IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF THE NORTH AMERICAN FREE TRADE AGREEMENT AND THE UNCITRAL ARBITRATION RULES (1976)

BETWEEN:

ELI LILLY AND COMPANY

Claimant/Investor

AND:

GOVERNMENT OF CANADA

Respondent/Party

(Case No. UNCT/14/2)

GOVERNMENT OF CANADA

OBSERVATIONS ON ISSUES RAISED IN *AMICUS* SUBMISSIONS

April 22, 2016

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I. OVERVIEW

1. Canada files its observations on issues raised in the six *amicus curiae* briefs submitted pursuant to the Tribunal's decision of February 23, 2016 (Procedural Order No. 4) and in accordance with section 18.2 of Procedural Order No. 1. While Canada has organized its observations by *amicus* for the convenience of the Tribunal, we note that there are three overall themes arising from the submissions of the six *amici curiae*.

2. First, as Canada has made clear throughout its previous submissions,[1] and as is clear from the submissions of the United States and Mexico as well,[2] when the conduct of the judiciary is at issue, the only possible claim is for a denial of justice – a claim expressly not made here. This is true as a matter of law, but as is evident from a review of the *amicus* submissions, there is also a need for deference as a matter of fact. As the National Association of Manufacturers points out, patent examiners and judges adjudicating patent disputes "are experts at administering patent laws and regulations."[3] Moreover, the decisions made by courts in assessing the validity of a patent are inherently fact-driven,[4] and deal with issues that are frequently "particularly complex and unsettled."[5] Importantly, the patent law requirements applicable in each case are "a

[1] *See* Respondent's Counter Memorial ("Resp. CM"), paras. 230-245, 316-325; Respondent's Rejoinder ("Resp. Rejoinder"), paras. 120-127, 244-255. *See also* Kathleen Liddell and Michael Waibel, *Fair and Equitable Treatment and Judicial Patent Decisions*, Legal Studies Research Paper Series, University of Cambridge, Paper No.4/2016 January 2016 ("Liddell-Waibel Paper"), pp. 17-25, **R-474** (noting at p. 20 that "[j]udicial conduct cannot give rise to indirect expropriation or a breach of FET, including legitimate expectations.")

[2] US 1128 Submission, paras. 21-24, 28-29; Mexico 1128 Submission, paras. 13-14, 20-21.

[3] Amicus Brief of the National Association of Manufacturers, February 12, 2006 ("NAM Amicus Brief"), para. 24.

[4] *See* Resp. CM, para. 79; Amicus Curiae Submission of the Canadian Generic Pharmaceutical Association, February 12, 2016 ("CGPA Amicus Brief"), para. 46; Liddell-Waibel Paper, p. 23, **R-474**. *See also, e.g.,* Gowling Lafleur Henderson LLP, Pharmacapsules @ Gowlings, May 4, 2009, p. 5, **R-494** (noting that, even under Canadian domestic law, "whether a prediction [of utility] is sound is a factual question").

[5] Liddell-Waibel Paper, p. 23, **R-474** ("For instance, in *Eli Lilly v. Canada*, an investment tribunal is not necessarily the right forum to examine complex, detailed aspects of Canadian pharmaceutical patent law. The revoked patents concerned 'new medical use' and 'selection' inventions, which are a particularly complex and unsettled area of patent law, and often very fact-specific.") The complexity of patent validity cases has also been acknowledged by Canadian courts. For example, the court in *Eli Lilly and Company v. Apotex Inc.*, 2009 FC 991, paras. 5-8, **R-475** described the "nearly one thousand pages of submissions" before it in a proceeding "instituted nearly twelve years ago" in which the parties had been "intensively

function of the context, the nature of the patent, what the patentee has chosen to say in the patent and the particularities of the discipline to which the patent relates."[6] These are assessments properly made by domestic court systems, not by international tribunals. The consequences of the Tribunal wading into these issues would be far-reaching, and no less than disastrous for both the international and domestic legal systems.

3. Second, patent systems require a fine balance of competing interests.[7] The systems are designed in such a way that all of the criteria work together to maintain the patent bargain. That is, all of the criteria work together to ensure that the law grants time-limited monopolies and, in exchange, "draws ingenious, useful and unobvious disclosures into the public domain, for the benefit of society at large."[8] To the extent an *amicus* submission focuses on one narrow aspect of the bargain to the exclusion of the others, it should be approached with caution. Canada has shown that the utility requirement can only be considered in the context of the patent bargain as a whole.[9] Moreover, there is substantial risk associated with the Tribunal reviewing the Courts' decisions in any manner other than for a denial of justice when it does not have a full appreciation of the entire national patent law framework.[10]

4. Third, because all three NAFTA Parties agree that NAFTA Chapter Eleven Tribunals are not the appropriate forum to determine the Parties' obligations under other

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litigating." The Court described its task as "daunting," which was "only partially reflected in these reasons which are, unfortunately, too long despite the fact that the Court could not really do justice to all the issues raised. It was simply not possible or even desirable to refer to all the evidence and the hundreds of cases put forth by the parties." The Court's reasons were 883 paragraphs long.

[6] CGPA Amicus Brief, paras. 34, 36. *See also* Norman Siebrasse, Sufficient Description Blog Excerpts ("Sufficient Description"), pp. 5, 28, 30, 63, 68, 77, **R-476**.

[7] *See* Resp. CM, paras. 7, 84, 100; Resp. Rejoinder, paras. 18, 20. *See also* Liddell-Waibel Paper, p. 23, **R-474** ("It is also important to realize that patent law involves a carefully *sic* balancing between multiple doctrines in order that the requirements for the acquisition of a patent are proportionate to the rights provided to the owner and the liability defenses available for third parties."); Amicus Curiae Submission of Samuelson-Glushko Canadian Internet Policy & Public Interest Clinic (CIPPIC) and Centre for Intellectual Property Policy (CIPP) February 12, 2016 ("CIPPIC/CIPP Amicus Brief"), para. 34; CGPA Amicus Brief, paras. 15-18.

[8] CGPA Amicus Brief, para. 22.

[9] *See, e.g.,* Resp. Rejoinder, paras. 19-27; Claimant's Reply ("Cl. Reply"), paras. 89, 157, fn 212.

[10] *See, e.g.,* Liddell-Waibel paper, pp 23-24, **R-474**.

treaties or under NAFTA Chapter Seventeen,[11] the majority of the submissions made by the *amici* have little bearing on the critical question before the Tribunal, i.e. whether there has been a denial of justice. Nevertheless, it is clear that international intellectual patent law treaties, such as TRIPS or NAFTA Chapter Seventeen, allow signatories significant flexibility in implementing their obligations. This is written directly into the TRIPS agreement, and acknowledged by both Canada and the United States in the context of this arbitration.[12] The flexibility of these systems acknowledges that "each patent system has its own complex technicalities and minutiae … based on 'distinct histories, politics and policies [and] cannot be easily erased'."[13] Tellingly, even one of the *amici* who argues that Canada's law on utility is "inconsistent with international norms" recognizes that States are not required to reach identical conclusions with respect to the same patents.[14]

5. Canada reviews these themes below in greater detail with respect to issues raised by the (Part II) academics from the US, including Dr. Burcu Kilic, Professor Brook K. Baker, Professor Cynthia Ho, and Mr. Yaniv Heled ("US Academics"); (Part III) Canadian Chamber of Commerce ("CCC"); (Part IV) Canadian Generic Pharmaceutical Association ("CGPA"); (Part V) Samuelson-Glushko Canadian Internet Policy and Public Interest Clinic and Centre for Intellectual Property Policy ("CIPPIC/CIPP"); (Part VI) group of seven intellectual property law professors ("IP Professors"); and (Part VII) National Association of Manufacturers ("NAM"). Canada has sought to comment on the issues most salient to the dispute at hand, and no inference should be drawn from the absence of comment on any issue not addressed below. Canada has organized its observations in the order of *amicus* set out by the Tribunal in Procedural Order No. 4.

[11] Resp. CM, para. 210; US 1128 Submission, para. 36; Mexico 1128 Submission, para. 22.

[12] Resp. CM, paras. 185-188; US 1128 Submission, para. 40.

[13] Liddell-Waibel Paper, p. 10, **R-474**, references removed.

[14] NAM Amicus Brief, fn 10. *See also* CGPA Amicus Brief, para. 74 ("It is neither necessary nor helpful to insist that concepts and principles from other jurisdictions be incorporated into Canadian law.")

II. ACADEMICS FROM THE US, INCLUDING DR. KILIC, PROFESSORS BAKER AND HO, AND MR. HELED ("US ACADEMICS")

6. Canada agrees with the US Academics' discussion of policy issues surrounding the practice of secondary patent filing.[15] They note that it has become "a key element of any life cycle management strategy … to extend patent protection beyond the basic patent term for as long as possible by filing secondary patents which are effective to keep generics off the market."[16] In addition, they point to intellectual property law practitioners who acknowledge that secondary patents "may give rise to difficulties in validity and enforcement" because the primary or basic patents generally constitute prior art, creating challenges for meeting the patentability criteria.[17] This view is consistent with reporting in Europe, the United States and Canada.[18]

7. The US Academics also point out that the practice of filing numerous secondary patent applications without disclosing an already proven or soundly predicted utility can "cordon off broad swaths of pharmaceutical research to prevent competition by others."[19] Canada agrees with the US Academics' assertion that the "patent system is not designed to grant monopolies on the basis of hunches, guesses, or hopes," even if those guesses

[15] Canada has addressed these issues in its submissions: Resp. CM, para. 97; Resp. Rejoinder, paras. 31-32; *see also* Sufficient Description, p. 110, **R-476**. Canada comments on other issues raised by the US Academics in paras. 11, 16, 24, 30.

[16] Amicus Curiae Submission of Dr. Burcu Kilic, Professor Brook K. Baker, Professor Cynthia Ho and Mr. Yanive Heled ("US Academics' Amicus Brief"), p. 4; Michael Burdon and Kristie Sloper, "The Art of Using Secondary Patents to Improve Protection," Vol. 3 International Journal of Medical Marketing (2003) < http://www.olswang.com/pdfs/secondary_patents_jun03.pdf>, p. 3, **R-477**.

[17] Ibid, http://www.olswang.com/pdfs/secondary_patents_jun03.pdf>, p. 4, **R-477**. These IP law practitioners also note that "there may be differences in the outcome of patent litigation in different jurisdictions. Such differences in outcome may result from a number of factors including differences in the substantive legislation (e.g. between the UK and US); differences in the procedural requirements of each jurisdiction; differences in the evidence put before the courts in each jurisdiction, and differences in the approach of the courts to interpretation of the relevant provisions of the legislation."

[18] *See* Resp. Rejoinder, paras.30-31.

[19] US Academics' Amicus Brief, p. 5. *See also* CGPA Amicus Brief, paras. 62-64; CIPPIC/CIPP Amicus Brief, para. 13.

later come to fruition.[20] Canadian law has always required that all elements of the patent bargain – including utility– be present at the time of filing.[21]

III. CANADIAN CHAMBER OF COMMERCE ("CCC")

8. The CCC self-describes as the "largest and most influential business association in Canada."[22] As noted in Canada's comments on *amicus* applications, the CCC's membership includes Claimant.[23] Canada offers four observations on arguments raised by the amicus submission filed by the CCC, arguments which Canada notes do not support Claimant's views that Canada's law on utility constitutes a breach of NAFTA Chapter Eleven.

9. First, contrary to Claimant, the CCC takes a tempered view of Canada's law on utility. It posits simply that the "promise of utility" has been "broadly interpreted" by Canadian courts, and that this "broad interpretation" "has implications" for sectors relying on patents.[24] This stands in stark contrast to the Claimant's characterization of it as a doctrine that is "arbitrary, unjust, and idiosyncratic."[25] Even the CCC's assertion that Canada's "intellectual property framework…deviates from international norms" (which it neither identifies nor elaborates)[26] is inconsistent with Claimant's views of the courts' allegedly arbitrary action. Importantly, the CCC makes no assertion that

[20] US Academics Amicus Brief, p. 5. *See also* Resp. Rejoinder, para. 25; Dimock First Report, para. 93; Dimock Second Report, para. 94.

[21] Resp. CM, paras. 119-120; Resp. Rejoinder, para. 25; Dimock First Report, paras. 110.

[22] Canadian Chamber of Commerce, Application of non-disputing parties for leave to file a written submission, February 12, 2016, pp. 1-2. Canada comments on other issues raised by the CCC in para. 31.

[23] Canada's Comments on Amicus Applications, p. 10.

[24] *See* Canadian Chamber of Commerce, Amici Curiae brief, February 12, 2016 ("CCC Amicus Brief"), pp. 3, 9.

[25] *See, e.g.,* Cl. Mem., para. 262; *see also* Sufficient Description, pp. 8, 15, 34, 38, 66, 74, 83, **R-476**.

[26] CCC Amicus Brief, p. 14. Canada sets out in its comments with respect to the IP Professors why deviation from international norms is neither accurate nor relevant: *see* Part VI.

Canada's utility law "radical[ly] shift[ed]"[27] or that it has changed in the significant way that Claimant alleges.[28]

10. Second, the CCC recognizes, as Canada has argued throughout this arbitration, that Canada's law on utility applies equally to industries other than pharmaceuticals.[29] It cites as an example the "implications for mechanical patents in the aerospace sector" arising from the *Eurocopter* case.[30] The National Association of Manufacturers takes a similar position, articulating that it "does not view this dispute as a pharmaceutical case but as an issue of broad importance to manufacturers across all sectors."[31] The position taken by both of these broad-based industry groups directly contradicts Claimant's allegation that Canada's law on utility discriminates against pharmaceutical patentees contrary to NAFTA Articles 1105 and 1709(7).[32]

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[27] *See, e.g.,* Cl. Reply, para. 69.

[28] For example, the CCC cites with approval a blog written by Ron Faggetter, the Managing Partner at a prominent Canadian intellectual property law firm, who describes the role that Canadian courts play in interpreting the utility requirement in Canada's *Patent Act*: "Canadian courts, in interpreting the requirement for utility, *have considered* that if a patent promises a particular utility for an invention, the invention must achieve this promised utility to avoid invalidity of claims directed to the invention. Thus, while there is no requirement to promise a specific utility, if a promise is made, the question of whether the invention has utility *has been assessed* by reference to the explicit promise" [emphasis added]: Smart & Biggar Fetherstonhaugh, "Federal Court of Appeal affirms invalidity of all but a single claim for failure to meet promises in a mechanical patent", 1 October 2013, **R-478**; CCC Amicus Brief, p. 9. The CCC and Mr. Faggetter also note that, as a matter of Canadian law, where there is an "explicit promise, utility is established if the promised utility is demonstrated by the date of filing the patent application or if the promised utility is soundly predicted as of the filing date": Ibid, **R-478**; CCC Amicus Brief, p. 10. The CGPA confirms that: "Holding patentees to the promises made in their patents has long been a central element of Canadian patent law, dating at least to *New Process Screw* in 1933", para. 28; "The Canadian law of utility has always required the patentee to have shown utility as at the time of filing;" para. 62; "While expressed in *AZT*, [the doctrine of sound prediction] was an element of Canadian law before *AZT*" (acknowledging that it had been 'explicitly received' into Canadian law in 1979 with the Supreme Court of Canada's *Monsanto* decision), para. 65 and fn 45. Canada comments on other issues raised by the CGPA in Part IV.

[29] CCC Amicus Brief, pp. 3 ("While this uncertainty primarily impacts pharmaceutical investment, it has implications for other sector such as biotech and aerospace…"), CCC Amicus Brief, p. 9 ("However, as noted, the implications of this direction by the courts impact other industries as well").

[30] CCC Amicus Brief, p. 9.

[31] NAM Amicus Brief, para. 6. Canada addresses other issues raised by the NAM in Part VII.

[32] *See, e.g.,* Cl. Reply, para. 195.

11. Third, the thrust of the CCC's submission is that Canada "needs new strategies to foster Canadian patent generation,"[33] so that Canada can "attract investment and generate wealth."[34] It links patent protection to innovation and investment, arguing in favour of a policy that ameliorates Canada's position in innovation rankings.[35] The CCC's fundamentally policy-oriented argument is misplaced in the context of this arbitration for two reasons. First and foremost, these are precisely the types of issues that NAFTA tribunals have said must be left to the discretion of government policy-makers. For example, the NAFTA Chapter Eleven tribunal in *Mesa v. Canada* recently held, "it is not for this Tribunal to second-guess a government's policy choices, or to ascertain whether the policy goals of the government would have been better served by resorting to other means."[36] Canada has shown that there is a rational basis for its approach to

[33] CCC Amicus Brief, p. 14.

[34] Canadian Chamber of Commerce, Application of non-disputing parties for leave to file a written submission, February 12, 2016, pp. 1-2.

[35] CCC Amicus Brief, pp. 6-9. While arguing that the Canadian courts' findings of inutility are directly linked to a decline in investment in Canada (p. 11), it fails to demonstrate the causal connection. For example, its first source is a publication by Industry Canada entitled "Canada's Pharmaceutical Industry and Prospects". However, this document describes that "[multi-national enterprises] with operations in Canada have and *are responding to market conditions and competitive global corporate dynamics* by rationalizing and reducing their level of direct investment": Industry Sector: Manufacturing & Life Sciences Sector, "Canada's Pharmaceutical Industry and Prospects" [emphasis added], Section 3.4, pp. 14-16, **R-479**. Among the market conditions discussed in the report are the expiry of blockbuster drug patents leading to decreased market share by brand pharmaceutical companies, and the revenue performance of new product launches that are not offsetting revenue losses from those patent expiries (see pp. 12-14; Section 3.3). The publication also states: "Closures of Canadian R&D facilities by MNEs are occurring because these facilities were engaged in therapeutic areas that are no longer areas of global corporate focus or as the result of outsourcing and in-licensing to minimize costs and risks associated with in-house product development. Moreover MNEs are consolidating research centres to clusters located closer to company headquarters, or are located in attractive geographic markets. Conditions of attractive markets include investment infrastructure and government incentive such as taxation." (pp. 16-18, Section 3.5). The CCC's conclusions should also be approached with caution because it relies on a publication made by the Global Intellectual Property Center ("GIPC"): *see, e.g.*, fns 8-9, and a KPMG report "commissioned by Canada Pharma (formerly Rx&D)" (which it does not cite) to support its arguments: *see* p. 12. The Tribunal already decided to reject the *amicus* application made by Innovative Medicines Canada, which was formerly Rx&D, for failing to "assist the Tribunal…by bringing a perspective, particular knowledge or insight that is different that of the disputing parties": Procedural order No. 4, para. 6. Similarly, GIPC is a branch of the United States Chamber of Commerce, and operates as an advocacy group to "promote and defend effective IP rules while working to strengthen enforcement efforts overseas": *see* GIPC, International Advocacy, online: <http://www.theglobalipcenter.com/initiatives/international-advocacy/>, **R-491**.

[36] *Mesa Power Group, LLC v. Canada*, NAFTA/UNCITRAL (PCA Case No. 2012-17), Award, March 24, 2016, ("*Mesa Award*"), paras. 632, 579, **RL-159**. *See also Glamis Gold, Ltd. v. United States of America*, (UNCITRAL) Award, 8 June 2009, para. 762 ("it is not for an international tribunal to delve into the details of and justifications for domestic law.") (**RL-006**).

utility – enforcing the patent bargain and preventing speculative patenting.[37] The Tribunal is precluded from assessing the policies any further. Moreover, the CCC's exclusive focus on innovation ignores that patent law also seeks to "coax otherwise private and undisclosed research into the public domain."[38] As the US Academics note "[e]very patent system has built-in checks and balances that seek to disseminate knowledge and promote access and innovation."[39] Both a real invention and its disclosure to the public are conditions precedent to the grant of patent protection.

12. Finally, Canada notes that the CCC's submission appears to take the view that this Tribunal should act as a supranational court of appeal. It incorporates into its submission commentary from patent law practitioners that states: "Until the Supreme Court of Canada or the tribunal in Lilly's NAFTA challenge deals with *sic* issue, the promise doctrine may remain a live issue."[40] As Canada has made clear in its submissions – and the other NAFTA Parties agree[41] – investment tribunals do not have plenary jurisdiction to serve as courts of appeal in domestic law matters.[42]

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[37] *Mesa Award*, para. 579, **RL-159** ("In particular, the Tribunal must determine whether Canada's conclusion of the GEIA lacked a justification, and whether there was a reasonable relationship between the justification supplied and the terms of the GEIA."). *See also* Respondent's Statement of Defence, paras. 13, 19-20; Resp. CM, paras 81-84, 100; Resp. Rejoinder, paras. 7, 25, 237, 273.

[38] CGPA Amicus Brief, para. 59. Canada comments on other issues raised by the CGPA in Part IV.

[39] US Academics' Amicus Brief, p. 1. Canada comments on other issues raised by the US Academics in Part II.

[40] CCC Amicus Brief, p. 13.

[41] US 1128 Submission, para. 23 ("it is well-established that international tribunal such as NAFTA Chapter Eleven tribunals are not empowered to be supranational courts of appeal on a court's application of domestic law."); *The Loewen Group Inc. and Raymond Loewen v. United States of America*, ICSID ARB(AF)/98/3, Second Submission of the United Mexican States, 9 November 2001, p. 6, **RL-023** ("the Tribunal does not sit as a court of appeal but rather as an international tribunal with a different governing law and jurisdiction.")

[42] See, e.g., Resp. CM, paras. 239,331; Resp. Rejoinder, paras. 246-247. *See also Mesa Award*, para. 579, **RL-159**; *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Final Award, 11 October 2002 ("*Mondev Award*"), para. 126, **RL-004**; R*obert Azinian, Kenneth Davitian & Ellen Baca v. United Mexican States*, ICSID Case No. ARB(AF)/97/2, Award, 1 November 1999, ("*Azinian Award*"), para. 99, **RL-002**; *The Loewen Group Inc. and Raymond Loewen v. United States of America*, ICSID ARB(AF)/98/3, Award on Merits, 26 June 2003 ("*Loewen Award*"), para. 51, **RL-013**; *Mr. Franck Charles Arif v. Republic of Moldova*, ICSID Case No. ARB/11/23, Award, 8, April 2013 ("*Arif Award*"), paras. 398, 416, 440-441, **RL-063**. *See also* Rudolf Dolzer and Christoph Schreuer, *Principles of International Law*, Oxford: Oxford University Press, 2008, pp. 165-166, **R-327**; *Loewen Group and Another v. United States of America*, Opinion of Christopher Greenwood Q.C, 26 March 2001, para. 64, **RL-025**.

IV. CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION ("CGPA")

13. Like Claimant, the CGPA's members are "regular litigants before the Federal Courts and the Supreme Court of Canada."[43] The CGPA, along with the International Generic and Biosimilar Medicines Association and their member organizations from the United States and Mexico, have expressed appropriate concern about subjecting domestic court decisions on domestic patent law to super-appellate review through NAFTA Chapter Eleven. All three NAFTA Parties have made clear in their submissions that they share these concerns.[44] Further, Canada agrees that this concern is particularly salient in a case like this where "the party purporting to challenge the domestic legal decisions expressly disavows any denial of natural justice or procedural fairness by the domestic courts,"[45] and where the challenging party takes a position before the international tribunal that is diametrically opposed to the position it took before the domestic courts whose decisions it seeks to have overturned.[46]

14. The CGPA also importantly confirms that "judge-made law has a role to play in clarifying what is otherwise a purely statutory area of law," both "in Canada and around the world."[47] As the Supreme Court of Canada has commented: "In the interpretation and application of patent statutes judge-made doctrine has over the years done much to clarify the abstract generalities of the statutes and to secure uniformity in their

[43] Application for *Amicus Curiae* Status by the Canadian Generic Pharmaceutical Association, February 12, 2016, paras. 2, 4. Canada comments on other issues raised by the CGPA in paras. 21-22, 29-30, and fns 28, 69, 80.

[44] Resp. CM, paras.239, 321; Resp. Rejoinder, para. 267; US 1128 Submission, para. 22, 24; Mexico 1128 Submission, para. 20; *The Loewen Group Inc. and Raymond Loewen v. United States of America*, ICSID ARB(AF)/98/3, Second Submission of the United Mexican States, 9 November 2001, para. 242, **RL-023**.

[45] CGPA Amicus Brief, paras. 15-17; Application for *Amicus Curiae* Status by the Canadian Generic Pharmaceutical Association, February 12, 2016, Appendix A, p. 2. The CGPA asserts that Claimant "enjoyed the full and extensive protection of the Canadian legal system," noting that the two matters "took up at least 73 days of court time and were considered by some 20 different judges": CGPA Amicus Submission, para. 16. Canada set out at length the full consideration Claimant received from the Canadian judicial system in its Counter-Memorial: *see* paras. 21-64.

[46] CGPA Amicus Brief, para. 7; Resp. CM, para. 53. Contrary to the position it takes in this arbitration that "the promise utility doctrine is new, and constitutes a radical shift in Canadian patent law," (Cl. Reply, para. 69), Claimant argued before the Supreme Court of Canada that the Federal Court of Appeal "did nothing more than follow established principles of patent law and the jurisprudence of this court", *Novopharm Limited v. Eli Lilly and Company*, Supreme Court of Canada Case No. 33870, Memorandum of Argument of the Respondent, Application for Leave to Appeal, 26 October 2010, para. 2 (**R-034**).

[47] CGPA Amicus Brief, para. 56; *see also* Sufficient Description, p. 132, **R-476**;

application."[48] Rather than changing the system dramatically and fundamentally as Claimant alleges, the Canadian Courts here were fulfilling their natural and integral common law adjudicative function of clarifying the "abstract generalities" of the *Patent Act*, and of consistently applying existing principles in Canadian patent law to new situations.[49] As Canada has set out in its submissions, private litigants drive and shape the manner in which these factually unique situations are put before the courts.[50]

V. SAMUEL-GLUSHKO CANADIAN INTERNET POLICY & PUBLIC INTEREST CLINIC & CENTRE FOR INTELLECTUAL PROPERTY POLICY ("CIPPIC/CIPP")

15. Canada agrees with the CIPPIC/CIPP submission when it confirms that the courts' role as ultimate arbiter of patent validity and underlying determinations of fact is long-standing.[51] The submission correctly explains the historical origins of the courts' supervisory function with respect to both applicants and the patent-granting State for the protection of the public. It also appropriately underlines the "historical balance" the courts have maintained between the interests of patent applicants and the public, and the restraint the courts have exercised on the executive's unfettered grant of monopolies in

[48] *Apotex Inc. v Sanofi-Synthelabo Canada Inc*., [2008] 3 SCR 265, para. 12, **R-13**; *see also* Norman Siebrasse "The Essential Elements Doctrine in Patent Infringement" (2011) 22 Intellectual Property Journal 223, at p. 226 (discussing the modern approach to statutory interpretation) (**R-480**).

[49] *See, e.g.,* Resp. Rejoinder, paras. 205-211, 228, 254-255; *see also* Sufficient Description, pp. 87, 136, **R-476**.

[50] Resp. Rejoinder, paras. 46-50. This has been particularly the case in the pharmaceutical context, where private parties have initiated significant amounts of litigation. For example, in the period between 2005 and 2014, there were approximately 6 times more invalidity challenges to pharmaceutical patents (127) than invalidity challenges to non-pharmaceutical patents (21 challenges): *see* Brisebois Statement, Table 1, p. 12; Levin Report, Annex C, pp. 9-20; *see also* Andrew Reddon IP Cases, Search Results Generated on WestlawNext Canada, April 19 2016, **R-481**; McCarthy Tetrault LLP, Expertise Detail, **R-482**. Canada has also explained that the relationship between patentability requirements shapes applicants' patent drafting and parties' litigation approach, and accordingly courts' decisions: *see* Resp. Rejoinder, paras. 32-36.; s*ee also Allergan Inc v Apotex Inc*, 2016 FC 344, **R-483;** *Uponor AB v. Heatlink Group Inc.*, 2016 FC 320**, R-484;** *Allergan Inc.. v. Minister of Health and Sandoz Inc.*, Memorandum of Fact and Law of the Applicants (Redacted), Federal Court File No. T-154-10, 18 July 2011**, R-485;** *Abbott Laboratories v. Minister of Health and Ratiopharm*, Memorundum of Fact and Law of the Appellants, Federal Court of Appeal File No. A-384-05, 7 December 2005, **R-486;** *Aventis Pharma Inc. v. Schering Corp.*, Memorandum of Fact and Law of Schering Corp., Federal Court File No. T-1742-03, 2005 IPPleadingF 4297, 24 January 2005, **R-487**; McCarthy Tetrault LLP, snIP/ITs Blog Post, 19 December 2011**, R-488**.

[51] Canada comments on other issues raised by CIPPIC/CIPP in paras 28, 36 and fn 80.

accordance with the applicable domestic law.[52] The courts' exercise of these functions demands significant deference at international law.[53]

16. CIPPIC/CIPP also correctly characterizes the nature of patent rights. Rather than constituting an "unconditional right to exclusive rights over an invention until a court has stated otherwise," 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."[54] The right's commercial value – including the ability to trade and attract financing – and accompanying protective procedural rights do not transform it into an absolute right.[55] As the US Academics point out, "the decision of the patent office to grant or reject a patent is always subject to review by the Courts."[56]

17. Finally, CIPPIC/CIPP rightly takes issue with Claimant's view that NAFTA Chapter Seventeen includes a "mere scintilla" "baseline" standard. It identifies a number of reasons for its views that Claimant's proposal is "in reality, a ceiling," including that it is more stringent than the utility or industrial application requirements of any of the three NAFTA Parties.[57] In contrast, CIPPIC/CIPP correctly submits that it is in fact necessary to view Chapter Seventeen as incorporating a flexible approach because all patent systems are required to adapt to changing technologies and business approaches

[52] *See, e.g.*, CIPPIC/CIPP Amicus Brief, paras. 2(a), 3-13.

[53] Resp. Rejoinder, paras. 236,267; US 1128 Submission, para. 23 ("*A fortiori*, domestic courts performing their ordinary function in the application of domestic law as neutral arbiters of the legal rights of litigants before them are not subject to review by international tribunals absent a denial of justice."); Mexico 1128 Submission, paras. 13-14 ("International tribunals defer to the acts of municipal courts not only because the courts are recognized as being expert in matters of a State's domestic law, but also because of the judiciary's role in the organization of the State.")

[54] CIPPIC/CIPP Amicus Brief, para. 4.

[55] CIPPIC/CIPP Amicus Brief, paras. 4, 11.

[56] US Academics' Amicus Brief, p. 6. The US Patent and Trademark Office agrees: "Every patent is presumed to be valid … The question of validity or invalidity is otherwise exclusively a matter to be determined by a court": Manual of Patent Examining Procedure, s. 1701, **R-490**. *See also* CIPPIC/CIPP Amicus Brief, paras. 11-12; Resp. CM, para. 391; Resp. Rejoinder, para. 43; *see also* Norman Siebrasse (2004) "A Remedial Benefit-Based Approach to the Innocent-User Problem in the Patenting of Higher Life Forms" 20(1) CIPR 79-134, at p. 98 ("The Patent Office does a public service in examining patents and rejecting those that are invalid, but despite their best efforts, invalid patents are regularly issued.") **R-489**; Sufficient Description, pp. 60, 96, **R-476;** McCarthy Tetrault LLP, snIP/ITs Blog Post, 29 March 2016**, R-488**.

[57] CIPPIC/CIPP Amicus Brief, paras. 14-23.

to technology.[58] For example, as discussed above, Canada's *Patent Act* provides the framework of "abstract generalities" that the courts then interpret and apply to ever-changing technologies and business approaches.[59] This kind of "normal evolution" of applying existing principles to new situations has occurred in all three NAFTA Parties since the treaty was signed.[60] Canada has set out its views on Claimant's "baseline" arguments in its Counter-Memorial and Rejoinder.[61]

VI. GROUP OF INTELLECTUAL PROPERTY LAW PROFESSORS ("IP PROFESSORS")

18. The IP Professors argue that Canada's promise utility doctrine "contravenes NAFTA Article 1709, a point that ultimately supports Eli Lilly & Company's claim against the Government of Canada under NAFTA Chapter 11."[62] As an initial matter, the IP Professors have inappropriately attempted to step into the Tribunal's shoes to determine whether there has been a breach of Canada's NAFTA obligations. The IP Professors' conclusions in this regard, which they repeat twice in their submission,[63] should be disregarded.

19. In addition, the IP Professors incorrectly claim that the United States supports their conclusion, asserting that it "appears to regard the promise doctrine as inconsistent with treaty obligations, and particularly targeting US companies."[64] However, the United States has specifically stated in the context of this arbitration that "decisions of domestic courts acting in the role of neutral and independent arbiters of the legal rights of litigants

[58] CIPPIC/CIPP Amicus Brief, para. 25.

[59] *See* para. 14 above. *See also Apotex Inc. v Sanofi-Synthelabo Canada Inc.*, [2008] 3 SCR 265, para. 12, **R-013;** Resp. Rejoinder, paras. 205-211, 228, 254-255; Norman Siebrasse, "Evidentiary Problems of Multidisciplinarity in the Litigation of Business Methods Patents" in Intellectual Property Law for the 21st Century: Interdisciplinary Approaches to IP (Irwin Law, 2014: Toronto), at p. 454 (quoting Justice Binnie in *Harvard College v. Canada* that "by definition the *Patent Act* must contemplate the unforeseeable") **R-492**; Sufficient Description, pp. 100, 112, **R-476**.

[60] CIPPIC/CIPP Amicus Brief, para. 26; Resp. CM, paras. 173,176; Resp. Rejoinder, para. 210.

[61] Resp. CM, paras. 351-352; Resp. Rejoinder, paras. 139ff.

[62] Non-Disputing Party *Amicus Curiae* Submission of Intellectual Property Law Professors, February 12, 2016 ("IP Professors' Amicus Brief"), p. 2.

[63] IP Professors' Amicus Brief, pp. 2, 18.

[64] IP Professors' Amicus Brief, p. 13.

do not give rise to a claim for expropriation under Article 1110(1)" in the absence of a denial of justice.[65] Moreover, all NAFTA Parties agree that Article 1110(7) "should not be read to provide a NAFTA Chapter Eleven tribunal with jurisdiction to review alleged inconsistencies or breaches of Chapter Seventeen."[66] Instead, Chapter Seventeen obligations are subject to the State-to-State dispute settlement provisions of Chapter Twenty.

20. The IP Professors rightly admit that the question of whether Canada's law on utility contravenes NAFTA Article 1709 is a separate and narrower issue than whether it contravenes "global norms concerning the industrial application requirement."[67] However, they then focus much of their time on the latter, and on the practices of non-NAFTA Parties to support their conclusion with respect to Article 1709. Indeed, to arrive at their conclusion, the IP Professors assert that Canada's promise utility doctrine "runs counter to the global trend" and is "inconsisten[t] with the function and goals of the patent system."[68] Consistency with global norms is not before this Tribunal. As such, the IP Professors' commentary on the status of patent law in jurisdictions other than the NAFTA Parties, for example in the European Union[69] and Japan, is irrelevant for this case. In any event, the IP Professors' position cannot be sustained for several reasons.

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[65] US 1128 Submission, para. 29.

[66] US 1128 Submission, para. 36. *See also* Mexico 1128 Submission, para. 22; Resp. CM, para. 210.

[67] Application for Leave to File a Non-Disputing Party *Amicus Curiae* submission by Intellectual Property law Professors, February 12, 2016, para. 2.

[68] IP Professors' Amicus Brief, p. 2.

[69] Notwithstanding the fact that there is no requirement that all systems be the same, the European and Canadian approaches are more similar than the IP Professors make out. For example, the IP Professors point to Boards of Appeal of the European Patent Office, Decision of October 27, 2004 T 0609/02 – 3.3.8 ("Board Decision T 0609/02), **R-493**, to show that "it is required that the patent provides some information in the form of, for example, experimental tests, to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se.": p. 4, from para. 9 of Board Decision T 0609/02, **R-493**. Similarly, Canadian law requires disclosure of a factual basis and a line of reasoning that a skilled reader would regard as adequately supporting the prediction of utility promised by the invention: Resp. CM, paras. 110-111; Dimock Report, paras. 99-100; McCarthy Tétrault LLP, "Federal Court of Appeal clarifies misunderstanding: factual basis and line of reasoning need not be disclosed in the patent", June 8, 2015, p. 1, **R-494**. In addition, the IP Professors note that T 0609/2 "stands in part for the proposition that an in vitro effect may be sufficient to establish industrial applicability and could be supported by post-published evidence of efficacy," p. 4. The IP Professors ignore that the Supreme Court of Canada's decision in *AZT*, which upheld the validity of the patent in question, involved *in vitro*, rather

21. First, the IP Professors incorrectly characterize the Canadian standard for utility. Rather than requiring "accurate predictions and proof of a product's specific value in the marketplace,"[70] Canadian law requires only that inventors either demonstrate or soundly predict the utility they themselves articulate for their inventions.[71] The CGPA points out: "These concepts are intended to hold patentees to account for statements made in patents – in language of the inventors' own choosing – regarding what the inventors chose to say their inventions will do."[72] The question of "promised utility" is particularly salient in the context of follow-on patents, such as selection patents or patents for new uses of existing compounds,[73] in which cases the asserted utility is the "gravamen of the invention."[74] As the CGPA observes, "[i]n the case of selection patents and secondary use patents … disclosure of the special advantage or new use *must be made*, otherwise the prior patent or other disclosure will in both cases anticipate the follow-on patent or

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than *in vivo*, support for the patent: *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153, paras. 72, 73, 93, **R-004,** and that the Board in T 0609/2 concluded that, "sufficiency of disclosure must be satisfied at the effective date of the patent, ie on the basis of the information in the patent application together with the common general knowledge then available to the skilled person. … The General principle that the extent of monopoly conferred by a patent should correspond to, and be justified by, the technical contribution to the art, has to be kept in mind": Board Decision T 0609/02, para. 8, **R-493**. Similarly, Canada grants patents to applicants only if "they have actually made an invention having the utility described in the patent as at the filing date … If patentees could retroactively validate speculative guesses of utility, then there would be nothing to distinguish a 'sound prediction' at the filing date from a mere idea that floated through the brain": Resp. CM, para. 114. As the CGPA points out: "Permitting reliance on post-filing evidence would stifle innovation as would-be patentees scrambled to file patent applications for any nascent idea, without regard to whether the would-be patentees had a realistic expectation that what was being claimed would work for the intended purpose": CGPA Amicus Brief, para. 63. Accordingly, the "Canadian law of utility has always required the patentee to have shown utility as at the time of filing": CGPA Amicus Brief, para. 62.

[70] IP Professors' Amicus Brief, p. 2.

[71] Dimock Report, para. 16. Indeed, the IP Professors ignore that the Supreme Court of Canada held that utility does not mean commercial acceptance: *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153, para. 54, **R-004** ("There may in such cases be some doubt about the commercial success of the invention, but utility in this context means useful for the purpose claimed, not commercial acceptance.") The Professors' ignorance of a key holding in one of the cases most directly at issue in this arbitration casts serious doubt on their understanding of Canadian law.

[72] CGPA Amicus Brief, para. 53.

[73] Resp. Rejoinder, para. 237.

[74] CGPA Amicus Brief, para. 43.

render it obvious."[75] These considerations are conspicuously absent from the IP Professors' submission.

22. Second, like Claimant, the IP Professors introduce rules of disclosure and other evidentiary standards in an attempt to demonstrate that Canada's utility requirement contravenes NAFTA Chapter Seventeen.[76] They ignore the fact that neither disclosure nor evidentiary rules are addressed in Chapter Seventeen. Instead, the NAFTA Parties all recognized the flexibility given to each system to implement the broad standards articulated in the Chapter, as well as more broadly in TRIPS.[77] The IP Professors themselves acknowledge this flexibility, admitting that: "NAFTA and other international patent agreements largely state their obligations broadly, leaving signatories latitude to establish and administer their patent laws."[78] Moreover, the connection drawn by the IP Professors between disclosure and utility rules[79] supports Canada's view – shared by WIPO and other *amici* in this case – that the "patentability requirements work together as checks and balances to ensure that the patent bargain is upheld."[80] The Tribunal

[75] CGPA Amicus Brief, para. 48 [Emphasis added]; *see also* Sufficient Description, pp. 25, 52, 56, 71, 92, 128, **R-476**.

[76] *See, e.g.*, IP Professors' Amicus Brief, pp. 1, 12. In any event, Canada has explained that there has been no change in its sound prediction and post-filing evidence rules, and that these are neither arbitrary nor discriminatory: Resp. CM, paras. 86, 125; Resp. Rejoinder, para. 147.

[77] *See, e.g.*, Resp. CM, paras. 185-188; US 1128 Submission, para. 40 ("Article 1709(1) provides each NAFTA Party with the flexibility to determine the appropriate method of implementing the requirements of Chapter Seventeen, including the utility requirement in Article 170991),within its own legal system and practice.") *See also* CIPPIC/CIPP Amicus Brief, paras. 22-30; Liddell-Waibel paper, pp. 7-11, **R-474** (discussing the flexibility retained by States, even after TRIPS, "to interpret and implement the TRIPS standards in different ways to advance their own technological and development needs.")

[78] IP Professors' Amicus Brief, p. 2.

[79] The IP Professors draw this connection generally at the outset of their submission, p. 1, and with respect to the European, pp. 4-6, and Japanese, p. 7, approaches (p. 7: "The Japanese approach to the relationship between the disclosure and utility is also similar to European practice, rejecting inventions that are not plausibly supported by the disclosure."). Notably, the IP Professors overlook the similar relationship that exists between the enablement, written description and utility rules in the United States: see para. 28 below.

[80] *See, e.g.*, Resp. Rejoinder, paras. 20-21; Dimock Second Report, para. 18; WIPO, "The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws, April 2001, p. 1, **R-407** (concluding that "the industrial applicability/utility requirement is closely linked, or sometimes overlaps, with other substantive patentability requirements, such as the sufficient disclosure (enablement) requirement, inventive step, exclusions from patentable subject matter and the definition of 'invention.' Therefore, for the purposes of full harmonization of substantive patent law, the industrial applicability/utility requirement cannot be considered separately from other substantive requirements of patentability."); CGPA Amicus Brief, para. 22 ("In order to draw ingenious, useful and unobvious

should be mindful of the "fine balance that Canadian courts have established in patent law."[81]

23. Third, the IP Professors incorrectly assert that there is, and has consistently been, harmonization of the utility standard across international jurisdictions. They write:

> All evidence suggests that the international standards for utility or industrial application were broadly similar when NAFTA was concluded in 1994, and have since continued towards increased harmonization such that the major economies and centers for innovation now follow essentially and substantively the same standard.[82]

24. The IP Professors make no attempt to analyze the NAFTA Parties' practices or intentions at the time of signing of NAFTA. Tellingly, there is not one mention of Mexico in their submission. Moreover, they assert that there is a "clear trend outside Canada … to converge toward liberal standards of utility,"[83] and that "the drive toward harmonization remains unabated."[84] Not only do they cite to very few sources to support these assertions,[85] but the WIPO publications they rely on support the opposite proposition.[86] For example, the 2001 informal paper prepared by WIPO's International Bureau concludes that "there is a wide range of differences among [Standing Committee on the Law of Patents] members concerning the interpretation and practice relating to the 'industrial applicability/utility' requirement."[87] The report prepared for WIPO's

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disclosures into the public domain, for the benefit of society at large, a patentee is given a monopoly for the limited period of 20 years. That is the patent bargain and it is balanced."); CIPPIC/CIPP Amicus Brief, paras. 34, 38-40 (recognizing that "each country's unique patent laws interact synergistically to address similar problems and reach similar outcomes."). *See also* Sufficient Description, pp. 118, 124, **R-476**.

[81] CGPA Amicus Brief, para. 16.

[82] IP Professors' Amicus Brief, p. 18.

[83] IP Professors' Amicus Brief, p. 11.

[84] IP Professors' Amicus Brief, pp. 10-11.

[85] Two of the sources they do rely on to support their assertion that "the drive toward harmonization remains unabated" are bilateral agreements concluded by the United States with Australia (came into force in 2005) and Korea (came into force in 2012). Neither of these agreements supports the allegation that there was broad-based harmonization between the NAFTA Parties at the time the NAFTA was signed or afterwards.

[86] *See* IP Professors' Amicus Brief, fns. 4, 8.

[87] WIPO, "The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws, April 2001, p. 1, **R-407**. The Informal Paper goes on to conclude that "the industrial

Standing Committee on the Law of Patents in 2003 similarly notes that, even between countries adopting the "industrial applicability" standard, "national and regional laws and practices …vary significantly."[88] The same held true of jurisdictions which require utility instead of industrial applicability.[89] If this was the case in 2003, there is no reason to believe that harmonization existed a decade earlier. Even further support for the absence of harmonization is the failed attempt – after NAFTA and TRIPS – to create "uniform standards of patentability through the World Intellectual Property Organization."[90] As Canada set out in its Counter-Memorial, "negotiations towards a Substantive Patent Law Treaty were abandoned by 2006," in part because utility and industrial applicability had not been an "easy target for negotiators."[91]

25. Moreover, the IP Professors cite the UK as an example of a jurisdiction that "once imposed a utility standard that was more stringent than major economies,"[92] but has now "recognized that its approach to industrial applicability was out of step with its international obligations."[93] The IP Professors focus on a single case of the UK Supreme Court, *Human Genome Sciences Inc. v. Eli Lilly and Company* ("*Human Genome*"),[94] imparting to it certainty and broad-based application, without attempting to ascertain the factual particularities of the case.[95] Contrary to the IP Professors' view, Claimant's

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applicability/utility requirement is closely linked, or sometimes overlaps, with other substantive patentability requirements, such as the sufficient disclosure (enablement) requirement, inventive step, exclusions from patentable subject matter and the definition of 'invention.' Therefore, for the purposes of full harmonization of substantive patent law, the industrial applicability/utility requirement cannot be considered separately from other substantive requirements of patentability."

[88] WIPO Standing Committee on the Law of Patents, "'Industrial Applicability' and 'utility' requirements: Commonalities and Differences'", para. 25, **R-230.**

[89] WIPO Standing Committee on the Law of Patents, "'Industrial Applicability' and 'utility' requirements: Commonalities and Differences'", para. 49, **R-230**.

[90] US Academics' Amicus Brief, p. 2. *See also* Resp. CM, paras. 189-199. Canada comments on other issues raised by the US Academics in Part II.

[91] Resp. CM, paras. 194-195; Gervais Report, paras. 46-47.

[92] IP Professors' Amicus Brief, p. 6.

[93] IP Professors' Amicus Brief, p. 6.

[94] *Human Genome Sciences Inc. v Eli Lilly and Company* [2011] UKSC 51, **R-495**

[95] IP Professors' Amicus Brief, pp. 6-7. For example, the UK Supreme Court was applying the principles of the European Patent Convention ("EPC"), the same principles the European Patent Office ("EPO") applied in its decision relating to the same patent: *Human Genome Sciences Inc. v Eli Lilly and Company* [2011] UKSC 51, para. 83, **R-495**. The court recognized that, even in that context: "'National courts may

expert, Professor Siebrasse, has opined that the "test of a 'plausible' use [in *Human Genome*] was not of general application, but was directed specifically to '[w]here a patent discloses a new protein and its encoding gene',"[96] further underlining the highly fact-specific nature of patent law. The IP Professors also ignore that the UK Supreme Court recognized that, while it may be a "laudable aim to seek to ensure that all aspects of the law of patents are identical throughout the world," the achievement of such an aim is "plainly not currently practicable."[97] The Court went on to state that there are "significant and fairly fundamental differences … between US patent law and the [European Patent Convention],"[98] and concluded:

> Accordingly, particularly when it comes to a nice question such as the precise delineation of boundaries between patentability and unpatentability on the ground of industrial application, it would be unsurprising if the law was not identical under the two jurisdictions.[99]

26. In addition, the IP Professors gloss over the fact that the *Human Genome* decision in the UK was rendered in 2011, which similarly undermines their argument that "all evidence suggests the international standards for utility or industrial application were broadly similar when NAFTA was concluded in 1994."[100] Even if the decision were to represent the UK's "embrace" of Europe's "more liberal standard" as the IP Professors assert, it would certainly evidence the absence of harmonization prior to 2011. The decision demonstrates that the concept of utility is still unsettled across the

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reach different conclusions as to the evaluation of the evidence in the light of the relevant principles' even though 'the principles themselves should be the same, stemming as they do from the EPC.' Thus, the EPO (or another national court) and a national court may come to different conclusions because they have different evidence or arguments, or because they assess the same competing arguments and factual or expert evidence differently, or, particularly in a borderline case, because they form different judgments on the same view of the expert and factual evidence": para. 85. The IP Professors also overlook the fact that the decision did not pertain to a new use or selection patent, like the cases at issue in this arbitration. Instead, it was a patent for the encoding nucleotide, amino acid sequence and certain antibodies of a novel human protein: *Human Genome Sciences Inc. v Eli Lilly and Company* [2011] UKSC 51, para. 3, **R-495**.

[96] Sufficient Description, p. 43, **R-476**. *See also* Sufficient Description, pp. 40, 47, 50, **R-476**; Norman Siebrasse (2011) "HGS v. Lilly: How Soon Is Too Soon to Patent" 24(1) Intellectual Property Journal 41, **R-496**.

[97] *Human Genome Sciences Inc. v Eli Lilly and Company* [2011] UKSC 51, para. 40 **R-495**

[98] *Human Genome Sciences Inc. v Eli Lilly and Company* [2011] UKSC 51, para. 40 **R-495.**

[99] *Human Genome Sciences Inc. v Eli Lilly and Company* [2011] UKSC 51, para. 41 **R-495.**

[100] IP Professors' Amicus Brief, p. 18.

world, and is not as "well-understood" as the IP Professors, and other *amicus* organizations, such as the NAM, might allege.[101] It also shows that, given the unsettled nature of these questions in many domestic jurisdictions, the Tribunal should refrain from interfering with the "incremental" and "well-reasoned" development of patent law.[102]

27. Fourth, the IP Professors overlook several important aspects of US patent law. For example, while their account of the utility requirement as a low threshold is accurate, the IP Professors disregard the reality that "different technologies will encounter the same utility requirement in different ways."[103] In fact, experts retained by both Claimant and Canada agree that "the nature of an invention can make it more difficult to establish utility and that this is the case with chemical and pharmaceutical inventions."[104] In addition, the IP Professors inaccurately assert that US patent applications need merely disclose a use in order to be valid under the utility requirement.[105] As Professor Holbrook has explained, this assertion is inconsistent with US case law, and further undermined by the requirement that an invention be reduced to practice by the time it applies for patent protection.[106] Particularly in the context of treatments directed to humans, US law requires "actual proof of utility and more than a mere unsupported recitation of an expectant utility."[107]

[101] *See* discussion in Part VII.

[102] *See* Liddell-Waibel paper, January 2016, p. 13, **R-474**.

[103] Holbrook Second Report, fn 9, paras. 11-12.

[104] Holbrook Second Report, para. 12; Merges Second Report, paras. 12-13.

[105] IP Professors' Amicus Brief, p. 9.

[106] Holbrook Second Report, paras. 13-20. The IP Professors also note with respect to *In re Fisher* that "some have argued that this is an allegedly heightened utility requirement": p. 8. As Professor Holbrook noted, Claimant's expert Mr. Kunin is among that group, characterizing the US Patent and Trademark Office's 2001 Guidelines as incorporating "a more stringent test for utility than [the USPTO's] earlier set of guidelines. …": Holbrook Second Report, para. 65; Stephen J. Kunin, *Written Description Guidelines and Utility Guidelines*, 82 J. Pat. & Trademark Off. Soc'y 77, 100 (2000), **R-119**.

[107] Holbrook Second Report, para. 24.

28. The IP Professors also completely ignore the enablement and written description requirements of US law, evidencing their flawed methodological approach to both patent law and comparative legal analysis.[108] Like Claimant, the IP Professors' myopic focus on the utility requirement "miss[es] the forest for the trees," particularly given that "the three doctrines (utility, enablement and written description) are closely related and often rise or fall together."[109] Moreover, a proper comparative analysis requires "comparison of rules that possess similar functions," rather than similar labels or precise rules.[110] Rules have similar functions "if they address the same underlying problem, even if they do so differently or under different names."[111] In the context of the US, the enablement and written description rules fulfill similar functions to Canada's utility requirement.[112] An appropriate comparison of the two legal systems thus demonstrates that the Canadian and American approaches "are not particularly divergent."[113]

29. Finally, the IP Professors argue that Canada's promise utility doctrine is inconsistent with the function and goals of the patent system because it results in "significant delay" in filing applications and conflates "two distinct, very different roles of government agencies" – the patent office and the health regulator.[114] The IP

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[108] *See* generally, Holbrook Second Report, paras. 6-8; Holbrook Second Report, para. 5; CIPPIC/CIPP Amicus Brief, paras. 32-42. Where the IP Professors ignore the proper comparative approach to discuss the Canadian and American approaches, they acknowledge the appropriateness of such an analysis in their discussion of Japan. Specifically, they recognize that "Japanese patent law … reaches results similar to Europe and the USA. It does so by different means, however, as the law requires industrial applicability but does not provide a statutory definition": IP Professors' Amicus Brief, pp. 7-8. The IP Professors' acknowledgment equally undermines their arguments with respect to harmonization.

[109] Holbrook Second Report, para. 25.

[110] CIPPIC/CIPP Amicus Brief, para. 33; see also Norman Siebrasse "Form and Function in the Law of Utility: A Reply to Gold & Shortt" Canadian Intellectual Property Review (forthcoming), at p. 2 (accepting that "a functional approach is useful to any comparative or policy analysis") **R-497**; Sufficient Description, p. 1, **R-476**.

[111] CIPPIC/CIPP Amicus Brief, para. 33.

[112] Holbrook Second Report, paras. 6-8. There are many other examples of different States using different tools to achieve the objectives of their patent systems: *see*, *e.g.*, Norman Siebrasse, (2012) "2011 in Review: Patent Law" 24 Intellectual Property Journal 119, at p. 124 (noting differences between Canadian and US approaches to the duty of candour) **R-498**; Sufficient Description, pp. 22, 90, 140, **R-476**.

[113] Holbrook Second Report, para. 5. *See also* Holbrook Report, paras. 6-8.

[114] IP Professors' Amicus Brief, pp. 13-15. The NAM makes a similar argument: NAM Amicus Brief, paras 24, 26. Canada addresses other issues raised by the NAM in Part VII.

Professors misstate Canadian law,[115] and ignore that, in order to qualify for patent protection, an applicant must have made an invention. If the applicant cannot demonstrate or soundly predict the utility of the subject-matter it seeks to patent, it cannot properly be said to have made an "invention".[116] This has always been the case in Canada.[117] In addition, the IP Professors overlook the fact that patent applications for drugs are "routinely filed on the basis of pre-clinical *in vitro* and *in vivo* animal studies,"[118] in which case they have not been "push[ed]…further down the path of commercialization."[119] In these cases, any claimed therapeutic efficiency in humans is necessarily based on the permissive doctrine of sound prediction. This demonstrates that, contrary to the IP Professors' argument, patent applicants need not have fully developed pharmaceutical products before qualifying for patent protection.[120]

30. Importantly, the IP Professors' arguments also downplay the "delicate balance that underpins the patent bargain."[121] On the one hand, the doctrine of sound prediction in Canadian law relieves potential patentees "from having to wait for the conclusion of

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[115] Canadian courts have long been clear that utility, on the one hand, and safety and effectiveness, on the other, are separate inquiries: *see Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153, para. 77, **R-004** ("The prerequisites of proof for a manufacturer who wishes to market a new drug are directed to a different purpose than patent law. The former deals with safety and effectiveness. The latter looks at utility, but in the context of inventiveness. The doctrine of sound prediction, in its nature, presupposes that further work remains to be done."); *Astrazeneca Canada Inc. v. Mylan Pharm. ULC*, 2011 FC 1023, para. 163, **C-237** ("The standard required to demonstrate utility is not equivalent to the regulatory standard required by the Minister to establish the safety and effectiveness of drugs.").

[116] Dimock Report, paras. 92-100; Dimock Second Report, paras. 87-88.

[117] Dimock Report, paras. 92-93; Dimock Second Report, para. 88.

[118] CGPA Amicus Brief, para. 69. For example, the patent at issue in *GlaxoSmithKline Inc. v. Pharmascience Inc*., 2011 FC 239, **C-249** was filed on the basis of a single initial mouse test. The patent was upheld on utility, with the Court finding the mouse study to be the "primary screen which formed the basis upon which a skilled person could conclude that the compound could progress to further testing": paras. 115-117. The patentee in that case had only promised that the compound over which it sought patent protection had a potential for use in the treatment of certain diseases: see para. 98. This case exemplifies the fact that patentees hold the pen in their applications, and that the decisions they make with respect to the contours of their inventions, how much or how little they promise, or how early or how late they choose to file, will impact all patentability requirements. Patentees must live with these decisions. *See also* Resp. Rejoinder, paras. 38-40; *Feherguard Products Ltd. V. Rocky's of B.C. Leisure Ltd.*, [1995] F.C.J. No. 620, para. 17, **R-488** (in considering the conflicting language used in two different claims of the patent in question, the court found that "[t]he inventor could not have his cake and eat it.").

[119] IP Professors' Amicus Brief, p. 13.

[120] *See also* Sufficient Description, p. 13, **R-476**.

[121] CGPA Amicus Brief, para. 64.

years-long clinical trials or experiment before having a basis to strike a bargain with the Canadian public … and enjoy the resulting monopoly."[122] On the other hand, the patent system is "not designed to grant monopolies on the basis of hunches, guesses or hopes."[123] The disclosure of a factual basis and line of reasoning for the prediction is the "hard coinage" the patentee pays in exchange for its monopoly. As the US Academics point out, sound prediction "aims to balance the public interest in early disclosure of new and useful inventions even before the utility has been fully verified by tests."[124] The IP Professors miss this key point.

VII. NATIONAL ASSOCIATION OF MANUFACTURERS ("NAM")

31. In its amicus submission, the NAM makes legal arguments with respect to the applicable standards under NAFTA Articles 1105 and 1110, and alleges that the promise utility doctrine "departs from established international norms" and is inconsistent with NAFTA Chapter Seventeen. At the outset, Canada remarks that the NAM is the mouthpiece for "more than 14,000 manufacturing companies, small and large, across every industry."[125] Like the CCC, it represents the interests of a specific segment of the population with specific interests in this arbitration – patent protection.[126] As noted above, this is but one goal of the Canadian patent framework. While organizations like the NAM, the CCC and Claimant need not concern themselves with the other purposes, Canadian legislatures and courts must balance the interests of these organizations against competing interests. That the results of this balancing exercise may not line up exactly with these organizations' desires does not mean a NAFTA breach has occurred.

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[122] CGPA Amicus Brief, para. 50.

[123] US Academics' Amicus Brief, p. 5; *see also* Norman Siebrasse, "The Rule Against Abstract Claims: History and Principles" (2011) 26 CIPR 220, at p. 217 "If a patent is given too far upstream in the innovation process, the practical benefit may never be realized.") **R-499**; Sufficient Description, p. 18, **R-476**; Norman Siebrasse, IPKat Blog Post Excerpts, p. 1, **R-500**.

[124] US Academics' Amicus Brief, p. 3.

[125] Application for Leave to File *Amicus Curiae* Submission by the National Association of Manufacturers, February 12, 2016, para. 1.

[126] NAM Amicus Brief, paras. 5-6. The NAM states that its "policy positions, approved by the NAM Board of Directors, identify international intellectual property protection as a top issue" (para. 4). As Canada pointed out in its comments on the *amicus curiae* applications, Mr. Enrique Conterno, one of Claimant's Senior Vice Presidents, sits on the NAM Board: Canada's Comments on *Amicus Curiae* Requests, February 19, 2016, p. 11.

32. Moreover, the NAM's submission on the applicable legal standards under NAFTA Articles 1105, 1110 and Chapter Seventeen should be disregarded. It is not the role of an amicus, such as an industry association, to interpret the obligations in NAFTA Chapter Eleven. There is no evidence that the NAM has any "particular knowledge or insight" with respect to NAFTA or to public international in general that could possibly assist the Tribunal. In any event, none of the NAM's interpretations can be supported.

33. First, the NAM argues for a standard of treatment in NAFTA Article 1105 that measures actions against whether they "violate a sense of fairness, equity and reasonableness."[127] Under this standard, it argues: "Canada's implementing its promise utility doctrine and departing from international patent protection practices" constitutes a cognizable claim.[128] Tellingly, the NAM never once mentions the customary international law rules applicable to domestic judiciaries. Nor could it, for under the NAM's view, court decisions should be subject to supranational appellate review on a reasonableness standard. International investment tribunals have consistently held that this is not their role under Article 1105.[129] The only rule that applies to court decisions under Article 1105 is denial of justice.[130] All three NAFTA Parties agree on this point.[131]

[127] NAM Amicus Brief, para. 33.

[128] NAM Amicus Brief, para. 33.

[129] *See, e.g., Mondev Award,* para. 126, **RL-004**; *Azinian Award,* para. 99, **RL-002**; *Loewen Award,* para. 51 (**RL-013**); *Arif Award,* paras. 398, 416, 440-441, **RL-063**; *Mesa Award*, para. 579, **RL-159**.

[130] Resp. CM, paras. 231-245; Resp. Rejoinder, paras. 245-247.

[131] *See, e.g.,* Resp. CM, para. 231; US 1128 Submission, para. 23 ("[A]n investor's claim challenging judicial measures under Article 1105(1) is limited to a claim for denial of justice under the customary international law minimum standard of treatment."); Mexico 1128 Submission, para. 14 ("…with respect to judicial acts, denial of justice is the only rule of customary international law clearly identified and established so far as part of the minimum standard of treatment of aliens."). Canada sets out other agreements between the all NAFTA Parties that directly contradict the NAM's views on NAFTA Article 1105 in its response to the Article 1128 Submissions by Mexico and the United States: Canada's Response to 1128 Submissions of Mexico and United States, Part V.

34. Second, the NAM's argument that judicial acts should constitute expropriations cognizable under NAFTA Article 1110 is unsupported,[132] and appears to be driven by its views that intellectual property rights (including patents) are worthy of protection from expropriation because they are "high valuable property and investments."[133] While Canada does not dispute the potential value of intellectual property rights, the question of whether judicial acts can constitute expropriations under Article 1110 at all is a question of international law wholly distinct from policy questions pertaining to the value of intellectual property rights. All three NAFTA Parties agree that, where there is an independent and neutral judicial ruling on the existence of property rights under domestic law, there can be no expropriation.[134]

35. Third, the NAM argues that Canada's promise utility doctrine is inconsistent with NAFTA Chapter Seventeen because it "retrospectively test[s] whether subjective 'promises' made in the patent disclosure have been met."[135] This, it argues, is contrary to what it coins the "objective threshold test" contained in Article 1709(1), which requires that "inventions having *some* utility be protected."[136] The NAM argues that utility is a "well-understood concept in patent law,"[137] and is "widely understood to be a threshold

[132] In fact, the one case the NAM does cite – *Azinian v. Mexico* – does not support its view. As Canada explained in its Counter-Memorial: "The tribunal dismissed the suggestion that the judgments of the Mexican courts could be called into question under NAFTA Chapter Eleven without a flagrant misapplication of the law, affirming that a claimant cannot 'seek international review of the national court decisions as though the international jurisdiction seized has plenary appellate jurisdiction' and found that there was no evidence that the Mexican courts had engaged in a 'pretense of form to achieve an internationally unlawful end'.": Resp. CM, para. 239; *Azinian Award*, para. 99, **RL-002**.

[133] NAM Amicus Brief, para. 5.

[134] Resp. Rejoinder, para. 120 ("Only where judicial proceedings are so flawed that they constitute a denial of justice can a domestic court's determination of whether an asserted right exists at domestic law constitute an expropriation"); US 1128 Submission, para. 29 ("Separately, decisions of domestic courts acting in the role of neutral and independent arbiters of the legal rights of litigants do not give rise to claim for expropriation under Article 1110(1)."); Mexico 1128 Submission, para. 19, ("When legal rights are declared a nullity, or void *ab initio*, by a court of competent jurisdiction, there cannot be a claim of expropriation.")

[135] NAM Amicus Brief, para. 22. While arguing that the actions of Canada's courts are inconsistent with NAFTA Chapter 17, the NAM states expressly that it should not be construed as arguing that "Canada's actions violate … other patent-related treaties, such as TRIPS": fn 7.

[136] NAM Amicus Brief, paras. 19, 21.

[137] NAM Amicus Brief, paras. 20-21. Canada also addressed this issue raised by the NAM in para. 26.

rather than comparative requirement."[138] The NAM's arguments on these points should be rejected.

36. As an initial matter, the sources supporting the NAM's assertions are scarce, and the few sources on which it does rely come exclusively from the U.S. domestic law context.[139] This is hardly helpful in determining the meaning that three sovereign nations (and many more in the context of TRIPS) gave to the words of Article 1709(1). In addition, the NAM's submission overlooks the absence of a definition of "utility" in Chapter Seventeen. As the United States points out in its Article 1128 submission, NAFTA "does not prescribe any particular definition of the terms, 'capable of industrial application,' or 'useful,' but the text notes that these two terms may be deemed to be synonymous."[140] Instead, the Parties' choice "reflect[ed] continuing differences of substantive law,"[141] and demonstrates the flexibility inherent in Article 1709(1).[142] As the CIPPIC/CIPP submission points out: "To read NAFTA as establishing a singular, common, baseline or standard of utility when it recognizes two different standards is irrational."[143]

37. Finally, the NAM misstates the Canadian standard and ignores the role utility plays in the context of secondary patents, where the assertion of new or unexpected advantages or uses forms the basis for the patent grant. In such cases, the "comparative" aspect of the invention with respect to the existing patented invention is the *quid pro quo* that "society obtains … before granting a monopoly to [the] inventor."[144] Canada has

[138] NAM Amicus Brief, para. 21.

[139] *See, e.g.*, NAM Amicus Brief, fns 14 and 15, citing to *Chisum on Patents* and two cases from the Third and Fourth Federal Circuits.

[140] US 1128 Submission, para. 40.

[141] Resp. CM, para. 188.

[142] *See, e.g.*, Resp. CM, paras. 185-188; US Academics' Amicus Brief, p. 2;

[143] CIPPIC/CIPP Amicus Brief, para. 22.

[144] NAM Amicus Brief, para. 21.

addressed these issues extensively in its written submissions, [145] and briefly in Parts II and VI above.

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Respectfully submitted

[signed]

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[145] For a discussion of the utility standard under Canadian law, and the necessity of considering it as part of the entire patent system and the bargain it seeks to maintain, see Resp. CM, paras. 88-107; Resp. Rejoinder, paras. 19-27. For a discussion of the particularities of secondary patents, see, e.g., Resp. CM, paras. 97-98; Resp. Rejoinder, paras. 28-36, 39-40.