

Case No. UNCT/14/2

**In the Arbitration under Chapter 11 of the  
North American Free Trade Agreement and  
the UNCITRAL Arbitration Rules**

BETWEEN:

**Eli Lilly and Company**

CLAIMANT/INVESTOR

- and -

**Government of Canada**

RESPONDENT/PARTY

---

---

*AMICUS CURIAE* SUBMISSIONS

**SAMUELSON-GLUSHKO CANADIAN INTERNET POLICY & PUBLIC INTEREST  
CLINIC  
&  
CENTRE FOR INTELLECTUAL PROPERTY POLICY**

---

---

**Samuelson-Glushko Canadian Internet  
Policy & Public Interest Clinic (CIPPIC)**

University of Ottawa, Faculty of Law,  
Common Law Section  
57 Louis Pasteur Street  
Ottawa, ON, K1N 6N5

David Fewer  
Jeremy de Beer  
Tel: (613) 562-5800 ext. 2558  
Fax: (613) 562-5417

**Counsel for the Proposed Intervenor**

**Centre for Intellectual Property Policy  
(CIPP)**

McGill University, Faculty of Law,  
3644 Peel Street  
Montreal, QC, H3A 1W9

E. Richard Gold  
Tel: 541-398-6636

**Counsel for the Proposed Intervenor**

## TABLE OF CONTENTS

|  |           |
|--|-----------|
| <b>PART I. OVERVIEW .....</b>  | <b>1</b>  |
| <b>PART II. ARGUMENT .....</b>   | <b>2</b>  |
| A. Canadian courts have always played a supervisory role over the Patent Office.....           | 2         |
| B. Nothing in NAFTA prohibits Parties' domestic laws and jurisprudence from evolving.....      | 5         |
| 1. No formal or informal international standards of utility exist.....                         | 5         |
| 2. NAFTA Chapter 17 does not undermine the natural evolution of the law.....                   | 7         |
| C. Trade law focuses on the overall effect of domestic laws, not individual patent rules.....  | 9         |
| D. A functional comparison of foreign laws reveals similarities in principles and results..... | 11        |
| <b>PART III. LIST OF SECONDARY MATERIALS.....</b>  | <b>13</b> |

## **PART I. OVERVIEW**

1. This arbitration raises important issues regarding the ability of NAFTA Parties to craft domestic patent laws that meet their unique social, economic, and legal circumstances. The Claimant's position places at issue the question of whether and to what extent NAFTA permits the continued evolution of the Parties' domestic laws and jurisprudence. This is a question of great import to the public interest. At stake is no less than the continued autonomy of each NAFTA Party to implement patent laws within its unique legal and social systems, and to permit patent law to evolve so as to respond to new technologies. This arbitration also raises questions about what NAFTA and other trade agreements have to say about the substantive content of patent law. Addressing these issues is crucial to maintaining a robust and dynamic marketplace for patented inventions. By implication, the Claimant raises questions about the substantive content of other intellectual property laws addressed by NAFTA and by other international trade instruments.
2. CIPPIC and CIPP offer the Tribunal four arguments that address these issues:
  - a. Throughout the history of Anglo-American patent law (including in Canada), courts have played a supervisory role to ensure that the State does not abuse the public by granting overly broad patents. This is why the Courts, and not the Patent Office, have the last word on the patentability of inventions and underlying determinations of fact.
  - b. NAFTA was never intended to prescribe substantive patentability requirements that are frozen in time. Rather, Chapter 17 of NAFTA establishes minimum requirements that each Party must address in its domestic patent laws that specifically eschew a common substantive standard of patentability; how to implement NAFTA standards are up to its Member States.
  - c. Trade law requires comparison of the overall effect of NAFTA Parties' patent laws, not their individual patent rules. The relevant question for the Tribunal is, therefore, whether Canadian patent law overall has a different effect from that of its trading partners.
  - d. A functional comparison of Canadian, American, and Mexican patent law reveals that utility in Canadian law is functionally equivalent to (a) the United States requirements of the utility branch of enablement, and (b) the Mexican requirements that an invention be capable of industrial application, have an inventive step, and be sufficiently described.

## PART II. ARGUMENT

### **A. Canadian courts have always played a supervisory role over the Patent Office.**

3. The Claimant contends that a patent issued by a patent office in Anglo-American legal systems is an unconditional property right.<sup>1</sup> This assertion is unsustainable in light of both the history and logic of the patent system. From the birth of the modern patent system in the early 17<sup>th</sup> century through to codifications of that system in both the United States and Canada, the patent system has been built on the premise that courts are needed to supervise both patent claimants and officers of the state granting patents to guard against “the great grievance and inconvenience” of the citizenry.<sup>2</sup> Thus, the patent system provides the courts, and not the patent offices, with the role of determining the validity and interpretation of exclusive rights.
4. The Claimant misunderstands the way in which the patent system in both Canada and the United States operates. Far from simply being “subject to a risk of litigation”,<sup>3</sup> an issued patent only provides its holder with a present right to later argue before a court that it has exclusive rights over a claimed invention. The patent document does not, in itself, actually guarantee those exclusive rights. The present right to later argue that one has an exclusive right is commercially valuable and is protected, in Canadian law, through various procedural rights. This right can be traded and provides the basis for attracting financing. What this right is not, however, is an unconditional right to exclusive rights over an invention until a court has stated otherwise.
5. The history of the patent system demonstrates the role of the courts in curbing abusive state power by actively supervising the function of that system. In the late 16<sup>th</sup> century, members of the UK Parliament sought to protect the “freedom of Englishmen”<sup>4</sup> by limiting Queen Elisabeth I’s power to create monopolies through letters patent. The Queen responded to these calls by agreeing to submit her patent

---

<sup>1</sup> Claimant’s Reply Memorial, para 35.

<sup>2</sup> *Statute of Monopolies*, 1624/1623 (UK), c 3 21 JacJa 1 c 3, Preamble, Introductory Text.

<sup>3</sup> *Supra* note 1 at para 41.

<sup>4</sup> Edward C. Walterscheid, “Early Evolution of the United States Patent Law: Antecedents (Part 2)” (1994) 76 J Pat & Trademark Off Soc’y 849 at 866.

grants to the common law courts.<sup>5</sup> Still not satisfied, in 1624 Parliament enacted section 4 of the *Statute of Monopolies* to empower anyone aggrieved by the grant of patent to seek redress before the common law courts.

6. By the end of the 18<sup>th</sup> century, English courts came to actively supervise granted patents, defining the boundaries of patent law and the substantive requirements necessary to justify a patent.<sup>6</sup> Of particular relevance to the present arbitration, courts began clarifying the link between patent specifications and the patentability of individual inventions. Describing it as “a basic tenet of modern patent law,” Walterscheid traces the development of “[t]he requirement as a condition of the patent grant that a patent have a specification containing a description of the invention adequate to permit one of ordinary skill in the art to practice and use the invention.”<sup>7</sup> The courts are responsible for entrenching this requirement in modern patent law. Tracing decisions from *Liardet v. Johnson*<sup>8</sup> to *Boulton v. Bull*,<sup>9</sup> Walterscheid concludes that “by the end of the [18<sup>th</sup>] century it had become settled law that the consideration for the patent was not the working of the invention *per se* but rather the disclosure of how to make and use it in the specification.”<sup>10</sup>
7. Concern over the state grant of patents crossed the Atlantic to the United States where Thomas Jefferson famously voiced concern, in a letter to James Madison in 1787 relating to the draft constitution, over “the omission of a bill of rights providing clearly and without the aid of sophisms for . . . restriction against monopolies.”<sup>11</sup> Madison’s response is instructive as it points to the critical role of the courts in ensuring that overly broad patents not be awarded: “Monopolies are sacrifices of the many to the few. Where the power is in the few it is natural for them to sacrifice the many to their own partialities and corruptions.”<sup>12</sup> The answer to Jefferson’s concerns was a strong judiciary whose role was to control against unwarranted monopolies including, specifically, those provided by patents.

---

<sup>5</sup> *Ibid.*

<sup>6</sup> Edward C. Walterscheid, “Early Evolution of the United States Patent Law: Antecedents (Part 3)” (1995) 76 J Pat & Trademark Off Soc’y 771 at 776.

<sup>7</sup> *Ibid* at 777.

<sup>8</sup> *Liardet v Johnson* (1778), Lord Mansfield.

<sup>9</sup> *Burt, Boulton & Hayward v Bull* (1895), 1 QB 276, 64 LJQB 232.

<sup>10</sup> *Supra* note 6 at 801.

<sup>11</sup> Letter from Thomas Jefferson to James Madison (20 December 1787), in Julian P. Boyd, ed, “*The Papers of Thomas Jefferson Volume 12, 7 August 1787 to 31 March 1788*” (Princeton: Princeton University Press, 1955).

<sup>12</sup> Letter from James Madison to Thomas Jefferson (17 October 1788), in Julian P. Boyd, ed, “*The Papers of Thomas Jefferson Volume 14, 8 October 1788 to 26 March 1789*” (Princeton: Princeton University Press, 1958).

8. Congress recognized the critical role of the courts when it enacted the first US patent statutes. For example, section 6 of the US Patent Act of 1790 incorporated the right to challenge an issued patent before the courts. Similar provisions were included in section 6 of the 1793 Act and section 15 of the 1836 Act, and are carried forward to this day. Notably, these Acts stated that the patent itself was only *prima facie* evidence of validity; nothing in these Acts required courts to defer to the officials who issued the patent nor to their determinations. As the United States Courts of Appeal for the Federal Circuit recently and unambiguously stated: “The initial determinations by the [Patent Office] in determining to grant the application are entitled to no deference...”.<sup>13</sup> Needless to say, a *prima facie* right is a far cry from an unconditional right. Contrary to the Claimant’s contentions, mere *prima facie* evidence of validity differs significantly from the rights of land-holders in a land title in common law Canada which is absolute. (See, for example, *Land Titles Act*, R.S.O. 1990, c. L-5).
9. As the court in *R v La Force* noted, Canada modelled its first patent statute on the US 1793 Act.<sup>14</sup> The *Patent Act* of 1869<sup>15</sup> provided for the impeachment of a patent and, similarly to the US Acts, did not call for any deference to patent office authorities or their determinations. The *Patent Act* of 1872<sup>16</sup> is to the same effect and this language continues in the present Act.
10. Of particular note is the use of the word ‘impeach’ in the Canadian statutes. The ordinary meaning of the word impeach is, according to the Oxford English Dictionary, “[t]o challenge, call in question, cast an imputation upon, attack; to discredit, disparage.”<sup>17</sup> According to the historical uses of the word set out in that dictionary, one impeaches someone’s modesty or credit, meaning that while there may have been an appearance (*prima facie*) of modesty or credit, neither was ever really present (*ab initio*). The only plausible reading of the Canadian statutes is, therefore, that an issued patent provides the appearance of validity but its true validity can only be assessed by a court presented with a full set of evidence.
11. Thus, the Claimant’s argument that once a patent office issues a patent, that patent is “unconditional property” faces insurmountable historical barriers. Over the last 400 years, in England, then the United States and Canada, patents have always been conditional upon the determination of validity by a court of competent jurisdiction. Further, the very wording of patent statutes in the United States and, more

---

<sup>13</sup> *Novo Nordisk v Caraco Pharmaceutical Labs*, 719 F 3d 1346 at 1357 (2013).

<sup>14</sup> *R v La Force* (1894) 4 Ex CR 14 at para 15.

<sup>15</sup> *The Canadian Patent Act of 1869*, being Part 31-32 & 33 Vict, Vic., c. 11, s 29.

<sup>16</sup> *The Patent Act of 1872*, 35 Vict, 32-36 Vic c. 26, s. 29.

<sup>17</sup> *The Oxford English Dictionary*, 2d ed, *sub verbo* “impeach”.

particularly, in Canada, belie the Claimant's contentions.

12. The actual functioning of the patent system further demonstrates the conditional nature of patent rights: almost half of all challenged patents in the US are found invalid. As the leading US analysis of patent validity rates found: "Forty-six percent of patents whose validity was decided in the 1990s were held invalid; today the invalidation rate is 43%."<sup>18</sup> This level of invalidity is incompatible with the view that patents are anything but conditional.
13. By reversing this historical balance in patent law, the Claimant's contentions have the effect of privileging the interests of patent applicants over those of the public and permitting the executive to grant unfettered monopolies. These assertions ignore four hundred years of law and dangerously imperil innovation by promoting underserved patents that both block research and undermine incentives to invest in innovation by those who actually deserve patent protection.

**B. Nothing in NAFTA prohibits Parties' domestic laws and jurisprudence from evolving.**

**1. No formal or informal international standards of utility exist.**

14. In its Response, the Claimant agrees that "Chapter 17 of NAFTA did not 'harmonize' substantive patentability requirements" across jurisdictions. (Para 15 of Response). Instead, it states that NAFTA establishes a 'baseline' level of utility that is, in reality, a ceiling on how stringently a Member State is able to assess an invention for its usefulness.
15. While stating that the 'baseline' is a "commonly understood criterion" (Para 19 of Response), the Claimant never actually describes this baseline or how to derive it. Instead, the Claimant simply asserts that the 'mere scintilla' utility standard, which it contends ought to underlie Canadian patent law, is consistent with that baseline and that the actual Canadian standard of utility is not. Why this is so is not explained.
16. There are good reasons that the Claimant does not describe the 'baseline' or why the 'mere scintilla' standard falls below its ceiling.
17. First, the 'mere scintilla' standard is not and has never been the utility standard in Canada or anywhere

---

<sup>18</sup> John R. Allison & Mark A. Lemley & David L. Schwartz, "Understanding the Realities of Modern Patent Litigation" 92 Texas L. Rev. 1769 at 1801.

else. Specifically, the Claimant has pointed to no Canadian case in which a court actually applied a ‘mere scintilla’ standard to determine utility. The phrase arose in a patent law text authored by a practitioner, not by a judge or government authority. To the extent that Courts have invoked the phrase ‘mere scintilla’, they have done so rhetorically in situations in which they have not applied it.

18. Second, the standard is absurd if used other than rhetorically. As ‘taking up space’ logically provides a mere scintilla of utility, the Claimant’s argument is that no patent claim can ever be held invalid if it has a mere physical presence. This contradicts patent theory and policy over the last 400 years.
19. Third, NAFTA’s ‘baseline’ must not be nearly as stringent a ceiling as the ‘mere scintilla’ standard, as the utility/industrial application requirements in each of the United States and Mexico greatly surpass it. United States patent law requires that an invention have a substantial, specific and credible utility. On this basis, taking up space or other *de minimus* utility is insufficient. Thus, “a short nucleotide sequence that represents a fragment of a cDNA clone” is not useful unless one knows the function of the tagged genes.<sup>19</sup> Similarly, a steroid that may eventually have been found to have a clinical use did not meet the US utility standard despite having physical and chemical properties.<sup>20</sup> The Mexican industrial application standard requires the invention to not merely fulfill any use, but a use that can be produced or used in any branch of economic activity.<sup>21</sup> This is more restrictive than a ‘mere scintilla’ of utility, which does not set out any parameters or restrictions on field of use.
20. Fourth, neither the text of NAFTA nor any other document support the existence of a ‘baseline’ of utility let alone its specific content. No agreement, including NAFTA, establishes a definition, baseline, or standard of utility. The very language of NAFTA contradicts the possibility of a common baseline or standard. It speaks of ‘industrial application’ and states that, for the limited purposes of article 1709, countries can substitute the separate and different concept of utility for it. That is, NAFTA explicitly acknowledges that there is no single standard of utility or industrial application.
21. Beyond the explicit text, the very different notions and functions of ‘industrial application’ and ‘utility’ point to the lack of common baseline. *Industrial application* speaks to field of use and the ‘technical’ nature of patents, whereas the *utility* requirement refers to a minimum level of both actual, present use

---

<sup>19</sup> *In re Fisher*, 421 F 3d 1365 (Fed Cir 2005).

<sup>20</sup> *Brenner v. Manson*, 383 US 519 (1966).

<sup>21</sup> *Industrial Property Law*, 1991 (as amended April 9, 2012) at Article 12(IV).

and evidence of that use.<sup>22</sup>

22. Rather than trying to overcome differences between the Anglo-American ‘utility’ and the civilian ‘industrial application’ approaches, NAFTA embraces those differences. To read NAFTA as establishing a singular, common, baseline or standard of utility when it recognizes two different standards is irrational.
23. NAFTA’s embrace of difference rather than uniformity reflects the international consensus that there is no single baseline or standard of industrial application/utility.<sup>23</sup> Further, this consensus, voiced not only by experts but by the leading United Nations organizations that have a mandate over patent law – the World Intellectual Property Organization, the World Trade Organization and the World Health Organization – is that countries are not only entitled but have an obligation to define the relevant concept to meet their national needs.<sup>24</sup> The views of these organizations are particularly persuasive given that they specifically refer to the requirements of TRIPs, upon which Chapter 17 of NAFTA is based and in respect of which the wording is almost identical. It makes little sense to assert that, while TRIPs imposes no baseline substantive standard of patentability, NAFTA Chapter 17 does.

## **2. NAFTA Chapter 17 does not undermine the natural evolution of the law.**

24. The Claimant’s arguments confuse the aims of trade law with that of intellectual property law. The parties to NAFTA aimed at ensuring trade in goods and services and crafted Chapter 17 to meet that need. They thus ensured that patents are available in all fields of technology (article 1709(1)), could not be curtailed out of proportion to the interest of patent holders (article 1709(6)), that the process of granting a compulsory license follow certain standards (article 1709(10), and that parties can exclude patentability on several policy grounds (articles 1709(1) to 1709(3)). They did not, and had no need to, overcome all differences among the patent systems of the Member States. They thus left issues such as the specific meaning of each of the patent criteria, to the determination of the parties. The Claimant has

---

<sup>22</sup> E Richard Gold & Michael Shortt, “The Promise of the Patent in Canada and Around the World” (2014) 30:1 CIPR 35 [Gold and Shortt].

<sup>23</sup> Jerome H Reichman, “Compliance of Canada’s Utility Doctrine with International Minimum Standards of Patent Protection” (Remarks delivered at the 102nd Annual Meeting of American Society of International Law, 11 April 2014).

<sup>24</sup> 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.

provided no evidence that would suggest the contrary.

25. This approach to interpreting Chapter 17 of NAFTA is necessary because both technology and business approaches to technology evolve. Industry practices toward the patenting of pharmaceutical products have changed significantly over the last century: from no patent protection in the first part of the 20<sup>th</sup> century,<sup>25</sup> to scattergun patenting as illustrated by the Claimant's patenting history with respect to the drugs in question in this arbitration. Similarly, the extension of patents to new technologies, such as computers, organic chemistry, biotechnology, nanotechnology, among others, has required courts to adapt well-worn principles to novel situations. These adaptations often enough run counter to industry expectations and desires, such as with respect to business and medical methods,<sup>26</sup> software<sup>27</sup> and genes<sup>28</sup> in the United States.
26. This normal evolution is exactly what occurred in Canada. The well-established principle that patent holders who make an explicit statement of the purpose of the invention are held to that statement was applied to pharmaceutical products. While this argument had always been available to those challenging pharmaceutical patents in courts, it only came to be used recently. The strategy and arguments of generic firms in patent litigation changed; the law itself did not.
27. The record before the Tribunal does not allow for any inference as to why generic firms decided to invoke this well-worn principle of patent law over the last decade or so. Possibilities include the particular skill of lawyers representing a generic firm in a particular litigation and the subsequent copying of that strategy by others, the increasing numbers of speculative patents filed and the increasing complexity of inventions.
28. To make out its claim that the law actually changed rather than simply applied an old rule to a new question, the Claimant would have needed to provide significant evidence as to (a) changing patent filing practice over the decades and (b) the number of cases prior to NAFTA in which a generic pharmaceutical firm actually raised the same utility question in respect of a second use or selection patent but failed. Instead, the Claimant has (a) put forward a haphazard list of patent suits where that list

---

<sup>25</sup> Peter Temin, "Technology, regulation, and market structure in the modern pharmaceutical industry" 10(2) *The Bell Journal of Economics* 429 at 435-36 (1979).

<sup>26</sup> *Bilski v Kappos*, 130 US 3218 (2010); *Mayo Collaborative Services v Prometheus Labs Inc.*, 132 S Ct 1289 (Sup Ct, 2012)

<sup>27</sup> *Alice Corporation Pty Ltd v CLS Bank International, et al*, 134 S Ct 2347 (2014).

<sup>28</sup> *Association for Molecular Pathology v Myriad Genetics Inc*, 133 S Ct 2107 (Sup Ct, 2013).

does not follow established principles of data collection, (b) selected arbitrary dates for its datasets, and (c) ignored alternative explanations (such as those set out above) in its statistical models. In so doing, the Claimant engages with the unsavoury practice of ‘P-hacking’, “also known as data-dredging, snooping, fishing, significance-chasing and double-dipping” or “trying multiple things until you get the desired result.”<sup>29</sup> No pharmaceutical company would engage in these same statistical games with respect to its regulatory filings.

29. Given the above, this Tribunal is not in a position to find that there has been any change in law.

**C. Trade law focuses on the overall effect of domestic laws, not individual patent rules.**

30. Trade law aims to harmonize the overall effect of Member States’ domestic laws in order to reduce boundaries for goods and services across borders and to establish free trade zones. Accordingly, Chapter 17 of NAFTA sets out, in broad undefined terms, the basic procedural elements of patent law that each Member State must address in its domestic laws. The question of how to implement those elements is left to each nation.

31. In determining compliance with trade agreements, trade law looks to overall effect, not to the particulars of a Member State’s law. That is, NAFTA requires compliance with outcomes, not individual, pre-packaged patent rules. The relevant question for the Tribunal is, therefore, whether Canadian patent law overall has a different effect from that of its trading partners, not whether individual patent rules are different.

32. A holistic, functional comparison of Canadian patent law to that of other jurisdictions is consistent with fundamental principles of comparative legal analyses. Leading texts explain “functionality” as the “basic methodological principle for all of comparative law.”<sup>30</sup>

33. Accepted comparative-law methodology requires comparison of rules that possess similar functions rather than rules with similar labels or whether one country has exactly copied the rules of another.<sup>31</sup> Rules have similar functions if they address the same underlying problem, even if they do so differently

---

<sup>29</sup> Regina Nuzzo, “Scientific method: Statistical errors” (2014) 506 Nature 150 at 152.

<sup>30</sup> Konrad Zweigert & Hein Kötz, *An Introduction to Comparative Law*, 3rd ed (Oxford: Oxford University Press, 1998) at 34, 39 [translated by Tony Weir]; John Reitz, “How to do Comparative Law” (1988) 46:4 Am J Comp L 617 at 620-622.

<sup>31</sup> Gold and Shortt, *supra* note 22 at 58-59.

or under different names. When comparing patent law from different legal systems—such as from Canada, the United States, and Mexico—this Tribunal ought not to simply look at whether a given system uses the word ‘promise’ or how it employs a concept called ‘utility’, since different legal systems achieve similar results using different legal concepts, or the same concept under a different label.<sup>32</sup> Rather, in comparing Canadian and foreign laws, this Tribunal should look at what those laws do, not how they are labelled.

34. Proper functional comparative legal analysis is done at a holistic level.<sup>33</sup> Taking a holistic approach when comparing national laws is particularly important with respect to the substantive criteria of patentability, since these are well known to be deeply interconnected.<sup>34</sup> The specifics of a country’s patent laws (e.g., patent claim construction, patentable subject-matter, presumptions of validity) vary considerably.<sup>35</sup> Further, each country’s unique patent laws interact synergistically to address similar problems and reach similar outcomes. Legal rules should not be examined in isolation from the broader systems in which they operate. To do so would overlook the subtle compromises and countervailing forces that exist in every legal system.<sup>36</sup> A holistic approach instead would allow the Tribunal to consider Canada’s patent system as a whole.
35. The World Intellectual Property Organization (WIPO) Standing Committee on the Law of Patents cautioned against fragmented approaches: “the industrial applicability/utility requirement cannot be considered separately from other requirements.”<sup>37</sup> The Supreme Court of the United States has also demonstrated a “holistic trend” in intellectual property law analyses.<sup>38</sup>
36. This Tribunal could benefit from a functional rather than formalistic comparative analysis. Canada’s patent law is the result of its distinct history and courts’ efforts to ensure, as stated by Justice Binnie in *Harvard College v Canada*, [2002] 4 SCR 45 at para 13, “that comparable jurisdictions with comparable intellectual property legislation arrive (to the extent permitted by the specifics of their own laws) at

---

<sup>32</sup> Ibid.

<sup>33</sup> Ibid; Ralf Michaels, “The Functional Method of Comparative Law” in *The Oxford Handbook of Comparative Law*, Mathias Reimann & Reinhard Zimmermann, eds (Oxford: Oxford University Press, 2006) 339.

<sup>34</sup> Gold and Shortt, *supra* note 22 at 58-59.

<sup>35</sup> Ibid.

<sup>36</sup> Ibid.

<sup>37</sup> WIPO Standing Committee on the Law of Patents, “The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws” (2001) SCP5/Inf at para 24.

<sup>38</sup> Peter Lee, “Patent Law and the Two Cultures” (2010) 120 Yale LJ 2 at 46.

similar legal results.”

37. CIPPIC and CIPP submit that a functional and holistic assessment of Canadian, American, and Mexican patent law is helpful and appropriate. This Tribunal ought not to compare narrow rules isolated from the context of the entire internal architecture of, and balance attained by, a nation’s patent system.

**D. A functional comparison of foreign laws reveals similarities in principles and results.**

38. When subjected to an appropriate, functional comparison, the substantive requirements of Canadian patent law result in similar outcomes to those of its NAFTA trading partners. A functional and holistic analysis of how NAFTA Member States decide what an invention does—variously called utility, industrial applicability, or promised utility—and the extent to which the specification must support that use, shows internationally consistent outcomes respecting the multidimensional patent bargain: (1) United States patent law enforces promises through the utility branch of enablement rules, (2) Mexican patent law enforces promises through industrial applicability, inventive step and sufficiency of description rules and (3) there is no evidence that Canadian patent law outcomes are different than elsewhere.

39. These arguments are addressed extensively by the Government of Canada in its Counter Memorial.<sup>39</sup> CIPPIC and CIPP support those submissions, and submit the following additional and related considerations.

40. First, Canadian patent law achieves the same principled balance as foreign laws by encouraging innovation through the award of limited term monopolies while facilitating follow-on innovation of new products and services and their use by Canadians. Canada achieves this balance through requirements of sufficiency of disclosure, consistent patent construction and holding patentees to their strategic assertions of utility.

41. Second, this Tribunal should be mindful that Federal Court determinations of utility are almost always questions of mixed fact and law. As the Government of Canada correctly identifies, the determination of utility is part of the exercise of claims construction generally.<sup>40</sup> This involves a subtle understanding and parcelling out of the evidence before the trier of fact. The Federal Court is best placed to address these

---

<sup>39</sup> Respondent’s Counter Memorial at p 36-56.

<sup>40</sup> Respondent’s Counter Memorial at p 44-48.

questions and make these determinations.

42. Third, while the outcomes of particular cases concerning the same invention may vary from country to country, there is no evidence on the record (nor any empirical research that suggests) that the pattern of outcomes is different in Canada than elsewhere. Indeed, there are many examples of patents that have been invalidated elsewhere, but remain valid in Canada.<sup>41</sup>

All of which is respectfully submitted this 12<sup>th</sup> day of February, 2016,

[signed]

---

David Fewer

Samuelson Glushko Canadian Internet Policy  
and Public Interest Clinic (CIPPIC)

[signed]

---

Richard Gold

Centre for Intellectual Property Policy  
(CIPP)

---

<sup>41</sup> See, e.g., Canadian Patents No 2415438, 2393298, 2420893 and 2446615, which remain valid in Canada despite the invalidity of their European or US counterparts as determined in T 1753/06, T 0415/11 and in *CreAgri Inc v Pinnaclife Inc*, No 11 CV 6635 LHK (ND Cal 2013),) and *Petito v Puritan's Pride*, No 13 Civ 8074 PAE (SD NY 2014)).

### PART III. LIST OF SECONDARY MATERIALS

Edward C. Walterscheid, “Early Evolution of the United States Patent Law: Antecedents (Part 2)” (1994) 76 J Pat & Trademark Off Soc’y 849.

- Available on Westlaw:  
<https://a.next.westlaw.com/Document/I872593515aec11dbbd2dfa5ce1d08a25/View/FullText.html?originationContext=docHeader&contextData=%28sc.Default%29&transitionType=Document&needToInjectTerms=False&docSource=33b7790bd1954220b7f91923553b8477>

Edward C. Walterscheid, “Early Evolution of the United States Patent Law: Antecedents (Part 3)” (1995) 76 J Pat & Trademark Off Soc’y 771.

- Available on Westlaw:  
<https://a.next.westlaw.com/Document/I4d6e24c15aeb11dbbe1cf2d29fe2afe6/View/FullText.html?originationContext=docHeader&contextData=%28sc.Default%29&transitionType=Document&needToInjectTerms=False&docSource=22a0db5125bf409a8524c6f1b7fd2ca9>

Letter from Thomas Jefferson to James Madison (20 December 1787), in Julian P. Boyd, ed, “The Papers of Thomas Jefferson Volume 12, 7 August 1787 to 31 March 1788” (Princeton: Princeton University Press, 1955).

- Letter available online at <http://www.let.rug.nl/usa/presidents/thomas-jefferson/letters-of-thomas-jefferson/jefl66.php>

Letter from James Madison to Thomas Jefferson (17 October 1788), in Julian P. Boyd, ed, “The Papers of Thomas Jefferson Volume 14, 8 October 1788 to 26 March 1789” (Princeton: Princeton University Press, 1958).

- Letter available online at <http://press-pubs.uchicago.edu/founders/documents/v1ch14s47.html>

John R. Allison & Mark A. Lemley & David L. Schwartz, “Understanding the Realities of Modern Patent Litigation” 92 Texas L. Rev. 1769.

- <http://www.texasrev.com/wp-content/uploads/AllisonEtAl-92-7.pdf>

E Richard Gold & Michael Shortt, “The Promise of the Patent in Canada and Around the World” (2014) 30:1 CIPR 35.

- <http://www.pijip.org/wp-content/uploads/2014/06/Gold-and-Shortt.pdf>

Jerome H Reichman, “Compliance of Canada’s Utility Doctrine with International Minimum Standards of Patent Protection” (Remarks delivered at the 102nd Annual Meeting of American Society of International Law, 11 April 2014).

- [http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=6067&context=faculty\\_scholarship](http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=6067&context=faculty_scholarship)

WHO, WIPO & WTO, Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade (Geneva: World Trade Organization, 2012).

- [https://www.wto.org/english/res\\_e/booksp\\_e/pantiwhowipowtweb13\\_e.pdf](https://www.wto.org/english/res_e/booksp_e/pantiwhowipowtweb13_e.pdf)

Peter Temin, "Technology, regulation, and market structure in the modern pharmaceutical industry" 10(2) The Bell Journal of Economics 429 (1979)

- <http://www.jstor.org/stable/3003345>

Regina Nuzzo, "Scientific method: Statistical errors" (2014) 506 Nature 150.

- <http://www.nature.com/news/scientific-method-statistical-errors-1.14700>

Konrad Zweigert & Hein Kötz, An Introduction to Comparative Law, 3rd ed (Oxford: Oxford University Press, 1998) [translated by Tony Weir].

John Reitz, "How to do Comparative Law" (1988) 46:4 Am J Comp L 617.

- [www.jstor.org/stable/840981](http://www.jstor.org/stable/840981)

Ralf Michaels, "The Functional Method of Comparative Law" in The Oxford Handbook of Comparative Law, Mathias Reimann & Reinhard Zimmermann, eds (Oxford: Oxford University Press, 2006).

- [http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2033&context=faculty\\_scholarship](http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2033&context=faculty_scholarship)

WIPO Standing Committee on the Law of Patents, "The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws" (2001) SCP5/Inf.

- [www.wipo.int/scp/en/meetings/session\\_5/doc/scp5\\_inf.doc](http://www.wipo.int/scp/en/meetings/session_5/doc/scp5_inf.doc)

Peter Lee, "Patent Law and the Two Cultures" (2010) 120 Yale LJ 2.

- <http://www.yalelawjournal.org/article/patent-law-and-the-two-cultures>