculty of Nursing; University of Quebec in Montreal	10
Government	Patented Medicine Prices Review Board; Government of Saskatchewan; Ontario Ministry of Health and Long-Term Care; Government of Manitoba; Vancouver Native Health Authority; Alberta Health and Wellness; North West territories Health and Social Services; Brunswick Department of Health and Wellness; Nova Scotia Department of Health	9
Research Groups and Think Tanks	Institute of Health Economics; The Fraser Institute; Vancouver Coastal Health Research Institute; Canadian Centre for Policy Alternatives; Institute of Health Economics; Saskatchewan Drug Research Institute; Canadian Institute for Health Information; Canadian Coordinating Office for Health Technology; Atlantic Institute for Market Studies; Anemia Institute for Research and Education	10
Unions	Canadian Union of Public Employees (Alberta Division); Saskatchewan Union of Nurses; Canadian Labour Congress; Canadian Union of Public Employees; Congress of Union Retirees of Canada; National Union of Public and General Employees; Canadian Auto Workers Union; United Steelworkers of America; Canadian Federation of Nurses Union	9
Health Interested Organizations	Better Pharmacare Coalition; British Columbia Health Coalition; British Columbia Persons With Aids Society; Society for Diabetic Rights; All Nation Hope AIDS Network; Canadian Arthritis Patient Alliance; Community Health Services (Saskatoon Association); Saskatchewan Health Coalition; The Arthritis Society (Saskatchewan Division); Addictions Foundation of Manitoba; Manitoba Centre for Health Policy; Best Medicines Coalition; Womens Health Clinic; Council of Canadians; Canadian Health Coalition; Canadian Cancer Society (Nova Scotia Division); Canadian Mental Health Association; Nova Scotia Citizens Care Network; P.E.I Health Coalition and MacKillop Centre for Social Justice; New; Atlantic Centre of Excellence for Womens Health; Coalition of Physicians for Social Justice; Committee of People Living with HIV of Quebec; Women and Health Protection, Drug Safety Canada, Multiple Sclerosis Society of Canada; Canadian	34

Network	Stakeholders	Number of Stakeholders in Network Type
	Arthritis Network; Canadian Cystic Fibrosis Foundation; Canadian Diabetes Association; Canadian Network for Asthma Care; Canadian Treatment Action Council; Osteoporosis Society of Canada; Alliance for Access to Medical Information; Medical Reform Group	
Consumer Associations	Downtown Eastside HIV/IDU Consumers' Board; Pharmawatch; Consumer's Association of Canada (Alberta); Union des consommateurs; Consumer Association of Canada	5
Pharmacists	Representative Board of Saskatchewan Pharmacists; Saskatchewan College of Pharmacists; British Columbia Pharmacy Association; Alberta College of Pharmacists; Coalition for Manitoba Pharmacy; Manitoba Society of Pharmacists; Manitoba Pharmaceutical Association; New Brunswick Pharmacists Association, Ordres des Pharmaciens du Québec; Canadian International Pharmacy Association; Canadian Pharmacists Association; Ontario College of Pharmacists; Ontario Pharmacists Association	14
HealthCare Workers	Canadian Nurses Association; Fédération des infirmières et infirmiers du Québec; Canadian Medical Association; The Royal College of Physicians and Surgeons of Canada	4
Brand Name Pharmaceutical Industry	Kerbapharma Inc.; Biogen Canada; Genzyme Canada Inc.; BIOTEC Canada; Rx & D - Canada's Research Based Pharmaceutical Companies; Gilead Science Inc.	6
Generic Pharmaceutical Industry	Canadian Generic Pharmaceutical Association	1
'Other' Health Industry	Market Media International Corp.; Canadian Association of Chain Drug Stores, Brogan Inc., Palmer D'Angelo Consulting Inc.; Le Groupe Jean Coutu (PJC) Inc.; Pharmex Direct Inc.; ESI Canada; Green Shield Canada; IMS Health, Montreal International	11
First Nations Groups	Assembly of First Nations, Indian Council of First Nations of Manitoba; Native Council of Canada (Alberta)	3
Regulatory Groups	Pharmaceutical Advertising Advisory Board	1
Aging Citizenry	Council of Senior Citizens Organizations of British Columbia; Seniors' Action and Liaison Team; Canada's Association for the Fifty-Plus; Canadian Pensioners Concerned Inc.; Alliance of Seniors to protect Canada's Social Programs	5
Individuals	John McConnell, John Bury; Kay Schwartzman; Michael Rachilis	4

Source: Standing Committee on Health (2004)

2.7.1 Stakeholder Networks

PAAB is composed of a number of associations which are themselves networks of stakeholders (see Table 2.4). Some of these stakeholders are part of multiple networks which constitute the PAAB self-regulatory body. For example, Sanofi, a brand name pharmaceutical drug manufacturer, is a constituent of four different associations which are, in turn, members of PAAB. Stakeholders who are part of multiple PAAB associations may have more power and influence in regulatory decision making as they can access multiple networks in pursuit of their agendas.

Table 2.4: Constituent Stakeholders Represented More Than Once by Pharmaceutical Advertising Advisory Board Members

Number of Times Represented by a PAAB Member	Organization
4	Sanofi
3	Pfizer
2	AstraZeneca, CMA, Pharmascience, Teva, Bayer, Boehringer Ingelheim, GlaxoSmithKline, Johnson & Johnson, Procter and Gamble, Bristol-Myers Squibb Canada Inc, Eli Lilly, Eisai Limited, Roche, Janssen Inc, Kalgene Pharma Inc, Merck, Novartis, Novo Nordisk, Proecocyte diagnostics, Purdue, Sunovian, Shire, Therapure.

Source: Pharmaceutical Advertising Advisory Board (2016)

PAAB is composed of a number of associations which are themselves networks of stakeholders (see again Table 2.4). Some of these stakeholders are part of multiple networks which constitute the PAAB self-regulatory body. For example, Sanofi, a brand name pharmaceutical drug manufacturer, is a constituent of four different associations which are, in turn, members of PAAB. Stakeholders who are part of multiple PAAB associations may have more power and influence in regulatory decision making as they can access multiple networks in pursuit of their agendas.

Of the 364 stakeholders identified in PAAB, 336 (92%) of the stakeholders were represented by one network. (See Appendix B for a full list of constituent members of PAAB associations.) There were 23 stakeholders represented by two networks, one stakeholder was represented by three networks, and one stakeholder was represented by four networks. Notably, of the 25 PAAB stakeholder constituent organizations

represented by more than one network, 20 are brand name pharmaceutical drug manufacturers, and 24 out of 25 are considered biotechnology companies. Pfizer and Sanofi, the only organizations to be represented by more than two networks, are international brand name pharmaceutical corporations operating in numerous countries. Brand name pharmaceutical corporations may have the most ability to further their pharmaceutical DTCA policy agendas or interests through their PAAB representatives as they have the multiple networks through which to exercise their influence through PAAB.

Figure 2.1 illustrates the connections between stakeholder associations, identified in PAAB and the Romanow Commission, and their constituent members. A number of associations or organizations may have multiple shared members with each other but none with others; for instance, BIOTECCanada (depicted in the top-center region of the figure) shares three members with Consumer Health Products Canada (bottom-left), but none with the Canadian Health Coalition (top-center/right). By examining the prior mentioned organizations & associations we can note that Sanofi, Johnston & Johnston, & Pfizer have at least two means of advancing their interest or positions (through either BIOTECCanada or Consumer Health Products Canada). Consumer Health Products Canada and BIOTECCanada both support maintaining current pharmaceutical DTCA regulations while the Canadian Health Coalition supports more regulated pharmaceutical DTCA.

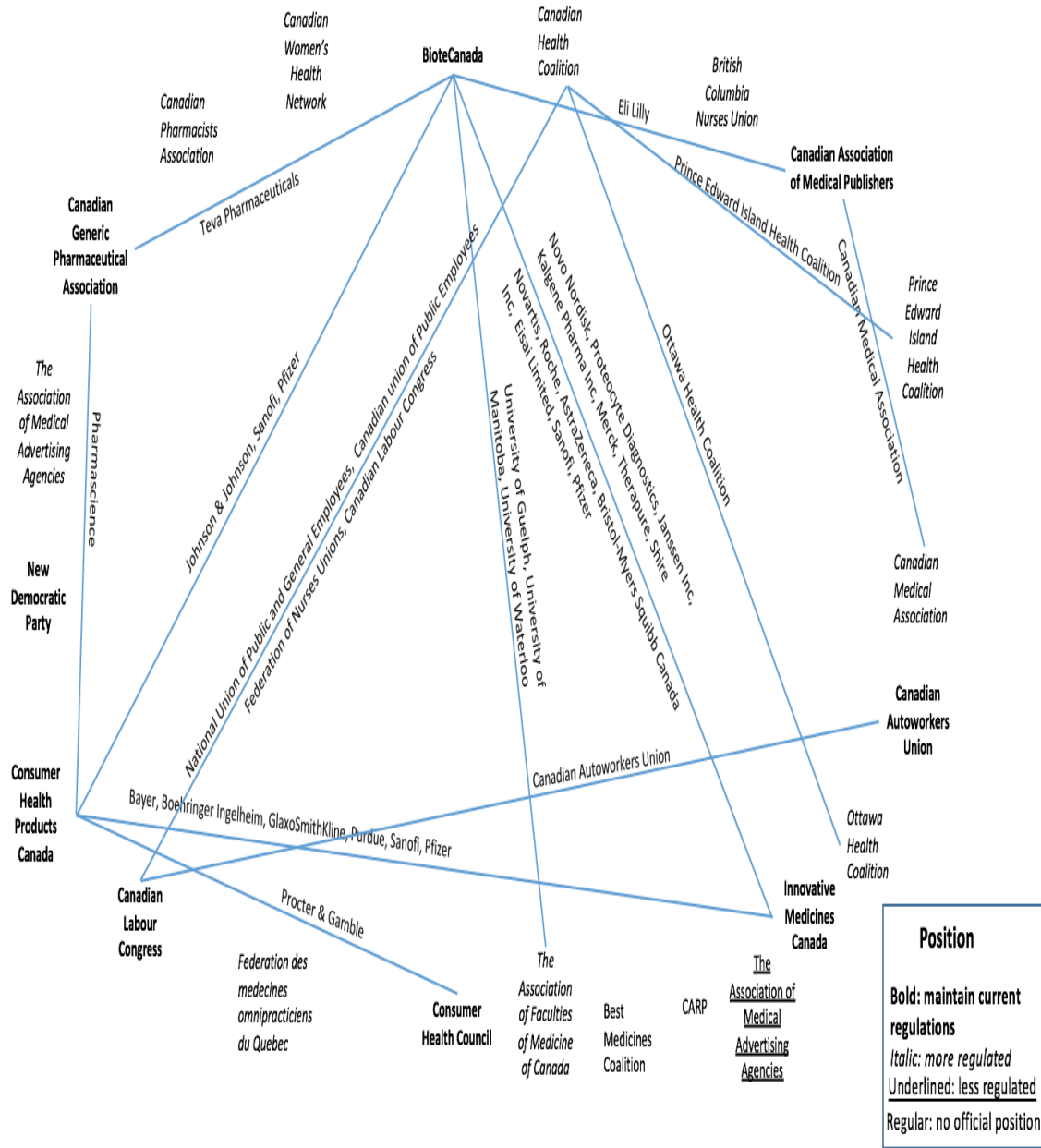


Figure 2.1: Shared Constituent Stakeholders Between Stakeholders in Romanow Commission Submissions & Pharmaceutical Advertising Advisory Board

Note: The names around the periphery of this diagram represent associations or organizations identified in PAAB and the Romanow Commission. Names positioned along the straight lines are members of both organizations on either end of the line.

2.7.2 Stakeholder Positions

The analysis of stakeholders identified in the Romanow Commission submissions and PAAB members involved identifying and recording both the members' positions with respect to the regulatory status of pharmaceutical DTCA, and the strength with which they held those positions. See Figure 2.2 below for details. Eight stakeholders, out of 22 (36%), occupied the "maintain current regulations" pharmaceutical DTCA policy position, five of whom held the position with "high strength", one held the position with "medium strength", and one held it with "low strength." Nine stakeholders occupied a position supporting more regulation of pharmaceutical DTCA, six of which held that position with "high strength" and three held it with "medium strength". Just one stakeholder, The Association of Medical Advertising Agencies, positioned itself in favour of less pharmaceutical DTCA regulation, and that position was held with "high strength". CARP and the Best Medicines Coalition have no publicly available position on pharmaceutical DTCA regulation.

Of note, most stakeholders occupy the "maintain current regulation" or "more regulated DTCA" position with medium or high strength, suggesting that there is little policy or political interest in changing the current pharmaceutical DTCA regulations. When examining these findings one should remember that the current regulations are quite prohibitive towards many forms of pharmaceutical DTCA, and that these pharmaceutical DTCA policy positions exist on a continuum of regulation ranging from "not regulated" to "prohibition". The "maintain current regulations" position occupies a space on that continuum nearer to "prohibition" than "not regulated", as does "more DTCA regulation". In context, these findings infer that most stakeholders favor a regulated pharmaceutical DTCA space, and that deregulation is not a popular policy position amongst stakeholders.

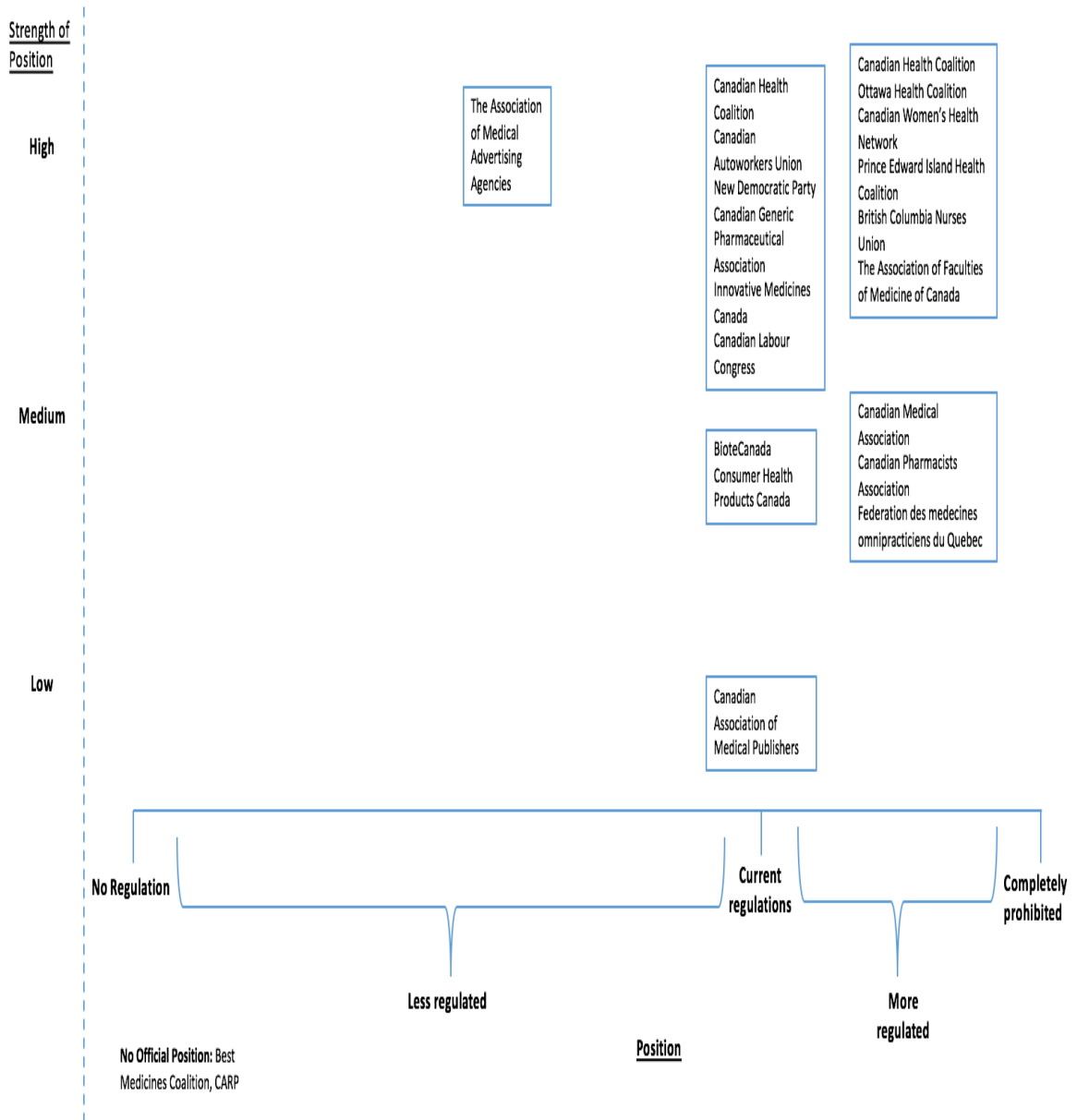


Figure 2.2: Stakeholders DTCA Positions & Strengths of those positions from Romanow Commission Submissions & Pharmaceutical Advertising Advisory Board

Notes: High = a strong statement on DTCA policy and policymaking actions that further their position. Medium = strength suggests either a strong statement on DTCA policy or policymaking involvement to advance their position. Low = A weak policy statement with respect to their position or that the position had to be inferred, and that there was few or no policymaking involvement to advance their position. See Appendix D for background information to this diagram represented in a table.

2.7.3 Stakeholder Power

As shown in Table 2.5, from the 22 stakeholders identified from PAAB and the Romanow Commission submissions, 17 or 77%, were categorized as “medium” or “low” power, with eight (36%) of these stakeholder groups coded as “medium” and nine (41%) coded as “low.” A smaller number of stakeholders, five (23%), were categorized as “high” power.

Table 2.5: Stakeholder Power (Resources) – Romanow Commission Submissions & Pharmaceutical Advertising Advisory Board

High	Medium	Low
<ul style="list-style-type: none"> • BIOTECCanada • Canadian Generic Pharmaceutical Association • Innovative Medicines Canada • New Democratic Party • Canadian Drug Manufacturers Association 	<ul style="list-style-type: none"> • The Association of Faculties of Medicine of Canada • Canadian Medical Association • Canadian Pharmacists Association • Consumer Health Products Canada • Canadian Association of Retired Persons • Canadian Health Coalition • Canadian Labour Congress • British Columbia Nurses Union 	<ul style="list-style-type: none"> • The Association of Medical Advertising Agencies • Canadian Association of Medical Publishers • Best Medicines Coalition • Federation des medecines omipraticiens du Quebec • Canadian Autoworkers Union • Ottawa Health Coalition Canadian • Prince Edward Island Health Coalition • Dr. John Bury (individual) • Women's Health Network

Notes: *High* = significant and obvious amounts of financial resources or organizational capital. *Medium* = Some financial resources or organizational capital. *Low* = very little financial resources or organizational capital

All the high power stakeholders, with the notable exception of the New Democratic Party, are pharmaceutical manufacturers associations, and all the high power stakeholders have considerable financial resources. The New Democratic Party is one of three major federal political parties and, as such, has considerable policymaking ability, including the power to advocate for particular issues directly from within Parliament,

participating in Parliamentary committee activities (including policy development), and supporting and voting on potential legislation. Notably, medium power stakeholders are mainly prominent health professional organizations with a mandate to advocate for health-related issues and also include an association of medical school faculties that produces evidence, the Consumer Health Products Association, and a national healthcare lobbying association – all of these organizations have a distinct interest in advancing patient or population health. Low power stakeholders are mainly cause or sectional groups which are advancing a specific issues. For example, the Association of Medical Advertising Agencies, in this low power group, is a single advertising agency which holds a membership position at PAAB and may be advancing its own interests in pharmaceutical advertising.

When the power and position of PAAB and Romanow Commission stakeholders are considered together there is a concentration of high power stakeholders focused towards one position, maintaining the current pharmaceutical DCTA regulations, with no high power stakeholders supporting either a more regulated or less regulated position. See Figure 2.3 for details. Four stakeholders are medium power and support maintaining the current regulations, while five medium stakeholders support more regulated pharmaceutical DTCA. Four low power stakeholders support more regulated pharmaceutical DTCA, one supports less regulated pharmaceutical DTCA, and one supports maintaining the current regulations. Most of the collective power in this Figure is concentrated on the ‘maintain current regulations’ position, suggesting that this policy might have the most support in future policy discussions.

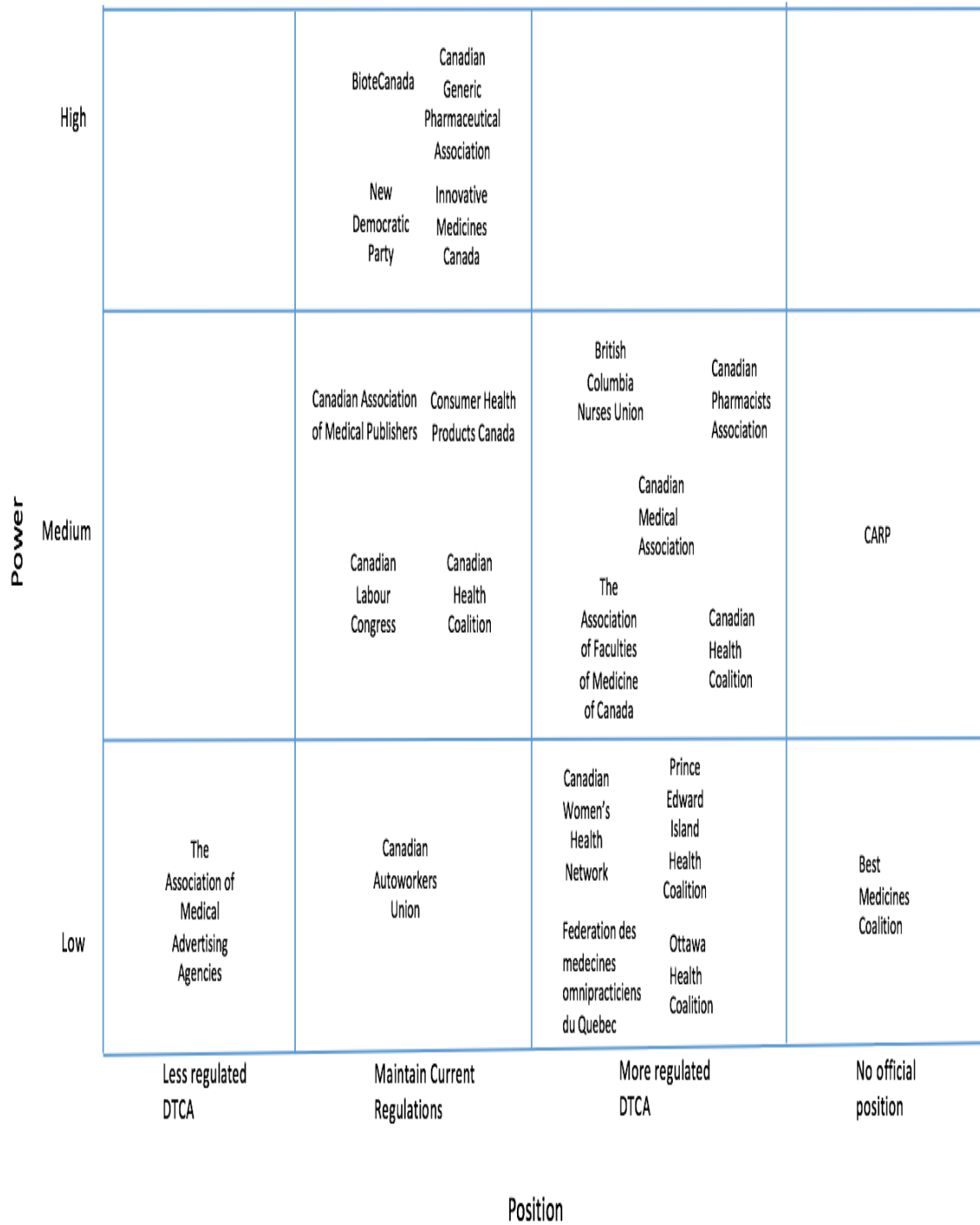


Figure 2.3: Power and Position of Stakeholders in Romanow Commission Submissions & Pharmaceutical Advertising Advisory Board

Note: The diagram is divided into a number of quadrants, each represented a different position and power combinations. Stakeholders in the same quadrant share the same position and power.

2.7.4 Stakeholder Interests

Interests were identified based on whether the stakeholders benefit from the current regulations, experience loss from the current regulations, or are neutral to the current pharmaceutical DTCA regulatory scheme. Whether the stakeholder experienced benefit, loss, or neutrality was decided based on finances, power, influence, or any other form of capital. Furthermore, if stakeholders had competing interests they were coded as “neutral” as were stakeholders who had nothing to gain or lose or were indifferent to the current regulations. See Table 2.6 for details.

Table 2.6: Interests – Stakeholders identified from Romanow Commission Submissions & Pharmaceutical Advertising Advisory Board

Benefit	Neutral	Loss
<ul style="list-style-type: none"> ▪ Canadian Generic Pharmaceutical Association ▪ Canadian Drug Manufacturers Association ▪ Innovative Medicines Canada ▪ BIOTECanada 	<ul style="list-style-type: none"> ▪ The Association of Faculties of Medicine of Canada, ▪ The Association of Medical Advertising Agencies, ▪ Best Medicines Coalition ▪ Canadian Association of Medical Publishers ▪ Canadian Association of Retired Persons ▪ Consumer Council of Canada ▪ Federation des medecines omipraticiens du Quebec ▪ Canadian Health Coalition ▪ New Democratic Party ▪ Ottawa Health Coalition ▪ Canadian Women's Health Network ▪ Prince Edward Island Health Coalition ▪ British Columbia Nurses Union ▪ John Bury ▪ Canadian Autoworkers Union ▪ Canadian Labour Congress 	<ul style="list-style-type: none"> ▪ Canadian Medical Association ▪ Canadian Pharmacists Association ▪ Consumer Health Products Canada ▪ Consumer Healthcare Providers

Notes: Romanow Submissions refers to submissions to the Commission on the Future of Healthcare in Canada during an open call for papers. PAAB refers to the Pharmaceutical Advertising Advisory Board. *Benefit* = stakeholder benefits in a financial or influential capacity as a result of the current regulations. *Neutral* = stakeholder does not gain or lose in a financial or influential capacity as a result of regulations. *Loss* = stakeholder losses in a financial or influential capacity as a result of the current regulations

Most stakeholders from PAAB and the Romanow Commission submissions have “neutral” interests with respect to the current pharmaceutical DTCA regulations: 14 out of 22 (64%) stakeholder groups are coded as having “neutral” interests, four stakeholder groups were coded as experiencing “benefit” from current regulations, and four stakeholder groups were coded as “loss” from current regulations. Most stakeholders have interests that do not conflict with, but do not necessarily benefit from, the current

pharmaceutical DTCA regulations. Although advertising is still partly restricted, brand name pharmaceutical manufacturers may benefit from the current regulations because the current regulations do not adequately address cross-border advertising from the United States and online advertising. Pharmaceutical drug manufacturers may benefit from some built-in flexibility in the current pharmaceutical DTCA regulations themselves, such as allowing reminder ads and help seeking ads, and a reliance on industry self-regulation such as PAAB for industry-led pre-clearance services for pharmaceutical ads. A re-opened policy conversation about pharmaceutical DTCA advertising may lead to more regulated DTCA, which is why brand name pharmaceutical companies may not be interested in attempting to change the current regulations. The groups that may experience loss from the current DTCA regulations are medical professional associations which have to contend with the influence of medical advertising on their members' relationships with patients, and consumer health associations which are concerned about the impact of the advertising of pharmaceuticals on the public. In general, stakeholders may not attempt to prompt pharmaceutical DTCA regulatory change if they are either neutral in respect of or benefit from the regulations, as the majority of stakeholders in these findings are.

2.7.5 Stakeholder Influence

Findings from the analysis of PAAB and Romanow Commission stakeholders' influence, as measured by the stakeholder's readiness to initiate policy change, suggest that most stakeholders (10 out of 22; 45%) had "medium" influence; that is, they participated in some policy functions. A smaller number of stakeholders, six (27%), were categorized as "low" influence, and participated in few or no policymaking functions (see Table 2.7).

Table 2.7: Influence (readiness to initiate changes in DTCA regulation) – Romanow Commission Submissions and Pharmaceutical Advertising Advisory Board

Low	Medium	High
<ul style="list-style-type: none"> • The Association of Medical Advertising Agencies • Canadian Association of Medical Publishers • Federation des medecines omipraticiens du Quebec • New Democratic Party • Prince Edward Island Health Coalition • John Bury* 	<ul style="list-style-type: none"> • The Association of Faculties of Medicine of Canada • Canadian Medical Association • Canadian Pharmacists Association • Best Medicines Coalition • Consumer Health Products Canada • Canadian Association of Retired Persons • Consumer Council of Canada • Canadian Labour Congress • Canadian Autoworkers Union • Canadian Women's Health Network • British Columbia Nurses Union 	<ul style="list-style-type: none"> • BIOTECanada • Canadian Generic Pharmaceutical Association • Innovative Medicines Canada • Canadian Health Coalition • Ottawa Health Coalition • Canadian Drug Manufacturers Association.

Notes: *High* - stakeholder participated in most or all policymaking functions. *Medium* - readiness infers the stakeholder participated in some of the policymaking functions. *Low* - readiness infers that the stakeholder has participated few or no policymaking functions. *John Bury is an individual citizen who made a submission to the Romanow Commission.

Finally, six stakeholders (26%) were categorized as “high” influence, and were found participating in all or most policymaking functions identified in this study. The high influence (readiness) stakeholders are able to initiate policy change if necessary, as they are positioned to do so through their policymaking functions. High influence (readiness) stakeholders were the pharmaceutical manufacturers and health lobbying bodies, medium influence (readiness) stakeholders were mainly health interested associations and unions, and low influence (readiness) stakeholders were groups that were either less focused on health itself (e.g. New Democratic Party), or not participating in policymaking functions (e.g. Canadian Association of Medical Publishers). See Table 2.8 for details.

Analyzing for influence on pharmaceutical DTCA policy, as measured by a stakeholder's ability to assert its position on pharmaceutical DTCA at the national level, most stakeholders (12 out of 22; 55%) from PAAB and the Romanow Commission largely occupied the "medium" influence category. There were four (18%) stakeholder associations coded as "little to none" influence on pharmaceutical DTCA policy and six (27%) stakeholders were coded as "High" influence. Resources, and therefore power, was a consideration in analyzing stakeholders for their ability to influence pharmaceutical DTCA policy. Findings suggest that high power stakeholder groups were generally aligned with high influence groups (e.g. BIOTECanada), and medium power stakeholder groups with medium influence groups (e.g. Best Medicine Coalition). However, these findings do not necessarily mean they will choose to use that influence to affect policy. Notably, the New Democratic Party has high power and high influence, but low readiness to initiate policy change.

Table 2.8: Influence (Able to assert position on a national level) – PAAB and Romanow Commission Submissions

Little to none	Medium	High
<ul style="list-style-type: none"> ▪ Ottawa Health Coalition ▪ Prince Edward Island Health Coalition ▪ Canadian Association of Medical Publishers ▪ Best Medicines Coalition 	<ul style="list-style-type: none"> ▪ Canadian Labour Congress ▪ Canadian Autoworkers Union ▪ Canadian Women’s Health Network ▪ British Columbia Nurses Union ▪ John Bury ▪ The Association of Faculties of Medicine of Canada ▪ The Association of Medical Advertising Agencies ▪ Canadian Medical Association ▪ Canadian Pharmacists Association ▪ Consumer Health Products Canada ▪ Canadian Association of Retired Persons ▪ Consumer Council of Canada 	<ul style="list-style-type: none"> ▪ Canadian Health Coalition ▪ New Democratic Party ▪ Canadian Drug Manufacturers Association ▪ BIOTECanada ▪ Canadian Generic Pharmaceutical Association ▪ Innovative Medicines Canada

Notes: *High* – high policymaking function participation and high resources. *Medium* – some policymaking function participation and medium, low, or high resources. *Little to none* – low amount of policymaking participation and low or medium resources

2.8 Discussion

The pharmaceutical DTCA policy environment has a number of stakeholders of varying power and influence participating in the policy environment. The roles of these stakeholders in pharmaceutical DTCA policymaking can be understood in a number of ways such as in terms of their position, power, interests, or influence. The aim of this stakeholder analysis was to identify and conduct an analysis of the stakeholders relevant to pharmaceutical DTCA in terms of their position, power, interests, and influence to impact future policy and legal proceedings pertaining to pharmaceutical advertising. Findings from this analysis suggest the following:

- 1) There is a wide-range of stakeholders from varying backgrounds in the pharmaceutical DTCA policy environment;

- 2) Many stakeholders are part of policy networks;
- 3) Stakeholders have varying positions, interests, and influence; and
- 4) There is a concentration of powerful stakeholders interested in maintaining current pharmaceutical DTCA regulations.

Discussion of these key findings follow.

2.8.1 Range and Number of Stakeholders

A wide range of stakeholders from varying backgrounds were identified in this study. A thematic analysis of the stakeholders found in the Standing Committee on Health Report (2004) yielded 127 different individuals and organizations potentially operating in the pharmaceutical DTCA policy environment. Those individuals and organizations were thematically grouped into 15 different categories of stakeholders. The stakeholders in each category may share interests or positions but are not necessarily part of the same policy networks.

In similar work, Robert Alford, in the 1960s and 1970s, identified three structural interest groups in health care politics: professional monopolists, the corporate rationalizers, and, thirdly (considered as one group), the equal health advocates and community health advocates (Alford, 1975). Buse and colleagues (2012) described the ‘professional monopolists’ conceptualized by Alford (1975) as “the doctors and to a lesser extent the other health professionals whose dominant interests are served by the existing economic, social and political structures of government and the health system” (Buse et al. p.120). Corporate rationalizers often challenge the professional monopolists, are interested in modern management methods and healthcare delivery, often in search of cost-savings or additional revenues. Examples of such groups are private insurers, commercial hospital chains, employers who want to lower the cost of insuring employees (Alford, 1975). The third and final group are the ‘equal health advocates’ and ‘community health advocates’ who are described as sectional and interest groups interested in access to healthcare, equal rights and patient rights, attention to the views of

patients in population healthcare, and other public health issues. They may often act in an activist or advocate capacity (Alford, 1975).

There is overlap between Alford's three structural interest groups and the stakeholders identified in this study, despite the 42 years separating the studies. The thematic category of pharmaceutical DTCA stakeholders named 'Health Care Workers' and 'Pharmacists' aligns with Alford's 'professional monopolists'. The groups identified in this study as 'Other Healthcare Industry', 'Generic Pharmaceutical Industry', 'Brand Name Pharmaceutical Industry', and 'Government' align with the Alford's 'Corporate Rationalizers'. Finally, the 'Health Interests Organizations', and 'First Nations Groups' in this study are consistent with Alford's 'equal health advocates' and 'community health advocates'.

However, not all the thematic categories in this study can be neatly described as falling into one of Alford's three structural interest groups (1975). Those categories that do not appear to fit into Alford's groups are: 'Universities/Academic Units', 'Unions', 'Research Groups & Think Tanks', 'Aging Citizenry', 'Consumer Associations', and 'Regulatory Groups'. This study identified additional groups which do not fit Alford's structural interest groups, and provides more detailed description of stakeholders in the pharmaceutical DTCA policy environment. The stakeholders identified here are those whose interests and positions are specific to pharmaceutical DTCA (yet within the environment of healthcare politics).

The identification of a wide range of stakeholders represents a broader and more nuanced view of the pharmaceutical DTCA policy environment than has been found in previous studies. For example, Roberts (2011) similarly to Alford identified three broad categories of stakeholders (referred to as "stakeholder groups"): Industry (representing pharmaceuticals), General Practitioners (representing physicians), and the Public (representing citizenry). This grouping of pharmaceutical DTCA stakeholders is very similar to the structural interest groups identified by Alford (1975) by way of identifying three broad categories of stakeholders. Roberts (2011) did not analyze the specific stakeholders within each of his three categories, did not provide a more in-depth

understanding of the different positions and interests held by stakeholders in each category, and did not sufficiently capture the entire range of stakeholders that have been identified in this study to have an interest in pharmaceutical DTCA policy. The present study provides a richer and more detailed understanding of the stakeholder groups operating in the pharmaceutical DTCA policy area than could be gleaned through Roberts' approach.

In Matear & Dacin's study of the American pharmaceutical DTCA stakeholders they identified five stakeholder groups: 1) consumers, 2) physicians, 3) insurance companies and formularies, 4) pharmacists, and 5) the government. Their findings are more nuanced than those of Roberts (2011), however they still do not capture the full field of stakeholder categories identified in this study, and, like Roberts, do not name the specific organizations that would be grouped into each of their categories. One important difference in our study is that insurance companies were not found to be a prominent group. This may be explained by the differences in American and Canadian healthcare systems and funding models, since private insurance companies play a larger role in the United States than they do in Canada (where government funded healthcare forms that largest part of the healthcare landscape) (Hacker, 1998).

While both Roberts (2011) and Matear and Dacin (2010) identified broad categories of stakeholders or policy networks in their studies of the Canadian and the American pharmaceutical DTCA, respectively, our work on pharmaceutical DTCA identified more categories and provides details about the specific individuals and organizations within these policy groupings. The significance of this finding is that the breadth of organizations and individuals with policy interests in Canadian pharmaceutical DTCA is larger than the breadth of players reported in those previous studies.

2.8.2 Policy Networks

This study also mapped the connections between various stakeholders and how they may be connected through shared membership in various networks. PAAB, the preclearance agency identified in Roberts (2006), is both an important regulatory organization and represents a network of stakeholders with competing positions and

interests in pharmaceutical advertising. The Romanow Commission (Commission on the Future of Healthcare in Canada, 2002) was also an important policy event which involved a number of stakeholders. A number of members of PAAB and witnesses to the Romanow Commission are themselves associations with constituent organizations or memberships which they have a mandate to represent. The power, positions, influence, and interests of those constituents and members inform the position of each association that is part of the PAAB network or made submissions to the Romanow Commission. A number of these associations shared constituents or members, and those shared constituents had more avenues through which they could advance their agendas. For example, Sanofi, a pharmaceutical company, is a member of four associations in PAAB, and can work through any of those associations to advance their pharmaceutical DTCA agenda. The findings suggest that the associations in PAAB and those making submissions to the Romanow Commission are best understood as sectional groups, which seek to advance the positions and interests of their memberships. The most powerful and influential of these sectional groups have been effective in leveraging their networks to support their positions and interests, which has been found in this study to be to maintain the current pharmaceutical DTCA regulations.

2.8.3 Positions, Interests, and Influence

Another finding of this study is that the Canadian pharmaceutical DTCA policymaking environment consists of numerous stakeholders and networks who hold positions on DTCA regulation that exist on a continuum ranging from no pharmaceutical DTCA regulation to completely prohibiting pharmaceutical DTCA. The stakeholders identified in this studied can be grouped into three broad positions on pharmaceutical DTCA policy (less pharmaceutical DTCA regulation, maintain current regulations, more pharmaceutical DTCA regulation). The stakeholders also pursue various interests (with respect to whether the current regulations cause benefit or loss to the stakeholder, or whether they are neutral), which informs their positions and how they choose apply their power and influence. For example, a brand name pharmaceutical company may want to maintain the current regulations so that a new pharmaceutical DTCA policy debate

doesn't open and potentially develop into a more regulated (and unfavourable, for this brand-name company) policy environment.

Stakeholders positions on pharmaceutical DTCA policy were focused mainly of one of two positions: to either maintain current DTCA regulations, or support more regulated pharmaceutical DTCA. Only the Association of Medical Advertising Agencies supported less regulated pharmaceutical DTCA. Eight stakeholders supported maintaining the current pharmaceutical DTCA regulations, and nine stakeholders supported more regulated pharmaceutical DTCA. These two positions are directions that can be expected to be pursued by stakeholders if pharmaceutical DTCA policy changes were to be made in the future, it is unlikely that many stakeholders would pursue less regulation.

Most stakeholders, 14 of the 22 (64%), have "neutral" interests in regards to the current pharmaceutical DTCA regulations, just four experience benefit, and four experience loss from the current regulations. This may help explain why there is a clustering of support on maintaining current regulations, but does not explain why a number of stakeholders support more pharmaceutical DTCA regulation. One possibility is that the mandate of the organization (such as a union) supporting more regulation may encourage them to support more regulation, even if the organization itself does not benefit directly.

Stakeholder power is usually indicative of the stakeholder's influence, for example Innovative Medicines Canada is a 'high power' stakeholder and has a 'high' ability to assert their position on a national level. However, there are some exceptions. For example, the Canadian Health Coalition is a 'medium power' stakeholder with a 'high' ability to assert themselves on a national level. For both categories of influence (Readiness to initiate change in DTCA regulation, and ability to assert position on a national level) most stakeholders had "medium" influence, suggesting that most stakeholders alone cannot significantly change the pharmaceutical DTCA policy. Those stakeholders "medium power" stakeholders are health professional organizations, unions, and health interested stakeholders.

By developing a more nuanced understanding of the positions, power, interests, and influence of the stakeholders, and therefore the capabilities of each stakeholder and how they may choose to apply themselves, our understanding pharmaceutical DTCA policy has been enhanced. This stakeholder analysis suggests that the majority of high power and high influence stakeholders tend to support the position to maintain current DTCA regulation; this finding suggests that there may not be a desire to modify current regulations in the near future. Typically, policy change is triggered by a “problem” or influenced by stakeholders to get an issue on government’s agenda (Buse et al., 2012). Our study findings suggest that there is little desire by stakeholders for government to act on DTCA policy at this time.

2.8.4 Power, Stakeholders, and Maintaining the Status Quo

A focus of this study has been to understand how power is held and potentially exercised by pharmaceutical DTCA stakeholders in Canada. Power can be distributed in a number of ways: two dominant theories of power distribution in policy-making are pluralism and elitism (Buse, Mays, Walt, 2012). Pluralism is the belief that power to influence and shape policy should be distributed amongst numerous stakeholders. These numerous stakeholders then engage in communication and bargaining to protect and further their interests, and influence policy. The contrasting theory to pluralism is elitism, which contends that power is centralized on a powerful minority of stakeholders who influence policy (Buse, Mays, & Walt, 2012). Understanding DTCA policy through the lens of pluralism or elitism can inform our understanding of pharmaceutical DTCA stakeholders, and which stakeholders have the most power or influence in shaping and advancing pharmaceutical DTCA policy. Findings from this stakeholder analysis suggest that there are a broad range of stakeholders – both individuals and organizations - participating in the pharmaceutical DTCA policy arena; this is consistent with pluralism. A number of stakeholder groups have formed coalitions or utilize networks to better communicate their positions and interests on DTCA policy. However, there were a few “high power” stakeholders, predominantly associated with the pharmaceutical industry, exercising their position and influence to protect their interests; this is more consistent with elitism. Findings from the analysis suggest that power in the pharmaceutical DTCA

policy arena aligns with a mixed pluralism and elitism approach (Buse et al., 2012). Power exercised by stakeholders in future pharmaceutical DTCA policy may continue to mirror this hybrid of a broad range of stakeholders along with influence from the elites, the pharmaceutical industry.

Those elites, mainly the pharmaceutical industry, have the highest concentration of power and currently wish to maintain the current Canadian pharmaceutical DTCA regulations. While stakeholders were split in their positions on whether to maintain current regulations or increase regulation of pharmaceutical DTCA, all the high power stakeholders (e.g, Canadian Generic Pharmaceutical Association) and 40% of medium-power stakeholders (e.g, Canadian Association of Medical Publishers) favoured maintaining the status quo. Because of the power held by these stakeholders it is likely that they would be able to influence policymakers to maintain the current pharmaceutical DTCA regulations. The stakeholders whose position is to maintain the current regulations (the most powerful grouping of stakeholders) may not agree with the recommendations of the former Health Council of Canada, (Health Council of Canada, 2006) or the Standing Committee on Health (Standing Committee on Health, 2004), which both called for more regulated pharmaceutical DTCA. This may explain why there has been no pharmaceutical DTCA policy change since the time these reports were released.

The majority of low power stakeholders (e.g. Canadian Women's Health Network) and 50% of medium-power stakeholders (e.g. Canadian Medical Association) favoured increasing regulation, they may be less powerful and may be less able to influence future pharmaceutical DTCA policy. Although equal numbers of stakeholders in our study supported increased regulation of pharmaceutical DTCA as supported maintaining the current pharmaceutical DTCA regulations, it is the stakeholders supporting the status quo who are likely more powerful. The diversity of stakeholders identified in this analysis suggests a more pluralistic approach to power and pharmaceutical DTCA policymaking in Canada. In this case, the pharmaceutical DTCA stakeholders have formed formal and informal networks that are able to share views and attempt to influence government (as evidenced by submissions to the Senate Standing Committee and Romanow Commissions). While the stakeholder analysis did identify a

few powerful “elites” (high power and high influence stakeholders), their impact on DTCA was either limited or they contributed to current DTCA policy environment standstill, which is consistent with their position on pharmaceutical DTCA regulations. Findings from this study also suggest there are networks where low-power stakeholders (e.g. Canadian Women’s Health Network) may join to network with higher power stakeholders (e.g. such as PAAB) to enhance their own power to further their positions and interests.

2.9 Conclusion

The important contributions of this work are a more detailed and granular description of specific Canadian pharmaceutical DTCA stakeholders than provided in previous research, which has tended to describe stakeholders in a limited number of broad categories. The mapping of the thematic groupings of stakeholders and the networks of stakeholders contributes to our understanding of which stakeholders may advance their interests and positions, and the influence they have in pharmaceutical DTCA policymaking. Finally, when assessing the power of stakeholders, and analyzing that power against their interests and positions, it is clear that the most power is concentrated on maintaining the current pharmaceutical DTCA regulations in Canada. These findings may help explain the current pharmaceutical DTCA policy environment and how stakeholders will position themselves in future pharmaceutical DTCA policymaking.

2.10 References

- Alford RR (1975). *Health Care Politics*. Chicago: University of Chicago Press
- Armstrong, P., Armstrong, H. (2002). *Planning for care: approaches to health human resource policy and planning*. (Discussion paper no.28). Retrieved from thQueens University website:http://qspace.library.queensu.ca/bitstream/handle/1974/6884/discussion_paper_3_e.pdf?sequence=38
- Arney, J., Street, R., & Naik, A. (2013). Consumers' curious and surprising responses to direct-to-consumer advertisements in magazine print. *Patient Preference and Adherence*, 7, 95–102.
- Auton, F. (2006). Direct-To-Consumer-Advertising (DTCA) of pharmaceuticals: An updated review of the literature and debate since 2003. *Institute of Economic Affairs*, 26(3).
- Basara, L. R. (1996). The Impact of a Direct-to-Consumer Prescription Medication Advertising Campaign on New Prescription Volume. *Drug Information Journal*, 30, 715–729. <http://doi.org/10.1177/009286159603000315>
- Brugha, R., & Varvasovszky, Z. (2000). Stakeholder analysis: a review. *Health Policy and Planning*, 15(3), 239–246. <http://doi.org/10.1093/heapol/15.3.239>
- Buse, K., Mays, N., Walt, G. (2012). *Making Health Policy* (2nd ed.). UK: McGraw-Hill Education.
- Canada. Parliament. House of Commons. Standing Committee on Health. (2004). *Evidence*. 2nd Session. 37th Parliament, 3rd Session. Retrieved from: <http://www.whpapsf.ca/pdf/OpeningtheMedicinecabinet.pdf>
- Canadian Drug Manufacturers Association. (2001). *Submission from the Canadian drug manufacturers association to the commission on the future of healthcare in Canada*. Retrieved from Library and Archives Canada website: <http://www.collectionscanada.gc.ca/webarchives/20061220024313/http://www.hc>

sc.gc.ca/english/pdf/romanow/pdfs/canadian+drug+manufacturers+association.pdf

Canadian Health Coalition. (2016). *What We Do*. Retrieved from:

<http://www.healthcoalition.ca/about-us/what-we-do/>

Canadian Medical Association. (2002). *Direct-to-consumer advertising (DTCA)*.

Retrieved from: <https://www.cma.ca/Assets/assets>

[library/document/en/advocacy/CMA_advertising_PD03-01-e.pdf#search=advertising](https://www.cma.ca/Assets/assets_library/document/en/advocacy/CMA_advertising_PD03-01-e.pdf#search=advertising)

Canadian Health Coalition. (2001). *Standing together for Medicare: A call to care*.

Retrieved from the Canadian Health Coalition website:

<http://www.collectionscanada.gc.ca/webarchives/20061220024446/http://www.hc-sc.gc.ca/english/pdf/romanow/pdfs/canadian+health+coalition.pdf>

Canadian Institute for Health Information. (2015). *National Health Expenditure Trends, 1975 to 2015*. Ottawa. Retrieved from:

https://secure.cihi.ca/free_products/nhex_trends_narrative_report_2015_en.pdf

Canadian Institute for Health Information. (2012). *Prescribed Drug Spending in Canada, 2012: A Focus on Public Drug Programs*. Ottawa. Retrieved from:

https://secure.cihi.ca/free_products/Prescribed_Drug_Spending_in_Canada_EN.pdf

Canadian Institute for Health Information. (2011). *Health Care Cost Drivers: The Facts*. Ottawa. Retrieved from

https://secure.cihi.ca/free_products/health_care_cost_drivers_the_facts_en.pdf

Canadian Labour Congress. (2001). *Statement by the Canadian Labour Congress to the Royal Commission on the Future of Health Care in Canada*. Retrieved from Library and Archives Canada:

<http://www.collectionscanada.gc.ca/webarchives/20061220024912/http://www.hc-sc.gc.ca/english/pdf/romanow/pdfs/canadian+labour+congress.pdf>

- Canadian Women's Health Network. (2001). *Canadian women's health network's submission to the commission on the future of health care in Canada*. Retrieved from Library and Archives Canada:
<http://www.collectionscanada.gc.ca/webarchives/20061220024844/http://www.hcsc.gc.ca/english/pdf/romanow/pdfs/canadian+womens+health+network.pdf>
- Canadian Pharmacists Association. (2009). CPhA position state on direct-to-consumer advertising (DTCA). Retrieved from: <http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/PPDirectToConsumerAdvertising.pdf>
- Cassels, A. (2015). Canada may be forced to allow direct to consumer advertising Committee (JISC) in the UK. *BMJ*. 332 (7556), 24–25.
- Commission on the future of Health Care in Canada., & Romanow, R. J. (2002). *Building on values: The future of health care in Canada*. [Saskatoon, Sask.]: Commission on the Future of Health Care in Canada.
- Donohue, J. M., Cevasco, M., & Rosenthal, M. B. (2007). A decade of direct-to-consumer advertising of prescription drugs. *The New England Journal of Medicine*, 357(7), 673–681. <http://doi.org/10.1056/NEJMsa070502>
- Food and Drugs Act*, Revised Statutes of Canada 1985, c F-27. Retrieved from Government of Canada Justice Laws website: <http://laws-lois.justice.gc.ca/>
- Food and Drug Regulations*, CRC 1985, c 870. Retrieved from Government of Canada Justice Laws Website: http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html
- Freeman R.E. (1984). *Strategic Management: A Stakeholder Approach*. Boston: Pitman.
- Frosch, D. L., Grande, D., Tarn, D. M., & Kravitz, R. L. (2010). A decade of controversy: Balancing policy with evidence in the regulation of prescription

Drug advertising. *American Journal of Public Health*, 100(1), 24–32.
<http://doi.org/10.2105/AJPH.2008.153767>

Gardner, David M., Barbara Mintzes, & Aleck Ostry. (2003). Direct-to-consumer prescription drug advertising in Canada: Permission by default? *Canadian Medical Association Journal* 169 (5), 425-427.

Gellad, Z. F., & Lyles, K. W. (2007). Direct-to-Consumer Advertising of Pharmaceuticals. *American Journal of Medicine*, 120(6), 475–480.
<http://doi.org/10.1016/j.amjmed.2006.09.030>

Geyer, R. (2011). The Politics of EU Health Policy and the Case of Direct-to-Consumer Advertising for Prescription Drugs. *British Journal of Politics and International Relations*, 13(4), 586–602. <http://doi.org/10.1111/j.1467-856X.2011.00460.x>

Gilbody, S., Wilson, P., & Watt, I. (2005). Benefits and harms of direct to consumer advertising: a systematic review. *Quality & Safety in Health Care*, 14(4), 246–50.
<http://doi.org/10.1136/qshc.2004.012781>

Gold, J. L. (2003). Paternalistic or protective? Freedom of expression and direct-to-consumer drug advertising policy in Canada. *Health Law review*, 11(2), 30-37.

Guba, E., & Lincoln Y. (1989). *Fourth Generation Evaluation*, 1st ed. Thousand Oaks, CA: Sage.

Hall, D. V, & Jones, S. C. (2008). Australian consumer responses to DTCA and other pharmaceutical company sponsored advertisements. *Australian and New Zealand Journal of Public Health*, 32(5), 471–8. <http://doi.org/10.1111/j.1753-6405.2008.00282.x>

Hacker, J. S. (1998). The historical logic of national health insurance: Structure and sequence in the development of British, Canadian, and US medical policy. *Studies in American Political Development*, 12(01), 57-130.

- Handlin, A., Mosca, J. B., Forgione, D. a., & Pitta, D. (2003). DTC pharmaceutical advertising: the debate's not over. *Journal of Consumer Marketing*, 20(3), 227–237. <http://doi.org/10.1108/07363760310472254>
- Hanney, S. R., Gonzalez-Block, M. a, Buxton, M. J., & Kogan, M. (2003). The utilisation of health research in policy-making: concepts, examples and methods of assessment. *Health Research Policy and Systems*, 1, 2. <http://doi.org/10.1186/1478-4505-1-2>
- Harker, M., & Harker, D. (2007). Direct-to-consumer-advertising of prescription medicines. *Leadership in Health Services*, 20(2), 76–84. <http://doi.org/10.1108/17511870710745411>
- Health Canada. (1996) The distinction between advertising and other activities. *Health Products and Food Branch*. Administrative update of January 12, 1996. Retrieved from: http://www.hc-sc.gc.ca/dhp-mps/advertpublicit/pol/actv_promo_vs_info-eng.php
- Health Canada. (2000). Advertising campaigns of branded and unbranded messages. *Health Products and Food Branch*. Administrative update of November 2000. Retrieved from: http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/advert-pub_camp-eng.php
- Health Canada. (2007). *Drug and Health Products Glossary*. Retrieved from: <http://www.hc-sc.gc.ca/dhp-mps/homologation-licensing/gloss/index-eng.php>
- Health Canada (2009). Commission on the Future of Health Care in Canada: The Romanow Commission. Retrieved from: <http://www.hc-sc.gc.ca/hcs-sss/com/fed/romanow/index-eng.php>
- Health Council of Canada. (2006). *Direct-to-consumer advertising of prescription drugs in Canada. What are the public health implications?* Retrieved from: http://www.healthcouncilcanada.ca/n3w11n3/2.38_hcc_dtcadvertising_200601_e_v6.pdf

- HESA Standing Committee on Health. (2015). *About: 42nd Parliament, 1st Session*. Retrieved from: <http://www.parl.gc.ca/Committees/en/HESA/About>
- Kravitz, R. L., Epstein, R. M., Feldman, M. D., Franz, C. E., Azari, R., Wilkes, M. S., ... & Franks, P. (2005). Influence of patients' requests for direct-to-consumer advertised antidepressants: a randomized controlled trial. *JAMA*, 293(16), 1995-2002.
- Law, M. R., Majumdar, S. R., & Soumerai, S. B. (2008). Effect of illicit direct to consumer advertising on use of etanercept, mometasone, and tegaserod in Canada: Controlled longitudinal study. *BMJ (Clinical Research Ed.)*, 337, a1055. <http://doi.org/10.1136/bmj.a1055>
- Law, M. (2009). Costs and consequences of direct-to-consumer advertising for clopidogrel in Medicaid. *Arch Intern Med*, 169(21), 1969-1974.
- Liu, Q., & Gupta, S. (2011). The impact of direct-to-consumer advertising of prescription drugs on physician visits and drug requests: Empirical findings and public policy implications. *International Journal of Research in Marketing*, 28(3), 205–217. <http://doi.org/10.1016/j.ijresmar.2011.04.001>
- Lukes, S. (1974). *Power: A Radical Approach*. London: Macmillan.
- Matear, M., & Dacin, P. A. (2010). Marketing and societal welfare: A multiple stakeholder approach. *Journal of Business Research*, 63(11), 1173-1178.
- Mintzes, B., Barer, M. L., Kravitz, R. L., Kazanjian, A., Bassett, K., Lexchin, J., ... & Marion, S. A. (2002). Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: two site cross sectional survey. *BMJ*, 324(7332), 278-279.
- Mintzes, B., Barer, M., Lexchin, J., & Bassett, K. L. (2005). Introduction of direct-to-consumer advertising of prescription drugs in Canada: an opinion survey on regulatory policy. *Research in Social & Administrative Pharmacy: RSAP*, 1(2), 310–30. <http://doi.org/10.1016/j.sapharm.2005.03.007>

- Mintzes, B., Morgan, S., & Wright, J. M. (2009). Twelve years' experience with direct-to-consumer advertising of prescription drugs in Canada: a cautionary tale. *PloS One*, 4(5), e5699.
- Morgan, S., Hurley, J. (2002). *Influences on the "health care technology cost-driver"*. (Discussion paper no.14). Retrieved from the Government of Canada website: <http://publications.gc.ca/site/archivearchived.html?url=http://publications.gc.ca/collections/Collection/CP32-79-14-2002E.pdf>
- Myers, S. D., Royne, M. B., & Deitz, G. D. (2011). Direct-to-consumer advertising: Exposure, behavior, and policy implications. *Journal of Public Policy & Marketing*, 30(1), 110–118. <http://doi.org/10.1509/jppm.30.1.110>
- Ottawa Health Coalition. (2001). *Canada's public health care system: protect it and improve it. Needs, hopes and expectations as perceived by some Canadians from the city of Ottawa*. Retrieved from Library and Archives Canada website: <http://www.collectionscanada.gc.ca/webarchives/20061220023904/http://www.hcsc.gc.ca/english/pdf/romanow/pdfs/ottawa+health+coalition.pdf>
- Peyrot, M., Alperstein, N. M., Doren, D. Van, & Poli, L. G. (1998). Direct-to-consumer ads can influence behavior: Advertising increases consumer knowledge and prescription drug requests. *American Marketing Association*, 18(2), 27–32.
- Pharma Marketing. (2011). DTC marketing mix: Radio and outdoor ad spending soars, Internet not so much. *Pharma Marketing*. Retrieved from: <http://pharmamkting.blogspot.ca/2010/06/dtc-marketing-mix-radio-outdoor-ad.html> Accessed on September 15, 2016.
- Poser, M. (2010). DTCA of prescription medicines in the European Union: is there still a need for a ban? *European Journal of Health Law*, 17, 471–484. <http://doi.org/10.1163/157180910X527897>
- Regis, C. (2005). Direct-to-consumer advertising for prescription drugs in Canada: beyond good or evil. *Health Law Review*, 14(2), 28-33.

- Roberts, C. (2011). *Addressing the health system impacts of domestic and international direct-to-consumer advertising in Canada*. (Unpublished Master's Major Research Project, Simon Fraser University).
- Schmeer, K. (1999). Stakeholder analysis guidelines. *Policy toolkit for strengthening health sector reform*, 1-43. Retrieved from the World Health Organization <http://www.who.int/workforcealliance/knowledge/toolkit/33.pdf>
- Standing Committee on Health. (2004). *Opening the medicine cabinet: First report on health aspects of prescription drugs*. Retrieved from <http://www.whp-apsf.ca/pdf/OpeningtheMedicinecabinet.pdf>
- Tomblin, S. (2002). *Creating a more democratic health system: A critical review of constraints and a new approach to health restructuring*. (Discussion paper no.3). Retrieved from the Queen University Website: http://qspace.library.queensu.ca/bitstream/handle/1974/6884/discussion_paper_3_e.pdf?sequence=38
- Vaismoradi, M., Turunen, H., & Bondas, T. (2013). Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nursing and Health Sciences*, 15(3), 398–405. <http://doi.org/10.1111/nhs.12048>
- Vakratsas, D., Kolasirici, C. (2014). How DTCA Influences Prescription Pharmaceutical Markets. In Ding, M., Eliashberg, J., Strenersch, J. (Eds.) *How DTCA Influences Prescription Pharmaceutical Markets in Innovation and Marketing in the Pharmaceutical Industry* (New York: Springer New York, 2014) (651-673).
- Varvasovszky, Z., & McKee, M. (1998). An analysis of alcohol policy in Hungary. Who is in charge? *Addiction*, 93(12), 1815–1827. <http://doi.org/10.1046/j.1360-0443.1998.931218157.x>
- Varvasovszky, Z., & Brugha, R. (2000). How to do (or not to do) ... A stakeholder analysis. *Health Policy and Planning*, 15(3), 338–345. <http://doi.org/10.1093/heapol/15.3.338>

- Ventola, C. (2011). Direct-to-consumer pharmaceutical advertising: therapeutic or toxic? *Pharmacy and Therapeutics*, 36(10), 669–84.
- Weissman, J. S. (2003). Consumers' reports on the health effects of direct-to-consumer drug advertising. *Health Affairs*. <http://doi.org/10.1377/hlthaff.w3.82>
- White, M., Marsh, E. (2006). Content analysis: a flexible methodology. *Library Trends*, 55(1), 22-45.
- Wilkes, M. S., Bell, R. a., & Kravitz, R. L. (2000). Direct-to-consumer prescription drug advertising: Trends, impact, and implications. *Health Affairs*, 19(2), 110–128. <http://doi.org/10.1377/hlthaff.19.2.110>
- Wu, X., Ramesh, M., Howlett, M., Fritzen, S. (2013). *The Public Policy Primer: Managing the policy process*. London and New York: Routledge.

3 Chapter Three: Analysis of Supreme Court Interveners

3.1 Litigation Related to Questions Involved in Pharmaceutical Advertising

3.1.1 Background on Pharmaceutical Advertising Regulation

Recall that research question #1, explored in Chapter 2, was:

Given that there is a literature gap on Canadian pharmaceutical DTCA stakeholders, what can be learned about these stakeholders? The subsidiary questions in Chapter 1 were:

- 1) Who are the direct-to-consumer pharmaceutical advertising stakeholders in the Canadian policy environment, and what are their interests, positions, power, and influence?
- 2) What is the potential for these stakeholders to shape future pharmaceutical DTCA policy?

This chapter continues the analysis of the pharmaceutical DTCA policy environment by employing a narrower analysis of legal pharmaceutical DTCA stakeholders. This chapter focuses on answering research question #2:

Given the relatively recent rise of interveners in the Supreme Court of Canada processes and the presence of interveners in the landmark 2001 tobacco advertising case in the Supreme Court of Canada, *RJR-MacDonald v Canada* (1995), are the stakeholders identified in the response to Research Question #1 found as interveners in current pharmaceutical-related Supreme Court litigation?

From the answer to this question there arises two subsidiary questions:

- 1) If there are interveners present in pharmaceutical patent litigation before the Supreme Court, what are the interests, positions, and influence in the broader policy environment;

2) If the *RJR-MacDonald* interveners are present, which stakeholders are they and to what extent are they intervening?

As discussed earlier, pharmaceutical advertising is a core function of pharmaceutical companies that intend to take their developed drugs to market, and an important source of income for companies whose business model is dependent on advertising revenues. Despite the perceived necessity of pharmaceutical advertising for these companies, there is debate about the impacts of the practice. Mounting concern about the ways advertising may alter pharmaceutical prescribing behavior by physicians (Health Council of Canada, 2006), may misconstrue or exaggerate effects of the drugs, and may contribute to increasing healthcare costs (Vakratsas, 2014) is prompting a conversation about legislative and regulatory action to limit this form of advertising. Most developed countries have decided to either comprehensively or partially ban direct-to-consumer advertising (DTCA), leaving only the United States and New Zealand with a far less regulated pharmaceutical advertising environment (Mintzes, 2005).

Pharmaceutical advertising in Canada is subject to the regulations under the *Food and Drugs Act* (RSC 1985, c. F-27, s 30). The specific parts of the Act which regulate pharmaceutical advertising are:

- Section 3(1), prohibiting consumer-directed advertisements for health products that make claims to treat, prevent, or cure any diseases listed in Schedule A to the Act;
- Section 9(1), prohibiting false, misleading, deceptive or erroneous advertising of products;
- Section 20(1), stating that no person shall label, package, treat, process, sell, or advertise any device in a manner that is false, misleading, or deceptive or is likely to create an erroneous impression regarding its design, performance, intended use, quantity, character, value, composition, merit or safety.

Pursuant to the *Food and Drugs Act*, the *Food and Drug Regulations* (*Consolidated Regulations of Canada* [CRC], c 87) have been enacted. Within these regulations, two sections of the Regulations, s C.01.044 and s C.08.002 (1), are

particularly relevant to this research. Section C.01.044 prohibits consumer directed prescription advertising beyond the drugs name, price, and quantity:

If a person advertises a prescription drug to the general public, the person shall not make any representation other than with respect to the brand name, the proper name, the common name and the price and quantity of the drug.

Section C.08.002 (1) prohibits the advertising of new drugs that have not been approved for sale by Health Canada. (Note that “person” in the context of these laws and regulations includes both individuals and corporations.)

There are two specific types of DTCA that do not violate the *Food and Drugs Act* or regulations: “help-seeking ads” and “reminder ads” (Health Council of Canada, 2006). A help seeking ad is defined as: “announcements that ask patients among the general public having a particular medical disorder or experience a given set of symptoms to consult a physician for discussion of treatment, or to call a 1-800 telephone number for further information” (Government of Canada, 1996, p. v). Help seeking ads may be considered non-promotional if a number of specific criteria are met: no specific drug is identified, there is no implication that a drug is the sole treatment available for the disease or condition, and no drug manufacturer’s name is mentioned. “Reminder ads” feature the brand name product but not the condition or treatment, and are less common (Government of Canada, 1996, p.v).

Canada once was perceived to have a more heavily regulated pharmaceutical advertising environment. However, Health Canada, the Ministry responsible for this area of federal government activity, modified its own interpretation of the *Food and Drugs Act* and *Food and Drug Regulations* in 1996, and again in 2000 (Government of Canada, 1996; Government of Canada, 2000). Under this most recent interpretation by Health Canada, the new regulatory environment can best be described as partial prohibition.¹

¹ Health Canada’s interpretation of the *Food and Drugs Act* provides guidance for pharmaceutical advertisers but is not law itself.

Although there has been no legislative or regulatory change in Canada, and Health Canada made public their policy statements on advertising in 2000, there has been a pervasive advance of advertising in the online sphere, and the increasing presence of cross-border American advertisements in Canada. This has effectively created a scenario where pharmaceutical advertising in Canada is, in effect, less² regulated than it was in the past (since these new forms of advertising distribution (online and cross-border) remain to be addressed by updated regulations and regulatory enforcement mechanisms). This situation has not gone unnoticed by government: in 2004 the House of Commons created a Standing Committee on Health (Government of Canada, Parliament, 2004), and, separately, in 2006 the Health Council of Canada³ produced a report on direct-to-consumer advertising of prescriptions drugs in Canada which drew heavily on the report by the Standing Committee on Health (Canada, Parliament 2004). Both the Standing Committee on Health and the Health Council of Canada independently produced recommendations to strengthen the regulations on pharmaceutical advertising (Government of Canada, Parliament, 2004, p 13; Health Council of Canada, 2006, p 11).

In the patent area, the pharmaceutical industry which are invested in DTCA are still active but the brand and generic pharmaceutical companies are clearly divided (See Table 3.1). The pharmaceutical industry can be grouped into two different factions: The “brand” name pharmaceutical industry and the “generic” pharmaceutical industry. The primary difference between them is that the “brand” industry is more often involved in the development of new pharmaceutical drugs. “Generic” pharmaceutical players will not usually develop a drug but will “copy” a brand-name drug after its patent expires, when

² An important distinction should be made between ‘less regulated’ and ‘deregulated’. ‘Less regulated’ is a more apt description of the Canadian pharmaceutical advertising environment because although Parliament and Health Canada have failed to address new forms of pharmaceutical advertising distribution, the *Act* and Regulations have not been modified to create a friendlier advertising environment (which would constitute a ‘deregulation’ consistent with free-market principles). In short, a legislative action would be required to ‘deregulate’, and none has been taken since the re-interpretation of the *Act* and Regulations by Health Canada in 2000.

³ The Health Council of Canada (2003-2014) was a federal council formerly mandated to monitor the progress of health care renewal in Canada as outlined in the 2003 Health Accord, Romanow Commission.

the brand company loses market exclusivity, and the “generic” can begin to distribute its “copy” free from patent infringement concerns.

Table 3.1: Pharmaceutical Companies at the Court as Parties to Pharmaceutical Litigation

Number of Appearances	Pharmaceutical Company	
	Brand	Generic
1	Pfizer, Merck, AstroZeneca, Bristol-Myers Squibb, Celgene	Teva, Nu-Pharm, Biolyse
2	Sanofi-Aventis/Synthelabo, GlaxoKlineSmith	NA
3	NA	NA
4	NA	Apotex

Source: Reviewing the decisions to identify litigants.

3.1.2 Background on the Supreme Court of Canada its Processes

Recognizing the Supreme Court’s own policy-making potential, the Supreme Court Rules (Rules of the Supreme Court, SOR/2002-156) provide for applications to intervene. This is a process through which an applicant can apply to join ongoing litigation in order to express its arguments, positions, and relevance to the questions and issues in the legal proceedings (Rules of the Supreme Court, ss 55-57). Intervening is a relatively new phenomenon in Canada: traditionally in Canada it is only the parties involved in litigation who participate⁴. The tradition of intervening is common in American legal proceedings (Kearney & Merrill, 2000, p. 756.).

The introduction of interveners into the Canadian judicial process creates another venue in which stakeholders may influence policymaking. Canada’s *Constitution Act* 1867 divides power between the courts and the legislatures, keeping them independent, each having the ability to act as a “check” on the other if it was ever to exceed its constitutional powers (Waddams, 2010). Given the independence of the judiciary, it may be of concern if certain stakeholders who have had policy-making influence on the

⁴ The definition of a party is: plaintiff or applicant and defendant, in an initiating action and, on appeal, appellant or defendant.

legislative side and with the executive branches also have influence on challenges made in the courts to the same policies of the legislative and subordinate branches of government.

These concerns multiply if the Supreme Court expands stakeholders' ability to intervene. In pharmaceutical advertising, there are powerful industry groups whose positions and interests, as demonstrated elsewhere in this thesis, are likely to be factors in legislative actions - the presence and power of these groups (if they exist as interveners in the courts), should be scrutinized to fully understand what the impact could be of these stakeholders on judicial proceedings, and therefore policy.

The 1980s marked an increase in the number of interventions occurring in the Canadian judicial system, an acknowledged move towards American court procedure, where third parties have traditionally provide input to the courts (Dickens, 1977).⁵ In 1989, Michael Mandel labeled the newfound influence of interest parties in the Canadian courts as the "legalization of politics" (Mandel, 1994).⁶

The relevant Canadian Supreme Court Rule states that:

The affidavit in support of a motion for intervention shall identify the person interested in the proceeding and describe that person's interest in the proceeding, including any prejudice that the person interested in the proceeding would suffer if the intervention were denied (Rules of the Supreme Court, s 57).

The Rule (Meehan, 1994) describes the potential intervener in a way that, *prima facie*, means an intervener must be a "stakeholder", the latter being an individual, group or organization interested in influencing the aims and actions of another organization or policy-direction (Brugha & Varvovszky, 2000). In combination with identifying the

⁵ Bernard Dickens, "A Canadian development: non-party intervention" (1977) 40 MLR 666-676

⁶ Michael Mandel, *The Charter of Rights and the Legalization of Politics in Canada* (Toronto: Wall & Thomson, Inc.) 71

intervener applicant's interests in the proceedings, the application for intervener status must identify the position that the applicant intends to take with respect to the questions in the proceedings, the applicant's relevance to the proceedings, and reasons why submissions will be useful to the Court and different from those of other parties (Rules of the Supreme Court, s 57(2ab)). An intervener may not raise new issues, but at the judges' discretion, may be permitted to make an oral argument in court in addition to submitting a factum⁷ (The judge deciding whether to grant intervener status imposes length limits on both the duration of the oral argument and the length of the factum) (Rules of the Supreme Court, ss 58-59). The length of that factum, as determined by the judge hearing the application for intervener status, may contribute to the impact that the factum may have on the ultimate decision. An oral argument may have more impact on the parties and judge than the written argument; the impact of the oral argument and the impact of the written argument be affected by its allowed length (Ring, 1980).

The process of intervening begins when any interested person⁸ makes a motion for intervention to a judge. The Court cannot accept non-applicants as interveners (with the exception of attorney generals); if the health-interested stakeholders do not apply they will not receive intervener status. In the case of an application for Leave to Appeal, the motion to intervene must be submitted within 30 days after the filing of the application for Leave to Appeal. In the case of the appeal, the motion to intervene must be submitted within four weeks after the filing of the Appellant's Factum. In the case of a Reference⁹, the appeal must be filed within four weeks after the filing of the Governor in Council's factum (Rules of the Supreme Court, s 56). Further, the Supreme Court Rules state that

The affidavit in support of a motion for intervention shall identify the person interested in the proceeding and describe that person's interest in the proceeding,

⁷ A factum is a written document, submitted to the court, which like the factums of the parties, describes the intervener's positions and arguments.

⁸ The legal term "person" encompasses both individuals and corporations as persons.

⁹ A reference raises certain issues in the Court.

including any prejudice that the person interested in the proceeding would suffer if the intervention were denied (Rules of the Supreme Court, s 57(1)).

The motion must also identify the position the interested person intends to take with respect to the questions in which it is intended the intervener, if accepted, will intervene, and the proposed intervener's reasons for believing the submissions would be useful to the court and different from the other parties (Rules of the Supreme Court, 57(2)). The judge then reviews the motion, either granting or rejecting the intervention application. The decision is announced but no oral or written reasons are provided for granting or rejecting intervener status. If the judge chooses to grant the intervention, limitations on the length of the factum that the intervener will submit may be imposed. The judge may also choose or decline to grant the intervener time to make an oral argument in the court.

This study is investigating the hypothesis that although there has been no pharmaceutical advertising case that has reached the Supreme Court, the very same stakeholders who would have a vested interest in acting as interveners on a prospective pharmaceutical advertising case at the Supreme Court will have already identified themselves as interested intervener parties in other pharmaceutical litigation before the Supreme Court. This current analysis will attempt to predict which stakeholders will attempt to become interveners in pharmaceutical advertising cases should there be litigation that reaches the Supreme Court of Canada and will predict whether, if they apply, each stakeholder will be successful or unsuccessful in becoming interveners.

3.1.3 The Current Leading Health-Related Advertising Case in Canada: *RJR-MacDonald v Canada*

RJR-MacDonald v Canada [1995] involved the *Tobacco Products Control Act* (S.C, 1985, c. 20) that broadly prohibited all advertising and promotion of tobacco products unless the packaging included health warnings and a list of toxic constituents (Parliamentary Research Branch, 2013). RJR-MacDonald Inc., a leading tobacco

company, sought a declaratory judgment that the whole Act was *ultra vires*¹⁰ (RJR-MacDonald v Canada [1995] 3 SCR 199) Parliament and invalid as an infringement of freedom of expression as guaranteed by section 2(b) of the *Canadian Charter of Rights and Freedoms* (1982); separately Imperial Tobacco Ltd sought the same relief.¹¹ The motions were heard together in the Quebec Superior Court which declared the whole Act *ultra vires* the Parliament of Canada and an unjustified infringement of s.2(b) of the *Charter* (RJR-MacDonald v Canada [1995] 3 SCR 199). The decision was appealed by the Attorney General (Canada) to the Quebec Court of Appeal where the decision was reversed (RJR-MacDonald v Canada [1995] 3 SCR 199). RJR-MacDonald and Imperial Tobacco appealed to the Supreme Court of Canada, which, like the Quebec Court of Appeal, ruled in their favour (RJR-MacDonald v Canada [1995] 3 SCR 199).

Two questions were addressed by the Supreme Court of Canada: (1) the legislative competence of Parliament to enact the legislation under the criminal law power or for the peace, order, and good government of Canada; and (2) whether the Act infringed on section 2 of the *Charter* and, if so, whether that infringement was “saved” under s.1. The Supreme Court found both that there was an infringement of s. 2(b) and that it did not constitute a reasonable infringement justified under s.1 of the *Charter*. The Act was struck down. (See Figure 3.1 for diagram).

¹⁰ Ultra vires is the Latin term for “outside the powers of”.

¹¹ Imperial Tobacco sought the same order but only in sections ss.4 and 5 of the Act, and 6 and 8 of the Act (advertisement of tobacco products and promotion of tobacco products, respectively). The Quebec Superior court heard the two motions together.

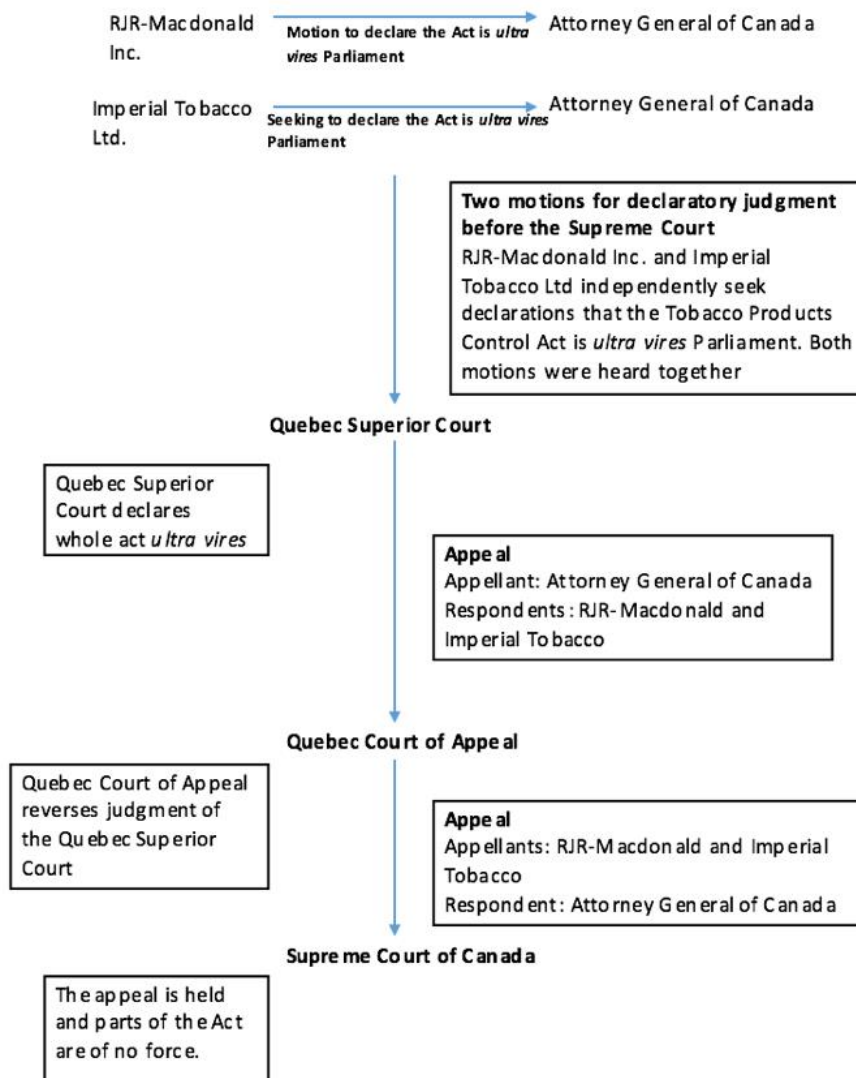


Figure 3.1: RJR-MacDonald Inc. v Canada, [1995] 3 SCR 199

There were six interveners to the Supreme Court in *RJR-MacDonald v Canada*, five formed a coalition. All five stakeholders either have an interest or mandate pertaining to health issues, and successfully applied for intervention. The sixth intervener, the Attorney General of Ontario, asked for and received leave to intervene without applying nor submitting a factum.¹² No interveners were rejected in *RJR-MacDonald*,

¹² The Attorney General does not submit a factum or make an oral argument.

clear evidence that the judges were interested in hearing the opinions of the health-interested stakeholders. The interveners in the case were:

- Canadian Cancer Society,
- Canadian Council on Smoking and Health
- Canadian Medical Association
- Heart and Stroke Foundation of Canada
- Canadian Lung Association
- Attorney General of Ontario

The five interveners in the coalition (all the interveners except the Attorney General of Ontario) applied in unison for intervener status and submitted a single factum.

Interestingly, each intervener was granted fifteen minutes for oral argument; from this it may be inferred that they together had an influential voice in the proceedings. These five interveners also had the support (although the nature of that support is unspecified) of twenty-two other prominent health organizations that are listed in the factum (Brief for Intervener Coalition, *RJR-MacDonald Inc. v Canada*, [1995] 3 SCR 199). These twenty-two organizations were (Brief for Intervener Coalition, *RJR-MacDonald Inc. v Canada*, [1995] 3 SCR 199, para 10):¹³

- Royal College of Physicians and Surgeons of Canada
- Canadian Nurses Association
- Canadian Public Health Association
- Allergy Foundation of Canada
- Canadian Association of Medical Oncologists
- Canadian Association of Occupational Therapists
- Canadian Association of Pathologists
- Canadian Centre on Substance Abuse
- Canadian Chiropractic Association

¹³ The Royal College of Physicians and Surgeons of Canada, the Canadian Nurses Association, and the College of Family Physicians of Canada are also present in Chapter 2.

- Canadian Dental Association
- Canadian Hospital Association
- College of Family Physicians of Canada
- National Cancer Institute of Canada
- Non-Smokers' Rights Association
- Physicians for a Smoke-Free Canada
- Canadian Centre for Drug Free Sport
- Canadian Thoracic Society
- Canadian Nurses' Respiratory Society
- Canadian Physiotherapy Cardio-Respiratory Society
- Canadian Haematology Society
- Canadian Urologic Oncology Group
- Canadian Pharmaceutical Association

Since pharmaceutical advertising and tobacco advertising are both scrutinized from a public health perspective, one might expect similar (or the same) stakeholders to involve themselves in any health-related legal case of importance as interveners.

3.1.4 The Only Pharmaceutical Advertising Litigation

While there has not yet been pharmaceutical advertising litigation before the Supreme Court, *RJR-MacDonald* may be expected to provide evidence of what will occur when such litigation does arise because the issues in the *RJR-MacDonald* case concerned advertising related to a health topic. Prior to *RJR-MacDonald*, tobacco advertising was a contentious form of marketing, just as pharmaceutical direct-to-consumer advertising is today. As has been established above, all the interveners in *RJR-MacDonald* were health-interested stakeholders.

An unsuccessful attempt to challenge the stipulations in the *Food and Drugs Act* that prohibit pharmaceutical advertising reached the Ontario Superior Court, *CanWest Media Works Inc. v Canada (Attorney General)* (Court File Number 05-CV-303001PD2; mentioned in *Women and Health Protection*, 2007).

CanWest MediaWorks Inc. also filed a motion for judicial review in the Federal Court (*CanWest MediaWorks Inc. v. Canada* [2007] FC 752). The Respondents in the Federal Court action (Health Minister and Attorney General of Canada) sought to have this application either dismissed or stayed until the final outcome of the action, mentioned above, brought by CanWest in the Ontario Superior Court was known. In the result, in fact, no decision in the Ontario Superior Court case was ever rendered because the case was adjourned, and never returned to court, due to the bankruptcy of CanWest Media Works Inc.¹⁴ Before that adjournment, a coalition of stakeholders successfully applied to intervene in the Ontario Superior Court case. Those interveners were:

- Canadian Federation of Nurses
- Canadian Health Coalition
- Canadian Union of Public Employees
- Communications, Energy and Paperworkers Union of Canada
- Society for Diabetic Rights
- Medical Reform Group
- Drug Safety Canada
- Women and Health Protection

In deciding to dismiss the judicial review application brought in the Federal Court, Justice Snider noted:

The fact is that a coalition of a number of interested parties has already successfully sought intervenor status in CanWest's Charter challenge in opposition to CanWest [in the Ontario Superior Court action]. It seems evident that there are individuals and groups in Canada who are supportive of the DTCA prohibitions and who may have public interest standing to bring an application for judicial review in this Court to determine the issues (assuming that there are reviewable issues). There may be many reasons why there has been no pursuit of an order of *mandamus* in our Court by any other party. Failure, to date, by other parties (with, for example, no commercial interest or with broader health concerns) to seek *mandamus* does not elevate CanWest's interest to one of "public interest".

¹⁴ There is no decision text available for the *CanWest Media Works Inc. v Canada* (Attorney General) because the proceedings were indefinitely adjourned.

Justice Snider's decision was unsuccessfully appealed by CanWest to the Federal Court of Appeal (*CanWest Mediaworks Inc v Canada (AG)*, 2008 FCA 207). The Federal Court of Appeal said:

[t]hese interveners (members of a coalition of organizations representing, among others, the interests of consumers of pharmaceuticals products, patients, a trade union, and those who rely on employer-provided health benefit plans) are more appropriate representatives of the public interest in the due enforcement of the law than CanWest (at para 5).

Justice Snider, in the first instance in the Federal Court, did not accept that CanWest had a public interest to present in the Federal Court. On the other hand, the members of the intervener coalition in *CanWest* at the Ontario Superior Court were a diverse group of health-interested and public-interest stakeholders (all of whom are identified in the previous chapter of this thesis).

The interveners in the *CanWest* litigation were not the same stakeholders as the intervener coalition in *RJR-MacDonald*. The *CanWest* interveners were more diverse than the interveners in *RJR-MacDonald*, who were strictly interested in health, but they were nonetheless similar because of the overlap in their public-interest mandates.

3.2 Previous Related Research

3.2.1 Background Research About Decision Making in the Supreme Court of Canada

Some context for the current pharmaceutical patent litigation can best be understood by reviewing “The Context of the Supreme Court’s Copyright Cases” by Margaret Ann Wilkinson (Wilkinson, 2013). Prior to this research on copyright decisions, there had been no study of intellectual property litigation decision patterns in the Supreme Court (both copyright and patent are considered aspects of intellectual property law): the studies either did not include copyright cases in their samples at all – or the numbers of copyright cases heard by the Court were so minute in comparison with the

scope of the study that it would be impossible to discern how the copyright cases fit. In her seminal work, Wilkinson focused on the ten copyright-related decisions of the Supreme Court between 2002 and 2012 and asked how these copyright decisions fit patterns previously identified in studies of other jurisprudence of the court (Wilkinson, 2013). In particular, Wilkinson reviewed four major studies about the Supreme Court's jurisprudence: 1) Songer & Siripurapu (2009), who studied unanimous decisions of the Court between 1970 and 2003; 2) Emmett Macfarlane, who also focused on the unanimous decisions of the Court (Macfarlane, 2010); 3) Peter McCormick focused on analysis of concurrent reasons rendered by the Court between April 1984 and the end of December 2006 (McCormick, 2008); and 4) Christine Joseph focused on solo dissents and examining all 133 solo dissent judgments rendered in the Court between 1974 and 2003 (Joseph, 2006).

Wilkinson studied all the copyright cases heard by the Supreme Court between 2002 and 2012. Wilkinson's conclusions were that there had been a demonstrable increase in interest by the Court for hearing copyright cases during those years, as compared to any previous period in the Court's history (Wilkinson, 2013). Moreover, in every case heard after the first in the study, in 2002, the Court chose to sit as the full Court of nine judges. There were three unanimous judgments – far fewer than the 63% of cases other researchers had found – which Wilkinson attributes to the unique nature of copyright making it harder for the court to achieve consensus (Wilkinson, 2013). Contrary to the expectation set by Songer and Siripurapu's work (2009) in other areas where unanimous judgments occurred, the unanimous judgments in copyright did not occur in cases with few issues involved but in the more complex ones (Wilkinson, 2013). The study found that six of twenty-two sets of reasons for judgment delivered across the eleven cases were written concurring with other judgments in the same decision (Wilkinson, 2013) and in McCormick's study of 1716 judgments between 1984 and 2006, he found 600 concurring judgments – but found that their frequency had peaked in 1995-6. This, he noted, was because the “dynamic period of flux and change [generated by the creation of the 1982 *Canadian Charter of Rights and Freedoms*] has come to an end ... and few policy-divergent responses need to be generated to prepare the field.” (McCormick, 2008 p. 166). He noted this propensity to multiple judgments, concurring in the result but putting

forward difference reasoning, was important because “divided decisions demonstrate a court that is both open to a variety of arguments... and willing to change its mind over time.” (McCormick, 2008 p. 166) Of the eleven cases in Wilkinson’s study, five of the courts were divided into a majority and minority dissents. In light of this, Wilkinson finds, based on McCormick’s patterns, that there is still high level of uncertainty in current Canadian copyright law. In looking the question of solo dissents raised by Joseph’s research, Wilkinson observed that there were no solo dissents across the eleven cases she studied. She further determined that the pattern in copyright decisions, where there is a lack of solo judgments, a relatively large number of concurring judgments, and a low number of unanimous judgments, differs from the overall pattern of the current Supreme Court found in the earlier studies (Wilkinson, 2013). Wilkinson’s conclusions will be returned to later in this manuscript where this study will examine how the patterns discovered in the Supreme Court pharmaceutical patent litigation examined here compare to copyright.

In his recently defended Masters of Law (LLM) thesis, “The Patented Medicines (Notice of Compliance) Regulations: An Examination of the Decision Making Patterns in these Cases at the Supreme Court of Canada,” Jason Newman identified a number of pharmaceutical patent cases which involved a Notice of Compliance [NOC] (Newman, 2016). His search produced six cases¹⁵ (*Merck-Frosst Canada Inc. v Canada* (Minister of National Health and Welfare) (1998), *Bristol-Myers Squibb v Canada* (Attorney General) (2005), *AstraZeneca Canada Inc. v Canada* (Minister of Health) (2006), *Apotex Inc. v Sanofi- Synthelabo Canada Inc* (2008), *Teva Canada Ltd v Pfizer Canada Inc.* (2012), *Sanofi-Aventis v Apotex Inc.*) (2015) (Newman, 2016). Of the cases he located, *Merck-Frosst Canada Inc. v Canada (Minister of National Health and Welfare)* was decided in 1998 and so falls outside the perimeters of this study on Interveners. Notably, for reasons which are unclear, Newman’s study does not include *Nu-Pharm Inc. v Canada* (2010), which is a pharmaceutical patent NOC cases that falls within the timeline of both studies and is included in this study’s analysis.

¹⁵ The years Newman used as his search parameters are not mentioned in the thesis text.

Newman found that the levels of volatility in decision-making in NOC intellectual property cases is much lower than that found by Wilkinson in copyright intellectual property cases (Newman, 2016). Neither Wilkinson nor Newman examined anything about interveners in the Supreme Court litigation they studied in their work.

3.2.2 Research on the Roles of Interveners in the Supreme Court of Canada

In 2000, Amanda Burgess studied the impact of intervenors in the Supreme Court by examining cases for the presence of interveners, and asking whether the presence of the interveners' arguments (or even presence) had an influence on the Supreme Court's decision. Burgess reviewed all the decisions written by members of the Supreme Court in 253 cases rendered from 1997 to 1999, but only the subset of those cases with interveners present were analyzed. Burgess did not include any pharmaceutical cases in her analysis, but any intellectual property cases rendered between 1997 and 1999 and included interveners were analyzed in her study. Burgess (2000) made fifteen main observations:

1. interveners were present in approximately one-third of cases;
2. there were on average four to five interveners per case when there is intervention;
3. there was a 43% chance that the intervener would be a public interest advocate;
4. there was a 42% chance the intervener would be a government intervener;
5. there was a 60% chance the government intervener would be the Attorney General of Canada, Quebec, Ontario, or Alberta;
6. there was a 15% chance that the intervener would be a trade union corporation, an aboriginal group or an individual;
7. there was a 2% chance the intervener would be the Canadian Civil Liberties Association;
8. eighteen interveners accounted for 45% of total interventions;
9. interveners were mentioned in the judgments written in over 40% of the cases in which interveners were present;
10. there was a greater chance of the interveners being mentioned in a decision if that intervener was one of two to nine interveners appearing in the case;
11. Justice Cory was the Justice most likely to mention an intervener;

12. Justice Cory was most likely to mention an intervener by name;
13. Justice L'Heureux-Dubé was least likely to mention an intervener in her written decision;
14. when an intervener was mentioned in the decision, the intervener's argument was linked to an argument put forth by the Appellant or the Respondent approximately one-third of time; and
15. cases which contained a constitutional argument comprised over 40% of the cases involving interveners (of these cases, 86% were likely to involve a Charter argument. (Burgess, 2000, p.136)

This study relies on data generated exclusively before Beverly McLachlan became Chief Justice of Canada (January 7, 2000): it does not overlap with the period of the present study. The cases studied were decided relatively early, during the period of the introduction of interveners into the Canadian legal system.

In “Interventions at the Supreme Court of Canada: Accuracy, Affiliation, and Acceptance” (Alarie & Greene, 2010). Benjamin Alarie and Andrew Greene examined interveners in the Court from January 2000 to July 2009. The researchers examined decisions and published intervener material. Alarie and Green did not include intellectual property (or patent) in their study. Their data set included only “Charter”, “criminal”, “labour”, “tax”, and “aboriginal rights” categories of cases. They identified at least three functions (accuracy, affiliation, and acceptance) that the practice of intervention can perform:

The first possibility is that hearing from interveners might provide objectively useful information to the court (i.e., interveners might promote the “accuracy” of the Court’s decision making). A second possibility is that the practice of intervention allows interveners to provide the “best argument” for certain partisan interests that judges might want to affiliate with. A third possibility is that interventions are allowed mainly (if not only) so that intervening parties feel they have had their voices heard by the Court and the greater public (Alarie & Green, 2010, p. 386).

Alarie and Green found 674 appeals in their categories were decided by the Supreme Court between January 1 2000 and December 31 2008, and, of those, 330 included submissions by interveners (Alarie & Greene, 2010). Interventions in the different areas of law studied were compared, and a finding was made that intervention in *Charter* cases was the most common, at 90% of *Charter* cases (Alarie & Greene, 2010). The authors also found that *Charter* cases had the highest average number of interventions per case (Alarie & Greene, 2010). The study found that the proportion of appeals with interveners rose more quickly over the eight years than the average number of interventions per appeal (Alarie & Greene, 2010). The study found that appeals with interventions had an average of 4.1 interveners, and that interveners (excluding Attorneys General) had an average acceptance rate of 90% when applying. However, Alarie & Green found that success in attaining status to intervene did not ensure that the intervener succeeded in impacting the decision.

3.3 Design of Research on Intervenors in Pharmaceutical Cases

As noted earlier, litigation about pharmaceutical advertising, specifically, has not reached the Supreme Court of Canada. However, patent litigation involving pharmaceuticals has become common patent litigation at the Supreme Court, and as discussed above, stakeholders who produce, manufacture and distribute pharmaceuticals have a vested interest in pharmaceutical advertising. When litigation does arise in the Supreme Court regarding pharmaceutical advertising, as in the single lower court case already concluded (*Women and Health Protection*, 2007), these pharmaceutical companies will be involved, if not as parties, certainly by intervention.

This study has only focused on pharmaceutical patent cases that reached the Supreme Court, the highest court in the country and the one that ultimately decided *RJR-MacDonald*. As established in the *Supreme Court Act*, a civil case that will reach the Supreme Court of Canada is only one that contains an issue of public importance. There is only a right to appeal to the Supreme Court in criminal matters, in all civil matters,

such as those under discussion in this thesis, parties can only appeal if given leave to do so by the Court itself. This permission can be given following an application for leave.¹⁶

It is clear that cases in the lower courts, and therefore the interveners who participate in those cases, are less likely to have the same national importance as cases and interveners in the Supreme Court. The Supreme Court does not hear a civil case unless it chooses to: in all other civil cases the highest court are the Courts of Appeal, and all cases decided by the Supreme Court can only be heard if first decided by the Court of Appeal and then appealed by the parties. Similarly, a case can be heard by the Court of Appeal if a decision has been heard by a lower court or tribunal and then appealed.

It is also the case that it is at the Supreme Court (as mentioned earlier) that interveners have the longest history in Canada. For these reasons, only Supreme Court cases and applicants for intervention are included in this study.

To identify cases relevant to pharmaceuticals, the Supreme Court Decision database was accessed. A search on the database was performed for “patent” cases. From the selection of decisions produced by the Supreme Court online database the short descriptions of each case were reviewed for relevance to pharmaceutical advertising. Fourteen such cases were produced, and the fourteen cases’ full decision text were then reviewed in detail to more accurately determine whether they met the inclusion criteria.¹⁷

¹⁶ Notwithstanding any other Act of Parliament but subject to subsection (1.2), an application to the Supreme Court for leave to appeal shall be made to the Court in writing and the Court shall **(a)** grant the application if it is clear from the written material that it does not warrant an oral hearing and that any question involved is, by reason of its public importance or the importance of any issue of law or any issue of mixed law and fact involved in the question, one that ought to be decided by the Supreme Court or is, for any other reason, of such a nature or significance as to warrant decision by it; **(b)** dismiss the application if it is clear from the written material that it does not warrant an oral hearing and that there is no question involved as described in paragraph (a); and **(c)** order an oral hearing to determine the application, in any other case.

¹⁷ In some cases, it is difficult to determine whether a case meets the inclusion criteria from the short description provided by the Supreme Court of Canada website database. In such situations the case was tentatively included and flagged for more in-depth review.

Of the fourteen cases, ten were relevant to pharmaceuticals, and therefore the study. Of the ten cases that met the inclusion criteria, six of the cases involved interveners. When aggregated, the number of interveners from the six cases is twelve, and there are 16 total applications for intervention. In none of the cases did interveners join the proceedings before the case reached the Supreme Court.

Of the ten Supreme Court decisions rendered in the select time period involving pharmaceutical patent issues,¹⁸ *Janssen-Ortho v Novopharm (Janssen-Ortho Inc. v Novopharm Ltd* [2005] SCC 33) (not included in Table 2) has not been included in the analysis. The case had to be disqualified from the study because although it appeared to meet the inclusion criteria, the case proceedings ended quite early – prior to the timeframe in which stakeholders were able to apply for leave to intervene.

Decisions, dockets, and intervener briefs were collected for analysis in each case¹⁹. The decision text and dockets were freely downloaded from the Supreme Court website, the intervener briefs were retrieved at a cost from the Supreme Court Records Center, which is contactable by email or phone call.²⁰ Reasons for accepting or rejecting interveners are not provided by the Court in decisions, intervener briefs, or dockets, and for that reason we have no record of the Court's logic in accepting or rejecting an applicant for intervention.

¹⁸ On February 21, 2017, the author of this study became aware of a case currently (at the time this paper is being written) before the Supreme Court, as of March 10, 2016. The case is not concluded, and there is no decision yet. For these reasons the case is not included in this study. *AstraZeneca Canada Inc et al Apotex Inc*, 2015 FCA 158.

¹⁹ Litigant factums were not collected, in part, because some were not publicly available. For instance, *Apotex v Sanofi-Synthelabo* (2008) was subject to a "sealing order" For further information on sealing order, see Irving & Creighton (2013).

²⁰ The records centre archives intervener briefs in three formats, offline, on the internal digital database, or hosted on the Supreme Court of Canada website. Fees of varying of amount may be incurred to access the files hosted either offline or on the records centre internal digital database. All records hosted on the Supreme Court of Canada website are free to download.; See appendix E for links to decisions and websites where these resources can be retrieved or requested from the Supreme Court.

The decisions were used to obtain information about the content of the case, the judges involved, the litigating parties,²¹ and the interveners. The case dockets were used to identify applicants for intervener status, which applications had been successful or unsuccessful, what submissions the successful intervener applications were allowed to provide to the Court during the appeal proceedings (written documents or both written documents and oral presentations) and the length of those representations (both written documents and oral arguments are limited to a prescribed maximum length by the judge who accepted the intervener application). The judge or prothonotary who accepted or rejected the intervener application submission was also recorded.

Intervener briefs were examined for evidence of positions and interests. The intervener briefs, when reviewed on their own and without context, are not sufficiently comprehensible to understand the stakeholder's positions or interests: intervener briefs are predicated on an understanding of the issues at trial.²² The decisions were studied and following that, the intervener briefs were studied.

3.4 Findings

3.4.1 Pharmaceutical Cases at the Supreme Court of Canada

Before a pharmaceutical is able to be part of the market in Canada, whatever its patent status (in patent or out of patent), the pharmaceutical company seeking to market and distribute the drug anywhere in Canada must obtain a Notice of Compliance (NOC) from Health Canada. The NOC is an indication that the manufacturer has met the regulatory requirements for the safety, efficacy and quality of the product (Health

²¹ A “party” in the decision is either the plaintiff or defendant. An intervener is not a party involved in the lawsuit but an outside stakeholder who has successfully applied for intervener status.

²² Decision in each case were examined prior to the analysis of Intervener Brief or Docket.

Canada, 2014). Three classifications of cases were identified amongst the nine under study here: notice of compliance cases,²³ general patent cases, and non-patent cases.

Figures 3.2 to 3.10 each represent, diagrammatically, the pharmaceutical cases studied in this research. The progress of each case through the court is indicated. The presentation of the Figures is divided into four sections: first, the cases in which there were no interveners are shown (Figures 3.2 and 3.3), second the cases where interveners did apply but none were accepted by the Court are shown (Figure 3.4), third, those cases are shown in which all the interveners who applied were accepted (Figures 3.5 to 3.7) and, finally, those cases where interveners were present but only some of those who applied were accepted by the Court (Figures 3.8 to 3.10). Within each of the four sections, the Figures of the cases are presented in chronological order

3.4.1.1 Cases Without Intervenors

3.4.1.1.1 Cases Where No Intervention Was Attempted

Apotex v Wellcome Foundation [2002]

GlaxoKlineSmith and Wellcome Foundation found that AZT, an antiretroviral medication, could be used as treatment for HIV (*Apotex Inc. v Wellcome Foundation Ltd* [2002] SCC 77, hereinafter “*Apotex v Wellcome Foundation*”). Following this discovery, and after testing by National Institutes of Health (NIH) scientists, GlaxoKlineSmith and Wellcome Foundation filed for a patent in the United Kingdom from which the Canadian patent claimed priority right.²⁴ Apotex and Novopharm, generic drug manufacturers, challenged the validity of the Canadian patent in the Canadian courts on the grounds that (a) necessary utility had not been established as of the priority date of the patent, (b) the

²³ Notice of Compliance (NOC) cases are a subset of intellectual property law, as are patent cases. NOC cases may involve patent, but the presence of an NOC process in the issues meets the criteria for an NOC case, and the exclusion from the Patent or

²⁴ The priority right is time limited and allows the patent claimant to file a subsequent application in a different country for the same invention, design, or trademark effective as of the date of filing the first application.

claims covered more than the invention, and (c) that the disclosure was misleading because the NIH in full was not mentioned. The trial judge rejected these arguments. The decision was appealed by Apotex to the Federal Court of Appeal, where the appeal was dismissed. The case was by Apotex appealed to the Supreme Court of Canada, where the appeal was dismissed (See Figure 3.2) (*Apotex Inc. v Wellcome Foundation Ltd* [2002] SCC 77).²⁵

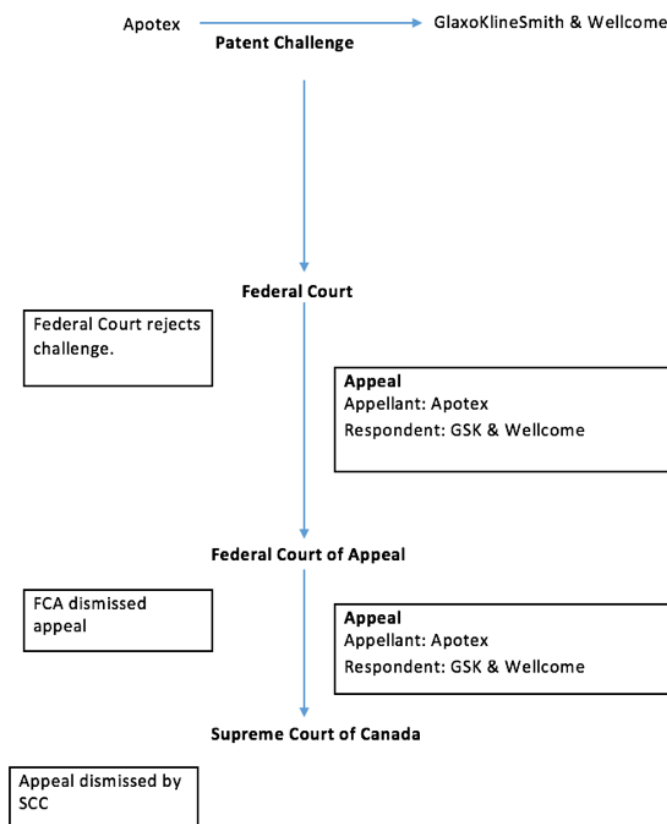


Figure 3.2: Apotex Inc. v Wellcome Foundation Ltd., [2002] 4 S.C.R. 153, 2002, SCC 77

²⁵ In each of the cases below, there is an accompanying figure which is a visual representation of the case. The litigants are displayed at the top (plaintiff on the left, respondent to the right) and the events are listed chronologically from the top to the bottom of the figure. The text under the horizontal indicates what sort of action was taken

Nu-Pharm Inc. v Canada (Attorney General) [2010]

Nu-Pharm unsuccessfully applied to Health Canada for an issuance of an NOC in Canada in 1997 (Nu-Pharm Inc. v Canada (Attorney General) [2010] SCR 648, hereinafter “*Nu-pharm*”). That decision was overturned on judicial review, and Health Canada issued the NOC, but that decision was again overturned, on appeal to the FCA – leaving Nu-Pharm without an NOC. In 2001, Nu-pharm initiated an application to Federal Court for judicial review alleging Health Canada was acting unlawfully in not authorizing Nu-Pharm to sell its drug, but this application was discontinued. In 2002, Nu-Pharm filed a statement of claim in Federal Court against the Crown seeking injunctive and mandatory relief and damages for various torts. The Crown was successful in getting this application dismissed by seeking summary judgment on the grounds that the Federal Court did not have the jurisdiction to hear the matter. This was appealed to the Federal Court of Appeal, where the court decided in favour of the Crown. The decision was appealed to the Supreme Court, which ruled in favour of the appellant.

Nu-Pharm (Nu-Pharm Inc. v Canada (Attorney General) [2010] SCR 648)

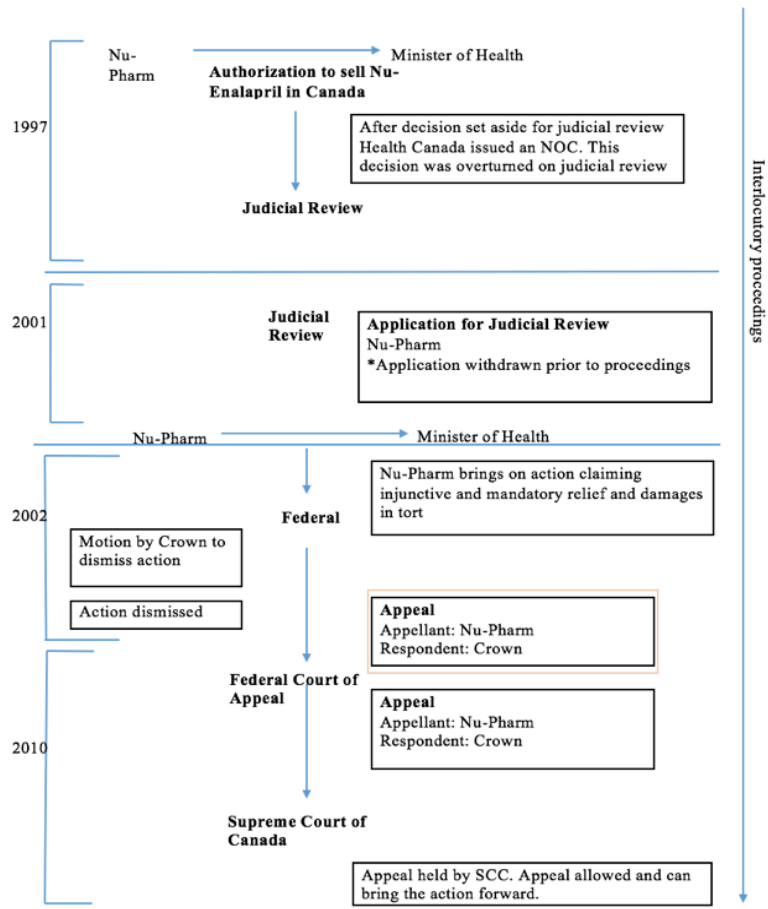


Figure 3.3: Nu-Pharm. v Canada (Attorney General), 2010 SCC 65, [2010] 3 S.C.R

3.4.1.1.2 Cases Where Intervention Was Attempted

Celgene Corp. v Canada (Attorney General) [2011]

Celgene is a New Jersey (US) based distributor of a pharmaceutical named Thalomid, that since 1996 has sold to Canadians through the Special Access Programme [SAP].²⁶ Celgene obtained a Canadian patent in relation to Thalomid in 2006 (*Celgene Corp. v Canada (Attorney General) [2011] SCR 3*, hereinafter “*Celgene*”), at which point the Patented Medicines Review Board requested pricing information from Celgene, starting from the time it began selling the drug in 1995. Celgene initially complied but later refused the requests as the medicine was “sold” in New Jersey and there the matter is outside the Board’s authority. The Board responded that Celgene’s sales to Canada under SAP were in the Canadian market and subject to its authority. The Board’s decision was reversed on judicial review, but an appeal to the Federal Court of Appeal agreed with the Board. On appeal by Celgene the Supreme Court ruled in favour of the Board (*Celgene Corp. v Canada (Attorney General) [2011] SCR 3*).

²⁶ The Special Access Programme, is described as Health Canada as: “provides access to non-marketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable. The SAP authorizes a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada. Drugs considered for release by the SAP include pharmaceutical, biologic, and radio-pharmaceutical products not approved for sale in Canada.” Retrieved from: <http://www.hc-sc.gc.ca/dhp-mps/acce>

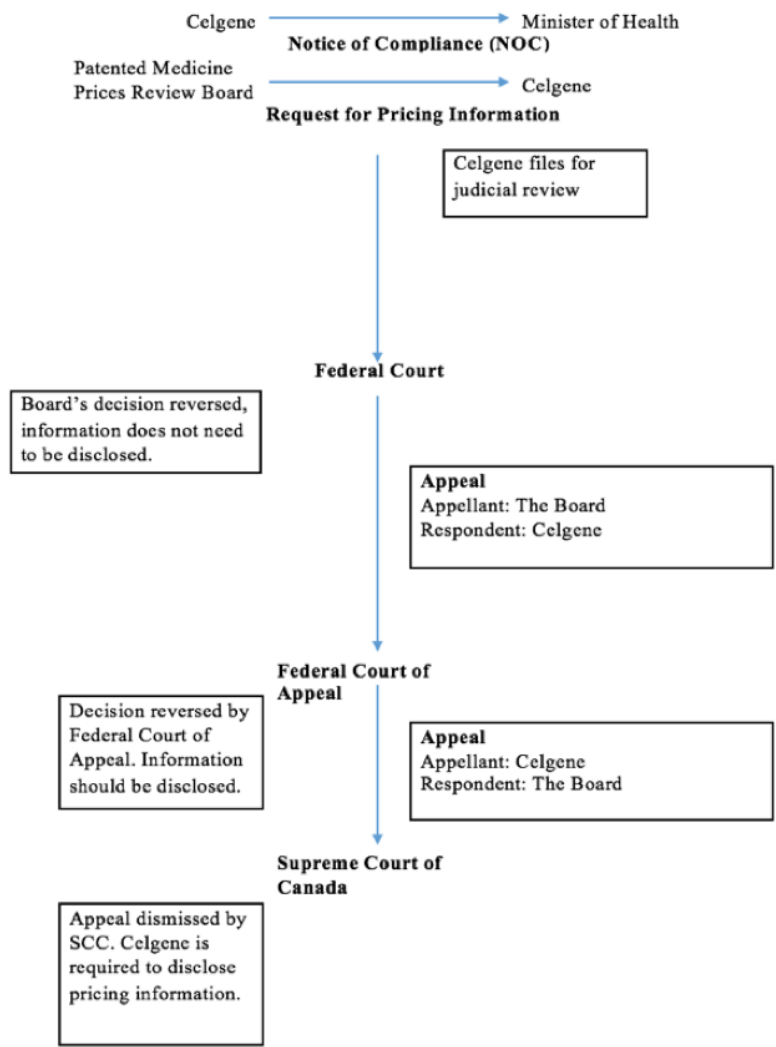


Figure 3.4: Celgene Corp. v Canada (Attorney General), 2011 SCC 1, [2011] 1 S.C.R. 3

3.4.1.2 Cases Where Interveners Appeal

3.4.1.2.1 Cases Where All Who Applied to Intervene Were Successful

Bristol-Myers Squibb Co. v Canada [2005]

Bristol-Myers Squibb (BMS) developed a drug containing paclitaxel, marketed as Taxol, which had anti-carcinogenic properties (*Bristol-Myers Squibb Co. v Canada (Attorney General)*, [2005] SCR 533, hereinafter “*Bristol-Myers Squibb Co.*”). BMS obtained a number of Canadian patents on the drug, but no on the active ingredient itself, Paclitaxel. Working independently of BMS, Biolyse found that paclitaxel could be extracted from a species of yew without killing the bush (therefore allowing the company to extract the paclitaxel compound in sufficient quantities for commercial distribution). Biolyse filed for a Notice of Compliance which BMS sought to quash. On application for judicial review, a motions judge found that because Biolyse had neither applied for or obtained regulatory approval on the basis of bioequivalence, the NOC should be quashed. The Federal Court of Appeal upheld this judgment. The Supreme Court reversed this decision (*Bristol-Myers Squibb Co. v Canada (Attorney General)*, [2005] SCR 533).

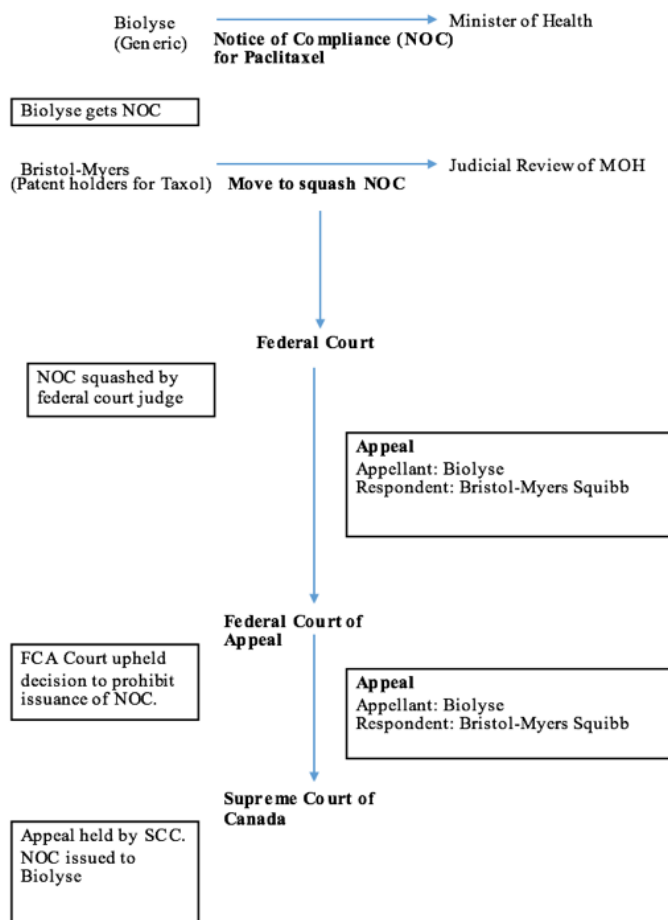


Figure 3.5: Bristol-Myers Squibb Co. v Canada (Attorney General), [2005] 1 S.C.R. 533

AstraZeneca Canada Inc. v Canada (Minister of Health) [2006]

In 1989, AstraZeneca obtained a NOC for *Losec 20* from 1989 until 1996, when AstraZeneca removed it from the market. In 2002, AstraZeneca obtained and registered two more patents for *Losec 20* with the Ministry of Health (MOH), despite the drug being off the market (*AstraZeneca Canada Inc. v Canada (Minister of Health)* [2006] SCR 560, hereinafter “*Biolyse*”). Meanwhile, in 1993 Apotex had filed an NOC for omeprazole, a generic version of *Losec 20*. The MOH determined that Apotex did not need to address the after-issued patents held by AstraZeneca and granted Apotex the NOC in 2004. AstraZeneca filed for judicial review, and the motions judge upheld the MOH’s decision.

The Federal Court of Appeal reversed this decision and Apotex's NOC was quashed. The Supreme Court of Canada then reversed the decision of the FCA (*AstraZeneca Canada Inc. v Canada* (Minister of Health) [2006] SCR 560).

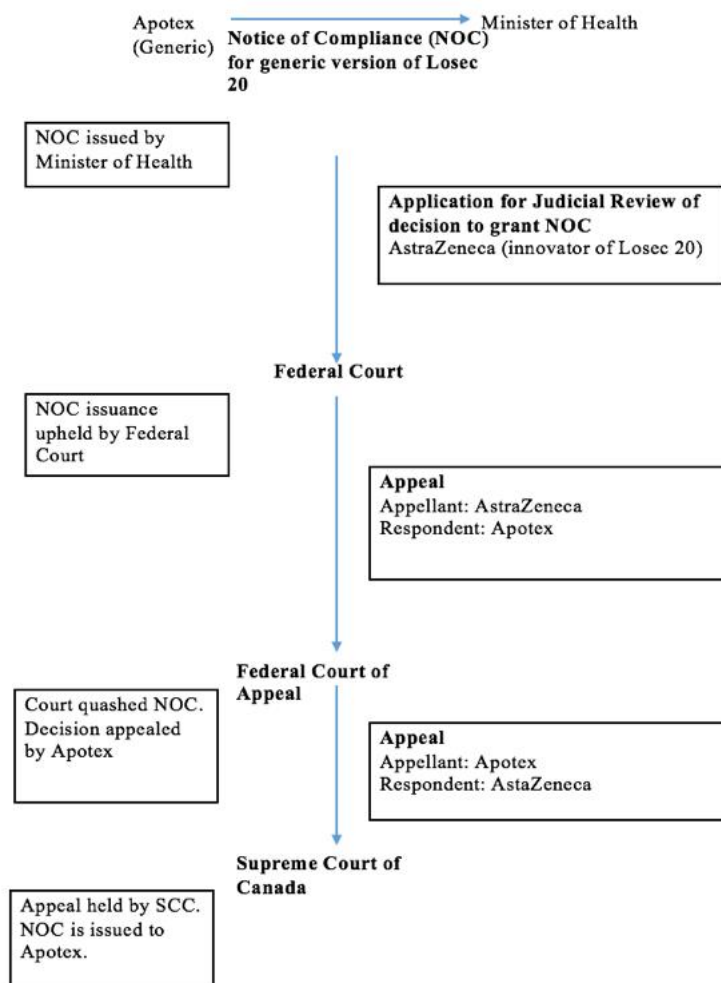


Figure 3.6: AstraZeneca Canada Inc. v Canada (Minister of Health), [2006] 2 S.C.R. 560, 2006 SCC 49

Apotex Inc. v Sanofi-Synthelabo Canada Inc [2008]

Sanofi-Synthelabo held the '875 patent which discloses a large class of over 250 000 combinations useful for inhibiting blood platelet aggregation activity (*Apotex Inc. v Sanofi-Synthelabo Canada Inc* [2008] SCR 265, hereinafter "*Apotex Inc. v Sanofi*"). Sanofi-Synthelabo also holds the subsequent '777 patent which discloses and claims

clopidogrel bisulfate, marketed by Sanofi-Synthelabo under the trade name of Plavix as an anti-coagulant. In 2003, Apotex, a generic manufacturer, served a notice of allegation on Sanofi to obtain an NOC from the MOH to market its generic version of Plavix; claiming the '777 patent was invalid. Sanofi successfully sought an order from the Federal Court to block the NOC on the grounds that Apotex infringed on the '777 patent. The Federal Court of Appeal upheld the decision. The decision was appealed the Supreme Court which dismissed the appeal (*Apotex Inc. v Sanofi-Synthelabo Canada Inc* [2008] SCR 265).

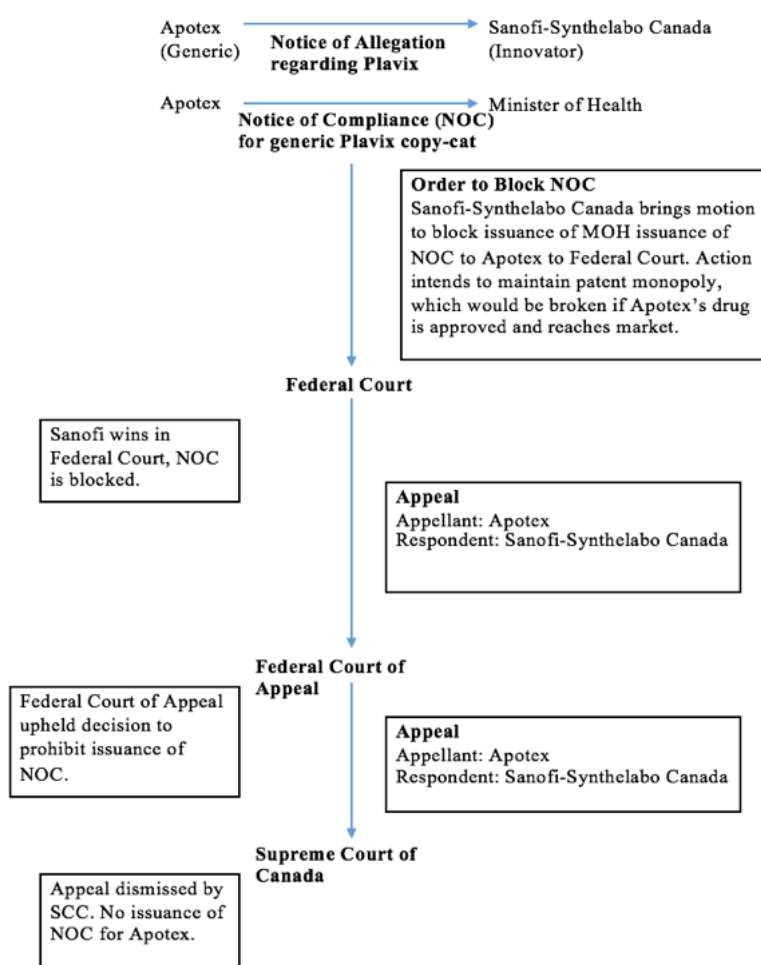


Figure 3.7: Apotex Inc. v Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R 265, 2008

SCC

3.4.1.2.2 Cases Where Only Some Who Applied Were Accepted *Merck Frosst Canada Ltd. V Canada [2012]*

Health Canada received an access to information request, from another party, related to two new drug submissions made by Merck Frosst (*Merck Frosst Canada Ltd. v Canada (Health)* [2012] 1 SCR 23, hereinafter “*Merck*”). Health Canada identified several hundred pages that could be disclosed by the access to information request. Health Canada then notified Merck of the access to information requests and the intention to disclose the identified pages to the requestor. Merck was given an opportunity to explain which of these pages should remain confidential before Health Canada fulfills the FOI request to the requestor. Health Canada agreed to further redactions but rejected most of Merck’s objections. Merck filed for a judicial review of Health Canada’s decision. The Federal Court found that Health Canada was about to contravene the *Information Act*, and that 200 pages must be exempted from disclosure (while the rest could be disclosed to the requestor). The Federal Court of Appeal allowed Health Canada’s appeal and ordered all the pages disclosed to the requestor. The Supreme Court ruled against the appellants (Merck Frosst) (*Merck Frosst Canada Ltd. v Canada (Health)* [2012] 1 SCR 23).

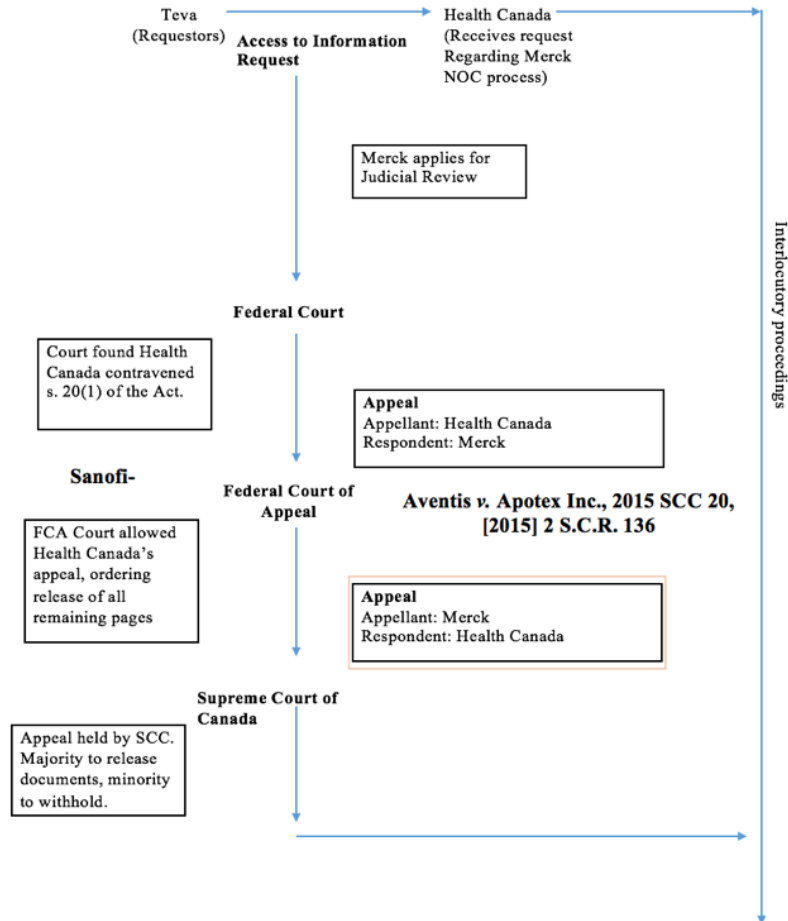


Figure 3.8: Merck Frosst Canada Ltd. v Canada (Health), 2012 SCC 3, [2012] 1 S.C.R 23

***Teva Canada Ltd v Pfizer Canada Inc.* [2012]**

Pfizer holds the Canadian Patent 2 163 446 for use of a “compound of formula (I)” or a “salt thereof” as a treatment for erectile dysfunction (*Teva Canada Ltd. v Pfizer Canada Inc* [2012] SCR 625, hereinafter *Teva*). The Patent’s specifications for seven cascading claims for successively smaller ranges of compounds. Sildenafil, the subject of Claim 7 and the active compound in Viagra, is shown to be, by Teva, effective in treating erectile dysfunction. Teva applied for an NOC to produce a generic version of Viagra. On appeal by Pfizer, the Federal Court blocked the Ministry of Health from issuing the NOC. Teva appealed to the Federal Court of Appeal and the decision by the Federal Court was

upheld. Teva appealed this decision to the Supreme Court which ruled in favor of Teva (*Teva Canada Ltd. v Pfizer Canada Inc* [2012] SCR 625).

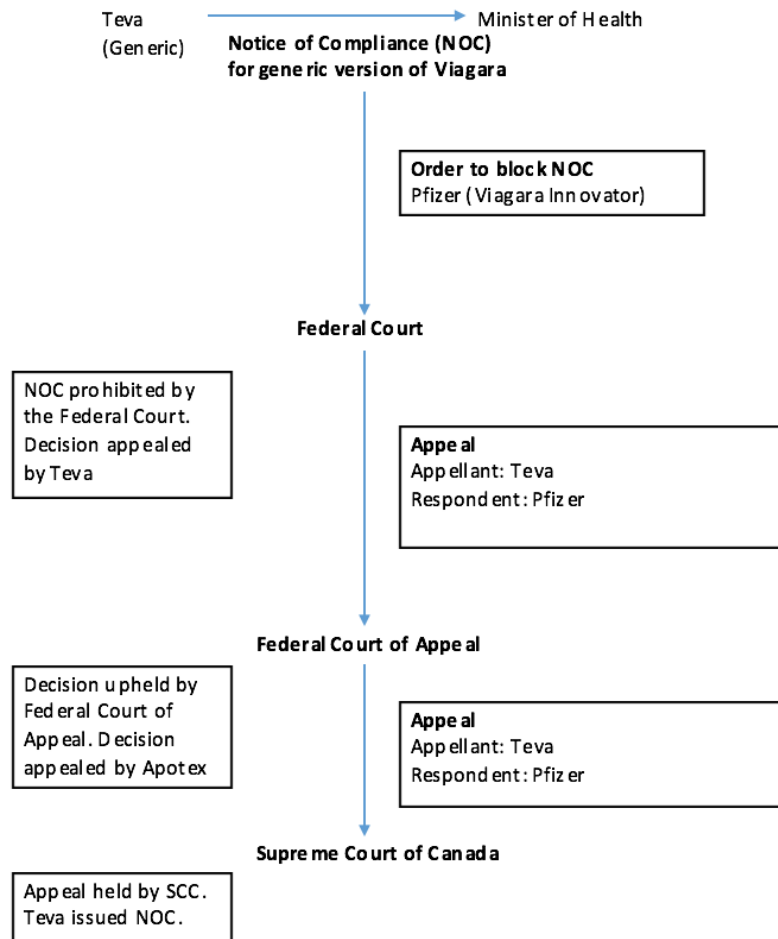


Figure 3.9: Teva Canada Ltd. Pfizer Canada Inc., 2012 SCC 60, [2012] 3 S.C.R 625

Sanofi Aventis v Apotex Inc. [2015]

Apotex filed with Health Canada for an issuance of NOC for a generic drug and received the NOC. Sanofi-Aventis and Bristol Myers Squibb applied to the Federal Court against Apotex, and were successful in having the NOC squashed (*Sanofi-Aventis v Apotex Inc* [2015] SCR 136, hereinafter *Sanofi*). Apotex then commenced an action in The Federal Court to invalidate Sanofi's patent. Sanofi then began an infringement action in the Federal Court against Apotex. Then simultaneously, the Federal Court, in the patent infringement action, decided in favor of Apotex and

invalidated Sanofi-Aventis's Patent. Sanofi appealed to the Federal Court of Appeal, where the decision of the Federal Court was upheld. The decision was appealed to the Supreme Court of Canada but dismissed summarily, with the Supreme Court unanimously agreeing with the FCA's reasoning (*Sanofi-Aventis v Apotex Inc* [2013] FCA 209, para 1-10).

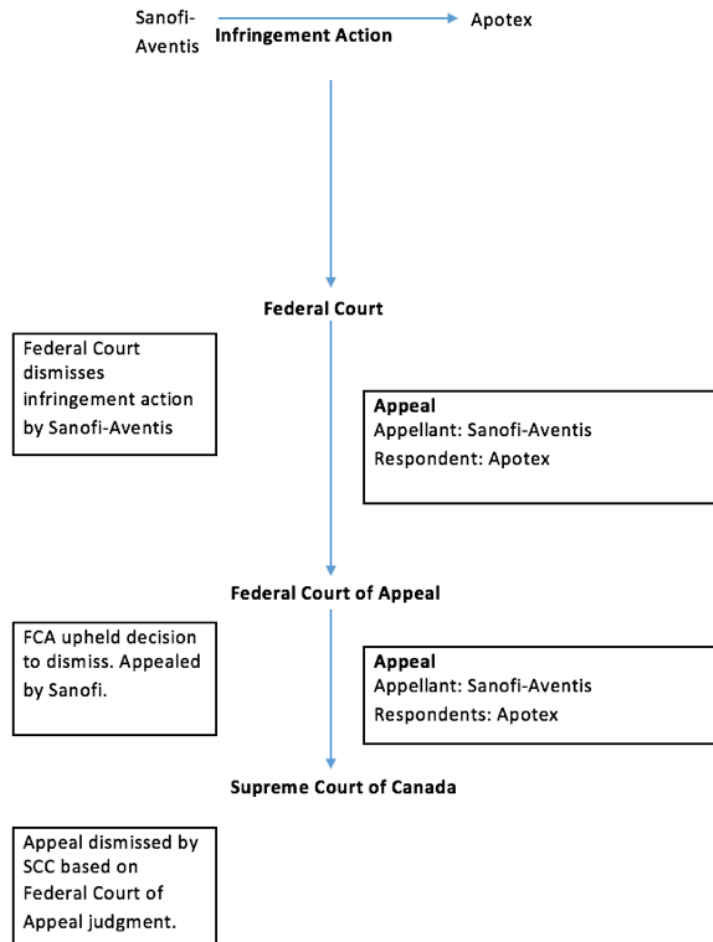


Figure 3.10: Sanofi-Aventis v Apotex Inc., [2015] 2 S.C.R. 136

3.4.2 Interveners Across All Decisions

Of the nine decisions identified, six involved interveners (see Table 3.2). There were a total of sixteen interventions applications (twelve successful, four unsuccessful) across the six cases

Table 3.2: Cases with and without interveners (Interveners in brackets)

Cases with Interveners	Cases without Interveners
<ul style="list-style-type: none"> • <i>Bristol-Myers Squibb Co. v Canada</i> (Attorney General), [2005] 1 S.C.R. 533, 2005 SCC 26 (CGPA & Pfizer) • <i>AstraZeneca Canada Inc. v Canada</i> (Minister of Health), [2006] 2 S.C.R. 560, 2006 SCC 49 (CPGA, CRPC) • <i>Apotex Inc. v Sanofi-Synthelabo Canada Inc.</i>, [2008] 3 S.C.R. 265, 2008 SCC 61 (BIOTE, CGPA, CRPC) • <i>Merck Frosst Canada Ltd. v Canada</i> (Health), 2012 SCC 3, [2012] 1 S.C.R. (BIOTE) • <i>Teva Canada Ltd. v Pfizer Canada Inc.</i>, 2012 SCC 60, [2012] 3 S.C.R. 625 (CGPA, CRPC) • <i>Sanofi-Aventis v Apotex Inc.</i>, 2015 SCC 20, [2015] 2 S.C.R. 136 (CGPA, CRPC) 	<ul style="list-style-type: none"> • <i>Apotex Inc. v Wellcome Foundation Ltd.</i>, [2002] 4 S.C.R. 153, 2002 SCC 77 • <i>Nu-Pharm Inc. v Canada</i> (Attorney General), 2010 SCC 65, [2010] 3 S.C.R. 648 • <i>Celgene Corp. v Canada</i> (Attorney General), 2011 SCC 1, [2011] 1 S.C.R. 3

Source: Reviewing decisions for intervener participation.

In the nine decisions involving pharmaceuticals a number of parties appealed repeatedly (See Table 3.1).

There were not attempts to intervene made in all nine cases – and where applications to intervene were made, results were mixed (see Table 3.3).

Table 3.3: Applications to the Court

	Cases with Interveners	Cases Without Interveners
Total Cases	6	3
Total Intervener Applications Made	15	1
Successful Applications	12	0
Unsuccessful Applications	3	1

Source: Reviewing case dockets for intervener applications.

Of the four instances in which an intervention application was rejected, one rejection of an application for intervention (that of the Information Commissioner of

Canada in *Merck Frosst Canada Ltd. v Canada*, 2012) was due to failure to submit the necessary documents by the necessary deadlines. Laboratoire Riva's application in *Sanofi-Aventis v Apotex Inc* (Court Docket, *Sanofi-Aventis v Apotex Inc* [2015] 2 SCR 136) was dismissed by Justice Karakatsanis, BIOTECanada's application in *Teva Canada Ltd. v Pfizer Canada Inc.* (2012) (Court Docket, *Teva Canada Ltd. v Pfizer Canada Inc* [2012] 3 SCR 625) was dismissed by Justice Deschamps: the same judge that accepted BIOTECanada's application in *Merck Frosst Canada Ltd. v Canada* (2012) in that same year, 2012. Aside from Justice Deschamps, no justice participated in the selection of interveners in more than two cases, and Justice Deschamps permitted intervener(s) to file a 10-page factums and give oral presentations in both *Merck Frosst Canada Ltd. v Canada* (2012) and *Teva Canada Ltd. v Pfizer Canada Inc.* (2012). Because a different judge was involved in the selection of interveners in every case (with the exception of Justice Deschamps, who is seemingly neutral towards BIOTECanada because they were accepted and rejected once by Deschamps) no single judge significantly influenced the acceptance or rejection of the intervener applications, there is no apparent bias in accepting or rejecting interveners by judges across the cases.

The majority of interventions were done by the Canadian Generic Pharmaceutical Association and Canada's Research-Based Pharmaceutical Companies, who represent the generic and brand name pharmaceutical industries, respectively (see Table 3.4 for a list of successful and unsuccessful intervener applications organized by applicant).

Table 3.4: Interventions Across All Decisions

Interveners	Frequency	
	Successful Application(s)	Unsuccessful Application(s)
Canadian Generic Pharmaceutical Association	5	0
Canada's Research-Based Pharmaceutical Companies	4	1
BIOTECanada	2	1
Pfizer	1	0
Laboratoire Riva Inc.	0	1
Information Commissioner of Canada	0	1

BIOTECanada represented the brand name pharmaceutical industry in one intervention, and an unrelated matter to generic or brand name companies in another case (Factum for BIOTECanada, *Merck Frosst Canada Ltd. v Canada (Health)*, [2012] 1 SCR 23). BIOTECanada had an application rejected on a case where both the Canadian Generic Pharmaceutical Association and Canada's Research Based Companies successfully intervened (*Teva Canada Ltd. v Pfizer Canada Inc.* [2012] 3 SCR 625). BIOTECanada and Canada's Research Based Companies have overlapping mandates, and the Court has shown that it will accept Canada's Research Based Companies intervener application over BIOTECanada's in certain instances where the both seek to represent brand name pharmaceutical interests. Pfizer, a member of Canada's Research-Based Pharmaceutical Companies, held positions which favour the brand name pharmaceutical industry during its intervention (Factum for Pfizer Canada, *Bristol-Myers Squibb Co. v Canada (Attorney General)* [2005] 1 SCR 533).

Unsuccessful applications to intervene fell into three categories: 1) they did not have interests or arguments which support the generic or pharmaceutical industry (as is the case in *Laboratoire Riva Inc.*'s application), 2) the argument raised was already addressed by another intervener, and did not make the criteria for originality (BIOTECanada's application in *Teva v Pfizer*), 3) there was no application by the opposite pharmaceutical camp (e.g., if a brand name intervener applied, there was no application by the generic parallel intervener), and so there would be a perceived imbalance in the arguments (as was the case with Canada's Research-Based Pharmaceutical Companies' application in *Celgene Corp. v Canada*).²⁷ The only case with no interveners and but an application is *Celgene Corp. v Canada* (2011) where only Canada's Research Based Companies submitted an application but was dismissed.

²⁷ The Information Commissioner of Canada initially submitted an application for intervention but missed the deadlines necessary to submit the necessary documents.

All the successful intervener applicants can be categorized as supporting generic or brand name companies, and at least one from each camp is involved if there is intervention on a case that might concern certain brand name or generic drugs.

In total, there were fifteen separate applications for intervener status, and twelve were successful. Six stakeholders were responsible for the fifteen intervener applications, and four stakeholders were successful in their applications. In cases with interveners, three cases had all intervener applications accepted, and three cases did not have all intervener applications accepted. In cases without successful intervener applications, there was one case with an application for intervener status, and three with no applications.

Table 3.5: Generics and Brand Name Parties²⁸

Type of Case	Number of Cases with Interventions/Total Number of Cases	Number of Successful Intervention Applications	Number of Unsuccessful Intervention Applications
Notice of Compliance	4/5	9	1
General Patent	1/2	2	1
Other, non-patent	1/2	1	2

The majority of intervention applications, ten out of sixteen (62.5%) are NOC cases, and 80% of NOC cases have interveners (See Table 3.5). NOC litigation has the highest proportion of interveners of the three classifications identified in this study. It appears likely that stakeholders view NOC litigation as uniquely important, and are willing to intervene. General Patent cases follow the same pattern of intervention (a brand name and generic intervener) but in lower numbers; only one of the two cases featured intervention, and they received only three out of fifteen total applications for intervention. The ‘other’, non-patent, cases only featured one intervener and did not follow the pattern of having a brand and generic intervener present.

²⁸ *Nu-Pharm* is excluded as it does not meet either criteria.

Litigants and interveners can be categorized as being representative of the brand name or generic pharmaceutical industry, or ‘other’. Table 3.6 lists the parties and interveners and their respective affiliations.

Table 3.6: Generic and Brand Name Parties²⁹

Classification of Party or Intervener	Litigants	Intervener
Brand Name	Pfizer, Merck, AstroZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Celgene, Sanofi-Aventis/Synetholab	Canada’s Research-Based Pharmaceutical Companies Pfizer Canada Inc. BIOTECanada
Generic	Apotex, Teva	Canadian Generic Pharmaceutical Association Laboratoire Riva
Other	Wellcome Trust	Information Commissioner of Canada

The Canadian Generic Pharmaceutical Association had five successful intervention applications and no unsuccessful applications, Canada’s Research-Based Pharmaceutical Companies had four successful applications and one unsuccessful application, BIOTECanada had two successful applications and one unsuccessful application, Pfizer had one successful application and no unsuccessful applications, Laboratoire Riva Inc. and the Information Commissioner of Canada each applied unsuccessfully.

3.4.3 Patterns in the Interventions

When the cases are organized chronologically and reviewed for the presence and length of written factums and oral arguments, it can be seen that oral arguments have become more common, but the length of both factums and oral arguments have been shortened in more recent cases (See Table 3.7).

²⁹ Nu-Pharm is excluded as it does not meet either criteria.

Table 3.7: Length and Time Allowances for Factums and Oral Arguments

Case	Length of Written Factum (pages)	Length of Oral Argument (minutes)
<i>RJR-MacDonald Inc. v Canada (A.G)</i>	20	15 (for each intervener in the coalition)
<i>Bristol-Myers Squibb Co. v Canada, 2005</i>	20	15
<i>AstraZeneca Canada Inc v Canada, 2006</i>	20	15
<i>Apotex Inc. v Sanofi-Synthelabo Canada Inc, 2008</i>	15	10
<i>Merck Frosst Canada Ltd v Canada, 2012</i>	10	10
<i>Teva Canada Ltd. V Pfizer Canada Inc, 2012</i>	10	10
<i>Sanofi-Aventis v Apotex Inc, 2015</i>	10	10

Source: Intervener factums of each the interveners in the cases listed above

In all the cases, with the exception of, *Bristol-Myers Squibb Co. v Canada* (2005), the interveners (if there was more than one) received the same length allowances for written factums and time allowances for oral arguments. In *Bristol-Myers Squibb Co. v Canada*, both the Canadian Generic Pharmaceutical Association and Pfizer were permitted a twenty-page factum, but only Pfizer was allowed to make a fifteen-minute oral argument in the Court, and the Canadian Generic Pharmaceutical Association was not allowed to make an oral argument. Pfizer's intervention in *Bristol-Myers Squibb Co. v Canada* is also the only intervention by a company instead of an association. Remarkably, Canada's Research Based Pharmaceutical Companies did not apply for intervention on that same case. In every other case the intervention is by an association, not a company.

Because of the shortening of interveners' written and oral arguments over time found in this study, it appears that each interveners' influence in the courts is diminished as there is less space and time to present a convincing argument. Of the cases with interveners, four of the six cases involved a full court and two did not. All three cases without interveners had full courts; the presence of a full court, or not, does not seem to have an impact on intervention.

Of the six cases with interveners, four had a unanimous judgments and two had majorities with minority dissents (none involved solo dissents). The three cases without

interveners all the cases were unanimous. This suggests that the presence of interveners may contribute to differing opinions amongst the justices in pharmaceutical patent cases and *RJR-MacDonald* (See Table 3.8).

In *RJR-MacDonald*, with a full court of nine judges, there are seven different judgments filed. Two dissents to the majority decision written: the dissenting judges were: La Forest J, with whom L-Heureux-Dube and Gonthier joined (*RJR-MacDonald Inc. v Canada* [1995] 3 SCR 199, para 2-119), and a solo dissent written by Cory (*RJR-MacDonald Inc. v Canada*, [1995] 3 SCR 199, para 121). There are five independently filed judgments which make up the majority: Iacobucci, McLachlin, Major, Lamer, Sopinka. The interveners' positions did not support the position taken by the majority judges, but their positions are aligned with the position taken by the dissenting judges (La Forrester J and Cory K).

Table 3.8: Judgments and Types of Dissent in Pharmaceutical Cases

Case	Unanimous	Split		
		Solo Dissent	Joint Dissent	Majority
Apotex Inc. v Wellcome Foundation Ltd., [2002] 4 S.C.R. 153, 2002 SCC 77 [Full Court]	McLachlin C.J. and L'Heureux-Dubé, Gonthier, Iacobucci, Major, Bastarache, Binnie, Arbour and LeBel JJ.	0	0	NA
Bristol-Myers Squibb Co. v Canada (Attorney General), [2005] 1 S.C.R. 533, 2005 SCC 26 [Full Court]	NA	0	Bastarache J. (Major and Charron JJ. concurring)	Binnie J. (McLachlin C.J. and LeBel, Deschamps, Fish and Abella JJ. concurring)
AstraZeneca Canada Inc. v Canada (Minister of Health), [2006] 2 S.C.R. 560, 2006 SCC 49 [Full Court]	Binnie J. (McLachlin C.J. and Bastarache, LeBel, Deschamps, Fish, Abella, Charron and Rothstein JJ. concurring)	0	0	NA
Apotex Inc. v Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265, 2008 SCC 61	Rothstein J. (Binnie, LeBel, Deschamps, Fish, Abella and Charron JJ. concurring)	0	0	NA

Case	Unanimous	Split		
		Solo Dissent	Joint Dissent	Majority
[Not Full Court– 7 Judges]				
Nu-Pharm Inc. v Canada (Attorney General), 2010 SCC 65, [2010] 3 S.C.R. 648 [Full Court]	Rothstein J., Binnie, LeBel, Deschamps, Abella, Charron and Cromwell JJ. concurring	0	0	NA
Celgene Corp. v Canada (Attorney General), 2011 SCC 1, [2011] 1 S.C.R. 3 [Full Court]	McLachlin C.J. and Binnie, LeBel, Deschamps, Fish, Abella, Charron, Rothstein and Cromwell JJ.	0	0	NA
Merck Frosst Canada Ltd. v Canada (Health), 2012 SCC 3, [2012] 1 S.C.R. [Full Court]3	NA	0	Deschamps J. (Abella and Rothstein JJ. concurring)	Cromwell J. (McLachlin C.J. and Binnie, LeBel, Fish and Charron JJ. concurring)
Teva Canada Ltd. v Pfizer Canada Inc., 2012 SCC 60, [2012] 3 S.C.R. 625 [Not Full Court – 7 Judges]	LeBel J. (McLachlin C.J. and Deschamps, Abella, Rothstein, Cromwell and Moldaver JJ. concurring)	0	0	NA
Sanofi-Aventis v Apotex Inc., 2015 SCC 20, [2015] 2 S.C.R. 136 [Full Court]	McLachlin C.J. (Abella, Rothstein, Cromwell, Moldaver, Karakatsanis, Wagner, Gascon and Côté JJ. concurring)	0	0	NA

3.4.4 Content of the Interventions

The formatting of every intervener factum will typically, loosely, follow the same basic format. The factum begins with a statement of the facts, the questions of the case (issues), the intervener arguments, a section concerning costs of the intervention, and a table of authorities. Depending on the issues in the case other sections may appear in the factum.

Recall that for an application for intervention to be successful the applicant must demonstrate:

1. The intervener's interests in the proceedings
2. The position the applicant intends to take with respect to the legal questions in the proceedings
3. The applicant's relevance to the proceedings
4. Reasons why the applicant's submissions will be useful to the Court
5. Any prejudice that the applicant would suffer if the intervention were denied

It is not possible to know for certain how each successful intervener satisfied the judge hearing the application for intervention on any or all of these five points: the reasons why the judge hearing the application for intervention accepts or rejects the application are not delivered in writing and are therefore unknowable. However, from interveners' subsequent factums submitted to proceedings, it may be determined how certain arguments made would also have formed a basis on which the judge hearing the application for intervention would have been able to find the criteria for intervention were satisfied. For instance, a factum which subsequently speaks to the facts and questions surrounding the issues in the case demonstrates that the intervener satisfies the requirement for intervention of proving the intervener's interest in the proceedings and its own interests.

The 'arguments' section of the factum also demonstrates how the intervener would have satisfied, during its application to intervene, the 'position' requirement, its relevance to the proceedings, and why its submissions would be useful to the Court. The interveners do not explicitly state their relevance to the Court in the factums, but arguments provided by the interveners are framed as coming from the position of the brand or generic pharmaceutical industry, which protect the interests of innovators (the brand argument) or represent cost savings and access to pharmaceuticals (the generic argument). These are perspectives which may not be represented by the litigants, would be useful to the Court, and satisfy the question of the intervener's usefulness to the Court. The final question, which asks if the applicant would experience any prejudice if the application were denied, is irrelevant by the time the factum is written because the applicant has already been accepted as an intervener and can no longer experience the prejudice incurred by a rejected application.

The majority of each intervener factum is always dedicated to the specific issues of the case. For instance, in *Bristol-Myers Squibb Co. v Canada*, the Canadian Generic Pharmaceutical Association argued against “evergreening” (Factum for Canadian Generic Pharmaceutical Association (CGPA), *Bristol-Myers Squibb Co. v Canada (Attorney General)* [2005] 1 SCR 533) which is specific to the issues of the case (evergreening refers to a company attempting to extend the length of its patent). The CGPA, throughout its factum, sides with the litigant Biolyse and makes an argument in support of Biolyse. Similarly, in *AstraZeneca Canada Inc. v Canada* (2006) the CGPA is again arguing against the same “evergreening” issue. In *Apotex Inc. v Sanofi-Synthelabo* the CGPA addresses double patenting, which stifles generic development. In *Teva Canada Ltd. v Pfizer Canada Inc* the CGPA support disclosure of information in patents, which promotes generics by allowing for emulation. Finally, in *Sanofi-Aventis v Apotex* the CGPA promotes an interpretation of the Patent Act and the Regulations that ensure a timely entry of competitive generic products and thereby reduce healthcare costs. There is no generic representation in *Merck Frosst Canada Ltd. v Canada* because the issues of the case revolved around a freedom of information request, which is not an issue which necessitates generic representation.

Turning again to *Bristol-Myers Squibb Co. v Canada*, Pfizer Canada argues that it is interested in protecting its brands and products through patent which, again, is an issue discussed in the case (*Bristol-Myers Squibb Co. v Canada (Attorney General)* [2005] 1 SCR 533). Pfizer Canada’s argument concerns a single issue brought up in the Court:

Pfizer's submissions are limited to one point only: this Court should make it clear in its reasons respecting this appeal that, even if s. 5 (11) of the PM(NOC) Regulations can apply to an innovator's NDS, s. 5(1.1) does not apply to a purely administrative NDS filed by a drug manufacturer to effect a name change, a change of address, and the like (Factum for Pfizer Canada, *Bristol-Myers Squibb Co. v Canada (Attorney General)* [2005] 1 SCR 533, p. 1).

Throughout the factum Pfizer discusses this issue with respect to innovative drug manufacturers, and argues against Biolyse, a litigant in the case and a generic

pharmaceutical company.

In *AstraZeneca Canada Inc. v Canada* Canada's Researched Based Pharmaceutical Companies was interested in the protection of intellectual property and brand. In *Apotex Inc. v Sanofi-Synthelabo Canada Inc* argued for protecting "selection patents" and the patent regime from being changed. In that same case, BIOTECCanada (another brand industry representative makes a similar argument, stating: "Selection patents advance patent law policy by rewarding the fruitful efforts of subsequent inventors who discover and disclose to the public the unexpected and advantageous properties of compounds in previously identified classes" (Factum for BIOTECCanada, *Sanofi-Synthelabo Canada Inc.* [2008] 3 SCR 265, para 2). BIOTECCanada also intervened in *Merck Frosst Canada Ltd. v Canada*, arguing for a non-pharmaceutical related issue related to document disclosure during a freedom of information requisition: "An innovative company that submits trade secrets, confidential information and commercially sensitive information to a government institution is vulnerable to release of that information." (Factum for BIOTECCanada, *Merck Frosst Canada Ltd. v Canada (Health)* [2012] 1 SCR 23, para 10). In *Teva Canada Ltd. v Pfizer Canada Inc.* the CRBPC Addressing improper interpretation of AZT case in lower courts and its effect on patentees. Finally, in *Sanofi-Aventis v Apotex Inc. (2015)* argued for an interpretation of the regulations what fairly determine what damages and compensation are fair and predictable.

In The Canadian Generic Pharmaceutical Association, another intervener in the case, also squarely addressed the questions before the Court. After positioning itself as an association of generic drug manufacturers, it describes its interest in the proceedings:

CGPA submits that the anticompetitive effect of the PM(NOC) Regulations arises in large part because first persons can trigger the 24-month automatic stay repeatedly in respect of a single second person drug product, by listing multiple patents over time (Factum for CGPA, *Bristol-Myers Squibb Co. v Canada (Attorney General)* [2005] 1 SCR 533, para 5).

This argument is expanded on throughout the factum, occupying most of the document.

The CGPA also addresses the issue of public policy and health policy in its factum, but the public interest argument is far less prominent, occupying less than a tenth of the total space in the factum. The CGPA addresses the public interest by speaking to access and the cost of drugs:

The resulting additional cost to the public for this single drug over the four years may be in the tens of millions of dollars. There are many drugs which have been or are being delayed for long periods of time by litigation under the Regulations at great cost to the public (Factum for CGPA, *Bristol-Myers Squibb Co. v Canada (Attorney General)* [2005] 1 SCR 533, para 37).

The pattern observed in the intervener factums in *Bristol-Myers Squibb Co. v Canada*, where the interveners mainly address the specific issues of the case and where the public interest is a minor and secondary argument, repeats itself throughout all the intervener factums analyzed for this study. It is also the case in all the factums that brand industry pharmaceutical interveners (like Pfizer in *Bristol-Myers*) will support the brand name litigant and generic pharmaceutical interveners (like the CGPA in *Bristol-Myers*) will support the generic litigant.

Across all the decisions, ten of the twelve interveners make a public-interest argument, typically a minor argument. Only in *Apotex v Sanofi-Synthelabo* did the interveners more prominently feature the public-interest issue, and, in that instance, doing so is a response to claims by Apotex pertaining to public-policy: thus it is the case that the finding that all factums address the issues of the case is consistent across all the cases, including *Apotex v Sanofi-Synthelabo* because the public policy conversation within that case is more prominent, and so a more prominent public-policy conversation in the intervener factums follows from that focus in the litigation itself (Factum for BIOTEC Canada, *Apotex Inc. v Sanofi-Synthelabo Canada Inc.* [2008] 3 SCR 265, para 27; Factum for Canada's Research Based Companies, *Apotex Inc. v Sanofi-Synthelabo Canada Inc.* [2008] 3 S.C.R. 265., p. 6; Factum for CGPA, *Apotex Inc. v Sanofi-Synthelabo Canada Inc.* [2008] 3 SCR 265, para 47). It is notable that none of the interveners are cited or mentioned in the text of the decisions themselves that were

rendered by the Supreme Court judges.

The coalition of interveners in *RJR-MacDonald* (The Canadian Cancer Society, The Canadian Council on Smoking and Health, The Canadian Medical Association, The Heart and Stroke Foundation of Canada, The Canadian Lung Association) do not follow the same pattern of content in their (collective) factum as the generic and brand industry interveners. The structure of the factum begins with an introduction of the coalition of interveners, followed by the perspective of the interveners on the Tobacco Products Control Act, an extended section on the medical facts supporting the legislative objective [of the TPCA], a section describing the aims of tobacco advertising, and the level of support behind a tobacco advertising ban. The interveners still meet the criteria for intervention because they were successful in intervening, and the four criteria for intervention present in the brand and generic pharmaceutical intervener factums (interests, position, relevance to the issues, usefulness to the Court) are still seen in the coalition factum in the “perspectives of the interveners” section and subsequent sections which present evidence for the ban that may not otherwise have been mentioned in the proceedings. The interveners are explicit in their goal to ban tobacco advertising as a matter of public health policy:

In the representations made to Parliament, the Interveners and other members of the Canadian medical and health community provided detailed background information concerning the medical consequences of tobacco use. The Interveners unanimously supported, and continue to support, the TPCA as part of a multi-faceted approach to reduce and ultimately eliminate disease and death caused by the use of tobacco products. A multi-faceted approach to achieving this objective is supported by both the U.S. Surgeon General and by the World Health Organization. The compelling medical testimony presented to the committees was consistent with the medical evidence which was subsequently adduced at trial in the present case (Factum for Intervener Coalition, *RJR-MacDonald Inc. v Canada*, [1995] 3 SCR 199).

The majority of the factum described the medical evidence supporting a ban on tobacco

advertising, the benefits to the public, and the broad public support to do so. A short part of the factum is dedicated to the facts and issues in the case.

The final set of interveners, from the *CanWest* Charter challenge litigation (Canadian Federation of Nurses Unions, Canadian Health Coalition, Canadian Union of Public Employees, Communications, Energy and Paperworkers Union of Canada, Society for Diabetic Rights, Medical Reform Group, Drug Safety Canada, Women and Health Protection) did not submit factums because the proceedings never reached the point in which they would have been able to do so.

3.5 Analysis and Questions

3.5.1 Is There a Relationship Between the Presence of Interveners and the Volatility of the Area of Law?

In her primary analysis of intellectual property cases in the Supreme Court, Wilkinson noted, with respect to copyright cases specifically, that based on earlier studies there is a level of volatility in the Supreme Court's decision-making in this the area of law that differs from the general level of volatility in Supreme Court decisions; this was supported by her findings that there are a large number of dissents and concurring reasons in copyright cases during the Chief Justice McLachlin's term. However, pharmaceutical patent litigation does not seem to exhibit the same patterns found by Wilkinson in copyright cases. As seen in Table 3.10 reporting on judgments and dissents on pharmaceutical patent decisions, there were six unanimous decisions, no concurring opinions, and three dissents (none of them solo dissents). In comparison to copyright cases there is a low level of volatility in pharmaceutical patent decisions. The decision in *RJR-MacDonald* is more volatile as there was a concurring dissent and a solo dissent, and more analogous to the decision-making pattern found by Wilkinson in copyright cases. The findings in this study concerning decision-making patterns in pharmaceutical patent cases before the Supreme Court are consistent with the findings of Newman (2016), where there was a low level of volatility.

Litigants before the court in the pharmaceutical patent cases mirror the same basic divisions as do the interveners: both litigants and interveners are divided between their

belonging to the generic pharmaceutical lobby and the name brand pharmaceutical groups, the only exception is the Wellcome Trust who are categorized as “other”. The only three litigants who are involved in more than one case are Apotex, a generic pharmaceutical company, who was involved in four cases, and Sanofi-Aventis/Synthelabo, who was involved in two cases, and GlaxoSmithKline, a name brand pharmaceutical company, involved in three cases.

Of the litigants, seven brand name pharmaceutical companies (Teva, Pfizer, Merck, Astro-Zeneca, Bristol-Myers Squibb, and Celgene) were each involved in one case as either plaintiffs or defendants, and Biolyse, a generic company, was only involved in one case. In five cases, generics and name brand corporations were litigating against one another, all these cases had interveners. One case featuring a generic company litigating against a brand name company did not have any interveners. The three cases that did not feature generic pharmaceutical companies and brand name pharmaceutical companies litigating against each other do not include interveners. For those stakeholders also present in the Supreme Court of Canada litigation analyzed in this Chapter 3, their interests, influence, and power are demonstrated in this environment of judicial proceedings in ways that parallel these demonstrated characteristics in Chapter 2. The “positions” of brand and generic companies, on the other hand, are opposed to each other in patent litigation whereas in the DTCA context they were found to be the same.³⁰

3.5.2 Is There a Relationship Between the Type of Issue and Those Who Intervene?

When one analyzes the causes of action that have given rise to pharmaceutical cases in the Supreme Court it becomes apparent the majority arise from NOC actions (See Table 3.9). Of the nine pharmaceutical cases identified, five were notice of compliance cases, two were general patent cases, and two were non-patent cases. Far less frequently, the cases arise from matters of pure patent law with two cases rising from their own particular circumstance, not related to NOCs or patent. These last two were

³⁰ Referring to the positions, power, interests, and influence found in Chapter 2.

classified as ‘other’. There is a pattern of intervention in NOC cases, general patent cases, and ‘other’ cases, each of which is different than the others.

Table 3.9: Cases With or Without Successful Interveners

	Cases with Only Successful Intervener Applications	Cases Which Involved Atleast One Unsuccessful Intervener Application	Cases Without Intervener Applications
Notice of Compliance	3	1	1
General Patent	1	0	1
Non-Patent	1	1	0

As can be seen in Table 3.10, every time there was an intervention by a generic industry association (The Canadian Generic Pharmaceutical Association), there was an intervention by a brand industry association or group (Canada’s Research-Based Pharmaceutical Companies, Pfizer Canada, BIOTECanada). The significance of this is that for each generic industry argument made by an intervener there is a corresponding argument by a brand industry intervener.

Table 3.10: Classification of Cases

Classification of Case	Case	Successful Intervener Applicants	Unsuccessful Intervener Applicants
NOC Cases	<i>Bristol-Myers Squibb Co. v Canada (Attorney General)</i> , [2005] 1 S.C.R. 533, 2005 SCC 26	Canadian Generic Pharmaceutical Association, Pfizer Canada Inc ³¹ .	None
	<i>AstraZeneca Canada Inc. v Canada (Minister of Health)</i> , [2006] 2 S.C.R. 560, 2006 SCC 49	Canadian Generic Pharmaceutical Association, Canada’s Research-Based Pharmaceutical Companies	None
	<i>Apotex Inc. v Sanofi-Synthelabo Canada Inc.</i> , [2008] 3	Canadian Generic Pharmaceutical Association, Canada’s	None

³¹ Pfizer substitutes Canada’s Research-Based Pharmaceutical Companies in *Bristol-Myers Squibb Co. v Canada (Attorney General)*.

	S.C.R. 265, 2008 SCC 61	Research-Based Pharmaceutical Companies, BIOTECanada	
	<i>Nu-Pharm Inc. v Canada (Attorney General)</i> , 2010 SCC 65, [2010]	No Intervener(s)	No Intervener(s)
	<i>Teva Canada Ltd. v Pfizer Canada Inc.</i> , 2012 SCC 60, [2012] 3 S.C.R. 625	Canadian Generic Pharmaceutical Association, Canada's Research-Based Pharmaceutical Companies	BIOTECanada
General Patent Cases ³²	<i>Sanofi-Aventis v Apotex Inc.</i> , 2015 SCC 20, [2015] 2 S.C.R. 136	Canadian Generic Pharmaceutical Association, Canada's Research-Based Pharmaceutical Companies	Laboratoire Riva
	<i>Apotex Inc. v Wellcome Foundation Ltd.</i> , [2002] 4 S.C.R. 153, 2002 SCC 77	No Intervener(s)	No Intervener(s)
Non-Patent Cases	<i>Merck Frosst Canada Ltd. v Canada (Health)</i> , 2012 SCC 3, [2012]	BIOTECanada	Information Commissioner of Canada
	<i>Celgene Corp. v Canada (Attorney General)</i> , 2011 SCC 1, [2011]	No Intervener(s)	Canada's Research-Based Pharmaceutical Companies

3.5.3 Does the Pattern of Intervention in Pharmaceuticals Mirror Intervention in *RJR-MacDonald* or *CanWest*?

RJR-MacDonald and *CanWest* litigation deal with issues of public-health, tobacco advertising and pharmaceutical advertising. The plaintiffs in both cases are challenging legislation which limits what advertising they can produce and distribute. In the *CanWest* (Women and Health Protection, 2007) charter challenge on DTCA which Ontario Superior Court, the coalition which intervened was entirely composed of health interested stakeholders (Women and Health Protection, the Canadian Federation of Nurses Unions, the Canadian Health Coalition, the Canadian Union of Public Employees, the

³² General patent cases and non-patent case are collectively referred to as non-NOC cases.

Communications, Energy and Paperworkers Union of Canada, the Society for Diabetic Rights, the Medical Reform Group, and Terence Young for Drug Safety Canada). These stakeholders more closely resemble the interveners in *RJR-MacDonald v Canada* (The Canadian Cancer Society, the Canadian Council on Smoking and Health, the Canadian Medical Association, the Heart and Stroke Foundation of Canada, and the Canadian Lung Association) than they do the interveners in the pharmaceutical patent cases by way of being public interest and health interested stakeholders. These health-interested stakeholders who are intervened in *RJR-MacDonald* and *CanWest* litigation are not intervening in pharmaceutical cases before the Supreme Court.

One hypothesis arising from the finding that the interveners from *RJR-MacDonald* are not attempting to intervene in pharmaceutical related Supreme Court proceedings is that they were uninterested in patent litigation. This was not unexpected because the issues of *RJR-MacDonald* were concerned with tobacco and tobacco advertising, whereas pharmaceutical related Supreme Court proceedings are mainly about pharmaceuticals and patent.

Another possible explanation is that the public interest is already represented by the brand name and generic pharmaceutical industry, and so health-interested organization are not compelled to intervene. The frequency and success of interventions by the generic and name brand pharmaceutical lobbies is evidence that the Supreme Court itself sees the arguments they present as geared towards the public interest. The name brand pharmaceutical industry often argues in its submissions for innovation, science, and medicine, whereas the generic industry will make an argument for healthcare costs and accessibility. This can explain why brand name and generic applications are so often successful. The absence of applications from a public health body, or health-interested stakeholders in these cases as intervener applicants may suggest that the public interest argument is already being presented by the brand and generic pharmaceutical stakeholders. With fewer resources (by comparison to pharmaceutical companies), and less available legal expertise they may not see the strategic need to intervene to make public-interest arguments.

3.6 Conclusions

Recall that the focus of this chapter is to answer research question #2:

Given the relatively recent rise of interveners in the Supreme Court of Canada processes in Canada and the presence of interveners in the landmark 2001 advertising case in the Supreme Court of Canada, *RJR-MacDonald v Canada*, are the stakeholders identified in the response to Research Question #1 found as interveners in current pharmaceutical related Supreme Court litigation?

The answer to this question must be contextualized by the fact that pharmaceutical advertising, although yet to have a landmark case in the Supreme Court, has a number of stakeholders who have interests in pharmaceutical patent. This study has identified prominent stakeholders in the pharmaceutical industry who have a recorded history of initiating and being involved in high-level cases and have the potential to influence DTCA policy on a national level. Most notably, the Canadian Generic Pharmaceutical Association and Canada's Research Based Companies have established a behavior and interest in intervening on such cases but Pfizer and BIOTEC Canada are also interested parties. All these parties were identified as pharmaceutical advertising stakeholders in the analysis reported in Chapter 2.

Most interventions were undertaken by a few stakeholders (see again Table 3.10, five of the interventions (33% of successful interventions, 45.4% of total applications) were by the Canadian Generic Pharmaceutical Association who are present in 80% of cases with interveners. Four of the interventions are by Canada's Research-Based Pharmaceutical Companies [brand] (33% of successful interventions, 26.7% of total applications) who are present in 66% of cases. Together the interventions by the Canadian Generic Pharmaceutical Association and Canada's Research-Based Pharmaceutical Companies represent nine of the twelve total interventions. Initially, it would seem that the generic pharmaceutical lobby is more successful at intervening than the name brand lobby, positioning it as the most powerful network of stakeholders. This conclusion however becomes less certain if one organizes interveners by their respective mandates and their arguments as they pertain to a case (as presented in their intervener

factums). Canada's Research Based Pharmaceutical Companies, BIOTEC Canada [brand], and Pfizer [brand] all represent the interests and positions of the name brand pharmaceutical industry. This rebalances the perception of influence, the name brand industry produced seven interventions across the data set, while generics produced five. Only two lobbies' positions, the brand industry and generic industry positions, were represented here as there was no evidence of any other successful interventions. The only application by an entity that is not in the brand name or generic pharmaceutical lobby was by the Information Commissioner of Canada, abandoned.³³

Table 3.10: Interventions Before and After December 2008

Cases Before December 2008		Cases After December 2008	
Cases With Interveners	Cases Without Interveners	Cases With Interveners	Cases Without Interveners
Bristol-Myers Squibb Co. v Canada (Attorney General) [2005]	Apotex Inc. v Wellcome Foundation Ltd. [2002]	Merck Frosst Canada Ltd. v Canada (Health) [2012]	Nu-Pharm Inc. v Canada (Attorney General) [2010]
AstraZeneca Canada Inc. v Canada (Minister of Health), [2006]	NA	Teva Canada Ltd. v Pfizer Canada Inc. [2012]	Celgene Corp. v Canada (Attorney General) [2011]
Apotex Inc. v Sanofi-Synthelabo Canada Inc. [2008]	NA	Sanofi Aventis v Apotex Inc., 2015 SCC 20 [2015]	NA

Source: Case decisions for intervener participation.

The majority of pharmaceutical cases found in this study have interveners. The six to three (66%) ratio of pharmaceutical cases with interveners (against cases without interveners) found in this study, between 2002 and 2016, is higher than the average proportion of cases with intervention found by Alarie & Green (2010) between January

³³ One group of stakeholders not addressed in this study are those who would be willing or are interested in submitting applications for intervener status but either lack the financial resources or expertise to submit an application. The ability of stakeholders to submit applications to the Supreme Court for intervention is a that should further have investigated in the future but is outside the scope of this study.

2000 and December 2008, which was 49% (330 of 674). However, in this study there are cases decided after December 2008. If the number of cases studied here are separated into those decided before 2008 (the same timeline as Alarie and Greene) and those decided after, three of four, (75%) of the pharmaceutical cases decided before December 2008 have interveners whereas only three of five (60%) of cases decided after December 2008 have interveners. Alarie and Green found that rates of intervention in the Supreme Court had been rising since 2000, reaching a high of 61.8% in 2007. This may explain why the findings in this study are not only higher than that found by Alarie and Greene but also *much* higher than the 33% acceptance rate that Burgess (Burgess, 2000) found in her study of the impact of interveners in the Supreme Court between 1997-1999. The very small numbers involved in this analysis of pharmaceutical cases may suggest that pharmaceutical patent litigation inventions before 2008 are in-line with the rates of intervention found in the Supreme Court by Alarie and Greene, although appearing somewhat higher.³⁴ However, when it is considered that cases containing a constitutional argument constituted over 40% of the 33% of cases involving interveners that Burgess (Burgess, 2000) found – and that there are no constitutional issues raised in any of the nine pharmaceutical cases studied here – the rate of acceptance of interveners by the Supreme Court in (non-constitutional) pharmaceutical litigation is high.

Alarie and Green found that an average of 4.1 interveners (Alarie & Greene, 2010) were present on an appeal with intervention – and this was consistent with Burgess’ finding of four to five interveners per case: in our study, a smaller number of interveners per case is found for pharmaceutical patent cases (an average of two interveners per appeal). The smaller number of interveners in each pharmaceutical case may reduce the impact of such interventions. It is certainly the case that no pharmaceutical judgments cited any interventions made, whereas, as discussed above, Burgess not only found interveners mentioned by the judges in judgments but also found

³⁴ Alarie & Greene’s study ceased data collection in 2008, whereas this study has collected cases up to 2015. A more recent analysis of intervention at the Supreme Court of Canada will be necessary to determine if the findings in this study are consistent with the broader rate of intervention

that this was more likely where there were between two and nine interventions in the case.

In pharmaceutical patent litigation in this study, of the fifteen total applications for intervener status, the acceptance of twelve interveners (80%) suggests that most interveners can expect to be successful if they choose to apply. However, even this high rate of acceptance is slightly lower than the 90% Supreme Court acceptance rate found by Alarie and Greene in their study of other types of litigation (Alarie & Greene, 2010).

Despite the differences in scope between this study and that conducted by Burgess, a number of the findings by Burgess resonate with those found in this study. She found that a relatively few interveners made up a large portion of interventions: in this study there is a very small pool of stakeholders intervening across all the cases. On the other hand, the type of intervener reported by Burgess differs completely from the predominant interveners found in this study of pharmaceutical litigation: here there is only one unsuccessful or incomplete attempt an intervention by a “government” figure – the Information Commissioner in the Merck litigation – whereas Burgess reported a high proportion of government-related interventions in her data. In this study, there are no interventions even attempted by the Canadian Civil Liberties Association, trade unions, individuals, or aboriginal groups found in Burgess’ study.

A central finding is that the interveners from *CanWest* litigation and *RJR-MacDonald* were not found to be intervening in pharmaceutical patent litigation, which raises the question: why are the Interveners from *RJR-MacDonald* and *CanWest* not involved in pharmaceutical patent litigation? Can we expect the stakeholders we have found intervening in pharmaceutical patent cases to intervene on pharmaceutical advertising cases that reach the Supreme Court?

The interveners from *CanWest* and *RJR-MacDonald* may not be intervening on pharmaceutical patent cases for a number of reasons. The two most likely reasons are: 1) They believe that the public interest argument is adequately represented by the brand name and generic pharmaceutical industry interveners or 2) They do not have the

expertise or resources to intervene on a growing number of pharmaceutical patent cases and prefer to allocate resources to higher impact actions.

Since there has been clear interest by health and public interest stakeholders to intervene in the Supreme Court in *RJR-MacDonald*, and that there has been demonstrated interest by health and public interest stakeholders to intervene on the *CanWest* DTCA case, it can be reasonably assumed that these stakeholders would apply to intervene on a pharmaceutical advertising case that reaches the Supreme Court of Canada.

Pharmaceutical patent interveners, in all cases, only joined the proceedings when they reached the Supreme Court. This may explain why they are not present in *CanWest*, as it only reached the Ontario Superior Court. Factoring in these stakeholder's history of intervening on pharmaceutical cases at the Supreme Court, it is likely they would continue to intervene, this includes if a DTCA which reaches the Supreme Court of Canada. However, the arguments of the brand name and generic pharmaceutical industry interveners may change.

3.7 References

Primary Legal Sources:

Apotex Inc. v Sanofi-Synthelabo Canada Inc., [2008] 3 SCR 265

Apotex Inc. v Sanofi-Synthelabo Canada Inc., [2008] 3 SCR. 265 (Factum of the Intervener BIOTEC Canada, court file no. 31881)

Apotex Inc. v Sanofi-Synthelabo Canada Inc., [2008] 3 SCR. 265 (Docket of the SCC, 31881) online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=31881>

Apotex Inc. v Sanofi-Synthelabo Canada Inc., [2008] 3 SCR. 265 (Factum of the Intervener Canadian Generic Pharmaceutical Association, court file no. 31881)

Apotex Inc. v Sanofi-Synthelabo Canada Inc., [2008] 3 SCR. 265 (Factum of the Intervener Canada's Research-Based Pharmaceutical Companies, court file no. 31881)

Apotex Inc. v Wellcome Foundation Ltd., [2002] 4 SCR 153

Apotex Inc. v Wellcome Foundation Ltd., [2002] 4 SCR. 153 (Docket of the SCC, 28287) online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=28287>

AstraZeneca Canada Inc. v Canada (Minister of Health), [2006] 2 SCR 560

AstraZeneca Canada Inc. v Canada (Minister of Health), [2006] 2 SCR. 560 (Docket of the SCC, court file no. 30985). Online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=30985>

AstraZeneca Canada Inc. v Canada (Minister of Health), [2006] 2 SCR. 560 (Factum of the Intervener Canadian Generic Pharmaceutical Association, court file no. 30985)

AstraZeneca Canada Inc. v Canada (Minister of Health), [2006] 2 SCR. 560 (Factum of the Intervener Canada's Research-Based Pharmaceutical Companies, court file no. 30985)

Bristol-Myers Squibb Co. v Canada (Attorney General), [2005] 1 SCR 533

Bristol-Myers Squibb Co. v Canada (Attorney General), [2005] 1 SCR 533 (Docket of the SCC, Court file no. 31881). Online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=29823>

Bristol-Myers Squibb Co. v Canada (Attorney General), [2005] 1 SCR 533 (Brief of the Intervener Canadian Generic Pharmaceutical Association, court file no. 31881)

Bristol-Myers Squibb Co. v Canada (Attorney General), [2005] 1 SCR 533 (Factum of the Intervener Pfizer Canada, court file no. 31881)

Canada v GlaxoSmithKline Inc., [2012] 3 SCR 3

Canada v GlaxoSmithKline Inc., [2012] 3 SCR. (Docket of the SCC, 33874) online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=33874>

Canadian Charter of Rights and Freedoms, Part I of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (UK), 1982, c 11

CanWest MediaWorks Inc. v. Canada [2007] FC 752.

CanWest Mediaworks Inc v Canada (AG) [2008] FCA 207.

Celgene Corp. v Canada (Attorney General), [2011] 1 SCR 3

Celgene Corp. v Canada (Attorney General), [2011] 1 SCR. 3 (Docket of the SCC, 33579) online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=33579>

Janssen-Ortho Inc. v Novopharm Ltd., [2005] 1 SCR 776

Janssen-Ortho Inc. v Novopharm Ltd., [2005] 1 SCR. 776 (Docket of the SCC, 30900) online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=30900>

Merck Frosst Canada Ltd. v Canada (Health), [2012] 1 SCR 23

Merck Frosst Canada Ltd. v Canada (Health), [2012] 1 SCR. (Docket of the SCC 33290 and 33320) online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=33290> and <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=33320>

Nu-Pharm Inc. v Canada (Attorney General), [2010] 3 SCR 648

Nu-Pharm Inc. v Canada (Attorney General), [2010] 3 SCR. 648 (Docket of the SCC, 32830) online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=32830>

RJR-MacDonald Inc. v Canada, [1995] 3 SCR 199

RJR-MacDonald Inc. v Canada, [1995] 3 SCR 199 (Factum of the Intervener the Attorney General of Ontario court file no. 23460 and 23490)

RJR-MacDonald Inc. v Canada, [1995] 3 SCR 199 (Factum of the Interveners [Coalition]: The Canadian Cancer Society, The Canadian Council on Smoking and Health, The Canadian Medical Association, The Heart and Stroke Foundation of Canada, The Canadian Lung Association, court file no. 23460 and 23490)

RJR-MacDonald Inc. v Canada, [1995] 3 SCR 199 (Dockets of the SCC, 23460 and 23490) online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=23490> and <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=23460>

Rules of the Supreme Court, SOR/2002-156, available online at <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2002-156/page-8.html#h-69>

Sanofi-Aventis v Apotex Inc., [2015] 2 SCR 136

Sanofi-Aventis v Apotex Inc., [2015] 2 SCR. 136 (Docket of the SCC, 35886) online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=35886>

Sanofi-Aventis v Apotex Inc., [2015] 2 SCR. 136 (Factum of the Intervener Canadian Generic Pharmaceutical Association court file no. 35886)

Sanofi-Aventis v Apotex Inc., [2015] 2 SCR. 136 (Factum of the Intervener Canada's Research-Based Pharmaceutical Companies court file no. 35886)

Sanofi-Aventis v Apotex Inc., [2013] FCA 209

Teva Canada Ltd. v Pfizer Canada Inc., [2012] 3 SCR 625

Teva Canada Ltd. v Pfizer Canada Inc., [2012] 3 SCR. 625 (Docket of the SCC, 33951)
 online: <http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=33951>
 Tobacco Products Control Act, S.C. 1998, c. 20

Government Publications:

Government of Canada, Parliament, House of Commons, Standing Committee on Health
 (April 2004), *Opening the Medicine Cabinet: First Report on Health Aspects of
 Prescription Drugs*, 37th Parliament, 2nd Sess.

Government of Canada, Health Products and Food Branch. (1996), *The Distinction
 Between Advertising and Other Activities*. Retrieved from: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/advert-publicit/actv_promo_vs_info-eng.pdf

Government of Canada, Health Products and Food Branch. (2000). *Advertising
 Campaigns of Branded and Unbranded Messages*. Retrieved from:
http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/advert-pub_camp-eng.php

Health Canada (2014). *Drugs and Health Products: Notice of Compliance*. Online:
<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/index-eng.php>

Health Council of Canada (2006), *What are the Public Health Implications: Direct-to-
 Consumer Advertising of Prescription Drugs in Canada*. Retrieved from:
http://www.healthcouncilcanada.ca/tree/2.38-hcc_dtc-advertising_200601_e_v6.pdf

Parliamentary Research Branch of the Library of Parliament (2013) *Tobacco and Health:
 Government Responses: Federal Legislation and Regulatory Action* (Ottawa).
 Retrieved from: <http://publications.gc.ca/Collection-R/LoPBdP/modules/prb98-8-tobacco/legislation.htm>

Secondary Sources:

- Alarie, B., & Green, A. Interventions at the Supreme Court of Canada: Accuracy, Affiliation and Acceptance. (2010). *Osgoode Hall Law Journal*, 48(3), 381-410.
- Brugha, R., Varvovszky, Z. (2000) Stakeholder analysis: a review. *Journal of Health Policy and Planning*. 15(3). <http://doi.org/10.1093/heapol/15.3.239>
- Burgess, A. (2000). *Intervenors before the Supreme Court of Canada, 1997-1999: A content analysis* (MA Thesis, Windsor University Department of Political Science) [unpublished]. Retrieved from: <http://www.collectionscanada.gc.ca/obj/s4/f2/dsk2/ftp03/MQ62193.pdf>
- Dickens, B. (1977). A Canadian development: Non-party intervention. *Modern Law Review*, 40 (6), 666-676.
- Irving, S. & Creighton, V. (2013). Sealing Orders since Sierra Club: Effective Ways to Obtain Expansive Confidentiality Protections. *Commercial Litigation* 15(3).
- Joseph, C. (2006). All but One: Solo Dissents on the Modern Supreme Court of Canada. *Osgoode Hall Law Review*, 44(501). Retrieved from: <https://litigation-essentials.lexisnexis.com/webcd/p?action=DocumentDisplay&crawlid=1&srctype=smi&srcid=3B15&doctype=cite&docid=44+Osgoode+Hall+L.J.+501&key=299e>
- Kearney, J. & Merrill, T. (2000), The Influence of Amicus Curiae Briefs on the Supreme Court. *University of Pennsylvania Law Review*. 148 (3), 744-811.
- Macfarlane, E. (2000). Consensus and Unanimity at the Supreme Court of Canada. *Supreme Court Law Review*, 52(2). Retrieved from: <http://www.emmettmacfarlane.com/resources/consensus%20and%20unanimity%20at%20the%20Court.pdf>
- Mandel, M. (1994). *The Charter of Rights and the Legalization of Politics in Canada*. Toronto: Wall & Thomson, Inc.

- McCormick, P. (2008). Standing Apart: Separate Concurrence and the Modern Supreme Court of Canada, 1984–2006. *McGill Law Journal*, 53(137). Retrieved from: <http://lawjournal.mcgill.ca/documents/McCormick.pdf>.
- Meehan, E. (1994). Intervening in the Supreme Court of Canada. *Advocates' Quarterly*, 16(2). Retrieved from: <http://heinonline.org/HOL/LandingPage?handle=hein.journals/aqerty16&div=14&id=&page=>
- Mintzes, B., Barer, M. L., Kravitz, R. L., Kazanjian, A., Bassett, K., Lexchin, J., ... & Marion, S. A. (2002). Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: two site cross sectional survey. *BMJ*, 324(7332), 278-279.
- Mintzes, B., Barer, M., Lexchin, J., Basset, K. (2005). Introduction of direct-to-consumer advertising of prescription drugs in Canada: An opinion survey on regulatory policy. *Research in Social & Administrative Pharmacy*, 1(2), 310-330.
- Newman, J. (2016). *The Patented Medicines (Notice of Compliance) Regulations: An Examination of the Decision Making Patterns in these Cases at the Supreme Court of Canada* (LLM Thesis, The University of Western Ontario, 2016) [published] online: <http://ir.lib.uwo.ca/etd/3807/>
- Priest, A. (2007). CanWest set to challenge ban on DTCA. *Canadian Medical Association Journal*, 176(1), 19-20.
- Ring, L. (1980). The Pros of Oral Argument. *Forum* 16 (451). Retrieved from: <http://heinonline.org/HOL/LandingPage?handle=hein.journals/ttip16&div=52&id=&page=>
- Songer, D. & Siripurapu, J. (2009). The unanimous decisions of the supreme court of Canada as a test of the attitudinal model. *42 Canadian Journal of Political Science*, 42(65). Retrieved from: <http://bit.ly/YcW2oH>

Vakratsas, D., Kolasirici, C. (2014). How DTCA Influences Prescription Pharmaceutical Markets. In Ding, M., Eliashberg, J., Strenersch, J. (Eds.) *How DTCA Influences Prescription Pharmaceutical Markets in Innovation and Marketing in the Pharmaceutical Industry* (New York: Springer New York, 2014) (651-673).

Waddams, S. (2010) *Introduction to the Study of Law* (7th Ed.). Toronto: Carswell.

Wilkinson, M. (2013). *The Context of the Supreme Court's Copyright Cases*. In Geist, M. (Eds.), *The Copyright Pentology: How the Supreme Court of Canada Shook the Foundations of Canadian Copyright Law* (71-92). Ottawa: University of Ottawa Press.

Women and Health and Protection. (2007). *CanWest Charter Challenge on direct-to-consumer advertising of prescription drugs*. Retrieved from: <http://www.whp-apsf.ca/en/documents/charter.html>

4 Chapter Four: Synthesis

4.1 Introduction

This fourth and final chapter will briefly summarize the studies described in Chapter 2 and Chapter 3. These findings will be compared to the findings of prior literature on pharmaceutical DTCA stakeholders. Finally, a discussion of the implications for further research on Canadian pharmaceutical DTCA policy, both advocacy directed toward government decision-making and advocacy directed toward influencing outcomes in court litigation, will follow.

4.2 Summary of Findings in Chapter 2: Analysis of Canadian Pharmaceutical Advertising Stakeholders

Recall that in Chapter 2, to address a literature gap on Canadian pharmaceutical DTCA stakeholders, a number of questions were posed: who are the direct-to-consumer pharmaceutical advertising stakeholders in the Canadian policy environment? what are their positions, power, interests and influence? what is the potential for these stakeholders to shape future pharmaceutical DTCA policy?

The findings were:

- 1) There is a wide-range of stakeholders from varying backgrounds in the pharmaceutical DTCA policy environment;
- 2) Stakeholders are part of policy networks;
- 3) Stakeholders have varying positions, power, interests, and influence;
- 4) There is a concentration of powerful stakeholders interested in maintaining current pharmaceutical DTCA regulations.

Discussion of these key findings follows.

4.2.1 There is a Wide Range of Stakeholders from Varying Background in the Pharmaceutical DTCA Policy Environment.

A thematic analysis of the stakeholders in the Standing Committee on Health Report (Standing Committee on Health, 2004) revealed 127 different individuals and organizations potentially operating in the pharmaceutical DTCA space. Those stakeholders were thematically grouped into 15 different thematic categories:

1. Universities/Academic Units
2. Government
3. Research Groups and Think Tanks
4. Unions
5. Health Interested Organizations
6. Consumer Associations
7. Pharmacists
8. Healthcare Workers
9. Brand Name Pharmaceutical Industry
10. Generic Pharmaceutical Industry
11. 'Other' Health Industry
12. First Nations Groups
13. Regulatory Groups
14. Aging Citizenry
15. Individuals

The identification of 15 different thematic categories of stakeholders presents a broader and more nuanced view of the pharmaceutical DTCA policy environment and its stakeholders than had previously been noted. Previous analyses of pharmaceutical DTCA stakeholders have broadly defined the categories of potential stakeholders but did not collect the names of the organizations and individuals within each stakeholder category, which limits the usefulness of those studies for understanding pharmaceutical DTCA policy. Roberts (2011) identified three categories of stakeholders: industry, general practitioners, and the public. Matear and Dacin (2010) identified five categories of stakeholders: consumers, physicians, insurance companies and formularies, pharmacists,

and the government. These are fewer categories of stakeholders than identified in this study, and there is no list of stakeholders who might be placed in each category. It is important to understand what types of stakeholders may be operating in the pharmaceutical DTCA space, and who exactly they are, and this is a major contribution of this study.

4.2.2 Stakeholders are Part of Policy Networks

The connections between stakeholders identified in this study have also been mapped in this study. The Pharmaceutical Advertising Advisory Board (PAAB) was identified as an important network, and a number of the stakeholders in PAAB are themselves associations with constituent members. A number of the stakeholders who made submissions to the Romanow Commission (Commission on the Future of Health Care in Canada, 2002) are also associations with constituent members. By cross-referencing the membership in the associations found in PAAB and the Romanow Commission it became apparent that some stakeholders' associations share members. The individuals and organizations who are part of multiple stakeholder associations have multiple avenues through which they can advance their agendas. For example, Sanofi (a brand pharmaceutical manufacturer) is a member of four associations in PAAB, and can work through any of those associations to advance its pharmaceutical DTCA agenda.

4.2.3 Stakeholders Have Varying Positions, Power, Interests, and Influence

Stakeholders in the pharmaceutical DTCA policy environment are numerous, and vary in their positions, power, interests and influence. The stakeholder positions exist on a continuum ranging from “no regulation” to “completely prohibited” but can be grouped into three positions: less regulated, maintain current regulations, and more regulated. Roberts (2011) conducted a rudimentary analysis of her three stakeholder groups (industry, general practitioners, and the public) and hypothesized about whether they would support or reject four policy options, but this was different from identifying the pharmaceutical DTCA policy positions of individual stakeholders as has been done in this study. Matear and Dacin (2010), in their secondary literature analysis, examined the

prevailing sentiment of categories of stakeholders towards pharmaceutical DTCA, but does not provide the positions of individual stakeholders on pharmaceutical DTCA policy. This study identifies both the positions of individual stakeholders on pharmaceutical DTCA and the positions of individual stakeholders on pharmaceutical DTCA policy.

4.2.4 Power, Stakeholders, and Maintaining the Status Quo

Findings from the stakeholder analysis in Chapter 2 suggest that the highest concentration of power is held by the stakeholders who wish to maintain current pharmaceutical DTCA regulations. Stakeholders in general were split in their positions, between maintaining current pharmaceutical DTCA regulation or increasing regulation of DTCA, but the all the high-power stakeholders (e.g. Canadian Generic Pharmaceutical Association) and 40% of medium-power stakeholders (e.g. Canadian Association of Medical Publishers) favoured maintaining the status quo. Because of the power held by these stakeholders, it is likely that they are able to influence policymakers to maintain the current pharmaceutical DTCA regulations. The majority of low-power stakeholders (e.g. Canadian Women's Health Network) and 50% of medium-power stakeholders (e.g. Canadian Medical Association) favoured more regulated pharmaceutical DTCA, but they are less likely to be able to influence policymakers to increase the regulation of pharmaceutical DTCA.

4.3 Summary of Findings in Chapter 3: Analysis of Interveners in the Supreme Court of Canada in Pharmaceutical Litigation

There has not yet been any litigation in the Supreme Court of Canada involving pharmaceutical DTCA. There was litigation in the mid-1990s in the Supreme Court that involved DTCA in the tobacco industry (*RJR-MacDonald*) -- and the opposition to the then regulatory environment for that industry was founded upon health concerns. It involved a number of interveners -- all of them active in health policy-making. None of these interveners came from the pharmaceutical sector.

Just as the tobacco industry advertised in a regulated environment in the mid-1990s, so too does the pharmaceutical industry in Canada currently advertise in a regulated environment. As established in Chapter 3, this Canadian pharmaceutical DTCA environment has remained unchanged by statute or regulation throughout this century. As established in Chapter 2, there are those involved in the pharmaceutical DTCA policy environment who would like to see it changed.

The regulatory environment for DTCA advertising affecting the tobacco industry was unalterably changed by the Supreme Court through its decision in *RJR-MacDonald*. The Supreme Court is increasingly allowing interventions such as occurred in *RJR-MacDonald*. Given the interests of the healthcare lobby in outcomes related to pharmaceutical DTCA, one might expect those who “lobbied” the Court, through intervention in the *RJR-MacDonald* case, to have a similar interest in “lobbying” the Court through intervention in pharmaceutical cases. However, there have been no such cases brought to the Supreme Court and this hypothesis cannot be directly tested. On the other hand, as described in Chapter 3, there has been a good deal of litigation brought to the Court involving other issues in the pharmaceutical industry, particularly litigation involving patents related to that industry – an industry key to health outcomes in this country. One might expect the same interveners in this litigation as were involved in the *RJR-MacDonald* health related advertising litigation – and if the same interveners had been found, this would have been a good predictor, one would have thought, of those who would seek to intervene in future pharmaceutical DCTA litigation. These were the premises underlying the research reported in Chapter 3.

It will be recalled that the overall research question posed in Chapter 3 was: given the relatively recent rise of interveners in the Supreme Court process in Canada and the presence of interveners in the landmark advertising case *RJR-MacDonald v Canada*, are the stakeholders identified in Chapter 2 found as interveners in current pharmaceutical related Supreme Court litigation?

There were two subsidiary questions involved in the Chapter 3 discussion: if the stakeholders identified in Chapter 2 were found as interveners in current pharmaceutical

related Supreme Court litigation, which interveners and to what extent? And, for those interveners identified in Chapter 2 also found to be present as interveners in Supreme Court of Canada litigation, do their interests, positions, influence, and power parallel that identified for them in Chapter 2 in the broader policy environment?

There were a number of key findings from the stakeholder analysis of interveners in Chapter 3. The interveners in the DTCA case of *RJR-MacDonald* in the Supreme Court were:

- Canadian Cancer Society,
- Canadian Council on Smoking and Health
- Canadian Medical Association
- Heart and Stroke Foundation of Canada
- Canadian Lung Association
- Attorney General of Ontario

The *CanWest* litigation, the only instance yet where a litigant has attempted to challenge the pharmaceutical DTCA law in Canada, saw a similar situation, with respect to interveners, at its very earliest court level, to the situation of interveners at the Supreme Court level hearing about DTCA law in *RJR-MacDonald*: although the *CanWest* case (Women and Health Protection, 2007) was indefinitely adjourned prior to the submission of the intervener factums (and never returned to court), a coalition of public-interest stakeholders applied for intervener status. Those interveners were:

- Canadian Federation of Nurses Unions
- Canadian Health Coalition,
- Canadian Union of Public Employees
- Communications, Energy and Paperworkers Union of Canada
- Society for Diabetic Rights
- Medical Reform Group
- Drug Safety Canada.
- Women and Health Protection

The interveners in *RJR-MacDonald* and *CanWest* do share a number of features. Despite not being the exact same coalition of stakeholders (which is to be expected when considering the issues of the case), the interveners are all public interest stakeholders. Furthermore, in each case these interveners apply as a coalition, and not as individual stakeholders, for intervener status. Both *RJR-MacDonald* and *CanWest* are cases where a plaintiff challenges restrictive advertising legislation involving health. Unfortunately, it is not possible to compare the factums of the interveners in *RJR-MacDonald* and *CanWest* because no factum(s) were submitted in *CanWest*.

On the other hand, in the Supreme Court cases involving pharmaceutical patent litigation that were collected and analyzed, four stakeholders have successfully applied for intervener status in these cases. Of the 12 successful applications for intervener status in these pharmaceutical cases, five were by the Canadian Generic Pharmaceutical Association four were by Canada's Research Based Pharmaceutical Companies, two were by BIOTECCanada, and just one was by Pfizer Canada.

- The Canadian Generic Pharmaceutical Association (in 5 cases),
- Canada's Research Based Pharmaceutical Companies (in 4 cases),
- BIOTECCanada (in 2 cases),
- Pfizer Canada (in 1 case)

These successful applicants for intervener status can be divided into two distinct groups: generic pharmaceutical industry interveners (The Canadian Generic Pharmaceutical Association) and brand pharmaceutical industry interveners (Canada's Research Based Pharmaceutical Companies, BIOTECCanada, Pfizer Canada). A pattern of intervention was discussed: in most cases, a brand intervener and a generic intervener will appear. Only in cases where the issues before the court did not directly concern the validity of pharmaceutical patents was there only one intervener.

The Canadian Generic Pharmaceutical Association is a generic pharmaceutical industry stakeholder: a high-power stakeholder whose position on pharmaceutical DTCA is to act to maintain the current regulations, who benefits from the current regulations, and is a high influence stakeholder.

Canada's Research Based Pharmaceutical Companies is identified as a brand name pharmaceutical industry stakeholder: it has had its name changed to Innovative Medicines Canada. Innovative Medicines Canada is a high power stakeholder whose position on pharmaceutical DTCA is to maintain the current regulations. It benefits from the current regulations and is a high influence stakeholder. BIOTECanada is also a brand name pharmaceutical industry stakeholder, though a medium-power stakeholder (compared to Innovative Medicines Canada's high power). BIOTECanada's position on pharmaceutical DTCA is also to maintain the current regulations and it also benefits from the current pharmaceutical DTCA regulations. Like Innovative Medicines Canada, it is a high-influence stakeholder. Pfizer is a pharmaceutical company who is represented by three associations in PAAB (BIOTECanada, Innovative Medicines Canada, and Consumer Health Products Canada), which makes it the organization with the second most avenues through which to achieve pharmaceutical DTCA policy change through PAAB (surpassed only by Sanofi, which is represented four times in PAAB because Innovative Medicines Canada represents two Sanofi subsidiaries).

These two brand association stakeholders, BIOTECanada and Innovative Medicines Canada, and the generic association, Canadian Generic Pharmaceutical Association, all support maintaining the current regulations on pharmaceutical DTCA, are all high-power, and are all associations of other organizations. The finding that they are all also interveners on pharmaceutical patent litigation at the Supreme Court both reaffirms this study's assertion that these stakeholders are in fact high power, but also suggests that to successfully, and individually, apply for intervener status at the Supreme Court, a stakeholder may need to be high-power. These high-power stakeholders are best positioned to intervene on a pharmaceutical advertising case which reaches the Supreme Court of Canada. These stakeholders' interest in court intervention may also be an indication of the policy expertise and resources at their disposal, and the lack of applications for intervention by other stakeholders could be explained by a possible lack of policy expertise and resources.

All the interveners identified in these pharmaceutical patent cases in the Supreme Court, and in the *CanWest* litigation, are among those identified in the stakeholder

analysis of pharmaceutical DTCA stakeholders in Chapter 2. *The RJR-MacDonald* interveners are not found in Chapter 2. It is likely the case that they are not present in the pharmaceutical DTCA stakeholder holder analysis because *RJR-MacDonald* was primarily a case about tobacco advertising, and so the stakeholders interested in the implications of tobacco advertising policy are different than those interested in pharmaceutical DTCA policy.

In *CanWest*, the coalition of interveners was different from that in *RJR-MacDonald* and yet dramatically similar. The Canadian Health Coalition is a health interested organization, medium-power, supports more regulated pharmaceutical DTCA, high influence, and has neutral interests (neither gaining nor losing) from the current pharmaceutical DTCA regulations. The other interveners in *CanWest* are not associations in PAAB and did not submit documents to the Romanow Commission (2002). However, most were found in the Standing Committee Report (Standing Committee on Health, 2004), and categorized: The Canadian Federation of Nurses Unions and Canadian Union of Public Employees are categorized as unions, and the Communications, Energy and Paperworkers Union of Canada can also be classified as union (although they did not participate in the Standing Committee, they fit the profile of a union). The Medical Reform Group, Drug Safety Canada, and the Society for Diabetic Rights, and Women and Health Protection are categorized in this study as Health Interested Organizations.

The pharmaceutical DTCA positions and interests of these organizations is not recorded, but they are a cross-section of health-interested organizations and unions. Like those who intervened in *RJR-MacDonald*, they applied as a coalition. Unlike the pharmaceutical patent interveners (discussed further below), with the exception of the Canadian Health Coalition, the interveners in *CanWest* are not associations of other organizations. There are a number of reasons why they may have chosen to apply as a coalition: 1) to improve the chances that the application would be accepted; 2) to increase the potential impact of the intervention; and 3) to pool financial and legal resources.

In none of the pharmaceutical cases at the Supreme Court did a coalition of health interested stakeholders – or even individual health interested stakeholders – apply to

intervene such as had collectively applied and intervened in *RJR-MacDonald* at the Supreme Court, or applied in the more recent lower court action involving *CanWest* (both DCTA cases). The only applicant which qualifies as a public-interest intervener in this study of pharmaceutical litigation before the Supreme Court was the Information Commissioner of Canada, which was ultimately unsuccessful in its application for intervener status.

The coalition of health-interested interveners in *RJR-MacDonald* did not follow the same pattern of intervention in their collective factum as was the pattern for the interveners in the pharmaceutical cases at the Supreme Court. The structure of the *RJR-MacDonald* health-interested interveners' factum begins with an introduction of the coalition of interveners, followed by the perspective of the interveners on the *Tobacco Products Control Act* (Factum of the Intervener Coalition, *RJR-MacDonald Inc. v Canada*, [1995] 3 SCR 199), an extended section on the medical facts supporting the legislative objective of that Act, a section describing the aims of tobacco advertising, and the level of support for a tobacco advertising ban. The interveners are explicit in their goal to ban tobacco advertising as a matter of public health policy, and this is the most prominent theme throughout the factum.

The content of the intervener factums in the pharmaceutical patent cases typically followed a different pattern: the majority of the factum was always dedicated to the specific issues of the case and a small section of the factum discussed public-policy issues. Dependent on whether a brand or generic pharmaceutical intervener submitted the intervener factum in hand, the arguments made by the intervener reflected those made by the brand or generic litigant in the case. The *RJR-MacDonald* interveners were solely concerned about the public health policy implications of the issues before the Court.

4.4 Conclusions of the Study

Chapter 2 identified a broad range of stakeholders interested in Canadian pharmaceutical DTCA policy, and Chapter 3 identified a small set from within that range who have applied and been admitted by the Supreme Court of Canada as interveners in recent pharmaceutical patent litigation in the Supreme Court. All the interveners admitted

to the lower court litigation involving pharmaceutical DCTA, *CanWest*, are also identified in the Chapter 2 stakeholder analysis of pharmaceutical DTCA stakeholders. To be an intervener in a court action, one must apply. That all these interveners admitted to the actions examined also appear in the Chapter 2 pharmaceutical DCTA stakeholder analysis confirms that some pharmaceutical DCTA stakeholders are taking the policy step of deciding to apply to intervene in judicial proceedings as well as being active in lobbying activities before Parliament and Cabinet. This adds an important new element to our understanding of stakeholders in pharmaceutical DTCA policy: at least those also directly interested in pharmaceutical policy, as well as pharmaceutical DTCA policy, have decided Supreme Court intervention activity is an important part of lobbying for change. This contributes an important new dimension to our understanding of pharmaceutical DTCA policy going forward.

It is also important to note that the type of pharmaceutical DCTA stakeholder active in previous Supreme Court DTCA litigation, involving not pharmaceutical DCTA but tobacco DCTA, has also been involved in the only known pharmaceutical DCTA litigation in Canada, though that litigation has never continued or been completed even at the trial level. That type of pharmaceutical DCTA stakeholder is not the stakeholder that has decided to become involved in pharmaceutical Supreme Court hearings not related to DCTA.

4.4.1 Pharmaceutical DTCA Stakeholders and Potential DTCA Policy and Litigation

This study is, fundamentally, a “snapshot” in time. However, long after its conclusion the stakeholders identified in pharmaceutical DTCA policy and pharmaceutical patent litigation will continue operating. Some liberty has been taken to anticipate how stakeholders may participate in a renewed discussion about pharmaceutical DTCA policy and potential legislative or regulatory change, or if pharmaceutical DTCA litigation, similar to *CanWest* or, in the tobacco context, *RJR-MacDonald*, ever reaches the Supreme Court of Canada.

The generic and brand industry pharmaceutical patent case interveners have opposing arguments on the issues of those cases. However, this research has demonstrated that both these types of stakeholders have a common policy position on pharmaceutical DTCA: to maintain the current pharmaceutical DTCA regulations. Considering the history of intervention at the Supreme Court by both these pharmaceutical stakeholder groups, they are likely to intervene on pharmaceutical DTCA litigation if it reaches the Supreme Court of Canada, and would both argue to maintain the current regulations. However, given their past patterns of court intervention, they would likely only intervene if such cases reach the Supreme Court of Canada.

There are a number of medium power stakeholders who support more regulated pharmaceutical DTCA (e.g. Canadian Pharmacists Association, British Columbia Nurses Union, Canadian Health Coalition), which may be likely candidates to intervene in a coalition of interveners. Other likely candidates to intervene are any stakeholders categorized as health interested organizations, unions, or healthcare workers. These stakeholders are likely to argue for more regulated pharmaceutical DTCA.

The likelihood of a pharmaceutical DTCA case reaching the Supreme Court of Canada is reduced, it would seem, because so few stakeholders identified in this study are interested in less pharmaceutical DTCA regulation. The situation is the same in terms of anticipating legislative or regulatory change to current pharmaceutical DTCA legislation or regulation: there is a large number of stakeholders interested in maintaining (with the largest number of strong stakeholders in this camp) or increasing regulation, and few whose policy position it is to reduce the regulations. This helps explain why there has been so little legislation, regulation or litigation concerning pharmaceutical DTCA in the past two decades.

4.5 Limitations

As is the case in most research, there were some limitations to these studies. In the first study (Chapter 2), only publicly available documents were collected and analyzed. Pharmaceutical DTCA policy has not been a major focus in recent years, and because of this, some of the policy documents available are dated. Further, the

assessment of position, power, interests, and influence was limited to information available in documents and websites, and, on occasion, some information was not available. In the second study (Chapter 3), it was not possible include a study of all the factums filed by the parties to each case being examined – although the study which was completed here, of all the intervener factums, was possible. The subject matter of patent litigation is, by its nature, very valuable information and secrecy is often a key element. For this reason, certain of the cases had “sealing orders” which prevented the collection or study of litigants’ factums. One other unavoidable gap in available evidence caused the study to take form that it has: the Judges of the Supreme Court who hear the applications for intervention in cases to be heard in their court do not ever reveal the reasons for their decisions to permit or deny an applicant. For this reason, it is only possible to make observations about whether or not an intervener receives leave, not why.

4.5.1 References

Commission on the future of Health Care in Canada., & Romanow, R. J. (2002). *Building on values: The future of health care in Canada*. [Saskatoon, Sask.]: Commission on the Future of Health Care in Canada.

Innovative Medicines Canada. (2017). Our History. Retrieved from:
<http://innovativemedicines.ca/about/our-history/>

Matear, M., & Dacin, P. A. (2010). Marketing and societal welfare: A multiple stakeholder approach. *Journal of business research*, 63(11), 1173-1178.

RJR-MacDonald Inc. v Canada, [1995] 3 SCR 199

RJR-MacDonald Inc. v Canada, [1995] 3 SCR 199 (Factum of the Interveners [Coalition]: The Canadian Cancer Society, The Canadian Council on Smoking and Health, The Canadian Medical Association, The Heart and Stroke Foundation of Canada, The Canadian Lung Association, court file no. 23460 and 23490)

Roberts, C. (2011). *Addressing the health system impacts of domestic and international direct- to-consumer advertising in Canada*. (Master's Major Research Project, Simon Fraser University).

Standing Committee on Health. (2004). *Opening the medicine cabinet: First report on health aspects of prescription drugs*. Retrieved from <http://www.whp-apsf.ca/pdf/OpeningtheMedicinecabinet.pdf>

Tobacco Products Control Act, S.C. 1998, c. 20

Appendices

Appendix A: Examples and Excerpts of Coded Text

Code	Coding Category	Example Organization	Example Quoted Text	Source
Position	More Regulated DTCA	Canadian Health Coalition	“That a prohibition on direct to consumer advertisements of prescription drugs be strictly enforced, given the lack of evidence of health benefits and the serious potential for harm. Federal legislation should ban advertising, which includes both the product’s name and indications for use, and ban cross-border direct to consumer advertising” (p.28)	Standing Together For Medicare: A Call to Care: A Submission to the Romanow Commission f the Future of Health Care in Canada – Canadian Health Coalition – November 2001
	Maintain Current Regulations	New Democratic Party	“We must also maintain our ban on direct-to-consumer drug advertising (DTCA)—a practice prohibited in almost all countries outside the United States and New Zealand.” (p.14)	New Democratic Party Submission to the Romanow Commission
	Less Regulated DTCA	Association of Medical Advertising Agencies (AMAA)	“I manage an Agency that creates advertising and content spanning various mediums, including the sales representative, print, digital, online, radio, and TV. My objective, to cross media disciplines with staff who can tackle everything from, tablet details to print to radio to TV, all with the smart thinking and rigor Bio-Pharmaceutical Advertising requires by law” (para. 1).	https://www.linkedin.com/in/terrycully/
Power	High	Canadian Generic Pharmaceutical Association	11 high-income pharmaceutical companies members, these members forming the executive	http://canadiangenetics.ca/about-us/committees/

			committee of the CGPA (coalition of generic industry companies)	http://canadiangenetics.ca/about-us/our-member-companies/
	Medium	Canadian Medical Association	<p>“Today the CMA has more than 85,000 members, and advocates on behalf of both members and their patients — on Parliament Hill, during federal election campaigns and in the media. The CMA also takes the lead on public health issues.” (Para. 3)</p> <p>Assets > 35,000,000. Revenues > 46,000,000</p>	<p>https://www.cma.ca/En/Pages/history-mission-vision.aspx</p> <p>https://www.cma.ca/Assets/assets-library/document/en/about-us/2013-CMA-Financial-Statements.pdf</p>
	Low	Canadian Women’s Health Network	<p>“In March 2013 we, along with the Centres of Excellence for Women’s Health and the Réseau québécois d’action pour la santé des femmes, lost our main source of funding from Health Canada. This major change has been both a loss and an opportunity to develop new strengths and direction while continuing to focus on what Canadian women, researchers and policy makers expect from us— objective, trustworthy and topical information about the health issues that matter most to Canadian women.” (p.3)</p>	http://www.cwhn.ca/sites/default/files/PDF/Annual_Report_2012-13.pdf
Interests	Benefit	Innovative Medicines Canada	<p>“We work tirelessly to further our members’ interests as outlined in our Strategic Objectives.” (Para. 3)</p>	http://innovativemedicines.ca/about/our-mission-and-vision/

	Neutral	Canadian Women's Health Network	<p>The Canadian Women's Health Network (CWHN):</p> <p>“Establishes a visible national presence for women's health in Canada. Provides user-friendly and reliable health information, resources and research. Works to change inequitable health policies and practices by contributing women's voices and expertise. Acts as a knowledge broker for researchers, clinicians, decision makers, media and the public. Encourages community-based participatory research. Monitors emerging issues and trends affecting women's health. Acts as a forum for debate on women's health research and policy issues.” (Para. 3).</p>	http://www.cwhn.ca/en/aboutus/mission
	Loss		“May strain the relationship between patients and providers, for example if a patient's request for an advertised prescription drug is refused” (Para. 3).	http://policybase.cma.ca/dbtw-wpd/PolicyPDF/PD03-01.pdf
Influence (able to assert position on a national level)	High	New Democratic Party	“Major Canadian political party with official opposition status and 103 MPs” (Para. 6). (Post-2015 election the NDP has 44 MPs in the house of commons).	http://www.ndp.ca/about-ndp
	Medium	Canadian Medical Association	Several submissions to government for policy changes.	https://www.cma.ca/En/Pages/submis

				sions-to-government.aspx
	Low	Ottawa Health Coalition	“The Ottawa Health Coalition brings together people across the Ottawa region to protect and improve public healthcare for all. We work to stop cutbacks and privatization, and promote democratic debate about healthcare policy that affects all of us” (Para. 1)	https://ottawahealthcoalition.ca/about/

Appendix B: Full List of PAAB Constituent Members

PAAB Association	Constituent Members	Number of Constituent Members
BIOTECanada	<p>AbbVie Canada, Accel-Rx Health Sciences, Acuitas Therapeutics, AdeTherapeutics Inc., Advanced Medical Research Institute of Canada, Aegerion Pharmaceuticals, Agricultural Institute of Canada, Agrisoma BioSciences Inc., Ag-West Bio Inc., Akshaya BIO Inc., Alethia Biotherapeutics Alexion Pharma Canada, AMGEN Canada Inc., AmorChem, Angiochem Inc., Antibe Therapeutics, Appili Therapeutics, Aqua Bounty Canada, Inc., Aquinox Pharmaceuticals Inc., AstraZeneca Canada Inc., Augurex Life Sciences Corp., Aurinia Pharmaceuticals Inc., AusBiotech Ltd., Avir Pharma Inc., Bayshore Specialty Rx Ltd., BELLUS Health Inc., BioAlberta, BioAmber Canada Inc., Biodextris , BioEnterprise Corporation, Biogen Canada Inc., Bioindustrial Innovation Canada, Bio-K Plus International Inc., BioMarin Pharmaceutical Inc., BioNB, BioNova, Biopham Management Inc., BIOQuébec, Biotechnology Industry Organization, BioVectra Inc., Blake, Cassels & Graydon, LLP, Blanchard Law Office, Bloom Burton & Co., BMS Canada Risk Services, Borden Ladner Gervais LLP, Bristol-Myers Squibb Canada Inc., Canada's Venture Capital and Private Equity Association, Canadian Seed Trade Association, Caprion Biosciences Inc., Cardiome Pharma Corp., CDRD Ventures Inc., Ceapro Inc., Celator Pharmaceuticals Corp., Celgene Inc., Cелverum Inc., Centre for Probe Development & Commercialization, Centre for the Commercialization of Antibodies and Biologics, Chelation Partners, CO2 Solutions Inc., Contextual Genomics Inc., CQDM, Critical Outcome Technologies Inc., CTI Life Sciences Fund, Cyclenium Pharma Inc., Cynapsus Therapeutics Inc., Dalton Pharma Services, Del Mar Pharmaceuticals, Drug Development and Innovation Centre, Eisai Limited, Eli Lilly Canada Inc., Encycle Therapeutics, Gene Inc. Ernst & Young LLP, ESSA Pharmaceuticals Inc., Farris, Vaughan, Wills & Murphy LLP, Fasken Martineau DuMoulin LLP Folia Biotech Inc., Formation Biologics Inc., Genentech, GenePOC Inc., Genome Canada, Genzyme Canada, Global Public AffairsGMD Pharma Solutions, Gowling Lafleur Henderson LLP, Grifols Highland Therapeutics, Hoffmann-La Roche, iCo Therapeutics Inc., Immunovaccine Inc., ImStar Therapeutics Inc., Innovation PEI, Innovative Targeting Solutions Inc., InnovoXL Inc. Institute for Research in Immunology and Cancer-Commercialization of Research, InSymbiosis Management Inc., Intercept Pharma Canada, International Centre for Infectious Diseases, Intrinsic Health Sciences Inc., Ipsen Biopharmaceuticals Canada Inc., iTP, Biomedica Corp., Janssen Inc., Johnson & Johnson – JLABS, Kairos Therapeutics, KalGene Pharma Inc., Kane Biotech Inc., KMT Hepatech Inc., Korea</p>	209

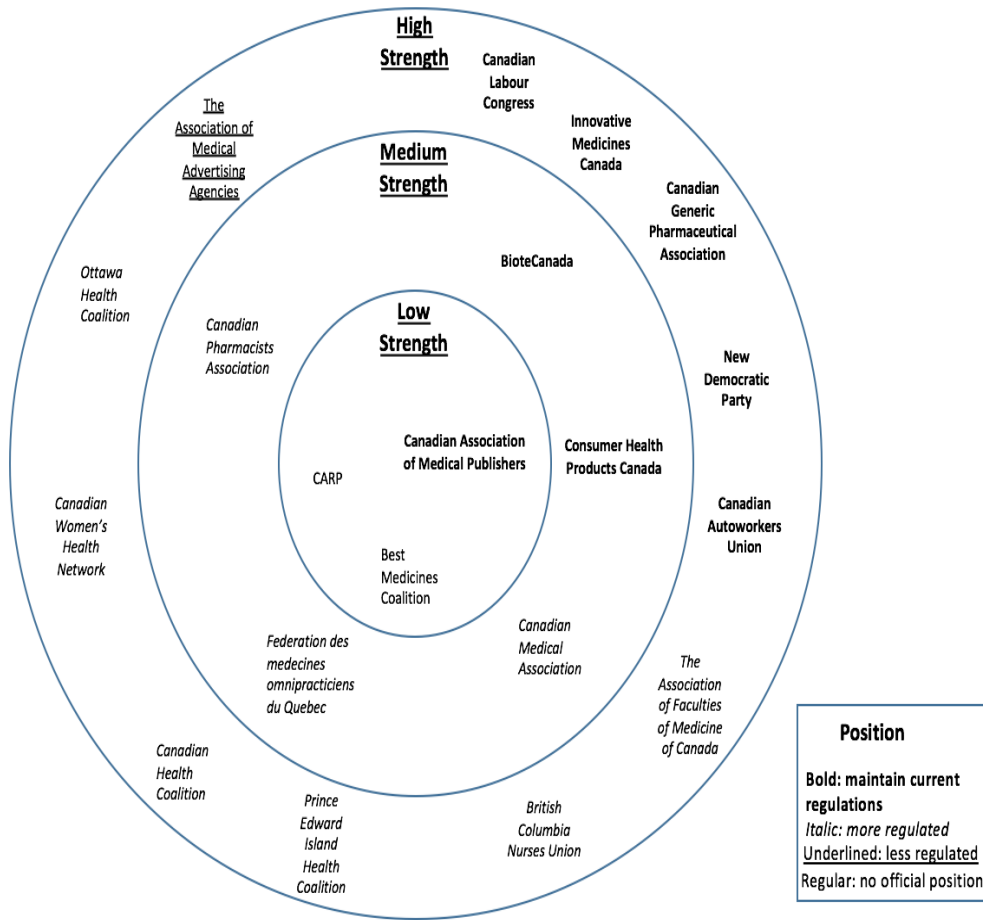
	<p>Biotechnology Industry Organization, KPMG, Laurent Pharmaceuticals Inc., Life Sciences, Association of Manitoba, LifeSciences Ontario (LSO), Life Sciences British Columbia, Linnaeus Plant Sciences Inc., MaRS Discovery District, Marsala Biotech Inc., McKesson Canada, MEDEC MedGenesis Therapeutix Inc., Medicago Inc., Medicure Inc., Mēdunik Canada, Merck Canada Inc., Milestone Pharmaceuticals, MSI Methylation Sciences Inc., National Research Council Canada, Neomed Institute, NeoVentures Biotechnology Inc., Neurodyn Life Sciences Inc., New Zealand Biotech, Newfoundland and Labrador Association of Technology Industries, NoNO Inc., Northern Biologics Inc., Norton Rose Fulbright LLP, Novartis, Pharmaceuticals Canada Inc., Novicol International Holdings, Novo Nordisk Canada Inc., Okanagan Specialty Fruits Inc., OncoGenex Technologies Inc., Oncolytics Biotech Inc., Ontario Bioscience Innovation Organization, Pangaea Group, Pan-Provincial Vaccine Enterprise, Patient Access Solutions Inc., PBR Laboratories, Pfizer Canada Inc., PlantForm Corporation, POS Bio-Sciences, Precision NanoSystems, Inc., Prevtex Microbia Inc., PricewaterhouseCoopers LLP, Prince Edward Island BioAlliance, Pro Bono Bio Inc., ProMIS Neurosciences, ProNAi Therapeutics Canada, PROOF Centre of Excellence, Protagenic Therapeutics Canada Inc., Proteocyte Diagnostics Inc., Qu Biologics, Raptor Pharmaceuticals, Renaissance Bioscience Corp., RepliCel Life Sciences, Replikins Ltd., Research Canada, Resverlogix, Royal Bank of Canada, Sanofi Pasteur Limited, SemiosBio Technologies Inc., Sequence Bio, Sernova Corp., Shire Pharma Canada ULC, Shoppers Drug Mart Specialty Health Network, SignalChem Lifesciences Corporation, SinoVeda Canada Inc., Sirona Biochem Corp., Smart & Biggar Fetherstonhaugh LLP, Sobi Inc., SolAeroMed Inc., Soricimed Biopharma Inc., Sound Insurance Services Inc., SPharm Inc., Taiga BioActives Inc., Takeda Canada Inc., TEC Edmonton, Teralys Capital Fund of Funds L.P., Teva Canada Innovation, Therapure Biopharma Inc., Thrasos Inc., Transition Therapeutics Inc., Trillium Therapeutics Inc., UCB Canada Inc., University of Guelph, University of Manitoba, University of Waterloo, Vaccine and Infectious Disease, Organization-International Vaccine Centre, Valeant Canada LP, Valneva Canada Inc., VBI Vaccines, Versant Ventures Canada Ltd., Vertex Pharmaceuticals Inc., Viable Healthworks Corp., viDA Therapeutics Inc., Viventia Biotechnologies Inc. VWR International, Wex Pharmaceuticals Inc., Wilson Sonsini, Goodrich & Rosati, Xagenic Canada Inc., Xenon Pharmaceuticals Inc., Zenith Epigenetics Corp., Zymeworks Inc.</p>	
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PAAB Association	Constituent Members of Association	Number of Constituent Members
The Association of Faculties of Medicine of Canada	Western University/Schulich School of Medicine and Dentistry, University of Toronto, University of Saskatchewan, University of Ottawa, University of Manitoba, University of Calgary/Cumming School of Medicine, University of British Columbia, University of Alberta, Université Laval, Université de Sherbrooke, Université de Montréal, Queens University, Northern Ontario School of Medicine, McMaster University, McGill University, Dalhousie University	16
The Association of Medical Advertising Agencies	Terry Cully	No constituent organization members
Canadian Association of Medical Publishers	Canadian Medical Association (CMA), Canadian Urological Association (CUAJ), The College of Family Physicians of Canada, Healthcare Media Partners Inc., JLS Media, Keith Communications Inc., Parkhurst Publishing, Pulsus Group, Rogers Healthcare Group A Division of Rogers Media, STA Healthcare Communications	10
Canadian Generic Pharmaceutical Association	Actavis Pharma Company, Apotex Inc., Fresenius Kabi Canada Ltd, Mylan, Pharmascience Inc., Sandoz Canada Inc., Taro Pharmaceuticals, Teva Canada Limited, ACIC	9
Canadian Medical Association	Canadian Physicians	Information Not Available
Canadian Pharmacists Association	Canadian Pharmacists	Information not available
Best Medicines Coalition	Arthritis Consumer Experts, Asthma Society of Canada: Better PharmaCare Coalition (BC), Canadian Arthritis Patient Alliance, Canadian Breast Cancer Network, Canadian Epilepsy Alliance, Canadian Hemophilia Society, Canadian Pain Society, Canadian Skin Patient Alliance, Canadian Society of Intestinal Research, Canadian Treatment Action Council, Cancer Advocacy, Coalition of Canada, Canadian Association of Retired Persons, Creating Synergy Health Coalition (AB), Gastrointestinal Society: Hepatitis C Council of British Columbia, Kidney Cancer Canada: , Lymphoma Foundation Canada, Ovarian Cancer Canada: Monique Beaupré-Lazu, Tourette Syndrome Foundation	20

Consumer Health Products Canada	Bayer Healthcare, Consumer Care, Blistex Corporation, Boehringer Ingelheim Canada Ltd., Church & Dwight Canada Combe Incorporated, Delivera, Dormer Laboratories Inc, GlaxoSmithKline Consumer Healthcare, Johnson & Johnson Inc. Lallemand Health Solutions, Pendopharma, a Division of Pharmascience Inc., Pfizer Consumer Healthcare, Procter & Gamble Inc., Purdue Pharma, Reckitti Benckiser	15
Innovative Medicines Canada	Amgen, Astellas , AstraZeneca, Bayer, Boehringer Ingelheim Bristol-Meyers Squibb Canada, Brunel , Ceapro, Charles River Laboratories, Conundrum Solutions, Council for continuing pharmaceutical education, Eli Lilly Canada, Eisai Limited, EMD Serono Canada, EC Endochemicals, Ferring Pharmaceuticals Genome Canada, Gilead, GlaxoSmithKline, GlyPharma, Roche Innoviva, JSS Research, Janssen, KalGene, Leo Pharma, MedicaGo, Merck, Novartis, Novo Nordisk, Nucro Technics Otsuka Canada pharmaceutical inc., Paladin, Pediapharm inc. Pfizer, Proteocyte diagnostics, Promometric, Purdue, Ropack, Sanofi, Sanofi Pasteur, Servier, Shire, Sunovion, Takeda, Therapure, Thera technologies, Vantage biotrials	48
Canadian Association of Retired Persons	300,000 individual members across Canada	No constituent organization members
Consumer Council of Canada	Canadian Fuels Association, Canadian Life and Health Insurance Association, Credit Union Central of Canada, Electrical Safety Authority, Enbridge Gas Distribution, Interac, Investment Funds Institute of Canada, Ontario Motor Vehicle Industry Council Procter and Gamble Canada, Real Estate Council of Ontario, RESCON, Retail Council of Canada, Technical Standards and Safety Authority, Visa Canada	14

Federation des medecines omipraticiens du Quebec	Association of General Practitioners of the Lower St. Lawrence, Association of General Practitioners in the Mauricie, Association of General Practitioners Bois-Francis, Association of General Practitioners of Montreal, Association of Quebec CLSC doctors, Association of Northwest General Practitioners of Quebec, Association of General Practitioners of the South Shore, Association West of General Practitioners of Quebec, Association of General Practitioners North Shore, Association of General Practitioners of Quebec, Association Estrie of General Practitioners, Association Richelieu-Saint-Laurent general practitioners, Physicians working in psychiatric facility, Association of General Practitioners in the Saguenay / Lac St-Jean, Association Gaspésie of General Practitioners, Association of Southwest General Practitioners, Association of General Practitioners Laurentides-Lanaudière, Association of General Practitioners of Yamaska, Association of General Practitioners Laval	19
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Appendix C: Alternative Position & Strengths of Position Diagram



Source: Stakeholder DTCA policy documents and websites.

**Appendix D: Stakeholder's DTCA Positions & Strengths of Those Positions From
PAAB & Romanow Submissions**

Strength of Position	Less Regulated DTCA	Maintain Current Regulations	More Regulated DTCA	No Official Position
High	The Association of Medical Advertising Agencies	Canadian Labour Congress; Canadian Autoworkers Union; New Democratic Party; Canadian Generic Pharmaceutical Association; Innovative Medicines Canada	Canadian Health Coalition; Ottawa Health Coalition; Canadian Women's Health Network; Prince Edward Island Health Coalition; British Columbia Nurses Union; The Association of Faculties of Medicine of Canada	None
Medium	None	BIOTECanada	Canadian Medical Association; Canadian Pharmacists Association; Federation des medecines omipraticiens du Quebec	None
Low	None	Canadian Association of Medical Publishers; Consumer Healthcare Providers	None	Best Medicines Coalition; Canadian Association of Retired Persons; Consumer Council of Canada

Source: stakeholder policy documents and websites

Notes: *High* = a strong statement on DTCA policy and policymaking actions that further their position. *Medium* = strength suggests either a strong statement on DTCA policy or policymaking involvement to advance their position. *Low* = A weak policy statement with respect to their position or that the position had to be inferred, and that there was few or no policymaking involvement to advance their position.

Appendix E: Cases, Intervener Briefs, Docket References

Case Reference	Intervener Brief Reference	Docket Numbers
RJR-MacDonald Inc. v Canada, [1995] 3 SCR 199	<p>Reference re RJR-MacDonald Inc. v Canada, [1995] 3 SCR 199 (Factum of the Intervener the Attorney General of Ontario court file no. 23460 and 23490)</p> <p>Reference re RJR-MacDonald Inc. v Canada, [1995] 3 SCR 199 (Factum of the Interveners: The Canadian Cancer Society, The Canadian Council on Smoking and Health, The Canadian Medical Association, The Heart and Stroke Foundation of Canada, The Canadian Lung Association, court file no. 23460 and 23490)</p>	Reference re RJR-MacDonald Inc. v Canada, [1995] 3 SCR 199 (Dockets of the SCC, 23460 and 23490) online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=23490 and http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=23460
Apotex Inc. v Wellcome Foundation Ltd., 2002 SCC 77, [2002] 4 S.C.R. 153	NA	Reference re Apotex Inc. v Wellcome Foundation Ltd., [2002] 4 S.C.R. 153 (Docket of the SCC, 28287) online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=28287
Janssen-Ortho Inc. v Novopharm Ltd., 2005 SCC 33, [2005] 1 S.C.R. 776	NA	Reference re Janssen-Ortho Inc. v Novopharm Ltd., 2005 SCC 33, [2005] 1 S.C.R. 776 (Docket of the SCC, 30900) online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=30900
Bristol-Myers Squibb Co. v Canada (Attorney General), 2005 SCC 26, [2005] 1 S.C.R. 533	Reference re Bristol-Myers Squibb Co. v Canada (Attorney General), [2005] 1 SCR 533 (Factum of the Intervener Pfizer Canada, court file no. 31881)	Bristol-Myers Squibb Co. v Canada (Attorney General), [2005] 1 SCR 533 (Docket of the SCC, Court file no. 31881). Online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=29823

Case Reference	Intervener Brief Reference	Docket Numbers
	Reference re Bristol-Myers Squibb Co. v Canada (Attorney General), [2005] 1 SCR 533 (Brief of the Intervener Canadian Generic Pharmaceutical Association, court file no. 31881)	
AstraZeneca Canada Inc. v Canada (Minister of Health), 2006 SCC 49, [2006] 2 S.C.R. 560	Reference re AstraZeneca Canada Inc. v Canada (Minister of Health), [2006] 2 S.C.R. 560 (Factum of the Intervener Canadian Generic Pharmaceutical Association, court file no. 30985)	Reference re AstraZeneca Canada Inc. v Canada (Minister of Health), [2006] 2 S.C.R. 560 (Docket of the SCC, court file no. 30985). Online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=30985
	Reference re AstraZeneca Canada Inc. v Canada (Minister of Health), [2006] 2 S.C.R. 560 (Factum of the Intervener Canada's Research-Based Pharmaceutical Companies, court file no. 30985)	
Apotex Inc. v Sanofi-Synthelabo Canada Inc., 2008 SCC 61, [2008] 3 S.C.R. 265	Reference re Apotex Inc. v Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265 (Factum of the Intervener BIOTECanada, court file no. 31881)	Reference re Apotex Inc. v Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265 (Docket of the SCC, 31881) online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=31881
	Reference re Apotex Inc. v Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265 (Factum of the Intervener Canadian Generic Pharmaceutical Association, court file no. 31881)	
	Reference re Apotex Inc. v Sanofi-Synthelabo Canada Inc., [2008] 3 S.C.R. 265 (Factum of the Intervener Canada's Research-Based Pharmaceutical Companies, court file no. 31881)	
Nu-Pharm Inc. v Canada (Attorney General), 2010 SCC 65, [2010] 3 S.C.R. 648	NA	Reference re Nu-Pharm Inc. v Canada (Attorney General), 2010 [2010] 3 S.C.R. 648 (Docket of the SCC, 32830) online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=32830

Case Reference	Intervener Brief Reference	Docket Numbers
Celgene Corp. v Canada (Attorney General), 2011 SCC 1, [2011] 1 S.C.R. 3	NA	Reference re Celgene Corp. v Canada (Attorney General), [2011] 1 S.C.R. 3 (Docket of the SCC, 33579) online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=33579
Merck Frosst Canada Ltd. v Canada (Health), 2012 SCC 3, [2012] 1 S.C.R.	Reference re Merck Frosst Canada Ltd. v Canada (Health), [2012] 1 S.C.R. (Factum of the Intervener BIOTEC Canada, court file no. 33290 and 33320)	Reference re Merck Frosst Canada Ltd. v Canada (Health), [2012] 1 S.C.R. (Docket of the SCC 33290 and 33320) online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=33290 and http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=33320
Canada v GlaxoSmithKline Inc., 2012 SCC 52, [2012] 3 S.C.R.	NA	Reference re Canada v GlaxoSmithKline Inc., [2012] 3 S.C.R. (Docket of the SCC, 33874) online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=33874
Teva Canada Ltd. v Pfizer Canada Inc., 2012 SCC 60, [2012] 3 S.C.R. 625	Reference re Teva Canada Ltd. v Pfizer Canada Inc., [2012] 3 S.C.R. 625 (Factum of the Intervener Canadian Generic Pharmaceutical Association court file no. 33951) Reference re Teva Canada Ltd. v Pfizer Canada Inc., [2012] 3 S.C.R. 625 (Factum of the Intervener Canada's Research Based Pharmaceutical Companies court no. 33951)	Reference re Teva Canada Ltd. v Pfizer Canada Inc., [2012] 3 S.C.R. 625 (Docket of the SCC, 33951) online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=33951
Sanofi-Aventis v Apotex Inc., 2015 SCC 20, [2015] 2 S.C.R. 136	Reference re Sanofi-Aventis v Apotex Inc., [2015] 2 S.C.R. 136 (Factum of the Intervener Canadian Generic Pharmaceutical Association court file no. 35886) Reference re Sanofi-Aventis v Apotex Inc., [2015] 2 S.C.R. 136 (Factum of the Intervener Canada's Research-Based Pharmaceutical Companies court file no. 35886)	Reference re Sanofi-Aventis v Apotex Inc., [2015] 2 S.C.R. 136 (Docket of the SCC, 35886) online: http://www.scc-csc.ca/case-dossier/info/dock-regi-eng.aspx?cas=35886

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