S.C.C. File No. 35562
(Federal Court of Appeal File No.: A-7-12)

IN THE SUPREME COURT OF CANADA
(ON APPEAL FROM THE FEDERAL COURT OF APPEAL)

B E T W E E N:

APOTEX INC. and APOTEX PHARMACHEM INC.

APPELLANTS
(Appellants/Respondents Below)

- and-

SANOFI-AVENTIS and BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP

RESPONDENTS
(Respondents/Appellants Below)

FACTUM OF THE RESPONDENTS
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(Pursuant to Rule 42 of the Rules of the Supreme Court of Canada)

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PART I – OVERVIEW AND FACTS

A. OVERVIEW

> There is no inherent common law right to a patent. An inventor gets his patent according to the terms of the *Patent Act*, no more and no less.[1]

1. Based on the factual findings of the trial judge, Canadian Patent 1,336,777 (the " '777 Patent") meets all of the statutory requirements set out in the *Patent Act* (the "*Act*"). It is novel, unobvious, sufficiently disclosed and useful.

2. Despite the '777 Patent's compliance with the *Act*, Apotex challenges its validity based on extra-statutory conditions. Apotex's appeal relies upon an approach that measures "utility" not on the basis of the statutory scintilla standard, but against a higher standard based on inferences from certain statements ("promises") in the patent's disclosure. In addition, Apotex's appeal depends upon a further non-statutory requirement: for a "promise" to be soundly predicted, a patent must include information not required by section 34(1),[2] as recently construed by this Court in *Viagra*.[3]

3. In any event, even if Apotex's expanded view of the law and its elevated promise of use in humans were applied, this appeal must be dismissed. The '777 Patent meets both statutory and any extra-statutory requirements, in view of the trial judge's findings that:

(a) The inventors had established that clopidogrel inhibited platelet aggregation well before the filing date (February 8, 1988);[4]

(b) Clopidogrel's advantages had been demonstrated before the filing date;[5]

(c) Use of clopidogrel in humans was soundly predicted by the filing date;[6]

(d) The '777 Patent satisfies the disclosure requirements of section 34(1);[7] and

(e) Clopidogrel is in fact useful in the treatment of human disorders.[8]

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[1] *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 [*Plavix 2008*] ¶12, Respondents' Authorities ("RBOA"), T5, citing *Commissioner of Patents v Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] SCR 49 at 57.
[2] Section 27(3) of the current *Patent Act*, RSC 1985, c P-4.
[3] *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 [*Viagra*] ¶40, Appellants' Authorities ("ABOA"), T87.
[4] Reasons for Judgment of Boivin J [*Trial Decision*] ¶¶396-397, Respondents' Record ("RR"), T1.
[5] Trial Decision ¶¶395, 399.
[6] Trial Decision ¶¶488, 563. The trial judge held that the invention "lacked" utility solely on the basis that the patent failed to meet a "heightened" disclosure requirement, in that it did not include the common general knowledge and all of the experiments conducted by Sanofi (Trial Decision ¶584).
[7] Trial Decision ¶¶303-305.

4. Apotex's appeal first depends upon this Court finding that the Federal Court of Appeal ("FCA") erred by not inferring that the '777 Patent "promised" use in humans. This attack cannot succeed because the promise doctrine is not part of Canadian law. Any attack predicated on statements ("promises") in the disclosure can only be based on section 53 of the *Act.* Further, to the extent that this doctrine exists, only explicit promises of a specific result (i.e., clopidogrel's beneficial properties) should be relevant, rather than applications of that result (i.e., use in humans). In any event, to the extent there are any "promises" in the '777 Patent, these had been demonstrated before the filing date.

5. With respect to Apotex's "heightened" disclosure argument, this is not mandated by the *Act*.[9] Nonetheless, the '777 Patent meets any "heightened" disclosure requirement, as the '777 Patent sets out both a factual basis and line of reasoning which, when read with the common general knowledge, allows clopidogrel's use in humans to be soundly predicted.[10]

6. For obviousness, the trial judge and this Court in 2008 held that the inventive concept of the '777 Patent was "a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity than the other compounds of the '875 patent and the methods for obtaining that compound."[11] These beneficial properties had been demonstrated before the filing date.[12]

7. However, the trial judge did not apply the correct legal criteria as set out by this Court. Rather than asking, without knowledge of the invention in question, whether the inventive concept was obvious, the trial judge instead asked simply whether the enantiomers could be separated.[13] This legal error was corrected by the FCA. As the material facts found by the trial judge are not different from those before this Court in 2008, this Court's conclusion with respect to obviousness should be the same.[14]

8. Apotex accuses Sanofi and the FCA of minimizing the required level of utility and inflating the inventive concept.[15] In reality, Apotex has taken an inconsistent approach. For

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[8] Trial Decision ¶1.
[9] *Viagra*, *supra* note 3 ¶40; *Consolboard Inc v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504 [*Consolboard*] at 521, RBOA, T16.
[10] '777 Patent, pp 1(25-28), 21(1-6), RR, T4.
[11] Trial Decision ¶653; *Plavix 2008*, *supra* note 1 ¶78.
[12] Trial Decision ¶¶395, 399.
[13] Trial Decision ¶663.
[14] Reasons for Judgment of the FCA [Appeal Decision] ¶¶77-82, Appellants' Record ("AR"), T2.
[15] Appellants' factum ¶¶5-6, 60.

utility, Apotex inflates the invention to include a "promised" use in humans, yet for obviousness it minimizes the inventive concept to mere separation of the enantiomers.[16] In contrast, Sanofi's position is consistent with the FCA's, who based its conclusions with respect to utility/promise and obviousness on a single inventive premise (clopidogrel's beneficial properties).[17]

9. Finally, there is no basis to interfere with the factual findings and determinations by both lower courts that Apotex's defences to infringement were not established.

B. FACTS

i. Background

10. Clopidogrel, the subject of the '777 Patent, belongs to a class of compounds known as thienopyridines. In 1978, a thienopyridine called ticlopidine was approved to treat disorders in humans by inhibiting platelet aggregation. However, ticlopidine had a poor side-effect profile.[18]

11. In an attempt to find an improved platelet aggregation inhibitor, Sanofi developed a class of thienopyridine derivatives. These were the subject of the prior art "genus" patent known as the '875 Patent.[19] As described by this Court in 2008, the '875 Patent:

> … disclosed a genus or class of compounds useful in inhibiting platelet aggregation activity in the blood which is important in treating coronary artery, peripheral vascular and cerebral vascular diseases. This genus patent discloses over 250,000 possible different compounds useful for this purpose.[20]

12. Thus, the '875 Patent taught that a genus of thienopyridine derivatives were inhibitors of platelet aggregation. As a result of this activity, this patent taught that these compounds were "very useful in human and veterinary therapeutic applications".[21]

13. One of the thienopyridine compounds disclosed in the '875 Patent is a racemate (PCR 4099). A racemate is a mixture of structurally different compounds called enantiomers or optical isomers: a dextro-rotatory isomer and a levo-rotatory isomer.[22]

14. Sanofi further developed the racemate which proceeded to human clinical trials, which

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[16] Appellants' factum ¶¶65-66, 85.
[17] Appeal Decision, *supra* note 14 ¶¶51-53, 70, 74, 79.
[18] Trial Decision ¶¶410-412, 442, 497, 542, 544, 553.
[19] '875 Patent, RR, T5; Trial Decision ¶429.
[20] *Plavix 2008, supra* note 1 ¶3. See also Trial Decision ¶¶166, 168.
[21] '875 Patent, p 15(1-5) (p 12 of English translation); Trial Decision ¶168.
[22] Trial Decision ¶495; *Plavix 2008, supra* note 1 ¶4;

showed that the racemate was, in fact, useful to inhibit platelet aggregation in humans.[23] Many years into the development of the racemate, the inventors of the '777 Patent separated the racemate into its isomers and tested them. It was discovered unexpectedly that the dextro-rotatory isomer (now known as clopidogrel) had all the platelet aggregation inhibiting activity, and was less toxic and better tolerated than both the racemate and the levo-rotatory isomer.[24]

15. These advantages were important as the work done with the racemate had revealed significant toxicity and tolerability problems. Clopidogrel showed less acute toxicity in rats than the racemate and the levo-rotatory isomer. Further, in long-term baboon toxicity studies, convulsions occurred with the racemate and the levo-rotatory isomer (but not clopidogrel).[25]

16. Based on these results, Sanofi stopped the development of the racemate and moved forward with clopidogrel.[26] Prior to the filing date, the clopidogrel work had advanced to human clinical trials which had shown positive results.[27]

ii. The '777 Patent

17. The '777 Patent claims clopidogrel, salts of clopidogrel, processes to make clopidogrel and pharmaceutical compositions containing clopidogrel. There are no use claims.[28]

18. The patent discloses that "only the dextro-rotatory enantiomer I_d exhibits a platelet aggregation inhibiting activity, the levo-rotatory enantiomer I_l being inactive. Moreover, the inactive levo-rotatory enantiomer I_l is the less well tolerated of the two enantiomers".[29]

19. In addition to teaching how to make clopidogrel and its salts, the patent also discloses the results of pharmacological studies on clopidogrel, the levo-rotatory isomer and the racemate.[30]

20. The first study measured the ability of these compounds to inhibit the aggregation of platelets. This method had been previously used in the development of the drug ticlopidine.[31]

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[23] Trial Decision ¶320; "Investigational Brochure of PCR 4099" (May 28, 1986), pp 82-97, RR, T14.
[24] Trial decision ¶¶392-399.
[25] Trial decision ¶¶392-395, 437, 449, 451-452.
[26] Trial Decision ¶458; «PCR 4099 développement» (16 avril 1987), RR, T15 & 19.
[27] Trial Decision ¶458; Hirsh Cross, pp 701(5) - 703(20), RR, T25; Shebuski Report ¶¶118-120, AR, T10; Maffrand Direct, pp 4837(24) – 4840(3), 4847(20) – 4850(25), 4880(10) – 4881(7), AR, T28; «Stratégie du SR 25990» (1 fev 1988), RR, T20; «Résumé de la réunion stratégie du SR 25990» (1 fev 1988), RR, T21.
[28] Trial Decision ¶¶95, 182; '777 Patent, pp 22-23, RR, T4.
[29] '777 Patent, p 1(25-28), RR, T4.
[30] '777 Patent, pp 11-19, RR, T4; Hirsh Cross, p 658(12-22), RR, T25; Shebuski Report ¶¶74-76, AR, T10; Vogel (1997) (Ex 9 to Shebuski Report), AR, T10-9.
[31] Trial Decision ¶544; Thébault (1975) (Ex 23 to Shebuski Report), AR, T10-23; Shebuski Report ¶113, AR, T10; Defreyn (1989) (Ex 15 to Shebuski Report), AR, T10-15; Saltiel (1987) (Ex 25 to Levy Report), AR, T14-25.

The results of this study showed that clopidogrel was active at inhibiting platelet aggregation, while the levo-rotatory isomer was inactive.[32]

21. The second study measured the ability of clopidogrel, the levo-rotatory isomer and the racemate to inhibit venous thrombosis in an *in vivo* rat model. This model was reported in a prior art publication by Kumada, which showed that ticlopidine was active in this model.[33] The results of this study showed that clopidogrel reduced the size of the thrombus, whereas the levo-rotatory isomer was inactive.[34]

22. The third study was an acute toxicity study in rats. The results of this study showed that clopidogrel was less toxic than the racemate and the levo-rotatory isomer.[35]

23. As summarized on page 12 of the '777 Patent:

> …. the results of this study … demonstrates another advantage of the invention, namely that the salts of the dextro-rotatory isomer [clopidogrel] have a better therapeutic index than the salt of the racemic mixture; in fact, the levo-rotatory isomer exhibits almost no platelet aggregation inhibiting activity and its toxicity is markedly higher than that of its dextro-rotatory homologue.[36]

24. The term "therapeutic index" refers to the difference between the dose at which the compound exhibits activity and the dose at which the compound exhibits toxic effects.[37] As explained by Dr. Sanders, Apotex's toxicology expert, one does not use humans to determine therapeutic index:[38]

> Q. So it is appropriate to determine therapeutic index using animals?
> A. Sure.
>
> Q. One doesn't use humans for that?
> A. That's correct.[39]

25. Apotex's expert Dr. Hirsh agreed that the results of the studies in the '777 Patent showed that clopidogrel had a better therapeutic index than the racemate or the levo-rotatory isomer.[40]

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[32] Trial Decision ¶¶90, 460; '777 Patent, pp 12-16, RR, T4.
[33] Shebuski Report ¶113, AR, T10; Kumada (1980) (Ex 8 to Shebuski Report), AR, T10-8; Trial Decision ¶581.
[34] Trial Decision ¶¶90, 460, 463-465; '777 Patent, pp 17-18, RR, T4.
[35] Trial Decision ¶¶90, 385; '777 Patent, pp 18-19, RR, T4.
[36] '777 Patent, p 12(1-6), RR, T4. See also *Plavix 2008*, *supra* note 1 ¶6.
[37] Rodricks Report ¶¶26, 35(b), 82-91, AR, T13.
[38] Thus, Apotex's argument that the term "therapeutic" refers to use in humans is incorrect: see Appellants' factum ¶¶4-6, 22, 64, 67.
[39] Sanders Cross, p 941(11-16), RR, T26. See also pp 955(5-20), 956(7) to 957(1).
[40] Hirsh Cross, pp 657(6) – 658(8), RR, T25.

iii. 2008 SCC Decision

26. The validity of the '777 Patent was before this Court previously, wherein it was held that Apotex's allegations of anticipation, obviousness and double patenting were unjustified.[41] With respect to obviousness, this Court looked to both the claims and the disclosure to find that the inventive concept was:

> … a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity than the other compounds of the '875 patent and the methods for obtaining that compound.[42]

27. In coming to its conclusion that the claims of the '777 Patent were not obvious, the key findings of fact relied upon by this Court were:

(a) Nothing in the '875 patent or common general knowledge provided a specific motivation for the skilled person to pursue the '777 invention;[43]

(b) The skilled person would not know the beneficial properties of clopidogrel over the racemate and the levo-rotatory isomer until it had separated the enantiomers and tested them;[44] and

(c) Before Sanofi decided to separate the racemate and to test the enantiomers, it had spent millions of dollars and several years developing the racemate up to the point of clinical trials.[45]

iv. The Trial Decision

(a) The Invention of the '777 Patent

28. The trial judge adopted the inventive concept – clopidogrel and its beneficial properties – as set out by this Court.[46] These properties were found by the trial judge to be demonstrated by Sanofi before the filing date of the '777 Patent.[47] Further, the trial judge found that the inventors had made their invention as of the date that these properties had been shown (i.e., November 6, 1987).[48] In other words, the "gravamen" of the invention – clopidogrel and its beneficial properties over the racemate and the levo-rotatory isomer – had been arrived at well before the

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[41] *Plavix 2008, supra* note 1.
[42] *Plavix 2008, supra* note 1 ¶78.
[43] *Plavix 2008, supra* note 1 ¶¶79, 90.
[44] *Plavix 2008, supra* note 1 ¶84.
[45] *Plavix 2008, supra* note 1 ¶91.
[46] Trial Decision ¶133.
[47] Trial Decision ¶¶392, 393, 395, 399.
[48] Trial Decision ¶¶599-600.

February 1988 filing date of the Canadian patent and before any testing had been done in humans. In this regard, the trial judge also rejected Apotex's insufficiency attack.[49]

(b) Utility and the "Promise"

29. Notwithstanding the above findings and even though these advantages are explicitly set out in the patent, the trial judge held that it "promised" a higher utility (i.e., use in humans). This was despite the fact that he found that the patent did not "guarantee" use in humans.[50] The trial judge further held that, even though Sanofi knew that clopidogrel was active in humans, this was not sufficient information "to be conclusive" of the "promised" use in humans.[51]

30. Consequently, the trial judge dealt with the patent as if the invention's "promised" utility was based upon a sound prediction. In this regard, the trial judge found that, based on the work done by Sanofi and in view of the common general knowledge, the inventors had a factual basis and a line of reasoning to predict that clopidogrel would be useful to treat humans.[52]

31. Despite these findings, the trial judge then held that the invention of the '777 Patent lacked utility since the patentee had not satisfied a "heightened" disclosure requirement,[53] even though the '777 Patent:

(a) states that clopidogrel has all of the activity of inhibiting platelet aggregation, and is less toxic and better tolerated than the levo-rotatory isomer and the racemate;

(b) sets out data from animal experiments which demonstrate the above properties; and

(c) includes a specific reference to the prior art '875 Patent, which taught that the genus of thienopyridine derivatives is useful in both human and veterinary therapeutic applications.[54]

32. In doing so, the trial judge made multiple errors: (1) applying a promised utility beyond that of the inventive concept (i.e., beyond the advantages); (2) requiring the patentee to disclose information not required by the *Act*; (3) confusing disclosure of the factual basis and proof of those facts; and (4) failing to consider whether the information disclosed in the '777 Patent, with the common general knowledge, was sufficient to predict clopidogrel's use in humans.

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[49] Trial Decision ¶¶303-305.
[50] Trial Decision ¶¶123, 131-132.
[51] Trial Decision ¶348.
[52] Trial Decision ¶¶488, 563.
[53] *Viagra*, *supra* note 3 ¶37. See also *Eli Lilly Canada Inc v Apotex Inc*, 2009 FCA 97 [*Raloxifene FCA*] ¶¶14-15, RBOA, T20; *Eli Lilly Canada Inc v Novopharm Ltd*, 2011 FCA 220 [*Atomoxetine FCA*] ¶47, ABOA, T40.
[54] '777 Patent, p 1(16-17, 25-28), 11-20, RR, T4; Trial Decision ¶581.

33. With respect to the first error, the invention of the '777 Patent is clopidogrel's beneficial properties, not its use in humans. Indeed, the fact that inhibitors of platelet aggregation (e.g., ticlopidine) could be used to treat certain disorders, was part of the common general knowledge.[55]

34. The trial judge's other errors flow from his view that the inventors were required to expressly set out in the patent the common general knowledge of the skilled person and all of the work that Sanofi had done.[56] The trial judge's approach violates the settled approach to patent construction that a patent is to be viewed with the knowledge of the person skilled in the art.[57] In addition, it is also contrary to this Court's teaching that there is no statutory requirement to "prove" utility in a patent.[58]

35. The trial judge thus failed to address whether the '777 Patent contained sufficient information to comply with a "heightened" disclosure requirement. Further, he confused the inclusion of a factual basis with proof of a factual basis.

36. This error is apparent from the testimony of Apotex's only expert in clinical medicine, haematology and thrombosis, Dr. Hirsh, who agreed that it was a reasonable hypothesis that clopidogrel would work in humans, based on the study results disclosed in the '777 Patent.[59]

(c) Obviousness

37. Similar to his first error with respect to utility, the trial judge also lost sight of the invention of the '777 Patent when applying the "obvious to try" test. Rather than asking whether the inventive concept of the Patent (clopidogrel and its beneficial properties) was obvious, he instead asked simply whether the enantiomers could be separated.[60] This legal error is apparent as the trial judge's material factual findings were the same as those before this Court in 2008.[61]

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[55] Trial Decision ¶¶168, 171, 173, 442, 553, 557, 559, 561, 608; Hirsh Cross, pp 514(21) – 515(22), 531(9) – 534(23), 546(16) – 548(20), 620(24) – 621(9), 622(18-24), AR, T25; Ch 81 in Colman (1987), AR, T8; Ch 47 in Barnett (1986), RR, T9; Picard-Fraire (1983), RR, T10; Panak (1984), RR, T11; Levy Cross, pp 2211(13) – 2213(3), RR, T27; DiMinno (1983) (Ex 23 to Levy Report), AR, T14-23; Saltiel (1987) (Ex 25 to Levy Report), AR, T14-25; Shebuski Report ¶¶113-114, AR, T10; Thébault (1975) (Ex 23 to Shebuski Report), AR, T10-23; Defreyn (1989) (Ex 15 to Shebuski Report), AR, T10-15.
[56] Trial Decision ¶571.
[57] *Consolboard*, *supra* note 9 at 522-525; *Free World Trust v Électro Santé Inc*, 2000 SCC 66 [*Free World Trust*] ¶31(e)(i), RBOA, T25; *Whirlpool Corp v Camco Inc*, 2000 SCC 67 [*Whirlpool*] ¶48, ABOA, T92.
[58] *Viagra*, *supra* note 3 ¶40; *Consolboard*, *supra* note 9 at 521.
[59] Hirsh Cross, pp 661(21) – 662(7), AR, T25.
[60] Trial Decision ¶663.
[61] Appeal Decision ¶81.

(d) Apotex's Limitations Period and US Settlement Agreement Defences

38. At trial, Apotex did not deny that it had infringed the '777 Patent. Notwithstanding the Prohibition Order upheld by this Court, Apotex imported bulk clopidogrel into Canada, manufactured tablets, and sold extensive quantities to the US and numerous other countries.[62] However, Apotex asserted that, with respect to some of its sales, Sanofi's infringement action was statute-barred and precluded by settlement of aspects of the US litigation.

39. As a first point, significant manufacture, use and sale took place within the two-year limitation period that Apotex alleges applies.[63] Thus, Apotex's request that the action be wholly dismissed as statute-barred cannot be granted.[64]

40. Regardless, the trial judge found that none of Sanofi's claims were statute-barred as the six-year limitation period under the *Federal Courts Act* was applicable as opposed to the two-year period under the Ontario *Limitations Act, 2002*. In reaching this conclusion, the trial judge heard extensive evidence about Apotex's global clopidogrel enterprise and made numerous factual findings which remain unchallenged. In particular, the trial judge held that Sanofi's cause of action did not arise solely within the province of Ontario. In fact, following the jurisprudence of this Court in *Monsanto Canada Inc v. Schmeiser*,[65] the trial judge held that Apotex's act of importation was sufficient to make this determination.[66]

41. The trial judge also rejected Apotex's argument that settlement of US litigation relating to a US patent precluded the damages claim for infringement of the '777 Patent. The trial judge found that it was unambiguous on the face of the US Settlement Agreements that Apotex was not absolved from liability under the '777 Patent. In this regard, he noted that there was no mention of the '777 Patent or the Canadian market in the US Settlement Agreements and declined Apotex's request to infer such a term.[67]

42. As such, the trial judge correctly held that Apotex's limitations period and US Settlement Agreement defences failed.

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[62] Trial Decision ¶¶202, 204, 205, 207, 210.
[63] Trial Decision ¶202; Clopidogrel International Billing Documents (Launch through 2011), RR, T33.
[64] See Appellants' factum ¶127.
[65] 2004 SCC 34 [*Schmeiser*] ¶44, RBOA, T36.
[66] Trial Decision ¶¶203, 251, 253-258.
[67] Trial Decision ¶¶279-281.

v. The Appeal Decision

43. In overturning the trial decision on the validity of the '777 Patent, the FCA identified the trial judge's failure to focus on the Patent's claimed invention when determining whether the invention was useful or was obvious.

44. The FCA reviewed the trial judge's determination that the '777 Patent "promised" use in humans. It applied the guidance previously set out in its *Olanzapine FCA* decision[68] that unless a patent contains an "explicit promise of a specific result", only a scintilla of utility is required.[69]

45. In its discussion of the "promise", the majority of the FCA relied upon its previous decisions and stated that: "[a]n inventor whose invention is described in a patent which would otherwise be valid can nonetheless promise more for his invention than required by the *Act* so as to render his patent invalid."[70]

46. While not necessary for this Court to decide the appeal in Sanofi's favour, it is submitted that this "promise doctrine" is not part of Canadian law as it can be found nowhere in the *Act* and is inconsistent with the legislative history of the statute. Adding such an extra-statutory requirement, particularly as it has been expanded by the courts, fundamentally and unfairly alters the bargain struck by the *Act* between patentees and the public.

47. Even though the '777 Patent was put to the enhanced "promise" standard, the FCA corrected the trial judge's construction of the promised utility (a question of law) and concluded on a purposive construction that the trial judge erred in finding a promise of use in humans where the Patent contained no such language (the Patent does not even use the word humans).[71]

48. Thus, based on the promise as construed by the FCA (clopidogrel's beneficial properties) and the fact that the trial judge found that the inventors had demonstrated clopidogrel's beneficial properties, the utility requirement had been met. As such, the FCA did not have to consider whether a "heightened" disclosure requirement was met.[72]

49. With respect to obviousness, the FCA corrected a fundamental error in the trial judge's approach. Specifically, the trial judge had failed to ask the proper question when considering

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[68] *Eli Lilly Canada Inc v Novopharm Ltd*, 2010 FCA 197 [*Olanzapine FCA*] ¶76, ABOA, T43.
[69] Appeal Decision ¶48.
[70] Appeal Decision ¶54.
[71] Appeal Decision ¶¶64-66, 71.
[72] *Viagra, supra* note 3 ¶43.

whether the invention was "obvious to try". Rather than asking whether the inventive concept (clopidogrel and its beneficial properties) was obvious, he asked whether the skilled person could separate the enantiomers.[73]

50. Further, the FCA noted the trial judge's key finding – consistent with the facts relied upon by this Court in 2008 – that nothing in the prior art directly or indirectly pointed to the racemate.[74] Thus, focusing the obviousness inquiry on whether the racemate could be separated into its isomers is contrary to this Court's holding that the question of obviousness is to be approached "without knowledge of the invention" (i.e., without the benefit of hindsight).[75]

51. The FCA took an approach consistent with this Court and asked, without knowledge of the invention, whether clopidogrel and its beneficial properties would be obvious. Once the error in the trial judge's approach to obviousness was corrected and given that the material facts were the same, the FCA held that there was no basis to reach a conclusion different from the one reached by this Court in 2008.[76]

52. Finally, given the factual findings made by the trial judge relevant to Apotex's limitation period and US Settlement Agreement defences, the FCA rejected Apotex's arguments that the decision of the trial judge ought to be varied.[77]

PART II – ISSUES

53. The issues that need to be addressed are the following:

(a) Does the "promise" doctrine exist in Canadian law?

(b) If there is such a doctrine, how should it be applied?

(c) Is there a "heightened" disclosure requirement if utility is based on a sound prediction?

(d) Is there any reason for this Court to come to a different conclusion than the FCA with respect to obviousness and Apotex's infringement defences?

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[73] Appeal Decision ¶¶75, 78.
[74] Appeal Decision ¶77; Trial Decision ¶612, 614, 645-647, 655; *Plavix 2008, supra* note 1 ¶79.
[75] *Plavix 2008, supra* note 1 ¶67.
[76] Appeal Decision ¶¶78, 81.
[77] Appeal Decision ¶¶109-113.

PART III – ARGUMENT

A. UTILITY VS PROMISE

54. The promise doctrine as applied by both lower Courts is based on the premise that there can be two levels of utility that may apply to a patent. In the Appeal Decision, the FCA stated:

> An inventor whose invention is described in a patent which would otherwise be valid can nonetheless promise **more** for his invention **than required by the *Act*** so as to render his patent invalid.…[78] (emphasis added)

55. The *Act* only requires that an invention be "useful" (i.e., a scintilla of utility).[79] In other words, this Court has stated that a claimed invention will lack utility only where it is "devoid" of utility.[80] Thus as long as there is some utility, such as having biological activity in an animal model or a Petri dish, then the invention meets the statutory requirement.

56. There is no doubt that the claimed invention of the '777 Patent meets the requirement that an invention be useful. As found by the trial judge, Sanofi had demonstrated that clopidogrel inhibited platelet aggregation before the filing date.[81]

57. The second level of utility (the "promise" doctrine) applied by the lower courts now measures utility, not as against the scintilla standard or even against the claimed invention, but based on "promises" (statements) made in the disclosure.

58. Thus, the within appeal does not turn on whether the claimed invention of the '777 Patent meets the requirement that an invention be "useful". Instead, the issue before this Court is whether an undefined extra-statutory requirement – the "promise" doctrine – should be imposed by the courts when the patent satisfies all statutory criteria for patentability.

B. DOES THE PROMISE DOCTRINE EXIST IN CANADIAN LAW?

i. What is the "promise" doctrine?

59. As set out in the quotation from the Appeal Decision above, in recent years, the Federal Courts have imposed an additional requirement on the patentee named "the promise of the

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[78] Appeal Decision ¶54. The FCA's citation to this Court's decision in *Free World Trust, supra* note 57, is misplaced. This Court underscored the primacy of the claims language and referred to the consequences of drafting a patent's claims too broadly or too narrowly, rather than to statements made in the patent's disclosure.
[79] *Patent Act*, RSC 1985, c P-4, s 2 "invention"; Appeal Decision ¶49; *Olanzapine FCA, supra* note 68 ¶76.
[80] *Monsanto Company v. Commissioner of Patents*, [1979] 2 SCR 1108 at 1117, RBOA, T37; *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 [*AZT*] ¶62, ABOA, T9; *Plavix 2008, supra* note 1 ¶105.
[81] Trial Decision ¶¶396, 398.

patent".[82] Pursuant to this standard, not only must a claimed invention meet the condition precedent of being "useful" under section 2, but it is also judged against statements made in the disclosure of the patent regardless of whether a given statement is material to the claims.[83]

60. In addition, the Federal Courts do not ask whether any "promise" made is false in fact. Instead, they inquire as to whether the "promise" was demonstrated or soundly predicted by the Canadian filing date. If the "promise" is based upon a sound prediction, then the Federal Courts have also imposed a non-statutory "heightened" disclosure requirement.

61. The "promise" doctrine has been described by a leading patent law academic as:

> … a claimed invention may have sufficient utility to support a patent and yet be held invalid for lack of utility because the disclosure is construed to promise a greater degree of utility – in some cases a much greater degree – than the required minimum.
>
> … Consequently, construing the promise of the patent, a practice that was almost unheard of less than 10 years ago, now typically occupies a distinct section of a judicial opinion.[84]

62. The Intellectual Property Institute of Canada has acknowledged that the "promise" standard now imposes a higher threshold for the utility requirement than other jurisdictions:

> In Canada, the required utility is normally determined by "the promise of the patent." That is, the patent itself is examined to see what utility the inventor has promised, and the patent will be invalid if that utility is not established. This makes utility more difficult to establish in Canada than in the US or Europe.[85]

63. These recent changes in the law have resulted in patents being invalidated for lack of utility when, in fact, the inventions are useful.[86] This is especially problematic, as the patents now being litigated were drafted, filed and examined at a time when there simply was no such thing as the "promise of the patent".

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[82] N Siebrasse "The False Doctrine of False Promise" (2013) 29 CIPR 3 at p 7, RBOA, T61.
[83] Occasionally, the term "promise" has been used with respect to statements in the claims as to the utility (see e.g., *Fournier Pharma Inc v Canada (Health)*, 2012 FC 741 [*Fournier*] ¶¶126-127, RBOA, T24) – this is no more than the statutory standard of "useful" being applied. However, the problematic nature of the promise doctrine occurs when the patent is judged against statements made in the disclosure: see Siebrasse "The False Doctrine of False Promise", *supra* note 82 at pp 4, 6, 35.
[84] Siebrasse, "The False Doctrine of False Promise", *supra* note 82 at pp 4-5.
[85] IPIC (2012) "A Comparative Overview of Canadian, US and European Pharmaceutical Patent Systems" at p 16, RBOA, T58.
[86] See e.g., *Raloxifene FCA*, *supra* note 53; *Atomoxetine FCA*, *supra* note 53; *Apotex Inc v Pfizer Canada Inc*, 2011 FCA 236 [*Latanoprost*], RBOA, T4; *Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288 [*Olanzapine 2*], RBOA, T22, aff'd 2012 FCA 232; *AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638 [*Esomeprazole*], RBOA, T7. See also Siebrasse, "The False Doctrine of False Promise" *supra* note 82 at pp 33-34.

64. As held by this Court, patent law is statutory.[87] Thus, a threshold question that this Court must address is whether this judicially-created "promise" doctrine exists under the *Act*. In answering this question, it is helpful to describe the UK origins of the doctrine and how it has been recently applied and expanded by the lower courts.

ii. What is the origin of the "promise" doctrine?

65. Most often cited for the proposition that the "promise" doctrine is part of Canadian law is the following quotation from this Court's decision in *Consolboard*:[88]

> There is a helpful discussion in Halsbury's Laws of England, (3rd ed.), vol. 29, at p. 59, on the meaning of "not useful" in patent law. It means "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do".[89]

66. However, it is problematic to rely on *Consolboard* as authority for the doctrine.[90] In particular, the issue in *Consolboard* was whether the *Act* requires a "distinct indication of the real utility of the invention in question?"[91] Justice Dickson (as he then was) answered this question in the negative holding that an inventor is not obligated "in his disclosure or claims to describe in what respect the invention is new or in what way it is useful."[92]

67. Most importantly, the quotation from *Consolboard* relies on pre-1977 UK law. Prior to 1977, UK law – unlike Canadian law – had a statutory foundation for a "false promise" doctrine. In particular, the pre-1977 UK Patents Acts included a ground of invalidity that was separate from the utility requirement, namely, "that the patent was obtained on a false suggestion or representation".[93]

68. However, the UK "false promise" doctrine did not extend to every statement in the patent's disclosure with respect to a use, purpose, application or result. For example, courts distinguished between a promise of a specific result and applications of that result:

> … there may be cases in which the result which the patentee claims to have produced can in fact be produced, but the patentee has gone on to detail the useful purposes to

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[87] *Plavix 2008, supra* note 1 ¶12. See also Siebrasse, "The False Doctrine of False Promise", *supra* note 82 at p 7.
[88] See Apotex's memorandum of fact and law ¶40.
[89] *Consolboard, supra* note 9 at 525.
[90] Siebrasse, "The False Doctrine of False Promise", *supra* note 82 at pp 22-24, 26.
[91] *Consolboard, supra* note 9 at 525.
[92] *Consolboard, supra* note 9 at 526. Upheld by this Court in *Viagra, supra* note 3 ¶40.
[93] *Patents Act, 1949*, 12, 13 & 14 Geo. 6, c. 87 [*UK Patents Act, 1949*], s 32(1)(g) & (j), RBOA, T69.

> which such result can be applied, and that in fact the result produced cannot be applied to one or more of such purposes. In such a case I do not think the patent is necessarily void, provided there are purposes for which the result is useful.[94]

69. The "false promise" ground of invalidity was further circumscribed by the fact that a patent would not be invalidated for lack of utility if it is of *some* use to the public, provided that the "false promise" was not "material and … coterminous with a relevant area covered by the claims."[95]

70. Further, the UK "false promise" ground of invalidity inquired as to whether a statement in the patent was true in fact (i.e., not whether the statement was "demonstrated" or "soundly predicted" before the filing date). Thus, this question was determined based on evidence available up until the hearing date, whereas Canadian patents are now being assessed on whether the promised utility had been demonstrated or soundly predicted by the filing date.

71. Since 1977, the UK *Patents Act* has not contained this statutory ground of invalidity. Thus, patents can no longer be held invalid on the basis of a false promise or suggestion.[96] UK patents however still must have some utility, which is measured on whether it is "plausible" that the invention is capable of industrial application, a very low threshold.[97]

iii. Has the application of the promise doctrine gone well beyond its UK origins?

72. Despite the "false promise" doctrine's origin, current Canadian patent law has gone well beyond its UK roots. Under pre-1977 UK law, for a false promise or representation to invalidate a claim, the promise had to be (1) material; (2) coterminous with the claim in question; and (3) false, in fact. In addition, UK law distinguished between promised results and applications of those results.

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[94] *Re Alsop's Patent* (1907), 24 RPC 733 (Ch) [*Alsop's Patent*] at 753, RBOA, T50. See also HG Fox, *Canadian Patent Law and Practice*, 4th ed (Toronto: Carswell, 1969) at pp 152-154, RBOA, T57. Further, cases decided prior to the enactment of the *Patent and Designs Act, 1919*, 9 & 10 Geo 5, c 80 must be approached with caution since patents were not yet evaluated on a claim-by-claim basis. Thus, any "false suggestion or representation" would invalidate every claim, even if the statements did not relate to every claim: see Fox, *infra*, at pp 154-155.

[95] *American Cyanamid v Ethicon Limited*, [1979] RPC 215 (Ch D) [*American Cyanamid*] at 261, RBOA, T2. This case was decided under the pre-1977 UK statute. See also EM Daniel, *A Complete Treatise upon the New Law of Patents, Designs and Trade Marks* (London: Stevens & Haynes, 1884) at pp 27 & 28, RBOA, T56; Siebrasse, *supra* note 82 at pp 19-20.

[96] *Pharmacia Corp. v. Merck & Co. Inc.*, [2001] EWCA Civ 1610 ¶54, RBOA, T48. *Patents Act 1977*, c 37, ss 1, 4, 72, RBOA, T70; Siebrasse, "The False Doctrine of False Promise", *supra* note 82 at pp 5, 20.

[97] *Human Genome Sciences, Inc v Eli Lilly & Co*, [2011] UKSC 51 [*HGS v Lilly*] ¶107(viii), RBOA, T26; Siebrasse, "The False Doctrine of False Promise", *supra* note 82 at p 42.

73. With respect to the requirement of materiality, if the unexpected advantages are the "gravamen" of the invention, then they would be material. However, the Federal Courts have not considered the condition of materiality when assessing whether a patent is invalid for lack of demonstrated or soundly predicted "promised" utility.[98] In other words, even though a patent may meet all of the statutory requirements (i.e., novelty, inventiveness and usefulness), the Federal Courts may still hold a patent invalid.

74. A second issue is that, contrary to settled law that one does not read limitations into the claims from the disclosure,[99] in some decisions the Federal Courts have focused on the disclosure, rather than the claims, in assessing the utility requirement.[100] This is inconsistent with sections 27(5) and 58 of the *Act* and this Court's recent holding that the fact that one claim is invalid for lack of utility does not affect other claims.[101]

75. As a third point, unlike under the old UK law, the Federal Courts have ignored whether a promise is true in fact;[102] they ask whether the promise was demonstrated or soundly predicted by the filing date. Thus, patents have been invalidated even though the patentee has a novel, non-obvious and useful invention that is sufficiently disclosed in the specification.

76. Finally, several lower court decisions, including the Trial Decision, fail to distinguish between a promise of a particular result and applications of this result. This is important for pharmaceutical patents which include compound claims (as distinguished from use claims, e.g., use of the compound to treat a particular disorder), since the compound's physiological properties (i.e., the specific result) is what allows it to treat different disorders (i.e., applications of this result). The utility of the compound is its physiological properties and not the application of these properties to treat disorders. This is especially apparent where it is part of the state of the art that compounds with such properties may be used to treat certain disorders, as is the situation in the within appeal.

77. Thus, recent Canadian law has expanded the UK doctrine of false promise.

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[98] Siebrasse, "The False Doctrine of False Promise", *supra* note 82 at p 41.
[99] *Whirlpool*, *supra* note 57 ¶52.
[100] See e.g., Trial Decision ¶¶162-164; *Esomeprazole*, *supra* note 86 ¶¶87-88; *Olanzapine 2*, *supra* note 86 ¶¶120, 124; *Apotex Inc v ADIR*, 2009 FCA 222 ¶¶39, RBOA, T3; *Eurocopter v Bell Helicopter Textron Canada Limitée*, 2012 FC 113 ¶¶215-216, RBOA, T23, aff'd FCA 219.
[101] *Viagra*, *supra* note 9 ¶42. See also *Plavix SCC*, *supra* note 1 ¶67, where this Court held that obviousness is to be assessed with respect to the inventive concept of the claim in question.
[102] See e.g., *Eli Lilly Canada Inc v Novopharm Ltd*, 2009 FC 1018 ¶151, RBOA, T21, rev'd on other grounds 2010 FCA 197.

iv. Has the "promise" doctrine's application gone well beyond the scope of the *Act*?

78. The only provision similar to the "false promise" provision in the old UK law is section 53(1) of the *Patent Act*:[103]

> A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading.
>
> Le brevet est nul si la pétition du demandeur, relative à ce brevet, contient quelque allégation importante qui n'est pas conforme à la vérité, ou si le mémoire descriptif et les dessins contiennent plus ou moins qu'il n'est nécessaire pour démontrer ce qu'ils sont censés démontrer, et si l'omission ou l'addition est volontairement faite pour induire en erreur.

79. This provision first entered the Canadian *Patent Act* in 1869.[104] Prior to this, the *Patent Act* of the Province of Canada had a provision very similar to the UK's "false promise" provision.[105] Thus, in 1869, Parliament chose to move in a different direction than the UK.

80. As noted by Biggar, this change to Canada's patent law was significant:

> In the result, it can only be said that, having regard to the terms of both the sections referred to [the versions of subsections 53(1) and (2) in force at the time], it would appear that the careless or inexpert draftmanship of a specification probably has less severe consequences in Canada than in either Great Britain or in the United States. The decisions of courts in these jurisdictions which turn on the making of unduly broad claims, upon the incompleteness of the specification, or upon inaccurate statements in it, are to be applied in Canada with the utmost caution when the incompleteness or the inclusion of the unduly broad claims or the inaccurate statements does not appear to have been due to an intention to mislead.[106]

81. Thus, as there is no foundation for the "promise" doctrine in Canadian statute, the Federal Courts' application of a variation of the UK's old "false promise" law goes well beyond the *Act*.[107]

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[103] Siebrasse, "The False Doctrine of False Promise", *supra* note 82 at pp. 7, 43, 49-52.
[104] *An Act respecting Patents of Invention*, SC 1869, (32 & 33 Vict) c 11, s 27, RBOA, T64.
[105] *An Act to consolidate and amend the Laws of Patents for Inventions in this Province*, S Prov C 1849, (12 Vict) c 24, s 17, RBOA, T63.
[106] OM Biggar, *Canadian Patent Law and Practice* (Toronto: Burroughs & Company, 1927) at pp 51-52, RBOA, T54. See also Fox, *supra* note 94 at pp 155-156.
[107] Siebrasse, "The False Doctrine of False Promise", *supra* note 82 at pp 47-52.

v. Conclusion

82. As there is no "common law" of patents,[108] utility should be judged only against the statutory requirement that a claimed invention be "useful", in the sense that it is not devoid of utility. This requires a claim-by-claim analysis. Where no specific utility is recited in the claims, only a scintilla of utility should be required.

83. Such a result would be consistent with US and European law. The European Patent Convention merely requires that the invention to be capable of industrial application.[109] In the US, evidence of biological activity is sufficient to meet the utility requirement under US law.[110]

84. In 1993, Parliament gave guidance as to the meaning of the word "useful" with the implementation of NAFTA into Canadian law.[111] Article 1709(1) of NAFTA provides that "useful" is synonymous with "capable of industrial application", the European standard.[112] Thus, there is a clear direction that Canadian law should be interpreted in a manner consistent with its trading partners.

85. As the trial judge found that clopidogrel inhibits platelet aggregation, the '777 Patent meets the requirement that an invention be "useful" under section 2 of the *Act*.[113]

C. IF THERE IS A PROMISE DOCTRINE, HOW SHOULD IT BE APPLIED?

86. While it is the respondents' position that there is no statutory support for the "promise" doctrine, should this Court decide otherwise, the respondents are in agreement with Apotex that this Court's guidance is needed.[114]

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[108] *Plavix 2008*, *supra* note 1 ¶12.
[109] European Patent Convention, 5 October 1973, 1065 UNTS 199, arts 52(1), 57, RBOA, T65.
[110] *In re Brana*, 51 F 3d 1560 (Fed Cir 1995) at 1567, 1568, RBOA, T27; *Cross v Iizuka*, 753 F 2d 1040 (Fed Cir 1985) at 1051; *Manual of Patent Examining Procedure*, 9th ed (March 2014), online U.S. Department of Commerce – USPTO [MPEP] at p 2100-36 to 2100-37, RBOA, T59. For a discussion of the claim-by-claim analysis in US law, see *Raytheon v. Roper*, 724 F 2d 951, 220 USPQ 592 (Fed Cir 1983) at 596-599, RBOA, T49.
[111] Section 3 of the *NAFTA Implementation Act* (SC 1993, c 44, RBOA, T67) requires that any statute that implements a provision of NAFTA or fulfils an obligation of the Government of Canada under NAFTA should be construed in a manner consistent with NAFTA. See *Novopharm Ltd v Wellcome Foundation Ltd*, [2001] 1 FC 495 ¶54, RBOA, T42, aff'd *AZT*, *supra* note 80.
[112] *NAFTA*, 17 December 1992, Can TS 1994 No 2 [*NAFTA*], Art 1709(1), RBOA, T66. See also *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1869 UNTS 299 (1994), Art 27(1), footnote 5, RBOA, T62.
[113] There is no basis to argue that the '777 Patent is invalid pursuant to s 53(1), as there are no untrue statements in the patent. Further, Apotex did not plead that there are any false statements in the patent, nor lead any evidence of an intention to mislead: Amended Statement of Claim of Apotex Inc in T-644-09, AR, T21-1; Second Amended Statement of Defence and Counterclaim of Apotex Inc and Apotex Pharmachem Inc in T-644-09/T-933-09, AR, T21-5.
[114] Apotex's leave application factum ¶¶1-2, 33-36, 40, 48-56, RR, T3.

i. The lower courts have applied the "promise" doctrine inconsistently

87. As acknowledged by Apotex in its leave application, the lower courts have approached the "construction" of the promise in three different ways, which has resulted in significant uncertainty:[115]

(a) They have looked for implied promises based on the types of disease mentioned[116] and references to pharmaceutical formulations (e.g., tablets);[117]

(b) They have looked for express statements in the disclosure portion of the specification "promising" a specific result;[118] or

(c) They have looked to the claims.[119]

ii. Guidance for application of the "promise" doctrine

(a) Only a scintilla of utility is required where there is no promise

88. Even under the old UK law, it was understood that not every patent contained a promise. Where no such promise exists, then there is no need to apply the "promise" doctrine at all. Only the statutory requirement that an invention be "useful" must be met.

(b) Claims are paramount

89. As with the requirements of novelty, obviousness and utility, the "promise" doctrine ought to be applied on a claim-by-claim basis.[120] Thus, it is important to remember that the claims – not the patent's disclosure – define the monopoly claimed. It is trite law that a patentee may claim more narrowly than what it has invented – what is not claimed is taken to be disclaimed.[121] A claim meeting the statutory requirement of utility as of the filing date should

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[115] Apotex's leave application factum ¶¶1, 31-44.
[116] *Atomoxetine FCA, supra* note 53 ¶¶22-30; *Apotex Inc v Pfizer Canada Inc*, 2011 FCA 236 [*Latanoprost*] ¶¶24-28, RBOA, T4.
[117] Trial Decision ¶163.
[118] See citations at note 100.
[119] See e.g., *Fournier, supra* note 83 ¶¶126-127; *Pfizer Canada Inc v Mylan Pharmaceuticals ULC*, 2014 FC 38 [*Celecoxib Mylan*] ¶¶34, 67, 70, RBOA, T47; *Mylan Pharmaceuticals ULC v Pfizer Canada Inc*, 2012 FCA 103 ¶¶55-56, RBOA, T39; *Mylan Pharmaceuticals ULC v AstraZeneca Canada Inc*, 2012 FCA 109 [*Anastrozole FCA*] ¶¶29-33, RBOA, T38; *Bristol-Myers Squibb Canada Co v Mylan Pharmaceuticals ULC*, 2012 FC 1142 ¶¶70-72, 74-76, RBOA, T10; *Pfizer Canada Inc v Apotex Inc*, 2014 FC 314 ¶36, RBOA, T46.
[120] *Patent Act*, RSC 1985, c P-4, ss 27(5), 58, RBOA, T68; *Viagra, supra* note 3 ¶42; *Canada (AG) v Amazon.com, Inc*, 2011 FCA 328 ¶¶38(c), 39-41, RBOA, T11; *Teva Canada Limited v. Novartis AG*, 2013 FC 141 [*Imatinib*] ¶¶174-180, RBOA, T51; *Pfizer Canada Inc v Apotex Inc*, 2007 FC 26 ¶¶41-44, RBOA, T45, aff'd 2007 FCA 195.
[121] *Whirlpool, supra* note 57 ¶42; *Noranda Mines v Minerals Separation Corp*, [1950] SCR 35 at 56, RBOA, T40; *The King v Irving Air Chute*, [1949] SCR 613 at 617, RBOA, T29; *JK Smit & Sons, Inc v McClintock*, [1940] SCR 279 at 287, RBOA, T28.

not fail because a statement in the disclosure was not soundly predicted. To find otherwise would defeat the purpose of having claims, as well as the principles of claims construction set down by this Court.[122]

90. Further, if a patentee "promises" a result in its disclosure, but these results are not claimed, the claims need only meet the statutory requirement of a scintilla of utility.[123] Thus, for claims to a chemical compound, any utility should be sufficient.

91. With respect to use claims, if different uses are claimed in different claims, each claim has to be considered separately. For example, if a patent contains two use claims: "Use of compound X to treat atherosclerosis" and "Use of compound X to treat certain cancers" then a finding that one of these was not soundly predicted cannot affect the validity of the other claim.[124]

92. Thus the validity of a claim should only be judged against a promise that is relevant to it. This is consistent with UK false promise doctrine that required a promise to be both material and coterminous with the claims.

(c) Statements in the Disclosure

93. To the extent that this Court applies the promise doctrine to statements which only appear in the disclosure (and not in the claims), it is submitted that the following principles should apply.

1. A promise should invalidate only when the promise is, in fact, false

94. If this Court holds that a claim can be invalidated on the basis of an enhanced "promise" taken from the disclosure, the claim ought to be invalidated only if it is false, in fact. In other words, questions as to whether the promise was demonstrated or soundly predicted by the filing date should be irrelevant. Thus, post-filing date evidence as to the truth of a "promise" ought to be permitted.[125]

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[122] Siebrasse, "The False Doctrine of False Promise", *supra* note 82 at p 46.In addition, construing the promise based on the disclosure often involves a "hair-splitting" analysis as to the meaning of words or phrases in the disclosure, which generates significant uncertainty for patentees and challengers alike: see Siebrasse, *infra*, at pp 6, 35-41.
[123] *Fournier*, *supra* note 83 ¶¶126-127.
[124] *Imatinib*, *supra* note 120 ¶¶108, 180, 194.
[125] Note that, under US and European law, post-filing date evidence of utility is considered: see *In re Brana*, *supra* note 110 at 1567, note 19; *HGS v Lilly*, *supra* note 97 ¶107(ix); N Siebrasse, "Must the Factual Basis for Sound Prediction be Disclosed in the Patent?" (2012) 28 CIPR 39 at p 65, note 130, RBOA, T60.

95. This principle is sound as the "promise doctrine" applies an extra-statutory requirement to patents that have met all of the statutory requirements of patentability by the filing date. In other words, the patentee will have paid the "*quid*" for the corresponding "*quo*" by the filing date. As an "enhanced" utility is not a condition precedent to receiving a patent, the question as to demonstration/sound prediction is irrelevant.[126]

2. Promises of a result versus applications of that result

96. As in the old UK "false promise" law, courts should be careful to distinguish between a promise of a specific result and applications of that result. Even under old UK law, failure to be able to apply the "promised" result to all applications listed did not invalidate the patent, so long as there are "purposes for which the result is useful".[127]

97. This has been acknowledged in some decisions by the courts below. For example, the concurring reasons in the Appeal Decision distinguished between a purpose to which an invention may be applied, and an explicit promise to achieve a specific result.[128]

98. Further, as held in both *Consolboard* and *Viagra*, there is no requirement that a patentee disclose the utility of an invention in the patent.[129] Thus, a patent should not be judged against statements in the disclosure as to applications of the invention. It is in the public's interest to encourage a patentee to disclose potential applications or uses of its invention. Requiring the invention to satisfy every statement as to a potential application or use upon pain of invalidity (even when such use is not claimed) would discourage patentees from disclosing such applications.[130]

3. Explicit promise of a specific result

99. Only those statements that are explicit promises of a specific, material result should be considered as promises.[131]

100. Apotex's position that a "purposive" construction permits the Court to look for and find inferred promises to invalidate a patent violates the bargain between the patentee and the public. A patentee should not be held to a promise he never made.

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[126] *Consolboard*, *supra* note 9 at 527.
[127] *Alsop's Patent*, supra note 94 at 753. See also Fox, *supra* note 94 at pp 152-154.
[128] Appeal Decision ¶126.
[129] *Consolboard*, *supra* note 9 at 521; Viagra, supra note 3 ¶40.
[130] Siebrasse, "The False Doctrine of False Promise", *supra* note 82 at pp 43-44.
[131] *Eli Lilly Canada Inc v Novopharm Ltd*, 2010 FCA 197 ¶76; *American Cyanamid*, *supra* note 95 at 251.

101. Moreover, Apotex has misstated the goal of purposive construction. As held by this Court, purposive construction is used to construe the claims of the patent.[132] The goal of the disclosure is to describe the invention and how to put it into practice.[133] The disclosure is not to be used "to enlarge or contract the scope of the claim as written and thus understood".[134] If a "promise" is read into the claims from the disclosure, an infringer should not be encouraged to twist the words of the patent to create a heightened promise of more than what was said. As held by this Court in *Whirlpool*, a patent "must be read by a mind willing to understand, not by a mind desirous of misunderstanding."[135]

102. Finally, not every statement in a patent disclosure is material to the grant of the patent. Only those statements that would affect whether a patent would or would not have been granted should be considered. With respect to the within appeal, the invention is not the discovery that inhibitors of platelet aggregation are useful in treating certain diseases. That fact was part of the prior art. The invention is clopidogrel and its beneficial properties (the differential activity and toxicity), which were determined by the animal studies.

(d) Section 53(1)

103. If this Court holds that an entire patent (and not just certain claims) can be invalidated on the basis of an enhanced "promise", the requirements of section 53(1) ought to be met. In particular, the promise must be (1) material, (2) wilfully made for the purpose of misleading, and (3) false, in fact.

104. In this regard, the Court should consider section 53(2), which states that:

Where it appears to a court that the omission or addition referred to in subsection (1) was an involuntary error and it is proved that the patentee is entitled to the remainder of his patent, the court shall render a judgment in accordance with the facts, and shall determine the costs, **and the patent shall be held valid for that part of the invention described to which the patentee is so found to be entitled**. (emphasis added)	S'il apparaît au tribunal que pareille omission ou addition est le résultat d'une erreur involontaire, et s'il est prouvé que le breveté a droit au reste de son brevet, le tribunal rend jugement selon les faits et statue sur les frais. **Le brevet est réputé valide quant à la partie de l'invention décrite à laquelle le breveté est reconnu avoir droit.** (caractères gras ajoutés)

[132] *Free World Trust, supra* note 57; *Whirlpool, supra* note 57.
[133] *Viagra, supra* note 3.
[134] *Whirlpool, supra* note 57 ¶52.
[135] *Whirlpool, supra* note 57 ¶49(c).

105. Thus, so long as the statutory conditions for patentability have been met, Parliament has directed that portions of the patent **must** be upheld even where the patent contains incorrect information, so long as the error was not willfully made to mislead.[136]

iii. The '777 Patent is Valid Even Under the "Promise" Doctrine

106. The claims of the '777 Patent are to clopidogrel, its salts, and pharmaceutical compositions containing clopidogrel or its salts.[137] These claims do not promise a particular result.

107. The disclosure of the '777 Patent does make explicit statements with respect to clopidogrel's beneficial properties over the levo-rotatory isomer and the racemate.[138] As noted by the FCA, these properties were held to have been demonstrated by the trial judge.[139]

108. However, Apotex argues that the promise of the '777 Patent is that clopidogrel would be "useful" in humans. Not only is there no explicit statement as to use in humans in the Patent, this alleged "promise" could not be said to be material to the grant since the inventive concept is not clopidogrel's use in humans, but its beneficial properties. The fact that compounds which inhibit platelet aggregation (e.g., ticlopidine) could be used to treat certain disorders in humans was part of the prior art.

109. Further, Apotex fails to distinguish between the promise of a result (clopidogrel having the ability to inhibit platelet aggregation) and potential applications of that result (use to treat certain disorders in which it is desirable to inhibit platelet aggregation).[140] As noted in the Appeal Decision "a goal is not necessarily a promise".[141]

110. In any event, clopidogrel is – in fact – useful in humans to inhibit platelet aggregation, and to treat certain disorders. Moreover, based on the initial clinical testing of clopidogrel, the use of clopidogrel in humans had been demonstrated before the filing date and thus issues of sound prediction and heightened disclosure do not arise.[142]

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[136] See Fox, *supra* note 94 at p 155.
[137] '777 Patent, pp 22-23, AR, T4.
[138] '777 Patent, pp 1(25-28), 12(1-6), 20(1-3), AR, T4.
[139] Appeal Decision ¶52; Trial Decision ¶¶392, 395, 399.
[140] See '777 Patent, p 21, AR, T4.
[141] Appeal Decision ¶67, citing *AstraZeneca Canada Inc v Mylan Pharmaceuticals ULC*, 2011 FC 1023 ¶61, aff'd *Anastrozole FCA*, *supra* note 119.
[142] See citations at note 27.

111. Even applying the concepts of sound prediction to this promise, the clear factual finding is that use of clopidogrel in humans was a sound prediction.[143] Thus, the '777 Patent satisfies even the highest promise alleged by Apotex.

D. "HEIGHTENED" DISCLOSURE

112. Apotex asserts that, based on section 34 of the *Act*, there is a "heightened" disclosure requirement where the promise is based on a sound prediction, but not where the promise had been demonstrated. This position is problematic as Apotex did not plead that section 34 includes such a requirement and, on appeal, did not challenge the trial judge's finding that the patent complied with section 34.[144]

113. This argument raises a number of issues:

(a) Does the *Patent Act* include such a requirement?

(b) Does this Court's decision in *AZT* support such a requirement?

(c) If there is such a requirement:

(i) Does it only apply to the statutory utility criteria (i.e., a scintilla) or does it also apply to the "promise" doctrine?

(ii) Does the patentee have to set out the prior art and all of the work done?

114. A related question is whether, in applying the doctrine of sound prediction, the Federal Courts have imposed too high a standard that is more akin to a certainty, rather than a *prima facie* reasonable inference.

i. There is no support for a "heightened" disclosure requirement in the *Patent Act*

115. The only disclosure requirement in the *Act* is that set out in section 34 (formerly section 36; now section 27(3)). As this Court recently confirmed, the purpose of this section is to inform the skilled person what the invention is and how to put it into practice.[145]

116. This Court has recently reaffirmed in *Viagra* that utility is not a disclosure requirement:

> In fact, there is no requirement whatsoever in section 27(3) to disclose the utility of the invention: see, eg, *Consolboard*, at p. 521, per Dickson J.: "I am further of the

[143] Trial Decision ¶¶488, 563.
[144] Trial Decision, ¶¶303-305; Second Amended Statement of Defence and Counterclaim of Apotex Inc and Apotex Pharmachem Inc in T-644-09/T-933-09 ¶¶117-121, AR, T21-5; Apotex's factum in A-7-12, AR, T2.
[145] *Viagra, supra* note 3.

> opinion that section 36(1) [now section 27(3)] does not impose upon a patentee the obligation of establishing the utility of the invention.[146]

117. In its memorandum, Apotex argues that section 34 is the basis for a heightened disclosure requirement. Acceptance of such an argument would require this Court to overturn both *Consolboard* and *Viagra*. In particular, as Justice Dickson held in *Consolboard*:

> ... I do not read the concluding words of section 36(1) [now section 27(3)] as obligating the inventor in his disclosure or claims to describe in what respect the invention is new or in what way it is useful. He must say what it is he claims to have invented. He is not obliged to extol the effect or advantage of his discovery, if he describes his invention so as to produce it.[147]

118. An extension of the drafting requirements to necessitate disclosure of a "factual basis" and "line of reasoning" would also be contrary to treaties that Canada has ratified and incorporated into our *Act*.[148] Under the Patent Cooperation Treaty ("PCT") a common application can now be filed in one country and is accepted as having been filed in up to 148 countries, including Canada. The purpose of this treaty is to achieve uniformity as to the content of a patent disclosure. If Canada has different disclosure requirements as to the form and content of a PCT application, then the *Act* is no longer compliant with the PCT.[149]

ii. There is no support for a "heightened" disclosure requirement in *AZT*

119. The purported genesis of the "heightened" disclosure requirement imposed by the lower courts is a misinterpretation of this Court's decision in *AZT*.[150]

120. In *AZT*, Justice Binnie set out a three-part "test" for sound prediction. First, there must be a factual basis for the prediction. Second, the inventor must have a line of reasoning from which the desired result can be inferred from the factual basis. Third, there must be proper disclosure.[151]

121. With respect to disclosure, Justice Binnie stated that "[n]ormally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the

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[146] *Viagra, supra* note 3 ¶40.
[147] *Consolboard, supra* note 9 at 526.
[148] *Patent Act*, RSC 1985, c P-4, s 12(1)(*i*); *Patent Rules*, SOR/96-423, r 51. This requirement also makes Canadian out-of-step with both the US and Europe: Siebrasse "Must the Factual Basis for Sound Prediction be Disclosed in the Patent?", *supra* note 125 at pp 41, 43, 59-65, 79.
[149] Patent Cooperation Treaty, 19 June 1970, 1160 UNTS 231, arts 5, 27(1), RBOA, T71.
[150] *Raloxifene FCA, supra* note 53 ¶¶14-15.
[151] *AZT, supra* note 80 ¶70.

manner in which it can be practiced". Further, Justice Binnie noted that "[i]t is generally not necessary for an inventor to provide a theory of why the invention works" but suggested (without deciding) that perhaps the factual basis and line of reasoning should be in the disclosure. However, Justice Binnie made no determination with respect to the nature of the disclosure requirement as the issue did not arise on the facts of the case.[152]

122. There is no citation to any prior jurisprudence or section of the *Act* in support of Justice Binnie's *obiter* remarks.[153] It may be that Justice Binnie was applying the accepted jurisprudence with respect to proof of the date of invention as expressed by this Court in *Christiani v. Rice*:

> The holding here, therefore, is that by the date of discovery of the invention is meant the date at which the inventor can prove he has first formulated, either in writing or verbally, a description which affords the means of making that which is invented. There is no necessity of a disclosure to the public.[154]

123. Thus, the "disclosure" requirement relates to proof of when the invention was made, not proof of utility in the patent. This interpretation also allows the *AZT* decision to be read in a manner consistent with *Consolboard* and *Viagra*.[155]

124. In any event, in considering the factual basis and line of reasoning for the sound prediction at paragraph 73 of his reasons, Justice Binnie clearly relied upon information that was not set out in the patent.[156] This is consistent with the patent involved in the origin of the sound prediction doctrine which had no disclosure of a factual basis or line of reasoning.[157]

125. However, the FCA initially misinterpreted Justice Binnie's remarks and felt that they were bound to apply a "heightened" disclosure requirement to all patents where the "utility" (or "promise") was based on a sound prediction.[158] A later panel acknowledged that the earlier panel was incorrect in holding that this Court set out such a requirement, but felt that they must follow the earlier panel's decision.[159] Thus, the FCA never considered the issue on first principles.

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[152] *AZT*, *supra* note 80 ¶70. See also *Atomoxetine FCA*, *supra* note 53 ¶47; Siebrasse, "Must the Factual Basis for Sound Prediction be Disclosed in the Patent?", *supra* note 125 at p 50.
[153] See Siebrasse, "Must the Factual Basis for Sound Prediction be Disclosed in the Patent?", *supra* note 125 at p 51.
[154] *Christiani and Nielsen v Rice*, [1930] SCR 443 [*Christiani v Rice*] at 456, RBOA, T14.
[155] Justice Binnie's *obiter* remarks in *AZT* have also recently been interpreted by the Federal Court as meaning that a "heightened" disclosure requirement only where the claim covers a use: *Esomeprazole*, *supra* note 86 ¶141.
[156] *AZT*, *supra* note 80 ¶70; Siebrasse "Must the Factual Basis for Sound Prediction be Disclosed in the Patent?", *supra* note 125 at pp 53-55; Canadian Letters Patent 1,238,227, ABOA, T26.
[157] *Olin Mathieson Corporation v Bioex Laboratories Ltd*, [1970] RPC 157 (Ch D) at 158-167, RBOA, T43; Siebrasse "Must the Factual Basis for Sound Prediction be Disclosed in the Patent?", *supra* note 125 at p 51.
[158] *Raloxifene FCA*, *supra* note 53 ¶¶14-15.
[159] *Atomoxetine FCA*, *supra* note 53 ¶¶47, 50.

126. It is clear that there is no provision of the *Act* that imposes such a requirement. Thus, unless this Court is prepared to impose a requirement not set out in the *Act*, there should be no requirement to set out in a patent disclosure proof of the prediction.

127. In addition, as the "heightened" disclosure requirement was created by the lower courts well after the filing date of the '777 Patent,[160] it runs contrary to the principles against retroactivity of the law and that there should be advance notice of the law. This Court held in *Hislop* that courts have the inherent power to limit the retroactive effect of a change in the common law. Thus, in the event that this Court confirms the creation of an extra-statutory "heightened disclosure" requirement, such a requirement should not apply retroactively to applications filed before this Court's decision on this appeal.[161]

128. In any event, even if there is a "heightened" disclosure requirement, the '777 Patent meets this requirement. To the extent there is a heightened disclosure requirement under section 34, the relevant date for determining sufficiency is the date of the patent's publication, namely August 1995.[162] By this date, use of clopidogrel in humans to treat diseases had been demonstrated and publically disclosed.[163]

iii. The '777 Patent meets any "heightened" disclosure requirement

129. By the filing date of the '777 Patent, the patentee had commenced a clinical trial of clopidogrel and had obtained positive results.[164] This should be sufficient to demonstrate any "promise" that the invention would be useful in humans.[165] If this Court agrees, then there is no need to even consider if the '777 Patent has to meet any heightened disclosure requirement.[166]

130. However, in the event that this Court does consider this question, it is important to keep in mind that the trial judge found that the inventors of the '777 Patent had both a factual basis and a line of reasoning to make a sound prediction of any "promised" use of the invention in humans.[167] The sole reason for invalidating the Patent based on "lack of sound prediction" was

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[160] The '777 Patent was also filed well before the "false promise doctrine" became a live issue in Canadian law: see Siebrasse, "The False Doctrine of False Promise", *supra* note 82 at p 34.
[161] *Canada (AG) v. Hislop*, 2008 SCC 10 ¶127, RBOA, T12.
[162] *Whirlpool*, *supra* note 57 ¶54.
[163] See e.g., Herbert (1993) (Ex 16 to Shebuski Report), AR, T10-16.
[164] See citations at note 27.
[165] Under US law, commencement of clinical trials generally establishes utility: MPEP, *supra* note 110 at 2100-48.
[166] *Viagra*, *supra* note 3 ¶43.
[167] Trial Decision ¶¶488, 563.

due to the "heightened" disclosure requirement not being met, as the Patent did not disclose the results of every study done by Sanofi and the common general knowledge.[168]

131. As a first point, even if there is a "heightened" disclosure requirement, there should be no requirement to set out the common general knowledge of the skilled person.[169] This would be redundant as it is understood that the skilled person reads a patent in light of the knowledge that they possess as of the publication date.[170] The state of the art was that inhibitors of platelet aggregation (such as clopidogrel) would be useful in both veterinary and human applications.[171] In addition, the '777 Patent included the results of the animal studies that demonstrated that clopidogrel inhibited platelet aggregation in two models and was less toxic than the levo-rotatory isomer and thus had a therapeutic advantage.

132. Second, it is clear that the disclosure of the '777 Patent includes both a factual basis and a line of reasoning to support both the advantages and a heightened promise of use in humans. It is important to distinguish disclosure of a factual basis as opposed to proof of the factual basis. The factual basis is that clopidogrel is the active enantiomer and is better tolerated. Proof of these facts is provided by the studies included in the Patent and confirmed by additional studies conducted by Sanofi. Insofar as the line of reasoning, this is set out on page 21, namely "on account of its interesting inhibitory properties towards platelet aggregation….the medicine of the invention can be usefully administered in the treatment of .. platelet disorders." [172]

133. Third, based on the facts and data set out in the '777 Patent when read with the state of the art, there is more than sufficient disclosure in order for the skilled person to predict that clopidogrel would be useful in humans. This is consistent with the testimony of the witnesses before the Court who were qualified in the area of haematology. Both Dr. Hirsh (for Apotex) and Dr. Shebuski (for Sanofi) testified that the testing disclosed in the '777 Patent would allow them to soundly predict that the clopidogrel would be useful in humans.[173]

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[168] Trial Decision ¶584.
[169] *Consolboard, supra* note 9 at 521-525; *Kirin-Amgen Inc & Ors v Hoechst Marion Roussel Ltd & Ors*, [2004] UKHL 46 ¶33, RBOA, T30.
[170] See citations at note 57.
[171] See citations at note 55.
[172] '777 Patent, p 21, RR, T4.
[173] Hirsh Cross, pp 661(21) – 662(7), RR, T25; Shebuski Report ¶¶113-114, AR, T10. See also Trial Decision ¶¶559-561.

134. Fourth, as this Court noted in *Viagra*, commercial success is also relevant to whether an invention is useful:

> Further, "[e]vidence as to utility may be found in the reception of the invention by the public. Enthusiastic reception by those to whom it is directed will tend to indicate that the invention is useful": Perry and Currier, at §7.12.[174]

135. There can be no question that clopidogrel is commercially successful and has been shown to be useful in humans to treat disorders related to platelet aggregation.[175] This alone should be sufficient to meet any question with respect to utility.[176]

iv. Unreasonably high standard for sound prediction imposed by the trial judge

136. This Court could also uphold the FCA's decision on another ground related to the doctrine of sound prediction. In particular, the standard that the trial judge required Sanofi to meet was unreasonably high given this Court's guidance in *AZT*.

137. The animus behind the *AZT* decision was a concern that patents could be filed on the basis of mere speculation.[177] While this concern is justifiable, since *AZT*, the doctrine of sound prediction has resulted in several patents whose inventions were <u>not</u> based on mere speculation to be held invalid for lack of utility.[178]

138. As stated by this Court in *AZT*, the purpose of the patent system is to encourage the early disclosure of inventions.[179] Requiring a patentee to do extensive trials before filing for a patent runs contrary to this purpose. The longer a patentee must wait before filing the patent, the greater the risk that the invention will be unfairly rendered "obvious" by advances in the field or that the patentee may destroy the novelty of the invention themselves.[180]

139. The European Patent Office's Board of Appeal and the UK Supreme Court have held that it is sufficient that the use is "plausible" or "reasonably credible", or based upon an "educated

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[174] *Viagra, supra* note 3 ¶41.
[175] Trial Decision ¶1; Herbert (1993) (Ex 16 to Shebuski Report), AR, T10-16; CAPRIE (1996) (Ex 36 to Hirsh Report), AR, T9-36; Trimarchi (2005 (Ex 34 to Shebuski Report), AR, T10-34.
[176] Allowing post-filing date evidence to support a sound prediction would bring Canadian law closer to that of the US and Europe: see citations at note 125.
[177] *AZT, supra* note 80 ¶¶37, 45, 69; Siebrasse "Must the Factual Basis for Sound Prediction be Disclosed in the Patent?", *supra* note 125 at p 46.
[178] See e.g., *Latanoprost, supra* note 86; *Olanzapine 2, supra* note 86; *Esomeprazole, supra* note 86; *Sanofi-Aventis v Apotex Inc*, 2009 FC 676, ABOA, T79. See also B Daley, "Does the Doctrine of Sound Prediction Make it Harder for Inventive People to Obtain Patents in Canada?" (2012) 27 CIPR 363 at 368, RBOA, T55.
[179] *AZT, supra* note 80 ¶37.
[180] In this regard, it has been argued that a clinical trial conducted by a patentee is novelty-destroying: see *Novopharm Ltd v Eli Lilly and Co*, 2010 FC 915 ¶¶81-87, RBOA, T41, aff'd *Atomoxetine FCA, supra* note 53.

guess". Meeting this standard does not require extensive studies on toxicity, metabolism or clinical trials. Instead, activity at the biochemical, cellular or biological level is sufficient.[181]

140. The European standard does not appear to be different from that enunciated by this Court in *AZT*. In particular, the key part of the "factual basis" supporting the claimed use of AZT for the treatment of AIDS in humans was an *in vitro* test (i.e., done in a test tube, not a living animal).[182] Further, Justice Binnie dismissed Apotex's arguments that "toxicity, metabolic features, bioavailability and other factors" needed to be established before an invention could be patented.[183]

141. The utility of clopidogrel was not based on mere speculation. The '777 Patent contains the results from accepted tests that showed that clopidogrel had all the platelet aggregation inhibiting activity (with the levo-rotatory enantiomer having none) and that clopidogrel was less toxic than the levo-rotatory isomer and the racemate. Clopidogrel was also more effective at inhibiting the growth of clots (thrombi) in the Kumada rat model.[184]

142. In this regard, the trial judge required Sanofi to meet too high a standard for sound prediction in that he required that the work done by the inventors support a conclusion rather than a prediction that clopidogrel would be useful in humans.[185] He did not even apply the "*prima facie* reasonable inference" standard set out by this Court and the FCA.[186] In particular, he found that a sound prediction would require information not required by this Court in *AZT* (i.e., metabolism).

143. Thus, it is submitted that this Court should clarify the principles set out in *AZT*, as they are currently being misapplied by the lower courts.

E. OBVIOUSNESS

144. In 2008, this Court concluded that the invention of the '777 Patent was unobvious. Not satisfied, Apotex commenced an impeachment proceeding to try to obtain an *in rem* decision in

[181] *HGS v Lilly*, *supra* note 97 ¶107.
[182] *AZT*, *supra* note 80 ¶¶72, 73(iv).
[183] *AZT*, *supra* note 80 ¶77.
[184] See citations at note 30.
[185] Trial Decision ¶402.
[186] *Olanzapine FCA*, *supra* note 68 ¶¶84-85; *AZT*, *supra* note 80 ¶¶60, 70.

respect of validity, and to try and introduce different facts that might lead to a different result. Apotex, however, did not succeed in this regard. There are no material differences between the factual findings of the trial judge and those relied upon by this Court in 2008.[187]

145. Consequently, the conclusion of the trial judge should have been the same as this Court's. However, the trial judge misdirected himself as to the correct legal question. Specifically, he was under the mistaken impression that if separating the racemate into its individual enantiomers or preparing salts of the enantiomers did not require substantial difficulty, then the invention was obvious. The correct question, as articulated by this Court, is whether it was "self-evident from the '875 Patent or common general knowledge what the properties of the dextro-rotatory isomer of the racemate would be or what the bisulfate salt's beneficial properties would be and therefore that was being tried ought to work."[188]

146. The FCA applied this question to the trial judge's factual findings and came to the same conclusion as this Court did in 2008.[189]

i. Key factual findings made by the trial judge were the same as those before the SCC

147. The same prior art was before this Court and the trial judge. The most relevant piece of prior art was the '875 Patent which disclosed a large genus of compounds that were said to have antiplatelet aggregation activity and thus would be useful in the treatment of both human and veterinary disorders. While Apotex attempted to create a difference in the common general knowledge by introducing documents that were not before this Court in 2008, the trial judge held that these documents were not part of the common general knowledge.[190]

148. Further, the trial judge agreed that the inventive concept of the claim was the same as that found by this Court in 2008.[191]

149. Given these findings, the trial judge agreed with this Court's enunciation of the differences between the state of the art and the inventive concept:[192]

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[187] Appeal Decision ¶81.
[188] *Plavix 2008, supra* 1 ¶92.
[189] Appeal Decision ¶¶74-81. The US courts also rejected Apotex's challenge that the US equivalent to the '777 Patent was invalid on the ground of obviousness: *Sanofi-Synthelabo v Apotex Inc*, 492 F Supp 2d 353 (SDNY 2007), aff'd 550 F 3d 1075 (Fed Cir 2008).
[190] Trial Decision ¶652.
[191] Trial Decision ¶653.
[192] Trial Decision ¶¶654-655; *Plavix 2008, supra* note 1 ¶¶79-80.

The evidence is therefore consistent with the Supreme Court of Canada's finding in *Plavix* at paras 79-80:

> [79] The '875 patent disclosed over 250,000 possible different compounds predicted to inhibit platelet aggregation. Twenty-one compounds were made and tested. Nothing distinguishes the racemate in this case from other compounds disclosed or tested in terms of therapeutic effect or toxicity. As stated above, there is no disclosure in the '875 patent of the specific beneficial properties associated with the dextro-rotatory isomer of this racemate in isolation; nor was there disclosure of any advantages which flow from using the bisulfate salt of the dextro-rotatory isomer. The '875 patent did not differentiate between the properties of the racemate, its dextro-rotatory isomer and levo-rotatory isomer or indeed the other compounds made and tested or predicted to work.
>
> [80] On the other hand, the '777 patent claims that the invention of the dextro-rotatory isomer of the racemate, clopidogrel, and its bisulfate salt discloses their beneficial properties over the levo-rotatory isomer and the racemate and expressly describes how to separate the racemate into its isomers.

ii. The trial judge did not ask the correct legal question

150. It was at the stage of assessing the ultimate question that the trial judge diverged from the approach of this Court. The correct question as set out in this Court's 2008 decision is whether, without the benefit of hindsight, "it is self-evident from the '875 Patent or common general knowledge what the properties of clopidogrel would be or what the bisulfate salt's beneficial properties would be and therefore what was being tried ought to work."[193] However, the trial judge framed the question as follows:

> The question of "whether it was more or less self-evident that what is being tried ought to work" is relevant to the issue of (a) the methods available to separate the enantiomers of PCR 4099 and (b) the methods available to obtain the salts. **The Court must determine whether it would have been self-evident to a person of ordinary skill in the art that choosing a method to separate and a method to obtain the salts ought to work.** (emphasis added)[194]

151. This paragraph embodies two key errors of law in the obviousness analysis. First, the trial judge did not ask whether the inventive concept (i.e., clopidogrel's beneficial properties of greater therapeutic effect and less toxicity) was obvious to try. As found by the FCA, based on

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[193] Apotex misinterprets this question as requiring that a compound's properties must be known before it is found to be obvious (see paragraphs 90-94 of its factum). The test as articulated by this Court is whether the inventive concept would have been more or less self-evident.

[194] Trial decision ¶663. Even based on the incorrect question posed by the trial judge, he should have still found the invention unobvious, based on his factual finding that "...Apotex has failed to convince the Court that the long existing Pasteur method would have worked": Trial Decision ¶677. See also Trial Decision ¶¶690-692, 707-708.

the findings of fact made by the trial judge, had he turned his mind to the correct question, he would not have invalidated the Patent.

152. The findings of fact made by the trial judge that are relevant to the "obvious to try" analysis were the same as those before this Court in 2008:

[84] As I have observed earlier, Shore J. found that the skilled person would not know, before separating this particular racemate into its isomers and then testing the separated isomers, that the properties of the dextro-rotatory isomer would be different from the properties of the racemate or the levo-rotatory isomer (para. 81). Similarly, he found that the person skilled in the art would not know before trying the different salts in combination with the dextro-rotatory isomer what the bisulfate salt's beneficial properties would be (para. 82).	[692] Moreover, it is only after the enantiomers are tested that one can know whether an isolated enantiomer would have advantages over the racemate and the other enantiomer, and whether it would possess all of the following properties: ▪ clopidogrel had antiplatelet aggregation activity; ▪ this activity was not present in the levo-rotatory enantiomer; ▪ clopidogrel was better tolerated than the levo-rotatory enantiomer; and ▪ the bisulfate salt of CL was more stable than other salts.
[90] … the prior patent did not differentiate between the efficacy and the toxicity of any of the compounds it covered. This suggests that what to select or omit was not then self-evident to the person skilled in the art.	[612] After reading the '875 Patent and considering the evidence, the Court is of the opinion that the '875 Patent does not, either directly or indirectly, point to PCR 4099 or to clopidogrel.
[91] … for several years prior to November 1985, Sanofi was in the process of developing the racemate in its salified form. ... [Sanofi] had "spent millions of dollars and several years developing [the racemate] up to the point of preliminary human clinical trials" without at least trying to see if the dextro‑rotatory isomer had advantageous properties to those of the racemate…	[444] During the trial, it became clear that Sanofi had invested significant amounts of time, money and resources to the development of PCR 4099. … [447] … important work was conducted on PCR 4099. This work included pre-clinical and clinical work and is summarized in the investigational brochure PCR 4099 – An Antithrombotic Agent (Trial Ex. D – 135, Tab 73(a) (SA305).

153. In trying to bolster its argument that the evidence before the trial judge was different than before this Court, Apotex relies upon the trial judge's finding that the work conducted by one of

the inventors revealed no substantial difficulty, even though it took several months to separate the enantiomers. Whether it was difficult to arrive at the invention is a factor that can be considered; however, as found by this Court in 2008, it is not determinative and, on the facts of this case, assumes "a small significance."[195] This is certainly the case where the inventive concept of the claims in question is not the method to separate the enantiomers, but clopidogrel and its beneficial properties.

154. The second of the key legal errors made by the trial judge is his hindsight approach to the "obvious to try" question. In other words, he approached the question "with knowledge of the invention in question", contrary to this Court's holding in 2008.[196]

155. The trial judge's error is made clear by the way in which the trial judge framed the "obvious to try" question (i.e., "…whether it would have been self-evident to a person of ordinary skill in the art that choosing a method to separate and a method to obtain the salts ought to work"[197]). Further, the trial judge forgot to apply his finding that the prior art did not point the skilled person directly or indirectly to separate the racemate in question. As held by the FCA:

> The Trial Judge found that "the '875 Patent does not directly or indirectly point to PCR 4099 or to clopidogrel": Reasons, at paragraph 612, (my emphasis). As noted above, the Trial Judge also noted that "PCR 4099 (not its properties) would form part of the common general knowledge that a person skilled in the art could find by making a reasonably diligent search of patent applications": Reasons, at paragraph 614. Furthermore, the properties of PCR 4099 would not have been discoverable by means of a reasonably diligent patent search: Reasons, at paragraph 645-647.[198]

156. Apotex attempts to differentiate the facts before this Court in 2008 and before the trial judge based on the trial judge's finding that those in the art would be generally motivated to resolve racemic medicines into enantiomers.[199] However, in doing so, Apotex ignores both the fundamental legal requirement that the obviousness analysis be approached without hindsight and the trial judge's findings as summarized by the FCA.

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[195] *Plavix 2008, supra* note 1 ¶89.
[196] *Plavix 2008, supra* note 1 ¶67.
[197] Trial decision ¶663.
[198] Appeal Decision ¶77.
[199] Apotex's memorandum of fact and law ¶89. The trial judge also erred in law in basing this finding upon documents not found to be part of the common general knowledge, including documents that were not publicly available before the date of invention of the '777 Patent: Events 4-7, Trial Decision ¶¶733-742. See *Beecham Canada Ltd v Procter & Gamble Co* (1982), 61 CPR (2d) 1 (FCA) at 27, RBOA, T8.

157. In other words, if the person skilled in the art would not be directed to the racemate in particular, they could not be motivated to separate the racemate without the benefit of hindsight. Further, they would not know if there would be any advantages before they separated and tested the enantiomers. As such, the invention was unobvious.

158. Thus, the FCA's finding with respect to obviousness ought not to be disturbed. On the basis of the law set out by this Court in 2008 and the same material facts, it is clear that the claimed invention of the '777 Patent is not obvious.

E. APOTEX'S DEFENCES TO INFRINGEMENT

i. Limitation Period

159. Apotex did not deny that it infringed the '777 Patent. However, Apotex asserts that it should avoid liability for some of the infringing product it imported, made and sold by operation of section 39(1) of the *Federal Courts Act* and the two-year limitation period prescribed by Ontario's *Limitations Act, 2002*.

160. A cause of action has been defined by this Court as a set of facts that provide the basis for an action in the Court.[200] The trial judge found that, because the cause of action arose otherwise than within a province, the six-year limitation period pursuant to section 39(2) of the *Federal Courts Act* applied.[201]

161. In making the factual determination as to where the cause of action arose, the trial judge considered extensive evidence relating to Apotex's global enterprise in respect of clopidogrel, which included activities that did not solely arise within a province. These included:

(a) entering into a joint venture arrangement with a foreign company, which manufactured the bulk clopidogrel in a foreign country and was imported into Canada by Apotex;

(b) the importation, by Apotex, of the material into Canada;

(c) the export of large quantities of clopidogrel tablets to the US (and other countries) by Apotex;

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[200] *Markevich v. Canada*, 2003 SCC 9 [*Markevich*] ¶27, RBOA, T33.

[201] Trial Decision ¶258. This is also consistent with the 6-year limitation period set out in section 55.01 of the post-1989 *Patent Act*, RSC 1985, c P-4, RBOA, T68.

(d) the acceptance of purchase orders from foreign entities and the export of millions of tablets to foreign countries facilitated by Apotex's regulatory agents in those countries; and

(e) the advertisement of clopidogrel for export sale on its website.[202]

162. The trial judge found that these activities amounted to infringement, as they interfered with the full enjoyment of the monopoly granted to Sanofi. In this regard, Apotex's act of importation of bulk clopidogrel from a foreign country into Canada is a sufficient basis to conclude that the cause of action was not confined to a single province.[203] Importation of infringing material or material made by an infringing process is an act of infringement.[204] When the goods arrived in Canada at Pearson Airport (an international airport and a federal work or undertaking connecting a province with a foreign country or extending beyond the limits of a province), the goods could not be said to be solely within any province.[205]

163. This reasoning would also apply to Apotex's export of clopidogrel from Canada to the US and other countries, as Apotex was the "exporter" (importer of record into the US) of the clopidogrel product ultimately sold under Apotex's marketing approva1.[206]

164. The trial judge gave a further reason for finding that the cause of action arose otherwise than in a province in that the damage was suffered outside Ontario.[207] The FCA disagreed on this point on the basis that a patentee can bring an action to enforce the exclusive rights granted under section 42 of the *Patent Act* without having suffered damage.[208]

165. However, Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (the "Partnership") was not suing as a patentee but as an exclusive licensee claiming under the patentee pursuant to section 55(1) of the *Patent Act*. As held by this Court in *Armstrong Cork Canada v Domco Industries Ltd*: "[a] licensee relying on [section 55(1)] is not claiming against the infringer for infringement of his rights under the licence, he is claiming for the damage he

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[202] Trial Decision ¶¶199-210, 231, 251-257.
[203] Trial Decision ¶253.
[204] *Schmeiser*, supra note 65 ¶44; *Eli Lilly and Co v Apotex Inc*, 2009 FC 991 ¶323, RBOA, T18, aff'd 2010 FCA 240.
[205] Appeal Decision at ¶¶110-112; *Air Canada v LCBO*, [1997] 2 SCR 581 ¶57; *City of Mississauga v Greater Toronto Airport Authority* (2000), 50 OR (3d) 641 (CA) ¶¶56-60; *Markevich, supra* note 200 ¶39.
[206] Trial Decision ¶207; US Customs Documents, p 2, AR, T20-E; Trucking Documents, AR, T-20-F.
[207] Trial Decision ¶¶250, 258.
[208] Appeal Decision ¶108.

has sustained in consequence of the infringement of the patent."[209] Thus, the damage sustained by the Partnership (which would include loss suffered outside of Ontario) constitutes a necessary factual element forming part of the cause of action under section 55(1).[210] Therefore, this is an additional factor which supports the conclusion reached by the lower courts to reject Apotex's limitations defence.

166. In its memorandum, Apotex has not shown any basis for interfering with the factual findings of the trial judge, nor has Apotex identified any legal error. In particular, the case law cited by Apotex, including the *Beloit* case,[211] did not consider whether section 39(1) or 39(2) of the *Federal Courts Act* applied based on the facts relating to the cause of action.

167. Finally, to the extent there is any question as to which limitation period applies, this Court has stated that "any ambiguity should be resolved in the favour of the person whose right is being truncated"[212] and that statutory provisions creating a limitation period "must be strictly construed in favour of the plaintiff".[213]

168. Thus, Sanofi's claims relating to Apotex's activities, in particular those relating to sales made to the US, are not statute-barred.

ii. US Settlement Agreements

169. In the courts below, Apotex also sought to be absolved from liability for any clopidogrel sales to the US (but not for sales to other countries) on the basis of US Settlement Agreements ("Agreements") relating to US litigation and a US patent. As found by the trial judge and upheld by the FCA, the Agreements do not absolve Apotex from liability arising from its infringement of the Canadian '777 Patent.

170. On the face of the Agreements, it is clear that they encompass only the settlement of the US litigation with respect to the US patent. The Agreements only refer to the US litigation and the US patent. There are no references to Canada or the '777 Patent.[214] For example, both of the 2006 Agreements begin with the following:

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[209] *Armstrong Cork Canada v Domco Industries Ltd*, [1982] 1 SCR 907 at 919, RBOA, T6.
[210] *Canada v. Maritime Group Inc.*, [1995] 3 FC 124 (CA) ¶¶7-8, RBOA, T13; *Kirkbi A.G. v. Ritvik Holdings Inc.* (2002), 20 CPR (4th) 226 (FCTD) at 233-285, RBOA, T31.
[211] See Appellants' factum ¶113.
[212] *Berardinelli v. Ontario Housing Corp.*, [1979] 1 SCR 275 at 280, RBOA, T9.
[213] *Ordon Estate v. Grail* [1998] 3 SCR 437 ¶36, RBOA, T44.
[214] Trial Decision ¶¶279-282.

> Sanofi and Apotex agree to settle the litigations between them involving U.S. Patent No. 4,847,265, 02CV-2255 and 05CV-3965, on the following terms…[215]

171. Further, while the Agreements conditionally grant a licence under the US Patent, no licence was granted under any other patent owned or controlled by Sanofi.[216]

172. The "Liability Exposure Provision" in the May 2006 Agreement expressly refers only to the US Patent and the US litigations.[217] As noted in the paragraph above, the "litigations" as specified at the beginning of the Agreement are only the US litigations. This provision provided a significant benefit to Apotex; for instance, it precludes a finding of treble damages under US law.

173. The trial judge found the terms of the Agreements to be unambiguous in this regard.[218] As this Court has stated, where the terms of a contract are without ambiguity, there is no reason to go beyond the plain language to alter the terms of the bargain.[219]

174. Contrary to the law as set out by this Court, Apotex seeks to have this Court read in a limitation of liability favourable to Apotex that contradicts the plain language of the Agreements. As before the lower courts, Apotex argues that it would be "commercially reasonable" to imply a term in the Agreements to preclude the Respondents' right to claim damages for infringement of the '777 Patent for sales made to the US.[220]

175. However, a term is not to be implied because a party thinks that it would be "reasonable" to have inserted it into the contract. It may only be implied if it is necessary in the business sense to give efficacy to the contract. Further, an implied term must not be contradictory to an express term in the contract.[221] The implied term that Apotex seeks to add to the Agreements would be contradictory to the express terms that state that they only extend to the US litigation and infringement of the US patent and to no other patents.

176. Further, the surrounding circumstances militate against implying such a term:

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[215] May 2006 Agreement at p 10, AR, T-20-B; March 2006 Agreement at p 3, AR, Tab 20-A; Trial Decision ¶280.
[216] May 2006 Agreement ¶¶4 & 12, AR, T-20B; March 2006 Agreement ¶4, AR, Tab 20-A; Trial Decision ¶¶268, 272.
[217] May 2006 Agreement ¶14(ii), AR, Tab 20-B.
[218] Trial Decision ¶279.
[219] *Eli Lilly & Co v. Novopharm Ltd*, [1998] 2 SCR 129 ¶55, RBOA, T19.
[220] Appellants' factum ¶119.
[221] *M.J.B. Enterprises Ltd v Defence Construction (1951) Ltd*, [1999] 1 SCR 619 ¶29, RBOA, T35; *Martel Building Ltd v Canada*, 2000 SCC 60 ¶82, RBOA, T34; *Zeitler v Zeitler Estate*, 2010 BCCA 216 ¶29, RBOA, T53; *Marinangeli v Marinangeli* (2003), 66 OR (3d) 40 (CA) ¶65, RBOA, T32.

(a) Apotex is a sophisticated party who could have asked for inclusion of a provision limiting its liability with respect to infringement of the '777 Patent, but did not.[222]

(b) It is trite law that a patent does not have extraterritorial reach. Thus, litigation in the US or settlement of US litigation relating to a US patent does not settle any issue relating to a Canadian patent.

(c) Even after the US court issued an injunction against Apotex and after the Agreements were entered into, Apotex continued to make, use and sell clopidogrel in Canada.[223]

(d) After the Agreements were entered into, Apotex continued with its 2008 appeal to this Court and commenced the impeachment action which has culminated in the within appeal.

(e) Term 3 of the Agreements states that "Apotex releases all claims that it brought or could have brought against Sanofi in connection with these litigations".[224] If these Agreements contemplated the '777 Patent, Apotex should have been estopped from bringing the impeachment action that culminated in the within appeal.

177. In any event, the abuse of process or licensee estoppel doctrines should bar Apotex from raising this "defence", as courts in both the US and in Canada have held that the Agreements extend only to the US litigation and the US Patent.[225]

178. Finally, Apotex invokes the doctrines of *res judicata*, election, alternative liability and abuse of process as applicable in the present circumstances, but without any legal argument in support. These arguments all hinge on the incorrect premise that the US litigation and the Agreements extend to the '777 Patent and all were rejected by the courts below.[226]

179. As a final point, Apotex seeks an order from this Court that the entirety of the action in Court File T-933-09 be dismissed as statute-barred or barred by the Agreements.[227] This mischaracterizes Apotex's defence as there are numerous infringing acts which occurred within the two-year limitation period and which are in no way related to the US sales.[228]

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[222] Trial Decision ¶283; *Toronto (City) v Toronto Terminal Railways Co* (1999), 45 OR (3d) 481 (CA) ¶¶28-29, RBOA, T52.
[223] Trial Decision ¶202; Clopidogrel International Billing Documents, Launch Through January, 2011, RR, T33.
[224] May 2006 Agreement ¶3, AR, T19-B; March 2006 Agreement ¶3, RR, T19-A.
[225] *Sanofi-Synthelabo v Apotex Inc* 02 Civ. 2255 (SHS) (SDNY), RR, T29; *Apotex Inc v Sanofi-Aventis*, 2008 CanLII 574 ¶¶17, 20 & 40-41 (Ont SCJ), RR, T30.
[226] Trial Decision ¶¶284-292; Appeal Decision ¶118.
[227] Appellants' factum ¶127.
[228] Trial Decision ¶202; Clopidogrel International Billing Documents, Launch Through January, 2011, RR, T33.

PART IV – SUBMISSIONS CONCERNING COSTS

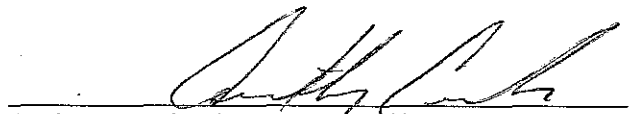
180. Sanofi requests costs from Apotex on this appeal and the leave application.

PART V – ORDER REQUESTED

181. For all the foregoing reasons, Sanofi requests that the Judgment of the Federal Court of Appeal be upheld and Apotex's appeal be dismissed.

DATED at Ottawa, Ontario, this 21st day of July, 2014.

ALL OF WHICH IS RESPECTFULLY SUBMITTED



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PART VI - AUTHORITIES RELIED UPON

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1.	*Air Canada v Ontario (Liquor Control Board)*, [1997] 2 SCR 581	162
2.	*American Cyanamid Co v Ethicon Ltd*, [1979] RPC 215 (Ch D)	69, 99
3.	*Apotex Inc v ADIR*, 2009 FCA 222	74, 87
4.	*Apotex Inc v Pfizer Canada*, 2011 FCA 236, 95 CPR (4th) 193 [*Latanoprost*]	63, 87, 137
5.	*Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, [2008] 3 SCR 265 [*Plavix 2008*]	6, 11, 13, 23, 25, 27, 50, 55, 64, 74, 82, 89, 145, 149, 150, 153, 154
6.	*Apotex Inc v Wellcome Foundation Ltd*, [2002] 4 SCR 153	55, 119, 120, 121, 124, 137, 138, 140
7.	*Armstrong Cork Canada Ltd v Domco Industries Ltd*, [1982] 1 SCR 907	165
8.	*AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638 [*Esomeprazole*]	63, 74, 87, 123, 137
9.	*Beecham Canada Ltd et al v Procter & Gamble Co* (1982), 61 CPR (2d) 1 (FCA)	156
10.	*Berardinelli v Ontario Housing Corp*, [1979] 1 SCR 275	167
11.	*Bristol-Myers Squibb Canada Co et al v Mylan Pharmaceuticals ULC et al*, 2012 FC 1142	87
12.	*Canada (AG) v Amazon.com Inc*, 2011 FCA 328, [2012] 2 FCR 459	89
13.	*Canada (AG) v Hislop*, 2007 SCC 10, [2007] 1 SCR 429	127
14.	*Canada v Maritime Group Inc*, [1995] 3 FC 124 (CA)	165
15.	*Christiani and Nielsen v Rice*, [1930] SCR 443	122
16.	*City of Mississauga v Greater Toronto Airport Authority* (2000), 50 OR (3d) 641 (CA)	162
17.	*Consolboard Inc v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504	5, 34, 65, 66, 95, 97, 117, 131
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19.	*Eli Lilly and Co v Apotex Inc*, 2009 FC 991, 80 CPR (4th) 1	162

NO.	AUTHORITY	PARA. REF.
20.	*Eli Lilly & Co v Novopharm Ltd,* [1998] 2 SCR 129	173
21.	*Eli Lilly Canada Inc v Apotex Inc*, 2009 FCA 97, 78 CPR (4th) 388 [*Raloxifene FCA*]	31, 63, 119, 125
22.	*Eli Lilly Canada Inc v Novopharm Ltd*, 2009 FC 1018 [*Olanzapine FC 1*]	75
23.	*Eli Lilly Canada Inc v Novopharm Ltd*, 2011 FC 1288 [*Olanzapine FC 2*]	63, 74, 87, 137
24.	*Eli Lilly Canada Inc v Novopharm Ltd*, 2010 FCA 197, 85 CPR (4th) 413	44, 55, 99, 142
25.	*Eli Lilly & Co v Novopharm Ltd,* 2011 FCA 220	31, 63, 87, 121, 125
26.	*Eurocopter v Bell Helicopter*, 2012 FC 113	74, 87
27.	*Fournier Pharma Inc v Canada (Minister of Health)*, 2012 FC 741, 107 CPR (4th) 32 [*Fournier*]	59, 87, 90
28.	*Free World Trust v Électro Santé Inc*, 2000 SCC 66, [2000] 2 SCR 1024	34, 101, 151
29.	*Human Genome Sciences Inc v Eli Lilly & Co*, [2011] UKSC 51, [2012] RPC 6 [*HGS v Lilly*]	71, 94, 135, 139
30.	*In re Brana,* 51 F 3d 1560 (Fed Cir 1995)	83, 94, 135
31.	*JK Smit & Sons Inc v McClintock,* [1940] SCR 279	89
32.	*The King v Irving Air Chute,* [1949] SCR 613	89
33.	*Kirin-Amgen Inc & Ors v Hoechst Marion Roussel Ltd & Ors*, [2004] UKHL 46, [2005] RPC 9	131
34.	*Kirkbi v Ritvik Holdings Inc*, 2002 FCT 585, 20 CPR (4th) 224	165
35.	*Marinangeli v Marinangeli* (2003), 66 OR (3d) 40 (CA)	175
36.	*Markevich v Canada*, 2003 SCC 9, [2003] 1 SCR 94	160, 162
37.	*Martel Building Ltd v Canada,* 2000 SCC 60, [2000] 2 SCR 860	175
38.	*MJB Enterprises Ltd v Defence Construction Ltd (1951),* [1999] 1 SCR 619	175
39.	*Monsanto Canada Inc v Schmeiser*, 2004 SCC 34, [2004] 1 SCR 902 [*Schmeiser*]	40, 162
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41.	*Mylan Pharmaceuticals ULC v AstraZeneca Canada, Inc*, 2012 FCA 109 [*Anastrozole FCA*]	87
42.	*Mylan Pharmaceuticals ULC v Pfizer Canada Inc*, 2012 FCA 103	87
43.	*Noranda Mines Ltd v Minerals Separation Corp*, [1950] SCR 36	89
44.	*Novopharm Ltd v Eli Lilly & Co*, 2010 FC 915, 87 CPR (4th) 301 [*Atomoxetine FC*]	138
45.	*Novopharm Ltd v Wellcome Foundation Ltd*, [2001] 1 FC 495 (CA) [*AZT FCA*]	84
46.	*Olin Mathieson Corporation v Bioex Laboratories Ltd*, [1970] RPC 157 (Ch D)	124
47.	*Ordon Estate v Grail*, [1998] 3 SCR 437	167
48.	*Pfizer Canada Inc v Apotex Inc*, 2007 FC 26, 59 CPR (4th) 183	89
49.	*Pfizer Canada Inc v Apotex Inc*, 2014 FC 314 [*Celecoxib Apotex*]	87
50.	*Pfizer Canada Inc v Mylan Pharmaceuticals ULC*, 2014 FC 38 [*Celecoxib Mylan*]	87
51.	*Pharmacia Corp v Merck & Co Inc*, [2001] EWCA Civ 1610	71
52.	*Raytheon v. Roper*, 724 F 2d 951 (Fed Cir 1983)	83
53.	*Re Alsop's Patent* (1907), 24 RPC 733 (Ch D)	68, 96
54.	*Sanofi-Aventis v Apotex Inc*, 2009 FC 676, 77 CPR (4th) 99	137
55.	*Sanofi-Synthelabo v Apotex Inc*, 492 F Supp 2d 353 (SDNY 2007)	189
56.	*Sanofi-Synthelabo v Apotex Inc*, 550 F 3d 1075 (Fed Cir 2008)	189
57.	*Teva Canada Ltd v Novartis AG*, 2013 FC 141, 109 CPR (4th) 1 [*Imatinib*]	89, 91
58.	*Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60	2, 5, 31, 34, 48, 74, 97, 101, 115, 116, 129, 134
59.	*Toronto (City) v Toronto Terminal Railway Co* (1999), 45 OR (3d) 481 (CA)	176
60.	*Whirlpool Corp v Camco Inc*, [2000] 2 SCR 1067	34, 74, 89, 101, 128, 151
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68.	Manual of Patent Examining Procedure, 9th ed. (March 2014), online U.S. Department of Commerce – United States Patent and Trademark Office <http://mpep.uspto.gov/RDMS>	83, 129
69.	N Siebrasse, "Must the Factual Basis for Sound Prediction be Disclosed in the Patent?" (2012) 28 CIPR 39	94, 118, 121, 122, 124, 135, 137
70.	N Siebrasse, "The False Doctrine of False Promise" (2013) 29 CIPR 3	59, 61, 63, 64, 66, 71, 73, 78, 81, 89, 98, 127
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71.	*Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 1869 UNTS 299, art 27	84
72.	*An Act to consolidate and amend the Laws of Patents for Inventions in this Province*, S Prov C 1849, (12 Vict) c 24, s 17	79
73.	*An Act respecting Patents of Invention*, SC 1869, (32 & 33 Vict) c 11, s 27	79
74.	*European Patent Convention*, 5 October 1973, 1065 UNTS 199, arts 52, 57	83
75.	*North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States*, 17 December 1992, Can TS 1994 No 2, art 1709(1)	84
76.	*North American Free Trade Agreement Implementation Act*, SC 1993, c 44, ss 3-4	84

NO.	AUTHORITY	PARA. REF.
77.	*Patent Act*, RSC 1985, c P-4, ss 2, 12, 27(3), 27(5), 53, 55.01, 58	2, 74, 78, 89, 104, 115, 118, 160
78.	*Patents Act, 1949 (UK)*, 12, 13 & 14 Geo VI, c 87, s 32	67
79.	*Patents Act 1977 (UK)*, c 37, ss 1, 4, 72	71
80.	*Patent Cooperation Treaty*, 19 June 1970, 1160 UNTS 231, arts 5, 27	118
81.	*Patent Rules*, SOR/96-423, r 51	118

PART VII – LEGISLATION AT ISSUE

A. *Patent Act*, RSC 1985, c P-4 (Pre-Oct. 1, 1989 Act)

1. Section 2

"invention" means any new useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine manufacture or composition of matter;	« invention » Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l'un d'eux, présentant le caractère de la nouveauté et de l'utilité.

2. Section 34

(1) An applicant shall in the specification of his invention (*a*) correctly and fully describe the invention and its operation or use as contemplated by the inventor; (*b*) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most closely connected, to make, construct, compound or use it; (*c*) in the case of a machine, explain the principle thereof and the best mode in which he has contemplated the application of that principle; (*d*) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions; and (*e*) particularly indicate and distinctly claim the part, improvement or combination that he claims as his invention.	(1) Dans le mémoire descriptif, le demandeur: *a*) décrit d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues l'inventeur; *b*) expose clairement les diverses phases d'un procédé, ou le mode de construction, de confection, de composition ou d'utilisation d'une machine, d'un objet manufacturé ou d'un composé de matières, dans les termes complets, clairs, concis et exacts qui permettent à toute personne versée dans l'art out la science dont relève l'invention, ou dans l'art ou la science qui s'en rapproche le plus, de confectionner construire, composer ou utiliser l'objet de l'invention; *c*) s'il s'agit d'une machine, en explique le principe et la meilleure manière dont il a conçu l'application de ce principe; *d*) s'il s'agit d'un procédé, explique la suite nécessaire, le cas échéant, des diverses phases du procédé, de façon à distinguer l'invention d'autres inventions; *e*) indique particulièrement et revendique distinctement la partie, le perfectionnement ou la combinaison qu'il réclame comme son invention.
(2) The specification referred to in subsection (1) shall end with a claim or claims stating distinctly and in explicit terms the things or	(2) Le mémoire descriptif se termine par une ou plusieurs revendications exposant distinctement et en termes explicites les choses

combinations that the applicant regards as new and in which he claims an exclusive property or privilege.

ou combinaisons que le demandeur considère comme nouvelles et dont il revendique la propriété ou le privilège exclusive.

3. Section 45

Every patent granted under this Act shall be issued under the signature of the Commissioner and the seal of the Patent Office, shall bear on its face the date on which it is granted and issued and shall thereafter, in the absence of any evidence to the contrary, be valid and avail the grantee and his legal representatives for the term mentioned therein.

Tout brevet accordé en vertu de la présente loi est délivré sous la signature du commissaire et le sceau du Bureau des brevets. Le brevet porte à sa face la date à laquelle il a été accordé et délivré, et il est par la suite, sauf preuve contraire, valide et acquis au titulaire et à ses représentants légaux pour la période y mentionnée.

4. Section 53

(1) A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading.

(1) Le brevet est nul si la pétition du demandeur, relative à ce brevet, contient quelque allégation importante qui n’est pas conforme à la vérité, ou si le mémoire descriptif et les dessins contiennent plus ou moins qu’il n’est nécessaire pour démontrer ce qu’ils sont censés démontrer, et si l’omission ou l’addition est volontairement faite pour induire en erreur.

(2) Where it appears to a court that the omission or addition referred to in subsection (1) was an involuntary error and it is proved that the patentee is entitled to the remainder of his patent, the court shall render a judgment in accordance with the facts, and shall determine the costs, and the patent shall be held valid for that part of the invention described to which the patentee is so found to be entitled.

(2) S’il apparaît au tribunal que pareille omission ou addition est le résultat d’une erreur involontaire, et s’il est prouvé que le breveté a droit au reste de son brevet, le tribunal rend jugement selon les faits et statue sure les frais. Le brevet est réputé valide quant à la partie de l’invention décrite à laquelle le breveté est reconnu avoir droit.

(3) Two office copies of the judgment rendered under subsection (1) shall be furnished to the Patent Office by the patentee, one of which shall be registered and remain of record in the Office and the other attached to the patent and made a part of it by a reference thereto.

(3) Le breveté transmet au Bureau des brevets deux copies authentiques de ce jugement. Une copie en est enregistrée et conservée dans les archives du Bureau, et l’autre est jointe au brevet et y est incorporée au moyen d’un renvoi.

5. Section 55

(1) Any person who infringes a patent is liable to the patentee and to all persons claiming under him for all damages sustained by the patentee or by any person, by reason of the infringement.

(1) Quiconque viole un brevet est responsable, envers le breveté et envers toute personne se réclamant du breveté, de tous dommages-intérêts que cette violation a fait subir au breveté ou à cette autre personne.

(2) Unless otherwise expressly provided, the patentee shall be or shall be made a party to any action for the recovery of damages referred to in subsection (1).

(2) Sauf disposition expressément contraire, le breveté est, ou est constitué, partie à toute action en recouvrement des dommages-intérêts en l'espèce.

6. Section 58

When, in any action or proceeding respecting a patent that contains two or more claims, one or more of those claims is or are held to be valid but another or others is or are held to be invalid or void, effect shall be given to the patent as if it contained only the valid claim or claims. .

Lorsque, dans une action ou procédure relative à un brevet qui renferme deux ou plusieurs revendications, une ou plusieurs de ces revendications sont tenues pour valides, mais qu'une autre ou d'autres sont tenues pour invalides ou nulles, il est donné effet au brevet tout comme s'il ne renfermait que la ou les revendications valides.

B. *Federal Courts Act,* RSC 1985, c F-7

1. Section 39

(1) Except as expressly provided by any other Act, the laws relating to prescription and the limitation of actions in force in a province between subject and subject apply to any proceedings in the Federal Court of Appeal or the Federal Court in respect of any cause of action arising in that province.

(1) Sauf disposition contraire d'une autre loi, les règles de droit en matière de prescription qui, dans une province, régissent les rapports entre particuliers s'appliquent à toute instance devant la Cour d'appel fédérale ou la Cour fédérale dont le fait générateur est survenu dans cette province.

(2) A proceeding in the Federal Court of Appeal or the Federal Court in respect of a cause of action arising otherwise than in a province shall be taken within six years after the cause of action arose.

(2) Le délai de prescription est de six ans à compter du fait générateur lorsque celui-ci n'est pas survenu dans une province.