In the Arbitration under the Arbitration Rules of the
United Nations Commission on International Trade Law and
the North American Free Trade Agreement

(Case No. UNCT/14/2)

ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

EXPERT REPORT OF ANDREW J. REDDON

Partner and Chair of National I.P. Litigation, McCarthy Tétrault LLP

I. Introduction & Background

1. I am a partner at the law firm of McCarthy Tétrault LLP, where I chair the firm's National Intellectual Property Litigation Group. In the past 16 years, I have practiced almost entirely in the area of patent litigation, with a focus on pharmaceutical patent litigation and the prosecution of applications brought pursuant to the Patented Medicine (Notice of Compliance) Regulations ("PM(NOC) Regulations"). My experience in litigating pharmaceutical cases includes acting as:

(i) lead counsel or co-lead counsel in 59 applications brought pursuant to the PM(NOC) Regulations, 13 appeals to the Federal Court of Appeal in respect of such applications, and 7 actions for damages brought pursuant to section 8 of the PM(NOC) Regulations, including lead counsel at the Supreme Court of Canada; and

(ii) lead counsel in 18 actions for patent infringement since 2003.[1]

2. Based on my experience as a patent practitioner in Canada in the pharmaceutical field, I have been asked to respond to the following practice-related points made in the report of Ronald Dimock in these proceedings:

(i) Canada's requirement of utility has not changed in law or in practice;[2]

(ii) a court's determination of the "promised utility" is not subjective, arbitrary or unpredictable;[3]

(iii) PM(NOC) decisions are of limited significance;[4] and

(iv) patent rights are considered "conditional".[5]

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[1] Based on data obtained from Westlaw, a Canadian database of jurisprudence, Mr. Dimock appears to have been named as counsel on 2 applications and 2 appeals to the Federal Court of Appeal in respect of applications pursuant to the PM(NOC) Regulations. There are no reported cases in which he was counsel in a pharmaceutical patent infringement action.

[2] Dimock Report, paras. 48, 52, 153.

[3] Dimock Report, paras. 83-84.

[4] Dimock Report, para. 44.

[5] Dimock Report, para. 164.

II. The Promise Utility Doctrine is New and Reflects Fundamental Changes to the Utility Requirement in Canada

3. I disagree with Mr. Dimock's assertion that there has been no recent "shift" in Canada's patent utility test. I have observed and responded to the shift first hand in my practice, and have advised clients contemporaneously with its occurrence. The shift relates primarily to:

(i) the courts' adoption of a practice of looking for "promises" of utility in the patent disclosure, which are then used as a standard for demonstrated or soundly predicted utility;

(ii) the bar on post-filing evidence to establish utility (now assessed by reference to "promises" derived from the patent), as well as the heightened scrutiny of pre-filing evidence; and

(ii) the adoption of a requirement that the factual basis for a sound prediction of utility be disclosed in the patent itself.[6]

4. Mr. Dimock's statement that "ascertaining the promise of utility and the level of such utility has long been considered through the eyes of the skilled person" does not accord with my experience.[7] Courts look to the patent disclosure where necessary to determine the scope of the claimed invention, and do so through the eyes of a person skilled in the art. However, it is only in recent years that the courts have scoured the patent disclosure to find "promises" of utility, even where unstated, that the patentee must demonstrate or soundly predict to work.

5. Under the new approach, counsel for generic companies scour patents for statements which appear difficult to support (especially by evidence available at the date of filing the patent), and assert that those statements are "promises". If counsel for the generic

[6] In the Claimant's Memorial and Expert Report of Norman V. Siebrasse dated September 29, 2014, these changes are referred to in the collective as Canada's "Promise Utility Doctrine". For ease of reference, I will use this same phrase when referring to Canada's current utility requirement, which includes all of these elements.

[7] Dimock Report, para. 84.

company, with the assistance of expert reports, can convince the Court to accept that there is some promise, the patent may be held invalid based on a lack of demonstrated or predicted utility. As a result, the "promise" has become a tactical tripwire used to invalidate claims even where those claims have unquestioned utility and even when the patented invention delivers on the "promise" in full measure.

6. The result of the courts' willingness to construe promises from the disclosure of the patent specification is to create heightened utility standards that the patentee must meet and deliver upon. The search for "promises" effectively jettisons the old law which held that a "mere scintilla" of utility would suffice for patentability. The "mere scintilla" standard was generally a low bar for pharmaceutical patentees to meet because, almost invariably, generic companies challenge patents because they are seeking to enter a lucrative market by copying a successful drug covered by a patent. Almost by definition, patent litigation arises *because* the patent claims subject matter demonstrated to be useful in the market.

7. In practice, what has made the courts' willingness to derive "promises" from the patent disclosure so problematic is the link drawn post-2005 between *Consolboard* [8] (only recently cited in support of construing "promises" from the disclosure) and the Supreme Court of Canada's 2002 decision in *AZT*[9], which required utility to be demonstrated or soundly predicted as of the date of filing. Specifically, instead of assessing whether the full scope of what the inventor *claimed* was demonstrated or soundly predicted at the date of filing (which was the requirement in *AZT*), this analysis is

[8] *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*., [1981] 1 SCR 504 (C-118).

[9] *Apotex Inc. v. Wellcome Foundation Ltd*., 2002 SCC 77 (C-213).

now applied to *promises construed from language in the patent disclosure*, even when those promises were not claimed as part of the invention, and even when implied.

8. Stated otherwise, the 2002 decision in *AZT* established that post-filing evidence could not be used to show that the utility requirement was met as of the date the patent was filed; this was itself a major change in the law.[10] According to *AZT*, patentees were required to show only that the *claimed* invention had some utility which was either demonstrated or could be soundly predicted as of the date of filing. Post-2005, by applying *AZT* together with the new reading of *Consolboard*, the courts have required patentees to show that all "promises" found within (or derived from) the patent *disclosure* were demonstrated or soundly predicted, based solely on evidence available pre-filing. In my experience, this was a significant shift in the law.

9. In addition to linking *AZT* to the new reading of *Consolboard*, the courts have also added an additional new requirement that the factual basis for sound prediction be in the patent itself. This requirement was not actually determined by the Supreme Court of Canada in *AZT*, but rather was expressly left open by Justice Binnie to be determined later. That later date turned out to be the decision in the *Raloxifene* case, which was the first case to impose a "heightened" disclosure obligation on patentees to substantiate a sound prediction. Specifically, the Federal Court of Appeal explained as follows when dismissing the appeal from Justice Hughes's order:

[10] In Mr. Dimock's report, at para. 102, he states that post-filing evidence could never be admitted to show that an invention had utility at the date of filing. This incorrect. Prior to *AZT*, post-filing evidence could be admitted for this purpose; the new law established in *AZT* is that post-filing evidence is no longer admissible to prove that so-called "promises" were either demonstrated or soundly predicted. Under current law, the only purpose for which a patentee can adduce post-filing evidence of utility is to rebut the generic company's allegation that a particular claim is not operable as of the date of challenge. A patentee cannot, however, rely on post-filing evidence to establish that the invention had the required utility at the date of filing, which is a direct result of the decision of the Supreme Court of Canada in *AZT*.

> In sound prediction cases there is a heightened obligation to disclose the underlying facts and the line of reasoning for inventions that comprise the prediction.[11]

10. Prior to *Raloxifene*, I had never considered that there was any need to establish that an inventor had met a "heightened" obligation to disclose facts supporting a prediction in the patent. My understanding, based on clear case law, was that a sound prediction could be established based on facts not contained in the specification.[12] Following *Raloxifene*, I gave presentations to clients and prospective clients during which I advised that, since 2009, the courts had imposed a heightened disclosure obligation.[13]

11. The *Raloxifene* rule has been difficult for patentees in practice. In my experience, in addition to the new exercise of construing "promises" from the disclosure that must be met as of the date of filing, the courts have also scrutinized the evidence in support of utility to a much greater extent than they did previously. When a generic company raises an allegation that the patentee has failed to demonstrate or soundly predict the "promises" of the patent, the litigation tactics include vigorous attempts to impugn the studies and other evidence relied on by the patentee to defeat the allegation.

12. As a result, the courts now undertake a detailed examination of the adequacy of such evidence, even though the patentee can rely only on evidence generated prior to filing the patent, which is necessarily limited. Given this scrutiny, it can be difficult for the patentee to establish that the "promised" utility was demonstrated prior to the filing date, and therefore the patentee must assert that the "promised" utility was

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[11] *Eli Lilly Canada Inc. v. Apotex Inc*., 2009 FCA 97 at para. 14 (C-119).

[12] *Monsanto Company v. Commissioner of Patents*, [1979] 2 SCR 1108 at 1113 (C-61).

[13] The same is true of my colleagues. *See* Steven Mason and David Tait, McCarthy Tétrault Case Alert (*Eli Lilly v. Apotex Inc.*) (September 17, 2009) (describing *Raloxifene* as a "watershed decision" that "requires, for the first time, that all data and studies that constitute the factual basis upon which the prediction is made should be disclosed clearly in the patent specification itself") (C-499).

soundly predicted. However, due to *Raloxifene,* the patentee can only rely on evidence that was included in the patent for sound prediction. Often, the patent will contain little to no evidence to support the "promised" utility for at least two reasons: (1) the patentee never contemplated that they were making the "promises" asserted by the generic company and accepted by the court; and (2) before *Raloxifene*, there was never any requirement to include evidence of utility (promised or otherwise) in the patent application.

13. The Promise Utility Doctrine as described above is new and was not a consideration for me, nor was it at issue in the cases I was handling, until after 2005. Now, by contrast, it is a central feature of most of the pharmaceutical litigation in which I am involved. The changes described above have fundamentally altered the Canadian utility requirement. In my experience, prior to 2005, utility rarely arose in court cases challenging the validity of a pharmaceutical patent. Today, it is challenged in most pharmaceutical patent cases that I litigate, with thousands of pages of evidence and days of testimony submitted to the court on this one issue.

III. The Courts' Determination of the "Promised" Utility

14. In my practice today, my clients' response to a generic company's allegation that a patent contains "promises" of utility, and that those "promises" were not demonstrated or soundly predicted, is a key challenge in every case where it is raised. The response is challenging because it will often hinge on the Judge's construction of phrases or data in the patent disclosure (versus construction of the claims), which is very difficult to predict or assess.

15. The *Latanoprost* litigation is an example of a case where the innovative company lost because of the Court's construction of the promise and other aspects of the Promise Utility Doctrine. While I was not directly involved in the case, I am very familiar

with the court decisions. Latanoprost is the active ingredient in Pfizer's drug XALATAN, which for many years was the leading prostaglandin drug in Canada for the treatment of glaucoma, and a drug that generated many millions of dollars in revenue in Canada each year.

16. In the first hearing before the Court, generic company Pharmascience's expert, Dr. Mitra, opined that the "patent promises an absence of adverse side effects". The trial Judge, Justice Heneghan, identified this as the "key" issue, but did not construe the patent to make that promise and held: "I am satisfied that the '132 Patent offers the public a useful choice from what was offered as the state of the art at the time of filing the patent application".[14] Pharmascience's allegation of inutility was held not to be justified. The Federal Court of Appeal dismissed Pharmascience's appeal and noted that the data in the patent showed utility in animal models (including humans). The Federal Court of Appeal did not adopt Pharmascience's construction of the "promise", even though it is a question of law on which they could have reversed the trial Judge.[15]

17. In a second application against generic company Apotex involving the same patent, Justice Heneghan again decided in favour of Pfizer. Notably, Apotex asserted a different promise of the patent than that asserted by Pharmascience in the previous litigation, but Justice Heneghan did not deviate from her previous construction.[16] On an appeal heard by a differently constituted panel of the Federal Court of Appeal, the Court granted Apotex's appeal on the basis that Justice Heneghan had improperly construed the "promise", which was held to be "chronic use" of latanoprost. The Court reached this

[14] *Pfizer Canada Inc. v. Canada (Health)*, 2009 FC 1294 at para. 140-141; para. 148 (C-49).
[15] *Pfizer Canada Inc. v. Pharmascience Inc. et al*, 2011 FCA 102 at paras. 32-36 (C-98).
[16] *Pfizer Canada Inc. v. Canada (Health) et al*, 2010 FC 447 at paras. 69-71 and 182 (C-303).

conclusion based not on its own analysis of the patent, but rather on an admission by Pfizer's own expert, Dr. Fechtner, about what he believed the patent promised.[17]

18. Though the same patent was at issue, the same expert had appeared for Pfizer, and construction of a patent is a question of law, the Court accepted a different construction of the promise. Because the Court held that chronic efficacy had not been demonstrated at the date of filing of the patent, Pfizer was put to the test of establishing that the skilled person would have soundly predicted the utility of latanoprost for chronic use, based solely on what was contained in the patent itself. The Court of Appeal held there was an insufficient factual basis and no line of reasoning to support the prediction of the promised utility.[18] The Court of Appeal made this finding even though there was no dispute that latanoprost was useful for chronic treatment (it was the leading drug in the class), and the generic company Apotex had sought approval for chronic use of the drug, and thereby represented to Health Canada that its drug, containing latanoprost, would be safe and effective for chronic use.

IV. Precedential Value of PM(NOC) Decisions

19. Canada's PM(NOC) Regulations establish a regime under which patent rights are linked to marketing approval. Under the regime, patentees list patents that relate to drugs that have been approved by Health Canada on the patent register. If a generic company seeks approval to market a generic version of the drug, Health Canada cannot grant approval until the generic company has "addressed" the patents listed on the patent register. The generic company addresses those patents by serving a "Notice of Allegation" that alleges invalidity of some or all of the listed patents. The patentee can then bring an

[17] *Apotex Inc. v. Pfizer Canada Inc. et al*, 2011 FCA 236 at paras. 25, 27 (C-99).
[18] *Apotex Inc. v. Pfizer Canada Inc. et al*, 2011 FCA 236 at paras. 40-49 (C-99).

application for an "Order of Prohibition" that will prevent the generic company from obtaining marketing approval in the form of a "Notice of Compliance". To obtain the Order of Prohibition, the patentee must prove that the generic company's allegations of invalidity are not justified.

20. Mr. Dimock attempts to downplay the significance of PM(NOC) decisions by stating that the proceedings "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".[19] Mr. Dimock is technically correct that the dismissal of the patentee's application for an Order of Prohibition does not have the effect of invalidating a patent. However, his statement that the patent remains valid and "can be asserted against the generic in a subsequent patent infringement action" wrongly diminishes the significance of PM(NOC) decisions.[20]

21. Many cases illustrate the precedential value of PM(NOC) decisions in actions in which invalidity is asserted pursuant to section 60 of the *Patent Act* (i.e. actions to impeach the patent, or where invalidity is asserted as a defence to an action for infringement). For example:

(i) In *Teva Canada Ltd. v. Pfizer Canada,*[21] the Supreme Court of Canada held in the context of a PM(NOC) proceeding that Teva had established its allegation that the '446 Patent was invalid for insufficiency. In a separate impeachment action, another generic company (Apotex) sought to invalidate the same patent. Immediately after the PM(NOC) decision was issued, Apotex filed for summary judgment in the impeachment action on the basis that there was no genuine issue for trial. Justice Zinn granted Apotex's motion on the basis that the issue had been determined by the Supreme Court of Canada, and Pfizer's appeal was dismissed by the Federal Court of Appeal.[22]

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[19] Dimock Report, para. 44.

[20] Dimock Report, para. 44.

[21] *Teva Canada Ltd. v. Pfizer Canada*, 2012 SCC 60 (C-197).

[22] *Apotex Inc. v. Pfizer Ireland Pharmaceuticals*, 2012 FC 1339 at paras. 33-34 (C-506); aff'd; *Pfizer Ireland Pharmaceuticals v. Apotex Inc*., 2014 FCA 13 at paras. 24-29 (C-507).

(ii) In *Apotex Inc. v. Synthlabo Canada Inc.*[23] the Supreme Court of Canada dismissed Apotex's appeal from a PM(NOC) decision that held that Apotex did not justify its allegations that the claims of the '875 Patent were invalid for being anticipated and obvious. Apotex then commenced an action to impeach the same patent. The trial judge held that the patent was invalid, including for reasons of obviousness. On appeal, the Federal Court of Appeal held that it was an error for the trial judge to have reached a different conclusion than the Supreme Court, even though different evidence was before the trial court. According to the Federal Court of Appeal, the material facts were the same, and the fact that the earlier decision arose in PM(NOC) proceedings was considered irrelevant.[24]

22. The precedential value of PM(NOC) decisions is also evident from their widespread citation and application. The PM(NOC) decision in *Apotex Inc. v. Sanofi-Synethelabo* is routinely cited as the leading authority on the test for obviousness,[25] and the decision in *Teva Canada Ltd. v. Pfizer* is routinely cited on the test for insufficiency.[26] Justice Hughes' ruling in the *Raloxifene* PM(NOC) proceeding is widely cited as *the* authority that established the additional disclosure requirement that now applies where utility is based on a sound prediction.[27] Given its precedential impact, the *Raloxifene* decision is one of seven decisions related to "utility" that are listed in the Federal Court of Canada's "Common List of Authorities", a list of patent decisions so highly cited that they do not need to be included in a party's book of authorities.[28]

23. Accordingly, I have advised my clients that questions of law decided in a PM(NOC) proceeding are likely to influence the court's decision in a subsequent action

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[23] *Apotex Inc. v. Synthlabo Canada Inc.*, 2008 SCC 61 (C-196).

[24] *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186, para. 81 (C-47).

[25] 2008 SCC 61 (including in 22 actions brought pursuant to section 60 of the *Patent Act*) (C-196).

[26] 2012 SCC 60 (including in 8 actions brought pursuant to section 60 of the *Patent Act*) (C-197).

[27] See, for example, *Apotex Inc. v. Sanofi-Aventis Canada Inc.*, 2011 FC 1486 at para. 567 (C-247).

[28] Normally, parties to a litigation must provide the court with a "book of authorities" that contains copies of the jurisprudence relied on. However, the court does not consider this to be necessary for cases that are commonly relied on in support of various points of law, and to that end has established a list of such commonly cited cases, see: Federal Court of Canada: "Common List of Authorities" (September 2013): http://cas-ncr-nter03.cas-satj.gc.ca/portal/page/portal/fc_cf_en/Notices/vol4_eng#patent (C-508).

and that appellate authority on a question of law from a PM(NOC) case is every bit as binding on a trial court as such authority from any other kind of case. In my practice, I do not preferentially rely upon decisions arising in section 60 actions as compared with PM(NOC) decisions. Rather, I consider the legal reasoning in each case and its applicability to the case at hand. Based on my observations, the Judges of the Federal Court approach cases in a similar way and are not concerned with the procedure by which the case came before the Court. In my view, several factors make this result unsurprising:

(i) While there are 42 Judges appointed to the Federal Court, there is a shorter list of Judges who hear most patent cases under section 60 as well as under the PM(NOC) Regulations. The same Judges are unlikely to reach different conclusions on the same legal question because of the procedure that brought the case before the Court, and I am unaware of any decisions showing this distinction.

(ii) Whether the Court considers the validity of the patent in an action or allegations of invalidity in a PM(NOC) application, the issues are adjudicated based on the same provisions of the *Patent Act* and the same jurisprudence interpreting those provisions. There is no separate body of case law for one or the other.

(iii) The primary difference between applications under the PM(NOC) Regulations and actions brought pursuant to section 60 of the *Patent Act* relates to the manner in which evidence is adduced (i.e. by affidavit or by viva voce testimony). This does not affect the substance of the law that is applied.

24. The result is that the test for utility in Canada has been and will be established through case law relating both to actions under section 60 of the *Patent Act* and to applications under the PM(NOC) Regulations. In practice, because the volume of decided cases is much greater in the context of PM(NOC) proceedings, those cases drive changes in the law, and have driven the creation of the Promise Utility Doctrine.[29]

[29] The fact that PM(NOC) decisions influence changes in the law underscores the need for balanced procedures to ensure that the process is not biased to favor either innovative companies or generic companies. The PM(NOC) Regulations create an asymmetry of appeal rights. When generic companies lose a PM(NOC)

V. Patent Rights Are Not Considered "Conditional"

25. At paragraph 164 of his report, Mr. Dimock states that patent rights are "conditional and could be lost at any time". The Government of Canada's Counter-Memorial (at paragraph 329) states that under section 42 of the *Patent Act*, patent rights are subject to the *Act* and to adjudication before the Federal Court, which may declare the patent invalid.

26. Mr. Dimock's and Canada's assertions in these paragraphs do not establish that the property rights associated with a patent are somehow considered "conditional" until adjudicated by the Federal Court. I have never heard any practitioner refer to patent rights as "conditional", nor is there any jurisprudence that I am aware of stating that patent rights are merely conditional. To the contrary, patents afford the patentee a bundle of property rights which can be and often are exploited immediately upon issuance of the patent. Those rights include:

(i) the right to prevent others from making, using or selling the claimed subject-matter;

(ii) the right to license to others the right to make, use or sell the claimed subject-matter;

(iii) injunctive rights;

(iv) for pharmaceutical patents, the right to list patents on the patent register to protect a valuable commercial market; and

(v) rights to damages for patent infringement.

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application, they have an appeal as of right to the Federal Court of Appeal. In contrast, when innovative companies lose a PM(NOC) application, Health Canada typically issues a Notice of Compliance to the generic company, the generic company comes on the market, and the innovative company's appeal, if sought at all, is dismissed for mootness. As recently stated by the Federal Court of Appeal, "Asking a court to prohibit a notice of compliance after it is issued is like asking someone to close the barn door after the horses have escaped". *Janssen Inc. v. Teva Canada Limited*, 2015 FCA 36, para. 7 (C-509).

27. Canadian law explicitly recognizes that patents are legally enforceable immediately upon issuance and confer certain rights and obligations. Section 42 of the *Patent Act* establishes that, from the time of grant, the patent confers "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used". Other provisions of the *Act* and other aspects of Canadian law recognize that patents are legally enforceable on issuance.[30]

28. As a practical matter, patentees can and often do exploit valuable rights in their patents following issuance, including by licensing to others the right to make, use and sell the subject-matter of the patent. Licensors and licensees do not wait until a patent has been adjudicated before a court (which may never occur) prior to entering a licensing agreement. To the contrary, the parties to the contract consider that there is a property right to license upon issuance. That patent rights are subject to adjudication by the courts is no different from any other form of property, title to which may be challenged in later litigation.

29. In paragraph 28 of his statement, Mr. Dimock also states that a declaration of invalidity "means that the patent is and always has been void (*i.e.*, void *ab initio*)". However, in my years of practice, I have never heard it stated that patent rights are considered "conditional" merely because the legal effect of an invalidation is that the patent is declared void *ab initio*. I have always understood that, from a practical

[30] For example, if an innovative pharmaceutical company markets a patented drug, that drug will be subject to pricing restrictions applied by Canada's Patented Medicines Prices Review Board. Also, under the PM(NOC) Regulations, upon issuance, patents that relate to an approved drug are listed on the Patent Register. If a generic company seeks approval for a generic version of the drug, it must first successfully address the listed patents. Innovative companies are given an automatic 24-month reprieve while the patent rights are adjudicated. If unsuccessful, the innovative company is liable to the generic company only for the generic company's losses associated with delayed market entry, and not for the innovative company's gains associated with its ability to exploit its exclusive patent right. Finally, once a patent is granted, even the Canadian government cannot use the patented invention, unless that use is authorized by the Commissioner of Patents according to the compulsory licensing regime set out in section 19 of the *Patent Act.*

perspective, this simply means a patentee cannot obtain damages for infringement if the patent is declared invalid. The fact that the patent is void *ab initio* as a matter of law does not mean that it is treated as if it never existed in practice, or that, upon issuance, valuable property rights were not conferred. Even after invalidation, patentees may still enjoy rights associated with the grant of the patent, such as payments made pursuant to licenses.

VI. Conclusion

30. It is my opinion that the Promise Utility Doctrine is new, having been only recently adopted and applied, and that the application of this new law has made utility challenges more frequent, more challenging and less predictable. Patents that claim subject matter with acknowledged utility have been invalidated based on the patentee's inability to show that supposed "promises" made in the patent were demonstrated at filing, or were predicted based on evidence found only in the patent. Patents have been invalidated based on this new law despite the fact that patentees could not address the change in the law because the patents in question were filed long before the change was adopted.

Signed at: Toronto, Canada

on: September 11, 2015

[signed]

Andrew J. Reddon