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)

RESPONDENTS' REPLY FACTUM TO THE INTERVENER FACTUMS (SANOFI-AVENTIS et al., RESPONDENTS)

(Pursuant to the Order of Rothstein J. dated August 12, 2014)

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A. OVERVIEW

1. By leave of this Court, Intervener Facta were filed by the Association for the Protection of Intellectual Property ("AIPPI"); BIOTECanada; Canada's Research-Based Pharmaceutical Companies ("Rx&D"); Fédération Internationale des Conseils en Propriété Intellectuelle ("FICPI"); Canadian Generic Pharmaceutical Association ("CGPA"); and Centre for Intellectual Property Policy ("CIPP").

2. The Respondents (collectively "Sanofi") disagree with the submissions made by the Interveners CGPA and CIPP. The Respondents have an additional concern with respect to the CGPA submissions in that they fail to accord with this Court's practice that an intervener should not argue the merits of the appeal and take a position on the outcome.[1]

3. The CGPA submissions not only seek to argue the merits of the appeal, but do so in a manner that mischaracterizes the decisions of both the Federal Court and the Federal Court of Appeal ("FCA") and the factual findings of the Trial Judge. Furthermore, the arguments advanced are premised on a misapplication of this Court's jurisprudence. Finally, CGPA asks this Court to revisit its own 2008 determination as to the non-obviousness of the patent at issue, thus clearly arguing for a particular outcome. Such advocacy, particularly where it misstates the record, should not be permitted.

4. The CIPP submissions advocate for fundamental policy changes based on disparate legal concepts and an outcome-directed selection of principles from foreign law. Notwithstanding that such policy considerations are largely irrelevant to the issue on appeal, which is the proper interpretation of the statutory utility requirement, the CIPP submissions fail to recognize the statutory nature of Canadian patent law and ignore this Court's jurisprudence on the appeal issues. CIPP argues for a "functional and holistic approach" to Canadian patent law, an approach this Court has rejected, and one that can only lead to unacceptable uncertainty in the law. In any event, such policy changes are a matter for the legislature.

B. CGPA SUBMISSIONS

CGPA's Comments on Obviousness of the '777 Patent Should be Disregarded

5. In 2008 (*Plavix 1*), this Court, in respect of the same patent at issue in this appeal, set out

[1] *Supreme Court Rules*, r 42(2)(c) and 42(3); see *Factum of the Intervener CGPA* at paras 1 and 29.

the legal test for obviousness including an "obvious to try" consideration.[2] The Court set out the circumstances where it would be appropriate to apply an "obvious to try" consideration. This Court found the claims of the '777 Patent to be inventive as of the relevant date in view of the common general knowledge of the person skilled in the art and the prior art.

6. In respect of the present appeal, the prior art before the Trial Judge was the same as before this Court in *Plavix 1* and the material facts were the same. However, the Trial Judge erred by not following the approach taken by this Court in 2008. Specifically, the trial Judge did not consider the question of whether the advantages were obvious (as this Court did) but instead asked if the separation could be achieved. The FCA applied the correct question and found the claimed invention was not obvious.

7. CGPA does not dispute the legal standards set out by this Court but takes issue with the application of that standard to the '777 Patent by the FCA. CGPA's entire argument on obviousness is an attack on the FCA following the approach of this Court, rather than a consideration of the appropriate legal principles. This is not a proper submission from an intervener and the paragraphs relating to obviousness should be ignored.[3]

8. The Respondents have an additional concern that CGPA attempts to characterize the evidence in the appeal and suggests that there are material differences with the evidence before this Court in *Plavix 1*. As illustrated in the Respondents' factum, at para. 152, this is incorrect.[4] An intervener must accept the record before the Court and should not contest the facts.

CGPA's Utility Argument Misreads the Patent

9. In arguing its position regarding utility, CGPA confounds the Trial Judge's conclusions with respect to the utility of the patent and mischaracterizes the determinations of the FCA.

10. For instance, the Trial Judge found that the inventors had demonstrated the advantages of clopidogrel, namely having all of the activity and being better tolerated. In addition, the Trial Judge found that Sanofi had also soundly predicted utility in humans. The only element of the law as understood by the Trial Judge that Sanofi did not meet was that it failed to include all of

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[2] *Sanofi-Synthelabo Canada Inc v Apotex Inc*, 2008 SCC 61 [*Plavix I*].
[3] Factum of the Intervener CGPA at paras 28-33.
[4] Factum of the Respondents Sanofi-Aventis et al. at para 152.

the information it had to support this prediction. The Trial Judge never considered if the information set out in the '777 Patent, when read with the common general knowledge, was sufficient to meet any disclosure requirement.[5]

11. In spite of these clear findings, CGPA argues[6] that the '777 Patent promised "therapeutic efficacy" that had not been demonstrated in humans and could not be predicted through the rat testing disclosed in the '777 Patent. In fact, the only mention of "therapeutic" in the '777 Patent is on page 12 and reads:

> "...the results of this study which demonstrates another advantage of the invention, namely that the salts of the dextro-rotatory isomer have a better **therapeutic** index than the salt of the racemic mixture;"[7]

12. The study which is referred to is the pre-clinical rat study that measured the platelet aggregation inhibition activity and toxicity of the compound of the invention. The evidence of the experts was that therapeutic index could only be measured in animals as it is inappropriate to do comparative toxicity studies in humans.[8] Thus, CGPA is not only advancing a construction contrary to that of the FCA, but also contrary to the words of the '777 Patent.

13. CGPA further mischaracterizes the determination made by the FCA to suggest that there was a "reading down" of the promised utility to match what the patent disclosed as having been demonstrated. A fair reading of the decision reveals the FCA did no such thing.

14. The FCA cited jurisprudence of this Court, including *Whirlpool* and *Consolboard*, and conducted a purposive construction to determine the promised utility of the '777 Patent. The FCA followed the prior judgment of the FCA in *Olanzapine* where Justice Layden-Stevenson indicated that, unless there is an explicit promise of a specific result, only a scintilla of utility is required.[9] The FCA found there was no explicit promise of therapeutic use in humans.[10] Contrary to CGPA's assertions, the FCA based its construction on a single inventive premise

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[5] At the same time the Trial Judge found the '777 Patent met the statutory disclosure requirement under s. 34.
[6] Factum of the Intervener CGPA at para 10.
[7] '777 Patent at 12, Respondent's Record Volume 3, Tab 4
[8] Factum of the Respondents, paras 24-25
[9] *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2013 FCA 186 at para 16; citing *Eli Lilly Canada Inc v Novopharm Ltd*, 2010 FCA 197 at 76 [*Olanzapine*].
[10] *Ibid* at para 69; though if there was such a statement it would have been both true and soundly predicted.

(clopidogrel's beneficial properties).[11]

15. Similarly, CGPA mischaracterizes the concurring reasons of Justice Gauthier with respect to the construction of the patent. Justice Gauthier correctly recognized that not every statement in a patent must be construed as an explicit promise. A reading of the patent as a whole through the eyes of a person skilled in the art is required to determine whether such an explicit promise is made. Justice Gauthier applied this approach and recognized that it would be unfair to the patentee to infer an explicit promise where the language of the patent and the information included, including the test data, would not require such a inference.[12]

16. More importantly, CGPA's arguments ignore the importance of the claims in construing a patent. This Court has recognized the paramount importance of the claims in defining the invention.[13] CGPA would have the Court read every compound or composition claim as a use claim and seeks to define the invention of the '777 Patent solely by one of its potential uses.

17. Similarly, CGPA is unfair to this Court's reasons in *Plavix 1*. At paragraph 21, CGPA omits the words "is a compound" from this Court's statement that "the inventive concept of the claims in the '777 Patent **is 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".[14]

18. Further, CGPA asserts that the '777 Patent must be construed to have a greater promise of utility than the '875 Patent since it was a selection patent. This Court has already decided that selection patents are not different in principle than other patents and has recognized that the '777 Patent disclosed the advantages of clopidogrel and that this was useful information.[15] Further as stated by Dr. Fox, the utility of a selection patent can be the same as the genus patent. It is the advantages that confer patentability on the selection, not a different utility.[16]

AZT Did Not Provide a "Clear and Consistent" Standard for Disclosure

19. CGPA's arguments on utility and promise are premised on an erroneous application of

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[11] *Ibid* at paras 14, 67, 71, 74, 76, and 81.
[12] *Ibid* at paras 124-129.
[13] *Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 31 [*Free World Trust*].
[14] *Plavix 1*, *supra* note 2 at para 78.
[15] *Ibid* at paras 100, 110.
[16] Donald H MacOdrum, *Fox on the Canadian Law of Patents*, 5th ed at 4-184.

this Court's jurisprudence, particularly with respect to *AZT*.[17] The statement that AZT has provided a "clear and consistent standard" for disclosure in cases of sound prediction is not supportable.

20. First, *AZT* did not impose any heightened disclosure requirement for sound prediction. Justice Binnie held that "precise disclosure requirements" did not arise given that the factual basis and line of reasoning had been disclosed and stated "I say no more about it".[18] This Court recognized recently in *Viagra* that the concept of "heightened disclosure" for sound prediction was not established[19] and the FCA in *Eurocopter* acknowledged that such a requirement was not imposed by the Court.[20]

21. Second, while some lower courts have recently applied a heightened disclosure requirement, it is not credible to suggest that a clear and consistent standard is applied. As the submissions of FICPI, AIPPI, Rx&D and BIOTEC highlight, these lower court decisions and the appearance of both the promise doctrine and heightened disclosure requirement have created significant uncertainty for patentees and other stakeholders.[21]

22. The imposition of a disclosure requirement outside of that which is defined by the statute not only introduces unacceptable uncertainty in the law but also contravenes this Court's statement that patent law is wholly statutory.[22] The sole disclosure requirement an applicant for a patent is required to meet is set out in the *Patent Act* (s. 34/27(3)).

23. After examination, and upon satisfaction of the terms set out in the Act, the Commissioner of Patents issues a patent which is in the nature of a Regulation.[23] This Court has stated that there is an onus on a person attacking a patent to show the Commissioner erred in allowing its grant and that the reasonableness standard applies to the Commissioner's decision.[24] The retroactive application of a technical requirement of disclosure unbounded by the statute,

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[17] *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 [*AZT*].
[18] *AZT*, *supra* note 17 at para 70; though it is apparent that at para 73 that Justice Binnie looked beyond the language of the patent in his analysis. Further, as indicated in the Factum of the Intervener RxnD, the true context of this discussions was inventorship, namely when had the invention been reduced to practice.
[19] *Pfizer Canada Inc v Novopharm Ltd*, 2012 SCC 60 at para 43 [*Viagra*].
[20] *Eurocopter c Bell Helicopter Textron Canada Ltée*, 2013 FCA 219 at paras 150-155 [*Eurocopter*].
[21] Factum of the Intervener FICPI at paras 9-10; Factum of the Intervener AIPPI at para 12; Factum of the Intervener Rx&D at para 42; Factum of the Intervener BIOTECanada at para 35.
[22] *Plavix 1*, *supra* note 2 at para 12.
[23] *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 49 [*Whirlpool*].
[24] *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34 at para 24 [*Schmeiser*]; *AZT*, *supra* note 17 at para 44.

particularly where the extent of the disclosure obligation is dependent upon a derivation of the so-called "promise", and whether that promise had been demonstrated or predicted, introduces irrational and untenable uncertainty.

24. The imposition of a non-statutory disclosure requirement also violates the doctrine against vagueness as a critical component of a society grounded in the rule of law.[25] Laws must provide fair notice to citizens. The promise doctrine and the heightened disclosure requirement, which did not exist at the date of the '777 Patent, exemplify a derogation from the principle of fair notice. As noted in the FICPI submission at paragraphs 12-13, these "standards" have a heavier burden on pharmaceutical patent holders notwithstanding that pharmaceutical patents should be judged by the same principles as any other invention.[26]

CGPA Contradicts *Consolboard* and *Viagra*

25. The CGPA submissions not only advocate for an expansion of the requirements for patentability beyond the statute, but contradict the interpretation of the statute by this Court. At paragraph 23, CGPA states that "*Consolboard* stands only for the proposition that a patentee is not obligated to state the "way" in which the utility is achieved or to "extol the effect or advantage of his discovery"'. Justice Dickson said this:

> I do not read the concluding words of s. 36(1) 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.[27]

26. Justice Dickson also adopted the statement from *American Optical* that "If an inventor has adequately defined his invention he is entitled to its benefit even if he does not fully appreciate or realize the advantages that flow from it or cannot give the scientific reasons for them".[28]

27. Finally, this Court concluded:

> With respect, I agree with the submission of counsel for the appellant that the

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[25] *R v Levkovik*, 2013 SCC 25 at para 32.
[26] Factum of the Intervener FICPI at paras 12-13.
[27] *Consolboard Inc v MacMillan Bloedel (Saskatchewan) Ltd*, [1981] 1 SCR 504 at 526 [*Consolboard*].
[28] *Ibid.*

> Federal Court of Appeal has confused the requirement of s. 2 of the Patent Act defining an invention as new and "useful", with the requirement of s. 36(1) of the Patent Act that the specification disclose the "use" to which the inventor conceived the invention could be put. The first is a condition precedent to an invention, and the second is a disclosure requirement, independent of the first.[29]

28. In the recent *Viagra* decision, this Court remarked on the soundness of the reasoning of Justice Dickson, considered this Court's decision in AZT, and confirmed that utility is not a disclosure requirement: "In fact there is no requirement whatsoever in s. 27(3) to disclose the utility of the invention".[30]

29. The approach to utility and disclosure advocated by CGPA is directly contradictory to the above statements by this Court. Utility would become a disclosure requirement and, where the utility is based on a prediction, the inventor would be required to explain how the invention was arrived at and why it works.[31] Such a fundamental change to the patent bargain is particularly unreasonable given the number of applications filed on the basis of the statute as interpreted by this Court.[32]

CGPA Ignores s. 53 of the *Patent Act*

30. Finally, CGPA's proposed utility framework completely ignores the presence and function of section 53 of the *Patent Act*.

31. As set out in the Respondents' factum and also articulated in the FICPI submissions[33], section 53 addresses false statements made in a patent. The patent will be void where a material statement is false and willfully made for the purpose of misleading. The effect of the framework proposed by CGPA would be to invalidate patents where, as in the present case, there is no suggestion any of the statements in the specification are false and the Court has found the invention sufficiently disclosed under s. 34. This would render section 53 nugatory. It is axiomatic that words in a statute have meaning.[34]

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[29] *Ibid* at 527.
[30] *Viagra*, *supra* note 19 at paras 40-41, 50.
[31] This may also include the prior art and common general knowledge which contradicts this Court's instruction that a patent is to be read through the eyes of a person skilled in the art.
[32] Factum of the Intervener AIPPI at para 32.
[33] Factum of the Intervener FICPI at paras 27-31.
[34] *Rizzo & Rizzo Shoes Ltd, Re*, [1998] 1 SCR 27 at para 21.

C. CIPP SUBMISSIONS

32. CIPP submits that Canadian patent law should be assessed "functionally and holistically".[35] While academic consideration of IP policy and potential reform is laudable, it is a discussion that is not practical or germane to the present appeal. Further, the proposed "functional and holistic" analysis is inconsistent with the statutory nature of the law. CIPP's submissions do not address the statutory framework for the utility and disclosure requirements including the effect of section 53. Lower courts have strayed from the statute as interpreted by this Court which can only be corrected by this Court.

33. Moreover, the concept of a "functional and holistic" approach to patent law is not only unclear, but is also problematic. This Court has already rejected any quest for the "spirit of the invention" in favor of an approach that is predictable and grants protection for that which actually has in good faith been invented.[36]

34. Further, undefined requirements would introduce ambiguity in the law, which this Court has stated should be avoided. This would create uncertainty among applicants, patentees, rights holders and other stakeholders.

35. Finally, patent law is wholly statutory and there is no basis in the *Patent Act* for such an approach.

CIPP Submissions Ignore The Statutory Framework and This Court's Jurisprudence

36. CIPP argues that the real issue in this Appeal is how the patent system treats "voluntary statements about what an invention does, i.e. its usefulness".[37] However, CIPP gives no consideration whatsoever of the effect of section 53 which relates to false statements made in a patent specification. Also, there is scant mention of *Consolboard* or *Viagra* and the principles established by this Court.

37. Instead, CIPP provides a highly selective review of mostly US and European decisions to

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[35] CIPP cites a paper by its counsel in support of its submission: R Richard Gold & Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2014) 30 CIPR 35 at 73. This paper was the subject of a responding publication by Norman Siebrasse, titled "Form and Function in the Law of Utility: A Reply to Gold & Shortt" (September 26, 2014). (Online: http://ssrn.com/abstract=2502024)

[36] *Free World Trust*, *supra* note 13 at para 42.

[37] Factum of the Intervener CIPP at para 17.

suggest that other requirements (enablement, inventive step) in those jurisdictions are consistent with the enforcement of "promises". CIPP provides an anecdotal review of how other jurisdictions have adjudicated the validity of certain patents.[38] In this regard, CIPP's reliance on selected case law from other jurisdictions to suggest an interpretation of Canadian law is not only incongruous but unnecessary given that this Court, in a series of decisions, has authoritatively defined the statutory framework.[39]

38. With respect to US law, CIPP selectively cites instances where it is said "tribunals" have found the "promise in the applicant's statement of intended purpose" and required that the specification provide an evidentiary basis to support this promise.[40] However, in each of the instances cited, the utility was cited in the claims. Thus, the US enablement and written description requirements would be assessed in view of the claimed invention. In any event, under US law only one utility need be demonstrated for a patent to be valid even when multiple utilities are identified in a patent.[41]

39. The EPC cases cited as supporting a consideration of what is "promised" by the specification do not do so in the context of utility.[42] Thus, this discussion is of little relevance. Neither the selected US nor EPC cases deal with utility and thus are of little assistance. The question in this case is the meaning of the word "useful", not enablement nor obviousness.

40. In any event, a wide-ranging review of foreign law is very different from an approach to statutory interpretation that is consistent with Canada's treaty obligations under NAFTA, TRIPS and PCT, which have been adopted into Canadian law. Harmonization with these principles is not only necessary, it is required. To the extent that CIPP believes a reform of Canadian patent law modeled on foreign laws is desirable, their advocacy would be more properly directed towards Parliament.

41. The CIPP analysis exemplifies the paradox experienced by lower courts in applying the

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[38] In this regard the Respondents object to the inclusion by CIPP of numerous patents in the Book of Authorities as "evidence" of their specifications given that such patents much less their various counterparts are not in the record.
[39] The AIPPI submissions comprise a detailed review of the utility and disclosure requirements in various jurisdictions as submitted by members in those jurisdictions.
[40] Factum of the Intervener CIPP at para 23.
[41] *Manual of Patent Examining Procedure*, 9th ed (March 2014), online U.S. Department of Commerce – USPTO at 2100-39 to 2100-40; *Raytheon v Roper*, 724 F 2d 951, 220 USPQ 592 (Fed Cir 1983) at para 5.
[42] Factum of the Intervener CIPP at paras 24-26.

promise doctrine. When reading the detailed description of the invention with a view to assessing whether given statements amount to a promise, the claims become secondary, an approach inconsistent with the instruction of this Court. Further, the concept of materiality imposed by section 53 can be lost. The result is that any statement of advantage or potential application may be construed as a "promise" of utility.

42. CIPP asserts that the "promise doctrine" is a straw-man theory and that it is merely an application of settled principles. Notwithstanding that this is contradicted by the submissions of other interveners, CIPP does not establish how such a requirement arises under the Canadian statute.[43] It is respectfully submitted that the jurisprudence of this Court does not support the position advanced by CIPP.

No Basis to Reconsider Obviousness

43. Finally, CIPP suggests that the holistic approach be applied to obviousness and invokes a recent US court decision as an exemplary approach. It appears that CIPP's view is that secondary indicia of obviousness should be emphasized.

44. This Court reformulated the test for obviousness in its 2008 decision in respect of the '777 Patent. This included secondary indicia of obviousness which the Court considered. There is no reason to revisit this Court's decision.

DATED at Ottawa, Ontario, this 30th day of September, 2014.

ALL OF WHICH IS RESPECTFULLY SUBMITTED

Anthony Creber/Marc Richard/Livia Aumand
Of counsel for the Respondents

[43] Factum of the Intervener *CIPP* at para 30. CIPP indicates that Canadian courts have not considered *how* useful an invention must be to warrant a patent. This is incorrect. The Federal Court of Appeal, citing *Olanzapine, supra* note 9, stated that only a "scintilla" is required unless there is an explicit promise of a specific result. CIPP cites to the 1885 decision of the Court of Appeal in Chancery in Badische as instructive on the threshold question but ignores the 2011 decision in *Human Genome Sciences Inc v Eli Lilly and Company*, [2011] UKSC 51 which set a low threshold for industrial application (utility).

AUTHORITIES RELIED UPON

NO.	AUTHORITY	PARA. REF.
1.	*Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 (pp.175, 186)	19, 20, 23
2.	*Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2013 FCA 186 (pp.5-8,25-29,31,45-47)	14, 15
3.	*Consolboard Inc v MacMillan Bloedel (Saskatchewan) Ltd,* [1981] 1 SCR 504 (pp.526-527)	25, 26, 27
4.	*Eli Lilly Canada Inc v Novopharm Ltd,* 2010 FCA 197 (pp.30)	14, 42
5.	*Eurocopter c Bell Helicopter Textron Canada Ltée*, 2013 FCA 219 (pp.53-55)	20
6.	*Free World Trust v Électro Santé Inc*, 2000 SCC 66 (pp.1043-1044,1049)	13, 33
7.	*Human Genome Sciences Inc v Eli Lilly and Company*, [2011] UKSC 51	42
8.	*Pfizer Canada Inc v Novopharm Ltd*, 2012 SCC 60 at para 43 (pp.641-645)	20, 28
9.	*Monsanto Canada Inc v Schmeiser,* 2004 SCC 34 (pp.917)	23
10.	*Raytheonv.Roper,* 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 (1984) (pp.598)	38
11.	*R v Levkovik,* 2013 SCC 25 (pp.215)	24
12.	*Rizzo & Rizzo Shoes Ltd,* Re, [1998] 1 SCR 27 (40-41)	31
13.	*Sanofi-Synthelabo Canada Inc v Apotex Inc,* 2008 SCC 61 (pp.274-275,296,302,306)	5, 17, 18, 22
14.	*Whirlpool Corp v Camco Inc,* 2000 SCC 67 (pp.1092-1096)	23
15.	HG Fox, Canadian Law of Patents, 5th ed (Toronto: Carsewell, 2013) (pp.4-184)	18
16.	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> (pp 2100-39 to 2100-40)	38
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