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The Patented Medicines (Notice of Compliance) Regulations: An Examination of the Decision Making Patterns in these Cases at the Supreme Court of Canada

Jason D. Newman
The University of Western Ontario

Supervisor
Samuel E Trosow
The University of Western Ontario

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Abstract

Generic drug approval cases involving Canada's *Patented Medicines (Notice of Compliance) Regulations* are adjudicated at the Federal Court through the judicial review process. The European Union alleges that this abbreviated process is unfair to litigants who hold patents on medicines, since it does not encompass all of the features of a trial, nor is it an actual suit for patent infringement. In addition, the process has unequal appeal rights for the patent holder and the patent challenger, where the generic challenger can appeal a decision at Federal Court, but the patent holder cannot.

When examining the pattern of decision making in *Patented Medicines (Notice of Compliance) Regulations* cases at the Supreme Court of Canada, there is little evidence to suggest that the Supreme Court Justices are making wrong or unfair decisions because the lower court cases were decided through the judicial review process. The decision making pattern is very similar to the pattern in the Supreme Court patent cases, and to Supreme Court jurisprudence overall, so there is little reason to think that wrong decisions on these cases are being made because of the abbreviated process. In addition, the pattern of decision making in the *Patented Medicines (Notice of Compliance)* cases is much different than the Supreme Court jurisprudence on copyright, an area of law that has been through a period of significant change due to issues surrounding digital music. The copyright cases are quite comparable to the *Patented Medicines (Notice of Compliance)* cases, in that the original adjudication of both case types was through the process of judicial review. However, the decision making pattern in the copyright cases contrasts the pattern in the *Patented Medicines (Notice of Compliance)* cases, in that there are few concurring opinions in the *Patented Medicines (Notice of Compliance)* cases and a high proportion of concurring opinions in the copyright cases, which indicates that the

interpretation of the *Patented Medicines (Notice of Compliance) Regulations* is not creating divided opinions amongst the Justices, nor is the abbreviated process of judicial review from the lower court contributing to significant judicial disagreement. This study therefore provides evidence that a full trial for patent infringement in these cases would not necessarily change the outcomes in these cases.

Keywords

Patented Medicines (Notice of Compliance) Regulations, judicial review, patent, novelty, non-obviousness, utility, patentable subject matter, infringement, impeachment, generic medicines, patented medicines, drug approval, appeal,

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Chapter One: An Overview of the Study

Canada's *Patented Medicines (Notice of Compliance) Regulations*[1] were implemented in 1993 to balance two objectives: protect patents to induce brand name pharmaceutical companies to invest in research and development in Canada, and to expedite the approval of generic copies of drugs that had lost patent protection. Patent terms had to be protected by preventing the launch of generic copies of brand name drugs before their patents expired. In some instances a generic company would simply infringe on the patent holder's rights, since the penalties incurred from infringement were significantly smaller than the profits. At the same time, the *Patented Medicines (Notice of Compliance) Regulations* were supposed to expedite the approval process for generic medications by preventing unnecessary delays brought about by clever patenting strategies by the patent holder.[2] Expediting the approval of generics is an important measure in containing health care costs. As generics are significantly less expensive than their brand name counterparts, it is prudent to have them available as soon as the patents on the innovative product have expired.

Before the *Patented Medicines (Notice of Compliance) Regulations* came into existence, generic manufacturers seeking approval to manufacture and sell copies of brand name drugs in Canada were required to undergo the same extensive safety and efficacy testing as brand name pharmaceuticals. In accord with new commitments under

[1] SOR/93-133 [*PM(NOC)*, or *PM(NOC) Regulations*, or "the *Regulations*"].
[2] This could include adding patents that were not necessarily related to the drug product in question, or evergreening patents to extend patent life. Evergreening is the process of adding successive patents onto an existing patent to block the copying of a medicine when the initial patents expire. This was addressed in the amendments to the *Patented Medicines (Notice of Compliance) Regulations* in 2006, S 5(4)(a) and (b), which freeze the patent register for a novel drug once marketing approval of that drug is granted.

the *North American Free Trade Agreement*[3] and the World Trade Organization's *Agreement on Trade Related Aspects of Intellectual Property Rights*,[4] Canada simplified its procedures for approving generics, allowing generic manufacturers to rely on the research and clinical and safety studies submitted for approval of the corresponding branded pharmaceuticals.

Over the course of the *Patented Medicines (Notice of Compliance) Regulations'* twenty-one year life span (1993 to 2016), several issues have arisen over their fairness to the litigants in a proceedings related to the approval process of a new generic drug. For one, litigation arising from the generic drug approval process operates by way of a summary process called judicial review, which is used to review the applicability of certain patents that may be holding up the genericization of a particular branded medicine. Eliminating or curtailing some elements of a full trial, the judicial review process concerns Canada's trading partners, because judges are making decisions about the approval of generic drugs on abbreviated information about the patents behind the innovative pharmaceutical, and are also deferring a great deal of expertise to Health Canada, who can decide to allow generic companies to bypass certain patents. Although Canada argued at a World Trade Organization complaint hearing that the *Patented Medicines (Notice of Compliance) Regulations* simply provide additional protection over and above the protection afforded in the *Patent Act*, the entire process has been viewed

[3] North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, T.S. No. 2 (1994), 32. I.L.M. 289 (between the Governments of Canada, Mexico, and the United States; entered into force Jan. 1, 1994), [NAFTA].

[4] Trade Related Aspects of Intellectual Property (TRIPS) Apr 15, 1994, Oct. 30, 1947, T.S. No. 27 (1947), 58 U.N.T.S. 187, (negotiated as part of the Uruguay Round (1986–1994) of the World Trade Organization's General Agreement on Tariffs and Trade [GATT]). Canada signed the TRIPS Agreement in 1994, and it was in force at the beginning of 1995. TRIPS is administered by the World Trade Organization. It establishes standards for the protection of intellectual property for World Trade Organization members.

by the European Union and its member states as an opportunity for the generic manufacturer to overturn patents and accelerate development times, simply because the *Patented Medicines (Notice of Compliance) Regulations* operate under a legal backdrop that does not encompass a complete dispute mechanism that adjudicates the validity of the patents themselves.[5]

The judicial review process that emanates from the *Patented Medicines (Notice of Compliance) Regulations* has also been criticized[6] for having unbalanced appeal rights, where the innovator is without an appeal at the moment a judge rules in favor of the generic manufacturer, since generic approval is granted immediately following an unsuccessful challenge by the patent holder to stop that approval.[7] Regulations within North American Free Trade Agreement, the Trade Related Aspects of Intellectual Property Agreement, and the Canada-European Union: Comprehensive Economic Trade Agreement[8] require that signatory countries provide brand and generic pharmaceutical companies equal appeal rights after a trial court decision, but the *Patented Medicines (Notice of Compliance) Regulations* do not allow for effective appeals, since a generic

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[5] World Trade Organization, *Canada – Patent Protection of Pharmaceutical Products, A Complaint by the European Communities and their Member States, Report of the Panel,* March 17, 2000, WT/DS114/R. This complaint will be discussed in detail later in Chapter Four, on page 56.

[6] Suzanne Porter, "*Canada's Patented Medicines (Notice of Compliance) Regulations: Removing Inefficiencies to Encourage Generic Competition"* (LLM Thesis, University of Toronto Faculty of Law, 2011). Suzanne Porter is an adjunct professor of law at the University of Toronto. Her master's thesis compared Canada's *Patented Medicines (Notice of Compliance) Regulations* to the United States' *Hatch-Waxman Act*, and concluded that the Canadian regulations could be made fair if the *Regulations* were amended to include a direct patent infringement suit when evaluating any patents under the generic medicines approval process, where the process would provide both litigants with equal appeal rights.

[7] *Supra* note 1, S. 7(2)(b). If the court declares that the patents are not valid, or that the patents will not be infringed, there is no longer a reason to hold up the approval of a generic drug, and the Notice of Compliance is issued, in accordance with S. 7(1)(e).

[8] The text of the Canada-European Union: Comprehensive Economic Trade Agreement (CETA) was finalized on September 26, 2014 and is currently awaiting ratification. The finalized text can be found at www.international.gc.ca/CETA. The provision for equal appeal rights is found in S 9 bis of CETA, Article 1709 of NAFTA, and Article 27 of TRIPS. Appeal rights are discussed in Chapter Four page 63.

company must be granted approval for its product if an initial challenge by a brand manufacturer is dismissed.

The legal burden of proof in judicial reviews over generic approval has been criticized as being unfair,[9] since it falls on the innovator company to defend its patents, even though it has already established patent protection for its pharmaceutical under the *Patent Act.*[10] Since the generic applicant can allege that the patents are invalid or inapplicable to the drug product in question, the patent holder becomes responsible for defending its previously issued patents, and if it does not do so, the Minister of Health will order a Notice of Compliance to approve the generic drug for manufacture and sale in Canada.[11]

The standard of review in these judicial review proceedings is the *reasonableness* of the Minister of Health in deciding to list or de-list a patent on the Patent Register, and not a determination of the *correct* patent status for the patents involved. For decisions made by government tribunals that are judicially reviewed, the question for the judge therefore becomes whether or not that government minister acted *reasonably*, and not whether he acted *correctly*. The standard of review of reasonableness goes hand in hand with the mechanism of judicial review to expedite decision making in these cases, where technical or scientific expertise is involved. With significant deference given to Health Canada's expertise in pharmaceuticals, there is concern amongst members of the

[9] *Supra* note 6.
[10] Frederick Rein and Patrick Smith. "A Discussion of Generic Drug Approval and Patent Systems in the United States and Canada." (2009) 25 CIPR 83 at 92.
[11] *Supra* note 1, S. 7(2)(b).

European Union that the rights afforded to patent holders do not encompass the full protection guaranteed to them under the *Patent Act*.[12]

In an attempt to reduce potential uncertainty vis-à-vis judicial review, specific adjustments to the *Patented Medicines (Notice of Compliance) Regulations* could make them similar to the *Hatch-Waxman Act*[13] in the United States, which employs a full action for infringement, complete with discovery, the adjudication of patent validity to a standard of correctness, and the opportunity to appeal[14] that automatically comes into play in the generic medicine approval process. When a generic manufacturer alleges that a patent on a drug is invalid or not applicable, that generic manufacturer is automatically deemed to have infringed on the patent, establishing a cause of action under the United States *Patents Act*.[15] Whether or not replacing the judicial review process with an action for infringement is correct depends on the nature of the issues associated with the *Patented Medicines (Notice of Compliance) Regulations*, and whether the Supreme Court Justices are having significant disagreement[16] because of the abbreviated nature of the judicial review process in *Patented Medicines (Notice of Compliance)* cases that have been granted leave to appeal to the Supreme Court. This paper will demonstrate that there is insufficient evidence that the process of judicial review is creating increased disagreement among the Supreme Court Justices; without a high level of disagreement

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[12] Porter, *supra* note 6 at 42.
[13] The *Hatch-Waxman Act* is also known as the *Drug Price Competition and Patent Term Restoration Act.* Its abbreviated name is from its sponsors, Republican senator Orrin Hatch and Democratic Congressman Henry Waxman. The Act is incorporated into *The Federal Food, Drugs, and Cosmetics Act*, 21 USC §355(j).
[14] *Supra* note 6 at 43.
[15] 35 USC (2006).
[16] A case where there is significant disagreement among the Justices may be decided differently in the presence of additional evidence, which would be the case if the cases were decided by way of an action rather than judicial review. This situation will be referred to as "difficulty" in various places throughout this thesis.

amongst the Justices, there is little evidence to support claims that these cases cannot be adjudicated properly through the judicial review process. This will therefore guide future research on how the *Regulations* should be amended, if at all.

By building a profile of the types of decisions made in the *Patented Medicines (Notice of Compliance)* cases at the Supreme Court and comparing that profile to other decision making patterns available from other studies, conclusions can be drawn as to whether there is evidence of significant disagreement and improper decision making. The primary purpose of this thesis is to determine if judicial review is really problematic in these cases, and it will help to determine if adjustments to the *Regulations* are necessary for respecting Canada's agreements in international trade.[17]

The Central Investigations of the Thesis

First, the decision making pattern in the *Patented Medicines (Notice of Compliance)* Supreme Court cases will be compared to the general patent cases at the Supreme Court of Canada. A similar pattern suggests that *Patented Medicines (Notice of Compliance)* cases are decided correctly, and that the Justices had no more difficulty in reaching a decision in the *Patented Medicines (Notice of Compliance)* cases than in the patent cases generally. This qualitative comparison will be combined with a qualitative examination of the six *Patented Medicines (Notice of Compliance)* cases at the Supreme Court to see which cases have significant patent adjudication issues. This qualitative comparison will also offer insight as to whether the cases are primarily about patent

[17] A study of the decision making patterns in *Patented Medicines (Notice of Compliance)* cases at the Federal Court could also be undertaken, but there are over one thousand cases to be researched. In addition, there are no decision making studies at the Federal Court level that can be used for comparison. The Supreme Court cases allow each litigant one hour to present an argument. The arguments are based on the evidence, law, and adjudication made at the Federal Court of Appeal, so the decisions at the Supreme Court are related to what has been presented at the lower court. See Future Research in Chapter Seven, p 114.

infringement, the *Patented Medicines (Notice of Compliance) Regulations*, or the judicial review process *itself*.

The second task will be to determine whether or not the *Patented Medicines (Notice of Compliance)* Supreme Court cases have a decision making profile that is similar to the Supreme Court copyright cases analyzed in Professor Margaret Ann Wilkinson's pentalogy article, "The Context of the Supreme Court's Copyright Cases" in *The Copyright Pentalogy*.[18] If there is the same proportion of unanimous decisions, majority decisions with concurring reasons, and solo dissents in patent infringement and invalidity cases as in the Supreme Court of Canada copyright decisions, then there is some evidence that the administrative component, the process of judicial review, is itself problematic, and further academic investigation into *this process* would be warranted.

The third research task will be to determine whether the Supreme Court decisions on the *Patented Medicines (Notice of Compliance)* cases fit into the general pattern of Supreme Court of Canada jurisprudence, which covers all disciplines of law. The study data will be compared to the pattern of unanimous, majority decisions with concurring reasons, dissent, and solo dissents in Supreme Court jurisprudence studies. This question is extends from the data collection required to investigate the comparison to copyright, since Wilkinson's article compared the copyright cases to the Supreme Court jurisprudence. The Supreme Court data provides an additional pattern of decision making that can be compared the *Patented Medicines (Notice of Compliance)* cases.

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[18] Margaret Ann Wilkinson, "The Context of the Supreme Court's Copyright Cases" in *The Copyright Pentalogy, How the Supreme Court of Canada Shook the Foundations of Copyright Law*, ed. Michael Geist (Ottawa: University of Ottawa Press, 2013) 71-92. Wilkinson is jointly appointed to the Faculty of Law and the Faculty of Information and Media Studies at the University of Western Ontario. She holds a law degree from the University of Toronto, a Bachelor of Arts degree (University of Toronto), a masters of legal studies (University of Toronto), and a Doctor of Philosophy degree (University of Western Ontario).

If the decision making patterns are similar to the Supreme Court patent cases or the general Supreme Court cases, it suggests that the *Patented Medicines (Notice of Compliance)* cases are adjudicated in a similar fashion to full actions, indicating that the process of judicial review is not causing more disagreement among the Justices than in any other cases. If there is no more disagreement among the Justices in the *Patented Medicines (Notice of Compliance)* cases than the general Supreme Court cases or the Supreme Court patent cases, then research on the *Patented Medicines (Notice of Compliance) Regulations* should focus on aspects other than the judicial review process. The results provide relevant information about the effect of the abbreviated process of judicial review to the specific complaint brought forward by the European Union about Canada's obligations under TRIPS.

A Hypothesis: Judicial Review is "Enough" Process

The Comparison of the *Patented Medicines (Notice of Compliance)* cases to the Supreme Court Patent Cases and the General Supreme Court Cases

Ronald Dworkin's philosophy of law provides a framework for understanding why judicial review provides enough process for adjudicating disputes arising from the *Patented Medicines (Notice of Compliance) Regulations.* Ronald Dworkin was the pioneer of the "right answer" theory of the law,[19] asserting that the role of judges is to use their extraordinary abilities to understand the law, then apply it to a fact situation to determine the "right" answer in a case. Dworkin believes that there is a single right answer to every case.

[19] Ronald Dworkin, *Taking Rights Seriously* (1977) Cambridge: Harvard University Press.

Dworkin does not believe that the law can be accurately encompassed in a theory that just *describes* the law as a scientific principle to which people adhere to by nature. Descriptive or "natural" models of the law describe an objective morality of the law, which is not created by human beings, but is discovered by them, as one could discover a law of physics: "Moral reasoning or philosophy is a process of reconstructing the fundamental principles by assembling concrete judgments in the right order, as a natural historian reconstructs the shape of the whole animal from the fragments of its bones that he has found."[20] Dworkin's theory, however, is constructive, in that it "treats institutions of justice not as clues to the existence of independent principles, but rather as stipulated features of a general theory to be constructed, as if the sculptor set himself to carve the animal that best fits a pile of bones he happened to find together."[21] In other words, the judge, as an architect, takes existing judgments and legislation, and assembles them in the right order to administer the law.

> This 'constructive' model does not assume, as the natural model does, that principles of justice have some fixed, objective existence, so that descriptions of these principles must be true or false in some standard way. It does not assume that the animal it matches to the bones actually exists. It makes the different, and in some ways more complex, assumption that men and women have a responsibility to fit the particular judgments on which they act into a coherent program or action, or, at least, that officials who exercise power over other men have that sort of responsibility.[22]

Dworkin reinforces his constructive model by stating that it is somewhat creative, but clarifies that it does not require inventing justice, but involves interpretation:

> The justification need not fit every aspect or feature of the standing practice, but it must fit enough for the interpreter to be able to see himself as interpreting that practice, not inventing a new one.[23]

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[20] Ronald Dworkin, "The Original Position" (1973) U Chi L Rev 40, 500.
[21] *Supra* note 19 at 160.
[22] *Supra* note 19 at 160.
[23] Ronald Dworkin, "Law's Empire" (1986) Harvard UP, 66.

In other words, law requires "constructive interpretation," where law is not a natural concept (that would emanate from a supreme being, for example, and be "natural" to follow), but requires "imposing purpose on an object or practice in order to make of it the best possible example of the form or genre to which it is taken to belong."[24] Imparting constructive interpretation means that Dworkin's model is therefore argumentative in nature: "constructive interpretations… try to show legal practice as a whole in its best light, to achieve equilibrium between legal practice as they find it and the best justification of that practice."[25]

> Dworkin delineates three stages of constructive interpretation:
>
> First, there must be a "preinterpretive" stage in which the rules and standards taken to provide the tentative content of the practice are identified…. Second, there must be an interpretive stage at which the interpreter settles on some general justification for the main elements of the practice identified at the preinterpretive stage…. Finally, there must be a postinterpretive or reforming stage, at which he adjusts his sense of what the practice "really" requires so as better to serve the justification he accepts at the interpretive stage.[26]

The three stages serve to form the basis of interpretation. A judge would gather the relevant cases and legislation required, then interpret the facts with respect to the cases and legislation, then reflect upon that decision and how it fits into the existing jurisprudence.

Dworkin also asserts that the interpretive attitude required in law requires value judgments. He affirmed that

> …propositions of law are not merely descriptive of legal history, in a straightforward way, nor are they simply evaluative in some way divorced from

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[24] *Ibid* at 52.
[25] *Supra* note 23 at 55.
[26] *Supra* note 23 at 65.

> legal history. They are interpretive of legal history, which combines elements of both description and evaluation but is different from both.[27]

Using the rules of courtesy as an example, Dworkin explains that the interpretive attitude requires an assumption that it has an objective value (or a purpose) and a further assumption that the interpretive attitude is sensitive to that value.

> The first is the assumption that the practice of courtesy does not simply exist but has value, that it serves some interest or purpose or enforces some principle – in short, that it has some point – that can be stated independently of just describing the rules that make up the practice. The second is the further assumption that the requirements of courtesy – the behavior it calls for or judgments it warrants – are not necessarily or exclusively what they have always been taken to be but are instead sensitive to its point, so that the strict rules must be understood or applied or extended or modified or qualified or limited by that point. Once this interpretive attitude takes hold, the institution of courtesy ceases to be mechanical; it is no longer unstudied deference to a runic order. People now try to impose *meaning* on the institution – to see its best light – and then to restructure it in the light of that meaning.[28]

It is clear that Dworkin is endorsing a moral reading of the practice of law - law and morality are part of the same system. He argues that the concept of values is integrated into law, stating that "[i]t would make little sense to treat the political values… as detached values."[29] He extends this integration of law and morality by avowing that a theory of the law

> Must find the place of each value in a larger and mutually supporting web of conviction that displays supporting connections among moral and political values generally and then places these in the still larger context of ethics.[30]

This does not mean that all judges will come to the same answer, as that would imply that there is a consensus as to what is 'right.' Rather, there is a right answer for a particular

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[27] Ronald Dworkin, "How Law is Like Literature" in *A Matter of Principle* (1985) Harvard UP at 147.
[28] *Supra* note 23 at 47.
[29] Ronald Dworkin, "Hart's Postscript and the Point of Political Philosophy" in *Justice in Robes* (2006) Harvard UP, at 158.
[30] *Ibid* at 168.

judge who applies his own principles correctly to the legal question at hand. A particular case may be difficult to judge, but it is the analysis of the judge, based on his upbringing, character, and education, that allows him to properly interpret the law, making *his* answer right, regardless of which side of the law the decision falls.

Considering Dworkin's one right answer thesis, framed within his principles of constructive interpretation of the law, integration of values into the law, and evaluation of legal history, a judge can solve a hard case by interpreting and applying existing law, and evaluating that outcome within the frame of reference of the law and his own sense of morality, which is infused into the law. By applying this formula, there is no new law created, but rather an application of existing law, with a legal and moral argument underpinning it, and one right answer is the result. To test his theory against difficult legal cases (where deciding the case in favour of one litigant over another is not easy), Dworkin created imaginary Judge Hercules:

> [A] lawyer of superhuman skill, learning, patience and acumen, whom I shall call Hercules… a judge in some representative American jurisdiction… [who] accepts the main uncontroversial constitutive and regulative rules of the law in his jurisdiction… that is, that statutes have the general power to create and extinguish legal rights, and that judges have the general duty to follow earlier decisions of their court or higher courts whose rationale… extends to the case at bar.[31]

This is consistent with Dworkin's position in *Justice for Hedgehogs*, where he explains how judges reach a decision in difficult cases by distinguishing between indeterminacy and uncertainty:

> But in all these aspects indeterminacy differs from uncertainty. "I am uncertain whether the proposition in question is true or false" is plainly consistent with "It is one or the other," but "The proposition is neither true nor false" is not.[32]

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[31] Ronald Dworkin, "Hard Cases" (1974) 88 Harvard L Rev at 1083.
[32] Ronald Dworkin, *Justice for Hedgehogs* (2011), Harvard UP, at 91.

Hercules allows Dworkin to separate indeterminacy from uncertainty, since it would be implausible for a judge to come to a conclusion on an indeterminate legal question, but realistic to think that there is one right answer to an uncertain legal question that can be constructed and interpreted from pre-existing legal materials in difficult cases, evaluated from both the underlying legal and moral principles then be integrated into the law.

Therefore Judge Hercules, reading factums, and affidavits of witnesses being examined and cross-examined in a generic medicine approval case, should be able to weave the law of the *Patented Medicines (Notice of Compliance) Regulations* into a case to reach the right decision, even if the process is not as thorough as an action, simply because his background and principles will lead *him* to the right answer. To state that *more process* is required means that a judge can do a better job if he just has more information, and diminishes the idea that the judge can make the right decision, based on his abilities and the information that he *does* have. If the process of judicial review is insufficient for adjudicating the cases, the process could be leading to uncertainty or indeterminacy, but the addition of a partial process, like judicial review, should not *create* indeterminacy, but only serve to remove it. If there is indeterminacy in the case, it is unclear how additional process would ever change that. Therefore, issues with indeterminacy should not be prevalent with Judge Hercules in *Patented Medicines (Notice of Compliance)* cases, but uncertainty *could*. If Judge Hercules is left with some uncertainty in these cases, Judge Hercules can still make a decision, because of his background and his skill at applying the law and his values to the problem. If there is *a lot* of uncertainty in these cases because of the process, and Judge Hercules is not always achieving the one right answer, this will be borne out by a different pattern of decision

making in the Supreme Court *Patented Medicines (Notice of Compliance)* cases than in the Supreme Court patent cases or the Supreme Court general jurisprudence. I am confident that the judicial review process provides enough process for the achievement of the one right answer by the Herculean effort of the Supreme Court Justices.

Dworkin's critics[33] state that the legal principles held by Judge Hercules may be insufficient to solve difficult cases, which could leave him in a dilemma. In technical cases involving the *Patented Medicines (Notice of Compliance) Regulations*, the question emerges as to whether the additional process involved in a full action, as opposed to a judicial review, would make it any easier for a judge to reach the right decision, or leave him in a dilemma. An analysis of the decision making pattern, and a comparison to the pattern of judgments in the Supreme Court patent group or the general Supreme Court group will help in this determination, where similar patterns would refute this idea, since difficult cases naturally to lead to more judicial disagreement.[34] A pattern of decision making that is *not* problematic would be similar to a pattern of decisions in similar cases that were adjudicated through a complete action, especially if the cases are somewhat related. If the pattern of decision making in the *Patented Medicines (Notice of Compliance)* cases is no different than the Supreme Court patent cases, or the general Supreme Court cases, and judges will be applying their principles to come up with the

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[33] Stephen Guest, *Ronald Dworkin*, (1992), Stanford UP, 137-147. At 145, Guest states that "Dworkin's thesis is… a defensive thesis to the criticism that there cannot be right answers in hard cases where there is no 'proof' or demonstration."

[34] Disagreement among Justices at the Supreme Court of Canada is discussed by Peter McCormick in Chapter Five: Peter McCormick, "Standing Apart: Separate Concurrence at the Modern Supreme Court of Canada 1984 to 2006" (2008) 53 McGill LJ 137. Professor Wilkinson also discusses concurring decisions and disagreement at the Supreme Court, which will be discussed in Chapter Five: Margaret Ann Wilkinson, "The Context of the Supreme Court's Copyright Cases" in *The Copyright Pentalogy, How the Supreme Court of Canada Shook the Foundations of Copyright Law*, ed. Michael Geist (Ottawa: University of Ottawa Press, 2013) 71-92.

right answer in any particular case, it lends credence to the idea that the abbreviated process at the Federal Court is not creating more disagreement among Justices at the Supreme Court. Innovative pharmaceutical firms are motivated for more process, since more process would lead to actual patent infringement actions, live witness testimony, and more time where the innovator's product is in a monopoly position in the marketplace.

Dworkin's one right answer hypothesis is not intended to be a holistic theory about the law of pharmaceuticals, generic approval, or judicial review. Rather, its constructivist features fit with the assertion that a full patent infringement trial equalizes fairness to patent holders in generic drug approval litigation. Although a full trial may provide a judge with a few more "bones" to construct, my assertion is that the judicial review process provides enough evidence in the *Patented Medicines (Notice of Compliance)* cases to make any difference between the two processes.

A Hypothesis about the Comparison of the *Patented Medicines (Notice of Compliance) Cases to the Copyright Cases*

If the pattern of the *Patented Medicines (Notice of Compliance)* cases is dissimilar to that of the copyright cases, the analysis does not support the idea that it is the abbreviated process of judicial review *itself* that is problematic in deciding these cases. The pattern in the *Patented Medicines (Notice of Compliance)* cases is not likely to be similar to the copyright cases, seeing that the copyright cases over the past two decades have involved digital rights over music, while the *Copyright Modernization Act* was not passed until 2012.[35] There is likely much more dissent and concurring opinions in the

[35] SC 2012, c20.

copyright cases than the *Patented Medicines (Notice of Compliance)* cases. A pattern of cases that is, instead, similar to the pattern in general Supreme Court jurisprudence supports the notion that the *Patented Medicines (Notice of Compliance)* cases are no more difficult to decide than other Supreme Court cases.

Decision Making Patterns as *Relative* Comparisons

The present study uses data from previous decision making patterns to draw *relative* comparisons among the groups of cases. But previous studies have focused on discovering the underlying motivations and beliefs of judges that could be affecting one particular group of decisions. Early studies of decision making attempted to link the political ideology and attitudes of judges to their judicial outcomes, but the relative comparison in *this* study alleviates the need to try to postulate about these "hidden" factors.

The political justifications for judicial attitudes in these previous studies do not necessarily align with Dworkin's one right answer theory. In accord with Dworkin's theory, a judge, because of his background and his knowledge of the law, should not allow political beliefs to sway interpretations of the law.

Chapter Two: Methodology for Answering the Central Questions

Data Collection

The first step in examining the *Patented Medicines (Notice of Compliance)* cases will be to collate all of the patent cases and *Patented Medicines (Notice of Compliance)* cases at the Supreme Court since 1970. This time period was chosen, since previous decision studies on the Supreme Court reach back to the early seventies. Thirty-one patent cases were heard at the Supreme Court during this period, providing an adequate number cases for comparison, across several different panels of Justices. Since the *Patented Medicines (Notice of Compliance) Regulations* received Royal Assent in 1993, there have only been six cases that have reached the Supreme Court (Table One). All six are included in the study.

Table 1: The Six *Patented Medicines (Notice of Compliance) Cases*

Merck-Frosst Canada Inc. v Canada (Minister of National Health and Welfare)[36]
Bristol-Myers Squibb v Canada (Attorney General)[37]
AstraZeneca Canada Inc. v Canada (Minister of Health)[38]
Apotex Inc. v Sanofi-Synthelabo Canada Inc.[39]
Teva Canada Ltd v Pfizer Canada Inc.[40]
Sanofi-Aventis v Apotex Inc.[41]

[36] [1998] 2 SCR 193, 1998 SCJ 58 [*Merck-Frosst*].
[37] [2005] 1 SCR 533, [2005] SCJ 26 [*Bristol-Myers*].
[38] [2006] 2 SCR 560, 2006 SCC 49 [*Astra-Zeneca*].
[39] [2008] 3 SCR 265, [2008] SCJ 63 [*Sanofi-Synthelabo*].
[40] [2012] 3 SCR 625, 2012 SCC 60 [*Teva*].
[41] [2015] SCC 20 [*Sanofi-Aventis*].

The composition of the court (the number of Supreme Court Justices) will be recorded, as well as the central issues in each case. The different categories of decisions for the cases will be tabulated: the number of unanimous decisions, the number of majority decisions with and without minority concurring reasons and with and without dissent. Dissents will be categorized and tabulated as unanimous,[42] non-unanimous (multiple dissents),[43] and solo.[44] The number of each type of judgment will also be counted, and the total number of *reasons* given out over all of the cases will be tabulated for comparative purposes. Case disposition data, defined as the percentage of allowed appeals for a given category of cases, will also be tabulated. The tabulation of data comprises the decision making pattern.

Wilkinson's Supreme Court copyright case data on decision making from the Pentalogy study will be referenced in similar format to the patent data. Wilkinson's data on general Supreme Court decision making patterns, referenced from other authors, will also be used, and supplemented with statistical information from the Supreme Court of Canada official website.

Analysis of the Central Question

Once the decisions have been tabulated and the issues have been recorded for the patent and *Patented Medicines (Notice of Compliance)* cases, a comparative analysis will be performed. To answer the first question, the decision making patterns in the *Patented Medicines (Notice of Compliance) Regulations* cases will be compared to the Supreme

[42] Unanimous dissent refers to a dissent agreed upon by more than one justice, where only one set of dissenting reasons is provided.
[43] Non-unanimous dissent would involve two or more dissents in a case, and could include multiple signatories on each, or two solo dissents, or a dissent with more than one signatory and a solo dissent.
[44] Solo dissents are dissents written by one justice, with no other judges in agreement with the dissent.

Court patent cases. Although decisions in *Patented Medicines (Notice of Compliance)* cases may *invalidate* patents (as in a traditional infringement or impeachment action), patenting and generic drug approval become linked, since the *Patented Medicines (Notice of Compliance) Regulations* invoke challenges to the validity of patents for the purpose of getting generic pharmaceuticals approved for sale in the Canadian market. If the comparison distinguishes the two types of cases, it suggests that the different pattern reflects different issues in the cases, or differences related to the way the two sets of cases are adjudicated.

Second, the decision making patterns in the *Patented Medicines (Notice of Compliance)* cases will be compared to the decision making patterns in Professor Wilkinson's Supreme Court copyright study. A similar pattern could indicate that judges have similar levels of disagreement with both types of cases, suggesting that the predominant issue with the *Patented Medicines (Notice of Compliance)* cases is more administrative than legislative in nature. As discussed, the administrative issues at play would primarily be related to the elements of judicial review and not the *Patented Medicines (Notice of Compliance) Regulations* themselves. Conversely, *differences* in the decision making patterns of the two sets of cases would not provide evidence of any common problem involving the process of judicial review in the *Patented Medicines (Notice of Compliance)* cases or the copyright cases.

Third, a comparison of decision making patterns will be made with Supreme Court cases generally to the *Patented Medicines (Notice of Compliance)* cases. Differing patterns could highlight the level of consensus among Supreme Court Justices when deciding the *Patented Medicines (Notice of Compliance)* cases. A low level of consensus

would provide evidence that the judicial review process is insufficient for deciding the cases. A high level of consensus suggests that the judicial review process is sufficient.

In summary, a comparison of *Patented Medicines (Notice of Compliance)* decisions at the Supreme Court of Canada to Wilkinson's copyright case data, Supreme Court patent case data, and general Supreme Court decision making data will help characterize the *Patented Medicines (Notice of Compliance)* decisions and point the way for future research. The data from this analysis will help to support or reject the idea that the process of judicial review leads to less agreement and potentially more wrong outcomes when decisions over the approval of generic medicines are made. Not only will each comparison provide information, but the three comparisons together will also help to create an overall picture as to whether or not the use of judicial review in these cases is increasing the level of disagreement and potentially incorrect outcomes.

Chapter Three: Pharmaceutical Companies, the Drug Approval Process and Patenting in Canada

This chapter will introduce fundamental concepts about generic and innovative pharmaceuticals and the pharmaceutical approval process in Canada. An overview of patenting will be provided to draw attention to how the elements of patent apply to medicines. Patent infringement and impeachment, and any ensuing litigation in Canada, as it applies to any patent, will also be outlined, as this process is available to holders of patents on pharmaceuticals. In addition, understanding the generic drug approval process requires an explanation of the history of compulsory licencing in Canada, and how Canada's international trade obligations led to the elimination of this practice and the introduction of the *Patented Medicines (Notice of Compliance) Regulations.*

Generic versus Brand (Innovative) Pharmaceuticals

Brand name pharmaceuticals, or innovative pharmaceuticals, are medicines that result from primary research and development. Research for creating new medicines is challenging, time-consuming, and expensive. Developing a new prescription medicine that gains market approval costs, on average, $802 million and takes over ten years to complete.[45] Of these costs, fifty percent is attributed to synthesizing novel molecules through complicated chemical processes.[46] Compounds that exhibit theoretical promise are investigated for safety, followed by efficacy, which means that they must be both safe for consumption and useful in treating specific medical conditions. Safety and efficacy

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[45] Joseph DiMasi, Ronald Hansen, and Henry Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," (Oct 2002) J Health Econ, at 180. This figure is provided in year 2000 dollars, and represents the out-of-pocket costs for development. The authors also provide an updated figure of $1,395 million, as of 2014, on the Tufts University Tufts Center for the Study of Drug Development at http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.

[46] The research often employs complex computer algorithms that can generate hundreds of thousands of compounds which are then screened. Promising compounds are developed through the synthesis outlined in the algorithm.

testing, filing for patents, and managing regulatory requirements accounts for the remaining fifty percent of the costs, but recent studies have shown that both the time and the costs involved in doing clinical trials has increased dramatically in the past ten years due to more complex regulatory requirements. Requirements for more study subjects, requirements for longer studies for drugs used for chronic conditions, and difficulty recruiting study subjects are among the reasons for the increased time and costs associated with clinical trials.[47]

Generic pharmaceuticals are "copies" of brand name pharmaceuticals, which are bioequivalent to the branded product. Bioequivalence means that the concentration of the drug in the bloodstream of the generic drug is the same as in the branded (or reference) product. Bioequivalence also requires that the maximum concentration of the generic drug in the bloodstream is the same as the maximum concentration in the branded product. For the purposes of bioequivalence, Health Canada defines bioequivalence as:

a. The 90% confidence interval of the relative mean area under the concentration versus time curve to the time of the last quantifiable concentration (AUC_T) of the test to reference product should be within 80.0% to 125.0% inclusive.
b. b) The relative mean maximum concentration (C_{max}) of the test to reference product should be between 80.0% and 125.0% inclusive.[48]

Generally, part a. means that a generic drug is considered "the same" or "equivalent" if the concentration of drug in the bloodstream falls between 80 percent and 125 percent of the branded product 90 percent of the time. Part b. indicates that the maximum

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[47] Dickson, Michael and Gagnon, Jean Paul, "Key Factors in the Rising Cost of New Drug Discovery and Development" (May, 2004) 3(5): Nature Reviews. Drug Discovery, 417 at 418.
[48] Health Canada Drugs and Health Products Guidance Document – Comparative Bioavailability Standards: Formulations Used for Systemic Effects. (May 2012), File No. 12-105972-31. The preamble states that "The purpose of these documents is to update and consolidate eleven existing Health Canada documents related to the conduct and analysis of comparative bioavailability studies and the standards to be met in those studies in order to comply with Sections C.08.002(2)(h), C.08.002.1(2)(c)(ii) and C.08.003(3) of the *Food and Drug Regulations*."

concentration in the bloodstream should be within 80 percent to 125 percent of the branded product.

These copied medicines are synthesized using the information disclosed in the patents registered on brand name pharmaceuticals. Significantly less research and development is required to *copy* a drug than to bring a new innovative drug to market. Consequently, generic pharmaceuticals cost a fraction of what brand name pharmaceuticals cost to develop. It is estimated that the development of a generic drug in Canada takes three to six years and costs $4 million to bring the drug to market.[49] Generic pharmaceuticals create savings for provincial governments, which pay or subsidize the cost of medications for many of their residents, including senior citizens, the disabled, and welfare recipients, so there is a strong motivation to genericize drugs once the drug's patents have expired.[50] In Canada, generic drug prices range from 56 percent to 31 percent of the brand drug price.[51] Generic companies have to wait for patents on innovative pharmaceuticals to expire, or they have to demonstrate that the existing patents on the innovative pharmaceuticals are invalid or irrelevant.

In 2013, there were $13.6 billion in sales of patented medicines, and $8.4 billion in sales of non-patented (mainly generic) medicines in Canada. Since 2011, research and

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[49] Canadian Generic Pharmaceutical Association, "Generic Prescription Drug Development" (July 2015) at p 10, online: http://www.canadiangenerics.ca/en/resources/docs/DDBookletWebEng.pdf

[50] See, for example, the Ontario Drug Benefit Formulary, which is a comprehensive list of drugs, or formulary, paid for by the Ministry of Health and Long Term Care in the Province of Ontario. The Ministry's formulary can be found online on their website at http://www.health.gov.on.ca/en/pro/programs/drugs/odbf_eformulary.aspx. By searching "pantoprazole," one can see the example of brand name Pantoloc 40mg. The drug has a listed price of $2.0803 per tablet, but the Ministry only covers up to $0.3628 per tablet, which is the price of the generic "copies" listed on the site. See "pms-pantoprazole 40mg ent tab" listed immediately above brand name Pantoloc 40mg.

[51] Patented Medicines Prices Review Board, *Generic Drugs in Canada, 2013* www.pmrb-cepmb.gc.ca

development expenditures in Canada have dipped below $1 billion, and pharmaceutical research and development in Canada has fallen by 29 percent since 2001.[52]

The Drug Approval Process in Canada

The drug approval process in Canada involves health law, patent law, and administrative law. Health law regulates the safety and efficacy of pharmaceuticals through the *Food and Drugs Act*,[53] which is administered through the Therapeutic Products Directorate of Health Canada. Patent law, as discussed, deals with the monopolies granted for innovation within the industry through the *Patent Act*, which is administered by the Canadian Intellectual Property Office. Administrative law plays an important role in linking patent law and health law through the *Patented Medicines (Notice of Compliance) Regulations* to facilitate the approval of pharmaceuticals in Canada. Administrative law also creates the framework for the judicial review of decisions related to approving generic medicines through the *Patented Medicines (Notice of Compliance) Regulations*, the *Federal Court Act*,[54] and the *Federal Court Rules*.[55]

The *Food and Drugs Act* and *The Food and Drug Regulations*[56] encompass the regulations for the safety and efficacy of pharmaceuticals required before approval to manufacture, market, and sell can be granted. Sections 8 to 15 of the *Food and Drugs Act* outline the general prohibitions on the manufacture, distribution, and sale of drugs in Canada, general requirements for sanitation and cleanliness, production facility

[52] Taken from Industry Canada's "Canadian Pharmaceutical Industry Profile (2014)" online: https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html. Investment decreased by 29 percent over the period of 2001 to 2014.
[53] RSC 1985, c F-27.
[54] RSC, 1985, c F-7.
[55] SOR/98-106.
[56] CRC, c 870, 2016.

inspections, labelling requirements, and standardization requirements.[57] Part C, Division 8, of the *Food and Drug Regulations*[58] provides specific guidelines for new drugs and generic drugs that are intended to be marketed and sold in Canada. Division Eight regulations include clinical and safety study requirements, labelling requirements, and any other requirements for obtaining a Notice of Compliance, which is a notice that a drug product has successfully completed these requirements, and can therefore be manufactured and sold. Division Eight also details the *types* of submissions allowed, and the specific requirements for each type. The first type is the standard New Drug Submission, which applies to drugs that have never been marketed and sold before in Canada. The second type is the Abbreviated New Drug Submission, which is for generic drugs, where a Notice of Compliance has already been granted to the innovator drug with the same active ingredient, in the same strength, and same dosage form. The third type of submission is the Extraordinary Use New Drug Submission, which sets out the regulatory provisions for new drugs where it is not possible to conduct clinical trials on human

[57] Data exclusivity is outlined in C.08.004.1 of the *Food and Drug Regulations*. This provision protects the safety and efficacy data of an innovative pharmaceutical for a minimum of eight years for a drug containing a new medicinal ingredient not previously approved by Health Canada from the date of filing for a Notice of Compliance. In this provision, a generic manufacturer cannot file for a submission for a copy of the data for the first six years of the eight year period. Subsection 5(5) of the *Patented Medicines (Notice of Compliance) Regulations* clarifies the data exclusivity provisions under Canada's Access to Medicines Regime, where the date for filing for the data is deemed to be six years after the issuance of a Notice of Compliance for the innovator pharmaceutical. Data exclusivity is not an issue for investigation in this thesis but is an issue for future study, as data exclusivity provisions can affect market exclusivity. An extension to the data exclusivity period was recently rejected by Canada during negotiations of the *Canada-European Union: Comprehensive Economic Trade Agreement.* However, it is likely to be an issue in future international trade negotiations.

[58] *Supra* note 56, c.08

subjects.[59] Health Canada publishes specific guidance documents for companies wishing to file a drug submission of any type.[60]

Original Research – The Process for Drug Approval

New drug research begins with scientists developing new chemical or biological substances. New substances are isolated and purified, then administered to tissue cultures, called *in vitro* testing, and observed for physiological, biological, or behavioural changes. Following promising *in vitro* results for a particular compound, *in vivo* testing (animal testing) for pharmacological efficacy, pharmacokinetics, and toxicity begins. Pharmacokinetic testing on animals tells researchers how that compound is distributed throughout the body, how it is metabolized and eliminated, and whether or not it could adversely affect human systems, like the reproductive system or the immune system. Pharmacokinetic testing enables researchers to determine safe dosage ranges for humans as well. Researchers also conduct experiments with high dosages to try to induce the development of cancer cells in various tissues, providing information on the potential carcinogenicity of a given compound. Through all of this experimentation and monitoring, researchers develop a profile of potential side effects from the compound as well. This stage of research, encompassing *in vitro* and *in vivo* testing on animals, is known as pre-clinical testing.

If the initial tests indicate that the drug will be safe in humans, researchers file a Clinical Trial Application[61] to Health Canada's Health Products and Food Branch

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[59] For example, it is not possible to test an antidote on a human for a certain venomous snake bite, as it would be impossible to infect the human subjects with the poisonous venom and then test the antidote.
[60] Canada, Health Canada, Guidance Document: *Patented Medicines (Notice of Compliance) Regulations*, File 15-101151-734, February 3, 2015. This document clarifies provisions within the *Regulations*.
[61] *Supra* note 56, C.05.005.

Inspectorate for authorization to conduct clinical trials in humans, for establishing the effectiveness of a compound for specific indications. If granted, researchers conduct Phase I Clinical Trials, where the drug is given to small groups of people, often between twenty and eighty. The researchers gather preliminary data on the effectiveness of a drug for a specified disease or condition. They try to attain clinical results in the test subjects while maintaining a tolerable level of side effects. They also perform more safety evaluation by determining safe dose ranges and the toxicity of the drug, and evaluate it for potential interactions with other pharmaceuticals.

Following successful Phase I Clinical Trials, researchers file another Clinical Trial Application[62] and begin Phase II Clinical Trials, where the compound is given to larger groups of people, typically of one hundred to three hundred, who have the condition for which the drug is intended to treat. The larger studies are undertaken to confirm the compound's effectiveness, monitor its side effects, compare it to other treatments for the same condition, and establish safety guidelines for safe use by the public.

After successful Phase Two Clinical Trials, the researcher files another Clinical Trial Application for Phase III Clinical Trials, with the primary objective of establishing the efficacy of the new drug at differing dosages. Phase III Clinical Trials involve one thousand to three thousand subjects with the targeted medical condition, often in multiple study locations. Because of the large number of test subjects, there is a higher likelihood that adverse reactions will be observed amongst the subjects, which are documented.

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[62] *Supra* note 58. An application process is required for each type of clinical trial.

If the results at the end of Phase III still look promising, a "New Drug Submission" can be filed with the Health Products and Food Branch Inspectorate, which includes the data contained in the clinical and preclinical studies. The data is submitted in conjunction with information on how and where the drug will be produced. The submission is reviewed to evaluate the safety and efficacy of the drug. If the Health Products and Food Branch Inspectorate determine that the benefits of the drug outweigh its potential risks, the drug is issued a Notice of Compliance and a Drug Identification Number, which authorizes the manufacturer to produce and sell the drug in Canada.[63] Post marketing surveillance of the new drug by the manufacturer is also required to ensure the safety and effectiveness of the drug, even after it has been made available to the public.

Following the issuance of a Notice of Compliance and a Drug Identification Number, the drug company makes a decision as to whether it will market the drug product. If it decides to move forward, the company submits its product summary information to the Patented Medicines Prices Review Board,[64] which reviews the information and sets a price that is intended to reflect a balance among several factors, including the cost of developing the product, the size of the market for the drug, and the affordability of the drug to the consumer.

Following the establishment of a price, the drug company begins consultation with federal and provincial drug plans to establish coverage for the product. Following

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[63] The review period for a New Drug Application is typically two months to seven years, with an average of two years. *Supra* note 47 at 418.

[64] The Patented Medicines Prices Review Board was established in s 91 of the *Patent Act* through amendment in 1987. The mandate, composition, and rules of the Board are set out from s 79(1) to s 103 of the *Patent Act*.

discussions about the efficacy of the product and a comparison to existing treatments, listing and reimbursement decisions are made.

Following the discussion with drug plans, the company launches the product, making it accessible to the public. Upon the launch, the company provides extensive communications with physicians in accordance with the Notice of Compliance. Specifically, the information must stipulate: the patient population for whom the drug can be prescribed, the indications that the drug can treat, and the dosages that can be administered. After the launch, additional therapeutic monitoring and cost-effectiveness studies are performed, as well as adverse drug reaction monitoring, all of which contribute to future decisions by both government and company officials about the continued availability of the product.

Generic Drug Development

It is the Abbreviated New Drug Submission that is of primary concern in this thesis, as this is the process for getting approval to manufacture and sell generic medicines in Canada. This abbreviated submission process allows generic manufacturers to sidestep the safety and efficacy requirements involved in the New Drug Submission, only being required to demonstrate bioequivalence with the original product – it must be the same product, and it must provide the same level of drug in the bloodstream, within very narrow limits. It is the *Patented Medicines (Notice of Compliance) Regulations* which come into effect after the generic manufacturer has established bioequivalence and wishes to have the product approved for marketing. If patents remain on the innovative product, but the generic manufacturer feels that those patents are invalid or will not be

infringed upon, it can allege these claims against the innovator, and invoke the *Regulations*, which will be discussed after an introduction to patents.

Patenting and Innovation[65]

For any invention that meets the requirements outlined in the *Patent Act*,[66] a patent is granted to the inventor by the Canadian Intellectual Property Office. The patent allows the inventor, or the *owner* of the patent, an exclusive time period to manufacture, distribute, and sell the invention. In Canada, this exclusive period is twenty years from the date of filing an application to patent the invention.[67] In exchange for the monopoly, the inventor must disclose a full description of the patent so that the information is available for others to use as a stepping stone to further innovation.[68] With respect to medicines, the patent is granted for the advancement to medicine and health, in exchange for disclosure of the patent, so that others may take that advancement and improve upon it.

Section 2 of the *Patent Act* defines an invention as any "new and useful art, process, machine, manufacture, or composition of matter, or any new and useful improvement in any art, process, machine, manufacture, or composition of matter."[69] From this definition, four key requirements can be set forth for all patents: novelty, utility, non-obviousness, and patentable subject-matter.

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[65] For an introduction to patent theory and practice, consult David Vaver's *Intellectual Property Law: Copyright, Patents, Trademarks,* (2011), Toronto: Irwin Law. David Vaver is a professor of law, specializing in the field of intellectual property at Osgoode Law School of York University.
[66] *Patent Act*, RSC 1985, c P-4.
[67] *Ibid* at s 42, 44.
[68] This is known as the traditional patent bargain, which was first legislated in the *Statute of Monopolies*, 1623, 21 Jac 1, c 23 (Eng). Although the idea of bargaining a monopoly for disclosure of the invention has been around for centuries, it is extremely important in the modern economy, where many developed nations have transitioned from an industrial economic base to a knowledge-intensive economic base.
[69] *Supra* note 66, s 2.

Novelty

The first requirement, that the subject matter is new,[70] is met if the invention has not yet been disclosed to the public.[71] This requirement, known as novelty, means that the patent cannot have been previously disclosed in Canada or elsewhere. An invention that has been deemed to have been part of the prior art of a particular industry is not novel. Paragraph 28.2(1) states that

> The subject-matter, defined by a claim in an application for patent in Canada (the "pending application") must not have been disclosed
> (a) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;
> (b) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere;
> (c) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date;…[72]

This provision also provides a grace period of one year for manufacturers who disclose their invention to the public but have not yet filed the patent application.

With respect to pharmaceuticals, the patents in question are molecules that represent new compositions of matter. These molecules may represent an "active ingredient" that has an effect on the body, or they can represent new molecules that are important aids in making sure that the active ingredient works, or is delivered to its intended tissue in the body.

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[70] The *Patent Act*, s 27(4) states that the subject matter of the patent must be defined explicitly in the claims section of the patent. It is the written claims that make up the patent, not the visual descriptions.
[71] *Supra* note 66, s 28.2(1). The subject matter defined in the claims must not have been disclosed more than one year before the filing date.
[72] *Supra* note 66, s 28.2(1)(a)(b)(c).

Utility

The second requirement, that the invention be useful, means that the subject matter of the patent must have some utility or benefit to the public, and therefore achieves a purpose related to why it was invented. The patent must do what it promises, and following the claims outlined in the patent should set out the method for making the invention. Utility must be proven at the time of the application, or demonstrated by the doctrine of sound prediction. This is particularly relevant for pharmaceuticals, since demonstrating the utility of a new molecule for health purposes is difficult to do before significant safety and efficacy testing can take place. This testing can take years; without the doctrine of sound prediction, there would be no way to establish patent protection for the new molecule. The doctrine of sound prediction is not set out within the *Patent Act*, rather, it has developed through jurisprudence with three elements:

1) There must be a factual basis for the prediction;…
2) the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis;….
3) There must be proper disclosure…of why the invention works.[73]

The opportunity to supply a theory as to why the invention works is contentious, as it is difficult to assess the merits of the theory ahead of the data and testing required, making it fairly easy to satisfy the element of utility. But the utility satisfied for the grant of a patent has no bearing on subsequent challenges *to* that utility, as proceedings for impeaching patents that do not meet the patent criteria after more data is made available,

[73] *Apotex Inc. v Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 SCR 153 at para 70. In this case, Justice Binnie states that it is "generally not necessary for an inventor to provide a theory of *why* the invention works….In this sort of case, however, the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly."

are set out in Section 60 of the *Patent Act*, and can be instituted at any time.[74] This is particularly relevant to pharmaceutical patents, where data about the efficacy of a particular drug can only be determined after several years of testing on humans.[75]

Non-Obviousness

The third requirement is that the invention has a non-obvious step, as outlined in s. 28.3 of the *Patent Act*, which states that "[t]he subject-matter must not have been obvious on the claim date to a person skilled in the art or science to which it pertains,…"[76] This means that some ingenuity was not part of the prior art of the particular industrial discipline of the invention. An invention can only be deemed to have an inventive step (or be considered non-obvious) if a person skilled in the art related to the industry of the invention would not have predicted the solution or mechanism contained within that invention.[77] If "any fool could have done that,"[78] as asserted by Justice Jugessen in *Beloit Canada*, there is no inventive step involved in the invention.

Obviousness can be a difficult concept. It may be obvious, for example, that two plus two is four, but it is less obvious that changing one subgroup on a complicated molecule that has been granted a patent could lead to a *new* patent for the new molecule. There may have been some inventiveness in the chemical process for getting that new

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[74] *Supra* note 66, s 60(1).
[75] This happens in phase two and phase three clinical trials. In Phase two clinical trials, a new drug is given to a group of one hundred or more people to obtain some initial data on the effectiveness of the drug for a specified disease or condition. In phase three, the drug is given to larger groups of people, typically one thousand or more, to confirm its effectiveness and compare it to common treatments for that same indication.
[76] *Supra* note 66, s 28.3. "The subject-matter must not "have been obvious on the claim date to a person skilled in the art or science to which it pertains." This is also known as the inventive step requirement, and its interpretation has been confirmed by Canadian jurisprudence, including *Burton Parsons v Hewlett Packard (Canada) Ltd.*, [1976] 1 SCR 555.
[77] *Beecham Canada Ltd. v Proctor & Gamble Co.*, [1982] 61 CPR (2d) 7 (Can).
[78] *Beloit Canada Ltd. v Valmet Oy* (1986), 8 CPR (3d) 289 at 293 (FCA), [*Beloit Canada*].

subgroup on the molecule, but that chemical process may be well-known to other chemists who have applied it to other molecules. However, application of that chemical step in this particular case, may lead to a compound with a new use, which *should* be sufficient to meet the requirement of obviousness.

In *Apotex Inc. v Sanofi-Synthelabo Canada Inc.*,[79] Justice Rothstein summarized a four-step approach to determine obviousness:

> (1) (a) Identify the notional "person skilled in the art";
> (b) Identify the relevant common general knowledge of that person;
> (2) Identify the inventive concept of the claim in question or, if that cannot readily be done, construe it;
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?[80]

However, Justice Rothstein warned against using the four-step approach as a rigid test of obviousness, explaining that "in most matters in which a judge or a jury is called upon to make a factual determination, rigid rules are inappropriate unless mandated by statute."[81]

The test does squarely situate a medicinal chemist, organic chemist, or pharmaceutical chemist as a notional person skilled in the art of making novel molecular compounds as the person to which the test of obviousness must be applied, and it identifies a body of knowledge held by these specialists. The test also states that the inventive concept must be identified (if possible) and compared to the art that already exists within the knowledge of that group of specialists. At this point, any differences

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[79] *Supra* note 39, [*Sanofi-Synthelabo*].
[80] *Ibid* at para 67.
[81] *Ibid* at para 63, quoted in *Corlac Inc. et al v Weatherford Canada Ltd.*, 2011 FCA 228 (FCA per Layden-Stevenson JA, Nadon and Evans JJA concurring) at para 67.

with the inventive step to the existing art are evaluated to determine if they are significant enough to constitute an invention.

The fourth part of the test in *Sanofi-Synthelabo,* known as the obvious-to-try test, has been applied in subsequent pharmaceutical cases, notably *Eli Lilly Canada Inc. et al v Novopharm Limited*,[82] where Justice Layden-Stevenson, for the majority, states that "the 'obvious to try' inquiry will be appropriate in areas of endeavour where advances are often won by experimentation, such as in the pharmaceutical industry."[83] Justice Layden-Stevenson then references *Sanofi-Synthelabo* to identify factors to be taken into account when assessing whether or not something was worth a try:

1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that trials would not be considered routine?
3. Is there a motive provided in the prior art to find the solution the patent addresses?[84]

The obvious-to-try doctrine reigns-in pharmaceutical companies from creating a blanket of patents across a range of related synthesized molecules. Companies could apply a battery of processes to one molecule and patent thousands of molecules, based on the ordinary application of chemistry across the entire range, with the hopes that one or more molecule in the entire range holds promise. Obviousness, and the obvious-to-try doctrine puts limits on this.

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[82] 2010 FCA 197 at paras 54-64.
[83] *Ibid* at para 55.
[84] *Ibid*.

Patentable Subject Matter

The fourth requirement is that the invention be patentable subject matter. Section 27(8) of the *Patent Act* provides that "No patent shall be granted for any mere scientific principle or abstract theorem." In general, what constitutes patentable subject matter is defined by the five categories in the *Patent Act* definition in Section 2: "art, process, machine, manufacture, or composition of matter."[85] "Art" has been defined as "the application of knowledge to effect a desired result."[86] A process is "the application of a method to a material or materials."[87] A process may be patentable even though the process does not produce a product that is patentable.[88] A machine is defined as "the mechanical embodiment of any function or mode of operation designed to accomplish a particular effect."[89] Manufacture "implies a product made by hand, by machine, industrially, by mass production and so forth, by changing the character or condition of material objects."[90] A composition of matter has been defined "as a combination of ingredients – a solid, a gas, or fluid – as a chemical union or a physical mixture."[91] This definition has come to include lower life forms, such as cells, enzymes, and genes, but excludes multicellular organisms and higher life forms.[92]

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[85] *Supra* note 66, s 2.
[86] *Shell Oil Co v Commissioner of Patents*, [1962] 2 SCR 536.
[87] *Commissioner of Patents v Ciba Ltd.*, [1959] SCR 278 at 383.
[88] Canadian Intellectual Property Office, *Manual of Patent Office Practice* (1998 ed., updated to December 2010), c. 12.02.02.
[89] *Ibid* at c. 12.02.03.
[90] *Ibid* at c. 12.02.04. In *Harvard College v Canada (Commissioner of Patents)*, [2002] 4 SCR 45 at para 155, "manufacture" and "composition of matter" were not considered to encompass higher life forms. This was won by a narrow five to four majority.
[91] David Vaver, *Intellectual Property Law: Copyright, Patents, Trade-Marks*, 2nd ed (Toronto: Iriwn Law, 2011) at 294.
[92] Patenting, and the distinction between higher life forms and simple life forms has been adjudicated through *Harvard College v Canada (Commissioner of Patents)*, [2002] 4 SCR 45 and *Monsanto Canada Inc. v Schmeiser* [2004] 1 SCR 902, 2004 SCC 34.

Infringement versus Impeachment

Patent infringement is the act of using the patent of another person or organization without authorization - valid patents are given protection from this under the *Patent Act*.[93] Impeachment refers to the process of challenging an existing patent in Federal Court to have it declared void.[94] With parties involved in patent litigation, impeachment is often a counterclaim to an infringement claim, and vice versa.

Patent Litigation

Regardless of the underlying type of patent, a full dispute resolution mechanism is available for litigating the validity of a patent.[95] The majority of patent disputes at the Supreme Court arise through the Federal Court of Canada, with leave to appeal to the Federal Court of Appeal, followed by leave to appeal to the Supreme Court of Canada.[96] There is, however, no law forbidding a patent infringement or invalidity case from being initiated in any provincial jurisdiction. For example, in *Beauchesne v Roy*,[97] Mr. Beauchesne had a patent on a drill, but Mr. Marcotte was issued a patent for an improvement upon Mr. Beauchesne's patent. Mr. Marcotte started producing his drill, and Mr. Beauchesne sought an injunction to stop the production, since the drill infringed *his* patent. The Quebec Superior Court of Appeal held that the drill produced by Mr. Marcotte did infringe on Mr. Beauchesne's drill, since the Mr. Marcotte's patented

[93] *Supra* note 66, s 42 to s 46 covers the rights granted to a patent holder. Manufacturing, using, and selling a patented invention by someone other than the patent holder constitutes infringement.
[94] *Supra* note 66, s 60.
[95] As will be discussed in Chapter Four, an alternate dispute mechanism for assessing patent invalidity applies during the Abbreviated New Drug Submission process for generic pharmaceuticals under the Patented Medicines Notice of Compliance program. Judicial review abbreviates some of the elements of a full trial, and only assesses whether Health Canada acted reasonably when adding patents to the Patent Register.
[96] Patent disputes can originate in any provincial trial court but most often arise in the Federal Court of Canada.
[97] JQ 11598, [2007] QCCS 4601.

improvement did not allow him to infringe Mr. Beauchesne's patent, which was still in force. This case demonstrates that patent infringement suits can originate in provincial court.

Regardless of the court, the dispute is brought as a patent infringement action under Section 42 of the *Patent Act*, which establishes the rights of the patent holder:

> Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.[98]

After a decision at trial court is rendered, Section 63 of *The Patent Act* facilitates appeal at any provincial appellate court or at the Federal Court of Appeal:

> Every judgment voiding in whole or in part or refusing to void in whole or in part any patent is subject to appeal to any court having appellate jurisdiction in other cases decided by the court by which the judgment was rendered.[99]

Similarly, the *Federal Courts Act*, Section 27(1), indicates that there is wide scope for appealing a decision at the Federal Court:

> An appeal lies to the Federal Court of Appeal from any of the following decisions of the Federal Court:
> (*a*) a final judgment;
> (*b*) a judgment on a question of law determined before trial;
> (*c*) an interlocutory judgment; or
> (*d*) a determination on a reference made by a federal board, commission or other tribunal or the Attorney General of Canada. [100]

As opposed to patent infringement, a dispute may also arise over the granting of a patent by the Commissioner of Patents at the Canadian Intellectual Property Office, Division of

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[98] *Supra* note 66, s 42.
[99] *Supra* note 66, s 65.
[100] *Supra* note 54 at s 27(1).

Patents. If a dispute arises as a result of an applicant who is denied a patent claim by the Commissioner of Patents, the applicant files for action against the Commissioner in Federal Court, as outlined in the *Patent Act*, Section 17:

> In all cases where an appeal is provided from the decision of the Commissioner to the Federal Court under this Act, the appeal shall be had and taken pursuant to the *Federal Courts Act* and the rules and practice of that Court.[101]

The jurisdiction of the Federal Court is confirmed in Section 41:

> Every person who has failed to obtain a patent by reason of a refusal of the Commissioner to grant it may, at any time within six months after notice as provided for in section 40 has been mailed, appeal from the decision of the Commissioner to the Federal Court and that Court has exclusive jurisdiction to hear and determine the appeal.[102]

A patent decision by a provincial court of final instance or by the Federal Court of Appeal can be appealed to the Supreme Court of Canada under Section 40 (1) of the Supreme Court Act:

> …an appeal lies to the Supreme Court from any final or other judgment of the Federal Court of Appeal or of the highest court of final resort in a province, or a judge thereof, in which judgment can be had in the particular case sought to be appealed to the Supreme Court, whether or not leave to appeal to the Supreme Court has been refused by any other court, where, with respect to the particular case sought to be appealed, the Supreme Court is of the opinion that any question involved therein 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 that 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, and leave to appeal from that judgment is accordingly granted by the Supreme Court.[103]

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[101] *Supra* note 66 at s 17.
[102] *Supra* note 66 at s 41.
[103] *Supreme Court Act*, R.S., 1985, c. S-26, s 40.

Pharmaceutical Companies and Patent Litigation

When an innovative pharmaceutical company has an opportunity to oppose a decision about generic approval, it is understandable that it would choose to do so, resulting in a delay that extends the market life and profits of its branded product,[104]whether it be through its rights under the *Patent Act* or through the *Patented Medicines (Notice of Compliance) Regulations*. To understand the enormity of the litigation problem for generics under the current *Patented Medicines (Notice of Compliance) Regulations*,

> Apotex recently claimed that in the last 10 years, it has spent $800 million on litigation. Extrapolating from this to the other generic and brand firms, it appears that annual litigation costs relating to pharmaceuticals in Canada are in the hundreds of millions of dollars, chiefly for litigation between generic and brand name firms. Indeed, there are in order of 100 Federal Court cases each year involving pharmaceutical patents.[105]

According to Grootendorst and Hollis, "Apotex alone has been a party in 432 different cases considered by the Federal Court and the Federal Court of Appeal since 1997."[106]

Innovative pharmaceutical companies are so opposed to generic competition that they oppose subsequent challenges by follow-on generic companies *even after losing the initial challenge from the first generic company*. Such was the case with Sanofi-Aventis' blockbuster hypertension drug Altace (with the generic name of ramipril), with its novel

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[104] Research on the motives behind innovator drug companies' patenting strategies has been undertaken by Ron Bouchard, an associate professor of Law, Medicine, and Dentistry at the University of Alberta. He has written over twenty publications in the area of intellectual property, many of which specifically deal with pharmaceuticals, and the issues surrounding patent invalidity, expiry, and genericization. See, for example, Ron Bouchard et al, "Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals" (2010) 8(2) Nw J Tech & IP 174. In this essay, he concluded that extensive patenting combined with linkage regulations allow innovator companies to block the generic entry of pharmaceuticals in a timely manner.

[105] Paul Grootendorst & Aidan Hollis, "Managing Pharmaceutical Expenditure" (2011) Cdn Hlth Srv Rsch Fdn at note 5, p 12, online: http://www.cfhi-fcass.ca/SearchResultsNews/11-02-18/85553e6f-379f-47d7-8817-4056e69360b7.aspx

[106] *Ibid*.

angiotensin converting enzyme mechanism.[107] Sanofi lost its first challenge from generic manufacturer Apotex,[108] which filed Notices of Allegations against several of Sanofi's patents. Apotex was subsequently issued a Notice of Compliance to produce the drug. When three generic manufacturers followed suit and issued Notices of Allegation over Sanofi's same patents, Sanofi still defended its patents, even though they had been found to be invalid.[109]

The best evidence of the aggressive posture of innovative pharmaceutical companies toward the generic manufactures is that approximately one-half to two-thirds of the litigated pharmaceutical patents through the *Patented Medicines (Notice of Compliance) Regulations* are found to be invalid or not infringed.[110] By challenging these patents, generic manufacturers allow entry of a generic earlier than would otherwise occur. Lipitor (atorvastatin), a popular cholesterol-lowering drug, has patent expiry dates as late as 2022, but generic challenges to these patents resulted in generic alternatives twelve years before the expiry of the last patent.[111]

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[107] For a basic understanding of pharmacology, see Stan Bardal, *Applied Phramacology*, 2nd ed, 2011 (Toronto: Elsevier).
[108] *Sanofi-Aventis Canada Inc. v The Minister of Health, the Attorney General of Canada, and Apotex Inc.*, 2006 FC 1559.
[109] Sanofi-Aventis defended the allegations under the *Patented Medicines (Notice of Compliance) Regulations* against Laboratoire Riva, Pharmascience, and Novopharm (now known as Teva). The relevant cases are: *Sanofi-Aventis Canada Inc. v Novopharm Limited* 2006 FC 1135, *Sanofi-Aventis Canada Inc. v Laboratoire Riva Inc.* 2007 FC 532, *Sanofi-Aventis Canada Inc. v Pharmascience Inc.* 2008 FC 782.
[110] Paul Grootendorst and Aidan Hollis, "Drug Market Exclusivity in the EU and Canada: Problems with Norton Rose's Comparative Analysis," Canadian Generic Pharmaceutical Association: 2012 at 6. The data was extracted from: Health Canada Notice, "Release of the Therapeutic Products Directorate Statistical Report 2010 for the *Patented Medicines (Notice of Compliance) Regulations* and Data Protection," July 28, 2011. The figure of two-thirds is computed by dividing the number of dismissed PM(NOC) S.6 Prohibition Applications over the total number of S.6 Prohibition Applications. For the period of 2005 to 2010, 40 out of 61 applications were dismissed. An updated figure is available from Health Canada Notice, "Therapeutic Products Directorate Statistical Report 2014/2015," July 2015. Over the period of 2010 to July, 2015, 33 S.6 Prohibition Applications were granted while 27 were dismissed. This reduces the two thirds rejection rate to 45 percent.
[111] *Ibid*.

A History of Compulsory Licencing and the *Patented Medicines (Notice of Compliance) Regulations*

Regulatory approval and patent protection of pharmaceuticals remained distinct until 1993, governed independently by the *Food and Drugs Act* and the *Patent Act*. In 1993, the *Patented Medicines (Notice of Compliance) Regulations* linked the two regimes in order to expedite the approval process of generic pharmaceuticals. Prior to 1993, Canada had a compulsory licencing system through the *Patent Act*, where a generic manufacturer could apply for a licence to manufacture and sell a patented pharmaceutical product without the consent of the holder of the patent:

> (a) Where the invention is a process, to use the invention for the preparation or production of medicine, import any medicine in the preparation or production of which the invention has been used or sell any medicine in the preparation or production of which the invention has been used, or (b) where the invention is other than a process, to import, make, use or sell the invention for medicine or for the preparation or production of medicine….[112]

In exchange for a compulsory licence, the generic manufacture was required to pay a four percent royalty to the brand manufacturer for the duration of any patents covering the drug.[113] Criteria for issuing a compulsory licence were never specified, and the issuance of licences to generic manufacturers was routine. In 1984, the Government of Canada established the Eastman Commission,[114] which determined that almost 80 percent of applications for compulsory licences in Canada were granted between 1969 and 1983,[115] which meant that there was really very little patent protection available for

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[112] *Supra* note 66, s 39(4) [removed].
[113] Canada, Library of Parliament, Law and Government Division. *Patent Protection for Pharmaceutical Products in Canada – Chronology of Significant Events* by Margaret Smith. Ottawa: 2000 (Cat No PRB 99-64B), online: http://dsp-psd.pwgsc.gc.ca/Collection-R/LoPBdP/BP/prb9946-e.htm
[114] Canada, Commission of Inquiry on the Pharmaceutical Industry, *The Report of the Commission of Inquiry on the Pharmaceutical Industry* ("Eastman Commission"), Minister of Supply and Services, Ottawa, 1985.
[115] Colleen Chien, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?" (2003) 18 Berkeley Tech LJ 853 at 875. The Eastman Commission

innovative pharmaceuticals. It did, however, indicate that compulsory licencing contributed to the growth of the generic pharmaceutical industry in Canada, which saved consumers $211 million in 1983 on medicine sales totalling $1.6 billion.[116] In 1987, the government passed Bill C-22, *An Act to Amend the Patent Act and to Provide for Certain Matters in Relation Thereto*[117] in order to address the recommendations of the Eastman Commission. Bill C-22 amended the *Patent Act* to guarantee new drugs given a Notice of Compliance a minimum of ten years of exclusivity before compulsory licences could be issued to imported copies of the drug, and seven years of exclusivity after the issuance of a Notice of Compliance before compulsory licences could be issued to companies manufacturing that drug in Canada.[118] For drugs *invented* and manufactured in Canada, additional protection was granted, in that a compulsory licence could not be granted to an imported copy of that drug at all.[119] Under these circumstances, a compulsory licence could only be granted for seven years after the issuance of the Notice of Compliance if the inventor did not manufacture the drug in Canada *for the purpose of supplying the Canadian market*.[120]

Bill C-22 also balanced the increased level of patent protection afforded to patented medicines producers by introducing price controls through the creation of the Patented Medicines Prices Review Board (PMPRB). The board's mandate was to ensure that the prices of patented medicines do not become excessive by setting the maximum

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was established by the federal government in 1984 to make recommendations about the patenting of pharmaceuticals in Canada.

[116] *Supra* note 114, at xviii and 317.

[117] SC 1987, c41, [Bill C-22].

[118] *Ibid* at ss 39.11 and 39.14.

[119] *Ibid* at ss 39.16.

[120] *Ibid*.

price at which the patentee can sell the medicine, thereby balancing the additional patent protection afforded under the bill.

Compulsory Licencing and International Trade Agreements

Two major developments in international trade led to the eventual removal of compulsory licences from the *Patent Act*: the *North American Free Trade Agreement*, and the *Agreement on Trade-Related Aspects of Intellectual Property Rights*.[121] Through NAFTA, the governments of Canada, Mexico, and the United States agreed to "foster creativity and innovation, and promote trade in goods and services that are the subject of intellectual property rights."[122] In addition, one of the objectives of NAFTA was to "provide adequate and effective protection and enforcement of intellectual property rights in each Party's territory."[123] Article 1704 permits each country to specify in its domestic laws licencing measures to prevent or control "abuse of intellectual property rights having an adverse effect on competition."[124] The specifics of compulsory licencing are established in paragraph ten, Article 1709,[125] which set out the duration, scope, remuneration, and that the purpose for compulsory licencing must be only to supply the domestic market of the country in question.[126]

The *General Agreement on Tariffs and Trade* (GATT) was a multilateral trade agreement established in 1947 to reduce international trade barriers among United Nations member states.[127] The Marrakesh Agreement was the final round of negotiations

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[121] Article 27.1 of TRIPS reads "in part…patents shall be available and patent rights enjoyable without discrimination as to…whether products are imported or locally produced."
[122] *Supra* note 3 in preamble.
[123] *Supra* note 3, Ch 1, Art 102(d).
[124] *Supra* note 3, Ch 17, Art 1704.
[125] *Supra* note 3, Ch 17, Art 1709.10.
[126] *Supra* note 3, Ch 17, Art 1709.10(c), 1709.10(f), 1709.109(h). See Appendix One for the entirety of Article 1709.
[127] Oct 30, 1947, 55 UNTS 194; 61 Stat pt 5; TIAS No 1700.

of GATT, which established the World Trade Organization (WTO) as the forum for negotiating agreements, reducing trade obstacles, and settling trade disputes:[128]

> The WTO shall provide the common institutional framework for the conduct of trade relations among its Members in matters related to the agreements and associated legal instruments included in the Annexes to this Agreement.[129]

TRIPS, a comprehensive multilateral intellectual property agreement annexed to the Marrakesh agreement, requires that domestic laws of signatory countries meet minimum standards related to all aspects of intellectual property, including patents, trademarks, copyright, industrial design, geographical indicators, plant variety protection, integrated circuit protection, trade secrets, and test data.[130] Ratification of TRIPS is a prerequisite to WTO membership,[131] and all 153 member states have ratified the agreement, including Canada. In 1991, the then Director-General of the GATT, Arthur Dunkel, compiled the Draft Final Act for the conclusion of the Uruguay Round of the GATT, which also contained the draft agreement on TRIPS. The text created by Dunkel was endorsed by the federal government in 1992 when it signed TRIPS. The text of NAFTA was also finalized in Chapter 17, which was largely based on the text of the TRIPS Agreement. TRIPS Article 31, "Other Use Without Authorization of the Right Holder"[132] addresses compulsory licencing, and is almost identical to Article 1709.10 of NAFTA.

The text of Article 31 of TRIPS became available to the governments of the United States, Canada, and Mexico while negotiating NAFTA in 1991, which explains

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[128] *Marrakesh Agreement Establishing the World Trade Organization*, Apr 15, `994, 1867 UNTS 154; 33 ILM 1144 (1994), Annex J, Art 2.
[129] *Ibid*, Art II, para 1.
[130] *Supra* note 4, Part I and II.
[131] *Supra* note 128 at Art XXXIV. This article states that the annexes to GATT are an integral part of the agreement. TRIPs is contained in Annex 1C of GATT.
[132] *Supra* note 4, Art 31.

the similarity in the provisions in Chapter 17 of NAFTA, covering copyright, sound recordings, trademarks, and patents. As indicated by a member of the Canadian TRIPS and NAFTA negotiating teams, "NAFTA closely tracks the language of the 1991 Dunkel draft of the TRIPS negotiating text. Therefore, NAFTA's Chapter 17 and TRIPS generally are textually close enough to ensure that interpretations of the meaning of one would be directly relevant to the interpretation of the other. Findings of NAFTA panels regarding intellectual property issues may therefore powerfully influence TRIPS interpretation and vice versa."[133]

On January 1, 1994, legislation implementing NAFTA came into force in Canada.[134] On January 1, 1995, Canada became a member of TRIPS.[135] Because of the obligations in Chapter 17 of NAFTA and Article 31 in TRIPS, Canada removed almost all of its compulsory licencing provisions from Section 39 of the *Patent Act* through Bill C-91, *the Patent Act Amendment Act*.[136] Since both agreements prohibited the discrimination by field of technology, Bill C-91 removed all provisions related specifically to food and medicine,[137] and provisions related to discrimination based on imported or domestically manufactured goods were also removed in the *NAFTA Implementation Act*.[138] This eliminated the provisions related to compulsory licences in Bill C-22.

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[133] *Supra* note 5. *Canada – Patent Protection of Pharmaceutical Products – Complaint by the European Communities and their Member States – Report of the Panel*, March 17, 2000, WT/DS114/R footnote 29, citing Canada-United States Law Journal, Vol 23 (1997).
[134] *North American Free Trade Agreement Implementation Act*, SC 1993, c 44.
[135] *World Trade Organization Agreement Implementation Act*, 1994, c 47.
[136] S 39 was repealed in 1993.
[137] *Patent Act Amendment Act*, SC 1993, c 2, s 3.
[138] *Supra* note 134.

Without compulsory licencing, there was no legal mechanism for challenging the validity of patents on innovative pharmaceuticals before expiry, short of initiating patent impeachment actions, which would have raised the cost and extended the time for developing generics. By implementing the *Patented Medicines (Notice of Compliance) Regulations* in 1993, the premature marketing and sale of generics was blocked, but generic manufacturers were given an opportunity to challenge patent status on innovative pharmaceuticals in advance of the expiration of their patents. This is articulated through Health Canada's stated pharmaceutical patent policy objective, which is to "balance the effective patent enforcement over new and innovative drugs with the timely entry of their lower priced generic competitors."[139] This aim of balancing motivations was recognized by the judiciary in *Bristol-Myers Squibb Co. v Canada (Attorney General)*, where Justice Binnie stated that "it seems clear that the NOC regulations were introduced to help generic drug companies and at the same time to curb potential patent abuse by them."[140]

The *Patented Medicines (Notice of Compliance) Regulations* are consistent with the protection of patents in the *Patent Act*, as explained by Section 55.2(4) of the *Patent Act*:

> The Governor in Council may make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1), including, without limiting the generality of the foregoing regulations: (a) respecting the conditions that must be fulfilled before a notice, certificate, permit or other document concerning any product to which a patent may relate may be issued to a patentee or other person under any Act of

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[139] Canada, Regulatory Impact Analysis Statement, Canada Gazette, Part II, October 18, 2006.
[140] [2005] 1 SCR 533 at para 47. In *Bristol-Myers Squibb Co. v. Canada*, the court also stated that the compulsory licencing regime was abolished in favor of the *Patented Medicines (Notice of Compliance) Regulations* "in order to protect the right of patentees by preventing generic manufacturers from marketing their products until the expiry of all relevant patents." (para 46).

> Parliament that regulates the manufacture, construction, use or sale of that product in addition to any conditions provided for by or under that Act.[141]

This section indicates that the government can make additional regulations for preventing infringement, and the *Patented Medicines (Notice of Compliance) Regulations* were borne out of this possibility. The *Regulations* define the conditions under which an application for a generic drug will be approved for manufacture, sale, and distribution in Canada. Besides outlining the terms for approval when the patents on an innovative drug expires, it outlines the conditions for challenging existing patents on medicines that may not be valid or relevant to the drug that the generic manufacturer wishes to copy. The provisions of the *Patented Medicines (Notice of Compliance) Regulations* will be explained in Chapter Four.

[141] *Supra* note 66 at s 55.2(4).

Chapter Four: The Patented Medicines (Notice of Compliance) Regulations - Elements and Issues involving Health Law, Patent Law, and Judicial Review[142]

The *Patented Medicines (Notice of Compliance) Regulations* are the roadmap for the approval of generic pharmaceuticals in Canada. The *Regulations* provide for a Patent Register where all patents on approved medicines in Canada must be registered, and also provide the framework for generic manufacturers to challenge the validity or applicability of those patents, which may be unnecessarily holding up the genericization of a particular medicine. A discussion of judicial review, and how a challenge through the *Patented Medicines (Notice of Compliance) Regulations* operates within the framework of judicial review is essential to the analysis in Chapter Six, since the *Patented Medicines (Notice of Compliance)* cases will be compared directly to the copyright cases, which also arrived at the Supreme Court after judicial review. Finding a similar pattern of decision making could suggest that it is the judicial review process that is problematic, providing a cue for further investigation into its elements. A discussion of the potential shortcomings of judicial review within the context of the *Patented Medicines (Notice of Compliance) Regulations* will also ensue.

Section Four – Health Canada's Patent Register

Through Section 4(1) of the *Patented Medicines (Notice of Compliance) Regulations*, the Minister of Health has a duty to maintain a Patent Register, which lists all of the patents that have been deemed to be relevant to a particular innovative pharmaceutical approved for sale in Canada. Any new drug product going through the

[142] This walk-through as to how the provisions of the *Patented Medicines (Notice of Compliance) Regulations* operate specifically guides the reader through the process that would apply to a generic manufacturer who is submitting a new generic pharmaceutical, based on an existing innovative pharmaceutical in Canada.

approval process must submit its associated patents to the Minister of Health,[143] who decides which patents for a given pharmaceutical qualify and can therefore be listed on the Patent Register. The Minister has a duty to determine which patents should or should not get listed, as well as which should be removed, should a patent expire or be declared invalid by the court for a particular pharmaceutical. The patents listed on the Register are given protection under the *Patented Medicines (Notice of Compliance) Regulations* so that generic companies cannot legally use them before expiry or a successful challenge to their inclusion on the Register. To be included on the Register, the patents must be filed at the same time as the overall submission and be of appropriate subject matter. [144] The patentable subject matter can include claims for the medicine itself (which would the actual molecule, known as the active ingredient), structural variants of the molecule that arise during its synthesis,[145] novel dosage forms for carrying the medicine,[146] and the medical *uses* of the medicine.[147] All of these claims must be relevant to the drug product undergoing approval. [148]

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[143] The Office of Patented Medicines Liaison, a branch of the Therapeutics Products Directorate at Health Canada, is the organization that performs this function on behalf of the Minister of Health. The Therapeutics Product Directorate will be referred to as "the Minister" in this paper on occasion.
[144] Section 4(5) of the *Patented Medicines (Notice of Compliance) Regulations* requires all patents eligible for listing be submitted at the time the new drug submission is filed. Section 4(6) allows for the additions of relevant patents after the filing of the new drug submission if it is done within 30 days of granting.
[145] Structural variation of molecules are often called polymorphisms. Molecules group into crystals, and different chemical or physical treatment of a particular molecule can lead to different crystals (called polymorphs), with different characteristics. Some polymorphs may have therapeutic effects while others do not.
[146] Dosage forms include suspensions, solutions (where one drug is dissolved in a liquid) tablets or capsules (oral solid dosage forms), tinctures (drugs dissolved in alcohol), and injections. Dosage forms aid in delivering a drug to its intended site of action in the body. They can meet the conditions for patent.
[147] *Supra* note 1, s 2. See the definition of "claims" in this section of the *Patented Medicines (Notice of Compliance) Regulations.*
[148] See *Ratiopharm v Wyeth*, 2007 FC 340, [2007] FCJ 462. This case affirmed that listed patents must be relevant to the drug product in question by citing Section 55.2(4) of the *Patent Act* (see p.14): the scope of the *Patented Medicines (Notice of Compliance) Regulations* can be interpreted to include *relevant* patents under its jurisdiction.

Section Five – Filing Notices of Allegation

Section Five of the Regulations requires that a manufacturer making an Abbreviated New Drug Submission for a generic medicine address the patents for the innovative pharmaceutical on the Patent Register. The generic manufacturer must either wait for the patents on the innovator product to expire before getting a Notice of Compliance[149] or allege that 1) the innovator's patents are invalid, 2) the innovator's patents are improperly included on the Patent Register, or 3) the innovator's patents will not be infringed by the generic manufacturer.[150] The section requires the generic manufacturer to address each relevant patent on the Patent Register and send separate Notices of Allegation to the innovator that outline the factual and legal details of each patent improperly listed.[151]

Section Six – Order of Prohibition Application and the Twenty-Four Month Stay

The innovator must respond to the allegations within forty-five days of receipt of the Notices of Allegation.[152] The innovator can accept the allegations, in which case a Notice of Compliance will issue to the generic company, allowing them to manufacture and sell the generic drug. But the innovator company usually commences an application for an Order of Prohibition in Federal Court to stop the Minister of Health from issuing a Notice of Compliance to the generic manufacturer.[153] When it is filed, a twenty-four month stay is automatically granted,[154] prohibiting the Minister of Health from issuing a Notice of Compliance within this period, unless the court decides in favour of the generic

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[149] *Supra* note 1, s (5)(1)(a).
[150] Summarized from *Patented Medicines (Notice of Compliance) Regulations*, *supra* note 1, SOR/93-133, S(5)(1)(b).
[151] *Supra* note 1, s (5)(3). Allegations for separate patents each require a separate Notice of Allegation.
[152] *Supra* note 1, s (6)(1).
[153] *Ibid*.
[154] *Supra* note 1, s (7)(1)(e).

company in the meantime, or the patents expire before the end of the stay.[155] Therefore, filing for the Order of Prohibition operates as an automatic injunction to stop the approval of the generic.[156] If the summary proceedings has not been completed within twenty-four months, the Minister is free to issue the Notice of Compliance.[157]

Section 7 – Conditions for Issuing a Notice of Compliance

Section 7 outlines the conditions that allow a Notice of Compliance to be issued, which include the expiration of the relevant patents, and the declaration of registered patents as being invalid or non-infringed. If approval is achieved through the *Patented Medicines (Notice of Compliance) Regulations*, a Notice of Compliance is issued, which allows for the manufacture, distribution, and sale of the pharmaceutical product in Canada.

Section 8 - Damages

Section 8 specifies damages awarded to generics if a judicial review is lost by an innovator company on appeal by a generic. The amount of damages is computed from the point in time when the generic could have been introduced into the market, if the innovator had not challenged the generic manufacturer's allegations.

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[155] *Supra* note 1, s (7)(2)(a).

[156] Noted by Binnie J., *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, 1 SCR 553 (citing *Merck Canada Inc. v Canada (Minister of National Health and Welfare)*, (1998) 2 SCR 193, (1998) 80 CPR (3d) 368 at para 33):

> …under this procedure the court hearing the prohibition application has no discretion to lift the stay even if it thinks the innovator's case for interim relief is weak. Nor does the court have any discretion to leave the contending parties to their remedies under the Patent Act. The 'second person's' application for a NOC simply goes into a deep-freeze until the statutory procedures have played themselves out.

[157] *Supra* note 1, s (7)(1)(e).

Litigation Following the Notice of Allegation

Proceeding in a Summary Way

Once the innovator files the application for an Order of Prohibition, the twenty-four-month stay is granted, and all ensuing litigation proceeds by way of judicial review through the Federal Court. Section 18.1(2) of the *Federal Courts Act*[158] facilitates the commencement of the judicial review process:

> An application for judicial review in respect of a decision or an order of a federal board, commission or other tribunal shall be made within 30 days after the time the decision or order was first communicated by the federal board, commission or other tribunal to the office of the Deputy Attorney General of Canada or to the party directly affected by it….[159]

Rule 300(a) of the *Federal Court Rules* directs that all applications for judicial review are subject to the rules in Part 5 of the *Federal Court Rules*.[160] Therefore, all applications for judicial review in questions arising from the *Patented Medicines (Notice of Compliance) Regulations* are subject to Part 5, Rules 300 to 334. Rule 300(b) reaffirms that "proceedings required or permitted by or under an Act of *Parliament* to be brought by application, motion, originating notice of motion, originating summons or petition are to be determined in a summary way…."[161]

Judicial Review Answers One Question Only

Rule 302 of the *Federal Court Rules* states that a judicial review is limited to a single order. This reaffirms that the purpose of the review is to determine *if the Minister shall be prohibited from granting the Notice of Compliance to the generic* and it therefore

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[158] *Federal Courts Act*, *Supra* note 54, s 18.1(2).
[159] The first mover, the innovator company, has thirty days to apply for judicial review under the *Federal Courts Act*, but has 45 days to respond to the Notice of Allegation under Section 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*.
[160] *Federal Court Rules*, *supra* note 55, s 300(a).
[161] *Ibid* at 300(b).

cannot be a determination of patent infringement or invalidity, as this would amount to a second and different order. Rule 302 promotes expediency in the process but it is the inability to adjudicate the validity of the patents combined with the abbreviated process of judicial review that creates the perception that the rules allow Canada to sidestep its international obligations under TRIPs and NAFTA.

In this context, judicial review focuses on the reasonableness of the Minister of Health in registering the innovator's patents on the Patent Register in light of the evidence from both sides. The Federal Court of Appeal confirmed that patent validity cannot be adjudicated during this process in *Merck Frosst v Minister of National Health and Welfare*.[162] The court appeared to also be somewhat mystified by the legislation, stating that the drafters must have "had in mind the possibility of there being a parallel proceeding instituted by the [generic] which might give rise to such a declaration and be binding on the parties."[163]

Presumption of Truth of the Allegations

Section 6(2) of the *Patented Medicines (Notice of Compliance) Regulations* states that "the court shall make an order pursuant to subsection [6](1) in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified."[164] Therefore, the allegations made by the generic applicant are presumed to be true until the innovator company proves otherwise, in which case the Notice of

[162] *Merck Frosst v. Minister of National Health and Welfare*, [1994] FCJ 662, (1994) 55 CPR (3d) 302 at para 23.
[163] *Ibid*. s 60 of the *Patent Act* still allows generic company to institute an action for impeachment if it feels that patents granted on the brand name pharmaceutical are invalid, so a parallel process is in place.
[164] *Supra* note 1, s 6(2).

Compliance will not be granted.[165] If the innovator cannot cast doubt on the allegations, the Minister is obliged to issue the Notice of Compliance.

Judicial Review – Reading the Evidence

Since the review proceeds summarily, both sides submit evidence, briefs, statements by expert witnesses, and cross examinations of those witnesses, with respect to the particular allegations of the generic company. The judge examines the written material, hears oral summary arguments, then renders a decision on whether or not the Minister acted reasonably when he added the patents to the Patent Register.

Hatch-Waxman Legislation in the United States – a Comparison to the *Patented Medicines (Notice of Compliance) Regulations*

Linkage regulations in the United States existed for nearly ten years before they did in Canada. In 1984, the United States passed the *Drug Price Competition and Patent Term Restoration Act*, also known as the *Hatch-Waxman Act.*[166] This legislation is similar to the *Patented Medicines (Notice of Compliance) Regulations* in that both provide a linked process for the expeditious approval of generic pharmaceuticals. Similar to the Canadian system, the generic applicant files an Abbreviated New Drug Application, where the applicant only must demonstrate bioequivalence to the branded product. Like the corresponding Canadian regulations, all of the safety and efficacy data provided by the manufacturer of the innovative pharmaceutical is relied upon, which greatly reduces the cost of the approval process. Also like the Canadian process, the *Hatch-Waxman Act* requires the generic manufacturer to address all of the patents for a

[165] See *Pfizer v Minister of Health*, 2008 FC 11 for judicial verification of the presumption of validity in Notice of Compliance proceedings.
[166] *Supra* note 13. Recall that this legislation is incorporated into 21 *United States Code*, §355(j), the *Federal Food, Drug, and Cosmetic Act*, 21 USC(1994).

particular innovative pharmaceutical, which are listed in the United States' Food and Drug Administration's "Orange Book."[167] The generic manufacturer must specify for each patent that: 1) the patent has expired, 2) the patent will expire before the generic is approved, 3) the patent has not been filed, or 4) the patent is invalid or will not be infringed by the generic manufacturer's actions. The generic manufacturer must submit an opinion to the patent holder, called a Paragraph IV Certification, as to the legal and factual reasons why certain patents are invalid, or will not be infringed.

When an Abbreviated New Drug Application is filed with a Paragraph IV Certification, the generic applicant is deemed to have infringed the innovator company's patents, giving it a cause of action for patent infringement.[168] The innovator has 45 days from the receipt of the Paragraph IV Certification to file an action for infringement.[169] Once the action is filed, the Abbreviated New Drug Application is automatically stayed for thirty months, unless the patents expire in the meantime, or judgment is passed in the action to deem the patents invalid or non-infringed.[170]

Since the litigation for infringement is an action, adjudication over the validity of the patents is made according to the rules established in the *United States Patents Act*. This highlights the key differences between the *Patented Medicines (Notice of*

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[167] For any particular innovative pharmaceutical, the Orange Book lists patents for the active ingredient, the formulation of the innovator's product, and the approved indication. Patents for processes, packaging, metabolites, and intermediates are not listed. The Food and Drug Administration lists the patents in the Orange Book, but makes no determinations as to whether the patents should be listed or not. This is outlined in 59 Fed Reg 50338, 50345 (Oct 3, 1994). This highlights the different roles of the Federal Drug Administration and the Office of Patented Medicines Liaison (as part of the Therapeutics Products Directorate of Health Canada) with respect to evaluating the patents listed, which could be a topic for future research. Recall that Section Four of the *Patented Medicines (Notice of Compliance) Regulations* lists criteria for inclusion on the Patent Register in Canada.

[168] *Patents*, 35 USC §271(e)(2)(A)(2006).

[169] *Ibid*, §271(5).

[170] *Supra* note 166, 21 USC §355(j)(5)(B)(iii)(1994).

Compliance) Regulations and the *Hatch-Waxman Act*: the *Hatch-Waxman Act* links generic market approval and patent validity by incorporating the process of infringement proceedings under the *Patent Act*, whereas the *Patented Medicines (Notice of Compliance) Regulations* only review whether or not Health Canada acted reasonably in including the innovator's patents on the Patent Register. The infringement action incorporated into the *Hatch-Waxman Act* provides both parties with the opportunity for full discovery, including the examination and cross examination of witnesses in person. It provides a binding court decision that affords equal rights of appeal for both the innovator and the generic company, but the legislation still allows the Food and Drug Administration to issue permission to market the product before an appeal.[171] The litigation is streamlined compared to that in Canada, in that there is no secondary litigation process beyond the action and an appeal. In Canada, judicial review can always be followed by a separate action for infringement. This can lead to a *perception* that the judicial review process is ineffective, because it is, indeed, inconclusive on the issue of patent validity.

Length of Proceedings: Actions take longer than Summary Proceedings

Seeing that the average time to complete a judicial review is fourteen months,[172] it is unlikely that a full determination of infringement or invalidity could be finalized within this time period, making the abbreviated process of judicial review advantageous. In the

[171] *Supra* note 166, 21 USC §355(j)(4). This automatic approval process is similar to Section 7(e) of the *Patented Medicines (Notice of Compliance) Regulations*, discussed earlier.
[172] Canada, Health Canada, Office of Submissions and Intellectual Property, "Therapeutic Products Directorate Statistical Report 2013/2014," File 14-1083555-86, Jul 2014, online: http://www.hc-sc.gc.ca/dhp-mps/pubs/drug-medic/patmrep_mbrevrap_2013-eng.php

United States, a thirty-month stay period is granted[173] for infringement actions, but that period is often exceeded,[174] so it is reasonable to expect that actions at the Federal Court in Canada would also take considerable time. The complexities of a trial necessarily slow its progression.

The current judicial review process affords several provisions related to expediting the process in Part 5 of the *Federal Court Rules*: [175]

1. … an application for judicial review shall be limited to a single order in respect of which relief is sought.[176]
2. …within 10 days after the issuance of a notice of application, the applicant shall serve it on (a) all respondents.[177]
3. A respondent who intends to appear in respect of an application shall, within ten days of being served with a notice of application, serve and file a notice of appearance in Form 305.[178]
4. Within 30 days after issuance of a notice of application, an applicant shall serve its supporting affidavits and documentary exhibits and file proof of service….[179]
5. Within 30 days after service of the applicant's affidavits, a respondent shall serve its supporting affidavits and documentary exhibits and shall file proof of service….[180]
6. Cross examinations on affidavits must be completed by all parties within 20 days after the filing of the respondent's affidavits….[181]
7. An applicant shall serve and file the applicant's record within 20 days after the day on which the parties' cross-examinations are completed or within 20 days after the day on which the time for those cross-examinations is expired, whichever day is earlier.[182]

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[173] *Supra* note 166, §355(j)(5)(B)(iii)(1994). The Food and Drug approval of the generic's submission is automatically stayed for the earlier of thirty months, the expiration of the relevant patents, or a judicial determination of invalidity or non-infringement.
[174] Patrick Smith and Frederick H. Rein, "A Discussion of Generic Drug Approval and Patent Systems in the United States and Canada" (2009) 25: Cdn Intel Prop Rev 83.
[175] *Supra* note 55 at 302 to 309.
[176] *Ibid*, s 302.
[177] *Ibid*, s 304.
[178] *Ibid*, s 305.
[179] *Ibid*, s 306.
[180] *Ibid*, s 307.
[181] *Ibid*, s 308.
[182] *Ibid*, s 309(1).

Therefore, the rules in Part 5 set out specific time frames in order to keep the judicial review process moving along efficiently. For actions initiated in Federal Court, the rules in Part 4 of the *Federal Court Rules* apply, and have similar timelines established in Regulations 203 to 207,[183] but because the proceedings include a trial, the rules are more extensive, covering the pleadings, rules for the statement of claim, rules for counterclaim, preliminary objections, motion rules, discovery, evidence rules, expert witness rules, and trial rules. Undoubtedly, pursuing a trial, with discovery and live witnesses will increase the time for adjudication. In addition, an action can encompass a complete statement of claim *for infringement* and a counterclaim *for impeachment*, so there can be multiple issues during the trial, lengthening the process. In contrast, the judicial review process adjudicates one question only, that being the reasonableness of the decision made by Health Canada to list the innovator's patents on the Patent Register.[184] Switching to an infringement action would therefore require a lengthening of the prohibition time from twenty-four months to thirty months, as under *Hatch-Waxman*, or to some length of time that fits with the expected duration of the trial.[185]

The *Patented Medicines (Notice of Compliance) Regulations* and the Agreement on *Trade-Related Aspects of Intellectual Property*

As a signatory to the *Trade-Related Aspects of Intellectual Property Agreement*,[186] Canada is obliged to comply with the protection given to patent holders under the agreement. The complaint brought forward by the European Communities and

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[183] *Ibid*, s 203 to 207.
[184] *Federal Court Rules*, *supra* note 55 at S 302, and *Merck Frosst v Minister of National Health and Welfare*, *supra* note 162.
[185] See Appendix Four for an overview of how proceedings under the *Patented Medicines (Notice of Compliance) Regulations* could have proceeded by way of an action instead of judicial review.
[186] *Supra* note 4, [TRIPS].

their Member States in 1997[187] alleged that Canada's *Patented Medicines (Notice of Compliance) Regulations* do not provide adequate protection for patent holders, since the legislation provided an opportunity for generic manufacturers to challenge a patent holder's rights through the judicial review process, which, as mentioned, does not encompass a full action, and has unequal appeal rights. The European Union alleged that the imposition of these *Regulations* meant that holders of pharmaceutical patents were treated less favourably than patent holders in other industries. Through the abbreviated process of judicial review, a generic manufacturer could be issued a Notice of Compliance, even though the patent holder still has patent rights conferred under the *Patent Act*. The European Member States stated that the rules that allowed Canada to treat pharmaceutical patent holders less favourably than patent holders in other industries, and was therefore in violation of Article 27.1, which states that

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[188]

However, the opposite view of Canada's *Patented Medicines (Notice of Compliance) Regulations* was taken by Canada – the *Patented Medicines (Notice of Compliance) Regulations* provide additional protection of the patent holder's rights for the term of the patent, and only allow for a Notice of Compliance of a generic challenger

[187] *Supra* note 5. The panel did rule on the issue of the abbreviated process, but the primary recommendations were related to the experimental and regulatory use exemption and the stockpiling provisions. The experimental use provision allows competitors of patents to begin developing the competitive product before the expiration of the patents. The stockpiling provisions allow a generic manufacturer to manufacture and stockpile inventory of a generic medicine, but not sell it until the relevant patents expire.

[188] *Supra* note 4 at art 27.1.

if it has been reasonably determined that the patents held were not applicable to the original drug product. The World Trade Organization decision panel agreed, stating

> In further examining the Canadian laws currently in force, one could see that they even went beyond the TRIPS Agreement by protecting, in addition, the rights of pharmaceutical patent holders through the *Patented Medicines (Notice of Compliance) Regulations*, which ensured and enhanced the realization of the exclusive rights during the term of the patent.[189]

Despite the report of the panel, Canada could adjust the *Regulations* to be similar to *Hatch-Waxman*, where the infringement action is automatically triggered when the Notices of Allegation are filed, as this would make Canada's linkage laws align with *Hatch-Waxman*, preventing future conflict. However, complaints about the process are not necessarily warranted. Judges review the cases and determine if Health Canada acted appropriately when it decided to disallow certain patents to hold up the generic approval process, and there is no clear evidence that this cannot be done accurately, and separately, from assessing infringement.[190]

Burden of Proof in a Summary Proceedings

The burden of proof is the onus on one litigant to establish the merits of the case brought to the court. The burden of proof for refuting the allegations made by the generic company about the invalidity of the innovator's patents is borne by the party that brought the application for an Order of Prohibition, which is the patent holder, who becomes the "mover" or the "first person."

The burden is established in Rule 301(e) of the *Federal Court Rule*s, which states that the applicant must include with its application "a complete and concise statement of

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[189] *Supra* note 5 at p 116.

[190] As discussed, further research on the decision making patterns of these cases at the Federal Court may provide insight into whether or not this is problematic, but there are potentially thousands of cases.

the grounds intended to be argued, including a reference to any statutory provision or rule to be relied on."[191] This was affirmed in *Frosst Canada Inc. et al v Canada (Minister of National Health and Welfare)*,[192] that a party moving under Section 6 of the *Patented Medicines (Notice of Compliance) Regulations* was judged to bear the burden of proof in the proceedings. At the commencement of the proceedings, the judge therefore presumes that the allegations made by the generic about patent invalidity are true (as discussed above), and the patent holder must demonstrate, on the balance of probabilities, that the allegations in the Notices of Allegation are not justified. Therefore, the patent holder bears the legal burden of establishing why his patents are valid by directing arguments against the allegations in the Notices of Allegation. The filer of the Notices of Allegation, the generic company, holds the evidential burden, which is the provision of evidence of patent invalidity in that notice. In *Hoffman-La Roche Ltd. v Canada (Minister of National Health and Welfare)*, the Federal Court of Appeal summarized the burden of proof:

> The initial burden of proof is known, in a civil case, as the persuasive burden or the legal burden and it is the burden of establishing a case to the civil standard of proof. By contrast, the evidential burden consists of a burden of putting an issue in play and means that a party has the responsibility to ensure that there is sufficient evidence of the existence or non-existence of a fact or an issue on the record to pass the threshold for that particular fact or issue.[193]

This affirms that the generic company produces the evidence of invalidity or non-infringement, while the innovator company bears the legal burden to refute the evidence

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[191] *Supra* note 55, s 301(e). According to David Tait, a lawyer who specializes in patent litigation with McCarthy Tétrault, the Notice of Allegation often just states that the patents are invalid, with no details, leaving the innovator company to establish a broader defence of its patents.
[192] *Supra* note 162, at para 23.
[193] [1996] FCJ 1333, [1996] 70 CPR (3d) 206 at para 8.

in a judicial review. The generic manufacturer would bear a legal burden for a separate action where the innovator is claiming *infringement* in a patent action, *but not in this case*, where it is applying for a judicial review under the *Patented Medicines (Notice of Compliance) Regulations*. This is the statutory burden of proof created in the *Federal Court Rules*, section 301(e).

If the legislation was instead drafted to be an infringement action, the generic manufacturer would be deemed to have infringed, and therefore bear the legal burden, consistent with the rules for an action and Canada's *Patent Act*. The presumption of validity in section 43(2) of the *Patent Act*, states that "After the patent is issued, it shall, in the absence of any evidence to the contrary, be valid and avail the patent holder and the legal representatives of the patent holder for the term mentioned in section 44 or 45, whichever is applicable."[194] The *Patented Medicines (Notice of Compliance) Regulations* reverse this onus, so that the patent holder defends its previously issued patents.

Judicial Review – the Standard of Review

The judicial review process is a summary proceeding which operates to oversee areas of administrative law, like decisions to list patents on the Patent Register, made by the Therapeutic Products Directorate's Office of Patented Medicines Liaison (a branch of the Therapeutic Products Directorate of Health Canada). The judge renders a decision, whether on the balance of probabilities, the allegations are justified. The innovator attempts to demonstrate that Health Canada acted reasonably when it decided to include

[194]*Supra* note 66, s 43(2).

the patents on the Patent Register, making the allegations of the generic manufacturer *unreasonable.*

The standard of review under the original *Patented Medicines (Notice of Compliance) R*egulations was "patent and reasonable." The determination of the standard of review of patent and reasonableness or correctness in a judicial review of a Notice of Compliance application was affirmed in *Ferring Inc. v Canada (Minister of Health),*[195] where the Court determined that the standard of review was correctness for questions of law, and patent and reasonableness for questions of fact, referring to *Astra-Zeneca Canada Inc. v Canada (Minister of Health)*.[196] Where there was mixed questions of law and fact, Richard C.J. stated that "the standard of review is patent and reasonableness unless the question of law is extricable from the question of fact in which case the question of law is determined on the basis of correctness."[197] Since legal rules were being applied to factual evidence regarding patents on the Patent Register, the standard of review was appropriately patent and reasonable.

Decisions made by way of judicial review, where the standard of review was deemed to be patent and reasonable, was changed to "reasonableness" by *Dunsmuir v New Brunswick*.[198] *Pharmascience Inc. v Canada (Attorney General)* affirmed the applicability of the standard of review for new drug submissions under the *Patented Medicines (Notice of Compliance) Regulations*:

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[195] [2007] FCA 276, [2007] FCJ 1138.
[196] [2004] FC 1277, at para 33.
[197] *Ibid* at para 7, 8.
[198] The test for reasonableness is described in *Dunsmuir v New Brunswick*, [2008] 1 SCR 190, 2008 SCC 9 at 47. Three of the six *Patented Medicines (Notice of Compliance)* cases had been decided by the time the standard was changed. Addressing the impact of the change on the cases may be a point for future research.

> A decision by the Minister of Health to accept or reject a new drug submission is a question of mixed fact and law. Accordingly, such a decision will be reviewed on the standard of reasonableness, where the issues involve both fact and law.[199]

This affirmed that the judge conducting a judicial review over the issuance of a Notice of Compliance to a generic manufacturer gives the Office of Patented Medicines Liaison significant deference when making a decision about including patents on the Patent Register. If the allegation by the generic company involves patent invalidity, the judge may in fact consider evidence in relation to the *Patent Act* as well as patent jurisprudence to decide the validity of patent claims, but the judgment will fall short of assessing actual patent infringement, which can only be determined through an infringement proceeding under the regular trial process, where the standard of review is correctness. Therefore, the standard of reasonableness applies to applications for judicial review of decisions to grant a Notice of Compliance, where deference is given to the Minister's decision for inclusion on the Patent Register. An actual determination of patent validity would occur under the standard of review of correctness.

In *Abbott Laboratories Limited v Attorney General of Canada (Minister of Health)*, Justice Hughes confirmed the standard of review:

> Given that we are in a post-*Dunsmuir* environment, a standard of patent unreasonableness no longer can apply. However, on the standard of reasonableness, considerable deference still should be given to decisions of the Minister where the questions are those of mixed fact and law as well as those of fact alone.
> In summary:
> 1. Patent claim construction is a matter of law to be reviewed on a standard of correctness.
> 2. The uses approved by the existing Notice of Compliance are questions of fact and are to be reviewed on this basis of reasonableness with considerable deference given to the Minister's decision.
> 3. The consideration as to how the uses claimed in the patent compare with those approved by the Notice of Compliance for purposes of section 4(2)(d) of the

[199] *Pharmascience Inc. v. Canada (Attorney General)* 2008 FCA 258, [2008] FCJ 1269 at para 5.

> *Notice of Compliance Regulations* involves mixed fact and law and considerable deference should be given to the Minister's decision.[200]

The applicability of reasonableness as the standard of review meshes with the determinations that are made by the Office of Patented Medicines Liaison at Health Canada. Since Health Canada is determining the suitability of medicines for treating specific diseases, it is Health Canada, as the evaluator of the facts that will allow the use of the medicine for specific conditions, and its personnel have the appropriate background for doing so. Even though the patents involved claim a use (usually based on the doctrine of sound prediction), the *actual use* becomes the medical conditions for which the medication is approved by Health Canada, and upon which the Notice of Compliance is issued to the innovator. It is therefore the factual evidence provided in support of that *actual use, applied to those particular patents upon which the approved clinical use is based* that becomes the decision making points for Health Canada in determining whether a patent should be listed on the Patent Register.[201] It is not making outright determinations of patent validity, which makes the judicial review process suitable.

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[200] *Abbott Laboratories v Canada (Minister of Health)*, (2008) FC 700, [2007] FCJ 543. Section 4(2)(d) states that "A patent on a patent list in relation to a new drug submission is eligible to be added to the register if the patent contains…(d) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission."

[201] When innovator pharmaceutical companies apply for patents on drug molecules, they have a theory and some empirical evidence from experimentation as to what health problem the molecule will treat, but they often do not have specific evidence, since all research at this point is at the molecular level. Allowing for such utility is accomplished through the *doctrine of sound prediction*, where the patent applicant is allowed to "soundly predict" what the utility of the molecule may potentially be. When patents are to be added to Health Canada's Patent Register, the uses claimed must relate to the official therapeutic uses claimed in the application for a Notice of Compliance.

Rights of Appeal

If a patent holder loses the judicial review at the Federal Court, the Notice of Compliance is granted, and there is no chance of an *effective* appeal for the patent holder, as the Minister of Health must issue the Notice of Compliance to the generic company through Section 7(2)(b), which states that the Minister must not withhold a Notice of Compliance if the court has declared that the patents are not valid, or would not be infringed. If the allegations are dismissed, the generic company has the right to appeal the decision to the Federal Court of Appeal for further judicial review, and possibly to the Supreme Court of Canada.[202]

Even if a patent holder has an unfavorable judgment from the judicial review, it does not stop the patent holder from filing a separate action for infringement. At this point, however, the generic company is not prohibited from selling the generic drug, and the patent holder suffers a massive erosion in the market share of its innovative drug[203] because of the price difference. It may also be difficult for the patent holder to get an injunction to stop the sale of the generic, since the judge will know that the summary proceedings determined that the patents should not have been registered on the Patent Register administered by Health Canada. Therefore, the judge may refrain from forming an opinion and making an injunction. This loss of an effective appeal also differentiates

[202] The cases emanating from *Patented Medicines (Notice of Compliance) Regulations* heard at the Supreme Court of Canada were listed in Table One, Chapter One. A qualitative analysis of the cases is presented in Chapter Six.

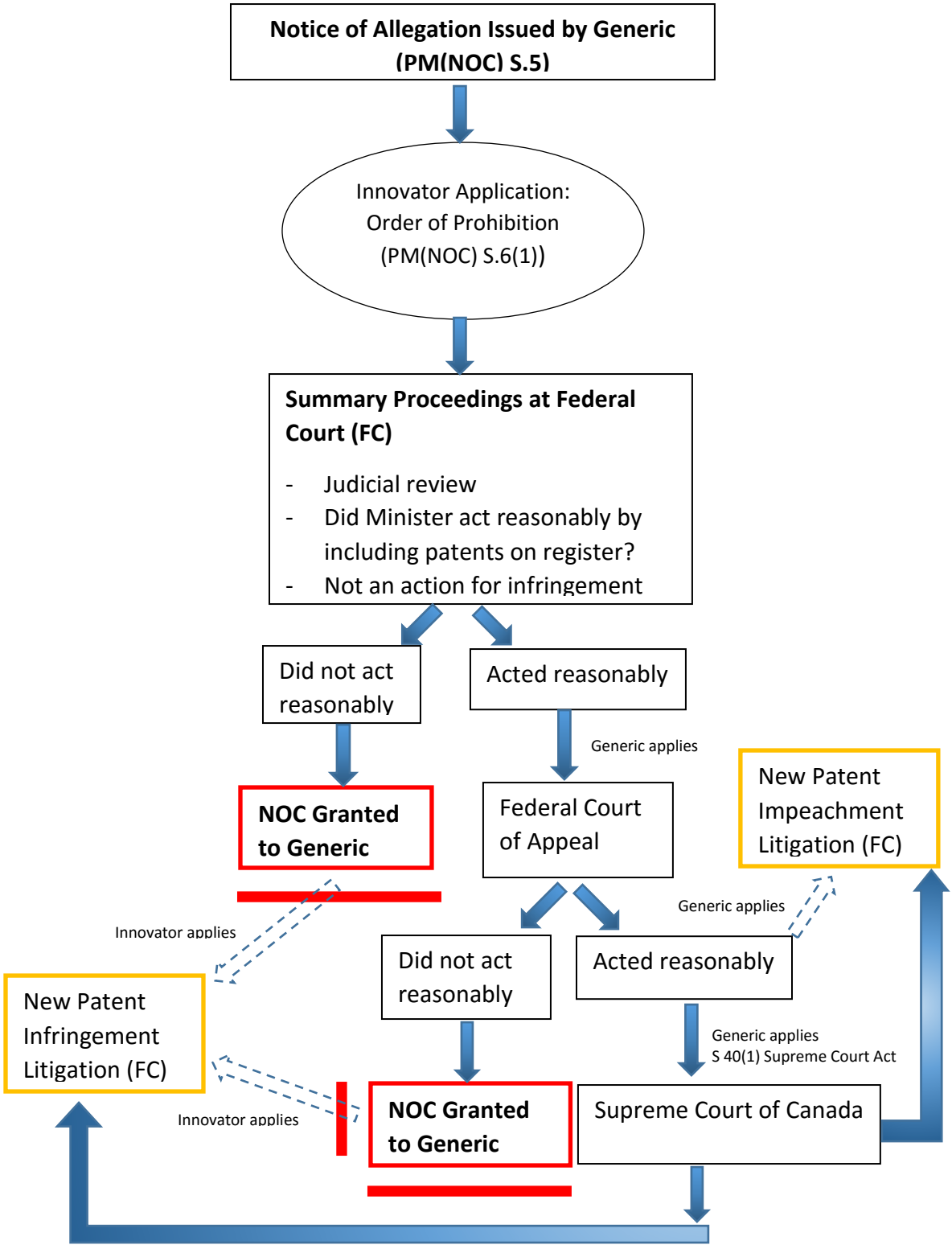
[203] The profits can be reclaimed as damages through Section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, but the law on damages is unclear when a determination of patent infringement has been made following a successful application for judicial review by a generic manufacturer and the granting of a Notice of Compliance.

the judicial review process under the *Patented Medicines (Notice of Compliance) Regulations* from an infringement action under the *Patent Act*.[204]

The appeal rights between the patent holder and the generic challenger are illustrated in Figure One, which shows the outcomes for each party when different decisions are handed down at different levels of court. The dashed arrows represent avenues where a summary proceedings under the *Patented Medicines (Notice of Compliance) Regulations* has finished, but the patent holder still has an opportunity for initiating a new action for patent infringement.

[204] As discussed earlier, the United State*s*' *Hatch-Waxman Act* does not hold up the approval process for a generic medicine once the initial challenge is lost either.

Figure 1: Summary of Litigation Proceeding from PM(NOC) Regulations



Chapter Five: A Review of Relevant Decision Making Studies

The first step in establishing the direction for future research on the *Patented Medicines (Notice of Compliance) Regulations* will be to document the decision making patterns in the cases and compare them to the Supreme Court patent case data, the copyright data, as well as the general Supreme Court decision making data. Previous decision making studies on the Supreme Court come from authors Donald Songer,[205] Julia Siripurapu,[206] Peter McCormick,[207] Emmett Macfarlane,[208] and Christine Joseph.[209] Songer and Siripurapu studied unanimous decisions at the Supreme Court between 1970 and 2003, with an emphasis on the period of 1982 to 2003, a period of new Charter of Rights and Freedoms activity at the Supreme Court. McCormick's contributions came through two publications, one of which provides data on unanimity at the Supreme Court[210] while the other provides data and analysis of concurring reasons at the Supreme Court between 1984 and 2006.[211] Macfarlane also studied unanimity at the Supreme Court, but focussed his research on interviews with Supreme Court Justices (current and retired), law clerks of the Justices, and other staff members. Joseph performed a comprehensive study of solo dissents at the Supreme Court, covering all of the 133 solo dissents between 1974 and 2003.

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[205] Donald Songer is a professor of political science at the University of South Carolina.
[206] Julia Siripurapu is an American lawyer at Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo Law Firm in Boston, Massachusetts.
[207] Peter McCormick is a professor of political science at the University of Lethbridge.
[208] Emmett Macfarlane was a postdoctoral fellow and visiting researcher at Harvard University when he studied Supreme Court unanimity. He is currently an assistant professor of political science at the University of Waterloo.
[209] Christine Joseph prepared her research note on solo dissents while pursuing her LL.B at the University of Victoria.
[210] Peter McCormick, "Blocs, Swarms, and Outliers: Conceptualizing Disagreement on the Modern Supreme Court of Canada" (2004) Osgoode Hall LJ Vol 42 Number 1 Article 3, 100 – 138.
[211] Peter McCormick, *Supra* note 34 at Table 1, 144.

However, the purpose of these previous studies was not to develop a pattern of decision making for comparison to other cases. Rather, the purpose of these articles was to try to determine what forces were driving judges to make decisions. My study moves away from looking for blanket reasons as to *why* the decisions of the Justices across the Supreme Court are made in the manner they are. Rather, the current study examines the relative decision making patterns among different categories of cases at the Supreme Court. This alleviates the need to point to political beliefs or the agendas of the Supreme Court Chief Justice. Instead the decision making patterns of various categories of cases are compared *relative* to each other, in an attempt to find *specific* reasons as to why the patterns are similar or different. The exercise starts with a description of the types of cases, and their similarities and differences, which can provide some insight into why their patterns are the same or different.

Decision Making Studies Focussing on Judicial Attitudes

Early studies of decision making that attempted to link the political ideology and attitudes of judges to their judicial outcomes include: Schubert (1965),[212] Peck (1969),[213] Rohde and Spaeth (1976),[214] and Segal and Spaeth (1993, 1996, 2002).[215] Robertson, and Segal and Spaeth were particularly adamant in their studies that political attitudes

[212]Schubert, Glendon. 1965. *The Judicial Mind: The Attitudes and Ideologies of Supreme Court Justices, 1946–1963*. Evanston: Northwestern University Press.
[213] Peck, Sidney R. 1969. "A Scalogram Analysis of the Supreme Court of Canada, 1958–1967." In *Comparative Judicial Behavior: Cross-Cultural Studies of Political Studies of Political Decision Making in the East and West*, ed. Glendon Schubert and David J. Danelski. New York: Oxford University Press.
[214] Robertson, David. 1998. *Judicial Discretion in the House of Lords*. Oxford: Clarendon Press.
[215] Segal, Jeffrey A. and Harold J. Spaeth. 1993. *The Supreme Court and the Attitudinal Model*. New York: Cambridge University Press, Segal, Jeffrey A. and Harold J. Spaeth. 1996. "The Influence of Stare Decisis on the Votes of the United States Supreme Court Justices." *American Journal of Political Science* 40: 971–1003, Segal, Jeffrey A. and Harold J. Spaeth. 2002. *The Supreme Court and the Attitudinal Model Revisited*. New York: Cambridge University Press.

represent a complete explanation for the voting behaviour of the Supreme Court Justices, but recent scholarship has challenged the assertion that political attitudes are the sole driving force behind judicial voting. For example, Emmett Macfarlane categorizes decision making studies into three main groups: studies focusing on overt political appointment process of judges, studies focusing on a tendency for political deference among judges, including a strong belief in parliamentary supremacy, and studies focusing on "strong norms of behaviour [that] govern the collegial and collaborative nature of those institutions and help to determine the relative level of consensus they achieve."[216] It is the third category, the strong norms of behavior at the Supreme Court that Macfarlane attributes to a high degree of unanimity of the decisions in the court.[217]

McCormick found that the average rate of unanimous decision making, from 1970 to 2002, was 63 percent. Macfarlane, studying this result, concluded that the high rate of unanimity was the result of "a natural by-product of the institution's norms and processes, rather than as an overt goal of the justices."[218] Of these norms, Macfarlane states that the Chief Justice has a major impact on the degree of consensus of the Court, and states that one of Chief Justice McLachlan's major goals as the Chief Justice of the Supreme Court was to increase the consensus of the Court.[219] Such statements try to move decision making studies into the realm of the absolute – looking for reasons or phenomena that can explain the nature of the patterns of decisions found. However, the

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[216] Emmett Macfarlane, "Consensus and Unanimity at the Supreme Court of Canada" (2010) 52 SCLR (2d) 379 at 380.
[217] The degree of unanimity at the Supreme Court was determined by Peter McCormick to be 63.7 percent between 1970 and 2002, in "Blocs, Swarms, and Outliers: Conceptualizing Disagreement on the Modern Supreme Court of Canada" (2004) Osgoode Hall LJ Vol 42 Number 1 Article 3, at 107.
[218] *Supra* note 216 at 383.
[219] *Supra* note 216, Macfarlane quoting Cristin Schmitz, "Communication, Consensus Among McLachlin's Targets," (November 19, 1999), 19(27) *The Lawyers Weekly*.

current study does not seek an absolute answer as to what underlying principles are affecting judicial decision making; it seeks to compare the patterns, using the previous studies as the data for the comparison.

Concurrences at the Supreme Court

Concurring decisions are separate reasons written by a judge or group of judges who agree with the outcome of a case, but for different reasons than the majority. In a study of cases from 1984 to 2006, McCormick found that concurrences were a regular part of the Supreme Court's decision making process. The incidence of concurring reasons peaked in 1995 and 1996,[220] and then began a slow but steady decline. He attributed the peak to the high instance of Charter cases before the Supreme Court:

> Dynamic period of flux and change has come to an end…[as] most of the major questions [raised by the Charter] have been answered; as a result, fewer "big" questions are coming before the Court, and few policy-divergent responses need to be generated to prepare the field within which these can be managed.[221]

The average rate of concurring decisions over the entire period was 36 percent.[222] McCormick asserts that "divided decisions demonstrate that a court that is both open to a variety of arguments and willing to change its mind over time."[223]

Dissent

Over the period of 1974 to 2003, Joseph studied the solo dissent rates of the individual Justices,[224] as well as the overall rates of solo dissent. She argues that "the

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[220] *Supra* note 34 at p 206. There were 75 concurrences in 43 cases in this one year period.
[221] *Supra* note 34 at p 166. Also cited by Wilkinson, *Supra* note 18 at 75.
[222] *Supra* note 34. This is calculated as the total number of concurrences in the period (610) over the total number of cases for the same period (1710).
[223] *Supra* note 34 at p 166, citing to MT Henderson, "From *Seriatim* to Consensus and Back Again: A Theory of Dissent", SSRN (1 April 2008), U of Chicago Law & Economics, Online Working Paper No. 363; U of Chicago, Public Law Working Paper No. 186 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1019074
[224] Christine Joseph, "All but One: Solo Dissents on the Modern Supreme Court of Canada" (2006) 44 Osgoode Hall LJ 501. The individual rates of solo dissent are included in Table 14, p 518.

exercise of solo dissent on the Supreme Court of Canada is judicial disagreement at its apex - a single judge sitting on the highest court in the nation breaking away from his or her colleagues who have purportedly 'gotten it wrong.'"[225] She found that the overall rate of dissent rose during this period to 6.3 percent of cases by the end of the study period.[226] She found that the McLachlin Court in 2003 had the highest rate of solo dissents, but also had the lowest rate of disagreement, at 34 percent, but she could not extrapolate this data to a relationship between the overall level of disagreement of the Court and the likelihood of a solo dissent. Joseph's data showed that the incidence of solo dissents increases as the panel size moves from five to seven, but decreases as it moves from seven to nine.

"The Context of the Supreme Court's Copyright Cases" by Margaret Ann Wilkinson

Margaret Ann Wilkinson's chapter, "The Context of the Supreme Court's Copyright Cases,"[227] in *The Copyright Pentalogy*, represented the first time decision making in Supreme Court of Canada copyright cases had been tabulated, and also marked a departure from the general decision making studies of the past that dealt with general reasons to explain the pattern of decision making. The objective of her study was to analyze the most recent eleven Supreme Court of Canada copyright judgments and compare the decision making pattern in these cases to the pattern of decisions in general Supreme Court of Canada jurisprudence. Five of the cases were simultaneously released

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<https://litigationessentials.lexisnexis.com/webcd/p?action=DocumentDisplay&crawlid=1&srctype=smi&srcid=3B15&doctype=cite&docid=44+Osgoode+Hall+L.J.+501&key=299ecfb0f32298b94e94916eba8f0682>; 175 dissents of all types were reported between January 2000 and October 2007.

[225] *Ibid* at 501.

[226] In 2003, at the end of the period, the Chief Justice was Beverly McLachlin.

[227] *Supra* note 18.

by the Supreme Court in the summer of 2012, just before Royal Assent of the new *Copyright Modernization Act*,[228] greatly enlarging the relatively small amount of Supreme Court copyright jurisprudence. An analysis at this point seemed relevant, as the decision making pattern may evolve with the modernization of the legislation, so the current data would serve as a good reference point for future research.

Wilkinson noted a difference in the pattern, which revealed that the nature of copyright jurisprudence in Canada has been different from the overall pattern of Supreme Court jurisprudence. Wilkinson suggested that the Supreme Court Justices must have had some degree of difficulty in deciding these cases, citing that Canada's existing copyright law existed before digital music, but had to be applied to modern digital copyright issues. Wilkinson concluded that the low rate of unanimous decision making in the study suggests that copyright law is in a more dynamic position, similar to that of Supreme Court jurisprudence from the mid-eighties to the mid-nineties, when Charter cases were flooding the Court docket. In addition, the lack of solo dissents indicated that copyright law was dynamic and complicated, requiring the members of the Supreme Court to discuss their viewpoints together and consider policy-based responses to copyright law questions.[229] In other words, the law was too complex for some of the judges to form their own opinions.

A valid comparison of *Patented Medicines (Notice of Compliance)* case decision making patterns heard at the Supreme Court to Wilkinson's work on copyright decisions can be made. Six patent-related cases heard by the Supreme Court since the early 1990's arose from disputes involving the *Patented Medicines (Notice of Compliance)*

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[228] *Supra* note 35.
[229] *Supra* note 18 at p 86.

Regulations,[230] which apply to both drug companies and government (Health Canada) when making decisions about approving generic pharmaceuticals for public use. These Supreme Court cases originated from applications for judicial review heard at Federal Court, and so did the copyright cases examined by Professor Wilkinson. Therefore, a similarity in the decision making pattern between the two sets of cases may provide some clues that something within the judicial review process itself is problematic.

The complaints filed by the European Communities and their Member States[231] with the World Trade Organization about the circumvention of patent rights established in TRIPS[232] by the *Patented Medicines (Notice of Compliance) Regulations* is essentially a complaint about the abbreviated process of judicial review. As such, a determination of the core issues in these cases at the Supreme Court, whether it be an actual issue over patent or an administrative law issue related to the judicial review process itself, should be undertaken so that an accurate characterization of the *Patented Medicines (Notice of Compliance) Regulations* can be made for the purposes of assessing the Regulations' compliance with Canada's international obligations for intellectual property. Without evidence that this sidestepping is leading to incorrect judicial outcomes, the *Patented Medicines (Notice of Compliance) Regulations* could be viewed as the opposite: *enhancing* patent protection by providing a process for evaluating patents over and above existing patent legislation.

The comparison to Wilkinson's copyright data will provide insight into this issue, as these eleven cases also arose following applications for judicial review at the Federal

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[230] *Supra* note 1, SOR/93-133 [*PM(NOC)*, or *PM(NOC) Regulations*, or "the *Regulations"*].
[231] *Supra* note 5.
[232] *Supra* note 4.

Court of Appeal from decisions made by Canada's Copyright Board. It will help to characterize the decision making patterns in the *Patented Medicines (Notice of Compliance)* cases, in an attempt to demonstrate whether they lead to increased disagreement among the Justices, where such disagreement could translate into international disagreement over the level of patent protection afforded to pharmaceutical patent holders in Canada.[233]

[233] As discussed, the comparison of the pattern in the *Patented Medicines (Notice of Compliance)* cases to the Supreme Court patent cases and general Supreme Court jurisprudence will also help to characterize the cases. For example, a high degree of unanimity could characterize the cases as easily decided by the Justices.

Chapter Six: Data and Analysis

Introduction

Chapters Three and Four provided an overview of patented (innovative) medicines, generic medicines, the drug approval process in Canada, and the interplay among health, patent, and administrative law in the approval of generic medicines. Chapter Four also examined aspects of judicial review, and how they operate within the context of the *Patented Medicines (Notice of Compliance) Regulations* and why they may be problematic. The highlight of these elements is significant, as the comparison to the copyright cases in this chapter may re-direct research toward them if similarities in the decision making patterns of these cases exists.

To answer the three central questions of the thesis, the study in this chapter will compare the decision making data in the *Patented Medicines (Notice of Compliance)* cases to the Supreme Court patent cases, to the Supreme Court copyright cases, and to Supreme Court cases generally. These comparisons will help to characterize the decisions in the *Patented Medicines (Notice of Compliance)* cases like one of the existing study groups, or as its own unique set. This characterization is useful, since a similar character of patent cases to the copyright cases suggests that future research should focus on the elements of judicial review and their application to the *Patented Medicines (Notice of Compliance) Regulations* discussed in Chapter Four. A dissimilarity provides evidence that the use of judicial review in *Patented Medicines (Notice of Compliance)* cases is *not* problematic, in the sense that the judicial review process is not hampering the evaluation of the patents in question *for the purpose of approving generic medicines*. If

the pattern is similar to that of the patent cases or the general Supreme Court cases, this provides additional support for the conclusion that judicial review is not problematic.

Patent Data

All patent cases between 1970 and 2012 were compiled through an electronic search on Lexis Nexis. The following Boolean search was conducted: "patent and not letters patent and not patently and not patent unreasonableness and not Crown patent." 323 results were achieved, which were divided into 141 Supreme Court of Canada Judgements and 182 Supreme Court of Canada Rulings on Applications. The 141 judgement results were examined, and eighteen cases that covered an aspect of patent law in Canada were selected. "Noting up" on these eighteen cases yielded eleven other Supreme Court of Canada patent cases for a total of 30, which included the *Patented Medicines (Notice of Compliance)* cases. The Supreme Court cases that primarily deal with the *Patent Act*, between 1970 and November, 2014, and the *Patented Medicines (Notice of Compliance)* cases, between 1998 and 2015 are in Appendix Two.[234] All motions were excluded. *Celgene Corp v Canada (Attorney General)*[235] was included, even though the primary issue was the importation of a medicine manufactured outside of Canada, and the applicability of provisions of the *Patent Act*, as opposed to a statutory interpretation issue with the *Patent Act* or an act of infringement or impeachment, which would necessarily involve applying the *Patent Act*.[236]

[234] The *Patented Medicines (Notice of Compliance) Regulations* were implemented in 1993, so all cases heard were after this, making the study period for these cases significantly shorter.
[235] [2011] 1 SCR 3, 2011 SCJ 1.
[236] As one case out of thirty, the inclusion or exclusion of this case has little bearing on the comparisons drawn to *Patented Medicines (Notice of Compliance)* cases.

From 1970 to the present, there have been thirty patent cases at the Supreme Court, out of a total of four hundred cases.[237] The subset of patent cases chosen is not a statistical sample – it represents the entire population of patent cases at the Supreme Court during this period.[238] Of these twenty-nine cases, six cases deal specifically with the *Patented Medicines (Notice of Compliance) Regulations.* Appendix Two lists all of the patent and *Patented Medicines (Notice of Compliance)* cases by citation, panel size, issue, and industry. Appendix Three contains the comprehensive decision making data for all of the Supreme Court patent and *Patented Medicines (Notice of Compliance)* cases since 1970. Although there were twenty-nine patent cases overall, two separate judgments were made in *Monsanto '04* for two distinct questions,[239] so *Monsanto '04* is considered as two separate cases in the data, for a total of thirty.

Patented Medicines (Notice of Compliance) Data

The *Patented Medicines (Notice of Compliance)* cases were extracted from the overall patent data cases in Appendix Two and are presented separately in Table Two.

[237] The total number of cases in this period is determined by visiting the Supreme Court of Canada's judgment website, *Judgments at the Supreme Court of Canada*, at http://scc-csc.lexum.com/scc-csc/scc-csc/en/2014/nav_date.do. The total number of cases can be totalled by year over the period of 1970 to 2015.

[238] Consideration must be given to what happens to the data if one group of cases is large enough to create a different pattern of judgements among the remaining cases. In this type of research, the researcher should re-check the proportions of each decision after removing the category of interest to examine how the remaining data is affected.

[239] The first significant question involved the validity of a patent on a gene for a genetically engineered variation of canola. The second significant question was whether or not Schmeiser infringed the patent on the gene for the canola by planting the resulting seeds.

Table 2: The *Patented Medicines (Notice of Compliance) Cases*

Case	**Panel Size**	**Drug in Question**	**Issue**	**Decision**
Merck-Frosst Canada Inc. v Canada (Minister of National Health and Welfare)[240]	7	Norfloxacin (brand name: Noroxin)	Filing procedure for a Notice of Allegation; sublicencing under a compulsory licencing regime	Unanimous
Bristol-Myers Squibb v Canada (Attorney General)[241]	9	Paclitaxel (a naturally occurring substance)	Bioequivalence; Interpretation of S.5(1.1) is a legal issue, so standard of review is correctness	Majority with dissent (not solo)
AstraZeneca Canada Inc. v Canada (Minister of Health)[242]	9	Omeprazole capsules (brand name: Losec)	Listing of new patents for a drug that the innovator company withdrew from the market (Losec)	Unanimous
Apotex Inc. v Sanofi-Synthelabo Canada Inc.[243]	7	Clopidogrel (brand name: Plavix)	Novelty and obviousness: mirror image of intended molecule is patentable	Unanimous
Teva Canada Ltd v Pfizer Canada Inc.[244]	9	Sildenafil (brand name: Viagra)	Sufficiency of disclosure of patent; obviousness; utility	Unanimous
Sanofi-Aventis v Apotex Inc.[245]	9	Ramipril (brand name: Altace)	Damages	Unanimous

The decision making pattern of the patent cases and *Patent Medicines (Notice of Compliance)* cases is summarized from Appendix Three in Table Three. The patent cases are presented with and without the *Patented Medicines (Notice of Compliance)* cases.

[240] [1998] 2 SCR 193, 1998 SCJ 58 [*Merck-Frosst*].
[241] [2005] 1 SCR 533, [2005] SCJ 26 [*Bristol-Myers*].
[242] [2006] 2 SCR 560, 2006 SCC 49 [*Astra-Zeneca*].
[243] [2008] 3 SCR 265, [2008] SCJ 63 [*Sanofi-Synthelabo*].
[244] [2012] 3 SCR 625, 2012 SCC 60 [*Teva*].
[245] [2015] SCC 20 [*Sanofi-Aventis*].

Table 3: Decision Making Patterns in Supreme Court Patent Cases and *Patented Medicines (Notice of Compliance)* Cases – As a Percentage of the Total Number of Cases in each Type

	Patent Cases (with PM(NOC) Cases)	**Patent Cases (without PM(NOC) Cases)**	**PM(NOC) Cases**
Unanimous	22/30 (73%)	18/24 (75%)	83%
Majority with concurring reasons and no dissent	1/30 (3.0%)	1/24 (4.2%)	0%
Majority judgments with no concurring reasons and at least one dissent (any type)	6/30 (20%)	5/24 (21%)	1/6 (17%)
Majority with concurring reasons and any dissent	0%	0%	0%
Multiple majority with dissent	0%	0%	0%
Majority judgments with unanimous dissent	6/30 (17%)	5/24 (21%)	1/6 (17%)
Judgments with non-unanimous dissent	1/30 (3.0%)	1/24(4.2%)	0%
Judgments with solo dissents	1/30 (3.0%)	1/24 (4.2%)	0%
Total number of Cases[246]	30	24	6

The data demonstrates that the *Patented Medicines (Notice of Compliance)* cases have a decision making pattern that is very similar to the patent cases overall. In addition, the removal of the *Patented Medicines (Notice of Compliance)* cases from the overall patent data does not significantly affect the pattern in the patent data. This is important, since it demonstrates that the removal of these cases for analysis preserves the existing data, so

[246] *Monsanto '04* is counted as two cases since there are two separate issues, each with its own set of judgments.

that observations about the patent data can be made independently of the extracted data. For subsequent comparisons, the patent data without the *Patented Medicines (Notice of Compliance)* cases will be used.

Overall, there is a high degree of unanimity with very few concurring reasons with the majority. Dissent was dissected in several ways to help illuminate any patterns that might exist in the data. Dissent was examined as all types together, unanimous dissent, non-unanimous dissent (which could include multiple dissents, any of which could have been written by a solo judge), and solo dissents. Overall, the level of dissent is small, with one solo dissent in one patent case.

A Qualitative Examination of the *Patented Medicines (Notice of Compliance)* Cases

Now that the six *Patented Medicines (Notice of Compliance)* cases heard at the Supreme Court of Canada have been isolated, it is pertinent to briefly examine their core issues. Two of the cases, *Merck-Frosst* and *Astra-Zeneca*, involved issues that were more procedure-oriented than science-oriented. In *Merck-Frosst*, it was deemed that a generic company could purchase a raw ingredient from another company that had already received a Notice of Compliance for that ingredient, and not infringe on the patent. In this case, Novopharm had acquired a compulsory licence to buy the active ingredient norfloxacin[247] before the compulsory licensing regime was removed from the *Patent Act* in 1993. Novopharm could produce norfloxacin tablets for sale in foreign markets, but the compulsory licence restricted them from selling it in Canada. Apotex began buying the norfloxacin from Novopharm so it could make its own copy of the antibiotic for sale

[247] Norfloxacin is an antibiotic. The trade name of Merck-Frosst's innovative product was Noroxin.

in the Canadian market. Apotex was seeking a Notice of Compliance for norfloxacin, but Merck-Frosst applied for an Order of Prohibition under the *Patented Medicines (Notice of Compliance) Regulations*, citing that Apotex's purchase of norfloxacin was a "sublicence" from Novopharm. Apotex's argument was that it was not a sublicence from Novopharm, and it was therefore not infringing on the patent. The judgment is specific to *Patented Medicines (Notice of Compliance)* cases since compulsory licencing and the issuance of a Notice of Compliance is specific to drug product approval in Canada, with its own regulations about the transference of substances from one company to another that have met the approval criteria.[248]

The *Astra-Zeneca* case dealt with the issue of listing new patents on a drug that *Astra-Zeneca* had withdrawn from the Canadian market, but the company still wanted to block the introduction of generics of that withdrawn product. In this case, Astra-Zeneca was the producer of Losec,[249] a drug used to suppress acid production in the gastrointestinal tract, for the purposes of treating various illnesses where a reduction in gastric acid production is warranted. Astra-Zeneca's original product was formulated as a *capsule*, but the company had subsequently formulated a *tablet* of the same drug to be released on the Canadian market *before* the expiry of the patents on the original capsule product, in an attempt to switch consumers to the new product and retain its market share. After the withdrawal of the omeprazole *capsule*, Astra-Zeneca listed *two new* patents for that product on Health Canada's Patent Register, in an attempt to block the generic

[248] A secondary issue in this case was whether or not Apotex's Notice of Allegation was justified, since the notice was filed on April 19, 1993, but Novopharm's compulsory licence did not permit it to produce norfloxacin until July 2, 1993.
[249] The generic name of the molecule in Losec is omeprazole. Future references to generic pharmaceutical names will be in parentheses following the trade name of the medicine.

company Apotex from copying the original molecule. However, the patents were never incorporated into the actual product. The case centered on the issue of whether or not Apotex was required to file Notices of Allegations as required by section 5(1) of the *Patented Medicines (Notice of Compliance) Regulations* for the patents listed when the drug was approved for sale by Health Canada, or if it had to file Notices of Allegations for the newer patents listed as well.[250] The panel decided unanimously in favour of the generic applicant, Apotex, stating that Astra-Zeneca was not entitled to list patents on drugs no longer available to the public. The Justices agreed that section 4(5) of the *Patented Medicines (Notice of Compliance) Regulations* required particular patents to be linked to particular submissions.[251] This linkage is unique to the *Patented Medicines (Notice of Compliance) Regulations* and is highlighted in *Astra-Zeneca*.

The *Bristol-Myers* case was about the bioequivalence of the same raw ingredient sourced from two different species of plant – one used by Biolyse and the other used by Bristol-Myers, who marketed the product first. In *Bristol-Myers*, the issue was whether or not Biolyse's product should be considered a generic since it used the same active ingredient, paclitaxel, as Bristol-Myer's product. However, Bristol-Myer's product had no patent over paclitaxel, since it is a natural compound contained within a flower. The case was decided by determining that the scope of section 5(1.1) of the *Patented*

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[250] Recall from note 2 that the filing of subsequent patents on a drug product that has already been approved and marketed is called evergreening. It is a strategy employed for the purposes of trying to extend the patent life of a product. This practice has since been addressed in a new version of the *Patented Medicines (Notice of Compliance) Regulations*, released in 2006. The new regulations in Section 6 impose a "freeze" on the patent status once the new molecule has achieved a Notice of Compliance.

[251] *Supra* note 1, at s 4(5), Section 4(5) states that "Subject to subsection (6), a first person who submits a patent list must do so at the time the person files the new drug submission or the supplement to a new drug submission to which the patent list relates." Therefore, the new patents had to be incorporated into the product to receive protection under the *Regulations.*

Medicines (Notice of Compliance) Regulations was for generic medicine applications only, and not innovative or unpatentable medicines:

> 5. (1) If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the submission, with respect to each patent on the register in respect of the other drug,
> (a) state that the second person accepts that the notice of compliance will not issue until the patent expires; or
> (b) allege that
>
> (i) the statement made by the first person under paragraph 4(4)(d) is false,
> (ii) the patent has expired,
> (iii) the patent is not valid, or
> (iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient.

Since Biolyse did not rely on any of Bristol-Myer's data, it was not considered a generic manufacturer applying to copy and produce a branded product. Therefore, this case is primarily about the legal interpretation of a provision within the *Patented Medicines (Notice of Compliance) Regulations* – there was never any contention over the issue of whether or not natural substances were patentable.[252] The court also determined that the appropriate standard of review for determining the scope of section 5(1.1) is *correctness*, since it is a purely legal issue. The dissent was in agreement with the majority on the issue of the standard of review.

A common issue across several industries is the interpretation of section 27(3) of the *Patent Act*, which involves sufficiency of disclosure, and the issue also arises when a pharmaceutical patent holder has not disclosed a patent well enough to allow the generic

[252] If so, this case would involve issues in both the *Regulations* and the *Patent Act*.

manufacturer to re-create the invention. In *Pfizer Canada Inc. v Novopharm Limited,*[253] Pfizer was seeking an Order of Prohibition through Section 6(1) of the *Patented Medicines (Notice of Compliance) Regulations* to block Teva from getting a Notice of Compliance to create a copy of its erectile dysfunction drug, Viagra (sildenafil). From this application, Kelen J. evaluated obviousness, utility, and disclosure of Pfizer's patents, even though he could not make a ruling of invalidity on the patents, and held that there was sufficient disclosure by the patent holder. Blais, C.J., Nadon J.A., and Trudel J.A. reviewed the Federal Court decision and upheld it.[254] The issue of sufficiency of disclosure at the Supreme Court referenced jurisprudence on sufficiency of disclosure in Section 27(3), including *Consolboard,* which concludes that sufficiency of disclosure is met when the invention is adequately described in the claims, as well as what the invention does.[255] Besides *Consolboard,* Appendix Two lists several patent cases where sufficiency of disclosure has been an issue, including *Burton Parsons, Monsanto '79, Gilcross, and Farbwerke.* The ruling on sufficiency of disclosure in this case established Teva's allegations under Section Five of the *Patented Medicines (Notice of Compliance) Regulations*.[256]

The *Sanofi-Synthelabo* case originated when Sanofi-Synthelabo applied for an Order of Prohibition under Section Six of the *Patented Medicines (Notice of Compliance) Regulations* to block the manufacture and sale of a generic copy of its blockbuster anticoagulant drug, Plavix.[257] Apotex challenged the validity of Sanofi-Synthelabo's

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[253] *Pfizer Canada Inc. v Novopharm Limited and the Minister of Health* [2009] FC 638.
[254] [2010] FCA, 242.
[255] [2012] 3 SCR 625, 2012 SCC 60.
[256] Specifically, it established its allegations under Section 5(3) and Subsection 5(1)(b)(iii).
[257] *Sanofi-Synthelabo v Apotex Inc.* [2005] FC 390. Anticoagulant drugs reduce the ability of the blood to coagulate or "clot," which can reduce the risks of subsequent heart attack, stroke, and embolism when certain medical conditions arise. The generic name of Plavix is clopidogrel.

patents on Plavix, since the chemical, when synthesized, was a mirror image of another molecule that Sanofi-Synthelabo had *intentionally* tried to develop (the genus patent). Since Sanofi had patented the intentioned molecule, Apotex claimed that the unintentioned "mirror-image" of that molecule, Plavix, was not patentable for two reasons: it was prior art, and it could be anticipated from the genus patent. The court upheld the patent on the "accidental" molecule, since a person skilled in the art of drug development would not have anticipated how to isolate the new substance, nor anticipate what it would be used for. The Federal Court of Appeal reviewed and upheld the decision[258] before it reached the Supreme Court and was subsequently dismissed. The issue of genus and species patents has been addressed by other Supreme Court cases, and so has the issue of anticipation. Therefore, the issues in *Sanofi-Synthelabo* are not unique to the *Patented Medicines (Notice of Compliance) Regulations*. The Supreme Court dealt with the genus/species patent issue in *C.H. Boehringer Sohn v Bell-Craig Limited*,[259] *Hoechst Pharmaceuticals v Gilbert and Company*,[260] and *Monsanto Company v Commissioner of Patents*.[261]

The *Sanofi-Aventis* case was a question of *Patented Medicines (Notice of Compliance) Regulations* section eight damages. Section eight is a compensation mechanism for generic manufacturers to receive payments if an innovator's Order of Prohibition is discontinued or dismissed by the court. The case addressed the issue of the point when damages are deemed to begin, called the "hypothetical start date," as well as the market share the generic company *would have had if the generic approval had not*

[258] *Apotex Inc. v Sanofi-Synthelabo* [2006] FCA 421.
[259] [1963] SCR 410.
[260] [1996] SCR 189.
[261] [1979] 2 SCR 1108.

been delayed by the opposition of the innovator.[262] The case was dismissed, with no reasons provided, suggesting agreement with the decision of the Federal Court of Appeal.

In summary, four of the cases, *Merck-Frosst*, *Astra-Zeneca*, *Bristol-Myers*, and *Sanofi-Aventis* primarily involve the *Regulations* themselves, while two of the cases, *Sanofi-Synthelabo* and *Teva*, primarily involve patent disputes that were adjudicated through the *Patented Medicines (Notice of Compliance) Regulations*. It is therefore not surprising that the pattern of decision making in these cases would be similar to the overall pattern of decision making in the patent cases.[263]

[262] [1982] 1 SCR 907.
[263] That similarity was demonstrated in Table Two on page 42.

Table 4: Primary Issues in the *Patented Medicines (Notice of Compliance)* Cases

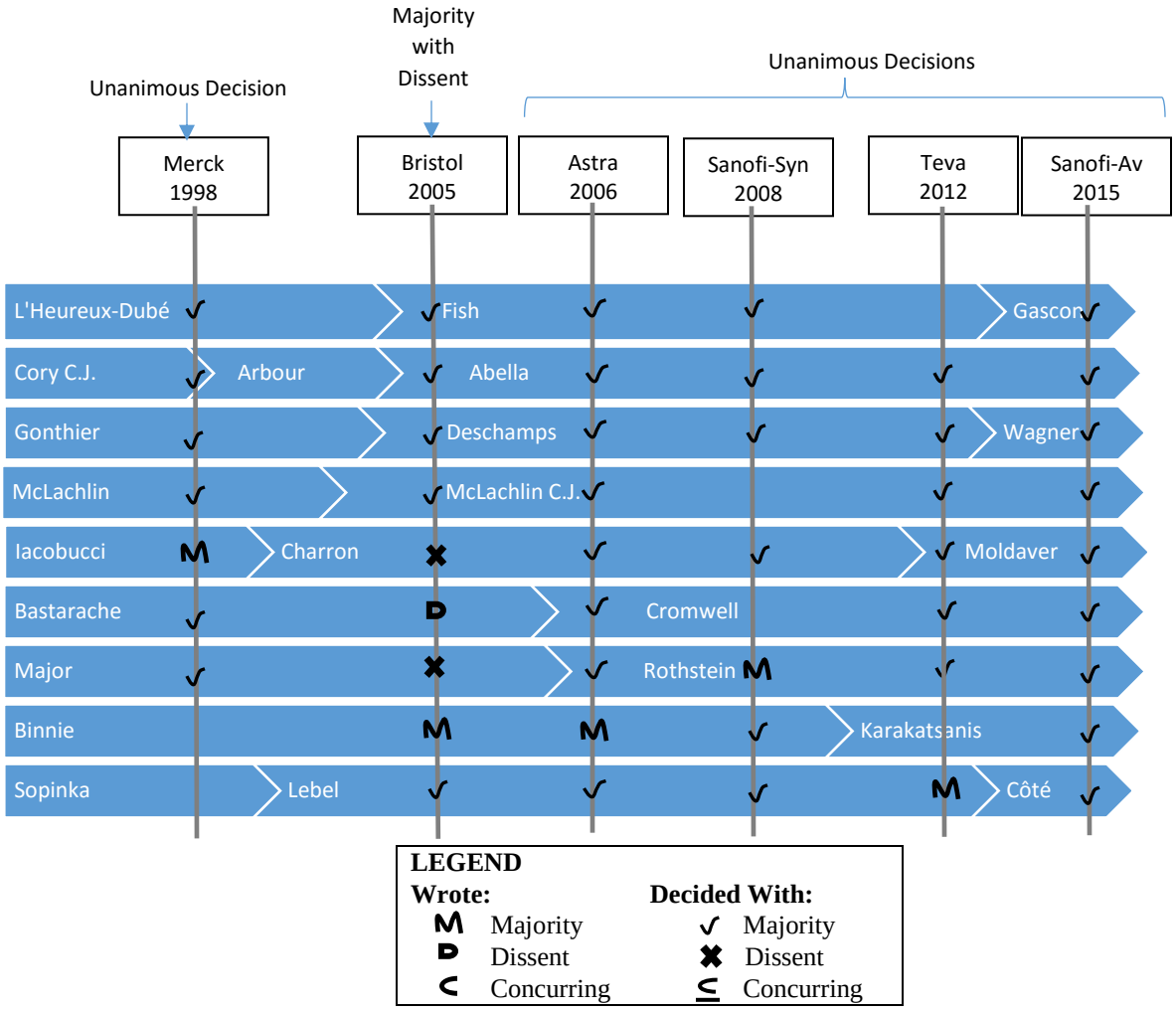
Case	**Issue**	**Primarily PM(NOC) or Patent?**
Merck-Frosst Canada Inc. v Canada (Minister of National Health and Welfare)[264]	Filing procedure for a Notice of Allegation; sublicencing under a compulsory licencing regime	*PM(NOC) Regulations*
Bristol-Myers Squibb v Canada (Attorney General)[265]	Bioequivalence; Interpretation of S.5(1.1) is a legal issue, so standard of review is correctness	*PM(NOC) Regulations*
AstraZeneca Canada Inc. v Canada (Minister of Health)[266]	Listing of new patents for a drug that the innovator company withdrew from the market (Losec)	*PM(NOC) Regulations*
Apotex Inc. v Sanofi-Synthelabo Canada Inc.[267]	Novelty and obviousness: mirror image of intended molecule is patentable	*Patent Act*
Teva Canada Ltd v Pfizer Canada Inc.[268]	Sufficiency of disclosure of patent; obviousness; utility	*Patent Act*
Sanofi-Aventis v Apotex Inc.[269]	Damages	*PM(NOC) Regulations*

[264] [1998] 2 SCR 193, 1998 SCJ 58 [*Merck-Frosst*].
[265] [2005] 1 SCR 533, [2005] SCJ 26 [*Bristol-Myers*].
[266] [2006] 2 SCR 560, 2006 SCC 49 [*Astra-Zeneca*].
[267] [2008] 3 SCR 265, [2008] SCJ 63 [*Sanofi-Synthelabo*].
[268] [2012] 3 SCR 625, 2012 SCC 60 [*Teva*].
[269] [2015] SCC 20 [*Sanofi-Aventis*].

The Composition of the Court

Figure Two describes the composition of the court in deciding *Patented Medicines (Notice of Compliance)* cases.

Figure 2: The Composition of the Court in Deciding *Patented Medicines (Notice of Compliance) Cases*



Lamer was the Chief Justice for one of the six cases, *Merck-Frosst*, but did not sit on that case. McLachlin has been the chief justice for the other five, and has sat on four of those five cases. It is unclear if this high level of consistency of the Chief Justice has contributed to the high level of unanimity in the case, but could be a subject of future study.

Three of the decisions were panels of seven, and three were panels of nine. Of the three panels of nine, one decision, *Bristol-Myers,* was an issue of the scope of section 5(1.1) of the *Patented Medicines (Notice of Compliance) Regulations*. Another, *Astra-Zeneca,* was about listing patents for a drug that had been removed from the Canadian market, and involved the proper interpretation of section 4(5). The third, *Sanofi-Aventis*, was a dismissed appeal on section eight damages, with no reasons given, just agreement with the decision of the Federal Court of Appeal. Interestingly, *Teva* and *Sanofi-Synthelabo*, both cases primarily about the validity of the patents for the purposes of approving a generic, were panels of seven, which suggests that the Supreme Court does not see the cases as of primary importance among all of the cases that it hears.

There is a high degree of consistency in the composition of the panels, since all six cases have been heard within a seventeen-year period. Excepting *Merck '98*, the remaining cases span only *ten* years. McLachlin C.J., Abella J., Deschamps J., and Lebel J. have sat on the most cases, each sitting on four. Of these four justices, Abella J., Deschamps, J., and Lebel J. all participated in the same three cases, and voted together in all.

It was not until *Sanofi-Aventis* was there a significant change in the Justices participating in the cases. *Sanofi-Aventis* saw the addition of Justices Gascon, Côté, and Wagner, with the retirement of Justices L'Heureux-Dubé, Gonthier, and Sopinka. The three new Justices participated with the others in a unanimous decision to dismiss the case.

Binnie J. has written two of the five majority judgments, while Lebel J., Rothstein J., and Iacobucci J. have each written one judgment for the majority.[270] The one dissenting judgment was written by Bastarache J., with Major J. and Iacobucci J. agreeing with the dissent. McLachlin J. has been a Supreme Court Justice during all six *Patented Medicines (Notice of Compliance)* cases, and has participated in four, but has never written the majority judgment. Therefore, the Justices have not deferred the judgment to one "expert" Justice in this field, which may have been the case if the decisions were too technical to adjudicate.

Copyright Data

The Wilkinson study in "The Context of the Supreme Court's Copyright Cases" included the five pentalogy cases released in the summer of 2012, plus the six most recent cases prior to them. All of the cases dealt with the same (older) version of the Copyright Act.[271] One additional non-copyright case with relevant links to copyright decisions was included.[272]

Appendix Five highlights the issues and the decisions in the eleven copyright cases. This decision making pattern data is summarized in Table Four, and is compared to the patent cases and the *Patented Medicines (Notice of Compliance)* cases.

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[270] As mentioned, *Sanofi-Aventis* was written without reasons, upholding the Federal Court of Appeal decision and referring to its reasons.
[271] *Copyright Act* RSC 1985.
[272] *Crookes v Newton*, 2011 SCC 47, [2011] 3 SCR 269 <http://scc.lexum.org/decisiascc-csc/scc-csc/scc-csc/en/item/7963/index.do> [*Crookes*].

Table 5: Decision Making Patterns in the Copyright Cases, PM(NOC) Cases, and the Patent Cases: Instances of Judgments[273]

	Copyright Pentalogy Cases	*PM(NOC)* Cases	Patent Cases 1970 - 2012[274]
Unanimous	3/11 (27%)	5/6 (83%)	18/24 (75%)
Majority with concurring reasons but no minority dissent	3/11 (27%)	0%	1/24 (4.2%)
Majority with or without concurring reasons and at least one dissent (any type)	5/11 (45%)	1/6 (17%)	6/24 (25%)
Majority with no concurring reasons and dissent	4/11 (36%)	1/6 (17%)	5/24 (21%)
Majority with Concurring Reasons and Dissent	1/11 (9%)	0%	0%
Multiple majority with Dissent	2/11 (18%)	0%	0%
Majority judgments with unanimous dissent	5/11 (45%)	1/6 (17%)	5/24 (21%)
Judgments with non-unanimous dissent	0%	0%	1/24 (4.2%)
Judgments with solo dissents	0%	0%	1/24 (4.2%)
Total number of Cases	11	6	24

Overall, the pattern of decision making is much different in the copyright cases. The level of unanimity is threefold higher in the patent cases as well as the *Patented Medicines (Notice of Compliance)* cases. The level of majority cases with dissent is more than twice as high in the copyright cases than the patent cases and the *Patented Medicines (Notice of Compliance)* cases, which characterizes the patent cases and the *Patented Medicines (Notice of Compliance)* cases as demonstrating a high level of unanimity, with little dissent. The copyright cases are at the opposite end of the spectrum, where most of the decisions are majority decisions accompanied by dissent.

[273] The copyright data was extracted from Professor Wilkinson's article, s*upra* note 18, Figure 2, page 82. Additional data was taken from various places in Section B, "The Decisions," pages 76 to 83.
[274] The patent cases data used exclude the *Patented Medicines (Notice of Compliance)* cases as discussed.

Concurring reasons play little part in the patent decisions, and no part in the *Patented Medicines (Notice of Compliance)* decisions. The level of concurrence in the copyright cases is more significant, where twenty-seven percent of the copyright cases have a majority with concurring reasons but no minority dissent, and another nine percent of the cases have concurring reasons with dissent, for a total of thirty-six percent as concurring decisions.

The presence of a majority with concurring reasons and dissent is low among all categories, including copyright. The presence of solo dissents across all of the cases is also low, with only one solo dissent written across all forty-one cases, which was a patent case, adjudicated through the *Patent Act*.

The three comparator groups were also examined by number and type of decision, with the results presented in Table Five.

Table 6: Number of Reasons Given in each Group of Cases

	Copyright Pentalogy[275]	PM(NOC) Cases	Patent Cases
Majority (includes unanimous)	13 (59%)	6 (86%)	25 (81%)
Concurring	7 (29%)	0	1 (3%)
Dissenting	5 (21%)	1 (17%)	7 (23%)
Number of Cases	11	6	24
Total number of reasons	24	7	33
Reasons/Case	2.2	1.2	1.4

The case data are broken down in this fashion to confirm, reject, or provide support for any possible inferences from the overall judgment data *by case*, as in Table Four. The higher percentage of majority reasons in the patent cases is strongly reflective of the

[275] *Supra* note 18 at 82, Figure 2. The values were derived from this Figure, as well as from various references in the text of the article.

higher level of unanimity in the patent cases and the *Patented Medicines (Notice of Compliance)* cases. The patent cases have many fewer cases with dissent judgments than copyright cases, but the overall percentage of dissenting *reasons* given for patent cases, approximates the copyright data. Therefore, when dissent *does* exist in the patent cases, it indicates that there is a significant amount of disagreement among the Justices.

Overall, however, there is still one more reason (of any type) in an average copyright case than in an average *Patented Medicines (Notice of Compliance)* case, and nearly the same ratio for the patent cases in comparison to the copyright cases. Fewer reasons being written in the patent and *Patented Medicines (Notice of Compliance)* cases may be related to the number of issues per case, since most of the patent and *Patented Medicines (Notice of Compliance)* cases in the study, on a general level, have one issue to be decided per case.[276] Wilkinson did not comment on the number of issues per case in her article, but Wilkinson does state that the issues in the three copyright cases with unanimous dissents range from "more straightforward to extremely complex,"[277] further differentiating them from the *Patented Medicines (Notice of Compliance)* cases. Fewer reasons overall also suggests that cases involving the *Patented Medicines (Notice of Compliance) Regulations* do not create significant disagreement over their interpretation among the Justices.

Supreme Court Decision Making Data

Wilkinson's article referenced several articles that dealt with decision making patterns at the Supreme Court of Canada. Those articles were sourced and referenced

[276] Recall that *Monsanto '04* had two distinct questions to be adjudicated. *Gilcross* had multiple issues, but they arose under one central question for the Supreme Court to decide through the *Patent Act*.
[277] *Supra* note 18 at 83.

directly. The decision making data on the Supreme Court was compiled from this data for comparison to the *Patented Medicines (Notice of Compliance)* cases and the patent cases.

Research undertaken by Peter McCormick concluded that the rate of unanimity among Supreme Court decisions is approximately 63 percent.[278] McCormick's study period started at the beginning of 1970 and extended to the end of 2002, covering 3,326 decisions in total. However, the rate of unanimity across this period was highly variable, ranging from a low of 43.4 percent in 1995[279] to a high of 90.2 percent in 1980.[280] The peak in unanimity occurred in 1980, just prior to the signing of the *Charter of Rights and Freedoms* in 1982, and decreased *steadily as Charter challenges at the Supreme Court grew in the 1980's and 1990's. Concurring decisions* peaked in 1995, and have declined ever since, correlating highly with the ensuing decline in Charter cases. Therefore, McCormick's "average" rate of unanimity has been calculated across a large range of values.

The 2004 to 2014 statistics on the Supreme Court of Canada's website present a more time-period relevant rate of unanimity for comparison,[281, 282] where the average rate

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[278] *Supra* note 210 at 106.
[279] *Ibid* at 107.
[280] *Ibid.* The incidence of non-unanimity was reached in 1980, at eleven cases. The total number of judgments by the Supreme Court that year is found by visiting the historical judgments page on the Supreme Court of Canada website at http://scc-csc.lexum.com/scc-csc/scc-csc/en/nav_date.do
[281] Supreme Court of Canada Statistics, 2004, 2014. Statistics on the Supreme Court of Canada's disposition rate are found on the Supreme Court of Canada website at http://www.scc-csc.gc.ca/case - dossier/stat/cat4-eng.aspx. The time period is more relevant since the Supreme Court heard four of the six *Patented Medicines (Notice of Compliance)* cases between 2004 and 2014.
[282] Supreme Court cases arrive at the court from three sources. If a party wishes to appeal the decision of another court, a panel of three judges of the Supreme Court can decide if leave to appeal will be granted to hear the case. The criteria for hearing a case are based on the importance of the issue at hand to the public, or if the case raises an important issue of law. Federal references require the Supreme Court to give an opinion on the questions referred to the Court by the Governor in Council, and are considered appeals as of right, as they are automatically approved to be heard. Certain serious criminal cases are also appeals as of right and must be heard by the Court. Of the 831 cases between 2004 and 2014, 170 (approximately twenty

of unanimity was 73 percent. The period is more relevant, since Charter cases are not comprising as high of a proportion of the cases heard as in the period covered by McCormick. The results are collated in Table Six, where the ratio of unanimous cases to the total caseload was totalled from the data, then compared to the copyright, patent, and *Patented Medicines (Notice of Compliance)* data.

Table 7: Split/Unanimous Judgments: A Comparison to the Copyright Pentalogy and the Supreme Court of Canada Generally

	Copyright[283]	PM(NOC)	Patent	Supreme Court
Split	8	1	4	226
Unanimous	3	5	21	600
Total	11	6	25	826
Split/Total	73%	17%	16%	27%
Unanimous/Total	27%	83%	84%	73%

The data show similar splits in the *Patented Medicines (Notice of Compliance)* and patent cases with the Supreme Court generally, but all three vary significantly from the copyright cases. The data is supportive of the previous findings on the high level of unanimity in patent and *Patented Medicines (Notice of Compliance)* cases earlier in this chapter.

During the period of 2004 to 2014, the Supreme Court heard four of the six *Patented Medicines (Notice of Compliance)* cases, where three of the four cases were unanimous. Over the time span of all of the *Patented Medicines (Notice of Compliance)*

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percent) cases heard were appeals as of right. Because twenty percent of the cases are appeals as of right, future research could involve revamping the data to remove the appeals as of right, to see if the pattern is different. If a significant portion of the appeals as of right are questions of criminal law, they may be imparting more disagreement into the decision making pattern. Comparing the *Patented Medicines (Notice of Compliance)* cases to Supreme Court cases that were only granted leave to appeal may prove to represent a more valid comparison.

[283] *Supra* note 18 at 82. The copyright data on split and unanimous decisions was calculated from Figure Two on page 82 of the Wilkinson article.

cases, 1998 to 2015, the average rate of unanimity climbed above both Supreme Court unanimity average calculations to 83 percent. However, there are few *Patented Medicines (Notice of Compliance)* cases, making the average highly sensitive to change - the addition of one more case would move that average by one-seventh, or fourteen percent.[284] Caution should be used in drawing any comparisons of the rate of unanimity of the *Patented Medicines (Notice of Compliance)* cases to the general level of Supreme Court unanimity, other than to state that they both have similarly high rates of unanimity. To state that the rate of unanimity is higher in the *Patented Medicines (Notice of Compliance)* cases may be premature until several more cases have been heard.

Based on 1,716 Supreme Court judgments between 1984 and 2006, McCormick states that the general rate of concurring reasons *written* is 36 percent.[285] This is much higher than having no concurring reasons among the *Patented Medicines (Notice of Compliance)* cases and the three percent for the patent cases. Having no concurring reasons in the *Patented Medicines (Notice of Compliance)* cases is inconsistent with McCormick's finding that "separate concurrences are a regular and ongoing aspect of the work [of the Supreme Court]."[286]

Case Disposition

The general Supreme Court disposition rate was calculated from the Supreme Court's published statistics, for the period 2004 to 2014.[287] The overall disposition rate

[284] Since there are currently six cases, each case impacts the average by one-sixth. If the case load grew to seven, each case would impact the average by one-seventh.
[285] Wilkinson, *Supra* note 18 at 83, quoting Peter McCormick, which can be referenced in note 130 at Table 1, page 144. There were 906 signatures on the 610 concurring reasons, among the 1716 reasons given during this period. The figure of 36 percent is achieved by dividing 610 by 1716 and converting to a percent.
[286] McCormick, *supra* note 34 at 163.
[287] See " Supreme Court Statistics 2004 to 2014," http://www.scc-csc.gc.ca/case-dossier/stat/index-eng.aspx

for the period was calculated to be 47 percent. The disposition rate, for the purposes of this paper, is the proportion of appeal cases allowed by the Supreme Court, expressed as a percentage of the total number of that type of case.

Since four of the six *Patented Medicines (Notice of Compliance)* cases were heard between 2005 and 2014, that reference data on case disposition is timely and relevant. However, the small number of *Patented Medicines (Notice of Compliance)* cases makes the disposition data highly sensitive - a change in the disposition of one case would affect the result by one in seven, or fourteen percent. However, comparing the overall disposition rate to the patent data together provides some insight, since thirty patent cases were in the study period.[288] If the pattern in the *Patented Medicines (Notice of Compliance)* cases is very close to the Supreme Court patent cases, then examining the disposition rate may provide some guidance as to future disposition rates for the *Patented Medicines (Notice of Compliance)* cases.

Table Seven provides the disposition of the Supreme Court patent and *Patented Medicines (Notice of Compliance)* cases. Table Eight summarizes the data in Table Seven and compares the disposition rate to Supreme Court cases between 2004 and 2014.

[288] Recall that the two Monsanto decisions in one case from 2004 rendered two separate decisions.

Table 8: Supreme Court of Canada Disposition on Patent Cases and *Patented Medicines (Notice of Compliance)* cases: Appeal Allowed or Dismissed[289]

Case Name	**Appeal Allowed or Dismissed**
Libbey-Owens-Ford Glass Co. v Ford Motor Co. of Canada	Dismissed.
Lacal Industries Ltd. v Slater Steel Industries Ltd.	Dismissed.
General Foods Ltd. v Struthers Scientific and International Corp.	Allowed.
Merck & Co. v S. & U. Chemicals Ltd.	Dismissed.
Tennessee Eastman Co., a division of Eastman Kodak Co. v Canada	Dismissed.
Gilcross Ltd. v Sandoz Patents Ltd.	Allowed. Cross appeal dismissed.
Burton Parsons Chemicals Inc. v Hewlett Packard (Canada) Ltd.	Allowed.
Dairy Foods Inc. v Co-operative Agricole de Granby	Dismissed.
Eli Lilly & Co. v S & U Chemicals Ltd.	Dismissed.
Farbwerke Hoechst AG Vormals Meister Lucius & Bruning v Halocarbon (Ontario) Ltd.	Allowed.
Monsanto Co. v Canada (Commissioner of Patents) (1979)	Allowed.
Consolboard Inc. v MacMillan Bloedel (Saskatchewan) Ltd.	Allowed.
Eli Lilly & Co. v Novopharm Ltd; Eli Lilly & Co. v Apotex Inc.	Allowed.
Armstrong Cork Canada v Domco Industries Ltd.	Dismissed.
Shell Oil Co. v Canada (Commissioner of Patents)	Allowed.
Pioneer Hi Bred Ltd. v Canada (Commissioner of Patents)	Dismissed.
Ciba-Geigy Canada Ltd. v Apotex Inc.	Allowed.
***Merck-Frosst Canada Inc. v Canada (Minister of National Health and Welfare)* (1998, PM(NOC))**	**Allowed**
Whirlpool Corp. v Camco Inc.	Dismissed.
Whirlpool Corp. v Maytag Inc.	Dismissed.
Harvard College v Canada (Commissioner of Patents)	Allowed.
Apotex Inc. v Wellcome Foundation Ltd.	Dismissed.
Monsanto Canada Inc. v Schmeiser (2004, first issue)	Allowed (in part).
Monsanto Canada Inc. v Schmeiser (2004, second issue)	Dismissed (in part).
Bristol-Myers Squibb v Canada (PM(NOC)	**Allowed**.
Astra Zeneca Canada Inc. v Canada (PM(NOC))	**Allowed.**
Apotex Inc. v Sanofi-Synthelabo (PM(NOC))	**Dismissed.**
Celgene Corp. v Canada (Attorney General)	Dismissed.
Teva Canada Ltd. v Pfizer Canada Inc. PM(NOC)	**Allowed.**
Sanofi-Aventis v Apotex Inc. (PM(NOC))	**Dismissed**

[289] Refer to Appendix Two for full citations for the patent cases. Cases in bold represent cases that arose to the Supreme Court after a *Patented Medicines (Notice of Compliance)* challenge.

Table 9: Summary of Patent and *Patented Medicines (Notice of Compliance) Case* Dispositions

	Patent Cases (with PM(NOC) Cases	Patent Cases (without PM(NOC) cases	PM(NOC) cases	General Supreme Court[290]
Total Cases[291]	30	24	6	822
Allowed	13	11	4	386
Dismissed	17	13	2	436
Disposition Rate (Percent of allowed cases of total)	43%	45%	67%	47%

The patent cases have a similar rate of allowed appeals as the Supreme Court generally, but the *Patented Medicines (Notice of Compliance)* cases have a slightly higher rate. Because the *Patented Medicines (Notice of Compliance)* cases are highly sensitive to changes in data, where the addition of one more case would change the disposition rate by fourteen percent, it is difficult to conclude that these cases have a higher overall disposition rate than the patent cases, or the Supreme Court cases generally. If that conclusion *could* be made, it could point to errors in interpretation of the *Patented Medicines (Notice of Compliance) Regulations* at the Federal Court or Federal Court of Appeal, in which case research could begin by identifying, categorizing, and studying the errors.

Solo Dissent

Joseph's study shows that the percentage of solo dissents written for cases primarily about private law has steadily decreased from 55 percent in the Laskin court to

[290] *Supra* note 287.
[291] Recall that Monsanto is counted as two cases, for a total of 30 cases. Gilcross is counted as one case that was allowed. Alternatively, it could be counted as one allowed appeal and one dismissed appeal but the overall result is not changed significantly.

ten percent in the McLachlin C.J. court.[292] This suggests that the Supreme Court Justices are generally not at odds with each other with respect to cases involving private litigants. Seeing that the *Patented Medicines (Notice of Compliance)* cases involve the Attorney General as a litigant (representing Health Canada), but are essentially private disputes between pharmaceutical companies, the lack of solo dissents across all of the *Patented Medicines (Notice of Compliance)* cases seems consistent with the low incidence of dissent in private cases in the McLachlin C.J. court.

Joseph also found that the solo dissent rate, as a percentage of *all* of the Supreme Court cases in the study, was steadily increasing, to a maximum of 6.3 percent in the McLachlin C.J. court, differing from the four percent rate of solo dissent in the patent cases and its non-existence in the *Patented Medicines (Notice of Compliance)* cases.[293] The solo dissent rates for Justices studied by Joseph who have sat on the Supreme Court since the first *Patented Medicines (Notice of Compliance)* cases in 1998 is set forth in Table Nine.[294] The percentage of solo dissents across the study categories is in Table Ten.

[292] *Supra* note 224 at 511, Table 7. Under the McLachlin C.J. court, sixty percent of solo dissents are written for criminal cases, and thirty percent are written for public cases.
[293] Refer to Table Two on page 81.
[294] Adapted from a similar table created by Professor Margaret Ann Wilkinson, *Supra* note 18 at 80. The original data was extracted from Joseph, *Supra* note 182 at 511, Table 7. Justices Abella, Charron, Cromwell, Rothstein, Karakatsanis, Gascon, and Moldaver are not included in Joseph's data.

Table 10: Solo dissent rates for Justices sitting in 2002 or appointed by the end of 2003

Justice (all sat on the Court for various PM(NOC) cases)	Frequency of Solo Dissent Reported by Joseph (up to and including 2003)	Number of PM(NOC) cases heard	Dissent
Major	More than average	2	1 (not solo)
Arbour	More than average	0	N/A
L'Heureux-Dubé	More than average	1	No
Bastarache	More than average	3	1 (not solo)
McLachlin	Average	4	No
LeBel	Average	4	No
Iacobucci	Less than average	1	No
Gonthier	Less than average	1	No
Deschamps	Less than average	4	No
Cory	Less than average	1	No
Binnie	Never	3	No
Fish	Never	3	No

Table 11: Percent of Solo Dissents of the Copyright, *PM(NOC)*, and Patent Caseloads

	Copyright Cases	*PM(NOC)* Cases	Patent Cases
Solo Dissents	0	0	1
Total Caseload	11	6	30
Percentage of Solo Dissents	0%	0%	3%

There is a complete lack of solo dissents in the *Patented Medicines (Notice of Compliance)* cases; with the small number of cases, it would not be prudent to distinguish them from the Supreme Court data generally. The lone case with *any* type of dissent was *Bristol-Myers*, an issue of statutory interpretation under section 5(1) of the *Patented Medicines (Notice of Compliance) Regulations*, where three dissenting judges felt that Biolyse should have been treated like a generic company applying to copy an innovative medicine. If this was the case, the *Patented Medicines (Notice of Compliance) Regulations* would apply, and the Biolyse product would be treated as a generic medicine. The majority, however, found that Biolyse was an innovator, and that the

Regulations did not apply to Biolyse's product. If section 5(1) was found to apply, the contentious issue of patenting natural substances would have also arisen, which would also involve the element of patentable subject matter, and not the *Patented Medicines (Notice of Compliance) Regulations*. With the level of dissent being so low, it is not surprising that the two Justices that have a higher frequency of solo dissent *generally* are the only ones that took part in the sole case with a dissent.

Chapter Seven: Conclusion

The purpose of this study was to evaluate the decision making pattern of the *Patented Medicines (Notice of Compliance)* cases and compare it to the pattern in the Supreme Court patent cases, the Supreme Court copyright cases in Wilkinson's study, and the pattern in general Supreme Court jurisprudence.

Comparing the *Patented Medicines (Notice of Compliance)* Cases to the Supreme Court Copyright Cases

With respect to the copyright cases, a similar pattern of decision making could indicate that the Justices were having similar issues with both types of cases. Since their commonality is the fact that they were all cases that arose following a judicial review at the Federal Court, a similar decision making pattern could point to problems with the judicial review process for these types of cases, providing guidance for future research. Areas of concern with employing judicial review for the generic approval cases include the reversed burden of proof and the standard of review of reasonableness. In addition, judicial review can only answer one question, and the process is therefore limited to answering whether or not Health Canada acted *reasonably* when it added patents to its Patent Register, so the process constrains the judge from determining the validity of the patents in question. Other potential problems include proceeding summarily (which disallows the examination of live witnesses), and lacking an effective appeal process for the patent holder. A dissimilar pattern between the two case groups suggests that the process of judicial review is *not* problematic, as asserted by the European Union Member States in their complaint.

The decision making pattern in the copyright cases is significantly different from the *Patented Medicines (Notice of Compliance)* cases. The rate of unanimous decisions

is 27 percent, compared to 83 percent in the *Patented Medicines (Notice of Compliance)* cases, and the rate of concurrence is 36 percent, compared to zero percent in the *Patented Medicines (Notice of Compliance)* cases. With a three-fold higher rate of unanimity, combined with no concurring opinions (with and without dissent), there appears to be much less divided opinion on matters related to the regulatory approval of generic drugs in Canada than to copyright.

The copyright cases also exhibit a rate of dissent that is almost double that of the *Patented Medicines (Notice of Compliance)* cases. If Wilkinson's conclusion is correct, that copyright law is "in a dynamic period of flux and change,"[295] "'big' questions are coming before the Court,"[296] and "policy-divergent responses would appear to need to be generated to prepare the field within which these can be managed,"[297] then the *regulations* linking patent and approval of generic pharmaceuticals *are not*. This conclusion is supported by the fact that the *Patented Medicines (Notice of Compliance)* cases generate an average of 1.2 written reasons per case, while the copyright cases generate 2.2 reasons per case.

A comparison of decision making patterns in Supreme Court *Patented Medicines (Notice of Compliance)* cases with Wilkinson's Supreme Court copyright cases does not support the conclusion that the two sets of cases are adjudicated with a similar underlying problem that could be related to judicial review in the lower courts. The primary cases in both sets were adjudicated by judicial review, but the study does not corroborate the view that the *Patented Medicines (Notice of Compliance)* cases are problematic *because of*

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[295] Wilkinson, *supra* note 18 at 84, citing McCormick, *supra* note 206 at 166.
[296] *Ibid*.
[297] *Ibid*.

judicial review. This is supported by a qualitative analysis of the six *Patented Medicines (Notice of Compliance)* cases, of which four dealt with cases *specific to those regulations*. And, of those four, *none* pointed to issues with the process of judicial review itself, or suggested that judicial review was causing a problem. The other two *Patented Medicines (Notice of Compliance)* cases dealt specifically with patent issues, where one appeal was allowed and the other was dismissed. A subsequent study of Federal Court and Federal Court of Appeal cases would provide additional evidence on the issue of judicial review, but comparative data on decision making patterns at the level of the Federal Court does not exist in the literature. A general database of decision making would have to be built before any comparisons could be made. Qualitative studies on subsets of these cases would be a mode of analysis that may be more realistic.

Comparing *Patented Medicines (Notice of Compliance)* Case Data to Supreme Court Patent Case Data

To complement this comparative analysis, the decision making pattern in the *Patented Medicines (Notice of Compliance)* cases was also compared to the Supreme Court patent cases from 1970 to 2014. In the event that the pattern was not found to be similar to that of the copyright cases, the pattern may be similar the patent subset of Supreme Court cases.

The *Patented Medicines (Notice of Compliance)* case decision making pattern is almost identical to the patent case pattern, so this comparison provides no evidence of excessive disagreement in adjudicating the *Patented Medicines (Notice of Compliance)* cases, and it *does* suggest that the cases are adjudicated similarly to the patent cases, despite the difference in the adjudication process. Two of the six *Patented Medicines*

(Notice of Compliance) cases directly involved issues requiring interpretation of the *Patent Act*, which supports this conclusion.

Eighty-three percent (five out of six) of the *Patented Medicines (Notice of Compliance)* cases were decided unanimously, only slightly higher than the 75 percent rate found in the Supreme Court patent cases generally. In addition, the number of majority judgments with concurring reasons was very low in both – four percent in the patent cases, and zero in the *Patented Medicines (Notice of Compliance)* cases. There were similar low levels of unanimous dissent in both, at 17 percent (one out of six cases) for the *Patented Medicines (Notice of Compliance)* cases and 21 percent (five out of twenty-four) for the patent cases. The patent cases had five out of thirty cases (17 percent) with unanimous dissent, while the *Patented Medicines (Notice of Compliance)* cases had one out of six (17 percent). The similar pattern of decision making is not surprising, given that two of the six *Patented Medicines (Notice of Compliance)* cases dealt with issues requiring interpretation of the *Patent Act*,[298] and the other four deal with the interpretation of a piece of legislation that is essentially outlines a procedure for getting generic approval.

Comparing *Patented Medicines (Notice of Compliance)* Case Data to Supreme Court Data

Both the Supreme Court cases overall, and the *Patented Medicines (Notice of Compliance)* cases have a high rate of unanimous decision making, with the Supreme Court at 73 percent and the *Patented Medicines (Notice of Compliance)* cases at 83 percent. Applying Songer and Siripurapu's conclusions, this suggests that there would be

[298] *Teva* and *Sanofi-Synthelabo*.

fewer issues per *Patented Medicines (Notice of Compliance)* case than the Supreme Court generally. Given that one or two issues per case were identified, this seems plausible when considering the breadth of cases that the Supreme Court hears. In contrast to the low rates of unanimity in the Charter of Rights and Freedom cases from the mid-eighties to the mid-nineties, the high rate of unanimity in *Patented Medicines (Notice of Compliance)* cases signals little flux or uncertainty with respect to the *Patented Medicines (Notice of Compliance) Regulations*. This is supported by a much lower level of concurrence as well.

Dissent – Comparing Supreme Court Jurisprudence to the *Patented Medicines (Notice of Compliance)* Cases

The lone *Patented Medicines (Notice of Compliance)* case with a dissent was *Bristol-Myers*. The dissent was written by Bastarache J., with Major J. in agreement. According to Joseph, both Major J. and Bastarache J. write *solo* dissenting opinions at a higher than average rate than their colleagues. Given the small number of cases, it is not surprising that there are no solo dissents, but the presence of *some* dissent, unanimous dissent in this case, written by higher-than-average dissenters (across all of the cases they judged), suggests that the rate of general dissent is similar to Supreme Court jurisprudence overall. With an overall low rate of dissent, it is difficult to conclude that the Justices have significant disagreement when adjudicating the *Patented Medicines (Notice of Compliance)* cases, regardless of how the process was adjudicated in the lower court.

The Composition of the Court in the Cases

There has been a high degree of consistency in the composition of the court in deciding the *Patented Medicines (Notice of Compliance)* cases. The same four Justices

have sat on four of the six cases. Of the four, three have sat on the same three cases and voted together on all. Binnie J. wrote two of the judgments, while the remaining four were written by different Justices, indicating that the issues in the cases can be managed by most Justices, not necessarily requiring a scientific background. The implications of the consistency of the court on the decision making pattern itself will be borne out as more cases are heard at the Supreme Court – there are presently too few cases to make any conclusions about the effect of the composition of the court.

Disposition Rates

Overall, four cases were overturned at the Supreme Court, while two were dismissed. Of the four allowed, two were about patent issues (*Merck '98* and *Teva*), and two were primarily about *Patented Medicines (Notice of Compliance) Regulations* issues (*Bristol-Myers* and *Astra-Zeneca*). Of the dismissed cases, one was primarily about patent (*Sanofi-Synthelabo*) and one was about the *Patented Medicines (Notice of Compliance) Regulations* (*Sanofi-Aventis*). The disposition rate for the *Patented Medicines (Notice of Compliance)* cases is higher than the disposition rate for the Supreme Court overall. With this small data set, it is difficult to conclude that the Federal Court and the Federal Court of Appeal have difficulty with the interpretation or application of the *Patented Medicines (Notice of Compliance) Regulations* because of the judicial review process, but it does provide direction for future study into the issue. A suitable investigation into the cases where appeals were allowed may reveal a common element, and whether or not it is related to the process of judicial review. The high overturn rate also suggests that the Federal Court of Appeal's treatment of the Federal

Court's decisions in *Patented Medicines (Notice of Compliance)* cases requires investigation.

Private Law and the Supreme Court

The small number of *Patented Medicines (Notice of Compliance)* cases overall is indicative that there are few significant problems of national concern with the adjudication of these cases, since only six cases have risen to the Supreme Court since the *Regulations* came into effect in 1993. Since the cases are primarily private economic law cases, it could be postulated that the Supreme Court justices choose not to hear the cases, and give little weight to these private matters when they do hear them. However, the current study does indicate that the Supreme Court Justices do not treat all private economic law cases the same. The different decision making pattern between the copyright cases, which are also private economic law, and the *Patented Medicines (Notice of Compliance)* cases indicates that the different realms of law are treated accordingly, and private economic law is not "blanketed" with any judicial policy. Three of the six *Patented Medicines (Notice of Compliance)* cases have been decided by a panel of nine, and all three of those cases required interpreting the *Patented Medicines (Notice of Compliance) Regulations,* suggesting that the Supreme Court may view issues in the *Patented Medicines (Notice of Compliance)* cases as important to Canadians as other types of unrelated cases.

Although both sets of cases are considered matters of private law, both have aspects that are relevant to all Canadians, and an examination into those aspects may reveal additional information about the decision making results.

Is Judicial Review Contributing to Injustice in the *Patented Medicines (Notice of Compliance) Cases?*

The analysis does not provide support for the assertion that the judicial review component of the *Patented Medicines (Notice of Compliance) Regulations* provides an avenue for creating disagreement that could lead to the incorrect adjudication in generic drug approval cases. Even though the process is short of a full trial, the study does not indicate that the Justices cannot incorporate aspects of health law, administration law, and patent law to properly adjudicate the cases at the federal level. This is also supported by the decision making pattern in the cases, which is nearly identical with the pattern for Supreme Court patent cases adjudicated since 1970.

If the high degree of unanimity in the *Patented Medicines (Notice of Compliance)* cases is indicative of what it stands for on its face – that high unanimity equates to less disagreement because of certainty in the interpretation, application, and issues before the law, then the results suggest that the *Regulations* present little difficulty for the justices in their current form. This suggests that the *Patented Medicines (Notice of Compliance)* cases *have, for the most part, a correct answer*, or, at least, an answer that can be adjudicated without extreme difficulty. The Justices exhibit a different pattern of decision making in the copyright cases, which are also private economic rights cases, which lends credence to the idea that the Justices are flexing their judicial muscle on a case-by-case basis, and not following a policy of overtly choosing unanimity.

Because the *Patented Medicines (Notice of Compliance) Regulations* involve three aspects of law – administrative, health, and patent law - any adaptation of the *Regulations* requires examining which of these aspects is problematic before meaningful changes can be made to the *Regulations*. This study indicates that the judicial review

process is not problematic, and therefore does not suggest that there are any issues associated with a process that only answers one question, nor the fact that it proceeds summarily. Neither does it elucidate any issues with the burden of proof, the standard of review, nor the appeal rights of the litigants. Judicial review appears to be suitable for this process, especially when one considers the fact that the assessment of any patents for the purpose of approving generics is performed in the context of the *uses approved by Health Canada only*.

Future Research

Further Study at the Federal Court and Federal Court of Appeal

Additional support for the conclusion that judicial review is not contributing to injustice in the *Patented Medicines (Notice of Compliance)* cases could be achieved by qualitatively examining the *Patented Medicines (Notice of Compliance)* cases at the Federal Court and the Federal Court of Appeal, where the cases will involve significantly more mixed questions of law and fact.

A *quantitative* examination of the *Patented Medicines (Notice of Compliance)* cases at the Federal Court, similar to the examination of the decision making pattern of the *Patented Medicines (Notice of Compliance)* cases at the Supreme Court could also be undertaken, but there are significantly more cases to study, and the actual number of cases is difficult to quantify. As mentioned, Sanofi-Aventis, the inventor of the hypertension drug Altace (ramipril), filed three suits in Federal Court to block the genericization of the medicine by three separate manufacturers, even though they had already lost an initial challenge from generic medicine producer, Apotex. An even bigger example, the litigation between Astra-Zeneca and Apotex over the blockbuster

gastroesophogeal reflux drug Losec (omeprazole) lasted seventeen years.[299] Apotex filed twelve separate Notices of Allegation against various Losec patents, which resulted in fifty-five decisions by the Federal Court and fifteen decisions by the Federal Court of Appeal (and one at the Supreme Court, as discussed).[300] Conservatively, if fifty medicines have lost patent status since the inception of the *Patented Medicines (Notice of Compliance) Regulations* in 1994, then there are potentially thousands of cases to examine. An initial study to determine how many drugs have lost patent status since 1994 is an initial step.

Data Exclusivity

Data exclusivity is another current issue that involves Division Eight of Canada's *Food Drug Regulations*[301] and section 5(5) of the *Patented Medicines (Notice of Compliance) Regulations*. Data exclusivity refers to the period of time where an innovator of a new pharmaceutical that has been issued a Notice of Compliance can protect their data from generic manufacturers who wish to copy the medicine. Currently, data exclusivity is eight years from the date the Notice of Compliance was granted, but a generic manufacturer can *apply* for access to the data within six years from the date of the Notice of Compliance. Canada rejected the European Union's proposal to extend data protection by an additional two years[302] in negotiations leading to the *Canada-European*

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[299] *Supra* note 105 at 12.
[300] *Ibid*.
[301] *Supra* note 56 at C.08.004.1.
[302] *Supra* note 110. The European Union also negotiated successfully to extend patent term by the amount of time equal to the difference between the filing date for a Notice of Compliance and the date the Notice of Compliance is granted. This extends patent life by over two years, and if the data exclusivity provisions were applied, the total time extension is estimated by Grootenorst and Hollis to be approximately five years.

Union: Comprehensive Economic Trade Agreement.[303] With additional proposals by the European Union to extend the basic patent term, acceptance of all of the proposals could have added five and a half years of market monopoly.[304] Extending data protection means that data exclusivity could have become another lever for extending patent term since it shortens the amount of time that a generic manufacturer has for developing the product which may mean that the generic version will not be ready by the time the relevant patents have expired. In addition, drugs that have lost patent protection may benefit from the additional exclusivity period and prevent manufacturers from copying the product, even though they have no patent protection. This push by the European Union did not consider the additional protection afforded to patent holders through the twenty-four month automatic stay in Section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, and only serves to lengthen the period of brand exclusivity, making drug therapy more costly for Canadians. Justification for Canada's current protection of pharmaceutical patents through the *Patented Medicines (Notice of Compliance) Regulations* needs to be elucidated and supported with data about the time required for generic drug development and approval to provide Canada with a defensible position for future international trade negotiations. Extending data exclusivity

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[303] The text of the agreement was finalized on September 26, 2014 and is currently awaiting ratification. The finalized text can be found at www.international.gc.ca/CETA.

[304] *Supra* note 110. Also see Paul Grootendorst and Aidan Hollis, "The 2011 Canada-European Union Comprehensive Economic and Trade Agreement: an economic impact assessment of the EU's proposed pharmaceutical intellectual property provisions," (2011) 8(2), J Gen Meds, 81-103 at 93. The European Union negotiated successfully to extend patent term by the amount of time equal to the difference between the filing date for a Notice of Compliance and the date the Notice of Compliance is granted (patent term restoration). This extended patent life by over two years, and if the data exclusivity provisions were applied, the total time extension is estimated by Grootenorst and Hollis to be approximately five and a half years.

complicates patenting in Canada, as market exclusivity would become affected by two separate levers that really serve the same purpose.

Equal Rights of Appeal

Article *9 bis* of the Canada-European Union: Comprehensive Economic Trade Agreement states that

> If a Party relies on "patent linkage" mechanisms whereby the granting of marketing authorisations (or notices of compliance or similar concepts) for generic pharmaceutical products is linked to the existence of patent protection, it shall ensure that all litigants are afforded equivalent and effective rights of appeal.[305]

However, there have been no adjustments to the *Patented Medicines (Notice of Compliance) Regulations* regarding an appeal process to date. Research needs to be undertaken to determine if current provisions, with the lack of an effective appeal for the patent holder, fulfill this provision. Consideration needs to be given to the full process that is still available through the *Patent Act*, and provisions for damages that apply if the patents are later upheld. An additional appeal functions as a patent extension, and changing the *Regulations* to allow for an appeal will have costly consequences for the court system, as well as for users of medicines in Canada.

Final Conclusions

Given the evidence in the pattern of decision making, it is difficult to conceive that there is any merit to amending the *Patented Medicines (Notice of Compliance) Regulations* to encompass a complete action for infringement. Suzanne Porter's conclusion that the *Patented Medicines (Notice of Compliance) Regulations* need to be amended to convert a generic patent challenge to a full action for infringement is not

[305] *Supra* note 303 at 9, 10.

supported by this study, in that there is no evidence that the process of judicial review at the Federal Court is causing more disagreement among the Supreme Court Justices than in the general Supreme Court jurisprudence. The assertion by the European Union that innovative drugs are not given full protection under the *Patent Act*, because of the *Patented Medicines (Notice of Compliance) Regulations*, is therefore not warranted, as the current process essentially adds an additional layer of patent protection, and the additional process is adjudicating the claims correctly. An action for infringement is still available by the innovator under the *Patent Act*, even though the generic manufacturer is free to start manufacturing and selling the generic. This is supports Canada's position in the complaint filed by the European Union in 2000, as well as the conclusions in the Report of the Panel.[306]

[306] *Supra* note 5 at p 116.

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Appendix 1: NAFTA Article 1709

1. Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of application. For purposes of this Article, a Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful," respectively.
2. A Party may exclude from patentability inventions if preventing in its territory the commercial exploitation of the inventions is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that the exclusion is not based solely on the ground that the Party prohibits commercial exploitation in its territory of the subject matter of the patent.
3. A Party may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than microorganisms; and
(c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production.
Notwithstanding subparagraph (b), each Party shall provide for the protection of plant varieties through patents, an effective scheme of *sui generis* protection, or both.
4. If a Party has not made available product patent protection for pharmaceutical or agricultural chemicals commensurate with paragraph 1:
(a) as of January 1, 1992, for subject matter that relates to naturally occurring substances prepared or produced by, or significantly derived from, microbiological processes and intended for food or medicine, and
(b) as of July 1, 1991, for any other subject matter,
that Party shall provide to the inventor of any such product or its assignee the means to obtain product patent protection for such product for the unexpired term of the patent for such product granted in another Party, as long as the product has not been marketed in the Party providing protection under this paragraph and the person seeking such protection makes a timely request.
5. Each Party shall provide that:
(a) where the subject matter of a patent is a product, the patent shall confer on the patent owner the right to prevent other persons from making, using or selling the subject matter of the patent, without the patent owner's consent; and
(b) where the subject matter of a patent is a process, the patent shall confer on the patent owner the right to prevent other persons from using that process and from using, selling, or importing at least the product obtained directly by that process, without the patent owner's consent.
6. A Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate

interests of the patent owner, taking into account the legitimate interests of other persons.
7. Subject to paragraphs 2 and 3, patents shall be available and patent rights enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced.
8. A Party may revoke a patent only when:
(a) grounds exist that would have justified a refusal to grant the patent; or
(b) the grant of a compulsory license has not remedied the lack of exploitation of the patent.
9. Each Party shall permit patent owners to assign and transfer by succession their patents, and to conclude licensing contracts.
10. Where the law of a Party allows for use of the subject matter of a patent, other than that use allowed under paragraph 6, without the authorization of the right holder, including use by the government or other persons authorized by the government, the Party shall respect the following provisions:
(a) authorization of such use shall be considered on its individual merits;
(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time. The requirement to make such efforts may be waived by a Party in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
(c) the scope and duration of such use shall be limited to the purpose for which it was authorized;
(d) such use shall be non-exclusive;
(e) such use shall be non-assignable, except with that part of the enterprise or goodwill that enjoys such use;
(f) any such use shall be authorized predominantly for the supply of the Party's domestic market;
(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, on motivated request, the continued existence of these circumstances;
(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
(i) the legal validity of any decision relating to the authorization shall be subject to judicial or other independent review by a distinct higher authority;
(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial or other independent review by a distinct higher authority;

(k) the Party shall not be obliged to apply the conditions set out in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anticompetitive. The need to correct anticompetitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions that led to such authorization are likely to recur;
(l) the Party shall not authorize the use of the subject matter of a patent to permit the exploitation of another patent except as a remedy for an adjudicated violation of domestic laws regarding anticompetitive practices.
11. Where the subject matter of a patent is a process for obtaining a product, each Party shall, in any infringement proceeding, place on the defendant the burden of establishing that the allegedly infringing product was made by a process other the patented process in one of the following situations:
(a) the product obtained by the patented process is new; or
(b) a substantial likelihood exists that the allegedly infringing product was made by the process and the patent owner has been unable through reasonable efforts to determine the process actually used.
In the gathering and evaluation of evidence, the legitimate interests of the defendant in protecting its trade secrets shall be taken into account.
12. Each Party shall provide a term of protection for patents of at least 20 years from the date of filing or 17 years from the date of grant. A Party may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.[307]

[307] *Supra* note 3, Ch 17, Art 1709.

Appendix 2: Patent Cases by Panel Size, Issue, Industry, and Primary Statute Involved

	Panel Size	**Case Type**	**Industry**
Libbey-Owens-Ford Glass Co. v Ford Motor Co. of Canada, [1970] SCR 833, 1970 SCJ 40 [*Libbey*].	5	Patentable subject matter	Auto (patent for curving glass on windshields)
Lacal Industries Ltd. v Slater Steel Industries Ltd., [1972] SCR 29, 1971 SCJ 86 [*Lacal*].	5	Patentable subject matter – prior art	Steel
General Foods, Ltd. v Struthers Scientific and International Corp., [1974] SCR 98, 1971 SCJ 142 [*General Foods*].	7	Jurisdiction to hear patent matters	Food
Merck & Co. v S. & U. Chemicals Ltd., [1974] SCR 839, 1972 SCJ 129 [*Merck '74*].	5	Royalty rates on compulsory licencing products	Pharmaceutical
Tennessee Eastman Co., a division of Eastman Kodak Co. v Canada (Commissioner of Patents), [1974] SCR 111 [*Tennessee*].	5	Patentable subject matter – methods not patentable	Medical
Gilcross Ltd. v Sandoz Patents Ltd., [1974] SCR 1336, 1972 SCJ 144 [*Gilcross*].	5	Inventive step	Pharmaceutical
Burton Parsons Chemicals Inc. v Hewlett-Packard (Canada) Ltd., [1976] 1 SCR 555, 1974 SCJ 154 [*Burton*].	9 (all present)	Inventive step (non-obviousness)	Chemical/pharmaceutical
Dairy Foods Inc. v Co-operative Agricole de Granby, [1976] 2 SCR 651, 1975 SCJ 95 [*Dairy Foods*].	9 (5 majority, 3 dissenting, Ritchie: solo dissent)	Inventive step	Chemical process where end product is food or drug
Eli Lilly and Co. v S & U Chemicals Ltd, [1977] 1 SCR 536, 1976 SCJ 36 [*Lilly '77*].	9 (Laskin Dickson, de Grandpre dissenting)	Compulsory licencing	Pharmaceuticals
Farbwerke Hoechst AG Vormals Meister Lucius & Bruning v Halocarbon (Ontario) Ltd., [1979] 2 SCR 929, 1979 SCJ 78 [*Farbwerke*].	7(Martland, Estey, Dickson dissenting)	1)Inventive step 2)Nonobviousness	Pharmaceuticals (anesthetics)

Monsanto Co. v Canada (Commissioner of Patents), [1979] 2 SCR. 1108, [1979] SCJ No. 89 [*Monsanto '79*].	9 (Martland and Dickson dissenting)	Claims too broad for patenting	Chemical Engineering
Consolboard Inc. v.MacMillan Bloedel (Saskatchewan) Ltd., [1981] 1 SCR 504, 1981 SCJ No. 44 [*Consolboard*].	5		Forest Products
Eli Lilly & Co. v Novopharm Ltd.; Eli Lilly & Co. v Apotex Inc., [1998] 2 SCR 129, [1998] SCJ No. 59 [*Lilly '98*].	7	Sublicensing under a compulsory licence	Pharmaceutical
Armstrong Cork Canada v Domco Industries Ltd., [1982] 1 S.C.R. 907 [*Armstrong*].	5	Damages assigned to a Patentee S.57 *Patent Act*	Building Materials
Shell Oil Co. v Canada (Commissioner of Patents), [1982] 2 SCR 536, 1982 SCJ 82 [*Shell*].	5(Estey, Martland, Chouinard, Lamer dissenting)	Inventive step	Chemical Engineering
Pioneer Hi Bred Ltd. v Canada (Commissioner of Patents), [1989] 1 S.C.R. 1623 [1989] S.C.J. No. 72 [*Pioneer*].	7 (Beetz and le Dain took no part in the decision); Sopinka and Wilson sat out	Patentable Subject Matter (S.2)	Life sciences (seeds)
Ciba-Geigy Canada Ltd. v Apotex Inc., [1992] 3 SCR 120, [1992] SCJ 83 [*Ciba*].	5 (Stevenson J took no part in the decision); Corey, Sopinka, Major, McLachlin out	Passing off (generic tablet takes on same shape and colour of brand name)	Pharmaceutical
Merck-Frosst Canada Inc. v Canada (Minister of National Health and Welfare), [1998] 2 SCR 193, 1998 SCJ 58 [*Merck-Frosst*].	7	Filing of Notice of Allegation; sublicencing under a compulsory licencing regime (PM(NOC))	Pharmaceutical

Whirlpool Corp. v Camco Inc., [2000] 2 S.C.R. 1067, [2000] S.C.J. No. 68 [*Whirlpool Camco*].	7	Overlapping claims; obviousness	Industrial(mechanical)
Whirlpool Corp. v Maytag Inc., [2000] 2 S.C.R. 1116, [2000] S.C.J. No. 68 [*Whirlpool Maytag*].	7	Overlapping claims; obviousness	Industrial(mechanical)
Harvard College v Canada (Commissioner of Patents), [2002] 4 SCR 45, *2002* SCC 76 [*Harvard*].	All 9 present	Patentable Subject Matter (not PM(NOC))	Life sciences (higher and lower life forms)
Apotex Inc. v Wellcome Foundation Ltd. [2002] 4 S.C.R. 153, [2002] S.C.J. No. 78 [*Apotex*].	All 9 present	Standard of review of mixed law and fact; utility (new use of an old compound); utility/inventorship (not PM(NOC))	Pharmaceutical
Monsanto Canada Inc. v Schmeiser, [2004] 1 SCR 902, 2004 SCC 34 [*Monsanto '04*].	9	Use of a patented invention (not PM(NOC))	Agriculture
Bristol-Myers Squibb v Canada (Attorney General), [2005] 1 SCR 533, [2005] SCJ 26 [*Bristol-Myers*].	All 9 present	Bioequivalence; standard of review: Correctness (PM(NOC)); brand vs brand	Pharmaceutical
Astra Zeneca Canada Inc. v Canada (Minister of Health), [2006] 2 SCR 560, 2006 SCC 49 [*Astra Zeneca*].	9	Listing of new patents for a drug that the innovator company withdrew from the market (Losec) (PM(NOC))	Pharmaceutical

Apotex Inc. v Sanofi-Synthelabo Canada Inc., 2008 SCC 61, [2008] 3 SCR 265, [2008] SCJ 63 [*Sanofi-Synthelabo*].	7	Novelty and obviousness (PM(NOC))	Pharmaceutical
Celgene Corp. v Canada (Attorney General), [2011] 1 SCR 3, 2011 SCJ 1 [*Celgene*].	7	Importing	Pharmaceutical
Teva Canada Ltd v Pfizer Canada Inc., [2012] 3 SCR 625, 2012 SCC 60 [*Teva*].	9	Sufficiency of disclosure of patent (PM(NOC))	Pharmaceutical
Sanofi-Aventis v Apotex Inc., [2015], 2015 SCC 20 [*Sanofi-Aventis*].	9	Damages (PM(NOC))	Pharmaceutical

Appendix 3: The Decision Making Data for all Supreme Court Patent and *Patented Medicines (Notice of Compliance)* Cases since 1970[308,309,310]

Case	**Issue**	**Decision**	**Majority Number of Signatures**	**Concurring Decision**	**Number of Concurring Reasons**	**Concurring Number of Signatures**	**Number of Dissents**	**Number of Dissent Signatures**
Harvard College v Canada [2002] 4 SCR 45	Patenting life	Majority with dissent	5	0	0	0	1	4
Astra Zeneca v Canada [2006] 2 SCR 560	Listing new patents on a drug withdrawn from the market	Unanimous	9	0	0	0	0	0
Bristol-Myers Squibb v Canada (Attorney General), [2005] 1 SCR 533	Bioequivalence; standard of review in PM(NOC) cases	Majority with dissent	6	0	0	0	1	3
Burton Parsons Chemicals Inc. v Hewlett-Packard (Canada) Ltd., [1976] 1 SCR 555	Inventive step (non-obviousness)	Unanimous	9	0	0	0	0	0
Celgene Corp v Canada (Attorney General), [2011] 1 SCR 3	U.S. manufactured product sent directly to Canada	Unanimous	9	0	0	0	0	0
Ciba-Geigy Canada Ltd. v Apotex Inc., [1992] SCJ 83	Passing off (generic looks identical to brand)	Unanimous	5	0	0	0	0	0
Dairy Foods Inc. v Co-operative Agricole de Granby, [1976] 2 SCR 651,	Inventive step (chemical process where end product is food or drug)	Majority with two dissents (one is solo)	5	0	0	0	2	4 (3 +1)
Eli Lilly and Co. v S & U Chemicals Ltd, [1977] 1 SCR 536	Compulsory licensing (safety)	Majority with concurring decision	6	1	1	3	0	0

[308] MCormick, Blocs, Swarms, p.111.
[309] Since 1993 for *Patented Medicines (Notice of Compliance)* cases, since the legislation was introduced in 1993.
[310] *Patented Medicines (Notice of Compliance)* cases are denoted in red.

Farbwerke Hoechst AG Vormals Meister Lucius & Bruning v Halocarbon (Ontario) Ltd., [1979] 2 SCR 929,	Inventive step; non-obviousness	Majority with dissent	6	0	0	0	1	3
Monsanto Co. v. Canada (Commissioner of Patents), [1979] 2 S.C.R. 1108, [1979] S.C.J. No. 89	Claims too broad cannot be used for patenting	Majority with dissent	7	0	0	0	1	2 (no reasons given)
Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd., [1981] 1 S.C.R. 504, 1981 S.C.J. No. 44.	In the specification, the inventor must specify how he invented his invention but not necessarily the end use of the invention	Unanimous	5	0	0	0	0	0
General Foods, Ltd. v Struthers Scientific and International Corp., [1974] SCR 98	Jurisdiction to hear patent matters	Unanimous	7	0	0	0	0	0
Gilcross Ltd. v Sandoz Patents Ltd., [1974] SCR 1336	Inventive step not required to be shown for each sub-product of the main product if it is the same	Unanimous	5	0	0	0	0	0
Lacal Industries Ltd. v Slater Steel Industries Ltd., [1972] SCR 29	Patentable subject matter – an economical way of doing what is already known is not patentable	Unanimous	5	0	0	0	0	0
Libbey-Owens-Ford Glass Co. v Ford Motor Co. of Canada, [1970] SCR 833	Patentable subject matter always includes the use of the subject matter	Unanimous	5	0	0	0	0	0
Merck & Co. v S. & U. Chemicals Ltd., [1974] SCR 839,	Assigning royalty rates under compulsory licensing	Unanimous	5	0	0	0	0	0

[1972] SCJ 129.								
Merck-Frosst Canada Inc. v Canada (Minister of National Health and Welfare), [1998] 2 SCR 193	Purchasing raw ingredient from another company with a Notice of Compliance is not infringement	Unanimous	7	0	0	0	0	0
Eli Lilly & Co. v. Novopharm Ltd.; Eli Lilly & Co. v. Apotex Inc., [1998] 2 S.C.R. 129, [1998] S.C.J. No. 59	Sublicernsing under a compulsory license	Unanimous	7	0	0	0	0	0
Merck Frosst Canada Ltd. v Canada (Health), [2012] 1 SCR 23, 2012 SCJ 3	Access to information under the Access to Information Act	Majority with dissent	6	0	0	0	1	3
Shell Oil Co. v Canada (Commissioner of Patents), [1982] 2 SCR 536	Patentable subject matter – new use of an old dose is patentable if it is part of a new mixture	Unanimous	5	0	0	0	0	0
Tennessee Eastman Co., a division of Eastman Kodak Co. v Canada (Commissioner of Patents), [1974] SCR 111	Patentable subject matter – a new use for an old substance; use cannot be claimed separately from substance	Unanimous	5	0	0	0	0	0
Teva Canada Ltd v Pfizer Canada Inc., [2012] 3 SCR 625	Sufficiency of disclosure in patent specification	Unanimous	*7*	0	0	0	0	0
Whirlpool Corp. v Maytag Corp., [2000] 2 SCR 1116	Overlapping claims; obviousness	Unanimous	7	0	0	0	0	0
Whirlpool Corp. v Camco Inc., [2000] 2 S.C.R. 1067	Overlapping claims; obviousness	Unanimous	7	0	0	0	0	0
Monsanto Canada Inc. v Schmeiser, [2004] 1 SCR	Patentable subject matter (genes, higher life forms); what is an	Unanimous (first issue – see below for second issue);	9	0	0	0	0	0

902, 2004 SCC 34	acceptable "use"							
Monsanto Canada Inc. v Schmeiser, [2004] 1 SCR 902, 2004 SCC 34	Patent infringement of patents on simple life forms (genes)	Majority with dissent (second issue)	5	0	0	0	1	4
Apotex Inc. v. Wellcome Foundation Ltd. [2002] 4 S.C.R. 153, [2002] S.C.J. No. 78	Standard of review; new use of an old compound	Unanimous	9	0	0	0	0	0
Apotex Inc. v. Sanofi-Synthelabo Canada Inc. [2008] 3 SCR 265, [2008] SCJ 63.	Novelty, obviousness	Unanimous	7	0	0	0	0	0
Sanofi-Aventis v. Apotex Inc SCC 20.	Damages	Unanimous	9	0	0	0	0	0
Total Cases	30							

Appendix 4: Proceeding by way of Judicial Review versus an Action for Infringement

The *Patented Medicines (Notice of Compliance) Regulations could* offer *correct* determinations of patent validity if the summary proceeding was replaced with an infringement action by an amendment to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*. This change would be particularly relevant if other evidence in this thesis supports the idea that *judicial review* provides an insufficient means of assessing patent validity.

However, section 6(1) of the *Patented Medicines (Notice of Compliance) Regulations* states that a first person may "…apply to a court for an order…"[311] which insinuates that the litigation proceed by way of application. Sections 6(3) and 6(4) also refer to an application, in support of litigation originating as an application, which proceeds by way of summary.

Section 18.4(1) of the *Federal Courts Act* dictates that summary proceedings take place in a short period of time: "…an application or reference to the Federal Court under any of sections 18.1 to 18.3 shall be heard and determined without delay and in a summary way."[312] This part of the act explains why Part 5 of the *Federal Court Regulations* imposes strict time frames for the delivery of documents, pleas, examinations, cross-examinations, and affidavits to the court, and to the parties for summary proceedings. But section 18.4(2) of the *Federal Courts Act* can facilitate the substitution of an action, and a subsequent complete trial, in place of a summary

[311] *Supra* note 1, s 6(1).
[312] *Supra* note 54, s 18.4(1).

proceeding: "The Federal Court may, if it considers it appropriate, direct that an application for judicial review be treated and proceeded with as an action."[313]

The jurisprudence record demonstrates that the request for an Order of Prohibition does not proceed as an action for infringement. In *Merck Frosst Canada Inc. v Canada*,[314] the Federal Court of Appeal affirmed that the sole purpose of litigation under the *Patented Medicines (Notice of Compliance) Regulations* is to decide whether a Notice of Compliance should issue as per the requirements laid out in the *Food and Drug Regulations*, and not whether patents are being infringed. Therefore, formal decisions on patent infringement must be adjudicated separately, applying the rules of the *Patent Act*.[315] However, it is interesting to note that Rouleau J. held previously in *Bayer AG v Canada*[316] that "although the Regulations contemplate proceeding by way of judicial review, I am satisfied that it would be appropriate to direct that these applications proceed by way of an action in accordance with subsection 18.4(2) of the Federal Court Act."[317] This was in light of the fact that *Patented Medicines (Notice of Compliance) Regulation* section 7(2)(b) refers to a declaration of the court, which had previously been interpreted as a declaration made by way of judicial review.[318] Rouleau stated that this was not necessarily the case, since the effect of the Order of Prohibition was an interlocutory injunction over an extended period of time,[319] and that such an extended

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[313] *Supra* note 54, s 18.4(2).
[314] [1994] FCJ 543, [1994] 55 CPR (3d) 1, at paras 5, 6.
[315] This usually happens through the Federal Court system, but can be initiated in any provincial jurisdiction.
[316] *Bayer AG et al v Minister of National Health and Welfare* [1993] FCJ 752, [1993] 51 CPR (3d) 87.
[317] *Ibid* at para 7.
[318] Rouleau quotes Judge McGillis, the motions judge, as making this statement June 8 and 10, 1993, in regards to a motion on the same case. Section 7(2)(b) deals with the declaration of the court as to the validity of the patents in question.
[319] The order of prohibition was thirty months at that time, but has since been reduced to twenty-four months in an amendment in 1997.

period of time meant that making the decision could not necessarily be done in an expeditious fashion, and therefore not akin to a quick proceeding via judicial review. He was therefore comfortable in ordering this case as an action.

However, in *Huntley v Canada (Minister of Citizenship and Immigration)*,[320] Pinard J. held that proceeding by way of action through section 18.4(2), the court "must find procedural or remedial inadequacies with the process of the underlying application."[321] In explaining the limited circumstances where an action is to be substituted for judicial review, Pinard J. summarized:

> It is, in general, only where facts of whatever nature cannot be satisfactorily established or weighed through affidavit evidence that consideration should be given to using subsection 18.4(2) of the Act. One should not lose sight of the clear intention of Parliament to have applications for judicial review determined whenever possible with as much speed and as little encumbrances and delays of the kind associated with trials as are possible. The "clearest of circumstances", to use the words of Muldoon J., where that subsection may be used, is where there is a need for *viva voce* evidence, either to assess demeanour and credibility of witnesses or to allow the Court to have a full grasp of the whole of the evidence whenever it feels the case cries out for the full panoply of a trial. [...][322]

The jurisprudence made by Pinard J. explains why proceedings arising out of the *Patented Medicines (Notice of Compliance) Regulations* have been adjudicated via judicial review from the beginning. Substituting judicial review for an action is reserved for specific cases where the credibility of witnesses is an issue, who need to be observed during cross-examination.[323] Moving to a full trial process could achieve correctness with respect to patenting, and would allow witnesses to be examined and cross-examined

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[320] [2010] FCJ 497.
[321] *Ibid* at para 7.
[322] *Huntley v Canada* [2010] FCJ 497, [2010] FC 407.
[323] Viva voce evidence refers to evidence that is adduced in person, where the observation of the witness is deemed to be important in determining the credibility of the witness.

in person.[324, 325] However, adjudicating generic approval disputes through a full trial as opposed to judicial review is only relevant if it is determined that the process of judicial review is inhibiting the proper evaluation of patent status.

[324] Whether or not the credibility of expert witnesses is issue (or *how much* of an issue it is) with the current regulations, it is interesting to consider that the credibility of expert witnesses may need to be treated more seriously, and further research could reveal more about the nature of such testimony from scientific experts who are paid to pick a side and submit evidence.

[325] The focus for allowing for the substitution of an action, however, could have been on different "procedural or remedial inadequacies," to demonstrate that deciding to include certain patents on the register was not reasonable, and that such an issue requires correctly determining the validity of patents.

Appendix Five: The Copyright Cases

Case	**Issue**	**Decision**	**Standard of Review**
Entertainment Software Association v Society of Composers, Authors and Music Publishers of Canada [*ESA*][326]	Right to communicate the work to the public by telecommunication	Majority judgment (2 sets) with minority dissent	Correctness
Rogers Communications Inc. v Society of Composers, Authors and Music Publishers of Canada [*Rogers*][327]	Right to communicate the work to the public by telecommunication	Majority with Concurring Reasons	Reasonableness
Society of Composers, Authors and Music Publishers of Canada v Bell Canada [*Bell*][328]	User's right of "fair dealing." Do music previews fall within the category of "research" under s.29?	Unanimous	Reasonableness
Alberta (Education) v Canadian Copyright Licensing Agency [*Alberta(Education)*][329]	User's rights for educational institutions provided under the *Copyright Act*	Majority with minority dissent	Reasonableness
Re: Sound v Motion Picture Theatre Associations of Canada [*Re: Sound*][330]	What is protected under the Copyright Act as "other subject matter"? Is a soundtrack recording in a movie within the S.2 definition of "sound recording"?	Unanimous	Not specified
Théberge v Galérie d'Art du Petit Champlain [*Théberge*][331]	Meaning of "reproduction" under the *Copyright Act*; moral rights	Majority(4) with unanimous minority dissent (not solo – three dissenting judges)	Reasonableness
CCH Canadian Ltd v Law Society of Upper Canada [CCH][332]	Test for originality; statutory exceptions to "fair dealing"	Unanimous	

[326] 2012 SCC 34, [2012] 2 SCR 231 [*ESA*].
[327] 2012 SCC 35, [2012] 2 SCR 283 [*Rogers*].
[328] 2012 SCC 36, [2012] 2 SCR 326 [*Bell*].
[329] 2012 SCC 37, [2012] 2 SCR 345 [*Alberta (Education)*].
[330] 2012 SCC 38, [2012] 2 SCR 376 [*Re: Sound*].
[331] 2002 SCC 34, [2002] 2 SCR 336 [*Théberge*].
[332] 2004 SCC 13, [2004] 1 SCR 339 [*CCH*].

Society of Composers, Authors and Music Publishers of Canada v Canadian Association of Internet Providers [*SOCAN v CAIP*][333]	Downloading of music online; transmission of music to one person – is it communication to the public?	Majority with concurring reasons	Correctness
Robertson v Thomson Corp [*Robertson*][334]	Publication of an article from a collection of articles in a database constitutes a removal of that article from the context of a collection of works; rights not held by the owner of the database	Majority (4) (two majority decisions) with unanimous minority dissent (not solo)	
Euro-Excellence Inc. v Kraft Canada Inc. [*Toblerone*][335]	Secondary infringement	Majority with concurring reasons (2 sets) and minority dissent (not solo)	
Crookes v Newton [*Crookes*][336]	The context under which an article is written; meaning of "publication" with respect to the Internet environment	Majority with concurring reasons and no dissent	

[333] 2003 SCC 45, [2004] 2 SCR 427 [*SOCAN v CAIP*].
[334] 2006 SCC 43, [2006] 2 SCR 363 [*Robertson*].
[335] 2007 SCC 37, [2007] 3 SCR 20 [*Toblerone*].
[336] 2011 SCC 47, [2011] 3 SCR 269 [*Crookes*].

Curriculum Vitae for Jason Newman

Education

Master of Laws *2014 - present*
University of Western Ontario, London, ON
- Expected Completion date: December, 2015

Bachelor of Laws *2005*
University of Western Ontario, London, ON

Master of Business Administration *2001*
Richard Ivey School of Business, London, ON
- Focus on finance, entrepreneurship, and operations management

Masters of Arts, Economics *1998*
University of Saskatchewan, Saskatoon, SK,
- Master's Project: Canadian public policy experiment on lifetime net tax rates of Canadians

Bachelor of Arts, Economics (high honours) *1997*
University of Saskatchewan, Saskatoon, SK,

Bachelor of Science, Pharmacy (distinction) *1995*
University of Saskatchewan, Saskatoon, SK,

Successes

Newmancorp, owner, director, and chief executive officer *May 2007 – present*
- Started Delaware Pharmacy in September, 2015
- Started Dorchester Pharmacy, 2011, sold in 2014
- Started Belmont Pharmacy, 2010, sold at one year mark
- Purchased, operated and sold Duncan's Pharmacy, Maple Creek, SK, 2007-2009
    - Pharmacy profitability grew by 25 percent over two and a half years
- Pharmacy and small business valuation services (current)

Employment

Community Pharmacist and Manager for Newmancorp *May 2007 – Current*
- Operating new pharmacy location in Delaware, ON

Community Pharmacist (Shoppers Drug Mart, London, ON *Oct. 2000 – 2007*

Community Pharmacist (Shoppers Drug Mart, Saskatoon, SK.) *1995 – 1999*

Activities, Skills, Awards, and Interests

- Father of four boys
- Licensed Pharmacist in Ontario
- Regular pharmacy continuing education seminar attendee

- Economics Master's Thesis: *Does a Balanced Budget Plan Represent Sustainable Fiscal Policy for Canada?* (1999)
- Fowke Prize for literary excellence in economics (1997)
- Chairman, Saskatchewan Economics Journal (1997 – 1998); completed and distributed premiere issue
- Graduate fellowship $13,000 (1997/1998)
- University of Saskatchewan Dean's honour Roll (1992 to 1997)
- Vice President, University of Saskatchewan Economics Students' Society (1996 to 1997)