Court File No. 35562

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
(Respondents in the
Federal Court of Appeal)

- and -

SANOFI-AVENTIS, and
BRISTOL-MYERS SQUIBB SANOFI
PHARMACEUTICAL HOLDING PARTNERSHIP

Respondents
(Appellants in the
Federal Court of Appeal)

FACTUM OF THE INTERVENER AIPPI

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FEDERATION INTERNATIONALE DES CONSEILS EN PROPRIETE INTELLECTUELLE, CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES, CENTRE FOR INTELLECTUAL PROPERTY POLICY, INTERNATIONAL ASSOCIATION FOR THE PROTECTION OF INTELLECTUAL PROPERTY ("AIPPI"), BIOTECANADA, and CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

Interveners

FACTUM OF THE INTERVENER AIPPI

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PART I – OVERVIEW AND STATEMENT OF FACTS

(A) Overview

1. Following the decisions of this Court in *AZT*[1] and *VIAGRA*,[2] there has been uncertainty with respect to the precise scope of the utility requirement under Canadian law and in particular the extent to which the utility of a patented invention should be disclosed or supported in the patent specification.

2. This Court has noted on prior occasions that in appropriate circumstances it is desirable not to interpret or apply the intellectual property laws of Canada in a jurisdictional vacuum, but rather to do so considering "like minded jurisdictions".

3. Accordingly, AIPPI's[3] submissions herein are intended to assist this Court in understanding how Canadian law compares to, and in some cases now differs from, that of other jurisdictions in respect of any disclosure requirements for utility. Those submissions may be summarized as follows:

(a) Many jurisdictions have a statute-based requirement of "utility" or "industrial applicability" for patentability;

(b) For many jurisdictions, the utility or industrial applicability must be indicated in the specification if it is not otherwise obvious;

(c) For many jurisdictions, there is no requirement that the proof or support for the utility or industrial applicability be provided in the patent specification; and

(d) As such, in a number of jurisdictions, it is relatively rare that utility or industrial applicability is a basis to deny the grant of a patent or for invalidating a granted patent.

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[1] *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77, [2002] 4 SCR 153 [*AZT*].
[2] *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60, [2012] 3 SCR 625 [*VIAGRA*].
[3] The Intervener, Association Internationale pour la Protection de la Propriété Intellectuelle / International Association for the Protection of Intellectual Property ("AIPPI").

(B) Statement of Facts

i. AIPPI

4. AIPPI is an international organization founded in 1897 and dedicated to the development, improvement, legal protection, and international harmonization of intellectual property. Its membership includes intellectual property practitioners, owners, academics and others from over 100 countries, with approximately 9000 members, including those from Canada. The work of AIPPI has been relied upon or referenced by the World Intellectual Property Organization (WIPO), other government and non-governmental organizations, and the courts, including in Canada.[4]

ii. AIPPI's Research Concerning Utility/Industrial Applicability

5. The subject of utility (or industrial applicability as it is called in many jurisdictions) has been a topic that has been the subject of substantial research conducted by AIPPI.

6. In particular, the requirement for utility or industrial applicability was considered by AIPPI Special Committee Q180 commencing in 2004. The work of the Committee included the canvassing of AIPPI's national and regional groups on various questions pertaining to the legal requirement for patentability of utility or industrial applicability in their respective jurisdictions. These questions included the nature of the utility and/or industrial applicability requirements which existed in each jurisdiction, the manner in which utility and/or industrial applicability is addressed during prosecution, and the manner in which utility and/or industrial applicability might be raised in invalidity proceedings. AIPPI received responses from over 30 of its national or regional groups and those responses were published (and remain available) on AIPPI's website.[5]

7. AIPPI has recently conducted further research of its national and regional groups specifically directed to utility, including any requirements for disclosure of that utility in the patent specification. AIPPI has received responses from approximately 20 national groups including the United States, Japan, Australia, and numerous European countries including

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[4] See *Merck & Co v Pharmascience Inc*, 2010 FC 510 at paras 34-37, 90 CPR (4th) 402.
[5] AIPPI Special Committee Q180 (2004), online: AIPPI <https://www.aippi.org/?sel=questions&sub=dissolvedcommittees&viewQ=180#180>.

France, Germany, Sweden, Switzerland and the U.K. Those responses are also available on AIPPI's website.[6]

PART II – QUESTIONS IN ISSUE

8. The following questions raised by the parties in this Appeal will be addressed by AIPPI:

   (a) The extent to which utility is required to be discussed or disclosed in the patent specification in other jurisdictions; and

   (b) What, if any, additional disclosure requirements are imposed on patentees when they are relying on the doctrine of sound prediction so as to satisfy the utility requirement for patentability.

PART III – STATEMENT OF ARGUMENT

(A) Uncertainty in the Canadian Law Following *AZT* and *VIAGRA*

9. In *AZT*, this Court restated the requirements for utility, holding *inter alia* that the utility required for patentability in accordance with section 2 of the *Patent Act*[7] must, as of the filing date, either be demonstrated or be a sound prediction based on the information and expertise then available.[8] In respect of sound prediction, this Court stated three requirements: (i) "there must be a factual basis for the prediction"; (ii) "the inventor must have at the date of the patent application an articulable and 'sound' line of reasoning from which the desired result can be inferred from the factual basis"; and (iii) "there must be proper disclosure".[9]

10. With respect to the third requirement, this Court did not delineate the precise ambit of any disclosure requirement specific to sound prediction.[10] However, following *AZT*, in interpreting the "proper disclosure" requirement, the Federal Court of Appeal (in the "*Raloxifene*" decision) stated that where a patent's utility is founded on a sound prediction, there

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[6] AIPPI National Group Reports, online: AIPPI submissions to the Supreme Court of Canada in Apotex v. Sanofi-Aventis (re: PLAVIX) <https://www.aippi.org/?sel&cf=aippiPlavixSubmissions> [AIPPI Group Reports].
[7] *Patent Act*, RSC 1985, c P-4.
[8] *AZT*, *supra* note 1 at para 56.
[9] *Ibid* at para 70.
[10] *Ibid*.

is a *heightened* disclosure requirement, which includes disclosure in the patent of the factual basis and line of reasoning giving rise to the prediction.[11]

11. This Court again considered utility and sound prediction in *VIAGRA*. While appearing to accept that in the case of demonstrated (as opposed to predicted) utility a patentee could rely upon data not disclosed in the patent specification,[12] this Court expressly declined to decide the scope of any disclosure requirement associated with sound prediction as it was not in issue.[13]

12. Thus the precise scope of any disclosure requirement associated with utility, and in particular sound prediction, remains an open question in the jurisprudence of this Court, and an area of significant uncertainty in Canadian law.

(B) Relevance of the International Context

13. This Court has noted on prior occasions that in appropriate circumstances it is desirable not to interpret or apply the intellectual property laws of Canada in a jurisdictional vacuum, but rather to do so considering "like minded jurisdictions", a notable example being this Court's prior decision with respect to PLAVIX and the patent at issue on this Appeal, wherein this Court considered both the United States and United Kingdom jurisprudence in respect of the "obvious to try" test for obviousness.[14]

14. The importance of the international context in respect of the issue of utility and any related disclosure requirements was recognized in the concurring reasons of Gauthier JA in the decision of the Federal Court of Appeal under appeal,[15] wherein she observed, in the context of the construction of any promised utility of the patent, that an applicant, having drafted a patent for filing in numerous jurisdictions, faces different requirements for patentability in Canada.[16]

(C) Utility/Industrial Applicability Requirement in Foreign Patent Systems

15. Article 27 to the *Agreement on Trade-Related Aspects of Intellectual Property* ("TRIPS

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[11] *Eli Lilly Canada Inc v Apotex Inc*, 2009 FCA 97 at paras 14-15, 78 CPR (4th) 388 [*Raloxifene FCA*]; See also *Eli Lilly and Co v Teva Canada Ltd*, 2011 FCA 220 at para 47, 94 CPR (4th) 95.
[12] *VIAGRA*, *supra* note 2 at para 40.
[13] *Ibid* at para 43.
[14] *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, [2008] 3 SCR 265 at para 60; See also *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 SCR 65 at paras 12-13 (Binnie J, dissenting); *Galerie d'art du Petit Champlain inc v Théberge*, 2002 SCC 34, [2002] 2 SCR 336 at para 6.
[15] *Sanofi-Aventis v Apotex Inc*, 2013 FCA 186, 114 CPR (4th) 1 (Gauthier J, concurring).

Agreement"),[17] to which Canada is a member, states that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application [emphasis added]."[18]

16. Footnote 5 to Article 27 of TRIPS stipulates that the term "capable of industrial application" may be deemed by a Member to be synonymous with the term "utility".[19]

17. Accordingly, in many countries there is a requirement that a patented invention has utility or industrial applicability, and that requirement typically comes by way of the applicable domestic patent legislation.

i. The United States

18. For example, in the United States, the statutory definition of "invention", which is similar to the Canadian definition, requires a patented invention to be "useful".[20]

19. To satisfy the utility requirement, the claimed invention must have, and the patent specification should disclose: (i) a specific utility (i.e. a well-defined and particular benefit to the public); (ii) a substantial utility (i.e. a significant and presently available benefit to the public); and (iii) a credible utility (i.e. it can be used by a person of ordinary skill in the art to achieve the specific and substantial utility asserted).[21] However, a patent may still be considered valid even if the specification does not explicitly disclose or assert the utility where a person skilled in the art would immediately appreciate why the invention is useful.[22] Additionally, a patent will not be held invalid for a lack of utility merely because some of the embodiments claimed do not achieve the stated purpose.[23]

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[16] *Ibid* at para 125.
[17] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 1869 UNTS 299, 33 ILM 1197 (1994), art 27 [TRIPS].
[18] *Ibid*.
[19] Similarly, Article 1709 of the *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, 32 ILM 289 and 605 (1993) [NAFTA], stipulates that a member state may deem the term "capable of industrial application" to be synonymous with "utility".
[20] 35 USC §101, online: Office of the Law Revision Counsel, United States Code < http://uscode.house.gov/>.
[21] See *In re Fisher*, 421 F3d 1365, 1371, 76 USPQ2d 1225 (Fed Cir 2005).
[22] See AIPPI Group Reports, *supra* note 6, US; Donald S Chisum, *Chisum on Patents* (Seattle: Matthew Bender, 2014) at §4.04 [Chisum].
[23] *Ibid* at §4.02.

ii. Australia

20. In Australia, pursuant to section 18(1)(c) of the *Patents Act 1990*,[24] a claimed invention must be "useful". This term has been construed as requiring that at least one embodiment of the invention as claimed must achieve the promised result and that an invention will not demonstrate lack of utility merely because some of the embodiments claimed do not achieve the promised result.[25] In 2013, the *Act* was amended to include a statement that an invention as claimed will not be taken as "useful" unless a "specific, substantial, and credible use for the invention" is disclosed in the specification, and the disclosure must be sufficient so that the said use can be appreciated by a skilled person.[26]

iii. European Patent Convention (EPC) and related European countries

21. Article 52(1) of the *European Patent Convention* (EPC) stipulates that:

> European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.[27] [Emphasis added]

22. As a result, the European nations that are contracting states to the EPC (there are over 35 such nations) will have similar provisions in their domestic patent legislation, including France, Germany, the Netherlands, Sweden, Switzerland and the U.K.[28] Pursuant to Article 57 of the

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[24] *Patents Act 1990*, No 83, as amended (compilation prepared on 24 June 2014), s 18(1)(c), online: Australian Government <http://www.comlaw.gov.au/Details/C2014C00301> [Australian *Patents Act*].

[25] William A Hoyng & Frank WE Eijsvogels, eds, *Global Patent Litigation: Strategy & Practice* (Netherlands, Kluwer Law International, 2008) (loose-leaf, supplement 4, 2008), Ch Australia at 5 [Hoyng & Eijsvogels]; *Martin Engineering Co v Trison Holdings Pty Ltd* (1989) 14 IPR 330 at 336-337 (QL); AIPPI Group Reports, *supra* note 6, Australia.

[26] Australian *Patents Act*, *supra* note 24, ss 7A, 18(1)(c). This amendment has not yet been judicially construed. However, the phrase "specific, substantial, and credible use" is intended to have the same meaning as that in the United States, see the Explanatory Memorandum to the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011*, at Item 6: Usefulness – 'specific, substantial and credible', online: Australian Government <http://www.comlaw.gov.au/Details/c2011b00114/Explanatory%20Memorandum/Text#_Toc295897423>; The Australian *Act* also requires a claimed invention to be a "manner of manufacture", which requires that the invention must offer some material advantage and be of value to the country in the field of economic endeavour (see Australian *Patents Act*, supra note 24, ss 18(1)(a) and 18(1A)(a)).

[27] *Convention on the Grant of European Patents (European Patent Convention)*, 5 October 1973, 1065 UNTS 199 (as amended 29 November 2000) [EPC 2000].

[28] In the U.K., the term "capable of industrial application" is used instead of "susceptible of industrial application", see *Patents Act 1977* (UK), c 37, s 1(1)(c).

EPC, an invention is "susceptible of industrial application" if it can be made or used in any kind of industry, including agriculture.[29]

23. Overall, the threshold to meet the "industrial application" requirement is regarded as low with the terms "industry" and "application" both being construed broadly. For example, in respect of the former this typically includes any type of technical or commercial activity. The term "susceptible" also suggests that an industrial application need only be possible, without the need to demonstrate an actual "application". For example, EPC and U.K. decisions have held that a "plausible" or "reasonably credible" claimed use, or an "educated guess", could suffice.[30]

iv. Japan

24. Similar to the language found in the EPC, Article 29 of the Japanese Patent Act requires inventions as claimed to be industrially applicable.[31]

(D) Requirement of Proof or Disclosure of Utility/Industrial Applicability in Patent Specification in Foreign Patent Systems

25. As noted above, in the United States, a patent may be valid even if the specification does not explicitly disclose or assert the utility of the claimed invention, provided that a person of ordinary skill in the art would immediately appreciate why the invention is useful, and the utility is "specific, substantial, and credible". In addition, evidence demonstrating or proving the utility is not required to be in the specification. Patentees may submit evidence before the USPTO (e.g. during prosecution of the application) or in Court if the utility of the invention is challenged, and

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[29] EPC 2000, *supra* note 27. The contracting states to the EPC again typically have similar type definitions in their domestic patent legislation, see Hoyng, *supra* note 25, Ch Germany at 5 and Ch The European Patent Convention (EPC) at 15; William Cornish & David Llewelyn, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 5th ed (London: Sweet & Maxwell, 2003) at at 173, 206; Mary Vitoria et al, eds, *Encyclopedia of United Kingdom and European Patent Law*, (London: Sweet & Maxwell, 1977) (loose-leaf, release 74, November 2013) Vol 1 at 1148/2-50; see AIPPI Group Reports, *supra* note 6, including France, Netherlands, Sweden, Switzerland and the U.K.

[30] See for e.g., *Human Genome Sciences Inc v Eli Lilly and Co*, [2011] UKSC 51 at paras 107-109, rev'g [2010] EWCA Civ 33, aff'g [2008] EWHC 1903 (Pat) [*Human Genome Sciences*], wherein the Supreme Court adopted the reasoning of previous EPO Board decisions which provided that a "plausible" or "reasonably credible" claimed use or an "educated guess" could suffice; See also AIPPI Group Reports, *supra* note 6, including France, Germany, Netherlands, Sweden, Switzerland and the U.K.

[31] Aoyama & Partners, Japan in Arnold & Siedsma, eds, *Manual for the Handling of Applications for Patents, Designs and Trademarks throughout the World* (Kluwer Law International, 1927) (Supplement No. 153, February 2014) at 5, 12; AIPPI Group Reports, *supra* note 6, Japan.

this evidence can include evidence that arises subsequent to (post-dates) the filing of the U.S. application.[32]

26. In Australia, prior to the amendments in 2013, utility was (and remains) a requirement of Australian law. However, there was no explicit requirement at law that the utility of the claimed invention be demonstrated in the specification. It was considered that evidence in the specification was sufficient where it leads a person skilled in the art reasonably to expect that what is claimed would be useful. The amendment in 2013 adding, *inter alia*, the requirement that the patent disclose a "specific, substantial, and credible use" for the invention has not been judicially construed but is intended to have the same meaning as that in the United States.[33]

27. In respect of the EPC and countries such as France, Germany, the Netherlands, Sweden, Switzerland and the U.K, typically, requirements as to the content of the patent specification with regard to the issue of industrial application are limited, and it is sufficient to disclose the technical field of the invention and the way in which it is industrially applicable when it is not obvious from the description of the invention. To the extent that a patentee is required to demonstrate the industrial application of the invention if challenged, evidence that the invention was "susceptible" of industrial application at the time of filing would be required but could be supplemented by post-filing evidence.[34]

28. With respect to Japan, the extent to which evidence of the utility of the invention is required to be disclosed in the patent specification may depend on the nature of the invention. If the invention is directed to a new chemical compound, a statement of utility may suffice. If the invention is directed to a pharmaceutical use of a known compound, experimental laboratory data ("wet lab data") will be required. If the patentee is required to prove the industrial applicability of the invention, it is likely that any evidence must be as of the date of the filing of the application and post-filing data would not be permitted.[35]

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[32] AIPPI Group Reports, *supra* note 6, US; Chisum, *supra* note 22 at §4.04.
[33] As noted in paragraph 20, in 2013 the Australian *Patents Act* was amended to provide a definition of "useful" that was meant to be the same as the United States, but has not yet been judicially construed.
[34] Pursuant to Rule 29(3) of the EPC 2000, *supra* note 27, the industrial application of a gene sequence is required to be disclosed in the patent application; AIPPI Group Reports, *supra* note 6, including France, Germany, Netherlands, Sweden, Switzerland and the U.K.; *Human Genome Sciences*, *supra* note 30.
[35] AIPPI Group Reports, *supra* note 6, Japan; The Japanese IP High Court confirmed this approach in *Astellas & Fujisawa v Commissioner Japan Patent Office*, Heisei 17 (gyo-ke) 10312 dated 30 Aug 2005 (Intellectual Property

(E) Practical Effect of Utility/Industrial Applicability on Patentability/Validity in Foreign Patent Systems

29. In the United States, despite the statutory basis for the utility requirement, the issue of utility is not often challenged. This is presumably a result of the fact that evidence demonstrating or proving the utility need not be in the patent specification, and if challenged the patentee may submit evidence in support of the utility, including post-filing evidence.[36]

30. In the context of the EPC and the contracting states, such as France, Germany and Sweden, an allegation of the patented invention having a lack of industrial application appears to only rarely be an issue before the courts.[37]

(F) Impact on Patent Applicants if Canada has a Different Standard of Disclosure for Utility as Compared with Foreign Jurisdictions

31. By virtue of a number of international treaties and conventions to which Canada is a signatory, and in particular the *Patent Cooperation Treaty* ("PCT")[38] and the *Paris Convention for the Protection of Industrial Property* ("*Convention*"),[39] many patent applications filed in Canada by both Canadians and foreigners have been drafted for filing in foreign jurisdictions in addition to Canada, and without necessarily having specific regard to Canadian laws, including the law of utility and related disclosure requirements.

32. For example, according to the 2012-2013 Annual Report of the Canadian Intellectual Property Office ("CIPO"),[40] a total of 35,848 patent applications were filed in Canada during the 12 month period covered by the Report. Of that total, 30,517 (85%) were filed by non-Canadians. Additionally, 72% of all applications filed in Canada (25,768) were PCT national phase filings. Of the 28% (10,080) direct Canadian filings (non-PCT), a large majority of applications would have claimed a *Convention* priority date based on an earlier filed application

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H Ct), Full text of this decision is not available in English; however, an English summary of the decision is provided online: Intellectual Property High Court <http://www.ip.courts.go.jp/app/files/hanrei_en/338/000338.pdf>.

[36] AIPPI Group Reports, *supra* note 6, US.

[37] *Ibid* including France, Sweden and Germany.

[38] *Patent Cooperation Treaty*, 19 June 1970, 1160 UNTS 231, art 11, online: WIPO <http://www.wipo.int/pct/en/texts/articles/atoc.htm>.

[39] *Paris Convention for the Protection of Industrial Property*, as last revised at the Stockholm Revision Conference, 14 July 1967, 21 UST 1583, 828 UNTS 303, art 4, online: WIPO <http://www.wipo.int/treaties/en/text.jsp?file_id=288514>.

in another country. Overall, a large majority of patent applications filed in Canada are based on specifications that were prepared for filing in jurisdictions in addition to Canada.

33. Accordingly, it is respectfully submitted that a determination on the disclosure requirements in Canada that is, to the extent permissible or practical, consistent with the disclosure requirements of other major jurisdictions can only lead to greater certainty and lower costs for patentees who seek patent protection in Canada.

PART IV – SUBMISSIONS ON COSTS

34. AIPPI does not claim costs in respect of its intervention on this Appeal.

PART V – ORDER SOUGHT

35. AIPPI takes no position in respect of the specific Order to be issued by the Court on this Appeal.

RESPECTFULLY SUBMITTED this 16th day of September, 2014

Steven B. Garland

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Solicitors for the Intervener, AIPPI

[40] Annual Report 2012-13, Canadian Intellectual Property Office (CIPO), online: CIPO <http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03785.html#patents>.

PART VI – AUTHORITIES RELIED UPON

NO.	AUTHORITY	PARA. REF.
	CASES	
1.	*Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, [2008] 3 SCR 265 at para 60	13
2.	*Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77, [2002] 4 SCR 153 [*AZT*]	1, 9, 10
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5.	*Eli Lilly and Co v Teva Canada Ltd*, 2011 FCA 220 at para 47, 94 CPR (4th) 95	10
6.	*Galerie d'art du Petit Champlain inc v Théberge*, 2002 SCC 34, [2002] 2 SCR 336 at para 6	13
7.	*Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 SCR 65 at paras 12-13	13
8.	*Human Genome Sciences Inc v Eli Lilly and Co*, [2011] UKSC 51 at paras 107-109, rev'g [2010] EWCA Civ 33, aff'g [2008] EWHC 1903 (Pat)	23, 27
9.	*In re Fisher*, 421 F3d 1365, 1371, 76 USPQ2d 1225 (Fed Cir 2005)	19
10.	*Martin Engineering Co v Trison Holdings Pty Ltd* (1989) 14 IPR 330 at 336-337 (QL)	20
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PART VII – STATUTES

1. 35 USC §101

§101. Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. *Patent Act,* RSC 1985, c P-4, s 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.

3. *Patents Act 1977* (UK), c 37, s 1(1)(c)

1 Patentable inventions.

(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say—

(a) the invention is new;

(b) it involves an inventive step;

(c) it is capable of industrial application;

(d) the grant of a patent for it is not excluded by subsections (2) and (3) below;

and references in this Act to a patentable invention shall be construed accordingly.

4. *Patents Act 1990,* No 83, as amended (compilation prepared 24 June 2014)

7A Meaning of useful

(1) For the purposes of this Act, an invention is taken not to be useful unless a specific, substantial and credible use for the invention (so far as claimed) is disclosed in the complete specification.

(2) The disclosure in the complete specification must be sufficient for that specific, substantial and credible use to be appreciated by a person skilled in the relevant art.

(3) Subsection (1) does not otherwise affect the meaning of the word ***useful*** in this Act.

18 Patentable inventions

Patentable inventions for the purposes of a standard patent

(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an inventive step; and

(iii) is useful; […]

Patentable inventions for the purposes of an innovation patent

(1A) Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an innovative step; and

(iii) is useful; and […]

Court File No. 35562

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
(Respondents in the
Federal Court of Appeal)

- and -

SANOFI-AVENTIS, and
BRISTOL-MYERS SQUIBB SANOFI
PHARMACEUTICAL HOLDING PARTNERSHIP

Respondents
(Appellants in the
Federal Court of Appeal)

BOOK OF AUTHORITIES OF THE INTERVENER AIPPI

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