

Under the Arbitration Rules of the
United Nations Commission on International Trade Law and
the North American Free Trade Agreement
(Case No. UNCT/14/2)

ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

**CLAIMANT'S COMMENTS ON NAFTA ARTICLE 1128 SUBMISSIONS
AND NON-DISPUTING PARTY (AMICUS) SUBMISSIONS**

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22 April 2016

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1. Claimant Eli Lilly and Company (“Lilly”) submits these comments on the non-disputing NAFTA Party submissions of the Governments of the United States of America and the United Mexican States (Part I), and on the non-disputing party submissions of the six groups of *amici* admitted in the Tribunal’s Fourth Procedural Order (Part II).

I. COMMENTS ON NON-DISPUTING NAFTA PARTY SUBMISSIONS UNDER ARTICLE 1128

A. The Role and Nature of Article 1128 Submissions

2. Canada’s memorials in this arbitration have portrayed Article 1128 submissions as constituting “subsequent agreement . . . and/or subsequent practice” under Article 31(3) of the Vienna Convention.¹ Accordingly, Canada maintains, such submissions should be entitled to special weight in the Tribunal’s evaluation of questions of treaty interpretation. At the outset, therefore, it bears clarification that NAFTA tribunals have repeatedly declined to accord such status to NAFTA Party pleadings of any sort, including Article 1128 submissions.²

3. NAFTA Article 2001 establishes the NAFTA Free Trade Commission, comprised of senior representatives of all three NAFTA Parties, as the sole authority entrusted with the power to issue interpretations of NAFTA and “oversee [the] further elaboration” of the Treaty. In contrast, NAFTA does not afford any authoritative status to Article 1128 submissions.

4. Unlike joint statements of the Free Trade Commission, Article 1128 submissions reflect the litigation positions of the NAFTA Parties, not their considered, joint view on the scope of NAFTA.³ In particular, it has long been recognized that

¹ *See, e.g.*, Resp. Rejoinder at ¶ 75 (internal quotation marks omitted).

² Kendra Magraw, *Investor-State Disputes and the Rise of Recourse to State Party Pleadings As Subsequent Agreements or Subsequent Practice under the Vienna Convention on the Law of Treaties*, 1 ICSID REV. 142, 165-166 (2015) (explaining that NAFTA tribunals have regularly declined to make such a finding) (CL-180).

³ *See* Céline Lévesque, “Inconsistency Inherent in International Investment Awards and the Role of State Interpretations: The Example of the Mexican Sweetener Trio of Cases under NAFTA,” in *YEARBOOK ON* (continued...)

Article 1128 submissions often reflect defensive concerns and “are unlikely to endorse interpretations and theories of recovery that enlarge . . . exposure to claims.”⁴ Rather, a NAFTA Party’s Article 1128 submission will often rely on the briefs submitted by the same party in previous arbitrations when it was the respondent.⁵ Once a NAFTA Party makes an Article 1128 submission, moreover, it often relies on that submission as support in later proceedings when the NAFTA Party is again the respondent.⁶ In other words, Article 1128 submissions are inextricably linked to NAFTA Parties’ litigation positions when they act as respondents.

5. Investment tribunals and other authorities have repeatedly made clear that such “argument[s] made by a party in the context of an arbitration” are entitled to no special deference, whether under Article 31(3) of the Vienna Convention or

INTERNATIONAL INVESTMENT LAW & POLICY 2013-2014, at 371 (Oxford 2015) (“[I]t appears easier to make Article 1128 submissions parallel to another party’s submissions, than for the three NAFTA Parties to agree on an FTC interpretation. Indeed, there have been over 60 Article 1128 submissions as compared to one FTC interpretation on substance since 1994 (the submissions of course do not all reflect separate or different agreements on interpretation, but the scale is revealing). FTC interpretations rise to the highest levels of government in the three NAFTA Parties, while submissions made in the course of arbitrations do not. One is closer to the political realm than the other. The point is not so much about the authority of parties’ counsel to make submissions but rather goes to the permanence and consistency of the interpretations they contain.”) (CL-181).

⁴ Clyde C. Pearce & Jack Coe, Jr., “Arbitration Under NAFTA Chapter Eleven: Some Pragmatic Reflections upon the First Case Filed Against Mexico,” 23 HASTINGS INT’L & COMP. L. REV. 311, 338 (2000) (CL-182); see Todd Weiler, “NAFTA Investment Law in 2001: As the Legal Order Starts to Settle, the Bureaucrats Strike Back,” 36 INT’L LAWYER 345, 348 (2002) (“In fact, there is no evidence available that any NAFTA government has ever provided an Article 1128 submission to a sitting tribunal that contained arguments in favor of the position of investors from its own territory. The days when a government would lend its support for a claim made by its investor against another country appear to have passed into history.”) (CL-183).

⁵ For example, the U.S. interpretation of Article 1105 in this arbitration is expressly based on the U.S.’s submissions as respondent in the *Methanex* and *ADF* cases, among others. See U.S. Art. 1128 Submission at ¶ 7 n.7. Further, the U.S. relies interchangeably on NAFTA Party submissions as respondents and as non-disputing parties to evidence what they describe as the agreement of the three NAFTA Parties. See *id.* at ¶ 17 n. 27.

⁶ See, e.g., Resp. Rejoinder at ¶¶ 245, 258 (and accompanying footnotes).

otherwise.⁷ Put differently, like other litigation submissions, Article 1128 submissions are afforded weight solely in proportion to their persuasive merit.

B. Article 1128 Submission of the United States of America

1. The United States Acknowledges that Granted Patents are Protected Investments.

6. The United States submits that “[p]atents properly granted in accordance with domestic law are intellectual property rights that qualify as investments under [NAFTA].”⁸ The United States further explains that, “[p]atents are properly granted in cases in which an invention is adequately disclosed that is new, involve[s] an inventive step (is non-obvious), and is capable of industrial application (is useful).”⁹ As Lilly has shown, this U.S. position – which is consistent with Lilly’s position – is supported by the plain language of NAFTA, common commercial practice, and the domestic law of Canada (which conferred upon Lilly rights that were “legally enforceable immediately upon issuance”).¹⁰

⁷ *Gas Natural SDG S.A. v Argentine Republic*, ICSID Case No. ARB/03/10, Decision of the Tribunal on Preliminary Questions on Jurisdiction (17 June 2005), at ¶ 47 n.12 (“We do not believe, however, that an argument made by a party in the context of an arbitration reflects practice establishing agreement between the parties to a treaty within the meaning of Article 31(3)(b) of the Vienna Convention on the Law of Treaties.”) (CL-184); see *Telefónica S.A. v Argentine Republic*, ICSID Case No. ARB/03/20, Decision of the Tribunal on Objections to Jurisdiction (25 May 2006), ¶¶ 112-113 (“[T]he Tribunal is not convinced that positions on interpretation of a treaty provision, expressed by a Contracting State in its defensive brief filed in an international direct arbitration initiated against it by an investor of the other Contracting State, amounts to ‘practice’ of that State, as this requirement is understood in public international law, nor does it appear relevant in order to ascertain ‘how the treaty has been interpreted in practice’ by the parties thereto.”) (internal quotations omitted) (CL-185); Kendra Magraw, *Investor-State Disputes and the Rise of Recourse to State Party Pleadings As Subsequent Agreements or Subsequent Practice under the Vienna Convention on the Law of Treaties*, 1 ICSID REV. 142, 166 (2015) (Surveying multiple awards, including NAFTA awards, and noting “[i]t is clear from the above jurisprudence that many tribunals are hesitant to determine that [state party pleadings] can constitute a subsequent agreement or subsequent practice under Articles 31(3)(a) and (b) of the VCLT.”) (CL-180).

⁸ U.S. Art. 1128 Submission at ¶ 27.

⁹ *Id.*

¹⁰ Cl. Reply at §§ I.C-D, IV.B.2; Expert Report of Andrew J. Reddon at ¶ 27.

7. Here, Lilly's Zyprexa and Strattera patents were granted following a thorough review by the Canadian Intellectual Property Office, conducted consistently with then-existing Canadian requirements of novelty, non-obviousness and utility.¹¹ The two patents are, accordingly, property rights and investments entitled to the treatment guaranteed by NAFTA Articles 1105 and 1110.¹²

2. The United States' Interpretation of NAFTA's Limitations Period Confirms It Is Not Implicated in this Arbitration.

8. The U.S. submission addresses the interpretation of NAFTA Articles 1116 and 1117. These articles have been briefed by the parties only in the context of Canada's belated jurisdictional objection, which is not properly before the Tribunal.¹³

9. Even if the Tribunal were to reach this issue, the U.S. Government's interpretation of Articles 1116 and 1117 confirms that Canada's objection is without merit. As Lilly has shown, "Canada . . . has identified no support for the counter-intuitive proposition that the treatment of one investment (the raloxifene patent) can start the limitations clock on claims regarding the future expropriation and mistreatment of two legally and factually distinct investments (the Strattera and Zyprexa patents)."¹⁴ Consistent with this position, the United States submits that the "time limitations period in Articles 1116(2) and 1117(2) must . . . relate to the *particular investment* for which the investor seeks a remedy for the breach and loss."¹⁵ Canada's proposed dates for the commencement of the limitations period simply do not relate to

¹¹ Cl. Mem. at ¶¶ 91, 124.

¹² Cl. Reply at ¶¶ 229-238.

¹³ See Cl. Opp. to Resp. Jur. Objection at § I. Because Article 1128 submissions are confined to issues of NAFTA interpretation, neither the United States nor Mexico have addressed the question whether Canada's jurisdictional objection may properly be considered by the Tribunal under the UNCITRAL Rules.

¹⁴ *Id.* at ¶ 35.

¹⁵ U.S. Art. 1128 Submission at ¶ 3 (emphasis added); see Cl. Opp. to Resp. Jur. Objection at ¶ 38 n.55 (noting, in reliance on *Grand River*, *Apotex*, *Bilcon* and *Cargill*, that "in delineating the boundaries of their jurisdiction, tribunals are routinely called upon to distinguish between legally distinct investments and legally distinct host state acts").

“the particular investment[s]” at issue in this arbitration – the Zyprexa and Strattera patents.¹⁶

10. The United States also submits that the limitations period in Articles 1116 and 1117 runs from the date the investor first acquires knowledge of the relevant breach and loss, and that “a continuing course of conduct . . . does not renew the limitations period.”¹⁷ This principle is not implicated in this arbitration. Lilly’s claim arises from the revocation of its Zyprexa and Strattera patents, which occurred within the three-year limitations period established in Articles 1116 and 1117. Lilly’s references to earlier decisions of the Canadian judiciary regarding legally distinct and unrelated patents provide factual context in support of Lilly’s claim.¹⁸ NAFTA tribunals have repeatedly found that the provision of such prior factual context does not trigger the limitations period.¹⁹

3. The United States Propounds an Unduly Narrow Interpretation of Article 1105.

11. In its submissions, Lilly identified three elements of Article 1105’s Fair and Equitable Treatment standard²⁰ breached by Canada’s measures: the protection against arbitrariness, the protection of legitimate expectations, and the protection against discrimination.²¹ While the United States does not dispute that Article 1105 protects against arbitrary governmental action, the U.S. does propound an interpretation of

¹⁶ See Cl. Opp. to Resp. Jur. Objection at ¶¶ 33-35, 38-40.

¹⁷ U.S. Art. 1128 Submission at ¶ 4.

¹⁸ See Cl. Opp. to Resp. Jur. Objection at ¶¶ 41-42, 47 (explaining that Lilly uses promise utility doctrine cases pre-dating the invalidation of Strattera and Zyprexa for a limited purpose: “to explain the development of the promise utility doctrine”).

¹⁹ *Id.* (citing to the awards in *Grand River v. United States*, *Mondev v. United States*, *Feldman v. Mexico*, *UPS v. Canada*, *Glamis Gold v. United States*, *Apotex v. United States* and *Bilcon v. Canada*).

²⁰ The “Fair and Equitable Treatment” standard under Article 1105(1) is linked to the minimum standard of treatment of aliens under customary international law (Minimum Standard of Treatment), and this Minimum Standard of Treatment, in turn, is shaped by the standard of Fair and Equitable Treatment that has been adopted by most international investment treaties in force today. See Cl. Reply at ¶ 326; Cl. Mem. at ¶¶ 253-254.

²¹ See Cl. Reply at § V.B.

Article 1105 that is unduly narrow with regard to legitimate expectations, discrimination, and judicial measures.

12. The United States Does Not Dispute that the Article 1105 Fair and Equitable Treatment Standard Includes a Protection Against Arbitrariness. Lilly has established that Article 1105's Fair and Equitable Treatment standard encompasses a protection against arbitrariness, and that Canada's measures are wrongful on this basis alone. The United States does not dispute that the Fair and Equitable Treatment standard applies in situations involving arbitrary governmental conduct, including conduct that is not justified by a legitimate, rational policy objective.²²

13. The Weight of Authority Rebutts the United States' Contention that Article 1105 Does Not Protect Legitimate Expectations or Guard Against Discrimination. The United States maintains that Article 1105 does not protect legitimate investment-backed expectations except in connection with specific governmental representations, and that it does not protect against discrimination.²³ In these respects, the U.S. submission is inconsistent with the weight of authority reflected in arbitral awards and commentary, which makes clear that Article 1105 requires a level of treatment that has evolved substantially beyond the standard articulated by the United States.

14. The protection of legitimate expectations is fundamental to Article 1105's Fair and Equitable Treatment standard. The recent *Electrabel v. Hungary* award, for example, classifies it as "the most important function" of the standard,²⁴ explaining that:

The Tribunal shares the well-established scholarly opinions (e.g. Dolzer and Schreuer, pp. 133-147); and decisions cited by *Electrabel (Bayindir, paragraph 178 and footnotes therein; Waguih Elie George Siag and Clorinda Vecchi v Egypt, paragraph 150)* that the obligation to provide fair and equitable treatment comprises several elements, including an

²² U.S. Art. 1128 Submission at ¶¶ 335, 344-348.

²³ *Id.* at ¶¶ 13-14.

²⁴ *Electrabel S.A. v. Republic of Hungary*, ICSID Case No. ARB/07/19, Decision on Jurisdiction, Applicable Law and Liability (30 November 2012), at ¶ 7.75 (CL-186).

obligation to act transparently and with due process; and to refrain from taking arbitrary or discriminatory measures or from frustrating the investor's reasonable expectations with respect to the legal framework adversely affecting its investment.²⁵

While the *Electrabel* tribunal's comments related to an autonomous treaty-based Fair and Equitable Treatment standard (as opposed to the customary standard), the tribunal made clear that the two standards provided "similar" protection.²⁶

15. The protection against discrimination – on any ground of "unjustifiable distinction"²⁷ – is also a recognized part of the Fair and Equitable Treatment standard.²⁸ The protection against discrimination is so well recognized, in fact, that it was recently jointly articulated by the claimant and the respondent in *Tenaris v. Venezuela*:

Notwithstanding the issue between the Parties as to whether or not the Treaty standard should be interpreted as an autonomous standard, both referenced the decision in the *Saluka* case as setting out the applicable test – namely: "any differential treatment of a foreign investor must not be based on unreasonable distinctions and demands, and must be justified by showing that it bears a reasonable relationship to rational policies not motivated by a preference for other investments over the foreign-owned investment."²⁹

²⁵ *Id.* at ¶ 7.74 (emphasis added).

²⁶ *Electrabel S.A. v. Republic of Hungary*, ICSID Case No. ARB/07/19, Decision on Jurisdiction, Applicable Law and Liability (30 November 2012), at ¶ 7.157-158 ("Hungary, for its part, submits that the minimum standard under international law constitutes a lower level of protection than the fair and equitable treatment standard under Article 10(1) of the ECT In regard to the development of investment protection in treaty law and customary international law, the Tribunal considers that the content of this standard is, at the present time, similar to the other standards expressly mentioned in Article 10(1) ECT, which also exist as standards of protection in customary international law.") (CL-186); *see also* Cl. Reply at ¶¶ 351-353.

²⁷ *See Saluka Investments BV (The Netherlands) v. The Czech Republic*, PCA/UNCITRAL Partial Award (17 March 2006), at ¶ 309 (CL-85).

²⁸ Cl. Reply at ¶¶ 365-369.

²⁹ *Tenaris S.A. v. Venezuela*, ICSID Case No. ARB/11/26, Award (29 January 2016), at ¶¶ 385-388 (interpreting two treaties, both of which, like Article 1105(1), referred to fair and equitable treatment "in accordance with international law") (CL-187); *see also Lemire v. Ukraine*, ICSID Case No. ARB/06/18, (continued...)

The *Saluka* test, as quoted above, is the test that Claimant has cited as appropriate in this arbitration.³⁰

16. As Lilly has previously explained, the substantial body of decisions establishing that the Fair and Equitable Treatment standard protects investment-backed expectations and protects against discrimination³¹ constitute evidence of *opinio juris* and state practice.³² Together with the commentary discussed in Lilly’s Memorial and Reply, they also reflect the considered view of a range of jurists and commentators.³³ These authorities squarely rebut the overly narrow interpretation put forward by the United States.

17. The United States Does Not Account for Judicial Measures that Violate Substantive Standards Under International Law (Regardless of Their Correctness Under Domestic Law). The United States does not contest that Article 1105 encompasses multiple protections against improper government conduct.³⁴ The United States argues, however, that “judicial measures may form the basis of a claim” under Article 1105 with respect to just one of these protections: the protection against denial of justice.³⁵ The denial of justice standard described by the United States is, like the standard articulated by Canada, focused on procedural propriety — *i.e.*, as the United States puts it, on the “administration of justice.”³⁶ As set out in Lilly’s Reply, however, tribunals and scholars have repeatedly recognized that a national judiciary may contravene not only procedural standards, but also substantive norms of international

Decision on Jurisdiction and Liability (14 January 2010), at ¶¶ 335, 356 (recognizing as improper under the minimum standard political discrimination in favor of a “political ally and supporter of [a previous] President of the Ukraine”) (RL-29).

³⁰ Cl. Reply at ¶ 366.

³¹ *See id.* at § V.B.3.

³² *See id.* at ¶¶ 351-352.

³³ *See id.* at ¶¶ 351-353.

³⁴ *Cf.* U.S. Art. 1128 Submission at ¶ 20 (“Article 1105(1) includes, *for example*, the customary international law obligation not to deny justice”) (emphasis added).

³⁵ *Id.* at ¶ 24.

³⁶ *Id.* at ¶ 21.

law (including substantive norms protected under Article 1105).³⁷ The United States itself recognizes that “‘new’ judge-made law” may “depart[] from previous jurisprudence.”³⁸ But it has proposed no method of addressing “new judge-made law” that is arbitrary, discriminatory, or otherwise contravenes the substantive protections of Article 1105.

18. Meanwhile, the U.S. position that “judicial measures may form the basis of a claim under . . . Article 1105(1) only . . . if it is proved that a denial of justice has occurred”³⁹ lacks authoritative support. In particular, the only source proposed by the United States that directly addresses the question whether Article 1105(1) protects against judicial violations of substantive international norms is an article by Professor Zachary Douglas.⁴⁰ Yet, as Lilly explained in its Reply, Professor Douglas’s article is not supported by a single citation to any award, article or other authority.⁴¹ The sole decision discussed by Professor Douglas in the relevant section of his article is *Frontier Petroleum v. Czech Republic*, which he acknowledges is inconsistent with his position.⁴² While the United States also relies on the award in *Mondev v. United States*,⁴³ Lilly’s Reply shows that the *Mondev* case is inapposite.⁴⁴ *Mondev* did not consider whether a new, judge-made rule of law could violate the substantive protections of Article 1105. This is clear from the *Mondev* award itself, which notes that “it is doubtful whether the SJC [the relevant domestic court] made new law.”⁴⁵

³⁷ Cl. Reply at ¶¶ 325-334.

³⁸ U.S. Art. 1128 Submission at ¶ 21.

³⁹ *Id.* at ¶ 24.

⁴⁰ *See id.* at ¶¶ 23-24 (quoting Zachary Douglas, “International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed,” *INT’L & COMP. L.Q.* 34 (September 2014)).

⁴¹ *See* Cl. Reply at ¶ 327 n. 657.

⁴² *Id.* Professor Douglas was counsel to the respondent in that case.

⁴³ U.S. Art. 1128 Submission at ¶ 21.

⁴⁴ Cl. Reply at ¶ 330.

⁴⁵ *Id.* (quoting *Mondev v. United States*, ICSID Case No. ARB(AF)/99/2, Award (11 October 2002), at ¶ 134).

19. Lastly, the United States argues that investment tribunals “will defer to domestic courts interpreting matters of domestic law unless there is a denial of justice.”⁴⁶ It states that investment tribunals may not act as “appellate courts on matters of the application of substantive domestic law.”⁴⁷ Lilly has not taken issue with these propositions, which are not implicated by this arbitration. As explained in Lilly’s Reply:

[I]t is clear that this Tribunal is *not* being asked to perform anything resembling an appellate function. *Lilly has not alleged that the Federal Court and Federal Court of Appeal misapplied Canadian law as it stood in 2010 and 2011.* Rather, Lilly is alleging – and, indeed, has shown – that the dramatic change in Canada’s domestic laws as reflected in the promise utility doctrine renders them fundamentally at odds with its *international commitments*.⁴⁸

20. In other contexts, the United States has recognized that a state’s judiciary may violate substantive international norms to the same extent as any other branch of government.⁴⁹ The same principle applies here.

⁴⁶ U.S. Art. 1128 Submission at ¶ 22.

⁴⁷ *Id.* at ¶ 24.

⁴⁸ Cl. Reply at ¶ 334 (emphasis added).

⁴⁹ See Request for Consultations by the United States, *China–Measures Affecting The Protection And Enforcement Of Intellectual Property Rights* (“China–IP Rights”), Doc. WT/DS362/1 (16 April 2007) (stating “the measures at issue include . . . measures by the courts and procuratorate that apply throughout China, including” two judicial interpretations of China’s criminal law by the Supreme People’s Court and the Supreme People’s Procuratorate) (CL-196); First Submission of the United States, *China–IP Rights* (30 January 2008), at ¶¶ 23-24 (emphasizing the “binding nature” of the judicial interpretations issued by an “independent legal supervisory system”) (CL-197); Panel Report, *China–IP Rights*, Doc. WT/DS362/R (26 January 2009) (noting the U.S. argument that two “[i]nterpretations by the Supreme People’s Court” of certain provisions of Chinese law violated Article 61 of the TRIPS Agreement concerning criminal enforcement of trademark laws) (R-404). The U.S. decision to challenge judicial measures in *China–IP Rights* was fully consistent with WTO law. See, e.g., Appellate Body Report, *US–Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (12 October 1998), at ¶ 173 (emphasizing that the fact that certain challenged measures were decisions of a U.S. court “does not relieve the United States of the legal consequences of the discriminatory impact of the decisions” and that the “United States, like all other Members of the WTO and of the general community of states, bears responsibility for acts of all its departments of government, including its judiciary”) (CL-199); see also WTO Dispute Settlement System Training Module at § 7.1, https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c7s1p1_e.htm (“Even if a government is unable to remedy a WTO violation because an independent (continued...)”).

4. The U.S. Submission Does Not Account for the International and Domestic Legal Authority Recognizing that *Any* Branch of Government May Effect an Expropriation.

21. The United States contends that judicial measures can only result in expropriations where they also qualify as denials of justice.⁵⁰ The United States has not, however, identified any authorities that support this position, and it has not addressed the authorities that Lilly relies on – including tribunal decisions specifically finding judicial measures to be expropriatory based on violations of substantive norms of international law.⁵¹

22. The United States argues that “domestic law” does not “recognize[] the concept of ‘judicial takings.’”⁵² That, however, is not correct – even as to U.S. law. In a 2010 case, *Stop the Beach Renourishment v. Florida Department of Environmental Protection*,⁵³ a plurality of the U.S. Supreme Court recognized that judicial measures *can* qualify as takings (*i.e.*, expropriations) of property under the Fifth Amendment to the U.S. Constitution. The court added:

There is no textual justification for saying that the existence or the scope of a State’s power to expropriate private property without just compensation varies according to the branch of government effecting the expropriation. Nor does common sense recommend such a principle. It would be absurd to allow a State to do by judicial decree what the Takings Clause forbids it to do by legislative fiat⁵⁴

judicial body committed it, the Member in question is fully responsible for this violation in WTO dispute settlement. It is a general principle of international law that it is not possible to invoke domestic law as justification for the failure to carry out international obligations.”) (C-516).

⁵⁰ U.S. Art. 1128 Submission at ¶¶ 28-29.

⁵¹ See Cl. Reply at ¶¶ 243-253 (citing, *inter alia*, to the *Saipem v. Bangladesh* and *ATA v. Jordan* awards). Given the awards cited in Lilly’s Reply, it is not the case that, as the United States suggests, there is a “dearth of precedents on whether judicial acts may be expropriatory.” U.S. Art. 1128 Submission at ¶ 29.

⁵² U.S. Art. 1128 Submission at ¶ 29.

⁵³ 560 U.S. 702 (2010) (RL-46).

⁵⁴ *Id.* at 714.

Furthermore, while the U.S. Department of Justice has taken the position in domestic litigation that the plurality opinion in *Stop the Beach* should not be followed, its position has been rejected by the Federal appeals court that hears all patent appeals.⁵⁵ The fact that the United States nevertheless adopts the same argument here underscores that Article 1128 submissions reflect current litigation positions rather than an objective view on questions of treaty interpretation under NAFTA.⁵⁶

23. The reasoning of the U.S. Supreme Court in *Stop the Beach* is compelling in the NAFTA context as well: “It would be absurd to allow a State to do by judicial decree what [it may not] do by legislative fiat.”⁵⁷ First, such a distinction would be artificial and unworkable. For example, the line between judicial and executive functions is blurred in the many national systems – including the U.S. system – that provide for administrative adjudication before executive branch agencies. Second, as Lilly’s Reply showed, distinguishing between judicial case law on the one hand, and legislative statutes and executive regulations on the other, may provide common law jurisdictions with an advantage over jurisdictions where judge-made law is less prevalent.⁵⁸ Yet, it is axiomatic that that a State’s sovereign choices with regard to the structure of its internal political system cannot prejudice its position under customary international law.⁵⁹ Confronted with the myriad ways that states organize themselves, international tribunals do not – and should not – prefer some over others. Rather, they must

⁵⁵ See *Smith v. United States*, 709 F.3d 1114, 1116 (Fed. Cir. 2013) (“In [*Stop the Beach*], the [Supreme] Court recognized that a takings claim can be based on the action of a court.”) (C-517). The Federal Circuit noted also that “it was recognized prior to *Stop the Beach* that judicial action could constitute a taking of property The Court in *Stop the Beach* did not create this law, but applied it.” *Id.* at 1116-1117. The Federal Circuit’s view in this regard carries particular weight because, in addition to hearing all patent appeals, it hears all appeals from the United States Court of Federal Claims, the only Federal court with nationwide jurisdiction over takings claims against the Federal government. See 28 U.S.C. § 1295 (C-518).

⁵⁶ See *supra* at § I.A.

⁵⁷ *Stop the Beach Renourishment v. Florida Dept. of Env’tl Protection*, 560 U.S. 702 (2010) (RL-46).

⁵⁸ Cl. Reply at ¶ 332.

⁵⁹ See *id.* at ¶¶ 332-333.

follow the rule that the “conduct of *any* State organ shall be considered an act of that State under international law.”⁶⁰

24. Perhaps recognizing that its proposed rule would create a sweeping immunity for judge-made law, the United States proposes an exception. According to the United States, a judicial measure may effect an expropriation without a denial of justice where the “judiciary is not separate from other organs of the State” and is used as “the conduit of executive or legislative action.”⁶¹ This proposed exception is subjective, and simply compounds the risk that states will be subject to different rules based on their different constitutional frameworks and internal political arrangements.

5. The United States Accepts this Tribunal’s Competence to Rule on Violations of Chapter 17, but Places Artificial Restraints on Its Ability to Do So.

25. The U.S. Submission Places Restraints on this Tribunal’s Authority that Are Not Supported by the FTC Statement on Article 1105(1). The United States contends that “an investor bringing an Article 1105(1) claim may not invoke an alleged host State violation of . . . Chapter 17.”⁶² The United States bases its position on the 31 July 2001 Statement of the NAFTA Free Trade Commission, which provides that, “[a] determination that there has been a breach of another provision of the NAFTA, or of a separate international agreement, does not establish that there has been a breach of

⁶⁰ Int’l Law Comm’n, Draft Articles on the Responsibility of States for Internationally Wrongful Acts (2001), art. 4, cmt. at ¶ 6 (noting also that “the principle of the separation of powers is not followed in any uniform way”) (emphasis added) (CL-188). This result follows from the fact that “a State cannot adduce as against another State its own Constitution with a view to evading obligations incumbent upon it under international law.” *Treatment of Polish Nationals*, Advisory Opinion, 1932 P.C.I.J. Ser. A/B, No. 44, p. 4 (CL-189). As a result, the division of lawmaking functions between the judiciary, the legislature and the executive cannot change the international standards applicable to the laws they create. *See, e.g.*, Int’l Law Comm’n, Draft Articles on the Responsibility of States for Internationally Wrongful Acts (2001), art. 3, comt. at ¶ 9 (“In the French version [of art. 3, which articulates the *Polish Nationals* principle] the expression *droit interne* is preferred to *législation interne* and *loi interne*, because it covers all provisions of the internal legal order, whether written or unwritten and whether they take the form of constitutional or legislative rules, administrative decrees or judicial decisions.”) (CL-188).

⁶¹ U.S. Art. 1128 Submission at ¶ 30.

⁶² *Id.* at ¶ 23.

Article 1105(1).” This Statement does not suggest that an investor “may not invoke,” or raise, another NAFTA chapter in the context of an Article 1105(1) claim, as the United States proposes. Rather, the FTC Statement provides only that a breach of another international obligation does not itself “establish” a violation of Article 1105(1). As Lilly explained in its Memorial, investors and investment tribunals may still “take[] notice of a breach of NAFTA or another international agreement as one factor among others in determining whether the state measure is arbitrary,” discriminatory or violates legitimate investment-backed expectations protected under Article 1105(1).⁶³

26. The United States Recognizes this Tribunal’s Competence to Rule on Violations of Chapter 17, but Places Arbitrary Limits on that Competence that Are Not Supported by Article 1110(7). The United States argues that, in connection with claims of expropriation under Article 1110, investment tribunals may review “alleged inconsistencies or breaches of Chapter Seventeen” after making “a threshold determination . . . that an expropriation otherwise occurred pursuant to Article 1110(1).”⁶⁴ In this way, the U.S. submission acknowledges that investment tribunals have the competence to rule on breaches of Chapter 17. The U.S. argues, however, that tribunals may use this competence only for the benefit of respondent States (as a “safe refuge”).⁶⁵ According to the United States, a tribunal must wear blinders when assessing an investor’s affirmative case, only to remove those blinders if a respondent State decides to invoke Chapter 17 as a defense.⁶⁶ This unbalanced approach lacks any support in NAFTA. As described below, it is equally appropriate for the Tribunal to consider Chapter 17 as part of Lilly’s affirmative case.

27. Lilly submits that a violation of Chapter 17 is relevant to, but not conclusive of, a finding of expropriation under Article 1110. In particular, a Chapter 17 violation may contribute to a finding of indirect expropriation by demonstrating the

⁶³ Cl. Mem. at ¶ 271 & n.499.

⁶⁴ U.S. Art. 1128 Submission at ¶ 36.

⁶⁵ *Id.*

⁶⁶ *Id.*

internationally “unlawful character of the actions” resulting in the expropriation.⁶⁷ Lilly’s position is supported by the proposition, accepted by the United States in other contexts, that the indirect expropriation analysis requires a “case-by-case, fact-based inquiry” that considers the full circumstances surrounding an alleged expropriation.⁶⁸

28. The plainest support for Lilly’s position, however, is the text of Article 1110 itself. Article 1110(7) provides that, “This Article does not apply to . . . the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property).” As explained in Lilly’s submissions, Article 1110(7) indicates that measures *inconsistent* with Chapter Seventeen *may* engage Article 1110.⁶⁹ Accordingly, Article 1110(7) provides one of the grounds through which this Tribunal can recognize Canada’s measures as expropriatory.⁷⁰

29. The United States advocates for a narrower interpretation of Article 1110(7), arguing that it requires investment tribunals to undertake a two-stage analysis. First, the Tribunal must analyze whether an expropriation has taken place without reference to Article 1110(7).⁷¹ Second, if and only if an expropriation is established, “the disputing NAFTA Party may invoke Article 1110(7) as a safe refuge.”⁷²

30. But Article 1110(7) does not refer to a two-step process, it does not describe itself as a “safe refuge,” and it is not cast as a “savings” or “for greater certainty” clause. In fact, there is nothing in the plain language of the article that supports the United States’ contention. Lacking any such support, the United States rests its position on a structural argument:

⁶⁷ See Cl. Mem. at ¶ 181 (quoting *Saipem S.p.A. v. The People’s Republic of Bangladesh*, ICSID Case No. ARB/05/7, Award (30 June 2009), at ¶ 134.). The standards in Chapter 17 may also inform an investor’s expectations, as relevant to both the Article 1105 and Article 1110 standards. See Cl. Reply at ¶¶ 318, 364.

⁶⁸ See United States Model Bilateral Investment Treaty (2012), at Annex B (CL-190).

⁶⁹ Cl. Mem. at ¶¶ 184, 241; Cl. Reply at ¶¶ 254-258.

⁷⁰ Cl. Reply at ¶¶ 316-318.

⁷¹ U.S. Art. 1128 Submission at ¶ 34.

⁷² *Id.*

This interpretation is confirmed by the context and structure of Article 1110, which is entitled “Expropriation and Compensation.” The Article’s first paragraph outlines the nature and scope of the obligation on NAFTA Parties not to expropriate covered investments, except in accordance with the stated conditions. The Article’s second through sixth paragraphs outline the requirements for providing compensation in the event of an expropriation. Paragraph 7 of Article 1110 begins with the phrase “[t]his Article,” clearly referring back to the obligations contained in paragraphs 1-6. Thus, the structure is plain that if a NAFTA Party’s measures did not first implicate “[t]his Article” (i.e., paragraphs 1-6), there would be no reason to examine whether the conduct is excluded from the scope of Article 1110(1) by virtue of Article 1110(7).⁷³

31. This structural argument is, however, incompatible with prior NAFTA decisions. If the placement of Article 1110(7) toward the end of Article 1110 requires a two-step analytical process, and confirms that the article can be used only “as a safe refuge” by NAFTA Parties, then the same must necessarily be true of the eighth and final paragraph of Article 1110, which provides that, “for greater certainty, a non-discriminatory measure of general application shall not be considered a measure tantamount to an expropriation of a debt security or loan covered by this Chapter solely on the ground that the measure imposes costs on the debtor that cause it to default on the debt.” Yet, as Lilly has shown, Article 1110(8) is *not* applied merely as “a safe refuge,” and has been used to interpret Article 1110 to the benefit of the claimant.⁷⁴

32. The United States argues that reading Article 1110(7) as anything other than a safe harbor “would subject the obligations set forth in Chapter Seventeen routinely to challenge by investors.”⁷⁵ But this is not the case. Not every violation of Chapter 17 is actionable under Article 1110. For example:

⁷³ *Id.* at ¶ 35.

⁷⁴ Cl. Reply at ¶¶ 257-258 (noting that, in *Waste Management v. Mexico* at ¶ 144, Article 1110(8) was read to imply that “the [NAFTA] drafters entertained a broad view of what might be ‘tantamount to an expropriation’”).

⁷⁵ U.S. Art. 1128 Submission at ¶ 34.

- As part of the *Canada–Patent Protection of Pharmaceuticals* dispute, a World Trade Organization (WTO) Panel found Canada in violation of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in connection with a so-called “stockpiling exception” that permitted generic pharmaceutical companies to manufacture and stockpile patented goods before patent expiry, for sale after patent expiry.⁷⁶ Even on the assumption that this TRIPS violation is also a NAFTA Chapter 17 violation, it would not trigger liability under Article 1110 as there is no indication that it involves a substantial deprivation of the underlying property right.
- Many violations of NAFTA Articles 1714 through 1717 (enforcement of IP rights) and Article 1718 (border controls regarding IP-infringing goods) would not result in a substantial deprivation that gives rise to an expropriation of intellectual property. By analogy, in the WTO case *China–Intellectual Property Rights*,⁷⁷ the re-sale of trademark infringing goods seized by Chinese authorities was found to violate the border enforcement provisions of the TRIPS Agreement. While that violation diminished the value of the property rights at issue, there is no indication that it involved a substantial deprivation of property rights that could trigger liability for expropriation.
- In another TRIPS Agreement case, *United States–Section 110(5) of the U.S. Copyright Act*,⁷⁸ U.S. rules permitting amplification of music broadcasts by food service and retail establishments without payment of a fee were found to violate treaty-based intellectual property obligations related to copyrights under the Berne Convention, as incorporated into the TRIPS Agreement. That violation, while diminishing the value of the property rights at issue, does not appear to involve a substantial deprivation of property rights that could trigger liability for expropriation.

As these examples illustrate, Lilly’s interpretation of Article 1110(7) would not allow foreign investors to routinely challenge government action under Chapter 17 by initiating proceedings under Chapter 11. Rather, under Lilly’s interpretation of Article 1110(7), an investor must establish a violation of Chapter 17 and also show that the measure at issue resulted in a substantial deprivation of property rights.⁷⁹

⁷⁶ See Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, Doc. WT/DS114/R (17 March 2000) (“*Canada–Pharmaceuticals*”) (CL-79).

⁷⁷ See Panel Report, *China–Measures Affecting The Protection And Enforcement Of Intellectual Property Rights*, Doc. WT/DS362/R (26 January 2009) (R-404).

⁷⁸ See Panel Report, *United States–Section 110(5) of the U.S. Copyright Act*, Doc. WT/DS160/R (15 June 2000) (CL-191).

⁷⁹ See Cl. Reply at ¶ 226.

6. The U.S. Interpretation of Chapter 17 Confirms that Canada Has Breached Its Obligations with Respect to the Treatment of Intellectual Property Investments.

33. The U.S. Position Is Consistent With Lilly’s Submission that NAFTA Imposes a “Mandatory Obligation”⁸⁰ to Make Patents Available for Inventions that Meet the Requirements in Article 1709(1). The United States submits that each NAFTA Party is under an obligation to “make patents available” for inventions that satisfy the criteria in Article 1709(1), including the criterion of utility.⁸¹ The United States explains that, while NAFTA “does not prescribe any particular definition of the terms, ‘capable of industrial application,’ or ‘useful,’” those terms must be interpreted in good faith and “in light of the object and purpose of the treaty.”⁸² As a consequence, while “[t]he Parties retain discretion to change or refine their domestic law, [...] that discretion is not without limits. Were it otherwise, the obligation stated in 1709(1) would be without meaning or effect.”⁸³

34. As these passages make clear, the United States (like Lilly) rejects Canada’s interpretation of Article 1709(1) as self-judging, requiring only that Canada have the word “useful” in its domestic patent law.⁸⁴ As Lilly has argued, “an interpretation [of Article 1709(1)] that bends to whatever new legal regime Canada wishes to adopt cannot be a good faith interpretation of its obligations under Article 1709(1), because such an interpretation imposes no obligation at all.”⁸⁵

⁸⁰ *Id.* at ¶ 259.

⁸¹ U.S. Art. 1128 Submission at ¶ 41.

⁸² *Id.* at ¶ 41 & n.67.

⁸³ *Id.* at ¶ 41.

⁸⁴ Resp. CM at ¶ 350 (“Canada is plainly in compliance with Article 1709(1) because, as is required by that provision, section 2 of the Patent Act states explicitly that patents are available for inventions in Canada provided they are ‘useful’. If Canada were to remove the condition of usefulness from the Patent Act, then there could be a question of noncompliance with NAFTA Article 1709(1). But that is not the case: Article 1709(1) and section 2 of the Patent Act are perfectly aligned with respect to the requirement that a patent be made available for an invention that is ‘useful’. The analysis need not go any further.”).

⁸⁵ Cl. Reply at ¶ 264.

35. The U.S. Submission Confirms that Article 1709(7) Prohibits Measures that Result in *De Facto* Field-of-Technology Discrimination. NAFTA Article 1709(7) protects against discrimination in the grant and enjoyment of patents based on, among other things, the field of technology of the underlying invention.⁸⁶ As Lilly's submissions make clear, the core question presented by Article 1709(7) is whether a measure, in terms of its actual effects, imposes differentially disadvantageous consequences on innovators within a certain field of technology.⁸⁷ Consistent with Lilly's view, the United States submits that Article 1709(7) reaches not just *de jure* but also *de facto* discrimination.⁸⁸

36. The U.S. grounds this view in a WTO Panel decision interpreting the TRIPS Agreement, *Canada–Patent Protection of Pharmaceutical Products* (“*Canada – Pharmaceuticals*”), that is also relied on by Lilly in its Memorial.⁸⁹ Citing to Paragraph 7.101 of the Panel's report, however, the U.S. suggests that *de facto* discrimination requires “both the presence of differentially disadvantageous effects of a measure and the existence of discriminatory objectives” or purposes.⁹⁰

⁸⁶ NAFTA Art. 1709(7) (“Subject to paragraphs 2 and 3, patents shall be available and patent rights enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced.”).

⁸⁷ See Cl. Mem. at ¶¶ 217-220. For Article 1709(7), as in WTO cases involving *de facto* discrimination under various agreements, the analysis is appropriately focused on overall patterns of discrimination. See, e.g., Appellate Body Report, *Chile–Taxes on Alcoholic Beverages*, Doc. WT/DS87/AB/R (13 December 1999), at ¶¶ 64-67 (affirming finding of discrimination under GATT even though many products subject to the higher tax were Chilean and certain foreign products were exempt) (CL-192); Appellate Body Report, *U.S.–Measures Affecting The Production and Sale of Clove Cigarettes*, Doc. WT/DS406/AB/R (4 April 2012), at ¶ 200 (affirming finding of discrimination under the Agreement on Technical Barriers to Trade even though certain flavored cigarettes subject to the challenged ban were made in the U.S. market) (CL-193); Appellate Body Report, *European Communities–Regime For The Importation, Sale and Distribution of Bananas* (“*EC–Bananas III*”), Doc. WT/DS27/AB/R (9 September 1997), at ¶¶ 243-244 (affirming finding of discrimination under the General Agreement on Trade in Services even though certain operators from the complainant countries were in the group receiving more favorable treatment and some European operators were in the less favored group) (CL-194).

⁸⁸ U.S. Art. 1128 Submission at ¶ 43.

⁸⁹ Compare *id.* (citing Panel Report, *Canada–Pharmaceuticals*, WT/DS114/R (Mar. 17, 2000)) with Cl. Mem. at ¶ 217 (same).

⁹⁰ U.S. Art. 1128 Submission at ¶ 43.

37. To the extent the United States is suggesting that *Canada–Pharmaceuticals* stands for the proposition that a claimant must introduce proof of the discriminatory purpose of a measure in order to show it is *de facto* discriminatory, this is simply not correct. The panel in that case did not indicate that evidence of intent is always required. Rather, since the record in *Canada–Pharmaceuticals* included no evidence of discriminatory effects – in sharp contrast to this proceeding, where there is ample evidence of the differentially disadvantageous consequences of Canada’s doctrine – the panel found that evidence of intent was relevant to the *de facto* discrimination inquiry.⁹¹ More generally, while the United States routinely argues that “purpose” should be an element of WTO discrimination claims, the WTO’s Appellate Body has rejected the U.S. position and found the United States liable for national treatment violations on the basis of a pure effects test.⁹² Canada expressly agrees with this effects-based approach to national treatment cases and, even as respondent in the *Canada–Pharmaceuticals* case, did not argue that purpose is an affirmative element of a *de facto* discrimination claim.⁹³ Consistent with these WTO positions, Canada has not argued in

⁹¹ On evidence of effects, the panel emphasized that it “received *no systematic information* on the range of industries that have actually made use of” the challenged measure, nor any practical reason why it would disadvantage producers of patented pharmaceutical products. Panel Report, *Canada–Pharmaceuticals*, WT/DS114/R, at ¶ 7.102 (17 March 2000) (emphasis added) (CL-79). With regard to intent, the panel concluded that “it was not proved that the . . . objective indications of purpose demonstrated a purpose to impose disadvantages on pharmaceutical patents in particular, as is often required to raise a claim of *de facto* discrimination.” *Id.* at ¶ 7.105. The panel found that the only evidence of discriminatory intent, taken from legislative debates, was not persuasive, noting that “the issue of purpose [is] not an inquiry into the subjective purposes of the officials responsible for the measure, but an inquiry into the objective characteristics of the measure from which one can infer the existence or nonexistence of discriminatory objectives.” *Id.* at ¶ 7.101.

⁹² See, e.g., First Written Submission of the United States, *United States–Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products: Recourse to Article 21.5 of the DSU by Mexico (US–Tuna II Art. 21.5)* (27 May 2014), ¶¶303-304 (disputing Mexico’s approach to GATT Article III:4, under which “the sole relevant consideration is the effect of the measure,” not the “underlying rationale” (emphasis in original)) (C-543); Appellate Body Report, *US–Tuna II Art. 21.5*, WT/DS381/AB/RW (20 November 2015), ¶¶ 7.337-7.340 (finding violations of GATT Articles I:1 and III:4 without analyzing intent or purpose) (CL-195).

⁹³ See Government of Canada, Executive Summary of Oral Statement to the Panel in *US–Tuna II Art. 21.5*, at Panel Report Appendix, WT/DS381/RW/Add.1 (14 April 2015), Annex C-4, p. C-11 (“Canada does not consider that a Member’s ability to regulate in the public interest would be undermined if a panel is not required to consider the underlying rationale or policy objective of a measure as part of the analysis under [GATT] Article III:4 Any attempt to introduce an additional inquiry of a measure’s (continued...)”).

this proceeding that Lilly is required to show an improper purpose in order to establish that Canada's measures are discriminatory.

38. The U.S. Submission Is Consistent with Lilly's Interpretation of Article 1709(8) as Precluding the Revocation of Patents Under Entirely New Rules of Law. NAFTA Article 1709(8) provides that a Party may revoke a patent only when, as relevant here, "grounds exist that would have justified a refusal to grant a patent."⁹⁴ The United States submits that Article 1709(8) does not "freeze [...] intellectual property laws."⁹⁵ The U.S. position is consistent with Lilly's. As explained by Professor Robert Merges, for example, U.S. patent law has seen "normal variation around the core content of traditional patentability requirements."⁹⁶ Such "normal variation" does not implicate Chapter 17. What *is* impermissible, however, is the "sea change in the Canadian law of utility," which has created a new and additional test for utility and caused Canadian utility practice to fall below the "baseline or minimum level of protection" reflected in Article 1709(1).⁹⁷ The United States, as explained above, agrees that such a baseline exists.⁹⁸

C. Article 1128 Submission of the United Mexican States

1. Mexico Identifies No Support for Its Position that the Invalidation of a Property Right May Be Insulated From Liability Simply Because It Is Couched as a Decision "*Ab Initio*."

39. Mexico argues that "contingent legal rights cannot constitute an 'investment' under NAFTA Article 1139" and that "[w]hen legal rights are declared a nullity, or void *ab initio*, by a court of competent jurisdiction, there cannot be a claim of

underlying rationale into the Article III:4 [national treatment] analysis would disrupt th[e] careful balance" set out between GATT Articles III:4 and XX (general exceptions) (C-521).

⁹⁴ NAFTA Art. 1709(8).

⁹⁵ U.S. Art. 1128 Submission at ¶ 44.

⁹⁶ Second Expert Report of Robert Merges at ¶ 51 (discussing the "subtle changes" and "normal variation around the core content of traditional patentability requirements" in the United States).

⁹⁷ See Cl. Reply at ¶¶ 304-305 (quoting First Expert Report of Norman Siebrasse at ¶ 105).

⁹⁸ See *supra* at ¶¶ 33-34.

expropriation.”⁹⁹ Mexico’s view is based solely on one arbitral decision: *Azinian v. Mexico*.¹⁰⁰ As Lilly has previously explained, that award does not support the view that an invalidation of a domestic property right may be insulated from liability as an expropriation under international law simply because it is couched as a decision “*ab initio*.”¹⁰¹ Rather, *Azinian* holds that when a measure’s legality has been confirmed by domestic courts, and there are “no complaints against [those] courts” (whether on procedure on substance), the measure will not be found expropriatory.¹⁰² At the same time, *Azinian* also confirms that “an international tribunal called upon to rule on a Government’s compliance with an international treaty is not paralysed by the fact that the national courts have approved the relevant conduct” so long as “the court decision itself constitutes a violation of the treaty.”¹⁰³

40. In any event, Lilly has shown that Canadian patent rights are not in any way “conditional.”¹⁰⁴ It has shown also that, as applied to the invalidation of its Zyprexa and Strattera patents, “the phrase ‘*ab initio*’ conveys a legal fiction”; it does not change the basic facts that a valid patent was first granted and later taken away.¹⁰⁵

2. Mexico Proposes a Relationship Between Article 1110 and Chapter 17 that Contradicts the Plain Text of NAFTA.

41. Like the United States, Mexico Recognizes this Tribunal’s Competence to Rule on Violations of Chapter 17. Mexico recognizes that, as a function of the plain text of Article 1110(7), NAFTA investment tribunals must have *some* authority to rule on

⁹⁹ Mex. Art. 1128 Submission at ¶¶ 18-19.

¹⁰⁰ *Id.* at ¶¶ 20-21.

¹⁰¹ *See* Cl. Reply at ¶¶ 250-251.

¹⁰² *Azinian v. Mexico*, ICSID Case No. ARB(AF)/97/2, Award (1 November 1999), at ¶ 100 (“Claimants have raised no complaints against the Mexican courts Without exception, they have directed their many complaints against the Ayuntamiento [(City Council)] of Naucalpan.”) (CL-61).

¹⁰³ *Id.* at ¶¶ 98-99 (emphasis omitted); *see* Cl. Reply at ¶¶ 250-251.

¹⁰⁴ Cl. Reply at ¶¶ 36-41.

¹⁰⁵ *Id.* at ¶¶ 43-44.

breaches of Chapter 17.¹⁰⁶ Moreover, and in contrast to the United States, Mexico does not argue that investment tribunals are restricted from exercising such authority until after they have determined that an expropriation has taken place (whereupon they are vested with full competence to review Chapter 17 as a “safe refuge”¹⁰⁷). Instead, Mexico argues that, while a Chapter 11 tribunal can consider Chapter 17 as part of its expropriation analysis, it is limited to determining whether there has been a “plainly obvious” violation of that Chapter.¹⁰⁸

42. Mexico’s “Plainly Obvious” Test Finds No Support in the Text of Article 1110(7). If the “plainly obvious” test were the standard, Lilly submits that its evidence of a fundamental shift in Canadian patent law and discrimination against pharmaceutical patents would satisfy it. But the “plainly obvious” test is not the standard. The phrasing of Article 1110(7) – which asks whether the revocation “is consistent with Chapter Seventeen” – makes clear that investment tribunals may examine the consistency of a revocation of intellectual property rights with NAFTA’s intellectual property protections, and are not limited to examining whether the revocation is “plainly [and] obvious[ly] . . . inconsistent” with those protections.¹⁰⁹

43. As Mexico recognizes, the effect of its position would be to allow the host state to prevail in any case where there is “a genuine dispute as to whether the impugned measure conforms with the requirements of Chapter Seventeen, in the absence of a finding of nonconformity by a Chapter Twenty dispute settlement panel.”¹¹⁰ But Mexico does not (and cannot) identify any NAFTA text or other authority to support this result. Instead, Mexico suggests that its narrow view of this

¹⁰⁶ Mex. Art. 1128 Submission at ¶ 31 (“the most a Chapter Eleven arbitral tribunal can do . . . is to determine whether or not it is plainly obvious or clear on its face that [a] measure . . . is inconsistent with Chapter Seventeen”).

¹⁰⁷ U.S. Art. 1128 Submission at ¶ 34.

¹⁰⁸ Mex. Art. 1128 Submission at ¶ 31.

¹⁰⁹ *Id.* at ¶ 31.

¹¹⁰ *Id.*

Tribunal's role in examining Chapter 17 is supported by the existence of NAFTA's Chapter 20 dispute resolution process for state-to-state disputes.¹¹¹

44. Lilly has not, however, alleged a freestanding violation of Chapter 17 outside the framework of Chapter 11 that would need to be adjudicated under Chapter 20. Rather, as explained above and in its previous submissions,¹¹² Lilly has shown that a violation of Chapter 17 informs the expropriation analysis under Article 1110(1) and the Fair and Equitable Treatment analysis under Article 1105(1). Nothing in NAFTA – and nothing in the 2001 FTC Statement – restricts tribunals from considering a breach of another NAFTA chapter as part of a broader Chapter 11 analysis.¹¹³

45. Mexico also seeks to support its “plainly obvious” test by drawing a contrast between Article 1110(7) and Articles 1116, 1117 and 1401(2), which it says “very clear[ly] . . . vest[]” Chapter 11 tribunals “with authority to consider and apply other provisions of the NAFTA.”¹¹⁴ Mexico implies that the clear language of these articles shows that, where the NAFTA Parties intended to allow adjudication of other NAFTA chapters, they “so provided expressly.”¹¹⁵ In fact, however, none of the three provisions cited by Mexico deal with the authority of Chapter 11 tribunals to consider violations of other NAFTA chapters.

46. The relevant provisions of Articles 1116 and 1117 articulate a rule of attribution, making clear that NAFTA Parties are responsible for the conduct of their sovereign enterprises and sovereign-sponsored monopolies. While these articles permit investors to bring investment claims for breaches of two provisions of NAFTA Chapter 15 (State Enterprises and Monopolies), they do not set out independent substantive protections. Rather, the relevant articles (Articles 1503(2) and 1502(3)(a)) make clear that state monopolies and enterprises are, like arms and agencies of host states, bound

¹¹¹ *Id.* at ¶¶ 24-30.

¹¹² *See supra* at § I.B.5; Cl. Reply at IV.B.2-4 and ¶ 356.

¹¹³ Cl. Reply at IV.B.2-4; *id.* at ¶ 356; Cl. Mem. at ¶ 271 n.499.

¹¹⁴ Mex. Art. 1128 Submission at ¶ 23.

¹¹⁵ *Id.* at ¶ 30.

to respect Chapter 11. As explained in a leading NAFTA commentary, “[b]y incorporating references to Article 1503(2) and 1502(3)(a) [in Articles 1116 and 1117] the NAFTA Parties sought to ensure that Parties could not avoid their NAFTA [Chapter 11] obligations by delegating responsibility to monopolies or State enterprises.”¹¹⁶

47. Article 1401(2) also has an entirely different purpose from Article 1110(7). Its purpose is to specify the limited extent to which the substantive protections in Chapter 11 apply to financial services investments under Chapter 14 (Financial Services).¹¹⁷ Under Article 1101(3), Chapter 11 “does not apply to measures . . . covered by Chapter 14.” Article 1401(2), however, reads certain limited Chapter 11 protections into Chapter 14 (specifically: Articles 1109, 1110, 1111, 1113 and 1114). In other words, Article 1401(2) does not address the nature of the substantive protections in Chapter 11; instead, it defines the limited number of Chapter 11 protections accorded to financial services investors under Chapter 14.

48. Simply put, Articles 1116, 1117 and 1401(2) say nothing about the jurisdiction of investment tribunals to consider violations of other NAFTA chapters. Given their distinct purposes, they have no bearing the proper interpretation of Article 1110(7).

49. Lilly’s views on the remaining points discussed in Mexico’s submission have already been set out, in substance, in Part I.B of this submission.¹¹⁸

¹¹⁶ Andrea K. Bjorklund, “NAFTA Chapter 11,” in COMMENTARIES ON SELECTED MODEL INVESTMENT TREATIES 502 (Oxford 2013) (CL-43).

¹¹⁷ See NAFTA Article 1101(3) (specifying that Chapter 11 “does not apply to measures . . . covered by Chapter 14 (Financial Services)”); NAFTA Article 1415 (setting out specialized procedures for investment disputes implicating financial services measures).

¹¹⁸ Mexico asserts that “neither a continuing course of conduct nor the occurrence of subsequent acts or omissions can renew or interrupt the three-year limitation period” (¶¶ 7-8); this proposition is not relevant to this arbitration because the measures invalidating the Strattera and Zyprexa patents took place within three years of the commencement of this arbitration. See *supra* at § I.B.2; Cl. Opp. to Resp. Jur. Objection at § II.B. Mexico argues that Article 1105’s Fair and Equitable Treatment standard does not protect the legitimate expectations of investors (¶ 15); in fact, such protections are at the core of the protection accorded under Article 1105. See *supra* at § I.B.3; Cl. Reply at § V.B.2. Mexico suggests that – “so far” – there is no “clearly identified and established” alternative to the denial of justice standard in (continued...)

II. COMMENTS ON OTHER NON-DISPUTING PARTY (AMICUS) SUBMISSIONS

A. Professors Gregory Dolin, Christopher Holman, Jay Kesan, Erika Lietzan, Adam Mossoff, Kristen Osenga and Mark Schultz (“Seven IP Scholars”)

50. The Seven IP Scholars Confirm that the Promise Utility Doctrine Results in a “Catch-22” for Pharmaceutical Innovators. The Seven IP Scholars are respected and independent academics who make several important points regarding Canada’s extraordinary promise utility doctrine. Of particular importance, the Seven IP Scholars provide independent confirmation of what Lilly has previously identified as a “Catch-22” inherent in the promise utility doctrine:¹¹⁹ if an inventor files for patent protection without substantial clinical trial data, the inventor risks invalidation under the promise utility doctrine’s arbitrary requirements; if an inventor waits to amass the data often required under the promise utility doctrine, the inventor risks invalidation for obviousness or lack of novelty.¹²⁰

51. This Catch-22, which results from a “conflat[ion]” of the “very different roles” of patent offices and health regulators,¹²¹ undermines the broader policy

assessing the conformity of judicial action with the Minimum Standard of Treatment (¶ 14); however, in light of the general rule that states are responsible for the acts of all their organs, equally, there is no basis for exempting judicial measures from these protections. *See supra* at § I.B.4; *see also* Cl. Reply §§ V.B.1, V.A.

¹¹⁹ Non-Disputing Party Submission of the Seven IP Scholars at 13 [hereinafter “Seven IP Scholars”]; *see also* Cl. Mem. at ¶¶ 28, 266-267; Cl. Reply at ¶¶ 192-194.

¹²⁰ Seven IP Scholars at 14-15 (“Such [clinical] research is not only expensive, but it moves the moment of patentability to just prior to commercial launch. During almost all of this time the invention would have to remain secret, as pre-patenting public disclosure would be grounds for denial of the patent.”); *see* Cl. Mem. at ¶ 266 (“Companies thus face a “Catch-22” under the promise utility doctrine. Either they file without clinical trial data and risk invalidation under the promise utility doctrine, or they wait for significant clinical trial data and, because such data are often published, they risk losing their patent to a determination that their invention is no longer patentable for lack of novelty or anticipation.”).

¹²¹ *See* Seven IP Scholars at 17 (“The promise doctrine conflates the role of the patent office with that of the regulator, because it would require a patent office and a patent examiner to address issues such as specific efficacy and to review extensive, complex evidence, such as clinical trials. An examiner would need access to and fully understand the reams of clinical trials data generated during the process of drug development, to understand if the drug is effective and fulfills the ‘promise’ made in the application stage. As US Courts once had to remind the US Patent and Trademark Office, the patent system should (continued…)”).

objectives of the patent system. As the professors detail, internationally, “patent system[s] contain[] many incentives for early disclosure” of inventions to the public (it is precisely for this reason that delayed filing can defeat patentability).¹²² These incentives “send a clear message to the inventor: ‘Disclose soon or risk losing your chance for a patent.’”¹²³ But, “contrary to all of these other incentives, the promise utility doctrine strongly urges an inventor to wait to further develop its invention before filing” for a patent and disclosing the invention publicly.¹²⁴

52. Put differently, while Canada repeatedly emphasizes adequate disclosure as the “hard coinage” of the patent bargain,¹²⁵ the Seven IP Scholars show that the practical effect of the promise utility doctrine may be to force inventors to keep that coinage tucked in their purses. This is because, as the Seven IP Scholars confirm,¹²⁶ inventors must keep their discoveries secret through the date of patent filing. As Lilly has elsewhere pointed out, for example, even inadvertent disclosures of clinical trials by outside experts, patients, patients’ doctors, patients’ family members or others could defeat patentability on grounds of novelty or obviousness.¹²⁷ Thus, by forcing inventors to delay in filing for patents, Canada’s promise utility doctrine undercuts the very objective Canada argues is at the core of the patent bargain.

53. The Seven IP Scholars Confirm Canada’s Failure to Understand the Imperatives Facing Innovative Pharmaceutical Companies. The constant threat of a patent-defeating disclosure, which investors face until they actually file for a patent, informs the second practical point made by the Seven IP Scholars: that the industry

not ‘confuse[] the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption.’”).

¹²² *Id.*; see also Cl. Mem. at ¶ 28.

¹²³ Seven IP Scholars at 15.

¹²⁴ Application for Leave of the Seven IP Scholars at ¶ 4.

¹²⁵ See Resp. CM at ¶ 84 (internal quotations omitted).

¹²⁶ Seven IP Scholars at 15 (“[D]isclosure, public use, or commercialization of the invention before filing may be grounds to invalidate a patent.”).

¹²⁷ See Cl. Mem. at ¶ 266; Second Witness Statement of Robert A. Armitage at ¶ 38.

practice of filing for patent rights at “an early place on [the] path” to commercialization of a medicine is not speculative (as Canada has suggested¹²⁸) but rather reflects legal and economic imperatives.¹²⁹

54. The legal imperative results from the risk, discussed above, that the right to a patent will be defeated by pre-filing disclosure. The economic imperative results from the “vastly expensive” process of bringing drugs through clinical trials and eventually to market.¹³⁰ As the Seven IP Scholars explain, filing patents early in the drug development process permits pharmaceutical innovators to “secure the investments necessary to develop an invention into a product and commercialize it.”¹³¹ By forcing pharmaceutical innovators to delay filing, and exposing them to the Catch-22 described above, the promise utility doctrine “undermines the opportunity to secure financing for product development” and “makes it less likely an investor can secure the necessary funding” to conduct the extensive clinical research that is necessary to bring a drug to market.¹³² And, as the professors point out, the burden of this regime falls not only on firms such as Lilly, but also on the individual inventors, universities, and small business that perform early-stage drug development, and that lack the independent resources to compile the heightened evidence Canada’s utility requirement demands.¹³³

55. The Seven IP Scholars Show that Utility Standards Outside of NAFTA Countries Are Also “Liberal”. While the submissions of the disputing parties have appropriately focused on the law of NAFTA Parties, the Seven IP Scholars also confirm

¹²⁸ Resp. Rejoinder at ¶¶ 54-55.

¹²⁹ Seven IP Scholars at 13.

¹³⁰ *Id.* at 14; *see also* H. Gupta et al., Patent Protection Strategies, 2(1) J. PHARM. & BIOALLIED SCIENCES 2 (2010) (C-522); Hultquist IP, The U.S. Patent Law and US FDA Law – Pharmaceutical Patent Strategies, available at <http://www.hultquistip.com/post-detail.php?id=998> (explaining that patent applications are typically filed at the lead compound generation stage, prior to clinical testing) (C- 523).

¹³¹ Seven IP Scholars at 13; *see* Second Witness Statement of Robert A. Armitage at ¶ 35 (“Given the vast costs involved in large scale clinical testing – not just money, but also the cost of scarce employee time and other research foregone – biopharmaceutical companies like Lilly must be confident that they have a secure legal right to the fruits of their investment.”).

¹³² Seven IP Scholars at 13-14.

¹³³ *Id.* at 14.

that the common understanding of utility articulated by Lilly is shared across major jurisdictions even outside NAFTA – including in continental Europe, the United Kingdom and Japan.¹³⁴ In particular, and in contrast to the testimony of Professor Daniel Gervais,¹³⁵ the professors make clear that this utility requirement is widely understood as a “liberal” one.¹³⁶ The professors explain that the major patent regimes across the world consistently set a “very low threshold” for utility that excludes from patentability “only highly generalized and abstract, incredible or implausible industrial applications.”¹³⁷ Against this backdrop, Canada’s promise utility doctrine is as “an extreme outlier that is not found in the contemporary patent law of any of Canada’s major trading partners or other significant patent-granting jurisdictions.”¹³⁸

B. The Canadian Chamber of Commerce (“Canadian Chamber”)

56. The Canadian Chamber Submission Illustrates Broad-Based Concerns Regarding the Promise Utility Doctrine. Filed by an organization representing over 450 chambers of commerce and boards of trade within Canada, as well as 200,000 Canadian businesses of all sizes,¹³⁹ the Canadian Chamber’s submission demonstrates the breadth of domestic concern regarding the promise utility doctrine and its detrimental impact on Canadian innovation. It likewise demonstrates the extent to which the promise utility doctrine is viewed as degrading Canada’s investment environment for investors

¹³⁴ *Id.* at 2-8. Reflecting this, 20 innovative pharmaceutical companies, many of whom have lost patents under the promise utility doctrine reported to the U.S. Government in February 2016 that they “are not aware of a single case invalidating or revoking one of the patents at issue [*i.e.*, patents invalidated under the promise utility doctrine] for lack of utility in any other jurisdiction.” See Canadian Patent Utility Coalition, Written Submission on the 2016 Special 301 Review (Docket No. STR-2015-00022) (5 Feb. 2016) (C-524). Lilly is still not aware of any such case.

¹³⁵ See, *e.g.*, First Expert Report of Daniel Gervais at ¶¶ 46-47 (“WIPO Member States who issued this proposal believed that fruitful discussions were possible on novelty (and non-obviousness / inventive step) but utility did not make the cut”); *id.* at ¶ 54 (“there is no consensus on a stable, uniform or narrowly defined notion of utility or of industrial applicability, even if one assumes that both notions may be “deemed” to be synonymous”).

¹³⁶ Seven IP Scholars, *passim*.

¹³⁷ *Id.* at 11.

¹³⁸ *Id.* at 12.

¹³⁹ See Application for Leave of the Canadian Chamber of Commerce at 1.

in innovative industries.¹⁴⁰ Quoting from a report prepared by “an independent advisory body mandated by the Government of Canada to provide confidential advice on science, technology and innovation (STI) policy issues,”¹⁴¹ the Canadian Chamber explains that:

Canada has fallen further behind comparator countries on key business innovation performance indicators and the gap between Canada and the world’s top five performers has widened. Of particular concern is the lack of research and development funding by businesses. Canada’s ranking in business expenditures on R&D fell to 26th in 2013 from 18th in 2006. Total investment over the same time dropped by \$1 billion.¹⁴²

57. The Canadian Chamber Shows that the Promise Utility Doctrine May Harm Small and Medium Enterprises. The Canadian Chamber echoes the warning of the Seven IP Professors concerning the negative effect of the promise utility doctrine on universities, and on small and medium enterprises (including Canadian Chamber members¹⁴³) that rely on robust intellectual property protection to realize the value of their work.¹⁴⁴ These points provide important context to the issues in this arbitration, demonstrating the broad concerns that the promise utility doctrine has engendered among foreign and domestic investors alike.

C. The National Association of Manufacturers (“NAM”)

58. NAM’s Submission Reflects the Expectations of Patent System Users as to the Baseline Level of IP Protection in NAFTA. Representing a wide range of industries

¹⁴⁰ See Non-Disputing Party Submission of the Canadian Chamber of Commerce at 11-12 (describing significant declines in Canadian pharmaceutical manufacturing, business expenditures, R&D spending, and sales) [hereinafter “Canadian Chamber”].

¹⁴¹ See Science, Technology and Innovation Council (Canada), <http://www.stic-csti.ca/eic/site/stic-csti.nsf/eng/Home> (C-525).

¹⁴² Canadian Chamber at 12-13 (quoting Science Technology and Innovation Council, *Canada’s Innovation Challenges and Opportunities* (2015)). The Canadian Chamber also notes that the Canadian Government’s own figures show that “[t]otal business expenditures on R&D by Canadian pharmaceutical companies has fallen below \$1 billion since 2011,” and that “[f]rom 2001 to 2013, industry R&D spending has fallen by 29 percent.” *Id.* at 12.

¹⁴³ See Application for Leave of the Canadian Chamber of Commerce at 1.

¹⁴⁴ See Canadian Chamber at 3-4.

that develop and invest in intellectual property,¹⁴⁵ NAM explains that the promise utility doctrine is out of line with investor expectations, creating an unpredictable and unstable legal framework that harms innovation.¹⁴⁶ NAM also explains, based on the experience of its members, that Canada's outlier promise utility test is inconsistent with the well-understood "baseline protection in NAFTA [...] that inventions having some utility be protected";¹⁴⁷ a level of protection that is provided in other NAFTA countries. Through its failure to meet these baseline obligations, NAM explains, Canada's promise utility doctrine burdens the very cross-border commerce that NAFTA was designed to promote.¹⁴⁸

59. NAM's Analysis Confirms the Evolution of the Minimum Standard of Treatment. NAM conducts a detailed analysis of the Fair and Equitable Treatment standard as applied in NAFTA cases. NAM's analysis confirms that "numerous Tribunals have rejected Canada's argument" that Article 1105's Fair and Equitable Treatment standard (which, as noted above, is linked to the Minimum Standard of Treatment under customary international law) should be viewed as frozen and fragmented.¹⁴⁹ Indeed, as Lilly has shown, the standard has "continually evolved and been shaped by more than 3,000 bilateral investment treaties (BITs) and regional investment agreements," which, among other things, protect the reasonable investment-backed expectations of foreign investors.¹⁵⁰

¹⁴⁵ Just one member of NAM's twenty-nine member Executive Committee is employed in the pharmaceutical industry (at Pfizer). See NAM, Board of Directors, <http://www.nam.org/About/Board-of-Directors/> (accessed 6 April 2016) (C-526). One Lilly employee sits on NAM's Board of Directors; NAM's Board, however, has approximately 150 members. *Id.*

¹⁴⁶ Non-Disputing Party Submission of the National Association of Manufacturers at ¶¶ 7, 24-26 [hereinafter "NAM"].

¹⁴⁷ *Id.* at ¶ 19.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* at ¶¶ 35, 43.

¹⁵⁰ Cl. Mem. at ¶ 254; see Cl. Reply at ¶ 351; NAM at ¶ 41 (quoting *International Thunderbird Gaming Corp. v. Mexico*, NAFTA/UNCITRAL, Award (26 January 2006), at ¶ 147).

D. The Canadian Generic Pharmaceutical Association (“CGPA”)

60. CGPA’s Members Derive Financial Benefit from the Promise Utility Doctrine. CGPA’s members include substantially every Canadian company that has benefitted from the invalidation of a patent under the promise utility doctrine.¹⁵¹ Among others, its members include Teva Canada (formerly Novopharm Ltd.) and Apotex Inc., large generic drug firms that brought invalidation proceedings against the Zyprexa and Strattera patents at issue in this case.¹⁵² CGPA’s submission, moreover, was authored by counsel for Teva Canada in the Zyprexa and Strattera proceedings in Canadian courts.¹⁵³ The submission is, in other words, filed on behalf of the firms that directly benefitted from Canada’s internationally wrongful revocation of Lilly’s patents, by an attorney that helped lead the charge. It is not – contrary to CGPA’s suggestion – a document written in “the public interest.”¹⁵⁴

61. CGPA Mischaracterizes the Course of Domestic Litigation Over Zyprexa and Strattera. CGPA’s brief focuses extensively on the procedural details of the domestic litigation over Zyprexa and Strattera.¹⁵⁵ CGPA’s account of this Canadian procedural history is not relevant to Lilly’s claims before this Tribunal, which do not depend on due process accorded in Canadian courts. Nevertheless, in the interest of maintaining an accurate record, it is necessary to correct three mischaracterizations put forward by CGPA.

- *First*, it is not correct that Lilly argued in the Supreme Court of Canada that, in applying the promise utility doctrine in the Zyprexa case, “[Canadian] courts . . .

¹⁵¹ See CGPA, Member Companies, <http://www.canadiangenerics.ca/en/about/members.asp> (accessed 6 April 2016) (C-527).

¹⁵² See *id.*; see also CGPA, Board of Directors, http://www.canadiangenerics.ca/en/about/board_committees.asp (accessed 6 April 2016) (showing that Apotex’s President chairs CGPA) (C-528).

¹⁵³ Application for Leave of CGPA at ¶ 11 (“Counsel for the CGPA was counsel in the proceedings that led to the invalidation of Lilly’s patents for atomoxetine (Strattera) and olanzapine (Zyprexa) in Canada, as well as in the CGPA’s most recent three interventions at the Supreme Court of Canada.”).

¹⁵⁴ *Id.* at ¶¶ 4-6; Non-Disputing Party Submission of CGPA at ¶ 78 [hereinafter “CGPA”].

¹⁵⁵ See CGPA at 1-4.

‘did nothing more than follow established principles of patent law.’”¹⁵⁶ Lilly made this statement not in response to the invalidation of its patent under the promise utility doctrine, but rather in response to a prior determination of the Federal Court of Appeals – made in a separate appeal – that Lilly’s Zyprexa patent could not be challenged on a completely different alleged ground of invalidity (as an “invalid selection patent”).¹⁵⁷

- **Second**, it is not correct that Lilly filed its first Notice of Intent to pursue a NAFTA claim in order to “to convince the Supreme Court of Canada that Lilly’s application for leave to appeal from” the invalidation of its Zyprexa patent under the promise utility doctrine “had merit.”¹⁵⁸ CGPA points to the fact that, “in addition to putting its Notice of Arbitration before the Supreme Court, Lilly supported its application for leave to appeal with affidavits from two prominent . . . jurists” (retired English Court of Appeal Justice Sir Robin Jacob and Judge Paul Michel, Chief Judge of the U.S. Court of Appeals for the Federal Circuit),¹⁵⁹ both of whom confirmed the outlier nature of Canada’s promise utility doctrine.¹⁶⁰ But the fact that Lilly made the court aware of the conflict between the promise utility doctrine and NAFTA, and filed a well-supported appeal brief in the Canadian litigation, lends no support to Canada’s contention that Lilly was not serious about pursuing this arbitration. To the

¹⁵⁶ Cf. *id.* at ¶ 6.

¹⁵⁷ As explained in Lilly’s Memorial, generic firms mounted two related challenges to the Zyprexa patent. First, they argued that the Zyprexa patent was not a “valid selection patent.” Cl. Mem. at ¶ 94. The Federal Court of Appeal held that this was not cognizable argument under Canadian law. *Id.* at ¶ 95. The generic challenger sought leave to appeal this determination in the Supreme Court of Canada, and it was in the context of this leave application – which did not present any issues of validity on grounds of utility – that Lilly stated that the Federal Court of Appeal “did nothing more than follow established principles of patent law.” Lilly’s Memorandum of Fact and Law in SCC 33870, October 26, 2010, ¶ 2 (R-034); see Cl. Reply at ¶ 212 n. 420. The case was subsequently remanded, and the patent invalidated solely on grounds of inutility. Cl. Mem. at ¶ 110.

¹⁵⁸ CGPA at ¶ 9.

¹⁵⁹ *Id.*

¹⁶⁰ See Affidavit of Chief Judge Paul R. Michel (Ret.), in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, SCC 35067, 5 November 2012, at ¶¶ 20-21 (“[T]he Canadian approach is virtually the opposite of the U.S. one.”; “Canadian judge-made law creates international disuniformity and may discourage drug development.”) (C-529); Affidavit of the Rt. Hon. Professor Sir Robin Jacob, in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, SCC 35067, 28 October 2012, at ¶ 5 (“If the Canadian view of the law of utility as understood and applied by O’Reilly, J. is correct, Canadian patent law is significantly out of kilter with that of other major industrial countries. These include not only the UK but the entire membership of the European Patent Union”) (C-530). Sir Robin also submitted an affidavit in *AstraZeneca Canada Inc. v. Apotex Inc.*, SCC 36654, 17 September 2015, ¶ 54 (C-531), in which he noted of the Canadian promise utility doctrine: “I know of no other patent law around the world (and particularly the common law world) which does anything like this. And I doubt many patents for new medicines would ever survive such a test.”

contrary, confronted with the invalidation of valuable patents on two groundbreaking medicines, Lilly has consistently pursued its rights in all appropriate fora.

- *Third*, it is not correct that Zyprexa and Strattera failed to meet the requirement of “substantial and particular advantage” imposed under the obviousness prong of patentability.¹⁶¹ Both patents were invalidated on the sole ground of inutility.¹⁶² CGPA’s suggestion to the contrary is particularly surprising, given that Canada’s courts specifically rejected obviousness challenges brought by CGPA’s counsel against Zyprexa and Strattera, finding both drugs to be inventive.¹⁶³

These mischaracterizations of the procedural history of the Zyprexa and Strattera litigations confirm that CGPA’s submission lacks neutrality and call into question the submission’s credibility.

62. CGPA Is Contradicted by Its Own Members. CGPA argues, alternatively, that (i) the promise utility doctrine “does not exist”¹⁶⁴ and (ii) the promise utility doctrine reflects “existing and longstanding Canadian jurisprudence” rather than “an important change in Canadian patent law.”¹⁶⁵ Yet one of CGPA’s largest members (Apotex Inc.) has recognized the promise utility doctrine’s existence – and also its arbitrariness and novelty. As to the doctrine’s arbitrariness, Apotex described the promise utility doctrine to the Supreme Court of Canada as a “free-for-all” and a “hopeless tangle of contradictory approaches.”¹⁶⁶ As to the doctrine’s novelty, Apotex

¹⁶¹ CGPA’s argument improperly conflates the distinct utility and nonobviousness requirements under Canadian law. See Cl. Reply at ¶¶ 85-90; see also *Genpharm v. Proctor and Gamble*, 2004 FCA 393, at ¶ 47 (Utility and obviousness are “different concepts and they are not to be conflated. The doctrine of sound prediction has no application to the doctrine of obviousness.”) (C-544).

¹⁶² Cl. Mem. at ¶¶ 110, 140.

¹⁶³ *Id.* at ¶ 127; see *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, ¶¶ 77, 79, 87-88 (Strattera) (C-160); *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, ¶¶ 3-4 (Zyprexa) (C-146).

¹⁶⁴ CGPA at ¶ 26.

¹⁶⁵ See *id.* at ¶¶ 14, 18-19.

¹⁶⁶ Notice of Application for Leave to Appeal of Apotex Inc. et al, *Apotex Inc. v. Sanofi-Aventis*, S.C.C. File No. 35562, at ¶ 14 (30 September 2013) (C-375). These statements severely undermine CGPA’s contention that a change in the promise utility doctrine “risks creating uncertainty and unpredictability in the eyes of the Canadian public, including for generic pharmaceutical manufacturers that rely on consistency and predictability in Canadian patent law.” CGPA at ¶ 19.

argued in a 2010 court filing that “the law changed” as a result of the Supreme Court of Canada’s 2002 decision in *AZT* – an argument the court accepted. Apotex noted specifically that, before *AZT*, there was no basis to challenge the utility of a drug that had “been made, clinically tested, and was successful.”¹⁶⁷

63. CGPA’s Suggestion that the Promise Utility Doctrine Applies Exclusively to “Follow-On Patents” Is Contradicted by Both Parties. CGPA suggests that the promise doctrine applies exclusively to “patents asserting a second monopoly over a previously patented invention,”¹⁶⁸ which it defines as “second or follow-on patents.”¹⁶⁹ In particular, CGPA asserts that, except in the case of such “follow-on patents,” inventors need not and do not include promises in their patents.¹⁷⁰ This argument rests on the fallacy that the promises found in patents by Canadian courts are made intentionally by inventors, rather than being the product of subjective, arbitrary and inconsistent interpretation by individual judges.¹⁷¹

¹⁶⁷ In that litigation, which began in 2000 before *AZT* but continued for years afterwards, the court summarized Apotex’s argument regarding the change in law effected by the Supreme Court in *AZT* as follows: “[Apotex’s counsel] had indicated at that time that there was no issue with respect to the sound prediction of nefazodone because nefazodone had, subsequent to the filing of the ‘436 Patent, been made, clinically tested, and was successful. Under the governing law of the time, as established in *Apotex Inc. v. Wellcome Foundation Ltd. [AZT]*, [2001] 1 F.C. 495, 262 N.R. 137 (F.C.A.), that was enough – all that was required was for an inventor to demonstrate utility or sound prediction at the time a patent was attacked. Apotex points out, however, that the law changed subsequent to [Apotex’s counsel’s] statement. In December of 2002, the Supreme Court of Canada in [AZT] directed that either actual utility or a sound basis for predicting utility was required as of the filing date of a patent. As such, Apotex argues that the statement made by [Apotex’s counsel] in February of 2002 was obviously no longer applicable: the fact that nefazodone had been shown to eventually have utility as an anti-depressant no longer necessarily meant that the ‘436 Patent was immune to attack based on lack of sound prediction as of the filing date.” See *Bristol-Myers Squibb Company v. Apotex Inc.*, 2010 FC 1304, ¶ 30 (C-532), *rev’d* 2011 FCA 34 (C-545). The court agreed with Apotex that *AZT* had indeed changed the law. See *id.* ¶¶ 31-32 (“I find that given the change of law regarding lack of sound prediction . . .”) (C-532); see also *Written Representations of the Defendant Apotex Inc., Bristol-Myers Squibb Company v. Aptoex Inc.*, T-2078-00 (29 November 2010), at ¶¶ 15-16 (“Change in law: the *Wellcome [AZT]* decision . . . The law changed following the decision of the Supreme Court of Canada in December 2002 in *Wellcome [AZT]*.”) (C-533).

¹⁶⁸ CGPA at ¶¶ 33, 37.

¹⁶⁹ *Id.* at ¶ 37.

¹⁷⁰ *Id.*

¹⁷¹ See Cl. Reply at ¶¶ 174-180.

64. Moreover, as Lilly pointed out in its Reply, not even Canada contends that the promise utility doctrine has applied only to patents that CGPA would describe as “follow-on patents.”¹⁷² To the contrary, Canada’s witness, Dr. Marcel Brisebois, concedes that at least five distinct “patent[s] directed to a new, previously-unknown base compound or composition” have been invalidated under the promise utility doctrine.¹⁷³

65. CGPA’s remaining arguments are addressed in Lilly’s papers.¹⁷⁴

E. Dr. Burcu Kilic, Professor Brook K. Baker, Professor Cynthia Ho and Mr. Yaniv Heled (“Four IP Scholars”)

66. The Four IP Scholars Falsely and Improperly Assert that Lilly Has Brought this Arbitration in Bad Faith. The Four IP Scholars assert that “Lilly’s initiation

¹⁷² See *id.* at ¶ 89 n.154.

¹⁷³ First Witness Statement of Marcel Brisebois at ¶¶ 41, 43 & fig. 6. In the six months since Lilly filed its Reply, Canada has revoked three pharmaceutical patents under the promise utility doctrine. Two of those patents were compound patents. See *Gilead Sciences v. Idenix Pharmaceuticals*, 2015 FC 1156 (SOVALDI/Sofosbuvir) (C-534); *Eli Lilly v. Hospira Healthcare Corp.*, 2016 FC 47 (ALIMTA/Pemetrexed) (C-535). One was not a compound patent. See *Allergan Inc. v. Apotex Inc.*, 2016 FC 344 (ZYMAR/Gatifloxacin (EDTA)) (C-536).

¹⁷⁴ CGPA argues that the “promise doctrine, as described by Lilly, does not exist” (¶ 26); as Lilly has already shown, this position finds no support in Canadian case law. See Cl. Reply at § II.A. CGPA argues that Canadian law simply considers whether “the claimed invention do[es] what the inventor has chosen to say it will do” (¶ 28); Lilly has shown that “the construction of a patent’s promise is driven not by the applicant’s pen, but by a subjective and unpredictable process of interpretation” through which “the Canadian courts scour the entire [patent] application and find promises in the patent’s disclosure, including ‘implied’ promises.” Cl. Reply at ¶¶ 174-180. CGPA argues that Canadian law has not changed (¶¶ 29, 34, 37); Lilly has shown that to be false. Cl. Reply at §§ II.A-B. CGPA conflates the utility requirement in patentability with requirements under other, distinct requirements of patentability (¶¶ 39-40); Lilly has shown why such conflation is improper. Cl. Reply at ¶¶ 89, 106, 107, 156-157, 218. CGPA suggests that Lilly’s patents on Zyprexa and Strattera were speculative (¶ 45) and argues that the promise doctrine prevents “patenting mere speculation” (¶ 64); Lilly has submitted evidence of the extensive development process that led to each patent, Cl. Mem. at ¶¶ 84-87 and 118-121, and also has shown that the promise utility doctrine serves no anti-speculative purpose. Cl. Reply at ¶¶ 185-186. Further, Lilly has shown that attempts to paint the Zyprexa and Strattera patents as speculative patents reflect a fundamental failure to engage with the economic realities of the pharmaceutical industry. *Id.* at ¶¶ 24-28. CGPA repeats Canada’s false claim that Lilly is arguing for “international harmonization” (¶¶ 73-75); Lilly has already made plain that patent law is *not* harmonized (whether among NAFTA states or more generally), but that NAFTA Chapter 17 provides for a baseline of protection that individual states must respect. Cl. Reply at § I.D.2.

of an arbitration claim has not been made in ‘good-faith’ [and] it abuses the arbitral process.”¹⁷⁵ This assertion is supported exclusively by the following two paragraphs:

Lilly seeks to place undue pressure on the Canadian parliament by bringing this case to the arbitration process. This purpose is confirmed by the chief patent counsel of the Claimant “[t]he Parliament could have stepped in and fixed Canada’s patent statutes, . . . [but] [t]o date they have looked the other way.”²²

22: See Adam Behsudi, *Eli Lilly Sues Canada on Drug Patents*, POLITICO, available at <http://www.politico.com/story/2013/09/elililysues-canada-over-drug-patents-96743.html> (quoting Doug Norman, Eli Lilly’s chief patent counsel, in an interview with POLITICO).

The Claimant’s efforts to put pressure on Canadian parliament are not limited to this arbitration. The Claimant appears to use this case to bring U.S. political pressure to bear against Canada to seek changes to Canada’s patent rules.²³ Therefore, amici argue that the Tribunal should defend against the Claimant’s use of arbitration process as a lobbying strategy.

23: See Ed Silverman, *Eli Lilly vs. Canada: The Patent War Moves to Washington*, The Wall Street Journal, available at <http://blogs.wsj.com/corporate-intelligence/2014/04/14/eli-lilly-vs-canada-the-patent-war-moves-to-washington/>.

67. The first article cited by the Four IP Scholars merely reflects that no branch of Canada’s government has taken steps to correct the promise utility doctrine and bring Canada’s patent law in line with its international obligations. The second article reports that Lilly, the pharmaceutical industry more broadly, and more than two dozen members of Congress have called upon the U.S. government to raise Canada’s troubling patent practices and demand that Canada bring its patent regime into compliance with international obligations.

68. From these thin reeds, the Four IP Scholars assert that Lilly is pursuing this arbitration “as a lobbying strategy” aimed at achieving a legislative correction to the promise utility doctrine.¹⁷⁶ This assertion is false. Lilly has brought this arbitration

¹⁷⁵ Non-Disputing Party Submission of the Four IP Scholars at 8 [hereinafter “Four IP Scholars”].

¹⁷⁶ *Id.* at 9.

because Canada's wrongful conduct cost Lilly millions of dollars, giving rise to a claim under NAFTA. Lilly's patents were valuable investments, reflecting the medical advances embodied in the inventions they protected. Canada, acting through its courts, expropriated Lilly's patent on Strattera – "the first non-stimulant [medicine] approved for use in the treatment of ADHD."¹⁷⁷ Canada then expropriated Lilly's patent to Zyprexa – a groundbreaking second generation antipsychotic medicine that "quickly became the world's top selling antipsychotic for the treatment of schizophrenia."¹⁷⁸ Lilly deserves compensation for these unlawful expropriations.

69. The Four IP Scholars' assertion also is irrelevant. Any future correction in Canadian patent law would not change the fact that Lilly has already lost two valuable investments in Canada. And it would have no effect on Lilly's entitlement to compensation for the treatment of its investments under Chapter 11 of NAFTA.

70. It is certainly true that Lilly is not the only pharmaceutical company whose patents have been struck down under the promise utility doctrine, and that other innovative companies are concerned with the erosion of core patent protections in Canada. Organizations such as PhRMA, Biotechnology Innovation Organization, the Canadian Patent Utility Coalition, the National Association of Manufacturers, the U.S. Chamber of Commerce, and the Intellectual Property Owners Association have all raised concerns with Canada's promise utility doctrine in formal submissions to the U.S. Trade Representative. Those trade associations, which have thousands members, have each called upon Canada to bring its patent laws in line with international norms.

71. The Four IP Scholars Deploy Alarmist Rhetoric to Suggest that Lilly's Case "Would Threaten Access to Affordable Medicines for Many People."¹⁷⁹ Again, this argument is false. This case has nothing to do with the price of patented medicines. This case is instead about Canada's obligation to provide – without discrimination against the pharmaceutical field of technology – a minimum standard of patent

¹⁷⁷ Witness Statement of Anne Nobles at ¶ 24.

¹⁷⁸ Witness Statement of Robert Postlethwait at ¶ 31.

¹⁷⁹ Four IP Scholars at 10.

protection to NAFTA investors. More specifically, this case is about the treatment accorded Lilly's patents on two specific products – Zyprexa and Strattera – that were prematurely revoked. There has been no suggestion, let alone evidence, that these patents were preventing Canadians who suffer from schizophrenia or ADHD from receiving access to either drug. Canada applies a detailed set of price regulations to patented medicines administered through a specialized body, the Patented Medicine Prices Review Board.¹⁸⁰ Lilly has not challenged those regulations, that body, or any of its decisions in this arbitration.

72. The remainder of the Four IP Scholars' submission raises points that are already addressed in Lilly's submissions.¹⁸¹

F. The Center for Intellectual Property Policy and the Canadian Internet Policy & Public Interest Clinic ("CIPP/CIPPIC")

73. The CIPP/CIPPIC Submission Lacks Credibility. CIPPIC – the Canadian Internet Policy & Public Interest Clinic – offers no special expertise on the law or policy

¹⁸⁰ See generally Patent Act (Can.), § 83 (C-50).

¹⁸¹ The Four IP Scholars state that "Lilly claims that NAFTA country patentability practices must be uniform . . . and that Canada's standards must remain static" (p. 1); harmonization is not at issue in this dispute; rather, this dispute concerns Canada's failure to respect even the *baseline* protections that Canada agreed to in ratifying NAFTA. Cl. Reply at § I.D.2. The Four IP Scholars argue that "Lilly completely ignores that patents are conditional rights" (p. 6); Lilly has dealt with this assertion as made by Canada, and has shown, among other things, that the Canadian government itself has repeatedly recognized that issued patents constitute a form of property just like any other. Cl. Reply at § I.C. The Four IP Scholars repeat Canada's characterization of Lilly's arguments as speculative (p. 5); Lilly's witnesses have recounted at length the decades-long development processes that led to the discoveries of Strattera and Zyprexa. Cl. Mem. at ¶¶ 84-87, 118-121. See also Second Witness Statement of Robert A. Armitage at ¶ 29 (explaining that both compounds were approved by the U.S. Food and Drug Administration as "new molecular entities" – i.e., drugs containing "active compounds never before marketed" in the United States). Lilly also has shown that the promise utility doctrine does not serve any anti-speculative policy, and that Canada's suggestions to the contrary reflect a fundamental misunderstanding of the pharmaceutical development. Cl. Reply at ¶¶ 24, 28, 185-186. The Four IP Scholars repeat Canada's argument that, "[g]iven the latitude of NAFTA provisions in not providing any definitions, Parties can determine when an invention is deemed to be a capable of industrial application or useful" (p. 2); this assertion is belied by the extensive expert testimony submitted by Lilly's Canadian, Mexican and U.S. legal and patent office experts, who have demonstrated the substantial commonalities in practice among NAFTA Parties, see Cl. Reply at § II.C, and also by the independent expertise offered by the Seven IP Scholars. See Seven IP Scholars at §§ I.A-D (discussing European, English, Japanese and American utility standards).

of pharmaceutical patents. Its core areas of focus, as reflected on its website, are: copyright, privacy, telecom policy, electronic surveillance, open information, digital expression and consumer protection.¹⁸² CIPP – the Center for Intellectual Property Policy – on the other hand, has a clear view on pharmaceutical patents: that of its founding director, and its counsel in this arbitration, Professor Richard Gold.

74. In the dispute between Lilly and Canada, Professor Gold has been a prominent partisan for Canada. He has acted as a *de facto* spokesman for the Canadian government, and Canada’s trade policy attaché in the United States distributes Professor Gold’s views to the public.¹⁸³ In addition to republishing Canada’s briefing,¹⁸⁴ Professor Gold has attacked not only Lilly,¹⁸⁵ but also third parties that disagree with his views on Canadian patent law.¹⁸⁶ Professor Gold’s conduct has been sufficiently irregular that his participation in an online discussion forum popular with intellectual property practitioners and academics (IPWatchdog.com) was suspended for

¹⁸² See Samuelson-Glushko Canadian Internet Policy and Public Interest Clinic, Home Page, <https://cippic.ca/en> (C-537).

¹⁸³ See @CdnCoryO and @IP_Policy, Extracted Tweets, at 10 February 2015 (“Interested in the Eli Lilly-#Canada #NAFTA #ISDS arbitration? Follow @IP_Policy. He’s tweeting excerpts of Canada’s submissions.”) (C-538).

¹⁸⁴ *Id.*

¹⁸⁵ @IP_Policy, Extracted Tweets, at 18 October 2014 (“Eli Lilly’s view of int’l patent law requires one to stand on 1 leg, close eyes 3/4, hop and cluck like a chicken”) (C-539); *id.*, at 23 October 2014 (“Rather than deal with missing revenue targets, Eli Lilly continues vacuous suit against Canada <http://bloom.bg/1xcBEls>”); *id.* at 22 December 2015 (“Eli Lilly management continues to cover up its repeated failures by bluster and mendacity. Hence its #ISDS re Cda”); “The \$500-million doctrine,” *The National* (Sept.-Oct. 2013), [http://www.nationalmagazine.ca/Articles/Sept-Oct-2013/The-\\$500-million-doctrine.aspx](http://www.nationalmagazine.ca/Articles/Sept-Oct-2013/The-$500-million-doctrine.aspx) (“These lawyers should know better than to raise a completely vacuous case. If they raise an argument, they should have enough respect for the courts to offer them something that isn’t so vacuous and misleading.”) (C-540).

¹⁸⁶ See, e.g., Richard Gold, Comment on Post, IPWatchdog.com (11 June 2014), <http://www.ipwatchdog.com/2014/06/11/a-nafta-challenge-to-canadas-patent-utility-doctrine-is-necessary/id=49994/> (“It is unfortunate that Mr. McDermid is so misinformed about Canadian patent law If you are interested in what the law actually is, rather than the opinion of someone who has no demonstrated knowledge of Canadian patent law or of international patent law, then read [Professor Gold’s own article on the promise of the patent].”) (C-541); @IP Policy, Extracted Tweets, 12 December 2012 (reflecting that Professor Gold tried, unsuccessfully, to have a law journal withdraw an article on the promise doctrine with which he disagreed) (C-539).

what a moderator described as “intellectual dishonest[y]” regarding the promise utility doctrine.¹⁸⁷ Simply put, Professor Gold lacks an objective perspective on this case.

75. The CIPP/CIPPIC Submission Is Compromised by Its Unsubstantiated Attack on Lilly’s Statistics. Professor Gold’s partisan approach to this arbitration is illustrated by CIPP/CIPPIC’s attack on the statistical testimony of Professor Bruce Levin. Without a single citation to the record, without any disclosed expertise in statistics, and without any suggestion that CIPP/CIPPIC has spent any effort reviewing the 920-entry appendix of raw data standing behind Professor Levin’s statistical conclusions, CIPP/CIPPIC assert the following:

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.” No pharmaceutical company would engage in these same statistical games with respect to its regulatory filings.¹⁸⁸

This is one of many assertions in the CIPP/CIPPIC submission that are not only offered without any support, but are also simply incorrect.¹⁸⁹

76. CIPP/CIPPIC Do Not Support Their Proposition that Patents Are “Conditional” Property Rights. CIPP/CIPPIC submit that “Claimant’s argument that once a patent office issues a patent, that patent is ‘unconditional property’ faces insurmountable historical barriers.”¹⁹⁰ In support of this assertion, CIPP/CIPPIC discuss: the use of letters patent in “the late 16th century”; the drafting history of the U.S. Constitution; the historical relationship between the U.S. and Canadian patent acts

¹⁸⁷ Gene Quinn, Comment on Post, IPWatchdog.com (12 June 2014), <http://www.ipwatchdog.com/2014/06/11/a-nafta-challenge-to-canadas-patent-utility-doctrine-is-necessary/id=49994/> (C-541).

¹⁸⁸ CIPP/CIPPIC at ¶ 28.

¹⁸⁹ Professor Levin “requested and received,” and performed statistical analyses on, a data set compiled pursuant to a single, pre-determined methodology. See Expert Report of Bruce Levin at ¶¶ 4-5. This data set is attached in full as Appendix C to his report.

¹⁹⁰ CIPP/CIPPIC at ¶ 11.

in the late 1700s and early 1800s; and the etymology of the word “impeach.”¹⁹¹ The extended discussion of these irrelevant authorities¹⁹² puts in sharp relief the complete absence of actual support for CIPP/CIPPIC’s core argument: that granted patents do not convey immediate property rights, but rather are “conditional upon the determination of validity by a court of competent jurisdiction.”¹⁹³

77. Not only do CIPP/CIPPIC cite no authority for this assertion,¹⁹⁴ their submission also does not address Lilly’s evidence that patent rights are clearly property rights under Canadian law, immediately upon issuance.¹⁹⁵ Nor do CIPP/CIPPIC explain why, if patents are not in fact enforceable property rights immediately upon

¹⁹¹ *Id.* at ¶¶ 5-13.

¹⁹² The letters patent issued by Queen Elizabeth I and King James I at the turn of the Seventeenth Century were not limited to patents for inventions, but rather were “[l]etters patent (open letters) issued under the Great Seal [that] cover[ed] a huge diversity of subjects, including grants of official positions, lands, commissions, privileges and pardons.” National Archives of the United Kingdom, Royal Grants in Letters Patent and Charters from 1199, <http://www.nationalarchives.gov.uk/help-with-your-research/research-guides/royal-grants-letters-patent-charters-from-1199/#4-what-are-letters-patent> (C-542). It should go without saying that Thomas Jefferson was *not* focused on intellectual property law in calling for a Bill of Rights to the U.S. Constitution — the passage of the Jefferson letter quoted by CIPP/CIPPIC reads, in full context, as follows: “I will now add what I do not like [about the draft U.S. Constitution]. First the omission of a bill of rights providing clearly & without the aid of sophisms for freedom of religion, freedom of the press, protection against standing armies, restriction against monopolies, the eternal & unremitting force of the habeas corpus laws, and trials by jury in all matters of fact triable by the laws of the land & not by the law of nations.” Letter from Thomas Jefferson to James Madison (December 20, 1787) (C-519). And the common historical origins of Canadian and U.S. patent law do not avail CIPP/CIPPIC’s position: under the U.S. “model[,]” patents clearly are “intellectual property rights that qualify as investments” and are “protected from expropriation” under NAFTA. *See* U.S. Art. 1128 Submission at ¶ 27.

¹⁹³ CIPP/CIPPIC at ¶¶ 11-13.

¹⁹⁴ CIPP/CIPPIC cite to a U.S. case holding that Federal courts in the United States do not accord deference to prior determinations of the U.S. Patent Office, but rather review those determinations afresh. *Id.* at ¶ 8. They suggest that this point of procedure calls into question a patent holder’s ability to rely on the grant of a patent. In fact, patents are — as a matter of statute — “presumed valid” in the U.S. 35 U.S.C. § 282. In any event, as noted above, the U.S. government has confirmed that, “[p]atents properly granted in accordance with domestic law . . . qualify as investments . . . [and] are protected from expropriation.” U.S. Art. 1128 Submission at ¶ 27.

¹⁹⁵ *See* Cl. Reply at ¶¶ 35-44 (showing that Lilly’s patents “accorded Lilly each of the powers and benefits normally accruing to an owner of property: those of use and exclusion, benefit, and encumbrance and transfer” and that these powers and benefits were effective “immediately upon issuance”).

issuance, intellectual property and other intangible property rights are protected by NAFTA¹⁹⁶ and by many other investment treaties, including recent treaties signed by Canada.¹⁹⁷ These treaties do not refer to “judicially confirmed intellectual property” or otherwise suggest that granted intellectual property should be treated differently from intellectual property that has survived litigation.

78. CIPP/CIPPIC Do Not Address Lilly’s Extensive Evidence of a Common Baseline Understanding of Utility. In its submissions, Lilly demonstrated that NAFTA “Article 1709(1) embodies a baseline obligation to make patents available for inventions that meet the Treaty’s ‘capable of industrial application’ requirement” and that “[t]his commonly understood criterion is consistent with Canada’s traditional “mere scintilla” utility standard.”¹⁹⁸ CIPP/CIPPIC take issue with this position, suggesting that Lilly “never actually describes [the] baseline [standard of utility] or how to derive it,” and that Lilly has provided “no evidence that would suggest” that NAFTA incorporates such a baseline.¹⁹⁹

79. To the contrary, Lilly showed in its Memorial, and further explained in its Reply, that “during the negotiation of NAFTA (and also today, at least outside Canada) utility was understood by all three NAFTA Parties simply to require that an invention have the capacity to be put to a specific, industrial use.”²⁰⁰ This interpretation is supported by the evidence of: a Canadian law professor whose articles have been cited by more than twenty distinct Canadian judicial decisions (Professor Norman Siebrasse);

¹⁹⁶ See NAFTA Art. 1139(g); see also U.S. Art. 1128 Submission at ¶¶ 26-27 (noting that “the first step in any expropriation analysis must begin with an examination of whether there is an investment” and concluding that “patents properly granted in accordance with domestic law are intellectual property rights that qualify as investments under Article 1139(g)”).

¹⁹⁷ See Trans-Pacific Partnership Art. 9.1 (defining “investment” to include “intellectual property rights”) (CL-198).

¹⁹⁸ Cl. Reply at ¶ 19.

¹⁹⁹ CIPP/CIPPIC at ¶¶ 14, 24. Like Canada, CIPP/CIPPIC make much of the fact that NAFTA uses both the language of “industrial application” and the language of “utility.” *Id.* at ¶¶ 20-23. It is express in NAFTA that the terms are interchangeable, and the ordinary and technical meanings of those terms are consistent and “lead to the same practical outcomes.” See Cl. Reply at ¶¶ 59-68.

²⁰⁰ Cl. Reply at ¶ 260.

a former acting Chair of Canada’s Patent Appeal Board and 35-year veteran of the Canadian Patent Office (Mr. Murray Wilson); a Professor of Law at the University of California, Berkeley, and co-author of the most widely adopted patent law casebook in U.S. law schools (Professor Robert Merges); a retired Deputy Commissioner of the United States Patent and Trademark Office (Mr. Stephen Kunin); two former senior members of Mexico’s intellectual property office (Ms. Gilda Gonzalez and Mr. Fabian Salazar); and a former Senior Director-Advisor of the World Intellectual Property Organization (Mr. Philip Thomas). It is supported also by thirty pages of Vienna Convention analysis in Lilly’s merits briefs.²⁰¹ CIPP/CIPPIC do not address any of this.

80. CIPP/CIPPIC Discussion of the Traditional “Mere Scintilla” Test for Utility Conflicts with the Submissions of Both Parties to this Arbitration. As Lilly has already made clear, the common understanding of utility among NAFTA states was reflected in Canada’s traditional “mere scintilla” test, which remains the principal test for utility in Canada today (the promise utility doctrine sits on top of this “mere scintilla” test).²⁰² CIPP/CIPPIC argue that the “mere scintilla” test does not actually exist under Canadian law. More specifically, they assert that “‘mere scintilla’ is not and has never been the utility standard in Canada or anywhere else.”²⁰³ But in this they are contradicted by the plain language of dozens of Canadian judicial opinions, not to mention the expert opinions of both Claimant’s expert, Professor Siebrasse,²⁰⁴ and Respondent’s expert, Mr. Dimock, who writes:

The standard of utility required is a contextual consideration dependent on the disclosure of the patent and particularly on whether it is silent about utility or whether it promises a result or certain level of utility. In the former case, the invention simply needs to have a “mere scintilla” of utility.²⁰⁵

²⁰¹ Cl. Mem. at pp. 84-97; Cl. Reply at pp. 128-144.

²⁰² Cl. Reply at ¶ 260.

²⁰³ CIPP/CIPPIC at ¶ 17.

²⁰⁴ Second Expert Report of Norman Siebrasse at ¶ 13.

²⁰⁵ First Expert Report of Ronald Dimock at ¶ 58; see Second Expert Report of Ronald Dimock at ¶ 10 (“I agree that the law currently recognizes a contextual utility standard with a ‘mere scintilla’ branch and a (continued…)”).

81. CIPP/CIPPIC argue also that the “mere scintilla” test cannot reflect the baseline understanding of utility in NAFTA because “the utility/industrial application requirements in each of the United States and Mexico greatly surpass it.”²⁰⁶ Again, this does not appear to be Canada’s view. As stated by Canada’s expert, Professor Daniel Gervais:

As Professor Holbrook, and Claimant’s experts Mr. Kunin and Mr. Merges, agree in their respective reports, the utility requirement in the U.S. is notoriously low As a result, in my opinion it is difficult to conceive of a utility standard lower than the current U.S. standard.²⁰⁷

82. CIPP/CIPPIC Fail to Confront the Plain Language of NAFTA. CIPP/CIPPIC argue that “trade law focuses on the overall effect of domestic laws, not individual patent rules”:

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.

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, prepackaged 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.²⁰⁸

83. CIPP/CIPPIC again offer no authority for their position. NAFTA Chapter 17 is part of a treaty, like any other, and must be interpreted consistent with the Vienna

‘promise’ branch”); Resp. Rejoinder at ¶ 23 (“If the patent makes no promises, then a mere scintilla of utility suffices.”).

²⁰⁶ CIPP/CIPPIC at ¶ 19.

²⁰⁷ See Second Expert Report of Daniel Gervais at ¶ 6; see Second Report of Timothy Holbrook at ¶ 8 (“Professor Merges, Mr. Kunin, and I all agree that, speaking generally and without regard to particular technologies, the utility requirement in the United States is low. The record is replete with cases and commentary, including my own, recognizing that fact.”).

²⁰⁸ CIPP/CIPPIC at ¶¶ 30-31.

Convention on the Law of Treaties (VCLT). CIPP/CIPPIC's generalized assertion about the goals of trade law cannot substitute for the detailed VCLT analysis offered by Claimant,²⁰⁹ nor can it take precedence over the actual language of NAFTA Article 1709 – which refers specifically to the novelty, obviousness and utility requirements of patentability.²¹⁰

84. CIPP/CIPPIC's remaining arguments have already been addressed in Lilly's papers.²¹¹

²⁰⁹ Cl. Reply at ¶¶ 262-289.

²¹⁰ NAFTA Art. 1709 (“Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms ‘inventive step’ and ‘capable of industrial application’ to be synonymous with the terms ‘non-obvious’ and ‘useful’, respectively.”)

²¹¹ CIPP/CIPPIC argue that Canada's promise utility doctrine is aligned with U.S. enablement rules and Mexican sufficiency rules (¶¶ 38-42); Lilly has shown that distinct requirements of patentability cannot so easily be conflated. Cl. Reply at § II.C. CIPP/CIPPIC argue that Canadian law has not changed (*see* ¶ 26); Lilly has demonstrated the sea change in Canadian law at length in its Memorial and Reply. *See* Cl. Reply at §§ II.A-B.

III. Conclusion

85. For the foregoing reasons, following the submissions of the non-disputing NAFTA Parties and other non-disputing parties, the record continues to compel the conclusion that Lilly is entitled to the relief requested in its Memorial.

Respectfully submitted,

[signed]

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