

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 OPPOSITION TO RESPONDENT'S
JURISDICTIONAL OBJECTION OF 8 DECEMBER 2015**

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22 January 2016

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INTRODUCTION

1. After expressly declining to object to the Tribunal's jurisdiction in this arbitration, Canada has inexplicably raised a jurisdictional objection for the first time in its Rejoinder. The substance of the objection is as peculiar as its timing: Canada objects to the Tribunal's jurisdiction *rationae temporis* under NAFTA Articles 1116(2) and 1117(2), but its objection is based not on the Zyprexa and Strattera patents at issue in this case, but on a distinct and entirely unrelated investment that is not at issue in this arbitration.

2. Canada's volte-face comes too late. As the UNCITRAL Rules state plainly, at Article 21(3): "A plea that the arbitral tribunal does not have jurisdiction shall be raised not later than in the statement of defence." UNCITRAL Article 21(3), by its terms, does not permit consideration of Canada's belated objection. *Infra* Part I.A.

3. Canada seeks to evade this rule, resting its new defense on an allegation that Lilly changed the substance of its claims between its September 2014 Memorial and its September 2015 Reply. The premise of Canada's objection is false. Lilly has consistently sought redress under NAFTA Chapter 11 for the revocation of two specific investments in Canada: its patents for Zyprexa and Strattera. And, consistently, Lilly has maintained that it is entitled to a remedy under NAFTA Chapter 11 because its patents were invalidated through the application of Canada's arbitrary and discriminatory promise utility doctrine. Accordingly, Canada's proposed justification for its untimely jurisdictional objection is simply not credible. *Infra* Part I.B.

4. Even if Canada's objection were properly before this Tribunal (which it is not), it would have to be rejected on both the facts and the law. On the facts, Canada's objection is grounded in a misstatement of Lilly's claims. As presented, Lilly's claims for the expropriation of, and denial of fair and equitable treatment to, its investments are grounded squarely in final judicial decisions revoking the Strattera and Zyprexa patents, not in the prior conduct of the Canadian courts. Lilly brought its claim within three years of these revocations. *Infra* Part II.A.

5. On the law, earlier decisions of the Canadian judiciary regarding legally distinct and unrelated patents provide important factual context illustrating the extent to which Canada's promise utility doctrine is arbitrary, discriminatory, and inconsistent with international law – and thus demonstrate the wrongfulness of Canada's treatment of the Zyprexa and Strattera investments at issue here. Multiple NAFTA awards make clear Lilly's right to rely on earlier decisions for this purpose. *Infra* Part II.B.

6. Plainly put, the mere fact that Lilly undertook to provide the Tribunal with the factual background and context necessary to understand Lilly's claims does not alter the substance of those claims. Nor does it place those claims outside the three-year limitation period contained in NAFTA Articles 1116(2) and 1117(2). As a result, Canada's belated jurisdictional objection *rationae temporis*, if considered at all, should be rejected in its entirety.

I. CANADA'S JURISDICTIONAL OBJECTION IS UNTIMELY AND SHOULD NOT BE ENTERTAINED.

A. Canada's Objection Is Untimely and Prejudicial.

7. Objections based on NAFTA Articles 1116(2) and 1117(2) are "plea[s] that the arbitral tribunal does not have jurisdiction" within the meaning of the UNCITRAL Rules.¹ Accordingly, under Article 21(3) of the UNCITRAL Rules, Canada was required to raise any and all objections to the Tribunal's jurisdiction *rationae temporis* no later than in its Statement of Defence.² Tribunals have often recognized that delayed

¹ UNCITRAL Rules (1976), Art. 21(3) ("A plea that the arbitral tribunal does not have jurisdiction shall be raised not later than in the statement of defence or, with respect to a counter-claim, in the reply to the counter-claim.").

² *Id.*; see also, e.g., *Merrill & Ring Forestry L.P. v. Canada*, NAFTA/UNCITRAL, Investor's Observations on Preliminary Objections (9 Nov. 2007), at ¶¶ 1-2 (time limitation objection under Article 1116(2) raised in Canada's Statement of Defence) (CL-167); *Pope & Talbot Inc. v. Canada*, NAFTA/UNCITRAL, Award in Relation to Preliminary Motion, (24 Feb. 2000), at ¶¶ 1-2 (time limitation objection raised in preliminary motion to strike paragraphs from Statement of Claim) (CL-168); *Glamis Gold, Ltd. v. United States*, NAFTA/UNCITRAL, Award (8 June 2009), at ¶¶ 194-95 [hereinafter *Glamis Gold*] (time limitation objection raised in Request for Bifurcation submitted the same day as Statement of Defence) (CL-116); *Grand River Enters. Six Nations, Ltd. v. United States*, NAFTA/UNCITRAL, Decision on Objections to Jurisdiction (20 July 2006), at ¶¶ 26-27 [hereinafter *Grand River (Jurisdiction)*] (time limitation objection under Articles 1116 and 1117 filed with Statement of Defence) (CL-169).

jurisdictional objections are procedurally improper and should not be considered.³ Despite these clear rules, the Tribunal is now faced with a jurisdictional objection raised for the first time in Canada's Rejoinder of 8 December 2015 – a submission filed over 18 months after Canada's Statement of Defence.⁴

8. Nothing foreshadowed this objection. At the Procedural Hearing held on 10 May 2014, Canada expressly stated that it was not challenging the competence of this Tribunal to hear this case.⁵ In its Statement of Defence, Canada reiterated that the Tribunal had jurisdiction "in this matter" regarding "alleged breaches of NAFTA Chapter Eleven Obligations."⁶ And, in its Counter-Memorial, Canada explicitly stated that it "is not seeking dismissal of the claim on the basis of lack of jurisdiction."⁷

9. Canada's jurisdictional objection is not only belated but also prejudicial. UNCITRAL Article 21(3) is grounded in notions of due process and fundamental fairness.⁸ In withholding its objection until after Lilly filed its final merits submissions,

³ See *European American Investment Bank AG v. Slovak Republic*, UNCITRAL, PCA Case No. 2010-17, Second Award on Jurisdiction (4 June 2014), at ¶¶ 118, 130 (rejecting certain jurisdictional objections under Rule 21(3) where respondent delayed six months before raising them without good cause) (CL-170); *Oostergetel et al. v. Slovak Republic*, UNCITRAL, Final Award (23 April 2012), at ¶ 137 ("Under Article[] . . . 21(3) UNCITRAL Rules (1976), objections to jurisdiction must be raised prior to defenses on the merits. Hence, this objection is belated.") (CL-171); *CME Czech Republic B.V. v. Czech Republic*, UNCITRAL, Partial Award (13 Sept. 2001), at ¶¶ 379-80 (holding that jurisdictional objections must be made in Statement of Defense and that "a Tribunal is not able to set aside or disregard a Party's waiver in respect to the defence of lack of jurisdiction.") (CL-172).

⁴ Respondent's Rejoinder ("Resp. Rejoinder"), at ¶¶ 63-103; compare *Chevron Research Co. v. National Iranian Oil Co.*, Case No. 19, 1 Iran-U.S.C.T.R. 334, 334 (19 Nov. 1982) (rejecting jurisdictional objections as untimely under Article 21(3) when respondent delayed "almost eight months" after its Statement of Defence without "any evidence or reason being given") (CL-173).

⁵ See Recording of First Procedural Hearing (10 May 2014), at 3:13-3:15 ("We are not, as I said, challenging the basic competence of this Tribunal to hear this matter inasmuch as we are within the four corners of having a U.S. plaintiff-claimant with investments in Canada alleging damages flowing from a measure attributable to the Government of Canada.").

⁶ See Respondent's Statement of Defence at ¶ 83 (accepting the Tribunal's jurisdiction regarding alleged NAFTA Chapter Eleven breaches).

⁷ See Respondent's Counter-Memorial ("Resp. CM") at ¶ 209 (stating that "Canada is not seeking dismissal of the claim on the basis of lack of jurisdiction").

⁸ See *Bureau Veritas, Inspection, Valuation, Assessment and Control, BIVAC B.V. v. Republic of Paraguay*, ICSID Case No. ARB/07/9, Decision on Jurisdiction (29 May 2009), at ¶ 52 [hereinafter *Bureau Veritas*] (rejecting (continued...))

Canada expressly sought to preclude Lilly from submitting any response whatsoever.⁹ Further, Canada has created the need for additional briefing after final submissions already were made in this case, thereby increasing arbitration costs and compromising procedural efficiency. Moreover, the parties have already spent over a year of their time and expense briefing the merits – only to find that Canada, suddenly, has come to the view that Lilly’s claims are time barred.

10. Cognizant of the need for orderly, predictable, and efficient proceedings, tribunals have consistently rejected twilight jurisdictional objections of the type Canada has raised. For example, in *Bureau Veritas v. Paraguay*, the respondent attempted, for the first time, to raise a jurisdictional objection relating to standing three weeks after the jurisdictional hearing took place.¹⁰ Citing extensively from its governing procedural order, the tribunal declined to consider the merits of respondent’s belated objection, finding it “would not be consistent with principles of due process and procedural economy”¹¹

11. Even where a party attempts to reserve its right to object at a later date, tribunals have refused to override UNCITRAL Article 21(3). In *Canfor v. United States*, the respondent attempted to reserve its right to raise jurisdictional objections on particular issues until after the filing of its Statement of Defence.¹² This request was

Paraguay’s delayed jurisdictional objection as “not [] consistent with principles of due process and procedural economy . . . when both parties had already agreed to an orderly procedural schedule, and where the parties had had ample opportunities to present their arguments”) (CL-174); *see also* UNCITRAL Rules (1976), Art. 20 (“[E]ither party may amend or supplement his claim or defence unless the arbitral tribunal considers it inappropriate to allow such amendment *having regard to the delay in making it or prejudice to the other party* or any other circumstances.”) (emphasis added).

⁹ *See* Letter of Mr. Shane Spelliscy to Ms. Marney Cheek of 18 Dec. 2015, at 2 (“[Lilly] has no right to file any additional written submissions.”); *see also* Letter of Mr. Shane Spelliscy to Ms. Marney Cheek of 8 Jan. 2016, at 2 (“[I]n the interests of avoiding a disruptive procedural dispute, Canada does not object to Claimant submitting a response to Canada’s jurisdictional arguments by January 22, 2016, provided that Canada is allowed a written response.”).

¹⁰ *See Bureau Veritas*, at ¶ 52 (CL-174).

¹¹ *Id.*

¹² *Canfor Corporation v. United States*, UNCITRAL, Decision on the Place of Arbitration, Filing a Statement of Defence and Bifurcation of the Proceedings (23 Jan. 2004), at ¶ 48 (CL-175).

promptly denied. Notwithstanding the “strategic advantage” the respondent gained from delaying its jurisdictional objections, the tribunal made clear that it shared Canfor’s “legitimate concern” that “all jurisdictional issues that the [respondent] intends to raise [be] articulated” without delay.¹³

12. In this proceeding, the Tribunal’s First Procedural Order reflects a similar concern regarding procedural fairness and the orderly conduct of proceedings.¹⁴ It requires, at Article 10.2, that the parties “include with their Reply and Rejoinder submissions only evidence responding to or rebutting matters raised by the other Disputing Party’s immediately preceding written submission” or by documents produced following that submission.¹⁵ As explained below, Canada’s assertion that Lilly changed the substance of its claim in its Reply is simply untrue. Therefore, Canada’s belated jurisdictional objection is not responsive to Lilly’s Reply – and thus conflicts with the plain language of the Tribunal’s Order.

13. Notably, Canada has not explained why the Tribunal should ignore UNCITRAL’s explicit requirement in order to entertain Canada’s untimely jurisdictional objection. Indeed, Canada’s Rejoinder does not even acknowledge or mention UNCITRAL Article 21(3), let alone attempt to justify a decision not to apply its straightforward terms.¹⁶

B. Canada’s Sole Justification for Delay – That Lilly Allegedly Changed its Claim – is Directly Contradicted by the Record Before the Tribunal.

14. Rather than engage UNCITRAL Article 21(3), Canada alleges that Lilly “shift[ed] its focus” or “recast” its claims between its opening Memorial and its Reply, thereby excusing Canada’s untimely jurisdictional objection.¹⁷ This is pure fiction. As shown below, both of Lilly’s submissions make precisely the same claim: that Canada

¹³ *Id.*

¹⁴ See Procedural Order No. 1, Art. 10.2.

¹⁵ *Id.*

¹⁶ See Resp. Rejoinder at Part III.

¹⁷ See Resp. Rejoinder at ¶¶ 63, 91.

violated its obligations under NAFTA by revoking Lilly's Zyprexa and Strattera patents. Canada's procedural gambit must, accordingly, be rejected.

15. Canada marshals no genuine support for a contrary result. Instead, Canada selectively cites and mischaracterizes Lilly's objections to Canada's Document Request No. 1 and certain statements in Lilly's Reply in an attempt to show that Lilly's claims have changed. In particular, Canada insists that Lilly is no longer challenging the "the specific Canadian court decisions that invalidated its patents for olanzapine and atomoxetine," but, instead, "has now recast its complaint to focus . . . on the law itself, that is, the judicial interpretation of the word 'useful' in Canada's *Patent Act* between 2002 and 2008."¹⁸ Canada's bid to rewrite Lilly's claims does not withstand scrutiny, as described below.

16. *First*, Canada relies prominently on a quote from Canada's *Redfern* schedule submitted during the document production phase of the case, which Canada alleges shows that Lilly "began to reorient its claims."¹⁹ In the first instance, a *Redfern* schedule does not trump Lilly's substantive submissions in this proceeding. But even if the *Redfern* schedule was relevant, it does not support Canada's argument that Lilly is now challenging the promise utility doctrine independent of its application to the Zyprexa and Strattera patents.

17. According to Canada:

[I]n its objections to Canada's document requests, Claimant alleged that the "measure" it was actually challenging in these NAFTA proceedings was as follows:

The measure at issue in this proceeding is Canada's development of a new utility doctrine (the promise utility doctrine), and its retroactive application of that doctrine to invalidate Claimant's '113 and '735 Patents. Both of

¹⁸ *Id.* at ¶ 63.

¹⁹ *Id.* at ¶ 85 (quoting Lilly's objection to Canada's Document Request No. 1 without clarifying that the substance of Lilly's objection to the request was expressly that the request did not adequately "relate to Claimant's expectation that the [Strattera] Patent satisfied the utility requirement under Canadian law").

those patents were invalidated by the Federal Court on a single ground: inutility.²⁰

One need only continue reading the sentence beyond the phrase underlined by Canada to see that Lilly's challenge is not to the promise doctrine itself, but to Canada's "retroactive application of that doctrine to invalidate Claimant's '113 and '735 Patents."²¹

18. *Second*, with respect to Lilly's Reply, Canada alleges that Lilly "definitively moved away from its previous claims with respect to the specific court decisions invalidating its atomoxetine and olanzapine patents."²² This allegation fares no better than the first.

19. Canada's only citations to the Reply evidencing an alleged "shift in focus" merely point to Lilly's description of the core elements of the promise utility doctrine.²³ In particular, Canada argues that Lilly's Reply contains new allegations relating to the promise utility doctrine's heightened evidentiary burden, promise construal, and disclosure rule.²⁴ However, these same three elements of the promise utility doctrine – which constitute critical factual background – were all discussed at length in each of Lilly's previous submissions in the very same context.

20. For example, in its Memorial, Lilly raised the promise utility doctrine's "heightened evidentiary burden" as a "core element" of the doctrine.²⁵ Lilly also explained that promise construal, another element of the promise utility doctrine, requires "the Federal Courts [to] scour the patent's disclosure to construe any and all 'promises.'"²⁶ Lilly's Memorial further described the promise utility doctrine's

²⁰ *Id.* (quoting Procedural Order No. 2 - Annex B, p. 2) (emphasis in original).

²¹ *Id.* (quoting Procedural Order No. 2 - Annex B, p. 2) (emphasis added).

²² *Id.* at ¶ 87.

²³ *Id.* at ¶¶ 87-91 (citing Cl. Reply at ¶¶ 48, 70, 72-73, 92-93, 104, 173, 211).

²⁴ *Id.* at ¶ 87 (asserting that "Claimant *now* challenges three aspects of Canadian law") (emphasis added).

²⁵ See Cl. Mem. at ¶ 66 ("The second core element of the promise utility doctrine is a heightened evidentiary burden.").

²⁶ *Id.* at ¶ 209.

disclosure obligations as “requir[ing] that evidence in support of a sound prediction of utility must have been disclosed in the patent application itself.”²⁷ Each of these three core elements of the promise utility doctrine received many paragraphs of briefing in Lilly’s Memorial.²⁸

21. Lilly’s 2013 Statement of Claim²⁹ also emphasized the promise utility doctrine’s “heightened evidentiary standard for proof of utility, which requires that the promised utility either be ‘demonstrated’ or be based on a ‘sound prediction’ of utility as of the date the patent application was filed,” and highlighted the “arbitrary and unpredictable approach whereby a judge subjectively construes the ‘promise of the patent’ from the patent specification.”³⁰ It is thus impossible to credit Canada’s assertion that “Claimant’s Reply contained a surprising reformulation of the measures it is challenging,”³¹ given that Lilly – from this proceeding’s inception – identified these very same core elements of Canada’s utility doctrine when describing the additional, more burdensome utility requirement applied to Lilly’s Strattera and Zyprexa patents.

22. *Third*, rather than accepting Lilly’s statements of its legal claims (*see infra* ¶¶ 25-27), Canada also rests its jurisdictional objection in part on Canada’s own theory of the case with regard to denial of justice. Specifically, Canada asserts that “[i]n its Reply, Claimant expressly admits that it has no grounds to allege a denial of justice[.]”³² Lilly did not “admit” that it has no denial of justice claim. Lilly simply stated a fact: that its claims of expropriation and denial of fair and equitable treatment are not premised on a denial of justice. To repeat a point Lilly raised in its Reply, Canada may prefer to defend a denial of justice case, but that is not the case Lilly has brought.

²⁷ *Id.* at ¶ 269.

²⁸ *See id.* at ¶¶ 56-75.

²⁹ Pursuant to Procedural Order No. 1, Lilly’s Notice of Arbitration of 12 September 2013 was designated as its Statement of Claim. *See* Procedural Order No. 1, Art. 10.1.

³⁰ *See* Notice of Arbitration (September 12, 2013), at ¶ 10.

³¹ *See* Resp. Rejoinder at ¶ 63 (“Claimant’s Reply contained a surprising reformulation of the measures it is challenging”).

³² *Id.* at ¶¶ 63, 87.

23. Canada supports its misconstrual of Lilly's position by citing three isolated paragraphs from the Introduction to Lilly's Reply and one footnote. The first paragraph Canada cites highlights the arbitrary application of the promise utility doctrine by the Federal Courts in Canada:

13. *The "standard process of adjudication" fallacy.* Canada denies that the promise utility doctrine is arbitrary in its application. Rather, Canada asserts, the Federal Courts are simply engaged in the standard process of adjudication, including by applying settled rules of construction and weighing evidence with the assistance of expert testimony. This might be a relevant response if Lilly were claiming a lack of procedural fairness, but it is not. Canada has put forward no explanation for the dramatic change in litigation outcomes since the advent of the promise utility doctrine, including the substantial increase in findings of inutility and a string of facially inconsistent rulings.

The second paragraph explains that Lilly's expropriation claim rests on the Canadian judiciary's substantive violations of international law:

17. Central to Canada's legal argument is the notion that because the Zyprexa and Strattera patents were revoked by the Canadian courts, the only way Lilly can prevail is by proving a procedural "denial of justice." Canada then proceeds to litigate a denial of justice claim by reciting – at length – the procedural history of the Zyprexa and Strattera cases. This may be the case that Canada prefers to defend, but it is not the case that Lilly has brought. Lilly's claims do not rest on denial of justice, but rather on a completely separate and equally well-established basis for liability: the Canadian judiciary's *substantive* violations of international law.

The third paragraph is the conclusion to Lilly's Introduction, which notes that Lilly is asking the Tribunal to review the revocations of Lilly's Zyprexa and Strattera patents under international law:

22. Throughout its Counter-Memorial, Canada warns that Lilly is asking this Tribunal to act inappropriately as a supranational "court of *de novo* review." There is no foundation for this alarmist rhetoric in Lilly's actual submissions. Lilly is *not* seeking *de novo* review of the Zyprexa and Strattera court decisions; in fact, Lilly is not asking this Tribunal to assess *at all* whether the court decisions were correctly

decided under *Canadian* law. Rather, what Lilly seeks – and, indeed, has proven – is a finding that Canada’s measures violate its commitments under *international* law, and that those violations engage Canada’s obligations under Chapter 11 to provide full reparations.

Finally, the footnote cited by Canada merely reiterates that Lilly’s claims focus on substantive law violations:

⁴³³ As discussed *infra* Part V.A, Lilly’s claims under Article 1110 and 1105 do not rest on the argument that Canada’s measures constituted a procedural “denial of justice.” Rather, Canada’s measures violate Article 1110 and 1105 because they are *substantively* arbitrary, discriminatory, and in violation of Canada’s obligations in NAFTA Chapter 17 and Lilly’s legitimate expectations.

24. In the first instance, these isolated paragraphs from Lilly’s rebuttal submission do not provide a complete summary of Lilly’s claims in this case. In any event, these paragraphs nowhere concede that Lilly lacks grounds to allege a denial of justice. Nor did Lilly disclaim a previous denial of justice allegation. Rather, Lilly merely reiterated that notwithstanding Canada’s preference to defend against a denial of justice claim, Lilly’s submissions have never included such a claim. That said, the simple fact that Lilly is challenging Canada’s measures based on a legal theory other than denial of justice in no way implies that Lilly is not challenging the revocations that resulted from the application of Canada’s promise utility doctrine to the Strattera and Zyprexa patents. Canada’s syllogism fails.

25. The record before the Tribunal is clear. Lilly’s claims have not changed, and nothing justifies Canada’s extreme delay in raising a jurisdictional objection for the first time in its final pleading in this case. As summarized in the Introduction to its Memorial and as reiterated throughout this arbitration, including in its Reply, Lilly has consistently argued that:

1. The “three [core] features of the promise utility doctrine,” summarized *supra* at ¶¶ 19-21, “operated together to deprive Lilly of its investments in the Zyprexa and Strattera patents in

contravention of Canada's obligations to protect investments under NAFTA Chapter 11."³³

2. Accordingly, "Canada's measures in respect of the Zyprexa and Strattera patents give rise to two cognizable claims under Chapter 11 that are within the competence of this Tribunal."³⁴

26. As movant, Canada has the burden of proving that Lilly's claims have changed, and it has not met that burden. No new theory of the case was presented in Lilly's Reply. Instead, Lilly made clear that the "protected investments at issue in this arbitration are *the Zyprexa and Strattera patents*,"³⁵ that the "the very measures" being challenged are "the revocation of Lilly's patents under the promise utility doctrine,"³⁶ and that "Lilly is challenging the decisions of the Canadian courts that applied the promise utility doctrine *to invalidate Lilly's patents*."³⁷

27. At no point in Lilly's Reply is the promise utility doctrine presented as a standalone basis for Lilly's claims. The two headings of the Reply's legal section are unambiguous in this regard:

IV. CANADA'S REVOCATION OF THE ZYPREXA AND STRATTERA PATENTS CONSTITUTED A WRONGFUL EXPROPRIATION UNDER ARTICLE 1110.

V. CANADA'S CONDUCT IN REVOKING THE ZYPREXA AND STRATTERA PATENTS FAILED TO MEET THE STANDARD OF FAIR AND EQUITABLE TREATMENT GUARANTEED IN NAFTA ARTICLE 1105(1).

28. In the *factual background* section of its Reply, Lilly set out the content and operation of the promise utility doctrine for two principal reasons: (i) to provide factual context for the invalidations of Lilly's Zyprexa and Strattera patents, demonstrating that

³³ Cl. Mem. at ¶ 10; *see also* Cl. Reply at ¶¶ 70–115.

³⁴ Cl. Mem. at ¶ 13; *see also* Reply at ¶¶ 238, 260, 314, 316, 370.

³⁵ Cl. Reply at ¶ 314 (emphasis in original).

³⁶ *Id.* at ¶ 227.

³⁷ *Id.* at ¶ 251 (original emphasis omitted and emphasis added).

those invalidations occurred through the application of an arbitrary, discriminatory, and internationally non-compliant utility test; and (ii) to respond directly to assertions by Canada in its Counter-Memorial regarding the purportedly “long-standing” nature of the promise utility doctrine applied to Lilly’s patents.³⁸

29. In other words, the discussion Canada has highlighted in Lilly’s Reply as “new” was directly responsive to Canada’s Counter-Memorial and presented factual issues related to Lilly’s claims. For example, Canada argued in its Counter-Memorial that its utility requirement had remained constant over decades. Lilly presented ample evidence to the contrary in its Reply, focusing on the significant changes in the utility doctrine since the early 2000s and explaining how Canada has moved beyond its mere scintilla utility test in creating a new and additional utility test that was later applied to invalidate the Strattera and Zyprexa patents.³⁹ This question (*i.e.*, what the test for utility was under Canadian law when Lilly applied for the Strattera and Zyprexa patents and what it is today) is a question of fact before this Tribunal. The submission of evidence on a factual question before this Tribunal does not change Lilly’s claims.

30. Similarly, Lilly’s limited discussion of its raloxifene patent in its Reply was in direct response to Canada’s factual arguments. Even though Lilly’s claims relate solely to its Strattera and Zyprexa patents, Canada’s Counter-Memorial (and the accompanying witness statement of Marcel Brisebois) contained extensive discussion of Lilly’s raloxifene compound.⁴⁰ Canada’s focus on Lilly’s raloxifene compound in its Counter-Memorial compelled Lilly to explain in its Reply that raloxifene “is not at issue in this case.”⁴¹

31. Canada’s own actions belie its assertion that Lilly changed its claims in these proceedings and did so in a “surprising” manner. If this were so, Canada should

³⁸ See Resp. CM at ¶¶ 81–134 (section entitled “Claimant’s Patents Were Invalidated on the Basis of Long-Standing Patent Law Rules That Are Grounded in the Patent Act and Serve Rational Policy Objectives”).

³⁹ See Cl. Reply at Part II.

⁴⁰ Resp. CM at ¶¶ 152, 160–164; Witness Statement of Marcel Brisebois at ¶¶ 47–68 and Annexes D-E.

⁴¹ Cl. Reply at ¶ 203.

have raised its objection immediately after Lilly submitted its objections to Canada's document production requests (or at the latest shortly after Lilly filed its Reply). Canada, however, did nothing for months, raising no objection. Such laches should not be rewarded. The Tribunal should adhere to UNCITRAL Article 21(3) and refuse to consider Canada's objection on the grounds that it is untimely.

II. CANADA'S JURISDICTIONAL OBJECTION FAILS AS A MATTER OF LAW.

32. If the Tribunal considers Canada's untimely jurisdictional objection, it should be rejected. Canada's objection is grounded in NAFTA Articles 1116(2) and 1117(2). Both provisions provide simply that an investor or enterprise may not make a claim "if more than three years have elapsed from the date on which the investor [or enterprise] first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the investor [or enterprise] has incurred loss or damage."⁴² Canada bears the burden of proving that Lilly's claim runs afoul of this limitation.⁴³

33. Canada has failed to meet its burden. In this arbitration, Lilly seeks relief for the expropriation and treatment of two specific investments: its Canadian patents on its Strattera and Zyprexa drugs. The final judicial decisions revoking those patents occurred in 2011 and 2013, respectively.⁴⁴ Lilly filed its Notice of Arbitration on 12 September 2013, within three years of both invalidations.

34. Canada does not contest this chronology. Instead – and in contravention of the principle that a claimant's case is defined by the *claimant's* submissions, not by

⁴² See NAFTA, Art. 1116(2); 1117(2) (CL-44).

⁴³ *Pope & Talbot Inc. v. Canada*, NAFTA/UNCITRAL, Award in Relation to Preliminary Motion (24 Feb. 2000), at ¶ 11 ("Canada's contention that the . . . claim is time barred is in the nature of an affirmative defence, and, as such, Canada has the burden of proof of showing factual predicate to that defence.") (CL-168).

⁴⁴ Canada's Supreme Court denied Lilly's leave to appeal the invalidation of its Strattera patent on 8 December 2011; the Federal Court of Appeal and Federal Court rulings issued on 5 July 2011 and 14 September 2010, respectively. Cl. Mem. at ¶¶ 139, 165. Canada's Supreme Court denied Lilly's leave to appeal the invalidation of its Zyprexa patent on 16 May 2013; the Federal Court of Appeal and Federal Court rulings issued on 10 September 2012 and 10 November 2011, respectively. Cl. Mem. at ¶¶ 112, 165.

straw men invented by the respondent – Canada’s jurisdictional objection sidesteps the invalidation of the Strattera and Zyprexa patents, and focuses instead on a third investment that is not at issue in this arbitration: Lilly’s patent on Evista (raloxifene).⁴⁵

35. Canada, however, 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).⁴⁶ Nor has Canada explained how Lilly possibly could have acquired “knowledge [of] loss or damage” to its Strattera and Zyprexa patents in 2009, more than a year before the Canadian courts issued any decision finding those patents lacked utility.⁴⁷ In any event, every NAFTA tribunal to have addressed the issue has made clear that acts occurring prior to NAFTA’s time bar – including acts that independently violate Chapter 11 – may provide necessary and vital context for the evaluation of host state actions that take place within the limitation period. Each reference to the development of the promise utility doctrine in Lilly’s submissions falls squarely within this permitted category.

A. Lilly Complied with the Three-Year Limitation Period in Articles 1116 and 1117 in Respect of the Two Investments at Issue in this Arbitration.

36. Lilly brought its claim within the three-year period prescribed by NAFTA. As Lilly has repeatedly made clear, “[t]his arbitration concerns two of Lilly’s patents that have been invalidated by the Canadian Federal Courts”: the ‘735 Patent on Strattera and the ‘113 Patent on Zyprexa.⁴⁸ After Lilly lost its appeal relating to the

⁴⁵ NAFTA itself makes clear that each patent constitutes a separate investment. *See* NAFTA, Art. 1139 (“investment means: . . . (g) real estate or other property, tangible or intangible”) (CL-44).

⁴⁶ The raloxifene litigation was in the context of a *PM(NOC)* proceeding. Canada’s reliance on this case is ironic, given its prior attempt to disavow 20 findings of inutility precisely because they arose in *PM(NOC)* proceedings, not in an infringement action. *See* Resp. CM at ¶ 148.

⁴⁷ *See* Resp. Rejoinder at ¶ 105 (asserting that Lilly “suffered a loss” on March 30, 2009, when the Minister of Health allowed Apotex to market its generic raloxifene product). As noted, the first judicial decisions invalidating the Strattera and Zyprexa patents for lack of utility were rendered on 14 September 2010 and 10 November 2011, respectively. *See supra* n.44.

⁴⁸ Cl. Mem. at ¶ 4.

validity of the Strattera patent, the Supreme Court of Canada rejected its application to appeal on 8 December 2011.⁴⁹ After Lilly lost its appeal relating to the validity of the Zyprexa patent, the Supreme Court of Canada rejected its application to appeal on 16 May 2013.⁵⁰ Lilly filed its Notice of Arbitration within three years of each of these final judgment dates.⁵¹

37. In making its belated jurisdictional objection, Canada has now elected to ignore the two investments that Lilly put at issue in this case. Instead, Canada has raised a jurisdictional objection grounded exclusively in litigation in 2008 and 2009 relating to a third and legally distinct investment, Lilly's patent on raloxifene.⁵²

38. As the *Glamis Gold* tribunal made clear, in considering a jurisdictional objection "the basis of the claim is to be determined with reference to the submissions of [the] [c]laimant."⁵³ While the raloxifene litigation was "the first case to impose a 'heightened' disclosure obligation on patentees" and is therefore a fact relevant to the development of the promise utility doctrine,⁵⁴ Lilly does not seek redress for Canada's revocation of the raloxifene patent. As explained in Part I.B, above, Lilly seeks compensation only for the legally distinct injuries it suffered in connection with the

⁴⁹ *Id.* at ¶ 139.

⁵⁰ *Id.* at ¶ 112.

⁵¹ See Cl. Notice of Arbitration (12 Sept. 2013).

⁵² See Resp. Rejoinder at ¶ 110 ("Claimant first acquired knowledge of all relevant aspects of what it calls Canada's 'promise utility doctrine' and a loss as a result of that doctrine . . . when the Supreme Court of Canada denied it leave to appeal the raloxifene decision."). Canada neglects to mention that Lilly continued to pursue its domestic remedies with respect to raloxifene. After the Supreme Court denied Lilly's application for leave in a *PM(NOC)*-related proceeding, Lilly and Apotex Inc. commenced new litigation over the validity of the patent, but eventually settled their dispute in April 2013. See, e.g., *Eli Lilly & Co. v. Apotex Inc.*, FC No. T-516-10, Docket Entry re Hearing of April 8, 2013 ("Trial Management Conference Result of Hearing: parties agree to resolve the matter, discontinuances to be filed later this week on a without costs basis.") (C-515).

⁵³ *Glamis Gold*, at ¶ 349 (emphasis added) (CL-116).

⁵⁴ Expert Report of Andrew J. Reddon at ¶ 9.

invalidation of its patents on Strattera and Zyprexa.⁵⁵ It is not open to Canada to expand or reframe Lilly's claim for its own tactical advantage.

B. Canada Has Not Cited a Single Case Applying a Time Bar to One Investment Based on Treatment of an Entirely Distinct Investment through a Legally Distinct Process.

39. Canada maintains that its reliance on the raloxifene litigation is justified because that case applied "all three aspects of Canadian patent law that Claimant now challenges[.]"⁵⁶ Specifically, Canada points to the jurisdictional award in *Grand River Enterprises v. United States*, suggesting that it stands for the proposition that "the fact that a measure . . . may be applied more than once . . . is irrelevant for the purposes of Articles 1116(2) and 1117(2)."⁵⁷ In support of its argument, Canada summarizes the *Grand River* arbitration as follows:

In that case, the claimant commenced a NAFTA Chapter Eleven arbitration . . . alleging NAFTA violations arising from a 1998 tobacco litigation Master Settlement Agreement (MSA) and subsequent state actions taken pursuant to the MSA The *Grand River* tribunal . . . [found] that claims based on the MSA and subsequent measures taken pursuant to the MSA were untimely."⁵⁸

⁵⁵ In delineating the boundaries of their jurisdiction, tribunals are routinely called upon to distinguish between legally distinct investments and legally distinct host state acts. See *Grand River (Jurisdiction)*, at ¶ 101 (finding certain claims time barred but stating that "the Tribunal is not persuaded that the time bars under 1116(1) and 1117(1) can be applied to preclude Claimants from seeking to show that they suffered legally distinct injury on account of legislative actions occurring within the three years prior to the filing of their claim (or even after it was filed)") (CL-169); *Apotex v. United States*, Award on Jurisdiction and Admissibility (14 June 2013), at ¶ 333 (discussed *infra* at ¶ 45) [hereinafter *Apotex*] (CL-176); *Bilcon of Delaware Inc. v. Canada*, PCA/UNCITRAL, Award on Jurisdiction and Liability (17 March 2015), at ¶ 266 (discussed *infra* at ¶ 46) [hereinafter *Bilcon*] (CL-166); see also *Cargill v. Mexico*, ICSID Case No. ARB(AF)/05/2, Award (18 Sept. 2009), at ¶ 537 (separating harm caused to claimed investment and harm to other distinct investments in defining scope of claim for damages purposes) (CL-102).

⁵⁶ Resp. Rejoinder at ¶ 94.

⁵⁷ *Id.* at ¶ 76.

⁵⁸ *Id.* at ¶ 70.

40. Canada's account of *Grand River* is incomplete and misleading. The "subsequent measures taken pursuant to the MSA"⁵⁹ over which the tribunal declined jurisdiction were each taken more than three years before the arbitration commenced.⁶⁰ In contrast, the final invalidity determinations of Lilly's Zyprexa and Strattera patents were issued within two years of the Notice of Arbitration in this case – a point that is not contested.⁶¹ In the *Grand River* tribunal's view, measures taken "pursuant to the MSA"⁶² remained a fair basis for claims so long as they were taken "within three years of the filing of the claim."⁶³ In this connection, the tribunal emphasized that:

The *Mondev* and *Feldman* tribunals both considered the merits of claims regarding events occurring during the three-year limitations period, even though they were linked to, and required consideration of, events prior to the limitations period or to NAFTA's entry into force. In *Mondev*, the Tribunal considered (and rejected) the Claimant's claim that it had suffered a denial of justice in connection with state court proceedings occurring after NAFTA entered into force, although the dispute underlying the litigation arose years before. In *Feldman*, the Tribunal awarded damages in respect of discrimination occurring during the three-year limitations period, but its analysis of this and other claims again required consideration of earlier events.⁶⁴

41. Lilly's claim does not ask the Tribunal to do anything more than follow the path well worn by *Grand River*, *Mondev* and *Feldman* – and also by the tribunals in *UPS v. Canada*,⁶⁵ *Glamis Gold v. United States*,⁶⁶ *Apotex v. United States*,⁶⁷ and *Bilcon v.*

⁵⁹ *Id.*

⁶⁰ See *Grand River (Jurisdiction)*, at ¶ 71 (CL-169).

⁶¹ See Resp. Rejoinder at ¶ 111 (recognizing that, had Lilly brought a denial of justice claim related to the proceedings resulting in the invalidations, that claim would not be time barred).

⁶² See *Grand River (Jurisdiction)*, at ¶ 24 (CL-169).

⁶³ *Id.* at ¶ 86.

⁶⁴ *Id.*

⁶⁵ As Canada points out at paragraph 78 of its Rejoinder, the *UPS* tribunal in fact went further and held that "continuing courses of conduct constitute continuing breaches of legal obligations and renew the limitation period accordingly." *United Parcel Service of America Inc. v. Canada*, Award (24 May 2007), at ¶¶ 28-30 [hereinafter *UPS*] (CL-178).

Canada.⁶⁸ Consistent with this long line of NAFTA awards, Lilly asks that the Tribunal consider the Federal Court’s development of the promise utility doctrine as a “factual predicate” to Canada’s invalidation of the Strattera and Zyprexa patents.⁶⁹

42. Lilly’s appropriate use of various early cases to explain the development of the promise utility doctrine is evident from its submissions.⁷⁰ Those cases trace the emergence and inconsistent application of Canada’s new promise utility doctrine,⁷¹ and Lilly’s limited references to the raloxifene litigation serve the same purpose.⁷²

43. As explained *supra* in Part I.B, these references to prior Canadian decisions, and the portions of the Memorial and Reply that contain them,⁷³ demonstrate the arbitrary and discriminatory nature of the doctrine, and the extent to which the

⁶⁶ *Glamis Gold*, at ¶¶ 348-50 (holding that claimant may rely on “factual predicates” beyond the three-year time period under NAFTA) (CL-116).

⁶⁷ *Apotex*, at ¶ 333 (rejecting claims related to an “FDA[] (administrative) ruling” as time barred but permitting claims related to judicial decisions on review of the very same administrative ruling, even though the permitted claims “would require at least some consideration” of the administrative ruling.) (CL-176).

⁶⁸ *Bilcon*, at ¶ 282 (“While Article 1116(2) bars breaches in respect of events that took place more than three years before the claim was made, events prior to the three-year bar . . . are by no means irrelevant. They can provide necessary background or context for determining whether breaches occurred during the time-eligible period.”) (CL-166).

⁶⁹ See *Glamis Gold*, at ¶¶ 348-50 (CL-116).

⁷⁰ See Cl. Mem. at Parts III, V; Cl. Reply Mem. at Part II.

⁷¹ As a “measure of general application” to the pharmaceutical industry, the advent of the promise utility doctrine could not in any event itself trigger NAFTA’s three year clock under Chapter 11. See *Bilcon*, at ¶ 281 (explaining that the limitation periods on particular claims were triggered by prior breaches because those breaches were “distinct and completed events, specifically brought about . . . in relation to the [investment]” and not measures “of general application”) (CL-166).

⁷² Lilly’s Memorial mentions the raloxifene compound twice, both times in the context of describing the requirement of additional disclosure for soundly predicted utility, an element of the promise utility doctrine first established in that case. See Cl. Mem. at ¶¶ 74-75. Lilly’s Reply reiterates that point and cites the case for the proposition that the promise utility doctrine “substantially increases the uncertainty a patent applicant faces” by “making it difficult for an investor to know what must be disclosed.” Cl. Reply at ¶¶ 113, 191. Lilly’s Reply mentions raloxifene 11 times in 194 pages. By contrast, Zyprexa and Strattera – the patents at issue in this case – are mentioned 138 and 150 times, respectively.

⁷³ Specifically, Parts I and II of Claimant’s Reply, which encompass each of the paragraphs (48, 72-78, 92-93 and 104) that Canada emphasizes at paragraphs 88-91 of its Rejoinder.

doctrine departs from Canada's international obligations and the established Canadian law that Lilly relied upon in investing in Canada. This description of Canada's law on utility serves as the factual predicate for Lilly's claims that the invalidation of its Strattera and Zyprexa patents constituted an expropriation of those patents under NAFTA Article 1110 and treatment inconsistent with the minimum standard of fair and equitable treatment required by NAFTA Article 1105.⁷⁴

44. None of the authorities cited by Canada take issue with references to facts outside NAFTA's three-year limitation period to shed light on a legally distinct act within the limitation period. To the contrary, both the *Apotex* and *Bilcon* cases discussed by Canada in its Rejoinder conclude that acts occurring outside NAFTA's limitation period may be relied upon as factual predicates for timely claims – even where such acts constitute independent NAFTA violations and may themselves have qualified as “the subject of a separate complaint under the NAFTA[.]”⁷⁵

45. In *Apotex*, for example, the tribunal considered claims concerning four distinct but interrelated governmental actions: (i) an administrative order issued outside the NAFTA limitation period; (ii) a trial court decision declining to overturn the administrative order; (iii) an appellate affirmance of the trial court ruling; and (iv) a second appellate order denying rehearing of the affirmance. The tribunal found the claims relating to the administrative order to be time barred, but explained that there was nevertheless “no time-bar difficulty with respect to [the] claims based upon” the later appellate decisions.⁷⁶

⁷⁴ Cl. Reply at ¶¶ 316-317 (“Lilly’s argument is that judicial measures may be expropriatory when they substantially deprive an investment of value and violate a substantive rule of international law”; “Canada’s measures may also be recognized as expropriations because they are arbitrary and in conflict with Lilly’s reasonable investment-backed expectations”); *id.* at ¶ 322 (“In its Memorial, Lilly showed that Article 1105(1) embraces protections against arbitrariness, violation of legitimate investment-backed expectations, and discrimination. Lilly further demonstrated that Canada’s use of the promise utility doctrine to invalidate the Zyprexa and Strattera patents violated each of these standards.”).

⁷⁵ *Apotex*, at ¶ 330 (CL-176).

⁷⁶ *Id.* at ¶ 333.

46. Similarly, in *Bilcon*, the tribunal considered a series of distinct governmental acts, commencing with the referral of an environmental assessment of the relevant investment (a proposed quarry) to a Joint Review Panel. The tribunal determined that claims relating to this referral were time barred, yet it considered – and based its finding of liability on – claims concerning the conduct of the very same Joint Review Panel.⁷⁷ Canada is well aware that “it [is] possible and appropriate . . . to separate a series of events into distinct components, some time-barred, some still eligible for consideration on the merits.”⁷⁸

47. Canada points to no support whatsoever for a contrary view – neither in tribunal decisions nor in the submissions of other NAFTA parties. Indeed, while Canada cites extensively to U.S. and Mexican submissions, it admits that these submissions stand only for the inapposite proposition that “an allegation that an alleged breach . . . is continuing does not stop the time-bar clock.”⁷⁹ Lilly has not alleged a continuing course of conduct, and has made no claim with respect to the raloxifene patent. Moreover, that principle in no way suggests that decisions regarding the raloxifene patent in 2008 and 2009 somehow *accelerated* the limitation period applicable to the subsequent invalidations, in 2011 and 2013, of Lilly’s distinct investments in the Strattera and Zyprexa patents.⁸⁰

* * *

48. Lilly’s claim seeks redress for the treatment that Canada accorded to two distinct investments. Lilly’s 2013 Notice of Arbitration was filed, therefore, squarely

⁷⁷ *Bilcon*, at ¶ 740 (noting that the “overall set of facts that came together to produce a finding of liability in this particular case include . . . an [improper] approach to [an environmental impact] assessment by the [Joint Review Panel] . . . [and] lack of prior notice to the investor of the unprecedented approach the [Joint Review Panel] was going to adopt”) (CL-166).

⁷⁸ *Id.* at ¶ 266.

⁷⁹ Resp. Rejoinder at ¶ 74. *But see UPS*, at ¶¶ 28-30 (holding that “continuing courses of conduct constitute continuing breaches of legal obligations and renew the limitation period accordingly”) (CL-178).

⁸⁰ Canada’s generic reliance on cases and submissions that describe NAFTA’s three-year limitation period as “rigid” are similarly uninformative. *See* Resp. Rejoinder at ¶ 77. The general proposition that the limitation period is rigid does not speak to the circumstances and manner in which it applies.

within the three-year limitation period established in NAFTA Articles 1116(2) and 1117(2). Canada's attempt to distract the Tribunal by focusing on litigation regarding the raloxifene patent does not change these fundamental facts. The raloxifene case, like many others, well illustrates the change in Canadian utility law and the development of the promise utility doctrine. Lilly is entitled to provide necessary factual context regarding prior cases that shaped the promise utility doctrine and doing so does not shorten the limitation period applicable to Canada's invalidations of the Strattera and Zyprexa patents. Canada has presented no authority that suggests otherwise.

III. CONCLUSION

49. For the foregoing reasons, the Tribunal should decline to entertain Canada's belated objection, as it is barred by the operation of UNCITRAL Article 21(3), and improper in light of the Tribunal's First Procedural Order. If the Tribunal nevertheless considers Canada's jurisdictional objection on the merits, it should reject it. Canada's objection is founded on a misreading of Lilly's claims that ignores Lilly's clear focus on Canada's revocations of the Strattera and Zyprexa patents. Further, on the substance of Canada's objection, Canada has failed to engage with the seven different NAFTA awards that support Lilly's right to rely on events predating the Strattera and Zyprexa revocations for the purpose of supplying the facts necessary to demonstrate the wrongfulness of those invalidations.

50. Lilly requests that this Tribunal (i) reject Canada's jurisdictional objection as untimely under UNCITRAL Article 21(3) or, in the alternative, reject Canada's objection on the merits; and, in either case, (ii) award Lilly all costs (including attorney's fees) incurred in connection with Canada's belated jurisdictional objection.⁸¹

⁸¹ In a letter provided to Canada five weeks before this submission, Lilly reaffirmed the constancy of its claims and offered Canada an opportunity to withdraw its objection given that it had no factual basis, thus saving the parties the time and expense of litigating the issue. Letter of Ms. Marney Cheek to Mr. Shane Spelliscy of 17 Dec. 2015, at 4. Canada declined to withdraw its claims. Letter of Mr. Shane Spelliscy to Ms. Marney Cheek of 18 Dec. 2015, at 1.

Respectfully submitted,

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