

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

BETWEEN:

**ASTRAZENECA CANADA INC, ASTRAZENECA AKTIEBOLAG, and ASTRAZENECA  
UK LIMITED**

APPELLANTS

- and -

**APOTEX INC and APOTEX PHARMACHEM INC**

RESPONDENTS

- and -

**INNOVATIVE MEDICINES CANADA AND BIOTECANADA, CENTRE FOR  
INTELLECTUAL PROPERTY POLICY, CANADIAN GENERIC PHARMACEUTICAL  
ASSOCIATION, FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ  
INTELLECTUELLE, INTELLECTUAL PROPERTY OWNERS ASSOCIATION, and  
INTELLECTUAL PROPERTY INSTITUTE OF CANADA**

INTERVENERS

---

---

**FACTUM OF THE INTERVENER**  
**CENTRE FOR INTELLECTUAL PROPERTY POLICY**

---

---

**Centre for Intellectual Property Policy  
(CIPP)**  
Faculty of Law, McGill University  
3644 Peel Street, Montreal, QC, H3A 1W9

Jeremy de Beer  
E. Richard Gold

Tel: (514) 398-6636  
Jeremy@Jeremy.deBeer.ca  
richard.gold2@mcgill.ca

**Counsel for the Intervener**

**Samuelson-Glushko Canadian Internet  
Policy & Public Interest Clinic (CIPPIC)**  
University of Ottawa, Faculty of Law, CML  
57 Louis Pasteur Street, Ottawa, ON, K1N 6N5

Tamir Israel

Tel: (613) 562-5800 EXT. 2914  
Fax: (613) 562-5417  
Email: tisrael@cippic.ca

**Agent for the Intervener**

**TO: THE REGISTRAR OF THE SUPREME COURT OF CANADA**

**COPY**

**TO:**

**Smart & Biggar**  
1100 – 150 York Street  
Toronto, ON, M5H 3S5

**Smart & Biggar**  
900-55 Metcalfe Street  
10th Floor, Ottawa, ON, K1P 6L5

Gunars A. Gaikis  
Yoon Kang

Colin Ingram

Tel: (414) 593-5514  
Fax: (416) 591-1690  
Email: ggaikis@smart-biggar.ca

Tel: (613) 232-2486  
Fax: (613) 232-8440  
E-mail: cbingram@smart-biggar.ca

**Counsel for the Appellant,  
AstraZeneca, AstraZeneca Aktiebolag  
and AstraZeneca UK Limited**

**Agent for the Appellant, AstraZeneca,  
AstraZeneca Aktiebolag and  
AstraZeneca UK Limited**

**AND TO: Goodmans LLP**  
3400 - 333 Bay Street  
Toronto, ON, M5H 2S7

**Nelligan O'Brien Payne LLP**  
1500-50 O'Connor Street  
Ottawa, ON, K1P 6L2

Harry B. Radomski  
Richard Naiberg  
Sandon Shogilev

Christopher Rootham

Tel: (416) 979-2211  
Fax: (416) 979-1234  
E-mail: hradomski@goodmans.ca

Tel: (613) 231-8311  
Fax: (613) 788-3667  
Email: Christopher.rootham@nelligan.ca

**Counsel for the Respondent, Apotex  
Inc and Apotex Pharmachem Inc**

**Agent for the Respondent, Apotex Inc  
and Apotex Pharmachem Inc**

**AND TO: Norton Rose Fulbright Canada LLP**  
Royal Bank Plaza, South Tower  
Suite 3800, 200 Bay St., PO Box 84  
Toronto, ON, M5J 2Z4

**Norton Rose Fulbright Canada LLP**  
45 O'Connor Street  
Suite 1500, Ottawa, ON, K1P 1A4

Patrick E. Kierans  
Kristen Wall

Jamie Macdonald

Tel: (416) 216-3904  
Fax: (416) 216-3930  
E-mail:  
patrick.kierans@nortonrose.com

Tel: (613) 780-8628  
Fax: (613) 230-5459  
E-mail:  
jamie.macdonald@nortonrosefulbright.  
com

**Counsel for the Intervener,  
Innovative Medicines Canada and  
BIOTECanada**

**Agent for the Intervener, Innovative  
Medicines Canada and  
BIOTECanada**

**AND TO: Aitken Klee LLP**  
100 Queen Street  
Suite 300, Ottawa, ON, K1P 1J9

Jonathan Stainsby  
Marcus Klee  
Devin Doyle  
Scott A. Beeser

Tel: (613) 903-5099  
Fax: (613) 695-5854  
E-mail: jstainsby@aitkenklee.com

**Counsel for the Intervener, Canadian  
Generic Pharmaceutical Association**

**AND TO: Fasken Martineau DuMoulin LLP**  
The Stock Exchange Tower, Suite  
3400, Victoria Square  
C.P. 242, Succ. Tour D/L Bourse  
Montréal, QC, H4Z 1E9

Julie Desrosiers  
Kang Lee  
Alain M. Leclerc

Tel: (514) 397-7400  
Fax: (514) 397-7600  
E-mail: jdesrosiers@mtl.fasken.com

**Counsel for the Intervener,  
Fédération international des conseils  
en propriété intellectuelle**

**AND TO: Borden Ladner Gervais LLP**  
World Exchange Plaza  
1100-100 Queen Street,  
Ottawa, ON, K1P 1J9

James Eliot Mills  
Chantal Saunders

Tel: (613) 369-4782  
Fax: (613) 230-8842

**Counsel for the Intervener,  
BioteCanada**

**Aitken Klee LLP**  
100 Queen Street  
Suite 300, Ottawa, ON, K1P 1J9

Marcus Klee

Tel: (613) 695-5858  
Fax: (613) 695-5854  
E-mail: mklee@aitkenklee.com

**Agent for the Intervener, Canadian  
Generic Pharmaceutical Association**

**Fasken Martineau DuMoulin LLP**  
55 Metcalfe Street, Suite 1300  
Ottawa, ON, K1P 6L5

Yael Wexler

Tel: (613) 696-6860  
Fax: (613) 230-6423  
E-mail: ywexler@fasken.com

**Agent for the Intervener, Fédération  
international des conseils en propriété  
intellectuelle**

**Borden Ladner Gervais LLP**  
World Exchange Plaza  
1100-100 Queen Street,  
Ottawa, ON, K1P 1J9

Nadia Effendi

Tel: (613) 237-5160  
Fax: (613) 230-8842

**Agent for the Intervener,  
BioteCanada**

**AND TO: Torys LLP**  
79 Wellington St. West  
Suite 3000, Box 270, TD South Tower  
Toronto, ON, M5K 1N2

Andrew Bernstein  
Yael S. Bienenstock

Tel: (416) 865-0040  
Fax: (416) 865-7380

**Counsel for the Intervener,  
Intellectual Property Owners  
Association**

**AND TO: Belmore Neidrauer LLP**  
TD South Tower  
79 Wellington Street West, Suite 2401  
TD Centre, Toronto, ON, M5K 1A1

Jason Markwell  
Marian Wolanski  
Stefanie Di Giandomenico

Tel: (416) 863-1771  
Fax: (416) 863-9171  
E-mail: jmarkwell@belmorelaw.com

**Counsel for the Intervener, Intellectual  
Property Institute of Canada**

**Gowling WLG (Canada) Inc.**  
160 Elgin Street, Suite 2600  
Ottawa, ON, K1P 1C3

Jeffrey W. Beedell

Tel: (613) 786-0171  
Fax: (613) 788-3587  
E-mail: jeff.beedell@gowlingwlg.com

**Agent for the Intervener,  
Intellectual Property Owners  
Association**

**Borden Ladner Gervais LLP**  
World Exchange Plaza  
100 Queen Street, suite 1300  
Ottawa, ON, K1P 1J9

Nadia Effendi

Tel: (613) 237-5160  
Fax: (613) 230-8842  
E-mail: neffendi@blg.com

**Agent for the Intervener,  
Intellectual Property Institute of  
Canada**

**TABLE OF CONTENTS**

**PART I. OVERVIEW..... 1**

**PART II. POSITION ON APPELLANTS’ QUESTIONS..... 1**

**PART III. ARGUMENT..... 1**

**A. The patent bargain involves diverse stakeholders, not just the inventor and state. .... 1**

**B. Utility is related to, not isolated from, other criteria for patentability. .... 2**

**C. An invention must be as useful as the applicant says it is, from a skilled reader’s view. .... 3**

Applying the word “useful” in context requires a skilled reader’s view of the invention..... 3

“Useful” in patent law has been consistently linked to applicants’ promises for a long time. .... 4

There are not two standards of utility; there is one standard involving distinct questions. .... 5

Proposed “scintilla” and “not devoid of” standards do not determine what an invention must do... 5

Patent applicants often specify an invention’s usefulness for strategic reasons..... 7

**D. Canada’s patent laws are consistent with foreign laws and international norms..... 8**

Canada’s utility rules are consistent with its key trading partners’ patent laws. .... 8

Canada’s utility rules are consistent with international norms and practices..... 8

**PART IV. SUBMISSIONS ON COSTS ..... 10**

**PART V. ORDER SOUGHT..... 10**

**PART VI. TABLE OF AUTHORITIES ..... 1**

**PART VII. STATUTORY PROVISIONS ..... 1**

## **PART I. OVERVIEW**

1. The Centre for Intellectual Property Policy (CIPP) invites the Court to reaffirm a central principle of Canadian patent law: As part of the patent bargain, an invention must do what the applicant says it does.
2. It is never enough that the claimed subject-matter has a scintilla of usefulness for something other than the use the specification indicates. An art, process, machine, manufacture or composition of matter that is merely not devoid of utility, in the abstract, is not an invention. The invention must be useful for the purpose asserted by the applicant in the patent specification. If an applicant says nothing about use, the invention must do what the skilled reader understands it to be useful for, based on common general knowledge and an objective reading of the whole specification.
3. This, CIPP submits, is the correct applicable standard for patent utility in Canada. Holding patent applicants to their promises maintains Canada's laws as consistent with its trading partners' laws and international norms. Any change to this patent bargain should be negotiated in Parliament, not the courts.

## **PART II. POSITION ON APPELLANTS' QUESTIONS**

4. CIPP takes no position on the outcome of this appeal. Regarding the questions at issue, CIPP submits:
  - A. The patent bargain involves diverse stakeholders, not just the inventor and state.
  - B. Utility is related to, not isolated from, other criteria for patentability.
  - C. An invention must be as useful as the applicant says it is, from a skilled reader's view.
  - D. Canada's patent laws are consistent with foreign laws and international norms.

## **PART III. ARGUMENT**

### **A. The patent bargain involves diverse stakeholders, not just the inventor and state.**

5. The principle that an invention must do what the applicant promises is rooted in the patent bargain at the heart of Canada's innovation system. CIPP agrees with the Appellants that the patent bargain is not "akin to a negotiated contract consisting of promises or guarantees."<sup>1</sup> It is more complex. In the context of the innovation system surrounding pharmaceuticals, the patent bargain involves inventors, funders, researchers, competitors, follow-on innovators, imitators, patients, hospitals, laboratories, health practitioners, public and private insurers, and others.

---

<sup>1</sup> Appellants' Factum at para 2.

6. The standard for patent utility should be determined bearing all of these stakeholders' perspectives in mind. Each one has an interest in ensuring an invention does what the applicant promised. Of course, as this Court has stated, "those who directly benefit from an invention should be asked ... to pay for it, at least in part."<sup>2</sup> But also, Canadians must gain "something more than speculation"<sup>3</sup> in exchange for monopoly rights. Courts should reduce uncertainty, otherwise "competition is 'chilled'."<sup>4</sup> In the words of the Supreme Court of the United States, "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."<sup>5</sup> Courts should ensure that "the granting of a patent is not abused to the financial detriment of Canadian patients and their insurers".<sup>6</sup> Perhaps most importantly, "patentees cannot be allowed to 'game' the system".<sup>7</sup>
7. Holding patent applicants to their promises about what an invention does supports Canadian innovation policy in several ways. It disciplines applicants to limit the scope of their claims to what they truly know. Consequently, it leaves follow-on innovators the incentive to conduct the hard work needed to translate an idea into practice. It coherently connects utility, non-obviousness, novelty, description, enablement, and other doctrinal aspects of patent law. That gives researchers and firms an objective basis on which to evaluate the validity of claims. It eliminates the clutter of speculative applications, so that patent examiners can focus attention on real inventions.

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

8. To properly uphold the patent bargain, patent law's utility requirement should be understood in relation to other criteria for patentability. One doctrine, such as utility, cannot be changed in isolation.
9. While the substantive requirements of novelty, non-obviousness, and utility are sometimes discussed separately, courts have recognized that they are deeply intertwined.<sup>8</sup> Canadian law is not unique in this respect. The World Intellectual Property Organization's Standing Committee on the Law of Patents explained that "for the purposes of full harmonization of substantive patent law, the industrial

---

<sup>2</sup> *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76 at para 25, [2002] 4 SCR 45, Binnie J, dissenting (Appellants' Book of Authorities, Volume 2, Tab 4).

<sup>3</sup> *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 at para 69, [2002] 4 SCR 153 (ABoA, V1, T9).

<sup>4</sup> *Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 42, [2000] 2 SCR 1024 (ABoA, V2, T22).

<sup>5</sup> *Brenner v Manson*, 383 US 519 at 536, (1966) (ABoA, V1, T15).

<sup>6</sup> *Celgene Corp v Canada (AG)*, 2011 SCC 1 at para 29, [2011] 1 SCR 3 (Intervener's Book of Authorities, V1, T2).

<sup>7</sup> *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 at para 80, [2012] 3 SCR 625 (ABoA, V2, T51).

<sup>8</sup> *Eli Lilly Canada Inc v Apotex Inc*, 2008 FC 142 at para 64, aff'd 2009 FCA 97 (IBoA, V1, T4); *Ratiopharm Inc v Pfizer Limited*, 2009 FC 711 at paras 154-156, aff'd 2010 FCA 204 (IBoA, V1, T6); *Sanofi-Aventis Canada Inc v Ratiopharm Inc*, 2010 FC 230 at para 51 (IBoA, V1, T7).

applicability/utility requirement cannot be considered separately from other requirements.”<sup>9</sup>

10. Since utility is integrally related to other criteria for patentability, CIPP supports the Appellants’ submission that “there is only one patent construction for all purposes: an invention cannot be read up for one purpose and down for another”.<sup>10</sup> This principle applies equally to all parties in patent disputes, including patent applicants. In particular, the utility requirement prevents applicants from exaggerating 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.
11. A corollary of the skilled reader’s single construction of the invention’s usefulness 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 submits that the statutory requirements of section 2 and subsection 27(3) are related.

**C. An invention must be as useful as the applicant says it is, from a skilled reader’s view.**

Applying the word “useful” in context requires a skilled reader’s view of the invention.

12. The word “useful” is not defined in the *Patent Act*. Its meaning must be interpreted purposively and applied in its statutory context. Canadian patent law relies on a skilled reader to construe the specification provided by the patent applicant. Assessing usefulness based on a skilled reader’s understanding of the patent applicant’s promise does not, therefore, impose a heightened or extra-statutory standard of utility.
13. Section 2 of the *Patent Act* defines “invention” as “any new and 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”. In French, « invention » is defined as « [t]oute 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. »<sup>11</sup>
14. The Appellants argue (with emphasis) that “subject-matter having *a* utility” is useful. CIPP submits that

---

<sup>9</sup> 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 (IBoA, V1, T24).

<sup>10</sup> Appellants’ Factum at para 29.

<sup>11</sup> *Patent Act*, RSC 1985 c P-4.



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

15. The place to begin any validity analysis is with the skilled reader.<sup>12</sup> She determines what are the essential and non-essential elements of the subject-matter. She then identifies that subject-matter's utility, which is what that subject-matter does. Based on a skilled reader's understanding, the court can determine whether the applicant's specified use is useful enough, and whether that usefulness is demonstrated or soundly predicted. This accords with the plain language of the Act, in both English and French, used to define "invention": One first determines what the claimed subject-matter is, and then one establishes whether it has the characteristic of being useful (*présentant le caractère ... de l'utilité*).

"Useful" in patent law has been consistently linked to applicants' promises for a long time.

16. While patent law is a creature of statute, courts have long interpreted statutory language in light of its history, purpose, and well-settled principles. Since 1787, courts in the United Kingdom have held that claimed subject-matter must possess the utility that a skilled reader determines the patent applicant asserted in the specification: "[I]f the process, as directed by the specification, does not produce that which the patent professes to do, the patent itself is void."<sup>13</sup>
17. Academics may dispute whether courts should have interpreted an older case one way or another.<sup>14</sup> But it cannot be disputed that practitioners, first in the UK and then in Canada, have understood that an invention must do what a skilled reader finds the patent specification asserts.
18. The leading reference on UK law, *Halsbury's Laws of England*, made this clear in 1937. The text explains that "not useful" means most importantly that "'the invention as described will not work,' *i.e.*, the invention will not do what the specification claims that it will do."<sup>15</sup>
19. Canada's foremost authority, Harold Fox, also explained in 1969 that an invention must do what the patent applicant indicates it does: "The true test of utility of an invention is whether it will, when put

<sup>12</sup> *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 43, [2000] 2 SCR 1067 (ABoA, V2, T56).

<sup>13</sup> *Turner v Winter* (1787), 1 TR 602 at 1276, 99 ER 1274 (IBoA, V1, T8).

<sup>14</sup> Norman Siebrasse, "The False Doctrine of False Promise" (2013) 29 CIPR 3 (ABoA, V3, T60); E Richard Gold & Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2014) 30 CIPR 35 (ABoA, V3, T57); Norman Siebrasse, "Form and Function in the Law of Utility: A Reply to Gold & Shortt" (2015) 30 CIPR 110 (ABoA, V3, T59). See also Wendy Lamson, "Utility: Unravelling the Real Differences with Our Closest Trading Partner" (2016) 32 CIPR 1 (IBoA, V1, T17).

<sup>15</sup> *Halsbury's Laws of England*, vol 24, 2nd ed (London, UK: Butterworths, 1937) at 1168 (IBoA, V1, T16) [citations omitted].

into practice by a competent person, do what it assumes to do ... for the purpose indicated by the patentee.”<sup>16</sup>

20. Similar language regarding promises continues to be used today in Canada, and in other jurisdictions including Australia, Israel and New Zealand.<sup>17</sup>

There are not two standards of utility; there is one standard involving distinct questions.

21. The trial decision being considered in this appeal states (at paragraph 90) the utility doctrine as requiring a scintilla of utility, except in cases where an explicit promise was made, but concludes: “In essence, ‘[t]he question is whether the invention does what the patent promises it will do.’”<sup>18</sup> This and other recent Federal Court decisions ostensibly create a two-tiered utility doctrine.
22. CIPP submits that applying one standard—that an invention must have *the* utility a skilled reader determines the applicant claims—avoids the oversimplified dichotomy between cases involving explicit promises and cases where nothing at all is said about an invention’s usefulness. A more robust framework would separate the question of *what* the subject-matter does from questions of *how much* the subject-matter does and *whether* that was sufficiently disclosed.
23. The promised utility doctrine, if such a “doctrine” exists, ensures an invention does what the applicant says it does. The other aspects of utility—whether how much the invention does is enough to cross the threshold of patentability, and whether utility was demonstrated or soundly predicted—are not at issue on the facts of this appeal.

Proposed “scintilla” and “not devoid of” standards do not determine what an invention must do.

24. The strength of Canada’s utility doctrine is its focus on a clear and objective standard for identifying what the claimed subject-matter does, based on the skilled reader’s view. Ignoring the applicant’s promises, and requiring only that an invention have an abstract scintilla of, or not be devoid of, utility

<sup>16</sup> Harold G Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed (Toronto: Carswell, 1969) at 150 (IBoA, V1, T15).

<sup>17</sup> AIPPI, “Questionnaire Apotex Inc v Sanofi-Aventis: Australia”, online: AIPPI Amicus Brief Committee <[http://aippi.org/wp-content/uploads/2015/02/Answ\\_Quest\\_Q221\\_Apotex\\_Australia1.pdf](http://aippi.org/wp-content/uploads/2015/02/Answ_Quest_Q221_Apotex_Australia1.pdf)> (IBoA, V1, T9); AIPPI, “Questionnaire Apotex Inc v Sanofi-Aventis: Israel”, online: AIPPI Amicus Brief Committee <[http://aippi.org/wp-content/uploads/2015/02/Answ\\_Quest\\_Q221\\_Apotex\\_Israel.pdf](http://aippi.org/wp-content/uploads/2015/02/Answ_Quest_Q221_Apotex_Israel.pdf)> (IBoA, V1, T11); *Hammar Maskin AB v Steelbro New Zealand Ltd*, [2010] NZCA 83 at para 76, aff’d [2010] NZSC 65, (IBoA, V1, T5).

<sup>18</sup> *AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638 at para 90, (Appellants’ Record V1, Part 1, T1) citing *Eli Lilly Canada Inc v Novopharm Limited*, 2010 FCA 197 at para 76 (ABoA, V1, T18).

would effectively read the word useful out of the *Patent Act*.

25. The word “scintilla” in patent law was traditionally used in the phrase “scintilla of invention”<sup>19</sup> to refer to the minimum quantum of inventiveness (non-obviousness) required. Harold Fox seems to be the first to reference “scintilla of utility” as the quantum of utility subject-matter must have: “no particular *quantum* of utility is necessary; and a mere scintilla of utility is sufficient for validity”.<sup>20</sup>
26. Courts began citing Fox for the proposition that a scintilla is enough utility in 2005 in *Aventis Pharma Inc v Apotex Inc*.<sup>21</sup> It was more recently—in an academic blog, and in an international trade dispute—that the so-called promised doctrine was criticized as new and different from the standard of a scintilla.<sup>22</sup> It is important, however, not to conflate how much usefulness is enough for a patentable invention and what the invention must be useful for. How useful an invention must be (the quantum) is a different question than what usefulness an invention must have (the promise).
27. The Appellants’ submit that unless a specific use is set out in a claim itself,<sup>23</sup> subject-matter is useful if it is not useless or not devoid of utility.<sup>24</sup> The phrase “not devoid of utility” is not present in the *Patent Act*. It has been derived from this Court’s decision in *Monsanto*.<sup>25</sup> CIPP submits that *Monsanto* does not support such a diluted and meaningless utility standard.
28. The issue in *Monsanto* concerned compounds that science might later establish to be “devoid of utility” in the sense that those compounds would not inhibit the premature vulcanization of rubber, which was the invention’s promised usefulness. Justice Pigeon did not mean the compounds might be devoid of *a* utility, in the abstract. He meant the compounds might be devoid of *the* utility indicated. This Court then examined whether the patentees’ “prediction of utility”<sup>26</sup> was sound and reasonable, but did not discuss the process through which the court had identified the promised utility.

---

<sup>19</sup> *Crosley Radio Corp v General Electric Co*, [1935] Ex CR 190 at 195 (IBoA, V1, T3).

<sup>20</sup> Harold G Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed (Toronto: Carswell, 1969) at 153 [emphasis in original] (IBoA, V1, T15).

<sup>21</sup> *Aventis Pharma Inc v Apotex Inc*, 2005 FC 1283 at para 271 (IBoA, V1, T1).

<sup>22</sup> Norman Siebrasse, “What is the Promise of the Patent?” (14 March, 2011), *Sufficient Description* (blog), online: <<http://www.sufficientdescription.com/2011/03/what-is-promise-of-patent.html>> (IBoA, V1, T21); *Eli Lilly and Company v Government of Canada*, “Government of Canada: Observations on Issues Raised in Amicus Submissions” at paras 15–17 (22 April 2016) UNCT/14/2 (Ch 11 Panel), online: <<https://icsid.worldbank.org/apps/ICSIDWEB/cases/Pages/casedetail.aspx?CaseNo=UNCT/14/2&tab=DOC>> (IBoA, V1, T13).

<sup>23</sup> Appellants’ Factum 86, 89, and 163.

<sup>24</sup> Appellants’ Factum at paras 61, 155.

<sup>25</sup> *Monsanto Co v Canada*, [1979] 2 SCR 1108 at 1117 [*Monsanto*] (ABoA, V2, T37).

<sup>26</sup> *Monsanto Co v Canada*, [1979] 2 SCR 1108 at 1122 [*Monsanto*] (ABoA, V2, T37).

29. The core problem with the “scintilla” standard is that it would entirely dilute the utility requirement. The core problem with the “not devoid of utility” standard is that it is tautological: It begs the question, *what* utility? In the abstract, every composition of matter and every process has *a* use, no matter how trivial. Reducing the standard of utility to “scintilla” or, alternatively, “not be devoid of utility” would mean the mere existence of the claimed subject-matter renders it useful. Parliament would not have put a word in section 2 of the *Patent Act* that has no practical meaning or effect.

Patent applicants often specify an invention’s usefulness for strategic reasons.

30. This Court has acknowledged that there is no obligation upon applicants to describe an invention’s utility.<sup>27</sup> Thus, the decision to disclose the demonstrated, predicted, or potential usefulness of subject-matter is sometimes more strategic than legal.
31. The simplest cases that might raise issues about utility are, as the Appellants allude,<sup>28</sup> new use claims. That is because a specific use is, by definition, stated explicitly in the claims. Yet, even in new use cases, the determination of the invention’s use may be determined more by the specification than by the claim. It may only be by reading the description that a skilled reader understands the nature of the use claim.
32. There are also other cases where an invention’s utility must, in practice, be stated elsewhere in the specification. The Appellants mention selection patents as an example where applicants are held to indications of use in the specification.<sup>29</sup> To show novelty and non-obviousness, applicants in these cases must describe specific advantages a selected species of compounds has over a previously patented genus. In practice, indicating advantages means stating the new (and normally improved) usefulness of the selected compounds in the patent description. Analogously, the ‘653 specification contains statements about the enantiomers’ improved profile over the previously patented racemate, omeprazole.
33. In other cases, the applicant may state little or nothing about an invention’s utility. An applicant’s silence about utility is usually because the subject-matter’s 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, but not because any abstract unspecified use would fulfil the utility requirement.
34. When applicants strategically indicate a utility, they usually do so in the description generally and not

---

<sup>27</sup> *Consolboard v MacMillan Bloedel*, [1981] 1 SCR 504 at 521 (ABoA, V1, T17).

<sup>28</sup> Appellants’ Factum at paras 86, 89, 118.

<sup>29</sup> Appellants’ Factum at para 125.

necessarily in the claims. An applicant’s statements about subject-matter’s “use as contemplated” and the steps or methods enabling others to “use” the invention cannot be ignored by a skilled reader assessing how exactly the invention is “useful”.

#### **D. Canada’s patent laws are consistent with foreign laws and international norms.**

Canada’s utility rules are consistent with its key trading partners’ patent laws.

35. The Appellants describe the utility requirement in Canada as “out of step with the corresponding requirements in other major jurisdictions.”<sup>30</sup> CIPP submits that other jurisdictions apply legal doctrines with the effect of ensuring that a putative invention does what a patent applicant says it does.
36. 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*.<sup>31</sup> Rules have similar functions if they address the same underlying problem, even if they do so differently.
37. United States patent law ensures that an invention does what the applicant asserts it will do through the enablement requirement and non-obviousness analysis.<sup>32</sup> The EPC holds patent applicants to assertions of function through a combination of the technicality requirement and the inventive step analysis.<sup>33</sup> Despite different court procedures, rules of evidence, presumptions of validity, and methods of patent construction, all of Canada’s trading partners’ patent systems hold applicants to their statements about a putative invention’s use.

Canada’s utility rules are consistent with international norms and practices.

38. Beyond the lack of evidence on the record<sup>34</sup> to support a claim that Canada is out of step with other jurisdictions, there is no international consensus on how countries must address the issues raised in this

---

<sup>30</sup> Appellants’ Factum at para 134.

<sup>31</sup> Konrad Zweigert & Hein Kötz, *An Introduction to Comparative Law*, 3rd ed (Oxford: Oxford University Press, 1998) at 34, 39 [translated by Tony Weir] (IBoA, V1, T25); John Reitz, “How to do Comparative Law” (1998) 46:4 Am J Comp L 617 at 620–2 (IBoA, V1, T19).

<sup>32</sup> E Richard Gold & Michael Shortt, “The Promise of the Patent in Canada and Around the World” (2014) 30 CIPR 35 at 66–70 (ABoA, V3, T57); Jacob S Sherkow, “Patent Law’s Reproducibility Paradox” (forthcoming 2017) 66 Duke LJ, online: <[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2735181](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2735181)> (IBoA, V1, T20).

<sup>33</sup> E Richard Gold & Michael Shortt, “The Promise of the Patent in Canada and Around the World” (2014) 30 CIPR 35 at 70–73 (ABoA, V3, T57); AIPPI, “Questionnaire Apotex Inc. v Sanofi-Aventis: Germany”, online: AIPPI Amicus Brief Committee <[http://aippi.org/wp-content/uploads/2015/02/Answ\\_Qest\\_Q221\\_Apotex\\_Germany.pdf](http://aippi.org/wp-content/uploads/2015/02/Answ_Qest_Q221_Apotex_Germany.pdf)> (IBoA, V1, T10).

<sup>34</sup> Respondents’ Factum at para 131.

appeal.<sup>35</sup> Rather, there is an international consensus that countries implement broad principles of patent law in a way that best advances their national interest. Variations in domestic patent law are normal.

39. The United Nations High Level Panel on Access to Medicines recently recommended, for example, that:

WTO members should make full use of the policy space ... by adopting and applying rigorous definitions of invention and patentability that are in the best interests of the public health of the country and its inhabitants. This includes amending laws to curtail the ever-greening of patents and awarding patents only when genuine innovation has occurred.<sup>36</sup>

40. Canadian patent law shows no unique pattern of either discriminating against pharmaceutical patents or holding those patents invalid due the criterion of utility. In particular, no data would support the assertion that there has been an increased rate of invalidating pharmaceutical inventions generally or specifically on the basis of utility. Looking at patent cases since 2000, there has been no statistically significant change in invalidity rates.<sup>37</sup>
41. Even if Canada sought perfect harmonization with other jurisdictions, it is unclear how this could be accomplished through the courts. There exist at least two different architectures for patent systems: the Anglo-American and the European approaches. 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 application. Despite similar functions, the substantive content of these rules differ. Therefore, if Canada is to harmonize internationally, it would have to do so through treaties. So far, none exist and none are being actively negotiated.
42. Finally, any significant change in the patent bargain within Canada should be made by Parliament, not the courts. The Government of Canada, defending an investor-state claim brought under the North American Free Trade Agreement by another pharmaceutical company, rejects the notion that Canadian

---

<sup>35</sup> Jerome H Reichman, “Compliance of Canada’s Utility Doctrine with International Minimum Standards of Patent Protection” (2014) 108 Am Soc’y Int’l L Proc 313 online: <[http://scholarship.law.duke.edu/faculty\\_scholarship/3377](http://scholarship.law.duke.edu/faculty_scholarship/3377)> (IBoA, V1, T18); 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 (IBoA, V1, T23).

<sup>36</sup> United Nations, *The Report of the UN Secretary-General’s High Level Panel on Access to Medicines* (September 2016) at 9, online: <http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HL+P+Report+FINAL+12+Sept+2016.pdf> (IBoA, V1, T22).

<sup>37</sup> CIPP, “Patent Litigation: Putting Assumptions to the Empirical Test”, *CIPP News* (28 July 2016) (blog), online: <<http://www.cippmccgill.ca/news/2016/07/28/patent-litigation-putting-assumptions-to-the-empirical-test/>> (IBoA, V1, T12).

courts have recently changed the law of utility, or that change is necessary.<sup>38</sup>


**PART IV. SUBMISSIONS ON COSTS**

43. The CIPP does not seek costs, and submits that it should not be liable for any costs.

**PART V. ORDER SOUGHT**

44. The CIPP seeks no specific order or disposition of this appeal. The CIPP requests permission to present oral submissions in support of its position.

ALL OF WHICH IS RESPECTFULLY SUBMITTED THIS 18 day of October 2016.

*for*   
\_\_\_\_\_  
Jeremy de Beer

*for*   
\_\_\_\_\_  
E. Richard Gold

Jeremy de Beer Professional Corporation  
470 Brierwood Avenue,  
Ottawa, ON CAN, K2A 2H3

Centre for Intellectual Property Policy  
Faculty of Law, McGill University  
3644 Peel Street  
Montreal, QC, H3A 1W9

Tel: 613-263-9155  
Email: [Jeremy@JeremydeBeer.ca](mailto:Jeremy@JeremydeBeer.ca)

Tel: 514-398-6636  
Fax: 613-562-5417  
Email: [Richard.Gold2@McGill.ca](mailto:Richard.Gold2@McGill.ca)

**Counsel for the Proposed Intervener, Centre for Intellectual Property Policy (CIPP)**

---

<sup>38</sup> *Eli Lilly and Company v Government of Canada*, “Government of Canada: Post-Hearing Submission” at 69-80 (25 July 2016) UNCT/14/2 (Ch 11 Panel), online: [https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC8733\\_En&caseId=C3544](https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC8733_En&caseId=C3544) (IBoA, V1, T14).

## PART VI. TABLE OF AUTHORITIES

<b>BoA Vol. Tab</b>	<b>CONTENTS</b>	<b>REFERENCE IN FACTUM</b>
<b>JURISPRUDENCE</b>		
ABoA V1 T9	<i>Apotex Inc v Wellcome Foundation Ltd</i> , 2002 SCC 77	6
ABoA V1 T6	<i>Apotex Inc v Pfizer Canada Inc</i> , 2014 FCA 250	21, 26
IBoA V1 T1	<i>Aventis Pharma Inc v Apotex Inc</i> , 2005 FC 1283	26
ABoA V1 T15	<i>Brenner v Manson</i> , 383 US 519, (1966) (SCOTUS)	6
IBoA V1 T2	<i>Celgene Corp v Canada (AG)</i> , 2011 SCC 1	6
ABoA V1 T17	<i>Consolboard v MacMillan Bloedel</i> , [1981] 1 SCR 504	30
IBoA V1 T3	<i>Crosley Radio Corp v General Electric Co</i> , [1935] Ex CR 190	25
IBoA V1 T4	<i>Eli Lilly Canada Inc v Apotex Inc</i> , 2008 FC 142	9
ABoA V1 T18	<i>Eli Lilly Canada Inc v Novopharm Limited</i> , 2010 FCA 197	21
ABoA V2 T22	<i>Free World Trust v Électro Santé Inc</i> , 2000 SCC 66	6
IBoA V1 T5	<i>Hammar Maskin AB v Steelbro New Zealand Ltd</i> , [2010] NZCA 83	20
ABoA V2 T4	<i>Harvard College v Canada</i> , 2002 SCC 76	6
ABoA V2 T37	<i>Monsanto Co v Canada</i> , [1979] 2 SCR 1108	27, 28
IBoA V1 T6	<i>Ratiopharm Inc v Pfizer Limited</i> , 2009 FC 711	9
IBoA V1 T7	<i>Sanofi-Aventis Canada Inc v Ratiopharm Inc</i> , 2010 FC 230	9



ABoA V2 T51	<i>Teva Canada Ltd v Pfizer Canada Inc</i> , 2012 SCC 60	6
IBoA V1 T8	<i>Turner v Winter</i> (1787), 1 TR 602, 99 ER 1274	16
ABoA V1 T15	<i>Whirlpool Corp v Camco Inc</i> , 2000 SCC 67	15
<b>SECONDARY SOURCES</b>		
IBoA V1 T9	AIPPI, “Questionnaire Apotex Inc v Sanofi-Aventis: Australia”, online: AIPPI Amicus Brief Committee < <a href="http://aippi.org/wp-content/uploads/2015/02/Answ_Quest_Q221_Apotex_Australia1.pdf">http://aippi.org/wp-content/uploads/2015/02/Answ_Quest_Q221_Apotex_Australia1.pdf</a> >	20
IBoA V1 T10	AIPPI, “Questionnaire Apotex Inc. v Sanofi-Aventis: Germany”, online: AIPPI Amicus Brief Committee < <a href="http://aippi.org/wp-content/uploads/2015/02/Answ_Quest_Q221_Apotex_Germany.pdf">http://aippi.org/wp-content/uploads/2015/02/Answ_Quest_Q221_Apotex_Germany.pdf</a> >	37
IBoA V1 T11	AIPPI, “Questionnaire Apotex Inc. v Sanofi-Aventis: Israel”, online: AIPPI Amicus Brief Committee < <a href="http://aippi.org/wp-content/uploads/2015/02/Answ_Quest_Q221_Apotex_Israel.pdf">http://aippi.org/wp-content/uploads/2015/02/Answ_Quest_Q221_Apotex_Israel.pdf</a> >	20
IBoA V1 T12	CIPP, “Patent Litigation: Putting Assumptions to the Empirical Test”, <i>CIPP News</i> (28 July 2016) (blog), online: < <a href="http://www.cippmcgill.ca/news/2016/07/28/patent-litigation-putting-assumptions-to-the-empirical-test/">http://www.cippmcgill.ca/news/2016/07/28/patent-litigation-putting-assumptions-to-the-empirical-test/</a> >	40
IBoA V1 T13	<i>Eli Lilly and Company v Government of Canada</i> , “Government of Canada: Observations on Issues Raised in Amicus Submissions” (22 April, 2016) UNCT/14/2 (Ch 11 Panel), online: < <a href="https://icsid.worldbank.org/apps/ICSIDWEB/cases/Pages/casedetail.aspx?CaseNo=UNCT/14/2&amp;tab=DOC">https://icsid.worldbank.org/apps/ICSIDWEB/cases/Pages/casedetail.aspx?CaseNo=UNCT/14/2&amp;tab=DOC</a> >	26
IBoA V1 T14	<i>Eli Lilly and Company v Government of Canada</i> , “Government of Canada: Post-Hearing Submission” (July 25, 2016) UNCT/14/2 (Ch 11 Panel), online: < <a href="https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&amp;actionVal=showDoc&amp;docId=DC8733_En&amp;caseId=C3544">https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&amp;actionVal=showDoc&amp;docId=DC8733_En&amp;caseId=C3544</a> >	42
IBoA V1 T15	Harold G Fox, <i>The Canadian Law and Practice Relating to Letters Patent for Inventions</i> , 4th ed (Toronto: Carswell, 1969)	19, 25
ABoA V3 T57	E Richard Gold & Michael Shortt, “The Promise of the Patent in Canada and Around the World” (2014) 30 CIPR 35	17, 37
IBoA V1 T16	<i>Halsbury’s Laws of England</i> , vol 24, 2nd ed (London, UK: Butterworths, 1937)	18
IBoA	Wendy Lamson, “Utility: Unravelling the Real Differences with Our	17

V1 T17	Closest Trading Partner” (2016) 32 CIPR 1	
IBoA V1 T18	Jerome H Reichman, “Compliance of Canada’s Utility Doctrine with International Minimum Standards of Patent Protection” (2014) 108 Am Soc’y Int’l L Proc 313, online: < <a href="http://scholarship.law.duke.edu/faculty_scholarship/3377">http://scholarship.law.duke.edu/faculty_scholarship/3377</a> >	38
IBoA V1 T19	John Reitz, “How to do Comparative Law” (1998) 46:4 Am J Comp L 617	36
IBoA V1 T20	Jacob S Sherkow, “Patent Law’s Reproducibility Paradox” (forthcoming 2017) 66 Duke LJ, online: < <a href="http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2735181">http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2735181</a> >	37
IBoA V1 T21	Norman Siebrasse, “What is the Promise of the Patent?” (14 March, 2011), <i>Sufficient Description</i> (blog), online: < <a href="http://www.sufficientdescription.com/2011/03/what-is-promise-of-patent.html">http://www.sufficientdescription.com/2011/03/what-is-promise-of-patent.html</a> >	26
ABoA V3 T60	Norman Siebrasse, “The False Doctrine of False Promise” (2013) 29 CIPR 3	17
ABoA V3 T59	Norman Siebrasse, “Form and Function in the Law of Utility: A Reply to Gold & Shortt” (2015) 30 CIPR 110	17
IBoA V1 T22	United Nations, <i>The Report of the UN Secretary-General’s High Level Panel on Access to Medicines</i> (September 2016), online: < <a href="http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf">http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf</a> >	39
IBoA V1 T23	WHO, WIPO, & WTO, <i>Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade</i> (Geneva: World Trade Organization, 2012)	38
IBoA V1 T24	WIPO, Standing Committee on the Law of Patents, <i>The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws</i> SPC5/Inf (2001)	9
IBoA V1 T25	Konrad Zweigert & Hein Kötz, <i>An Introduction to Comparative Law</i> , 3rd ed (Oxford: Oxford University Press, 1998) [translated by Tony Weir]	36

## PART VII. STATUTORY PROVISIONS

*Patent Act, RSC 1985, c P-4*

### Interpretation

#### Definitions

**2** In this Act, except as otherwise provided,

...

*invention* means any new and 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*)

...

### Application for Patents

#### Commissioner may grant patents

**27 (1)** The Commissioner shall grant a patent for an invention to the inventor or the inventor's legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for the issuance of a patent under this Act are met.

...

#### Specification

**(3)** The specification of an invention must

- (a)** correctly and fully describe the invention and its operation or use as contemplated by the inventor;
- (b)** set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
- (c)** in the case of a machine, explain the

### Définitions

#### Définitions

**2** Sauf disposition contraire, les définitions qui suivent s'appliquent à la présente loi.

...

*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. (*invention*).

...

### Demandes de brevets

#### Délivrance de brevet

**27 (1)** Le commissaire accorde un brevet d'invention à l'inventeur ou à son représentant légal si la demande de brevet est déposée conformément à la présente loi et si les autres conditions de celle-ci sont remplies.

...

#### Mémoire descriptif

**(3)** Le mémoire descriptif doit :

- a)** décrire d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues son inventeur;
- b)** exposer clairement les diverses phases d'un procédé, ou le mode de construction, de confection, de composition ou d'utilisation d'une machine, d'un objet manufacturé ou d'un composé de matières, dans des termes complets, clairs, concis et exacts qui permettent à toute personne versée dans l'art ou la science dont relève l'invention, ou dans l'art ou la science qui s'en rapproche le plus, de

principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and

**(d)** in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

confectionner, construire, composer ou utiliser l'invention;

**c)** s'il s'agit d'une machine, en expliquer clairement le principe et la meilleure manière dont son inventeur en a conçu l'application;

**d)** s'il s'agit d'un procédé, expliquer la suite nécessaire, le cas échéant, des diverses phases du procédé, de façon à distinguer l'invention en cause d'autres inventions.