

**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)

MEMORANDUM OF ARGUMENT

PART I – OVERVIEW AND STATEMENT OF FACTS

OVERVIEW

1. The Association Internationale pour la Protection de la Propriété Intellectuelle / International Association for the Protection of Intellectual Property (“AIPPI”) seeks leave to intervene in this appeal.

2. 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 by the World Intellectual Property Organization (WIPO), other government and non-governmental organizations, and the courts, including in Canada. AIPPI has also intervened before other courts in respect of intellectual property issues, including the Supreme Court of the United States, the European Court of Justice, and the European Patent Office (Enlarged Board of Appeal).

3. As such, AIPPI is well positioned to assist this Court with respect to the issues of patent utility and disclosure which are raised by the within appeal. In particular, AIPPI is able to provide the Court with a unique, international perspective, to permit this Court to understand how Canadian law compares to, and in some cases now differs from, that of other national or regional jurisdictions, including for example the United States, various countries within Europe, and Japan.

STATEMENT OF FACTS

(A) The Association Internationale pour la Protection de la Propriété Intellectuelle / International Association for the Protection of Intellectual Property (“AIPPI”)

2. AIPPI is an international organization, founded in 1897, dedicated to the development, improvement, legal protection, and harmonization of intellectual property. AIPPI is a politically neutral, non-profit organization headquartered in Switzerland having approximately 9000 members representing over 100 countries, including Canada.

Affidavit of Stephan Freischem sworn on June 17, 2014, para 5.

3. The members of AIPPI include intellectual property lawyers, patent, copyright and trademark attorneys, and patent agents in corporate and private practice throughout the world, as well as academics and other persons interested in intellectual property, and include members from North America, South America, Europe, Asia, Australia and Africa. AIPPI is organized into 64 National and Regional Groups, and its members participate by joining one of these groups. In countries where no Group exists, membership is attained as an Independent Member of AIPPI.

Affidavit of Stephan Freischem sworn on June 17, 2014, para 6.

4. AIPPI promotes the protection of intellectual property on a national and international basis by studying and comparing existing national and regional laws and proposing new laws and international and regional treaties and agreements relating to intellectual property so as to achieve the international harmonization of intellectual property where appropriate. In its long history, AIPPI has adopted more than 700 Resolutions and Reports. AIPPI's Resolutions are published in English, French, Spanish and German, and are provided to international and national intellectual property organizations around the world. The presentation of these Resolutions and Reports to international Governmental Organizations, such as the World Intellectual Property Organization ("WIPO"), has contributed considerably to the development, improvement and harmonization of the international protection of intellectual property.

Affidavit of Stephan Freischem sworn on June 17, 2014, para 7.

5. The work of AIPPI has been relied upon by WIPO, the World Trade Organization ("WTO"), other government and non-governmental organizations, and the courts, including in Canada. AIPPI has also intervened before other courts and tribunals in respect of intellectual property issues, including the Supreme Court of the United States, the European Court of Justice, and the European Patent Office (Enlarged Board of Appeal).

Affidavit of Stephan Freischem sworn on June 17, 2014, para 7;and

***Merck & Co, Inc v Pharmascience Inc*, 2010 FC 510 at paras 34-37, quoted by Boivin J in the trial decision leading to the within appeal, *Apotex Inc v Sanofi-Aventis* 2011 FC 1486 at para 66.**

6. The objects of AIPPI, and the manner in which AIPPI pursues its objects, are codified in Article 2 of the Statutes of AIPPI, reproduced below.

Article 2 - Objects of the Association

2.1 The Association shall have the following objects:

- a) to promote the understanding of the necessity at both the national and international level for intellectual property protection in the broadest sense as well as the repression of unfair competition, and to encourage further development of the protection of intellectual property;

- b) to study and compare existing laws and proposed new laws, to propose improvements to them and to promote their harmonisation;
- c) to work for the development, expansion and improvement of international conventions and agreements concerning the protection of intellectual property.

2.2 The Association shall pursue its objects by, in particular:

- a) disseminating information, including preparing and distributing publications;
- b) organizing congresses and other meetings;
- c) making representations to governments and intergovernmental bodies, as well as to national, regional, and international organizations.

Affidavit of Stephan Freischem sworn on June 17, 2014, para 8 and Ex A.

(B) Utility – Prior Research of AIPPI

7. The subject of utility (or industrial applicability as it is called in some jurisdictions), has been a topic which has been the subject of substantial research conducted by AIPPI in the past.

Affidavit of Stephan Freischem sworn on June 17, 2014, para 9.

8. 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 of patent applications in each jurisdiction, and the manner in which utility and/or industrial applicability might be raised in invalidity proceedings (including post-grant opposition proceedings and court proceedings) in each jurisdiction.

Affidavit of Stephan Freischem sworn on June 17, 2014, paras 10-12 and Ex B.

9. The work of AIPPI's Q180 Committee was summarized in a number of reports. Of note:
- (a) Utility and industrial applicability, while sharing a common purpose, are in some jurisdictions technically different concepts. Industrial applicability often refers to the ability to make or use the invention in any kind of industry. Utility typically refers to the usefulness of the invention.
 - (b) It is relatively rare in many jurisdictions that industrial applicability or utility will serve as a basis for refusing to grant a patent, or as a basis for invalidating an issued patent.

Affidavit of Stephan Freischem sworn on June 17, 2014, paras 13-16 and Exs C-F.

10. Additionally, at the AIPPI Gothenburg Congress in 2006, the following resolution was passed in respect of the work of Special Committee Q180:

1) Both in patent systems applying the utility criterion and in those applying the industrial applicability criterion, an invention without any use should not be patentable.

2) The subject matter of a claim is both useful and industrially applicable if at least one use would be understood by a skilled person in light of the specification at the filing (or priority) date.

3) As a result of sections 1) and 2), [a]... criterion [for patentability] should be based on use.

Affidavit of Stephan Freischem sworn on June 17, 2014, paras 18-17 and Ex G.

(C) Utility – Research Undertaken for this Appeal

11. AIPPI has recently conducted further research of its national and regional groups on utility issues for the purposes of this appeal.

Affidavit of Stephan Freischem sworn on June 17, 2014, para 19.

12. AIPPI has sent a questionnaire to AIPPI's national and regional groups for consideration. This most recent questionnaire is specifically directed to certain of the issues which are expected to be considered by this Court on this appeal, including the nature of any requirement for utility,

and any corresponding requirements for disclosure of that utility in the patent specification. AIPPI has received responses from its members in numerous jurisdictions including the United States, the United Kingdom, Japan, and numerous European countries including France, Switzerland, Sweden and Germany.

Affidavit of Stephan Freischem sworn on June 17, 2014, para 20 and Ex H.

(D) The Application for Leave to Intervene

13. This appeal can be expected to consider important issues with respect to the law of utility in Canada, including the degree to which utility should be disclosed or discussed in a patent. As set out above, the law of utility (and industrial applicability) has been an area of significant research and study by AIPPI.

14. In the time since the decision of *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77, the Canadian law of utility has developed in a manner which is different from many other jurisdictions. Notably, the concept of a “promise” of utility, the corresponding requirements to “demonstrate” or “soundly predict” any promised utility, and the disclosure requirements associated with demonstrated or soundly predicted utility, differ from those found in other major jurisdictions.

15. As an organization dedicated to the study and harmonization of international patent laws, the development of the law of utility in Canada is of significant interest to AIPPI. Where the law of one jurisdiction differs from the laws of other jurisdictions, this can present significant challenges to patent applicants who may seek global patent protection. Notably, many patent applications are drafted and filed in a single jurisdiction (e.g. the United States), and then the same application is filed in other jurisdictions using the mechanisms of international treaties and conventions such as the *Patent Cooperation Treaty* (“PCT”) and the *Paris Convention*. Where the law of one jurisdiction differs significantly from other jurisdictions, in particular where such law affects the content of the patent specification, the risk to applicants is that the specification may not meet the legal requirements of that specific jurisdiction. This may force the applicant to assess and amend its specification just to meet the requirements of that single jurisdiction, or otherwise jeopardize its opportunity to obtain patent rights in that jurisdiction. Overall, this can

result in greater uncertainty and/or cost associated with the acquisition of corresponding patent rights on an international basis.

16. It is AIPPI's belief that it can contribute to this appeal, and to assist this Court in understanding how Canadian law compares to that of other major jurisdictions. Its perspective is different from and broader than the parties to the appeal. AIPPI will be able to put forward its considerable knowledge, expertise, and experience in having studied utility and industrial applicability on an international basis. In the absence of an intervention from AIPPI, the Court will be left without this international perspective and insight, to the potential prejudice of applicants interested in filing patent applications in Canada, including applicants represented by AIPPI's membership.

PART II – QUESTIONS IN ISSUE

17. The issue on this motion is whether AIPPI should be granted leave to intervene subject to the following terms and conditions:

- (a) That AIPPI be permitted to file a factum not exceeding 20 pages; and
- (b) That AIPPI be permitted oral argument at the hearing of this appeal, not exceeding 20 minutes.

PART III – STATEMENT OF ARGUMENT

(A) The Law of Intervention

18. To be granted intervener status, an applicant must establish that it has a sufficient interest in the appeal, and that its submissions on the appeal will be relevant, useful and different from those of the parties.

Rules of the Supreme Court of Canada, Rule 57;

Ref Re Workers' Compensation Act, 1983 (NFLD), [1989] 2 SCR 335 at 339-340; and

R v Finta, [1993] 1 SCR 1138 at 1142-1143.

(B) AIPPI has a Sufficient Interest in the Appeal

19. On the present appeal, this Court is being asked to consider important issues with respect to the law of utility in Canada. AIPPI has a direct interest in the treatment given to these issues by this Court on the present appeal for at least the following reasons.

20. First, as an organization whose objects include the harmonization of international patent laws, AIPPI has a direct interest in the development of the law of utility in Canada, including the extent to which the utility of an invention is required to be disclosed or discussed in the patent specification.

21. Second, this is a specific topic on which AIPPI has previously conducted extensive international research, and on which it has passed a resolution pertaining to the international harmonization of the same. AIPPI has also further investigated this topic in view of the present appeal. Therefore, AIPPI has a perspective and information relevant to development of the laws of utility in Canada as compared to that of other jurisdictions.

22. Third, members of AIPPI include intellectual property practitioners and intellectual property owners from around the world who file, or oversee the filing of, patents in Canada, and will be impacted to the extent that the law in Canada on utility develops in a manner which is different or inconsistent with that of other jurisdictions where corresponding patent protection is sought.

(C) The Proposed Submissions of AIPPI

23. Having regard to its interest in the development of the law of utility in Canada, AIPPI wishes to address the following issues as raised in the Appellants' factum in this appeal:

- (a) The extent to which utility is required to be discussed or disclosed in the patent specification; 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.

24. In relation to these issues, if granted leave to intervene, AIPPI will make submissions on the utility or industrial applicability requirements for patentability in other jurisdictions, including the following:

- (a) Many national and regional jurisdictions have a requirement of “utility” or “industrial applicability” for patentability. The requirement of utility or industrial applicability is most often expressly established by statute;
- (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;
- (d) In many jurisdictions, it is relatively rare that utility or industrial applicability is used as a basis to deny the grant of a patent. Similarly, it is relatively rare that utility or industrial applicability is used as a basis to invalidate a granted patent; and
- (e) By virtue of treaties and conventions to which Canada is a signatory, many patent applications filed in Canada have been drafted for filing in multiple foreign jurisdictions, and without having specific regard to Canadian laws, including the law of utility. Development of the law in Canada in a manner which is different or inconsistent with that of other major jurisdictions will lead to significant uncertainty and added costs for patentees who seek corresponding patent protection in Canada.

(D) The Proposed Submissions of AIPPI Are Relevant, Useful and Different from those of the Other Parties

25. In the preceding section, the proposed submissions of AIPPI have been related to the issues presented in the Factum of the Appellants on this appeal. It is therefore submitted that AIPPI’s proposed submissions are relevant to the issues, at least as presented by the Appellants on the appeal.

26. However, AIPPI brings a perspective that is different from both the Appellants and the Respondents.

27. AIPPI presents the perspective of an international, politically-neutral, non-profit organization dedicated to the development, improvement, protection, and international harmonization of intellectual property. Its perspective is therefore fundamentally different from that of generic and innovative pharmaceutical companies, in the case of the Appellants and the Respondents, respectively.

28. Overall, in making its submissions, AIPPI will rely upon its recognized expertise in relation to the study and comparison of existing national and international law and in proposing measures to achieve harmonization of those laws.

PART IV – SUBMISSIONS ON COSTS

29. AIPPI does not claim costs in respect of its motion to intervene on the present appeal.

PART V – ORDER SOUGHT

30. AIPPI respectfully requests an Order granting it leave to intervene on the present appeal, subject to the following terms and conditions:

- (a) That AIPPI be permitted to file a factum not exceeding 20 pages; and
- (b) That AIPPI be permitted oral argument at the hearing of this appeal, not exceeding 20 minutes.

RESPECTFULLY SUBMITTED this 23rd day of June, 2014

Steven B. Garland

Colin B. Ingram

Solicitors for the Proposed Intervener,
AIPPI

PART VI – TABLE OF AUTHORITIES

	<i>Paragraph</i>	<i>Volume Tab</i>
Statutes and Regulations:		
<i>Rules of the Supreme Court of Canada, Rule 57</i>	18	Vol. 1 Tab 5
Cases:		
<i>Merck & Co, Inc v Pharmascience Inc, 2010 FC 510</i>	5	Vol. 2 Tab 1
<i>R v Finta, [1993] 1 SCR 1138</i>	18	Vol. 2 Tab 2
<i>Ref Re Workers' Compensation Act, [1989] 2 SCR 335</i>	18	Vol. 2 Tab 3

PART VII – STATUTES AND REGULATIONS



CANADA

CONSOLIDATION

CODIFICATION

Rules of the Supreme Court of Canada

Règles de la Cour suprême du Canada

SOR/2002-156

DORS/2002-156

Current to May 27, 2014

À jour au 1^{er} mai 2014

Last amended on January 1, 2014

Dernière modification le 1 janvier 2014

Registrar shall send a notice of hearing of the motion in Form 69, with any modifications that the circumstances require, to all parties.

SOR/2006-203, s. 28; SOR/2011-74, s. 27; SOR/2013-175, s. 36.

PART 11

PARTICULAR MOTIONS

MOTION FOR INTERVENTION

55. Any person interested in an application for leave to appeal, an appeal or a reference may make a motion for intervention to a judge.

56. A motion for intervention shall be made

- (a) in the case of an application for leave to appeal, within 30 days after the filing of the application for leave to appeal;
- (b) in the case of an appeal, within four weeks after the filing of the appellant's factum; and
- (c) in the case of a reference, within four weeks after the filing of the Governor in Council's factum.

SOR/2006-203, s. 29; SOR/2013-175, s. 37(E).

57. (1) The affidavit in support of a motion for intervention shall identify the person interested in the proceeding and describe that person's interest in the proceeding, including any prejudice that the person interested in the proceeding would suffer if the intervention were denied.

(2) A motion for intervention shall

- (a) identify the position the person interested in the proceeding intends to take with respect to the questions on which they propose to intervene; and
- (b) set out the submissions to be advanced by the person interested in the proceeding with respect to the questions on which they propose to intervene, their relevance to the proceeding and the reasons for believ-

envoi à toutes les parties un avis d'audition conforme au formulaire 69, avec les adaptations nécessaires.

DORS/2006-203, art. 28; DORS/2011-74, art. 27; DORS/2013-175, art. 36.

PARTIE 11

REQUÊTES SPÉCIALES

REQUÊTE EN INTERVENTION

55. Toute personne ayant un intérêt dans une demande d'autorisation d'appel, un appel ou un renvoi peut, par requête à un juge, demander l'autorisation d'intervenir.

56. La requête en intervention est présentée dans les délais suivants :

- a) dans le cas de la demande d'autorisation d'appel, dans les trente jours suivant son dépôt;
- b) dans le cas d'un appel, dans les quatre semaines suivant le dépôt du mémoire de l'appelant;
- c) dans le cas d'un renvoi, dans les quatre semaines suivant le dépôt du mémoire du gouverneur en conseil.

DORS/2006-203, art. 29; DORS/2013-175, art. 37(A).

57. (1) L'affidavit à l'appui de la requête en intervention doit préciser l'identité de la personne ayant un intérêt dans la procédure et cet intérêt, y compris tout préjudice que subirait cette personne en cas de refus de l'autorisation d'intervenir.

(2) La requête expose ce qui suit :

- a) la position que cette personne compte prendre relativement aux questions visées par son intervention;
- b) ses arguments relativement aux questions visées par son intervention, leur pertinence par rapport à la procédure et les raisons qu'elle a de croire qu'ils seront utiles à la Cour et différents de ceux des autres parties.

DORS/2013-175, art. 38.

ing that the submissions will be useful to the Court and different from those of the other parties.

SOR/2013-175, s. 38.

58. At the end of the applicable time referred to in Rule 51, the Registrar shall submit to a judge all motions for intervention that have been made within the time required by Rule 56.

SOR/2006-203, s. 30.

59. (1) In an order granting an intervention, the judge may

(a) make provisions as to additional disbursements incurred by the appellant or respondent as a result of the intervention; and

(b) impose any terms and conditions and grant any rights and privileges that the judge may determine, including whether the intervener is entitled to adduce further evidence or otherwise to supplement the record.

(2) In an order granting an intervention or after the time for filing and serving all of the memoranda of argument on an application for leave to appeal or the facta on an appeal or reference has expired, a judge may, in their discretion, authorize the intervener to present oral argument at the hearing of the application for leave to appeal, if any, the appeal or the reference, and determine the time to be allotted for oral argument.

(3) An intervener is not permitted to raise new issues unless otherwise ordered by a judge.

SOR/2006-203, s. 31.

MOTION TO STATE CONSTITUTIONAL QUESTION

60. (1) Within 30 days after leave to appeal has been granted or after the filing of a notice of appeal in an appeal for which leave is not required, an appellant, respondent or attorney general shall make a motion to the Chief Justice or a judge to state a constitutional question if that appellant, respondent or attorney general intends to raise a question of

58. À l'expiration du délai applicable selon la règle 51, le registraire présente au juge toutes les requêtes en intervention présentées dans les délais prévus à la règle 56.

DORS/2006-203, art. 30.

59. (1) Dans l'ordonnance octroyant l'autorisation d'intervenir, le juge peut :

a) prévoir comment seront supportés les dépens supplémentaires de l'appelant ou de l'intimé résultant de l'intervention;

b) imposer des conditions et octroyer les droits et privilèges qu'il détermine, notamment le droit d'apporter d'autres éléments de preuve ou de compléter autrement le dossier.

(2) Dans l'ordonnance octroyant l'autorisation d'intervenir ou après l'expiration du délai de dépôt et de signification des mémoires de demande d'autorisation d'appel, d'appel ou de renvoi, le juge peut, à sa discrétion, autoriser l'intervenant à présenter une plaidoirie orale à l'audition de la demande d'autorisation d'appel, de l'appel ou du renvoi, selon le cas, et déterminer le temps alloué pour la plaidoirie orale.

(3) Sauf ordonnance contraire d'un juge, l'intervenant n'est pas autorisé à soulever de nouvelles questions.

DORS/2006-203, art. 31.

REQUÊTE EN FORMULATION D'UNE QUESTION CONSTITUTIONNELLE

60. (1) Dans les trente jours suivant l'octroi de l'autorisation d'appel ou le dépôt de l'avis d'appel dans le cas d'un appel de plein droit, l'appelant, l'intimé ou le procureur général qui entend soulever l'une ou l'autre des questions ci-après doit présenter au Juge en chef ou à un autre juge une requête en formulation d'une question constitutionnelle :