SCC Court File No.: 36654

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

B E T W E E N:

ASTRAZENECA CANADA INC.
ASTRAZENECA AKTIEBOLAG and
ASTRAZENECA UK LIMITED

Appellants
(Appellants)

– and –

APOTEX INC. and APOTEX PHARMACHEM INC.

Respondents
(Respondents)

MOTION RECORD OF THE PROPOSED INTERVENER
CENTRE FOR INTELLECTUAL PROPERTY POLICY

(Motion for Intervention pursuant to Rules 47, 55, 56, 57 and 59 of the *Rules of the Supreme Court of Canada*)

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NOTICE OF MOTION OF THE PROPOSED INTERVENER
CENTRE FOR INTELLECTUAL PROPERTY POLICY

(Motion for Intervention pursuant to Rules 47, 55, 56, 57 and 59
of the *Rules of the Supreme Court of Canada*)

TAKE NOTICE that the Centre for Intellectual Property Policy ("CIPP") hereby applies to a judge of this Court, pursuant to Rules 47, 55, 56, 57 and 59 of the *Rules of the Supreme Court of Canada*, for an order granting CIPP leave to intervene in this appeal, to file a factum not to exceed 15 pages in length and to make oral argument at the hearing of the appeal for not more than 15 minutes, and any further or other order as this Court may deem appropriate.

AND FURTHER TAKE NOTICE that the following documentary evidence will be relied upon in support of this motion:

1. the affidavit of Dean Robert Leckey, Chair of the Board of Directors of CIPP, sworn July 25th, 2016; and

2. such further and other material as counsel may advise and this Court may permit.

AND FURTHER TAKE NOTICE that the motion shall be made on the following grounds:

The appeal

3. By order dated March 10, 2016, the Appellants were granted leave to appeal from the judgment of the Federal Court of Appeal (A-420-14, 2015 FCA 158), dated July 6, 2015.

4. The appeal relates to the invalidity of a patent for esomeprazole. Esomeprazole is a proton-pump inhibitor, and is marketed and sold by the Appellants as the pharmaceutical product Nexium.

5. The appeal raises both narrow and general issues. Narrowly, it deals with the utility of the putative invention claimed by the Appellant. More generally, it puts in issue the meaning of the word "useful" in the *Patent Act*. The correct applicable standard for patent utility in Canada and the existence of a promised utility doctrine are matters that this Court has never considered.

6. One point raised in the appeal is whether the patent bargain is or is not "akin to a negotiated contract consisting of promises or guarantees."[1] The Appellants' submission (that it is not) triggers questions about the nature of the bargain that lies at the heart of the patent system.

7. The Appellants submit that the requirement of being "useful" in section 2 of the *Patent Act* is independent of the requirement for disclosure of "use" in section 27(3).[2] This argument raises an issue regarding the relationships among the criteria for patentability, disclosure and enablement.

8. The Appellants also submit that the word "useful" means "not devoid of utility."[3] The proper interpretation of the word "useful" in section 2 of the *Patent Act* is, therefore, an issue in the appeal.

[1] *Astrazeneca Canada Inc et al v Apotex Inc et al*, SCC 36654 (Appellants' Factum at para 2).
[2] *Astrazeneca Canada Inc et al v Apotex Inc et al*, SCC 36654 (Appellants' Factum at para 91).
[3] *Astrazeneca Canada Inc et al v Apotex Inc et al*, SCC 36654 (Appellants' Factum at para 61).

9. The Appellants have described the utility requirement in Canada as "out-of-step with the corresponding requirements in other major jurisdictions."[4] The Appellants' argument raises questions about the appropriate basis for comparing Canadian patent law and its particular doctrinal elements to that of other jurisdictions, as well as the empirical basis for that assertion.

CIPP has an interest in the issues arising in this appeal

10. CIPP possesses over a decade of intensive work on Canadian, American, and European patent law, comparative patent law, international patent law and international trade in relation to patent law. At the core of its mission, CIPP brings up-to-date knowledge about patent law and innovation to assist governments, policy-makers, firms and courts in Canada and internationally.

11. At the centre of this appeal is the public interest that lies at the heart of the patent system: to provide an incentive to inventors through limited term monopolies while promoting follow-on innovations and the ability of Canadians to use them. CIPP is uniquely positioned to highlight the public interest at stake in the appeal due to its non-profit nature and its extensive expertise in Canadian, comparative, and international patent law, as well as innovation policy. This different point of view will be useful to the Court. Ensuring that it is heard will advance the mission of CIPP. Therefore, CIPP has an interest in this appeal.

CIPP's submissions will be useful and different from the other parties

12. CIPP possesses significant and respected expertise in patent law in general and on the issues arising in this appeal in particular. CIPP is also completely independent of the interests of both the brand name and generic pharmaceutical industries, receiving no funding from either. Sitting within McGill University's Faculty of Law with its world-recognized expertise in comparative law, it also brings a critical understanding of how and on what basis to compare the patent laws of Canada, Europe, and the United States. As the leading independent Canadian think tank on comparative patent law and innovation policy, CIPP will provide the Court with a valuable and unique perspective on the issues arising in this appeal.

[4] *Astrazeneca Canada Inc et al v Apotex Inc et al*, SCC 36654 (Appellants' Factum at para 134).

13. Should leave be granted, CIPP intends to make submissions that:

a. the patent bargain between the inventor and state affects many other stakeholders;
b. utility is related to, not isolated from, other criteria of patentability;
c. applying the word "useful" involves a skilled reader's view of the invention;
d. Canada's patent laws are holistically consistent with trading partners' laws; and
e. such further and other submissions as counsel may advise and this Court may permit.

14. The proposed intervention will not cause delay or prejudice to the parties. CIPP will not seek costs and asks that it not be liable for costs to any other party should leave be granted.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 28th day of July 2016.

Jeremy de Beer
E.R. Gold

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NOTICE TO THE RESPONDENT TO THE MOTION: A respondent to the motion may serve and file a response to this motion within 10 days after service of the motion. If no response is filed within that time, the motion will be submitted for consideration to a judge or the Registrar, as the case may be.

If the motion is served and filed with the supporting documents of the application for leave to appeal, then the Respondent may serve and file the response to the motion together with the response to the application for leave.

SCC Court File No. 36654

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Appellants
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- and -

APOTEX INC. and APOTEX PHARMACHEM INC.

Respondents
(Respondents)

- and -

CENTRE FOR INTELLECTUAL PROPERTY POLICY ("CIPP")
FACULTY OF LAW, McGILL UNIVERSITY

Proposed Intervener

AFFIDAVIT OF ROBERT LECKEY

(Pursuant to Rules 47, 55, 56, 57 and 59 of the *Rules of the Supreme Court of Canada*)

I, **ROBERT LECKEY**, of the City of Montreal in the Province of Québec, AFFIRM AS FOLLOWS:

1. This affidavit is sworn in support of the Centre for Intellectual Property Policy at the Faculty of Law, McGill University (CIPP)'s motion for leave to intervene in this appeal.

2. I am the Dean of the Faculty of Law of McGill University, where I am Full Professor, Chair of the CIPP Board of Directors, and a member of the Law Society of Upper Canada.

3. Except as otherwise indicated, I have personal knowledge of the matters to which I depose in this Affidavit. Where I lack such personal knowledge, I have indicated the source of my information and I verily believe such information to be true.

CIPP has a direct and compelling interest in the issues on appeal

4. CIPP is an internationally recognized, independent, not-for-profit think tank within McGill University's Faculty of Law.

5. Founded in 2003, CIPP encourages multidisciplinary research in fields such as law, management, philosophy, ethics, science, international relations, and economics. It includes members and associate members from a variety of fields, including scholars, policy-makers and others from a variety of institutions and countries.

6. CIPP's management structure is designed to ensure both its independence and its responsibility to its members. There currently are eight members on the Centre's board of directors: McGill's Vice-Principal (Research and International Relations) Rose Goldstein; one external member, Professor Vincent Gautrais, Director of the *Centre de recherche en droit public* of Université de Montréal's Law Faculty; myself, Robert Leckey, as Dean of McGill's Faculty of Law; two CIPP members, professors Allison Christians and Richard Gold; Pierre-Emmanuel Moyse, Director of the Centre; and two student representatives. I serve as Chair of the board.

7. Guided by McGill's Faculty of Law's tradition of openness to different legal systems and cultures, CIPP's core mission is to teach and to translate academic and experiential knowledge on intellectual property law (including patent law) for students, policy-makers, courts, universities and firms. To achieve this mission, the Centre focuses on four interconnected priority areas: (i) interdisciplinary research to understand how intellectual property policies and rules contribute to creativity and innovation. In particular, CIPP examines the extent to which intellectual property contributes to broad social goals such as improved health, increased cultural development, greater access to information and economic growth; (ii) advancing research that is relevant and responsive

to policy needs in Canada and abroad, while ensuring that the Centre's work is empirically based and open to multiple viewpoints, that it addresses concrete policy needs in real contexts, and that its research is communicated clearly and openly to those who need the information; (iii) examining both the laws that govern intellectual property and the ways in which institutions and practices interact to govern innovation systems more broadly, with the aim of being among the world's foremost authorities in intellectual property research and policy; and (iv) enhancing understanding of intellectual property and innovation systems among students at McGill University at the undergraduate, graduate and executive level, as well as within professional, policy and civil society communities.

8. CIPP disseminates its research through workshops, conferences and publications. The Centre operates in both English and French and in relation to the common law, civil law and indigenous legal systems.

9. CIPP possesses over a decade of intensive work on Canadian, American, and European intellectual property law, comparative intellectual property law, international intellectual property law, and on international trade in relation to intellectual property law. It is a world leader in comparative intellectual property law, drawing on the McGill Faculty of Law's international reputation in comparative law. It brings legal, political, ethical, statistical, management, and tax expertise to the study of intellectual property. In accordance with its core mission, CIPP diffuses up-to-date knowledge on intellectual property law and innovation to assist governments, policy-makers, firms, and courts in Canada and internationally, by advancing research that is relevant and responsive to policy needs.

10. It is central to CIPP's mission to intervene in litigation in which the balance of patent law is at stake. An internationally peer-reviewed, large-scale project directly supports these efforts. PACEOMICS (Personalized, Accessible, Cost-Effective Applications of 'Omics Technologies), a project sponsored by Genome Canada, Genome Alberta, Genome Québec, Alberta Innovates – Health Solutions and the Canadian Institutes for Health Research, specifically funds direct engagement in litigation.

11. In CIPP's view, the issues in the present appeal must be determined solely in accordance with Canadian law and patent policy. Recent developments in scholarship, advocacy and in judicial decisions have created uncertainty regarding the utility standard of Canadian patent law. This standard needs clarification, in particular in regards to its function, substantive content and its general application. CIPP would submit that an invention's utility is linked to novelty and inventiveness. In its view, there is a single, consistent and straightforward test for utility that applies to all inventions.

12. Led by its objective of ensuring a fair and balanced patent regime, CIPP has a direct and compelling interest in the issues on appeal.

CIPP's arguments will be useful to the Court

13. The present appeal raises four key issues concerning the internal balance of the patent system. Questions concerning the nature of the bargain underlying patent law, implications of the statutory nature of patent law, the way in which the correct standard of utility of a patent is determined, and the placement of Canadian patent law within its international context are raised, each of which the CIPP is uniquely positioned to address from a public interest perspective.

14. CIPP can offer an in-depth understanding of the foundational principles underlying the dispositions of the appeal. It has conducted research precisely on the issues raised in this appeal and this research has been submitted to peer review and published in both academic and professional journals.

15. On account of its expertise, CIPP, through its members, has been invited to present testimony to Committees of the House of Commons such as the Standing Committee on Industry, Science and Agriculture (2012), the Standing Committee on Agriculture and Agri-Food (2011), and the Legislative Committee on Bill C-32 (2010). Internationally, its Members have been invited to make formal presentations before the United States Secretary of Health's Advisory Committee on Genetics, Health, and Society and the World Health Organization. CIPP and its Members have also regularly provided research and policy advice to other organizations, such as the World

Intellectual Property Organization, the Organisation for Economic Co-operation and Development, the World Health Organization and government agencies in Canada and abroad.

16. Through its Members, CIPP submitted *amicus curiae* briefs on the patentability of human genes in the *AMP v Myriad Genetics* 569 US 12-398 (2013) case before the Supreme Court of the United States, and the United States Court of Appeals for the Federal Circuit. CIPP was granted leave to intervene and to present oral arguments before this Court in *Apotex v. Sanofi-Aventis et. al.* (Case No. 35562) on questions similar to those arising in the present case. CIPP was granted leave to intervene and to give oral argument in *Canadian Broadcasting Corp. v. SODRAC 2003 Inc*. (Case No. 35918).

17. Most recently, CIPP intervened as amicus in an arbitration between Eli Lilly and Company and the Government of Canada pursuant to a complaint by the former that Canadian patent law on utility constitutes a violation of Chapter 11 of the North American Free Trade Agreement. Both parties to the arbitration agreed that CIPP had the requisite interest and expertise to intervene and the tribunal agreed, granting leave. The Government of Canada referred positively to several CIPP arguments raised in that intervention. Given the similarity in some of the issues raised in that arbitration and the present case, the CIPP is particularly well positioned to provide additional context to the Court in the present appeal.

CIPP offers a different and unique perspective

18. The CIPP brings a unique perspective to this appeal. The pursuit of fair and balanced intellectual property systems has historically informed, and continues to inform, the research and policy agenda of CIPP and the teaching of intellectual property that flows from that research. CIPP's dedication to translating this knowledge to assist courts, policy-makers, firms and civil society also contributes to its uniqueness.

19. As CIPP is not influenced by private industry – in particular, it receives no direct or indirect funding from brand name or generic pharmaceutical firms (but receives small levels of support from law firms and from Lallemand, a global yeast and bacteria producing firm, to support speakers, workshops and one research assistant unconnected to its work on patent law and policy) – it is uniquely positioned to advance submissions that are solely motivated by its mission of

enabling fair and balanced patent regimes. CIPP has no economic stake in the outcome of this case, but because of its commitment to the public interest, it is deeply concerned with the implications of the issues on appeal.

20. There is no similarly independent institution with an equivalent mission to that of CIPP likely to intervene in and address the foundational principles underlying the disposition of the appeal. Only CIPP is likely to seek assurance that Canadian patent law attains an appropriate balance between providing incentives for inventors and enabling subsequent innovation of new products and services for use by the Canadian public.

21. Should CIPP's motion for leave to intervene be granted, CIPP does not intend to seek costs and asks that it not have costs awarded against it.

22. I make this Affidavit in support of CIPP's Motion for Leave to Intervene in this appeal and for no improper purpose.

Affirmed before me at the City of Montreal)
in the Province of Quebec)
this 25th day of July, 2016.) **ROBERT LECKEY**

Me Véronique Bélanger, Member of the Barreau du Québec # 191079-5

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Respondents
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MEMORANDUM OF ARGUMENT OF THE PROPOSED INTERVENER CENTRE FOR INTELLECTUAL PROPERTY POLICY

(Motion for Intervention pursuant to Rules 47, 55, 56, 57 and 59 of the *Rules of the Supreme Court of Canada*)

Part I. STATEMENT OF FACTS

1. The Centre for Intellectual Property Policy ("CIPP") asks this Honourable Court to grant it leave to intervene, file a factum and make argument in the herein appeal, pursuant to Supreme Court Rule 55.

2. The Federal Court of Appeal upheld the Federal Court Trial Division's decision invalidating Canadian Letters Patent No. 2,139,653 (the "'653 patent"). In doing so, the lower courts held that the Appellants failed to demonstrate that they knew or soundly predicted that esomeprazole was useful to inhibit gastric acid secretion with an improved therapeutic profile such as a lower degree of interindividual variation.

3. CIPP is an internationally recognized and independent think tank that conducts research on and develops policy with respect to intellectual property and innovation in Canada and

internationally. Its views and advice are sought by international organizations, governments, governmental committees, universities, hospitals and private actors.[1] Its mission is to ensure that intellectual property laws and policies reach and maintain an appropriate balance by encouraging invention through limited monopolies while ensuring that Canadians benefit from new products and services on a long-term basis.[2]

4. CIPP has a mandate and experience intervening in patent cases and assisting governments in patent policy. For example, through its Members, it intervened on the issue of the patentability of human genes before the Supreme Court of the United States and the United States Court of Appeals for the Federal Circuit.[3] Its Members have also been invited to speak to Parliamentary committees as well as foreign governmental and international organization committees on intellectual property matters.[4] CIPP was granted leave to intervene by this Honourable Court in a previous case about patent utility, and by an arbitration tribunal adjudicating a complaint about Canada's utility standard in relation to the North American Free Trade Agreement.[5]

Part II. QUESTION IN ISSUE

5. Should the Court grant CIPP leave to intervene in the appeal?

Part III. ARGUMENT

6. As interpreted by this Court, Supreme Court Rule 55 provides that leave to intervene be granted where a party has (a) an interest in the subject-matter in the appeal; and (b) the proposed intervener will be able to make submissions that are useful and different from that of the parties to the appeal.[6]

7. The issues arising in the appeal affect the ability of CIPP to pursue its mission of ensuring a fair and balanced patent system. CIPP will put forward useful arguments that address the

[1] Affidavit of Robert Leckey on behalf of the Centre for Intellectual Property Policy at para 15 [Leckey, Affidavit].
[2] Leckey, Affidavit, at para 7.
[3] Leckey, Affidavit, at para 16.
[4] Leckey, Affidavit, at para 15.
[5] Leckey, Affidavit, at para 17.
[6] *Rules of the Supreme Court of Canada*, SOR/2002-156, s 55-57; *R v Finta,* [1993] 1 SCR 1138; *Reference re Workers' Compensation Act, 1983 (Nfld)*, [1989] 2 SCR 335.

underlying principles of patent law arising from the matters in this appeal from a different perspective than the Appellants, Respondents and likely other interveners.

A) CIPP has an interest in the subject matter of this appeal

8. CIPP has, since its founding in 2003, worked with governments, universities and private firms in seeking to improve the Canadian patent system.[7] One of its core missions is to teach and to translate academic and experiential knowledge on intellectual property law (including in relation to patents) for students, policy-makers, courts, universities and firms.[8]

9. This appeal raises issues that are fundamental to the fairness and effectiveness of Canada's patent system. These are as follows: the nature of the patent bargain and whether it only relates to the patentee and the state or includes other stakeholders; whether the requirement of utility is understood as interacting with other criteria of patentability, disclosure, and enablement or is isolated from these; the role of the courts in elucidating undefined terms in the *Patent Act* such as "useful"; and comparative law methodology as applied to patent law. Because the balance inherent in Canadian patent law is in issue in all of these respects, CIPP is directly affected by this appeal. If arguments addressing this balance are not presented to the Court then CIPP's mission of ensuring balance will be at risk, to the prejudice of CIPP, its members and the public interest it represents.

B) CIPP will make useful and different submissions

10. Leave to intervene will be granted to a party who is able to "present argument from a different perspective"[9] and where "the intervener will provide the Court with fresh information or a fresh perspective on an important constitutional or public issue."[10]

11. As an independent, not-for-profit think tank at the forefront of research and policy development in the area of intellectual property and innovation in Canada, CIPP brings fresh knowledge and a new perspective to the important public policy issues underlying the appeal.

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[7] Leckey, Affidavit, at para 5.
[8] Leckey, Affidavit, at para 9.
[9] *Norberg v Wynrib*, [1992] 2 SCR 224 at 225.
[10] *Reference re Workers' Compensation Act, 1983 (Nfld),* [1989] 2 SCR 335 (Application to Intervene at para 12).

12. CIPP would focus its submissions on the correct applicable standard for patent utility in Canada and the proper existence of a promised utility doctrine in Canadian law. It would take no position on alleged errors by the lower courts or the substantive outcome of this appeal.

13. CIPP would submit that this Court should reject the "promise doctrine" in the form articulated by the Federal Court of Appeal. Creating two different standards of utility, which vary depending on a patent applicant's explicit statements, is, as the Appellant argues, "illogical and not intended by the *Act*".[11] Further, a two-tiered approach to utility breaks from the long history of patent law. There is one correct applicable standard for patent utility in Canada, which is that a putative invention must be useful in the way the skilled reader understands the applicant has claimed it is.

14. While CIPP shares many of the Appellants' concerns about the so-called promise doctrine, and supports many of the Appellants' arguments, it would offer different solutions to the legal problems. Hearing and considering different solutions based on a careful reading of jurisprudence and a more inclusive understanding of the balance inherent in patent law will be useful to this Court. CIPP's submissions would be different and useful in the following ways.

An invention must be as useful as the skilled reader understands the applicant claimed it is.

15. To support its submission that a putative invention must be as useful as the skilled reader understands the applicant has claimed it is, CIPP will address four points raised by the decisions of the lower court and the Appellants' arguments:

a. the patent bargain between the inventor and state affects many other stakeholders;
b. utility is related to, not isolated from, other criteria for of patentability;
c. applying the word "useful" involves a skilled reader's view of the invention;
d. Canada's patent laws are holistically consistent with trading partners' laws; and
e. such further and other submissions as counsel may advise and this Court may permit.

[11] *Astrazeneca Canada Inc et al v Apotex Inc et al*, SCC 36654 (Appellants' Factum at para 98).

The patent bargain between the inventor and state affects many other stakeholders.

16. CIPP agrees with the Appellant that "the patent bargain between the inventor and the public is not akin to a negotiated contract consisting of promises or guarantees."[12] However, CIPP would offer different submissions about why and how the patent bargain is more complex than a bilateral contract.

17. CIPP would submit that the patent bargain is multifactorial, concerning not only inventors and the state, but also follow-on innovators, users of inventions, research funders and other stakeholders. The fuller understanding of the patent bargain balances the rights and responsibilities of innovation system stakeholders: users must pay a fair share of the costs of innovation, patent applicants must not game the system and the public must receive reasonable access to new products and services. If granted leave to intervene, CIPP would explain how a multifactorial understanding of the patent bargain aligns this Court's patent jurisprudence with other intellectual property law[13] and helps to balance individual rights and social values.[14] CIPP would particularly highlight how this balance relates to the law on utility.

Utility is related to, not isolated from, other criteria for patentability.

18. To properly uphold the patent bargain, patent law's utility requirement must be understood in relation to other criteria for patentability. An invention's utility cannot be identified in isolation from the disclosure describing that invention. A skilled reader's view of the art, process, machine, manufacture or composition of matter, informed by her prior knowledge and the whole specification, determines what the invention is and does (*i.e.* its usefulness), its novelty and its non-obviousness.

19. Since utility is integrally related to other criteria for patentability, CIPP would support the Appellants' submission that "there is only one patent construction for all purposes: an invention

[12] *Astrazeneca Canada Inc et al v Apotex Inc et al*, SCC 36654 (Appellants' Factum at para 2).
[13] *Théberge v Galerie D'Art du Petit Champlain inc*, [2002] 2 SCR 336 at para 30.
[14] Jeremy Waldron, "From Authors to Copiers: Individual Rights and Social Values in Intellectual Property" (1992) 68:2 Chicago-Kent L Rev 841 at 862.

cannot be read up for one purpose and down for another".[15] CIPP would add that this principle applies equally to all parties in patent disputes, including patent applicants.

20. Assessing utility in connection with other criteria helps prevent applicants from gaming the patent system.[16] Applicants cannot exaggerate statements, perhaps intending to persuade examiners of an invention's novelty or non-obviousness, without being bound to those statements when assessing an invention's utility.

21. A corollary of the skilled reader's single construction of the invention's utility is that the specification as a whole, not merely the claims, are important in assessing utility. An applicant's statements about an invention's "use as contemplated" and the steps or methods enabling others to "use" the invention cannot be ignored in a skilled reader's assessment of how exactly the invention is "useful". CIPP would submit that the statutory requirements of section 2 and subsection 27(3) are related.

22. While the requirements of novelty, non-obviousness, utility, disclosure and enablement are often discussed separately, courts have long recognized that they are deeply intertwined.[17] The World Intellectual Property Organization's Standing Committee on the Law of Patents has also recognized the synergy between the substantive patent criteria: "Therefore, for the purposes of full harmonization of substantive patent law, the industrial applicability/utility requirement cannot be considered separately from other requirements."[18] The existence of this synergy poses a particular risk for any attempt to modify one isolated rule in patent law.

<u>Applying the word "useful" in context involves a skilled reader's view of the invention.</u>

23. The word "useful", CIPP would submit, must be interpreted and applied in its statutory context. The word is not defined in the *Patent Act*, and its meaning is not plain and obvious. The Appellants argue with emphasis that "subject-matter having *a* utility" is useful. CIPP would submit

[15] *Astrazeneca Canada Inc et al v Apotex Inc et al*, SCC 36654 (Appellants' Factum at para 29).
[16] *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 at para 80, [2012] 3 SCR 625.
[17] *Eli Lilly Canada Inc v Apotex Inc,* 2008 FC 142 at para 64, aff'd 2009 FCA 9; *Ratiopharm Inc v Pfizer Limited*, 2009 FC 711 at para 156, aff'd 2010 FCA 204; *Sanofi-Aventis Canada Inc v Ratiopharm Inc*, 2010 FC 230 at para 51.
[18] WIPO, Standing Committee on the Law of Patents, *The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws*, SPC5/Inf (2001) at para 24.

that patentable subject-matter must have *the* utility that a skilled reader determines the patent applicant claims.

24. The Federal Court of Appeal has, in one case, articulated a two-tiered utility doctrine, distinguishing situations where an applicant explicitly promises a particular usefulness from those where an applicant does not. The Appellants seemingly accept that explicit promises of utility can sometimes be binding on patent applicants, but would confine this to the category of new use claims.[19] CIPP's submissions would avoid this oversimplified dichotomy with a more robust framework for determining whether a putative invention is useful enough to fulfil the patent bargain.

25. The framework CIPP would explain is solidly grounded in the statute and governing case law. CIPP would submit that the proper analysis starts with a skilled reader's determination of the essential and non-essential elements of the art, process, machine, manufacture or composition of matter and determining its usefulness (function). The resulting invention – an art, process, machine, manufacture or composition of matter that is matched to its use – determines whether an applicant has met any or all of the criteria for patentability, including novelty, non-obviousness and utility (as well as subject matter, sufficiency of disclosure and other criteria).

26. The simplest cases that might raise issues about utility are, as the Appellants note, new use claims. That is because a specific use is, by definition, stated explicitly in the claims.

27. There are also other cases where an invention's usefulness must, in practice, be stated explicitly elsewhere in the specification. CIPP will submit that selection patents in the pharmaceutical industry are the most notable example of this category of cases. In order to satisfy the novelty requirement, applicants in these cases are required to describe the specific advantages a selected species of compounds has over a previously patented genus including those compounds. In practice, this requires making statements related to the new (and normally improved) usefulness of the selection.

[19] *Astrazeneca Canada Inc et al v Apotex Inc et al*, SCC 36654 (Appellants' Factum at paras 86, 89, 163).

28. In other cases, an applicant will state little or nothing about an invention's usefulness. CIPP will submit that an applicant's implications or silence about usefulness is usually because the contemplated use is self-evident to the skilled reader. An applicant may choose not to claim or describe specific uses because she relies upon the skilled reader's inferences, not because any abstract unspecified use would fulfil the utility requirement.

29. CIPP would submit there is no jurisprudential or statutory support for the 'devoid of utility' or 'scintilla' standard of utility suggested by the Appellants. With leave, CIPP would explain the relevance of this Court's decision in Monsanto Co v Canada,[20] and trace the history of references to the supposed scintilla standard from Harold Fox's and other academic writing.[21]

Canada's patent laws would be holistically consistent with trading partners' laws.

30. CIPP would submit that, if this Court determines a putative invention must be as useful as the skilled reader understands the applicant has claimed it is, Canada's patent laws would be holistically consistent with those of its trading partners. In comparing Canadian patent law to that of other jurisdictions, courts should conduct a functional analysis of how different systems deal with similar problems.

31. The Appellants describe the utility requirement in Canada as "out-of-step with the corresponding requirements in other major jurisdictions."[22] CIPP would submit that the two-tiered approach toward the standard of patent utility recently articulated by Canada's Federal Courts has no direct parallel in the utility analyses adopted in other jurisdictions. However, other jurisdictions do apply legal doctrines with the functional effect of ensuring that a putative invention does what a patent applicant claims it does.

32. CIPP would submit that Canadian law is out-of-step only to the extent that the Federal Courts intended to articulate a two-tiered approach to patent utility. (Whether the Federal Courts intended to create a two-tiered approach is unclear). There is only one correct applicable standard of utility, CIPP

[20] *Monsanto Co v Canada*, [1979] 2 SCR 1108 at 1117 and 1122.
[21] H. G. Fox, The Canadian Law and Practice Relating to Letters Patent for Inventions, 4th ed (Toronto: Carswell, 1969) at 148-161.
[22] *Astrazeneca Canada Inc et al v Apotex Inc et al*, SCC 36654 (Appellants' Factum at para 134).

would submit, which is what the skilled reader determines the applicant had claimed the invention's usefulness to be. The alternative suggested by the Appellants, a single standard requiring only that an invention be not devoid of a scintilla of abstract utility, would be inconsistent with the patent laws of Canada's trading partners. Other jurisdictions, including the United States, require that an invention's usefulness be specific, substantial, and credible.

33. Accepted comparative law methodology requires that when comparing law from different legal systems – such as from Canada, the United States, and under the European Patent Convention ("EPC") – one compares rules with similar *functions* rather than rules with similar *labels*. Rules have similar functions if they address the same underlying problem even if they do so differently and under different names.

34. Despite different court procedures, rules of evidence, presumptions of validity and methods of patent construction, all patent systems hold patentees to their statements about a putative invention's uses and usefulness. Canadian patent law shows no unique pattern of either discriminating against pharmaceutical patents or holding those patents invalid due to the criterion of utility. CIPP would submit that there is no empirical support for the assertion that the so-called promise doctrine has increased rates of invalidity, whether over all inventions, just pharmaceutical inventions, or only on the basis of utility.

35. Moreover, even if Canadian law is different, which it is not when seen in the holistic context of patent law, CIPP would submit that variations in domestic patent law are normal. CIPP would highlight for the Court the consensus that no formal or informal standard of utility exists in international patent law.[23] There exist at least two different architectures for patent systems, one represented by the Anglo-American approach and the other by the European approach. Under the former, inventions must be new, non-obvious and useful. Under the latter, inventions must be technical in nature, be new, make an inventive contribution to the art and be capable of industrial

[23] Jerome H Reichman, "Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection" (102nd Annual Meeting of American Society of International Law, vol 108, 2014), online: <http://frederickabbott.com.webmatrix-appliedi.net/Portals/0/Documents/ASIL%20-%202014%20-%20FA-SS-JR%20consolidated.pdf>; WHO, WIPO, & WTO, *Promoting Access to Medical Technologies and Innovation*: *Intersections Between Public Health, Intellectual Property and Trade* (Geneva: World Trade Organization, 2012) at 57 [WHO, WIPO, & WTO].

application. As the terms used suggest, the substantive content of these rules differ both in emphasis and in content.

36. International agreements avoid discussion of the substantive requirements of patent law, leaving those issues to the discretion of States. As the World Health Organization, the World Intellectual Property Organization and the World Trade Organization jointly concluded in 2012: "[T]here is no agreed international understanding about the definition and interpretation of these criteria. This creates some policy space regarding their establishment under the applicable national law. Accordingly, patent offices and courts interpret and apply national patentability requirements on a case-by-case basis within the applicable legal framework."[24]

37. CIPP would submit that any additional development of Canadian patent law should be considered with due regard to the internal architecture and history of Canadian patent legislation and associated jurisprudence, rather than as a reaction to any alleged claim that Canadian patent law is "out-of-step" with that of other nations.

Part IV. SUBMISSIONS ON COSTS

38. CIPP does not seek costs and submits that it should not be liable for any costs.

Part V. ORDER SOUGHT

39. CIPP seeks an Order:

(a) granting leave to intervene in the hearing of this appeal pursuant to Rule 55 of the Supreme Court Rules;

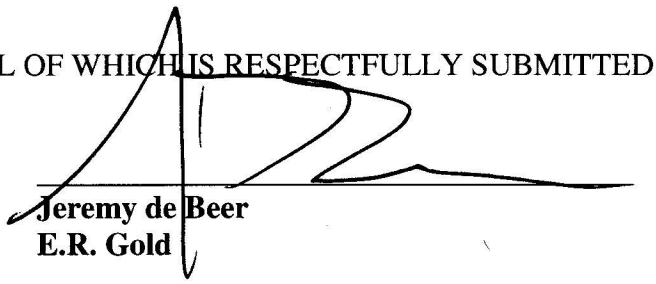
(b) granting leave to file a factum of up to 15 pages in length;

(c) granting leave to make oral submissions at the hearing of this appeal, up to 15 minutes in length; and

(d) that CIPP not be held liable for any costs.

[24] WHO, WIPO, & WTO at 57.

ALL OF WHICH IS RESPECTFULLY SUBMITTED THIS 28th day of July, 2016.



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Part VI. TABLE OF AUTHORITIES

Authority **Reference in Argument**

Cases		**Para**
1	*Eli Lilly Canada Inc v Apotex Inc,* 2008 FC 142	22
2	*Monsanto Co v Canada*, [1979] 2 SCR 1108	29
3	*Norberg v Wynrib*, [1992] 2 SCR 224	10
4	*Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60, [2012] 3 SCR 625	20
5	*R v Finta,* [1993] 1 SCR 1138	6
6	*Ratiopharm Inc v Pfizer Limited*, 2009 FC 711	22
7	*Reference re Workers' Compensation Act, 1983 (Nfld)*, [1989] 2 SCR 335	6, 10
8	*Sanofi-Aventis Canada Inc v Ratiopharm Inc*, 2010 FC 230	22
9	*Théberge v Galerie D'Art du Petit Champlain inc*, [2002] 2 SCR 336	17
Secondary Materials		
10	Harold G Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed (Toronto: Carswell, 1969)	29
11	Jeremy Waldron, "From Authors to Copiers: Individual Rights and Social Values in Intellectual Property" (1992) 68:2 Chicago-Kent L Rev 841	17
12	Jerome H Reichman, "Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection" (102nd Annual Meeting of American Society of International Law, vol 108, 2014), online: <http://frederickabbott.com.webmatrix-appliedi.net/Portals/0/Documents/ASIL%20-%202014%20-%20FA-SS-JR%20consolidated.pdf >	35
13	WIPO, Standing Committee on the Law of Patents, *The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws*, SPC5/Inf (2001)	22
14	WHO, WIPO & WTO, *Promoting Access to Medical Technologies and Innovation*: *Intersections Between Public Health, Intellectual Property and Trade* (Geneva: World Trade Organization, 2012)	35, 36
Statutory Provisions		
15	*Rules of the Supreme Court of Canada,* SOR/2002-156, as amended	6

Part VII. STATUTORY PROVISIONS

Rules of the Supreme Court of Canada, SOR/2002-156

English	Français
47. (1) Unless otherwise provided in these Rules, all motions shall be made before a judge or the Registrar and consist of the following documents, in the following order:	**47.** (1) Sauf disposition contraire des présentes règles, toute requête est présentée à un juge ou au registraire et comporte dans l'ordre suivant :
(*a*) a notice of motion in accordance with Form 47;	*a*) un avis de requête conforme au formulaire 47;
(*b*) an affidavit;	*b*) un affidavit;
(*c*) when considered necessary by the applicant, a memorandum of argument in accordance with paragraph 25(1)(*e*), with any modifications that the circumstances require;	*c*) si le requérant le considère nécessaire, un mémoire conforme à l'alinéa 25(1)*e*), avec les adaptations nécessaires;
(*d*) the documents that the applicant intends to rely on, in chronological order, in accordance with subrule 25(3); and	*d*) les documents que compte invoquer le requérant, par ordre chronologique, compte tenu du paragraphe 25(3);
(*e*) a draft of the order sought, including costs.	*e*) une ébauche de l'ordonnance demandée, notamment quant aux dépens.
(2) Parts I to V of the memorandum of argument shall not exceed 10 pages.	(2) Les parties I à V du mémoire de la requête comptent au plus dix pages.
(3) There shall be no oral argument on the motion unless a judge or the Registrar otherwise orders.	(3) Sauf ordonnance contraire d'un juge ou du registraire, aucune plaidoirie orale n'est présentée à l'égard de la requête.

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.

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.

57. (2)(b) A motion for intervention shall…set out the submissions to be advanced by the person interested in the proceeding, their relevance to the proceeding and the reasons for believing that the submissions will be useful to the Court and different from those of the other parties.

57. (2)(b) La requête expose ce qui suit…ses s, 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.