

**IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF THE
NORTH AMERICAN FREE TRADE AGREEMENT**

AND THE UNCITRAL ARBITRATION RULES (1976)

BETWEEN:

ELI LILLY AND COMPANY

Claimant/Investor

AND:

GOVERNMENT OF CANADA

Respondent/Party

(Case No. UNCT/14/2)

EXPERT REPORT OF RONALD E. DIMOCK

JANUARY 26, 2015

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I. Introduction

A. Background and Qualifications

1. I am a barrister and solicitor based in Toronto, Canada and the founding partner of the Canadian law firm Dimock Stratton LLP which focuses exclusively on intellectual property matters.
2. I attended Queen's University in Kingston, Ontario where I graduated with a Bachelor of Science (Honours) in Engineering and Mathematics in 1971, and a Bachelor of Laws in 1974.
3. Since my call to the Bar of Ontario in 1976, I have practiced exclusively in the area of intellectual property litigation, most of which has been patent litigation. I have appeared as trial counsel in more than thirty-five patent trials in the Federal Court and as appellate counsel in over twenty appeals from patent trials in the Federal Court of Appeal and the Supreme Court of Canada.
4. Since 1993, I have been certified by the Law Society of Upper Canada as a specialist in both Intellectual Property Law and Civil Litigation. I have been a Fellow of the Intellectual Property Institute of Canada for over twenty five years, a Fellow of the American College of Trial Lawyers since 2007, and a Fellow of the Chartered Institute of Arbitrators since 2013.
5. Over the course of my career I have remained active in teaching and writing on intellectual property law topics. I have taught a Master's level course on intellectual property remedies at Osgoode Hall Law School since 1998, and have given annual lectures on patent law at Osgoode Hall Law School since 2003. I speak regularly at conferences on patent law matters to members of the profession, the public, and the judiciary, and have authored publications on Canadian intellectual property law.
6. I have extensive patent litigation experience involving pharmaceuticals. This includes actions under the *Patent Act*¹ and applications pursuant to the *Patented Medicines (Notice of Compliance) Regulations* ("PM (NOC) Regulations").²
7. Throughout my involvement in pharmaceutical litigation matters, I have represented both brand and generic litigants. I have acted for several innovator companies, including: Bayer, Abbott Laboratories, Novartis, Procter & Gamble, and Fournier Pharma.³ I have also acted for several generic companies, including: Ranbaxy, Sandoz, IVAX Pharmaceuticals, and Richter Gedeon.

¹ *Patent Act*, RSC 1985, c P-4 [*Patent Act*] (R-001).

² *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*PM (NOC) Regulations*] (R-031).

³ I have previously served as an expert witness for Eli Lilly through its solicitors Gowling Lafleur Henderson LLP. The issues on which I testified in that case were unrelated to those in the present arbitration.

8. Included as Appendix A to my report is my curriculum vitae.

B. Mandate

9. The mandate for my Report, as outlined to me by counsel for the Respondent, is as follows:

- to provide an overview of the basic goals and structure of the Canadian patent system;
- to provide an overview of the law of utility in Canada having regard to the Claimant's characterization of this area of law;
- to address the Claimant's allegations and the relevant statements made in the Claimant's expert reports concerning the substance of Canadian law when it filed its patent applications for olanzapine (Zyprexa) and atomoxetine (Strattera);
- to address the Claimant's account and the relevant statements made in the Claimant's expert reports of the judicial proceedings resulting in the invalidation of its patents for olanzapine and atomoxetine; and,
- to address the Claimant's allegation and the relevant statements made in the Claimant's expert reports that Canadian patent law discriminates against pharmaceutical inventions.

C. Undertaking as an Expert Witness

10. From over thirty eight years of litigation experience, I understand the importance of the overriding duty of an expert in any proceeding to assist the trier of fact impartially on matters relevant to their expertise. My report was drafted with this duty at the front of my mind. Included as Appendix B to my report is the Federal Court of Canada's Code of Conduct for Expert Witness and a signed Certificate Concerning Code of Conduct for Expert Witnesses recognizing that I have read and agreed to the Code of Conduct. Every expert offering evidence to the Federal Court of Canada must review and sign this document.⁴

11. Other than in this arbitration, I confirm that I have no relationship to the Respondent.

II. Fundamentals of the Canadian Patent System

A. Background and Objectives

12. A patent is not given as a public recognition of ingenuity but rather as an enticement to coax inventive solutions to practical problems into the public domain in return for a time limited monopoly.⁵ This bargain is the foundation of the Canadian patent system. The inventor discloses to the public a new, useful and unobvious invention, and in return the

⁴ *Federal Courts Rules*, SOR/98-106, s 52.2 (**R-142**).

⁵ *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153 at para. 37 ("*AZT*") (**R-004**).

public offers the inventor exclusive monopoly rights for a finite period of time. The goal of the bargain is the public benefit from the improvement in the state of knowledge.⁶

13. There is no common law right to a patent.⁷ The patent system is entirely rooted in legislation. To obtain and maintain patent rights in Canada, an applicant must comply with the provisions of the *Patent Act*.⁸ As explained by the Supreme Court of Canada, “[a]n inventor gets his patent according to the terms of the *Patent Act*, no more and no less.”⁹
14. The anticompetitive effects of the patent monopoly, such as higher prices and short term obstacles to innovation, are recognizably serious.¹⁰ To justify such negative effects, the *Patent Act* requires that patent rights be purchased with “hard coinage” in the form of five requirements for patentability.¹¹ Under the *Patent Act*, the invention must be new, useful, non-obvious, constitute patentable subject-matter, and be sufficiently disclosed in the patent.¹²
15. Sections 2 and 28.2 of the *Patent Act* require the invention to be new. This is also known as the novelty requirement. An invention failing to satisfy this requirement is said to be “anticipated”. In patent law terms, novelty (or “absolute novelty” as it is sometimes called) means that the invention has not been made available to the public anywhere in the world prior to first filing for a patent. In Canada, absolute novelty is tempered by allowing the inventors a grace period of one year to file from the time they themselves make the invention available to the public. For a claimed invention to be anticipated (and therefore lack novelty), a single, prior art reference must not only disclose the essential elements of the claimed invention but, as well, provide enough information to enable a person of ordinary skill in the art to make the invention. Contrary to the assertion of the Claimant, it is very difficult to invalidate a patent on novelty grounds.¹³ As noted, the *Patent Act* requires that the subject-matter be novel as of the claim date.^{14,15}

⁶ *Teva Canada Ltd. v. Pfizer Canada Inc.*, [2012] 3 SCR 625 at para. 32 (“Pfizer”) (R-006).

⁷ *Canada (Commissioner of Patents) v. Farbwerke Hoechst Aktien-Gesellschaft Vormals Meister Lucius & Bruning*, [1964] SCR 49 at p. 57 (“Farbwerke Hoechst”) (R-143).

⁸ *Farbwerke Hoechst* at p. 57 (R-143).

⁹ *Farbwerke Hoechst* at p. 57 (R-143).

¹⁰ *AZT* at paras. 37 and p. 45 (R-004).

¹¹ *AZT* at para. 37 (R-004).

¹² *Patent Act*, s 2, 27(3), 27(8), 28.2(1), 28.3 (R-001).

¹³ “The test for anticipation is very rigorous and an attack on the validity of a patent on this ground seldom succeeds.” (*Lubrizol Corp. v. Imperial Oil Ltd.*, (1990), 33 CPR (3d) 1 at 23 (FCTD) (R-249); reversed in part on other grounds, *Lubrizol Corp. v. Imperial Oil Ltd.*, (1992), 45 CPR (3d) 449 (FCA)) (R-144).

¹⁴ *Patent Act*, s 28.1 (R-001).

¹⁵ The latest applicable claim date for a patent is the filing date of the patent application in Canada (*Patent Act*, s. 28.1). Where the patent application is filed under an international treaty, as is common, the claim date will be earlier

16. The second requirement for patentability is that the subject-matter forming the invention be useful. This is also known as the “utility” requirement and is outlined in section 2 of the *Patent Act*. As this requirement is at the root of this dispute, it is discussed in greater detail later in my report. Utility must also be demonstrated or soundly predicted by the inventor as of the filing date, meaning the date when the patent application was filed in Canada.¹⁶ The level of utility to be established is another question which is also discussed later in my report.
17. The third requirement is that the subject-matter of the invention must possess some inventive ingenuity over the state of the art to which it pertains. This is commonly known as the requirement of non-obviousness and is outlined in section 28.3 of the *Patent Act*. This ensures that the public receives something inventive in consideration for the monopoly, not merely advancements that “any fool” would make.¹⁷ The requirement of non-obviousness must be met as of the claim date.¹⁸
18. The fourth requirement concerns the nature of the subject-matter constituting the invention. Section 2 of the *Patent Act* outlines that any “art, process, machine, manufacture, or composition of matter” may validly form the subject-matter of a patentable invention. This broad class of subject-matter is further narrowed by the *Patent Act* which outlines that no patent shall be granted for “any mere scientific principle or abstract theorem”.¹⁹ As well, courts have refused certain subject-matter, including higher life forms, methods of medical treatment and methods employing professional skills.²⁰
19. The final requirement, sufficient disclosure, lies at the core of the patent bargain.²¹ The patent specification must fully and correctly describe the invention and its operation or use as contemplated by the inventor.²² Disclosure of the invention is the consideration the public receives for the grant of monopoly rights to the inventor.²³

and will correspond to the priority date as mandated by the particular treaty (*Patent Act*, s. 28.1). An example of this is the Patent Co-operation Treaty.

¹⁶ *AZT*, at para. 52 (**R-004**).

¹⁷ *Beloit Canada Ltd. v. Valmet Oy*, (1986), 8 CPR (3d) 289 (FCA) p. 293 (**R-145**).

¹⁸ *Patent Act*, s 28.3 (**R-001**).

¹⁹ *Patent Act*, s 27(8) (**R-001**).

²⁰ *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 SCR 45 (“*Harvard College*”) (**R-146**); *Lawson v. Commissioner of Patents*, (1970), 62 CPR 101 (Ex Ct) (**R-147**); *Tennessee Eastman Co. v. Canada (Commissioner of Patents)*, [1974] SCR 111 (**R-148**).

²¹ *Pfizer*, at para. 31 (**R-006**).

²² *Patent Act*, s 27(3) (**R-001**).

²³ *Pfizer* at paras. 32-35 (**R-006**), citing *Tubes, Ltd. v. Perfecta Seamless Steel Tubes Company, Ltd.*, (1902), 20 RPC 77 at pp. 95-96.

B. Patent Office

20. The Patent Office, which is part of the Canadian Intellectual Property Office (“CIPO”), administers the patent system in Canada.²⁴ Under the *Patent Act*, the Commissioner of Patents is responsible for the granting and issuing of patents.²⁵ This includes the application process, the collection of fees, and the maintenance of records.
21. The examination process is the part of the application process in which the subject-matter sought to be patented is assessed for its compliance with the *Patent Act*.²⁶ This process includes a series of interactions between the inventor (almost always represented by an agent) and a patent examiner, on behalf of the Commissioner. The patent examiner is employed by the Patent Office and carries out the Commissioner’s statutory role as examiner of patents. During the examination process, a patent examiner reviews each application to ensure its compliance with the provisions of the *Patent Act* and its subordinate legislation, the *Patent Rules*. The Commissioner must grant a patent for an invention if the application complies with the *Patent Act* and *Patent Rules*.²⁷
22. The Commissioner of Patents “ought not to refuse an application for a patent unless it is clearly without substantial foundation.”²⁸ Patent examination is not an adversarial inquiry into patent validity. The Commissioner of Patents and his examiners do not have the benefit of the extensive evidence and argument that may be brought forward in the context of a patent trial.²⁹ The *Patent Act* makes clear that an issued patent is only valid “in the absence of any evidence to the contrary” and that the patent may later be subject to court review for validity.³⁰ In other words, the grant of a patent is not the final word on patent validity.
23. One tool used by patent examiners when examining patents is the Manual of Patent Office Patent (“MOPOP”). MOPOP is a set of guidelines prepared by the Patent Office to provide guidance to patent examiners, patent agents, and the general public. MOPOP is based on the *Patent Act*, *Patent Rules*, judicial decisions and Commissioner’s decisions.
24. While MOPOP may draw on binding authority, the document itself does not have the force of law and is not binding.³¹ MOPOP is not a comprehensive guide to Canadian patent law. Nor is it understood to reflect all developments in Canadian patent law at a

²⁴ *Patent Act*, s 3 (R-001).

²⁵ *Patent Act*, s 4(2) (R-001).

²⁶ *Patent Act*, s 35(1) (R-001).

²⁷ *Patent Act*, s 27(1) (R-001).

²⁸ *Vanity Fair Silk Mills v. Canada (Commissioner of Patents)*, [1939] SCR 245, at para. 3 (R-149); *Monsanto Company v. Commissioner of Patents*, [1979] 2 SCR 1108, (“Monsanto1979”), para. 20 (R-023).

²⁹ *AZT*, at para. 43 (R-004).

³⁰ *Patent Act*, ss 42, 43(2), 60(1) (R-001).

³¹ *Belzberg v. Canada (Commissioner of Patents)*, 2009 FC 657 at para. 10 (“Belzberg”) (R-150); *Bayer AG v. Apotex Inc.*, (1998), 84 CPR (3d) 23 (FCTD) at para. 49 (R-151).

given point in time. Its provisions must give way when in conflict with the *Patent Act*, *Patent Rules*, or jurisprudence. At best MOPOP can be described as a “guide” or an interpretive tool.³²

25. When objecting to an aspect of a patent application during the examination process, the examiner issues an Office Action to the applicant. The Office Action outlines the defect and invites the applicant to make the necessary corrections within a period of time as outlined in the *Patent Rules*. The application may eventually be accepted and the patent granted. If there are further defects, or the applicant fails to correct previously identified defects, further Office Actions may issue. If the applicant and the examiner reach an impasse over a defect in the application, a Final Action is issued. If the applicant’s response to the Final Action does not convince the examiner that the application is allowable, the matter is referred to the Commissioner for review, giving the applicant the opportunity to be heard.
26. Although a Final Action refers the matter to the Commissioner, the matter is actually considered by the Patent Appeal Board. The Board is a non-statutory tribunal within the Patent Office whose function is to review certain patent applications and make recommendations to the Commissioner of Patent to allow or reject applications.³³ Following review by the Board, the recommendation to allow or refuse the application is forwarded to the Commissioner for approval.

C. Post-Grant Invalidation of Patents: the Role of the Court and the Patent Office

27. The grant of a patent affords the patentee the exclusive right, privilege and liberty of making, constructing and using the invention, and selling it to others to be used, for defined period of time, subject to the terms of the *Patent Act*.³⁴ The exclusive rights of a patentee are not unreviewable or irrevocable following the initial grant. For example, the *Patent Act* provides that the Federal Court³⁵ may adjudicate on the validity of granted patents, and may find them invalid.³⁶ The *Patent Act* also contemplates various processes through which the Patent Office may revoke a patentee’s exclusive rights.
28. Invalidation proceedings most commonly arise in the Federal Court pursuant to section 60 of the *Patent Act*. Under this provision, the Federal Court has jurisdiction to determine

³² *Belzberg* at para. 10 (R-150); *GlaxoSmithKline Inc. v. Canada (Minister of Health)*, 2004 FC 116 at para. 28 (R-152).

³³ *President of Harvard College v. Canada (Commissioner of Patents)*, [2000] 4 FC 528, at para. 49 (R-250); rev’d on other grounds in *Harvard College* (R-146).

³⁴ *Patent Act*, s 42 and 44 (R-001).

³⁵ The Federal Court of Canada is a statutorily created court under Canada’s Constitution. Its jurisdiction is prescribed by statute, this includes jurisdiction over patent matters. Most patent litigation in Canada occurs in the Federal Court. Appeals from the Federal Court are to the Federal Court of Appeal, subsequent appeals may be made to the Supreme Court of Canada.

³⁶ *Patent Act*, ss 42 and 60(1) (R-001).

the validity of the patent and its claims at the instance of any interested person.³⁷ In practice this occurs either as a defence and counterclaim to an allegation of infringement, or as a stand-alone patent impeachment action. A successful claim will result in a declaration of invalidity. Such declaration means that the patent is and has always been void (*i.e.* void *ab initio*).³⁸

29. In considering the validity of a patent under section 60, the Court must have regard to the statutorily imposed presumption of validity which reflects the fact that the Commissioner previously granted the patent.³⁹ This presumption is “weakly worded” as only in the absence of evidence to the contrary does the presumption exist.⁴⁰ Once evidence is introduced showing invalidity, the determination is made on a balance of probabilities.
30. The Patent Office has the authority to revoke a patentee’s rights for several reasons, including: failure to pay maintenance fees, re-examination, or the abuse of the patentee’s exclusive rights.
31. Maintenance fees must be paid annually upon the grant of a patent. Failure to make payment will result in expiry of the patent.⁴¹
32. Re-examination of a patent may be requested by any interested person by filing prior art with the Patent Office.⁴² The Commissioner of Patents will then convene a re-examination board to review whether the request raises “a substantial new question of patentability affecting any claim of the patent”.⁴³ If the request raises such a question, the patentee is invited to submit a response which the board will consider in its review.⁴⁴ The board may confirm, cancel or amend any claims following re-examination.⁴⁵ An appeal of any re-examination decision may be made to the Federal Court.⁴⁶
33. If there has been abuse of the exclusive rights under a patent, the Commissioner has the authority to revoke the patent.⁴⁷ The Attorney General of Canada or any person interested

³⁷ *Patent Act*, s 60(1) (R-001).

³⁸ *Apotex Inc. v. Pfizer Ireland Pharmaceuticals*, 2012 FC 1339, at para. 27 (R-153).

³⁹ *Patent Act*, s 43(2) (R-001); NB: the Federal Court also has the authority to revoke a patent as a result of anticompetitive acts undertaken with the exclusive rights and privileges of the patent (*Competition Act*, RSC 1985, c C-34, s 32) (R-154).

⁴⁰ *Diversified Products Corp v. Tye-Sil Corp.*, (1991), 35 CPR (3d) 350, at paras. 13-16 (FCA) (R-155), *AZT* at para. 43 (R-004).

⁴¹ *Patent Act*, s 46 (R-001).

⁴² *Patent Act*, s 48.1 (R-001).

⁴³ *Patent Act*, s 48.2 (R-001).

⁴⁴ *Patent Act*, s 48.2(5) (R-001).

⁴⁵ *Patent Act*, s 48.4 (R-001).

⁴⁶ *Patent Act*, s 48.5 (R-001).

can apply, after three years from the grant of the patent, to the Commissioner alleging the impugned conduct. An appeal of any decision lies to the Federal Court.⁴⁸

D. Major Changes in the Patent System Since the mid-1980s

34. Since the mid-1980s, Canadian patent law has undergone several notable legislative changes. These included adopting absolute novelty with a limited grace period (as explained earlier), changing priority as between respective applicants from the first-to-invent to the first-to-file and codifying the requirement of non-obviousness. Three other notable legislative changes in this period that applied specifically to pharmaceuticals included: permitting patents to be granted for pharmaceutical compounds, eliminating the compulsory license scheme and adopting a “patent-linkage” market approval process for pharmaceuticals.

Pharmaceutical Patents

35. For many years, Canada, like many other countries, did not permit patents that claimed a medicine or food. In 1987, however, section 41 of the *Patent Act*, which prohibited such claims, was repealed. Until then, a pharmaceutical compound could only be claimed in connection with the process by which it was made.⁴⁹ Thereafter claims to a pharmaceutical compound were permitted, without any limitation to a process, provided the requirements for patentability were otherwise satisfied (that is, the compound was new, useful and non-obviousness).
36. The repeal of section 41 resulted in an increase in patents, as patent applications with a wider variety of claims could be filed in the pharmaceutical field. In addition to claims to the process by which the drug was made, the drug and any derivatives could be claimed.

Market Approval for Pharmaceuticals

37. A pharmaceutical manufacturer must first obtain a Notice of Compliance (“NOC”) from the Minister of Health before it can market a pharmaceutical product in Canada. The NOC signifies that the drug is safe and effective for the subject indication. Prior to 1993, when a compulsory licence scheme was in place, the Minister of Health was largely unconcerned about patent rights during the review process leading to a NOC.⁵⁰
38. This pre-1993 compulsory licensing scheme permitted a generic manufacturer to obtain a licence directly from the Commissioner of Patents under any patent covering a pharmaceutical product. The licensing process did not involve the patentee, who was usually the pharmaceutical manufacturer who had obtained the NOC. In granting a licence, the Commissioner considered “the desirability of making the medicine available to the public at the lowest possible price” having regard to giving the patentee due reward

⁴⁸ *Patent Act*, s 71 (R-001).

⁴⁹ *Parke, Davis & Co. v. Fine Chemicals of Canada Ltd.*, [1959] SCR 219, para. 4 (R-156).

⁵⁰ *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, [2005] 1 SCR 533, (“*Bristol-Myers*”) at para. 8 (R-157).

for the research leading to the invention.⁵¹ The compulsory licence was almost always granted.

39. This pre-1993 scheme was generous to generic manufacturers and factored heavily into the worldwide success of the Canadian generic pharmaceutical industry. The compulsory licencing scheme hardly considered the interests of patentees and failed even to involve the patentee. The royalties paid to patentees under this scheme were negligible, generally fixed at 4 percent to 5 percent of the net selling price of the drug.⁵² Since generic manufacturers could access the market under a compulsory licence, and innovator companies could not prevent them from doing so by asserting patent rights, there was relatively little pharmaceutical litigation under the compulsory licensing regime.
40. Canada eliminated the compulsory licensing scheme in 1993 in response to lobbying by the innovator pharmaceutical companies. In addition, the change was made to recognize Canada's international obligations under the *Agreement on Trade-Related Aspects of Intellectual Property Rights* ("TRIPS") and NAFTA, in particular NAFTA Article 1709(10).⁵³
41. The compulsory licensing scheme was replaced with the current "patent-linkage" approach through the enactment of the *PM (NOC) Regulations*. The *Regulations* aim to respect the interests of the patentee while at the same time acknowledging the public interest in early access to medications.⁵⁴ The current system under the *Regulations* makes it significantly more difficult for generic manufacturers to obtain early market approval than was the case under the prior compulsory license system.
42. The *PM (NOC) Regulations* create a system where an innovator manufacturer is entitled to list patents on the Patent Register with respect to a particular pharmaceutical product for which it has an NOC. Patents claiming the medicinal ingredient, the formulation, the dosage form and the use of the medicinal ingredient, may be listed on the Patent Register. A generic company cannot receive an NOC until either all the patents on the Register for the product have expired, or the merits of any potential infringement or alleged invalidity with respect to these patents have been addressed.
43. The process of addressing the listed patents begins when a generic serves a Notice of Allegation on the innovator alleging in detail that the listed patents are invalid and/or that its product will not infringe some or all of the patents. Once the Notice of Allegation has been delivered, the innovator has forty-five days to respond, or it cannot rely on its listed patents to prevent market approval of the generic product. An innovator responds, if it so decides, by bringing an application in the Federal Court to prohibit the Minister from issuing an NOC. During the pendency of these proceedings and for up to twenty-four

⁵¹ *Bristol-Myers*, at para. 8 (R-157).

⁵² *Bristol-Myers*, at para. 8 (R-157).

⁵³ *Bristol-Myers*, at para. 10 (R-157).

⁵⁴ *Apotex Inc. v. Abbott Laboratories*, 2013 ONSC 356 at para. 15(R-158); aff'd, *Apotex Inc. v. Abbott Laboratories*, 2013 ONCA 555 (R-251).

months, the Minister is prohibited from issuing an NOC. Only if there is no Court decision within those twenty-four months, or if there is one in favour of the generic, can the Minister issue an NOC.

44. The proceedings under the *PM (NOC) Regulations* do not resolve issues as to whether a listed patent is actually invalid or not infringed as between the parties or as against the world.⁵⁵ Rather, the proceedings are limited to determining whether an allegation of non-infringement or invalidity justifies the issuance of an NOC by the Minister of Health for a particular generic pharmaceutical product. A decision that an allegation of invalidity is justified may lead to an NOC being issued but does not render the patent invalid under section 60 of the *Patent Act*. Rather the patent remains valid and can be asserted against the generic in a subsequent patent infringement action or be involved again with other generics in separate proceedings under the *PM (NOC) Regulations*. This has become a reality in some disputes.
45. In sum, the shift in Canada from compulsory licensing to the *PM (NOC)* regime is one that has strengthened protection of intellectual property for pharmaceuticals, but with the result of increased litigation over those rights.

III. The Law of Utility in Canada

A. The Claimant's Characterization of the Issues

46. Claimant's expert, Professor Siebrasse suggests that there was a dramatic shift in the substantive, evidentiary and disclosure aspects of Canada's law of utility from 2002 to approximately 2008. In his opinion, each of the individual changes makes it easier to invalidate a patent, and combined, these changes are a "perfect storm" which discriminately invalidates pharmaceutical patents. Professor Siebrasse describes the collective changes as Canada's "Promise Utility Doctrine".
47. The principal change, as Professor Siebrasse sees it, is a change in the standard by which utility is assessed. Specifically, Professor Siebrasse states that the Courts previously assessed utility solely against an "objective standard" or "*mere scintilla* of utility", whereas now a two branch approach is used: "the mere scintilla" branch and what he refers to as the "promise" branch.
48. I do not agree that there has been any "shift" in the Canadian legal standard of utility, as described by Professor Siebrasse. Rather, the two "branches" (adopting Professor Siebrasse's description) previously mentioned have long been aspects of Canadian patent law, recognized by judges and patent counsel alike.
49. As just one example, Donald Hill, a well-respected patent lawyer at Smart & Biggar, one of Canada's leading intellectual property law firms, neatly summarized the standard for utility in the Canadian Patent Reporter in 1960:

⁵⁵ *Pharmacia Inc. v. Canada (Minister of National Health & Welfare)*, [1995] 1 FC 588, at para. 13 (FCA) (R-159).

One standard for measuring utility is of course that provided by the patentee himself; if certain results are promised specifically, or may reasonably be inferred from the specification, and these are not yielded by practice of the invention, the patent will fail. In the absence of specific promises, however, the courts do not seem to be overly anxious to strike down a patent on the ground of lack of utility so long as *some* measure of usefulness can be obtained.⁵⁶

50. Professor Siebrasse further comments on what he views as a shift in the evidentiary and disclosure aspects of the Canadian law of utility, stemming from the supposed development of the “promise” branch of utility. He suggests that Canadian courts suddenly broke tradition in the mid-2000s to no longer accept post-filing evidence of utility and to require disclosure in the specification of the patent when an applicant has predicted the utility of an invention. Again, I have to disagree. The rejection of post-filing evidence of utility and the requirement for disclosure of the predicted utility of an invention have long been aspects of Canadian patent law, recognized by judges and patent counsel alike.
51. The individual changes or components which Professor Siebrasse has combined and characterized as the “Promise Utility Doctrine”, are really three distinct aspects of Canadian patent law which have remained virtually unchanged for as long as I have been a lawyer. These are: determining what the invention is, whether the invention has been made, and whether the invention has been adequately disclosed. In each individual case, working through each of these considerations will determine whether the patent bargain has been met.
52. Below, I set out in further detail the law and practice that have existed in Canada with respect to the requirement of utility for at least as long as I have been a lawyer.

B. What is the Invention?

53. The first question in any analysis of a patent is “what is it that the inventor claims to have invented?” or simply “what is the invention?” As described earlier, the patent system is based on the bargain theory whereby the inventor discloses a new, useful and non-obvious invention to the public in return for monopoly rights. Utility is thus integral to the “hard coinage” the applicant provides to the public, as an essential part of its invention.
54. The requirement that an invention be “useful” is outlined in section 2 of the *Patent Act* in the definition of “invention”:

“invention” means 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

⁵⁶ Donald Hill, “Claim Inutility” (1960), 35 CPR 185 at 186 (“*Hill*”) (R-160).

composition of matter.⁵⁷

[underlining added]

55. In this context, the term “useful” is synonymous with “utility”. The terms “useful” and “utility” are neither defined nor mentioned anywhere else in *Patent Act*. Thus, contrary to the opinion of Professor Siebrasse, there is no required standard of utility expressly set out by the *Patent Act*, whether the “mere scintilla” standard or otherwise.⁵⁸ However, there is ample judicial authority interpreting the meaning of the terms and the corresponding utility requirements in Canadian patent law.
56. In the leading case on the law of utility, Justice Brian Dickson of the Supreme Court of Canada (who later went on to become the Chief Justice of the Court) provided the meaning of useful – or rather to be more precise, the meaning of “not useful” – in the 1981 decision in *Consolboard v. MacMillan Bloedel (Sask) Ltd* (“*Consolboard*”):

There is a helpful discussion in *Halsbury’s Laws of England*, (3rd ed.), vol. 29, at p. 59, on the meaning of ‘not useful’ in patent law. It means ‘that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do’. There is no suggestion here that the invention will not give the result promised. The discussion in *Halsbury’s Laws of England*, *ibid.*, continues:

... the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested. [Footnotes omitted.]

and concludes:

... it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice. [Footnotes omitted.]

Canadian law is to the same effect...⁵⁹

[underlining added]

57. One of the issues before the Supreme Court in *Consolboard* was whether the disclosure requirements of the *Patent Act* placed an obligation on the patentee to explicitly describe the utility of the patented invention. As noted above, an invention will be held to be “not

⁵⁷ *Patent Act*, s 2 (R-001).

⁵⁸ See Siebrasse report, at paras. 16-17.

⁵⁹ *Consolboard v. MacMillan Bloedel (Sask) Ltd.*, [1981] 1 SCR 504 at paras. 36 and 37 (“*Consolboard*”) (R-011).

useful” if it does not do what the specification⁶⁰ promises to do, but significantly, the Court confirmed that there is no general obligation on the patentee to describe the invention’s utility within the patent:

...I do not read the concluding words of s.36(1) [now s. 27(3)] as obligating the inventor in his disclosure or claims to describe in what respect the invention is new or in what way it is useful. He must say what it is he claims to have invented. He is not obliged to extol the effect or advantage of his discovery, if he describes his invention so as to produce it.⁶¹

[underlining added]

58. The standard of utility required is a contextual consideration dependant on the disclosure of the patent and particularly on whether it is silent about utility or whether it promises a result or certain level of utility. In the former case, the invention simply needs to have a “mere scintilla” of utility. In the latter case, the invention must achieve the promised result. If the required standard is not met, the invention, as described in the patent, is held to lack utility.
59. The issue of “promised utility” will typically arise in cases where that utility lies at the core of the invention. Examples would include cases of an alleged new pharmaceutical use of a known compound or where the invention is a selection from a previously known genus, concepts which I will discuss in greater detail below.
60. I worked with Donald F. Sim, QC as a junior on *Consolboard*, helping him prepare the case for trial and the subsequent appeals in the Federal Court of Appeal and Supreme Court of Canada. Despite having been penned over thirty years ago, to this day *Consolboard* is generally considered to be the leading authority concerning the basic utility requirements of Canadian patent law. The case continues to be applied by judges and was applied to Claimant’s patents. In a decision rendered on October 30, 2014, the Federal Court of Appeal referred to *Consolboard* as “the source of the promise doctrine in Canadian law”.⁶²
61. It should be noted that although *Consolboard* is the leading authority on the standard of an invention’s utility, it is not really the originating source of the “promise doctrine” in Canada. Indeed, as noted by Justice Dickson within *Consolboard* itself, the Supreme Court of Canada in 1961 affirmed that an invention must achieve any results promised by the specification:

⁶⁰ Although the “specification” of a patent is defined as the combination of both the “disclosure” and the “claims” of the patent, it used interchangeably with “disclosure” in some cases.

⁶¹ *Consolboard*, at para. 37 (R-011).

⁶² *Apotex Inc. et al v. Pfizer Canada Inc. et al*, 2014 FCA 250 at paras. 4-66 (R-161).

Canadian law is to the same effect. In *Rodi & Wienerberger A.G. v. Metalliflex Limited*, (affirmed in this Court [1961] S.C.R. 117) the Quebec Court of Appeal adopted at p. 53 the following quotation from the case of *Unifloc Reagents, Ld. v. Newstead Colliery, Ld.* at p. 184:

If when used in accordance with the directions contained in the specification the promised results are obtained, the invention is useful in the sense in which that term is used in patent law. The question to be asked is whether, if you do what the specification tells you to do, you can make or do the thing which the specification says that you can make or do.⁶³

[underlining added]

62. Another early decision concerning the standard against which utility is assessed is *New Process Screw Corp v. PL Robertson Mfg Co Ltd.*⁶⁴ In the editorial note published with the reported decision in 1961, Gordon Henderson, QC⁶⁵ highlighted that the required standard or quantum of utility is determined when ascertaining the invention itself (*i.e.* a promised level of utility or, in the absence of a promise, a mere scintilla of utility).

In the present case, it will be noted that in respect of one of the three patents in suit, the failure of the patentee to achieve a commercially good product in carrying out the disclosure rendered the patent invalid on the ground that the promise made in the specification was not fulfilled...

These findings illustrate the different senses in which utility has been used in patent law. It has been used in the sense of quantum of usefulness. In the absence of a promise or representation of a specific usefulness, it is clear that only a limited degree of usefulness is required. If the patentee makes a specific promise in the specification, the promise must be fulfilled or the patent is invalid...⁶⁶

63. This distinction, highlighted by Mr. Henderson, is an important one. The distinction is between the utility required if no promise is made, and that required if a promise is made.

⁶³ *Consolboard*, at para. 37 (R-011).

⁶⁴ *New Process Screw Corp. v. PL Robertson Mfg Co. Ltd.*, (1961), 39 CPR 31 (Ex Ct) (“*New Process Screw*”) (R-162).

⁶⁵ Gordon Henderson, QC (1912-1993), the managing partner for many years of the well-known law firm Gowling Lafleur Henderson LLP (commonly referred to as “Gowlings”), was a leader of the Canadian intellectual property bar for as many years, and was the founding editor of the *Canadian Patent Reporter*. Gowlings represents the Claimant in this Arbitration.

⁶⁶ *New Process Screw*, at pp. 33-34 (R-162).

64. One of the patents at issue in *New Process Screw* pertained to improved rolling dies for producing double threaded screws. The specification of the patent outlined that dies utilizing a particular range of pitch angles would produce double threaded screws. However, the evidence before the court illustrated that certain of the pitch angles described in the patent could produce single or triple-threaded screws (which presumably would satisfy a “mere scintilla” of utility), but not double-threaded screws—the desired result of the patent. As a result, the Court concluded that the patent was invalid because the invention failed to satisfy the promise of the patent:

...Thus it was conclusively proved that if dies with the pitch angles referred to in the specification and specified in the claims were used they would not produce the desired results, that is to say, dies with a pitch angle of 12° would not produce a No. 2 double threaded screw and dies with a pitch angle of 22° would not produce a No. 18 double threaded screw. Thus there was a failure of the promise of the patent which was fatal to it.⁶⁷

[underlining added]

65. Beyond case law, the notion that a result promised within a patent’s specification would be the standard used to test the utility of an invention was also well recognized in the writings of prominent patent counsel. This includes Mr. Henderson’s editorial note, above, and the article I previously cited by Donald Hill, within which he noted that the fact that a patent will be declared invalid if the invention fails to achieve the promised utility is “so obvious that it hardly needs stating”:

Where, however, the patentee has promised in his specification results of a certain kind or order, and these are not yielded when the invention is put into practice, the patent of course will be invalid. This is so obvious that it hardly need stating; it is referred to here, however, to warn against a lack of candour in a patent specification concerning the limitation of one’s invention. There are of course no positive requirements for reciting in the disclosure disadvantages or limitations of one’s invention.⁶⁸

66. Similarly, Dr. Harold G. Fox⁶⁹ described in the *Utility* chapter of his 1969 text, *Canadian Patent Law and Practice* the same approach in considering the standard of utility as is used today:

⁶⁷ *New Process Screw*, at p. 46 (R-162).

⁶⁸ *Hill*, at p. 188 (R-160).

⁶⁹ Dr. Fox is widely recognized as one of Canada’s leading intellectual property scholars and advocates, whose writings (particularly his text *Canadian Patent Law and Practice*) have been heavily cited and relied upon by the Courts. Additional information about Dr. Fox is available at: <http://www.thefoxfund.com/harold.htm>.

Utility as Specified: The true test of utility of an invention is whether it will, when put into practice by a competent person, do what it assumes to do, and be practically useful at the time when the patent is granted, for the purpose indicated by the patentee. “If when used in accordance with the directions contained in the specification, the promised results are obtained, the invention is useful in the sense in which that term is used in the patent law...

...

Promised Results: But a distinction must be drawn here between a case where a patentee claims a result and bases his claim for a patent on the production of that result, and a case where a patentee merely points to certain advantages that will accrue from the use of his invention. In the former case failure to perform the promise of the specification is fatal to the patent.

...

Cases of this type are of importance in that a distinction must be made between them and those cases where the specification contains no promise of results. In the latter case no particular *quantum* of utility is necessary; and a mere scintilla of utility is sufficient for validity. But in those cases of patents that are based upon a promise of results contained in the specification it is not sufficient that the patent be useful for a part only of the result, or for that result only in a manner inferior to that claimed.⁷⁰

[underlining added]

67. Having regard to all the above references, and adopting Mr. Hill’s language previously cited above, it seems “so obvious that it hardly needs stating” that to assess the standard of utility of an invention, the Courts would necessarily have had to construe the patent to determine whether the patent was silent on the issue of utility, or whether certain results had been promised.⁷¹ Yet, Professor Siebrasse indicates at paragraph 44 of his opinion that “[n]o case prior to 2005 included this type of analysis”. In his view, the Court has changed its approach in analyzing the utility requirement, with a focus on construing the patent. Specifically, he writes:

⁷⁰ Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969) at pp. 150-153 (“Fox”) (**R-163**). As noted in the Preface of Dr. Fox’s text, the 4th edition herein referred to “is intended to state the law [in Canada] as at March 1, 1969”.

⁷¹ To construe the patent is to interpret its words through the eyes of the person skilled in the art. It serves to give the patent the meaning it would have to the skilled person in the particular art to which it pertains.

The Court of Appeal has emphasized that “[t]he promise of the patent is fundamental to the utility analysis,” and “is to be ascertained at the outset of an analysis with respect to utility”.⁷²

68. However, this “new” approach identified by Professor Siebrasse is strikingly similar to the “old” approach described by Dr. Fox in 1969:

The plea of non-utility based on a failure to produce the promised results of a specification is similar to, and cannot always be separated from, the plea of false representation, or failure of consideration as it is sometimes called. It necessarily involves a construction of the specification in order to ascertain what the ordinary workman would apprehend by its disclosure. It is, therefore of the utmost importance to decide whether the specification makes a promise of a result and whether the ordinary workman would understand that that particular result is promised. If the ordinary workman would so read the specification as promising a certain result, and that result is performed by following the specification, the specification is sufficient and the patent cannot be held void on the ground of inutility.⁷³

[underlining added]

69. Indeed, leading practitioners have long recommended against including unnecessary “lists of advantages or objects” in a patent specification due to the recognized risk that such references may be taken as a promise. For example, in a “problem and comment” prepared for the Patent and Trademark Institute of Canada’s⁷⁴ March 1970 tutorials offered to patent agent trainees, William L. Hayhurst, QC⁷⁵ cautioned:

In the introductory parts of the specification one must be chary of promising advantages that are not achieved by everything that falls within the broadest claim. If you make false promises you may get an invalid patent. The patent should survive if the promised advantage does not constitute the utility upon which the entire grant is based, as in a case where it is made clear that an advantage may be achieved but is not necessarily always achieved...

Most lists of advantages or objects composed by the patent agent are of no assistance to anyone, since a person skilled in the art could

⁷² See Siebrasse Report at para. 44.

⁷³ Fox, at p. 153 (R-163).

⁷⁴ The Patent and Trademark Institute of Canada (PTIC) is the predecessor to what is now the Intellectual Property Institute of Canada (IPIC), an association of more than 1,700 intellectual property professionals in Canada.

⁷⁵ William Hayhurst, QC (1925-2011) was a partner at Ridout & Maybee LLP who practiced intellectual property law for over 40 years. He is considered one of the leading IP lawyers of his generation and wrote prolifically in the area of patents. His writings have been cited by many courts, including the Supreme Court of Canada.

easily compose an equally accurate or inaccurate list. There is much to be said for avoiding a sales pitch in the disclosure, and thus avoiding statements of objects and advantages. You can argue the merits of the invention, if you have to, in your arguments filed in the Patent Office or presented in the Courts...

Since claims, to be valid, must not extend to useless things, but must be confined to things which have the utility promised by the disclosure, the agent should be careful not to promise too much.⁷⁶

[underlining added]

70. Professor Siebrasse claims that *Consolboard* was often cited in the twenty five years from the time it was decided until 2005, but never in support of the exercise by which the court construes a “promise against which utility is assessed”. This statement is entirely inconsistent with my own experience in litigating and reading patent cases; *Consolboard* and the promise of the patent were inextricably linked together long before 2005. One example of a court decision around the time of the application dates of the olanzapine and atomoxetine patents was *Mobil Oil Corp. v. Hercules Canada Inc.* (“*Mobil Oil*”)⁷⁷.

71. In *Mobil Oil*, the validity of the patent in suit was challenged on utility grounds for failing to meet the utility promised in the patent. Justice Wetston explained the applicable law from *Consolboard*, but held that the invention did meet the standards described:

In order to be an invention worthy of protection, the patent must disclose and claim an invention which works, *i.e.* which achieves the promise it sets out (*Consolboard, supra*, at 525 S.C.R., 160 CPR).

...

The patent specification promises an oriented polypropylene film substrate having enhanced adhesion to a metallized coating. The evidence indicates that this was indeed achieved. The bond strength test results and the observed metal pick-off rates for the samples tested all indicate an adhesion well above commercial industry standards of 90 grams/inch. Further, the presence of slip agent in the film, particularly in the sealing layer, will operate to reduce the coefficient of friction and prevent the blocking problems and machine handling problems alleged by the defendant. Therefore, the patent is not invalid for inutility.⁷⁸

⁷⁶ W.L. Hayhurst, “Disclosure Drafting” (1971), 28 PTIC Bull (7th) 64 at pp. 73-74 (R-164).

⁷⁷ *Mobil Oil Corp. v. Hercules Canada Inc.*, (1994), 57 CPR (3d) 488 (FC) (“*Mobil Oil*”) (R-165); rev’d on other grounds in *Mobil Oil Corp. v. Hercules Canada Inc.*, (1995), 63 CPR (3d) 473 (FCA) (R-252).

⁷⁸ *Mobil Oil*, at pp. 507- 508 (R-165).

[underlining added]

72. The long-standing principle of enforcing the promised level of utility serves an important public policy function in ensuring that the public has received their end of the patent bargain. As described earlier, a patent has serious anticompetitive effects by increasing prices and stifling research. If a patentee is not held accountable for their promises, the public is subject to the negative effects of the patent in exchange for less than what was agreed to through the patent bargain at the outset.
73. This policy rationale is particularly germane where the promised utility is at the core of the invention. As I will discuss below, some inventions must make a promise of a particular utility in order to be patentable. That could occur where what the inventor has done is identify a “new use” for a known substance or object, or where the inventor claims a “selection” from a previously patented genus. In these types of situations, a promise of utility is the basis for the grant of a patent. Failure to deliver the promised utility breaches the patent bargain.
74. Holding patentees to their promises also promotes the quality and accuracy of patent disclosures, which are the consideration that the public receives in exchange for the patent monopoly. These disclosures enable the public to build upon the invention in new lines of research, and to practice the invention upon expiry of the patent. The quality of these disclosures is enhanced by a rule that holds patentees to the promises that they make. By holding patentees to their promises, the public can be more confident that practicing the invention will achieve the promised result.

Overbreadth and Sufficiency of Disclosure: Functional Similarities

75. The principles underlying promised utility also arise in overbreadth, another long standing principle of Canadian patent law. This is also known as “covetous claiming” (also referred to as “claims broader”). The general principle is that a patentee cannot claim more than what was invented or described in the patent.⁷⁹ In the first case, the patentee claims more than he has actually invented. In the second, the patentee claims more than is supported by the description in the patent. In other words, in one inquiry the focus is on the nexus between the claims and the actual invention made, and the other concerns the nexus between the claims and the enabling disclosure in the patent.
76. In *Amfac Foods Inc. v. Irving Pulp & Paper Ltd.* (“*Amfac Foods*”), a 1986 decision of the Federal Court of Appeal, the claim in issue, claim 16, was a claim to an apparatus that did not reflect the apparatus described in the patent, in that it did not achieve the purpose of the described invention.⁸⁰ Even though the apparatus of claim 16 did achieve commercial success and was useful in fact, it was nevertheless declared invalid for being broader than

⁷⁹ *Smith Incubator Co. v. Seiling*, [1937] SCR 251(**R-166**); *Leithiser et al. v. Pengo Hydra-Pull of Canada Ltd.*, (1974), 17 CPR (2d) 110 (FCA) (**R-167**).

⁸⁰ *Amfac Foods Inc. v. Irving Pulp & Paper, Ltd.*, (1986), 12 CPR (3d) 193 (FCA) (“*Amfac Foods*”) (**R-168**).

the invention described. The Court of Appeal had this to say at page 201 of the reported decision:

The contrast, thus, between claim 16 and most of the other claims is startling in that it fails to limit the scope of the claim by confining itself to achieving the purpose of the invention...⁸¹

[underlining added]

77. The *Amfac Foods* decision was a stark example of a patent running afoul of the warnings of the Supreme Court of Canada in *Consolboard*: that there is no obligation to indicate the utility of the invention in the patent, but if so indicated, the patent will be held to that utility. That said, if a certain result is material to the invention, then it must be disclosed and achieved by the claimed invention.
78. Shortly after the decision, in a newsletter of my law firm, Sim Hughes Dimock, I warned against the dangers of including object clauses in patents and that such clauses should be avoided altogether, or if their inclusion was absolutely necessary, to draft them very carefully. In a short note entitled “The Danger of Object Clauses in Patents”, I wrote:

In the case of *Consolboard v. MacMillan Bloedel* (1981) 56 CPR (2d) 145, it was made very clear by the Supreme Court of Canada that it is unnecessary to indicate what the real utility of the invention is or describe in what way the invention is useful. In short, object clauses need not appear.

The Federal Court of Appeal decision in *Amfac v. Irving* makes it clear that object clauses should be avoided or very carefully drafted since they can unnecessarily restrict the scope of patents.⁸²

[underlining added]

79. I was not the only person at the time commenting on the dangers of object clauses or making promises in the patent in the wake of the *Amfac Foods* decision. In 1987, William Hayhurst, QC, wrote:

The case [*Amfac Foods*] is a good illustration of the risk that a patent agent runs when he follows the U.S. style of larding a patent specification with statements of objects and advantages...⁸³

Mr. Hayhurst’s comments were virtually identical to mine in that *Consolboard* had previously warned against such statements. He went further by noting that Justice

⁸¹ *Amfac Foods*, at p. 201 (R-168).

⁸² Sim, Hughes, Dimock and Sim & McBurney Newsletter, Issue No 4, Spring 1987, at p. 4 (R-169).

⁸³ William L. Hayhurst, Q.C., “Patent Claims—Excess Width—The Case of the Sliced Potatoes” (1987) 3 IPJ 216, at p. 217 (R-170).

Dickson in *Consolboard* echoed the words of Lord Justice Fletcher Moulton in *Clay v. Allcock & Co*⁸⁴ in 1906 where he referenced the well-known principle in patent law that “a man need not state the effect of the advantage of his invention, if he describes his invention so as to produce it.”⁸⁵

80. The similarity between overbreadth and promised utility is again evident in the 1995 decision of the Federal Court of Appeal in *Unilever PLC v. Procter & Gamble Inc.*⁸⁶ One attack against the validity of the patent on a dryer softener sheet was that the claims were covetous for failing to fulfill the promised result.⁸⁷ A key element of the patented invention was the addition of a distributing agent to increase dispersal of the fabric softener onto the clothes in the dryer. The question was whether it was an object of the invention that the distributing agent would also reduce staining. If this were the case and the distributing agent did not reduce staining, the argument was that claims would then be invalid. The argument failed, based on the facts and the construction of the patent. The Federal Court of Appeal wrote:

I turn next to the issue of validity.

The issue was argued in three different ways. The first is that the Patent fails to fulfil its promise that ‘a distributing agent’ causes less staining when, in fact, SMS causes more staining; ...

I turn then to the first argument against validity [covetousness]. The law is clear that a claim is invalid if it purports to monopolize more than what was invented as disclosed in the specification: *Amfac Foods Inc. v. Irving Pulp & Paper Ltd.*...[citations omitted]. The argument here is that one of the Patent’s stated objectives is to reduce staining by the addition of a ‘distributing agent’, and that if it does not do so, the Patent fails to fulfil its promise and is invalid...I have already expressed the view that we ought not to interfere with the trial judge’s finding and conclusion that the primary purpose of the invention is to more evenly distribute a softener onto clothes in a dryer. If that is the correct analysis, the premise upon which the first argument for invalidity is constructed simply disappears and requires no further consideration.⁸⁸

⁸⁴ *Clay v. Allcock & Co Ltd.*, [1906] 23 RPC 745 (R-171).

⁸⁵ While *Clay v. Allcock & Co Ltd.* referenced that a patentee need not state the effects or advantages of the invention, the decision actually stands for the *caveat* that an effect or advantage must be stated where it is of the essence of the invention. In this case, an effect of the invention was to cause a “jerk” in a fishing line when the hook was taken by a fish. To avoid anticipation by the prior art, this effect had to be described and claimed in the specification. This principle is central to later discussion in my report regarding selection patents.

⁸⁶ *Unilever PLC v. Procter & Gamble Inc.*, (1995), 61 CPR (3d) 499 (FCA) (“*Unilever*”) (R-172).

⁸⁷ *Unilever*, at p. 505 (R-172).

⁸⁸ *Unilever*, at pp. 511-512 (R-172).

[underlining added]

81. Alongside overbreadth, courts have also considered the overlap of promised utility with adequate or sufficient disclosure. A patent is not sufficient or not enabling if it fails to fully describe the invention and how to put it into practice to achieve the same successful use as that contemplated by the inventor. In *American Cyanamid Company v. Ethicon Limited*,⁸⁹ a 1979 decision of the UK High Court of Justice, Chancery Division, Graham J noted the overlap of these legal principles, as well, in similar fashion to *Consolboard*, he outlined the danger of making promises:

The directions in a specification must be sufficient to enable the notional instructed reader, armed with the knowledge and experience expected of a man skilled in the art, to make a fibre which falls within the words of the claim and which adequately fulfills any promise in the specification which it is stated or necessarily implied that any fibre falling within the claims will meet. A patentee is not under any obligation to make promises in respect of the articles which he claims, but, if he does so and if it is fair as a matter of construction to treat the promise as material and as coterminous with a relevant area covered by the claims, then it seems to me a product falling within that area must be tested by that promise when considering whether there is present insufficiency, inutility or false suggestion.⁹⁰

[underlining added]

82. Enforcing the promise of the patent and invalidating claims that are not useful enough or are overly broad ensures that the patentee has conducted enough research and development to communicate how the invention works in its entirety. Claims that encompass results or embodiments of the invention not meeting the promised utility are not useful enough or are overly broad and do not reflect what the inventor can legitimately say to have invented.

Determining the Promised Level of Utility is Not Subjective or Arbitrary

83. At paragraph 57 of the Claimant's Memorial, the Claimant argues that a court's determination of the promised utility is subjective, arbitrary and unpredictable; it is a marked deviation from the traditional, objective approach to utility which did not require a court to interpret the patent; and, determining the promised utility is an improper usage of the specification of the patent.
84. This is contrary to what I have encountered in practice. Ascertaining the promise of utility and the level of such utility has long been considered through the eyes of the skilled person. As already noted above, Dr. Harold Fox described this approach in 1969:

⁸⁹ *American Cyanamid Company v. Ethicon Limited*, [1979] RPC 215 (R-173).

⁹⁰ *Id.*, at p. 38 (R-173).

...It necessarily involves a construction of the specification in order to ascertain what the ordinary workman would apprehend by its disclosure. It is, therefore, of the utmost importance to decide whether the specification makes a promise of a result and whether the ordinary workman would understand that that particular result is promised.⁹¹

[underlining added]

85. This is not a “subjective” and “arbitrary” process but a fair interpretation of the patent in accordance with the “purposive” and “informed” approach to patent construction, as described by the House of Lords in *Catnic Components Ltd. v. Hill & Smith Ltd* in 1982.⁹² The *Catnic* decision was immediately adopted by the Federal Court of Appeal and its place in Canadian law was later confirmed by the Supreme Court of Canada in *Whirlpool Corp. v. Camco Inc.*⁹³ The patent must be read through the eyes of the skilled reader, since this is the person to whom the patent is addressed.⁹⁴ The skilled reader is understood to be equipped with the common general knowledge in the relevant field. Expert evidence on how a skilled reader would understand the patent may be adduced. This places the trial judge in the position of being able to interpret the patent claims in a knowledgeable way.⁹⁵ The patent must be construed having regard to the patent as a whole, including both the disclosure and the claims. As the Supreme Court of Canada stated in *Consolboard* and later confirmed in *Whirlpool*:

We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance, [citation omitted], being neither benevolent nor harsh, but rather seeking a construction which is reasonable and fair to both patentee and public.⁹⁶

86. The Federal Court of Appeal explained the process of construing a patent, including its promise, in similar terms in *Apotex Inc. v. Pfizer Canada Inc.* at para. 17:

Like claims construction, the promise of the patent is also a question of law (*Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197 [Eli Lilly]). In this particular case, the Applications Judge, assisted with expert evidence, needed to purposively ascertain the promise of the patent “within the context of the patent as a whole, through the eyes of the person of skill in the art (POSITA) in relation to the science and

⁹¹ *Fox*, at pp. 152-153 (R-163).

⁹² *Catnic Components Ltd. v. Hill & Smith Ltd.*, [1982] RPC 183, at p. 243 (HL) (R-174).

⁹³ *Procter & Gamble Co v. Beecham Canada Ltd.*, (1982), 61 CPR (2d) 1, at para. 276 (FCA) (R-175); *Whirlpool Corp. v. Camco Inc.*, [2000] 2 SCR 1067 (“*Whirlpool*”) (R-022).

⁹⁴ *Whirlpool*, at para. 44 (R-022).

⁹⁵ *Whirlpool*, at para. 57 (R-022).

⁹⁶ *Consolboard*, at pp. 520-521 (R-011); *Whirlpool*, at para. 49 (R-022).

information available at the time of filing” (Eli Lilly, at paragraph 80).⁹⁷

87. These settled principles of patent construction were applied by the Federal Court in the proceedings concerning Claimant’s patents for atomoxetine and olanzapine.
88. I also disagree with Professor Siebrasse’s view that it is improper for Canadian courts to have regard to the descriptive portion of the patent in construing the promised utility.⁹⁸ It has long been known that the specification as a whole (both the disclosure and claims) is to be construed in an informed manner through the eyes and mind of the person skilled in the art.⁹⁹ This means that reference may be made to the descriptive portion of the patent in construing its promise.
89. I also note that the promises in Claimant’s atomoxetine and olanzapine patents were based on the claims themselves. For example, the first claim of the atomoxetine patent (upon which all other claims depended) read: “The use of tomoxetine [atomoxetine] for treating attention-deficit/hyperactivity disorder in a patient in need thereof.”¹⁰⁰ The Federal Court determined the promise of the patent by construing this claim following settled principles of patent construction. The same is true of Claimant’s olanzapine patent, where the starting point of the Federal Court’s analysis of promise was the express wording of the relevant claims.¹⁰¹ The Federal Court then proceeded to construe these claims in the context of the patent as a whole, and in light of expert evidence.¹⁰²
90. I also cannot agree with Claimant and Professor Siebrasse’s suggestion that there is anything unusual about Canadian courts hearing expert evidence on the construction of a promise contained in a patent.¹⁰³ This follows from the settled principles of patent construction just discussed. The court must construe the entire patent, including any promise, through the eyes and mind of the skilled reader. To do so knowledgeably, a judge will have regard to expert evidence brought by the parties on how a skilled reader would

⁹⁷ *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, at para. 17 (**R-177**).

⁹⁸ See Siebrasse Report, at paras. 52-53.

⁹⁹ *Burton Parsons (R-176)*; *Western Electric Co v. Baldwin International Radio of Canada*, [1934] SCR 570, at p. 572 (**R-178**); *Whirlpool*, at para. 48 (**R-022**).

¹⁰⁰ Patent Specification CA 2,209,735 (**R-026**).

¹⁰¹ *Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288 (“*Olanzapine FC I*”), para. 94 (**R-016**).

¹⁰² The claims in issue in the olanzapine proceeding included “The use of olanzapine for the manufacture of a drug for the treatment of schizophrenia.” However, since the olanzapine patent was a selection patent, the claimed invention had to offer more than the previously claimed genus patent. The court construed the claims in the context of the patent as a whole and in light of expert evidence. The description expressly asserted that the invention showed a marked superiority and a better side effects profile in clinical situations than prior known antipsychotic agents. On this basis, the Federal Court concluded that the claimed invention promised marked superiority in the clinical treatment of schizophrenia than other known antipsychotics. *Olanzapine FC II*, at paras. 94, 110, 120, 124 (**R-016**).

¹⁰³ See for example, Claimant’s Memorial, at para. 62 and see Siebrasse report at para. 44.

have read the patent. Canadian courts have received expert evidence on matters of patent construction for decades.¹⁰⁴

91. Certainly, over the course of my career, there has been a marked increase on the use of expert witnesses in patent trials. However, this phenomenon is by no means unique to the issue of construing the promise of a patent. Battles between expert witnesses are driven by the parties to litigation themselves, who choose what evidence to call, including whether they will rely on expert witnesses, and if so, how many.

C. Has the Invention Been Made?

92. The determination of the standard of utility, as discussed above, simply provides the “measuring-stick” to which the utility of the invention is to be compared. However, this “standard” does not address when that utility must be established. In Canada, the utility of the invention must either be demonstrated or soundly predicted as of the Canadian filing date of the patent application.¹⁰⁵ On this point, Professor Siebrasse and I appear to be in agreement.¹⁰⁶
93. To be entitled to a patent, an inventor must have made the invention having the utility described in the patent when the application for the patent was filed. Making the invention is a term of art in patent law. As stated by Justice Taschereau in the Supreme Court of Canada’s decision, *Wandscheer et al. v. Sicard Ltd.*, an invention has been made where it has been reduced to a “definite and practical shape”:

It is not sufficient, in order to obtain a valid patent, as Viscount Cave said in *Permutit Co. v. Borrowman*,

for a man to say that an idea floated through his brain; he must at least have reduced it to a definite and practical shape before he can be said to have invented a process.

The alleged invention must be susceptible of fulfilling its purpose, and it must enable a person skilled in the art to carry it out.¹⁰⁷

¹⁰⁴ See for example, *Burton Parsons (R-076)*; See also William L. Hayhurst, Q.C., “Recent Developments in Canadian IP Law”, (1987), at p. 148 (**R-254**) (writing that in Canada “it is clear that construction of the patent specification is for the court; however, adducing expert evidence on such “ultimate issues” has become commonplace, with the court concerning itself with the weight rather than the admissibility of such evidence).

¹⁰⁵ *AZT*, at paras. 52 and 70 (**R-004**).

¹⁰⁶ See for example, Siebrasse Report, at paras. 16, 29. Previously, when Canada had a first-to-invent patent system, rather than a first to file system, the material date for assessing utility was the date of invention, rather than the date of filing Fox, at p. 160. See also *Aventis Pharma v. Apotex* (2005), 43 CPR (4th) 161, at paras. 88-97 (**R-180**).

¹⁰⁷ *Wandscheer et al. v. Sicard Ltd.*, [1948] SCR 1, at p. 4 (**R-181**), quoting *Permutit Co. v. Borrowman*, (1926) 43 RPC 356 at 359; also see *Canadian Raybestos Co. v. Brake Service Corp.*, [1928] SCR 61 (**R-182**), aff’g., [1926] Ex CR 187 (Ex. Ct.) (**R-253**); *Procter & Gamble Co. v. Bristol-Myers Canada Ltd.* (1979) 42 CPR (2d) 33, paras. 14-15 (FCA) (**R-183**).

[underlining added]

94. Following this principle, the invention, including its utility, must have been reduced to a definite and practical shape before the invention can be said to have been made. Similar to the above, the Federal Court stated in *Comstock Canada v. Elected Ltd.*, “By merely putting forward an idea, or suggestion, in terms of an objective or end result one has not thereby invented anything which is necessarily validly patentable.”¹⁰⁸
95. One manner in which reduction to a definite and practical shape occurs is where the invention has been built or used, thereby fulfilling its purpose or achieving its promised result (if a promise was made).¹⁰⁹ Where this is the case, the utility is demonstrated.
96. While the principle of building or using an invention is generally an appropriate way to reduce an invention to definite and practical shape in the mechanical arts, it is often unsuited to chemical or pharmaceutical inventions. These inventions may lie in a particular compound, and slight variations will offer the same benefits and produce the same results. To prevent a competitor from avoiding infringement through the use of a slight variation, it is common to claim entire classes of compounds¹¹⁰ or multiple variants thereof. At the same time, it may be impossible or unreasonable for the patentee to actually make or test all of these embodiments. Indeed, this is a long-standing problem inherent to claim drafting, as described by the Supreme Court of Canada:
- It is stressed in many cases that an inventor is free to make his claims as narrow as he sees fit in order to protect himself from the invalidity which will ensue if he makes them too broad. From a practical point of view, this freedom is really quite limited because if, in order to guard against possible invalidity, some area is left open between what is the invention as disclosed and what is covered by the claims, the patent may be just as worthless as if it was invalid. Everybody will be free to use the invention in the unfenced area.¹¹¹
97. As described by the Supreme Court of Canada in the above passage, the inventor must be cautious about casting the claim too broadly; this would include claiming compounds where the utility was unknown. However, obligating an inventor to demonstrate the utility of every instantiation of their invention would be unduly onerous and delay the disclosure of potentially beneficial inventions.¹¹²

¹⁰⁸ *Comstock Canada v. Elected Ltd.*, (1991), 38 CPR (3d) 29, 45 FTR 241, at para. 71 (FC) (R-184).

¹⁰⁹ *Christiani v. Rice*, [1930] SCR 443, at paras. 31-37 (R-185).

¹¹⁰ In some instances, including up to “260 quintillion” different compounds – *Pfizer*, at para. 4 (R-006).

¹¹¹ *Burton Parsons*, at para. 16 (R-176).

¹¹² *AZT*, at para. 66 (R-004).

98. Since at least the 1960s, Canadian courts have considered the question of whether a claimed invention concerning a broad class of chemical compounds could be said to have been made, when only a small number of the claimed embodiments had actually been tested.¹¹³ Ultimately, Canadian courts adopted the doctrine of sound prediction to address this issue.
99. Sound prediction permits a patentee to claim an invention even where he has not actually demonstrated the utility of all of the claimed embodiments.¹¹⁴ Under this doctrine, a patentee is entitled to frame a claim which does not go beyond the limits within which the prediction remains sound.¹¹⁵ This provides a more flexible test whereby utility will be presumed where the patentee makes a sufficient disclosure (discussed in further detail below) in the patent from which the invention can be soundly predicted by the person of ordinary skill in the art.
100. Sound prediction is a rather useful doctrine for patent applicants such as pharmaceutical companies as it permits a patent to be granted and upheld even where the utility of the invention has not been demonstrated at the filing date across the full scope of the claimed invention. I disagree with Claimant's suggestion that a pharmaceutical invention cannot meet Canada's utility requirement in the absence of clinical trials.¹¹⁶ Numerous pharmaceutical patents have been upheld in the absence of clinical trials, including on the basis of sound prediction.¹¹⁷ The extent of the factual basis needed to support a sound prediction will depend on the context. The key principle is the patent must disclose a sufficient factual basis and line of reasoning so that a skilled reader would recognize the prediction of utility as a sound one.
101. This is best illustrated in the 1979 Canadian case of sound prediction in *Monsanto Co. v. Canada (Commissioner of Patents)*.¹¹⁸ The patent disclosed three compounds having particular effects on rubber but claimed a class of 126 compounds having a similar structure to the disclosed compounds. The lower court held the claims invalid as being broader than the invention disclosed.¹¹⁹ The Supreme Court reversed and held that it was possible to make a sound prediction of utility across the entire breadth of the claim based on the disclosure. More will be said about the *Monsanto* case later in my report.

¹¹³ See for example *Société des Usines Chimiques Rhône-Poulenc v. Jules R. Gilbert Ltd.*, (1967), 35 Fox Pat. C. 174, at para. 48 (Ex. Ct.) (**R-186**).

¹¹⁴ *Goldfarb v. W.L. Gore & Associates Inc.*, (2001), 11 CPR (4th) 129, at para. 112 (FC) (**R-187**).

¹¹⁵ *Monsanto 1979*, at para. 10 (**R-023**).

¹¹⁶ See Claimant's Memorial at para. 66.

¹¹⁷ See for example, *Pfizer Canada Inc. v. Novopharm Ltd.*, 2009 FC 638, at paras 86-87 (**R-188**), *Allergan Inc. v. Canada (Minister of Health)*, 2011 FC 1316, at para. 69 (**R-189**).

¹¹⁸ *Monsanto 1979* (**R-023**).

¹¹⁹ At the time, appeals from the Patent Appeal Board were heard by the Federal Court of Appeal. This is unlike practice today, where appeals from the Board are heard by the Federal Court.

102. Whether utility is established by demonstration or sound prediction, it has long been understood in Canadian patent law that post-filing evidence is not available to prove that an inventor had made the invention by the filing date of the patent application (including satisfaction of the utility requirement). As observed by the Supreme Court of Canada in *AZT*, the *Patent Act* does not postpone the requirement of utility, whether established by demonstration or sound prediction, to the time when utility may be challenged, which could be any time up to and even beyond the end of the twenty-year patent term.¹²⁰
103. Put simply, the patent bargain is made at the time of filing, not later. Indeed, the whole purpose of the introduction of the doctrine of sound prediction was to permit patentees to satisfy the utility requirement at the time of filing without having actually demonstrated utility at that point. I therefore do not agree with Professor Siebrasse's view that the doctrine of sound prediction represents a more onerous utility requirement.
104. In his report, Professor Siebrasse makes reference to "post-filing" or "after-the-fact" evidence (*i.e.* evidence of utility based on tests or facts after the patent application was filed) having been available to the Courts prior to 2002. Specifically he indicates at paragraph 30 of his report that post-filing evidence was routinely used in assessing the utility of an invention; but then qualifies this statement in a footnote: "The courts did not distinguish between pre- and post-filing evidence, but it is normally possible to determine from the facts whether the evidence actually relied on was post-filing evidence". However, even further qualification is required with respect to the legal "sense" in which the term "utility" has been used in these cases.
105. The post-filing "evidence" used by Canadian courts does not relate to whether an invention was demonstrated or soundly predicted at the time of filing (thus, whether one has actually made an invention) but rather relates to the utility-in-fact (operability) of the invention described in the patent. Operability is concerned with whether the embodiments of the claimed invention will actually work to the level promised, and does not consider when the invention was made. Post-filing evidence has long been admissible, and continues to be so today, with respect to issues of operability. In all but one of the cases cited by Professor Siebrasse, such "post-filing" evidence was provided to rebut allegations of invalidity, in that the invention was obvious or it was not operable.¹²¹ In these cases, there was no issue as to whether the patentee had "reduced to a definite and practical shape" his alleged invention at the time of application. The issue was whether that invention was operable in fact. In contrast, in cases where demonstration or sound prediction of utility is at issue, the question is precisely whether the patentee had "reduced to a definite and practical shape" his invention at the time of filing, or in other words, whether he had actually invented something when he filed.
106. The only case that I am aware of that may be construed as relying on post-filing evidence in support of demonstrating or soundly predicting utility at the time of filing is the *Ciba-*

¹²⁰ *AZT* at para. 80 (R-004).

¹²¹ See Siebrasse Report, at paras. 30-32.

*Geigy AG v. Canada (Commissioner of Patents)*¹²² (“*Ciba-Geigy*”) decision cited by Professor Siebrasse. Notably, and as mentioned in his report, the Patent Office refused to consider post-filing evidence when an objection arose concerning the soundness of the predicted utility, and rejected the application. The decision of the Patent Office was later overturned by the Federal Court of Appeal.

107. The *Ciba-Geigy* decision was directly addressed by the Supreme Court of Canada in *AZT*. The patentee, Glaxo/Wellcome, argued that a sound prediction of utility could be validated with post-filing evidence (“after-the-fact” validation), on the basis of the following statement from *Ciba-Geigy*:

...if indeed what is in the patent specification was mere speculation or prediction, the speculation or prediction having turned out to be true, ought to be considered to have been well founded at the time it was made. Even at the time it was made it is not improbable that it would have been considered well founded.¹²³

108. The Supreme Court of Canada dismissed any notion that *Ciba-Geigy* was authority for “after-the-fact” validation. Justice Binnie noted that “the two sentences [in *Ciba-Geigy*] do not stand alone”, and quoted the words of the Federal Court of Appeal justifying a finding that a sound prediction had been made at the time of filing, without the benefit of post-filing evidence:

Moreover, on the facts of *Ciba-Geigy* itself, Thurlow C.J. says, as quoted above, that ‘[e]ven at the time it was made it is not improbable [*i.e.*, it is probable] that it [the invention] would have been considered well founded [*i.e.*, a sound prediction]’.¹²⁴

109. Thus, there was no need to consider post-filing evidence in *Ciba-Geigy*, and as noted by Justice Binnie, “to the extent *Ciba-Geigy* stands for a contrary position”, it should not be followed.
110. This was not a reversal of Canadian law, but a confirmation of a well-established rule. As observed in a newsletter from Smart & Biggar¹²⁵ immediately following the *AZT* decision, the “Court reaffirmed a long-standing position that sound prediction will not

¹²² *Ciba-Geigy AG v. Canada (Commissioner of Patents)*, (1982), 65 CPR (2d) 73 (FCA) (“*Ciba-Geigy*”) (**R-190**).

¹²³ *Ciba-Geigy*, at p. 77 (**R-190**).

¹²⁴ *AZT*, at para. 84 (**R-004**).

¹²⁵ Smart & Biggar/Fetherstonhaugh, as mentioned earlier in report at paragraph 47, is one of Canada’s leading patent law firms.

successfully support a patent claim if ... the prediction at the date of the application was not sound¹²⁶

111. As explained by the Supreme Court in *AZT*, reliance on post-filing evidence to support that a prediction was sound at the time of filing violates the bargain principle founding our patent system:

In the broader context of the *Patent Act*, as well, there is good reason to reject the proposition that bare speculation, even if it afterwards turns out to be correct, is sufficient. An applicant does not merit a patent on an almost-invention, where the public receives only a promise that a hypothesis might later prove useful; this would permit, and encourage, applicants to put placeholders on intriguing ideas to wait for the science to catch up and make it so. The patentee would enjoy the property right of excluding others from making, selling, using or improving that idea without the public's having derived anything useful in return.¹²⁷

112. Reliance on post-filing evidence to establish utility at the time of filing (rather than with respect to issues of operability) can be described as a “file now, pay later” approach which ignores the above principles and falls squarely within the concerns of the Supreme Court of Canada in *AZT*. As noted above, the patentee in *AZT*, Glaxo/Wellcome, argued that utility was satisfied as post-filing evidence clearly showed the invention was useful. In addition to dismissing any possible legal authority for the principle stemming from *Ciba-Geigy*, Justice Binnie noted that the theory was unsound in both law and policy, and outlined the abuses of the patent system that could follow:

In my view, with respect, Glaxo/Wellcome's proposition is consistent neither with the Act (which does not postpone the requirement of utility to the vagaries of when such proof might actually be demanded) nor with patent policy (which does not encourage the stockpiling of useless or misleading patent disclosures). Were the law to be otherwise, major pharmaceutical corporations could (subject to cost considerations) patent whole stables of chemical compounds for all sorts of desirable but unrealized purposes in a shot-gun approach hoping that, as in a lottery, a certain percentage of compounds will serendipitously turn out to be useful for the purposes claimed. Such a patent system would reward deep pockets and the ingenuity of patent agents rather than the ingenuity of true inventors.¹²⁸

¹²⁶ “Supreme Court of Canada Reaffirms the Doctrine of Sound Prediction in Canadian Patent Law,” *IP Perspectives Intellectual property & Technology Newsletter*, Smart & Biggar / Fetherstonhaugh, February 2003 [underlining added] (R-191).

¹²⁷ *AZT*, at para. 84 (R-004).

¹²⁸ *AZT*, at para. 80 (R-004).

113. While confirming the rule against post-filing evidence, it should be noted that the Supreme Court of Canada upheld the validity of Glaxo/Wellcome's patent in *AZT*, as the utility in that case had been soundly predicted.

D. Has the Invention Been Disclosed?

114. Disclosure lies at the "very heart of the patent bargain". The reason for this is simple: the patent system seeks to entice advancements in the state of the art into the public domain and it is through the patent specification that any such advancement is conveyed. Thus, adequate or sufficient disclosure is a must for patentability initially and validity ultimately.¹²⁹ The fundamental role of the specification in the patent bargain was described by Lord Halsbury in 1902, and his reasoning was later adopted by the Supreme Court of Canada in *Consolboard* and *Pfizer*:

...if one has to look at first principles and see what the meaning of a Specification is ... why is a Specification necessary? It is a bargain between the State and the inventor: the State says, "If you will tell what your invention is and if you will publish that invention in such a form and in such a way as to enable the public to get the benefit of it, you shall have a monopoly of that invention for a period of fourteen years." That is the bargain. The meaning which I think, in my view of the patent law, has always been placed on the object and purpose of a specification, is that it is to enable, not anybody, but a reasonably well informed artisan dealing with a subject-matter with which he is familiar, to make the thing, so as to make it available for the public at the end of the protected period.¹³⁰

115. The concern about sufficiency is whether or not the specification correctly and fully describes the invention and the method of producing or constructing it.¹³¹ The skilled person must be able to produce the invention having only the instructions contained in the disclosure and the common general knowledge in the art.¹³²
116. As noted in my discussion above concerning the determination of the standard of utility, the Supreme Court of Canada confirmed in *Consolboard* that there is no *general* obligation on the patentee to describe the invention's utility within the patent.
117. However, there are instances in which such a description of the utility of an invention is required. As explained further below, these instances are not an exception to the rule mentioned above from *Consolboard*, but rather arise out of the statutory requirement to

¹²⁹ *Pfizer*, at para. 31(R-006).

¹³⁰ *Consolboard*, at para. 32 (R-011) and *Pfizer*, at paras 32-35 (R-006), both citing *Tubes, Ld. v Perfecta Seamless Tube Company, Ld.* (1902), 20 RPC 77 at pp 95-96.

¹³¹ *Pfizer*, at para. 50 (R-006).

¹³² *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 SCR 1623 (R-193).

“correctly and fully describe the invention and its operation or use as contemplated by the inventor”¹³³ and the corresponding prohibition against what is known as *covetous claiming* (i.e., claiming more than what was invented or disclosed in the specification).

118. In particular, where a specific utility lies at the core of the invention itself, it necessarily follows that the “invention” cannot be fully and completely described without disclosing that utility. A “new use” patent, such as Claimant’s patent for the use of atomoxetine, is an obvious example of this concept, where the invention lies in the disclosure of a previously unrecognized use for a known compound or construct. If the new use were not disclosed, and claimed, the patent would fail for anticipation, obviousness, or double-patenting in that the compound itself had already been disclosed.
119. “Selection” patents are another type of patent in which a particular utility or “advantage” forms the basis of the invention and which must be disclosed within the patent specification. Such patents are directed to a subset or “selection” of members of a previously known group, based on the discovery that those members have a previously unidentified advantage over the other members in the group. Of particular relevance to this arbitration, Eli Lilly’s olanzapine patent was a selection patent. Citing the reasons of Lord Maugham in *IG Farbenindustrie AG’s Patents*¹³⁴ as the “*locus classicus* describing selection patents”, the Supreme Court of Canada explained that selection patents have at least the following three general characteristics:

1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members;
2. The whole of the selected members (subject to ‘a few exceptions here and there’) possess the advantage in question; and
3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be of a special character.¹³⁵

[underlining added]

120. The application of these three conditions in Canadian patent law has been acknowledged by our Courts since at least as early as 1964.¹³⁶ However, the Federal Court of Appeal in

¹³³ *Patent Act*, s 27(3) (R-001).

¹³⁴ *IG Farbenindustrie AG’s Patents*, (1930), 47 RPC 289 (ChD) (R-194).

¹³⁵ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, [2008] 3 SCR 265, (“*Sanofi-Synthelabo*”) at para. 10 (R-013).

¹³⁶ See for example, *Hoechst Pharmaceuticals of Canada Limited et al. v. Gilbert & Company et al.*, (1964), Fox Pat C 28 (Ex Ct), at paras. 26- 27 (R-195).

Eli Lilly Canada Inc. v. Novopharm Ltd. clarified that the absence of one or more of these conditions does not constitute an independent basis to challenge the validity of a selection patent. Rather they are intended to “serve to characterize the patent and accordingly inform the analysis” corresponding to the requirements that an invention be new, useful, non-obvious and sufficiently disclosed:

28 As noted in *Sanofi*, the conditions set out in *I.G. Farbenindustrie* describe selection patents (para. 9). In other words, the conditions are akin to a definition. Rothstein J. found *I.G. Farbenindustrie* to be a useful starting point for the analysis to be conducted (para. 11). It only stands to reason that in undertaking an analysis of novelty, obviousness, sufficiency and utility, one should know the nature of the beast with which one is dealing.¹³⁷

[underlining added]

121. Thus, like any other patent, a selection patent must therefore correctly and fully describe the invention to satisfy the disclosure requirements of section 27(3) of the *Patent Act*. In the case of selection patents, the Supreme Court has stated that in order to meet this requirement:

[I]t is necessary that the specification of the selection patent define in clear terms the nature of the characteristic which the patentee alleges to be possessed by the selection for which he claims a monopoly.¹³⁸

122. Put another way, the Federal Court of Appeal subsequently explained that the invention of a selection patent is a selection having the advantage to be gained or disadvantage to be avoided, therefore this must be disclosed in the specification of the patent:

In the case of selection patents, as we have seen, the novelty of selection and its advantages (including disadvantages to be avoided) are the invention and must be described in the patent...¹³⁹

123. The need to disclose the basis for the selection justifying a second patent is undoubted. In cases where the utility of the invention is founded on a sound prediction, the basis for that prediction need also be set out in the disclosure of the patent to satisfy the disclosure requirements of the *Patent Act*. As explained by Mr. Hayhurst in the 1970 patent tutorials:

Not only must you instruct those skilled in the art. You must also provide a disclosure which justifies the claims you are making... You must include sufficient examples to justify a sound prediction that

¹³⁷ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, (“*Olanzapine FCA I*”), at para. 28 (R-015).

¹³⁸ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, [2008] 3 SCR 265, (“*Sanofi-Synthelabo*”) at para. 114 (R-013).

¹³⁹ *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186, at para. 51 (R-014).

everything falling within the scope of the claims will have the promised utility.¹⁴⁰

[underlining added]

124. As noted above, the Supreme Court of Canada's decision in *Apotex Inc. v. Wellcome Foundation Ltd.* ("AZT") is often referred to as the leading Canadian authority concerning sound prediction.¹⁴¹ In particular, writing for the court, Justice Binnie¹⁴² structured the elements of sound prediction and restated them as follows:
- ...there must be a factual basis for the prediction...
- ...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...
- ...there must be proper disclosure...¹⁴³
125. With respect to the third component, proper disclosure, Justice Binnie noted that a patent specification is sufficient only if it provides "a full, clear and exact description of the nature of the invention and the manner in which it can be practiced" and that the "sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly". However, Justice Binnie noted that there was no issue concerning the disclosure of the patent in the dispute before the Court in that case, because the underlying facts and line of reasoning were in fact disclosed in the specification. Accordingly, Justice Binnie would "say no more about [the issue]".¹⁴⁴ It should be noted here that the patent agents for Wellcome Foundation must have recognized the requirement to disclose the underlying facts and line of reasoning in the disclosure.
126. In contrast, the issue of whether a patent specification sufficiently supported a sound prediction was squarely at issue before the courts in the *Monsanto v. Commissioner of Patents* case in the late 1970s. In that case, evidence was led and submissions made concerning whether or not the skilled person in the art (*i.e.*, the person to whom the patent is understood to be addressed) would have been able to soundly predict the utility of untested compounds, based on the disclosure of the patent. Of note, in restating the test

¹⁴⁰ W.L. Hayhurst, "Disclosure Drafting" (1971), 28 PTIC Bull (7th) 64, at pp. 77-78 (R-164).

¹⁴¹ AZT (R-004).

¹⁴² Justice Binnie also wrote the decisions for the Court in *Whirlpool* and *Free World Trust*, the two seminal cases on patent claim construction in Canada. As a lawyer, he was lead counsel for Unilever in the *Unilever v. Procter & Gamble* patent litigation referred to earlier.

¹⁴³ AZT, at para. 70 (R-004).

¹⁴⁴ AZT, at para. 70 (R-004).

for sound prediction in *AZT*, Justice Binnie explained that “[t]he doctrine was explicitly received into our law in *Monsanto*.”¹⁴⁵

127. In the *Monsanto* case, the primary issue was whether a patent claim for 126 different compounds was sufficiently supported by the patent specification which disclosed just three examples (which were in fact the only claimed compounds that had been prepared as of the filing date of the application). I worked as a junior to Donald F. Sim, QC on behalf of our client, Monsanto, in this case.
128. As noted by the Patent Appeal Board, “[c]laims 9 and 16 were rejected under s. 36 [now s. 27] of the *Patent Act*, R.S.C. 1970, c. P-4, and Rule 25¹⁴⁶ on the grounds that they are too broad, covering subject-matter going beyond what was invented”.¹⁴⁷ During prosecution of the patent, the Examiner raised the following objection:

In order to sustain claims to a broad group of compounds, the specification must illustrate with reasonable certainty that all members of the group are capable of being prepared by the disclosed process of preparation and have the same utility (inhibiting premature vulcanization) upon which their patentability is based. Certainly broad product claims must be adequately supported by a sufficient number of examples.¹⁴⁸

[underlining added]

129. The Patent Appeal Board acknowledged that the objection was not concerned with whether the specification was sufficient to teach the skilled person how to prepare the compounds, but rather, was directed at whether the specification sufficiently supported the sound prediction on which “the invention” was based:

We come to the conclusion that the disclosure provides sufficient direction so that a skilled chemist could prepare the compounds using methods previously known in the art. We also recognize that the disclosure has mentioned all the compounds covered by claim 16. The Board is left, however, with a more difficult problem, one of assessing whether the rejected claims are too broad in the sense that they cover more than the invention made. We are concerned about such issues as ‘speculative claiming’, and ‘paper inventions’. Section 36 is satisfied

¹⁴⁵ *AZT*, at para. 61 (R-004).

¹⁴⁶ At the time, Rule 25 of the *Patent Rules* provided that claims must be adequately supported by the disclosure. A similar requirement remains within today’s version of the *Rules*. Specifically, Rule 84 provides: “The claims shall be clear and concise and shall be fully supported by the description independently of any document referred to in the description” [emphasis added].

¹⁴⁷ *Monsanto Co. v. Commissioner of Patents (The Board)*, (1977), 34 CPR (2d) (“*Monsanto 1977*”) 1, at p. 3 (R-197).

¹⁴⁸ *Monsanto 1977*, at p. 7 (R-197).

in that the applicant has fully described something, but is it his invention which he has described? What we must now determine is whether the applicant completed the invention in sufficient detail that it can be fairly said that he invented all the compounds of the two claims.¹⁴⁹

[underlining added]

130. In a survey of Canadian patent cases for the period 1973 to mid-1978,¹⁵⁰ Mr. Hayhurst described the Patent Office proceedings in this case as follows:

In *Monsanto*, the Patent Office concluded that, based on the data in the disclosure, there could be no sound or reasonable prediction that all the claimed compounds would possess the promised utility. On this finding the objection was clearly substantive and not based on a mere technical discrepancy between the disclosure and claims.¹⁵¹

[underlining added]

131. In response to the Examiner's objection concerning the sufficiency of the specification, Monsanto had filed two expert affidavits from persons skilled in the art indicating that the utility of all the claimed compounds could be soundly predicted based on the disclosure provided in the patent specification. For example, the Patent Appeal Board recited the following from our response to the Examiner:

To this end, attention is respectfully directed to both Affidavits submitted, where the affiants have sworn that the unexpected utility of the tested members of the class of compounds disclosed... in their opinion, and as person skilled in this art, definitely afford a sound prediction that all or substantially all of the members of the class of compounds possess the utility. Thus, not only can the complete class of compounds be prepared as sworn to by the affiants, but also, each of these affiants has clearly and positively sworn and stated that the class could be expected to have the utility as disclosed in this application and as supported by the examples given in this case.¹⁵²

132. During the proceedings before the Patent Appeal Board, the same submission was reiterated as above, and the two expert affiants testified in person. Again, this evidence was specifically cited by the Patent Appeal Board in its reasons:

¹⁴⁹ *Monsanto* 1977, at p. 9 (R-197).

¹⁵⁰ W.L. Hayhurst, Q.C., "Annual Survey of Canadian Law – Industrial Property" (1979), 11 *Ottawa L. Rev.* 391, at p. 394 (R-198).

¹⁵¹ *Id.*, at p. 433 (R-198).

¹⁵² *Monsanto* 1977, at p. 7 (R-197).

[The applicant] has submitted affidavits from undoubted experts in this field to show that in their view both that skilled chemists would have received adequate direction from the specification so that they could have prepared all the compounds covered by the claim, and further to suggest that it would have been equally apparent to them what utility the compounds would have possessed. At the hearing those conclusions were reaffirmed by the two affiants who were present, though on questioning they did state that none of the compounds (other than the three described in the application) had actually been prepared before the application was filed.¹⁵³

[underlining added]

133. Unfortunately for Monsanto, the Patent Appeal Board disagreed with its experts, and affirmed the refusal of the claims at issue, stating:

[Claim 9] is extremely broad, covers a vast number of compounds, and we think it goes beyond the area of reasonable prediction. The compounds covered by it are all new, and we are not satisfied that three specific examples are adequate support for the breadth of the claim.¹⁵⁴

134. In a brief set of reasons, the Federal Court of Appeal affirmed the Board's refusal was "justified on the ground alone that the disclosure in the appellant's application is not sufficient to support the claim to such a broad range of new compounds". The Court's decision appears to be based largely on its finding that the Board was entitled to defer to its own scientific expertise above that of the expert witnesses that had testified:

...the Commissioner was entitled to weigh the expert opinion as to whether there could be a sound or reasonable prediction that all the compounds would possess utility and to arrive at a contrary judgment or opinion on the basis of the finding and recommendation of his own advisors acting as the Patent Appeal Board.¹⁵⁵

135. The Board's refusal of the claims and the Federal Court of Appeal's decision, however, were overturned by the Supreme Court of Canada¹⁵⁶ in the decision mentioned by Justice Binnie in *AZT* as having "explicitly received" the doctrine of sound prediction into Canadian law. The Supreme Court's findings in *Monsanto* were succinctly summarized by Mr. Hayhurst in his 1983 survey of Canadian Patent law, as follows:

¹⁵³ *Monsanto* 1977, at pp. 7-8 (R-197).

¹⁵⁴ *Monsanto* 1977, at p. 14 (R-197).

¹⁵⁵ *Monsanto* 1977, at p. 16 (R-197).

¹⁵⁶ See *Monsanto* 1979 (R-023).

In *Monsanto Co. v. Commissioner of Patents*, discussed in the last Survey... [t]he Supreme Court of Canada reversed these decisions having regard to the applicant's evidence of undoubted experts that the disclosure of the three compounds provided a sound basis for predicting the promised utility of the others".¹⁵⁷

[underlining added]

136. In its reasons, the Supreme Court in *Monsanto* emphasized that a sound prediction must not go beyond the consideration provided by the disclosure. The Court quoted the following passage from the British case *Olin Mathieson*, and held that the last sentence, which refers to whether a claim is fairly based on the disclosure, captures “what is meant by a sound prediction”:

Where, then, is the line to be drawn between a claim which goes beyond the consideration and one which equiparates with it? In my judgment this line was drawn properly by Sir Lionel when he very helpfully stated in the words quoted above that it depended upon whether or not it was possible to make a sound prediction. If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so. Of course, in so doing he takes the risk that a defendant may be able to show that his prediction is unsound or that some bodies falling within the words he has used have no utility or are old or obvious or that some promise he has made in his specification is false in a material respect; but if, when attacked, he survives this risk successfully, then his claim does not go beyond the consideration given by his disclosure, his claim is fairly based on such disclosure in these respects, and is valid.¹⁵⁸

[underlining added]

137. The *Monsanto* proceedings all took place in the late 1970s, which as I understand it, was several years after the Claimant's expert, Mr. Murray Wilson began working as an examiner in the mechanical division of the Canadian Patent Office and shortly before he became a senior examiner.¹⁵⁹ Thus, I was surprised to read at paragraph 30 of his report that, in his view, subsequent to the Supreme Court's decision in *Monsanto*, “it was neither required nor typical for applicant to provide much if any, data derived from real world use” with respect to cases of predicted utility. Rather, I find that Michael Gillen's observation, at paragraph 46 of his report, that “in relying upon sound prediction,

¹⁵⁷ W.L. Hayhurst, Q.C., “Survey of Canadian Law – Industrial Property: Part I” (1983), 15 Ottawa L. Rev. 38, at p. 69 (R-199).

¹⁵⁸ *Monsanto 1979*, para. 13 (R-023).

¹⁵⁹ At paragraph 5 of his report, Mr. Wilson indicates that he “started working in the Canadian Patent Office in 1971 as a patent examiner in the Mechanical Division”.

applicants would typically provide as many working examples as possible, to ensure that the full scope of the claims was supported” is consistent with my understanding.

138. Likewise, Professor Siebrasse’s statement that “the heightened disclosure requirement for utility based on sound prediction was introduced by the trial courts in 2008” based on “the third part of the test for sound prediction set out by the Supreme Court in *Wellcome/AZT*”¹⁶⁰ is simply contrary to my understanding and experience in litigation and reading patent cases.
139. The trial court decision referred to by Professor Siebrasse is a decision by Justice Hughes, my former law partner, concerning the drug raloxifene in *Eli Lilly Canada Inc. v Apotex Inc.* (“*Raloxifene*”).¹⁶¹ As in the *Monsanto* case, one of the questions before Justice Hughes was “whether the disclosure in the patent was adequate to tell a person skilled in the art how to practice the invention or whether it discloses enough so that a person skilled in the art could “soundly predict” that it would work”.¹⁶²
140. On first blush, *Raloxifene* appears to be somewhat controversial, in that Justice Hughes concluded that Eli Lilly had a factual basis and sound line of reasoning prior to its Canadian filing date, but that the patent specification did not adequately support such a prediction, therefore justifying the allegation of invalidity raised by Apotex. However, on a careful reading of the case, it becomes apparent that *Raloxifene* was well considered and reasoned, and follows the same principles applied more than 25 years prior in *Monsanto*.
141. The patent at issue in *Raloxifene* was a “new use” patent – meaning that raloxifene was previously known to be useful for treating breast cancer, but that the “invention” related to the previously unrecognized ability to use the drug for the prevention and treatment of osteoporosis and bone loss in a human (note that Eli Lilly’s atomoxetine patent is also a “new use” patent). The *Raloxifene* case is an example of a patent in which the invention necessarily specified utility (*i.e.* the new use of the drug).
142. Prior to the Canadian filing date of the patent at issue in the case, the 356 Patent, Eli Lilly had conducted a human clinical trial on 251 subjects, referred to as the Hong Kong Study, which provided a sound line of reasoning to predict the claimed utility of raloxifene. However, Lilly had not disclosed the study or any of its results in the specification of the patent.
143. In fact, the specification of the patent only disclosed certain “rat studies” to support the predicted utility. The specification proposed a human trial, but no data was provided nor was it clear that a trial had actually started. Notably, rat studies conducted by others in the field (*i.e.* having no relation to Eli Lilly) were previously published and known in the prior art, including what was referred to as the “Jordan” paper. Justice Hughes noted the

¹⁶⁰ See Siebrasse report at para. 86.

¹⁶¹ *Eli Lilly Canada Inc. v. Apotex Inc. et al*, 2008 FC 142 (“*Raloxifene*”) (R-200).

¹⁶² *Raloxifene*, at para. 96 (R-200).

similar content of Jordan and the disclosure of the '356 Patent.¹⁶³ The only substantive difference was that the '356 Patent stated a conclusion that raloxifene was appropriate for use in humans, however did not offer any further supporting disclosure.¹⁶⁴

144. Thus, if the disclosure of Lilly's 356 Patent was sufficient to predict the utility based on the evidence before him, Justice Hughes found that Jordan "was very, very good at predicting" the same level of utility, but by the same token would have rendered the Patent obvious.
145. On the evidence before him, Justice Hughes held that the Jordan studies did not render the claimed invention obvious. It logically flowed from that finding that Eli Lilly's own rat studies were not sufficient to support a sound prediction of the claimed utility. In this case, Eli Lilly's "Hong Kong Study", where humans were in fact treated, was the extra step that provided a sound line of reasoning for the prediction. However, as noted by Justice Hughes, Eli Lilly did not disclose any more in its patent specification than what was already known in the relevant field:

It is clear that the '356 patent does not disclose the study described in the Hong Kong abstract. The patent does not disclose any more than Jordan [an earlier study forming part of the prior art] did. The person skilled in the art was given, by way of disclosure, no more than such person already had. No 'hard coinage' had been paid for the claimed monopoly. Thus, for lack of disclosure, there was no sound prediction.¹⁶⁵

146. Citing the Supreme Court in *AZT*, Justice Hughes reiterated the policy concern that "the *quid pro quo* offered in exchange for the monopoly is disclosure".¹⁶⁶ Justice Binnie's more fulsome comment on this policy, as set out in *AZT*, is reproduced below:

A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*. Monopolies are associated in the public mind with higher prices. The public should not be expected to pay an elevated price in exchange for speculation, or for the statement of 'any mere scientific principle or abstract theorem' (s. 27(3)), or for the 'discovery' of things that already exist,

¹⁶⁵ *Raloxifene*, at para. 163 (R-200).

¹⁶⁶ *Raloxifene*, at para. 164 (R-200).

or are obvious. The patent monopoly should be purchased with the hard coinage of new, ingenious, useful and unobvious disclosures.¹⁶⁷

147. I note however, that these are the same considerations that have been considered for decades. For example, in *Monsanto*, the Patent Appeal Board noted the following concern about the potential harm that can arise out of speculative claiming:

Since claims are defective if they are speculative, there are important limitations upon an inventor's right to claim in generalization from his disclosure. We now turn to the jurisprudence which examines such issues...¹⁶⁸

The problem before us is not peculiar to Canadian or British jurisprudence. It has been considered, for example, in *Re Shokal et al.* (1957), 113 U.S.P.Q. 283. The practical problems which can develop from permitting broad speculative claims are illustrated by the reasons leading to the introduction of both s. 41 into the Canadian *Patent Act* in 1923 (Can.), c. 23, and s. 38A into the British *Patent and Designs Act* in 1919 (U.K.), c. 80, s. 11. Section 38A came into being to remedy an abuse which led to the domination of the British dye industry by foreign interests who obtained broad chemical claims covering substances which they had never made or tested, and who subsequently used such claims to restrict the activities of their competitors ("Transactions of the Chartered Institute of Patent Agents", vol. 62, p. 92).¹⁶⁹

[underlining added]

148. The Patent Appeal Board then adopted the words of Graham J. from the British case *Olin Mathieson*, as reflecting what it had "been able to distil from the jurisprudence" it had previously reviewed:

Where, then, is the line to be drawn between a claim which goes beyond the consideration and one which equiparates with it? In my judgment this line was drawn properly by Sir Lionel when he very helpfully stated in the words quoted above that it depended upon whether or not it was possible to make a sound prediction. If it is possible for the patentee to make a sound prediction and to frame a claim which does not go beyond the limits within which the prediction remains sound, then he is entitled to do so.¹⁷⁰

¹⁶⁷ *AZT*, at para. 37 (R-004).

¹⁶⁸ *Monsanto 1977*, at 9 (R-197).

¹⁶⁹ *Monsanto 1977*, at p. 12 (R-197).

¹⁷⁰ *Monsanto 1977*, at p. 14 (R-197).

[underlining added]

Significantly, the Supreme Court of Canada explicitly endorsed this aspect of the Board's reasons:

This last paragraph puts succinctly what we have been able to distil from the jurisprudence discussed above' say the Board. As to this, I should say immediately that I am in full agreement with the decision of Graham J. in *Olin Mathieson*....¹⁷¹

149. In fact, leading practitioners in Canadian patent law had long considered that there existed an obligation to properly support a sound prediction within the patent specification on the basis of *Olin Mathieson*. For example, in the P.T.I.C.'s 1970 patent tutorial, Mr. Hayhurst cited *Olin Mathieson* when instructing that:

Not only must you instruct those skilled in the art. You must also provide a disclosure which justifies the claims you are making. Here emphasis shifts from the adequacy of the disclosure to the validity of the claims...[y]ou must include sufficient examples to justify a sound prediction that everything falling within the scope of the claims will have the promised utility.¹⁷²

[underlining added]

150. Nearly a decade later, Mr. Hayhurst wrote about the subject again, noting that the disclosure requirement protected the public from "excessively broad claims [that] may be drafted inadvertently or deliberately".¹⁷³

The public is adequately protected by two other principles... and secondly, that the claim is invalid, for covering more than was invented, where it covers more useful territory than could soundly have been predicted to be useful on the basis of what is disclosed.¹⁷⁴

[underlining added]

151. In a piece of prescient writing, later in the same article Mr. Hayhurst described the status of the *Monsanto* case and appears to have suggested that the Supreme Court would overturn the Board's decision, not on the basis of including a disclosure requirement

¹⁷¹ *Monsanto 1977*, at p. 11 (R-197).

¹⁷² W.L. Hayhurst, "Disclosure Drafting" (1971), 28 PTIC Bull (7th) 64, at pp. 77-78 (R-164).

¹⁷³ W.L. Hayhurst, Q.C., "Annual Survey of Canadian Law – Industrial Property" (1979), 11 *Ottawa L. Rev.* 391, at p. 427 (R-198).

¹⁷⁴ *Id.*, at p. 427 (R-198).

when a sound prediction was made, but rather, on the Board's failure to accept what it had acknowledged was "undoubted" expert evidence of persons skilled in the art that the inventor was capable of making a sound prediction based on the three examples disclosed.¹⁷⁵

152. And yet again, in the early 1990s Mr. Hayhurst described the disclosure requirement necessitating that the patent specification support a sound prediction – this time citing the Supreme Court's *Monsanto* decision—in a seminar presented to the Canadian judiciary in 1993, which I also attended to present a talk on Anticipation:

It was noted earlier in the discussion of disclosure of the invention that a patent specification must be read as a whole to determine what invention is disclosed, and that for this purpose the claims cannot be ignored, subject to the caveat that claims must not extend beyond sound prediction of what is suggested by the descriptive portion of the specification.¹⁷⁶

[underlining added]

E. Context Necessary to Understand any Evolution in the Law

153. While I disagree that there has been any significant changes in the law of utility in Canada since the Claimant's patents were filed, it cannot be denied that the frequency of which these issues have been litigated has increased over the past fifteen or more years. This is directly attributable to the *PM (NOC) Regulations* referred to earlier in my report.
154. It was not long after the *Regulations* came into force in 1993, that litigation under the *PM (NOC) Regulations* became the most contentious and voluminous of all patent proceedings in the Federal Court. As explained earlier in my report, the *PM (NOC) Regulations* created a scheme in which a potential generic entrant was required to address the rights held by the innovator under any patents listed on the Patent Register for the specific pharmaceutical product it sought to market. The generic manufacturer delivered its notice of allegation (of non-infringement or invalidity); the innovator usually responded with an application to the Federal Court for an order to prevent the generic from getting an NOC. In the result, the Federal Court was inundated with proceedings under the *PM (NOC) Regulations*.
155. For a given pharmaceutical, patents may be listed on the Register in relation to the medicinal ingredient, the formulation, the dosage form, and the use of the medicinal ingredient¹⁷⁷. This incentivized innovators to list as many patents as possible for a given pharmaceutical, regardless of the quality of the patent. This too led to more litigation.

¹⁷⁵ *Id.*, at p. 433 (R-198).

¹⁷⁶ William L. Hayhurst, Q.C., "The Art of Claiming and Reading a Claim" in Gordon F. Henderson, *Patent Law of Canada* (Toronto: Carswell, 1994), at p. 206 (R-201).

¹⁷⁷ *PM (NOC) Regulations*, s 4(1) (R-031).

156. As noted earlier in my report, proceedings under the *PM (NOC) Regulations* do not result in any final disposition with respect to the patent rights at issue. In other words, they do not diminish the patent rights of the patentee. If an innovator is unsuccessful at blocking the issuance of an NOC to a generic manufacturer, its patent nevertheless remains valid and could be asserted in an infringement action or become subject to an impeachment action.
157. Whether litigated as applications under the *PM (NOC) Regulations* or as patent actions for infringement or impeachment, pharmaceuticals have been the dominant source of patent law in Canada for almost two decades.

F. Canadian Patent Law Does Not Discriminate Against Pharmaceutical Inventions

158. I do not agree with the Claimant's assertion that Canadian patent law discriminates against pharmaceutical inventions. Nothing in the *Patent Act* or in the case law indicates that there is any discrimination.¹⁷⁸ The law of utility is the same for all inventions whether they be pharmaceutical or some other subject matter. Although there are more reported decisions in recent years about the issues of utility concerning pharmaceuticals than any other subject matter, that is explained by the large volume of pharmaceutical cases in the Federal Court due to the *PM (NOC) Regulations*, not that pharmaceutical inventions are treated differently under the law of utility.
159. I have referred to several cases prior to the turn of the 21st century which considered promised utility outside the context of pharmaceuticals.¹⁷⁹ Recently, the law relating to promised utility was considered in the mechanical context in *Bell Helicopter Textron Canada Limitée v. Eurocopter*¹⁸⁰ and in the polymer chemical context in *Dow Chemical Company v. NOVA Chemicals Corporation*.¹⁸¹
160. It is also unwarranted criticism that sound prediction discriminates against pharmaceutical inventions. Sound prediction allows patents to be granted despite the fact that the inventor has not demonstrated utility across the full scope of the claims at the filing date.
161. Initially, pharmaceutical inventions did not benefit from the doctrine of sound prediction, because pharmacological predictability was regarded as inherently less predictable than chemical reactions. The first application of sound prediction in the pharmaceutical field was in *Ciba-Geigy* in 1982. Indeed, the court in *Ciba-Geigy* still warned that predictions of pharmacological utility should not be confused with the more predictable science of

¹⁷⁸ See Claimant's Memorial, at para. 17.

¹⁷⁹ For example: *Mobil Oil (R-165)*; *New Process Screw (R-162)*; *Amfac Foods (R-168)*; *Rodi & Wienenberger A.G. v. Metalliflex Limited*, (1959) 32 CPR 102 ("*Metalliflex*") (R-008); and *Consolboard (R-011)*.

¹⁸⁰ *Bell Helicopter Textron Canada Limitée v. Eurocopter*, 2013 FCA 219 (R-204).

¹⁸¹ *Dow Chemical Company v. NOVA Chemicals Corporation*, 2014 FC 844 (R-205).

chemical reactions.¹⁸² The Supreme Court in *AZT* removed any remaining uncertainty that sound prediction was available for pharmaceutical inventions. Since that time, innovator litigants have frequently sought, often successfully, to uphold the validity of their patents through its application.

IV. Olanzapine and Atomoxetine Invalidation Proceedings

A. The Claimant's Expectations at Filing

162. Both the olanzapine and atomoxetine patents were filed and prosecuted by patent agents at Gowling Lafleur Henderson LLP (referred to earlier as Gowlings), a large law firm with one of Canada's premier patent prosecution and litigation practices. In addition, the Claimant had a long history of obtaining and litigating patents in Canada at the time the patent were filed. Certainly, the Claimant would have had access to high-quality advice on Canadian patent law when it filed its patents.
163. At the filing date of the patents, the Claimant could only have expected a defined period of market exclusivity as outlined by the *Food and Drug Regulations*. This was dependant on receiving regulatory approval in the form of an NOC. As of the olanzapine filing date, after the regulatory exclusivity period, the Claimant could have expected a compulsory licence to issue. As of the atomoxetine filing date, the Claimant would have been exposed to litigation under the *PM (NOC) Regulations*.
164. Despite the changing landscape with the coming-into-force of the *PM (NOC) Regulations*, the Claimant would have known that its patent rights were conditional and could be lost at any time. As outlined earlier, there are several mechanisms whereby a patent may be voided by the Commissioner of Patents or by the Federal Court.

B. Reasonableness and Fairness of the Court's Application of the Law

Olanzapine

165. The olanzapine patent, Canadian Patent No 2,041,113, is titled "Thienobenzodiazepine Derivatives and Their Use as Pharmaceuticals". The patent abstract states "[olanzapine], or an acid salt thereof, has pharmaceutical properties, and is of particular use in the treatment of disorders of the central nervous system". The olanzapine Patent was a selection patent. The active pharmaceutical ingredient, olanzapine, had been previously claimed in Canadian Patent No 1,075,687 ("687 Patent") as part of a large class of compounds.
166. The olanzapine patent was invalidated by counterclaim to an infringement action brought by the Claimant against Novopharm (now Teva). At first instance, Justice O'Reilly found the patent invalid on several grounds, namely, obviousness, anticipation, double-patenting, inutility and insufficiency.¹⁸³

¹⁸² *Ciba-Geigy*, at p. 5 (R-190).

¹⁸³ *Eli Lilly Canada Inc. v. Novopharm Limited*, 2009 FC 1018 ("*Olanzapine FC P*") (R-033).

167. The judgment was overturned on appeal. Justice Layden-Stevenson, for the Federal Court of Appeal, held that the trial judge erred in holding the patent invalid by strict reference to the characteristics of selection patents. Justice Layden-Stevenson reiterated the principle that a selection patent is subject to the same requirements for validity as any other patent. Of course, the application of such requirements will reflect the specific characteristics of a selection patent (*e.g.* the patent must assert an enhanced utility vis-à-vis the genus or it will fail to make an inventive contribution and will fail for obviousness, anticipation, or double-patenting). The matter was remanded for reconsideration on utility and sufficiency. Novopharm unsuccessfully sought leave to appeal to the Supreme Court of Canada. Eli Lilly opposed the application for leave by arguing that all areas of law considered by the Federal Court of Appeal (which included “promised utility,” sound prediction, and disclosure) were well settled.
168. On remand, the evidence was based on the evidentiary record of the first proceeding, as agreed by the parties.¹⁸⁴ Justice O’Reilly reviewed the reasons of the Court of Appeal and noted that the Court relied on the *Consolboard* standard of utility. He then considered the utility standard and the required proof in the context of selection patents, in particular, the requirement that it possess a substantial advantage over the genus patent. At paragraphs 86-88 he noted:

I take this to mean that, to be valid, a selection patent must contain an explicit promise of an advantage [over the already patented genus], and the alleged invention must meet that promise. Justice Layden-Stevenson went on to confirm that the advantage must be substantial, although it may lie in a single beneficial property or be made up of a number of lesser ones.

A trial judge, therefore, must construe the selection patent to determine whether it contains an explicit promise of a substantial advantage, and to identify what it is. The judge construes the patent through the eyes of the skilled person.

From there, the judge must consider whether the patent holder was able, as of the filing date of the patent, to demonstrate or soundly predict the patent’s promise. In defining a sound prediction, Justice Layden-Stevenson cited *AZT*, above. From Justice Binnie’s analysis of sound prediction, she drew what she described as the proper ‘threshold’ of sound prediction: ‘a *prima facie* reasonable inference of utility’.¹⁸⁵

169. Justice O’Reilly’s approach correctly considered and interpreted the applicable law at the time. Furthermore, as the matter was on remand, the law was previously set out by the Federal Court of Appeal in light of the same factual context.

¹⁸⁴ *Olanzapine FC II*, at para. 5 (R-016).

¹⁸⁵ *Olanzapine FC II*, at paras. 86 -88 (R-016).

170. Justice O'Reilly construed the patent from the perspective of a person skilled in the art, guided by the expert evidence. To decide whether the selection would merit a patent beyond the genus patent, Justice O'Reilly had to consider the various advantages stated in the patent as constituting the promised utility. This was due, in part, to the fact that the entire patent was based on comparisons between olanzapine and previously known antipsychotics, including the compounds of the genus patent.¹⁸⁶ The promised utility was summarized at paragraph 124:

Therefore, the promise of the '113 patent is that olanzapine is substantially better ('marked superiority') in the clinical treatment of schizophrenia (and related conditions) than other known antipsychotics, with a better side-effects profile, and a high level of activity at low doses. This promise expresses a substantial advantage for olanzapine over the other '687 compounds, which had never actually been used to treat schizophrenia. The individual advantages asserted in the patent (other than in relation to cholesterol) form the foundation for the overall promise of the patent.¹⁸⁷

[underlining added]

171. Justice O'Reilly considered whether there was, at the filing date of the patent, evidence demonstrating or soundly predicting the promised level of utility. The Claimant relied on several *in vitro* studies and five studies in humans. The *in vitro* studies and one human study, the E001 Study, were disclosed in the patent.
172. None of the human studies outside of the patent showed decreased side effects. None of these studies was conducted in patients with schizophrenia.
173. The E001 Study was the Claimant's main evidence in support of utility. As noted above, it was included in the patent. The study was conducted in schizophrenic patients, and was intended to include ten patients over four weeks.¹⁸⁸ Only seven patients completed the study.¹⁸⁹ The patient withdrawals were as a result of increased adverse effects.
174. Justice O'Reilly noted the limitations of the study in its sample size and methodology.¹⁹⁰ At best, it showed that olanzapine might have efficacy similar to conventional antipsychotics.¹⁹¹ However, there was evidence from several experts that the study proved nothing. The authors of the study also doubted its weight, as outlined at paragraphs 156-159 of Justice O'Reilly's reasons for judgment:

¹⁸⁶ *Olanzapine FC II*, at para. 118 (R-016).

¹⁸⁷ *Olanzapine FC II*, at para. 124 (R-016).

¹⁸⁸ *Olanzapine FC II*, at para. 144 (R-016).

¹⁸⁹ *Olanzapine FC II*, at para. 145 (R-016).

¹⁹⁰ *Olanzapine FC II*, at paras. 153-154, 156 (R-016).

¹⁹¹ *Olanzapine FC II*, at para. 152 (R-016).

....As Dr. Goodwin described it, the E001 trial was a pilot study, a study in which one forms clinical impressions without attempting to prove things statistically'...It was a hypothesis-generating study that gave Lilly some preliminary information about olanzapine. Even the authors of the study stated that it would be 'difficult to make conclusions on the efficacy of [olanzapine] on the basis of an open study with so small a sample of patients'.

...Dr. Newcomer believed that E001 would not even support a conclusion that olanzapine was active: 'I mean, you've brought people in off the street and are taking good care of them, and you can get certainly a placebo response'...

Dr. Healy testified that these kinds of studies are 'not going to establish anything with reasonable reliability. . . .[Y]ou could find that the profile of the compound would be just the opposite to what these studies appear to show' (Transcript, Vol 15, p 54, lines 9-13). Further, '[a]t the time Lilly made the statements in the '113 Patent about olanzapine as compared to the other drugs in the '687 Patent and as compared to other antipsychotics, it neither had the data to support the statements nor any sound basis for predicting that they would be true. At most, Lilly had a hope that these statements might someday turn out to be true'...¹⁹²

[underlining added]

175. The above passages indicate that the E001 Study was inadequate as evidence to demonstrate the promised level of utility. As well, contrary to the promised utility of the patent, the E001 Study indicated increased side effects, in particular increased liver enzymes and CPK levels.
176. Justice O'Reilly compared the results of the E001 Study with what was known in the art regarding previous antipsychotics, including certain compounds in the '687 Patent. For example, the side effect profile for olanzapine was no better than that of flumazepine, another member of the previously patented genus.¹⁹³ Other comparisons showed that olanzapine had some antipsychotic effect on some schizophrenic patents, but in a magnitude comparable to conventional antipsychotics.¹⁹⁴
177. Based on the above factual basis, it was fair and reasonable for Justice O'Reilly to conclude that the evidence did not demonstrate olanzapine's capacity to treat

¹⁹² *Olanzapine FC II*, at paras. 156-159 (R-016).

¹⁹³ *Olanzapine FC II*, at paras. 168, 179 and 183 (R-016). Flumazepine is a compound claimed by the '687 genus patent which nearly made it to market following several investigational studies.

¹⁹⁴ Full comparisons in *Olanzapine FC II*, at para. 207 (R-016).

schizophrenia in a clinical setting in a markedly superior fashion and with fewer side-effects than conventional antipsychotics.¹⁹⁵

178. With respect to sound prediction, the evidence supported a prediction of certain properties of olanzapine. However, the promised utility related to advantages of olanzapine over known antipsychotics. These properties were largely known through the '687 Patent. The extensive expert evidence that Justice O'Reilly reviewed indicated that the inventors would not have had a *prima facie* reasonable inference of the promised utility at the filing date. The olanzapine patent simply claimed a level of utility that it could not prove with the evidence available at the necessary time.
179. Justice O'Reilly's decision was affirmed by the Federal Court of Appeal. Eli Lilly sought leave to appeal to the Supreme Court of Canada, but leave was denied.
180. The invalidation of the olanzapine patent was based on the correct legal principles at the time. Consideration and weighing of the evidence was lengthy and detailed, consisting of over eighty paragraphs of reasons. The decision was made in a reasonable, fair and just manner.

Atomoxetine

181. The atomoxetine patent was invalidated by the Federal Court in an impeachment action initiated by Novopharm under subsection 60(1) of the *Patent Act*.¹⁹⁶ The decision was affirmed on appeal, and leave to appeal the decision to the Supreme Court of Canada was denied.
182. The atomoxetine patent, Canadian Patent No 2,209,735, is entitled "Treatment of Attention-Deficit/Hyperactivity Disorder". The Patent's abstract states "Tomoxetine [atomoxetine], a norepinephrine uptake inhibitor, is used to treat attention-deficit/hyperactivity disorder".¹⁹⁷
183. The atomoxetine patent claims the new use of the drug atomoxetine as a treatment for attention-deficit/hyperactivity disorder ("ADHD"). Atomoxetine had already been used for other treatments or indications. Unable to claim atomoxetine *per se* or previously known uses, the Claimant was left to claim its new use only.¹⁹⁸ All sixteen claims of the patent were dependent on claim 1, which read:

¹⁹⁵ *Olanzapine FC II*, at para. 209 (**R-016**).

¹⁹⁶ *Novopharm Ltd. v. Eli Lilly and Co.*, 2010 FC 915 ("*Atomoxetine FC*") (**R-027**).

¹⁹⁷ The patent abstract is found at the beginning of the patent document and serves as a concise summary of the matter contained in the application. It must provide a clear understanding of the technical problem, the solution to that problem, and the principle use of the invention. The patent abstract may not be used, however, for the purposes of claim construction (*Patent Rules*, SOR/96-423, s 79 (**R-206**)).

¹⁹⁸ At the time of writing this report, the Claimant owned three patents and eleven pending applications claiming various uses, formulations, and methods of preparing atomoxetine.

1. The use of tomoxetine for treating attention-deficit/hyperactivity disorder in a patient in need thereof.
184. The remaining dependent claims cover the use of the drug in adolescents, adults and children. As well, the dependent claims outline the use of the drug for two subtypes of ADHD that are claimed in relation to the three demographics.
185. Atomoxetine was a known pharmaceutical in the late 1970s. Early investigations studied its use as an antidepressant. Ultimately studies showed no benefit and investigations into the drug's use as antidepressants were terminated in 1991. The Claimant was unable to establish atomoxetine's efficacy for that indication.
186. As noted by Justice Barnes, the atomoxetine patent sets out the long history of ADHD treatment and then-current treatments of choice for the disorder.¹⁹⁹ It notes that the common side-effects of traditional treatments and their usage limitations created a need for a safe and convenient treatment of ADHD and led to the invention described in the patent.²⁰⁰ Also noted by Justice Barnes, the specification states the following:

Tomoxetine [atomoxetine] is quite active in that function [norepinephrine reuptake inhibitor], and moreover is substantially free of other central nervous system activities at the concentrations or doses at which it effectively inhibits norepinephrine reuptake. Thus, it is quite free of side effects and is properly considered to be a selective drug.

Tomoxetine is a notably safe drug, and its use in ADHD, in both adults and children, is a superior treatment for that disorder because of its improved safety.²⁰¹
187. Justice Barnes correctly relied on *Consolboard* and *AZT* for promised utility and sound prediction respectively.²⁰² Justice Barnes outlined that utility would be measured against the inventive promises in the patent. Utility would be satisfied where, at the filing date, it could be demonstrated or soundly predicted that atomoxetine was clinically useful in treating some patients. Justice Barnes correctly noted that the level of evidence to show patentable utility — that atomoxetine only had to be useful in treating *some* patients — is a far cry from that required to obtain regulatory approval.²⁰³
188. As noted above, the patent's disclosure contains detailed diagnostic and therapeutic information and preferred dosage ranges regarding ADHD. There is no indication that the

¹⁹⁹ *Atomoxetine FC*, at para. 33 (R-027).

²⁰⁰ *Atomoxetine FC*, at paras. 33, 35 (R-027).

²⁰¹ *Atomoxetine FC*, at para. 34 (R-027).

²⁰² *Atomoxetine FC*, at paras. 91-92 (R-027).

²⁰³ Barnes J noted that the patent does not assert nor would it have been expected by a person of skill that atomoxetine would work for every person (*Atomoxetine FC*, at para. 32(R-027)).

use of atomoxetine for ADHD was exploratory or simply promising; rather the patent uses strong language as to its effectiveness, for example:

Tomoxetine is a notably safe drug, and its use in ADHD, in both adults and children, is a superior treatment for that disorder because of its improved safety. Further, tomoxetine is effective at relatively low doses...

...

The method of the present invention is effective in the treatment of patients who are children, adolescents or adults, and there is no significant difference in the symptoms or the details of the manner of treatment among patients of different ages.²⁰⁴

189. Based on the above, as well as the clear language of the claim itself, which refers to treating ADHD in a patient, it is not surprising that the inventive promise of the invention was construed as clinical use of atomoxetine to treat ADHD. Justice Barnes outlined that there was “no dispute” about this. The parties agreed that the patent was addressed to a skilled person who would have a thorough knowledge of ADHD and its treatment, and in particular, the development, research or clinical use of ADHD drug therapies.²⁰⁵
190. The Claimant relied on a clinical trial referred to as the Massachusetts General Hospital Study (“MGH Study”) for evidence of utility. The Claimant sponsored the MGH Study and provided the necessary resources for its completion.²⁰⁶ Surprisingly, the Claimant did not offer any witnesses with direct knowledge of the MGH Study during the proceedings.²⁰⁷ All evidence of the MGH Study was through the experts and their interpretation of its results.
191. The MGH Study was found to be insufficient to demonstrate the promised utility of the atomoxetine patent. Its results were speculative and its value questioned by the very authors of the study in the study itself:

This study was not designed to assess the efficacy of atomoxetine relative to other compounds used to treat adult ADHD and therefore did not include an active comparator. Among children, the efficacy of atomoxetine compared with stimulants has not been established...²⁰⁸

192. Expert evidence revealed significant limitations in the methodology of the MGH Study. The MGH Study involved a small sample size and was too short in duration to provide

²⁰⁴ “Treatment of ADHD”, Patent Specification CA 2,209,735 (January 4, 1996), at p. 2, lines 28-31; at p. 7, lines 19-23 (R-026).

²⁰⁵ *Atomoxetine FC*, at para. 7 (R-027).

²⁰⁶ *Atomoxetine FC*, at para. 5 (R-027).

²⁰⁷ *Atomoxetine FC*, at para. 5 (R-027).

²⁰⁸ *Atomoxetine FC*, at para. 105 (R-027).

“anything more than interesting but inconclusive data”. The MGH Study failed to show clinical utility in adults, let alone adolescents and children.

193. Beyond the issue of their quality, the results of MGH Study were neither included nor referenced in the atomoxetine patent. In fact, the MGH Study was not published until two years *after* the application for the atomoxetine patent was filed.²⁰⁹ The only factual basis for a sound prediction included in the patent was the reference to an article describing atomoxetine’s activity as a norepinephrine reuptake inhibitor. The article was published three years before the patent was filed. Justice Barnes determined that the MGH Study, as a basis for a sound prediction, had to be outlined in the patent to constitute the *quid pro quo* for the monopoly. Without this, nothing is given to the public in return, as noted in paragraph 51 of the Appeal Reasons:

Indeed, if disclosure in the patent of the factual basis of the prediction of utility was not required for sound prediction, it would be difficult to see what Lilly could be said to have given to the public, in exchange for the grant of the monopoly that it did not already have. When utility is based on a sound prediction, disclosure of its factual foundation goes to the essence of the bargain with the public underlying patentability²¹⁰.

194. Justice Barnes’ consideration of sound prediction was fair and reasonable and is in accordance with the principled reasoning of the Supreme Court in *AZT*, the applicable law at the time.
195. The Claimant challenged the utility findings on appeal, however the decision was affirmed. Notably, the Federal Court of Appeal determined that, upon reading Justice Barnes’ reasons as a whole, he had not found an implicit promise in the patent but was simply construing what the patent claims themselves explicitly promised (*i.e.* the use of atomoxetine for the treatment of ADHD).²¹¹ The Federal Court of Appeal also held that the trial judge did not err in finding that there was insufficient evidence at the filing date to demonstrate the promised clinical effectiveness of atomoxetine regardless of the length of time for which it was taken.²¹²
196. Eli Lilly sought leave to appeal to the Supreme Court of Canada, but leave was denied.

C. Claimant’s Characterization of the Proceedings

Olanzapine

²⁰⁹ *Atomoxetine FC*, at paras. 94-96 (**R-027**).

²¹⁰ *Atomoxetine FCA* (**R-028**).

²¹¹ *Atomoxetine FCA*, at para. 21 (**R-028**).

²¹² *Atomoxetine FCA*, at para. 29 (**R-028**).

197. As described in the previous section, Justice O'Reilly's analysis of the issues correctly considered and applied the applicable law at the time.
198. Professor Siebrasse is of the opinion that the olanzapine patent would have been valid under the so-called prior law. First, he calls out the fact that Claimant's olanzapine-based drug was a commercial success and was known as a relatively safe and effective medicine for treating schizophrenia and this was unfairly disregarded by the application of the rule against post-filing evidence. Second, he supposes the Claimant would have been able to prove utility under the traditional "mere scintilla" branch of utility, had Justice O'Reilly's construction of the standard of utility not been set too high.
199. I respectfully disagree with the criticisms aimed at the Court by Professor Siebrasse and the Claimant and the basis for their criticisms. While Professor Siebrasse accepts that the olanzapine patent is a selection patent, he does not consider the necessary requirements for a valid selection patent.
200. Justice Layden-Stevenson outlined the principle that inherent to the invention in a selection patent is an advantage to be gained, or disadvantage to be avoided by making the selection. Thus, for utility, the claimed selection *must* promise an advantage, otherwise there is nothing to distinguish the selection from the larger set of compounds in the genus patent (the '687 patent) to avoid a finding of anticipation, obviousness or double patenting. There is no dispute that such promise of advantageous utility must be sufficiently disclosed in a selection patent. Canadian law has long held patentees to such promises.
201. Professor Siebrasse's arguments that Justice O'Reilly incorrectly considered the evidence of utility against a higher standard than simply "a compound with potential antipsychotic properties that might have relatively low EPS liability" is incorrect in light of the above considerations for selection patents. The problem with Professor Siebrasse's approach is even more pronounced when he claims that as "all of the compounds of the '687 patent satisfied the utility requirement of the Act...it follows that olanzapine, as a member of that genus, must also have satisfied the utility requirement". The olanzapine patent had to have promised utility distinct from the genus patent in order to be valid.
202. When considering post-filing evidence, Professor Siebrasse notes that Justice O'Reilly, in his introduction of the first olanzapine decision, noted the following:
- Olanzapine is regarded as a relatively safe, and often effective, medicine for treating schizophrenia. Olanzapine is widely prescribed and is a commercial success.²¹³
203. This, according to Professor Siebrasse, is enough to prove utility under the prior law.²¹⁴ Professor Siebrasse, however, conflates the commercial success of an embodiment of a

²¹³ See for example, Siebrasse report, at para. 92.

²¹⁴ Siebrasse report, at para. 98.

claim with the utility that the claim must possess as a result of any promise made about the invention in the disclosure of the patent. However, even if this evidence were to be accepted, it merely proves the utility of the genus patent and does not meet the standard of utility required of the olanzapine patent, which was a selection patent.

204. Finally, Professor Siebrasse’s arguments do not consider the principles against the acceptance of post-filing evidence long present in Canadian law and notably outlined in *AZT*. I refer to this earlier in my report, but put simply, the patent bargain is made at the time of filing, not later. To accept post-filing evidence to support the utility of a speculative invention at the time of filing would undermine the patent bargain.

Atomoxetine

205. Again, with respect to the atomoxetine decision, Professor Siebrasse takes issue with the rule against post-filing evidence. For the reasons above, this argument has no regard for the patent bargain, which requires the patentee to have made an invention, including establishing its utility, at the time of filing.
206. In his report, Professor Siebrasse also expresses his view that the atomoxetine patent would have been valid under prior law as utility would have been measured against the “mere scintilla” standard. Again, actual utility has long been weighed against the utility promised in the patent. Justice Barnes was correct to rely on this principle when dismissing the same argument at trial.
207. Finally, Professor Siebrasse argues that the MGH Study would have been admissible under the prior law as traditionally there was no so-called heightened disclosure requirement for sound prediction (*i.e.* there was no requirement to disclose the basis for the sound prediction in the patent).
208. This runs counter to the historical authorities discussed earlier in my report, and to basic principles of patent law. Where utility is based on a sound prediction, the prediction is the *quid pro quo* that the applicant offers in exchange for the grant of the monopoly. The MGH Study was not included in the patent; in fact, it was not published until 1998 - two years *after* the Atomoxetine Patent was filed.²¹⁵ Thus, the sound prediction based on the MGH Study—the consideration which the Claimant offered for the patent rights—was never offered to the public. The public received nothing in exchange for granting the patent as outlined by the Court of Appeal when it rejected the same argument:

Indeed, if disclosure in the patent of the factual basis of the prediction of utility was not required for sound prediction, it would be difficult to see what Lilly could be said to have given to the public, in exchange for the grant of the monopoly, that it did not already have. When utility is based on sound prediction, disclosure of its factual

²¹⁵ *Atomoxetine FC*, at paras. 94-96 (R-027).

foundation goes to the essence of the bargain with the public underlying patentability.²¹⁶

D. Extent of Due Process Received by the Claimant

Olanzapine

209. The litigation history with respect to the olanzapine patent was both lengthy and convoluted. Litigation continued for over six years and involved proceedings under both the *Patent Act* and the *PM (NOC) Regulations*.
210. As the olanzapine patent was listed on the Patent Register, it was a target of any generic manufacturer seeking regulatory approval. In the first application brought against Apotex, under the *PM (NOC) Regulations*, the Claimant was successful in obtaining an order prohibiting Apotex from entering the market until expiry of the patent.²¹⁷
211. Shortly thereafter, in proceedings against Novopharm (now Teva), Justice Hughes dismissed the Claimant's application to prohibit Novopharm from obtaining regulatory approval.²¹⁸ The Claimant's appeal was dismissed as academic, as Novopharm had already obtained a NOC.²¹⁹ Application for leave to appeal to the Supreme Court of Canada was dismissed.²²⁰
212. As proceedings under the *PM (NOC) Regulations* do not decide the validity of a patent, the olanzapine patent was still presumed valid. In a second attempt to keep Novopharm off the market, the Claimant brought a patent infringement action under the *Patent Act*. This began the process leading to the invalidation of the olanzapine patent at the heart of this Arbitration.
213. The first trial lasted forty-four days and included testimony from over thirty witnesses. In the end, Justice O'Reilly dismissed the infringement action and allowed Novopharm's counterclaim for invalidity.²²¹ The Claimant's appeal was allowed as the Federal Court of Appeal disagreed with the trial judge's application of the law pertaining to selection patents, and the matter was remanded to the Federal Court for reconsideration on the issues of utility and sufficiency of disclosure.²²² On remand, Justice O'Reilly again found the patent invalid, this time for inutility.²²³ The appeal taken from this decision was

²¹⁶ *Atomoxetine FCA (R-028)*.

²¹⁷ *Eli Lilly Canada Inc. v. Apotex Inc.*, 2007 FC 455 (**R-207**).

²¹⁸ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596 ("*Olanzapine NOC*") (**R-032**).

²¹⁹ *Eli Lilly Canada Inc. v. Novopharm Limited*, 2007 FCA 359 (**R-208**).

²²⁰ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 386 NR 381 (**R-203**).

²²¹ *Olanzapine FC I (R-033)*.

²²² *Olanzapine FCA I (R-015)*.

²²³ *Olanzapine FC II (R-016)*.

dismissed by the Federal Court of Appeal.²²⁴ The Claimant's application for leave to appeal to the Supreme Court of Canada was also dismissed.

214. The Claimant was involved in undoubtedly one of the most protracted set of legal proceedings in Canada concerning a single patent, pursued every available option to protect its rights available under Canadian law and received due process under the law.

Atomoxetine

215. As noted earlier, litigation with respect to the atomoxetine patent was initiated by Novopharm as an impeachment action under section 60(1) of the *Patent Act*.
216. After an eighteen day trial involving testimony from six witnesses, Justice Barnes held the patent invalid for inutility. The decision was affirmed on appeal and leave to appeal to the Supreme Court of Canada was denied.²²⁵ The decisions in both the Federal Court and Court of Appeal, as previously discussed, were based on a reasonable application of the applicable laws at the time.
217. The Claimant pursued every available option to protect its rights available under Canadian law and received due process under the law.

V. Summary of Opinion

218. What Professor Siebrasse describes as a unitary "Promise Utility Doctrine" introduced by Canadian courts only as of the mid-2000s, is in fact a set of distinct rules and principles established in Canadian patent law long before Claimant filed its patents for atomoxetine and olanzapine. These rules and principles serve rational policy objectives, upholding the bargain between the patentee and the public that is at the heart of the *Patent Act*.
219. Professor Siebrasse suggests, incorrectly in my view, that as long as a claimed invention offers a "scintilla" of utility, then the utility requirement in s. 2 of the *Patent Act* should be met. This ignores, however, the well-established rule in Canadian jurisprudence and legal literature for at least the past sixty years that if a patent promises a certain utility then such utility must be attainable by the claimed invention, otherwise the patent and its claims are invalid. This rule ensures that the public receives its end of the patent bargain, particularly for patents such as "new use" patents and "selection patents," where a particular promised utility is the only consideration that the public receives in exchange for the monopoly that it confers. Consistent with this longstanding rule, Claimant's patents for atomoxetine and olanzapine were held to the level of utility promised in those patents.
220. Canadian courts, when called to do so, identify whether a patent contains a promise using interpretive principles that had long established in Canadian law when Claimant filed its

²²⁴ *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2012 FCA 232 ("Olanzapine FCA IIP") (R-035).

²²⁵ *Eli Lilly and Company v. Teva Canada Limited*, 2011 FCA 220, [2011] SCCA No. 362 ("Atomoxetine FCA") (R-028).

patents and consistent with those applicable to all aspects of patent construction. Courts construe patents purposively, having regard to the whole of the patent, in an informed manner on the basis of expert evidence, that is rational and fair to both the patentee and the public. These principles of purposive and informed interpretation were properly applied by the courts in construing the promises in Claimant's patents for atomoxetine and olanzapine.

221. The utility of an invention must be established at the filing date for the patent. This can be done by demonstration or by sound prediction. Canadian law does not permit patentees to prove that they had established utility at the filing date with evidence generated afterwards (post-filing). Such a "file now, invent later" approach would be inconsistent with the *Patent Act* and its policy objectives. The patent bargain is made at the time of filing, not later. The court decisions invalidating Claimant's patents for atomoxetine and olanzapine were consistent with this rule, which has not changed since those patents were filed.
222. When the utility of an invention has not been demonstrated at the filing date, and the patent relies on a sound prediction of utility, the basis for that prediction must be disclosed in the patent. The disclosure must be sufficient to place the skilled reader in a position of recognizing the prediction as sound. This rule had long been established and practiced in Canada and was properly applied to Claimant's patent for atomoxetine, and did not bear on the validity of Claimant's patent for olanzapine.
223. Canadian patent law does not discriminate against pharmaceutical inventions. The *Patent Act*, including the utility requirement, applies equally across all fields of technology. The promise standard and the doctrine of sound prediction have been applied outside of the pharmaceutical context. The validity of pharmaceutical patents has also been confirmed in many cases where these rules are applied. The increased volume of litigation in the pharmaceutical field over the past two decades is attributable to the expansion of patent rights for pharmaceuticals, both through the expansion of permissible patent claims and the transition from compulsory licensing to the *PM (NOC) Regulations*.
224. The invalidations of Claimant's patents for atomoxetine and olanzapine were done in a manner consistent with the principles and procedures that had long been established in Canada prior to the Claimant's applications for those patents. Claimant had to know that the initial patent grant was subject to court review for validity in any subsequent litigation. In the proceedings leading to invalidation, Claimant had the benefit of extensive due process and thorough appellate review. The court decisions invalidating Claimant's patents properly applied the applicable law, were supported by the evidence and were well reasoned.

Signed at: Toronto on: January 26, 2015

[signed]

Ronald E. Dimock

Appendix A

RONALD E. DIMOCK

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EDUCATION AND PROFESSIONAL QUALIFICATIONS:

Barrister and Solicitor and Professional Engineer (Ontario)

Educated at Queen's University, Kingston, Ontario: Bachelor of Science (Engineering Mathematics with Honours) 1971 and Bachelor of Laws, 1974

Called to the Ontario Bar in 1976

Certified by the Law Society as a Specialist in Civil Litigation since 1993

Certified by the Law Society as a Specialist in Intellectual Property (Patent, Trade-mark and Copyright) Law since 1993

Harvard Law School, Mediation Workshop, June 1999.

Chartered Institute of Arbitrators, Advanced Workshop, December 2012

PROFESSIONAL RANKING, ENDORSEMENTS AND HONOURS

“Leading light Ronald Dimock brings in the big cases. He is a huge name in Canada’s IP world”.
A true trial lawyer, “he is a super-brilliant guy; he is very, very busy”. - WTR 1000 - 2014

“Ron Dimock is the name most people think of when asked to name a pre-eminent trial lawyer in the patent space. Outside of pharmaceuticals he is probably the busiest litigator. He is sharp and practical, and has built a superb group. And he is a very charming individual” - IAM Patents 1000 – 2014

An industry practitioner characterized Dimock as extremely adaptable, saying "Ronald Dimock is strong litigating issues across the board. He's a strong patent litigator and one who is not married to any particular technology or industry" - LMG Life Sciences - 2014

Ronald Dimock is a well-known name within Canadian IP litigation circles. One source said: "We use him for the toughest litigation we have. He is impressive because he does a very good job of convincing the other side they are wrong." - Chambers - 2014

One patent client described Ron Dimock as "very talented and willing to compromise and listen." - MIP - 2014

Ronald Dimock is a “pre-eminent” patent litigator who is considered “unrivalled” by clients and peers alike. FOR LIFE SCIENCES - Ronald Dimock is a "pre-eminent" IP litigator. He continues to impress with his "astute legal mind"- Who’s Who - 2014

One client stated, "Ron Dimock has a borderline encyclopedic knowledge of IP law, and nothing intimidates him. He's a first-rate strategic thinker and he always has the client's goals, and the achievement of those goals, at the forefront of his mind. Aside from being ferociously talented, he's also a great guy. I learned of Ron from people that had litigated against him, demonstrating that he impresses both his clients and his opposing counsel alike - that's relatively rare." - Benchmark -2014

Patent Litigator of the Year – Benchmark Litigation 2013

Recipient of its Intellectual Property Lawyer of the Year Award for Toronto 2010 and 2013 – Best Lawyers

The “Dean of the Patent Bar” – Who’s Who Patents 2013

“A fantastic performer in court” and “often first choice for some of the most complex disputes” – WTR1000 Guide – 2013

“Most frequently recommended” IP litigation lawyers for the past 10 years - Lexpert (Canada)

“Companies go to Ronald and the firm when they have a ‘bet-the-company’ type litigation, and it usually pays off,” explains one attorney. – LMG Life Sciences – 2013

“Ronald Dimock generates the lion's share of recognition. An all-purpose IP practitioner and cheered by peers and client alike for his "keen acumen with a mind-boggling array of patent issues." One client stated, "Ron Dimock is one of the most skilled lawyers I've ever met,

anywhere. In negotiations he exudes a kind of quiet and persuasive competence that earns him a lot of respect from his adversaries. I want to point out that during our search some of the strongest recommendations for Dimock Stratton came from attorneys that Ron and his firm had litigated against. That made an impression" – Benchmark – 2013

"At the vanguard is Ronald Dimock, "chairman of the board for Canadian patent lawyers". His "appeal is astronomical" and allows the firm to "retain instruction on the strength of his name alone". Dimock's recent track record is formidable, encompassing major actions for key players in the chemical, outdoor equipment and pharmaceutical industries – IAM Patent 1000 – 2013

Is a "A-list, top-class litigator", and "one of the most seasoned and capable IP advocates on the market" – WTR 1000 – 2013

"Ronald Dimock is a highly experienced litigator on patent, copyright and trade mark cases" – Chambers 2013

"Ron Dimock continues to earn high praise from competitors as one of the top litigators in the country" – MIP 2013

"Peers recommend Ron Dimock as among Canada's top litigators. "He is one of the most outstanding trial lawyers," says one lawyer. "He has a lot of experience and is very effective." "Ron Dimock has earned his reputation," says another" – MIP 2012

"Ronald Dimock is viewed as one of the top IP practitioners in Canada. "The beauty of talking to him is that he's so even-handed, both as a lawyer and as someone to discuss the industry" – Chambers 2012

"The firm is home to some of the biggest names in Canada, such as "top-notch litigator" Ron Dimock. "He has some of the best trial skills in the market and is just a fantastic performer in court", and is often first choice for some of the most complex disputes" – WTR 1000 – 2012

"Longstanding figurehead Ronald Dimock "consistently draws an outstanding clientele"; he has a track record that few can match, encompassing chemicals, electronics, and pharmaceuticals disputes" – IAM Patent 2000 – 2012 and IAM Patent 1000 2012

"I think of him as thoughtful and hardworking." Dimock is an all-purpose IP practitioner, but his experience in this arena has allowed him to channel this into strategies to be seamlessly employed at trial. He has successfully steered his clients through 35 contentious patent trials. "I never thought of Ron as a typical 'litigator' but even I was surprised when I stopped and took stock of how frequently I see him in trial. And he continues to impress." "I chose Ron Dimock based on his personality and reputation with our Canadian customer base."

"Ron Dimock is a big brain and definitely 'the man' at his firm..." – Benchmark 2012

"Ron Dimock is a litigator, mediator and arbitrator specializing in IP matters and has appeared on numerous occasions before the Supreme Court of Canada. Ron Dimock is hailed as "one of

the leading disputes lawyers in Canada" for his work in IP litigation, mediation and arbitration proceedings. He has been involved in such leading Supreme Court trademark cases as *Lego v. Mega Bloks* and peers "would not hesitate" to recommend him." – Who's Who Legal – Lawyer Listings only - 2012

"Ron Dimock handles patent infringement, licensing and validity disputes, including trials before the federal courts and appeals before the Supreme Court." - Who's Who Legal – Lawyer Listings only - 2011

"Ron is a remarkable lawyer" – Who's Who Legal – Canada 2011

"One of the top IP litigators in Canada", sources say he is very "careful, thorough and courteous"; in the words of one source: "Everybody likes him." – Chambers and Partners Global Guide 2011

"A top notch litigator", "widely respected for his extensive trial experience" and "the ideal choice for any cutting edge or complex IP litigation" – World Trademark Review 2011

"Peers consistently ranked Ron Dimock among "the nation's best" and "others describe him as a smart capable litigator who thinks on his feet very well" and "has more patent trial experience than anyone else" – MIP Handbook 2011

"A luminary with considerable experience in patent litigation with a high degree of common sense backed up by a deep understanding of the law and the ability to coordinate highly complex cases" – IAM 250 in The World's Leading Patent Litigators 2011

"Best IP Lawyer in Toronto" for 2010 - Best Lawyers

The "most nominated patent lawyer" in Canada and "sixth" in the world and considered "one of the best litigators in the country" and described as "erudite and resourceful" – Who's Who Legal in Canada 2010.

"Everyone knows Ron Dimock because Ron Dimock is everywhere," – 2010 World IP Handbook – Managing Intellectual Property.

"A class act" - 2010 Chambers & Partners, Global Guide to the World's Leading Lawyers for Business.

"Ron Dimock is widely recognized for his patent successes and maintains a broad IP practice. Sources say he is "an expert litigator" – IAM 250 Life Sciences 2010

"A star individual", "the guru of IP law in Canada" and is admired for his "pleasant personality and good rapport with the courts" and also "knows when to be tough, but always wisely so" – 2009 Chambers & Partners, Global Guide to the World's Leading Lawyers for Business

“The guru of IP law in Canada” and is admired for his “pleasant personality and good rapport with the courts” and also “knows when to be tough, but always wisely so”. Ranked as a “star individual” – 2009 Chambers & Partners, Global Guide to the World’s Leading Lawyers for Business

“Respected and well liked” and “an excellent and top litigator” – 2008 Chamber & Partners Global Guide to Leading Law Firms and Lawyers

“Outstanding talent” – Who’s Who Legal Directory 2007

“One of the bright lights of the profession” Said to be “on every bloody case”... “Dimock Stratton has become the go-to firm for IP litigation largely on the strength of Dimock’s reputation for handling cases with skill and class” – 2007 World IP Handbook – Managing Intellectual Property

“Clients could not praise Dimock highly enough” and “has the ability to boil down issues into simple terms, to look at risk assessment and be practical in his approach” – 2007 Chambers & Partners, Global Guide to Leading Law Firms and Lawyers

Mr. Dimock is "one of our top Canadian patent lawyers . . ."

"Are Courts of General Jurisdiction the Proper Forum for Cases Involving Computer Technology, or Should Such Cases be Directed to a Court Which Deals with Technical Cases on a Regular Basis."

A paper by the Honourable Madam Justice Barbara Reed
Federal Court of Canada
January, 1990

"Mr. Dimock is a well-qualified patent litigator of 17 years' experience and has taken many trials and appeals, including appeals to the Supreme Court of Canada. As well, he is a highly regarded author in his field and I was impressed with his evidence and the manner in which he gave it."

Reasons for Judgment re Green and Copperthorne by Master Clark
Ontario Court (General Division)
July, 1993

"Av" rating by Martindale-Hubbell International Law Directory and listed in its Bar Register since 1994

ACADEMIC AWARDS

Academic Awards: Ontario Scholarship in 1967; Queen's 125th Anniversary Scholarship in 1967; INCO Scholarship in 1967; R.L. Dorrance Scholarship (Chemistry) in 1968; W.C. Baker Book Prize (Physics) in 1968; INCO Scholarship in 1968, 1969 and 1970; Queen's Law School Entrance Scholarship in 1971.

PROFESSIONAL EXPERIENCE:

Partner in DIMOCK STRATTON LLP, Barristers and Solicitors and Patent and Trade-Mark Agents (1994 - present)

Partner in Sim, Hughes, Dimock, Barristers and Solicitors, and Sim & McBurney, Patent and Trade-mark Agents (1982 - 1994) practising primarily in intellectual property and civil litigation

Associate Lawyer, Donald F. Sim, Q.C. (1976 - 1982) practising primarily in intellectual property and civil litigation

Articled Student-at-Law, Donald F. Sim, Q.C. (1974-1975)

PROFESSIONAL ASSOCIATIONS:

Law Society of Upper Canada, member since 1976.

Law Society of Upper Canada (Ontario), Founding Chair, Intellectual Property Law Specialty Committee (1990-1998).

Canadian Bar Association, member since 1974.

Canadian Bar Association, Chair, Court Practice Committee, Intellectual Property Law Section (1988-1993).

Advocates' Society, member since 1982, Director (1998-2000)

Advocates' Society, Education Committee (2001-2002)

Advocates' Society, Sub-committee drafting Principles of Civility for Advocates (2000)

Association of Professional Engineers of Ontario, member since 1982

Patent and Trade-Mark Institute of Canada, Fellow, member since 1976

P.T.I.C. Trade-Marks Office Liaison Committee (1982-1984)

American Bar Association, member since 1986

American Bar Association, Chair, International Law Subcommittee of Patents and Trade-marks (Canada) (1990-1992)

American Intellectual Property Law Association, member since 1986

International Bar Association, member since 1990

American Counsel Association (Intellectual Property), member since 1991

International Trade-mark Association, Canadian Panel of Neutrals for Mediation and Arbitration

American College of Trial Lawyers, Complex Litigation Committee, Fellow since 2007

Chartered Institute of Arbitrators, Fellow 2013

EDITORIAL APPOINTMENTS:

Editor-in-Chief, Intellectual Property – Disputes, Resolutions and Remedies, Thomson-Reuters Publishing

Contributing Editor, Intellectual Property Journal, Federated Press, 1996-2003

Editor-in-Chief, Intellectual Property Journal, Federated Press, 2004-2012

Contributing Editor, Editorial Board of Canadian Commercial Law Guide, CCH Canadian, (1995 – 2000)

TEACHING APPOINTMENTS:

Lecturer in LL.M. program for Osgoode Hall Law School of York University (Intellectual Property Remedies), since 1998 to present (six week course every three years)

Lecturer in Guest Speaker Series in Patents at Osgoode Hall Law School on “Patent Specifications, Claim Construction and Patent Infringement”, annually since 2003

Lecturer at “Understanding the Business of Copyright – Exclusive Rights in Copyright and Some Neighbouring Rights, Too”, IPIC Course in Copyright, McGill, annually from 2002 to 2008

Lecturer in LL.B. program for Queen’s University Law School (Advanced Patents), autumn semester, 2000

BOOKS:

Dimock, Ronald E., “Intellectual Property – Disputes, Resolutions and Remedies”, Carswell, published December, 2002 (2 Volume – loose leaf – updated semi-annually)

Dimock, Ronald E., “Bullen & Leake & Jacob's Canadian Precedents of Pleadings”, Carswell (co-author of Intellectual Property chapter), 2014

Dimock, Ronald E., Intellectual Property chapter, Canadian Commercial Law Guide, CCH (co-author), 2014.

Dimock, Ronald E., Patents and Trade Secrets chapter, Canadian Forms and Precedents, LexisNexis (co-author), 2014

Dimock, Ronald E., Canadian Chapter, “The International Comparative Legal Guide to: Patents 2014” (4th Edition), Global Legal Group, Sept. 2013 (co-author)

Dimock, Ronald E., co-author, chapter on Anticipation in Law Society of Upper Canada's Benchbook on Patents, published 2012.

Dimock, Stratton, Clarizio, "I Thought of That", A Handbook of Intellectual Property Law, CCH Canada, published 1999

Dimock, Stratton, Clarizio, "Intellectual Property" chapter of Commercial Law Guide, CCH Canada, published since 1997 (updated 2003)

Dimock, Ronald E., "Patent Anticipation", chapter of "Patents" Thomson Publishing (Carswell) edited by Gordon E. Henderson, published in 1995

Dimock, Ronald E., Cameron, Donald M. and Boardman, Brenda L. - "EUREKA! Now What? An Introduction to Patents, Trade-marks and Copyright", CCH Canada, published in 1993

Dimock, Ronald E., co-author, "Patents and Trade Secrets" chapter of "Canadian Forms and Precedents", Butterworths, LexisNexis, published since 1992. (Updated 2007)

Dimock, Ronald E. "Canadian Law of Marketing", Thomson Publishing (Carswell/DeBoo), published in 1991

Dimock, Ronald E. and MacKinley, John, "Trade Secrets and Intellectual Property", chapter of "Trade Secrets", Law Society of Upper Canada, published in 1990

ARTICLES and other PUBLICATIONS:

"Remedies for Infringement of Canadian Patents", *2011 Guide to the World's Leading Patent Law Practitioners*, Euromoney Trading Limited, December 2010.

"So You Want to Be a Rock-N-Roll Infringer...Or Not", *Commercial Times*, Number 492, July, 2008.

"Fair Dealing: A User Right or Defence?", *Canadian Intellectual Property Review*, Vol. 22, No. 1, p. 11 (2005)

"Reassessing Copyright Law in a Digital Era", *Intellectual Property Journal*, Federated Press, 2003

"Don't Short-Change the Implications of the Dutch Industries Decision", *Intellectual Property Journal*, Federated Press, 2001

"Claim Construction Before Trial: A Spin on Whirlpool & Free World Trust", *Intellectual Property Journal*, Federated Press, 2001

“Coca-Cola v. Pardhan: Grey Marketing Becomes Black and White”, Intellectual Property Journal, Federated Press, 2000

“Supreme Court of Canada’s Top 10 IP Cases”, Intellectual Property Journal, Federated Press, 2000

“Patent Infringement Relief - Comic or Otherwise” - No. 2 (1999), Canadian Intellectual Property Review, Volume 16, No. 1, September, 1999, 1

“Privilege and Patent Agency Practice in Canada”, Canadian Intellectual Property Review, Volume 16, No. 1, September, 1999, 107

“Copyright Reviews on Interviews”, Intellectual Property Journal, Federated Press, 1999

“Claims for Solicitor-Client Privilege and Litigation Practice”, Intellectual Property, Federated Press, 1999

“The New Rules of the Federal Court”, Intellectual Property Journal, Federated Press, 1998.

“Accounting of Profits”, Intellectual Property Journal, Federated Press, 1997.

"Patent Law Developments", Business and the Law, April, 1992.

"Recent Developments - Intellectual Property - Canada", American Bar Association (ABA), Patent and Trade-mark Newsletter, February, 1992

"Intellectual Property Litigation in Canada", American Intellectual Property Law Association (AIPLA) Selected Papers, December, 1991.

"Patent Infringement Relief - Comic or Otherwise - No. 1" (1989), 5 Can. Intellectual Property Review 315

"Trade Secrets and Industrial Property Law - Where Does Each Begin and End?", chapter in "Trade Secrets" LSUC Education Dept., 1990.

"Federal Court Upholds Unfair Competition Legislation", Business and the Law, November, 1987.

"Section 58 - Patent Act - Recent Developments - Its Interpretation", PTIC Bulletin, Series, Vol. 15, May, 1982.

SPEECHES, SEMINARS and PANELS:

“The Drafting of Contracts”, Osgoode Hall Law School, Toronto, November 27, 2014 (panellist)

“Patent Primer” – National Judicial Institute Joint Federal Court of Appeal and Federal Court Education Seminar on Intellectual Property Conference - Mont Tremblant, Quebec - October 1, 2014 (speaker)

“Arbitration of IP”, IPIC webinar, Toronto – September 11, 2014 (panellist)

“Working with Expert Witnesses” - Advocates Society – May 28, 2014 (panellist)

“Patent Litigation in Canada” - Trade, Intellectual Property and Recovering Economies: A search for best practices, The Federal Circuit Bar Association, Washington, May 23, 2014 (Panellist)

“Ron & Don’s Top 10 Recent IP Cases” - World Intellectual Property Day Celebration, LES, Toronto, April 23, 2014 (speaker)

“Patent Law Update” for CIPO examiners, CIPO, Ottawa, April 16, 2014 (co-presenter)

“IP Trial Lessons Learned” – Toronto Intellectual Property Group – Toronto, Ontario – February 19, 2014 (speaker)

“2014 Patent Law Update” for webinar, IPIC, February 13, 2014 (panellist)

“The Views from the Court”, Trade, Intellectual Property and Recovering Economies: A search for best practices, The Federal Circuit Bar Association, Toronto, September, 2013 (moderator of judicial panel)

“Lunch ‘n Learn” for lawyers from Thornton Grout Finnegan, at Dimock Stratton, Toronto, June 19, 2013 (speaker)

Ron & Don’s Top 10 Recent IP Cases, World Intellectual Property Day Celebration, LES, Toronto, April 24, 2013 (speaker)

“Patent Law Update” for CIPO examiners, CIPO, Ottawa, April 10, 2013 (co-presenter)

“The Drafting of Contracts”, Osgoode Hall Law School, Toronto, March 26, 2013 (panelist)

“2013 Patent Law Update” for webinar, IPIC, February 20, 2013 (speaker)

“17th Annual Intellectual Property Law, The Year in Review”, Law Society of Upper Canada, Toronto, January 10, 2013 (guest speaker)

“IP and Antitrust: Balancing the Tension”, 2012 Annual Competition Law Fall Conference, CBA, Gatineau, September 20-21, 2012 (panellist)

“Patent Law Update” for CIPO examiners, CIPO, Ottawa, April 30, 2012 (co-presenter)

Ron & Don’s Top 10 Recent IP Cases, World Intellectual Property Day Celebration, LES, Toronto, April 26, 2012 (speaker)

“2012 Patent Law Update” for webinar, IPIC, February 24, 2012 (panellist)

“16th Annual Intellectual Property Law, The Year in Review”, Law Society of Upper Canada, Toronto, January 12, 2012 (guest speaker)

“10th Annual Forum on Pharma Patents – Predicting and Preparing for Patent Challenges for Obviousness and Anticipation”, Canadian Institute, Toronto, October 26, 2011 (speaker)

“Dialogue with the Bench and Bar: Tools and Tactics to Improve Your Advocacy Skills, OBA, Toronto, October 4, 2011 (speaker)

“The Art of Settling a Dispute”, Canadian Legal Conference and Expo, CBA, Halifax, August 14-16, 2011 (speaker)

“Patent Law Update” for CIPO examiners, CIPO, Ottawa, May 31, 2011 (co-presenter)

“2011 Patent Law Update” for webinar, IPIC, March 23, 2011 (Moderator)

“IP Mediation”, Luncheon, McCarthys, Toronto, February 23, 2011 (speaker)

“15th Annual Intellectual Property Law, The Year in Review”, Law Society of Upper Canada, Toronto, January 13, 2011 (guest speaker)

“Lunch ‘n Learn on various IP topics”, Luncheon, Bereskin & Parr LLP, Toronto, October 26, 2010 (speaker)

“Patent Law Update” for CIPO examiners, CIPO, Ottawa, June 21, 2010 (co-presenter)

“IP Law in Canada & Patented Medicine”, Luncheon, Davies Ward Phillips & Vineberg LLP, Toronto, May 5, 2010 (speaker)

“Patent Law Update” for webinar entitled “2010 Year-in-Review”, IPIC, April 29, 2010 (co-author)

“Interface Between IP and Competition Law in Canada”, CBA National Competition Law Section, Young Lawyers Committee, Toronto, April 27, 2010 (co-speaker)

Ron & Don’s Top 10 Recent IP Cases, World Intellectual Property Day Celebration, LES, Toronto, April 26, 2010 (co-organizer with Donald MacOdrum)

Master of Ceremonies – Gala Awards Dinner – Harold G. Fox IP Moot, Toronto, February 20, 2010

“14th Annual Intellectual Property Law, The Year in Review”, Law Society of Upper Canada, Toronto, January 14, 2010 (guest speaker)

“Introduction to the Practice of Intellectual Property Law or Why Would Anyone Want To Be an IP Lawyer”, Queen’s University – Law Alumni Speaker Series, Kingston, November 30, 2009 (speaker)

Mediation of Intellectual Property Disputes, LES Luncheon, Toronto, November 26, 2009 (speaker)

“IP Issues on Competition Law”, CBA Competition Law Forum, Toronto, May 12, 2009 (panelist)

“Data Protection”, Second International Conference on Intellectual Property, The College for Magistrates and Judges of the Federal Judiciary, the Mexican Institute of Industrial Property and the National Copyright Institute, Monterrey, Mexico, March 25, 2009 (panelist)

Master of Ceremonies – Gala Awards Dinner – Harold G. Fox IP Moot, Toronto, February 21, 2009

“13th Annual Intellectual Property Law, The Year in Review”, Law Society of Upper Canada, Toronto, January 15, 2009 (guest speaker)

“Winning with Experts: Issues, Trends and Tactics”, The Advocates’ Society, Toronto, December 11, 2008 (speaker)

“Advocacy Before the Federal Court in Intellectual Property Matters – Expert Witnesses”, Canadian Bar Association, Ottawa, May 8, 2008 (speaker)

“12th Annual Intellectual Property Law, The Year in Review”, Law Society of Upper Canada, Toronto, January 17, 2008 (panelist).

“Intellectual Property Law Primer: Focus on Patent Law”, Law Society of Upper Canada, , Toronto, September 18, 2007 (speaker)

Ron & Don's Top 10 Recent IP Cases or "Ron & Don's All New, Original, Inventive and Distinctive Top 10 IP Cases", Toronto Informals Group, Toronto, June 21, 2007 (co-organizer with Donald MacOdrum)

"Patent Law – Then and Now", Institute for the History and Philosophy of Science and Technology Victoria College, University of Toronto, Toronto, March 5, 2007 (speaker)

"Iphone", Interview on ROB TV, Toronto, Ontario, January, 2007 (interviewed)

"Enforcing and Defending Intellectual Property Rights", Canadian Institute, Toronto, November 27, 2006 (co-speaker)

"Official Marks: An Update", IPIC Annual Meeting, St. Andrews, N.B., September 28, 2006 (speaker/panelist)

"Managing Intellectual Property Disputes & Litigation", The New Intellectual Property Economy, Toronto, June 16, 2006 (panelist)

Ron & Don's Top 10 Recent IP Cases or "Ron & Don's All New, Original, Inventive and Distinctive Top 10 IP Cases", Toronto Informals Group, Toronto, June 15, 2006 (co-organizer with Donald MacOdrum)

Introduction of Guest Speaker Justice Marshall Rothstein, Canadian Bar Association, Ottawa, May 18, 2006.

"Federal Court and Federal Court of Appeal Education Seminar: Intellectual Property", - National Judicial Institute - Ottawa, Ontario, April 22, 2005 (Lecturer)

"Hot Topics in IP", IP Source, Ottawa – October 26, 2005, Toronto – October 28, 2005 (speaker)

"Bill C-60 and Copyright Reform in Canada", Osgoode Hall Law School of York University, Toronto, October 25, 2005 (speaker/panelist)

"What Business Executives Must Know about IP Litigation", LES Annual Meeting, Phoenix, Arizona, October 18, 2005 (speaker/panelist)

"IP Law Before the Supreme Court of Canada", IPIC Annual Meeting, Mont. Tremblant, Quebec, October 14, 2005 (speaker/panelist)

"IPOD – Apple/Microsoft", Interview on ROB TV, Toronto, Ontario, August 25, 2005 (interviewed)

"Some Impacts of Digital Technology on Copyright Law and Practice in North America", Oxford IP Symposia, Oxford, UK, June 24, 2005 (speaker)

Ron & Don's Top 10 Recent IP Cases or "Ron & Don's All New, Original, Inventive and Distinctive Top 10 IP Cases", Toronto Informals Group, Toronto, June 9, 2005 (co-organizer with Donald MacOdrum, co-chair and participant)

Introduction of Honouree Justice Arthur Stone, Canadian Bar Association, Ottawa, May 19, 2005

"Copyright Law in Recording Industry", Ontario Bar Association, Toronto, Ontario, May 10, 2005 (speaker)

"Current Case Law: The Latest Patent Cases", 4th Annual Drug Patents, Insight Information Co., Toronto, Ontario, March 31, 2005 (speaker)

"The Music Industry After BMG v. John Doe", Sound Bytes Sound Rights, Canada at the Crossroads of Copyright Law, TIP Group, University of Toronto Faculty of Law, Toronto, Ontario, February 11, 2005 (panelist)

"9th Annual Intellectual Property Law, The Year in Review", Law Society of Upper Canada, Toronto, Ontario, January 13, 2005 (panelist).

"Roundtable: Tips and Techniques for Protecting or Attacking Pharma Patents Now", 3rd Annual Forum Pharma Patents The Legal and Strategic Guide, The Canadian Institute, Toronto, Ontario, November 9-10, 2004 (panelist)

"Fair Dealing, Or Fair Use, In Canada, U.S. & Europe", IPIC Annual Meeting, Banff, Alberta, October 14-16, 2004 (co-speaker)

"Protecting IP Rights", Negotiating & Drafting IP Licensing Agreements, Federated Press, Toronto, Ontario, June 7-9, 2004 (speaker)

Ron & Don's Top 10 Recent IP Cases or "IP Update Hot Off the Press", Toronto Informals Group, Toronto, May 5, 2004 (co-organizer with Donald MacOdrum, co-chair and participant)

"Is Intellectual Property Litigation in Canada Broken (and Needs Fixing – Fast)?", Spring 2004 IPLLL Event, Court Practices Committee of the Canadian Bar Association, Toronto, Ontario, April 14, 2004 (moderator)

"Eighth Annual Intellectual Property Law, The Year in Review", Law Society of Upper Canada, Toronto, Ontario, January 15, 2004 (panelist).

"Do Patent Litigation Lawyers Need A Science or Engineering Background?", Fall 2003 IPLLL Event, Court Practices Committee of the Canadian Bar Association, Toronto, Ontario, November 18, 2003 (moderator)

“Intellectual Property – Damages and Profits”, The Fifth Annual Investigative and Forensic Accounting, CICA, Toronto, October 27-28, 2003 (co-participant)

“The Intellectual Property Alternative Dispute Resolution Symposium – Skills Development-Mediation”, CLE Conference, Canadian Bar Association, Ottawa, October 9, 2003 (panelist)

“Lego v. Mega Bloks or Do functional trade-marks have a “lego” to stand on?”, IPIC Annual Meeting, Halifax, September 18-20, 2003 (speaker)

“The Realsearch v. Brunette Decision: Are Markman Hearings Coming to Canada”, IPIC Annual Meeting, Halifax, September 18-20, 2003 (co-speaker)

“Ron & Don’s Top 10 Recent IP Cases or “Of Mice and Markman””, Toronto Informals Group, Toronto, June 26, 2003 (co-organizer with Donald MacOdrum, co-chair and participant)

“Advocacy in the Federal Court of Appeal”, Canadian Bar Association, National Section on Intellectual Property, Ottawa, Ontario, May 15, 2003 (speaker)

“Are the Drug Cases Choking the Federal Court?”, First IPLLL Event, Court Practices Committee of the Canadian Bar Association, Toronto, Ontario, April 10, 2003 (moderator)

“CIRQUE+ 2003, Iron Ring: Engineering Your Career”, 20th Conference on Industry and Resources, Queen’s University Engineering, Kingston, Ontario, January 24-25, 2003 (speaker)

“Seventh Annual Intellectual Property Law, The Year in Review”, Law Society of Upper Canada, Toronto, Ontario, January 16, 2003 (panelist)

“Patent Claim Construction”, National Judicial Institute, Montebello Quebec, 2003 (speaker)

“Intellectual Property Disputes: Resolutions and Remedies”, Insight Information and Carswell, Toronto, November 4 and 5, 2002 (chair)

“Copyright Law and the Internet”, Centennial College Lecture, Toronto, October 31, 2002

“International Patent Enforcement: Enforcing Patents in a Global Economy”, DuPont’s 16th Annual CLE Intellectual Property Law Seminar, Wilmington, Delaware, October 21-22, 2002 (speaker)

“Understanding the Business of Copyright”, IPIC and McGill University, August 26-30, 2002 (participant)

“Comparative Analysis of Confidential Information”, Osgoode Hall Law School of York University, Trade Secrets and Confidential Information, Toronto, May 29, 2002.

“From Small Entities To Big Bad Infringers, Top 10 IP Cases for 2001-2002”, Toronto Informals Group, Toronto, May 29, 2002 (co-organizer with Donald MacOdrum, co-chair and participant)

“The Patenting of Software and Business Methods in Canada”, Canadian IT Law Association, First Annual (Western) IT Law Spring Training Program, Vancouver, May 15, 2002

“Serendipity and Enforceability”, Georgian Triangle Lifelong Learning Institute, Collingwood, May 10, 2002 (participant)

“What’s The Score? Top 20 Things You Should Know About IP Remedies”, The Advocates’ Society, Toronto, March 26, 2002 (organizer, chair and participant)

“History of Patent Law”, University of Toronto, Toronto, March 25, 2002

2002 Courthouse Series, Toronto, The Advocates’ Society, February, 2002 (organizer and co-chair)

“Damages for Copyright Infringement”, ALAI Canada, Annual Conference, Montreal, November 14, 2001.

“Accounting Expert Witness Testimony or Quantified by the Qualified”, The Canadian Institute of Chartered Accountants, Alliance for Excellence in Investigative and Forensic Accounting, 2001 Conference, Toronto, October 11-12, 2001.

“IP Due Diligence”, Law Society of Upper Canada, New Directions in Mergers and Acquisitions, Toronto, September 20, 2001.

“Patent Practice Update”, Infonex, Toronto, June 18, 2001 (course chair)

“A Spin on Whirlpool or Keep on Washing in the Free World”, Toronto IP Informals Group, April 25, 2001.

“Dealing with Expert Evidence”, The Advocates’ Society 2001 Courthouse Series, March 24, 2001 (participant, organizer and co-chair)

“Civility in Practice”, The Advocates’ Society, Toronto, October 31, 2000 (panelist)

“How to Conduct a Patent Trial”, York University, Osgoode Hall, Toronto, May 11-12, 2000 (chair of program)

Remedies for Intellectual Property Infringement “How do you spell relief?”, Intellectual Property Institute of Canada, Mid-winter Meeting, Ottawa, March 20, 2000.

“The Top Ten Cases in the 1990’s”, Toronto IP Informals Group, March 1, 2000.

“Coping with the Unexpected”, The Advocates’ Society 2000 Courthouse Series, February 17, 2000 (participant, organizer and co-chair)

“Enforcement – IP Licensing Agreements”, Canadian Institute, Toronto, November 4, 1999.

“Privilege in Patent Matters”, FICPI Canadian Group, Bromont Quebec Meeting, February 19, 1999.

“Intellectual Property Year in Review - 1998”, Law Society of Upper Canada, Toronto and Ottawa, Ontario, January 24 and 30, 1999 (chair).

“Preventing Disclosure in Commercial Litigation Through the Claim of Privilege or The “Unopen and Shut” Case of Privilege”, Federated Press, October 27, 1998.

“The Comic Side of IP Trials” - Luncheon Speaker, Patent and Trademark Institute of Canada Annual Meeting, St. John’s, Newfoundland, October 1998.

“Privilege in Commercial Law Litigation”, Toronto Federated Press, September 1998.

“Aggressive Patent Enforcement”, ABA Annual Meeting, Toronto, Ontario, August 3, 1998.

“The New Rules of the Federal Court”, P.T.I.C. Semi Annual Meeting, Ottawa, Ontario, March 25, 1998 (panelist)

“Intellectual Property Year in Review - 1997”, Law Society of Upper Canada, Toronto, Ontario, January 23, 1998 (chair)

“Privilege in Intellectual Property”, Patent Informals Group, Toronto, Ontario, January 15, 1998.

After Dinner Speaker, Federal Court of Canada Judges Dinner, Ottawa, Ontario, May 1997.

“Intellectual Property Year in Review - 1996”, Law Society of Upper Canada, Toronto, Ontario, January 17, 1997 (chair)

“Privilege in Intellectual Property”, Patent & Trade-mark Institute of Canada, Victoria, British Columbia, Annual Meeting, October 31, 1996

“Patent and Trade-mark Litigation”, Canadian Institute, Toronto, Ontario, October 5 and 6, 1995

“Intellectual Property Litigation - Before and After NAFTA”, Patent and Trade-Mark Institute of Canada - New York Intellectual Property Lawyers Association Joint Meeting, Lake George, New York, October 8, 1994.

“Pharmaceutical Patent Litigation”, Canadian Institute, Ottawa, Ontario, September 30, 1994 (moderator)

“Intellectual Property Licensing - Remedies & Disputes” or “Breaking Up is Hard To Do”, Canadian Institute, Toronto, Ontario, May 31, 1994.

“Enforcing Intellectual Property Rights in Canada”, LES Ottawa, Ontario, April 26, 1994.

“Intellectual Property Law Opinions”, Canadian Institute, Toronto, Ontario, March 2, 1994.

"Mock Patent Binding Arbitration Hearing", Patent and Trade-mark Institute of Canada Annual Meeting, Montreal, Quebec, October 14, 1993 (moderator)

"Expunging Trade-mark Registrations", Canadian Institute, Toronto, Ontario, October 4th, 1993

"Enforcing Trade-mark Rights", Law Society of Upper Canada CLE, Toronto, Ontario, September 29, 1993

"Patent Litigation - Effective Management of a Patent Trial from Beginning to End, Canadian Institute, Toronto, Ontario, June 22, 1993.

"Mock Patent Trial", Canadian Institute, Toronto, Ontario, June 22, 1993 (moderator)

"Patent Anticipation or What's New Patent Act?"; Canadian National Judicial Institute, Ottawa, Ontario, February 4, 1993.

"Intellectual Property Interlocutory Injunctions"; Canadian Bar Association (Ontario), November, 26, 1992.

"The Certification of I.P. Specialists or The First Thing We Do, Let's Kill all the Lawyers", Toronto Patent and Trade-mark Informals Group, Toronto, Ontario, November 21, 1992

"Patent Litigation, A review of the Windsurfing patent litigation", Canadian Institute, Toronto, Ontario, October 21, 1992

"Protecting Intellectual Property", with Donald M. Cameron; The Canadian Institute, Toronto, Ontario; August 13, 1992 (panelist).

"Trade-mark Opposition Hearings", Insight Canada, Toronto, Ontario, May 22, 1992

"A Decade of Development in Canadian Intellectual Property Litigation", Licensing Executive Society, Monterey, California, April 24, 1992

"The Effect of NAFTA in Intellectual Property", American Bar Association, New York, New York, April 10, 1992.

"Comparative Advertising", Marketing and the Law Conference, Toronto, Ontario, April 2, 1992.

"Patent Litigation - A History and Introduction", Canadian Institute, Toronto, Ontario, March 31, 1992.

"Patent Litigation Seminar", Canadian Institute, Toronto, Ontario, March 21, 1992 (chair)

"Damages/Profits in Intellectual Property Litigation", Canadian Bar Association, Ottawa, Ontario, March 5, 1992.

"Patent Litigation, An Introduction", Canadian Institute, Toronto, Ontario, February 26, 1992.

"Patents of Invention", Bedford Park Public School, January 28, 1992.

"Intellectual Property Litigation in Canada", American Intellectual Property Law Association, Annual Meeting, Washington, D.C., October 18, 1991.

"New Federal Court Rules Seminar", Canadian Bar Association, November, 1990 (panelist)

Master of Ceremonies, Federal Court of Canada Judges' Dinner, Ottawa, Ontario, March 1990, 1991 and 1992

"Trade Secrets and Intellectual Property", The Law Society of Upper Canada, CLE, Toronto, November 24, 1989.

"New Procedures Concerning Production of Documents and Examination for Discovery", The Law Society of Upper Canada, Dept. of Education, Federal Court Practice, November 25, 1988.

"Patent Infringement Relief - Comic or Otherwise - No. 1", PTIC Annual Meeting, St. Jovite, Quebec, September 30, 1988.

"Patents, Litigation and Licensing", Young Lawyers Division Canadian Bar Association Intellectual Property, November 12, 1983.

"Section 58 Patent Act - Recent Developments in its Interpretation", Mid-Winter Meeting, PTIC, Ottawa, Ontario, March, 1982.

"Big Brothers" Junior Achievement Night, Junior Board of Trade, Toronto, Ontario, February 5, 1980.

TRADE-MARK INFRINGEMENT TRIAL APPEARANCES:

1. Orkin v. Pestco Company Exterminating (1984), 80 C.P.R. (2d) 153
2. Asbjorn Hogard v. Gibbs Nortac (1986), 9 C.P.R. (2d) 341
3. White Industries v. Beam Canada (1991), 39 C.P.R. (3d) 94
4. Big Sisters Association v. Big Brothers of Canada (1997), 75 C.P.R. (3d) 177
5. Molson Canada v. Oland Breweries, (2001) 11 C.P.R. (4th) 199
6. Kirkbi AG v. Ritvik Holdings Inc. (2002) 20 C.P.R. (4th) 224
7. A&W v. McDonalds (2005), 40 C.P.R. (4th) 126
8. BMW v. Nissan (2007), 57 C.P.R. (4th) 81

COPYRIGHT AND DESIGN INFRINGEMENT TRIAL APPEARANCES:

1. R. v. Premier Cutlery Ltd. (1981), 55 C.P.R. (2d) 134
2. Algonquin Mercantile Corporation v. Dart Industries (1983), 71 C.P.R. (2d) 11
3. Milionis v. Petropoulos (1988), 23 C.P.R. (3d) 52
4. Canada Law Book et al v. Law Society of Upper Canada (2000), 2 C.P.R. (4th) 129

TRADE SECRETS

1. Safeway Products v. Andico Manufacturing (1984) 81 C.P.R. (2d) 165

PATENT TRIAL APPEARANCES

1. Xerox of Canada v. IBM Canada (1978), 33 C.P.R. (2d) 24 (photocopier)
2. Owens-Illinois v. Koehring Ltd. (1978), 40 C.P.R. (2d) 72 (tree harvester)
3. Procter & Gamble v. Bristol-Myers (1979), 39 C.P.R. (2d) 145 (clothes softener sheet)

4. Hydro-Air v. Tested Truss, Court No.: T-3365-74 (unreported - settled after trial February, 1979) (roof truss jig)
5. Teledyne Industries v. Lido (1980), 45 C.P.R. (2d) 18 (showerhead)
6. Saunders et al v. Airglide Deflectors (1981), 50 C.P.R. (2d) 6 (tractor trailer air deflector)
7. Globe-Union v. Varta Batteries (1981), 57 C.P.R. (2d) 132 (car battery)
8. Procter & Gamble v. Calgon (1981), 56 C.P.R. (2d) 214 (clothes softener sheet)
9. Scott Paper Co. v. 3M (1981), 53 C.P.R. (2d) 26 (lithography)
10. Teledyne Industries v. Lido (1983), 68 C.P.R. (2d) 204 (Accounting of Profits) (showerhead)
11. Amfac Foods v. Irving Pulp & Paper (1984), 80 C.P.R. (2d) 59 (French fry potato cutter)
12. Ductmate Industries v. Exanno (1985), 2 C.P.R. (3d) 289 (air duct)
13. Windsurfing v. Trilantic (1985), 3 C.P.R. (3d) 95 (windsurfer)
14. Tinsel Manufacturing v. Noma Canada Inc. (1985), 3 C.P.R. (3d) 433 (artificial tree)
15. Crila Plastics v. Ninety-Eight (1986), 10 C.P.R. (3d) 226 (door edge guard)
16. Reading & Bates v. Baker Energy (1986), 13 C.P.R. (3d) 410 (pipeline installation)
17. Ductmate Industries v. Exanno (1987), 13 C.P.R. (3d) 193 (Accounting of Profits) (air duct)
18. Cabot Corp. v. 318602 Ontario Ltd. (1988), 20 C.P.R. (3d) 132 (ear plug)
19. Domco Industries Ltd. v. Mannington Mills (1988), 23 C.P.R. (3d) 96 (floor tile)
20. Control Data v. Senstar (1989), 23 C.P.R. (3d) 449 (perimeter detector)
21. AT&T Technologies Inc. v. Mitel Corp. (1989), 26 C.P.R. (3d) 238 (transistor)
22. Computalog v. Comtech (1990), 32 C.P.R. (3d) 289 (oil well closure)
23. Reading & Bates v. Berco (1992), 44 C.P.R. (3d) 93 (Accounting of Profits) (pipeline installation)

24. Unilever v. Procter & Gamble, (1993) 47 C.P.R. (3d), 479 (clothes softener sheet)
25. CFM v. Wolf Steel, (1993), 50 C.P.R. (3d) 215 (fireplace)
26. Airseal Controls v. M&I Heat Transfer (1993), 53 C.P.R. (3d) 259 (air baffle)
27. Andersen v. Les Machineries Beaudoin (1994), 58 C.P.R. (3d) 449 (hay bale wrapper)
28. Almecon v. Nutron (1996), 65 C.P.R. (3d) 417 (seismic plug)
29. Whirlpool Corp. v. General Electric Co. (1998), 76 C.P.R. (3d) 150 (washing machine)
30. Imperial Oil v. Lubrizol (2000) 6 C.P.R. (4th) 417 (Trial of an Issue of Fraud) (oil additive)
31. Almecon v. Anchortek (2001), 17 C.P.R. (4th) 74 (seismic plug)
32. Calgon v. North Bay & Trojan (2005) 41 C.P.R. (4th) 78 (water purification)
33. J&J v. Boston Scientific (2008) 71 C.P.R. (4th) 123 (coronary stent)
34. Valence v. Phostech (2011) 92 C.P.R. (4th) 123 (lithium battery cathode materials)
35. The Dow Chemical Company v. Nova Chemicals 2014 FC 326 (polyethylene compositions)
36. Francesco Munoz v Deb (unreported – settled during trial – January, 2014) (hand sanitizer)
37. Blue Gentian v. TeleBrands 2014 FC reports (garden hose)
38. SNF v. Ciba and BASF – September 29 to Nov 7, 2014 - under reserve – (process of treating tailings)

Appendix B

CODE OF CONDUCT FOR EXPERT WITNESSES

General Duty to the Court

1. An expert witness named to provide a report for use as evidence, or to testify in a proceeding, has an overriding duty to assist the Court impartially on matters relevant to his or her area of expertise.
2. This duty overrides any duty to a party to the proceeding, including the person retaining the expert witness. An expert is to be independent and objective. An expert is not an advocate for a party.

Experts' Reports

3. An expert's report submitted as an affidavit or statement referred to in rule 52.2 of the *Federal Courts Rules* shall include
 - (a) a statement of the issues addressed in the report;
 - (b) a description of the qualifications of the expert on the issues addressed in the report;
 - (c) the expert's current *curriculum vitae* attached to the report as a schedule;
 - (d) the facts and assumptions on which the opinion in the report are based; in that regard, a letter of instructions, if any, may be attached to the report as a schedule;
 - (e) a summary of the opinions expressed;
 - (f) in the case of a report that is provided in response to another expert's report, an indication of the points of agreement and of disagreement with the other expert's opinions;
 - (g) the reasons for each opinion expressed;
 - (h) any literature or other materials specifically relied on in support of the opinions;
 - (i) a summary of the methodology used, including any examinations, tests or other investigations on which the report has relied, including details of the qualifications of the person who carried them out, and whether a representative of any other party was present;
 - (j) any caveats or qualifications necessary to render the report complete and accurate, including those relating to any insufficiency of data or research and an indication of any matters that fall outside the expert's field of expertise; and

- (k) particulars of any aspect of the expert's relationship with a party to the proceeding or the subject matter of his or her proposed evidence that might affect his or her duty to the Court.
4. An expert witness must report without delay to persons in receipt of the report any material changes affecting the expert's qualifications or the opinions expressed or the data contained in the report.

Expert Conferences

5. An expert witness who is ordered by the Court to confer with another expert witness:
- (a) must exercise independent, impartial and objective judgment on the issues addressed; and
 - (b) must endeavour to clarify with the other witness the points on which they agree and the points on which their views differ.

CERTIFICATE CONCERNING
CODE OF CONDUCT FOR EXPERT WITNESSES

I, Ronald E. Dimock, having been named as an expert witness by the Respondent Government of Canada, certify that I have read the Code of Conduct for Expert Witnesses set out in the schedule to the *Federal Courts Rules* and agree to be bound by it.

January 26, 2015

[signed]

Mr. Ronald E. Dimock