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

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I. INTRODUCTION

1. I have already prepared a first expert report dated January 26, 2015 ("First Report").[1] This, my second report, is my response to the Second Expert Report of Professor Norman Siebrasse, dated September 10, 2015, and the Expert Report of Mr. Andrew Reddon, dated September 11, 2015.[2,3]

2. This report will cover only those statements made by Professor Siebrasse and Mr. Reddon that actually call for a response. I do not concede, however, that I agree with all their other statements. Many are just their expressions of disagreement with the opinions that I gave in my First Report. I will not repeat what is in my First Report, but will refer back to it on occasion to further explain some of my remarks.

3. Professor Siebrasse criticizes my reliance on the opinions and writings of certain legal commentators, text book authors, and even decisions of some judges that get in the way of his own opinions. I feel I am in good company despite what Professor Siebrasse thinks. The commentators and text book writers I relied upon, such as Harold Fox, Gordon Henderson, and William Hayhurst, were some of the leading practitioners of Canadian patent law over the last half-century who have substantially influenced how patent law is practiced in Canada.

4. Mr. Reddon seems to suggest by his first footnote that the opinions in my First Report are not drawn from enough experience in pharmaceutical patent cases.[4] While pharmaceutical patent experience is important, it must be kept in mind that the law concerning promised utility and its related issues was developed long before pharmaceuticals became the driver of patent law in Canada in the last two decades. In any event, contrary to what Mr. Reddon implies, I do have significant experience in pharmaceutical patent cases. In my First Report at paragraphs 6 and 7, I refer to this experience in a general way. To be a bit more specific about my pharmaceutical patent experience, I am providing additional details in Annex A of this report.

5. I set out my response to Professor Siebrasse and Mr. Reddon in the following sections of this second expert report, as follows:

    (i) Part II addresses the changes in Canadian law alleged by Professor Siebrasse and Mr. Reddon;

    (ii) Part III responds to certain points raised by Mr. Reddon on the nature of patent rights in Canada;

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[1] Expert Report of Ronald E. Dimock, dated January 26, 2015 ("Dimock First Report").

[2] Second Expert Report of Norman V. Siebrasse, dated September 10, 2015 ("Siebrasse Second Report").

[3] Expert Report of Andrew J. Reddon, dated September 11, 2015 ("Reddon Report").

[4] Reddon Report at para. 1.

(iii) Part IV deals with Mr. Reddon's comments on the significance of proceedings pursuant to the *PM (NOC) Regulations* within the Canadian patent system;

(iv) Part V provides an overall conclusion to my report; and

(v) Annexes A (a list of pharmaceutical matters I have worked on), B (an historical list of promise utility cases and commentaries), and C (comments on selected cases referenced in the Second Witness Statement of Dr. Marcel Brisebois).

II. CANADA'S LAW OF UTILITY HAS NOT CHANGED

6. As I explained in my First Report, Claimant's patents for the use of *atomoxetine* and *olanzapine* were invalidated on the basis of rules that have been part of Canadian patent law since long before Claimant filed its patent applications. These rules relate to three fundamental questions that any patent system must confront in deciding whether to confer patent rights: what is the invention; was the invention actually made; and was the invention properly disclosed? I will address the main points of disagreement I have with Professor Siebrasse and Mr. Reddon on how the Canadian patent system currently answers, and has historically answered, these three fundamental questions.

A. What is the Invention?

7. One necessary element of an "invention" is utility. Both Professor Siebrasse and Mr. Reddon argue that Canadian courts suddenly introduced a new standard of utility after 2005 which requires that an invention have the utility promised by the patent.[5] Both consider promised utility to be the first element of their so-called Promise Utility Doctrine.[6]

8. I disagree that this is a standard first introduced in 2005. In the course of responding to Professor Siebrasse and Mr. Reddon, I will further clarify the following: (1) the promise standard, (2) why patentees make promises, (3) the historical authority for the promise standard, (4) how the overlapping doctrine of overbreadth provides further historical support for the promise standard, and (5) that Canadian courts do not "scour" patents for promises, but fairly construe patents based on the evidence and argument put forward by counsel.

1) *Inventions are Held to their Promised Utility*

9. In his Second Report, Professor Siebrasse repeats his opinion that "the first change in Canada's utility requirement…is that the standard against which utility is assessed now

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[5] First Expert Report of Norman V. Siebrasse, dated September 29, 2014 ("Siebrasse First Report") at paras. 71-72; Reddon Report at para. 7.

[6] Siebrasse Second Report at para. 4; Reddon Report at para. 3.

has two branches: if the court finds a promise in the patent, utility is assessed in terms of that standard; if not, a "mere scintilla" of utility will suffice".[7] Mr. Reddon goes further to suggest at paragraph 6 of his Report that "promised utility" is not only new, but "effectively jettisons" the traditional "mere scintilla" standard.

10. While I agree that the law currently recognizes a contextual utility standard with a "mere scintilla" branch and a "promise" branch, I do not agree that this is new. I outlined in my First Report that the two branches of utility have long been recognized in Canadian law and reflect the general principle that utility is assessed against the standard articulated in the patent itself.[8] Where there is no indication of the utility of the invention in the disclosure or claims in the nature of a promise, all that it is required is some utility (i.e., a "mere scintilla"). In the case where a particular utility is promised, utility is assessed against this standard.

11. Before turning to the historical basis of the promise standard, it is worth considering why a patentee would include a promise in the patent. A significant part of the answer lies in the interaction between the different patentability requirements that must be satisfied for the grant of a patent.

2) *Why Patentees Make (and Emphasize) Promises*

12. A statement of utility included in a patent specification does not typically appear by accident. Rather, there is often a significant motivation for the patentee and its counsel to make and emphasize such promises of utility. Often this motivation is tied directly to the requirement that an invention be inventive (non-obvious) and novel in order to be patentable.

a) Promises to Overcome Obviousness

13. To clear the hurdle of obviousness, an invention must demonstrate inventive ingenuity over and above the existing state of the art. The question of whether an invention is obvious is largely concerned with whether the differences – or the gap – between the state of the art and the purported inventive concept constitute steps which would have been obvious to the person skilled in the art, or in contrast, would have required a degree of invention.[9]

14. The motivation to specify a statement of utility in the patent arises where the invention relates to an incremental advance over the prior art (for example, either because it relates to previously known compounds or concerns a well-developed field of technology that may be "crowded" with patents). In these cases, a heightened level of utility or comparative advantage is intentionally asserted in order to widen or heighten the "gap" between the invention and the state of the art to establish non-obviousness.

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[7] Siebrasse Second Report at para. 13.

[8] Dimock First Report at paras. 48, 58.

[9] See the four-step approach endorsed by the Supreme Court of Canada for use in an obviousness inquiry, at *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 at para. 67 (**C-196**).

15. Similarly, it has become routine for some patent holders to adopt a strategy during litigation known as "reading up the invention." In such cases, counsel for the patent holder argue that passages from the patent disclosure which assert the advantages of the invention should be read-into the claims. The goal is to enhance the inventive concept of the claimed invention, widening or heightening the gap between the prior art and the invention, for purposes of defending an attack of obviousness.

16. For example, Mr. Reddon himself used such a strategy on behalf of his client in *Allergan Inc. v. Canada*,[10] in which he asserted that claims for a combination product (i.e., where two previously known drugs are combined into one product) used to treat glaucoma ought to incorporate some of the advantages described in the disclosure, despite there being no mention of those advantages in the claims.[11] Even though the Judge noted that there was nothing inventive about using the two previously known drugs together[12], he accepted the "read up" inventive concept asserted by Mr. Reddon, and dismissed the allegation of obviousness.

17. While the practice of "reading up the invention" is becoming routine,[13] some patent owners bemoan the logical consequence that the same passages emphasized to show that their invention was non-obvious are then also treated as promises of utility that must either be demonstrated or soundly predicted at the time of filing the patent application. Professor Siebrasse appears to be of like mind, suggesting that assertions of usefulness relied upon by a patentee to establish the inventiveness of a selection patent should not be taken into consideration under the utility analysis.[14]

18. However, this view ignores how the various patentability requirements work together as checks and balances to ensure that the patent bargain with the public is upheld. As well, the tactic of "reading up the invention" for obviousness and "reading it down" for the purposes of utility has generally been rejected by the courts. For example, in *Hoffmann-La Roche Ltd. v. Apotex Inc.*, the Court highlighted the contradictory and unfair nature of this tactic:

> As Apotex argued, where advantages form part of the stated invention, it would be unfair to allow the patent holder to rely on those advantages to show that the invention was unobvious and, at the same time, dismiss those advantages as being irrelevant to

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[10] *Allergan Inc. et al. v. Canada et al.*, 2011 FC 1316 ("*Allergan*") (**R-189**).

[11] *Allergan* at paras. 64-67 (**R-189**).

[12] *Allergan* at para. 75 (**R-189**).

[13] See for example *Alcon Canada Inc. v. Cobalt Pharmaceuticals Co.*, 2014 FC 149 (*"Alcon"*) at paras. 59-63 (**C-353**) ("In essence, Alcon argues that for the purposes of obviousness, the inventive concept includes the teaching that the excluded excipients do not enhance the physical stability of the solution, but for the purposes of utility, there is no such promise of non-enhancement.")

[14] Siebrasse Second Report at paras. 48-50.

> utility. A patent holder cannot read up the invention for obviousness and read it down for utility.[15]

19. Other courts have reached the same conclusion, emphasizing that the interpretation of the patent should be as consistent as possible for each aspect of patentability.[16]

b) Promises to Show Novelty

20. As mentioned above, there is also motivation to make and emphasize promises of advantages or enhanced utility within a patent to satisfy the requirement that the invention made is new (or "novel"). A claimed invention will fail for novelty if it has been anticipated in the prior art. A patentee may need or wish to specify a particular utility in the patent to show that the invention was not anticipated.

21. I touched on this topic in my First Report, where I mentioned that the issue concerning the promise of the patent was particularly germane to inventions concerning a "new use" or a "selection".[17] In these cases, a particular utility is the essence of the invention – that is, without the promised utility, the named inventor has not invented anything at all.

22. This is because a previous patent (sometimes referred to as an "originating" patent) or several patents related to the claimed subject matter have already been granted. So long as a new, inventive improvement or further contribution to the state of the art is made, a subsequent patent (or patents) may follow-on from the previous patent. In the case of "selection" and "new use" patents, the inventive contribution is, respectively, the establishment of a specified subset of a previously patented class of compounds having surprising advantages over the rest of the class, and the establishment of a new use for a previously known thing. Claimant's *olanzapine* and *atomoxetine* patents fall within these categories of follow-on patents.

23. At paragraph 46 of his Second Report, Professor Siebrasse suggests that my reference to the particular relevance of promises made in selection and new use patents is "an *ad hoc* justification tailored to the patents at issue" (i.e. the *olanzapine* and *atomoxetine* patents). I disagree and note that similar comments to my own have been made by

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[15] *Hoffmann-La Roche Ltd. v. Apotex Inc.*, 2011 FC 875 at para. 22 (**R-357**).

[16] See for example, *Alcon* at paras. 59-63 (**C-353**) ("… I find it incongruous, in the context of this patent, to argue that the inventive concept is something different from the promise made in the patent …"); *Allergan Inc. v. Canada (Minister of Health)*, 2014 FC 566 at para. 24 (**R-358**) ("the interpretation of the patent should be as consistent as possible across the various issues in play. A patentee should not, for example, be able to "read up the invention for obviousness and read it down for utility". To do so would be unfairly advantageous for a patent holder who might wish to assert that its invention was an unforeseeable innovation (and, therefore, not obvious) and, at the same time, contend that the invention's useful properties could be readily inferred (and, therefore, soundly predictable).").

[17] Dimock First Report at paras. 58-59, 73, 117 – 122.

others, including the Courts, well before either of the Claimant's *olanzapine* and *atomoxetine* cases were decided.[18]

24. Professor Siebrasse also argues at paragraph 46 of his Second Report that the distinction I drew concerning "new use" and "selection" patents is not valid because the "promise" issue has been raised in other cases which dealt with novel compounds. I agree that the promise standard does not exclusively apply to "new use" or "selection" patents. It is part of the utility standard for all inventions. But this does not mean that the motivation of patentees to make a promise is the same for "new use" or "selection" patents.

25. Indeed, the very cases cited by Professor Siebrasse suggest that promises in the patent play a larger role for "new use" and "selection" patents than for novel compounds.[19] When considering the issue of utility in these cases, the court rejected the "promised" or stated utility asserted by the generic party challenging the patent in every case cited by Professor Siebrasse on this point.[20, 21] It is necessary to look not only at why the party challenging the validity of a patent has made such an allegation, but also at how the court has dealt with these allegations. These cases would seemingly support the view that any alleged promised utility in these patents was of less import than in cases of new uses or selections – even though a party alleging invalidity is free (and often will) raise as many challenges as possible.

3) *The Promise Standard has Existed in Canadian Law for Over a Half-Century*

26. As I noted in my First Report, the law of utility - including the promise standard - was accurately described by the Supreme Court of Canada in 1981 in *Consolboard v. MacMillan Bloedel (Sask) Ltd*.[22] This, however, was not the first recognition of the promise standard in Canadian law. By arguing that the standard of promised utility was

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[18] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153 ("*AZT"*), at para. 52 (**R-004**) ("It is important to reiterate that the *only* contribution made by Glaxo/Wellcome in the case of AZT was to identify a new *use*.).

[19] Siebrasse Second Report at footnote 62.

[20] *Pfizer Canada Inc. v Apotex Inc*., 2005 FC 1205 (**C-250**), rev'd on other grounds 2007 FCA 209 (**C-215**); *Aventis Pharma Inc. v Apotex Inc.*, 2005 FC 1283, 43 CPR (4th) 161 (**C-209**), aff'd 2006 FCA 64, 46 CPR (4th) 401 (**C-214**); *Laboratoires Servier v Apotex Inc.*, 2008 FC 825(**C-474**), aff'd 2009 FCA 222 (**R-411**); *GlaxoSmithKline Inc. v Pharmascience Inc*., 2011 FC 239 (**C-249**); *Astrazeneca Canada Inc. v Mylan Pharmaceuticals ULC*, 2011 FC 1023, 96 CPR (4th) 159 (**C-237**), aff'd 2012 FCA 109 (**C- 236**); *Novartis Pharmaceuticals Canada Inc. v Teva Canada Ltd.*, 2015 FC 770 (**C-471**).

[21] Although the Application Judge in *Pfizer Canada Inc. v. Apotex Inc.*, 2005 FC 1205, paras. 107-108 (**C-250**) initially adopted the generic party's construction of a promise, this was done in the context of an allegation that the claims were broader than the scope of the invention actually made. With respect to the issue of whether the utility of the claimed invention could be soundly predicted, the Court found in favour of the patentee. The finding that the claims were overly broad was overturned on appeal (*Pfizer Canada Inc v. Apotex Inc*, 2007 FCA 209 (**C-215**)). In particular, the Federal Court of Appeal adopted a broader construction of the invention – thereby reading down the promise found by the lower court (despite Professor Siebrasse's claim that the decision was reversed on other grounds).

[22] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] SCR 504, 1981 CarswellNat 582, ("*Consolboard*") (**R-011**).

somehow a new and never before seen interpretation of the law of utility in 2005, both Professor Siebrasse and Mr. Reddon are curiously at odds with decades of case law and legal commentary as briefly listed below and set out in more detail in Annex B[23]:

1941: *Wanscheer et al v. Sicard Limitee*

1959: *Rodi & Wienenberger Aktiengesellschaft v. Metalliflex Ltd.*

1960: Donald Hill in *Claim Inutility*

1961: *New Process Screw Corporation v. P.L. Robertson Mfg. Co. Ltd*.

1961: Gordon F. Henderson in the Editorial Note to the case report of *New Process Screw*

1969: Harold G. Fox in *Canadian Patent Law and Practice*, 4th Ed.

1978: *Consolboard v. MacMillan Bloedel (Sask) Ltd.* (Federal Court)

1981: *Consolboard v. MacMillan Bloedel (Sask) Ltd.* (Supreme Court)

1984: *Corning Glass Works v. Canada Wire & Cable Ltd.*

1991: *TRW Inc. v. Walbar of Canada Inc.*

1994: *Fehergaurd Products Ltd. v. Rocky's of B.C. Leisure Ltd.*

1994: *Mobil Oil Corp. v. Hercules Canada Inc.*

1995: *Wellcome Foundation Ltd. v. Apotex Inc.*

1995: Donald H. MacOdrum in *Patent Law in Canada: Cases and Materials*

2001: *Almecon Industries Ltd. v. Anchortek Ltd***.**

2001: *Goldfarb v. W. L. Gore & Associates, Inc.*

27. Given this long, non-exhaustive, list of authorities that recognize the promise standard of utility, Professor Siebrasse and Mr. Reddon are wrong in suggesting that this is a new aspect of Canadian patent law that suddenly arose in 2005.

a) Consolboard is Good Authority for the Promise Standard

28. Among the above listed authorities, the Supreme Court's 1981 decision in *Consolboard* stands out as the highest Canadian authority on the promise standard. Professor Siebrasse contends that *Consolboard* cannot fairly be read as affirming the place of the promise in Canada's law of utility. He puts forward three main arguments to this effect.

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[23] Please see Annex "B" to this report for selected excerpts from these case reports and commentaries.

I disagree with each of Professor Siebrasse's arguments and his overall conclusion on the proper interpretation of *Consolboard*.

i. Consolboard Dealt with the Issue of Utility

29. Professor Siebrasse considers *Consolboard* to be primarily a case relating to sufficiency of disclosure, not utility.[24] While I agree that the utility issue was raised in the context of sufficiency of disclosure, I do not agree that utility was a non-issue and certainly not in the mutually exclusive manner Professor Siebrasse suggests.

30. At trial, the disclosure issue was raised in conjunction with an allegation that the claims were broader than the invention described. Although the sufficiency argument was rejected, several claims were invalid for overbreadth.[25] On appeal, the Court reversed on the disclosure point, and held that sufficient disclosure requires "all aspects of the invention (in the sense defined by section 2 of the *Patent Act*) and particularly its utility" to be disclosed.[26] Because the particular utility was not described, the claims were invalidated by the Court of Appeal.[27]

31. On appeal to the Supreme Court, utility was a prominent feature of the dispute. This is evident in the Court's framing of the issues:

> The appellant submits that the Court of Appeal made seven fundamental errors…(iii) in wrongly construing s. 36(1) to require that the attributes of the patentability be set forth in the patent specification, i.e. novelty, inventive step and utility; (iv) in confusing the "utility" of an invention with the theory or effect of the invention;[28,29]

32. The Supreme Court decided that the Court of Appeal erred by applying an incorrect interpretation of the disclosure requirements and concluded that sufficient disclosure does not require an indication of the invention's utility. In reaching this conclusion, however, it was necessary for the Court to define the meaning of utility. Thus utility was at issue, contrary to Professor Siebrasse's assertions.

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[24] Siebrasse Second Report at para. 21.

[25] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* (1978), 39 CPR (2d) 191 at paras. 63-75 ("*Consolboard FCTD*") (**R-359**).

[26] *MacMillan Bloedel (Saskatchewan) Ltd. v. Consolboard Inc.*, 41 CPR (2d) 94, ("*Consolboard FCA*") at p. 96 (FCA) (**C-473**).

[27] *Consolboard FCA* at pp. 96-97 (**C-473**).

[28] *Consolboard* at para. 21 (**R-011**).

[29] Note that the Court also refers to the issue as the utility ground.

ii. Consolboard was Relied on For the Principle of Promised Utility Prior to 2005

33. Professor Siebrasse also discredits *Consolboard* as authority for promised utility in light of its subsequent judicial treatment. He asserts that between 1981 and 2005 the decision was rarely cited for the law of utility and was never cited for the promised utility aspect of his so-called Promise Utility Doctrine.[30] I disagree with this point, and in my First Report I referred to the *Mobil Oil*[31] case as one instance of a court looking to *Consolboard* as authority for promised utility. There are several other cases and legal commentary that I did not mention in my First Report which show that *Consolboard* was cited as authority for promised utility during this time frame. These authorities are referred to in Annex B and some are explained in more detail below in paragraphs 38 to 40.

34. Regarding *Mobil Oil*, at paragraphs 34 and 35 of his Second Report, Professor Siebrasse argues that the case is "inconsistent with the promise aspect of the Promise Utility Doctrine" on the basis that the Court did not equate the promise with the levels of adhesion achieved in the example provided in the patent specification (i.e. 250 g/in. bond strength). I disagree.

35. As referenced in my First Report, the trial judge explicitly found that "The patent specification promises an oriented polypropylene film substrate having enhanced adhesion…".[32] The judge continued to explain that "[t]he bond strength test results… all indicate an adhesion well above commercial industry standards of 90 grams/inch".[33] Thus, the promise was of "enhanced adhesion", which the Court appears to have construed as meaning at least "well above" commercial industry standards. Any "scintilla" of adhesion would not suffice.

36. The fact that the Court did not find that the exceptionally high level of adhesion described in one example in the patent description to be the promised level of utility does not mean that the patent was not held to the promised utility of enhanced adhesion. Rarely, if ever, are the claims of a patent to be limited to the examples provided in the patent description. In fact, included in Professor Siebrasse's excerpt is the Court's explicit finding that "[t]he data presented in the patent does not define the promise of the patent. It is merely provided as an example of the enhanced adhesion which may be achieved…".[34]

37. Likewise, despite Professor Siebrasse's contention that the Court of Appeal in *Mobil Oil* did not deal with this matter as an issue of utility, it too confirmed the patent's promised utility of enhanced adhesion:

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[30] Siebrasse Second Report at para. 19.

[31] *Mobil Oil Corp. v. Hercules Canada Inc.* (1994), 57 CPR (3d) 488 ("*Mobil Oil*") (**R-165**).

[32] *Mobil Oil* at p. 508 (**R-165**).

[33] *Mobil Oil* at p. 508 (**R-165**).

[34] *Mobil Oil* at p. 513 (**R-165**), cited at para. 35 of Siebrasse Second Report.

> As to the contention that the invention would be useless…the patent solved the problem it set out to solve, namely the provision of an oriented film substrate having enhanced adhesion…"[35]

38. Other cases in the period from 1981 to 2005 also cite *Consolboard* as authority for the promise standard of utility, contrary to Professor Siebrasse's assertion. For example, the Federal Court's 1994 decision in *Feherguard Products Ltd. v. Rocky's of BC Leisure Ltd.*[36] cited *Consolboard* as follows:

> In patent law, a patent is "not useful" if 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: *Consolboard Inc. v MacMillan Bloedel (Saskatchewan) Ltd.* (1981)…
>
> [citations omitted]

39. The same statement from *Consolboard* on the law of utility – including the promise standard – was also cited by the Federal Court in *Almecon Industries Ltd. v. Anchortek Ltd*.[37] and *Goldfarb v. W. L. Gore & Associates, Inc.*,[38] both decided in 2001.

40. Legal commentators also considered *Consolboard* as authority for utility and promised utility prior to 2005, when Professor Siebrasse suggests that the promise standard was adopted by Canadian courts. For example, Mr. Donald MacOdrum provides a concise summary of the law of utility in his 1995 text, *Patent Law in Canada: Cases and Materials*.[39] He notes the low threshold of utility where the patent is silent on the issue, but also that where some specific utility is promised, the patentee must meet this level of utility. Mr. MacOdrum cited the *Consolboard* decision as the leading case on utility and included, in particular, the passage from *Halsbury's Laws of England* relied upon in *Consolboard* to articulate the promise standard.[40]

iii Consolboard did not Improperly Rely on English Doctrine

41. In addition to his opinion that recent courts have misinterpreted and misapplied *Consolboard* as authority for promised utility, Professor Siebrasse questions the soundness of the Supreme Court's reasoning in the decision itself. In particular, he

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[35] *Mobil Oil Corp. v. Hercules Canada Inc.* (1995), 63 CPR (3d) 473 (FCA), at para. 19 (**R-252**).

[36] *Feherguard Products Ltd. v. Rocky's of B.C. Leisure Ltd.* (1994), 53 PCR (3d) 417 (FCTD) at para. 23 (**R-360**).

[37] *Almecon Industries Ltd. v. Anchortek Ltd.* (2001), 17 CPR (4th) 74 (FCTD) (**C-230**). I was trial counsel for Almecon.

[38] *Goldfarb v. W.L. Gore & Associates, Inc.* (2001), 11 CPR (4th) 129 (FCTD) ("*Goldfarb*") (**R-187**).

[39] Donald H. MacOdrum, *Patent Law in Canada: Cases and Materials* (Lang Michener LLP, 1995) ("*MacOdrum Text*") at 5-2 (**R-361**). Donald MacOdrum is a top-notch patent lawyer practicing at the law firm of Bereskin & Parr LLP in Toronto. He is a leading authority on patent law and one of the most senior patent lawyers in Canada, having practiced for over forty-five years. He is the current author of the classic textbook: "Fox on Patents".

[40] *MacOdrum Text* at 5-1 (**R-361**).

considers the Court's reliance on the passage from *Halsbury's Laws of England* as improper authority as it is based on English cases concerning the distinct doctrine of "false suggestion" (also known as "false promise" or "false representation").[41]

42. Professor Siebrasse provides various reasons as to why "false suggestion" is a distinct legal principle from utility, and correctly notes that the provisions of the U.K. *Patents Act* which established the doctrine had been repealed by the time *Consolboard* was decided.[42] While I agree that the passage from *Halsbury's* is based on cases which dealt in part with "false suggestion", namely *Hatmaker v. Joseph Nathan & Co. Ltd.*, *Unifloc Regents, Ld. v. Newstead Colliery, Ld.*, and *Re Alsop's Patent*, I do not agree that these cases have no place in Canadian law.

43. As a preliminary matter, I am surprised by the sharp distinction that Professor Siebrasse draws between the English doctrine of "false suggestion" and inutility. The similarity between the two, particularly the fashion in which they are expressed, has led English courts and scholars away from attempts to distinguish them. One example is from a case I referred to in my First Report, the 1979 decision of the U.K. High Court of Justice-Chancery Division in *American Cyanamid Company v. Ethicon Limited*.[43,44] In a section of the decision titled "Insufficiency, Inutility and False Suggestion", Justice Graham stated the following:

> 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.[45]
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> [underlining added]

44. Another example which runs counter to Professor Siebrasse' position is Thomas Blanco White's[46] 1950 classic text "Patents for Inventions" where, in the utility chapter, he writes:

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[41] Siebrasse Second Report at paras. 22-24, 27.

[42] Siebrasse Second Report at paras. 24-26.

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

[44] This decision was relied on by the Federal Court of Appeal in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FCA 108 (**R-021**), where Nadon JA, for the Court, stated at paragraph 53 that the decision (*American Cyanamid*) "stands for the proposition that although a patentee is not obligated to promise a result in the patent, if he does make such a promise, he will be held to it".

[45] *American Cyanamid* at p. 261 (**R-173**).

[46] T. A. Blanco White, Q.C., "*Patents for Inventions*" (London: Stevens and Sons, 1983) at p. 121 (**R-362**). Thomas Blanco White was described in The Times as "the best intellectual property lawyer to have practiced in England since Fletcher Moulton—and there can be no higher praise". He was the leading patent lawyer in the U.K. for many years and his text "Patents for Inventions" is considered a classic authority on patent law.

Relation to 'false representation'

> It is not easy to distinguish between the sort of failure to fulfil a promise of results made in the specification that will amount to lack of utility and the sort that merely amounts to a false representation... The distinction has been phrased as one between a promise of results and a mere wrong statement of the purposes for which that which is attained can be used…
>
> [citations omitted]
>
> [underlining added]

45. Nevertheless Professor Siebrasse's critiques of *Consolboard* based on the distinction between false promise and inutility in English law are immaterial. *Consolboard* restated the law of utility in Canada. The "false promise" cases were already understood by courts and commentators to be part of the Canadian law of utility prior to the Supreme Court's decision, regardless of their basis in purportedly distinct legal principles. The Court in *Consolboard* expressly recognized this and noted that the passage from *Halsbury's* accurately stated the law of utility in Canada:

> Canadian law is to the same effect. In Rodi & Wienenberger A.G. v. Metalliflex Limited [(1959), 19 Fox Pat. C. 49] (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. [(1943), 60 R.P.C. 165] 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…[47]
> >
> > [underlining added]

46. Other Canadian court decisions prior to the Supreme Court's ruling in *Consolboard* had also recognized and applied the promise standard as part of Canada's law of utility. In these cases, courts applied the promise standard of utility to invalidate claims that clearly had a "mere scintilla" level of utility, despite Professor Siebrasse suggestion that there are no cases along these lines.

47. I discussed the *New Process Screw*[48] decision in my First Report as an early case regarding promised utility. One of the patents at issue described an invention comprising dies to produce double threaded screws. The patent specification described

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[47] *Consolboard* at para. 37 (**R-011**).

[48] *New Process Screw Corp. v. PL Robertson Mtg. Co. Ltd.*, (1961), 39 CPR 31 (Ex Ct) ("*New Process Screw*") (**R-384**).

a range of pitch angles to produce double threaded screws. However, when the specified pitch angles were put into practice, either the screws produced were crude and not of commercial quality, or failed to produce double thread screws entirely.[49] The invention did not meet the promised level of utility which was "fatal to it".[50]

48. Professor Siebrasse contends that this case did not concern promised utility, instead characterizing it as an operability case.[51] I do not agree. The invention worked to an extent and produced either crude screws of a non-commercial quality, or screws that were not double-threaded. In this sense there was a "mere scintilla" of utility, however, the finding of inutility was based on a higher standard described by the inventor.

49. Similarly, the trial decision in *Consolboard* [52] recognized the place of promised utility in Canadian law. Utility was squarely in issue at trial, with inutility alleged for the '232 and '282 patents, two of the four patents at issue.[53] As I mentioned in my First Report, I worked on preparing the case for trial.

50. The '232 Patent described a method and apparatus for felting fibrous elements on a moving collecting surface.[54] The felts were used in the production of particle board. The method and apparatus described were said to result in a continuous uniform deposit or concentration of the material on the collecting surface. The '282 Patent was an improvement over the '232 Patent.[55]

51. In the '232 Patent, the specification used the terms "uniform distribution", "substantially uniform thickness" and "uniform deposition" to describe the uniform mat created by the felting process described in the patent.[56] However, the expert evidence showed that the flow of material through the apparatus of the patent would be intermittent, thus resulting in a non-uniform distribution.[57] The invention clearly worked (i.e., it produced mats that were non-uniform) and thus possessed a 'mere scintilla' of utility. However, as the utility was measured against the standard stated in the patent, the claims were invalid for inutility by failing to produce the promised results.[58]

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[49] *New Process Screw* at p. 46 (**R-384**).

[50] *New Process Screw* at p. 32 (**R-384**).

[51] Siebrasse Second Report at para. 36.

[52] *Consolboard FCTD* (**R-359**).

[53] These two patents were not the subject of the appeals to the Federal Court of Appeal and Supreme Court of Canada.

[54] *Consolboard FCTD* at paras. 146-147 (**R-359**).

[55] *Consolboard FCTD* at paras. 146-147 (**R-359**).

[56] *Consolboard FCTD* at para. 164 (**R-359**).

[57] *Consolboard FCTD* at paras. 165-166 (**R-359**).

[58] Justice Collier relied on the passage from Dr. Fox's 1969 Text, cited in Dimock Report at para. 66: H.G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. (Toronto: Carswell, 1969) (**R-019)**.

4) *Patentees Have Also Long Been Held to Promises through Overbreadth*

52. The cases discussed above show the long lineage of the promise standard in Canada's law of utility. However, the utility requirement is not the only doctrine under which patentees have long been held to promises of utility. In my First Report, I described the similarity between promised utility and the doctrine of overbreadth, noting that "the principles underlying promised utility also arise in overbreadth".[59] Professor Siebrasse disagrees with my opinions regarding overbreadth and reasons that "overbreadth is a ground of objection to a patent quite distinct from utility".[60] I disagree. After reading Professor Siebrasse's Second Report, my opinions on the relationship between overbreadth and promised utility have not changed.

53. In my experience, distinguishing promised utility, overbreadth, and other staples of patent law based on form and labels does not recognize that aspects of patent law often overlap. To comment on whether the current law of promised utility is new, it is essential to look "not simply at the bare legal principle, but also at the reasoning which underlies the principle".[61] The case law on overbreadth and utility cannot be neatly divided into distinct categories, as Professor Siebrasse suggests. The courts have expressly warned against treating patent law concepts as watertight compartments.[62]

54. The overbreadth jurisprudence, which I will discuss below, further demonstrates that the current law of promised utility is not new, as Professor Siebrasse contends. Rather, the law is based on principles that were long known, not only under the heading of utility but also under that of overbreadth. The two doctrines share the same common end in prohibiting an inventor from claiming subject-matter which they did not, in fact, invent or describe in their patent. Indeed, the doctrine of sound prediction, acknowledged by Professor Siebrasse as an aspect of the law of utility and fundamental to his so-called "Promised Utility Doctrine", actually arose as a defence to an allegation of overly broad claims. [63]

55. While the form in which the principles are asserted may have changed over time, this is an inherent attribute of patent law. [64] In this regard I note that earlier in my career, it was popular for defendants in patent cases to attack patents as an issue of overbreadth. Today, attacks on claims that are overbroad are often being pursued as a utility issue. However, when the principles underlying inutility and overbreadth are considered, it is

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[59] Dimock First Report at para. 75.

[60] Siebrasse Second Report at para. 37.

[61] *MacOdrum Text* at p. 2 (**R-361**).

[62] See for example *Purdue Pharma v. Pharmascience Inc.*, 2009 FC 726 at paras. 51-52 (**C-246**).

[63] Siebrasse First Report at paras. 17, 25-28; Siebrasse Second Report at para. 4.

[64] Donald MacOdrum, "A claim of patent infringement typically provokes not only a denial infringement, but also an attack on the validity of the patent on a number of interrelated grounds." *See MacOdrum Text,* at p. 1 (**R-361**). More recently, Hughes J recognized the overlapping nature of the various aspects of patent law and cautioned against pigeonholing arguments into various categories. *See Eli Lilly Canada Inc. v. Apotex Inc. et al*, 2008 FC 142, ("*Raloxifene*") (**R-200**).

evident that in many situations involving a promise of utility made in the patent, both inutility and overbreadth could be raised in the alternative, as the flip sides of the same coin of invalidity.

a) Overbreadth and Promised Utility

56. As stated in my First Report, overbreadth is a "long standing principle of Canadian patent law" that serves the function, among others, of holding patentees to promises of utility made in the patent.[65] Put simply, the principle prohibits an inventor from claiming more than they have invented or disclosed in the patent. If an invention does not deliver the utility claimed in the patent, it could be regarded as overbroad. The principle of overbreadth was succinctly stated by Thurlow J., in 1965:

> There are two fundamental limitations on the extent of the monopoly which an inventor may validly claim. One is that it must not exceed the invention which he has made, the other is that it must not exceed the invention he has described in his specification.[66]

57. An important overbreadth case is *Amfac Foods v. Irving Pulp and Paper* which I discussed in my First Report.[67] I raised the case as an example of a patent being held invalid for failing to achieve the promised utility. Professor Siebrasse contends that *Amfac* was an overbreadth case and that "utility was not in issue."[68] While I agree that the patent in *Amfac* was invalidated on the basis of overbreadth, I do not agree that promised utility was not in issue and believe that this case is a good example of how the two areas of law often overlap.

58. In *Amfac*, the disclosure was construed *as a whole* to determine the nature of the invention: a device capable of cutting potatoes into French fries *and* separating the outside slabs of potatoes from the centre portion of the potatoes at the point of cutting. However, the claim at issue was invalid for overbreadth as it claimed devices that did not separate the outer slabs of the potato from the centre portion. The plaintiff patentee, Amfac Foods, actually had to give this broad interpretation of the claim to prove infringement. In the end, the claimed device did not deliver the utility as promised in the disclosure and therefore was broader than the invention disclosed.

59. Based on my familiarity with the case as counsel for the plaintiff, I believe that although the defendants opted for overbreadth, they could have just as easily succeeded on an issue of inutility. Although the claimed device worked to cut potatoes into French fries (and so had a "mere scintilla" of utility), it did not achieve its promised utility. I

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[65] Dimock First Report at para. 75.

[66] *Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning v. Canada (Commissioner of Patents),* [1966] Ex CR 91 at para. 21 (**R-379**).

[67] *Amfac Foods v. Irving Pulp and Paper* (1986), 12 CPR (3d) 193 (FCA) ("*Amfac Foods*") (**R-168**). I argued the appeal for Amfac Foods, whose patent was declared invalid at trial.

[68] Siebrasse Second Report at para. 37.

am not alone in that view. In their article "The Promise of the Patent in Canada and Around the World", Professor Richard Gold and Mr. Michael Shortt refer to the *Amfac* decision as "another important promise case".[69]

60. Both older and more recent cases show the interplay of overbreadth and inutility.[70] In *Wellcome Foundation Ltd. v. Apotex Inc.*, the Court of Appeal treated the questions of overbreadth and utility together, noting that "Appellant's counsel argued on the appeal, as he did at trial, that the process claims of the '014 patent were over-broad and lacked utility."[71] Another example is *Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.*,[72] where the patent claimed a formulation of irbesartan containing different ingredients in widely varying amounts and promised that the formulation could deliver a particular dissolution profile. The Court held that the patent description failed to teach a skilled reader which proportions would yield the promised result. The Court also found that the claims of the patent in suit went beyond the scope of the disclosure and the inventor could establish neither utility nor sound prediction.[73] In short, the Court found that the overbreadth of the claims did not "achieve the promise".[74]

61. In a recent decision of the Federal Court of Canada in *Alcon Canada Inc. v. Cobalt Pharmaceuticals Co.*[75], the allegations of overbreadth and inutility were raised in Cobalt's Notice of Allegation. Justice Gleason (now of the Federal Court of Appeal) described the allegation of overbreadth as "simply another way of articulating the utility requirement":

> While one paragraph makes reference to "inutility" and the other to the claims being "broader", these passages of the NOA actually both refer to the same issue of claims broader, since Cobalt's allegation of overbreadth is related to the allegation that the patent claims something that does not work. As Justice MacKay says at para 126 of *Wellcome v Apotex*: "If the patent claims a process that does not in fact work the claim is too broad because its promise fails".
>
> Therefore, this allegation of overbreadth is simply another way of articulating the utility argument, but from the perspective of claims drafting rather than from the perspective of the demonstration or

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[69] Richard E. Gold and Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2014), 30:1 CIPR 35 at p. 56 (**R-050**).

[70] See for example *Abbott v. Ratiopharm*, 2005 FC 1095 (**C-441**); *Abbott Laboratories v. Canada (Minister of Health)*, 2005 FC 1332, aff'd 2007 FCA 153 (**C-113**); *Sanofi-Aventis Canada Inc v. Apotex Inc*, 2009 FC 676, aff'd 2011 FCA 300 (**C-248**).

[71] *Wellcome Foundation Ltd. v. Apotex Inc.* (1995), 60 CPR (3d) 135 at p. 153 (FCA) (**R-401**).

[72] *Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.*, 2010 FC 230 (*"Ratiopharm")* (**C-465**).

[73] *Ratiopharm* at para. 71(**C-465**).

[74] *Ratiopharm* at para. 67 (**C-465**).

[75] *Alcon* (**C-353**).

> sound prediction of utility. As I have already found above that the 924 Patent fails to meet the promises advanced by the asserted claims, it follows that the claims are drafted more broadly than is warranted; they contain promises that are broader than what can be demonstrated or soundly predicted to be useful by the disclosure in the patent.
>
> [underlining added]

b) The Doctrine of Sound Prediction Arose in Overbreadth Cases

62. The intertwined nature of overbreadth and promised utility can be seen in the origins of the doctrine of sound prediction. The doctrine of sound prediction is a bridging principle which ties together overbreadth and recent cases dealing with promised utility.

63. I wrote in my First Report that the doctrine of sound prediction permits inventors to satisfy the utility requirement *in lieu* of demonstrating utility, where they can prove the utility would have been soundly predicted based on a factual basis and an articulable and sound line of reasoning.[76]

64. Professor Siebrasse acknowledges that sound prediction is part of the law of utility and of his so-called Promised Utility Doctrine, but ignores that its origins were in overbreadth. [77] Instead, he contends that overbreadth and utility are "quite distinct."[78] This is a surprising position in light of the early seminal cases on sound prediction. In effect, a patentee could overcome an objection of overbreadth on the basis that the description of the invention soundly predicted the promised utility of the invention across the full breadth of the claims.

65. In the 1964 decision of the Exchequer Court of Canada in *Hoechst Pharmaceuticals of Canada Ltd. v. Gilbert & Co.*,[79,80] the validity of a claim for a process for producing a class of compounds was at issue. The Court relied on the specification to construe the invention as the production of new compounds for lowering and controlling blood glucose levels in patients suffering from conditions such as diabetes over known methods.[81,82]

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[76] Dimock First Report at paras. 99-100.

[77] Siebrasse First Report at paras. 17, 25-28; Siebrasse Second Report at para. 4.

[78] Siebrasse Second Report at para. 37.

[79] *Hoechst Pharmaceuticals of Canada Limited et al. v. Gilbert & Company et al.* (1964), 28 Fox Pat C. 120 (Ex Ct) ("*Gilbert*") (**R-195**).

[80] The Exchequer Court of Canada (1875-1971) was the predecessor to the Federal Court of Canada—Trial Division (1971-2001), now known as the Federal Court of Canada.

[81] The utility of the compounds was not expressly indicated in the claim which was limited to claiming the products of the particular reaction. The utility was inferred *purely* from the disclosure portion of the specification. This is contrary to Professor Siebrasse's position that promised utility was traditionally construed based only on the claims.

66. The allegation of overbreadth was raised. The claim at issue encompassed a "limitless" number of compounds, but the disclosure listed only a small subset that had been produced and tested to show the desired effects.[83] To rebut the overbreadth attack, the inventor argued that the utility of the untested compounds could be predicted. The Court determined that the issue was whether it could be "predicated (*sic*) of all products of the process claim" that they have the promised utility of the invention:

> The question as to utility for which I propose to seek an answer on the evidence is accordingly…Can it be predicated (*sic*) of all products of the process claim in claim 1 of each of the patents—or of substantially all of such products—that they have advantages for lowering and controlling the blood sugar level of patients suffering from diseases such as diabetes over the known methods of (1) dieting; and (2) the administration of insulin?[84]

67. The expert evidence on this issue indicated that the pharmacological effects of new and untried substances were not generally predictable.[85] The Court concluded that it was highly improbable that all, or substantially all, of the members of the claimed class possessed the promised utility.[86] The claim was invalid.[87]

68. The relationship between overbreadth and utility was again evident in *Monsanto Co. v. Commissioner of Patents*,[88] the 1979 Supreme Court of Canada decision that explicitly received the doctrine of sound prediction in Canadian law and which I discussed in my First Report. The primary issue was whether the claim was broader than the invention described as it claimed 126 different compounds having a particular utility, but only disclosed three compounds that had in fact been made and their utility known.

69. The Patent Appeal Board denied the claims as they were broader than the invention described or made, or which could be reasonably predicted. The principle concern with this claiming was "speculative claiming" and "paper inventions" where only a subset of the claimed products were in fact made and tested. The Court of Appeal upheld this finding.[89]

70. The Supreme Court allowed the appeal. Despite the fact that the utility of many of the compounds had not been proven, the inventor was capable of making a sound

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[82] *Gilbert* at paras. 27 and 28 (**R-195**).

[83] *Gilbert* at para. 27 (**R-195**).

[84] *Gilbert* at para. 29 (**R-195**).

[85] *Gilbert* at para. 31 (**R-195**).

[86] *Gilbert* at para. 35 (**R-195**).

[87] The appeal to the Supreme Court of Canada was dismissed, with the Court upholding and relying the principles applied by the Exchequer Court. *Hoechst Pharmaceuticals of Canada Ltd v. Gilbert & Co.*, [1966] SCR 189, 50 CPR 26 at p. 194 (**C-301**).

[88] *Monsanto Co. v. Commissioner of Patents* [1979] 2 SCR 1108 (**R-023**).

[89] *Monsanto Co. v. Commissioner of Patents* (1977), 34 CPR (2d) 1 ("*Monsanto 1977*") (**R-197**).

prediction of the utility of the compounds based on the three examples disclosed in the patent. The Court ordered the Commissioner of Patents to accept the claim.[90]

71. Similarly, in the 1988 decision of the Federal Court in *Cabot Corp. v. 318602 Ontario Ltd.*, the attack of overbreadth was rebutted by the application of sound prediction. [91] I acted as trial counsel for Cabot Corp. The invention was a foam, cylindrical earplug, and the defendant argued that the claims extended beyond the type of foam outlined in the specification and examples. The trial judge relied on the *Monsanto* decision and held that the use of other types of foam could be soundly predicted to produce the claimed invention.[92]

72. The above cases show that the doctrine of sound prediction arose as a response to allegations of overbreadth. Where an inventor had not made all the various versions of the invention claimed, the patent could be challenged on the ground that the claim was cast too broadly. The courts recognized that in many cases, invalidating on this ground would be unfair as the invention may encompass many embodiments having only slight differences. The doctrine of sound prediction was adopted as part of the law of utility to bridge the leap between what the inventor had claimed, and what he had actually made or described.

5) *How Canadian Courts Construe the Promise of a Patent*

a) Canadian Courts are Not 'Scouring for Promises'

73. The foregoing shows that the promise standard of utility has long been part of Canadian law, both as part of the meaning of "useful" under s. 2 of the *Patent Act* and through the doctrine of overbreadth. Apart from their revisionist view of when the promise standard was adopted, Professor Siebrasse and Mr. Reddon take issue with the way that Canadian courts go about determining that there is a promise in the patent, and the nature of that promise.

74. Mr. Reddon, in his Report at paragraphs 6 and 7, suggests that Federal Court judges have for a decade or so taken it upon themselves and showed unhesitating willingness to construe and derive promises from patent disclosures. Mr. Reddon goes so far as to say, in paragraph 4 of his Report, that the judges "have scoured the patent disclosure to find promises of utility". Professor Siebrasse says much the same in paragraph 16 of his Second Report. Both Mr. Reddon and Professor Siebrasse use "scour" to describe the search for promises. This language is unique to their reports.

75. Their views, in my opinion, are far from correct. The courts are not "scouring the patents for promises", as both Professor Siebrasse and Mr. Reddon seemingly independently state. Rather it is the parties in pharmaceutical litigation – and not the

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[90] *Monsanto Co. v. Canada (Commissioner of Patents),* [1979] 2 SCR 1108, 42 CPR (2d) at p. 1108 (**C-61**).

[91] *Cabot Corp v. 318602 Ontario Ltd*. (1988), 20 CPR (3d) 132 ("*Cabot*") (**R-363**).

[92] *Cabot* at paras. 129-130 (**R-363**).

courts – that are now placing promises made in the patents front and centre before the courts.

76. I described above at paragraphs 12 through 25 some of the reasons why a patentee may want to emphasize promises in the patent during litigation. This tendency is evident in pharmaceutical litigation, where the patent holder will often try to "read-up" the advantages of the invention to overcome the novelty and non-obviousness requirements. This places promises of utility front and centre before the court. I provided some examples of this above. Another was in the case of *Alcon Canada Inc. v. Cobalt Pharmaceuticals Co.*,[93] where the court observed:

> In essence, Alcon argues that for the purposes of obviousness, the inventive concept includes the teaching that the excluded excipients do not enhance the physical stability of the solution, but for the purposes of utility, there is no such promise of non-enhancement.
>
> … I find it incongruous, in the context of this patent, to argue that the inventive concept is something different from the promise made in the patent and, therefore, accept the position of Cobalt on this point.

77. As discussed above, the incentives for patent holders to make and emphasize promises in the patent are particularly acute in the context of follow-on patents, such as new use and selection patents. Often, pharmaceutical patents fall within these categories, as do the Claimant's patents for *atomoxetine* and *olanzapine*.

78. Contrary to Professor Siebrasse's suggestion, increased attention to utility issues in the context of follow-on patents does not mean that the law has changed. As indicated in my First Report, a range of factors is contributing to these issues being brought increasingly to the fore—not the least of which is patent counsel's efforts to overcome an obviousness attack as discussed above—but this does not mean that the law has changed.[94] The courts are applying the same principles that have always been a part of Canadian patent law.

b) Courts Have Not Changed the Way They Construe the Patent

79. In paragraph 14 of his Report, Mr. Reddon refers to the challenge his clients (pharmaceutical patentees) face in responding to allegations of invalidity relating to inutility and suggests that the success in doing so hinges on how a judge will construe or interpret the disclosure of the patent in suit. He then goes further and faults judges for making their constructions "very difficult to predict or assess".[95]

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[93] *Alcon* at paras. 59-63 (**C-353**).

[94] Dimock First Report at paras. 153-157.

[95] Reddon Report at para. 14.

80. From my perspective as a patent trial lawyer, the proper construction to be given to a patent disclosure depends on the ability of counsel through expert evidence to give the judge the right framework to interpret phrases in the disclosure and the entire patent. This is the same approach that is used to identify the inventive concept of the patent under the obviousness analysis. Counsel have the responsibility to introduce evidence about the common general knowledge and how the notional skilled person possessed of that knowledge would interpret such phrases. Judges interpret patents only through the eyes and mind of that skilled person whose perspective on the patent must come from evidence adduced by counsel. Therefore, in my opinion, the blame for Mr. Reddon's apparent concern about the predictability and assessment of what construction should be given to a patent's disclosure and claims lies with counsel, and not with the court.

81. Mr. Reddon and Professor Siebrasse both discuss the *latanoprost* litigation,[96] with Professor Siebrasse describing it as illustrating the "vagaries of the exercise of construing the promise".[97] In particular, Professor Siebrasse and Mr. Reddon note that two different panels of the Federal Court of Appeal reached a different interpretation of the promise of the same patent in two different proceedings. In the second proceeding, the Court of Appeal found that the patent promised "chronic treatment" whereas no such promise was found in the first proceeding.

82. In my opinion, this does not suggest that the approach to patent construction applied in either case was subjective or arbitrary. What Professor Siebrasse and Mr. Reddon gloss over are the significant differences in evidence before the courts in the two proceedings. The court's duty is always to interpret the patent through the eyes and mind of a skilled person, based on the expert evidence put before it by the parties. In the second proceeding – but not the first – the patent holder's own expert gave testimony that the patent promised chronic treatment. As the Court of Appeal noted in the second proceeding, the issue of chronic treatment was not at issue in the first proceeding.[98] The court could not ignore the new evidence before it from the patent holder's own expert when construing the patent's promised utility.

83. As I explained in my first report, the way in which courts construe the promise of a patent is consistent with longstanding approaches to patent construction. Professor Siebrasse contends that courts have changed their practice by looking to the disclosure to determine whether the patent promises a particular utility. I disagree with Professor Siebrasse for the reasons given at paragraphs 67-69 and 83-91 of my First Report.

84. In addition to the authorities considered in my First Report, some of the additional utility and overbreadth cases discussed above further illustrate that courts have long considered statements in the disclosure to construe the promised utility of the invention. In *Hoechst Pharmaceuticals of Canada Ltd. v. Gilbert & Co.*, the court construed the

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[96] *Pfizer Canada Inc. v. Pharmascience Inc*., 2009 FC 1294 (**C-49**), aff'd 2011 FCA 102 (**C-98**); *Pfizer Canada Inc. et al. v. Minister of Health et al*,, 2010 FC 447 (**C-303**), rev'd *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236 (**C-99**).

[97] Reddon Report at paras. 15-18; Siebrasse First Report at para. 51.

[98] *Pfizer Canada Inc. v. Canada (Minister of Health),* 2011 FCA 236 at paras. 21-22 (**C-99**).

invention by looking to the pharmacological effects promised in the disclosure.[99] Similarly, in *Amfac* the court looked to an object clause and other passages in the disclosure to note that the invention promised a certain result.[100] As well, in *Wellcome Foundation Ltd. v. Apotex*,[101] the Federal Court engaged in an extensive analysis of the patent *as a whole*, interpreted with assistance of expert evidence, to determine the promised utility of the patent.[102] The Court of Appeal affirmed this approach, writing that "Since the utility of a patent must ultimately be judged against its promise the exercise requires that the specification be carefully construed to determine exactly what that promise is".[103] These cases are examples of the claimed scope of the invention being assessed in light of the specification as a whole, as is consistent with current principles of patent construction.

85. Beyond questioning the historical basis for considering the disclosure to construe the promised utility of the invention, Professor Siebrasse disagrees with this approach as a matter of policy. At paragraph 45 of his Second Report, he criticizes my view that the quality of the patent disclosure is "enhanced by a rule that holds patentees to the promises they make." He claims that "the promise of the patent is inimical to the quality of the patent disclosure".[104]

86. I disagree. More material in the patent disclosure does not enhance its quality if what is disclosed are speculative promises of utility. Greater focus on the specification ensures that inventors do not overstate their inventions, while at the same time providing a clear and full disclosure to support the claims, as required by the sufficient description requirement under s. 27(3) of the *Patent Act*.

B. Has the Invention Been Made?

1) *Utility Must be Established For There to Be an Invention*

87. Today, when the courts consider whether the utility of an invention has been demonstrated or soundly predicted at the time of filing, the real question being asked is whether the inventor had actually made the invention as disclosed in the application for a patent.

88. As explained in my First Report, it has never been permissible under Canadian law to obtain a patent for an invention whose utility has not been established by the time of filing the application. Utility is an essential element of an invention. If the utility of the

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[99] *Gilbert* at paras. 27 and 28 (**R-195**).

[100] *Amfac Foods* (**R-168**).

[101] *Wellcome Foundation Ltd. v. Apotex Inc.* (1991), 39 CPR (3d) 289 (FCTD) (**R-397**).

[102] *Ibid* at pp. 342 to 352 (FCTD) (**R-397**).

[103] *Wellcome Foundation Ltd. v. Apotex Inc.* (1995), 60 CPR (3d) 135 (FCA) at pp. 154-157 (**R-401**).

[104] Siebrasse Second Report at para. 45.

invention has not been established when a patent application is filed, then no patent should be granted, because no invention has been made.[105]

89. It is incorrect as a matter of law – and seems illogical to me – to posit that an inventor can rely on post-filing evidence of work done after the application for a patent was filed to retroactively prove that the invention was made, and its utility established, before filing. Yet Professor Siebrasse suggests as much and criticizes my view that there is a long standing rule in Canadian patent law and practice, predating the Claimant's applications for the *olanzapine* and *atomoxetine* patents, which prohibits such post-filing evidence.[106]

90. His criticism continues to obscure the distinction between proof of the operability of the invention and establishing the utility of the invention, discussed in my First Report at paragraph 105. The first concept, operability, is concerned with whether an invention is useful in fact, and can be proved on the basis of post-filing evidence. The second concept, establishing utility, is concerned with whether the patentee has actually made an invention – including establishing the utility of the invention – at the time he claims a monopoly. After-the-fact evidence has never been admissible for this purpose.

91. Professor Siebrasse ignores the jurisprudence on this point that developed under Canada's "first-to-invent" patent regime. While Canada changed to a "first-to-file" regime in 1989 (referenced at paragraph 34 of my First Report), this did not change the law of whether the utility of an invention had to be established before a patentee could claim a monopoly.

2) *The Old "First-to-Invent" System Required Utility to be Established by the Claimed Date of Invention*

92. Under the old "first to invent" system, which applied to patent applications filed before 1989, the person entitled to a patent was the first person to make the invention, so long as it "was not known or used by any other person before he invented it".[107] Issues relating to the making of the invention in the pre-1989 regime not only arose in disputes concerning entitlement to the patent (i.e., who was the first to make the invention) but also in those in which attacks were made on the validity of the patent based on proving with prior art that the invention was obvious at the time it was made. In these latter disputes, the patentee often led evidence to disqualify prior art by showing that the making of the invention preceded the prior art. In each of these disputes, the issue was concerned with identifying when the invention of the patent in suit was made.

93. To show when the invention was made, the utility of the invention had to have been established by the relevant date – just as it is today. The main difference between the pre- and post-1989 regimes being the relevant date: before it was the asserted "date of invention" whereas now it is the filing date of the patent application.

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[105] Dimock First Report at para. 92.

[106] Siebrasse Second Report at paras. 7, 8, and 51.

[107] *Patent Act* [pre-Oct. 1, 1989], RSC 1985, c. P-4, s.27(a) (**R-385**).

94. A large body of case law developed on the point that the utility of the invention had to be established before it could be said that any invention had been made. As I described in my First Report, in order to have made the invention it had to be reduced to a "definite and practical shape", described in *Wandscheer et al v. Sicard Ltd.*:

> It is not sufficient in order to obtain a valid patent, as Viscount Case 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.[108]
>
> [underlining added]

95. Here, the Court cited a number of the cases I referenced at paragraphs 92 through 95 of my First Report, as well as others, in which judges were asked to consider when an invention had been made. Repeatedly, they emphasized that an invention was not reduced to a definite and practical shape (i.e. was not made) if its utility had not been established.

96. This arose in the case of *Control Data Canada Ltd. v. Senstar Corp.*, in which I was trial counsel for Control Data Canada. In its judgment, the Court explained that to make an invention, the inventor had to have done enough work to establish utility or "the workability of the invention"[109]:

> … an apparatus or device is reduced to practice when it is assembled, adjusted and used. It can be an experiment; it need not be a commercial use (*Corona*) … [and that] reduction to practice is the testing of the invention to demonstrate utility but not mechanical perfection. The operative means must merely accomplish the desired result. Improvements obvious to the skilled workman to increase its practical efficiency or perfect its operation may still be made to an invention already reduced to practice. Thus commercial feasibility is not necessarily relevant to the question of "reduction to practice" so long as the experimental equipment proves the workability of the invention. It does not have to be mechanically perfect.
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> [underlining added]

97. This line of jurisprudence is also reflected in the January 1990 version of the Patent Office's *Manual of Patent Office Procedure* ("MOPOP"), which made clear that an

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[108] *Wandscheer v. Sicard Ltd.*, [1948] SCR 1 at p. 4 (**R-181**).

[109] *Control Data Canada Ltd. v. Senstar Corp.* (1989), 23 CPR (3d) 449 at para. 137 (**R-364**).

inventor could not claim to have made an invention until the utility of the invention was established:

18.20 **DATE OF INVENTION**	**18.20** **DATE D'INVENTION**
The earliest date which will be accorded is the date on which the inventor disclosed both the invention and its utility to someone else.	La date la plus antérieure qui sera accordée est celle à laquelle l'inventeur a divulgué à un autre et l'invention et son utilité.
…	
18.20.02 **Utility Essential to Invention**	**18.20.02** **L'utilité--essentielle à l'invention**
An invention, such as that relating to a new substance, may not be said to be invented until such date as the utility for it is known. In some instances the utility may be apparent once the substance is made. If the use is not obvious the inventor will not be accorded a date prior to that when he discovered and disclosed to others the use for the invention.	Une invention, en ce qui a trait à une nouvelle substance, ne peut être dite inventée avant la date à laquelle son utilité est connue. Dans certains cas, l'utilité peut être apparente une fois la substance produite. Si l'utilité n'est pas évidente, on n'accordera pas au demandeur une date antérieure à celle à laquelle il a découvert et divulgué à d'autres l'utilité de l'invention.
…	
18.20.05 **Diligence**	**18.20.05** **Diligence**
Diligence, in the sense of the U.S. patent practice, does not apply to Canadian conflict proceedings. Once an inventor has made his invention and disclosed it to others, he need not be diligent in carrying out further development of the invention or in applying for a patent. No matter how long he delays, he may go back to the date when he can prove he first made and disclosed the invention as to when he made the invention.	La diligence, au sens ou elle est employée dans la pratique des États-Unis d'Amérique, ne s'applique pas aux procédures canadiennes de conflit. Une fois qu'un inventeur a réalisé son invention et l'a divulguée à d'autres, il n'a pas à exercer de diligence dans la mise au point de l'invention ou pour faire une demande de brevet. Quelque soit son retard, il peut toujours référer à la date à laquelle il peut prouver qu'il a pour la première fois réalisée et divulguée l'invention.

98. Evidence that an inventor has made or worked the invention at *a later date* (i.e. post-invention/filing), which Professor Siebrasse suggests should be permitted, cannot be proof that the patentee had established its utility at an *earlier date* (i.e. the asserted date of invention). This is illustrated by the 2001 decision of *Goldfarb v. W.L. Gore & Associates, Inc.*[110] The case is one of the last "conflict" decisions decided under the "old" *Patent Act* provisions designed to determine the first person to make the invention. The court explained that whether the utility of the invention was actually proved (demonstrated) or soundly predicted, this must have been done by the claimed date of invention:

[110] *Goldfarb* (**R-187**).

> Proving actual utility at the claimed date of invention is not the only way of establishing it. Canadian patent law holds, in certain circumstances, sufficient if the inventor has soundly predicted the utility of the invention at that date.
>
> [underlining added]

99. All the above authorities pre-date the Supreme Court of Canada's 2002 decision in *AZT*, when Professor Siebrasse claims that Canadian law changed to prohibit post-filing evidence of utility.

100. Nevertheless, Professor Siebrasse cites several cases at paragraph 58 of his Second Expert Report, arguing that the courts distinguished operability from utility, and clearly admitted post-filing evidence on the question of utility.[111] I disagree with this reading of the cases. One authority relied upon by Professor Siebrasse is *Omark Industries (1960) Ltd. v. Gouger Saw Chain Co.*[112] Professor Siebrasse cites an isolated passage from the judgment, where the Court appears to distinguish operability from utility and to consider evidence of commercial success as going to utility. Read in context, the entire discussion was about operability. Professor Siebrasse suggests that utility was a "separate ground of attack," but I am unable to find reference to any "separate ground of attack" of utility in the case, beyond the issue of "inoperability", as defined by the judge. Indeed, other aspects of the case actually emphasized that contemporaneous evidence must be adduced to prove when an invention was first made (on the facts, to avoid prior art). The Editorial Note at the beginning of the case is telling:[113]

> It is also made clear that the patentee in proving the date must adhere strictly to the rules of evidence… Since Courts must deal with admissible and believable evidence, the requirement of the Court is understandable. Where, however, the date is one to be established many years in the past, it is not always easy to find living persons available to testify to the facts. Great care should be taken by inventors to establish a date by signed and witnessed note books as well as corroborative material such as purchase orders and correspondence. Records applicable to a date of invention should not be destroyed.

101. Likewise, Professor Siebrasse mischaracterizes the issue of utility in *Reliable Plastics Ltd. v. Louis Marx & Co.* At paragraph 58 of his Second Report, Professor Siebrasse writes:

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[111] Siebrasse Second Report at para. 58.

[112] *Omark Industries (1960) Ltd. v. Gouger Saw Chain Co.* (1964), 45 CPR 169 (**C-224**).

[113] Editorial Note to *Omark Industries (1960) Ltd. v. Gouger Saw Chain Co.* (1964), 45 CPR 169 at p. 173 (**C-224**), written by Gordon Henderson, one of the greatest Canadian patent lawyers of all time.

> In *Reliable Plastics*, the court noted that apart from some attacks on the ground that the devices "would not work," "utility" was proved "beyond dispute" by post-filing evidence.

102. In contrast, the case specifies that there was no such dispute:[114]

> Apart from attacks on some of the claims on the ground that they contemplated devices that would not work, there was no attempt to dispute the utility of the defendants' game.
>
> [underlining added]

103. In his reference to *Cochlear Corp. v. Cosem Neurostim*, Professor Siebrasse cites the following excerpt from the case:[115]

> "…[the] utility of a patent may be proven by the reception received from the public, i.e. its commercial success," and continued in the very next sentence to state expressly that utility "is … to be judged at the date of the making of the invention, in light of the knowledge existing at the time".
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> [underlining added]

104. However, the underlined portion above reads in its entirety: "Utility is also to be judged at the date of the making of the invention."[116] When *Cochlear* is read in its full context, it is clear that the Court has distinguished between considerations of utility in matters concerning operability (when "post-filing" evidence is acceptable) from those matters of "making the invention" (when "post-filing" evidence is unacceptable). This case was concerned with operability.

105. Having regard to "post-filing evidence" to show operability makes sense. When a patent is challenged for inoperability, the challenger is saying that the invention described in the patent does not work in fact. Evidence that the invention works today, for example evidence of commercial use, may be relevant and is admissible to rebut this allegation. While operability is necessary to satisfy the utility requirement, it is not sufficient. A patentee must also show that it had actually made an invention – including establishing its utility – at the claimed date of invention. This is something that "post-filing evidence" cannot show.

106. With respect to the other cases referenced by Professor Siebrasse in paragraph 58, *Boehringer Sohn v. Bell-Craig Ltd.*[117] and *Hoechst Pharmaceuticals of Canada Ltd. v.*

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[114] *Reliable Plastics Ltd. v. Louis Marx & Co*. (1958), CPR 113), at p. 126 (**C-218**).

[115] Siebrasse Second Report at para. 58.

[116] *Cochlear Corp. v. Cosem Neurostim Ltée* (1995), 64 CPR (3d) 10 (FCTD) at p. 35 (**C-228**).

[117] *Boehringer Sohn v. Bell-Craig Ltd*., 1962 Ex CR 201 (**C-221**), aff'd [1963] SCR 410, 41 CPR 1 (SCC).

Gilbert & Co.,[118] he notes that the claims at issue were held invalid for lack of sound prediction. Accordingly, they provide little guidance. The patentees in those cases advanced post-filing evidence, but the courts found that this could not establish the utility of the invention.

3) *The New "First-to-File" System Does not Permit Filing First and Inventing Later*

107. As mentioned above, Canada adopted a "first-to-file" system for patent applications in October 1989. Under this new regime, patents are awarded to the first inventor to file a patent application, even if someone else actually invented earlier but filed later. However, this system did not do away with the requirement to have actually invented something – including establishing its utility – at the relevant date. What changed is that the relevant date is now fixed as the Canadian filing date, rather than some earlier "asserted date" of invention.

108. Under the "first to file" regime, when considering whether an invention had been made at the time the patent application was filed, the same analysis and law that were used to identify when an invention was made under the previous "first to invent" regime are still applicable and necessarily prohibit "post-filing evidence". Such evidence continues to be irrelevant for purposes of proving that utility was established by the key date.

109. The switch to first-to-file was not intended to change Canada's system to one in which patents can be granted for mere speculation. The system is therefore best described as a "first (inventor) to file" system. A patentee cannot claim a monopoly before having made an invention – including establishing its utility.

C. Has the Invention Been Disclosed?

1) *The Basis for a Prediction of Utility Must Be Disclosed*

110. At the top of page 29 of his Second Report, Professor Siebrasse provides a section in which he argues that several of the references cited in my First Report supposedly do not support my view that adequate disclosure in a patent has historically been required to support a sound prediction of utility. I disagree.

111. For example, at paragraphs 65 through 67 of his Second Report, Professor Siebrasse attempts to dismiss the comments on disclosure requirements made by Mr. William Hayhurst in 1970 as simply relating to patent drafting tips "as a matter of good practice" rather than what was legally required. Not only is this contention contrived, it is inconsistent with Mr. Hayhurst's other writings I also referred to, which were surveys of the jurisprudence as opposed to patent tutorials. [119]

112. To argue his point, Professor Siebrasse gives his own interpretation of how one of the cases cited by Mr. Hayhurst – *Olin Mathieson Chemical Corp. v. Biorex Laboratories*

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[118] *Gilbert* (**R-195**), aff'd [1966] SCR 189, 50 CPR 26 (**C-301**).

[119] Dimock First Report at paras. 130 and 135.

Ltd.[120] – ought to be read. Professor Siebrasse plainly did not agree with Mr. Hayhurst's reading of *Olin Mathieson*. Apart from this, Professor Siebrasse completely ignores Mr. Hayhurst's second reference included in the same footnote.[121] Citing this second reference, Mr. Hayhurst noted "[m]ere insertion of a consistory clause would not suffice". Here, Mr. Hayhurst was explaining that a consistory clause (i.e. a formal recitation of the claims near the beginning of the patent specification) was held not to be sufficient on its own (i.e. without additional description provided in the patent specification) to support the utility of the broad class of compounds specified in the claim. Importantly, in this note, Mr. Hayhurst was referring to the proceedings of an actual patent application, and therefore referencing what would be understood as a legal requirement – not just "good practice" as Professor Siebrasse suggests.[122]

2) *Olin Mathieson had Support for the Predicted Utility in the Disclosure*

113. I also disagree with Professor Siebrasse's reading of the *Olin Mathieson* case, in particular where he states that the patent in that case provided no basis for the sound prediction being considered by the Court. The Court in *Olin Mathieson* considered and understood that such a prediction could have been made based on the disclosure of the examples provided in the patent itself.

114. The patent at issue in *Olin Mathieson* was directed to a class of compounds that were particularly useful as tranquilizers. As characterised by counsel for the patentee, "the real merit of the invention" was the modification of a specific part of compounds that were already known and used in this field.[123]

115. The particular issue of interest in the case was an allegation that the claims of the patent were invalid for not being "fairly based on the matter disclosed in the specification". This allegation, as set out in the case, was characterized as follows:

> a broad objection directed against …[where] the consideration given by the patentee by the disclosure of his invention in his specification was less than he should have given having regard to the width of his claims. In other words… that a claim which is a "covetous" claim, or one in which the claim does not "equiparate" with the consideration given by the disclosure, is a bad claim. This requirement, said Sir Lionel, has always been fundamental in our patent law…[124]

116. As an aside, I note that this "fairly based" objection is the same "principle of fair basis" mentioned by Justice Binnie in the Supreme Court of Canada's *AZT* decision, where he

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[120] *Olin Mathieson Chemical Corp. v. Biorex Laboratories Limited*, [1970] RPC 157 ("*Olin Mathieson*") (**C-461**).

[121] *Re Cavallito*, (1962) 785 OG 35 at 41(**R-365**).

[122] W.L. Hayhurst, "Disclosure Drafting" (1971) 28 PTIC Bull (7th) 64 (**R-164**).

[123] *Olin Mathieson* at p. 169 (**C-461**).

[124] *Olin Mathieson* at p. 181 (**C-461**); *also see* p. 192, where the Court explicitly accepts this submission.

comments on sound prediction being connected to the principle that the claims be "fairly based" on the patent disclosure.[125]

117. In the *Olin Mathieson* case, the Court noted that determining whether a claim goes beyond the consideration provided by the patentee from one which "equiparates with it" depends on "whether or not it was possible to make a sound prediction" based on the disclosure:

> 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".[126]
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> [underlining added]

118. As acknowledged by the patentee's own counsel, this type of objection "must be considered on the language of the specification, without taking into account extraneous circumstances".[127] However, he also highlighted that the extent of the disclosure required will depend on the extent of accepted knowledge in the field:

> The other important point is that there is a world of difference between making a very broad claim in an unexplored field, and making one, as is the case here, where… the field has been so well explored by others that one may rely upon their work in making a reasonable prediction as to the usefulness of all the compounds within the claim.[128]

119. The Court concluded that based on the skilled person's reading of the disclosure alone, the patent description provided more than ample support for basing a sound prediction of the stated utility. It reached this conclusion in light of the following:

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[125] *AZT* at para. 59 (**R-004**).

[126] *Olin Mathieson* at p. 193 (**C-461**).

[127] *Olin Mathieson* at p. 170 (**C-461**).

[128] *Olin Mathieson* at p. 169-170 (**C-461**).

(a) the processes used to make ten different example compounds belonging to the claimed class were described in the specification itself (reproduced in the reported decision);[129]

(b) compounds with similar "base" structures were previously disclosed in competitors' patents and known to have therapeutic activity[130]; and

(c) the skilled person's expectations based on the common general knowledge and understanding in what was described as a "well worked field".[131]

120. Professor Siebrasse acknowledges at footnote 106 of his Second Report that current Canadian law does not require common general knowledge of the skilled person in the art to be disclosed in the patent (since as I explained in my First Report, the intended reader of the disclosure is assumed to be equipped with that knowledge), and that there was at least some evidence of common general knowledge at trial, but it was not clear what evidence this encompassed. However, notwithstanding the submissions and findings that I have highlighted above, Professor Siebrasse takes the strained view that the Court's findings could not have been founded on the information contained in the disclosure read in light of common general knowledge.

3) *Monsanto Allowed a Sound Prediction Based on Support in the Disclosure*

121. Beginning at paragraph 68 of his Second Report, Professor Siebrasse goes on to argue that I have misinterpreted the Supreme Court's decision in *Monsanto*. I disagree, and having specifically worked on that case (as mentioned in my First Report), am confident that I have a fair grasp of what issues were at play in that proceeding, and need not repeat the discussion from my First Report.[132]

122. However, I note that at paragraph 71 of his Second Report, Professor Siebrasse quotes a passage from the *Monsanto* decision that I had previously referred to, and asserts that I misinterpreted its meaning because "This disclosure referred to by the Court is simply the traditional requirement of how to make and use the invention, which…can be satisfied without disclosing any evidence of utility in the patent itself". Once again, I disagree. The passage he referenced was taken by the Supreme Court from the *Olin Mathieson* decision. As discussed above, the issue squarely before the court was whether the scope of the claimed genus could be "fairly based" on the language of the specification (i.e. was it possible to make a sound prediction of utility based on the disclosure). Whether the invention could be made or used was not in dispute in that case.

123. Beginning at paragraph 75 through to 77 of his Second Report, Professor Siebrasse posits that *Monsanto* must not support the requirement that a patent disclosure must

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[129] *Olin Mathieson* at p. 160-164 (**C-461**).

[130] *Olin Mathieson* at p. 168 (**C-461**).

[131] *Olin Mathieson* at p. 168 (**C-461**).

[132] See Dimock First Report at paras 127-137 and 147-152.

provide the basis for a sound prediction because the courts and counsel have curiously, since the release of the Supreme Court's decision in *AZT*, typically cited the most recent restatement of the law by the Supreme Court of Canada (i.e. *AZT*), rather than referring back to *Monsanto*. Unlike Professor Siebrasse, I am not surprised by this and, in fact, would have expected as much.

124. While Canadian patent counsel have not needed to go back beyond the binding authority of *AZT* in their submissions in recent years, legal commentary has continued to draw the link between *Monsanto* and the disclosure requirement for sound prediction. For example, Ms. Carol Hitchman, an experienced and well respected counsel with a practice focussed on pharmaceutical patent litigation, made the following observation in 2012:

> Using the contract concept of patents, the Court noted that if the claim does not go "beyond the consideration given by his disclosure, his claim is fairly based". Thus, the need for proper disclosure was raised in the *Monsanto* case. [133]

125. Likewise, in 2004, Mr. Adrian Zahl, one of the Associate Editors of the Canadian Patent Reporter and a partner in the firm of Ridout and Maybee LLP, a long established Canadian patent law firm, published a similar observation:

> The Supreme Court in *Monsanto* ruled that a patent is justified by the "consideration" of the patent disclosure if a person skilled in the art could make a "sound prediction" based on the disclosure that the subject matter of the claim could be made by using the teachings in the disclosure and that it would have the utility promised by the disclosure.[134]
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> [underlining added]

4) *AZT Confirmed the Need for Disclosure of the Support for a Sound Prediction*

126. Beginning at paragraph 72 of his Second Report, Professor Siebrasse also challenges comments I previously made about the Supreme Court of Canada's *AZT* decision. The most surprising criticism is at paragraph 73 where Professor Siebrasse writes "…it is possible that the information that was disclosed in the patent could have formed a sufficient basis for a sound prediction by a person skilled in the art. However, absent an express finding by the trial judge, this is simply speculation". Based on the evidence in the record and submissions of the parties, the Supreme Court did indeed make such an express finding when it wrote:

> Precise disclosure requirements in this regard do not arise for decision in this case because both the underlying facts (the test

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[133] Carol Hitchman, "The History of the Doctrine of Sound Prediction" (2012), 27 CIPR 343 at p. 350 (**R-366**).

[134] Adrian Zahl, "Covetous Patent Claims" (2004), 21 CIPR 141 at p. 147 (**R-310**).

> data) and the line of reasoning (the chain terminator effect) were in fact disclosed, and disclosure in this respect did not become an issue between the parties. I therefore say no more about it.[135]
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> [underlining added]

127. Professor Siebrasse also mischaracterizes my position on the Supreme Court's reference to what constitutes "proper disclosure" in *AZT*.[136] The Supreme Court was not silent on the issue. As the above passage shows, the Supreme Court indicated that there was no issue as to disclosure in *AZT* precisely because both the factual basis and line of reasoning were disclosed in the patent.

128. Professor Siebrasse also suggests, at paragraph 74 of his Second Report, that examples of cases where consideration of data for the purposes of establishing that a sound prediction was made, but not disclosed in the patents, is somehow inconsistent with my understanding that adequate disclosure historically has been required to support a sound prediction of utility. I do not see it that way.

129. First, as explained in the cases mentioned above, such as in *Olin Mathieson*, the patent must provide sufficient disclosure so the skilled person could also soundly draw the prediction. This does not mean that the patent must specify every experiment, test, calculation or piece of reasoning that the inventor applied in developing the invention. For example, as noted above, Professor Siebrasse and I agree that the disclosure need not contain references to the common general knowledge even though it would be surprising if elements of the common general knowledge were not integral in supporting the prediction.

130. Second, the assessment of whether or not there is sufficient disclosure of the sound prediction is the third part of the tri-partite test, and should not be conflated with the first two. The patentee must first establish that, at the relevant date, the inventor had made the invention – i.e. that based on his own work and knowledge, he had i) a factual basis for the prediction, and ii) a sound line of reasoning for the prediction. As described by the Supreme Court in *AZT*: "… the soundness (or otherwise) of the prediction is a question of fact. Evidence must be led about what was known or not known at the priority date, as was done here".[137] If a patentee did not have a factual basis or sound line of reasoning at the time of filing, there can be no question as to whether this information was properly disclosed in the patent. It did not exist at all.[138]

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[135] Siebrasse Second Report at paras. 169-170.

[136] Siebrasse Second Report at para. 72.

[137] *AZT* at para. 71 (**R-004**).

[138] This was the case in the *Aventis Pharma Inc. v. Apotex Inc.* case cited by Professor Siebrasse at footnote 121 of his Second Expert Report. The court concluded that the patentee did not have a factual basis or sound line of reasoning at the time of filing. The issue therefore did not arise as to whether such basis was properly disclosed. *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283, 43 CPR (4th) 161 (**C-209**), aff'd 2006 FCA 64 **(C-214)**.

131. In summary, for all the reasons outlined in this report and in my First Report, I disagree with Professor Siebrasse and Mr. Reddon that the requirement in Canadian patent law that the patent disclosure must provide the basis for a sound prediction of utility is a new idea in Canadian patent law originating either with the Supreme Court of Canada's *AZT* decision in 2002 or with the Federal Court decision concerning the Claimant's *Raloxifene* patent in 2009. Rather, it can be traced back in Canadian law to *Monsanto*, which itself drew upon principles articulated in even earlier English authorities such as *Olin Mathieson*.

III. THE NATURE OF PATENT RIGHTS

132. In his Report at paragraph 26, Mr. Reddon disagrees with my use of the term "conditional" in reference to patent rights and, in particular, with my statement that patent rights are "conditional and could be lost at any time". Mr. Reddon claims that in practice, patents are never referred to as "conditional".[139] He continues to state that a patent, once granted, affords the patentee certain rights that are immediately exploitable, often through a licence.[140] He also states that "there is no requirement for validity of a patent to be adjudicated by a court prior to the public recognizing the patent as valid."[141]

133. I agree with Mr. Reddon that, in practice, patents are not referred to as "conditional". However, the remainder of Mr. Reddon's comments on the issue show a misunderstanding of my use of the term "conditional". I did not intend to use the term to mean the validity of a patent is conditional upon the adjudication of a court prior to being recognized as valid by the public. My use of the term was a reference to an earlier section of my First Report where I described the various ways in which patent rights can be lost before the end of its term, including a failure of the patentee to pay annual maintenance fees or the patentee's misuse of the patent monopoly.[142] As I noted, failure to pay maintenance fees, as one example, will result in the expiration of the patent and the rights afforded by it. In this sense, a patent or patent rights could be considered conditional (i.e. conditional upon payment being made).[143]

134. Mr. Reddon also mischaracterizes the nature of patent rights. He states that as "patent rights are subject to adjudication by the court [they are] no different from any other form of property, title to which may be challenged in later litigation".[144] Mr. Reddon's comparison to other forms of property implies a greater sense of certainty of patent rights than should be understood. I disagree with his position.

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[139] Reddon Report at para. 26.

[140] Reddon Report at para. 28.

[141] Reddon Report at para. 28.

[142] Dimock Report at paras. 30-33.

[143] Dimock Report at para. 164.

[144] Reddon Report at para. 28.

135. Although title to a patent is occasionally the subject of litigation, this is not the case in the vast majority of patent litigation. [145] Validity, which is at issue in most patent cases, is not a question of title but rather a question of the very existence of the rights. To my knowledge, this is very different than most other forms of property where the existence of the property is not an issue.

136. The rights afforded through the grant of a patent differ from most other forms of property. A patent is a "chose in action", meaning that it simply affords the patentee and those claiming under it (patentee and licensee) a right to sue. The nature of a patent was discussed by the British Columbia Court of Appeal in *Forget v. Specialty Tools of Canada Inc.*[146]:

> …it is also important to keep in mind the true nature of a patent. It is, of course, a chose in action, not a chattel or anything analogous thereto. As such, it is a personal right of property which can only be claimed or enforced by action, and not by taking physical possession; see: Torkington v. Magee, [1902] 2 K.B. 427, per Channell J. at p. 430, rev'd on other grounds, [1903] 1 K.B. 644 (C.A.). More significantly, the effect of a patent is to exclude others from the exploitation of an invention, rather than to confer rights with respect to that invention on the patent holder(s)…

137. As noted in the passage above, any rights and their corresponding remedies must be exercised through the courts. It is not an easy task to assert patent rights. Although a patent's validity is "presumed", this presumption falls when evidence to the contrary is led at a trial. This brings me back to my First Report where I noted that in almost every case of alleged infringement, the validity of the patent is attacked as a defence. I advise my clients that asserting their patent rights is an uncertain and risky endeavour. In this sense, I consider patents to be a very different form of property.

138. It cannot be said for any patent that it is unconditionally valid or would never be subject to attack or could never be invalidated. Patent rights are never guaranteed and never for certain. For that reason I caution my clients when asserting their rights outside of the formal litigation processes due to potential liability under the *Trademarks Act* and/or *Competition Act.* In certain circumstances under these statutes, a party may be liable for making false and misleading statements to the public. This can occur where patent holders send cease and desist letters or other notifications to the public with allegations of the infringement or validity of the patent. In cases where the patent is later found invalid, this can attract liability under these statutes.[147] This is another issue where the understanding that patent rights are certain can put the patentee at risk.

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[145] *Comstock Canada v. Electec Ltd.* (1991), 38 CPR (3d) 29, 45 F.T.R. 241 (**R-184**)*; Drexan Energy Systems Inc. v. Canada (Commissioner of Patents),* 2014 FC 887 (**R-368**).

[146] *Forget v. Specialty Tools of Canada Inc.* (1995), 62 CPR (3d) 537 (BCCA) (**R-369**).

[147] *Trademarks Act*, RSC, 1985, c. T-13, s. 7(a) (**R-367**); *Competition Act*, RSC 1985, c C-34, s. 52(1) (**R-154**); *S & S Industries Inc. v. Rowell,* [1966] SCR 419 (**R-370**); *Riello Canada, Inc. v. Lambert* (1986), 9 CPR (3d) 324 (FCTD) (**R-371**).

Void ab Initio

139. As outlined in my First Report, the most common route for the court invalidation of a patent is under section 60 of the *Patent Act.* A declaration of invalidity under this provision means that the patent is *void ab initio* (i.e. it was never valid).[148] Mr. Reddon does not agree, and states that a declaration of invalidity "does not mean that it [a patent] is treated as if it never existed in practice, or that, upon issuance, valuable property rights were not conferred".[149] I disagree with Mr. Reddon. Once a patent is invalid, there are no rights to exploit whatsoever. This does not mean "a patentee cannot obtain damages for infringement", it means they cannot make *any* recovery under the patent, including for the period prior to the invalidation of the patent.

140. Mr. Reddon also notes that after invalidation "patentees may still enjoy rights associated with the grant of the patent, such as payments made pursuant to licences". This statement is misleading. Under Canadian law, where a licenced patent is subsequently held invalid or expires, the licence will not automatically terminate unless expressly outlined in the licence. It is important to point out, however, that any benefit from the patent arises *solely* by virtue of the agreement and not from the patent having once been presumed to be valid.[150] Any licence in this context is thus akin to a licence to "know how" and is also enforceable as between the parties through contract law, not against the world as in the case of a patent.

IV. THE SIGNIFICANCE OF DECISIONS UNDER THE *PM (NOC) REGULATIONS*

141. Beginning at paragraph 20 of his Report, Mr. Reddon accuses me of trying to "downplay the significance of PM (NOC) decisions" and aims to rebut what he perceives to have been my attempt to do so. However, I made no such attempt and suggest that his misperception appears to be the result of his failure to look at the treatment of patent law in the broader historical context beyond PM (NOC) cases.

142. As I noted in my First Report at paragraph 44, PM (NOC) decisions are not the end of the road for patentees and generics alike. A subsequent trial on the merits of the patent's infringement and validity can come to the avail of either side. Prior PM(NOC) proceedings do not create or abolish any rights of action between the parties, nor are they adjudicative or binding on subsequent actions for infringement and validity. In this regard, PM (NOC) proceedings are favourable to innovator litigants as they have "a second chance" through a patent infringement action.

143. The "second chance" resulting from the *PM (NOC) Regulations* is exemplified in the case of *Janssen-Ortho Inc. v. Novopharm Ltd.*[151] The innovator, Janssen-Ortho, was

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[148] *Apotex Inc. v. Warner-Lambert Co. LLC*, 2012 FC 202 (**R-372**). In the very recent judgment in *SNF Inc. v. Ciba Specialty Chemicals Water Treatments Ltd*., 2015 FC 997 (**R-373**) the impeached patent was found to be "*void ab initio*". Gowlings, the Claimant's law firm, acted for Ciba, the patentee; I was trial counsel for SNF.

[149] Reddon Report at para. 29.

[150] *Culzean Inventions Ltd. v. Midwestern Broom Co.* (1984), 82 CPR (2d) 175 (Sask. QB) (**R-374**).

[151] *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FC 1234 (**C-242**), aff'd 2007 FCA 217 (**R-412**).

unsuccessful in its application under the *PM (NOC) Regulations* as it could not show that Novopharm's allegation of obviousness was not justified. An NOC issued to the generic manufacturer, Novopharm, which began marketing its version of the drug. As the application under the *Regulations* did not affect the validity of the patent, Janssen-Ortho brought a subsequent infringement action and was successful in proving infringement and defending the validity of the patent. Janssen-Ortho was granted several remedies, including monetary damages, and Novopharm was enjoined from manufacturing and selling its version of levofloxacin.

144. That said, I did recognize at paragraph 158 and elsewhere in my First Report that although PM (NOC) proceedings were driving our patent law and were far more prevalent than any other type of patent proceeding in the last two decades, they were nonetheless not creating any new ways or raising any new issues to invalidate patents that were not already existing in our patent law when they were brought into being in the mid-1990s.

145. My reason for including a description of the PM (NOC) regime in Canada was because of the important role the regulations play in providing the historical context required to understand how the legislative regime has changed, and why certain issues have gained more notoriety of late. Indeed the portions of my First Report cited by Mr. Reddon highlight that there was neither a need nor motivation for a generic company to challenge a patent under the compulsory licensing regime that preceded the *PM(NOC) Regulations*.[152] This change explains in large part why pharmaceutical patent litigation is so prevalent in Canada today.

146. However, the introduction of the *PM(NOC) Regulations* is not the only reason for the substantial increase in volume of pharmaceutical litigation in Canada over the last two decades. Other reasons that have also contributed to this increased volume include: the strength of the generic industry in Canada arising out of the compulsory drug era, the increased number of pharmaceutical patents and the types of inventions that can be patented, the increased commercial incentives to litigate over very commercially successful drugs, and the ready availability of the Federal Court to hear and decide complex pharmaceutical patent cases.

V. CONCLUSION

147. Having reviewed the expert reports of Professor Siebrasse and Mr. Reddon, my opinions as set out in my First Report, remain unchanged. The grounds for the invalidity of Claimant's patents for the use of *atomoxetine* and *olanzapine* were part of Canadian law long before Claimant filed its patents. Certainly, the jurisprudence has become more refined over time, as new facts and notably new technologies have come before the courts, but the principles underpinning the patent bargain have been there for decades.

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[152] Dimock First Report at para. 39.

148. Professor Siebrasse's expert reports attempt to compartmentalize Canadian patent law, and singularly focus on the compartment labelled "utility." He doubts whether the old English "false promise" cases have been considered under the right doctrinal label in Canada. He disregards how the overbreadth doctrine has held patentees to promises for decades, because he considers this label "quite distinct" from utility, despite the deep historical and conceptual links between the two. He also ignores the interaction of utility with non-obviousness and novelty, and the incentives that patent holders have to make promises of utility to satisfy these other requirements of patentability. Such compartmentalizing misses the real substance of patent law. It does not take account of how different patent rules work together to uphold the patent bargain.

149. Mr. Reddon's report also has a singular focus, which is the pharmaceutical industry. Once again, this misses the broader context of Canadian patent law, which has developed across all fields of technology. The historical roots of the law of utility in Canada do not come from pharmaceutical cases, as there was very little pharmaceutical litigation in Canada before the mid-1990s. Since that time, an explosion in the volume of litigation has occurred, for various structural and market reasons that I have canvassed in my two reports. Those reasons are unrelated to the law of utility. It is largely the arguments and evidence put forward by pharmaceutical patent counsel – for both brands and generic companies – that have drawn greater attention to issues of utility. The courts have been fairly adjudicating the disputes put before them, not "scouring" patents for promises to the detriment of inventors.

150. To summarize my opinion, long before the Claimant filed its patent applications, Canadian patent law required (1) promises of utility in the patent to be met, (2) utility to be established *before* an inventor can claim a monopoly, and (3) where utility is established by a mere prediction, disclosure of support for that prediction in the patent. These principles work together, and with other elements of patent law, to ensure that the bargain between the patentee and the public is upheld.

Signed at: Toronto on: December 4, 2015

[signed]

Ronald E. Dimock

VI. ANNEX A

151. I have provided expert evidence in the following pharmaceutical patent proceedings:

(a) *Eli Lilly Canada Inc., Eli Lilly and Company, Eli Lilly and Company Limited, and Eli Lilly, SA v. Novopharm Limited*, Federal Court File No. T-1048-07. I prepared an affidavit for Gowling Lafleur Henderson LLP (counsel for Eli Lilly), on procedural timing under the *Federal Courts Rules* as it related to the existing proceedings in the patent infringement action concerning *olanzapine*.

(b) *Teva Canada Limited v. Novartis AG*, Federal Court File No. T-2021-10. I prepared an affidavit for Gowling Lafleur Henderson LLP (counsel for Novartis) on the implications of various procedural options in a patent impeachment action related to imatinib mesylate.

(c) *Sanofi-Aventis, Sanofi-Synthelabo Inc., Bristol-Myers Squibb Company and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership v. Apotex Inc. and Apotex Corp.* (U.S.D.C. of Southern New York – 02-CV-2255). My client was the American law firm Cravath, Swaine & Moore LLP (Sanofi's counsel). I provided a draft expert report on the "preclusive effect" of a decision under the *Patented Medicines (Notice of Compliance) Regulations* on later proceedings, but was subsequently instructed to discontinue work on the file as the report would no longer be needed.

(d) *Apotex v. Sanofi-Aventis, Sanofi-Synthelabo Inc., Bristol-Myers Squibb Company and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership* (Ontario Superior Court File No. 07-CV-331399PD2). My clients were the Canadian law firms Lenczner Slaght Royce Smith Griffin LLP (counsel for Bristol-Myers Squibb) and McCarthy Tétrault LLP (counsel for Sanofi), where Mr. Reddon is a partner. I provided an expert report explaining the *Patented Medicines (Notice of Compliance) Regulations* and its procedures and practice in Canada.

(e) *Apotex Pty Ltd. v. Sanofi-Aventis*, NSD1639/2007 New South Wales – Federal Court of Australia. My client was the Australian law firm, Allens Linklater, who were acting for Sanofi. I was asked to set out in an expert report the remedies available under Canadian patent law to a patentee whose Canadian patent is infringed, particularly in the context of the Canadian *clopidogrel* litigation between Sanofi and Apotex.

152. In the context of pharmaceutical litigation, I have acted for both originator and generic pharmaceutical companies in the past. For example, I have acted for at least the following originators on pharmaceutical/biological related matters:

(a) Bayer Inc.: *Bayer Inc. v. Canada (AG) et al*, Federal Court and Federal Court of Appeal file nos. T-1154-97, A-743-98, A-745-98, A-679-98.

(b) Abbott Laboratories, Limited:

(i) *Abbott Laboratories, Limited et al v. Apotex, Inc. et al*, Federal Court file no. T-1395-97;

(ii) *Novartis Pharmaceuticals Canada Inc v. Abbott Laboratories, Limited*, Federal Court and Federal Court of Appeal file nos. T-160-99, A-525-99;

(iii) *Abbott Laboratories, Limited et al v. Apotex, Inc. et al*, Ontario Superior Court of Justice file no. 98-CV-139956;

(iv) *Abbott Laboratories, Limited et al v. Novopharm Ltd*., Federal Court file no. T-1170-98;

(v) *Abbott Laboratories Limited et al v. Pro-Doc Ltée et al*, Federal Court file no. T-1185-98;

(vi) *Abbott Laboratories, Limited et al v. Apotex Inc*., Federal Court and Federal Court of Appeal file nos. T-1652-97, A-636-97, A-646-97;

(vii) *Abbott Laboratories, Limited et al v. Nu-Pharm Inc. et al*, Federal Court and Federal Court of Appeal file nos. T-1653-97, A-637-97, A-647-97; and

(viii) *Abbott Laboratories et al v. Lifescan Canada Ltd. et al*, Federal Court file no. T-2061-99.

(c) Novartis AG, Novartis Pharmaceuticals Canada Inc.: *Apotex Inc. v. Novartis AG et al*, Federal Court file no. T-485-04.

(d) Novartis Vaccines and Diagnostics, Inc.: *GlaxoSmithKline Biologicals SA v. Novartis Vaccines and Diagnostics, Inc*., Federal Court file no. T-2113-06.

(e) Procter & Gamble Pharmaceuticals Canada Inc., The Procter & Gamble Company:

(i) *Procter & Gamble Pharmaceuticals Canada Inc. v. Novopharm Ltd*, Federal Court file no. T-353-96;

(ii) *Procter & Gamble Pharmaceuticals Canada Inc. and The Procter & Gamble Company v. Canada (Minister of Health), Genpharm Inc.*, Federal Court and Federal Court of Appeal file nos. T-155-02, A-135-04;

(iii) *Procter & Gamble Pharmaceuticals Canada Inc. and The Procter & Gamble Company v. Canada (Minister of Health), Genpharm Inc*., Federal Court and Federal Court of Appeal file nos. T-1970-99, A-615-01; and

(iv) *Genpharm Inc. v. Canada (Minister of Health) et al*, Federal Court file no. T-1420-01.

(f) Fournier Pharma Inc., Laboratoires Fournier S.A.:

(i) *Fournier Pharma Inc. and Laboratoires Fournier SA v. Minister of Health and Apotex Inc.*, Federal Court file no. T-907-04;

(ii) *Fournier Pharma Inc. and Laboratoires Fournier SA v. Minister of Health and Apotex Inc.*, Federal Court file no. T-1800-02; and

(iii) *Fournier Pharma Inc. and Fournier Pharma Inc. and Laboratoires Fournier SA v. Minister of Health, Cipher Pharmaceuticals Ltd*, Federal Court file no. T-371-03.

153. I have also acted for at least the following generics on pharmaceutical/biological related matters:

(a) Ranbaxy Laboratories Limited:

(i) *Pfizer Canada Inc. and Warner-Lambert Company, LLC v. The Minister of Health and Ranbaxy Laboratories Limited*, Federal Court and Federal Court of Appeal file nos. T-507-05, A-458-07; and

(ii) Provided strategic advice on other matters handled by my firm.

(b) Sandoz Canada Inc.: Provided strategic advice on matters handled by my firm.

(c) IVAX Pharmaceuticals, Inc. (formerly known as Zenith Goldline Pharmaceuticals, Inc.): *IVAX Pharmaceuticals, Inc. v. Bristol-Myers Squibb Company*, Federal Court file no. T-47-99.

(d) Richter Gedeon Vegyészeti Gyar RT:

(i) *Richter Gedeon Vegyészeti Gyar RT v. Merck & Co Inc. et al*, Federal Court file no. T-2615-92;

(ii) *Richter Gedeon Vegyészeti Gyar RT v. Apotex Inc.*, Federal Court and Federal Court of Appeal file nos. T-2520-93, A-704-02; and

(iii) *Apotex Inc. v. Richter Gedeon Vegyészeti Gyar RT et al*, Ontario Superior Court file no. 06-CV-312174 PD3.

154. I have never acted for the generic pharmaceutical companies, Apotex or Teva, although from 1995 to 1997 I acted for Delmar Chemicals Limited, a supplier at the time of the active pharmaceutical ingredient enalapril maleate to Apotex, in a breach of contract proceeding against Novopharm (now Teva).

155. I have acted against Apotex on the following occasions:

(a) From 1997 to 1998, I acted for Abbott Laboratories, Limited, against Apotex in relation to the drug terazosin (Abbott claimed that Apotex was engaging in "passing off" by marketing its terazosin tablets in the same size, shape and colour as the Abbott tablets).

(b) In 2000, I acted as co-counsel (with Lori Stoltz of Goodman & Carr LLP) for Dr. Nancy F. Olivieri in a moral rights case against Apotex related to protocols and the plaintiff's interpretations and compilations of data with respect to clinical trials and related investigations on the drug deferiprone.

(c) From 2003 to 2004, I acted in a patent infringement proceeding for the patentee, Richter Gedeon Vegyészeti Gyar RT, against Apotex in relation to the drug famotidine.

(d) Between 2002 and 2010, I acted for Fournier Pharma Inc. and Laboratoires Fournier S.A. in various proceedings against Apotex, including an infringement action related to patents and trade-marks, an application by Fournier under the *PM (NOC) Regulations* with respect to the drug fenofibrate, and an application by Apotex for damages under the *PM (NOC) Regulations* with respect to fenofibrate. My firm ceased its representation of Fournier in 2010.

(e) I acted for Novartis AG and Novartis Pharmaceuticals Canada Inc. defending an action brought by Apotex for damages under the Regulations related to the drug terbinafine hydrochloride. The action was discontinued in 2008.

(f) I am currently acting for Richter Gedeon Vegyészeti Gyar RT against Apotex, again concerning famotidine, relating to allegations of inducement to breach a contract.

VII. ANNEX B

1944: *Wandscheer et al v. Sicard Limitee*[153]:

> It is idle to say that utility is an essential quality of an invention. The test of utility of an invention is that it should do what it is intended to do and that it be "practically useful", at the time when the patent is issued, for the purposes indicated by the patentee.
>
> [underlining added]

1959: *Rodi & Wienenberger Aktiengesellschaft v. Metalliflex Ltd.*[154]:

> The answer is to be found in Fox - Canadian Patent Law & Practice - 3rd Ed. … :
>
> > The invention must ... be useful as specified and for the purpose stated in the specifications and claims …
> >
> > [underlining added]
>
> As to the meaning of "utility as specified", …:
>
> > If when used in accordance with the directions contained in the specifications, the promised results are obtained, the invention is useful in the sense in which that term is used in the 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.
> >
> > [underlining added]

1960: Donald Hill in "Claim Inutility"[155]:

> One standard for measuring utility is of course that provided by the patentee himself; if certain results are promised specifically, or may reasonably inferred from the specification, and these are not yielded by practice of the invention, the patent will fail.

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[153] *Wandscheer et al. v. Sicard Ltd.*, (1944), 4 CPR 5 at 16 (Ex Ct) (**C-259**), aff'd [1948] SCR 1 (**R-413**).

[154] *Rodi & Wienenberger Aktiengesellschaft v. Metalliflex Ltd.* (1959), 32 CPR 102 at paras. 16-17 (**R-008**), aff'd (1960), 35 CPR 49 (SCC) (**R-414**).

[155] Donald Hill, "Claim Inutility" (1961), 35 CPR 185 at 186 (**R-160**).

[underlining added]

1961: *New Process Screw Corporation v. P.L. Robertson Mfg. Co. Ltd.*[156]:

> … it was conclusively proved that if dies with the pitch angles referred to in the specification and specified in the claim were used they would not produce the desired results … Thus there was a failure of the promise of the patent which was fatal to it.

[underlining added]

1961: Gordon F. Henderson in the Editorial Note to the *New Process Screw* case[157]:

> … 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 ….

[underlining added]

1969: Harold G. Fox in *Canadian Patent Law and Practice*, 4th Ed[158]:

> 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…

[underlining added]

1978: *Consolboard v. MacMillan Bloedel (Sask) Ltd.* (Federal Court)[159]:

> The law is accurately stated, to my mind, in Fox Canadian Patent Law and Practice (4th ed.) … :
>
> 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

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[156] *New Process Screw* at p. 32 (**R-384**).

[157] *New Process Screw* at p. 34 (**R-384**).

[158] Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969) at p. 150 (**R-163**).

[159] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* (1978), 39 CPR (2d) 191 at para. 216 (**R-359**).

> 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…
>
> [underlining added]

1981: *Consolboard v. MacMillan Bloedel (Sask) Ltd.* (Supreme Court)[160]:

> …There is a helpful discussion in Halsbury's Laws of England … 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".
>
> [underlining added]

1984: *Corning Glass Works v. Canada Wire & Cable Ltd.* [161]:

> *(iii) Inutility ...*
>
> … it was argued that claims 1 and 6 of patent No. 951,555 over-claim because they are not confined to fibres with a sufficiently low level of impurities to make them commercially useful as optical waveguides …
>
> In my view these contentions cannot be sustained. As noted at the outset of this judgment, patent No. 951,555 nowhere promises a particular result to be achieve by the use of the optical waveguides which it describes and claims…
>
> [underlining added]

1991: *TRW Inc. v. Walbar of Canada Inc.*[162]:

> Walbar contends that the want of utility for the production of compressor blades requires the Patent to be declared invalid, and relies on the following view of Thorson P. in *New Process Screw …*:
>
> > 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

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[160] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] SCR 504, 1981 CarswellNat 582 at para. 36 (**R-011**).

[161] *Corning Glass Works v. Canada Wire & Cable Ltd.*(1984), 81 CPR (2d) 39 (FCTD) at p.18 (**R-375**).

[162] *TRW Inc. v. Walbar of Canada Inc.*(1991), 39 CPR (3d) 176 (FCA) at para. 30 (**R-376**).

> produce the desired results…Thus there was a failure of the promise of the patent which was fatal to it.
>
> [underlining added]

1994: *Feherguard Products Ltd v. Rocky's of B.C. Leisure Ltd* [163]:

> In patent law, a patent is "not useful" if 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: *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd. ...*
>
> [underlining added]

1994: *Mobil Oil Corp. v. Hercules Canada Inc.*[164]:

> 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* …) …
>
> The patent specification promises an oriented polypropylene film substrate having enhanced adhesion to a metallized coating. The evidence indicates that this was indeed achieved….Therefore, the patent is not invalid for inutility.
>
> [underlining added]

1995: *Wellcome Foundation Ltd. v. Apotex Inc.* (Federal Court of Appeal)[165]

> Since the utility of a patent must ultimately be judged against its promise the exercise requires that the specification be carefully construed to determine exactly what that promise is.

1995: Donald H. MacOdrum in *Patent Law in Canada: Cases and Materials*[166]:

> In general, the level of utility is not high … However, the situation is different where some specific utility is promised by the disclosure.

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[163] *Feherguard Products Ltd. v. Rocky's of B.C. Leisure Ltd.* (1994), 53 CPR (3d) 417 at para. 23 (FCTD) (**R-360**).

[164] *Mobil Oil Corp. v. Hercules Canada Inc.* (1994), 57 CPR (3d) 488 (FC) at p. 507-508 (**R-165**), rev'd on other (1995), 63 CPR (3d) 473 (FCA) (**R-252**).

[165] *Wellcome Foundation Ltd. v. Apotex Inc.*, [1995] FCJ No 226, 60 CPR (3d) 135 at p. 154 (FCA) (**R-401**).

[166] Donald H. MacOdrum, *Patent Law in Canada: Cases and Materials* (Lang Michener LLP, 1995), p. 5-1 (**R-361**).

[underlining added]

2001: *Almecon Industries Ltd. v. Anchortek Ltd*[167]:

> It ["not useful"] 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 it will do.[168]
>
> [underlining added]

2001: *Goldfarb v. W.L. Gore & Associates, Inc.*[169]:

> The concept of utility is incorporated into the definition of "invention" in section 2 of the Act through the term "useful".
>
> The Supreme Court of Canada in Consolboard … discussed this concept. Dickson J. … explored … the meaning of "not useful" in patent law. He said, quoting from Halsbury's Laws of England … :
>
> 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".
>
> [underlining added]

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[167] *Almecon Industries Ltd. v. Anchortek Ltd.* (2001), 17 CPR (4th) 74, at para. 46 (FCTD) (**C-230**).

[168] Note, the Court at paragraph 45 of its reasons also relied on a lengthy passage from the trial level Federal Court decision in *Consolboard* on the law of utility, including the excerpt from that decision noted above..

[169] *Goldfarb v. W.L. Gore & Associates, Inc.* (2001), 11 CPR (4th) 129, at paras. 108-109 (FCTD) (**R-187**).

VIII. ANNEX C

I have been asked to provide my views on the manner in which utility was disposed of in the cases below for the purposes of the Second Witness Statement of Dr. Marcel Brisebois.

- *Wenzel Downhole Tools Ltd. v. National-Oilwell Canada Ltd.*[170]

Mr. Wenzel and his company ("Wenzel") owned a patent for a piece of equipment intended for use in the drilling of oil and gas wells. Wenzel commenced an infringement action against National-Oilwell, who counterclaimed for a declaration of invalidity of the patent. National-Oilwell alleged that Wenzel's patent was invalid for anticipation, obviousness, and lack of utility.

On the question of utility, the trial judge noted that National-Oilwell had failed to "clearly define the promise of the" patent.[171] While she observed that she would "likely conclude that the Defendants have not met their burden of demonstrating that the '630 Patent lacks utility", she ultimately determined that it was "not necessary to make any definitive finding on this issue."[172] The trial judge clarified again in the conclusion of her analysis that, because of her findings that the patent was anticipated and obvious, she "need not reach any definitive conclusions with respect to the other issues raised by the parties in their pleadings."[173]

The case was appealed to the Federal Court of Appeal, which upheld the trial judge's decision. In so doing, the Court of Appeal noted that the trial judge "held that it was not necessary to discuss the other issues raised in this case, such as lack of utility."[174]

- *Eurocopter v. Bell Helicopter Textron Canada Ltée*[175]

Eurocopter owned a patent for helicopter landing gear, and commenced an infringement action against Bell Helicopter. Bell Helicopter counter-claimed, arguing that Eurocopter's patent was invalid on many grounds, including inutility, insufficient disclosure, and overbreadth.[176]

One aspect of the inutility allegations concerned two claimed embodiments of the invention: one in which a skid has a front cross piece offset forwards (Claim 15), and one in which a skid has a front cross piece offset backwards (Claim 16).[177] The trial judge held that the embodiment in Claim 15 (offset forwards) was useful, but that the embodiment in Claim 16 (offset backwards)

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[170] *Wenzel Downhole Tools Ltd. v. National Oilwell Canada Ltd.*, 2011 FC 1323, aff'd 2012 FCA 333 ("*Wenzel Downhole Tools*") (**R-377**).

[171] *Wenzel Downhole Tools* at para. 211 (**R-377**).

[172] *Wenzel Downhole Tools* at para. 213 (**R-377**).

[173] *Wenzel Downhole Tools* at para. 216 (**R-377**).

[174] *Wenzel Downhole Tools Ltd. v. National Oilwell Canada Ltd.*, 2012 FCA 333 at para. 42 (**R-378**).

[175] *Eurocopter v. Bell Helicopter Textron Canada Ltée*, 2012 FC 113, aff'd 2013 FCA 219 ("*Eurocopter*") (**C-120**).

[176] *Eurocopter* at para. 32 (**C-120**).

[177] *Eurocopter* at para. 334 (**C-120**).

lacked utility.[178] As Claims 1-14 and Claim 16 covered the "offset backwards" embodiment, the trial judge held Claims 1-14 and 16 invalid for lack of utility.[179]

The case was appealed to the Federal Court of Appeal, which upheld the trial judge's decision.[180]

- *Apotex Inc. v. Pfizer Canada Inc.*[181]

Pfizer owned a patent for a solution of latanoprost for the treatment of glaucoma or ocular hypertension, which it had listed on the Patent Register for its product XALATAN®. Pfizer commenced an application under the *PM(NOC) Regulations* for an order prohibiting the Minister of Health from issuing a Notice of Compliance to Apotex for its version of the product.

Apotex alleged that Pfizer's patent was invalid on a number of grounds, including inutility. The trial judge found that Apotex had not justified its allegations of invalidity, and held Pfizer's patent useful on the basis of a sound prediction.[182]

The case was appealed to the Federal Court of Appeal, which overturned the trial judge's decision on sound prediction. The Court of Appeal found that the trial judge had erred in her construction of the claim, and that this error led to her to erroneously conclude that the patent's utility could be soundly predicted.[183] It held that Apotex's allegations of invalidity were justified on this basis, and Pfizer's application for a prohibition order was dismissed.

- *Novartis Pharmaceuticals Canada Inc. v. Teva Canada Limited*[184]

Novartis listed a patent on the Patent Register for its product EXJADE®. The product contained the active ingredient deferasirox which binds to iron and can be used to treat conditions involving an excess of iron. Novartis commenced an application under the *PM(NOC) Regulations* for an order prohibiting the Minister of Health from issuing a Notice of Compliance to Teva for its version of the product.

Teva alleged that Novartis' patent was invalid on a number of grounds, including inutility. The trial judge determined that the patent claimed both novel compounds (claims 5-37), including desafirox, and specific uses of both existing compounds (claims 1-4) and the novel compounds (claims 40-42).[185] He found that while Teva had not justified its allegations of invalidity with respect to the novel compound claims, it had justified its allegations with respect to the use

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[178] *Eurocopter* at para. 360 (**C-120**).

[179] *Eurocopter* at para. 371 (**C-120**).

[180] *Eurocopter v. Bell Helicopter Textron Canada Ltée*, 2013 FCA 219 at para. 194 (**C-304**).

[181] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2010 FC 447, rev'd *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236 (**C-303**).

[182] *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2010 FC 447 at paras. 175, 186 (**C-303**).

[183] *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236 at para. 54 (**R-177**).

[184] *Novartis Pharmaceuticals Canada Inc. v. Teva Canada Limited*, 2015 FC 770 ("*Novartis Pharmaceuticals*") (**C-471**).

[185] *Novartis Pharmaceuticals* at paras. 14 and 33 (**C-471**).

claims.[186] The use claims were neither demonstrated nor soundly predicted at the time the patent was filed.[187] The court ultimately granted Novartis' prohibition order, finding that Teva's allegations of invalidity were unjustified with respect to the compound claims.[188]

The decision was not appealed.

[186] *Novartis Pharmaceuticals* at paras. 3, 39-42 (**C-471**).

[187] *Novartis Pharmaceuticals* at paras. 3, 41 (**C-471**).

[188] *Novartis Pharmaceuticals* at para. 64 (**C-471**).