

**INTERNATIONAL CENTRE FOR SETTLEMENT OF INVESTMENT DISPUTES**

IN AN ARBITRATION UNDER CHAPTER ELEVEN OF THE NAFTA  
AND THE UNCITRAL ARBITRATION RULES, 1976

between

**ELI LILLY AND COMPANY**

Claimant

and

**GOVERNMENT OF CANADA**

Respondent

**Case No. UNCT/14/2**

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**FINAL AWARD**

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*Members of the Tribunal*

Professor Albert Jan VAN DEN BERG (President)

Sir Daniel BETHLEHEM QC

Mr. Gary BORN

*Secretary of the Tribunal*

Ms. Lindsay GASTRELL

*Date of dispatch to the Parties: 16 March 2017*

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## LIST OF DEFINED TERMS

'113 Patent	Canadian Patent No. 2,041,113, relating to the drug Zyprexa (active ingredient olanzapine), filed in Canada on 24 April 1991
'687 Patent	Canadian Patent No. 1,075,687, filed in Canada in 1975
'735 Patent	Canadian Patent No. 2,209,735, relating to the drug Strattera (active ingredient atomoxetine), filed in Canada on 4 January 1996
ADHD	Attention-deficit/hyperactivity disorder
C-CS	Claimant's Submission on Costs, filed on 22 August 2016
C-PHM	Claimant's Post-Hearing Memorial, filed on 25 July 2016
C-RPHM	Claimant's Reply Post-Hearing Memorial, filed on 8 August 2016
Canada	Government of Canada, Respondent
CIPPO	Canadian Intellectual Property Office
Counter-Memorial	Respondent's Counter-Memorial, filed on 27 January 2016
Claimant	Eli Lilly and Company
FTC	NAFTA Free Trade Commission
FTC Note	NAFTA Free Trade Commission's Notes of Interpretation of Certain Chapter Eleven Provisions dated 31 July 2001
Health Canada	Canada's health regulatory agency

Hearing	Hearing for these proceedings held from 30 May to 9 June 2016 at the World Bank offices in Washington D.C., United States of America
ICSID	International Centre for Settlement of Investment Disputes
IP	Intellectual Property
Lilly	Eli Lilly and Company, Claimant
Lilly Canada	Eli Lilly Canada Inc.
Memorial	Claimant’s Memorial, filed on 29 September 2014
Mexico	United Mexican States
MGH	Massachusetts General Hospital
MOPOP	Manual of Patent Office Practice
NAFTA	North American Free Trade Agreement between Canada, Mexico, and the United States of America as entered into force on 1 January 1994
NAFTA Parties	Canada, Mexico and the United States
NoA	Notice of Arbitration, filed by Claimant on 12 September 2013
NOC	Notice of Compliance, issued by the Canadian Minister of Health
Novopharm	Canadian drug manufacturer Novopharm Limited (now Teva Canada Limited)
PCT	Patent Cooperation Treaty as entered into force on 24 January 1978

Parties	Claimant and Respondent collectively
Party	Claimant or Respondent individually
Patent Act	Canadian Patent Act as entered into force in 1985
PM(NOC)	Canada's Patented Medicines (Notice of Compliance) Regulations, SOR/93-133
PO 1	Procedural Order No. 1, issued by the Tribunal on 26 May 2014
PO 2	Procedural Order No. 2, issued by the Tribunal on 6 April 2015
PO 3	Procedural Order No. 3, issued by the Tribunal on 15 January 2016
PO 4	Procedural Order No. 4, issued by the Tribunal on 23 February 2016
R-CS	Respondent's Submission on Costs, filed on 22 August 2016
R-PHM	Respondent's Post-Hearing Memorial, filed on 25 July 2016
R-RPHM	Respondent's Reply Post-Hearing Memorial, filed on 8 August 2016
Raloxifene Decision	Canadian Federal Court decision dated 5 February 2008, relating to the Raloxifene Patent
Raloxifene Patent	Canadian patent relating to a drug with the active ingredient raloxifene
Rejoinder Memorial	Respondent's Rejoinder Memorial, filed on 8 December 2015
Reply Memorial	Claimant's Reply Memorial, filed on 11 September 2015
Respondent	The Government of Canada

SoC	Claimant's NoA, designated as its Statement of Claim by letter dated 14 May 2014
SoD	Respondent's Statement of Defence, filed on 30 June 2014
Strattera Decision	Canadian Federal Court decision dated 14 September 2010, finding the Strattera Patent to be invalid for lack of utility
Strattera Patent	The '735 Patent
SPLT	Substantive Patent Law Treaty
Transcript	Transcript of the Hearing
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights administered by the World Trade Organization and effective as of 1 January 1995
UNCITRAL Rules	The United Nations Commission on International Trade Law's Arbitration Rules as adopted by General Assembly Resolution 31/98 on 15 December 1976
United States	United States of America
USTR	United States Trade Representative
VCLT	Vienna Convention on the Law of Treaties
WIPO	World Intellectual Property Organization
Zyprexa Decision	Canadian Federal Court decision dated 10 November 2011, finding the Zyprexa Patent to be invalid for lack of utility
Zyprexa Patent	The '113 Patent

## **I. INTRODUCTION**

### **A. Parties**

1. The claimant in this arbitration is Eli Lilly and Company (“**Claimant**” or “**Lilly**”), a pharmaceutical company incorporated in the United States of America (“**United States**”) under the laws of the State of Indiana, with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana, 46205. Claimant brings its claims on its own behalf and on behalf of its indirectly owned subsidiary, Eli Lilly Canada Inc., a Canadian enterprise with its principal place of business located at 3650 Danforth Avenue, Toronto, Ontario, M1N 2E8 (“**Lilly Canada**”).
2. Claimant is represented in this arbitration by its representatives listed on page i above.
3. The respondent in this arbitration is the Government of Canada (“**Respondent**” or “**Canada**”). Respondent is represented in this arbitration by its representatives listed on page i above.

### **B. Overview**

4. Claimant has submitted the present dispute to international arbitration pursuant to Chapter Eleven of the North American Free Trade Agreement, which entered into force on 1 January 1994 (“**NAFTA**”), and the United Nations Commission on International Trade Law’s Arbitration Rules as adopted by General Assembly Resolution 31/98 on 15 December 1976 (“**UNCITRAL Rules**”). By agreement of the Parties, the International Centre for Settlement of Investment Disputes (“**ICSID**”) serves as the administering authority for this proceeding.
5. In this arbitration, Claimant asserts claims arising from the invalidation of its Canadian patents protecting the drugs marketed in Canada as Strattera and Zyprexa. The Canadian courts invalidated these two patents in 2010 and 2011, respectively, on the ground that they did not meet the requirement under Canadian patent law that an invention be “useful”. According to Claimant, the basis for the Canadian courts’ decisions was their adoption in the mid-2000s of the “promise utility doctrine”, which Claimant considers to be radically

new, arbitrary and discriminatory against pharmaceutical companies and products. Claimant argues that the promise utility doctrine is inconsistent with Respondent's obligations related to patent protection under NAFTA Chapter 17. Further, Claimant contends that the retroactive application of the doctrine to Claimant's patents has resulted in (i) the unlawful expropriation of Claimant's investments under NAFTA Article 1110, and (ii) a breach of Respondent's obligation to provide the minimum standard of treatment under NAFTA Article 1105. Claimant submits that Respondent's jurisdictional objection should be dismissed as untimely, and that in any event, it lacks merit; it asserts that this Tribunal has jurisdiction *ratione temporis* over Claimant's claims.

6. Respondent's position is that the Tribunal should dismiss all of Claimant's claims for the following four separate reasons: (i) the sole legal basis on which a national court decision could result in a breach of NAFTA Chapter Eleven is a denial of justice, which Claimant has not alleged; (ii) the Tribunal lacks jurisdiction *ratione temporis* because Claimant's claim is time-barred under NAFTA Articles 1116(2) and 1117(2); (iii) there has been no dramatic change in Canadian courts' interpretation of the requirement under the Canadian patent law that an invention be "useful"; and (iv) the invalidation of Claimant's patents does not constitute a breach of NAFTA Chapter Eleven or any other international obligation. In this regard, Respondent argues that consideration of Canada's compliance with NAFTA Chapter 17 or other international obligations outside of Chapter Eleven is beyond the mandate of this Tribunal.
7. The Parties' specific requests for relief are set forth in Section IV below, and a fuller summary of their positions is contained in Sections VI.B, VI.B(2) VII.A, VIII.A, and IX.A below. In its analysis, the Tribunal has considered not only the positions of the Parties as summarized in this Award but the numerous detailed arguments made in the Parties' written and oral pleadings as well. To the extent that these arguments are not referred to expressly, they should be deemed to be subsumed into the Tribunal's analysis.
8. The Tribunal has also received and considered written submissions from the United States and the United Mexican States ("**Mexico**") under NAFTA Article 1128 and from the *amici curiae* identified in Section II below.

## II. PROCEDURE

9. On 7 November 2012, Claimant delivered a Notice of Intent to Submit a Claim to Arbitration to Respondent in respect of its patent for Strattera. Subsequently, on 13 June 2013, Claimant delivered a second Notice of Intent to Submit a Claim to Arbitration to Respondent, which contained claims identical to those raised in the first Notice of Intent, but added the Zyprexa patent to the complaint. Claimant later withdrew the first Notice of Arbitration.
10. Claimant commenced this arbitration by its Notice of Arbitration dated 12 September 2013 (“**NoA**”), submitted pursuant to Article 3 of the UNCITRAL Arbitration Rules, and Articles 1116, 1117, and 1120 of the NAFTA.
11. As envisaged in NAFTA Article 1123, the Parties agreed that the Tribunal would comprise three arbitrators, one arbitrator appointed by each of the disputing parties and the third, presiding arbitrator appointed by agreement of the disputing parties.
12. Claimant appointed Mr. Gary Born, a national of the United States, as arbitrator, and Mr. Born accepted the appointment by letter of 18 November 2013. Together with his acceptance, Mr. Born provided the Parties with a declaration of his independence and impartiality and a disclosure statement.<sup>1</sup>
13. Respondent then appointed Sir Daniel Bethlehem, a national of the United Kingdom based in London, as arbitrator, and Sir Daniel accepted the appointment on 17 December 2013. Together with his acceptance, Sir Daniel provided the Parties with a declaration of his independence and impartiality and a disclosure statement.<sup>2</sup>
14. On 4 March 2014, Claimant requested that the Secretary-General of ICSID appoint the third, presiding arbitrator pursuant to NAFTA Article 1128. Claimant informed the

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<sup>1</sup> By letters of 9 June 2015, 10 and 22 July 2015, 7 September 2015, 22 April 2016, 27 June 2016, 4 October 2016 and 14 March 2017 Mr. Gary Born provided the Parties with supplemental disclosure statements. No Party raised any objections or queries regarding these statements.

<sup>2</sup> By letter of 3 February 2017, Sir Daniel Bethlehem provided the Parties with a supplemental disclosure statement. No Party raised any objections or queries regarding this statement.

Secretary-General of an agreement of the Parties that this appointment be made through a strike-and-rank list of seven candidates. The Secretary-General accepted Claimant's request by letter of 6 March 2014.

15. On 18 March 2014, in accordance with the Parties' agreed procedure, the Secretary-General provided the Parties with a list of seven candidates. Each party submitted its ranking of candidates on 1 April 2014.
16. By letter of 2 April 2014, the Secretary-General informed the Parties that the overall most preferred candidate was Professor Albert Jan van den Berg, a national of the Netherlands based in Brussels, and that he was therefore appointed as President of the Tribunal. The Tribunal was deemed to have been constituted on that date in accordance with the UNCITRAL Arbitration Rules and NAFTA Chapter Eleven.
17. In consultation with the Tribunal, the Parties agreed that ICSID would serve as administering authority for the arbitration. By Claimant's letter of 10 April 2014 to the Secretary-General of ICSID, the Parties requested that ICSID provide full administrative services. On the same day, the Secretary-General confirmed that ICSID would provide such services and informed the Parties that Ms. Lindsay Gastrell, ICSID Counsel, would serve as Secretary to the Tribunal.
18. In response to a request from the Tribunal, the Parties filed a joint submission on procedural issues and confidentiality (including a jointly proposed Procedural Order No. 1, jointly proposed Confidentiality Order, and a proposed Procedural Calendar from each Party) on 14 April 2014. As there were a number of issues upon which the Parties could not reach agreement, the Tribunal invited each Party to submit its observations on the outstanding issues. On 2 May 2014, Claimant filed its Observations on Outstanding Issues for the First Procedural Hearing, and Respondent filed its Submission on Procedural Issues.
19. The Tribunal held a procedural hearing with the Parties on 10 May 2014, with the President of the Tribunal and the Parties attending in person at the World Bank Headquarters in Washington, D.C., and the co-arbitrators participating by videoconference from the World Bank office in London.

20. The following individuals attended procedural hearing:

<b>TRIBUNAL</b>	
Professor Albert Jan van den Berg	President
Mr. Gary Born	Arbitrator (participating via VC, World Bank London)
Sir Daniel Bethlehem QC	Arbitrator (participating via VC, World Bank London)
<b>ICSID SECRETARIAT</b>	
Ms. Lindsay Elizabeth Gastrell	Secretary of the Tribunal
<b>CLAIMANT</b>	
<i>Counsel:</i>	
Ms. Marney Cheek	Covington & Burling LLP
Mr. John Veroneau	Covington & Burling LLP
Mr. James (Jay) Smith	Covington & Burling LLP
Mr. Nikhil Gore	Covington & Burling LLP
Ms. Celia Choy	Covington & Burling LLP
Ms. Karina Watts (Paralegal)	Covington & Burling LLP
Ms. Whitney Knowlton (Paralegal)	Covington & Burling LLP
Ms. Wendy Wagner	Gowling Lafleur Henderson LLP
<i>Parties:</i>	
Mr. Arvie Anderson	Eli Lilly and Company
<b>RESPONDENT</b>	
<i>Counsel:</i>	
Mr. Christophe Bondy	Trade Law Bureau, Government of Canada
Ms. Yasmin Shaker	Trade Law Bureau, Government of Canada
Mr. Maxime Dea	Trade Law Bureau, Government of Canada
Mr. Adrian Johnston	Trade Law Bureau, Government of Canada
<i>Parties:</i>	
Mr. Lucas McCall	Department of Foreign Affairs, Trade and Development Canada
Ms. Sara Amini	Industry Canada
Mr. Gregoire Major	Industry Canada Legal Services

21. At the procedural hearing, the Tribunal heard the Parties' oral argument on procedural issues, including the issue of the legal seat of the arbitration. Following deliberations on this issue during a break in the hearing, the Tribunal informed the Parties of its decision that the legal seat of this arbitration shall be Washington, D.C.
22. Following the procedural hearing, on 14 May 2014, the Tribunal provided the Parties with a draft Procedural Order No. 1 and a draft Confidentiality Order, reflecting the Tribunal's

decisions on issues addressed by the Parties during the hearing, and invited any final comments from the Parties.

23. By letter of the same date, Claimant designated the NoA as its Statement of Claim (“**SoC**”), as had been discussed during the first procedural hearing.
24. On 26 May 2014, the Tribunal issued Procedural Order No. 1 (“**PO 1**”) embodying the agreements of the Parties and the decisions of the Tribunal on procedural matters. Section 5.1 of PO 1 recorded the Tribunal’s decision that the seat of arbitration would be Washington, D.C. Section 9.1 provided that the proceeding would be bifurcated into two phases, a merits phase and, if necessary, a quantum phase. Annex B of PO 1 set out a timetable for the merits phase of the proceeding.
25. With respect to the hearing, PO 1 set forth the agreement of the Tribunal and the Parties that the hearing would be open to the public, except when necessary to protect confidential information. At Claimant’s request, PO 1 further stated that:

The hearing shall be made accessible to the public in real time via closed-circuit television broadcast to a World Bank room other than the room in which the hearing is held, subject to a time delay and any other arrangements needed to safeguard confidential information.

26. Also on 26 May 2014, the Tribunal issued the Confidentiality Order, which both Parties signed on the same date.
27. As contemplated in Annex B of PO 1, on 30 June 2014, Respondent submitted its Statement of Defence (“**SoD**”), together with Exhibits R-001 to R-035 and Authorities RL-001 to RL-009.
28. On 29 September 2014, Claimant submitted its Memorial (“**Memorial**”), with Exhibits C-001 to C-307 and Authorities CL-001 to CL-122, and the following four witness statements and seven expert reports:
  - First Witness Statement of Mr. Robert A. Armitage dated 27 September 2014 (“**Armitage First Statement**”);

- Witness Statement of Ms. Anne Nobles dated 25 September 2014 (“**Nobles Statement**”);
  - Witness Statement of Mr. Robert Postlethwait dated 25 September 2014 (“**Postlethwait Statement**”);
  - Witness Statement of Mr. Peter G. Stringer dated 25 September 2014 (“**Stringer Statement**”);
  - First Expert Report of Prof. Jay Erstling dated 27 September 2014 (“**Erstling First Report**”);
  - First Expert Report of Ms. Gilda González Carmona dated 26 September 2014 (“**González First Report**”), in English and Spanish originals;
  - First Expert Report of Mr. Steven G. Kunin dated 26 September 2014 (“**Kunin First Report**”);
  - First Expert Report of Prof. Robert P. Merges dated 29 September 2014 (“**Merges First Report**”);
  - First Expert Report of Mr. Fabián Ramón Salazar dated 26 September 2014 (“**Salazar First Report**”), in Spanish with English translation;
  - First Expert Report of Prof. Norman V. Siebrasse dated 29 September 2014 (“**Siebrasse First Report**”); and
  - First Expert Report of Mr. Murray Wilson dated 25 September 2014 (“**Wilson First Report**”).
29. On 27 January 2015, Respondent submitted its Counter-Memorial (“**Counter-Memorial**”), accompanied by Exhibits R-036 to R-356 and Authorities RL-010 to RL-078, and the following three witness statements and five expert reports:
- Witness Statement of Ms. Kimby Barton dated 26 January 2015 (“**Barton Statement**”);
  - First Witness Statement of Dr. Marcel Brisebois dated 26 January 2015 (“**Brisebois First Statement**”);
  - First Witness Statement of Dr. Michael Gillen dated 26 January 2015 (“**Gillen First Statement**”);
  - First Expert Report of Mr. Ronald E. Dimock dated 26 January 2015 (“**Dimock First Report**”);

- First Expert Report of Dr. Daniel J. Gervais dated 23 January 2015 (“**Gervais First Report**”);
  - First Expert Report of Mr. Timothy R. Holbrook dated 26 January 2015 (“**Holbrook First Report**”);
  - First Expert Report of Ms. Hedwig “Heidi” Lindner dated 26 January 2015 (“**Lindner First Report**”), in Spanish with English translation; and
  - First Expert Report of Mr. T. David Reed dated 26 January 2015 (“**Reed First Report**”).
30. As contemplated in PO 1, the Parties then exchanged requests for the production of documents. On 25 March 2015, the Parties submitted their outstanding document requests for resolution by the Tribunal. Claimant submitted its completed Redfern Schedule, observations and Authorities CL-123 to CL-145; Respondent submitted its completed Redfern Schedule, observations and Authorities RL-079 to RL-087.
31. On 6 April 2015, the Tribunal issued its decisions with respect to the outstanding requests in Procedural Order No. 2, including Annexes A and B (“**PO 2**”), indicating which documents the Parties were ordered to produce.
32. On 25 June 2015, Respondent informed the Tribunal and ICSID that Mr. Christophe Douaire de Bondy would no longer be representing Respondent in this matter and that all future case correspondence should be directed to Mr. Shane Spelliscy and Mr. Mark Luz of the Trade Law Bureau.
33. On 11 September 2015, Claimant submitted its Reply Memorial (“**Reply**”), accompanied by Exhibits C-308 to C-514 and Authorities CL-146 to CL-166 and the following witness statement and ten expert reports:
- Second Witness Statement of Mr. Robert A. Armitage dated 11 September 2015 (“**Armitage Second Statement**”);
  - Second Expert Report of Prof. Jay Erstling dated 10 September 2015 (“**Erstling Second Report**”);
  - Second Expert Report of Ms. Gilda González Carmona dated 10 September 2015 (“**González Second Report**”), in English and Spanish originals;

- Second Expert Report of Mr. Steven G. Kunin dated 9 September 2015 (“**Kunin Second Report**”);
  - Expert Report of Prof. Bruce Levin dated 7 September 2015 (“**Levin Report**”);
  - Second Expert Report of Prof. Robert P. Merges dated 10 September 2015 (“**Merges Second Report**”);
  - Expert Report of Mr. Andrew J. Reddon dated 11 September 2015 (“**Reddon Report**”);
  - Second Expert Report of Mr. Fabián Ramón Salazar dated 10 September 2015 (“**Salazar Second Report**”), in Spanish with English translation;
  - Second Expert Report of Prof. Norman V. Siebrasse dated 10 September 2015 (“**Siebrasse Second Report**”);
  - Expert Report of Mr. Philip Thomas dated 7 September 2015 (“**Thomas Report**”); and
  - Second Expert Report of Mr. Murray Wilson dated 9 September 2015 (“**Wilson Second Report**”).
34. By letter of 29 October 2015, ICSID notified Mexico and the United States of the deadline for written submissions by the non-disputing NAFTA Parties pursuant to NAFTA Article 1128. In addition, an announcement was posted on the ICSID website stating the deadline and instructions for submitting an application for leave to file a non-disputing party (*amicus*) submission.
35. On 8 December 2015, Respondent submitted its Rejoinder Memorial (“**Rejoinder**”), together with Exhibits R-357 to R-473, amended Exhibits R-243, R-333 and R-345, Authorities RL-088 to RL-118, and the following two witness statements and five expert reports:
- Second Witness Statement of Dr. Marcel Brisebois dated 7 December 2015 (“**Brisebois Second Statement**”);
  - Second Witness Statement of Dr. Michael Gillen dated 7 December 2015 (“**Gillen Second Statement**”);
  - Second Expert Report of Mr. Ronald E. Dimock dated 4 December 2015 (“**Dimock Second Report**”);
  - Second Expert Report of Dr. Daniel Gervais dated 7 December 2015 (“**Gervais Second Report**”)

- Second Expert Report of Mr. Timothy R. Holbrook dated 5 December 2015 (“**Holbrook Second Report**”);
  - Second Expert Report of Ms. Hedwig “Heidi” A. Lindner dated 7 December 2015 (“**Lindner Second Report**”), in Spanish with English translation; and
  - Second Expert Report of Mr. T. David Reed dated 7 December 2015 (“**Reed Second Report**”).
36. In a letter to Respondent dated 17 December 2015, copied to the Tribunal, Claimant requested that Respondent unilaterally withdraw its objection to jurisdiction *ratione temporis* raised for the first time in the Rejoinder. In response, by letter dated 18 December 2015, Respondent declined to withdraw its jurisdictional objection. On 21 December 2015, Claimant informed Respondent that it would seek relief from the Tribunal for non-compliance with Article 21(3) of the UNCITRAL Arbitration Rules and Section 10.2 of PO 1 immediately following the holidays.
37. By letter of 5 January 2016 to the Tribunal, Claimant set forth observations on the timing of Respondent’s objection to jurisdiction *ratione temporis* and sought leave to respond in writing to the objection.
38. By letter of 8 January 2016, Respondent stated that it did not object to Claimant submitting a response to its jurisdictional arguments, provided Respondent would be allowed to respond in writing to Claimant’s submission. Respondent also proposed that if the Tribunal were to grant Claimant’s request for additional written submissions, the deadline for the NAFTA Article 1128 submissions and applications for leave to file *amicus* submissions should be postponed.
39. On the same date, Claimant informed the Tribunal that it agreed with an extension of the deadline of the NAFTA Article 1128 submissions but objected to altering the *amicus* filing deadline. Additionally, Claimant proposed to shorten the period for the Parties to respond to the NAFTA Article 1128 submissions.
40. Also on 8 January 2016, Mexico and the United States submitted letters to the Tribunal proposing an extension to the filing deadline for the non-disputing NAFTA Party submissions under NAFTA Article 1128.

41. Following a further exchange of comments by the Parties in relation to the procedural calendar (Respondent's letter of 12 January 2016 and Claimant's letter of 13 January 2016), the Tribunal issued Procedural Order No. 3 dated 15 January 2016 ("**PO 3**"). In PO 3, the Tribunal ordered that: (i) Claimant would be allowed to respond to Respondent's objection to jurisdiction *ratione temporis* raised in the Rejoinder; (ii) further submissions from Respondent on its jurisdictional objection were not necessary; and (iii) the deadlines for Article 1128 submissions and applications for leave to file *amicus* submissions would be extended. PO 3 contained a revised procedural calendar reflecting these decisions.
42. ICSID informed Mexico and the United States of the extended deadline for the non-disputing NAFTA Party submissions under NAFTA Article 1128 and posted an announcement on its website regarding the new deadline for applications for leave to file *amicus* submissions.
43. On 22 January 2016, Claimant submitted its Opposition to Respondent's Jurisdictional Objection ("**Opposition on Jurisdiction**"), together with Exhibit C-515 and Authorities CL-167 to CL-177.
44. Nine applications for leave to file an *amicus curiae* submission were submitted on 12 February 2016. The applicants were: (i) a group of academics from the United States, the United Kingdom, Switzerland, South Africa and Nepal; (ii) the Canadian Chamber of Commerce; (iii) the Canadian Generic Pharmaceutical Association; (iv) the Samuelson-Glushko Canadian Internet Policy and Public Interest Clinic and the Centre for Intellectual Property Policy; (v) Dr. Henning Grosse Ruse-Khan, Dr. Kathleen Liddell and Dr. Michael Waibel of the University of Cambridge; (vi) Innovative Medicines Canada and BIOTECanada; (vii) seven intellectual property law professors from universities in the United States; (viii) the National Association of Manufacturers; and (ix) Pharmaceutical Research and Manufacturers of America, Mexican Association of the Research Based Pharmaceutical Industry, and Biotechnology Innovation Organization.
45. In accordance with the revised procedural calendar, on 19 February 2016, each Party submitted comments on the applications for leave to file *amicus* submissions. Claimant

attached to its comments Authorities CL-178 to CL-179, and Respondent attached to its letter an Annex A.

46. On 23 February 2016, the Tribunal issued Procedural Order No. 4 (“**PO 4**”) concerning the applications for leave to file *amicus* submissions. The Tribunal granted six of the applications, accepting into the record the submissions of the following *amici*:
- a. *Dr. Burcu Kilic, Professor Brook K. Baker, Professor Cynthia Ho and Mr. Yaniv Heled*: In summary, the position of these intellectual property law experts is that NAFTA does not impose a uniform standard of patentability criteria, and that Respondent has acted well within its rights under NAFTA to set its own utility requirement. They also contend that Claimant’s initiation of this arbitration is an abusive attempt to influence the Canadian Parliament to change the law on utility.
  - b. *Canadian Chamber of Commerce*: In summary, this submission states that deviation from international norms on utility and sound prediction will negatively affect Canada’s economy, and that the Canadian courts’ interpretation of promise utility can be linked to declining investments in the Canadian pharmaceutical sector.
  - c. *Canadian Generic Pharmaceutical Association (“CGPA”)*: In summary, CGPA urges the Tribunal to dispose of this arbitration without commenting upon any substantive principles of Canadian patent law, which it argues could upset longstanding Canadian jurisprudence. According to CGPA, the “promise doctrine” as described by Claimant does not exist, and is a only construct to support its arguments in this proceeding.
  - d. *Samuelson-Glushko Canadian Canadian Internet Policy & Public Interest Clinic and Centre for Intellectual Property Policy*: In summary, this submission raises several points in objection to Claimant’s case, including: (i) a patent is not an unconditional property right, as it is always subject to a risk of litigation and invalidation by the court; (ii) there are no formal or informal international standards of utility, including under NAFTA; and (iii) Claimant’s arguments confuse the aims of trade law with those of intellectual property law.

- e. *Gregory Dolin (University of Baltimore School of Law), Christopher Holman (University of Missouri-Kansas City School of Law), Jay Kesan (University of Illinois School of Law), Erika Lietzan (University of Missouri-Columbia School of Law), Adam Mossoff (George Mason University School of Law), Kristen Osenga (University of Richmond School of Law), and Mark Schultz (Southern Illinois University School of Law)*: In summary, these intellectual property law professors challenge many aspects of Respondent’s law on utility, which in their view departs from NAFTA Article 1709(1). They argue that Respondent’s approach runs counter to global norms and the long historical trend toward increasing harmonisation of the utility standard in a liberal direction.
- f. *National Association of Manufacturers*: In summary, this manufacturing association based in the United States submits that Respondent’s promise utility doctrine is inconsistent with established international norms for patent protection and in violation of NAFTA Chapter Eleven. In its view, Respondent has injected uncertainty into the system and put at risk manufacturers’ ability to file a single global patent application under the Patent Cooperation Treaty (the “**PCT**”).
47. On 18 March 2016, Mexico and the United States filed written submissions pursuant to NAFTA Article 1128 (“**Mexico Article 1128 Submission**” and “**United States Article 1128 Submission**”). These submissions are discussed where applicable in the sections below.
48. On 8 April 2016, the Parties provided the Tribunal with a jointly proposed draft Procedural Order No. 5 concerning the procedural rules for the hearing on jurisdiction and merits. After considering the Parties’ proposed draft order, on 12 April 2016, the Tribunal provided the Parties with a draft agenda for the pre-hearing procedural teleconference. At the same time, the Tribunal sought the Parties’ views on certain outstanding procedural items relating to the hearing. Once the Tribunal received and considered the Parties’ comments, it provided the Parties with an updated draft Procedural Order No. 5.

49. On 22 April 2016, the Parties filed the following submissions:
- a. Respondent’s Observations on Issues Raised in 1128 Submissions of Mexico and the United States (“**Respondent’s Observations on 1128 Submissions**”);
  - b. Respondent’s Observations on Issues Raised in *Amicus* Submissions (“**Respondent’s Observations on Amicus Submissions**”); and
  - c. Claimant’s Comments on NAFTA Article 1128 Submissions and Non-Disputing Party (*Amicus*) Submissions (“**Claimant’s Observations on 1128 and Amicus Submissions**”).
50. On 27 April 2016, the President of the Tribunal held a pre-hearing teleconference with the Parties. Following the teleconference, on 29 April 2016, the Tribunal issued Procedural Order No. 5 (“**PO 5**”), reflecting the Parties’ agreements and the Tribunal’s decisions on the procedural rules to govern the hearing.
51. Also on 29 April 2016, each Party notified the other Party and the Tribunal of the witnesses and experts it intended to call during the hearing.
52. As contemplated in PO 5, on 6 May 2016, the Tribunal issued to the Parties a list of questions to be addressed during their opening statements.
53. The same day, a news alert was posted on the ICSID website announcing that the hearing would be open to the public and providing instructions for accessing the public viewing room.
54. By letter of 25 May 2016, Respondent requested “that the Tribunal clarify for the Parties that the documents referenced by the non-disputing parties in their *amicus curiae* submissions are, in fact, considered part of the record in this arbitration”. Claimant responded the following day, opposing “Canada’s attempt to introduce hundreds of new exhibits into the record five days before the beginning of the hearing”. The Tribunal addressed this issue in Procedural Order No. 6 (“**PO 6**”), issued on 27 May 2016. In PO 6, the Tribunal decided, *inter alia*, that either Party would be permitted to rely on documents

referenced in the *amicus curiae* submissions that were not already part of the record, as long as that Party notified the other Party and the Tribunal at least 24 hours in advance.

55. The hearing on jurisdiction and merits was held at the World Bank Headquarters in Washington, D.C. from 30 May to 8 June 2016 (excluding Sunday, 5 June and Tuesday, 7 June 2016) (the “**Hearing**”).<sup>3</sup> In accordance with PO 1, the Hearing was broadcast to a public viewing room at the World Bank Headquarters.

56. The following individuals were present at the Hearing:

TRIBUNAL	
Professor Albert Jan van den Berg	President
Mr. Gary Born	Arbitrator
Sir Daniel Bethlehem QC	Arbitrator

ICSID SECRETARIAT	
Ms. Lindsay Gastrell	Secretary of the Tribunal

CLAIMANT	
<b>Counsel:</b>	
Ms. Marney L. Cheek	Covington & Burling LLP
Mr. Alexander A. Berengaut	Covington & Burling LLP
Mr. James M. Smith	Covington & Burling LLP
Mr. Michael A. Chajon	Covington & Burling LLP
Mr. John K. Veroneau	Covington & Burling LLP
Ms. Gina M. Vetere	Covington & Burling LLP
Ms. Natalie M. Derzko	Covington & Burling LLP
Mr. Nikhil V. Gore	Covington & Burling LLP
Ms. Lauren S. Willard	Covington & Burling LLP
Mr. Alexander B. Aronson	Covington & Burling LLP
Ms. Tina M. Thomas	Covington & Burling LLP
Ms. Elizabeth Fouhey	Covington & Burling LLP
Ms. Idun Klakegg	Covington & Burling LLP
Mr. Richard G. Dearden	Gowling WLG
Ms. Wendy J. Wagner	Gowling WLG
Mr. Alejandro Luna Fandino	Olivares
<b>Parties:</b>	
Mr. Arvie J. Anderson	Eli Lilly and Company
Mr. Steven P. Caltrider	Eli Lilly and Company
Ms. Arleen Palmberg	Eli Lilly and Company

<sup>3</sup> PO 5 provided that the Hearing would take place from 30 May to 9 June 2016, excluding only Sunday, 5 June 2016. During the course of the hearing, the Parties conferred and agreed to a modified schedule, pursuant to which the Hearing would be adjourned on 4, 7 and 9 June 2016. Later, the Parties informed the Tribunal that in order to complete their presentations, they would need the Hearing to proceed on 4 June 2016.

<b><i>Witnesses:</i></b>	
Mr. Robert A. Armitage	Retired, formerly with Lilly
Ms. Anne Nobles	Retired, formerly with Lilly
Mr. Robert Postlethwait	Retired, formerly with Lilly
Mr. Peter George Stringer	Independent consultant, formerly with Lilly
<b><i>Experts:</i></b>	
Professor Jay Erstling	William Mitchell College of Law
Professor Gilda Gonzalez Carmona	Universidad Nacional Autonoma de México, formerly with Instituto Mexicano de la Propiedad Industrial
Mr. Stephen G. Kunin	Oblon, Spivak, McClelland, Maier & Neustadt, LLP
Professor Bruce Levin	Columbia University
Professor Robert P. Merges	UC Berkeley School of Law
Mr. Andrew J. Reddon	McCarthy Tétrault LLP
Mr. Fabian Ramon Salazar	Independent consultant, formerly with Instituto Mexicano de la Propiedad Industrial
Professor Norman V. Siebrasse	University of New Brunswick
Mr. Philip Thomas	Retired, formerly with World Intellectual Property Organization
Mr. Murray Wilson	Retired, formerly with the Canadian Patent Office

<b>RESPONDENT</b>	
<b><i>Counsel:</i></b>	
Ms. Sylvie Tabet	Trade Law Bureau, Government of Canada
Mr. Shane Spelliscy	Trade Law Bureau, Government of Canada
Mr. Adrian Johnston	Trade Law Bureau, Government of Canada
Ms. Krista Zeman	Trade Law Bureau, Government of Canada
Mr. Mark Luz	Trade Law Bureau, Government of Canada
Ms. Mariella Montplaisir	Trade Law Bureau, Government of Canada
Ms. Shawna Lesaux	Trade Law Bureau, Government of Canada
Mr. Marc-Andre Leveille	Trade Law Bureau, Government of Canada
<b><i>Parties:</i></b>	
Ms. Michelle Hoffman	Investment Trade Policy, Government of Canada
Mr. Denis Martel	Industry Canada, Government of Canada
Mr. Sanjay Venugopal	Industry Canada, Government of Canada
Mr. Brad Jenkins	Industry Canada, Government of Canada
<b><i>Witnesses:</i></b>	
Mr. Marcel Brisebois	Industry Canada, Government of Canada
Dr. Michael Gillen	Retired, Government of Canada
<b><i>Experts:</i></b>	
Professor Tim Holbrook	Emory University
Mr. Ron Dimock (assisted by Mr. Ryan Evans)	Dimock Stratton LLP
Professor Heidi Lindner (assisted by Mr. Manuel Morante)	Arochi & Lindner
Mr. Dave Reed	Retired
Professor Daniel Gervais	Vanderbilt University Law School

57. Ms. Diana Burden and Ms. Laurie Hendrex provided court reporting services, and Mr. Daniel Giglio, Mr. Charles Roberts and Mr. Luis Arango provided simultaneous Spanish-English interpretation for the Parties' experts on Mexican law.
58. In addition to the attendees listed above, representatives from Mexico and the United States attended the Hearing in the hearing room.
59. On the final day of the Hearing (Day 8), the United States (through its representative Ms. Lisa Grosh) sought leave to make an oral submission to present further views in connection with its NAFTA Article 1128 written submission of 18 March 2016. At the Tribunal's invitation, the Parties' made oral observations on the issue, by which Claimant asked the Tribunal to deny the United States' request, and Respondent sought to have it granted. The Tribunal took a short recess to deliberate and then ordered that the United States would not be permitted to make an oral submission during the Hearing because it had not provided the required advance notice under NAFTA Article 1128. Instead, the Tribunal invited the United States to submit a written note setting forth its views by midday. By email of later that day, the Supplemental Submission of the United States was provided to the Parties and the Tribunal. The Parties were then given an opportunity to make oral observations on the United States' position.
60. At the close of the Hearing, the Tribunal and the Parties discussed a number of post-Hearing procedural steps. The Tribunal then confirmed the agreed post-Hearing schedule by letter on 9 June 2016.
61. In accordance with that schedule (as revised by the Parties' agreement), on 25 July 2016, each Party submitted its Post-Hearing Memorial ("**C-PHM**" and "**R-PHM**"). On 8 August 2016, each Party submitted its Reply Post-Hearing Memorial ("**C-RPHM**" and "**R-RPHM**").
62. On 22 August 2016, Claimant submitted its submission on costs, together with Authorities CL-200 to CL-206 ("**C-CS**"), and Respondent submitted its submission on costs, together with Authorities RL-160 to RL-173 ("**R-CS**").

### III. BACKGROUND TO THE DISPUTE

#### A. Canadian Patent Law

63. The patent system in Canada is rooted in the Canadian Patent Act (the “**Patent Act**”).<sup>4</sup> As explained by the Supreme Court of Canada, an “inventor gets his patent according to the terms of the Patent Act, no more and no less”.<sup>5</sup>
64. Under the Patent Act, the day-to-day administration of the patent system is carried out by the Patent Office, which is part of the Canadian Intellectual Property Office (“**CIPO**”). The Commissioner of Patents has ultimate responsibility for granting and issuing patents, and patent examiners work on his or her behalf to review each patent application for compliance with the Patent Act and the Patent Rules.<sup>6</sup> Decisions of patent examiners may be appealed to the Commissioner, although the review is in fact conducted by the Patent Appeal Board, a body within the Patent Office, and then approved by the Commissioner.<sup>7</sup>
65. Both Parties have referred to the patent system as a bargain between society and the inventor. On one side, the invention must be new, useful and non-obvious, and the inventor must adequately describe it to the public.<sup>8</sup> In exchange, the inventor is given certain exclusive rights to the invention for a prescribed period.
66. Accordingly, the Patent Act defines “invention” as “any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement”, and sets forth requirements pertaining to disclosure.<sup>9</sup> One of these requirements—that an invention be useful—is at the heart of this dispute. Section VIII below elaborates the Parties’ positions on the utility requirement in the Patent Act and its application by Canadian courts.

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<sup>4</sup> Siebrasse First Report ¶3 (“Patent rights in Canada are wholly a creature of statute”); Dimock Report ¶13 (“There is no common law right to a patent. The patent system is entirely rooted in legislation.”).

<sup>5</sup> **R-143**, *Canada (Commissioner of Patents) v. Farbwerke Hoechst Aktien-Gesellschaft Vormals Meister Lucius & Bruning*, [1964] SCR 49, p. 57.

<sup>6</sup> **C-050/R-001**, Patent Act, R.S.C. 1985, c. P-4, §4(2).

<sup>7</sup> Dimock First Report §I.C.

<sup>8</sup> See Dimock First Report §I.B; Siebrasse First Report §II.

<sup>9</sup> **C-050/R-001**, Patent Act, RSC, 1985, c. P-4, §2.

67. Here, the Tribunal simply notes that, under Canadian judicial authority, utility may be either demonstrated or “soundly predicted”. The doctrine of sound prediction was adopted by the Supreme Court of Canada in *Monsanto Co. v. Canada (Commissioner of Patents)*.<sup>10</sup> Sound prediction has particular applicability to patents for pharmaceuticals, as it allows an inventor to predict that untested chemical compounds would behave in the same way to other structurally similar compounds. The doctrine of sound prediction may permit those untested compounds to be patented.<sup>11</sup>
68. Since 1987, the Patent Act has allowed inventors to patent pharmaceutical compounds, provided that the patentability requirements identified above are satisfied.<sup>12</sup> Initially, however, Canada maintained a compulsory licensing system under which generic pharmaceutical manufacturers could license and produce patented pharmaceutical products before the expiry of the patent.<sup>13</sup> Generic manufacturers that paid a statutory fee of four or five per cent to the patentee were permitted to bring the generic to market.<sup>14</sup>
69. In 1993, Canada eliminated the compulsory licensing regime, partly in recognition of its international obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (“**TRIPS**”) and NAFTA.<sup>15</sup> It was replaced with a set of regulations entitled Patented Medicines (Notice of Compliance Regulations) (“**PM(NOC)**”), which are uniquely applicable to the pharmaceutical sector.<sup>16</sup> PM(NOC) requires any pharmaceutical market entrant, such as a generic manufacturer, to obtain a Notice of Compliance (“**NOC**”)

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<sup>10</sup> **C-061/R-023**, *Monsanto Co. v. Canada (Commissioner of Patents)*, [1979] 2 SCR (“*Monsanto*”) at 1113-14 (finding that an inventor who had tested three related compounds to inhibit the vulcanization of rubber could soundly predict the utility of the remaining compounds in the same genus without testing each one).

<sup>11</sup> See Memorial ¶51, citing **C-61/R-023**, *Monsanto* at 1113-14. Siebrasse First Report ¶28; see also **C-201**, *Burton-Parsons Chemicals, Inc v Hewlett-Packard (Canada) Ltd*, [1976] 1 SCR 555, at 565.

<sup>12</sup> Siebrasse First Report ¶35. (“For many years, Canada, like many other countries, did not permit patents that claimed a medicine or food. In 1987, however, section 41 of the Patent Act, which prohibited such claims, was repealed. Until then, a pharmaceutical compound could only be claimed in connection with the process by which it was made”).

<sup>13</sup> **C-323**, Patent Act, S.C. 1923, c. 23, §17.

<sup>14</sup> **CL-079**, WTO Report, “Canada – Patent Protection of Pharmaceutical Products”, ¶4.6. Respondent’s expert Mr. Dimock agreed that the compulsory licensing system “hardly considered” the interest of patentees. Dimock Report ¶39. See **C-321**, Comm’n on Pharm. Servs., Canadian Pharm. Ass’n, *Pharmacy in a New Age: Report of the Commission on Pharmaceutical Services* 25 (1971) (recognizing that the Canadian patent law regime effectively denies market exclusivity to pharmaceuticals); **C-322**, *Celotex Corp. v. Donnacona Paper Co.*, (1939) 2 C.P.R. 26, at 41 (Ex. Ct.) (recognizing the pharmaceutical patent regime as impractical and oppressive).

<sup>15</sup> Dimock First Report ¶40.

<sup>16</sup> Dimock First Report ¶41.

from the Minister of Health.<sup>17</sup> However, before any NOC is issued, the patent-holder has an opportunity to bring an application in the Federal Court to prohibit the Minister from issuing an NOC.<sup>18</sup>

70. Patent law cases can also come before the Federal Court in other ways, such as on appeal from a decision of the Patent Commissioner.<sup>19</sup> In addition, under the Patent Act, “any interested person” may challenge a patent in invalidation proceedings before the Federal Court.<sup>20</sup>

## **B. Zyprexa Patent (Olanzapine)**

71. In 1975, Lilly Industries Limited U.K. filed for a Canadian patent covering 15 trillion compounds, including olanzapine, which was one of the “most preferred compounds”.<sup>21</sup> In 1980, this patent was issued with Canadian Patent No. 1,075,687 (the “**687 Patent**”).<sup>22</sup>
72. According to Claimant, Zyprexa was first synthesized in 1982 in the United Kingdom.<sup>23</sup>
73. On 24 April 1991, Eli Lilly and Company Limited U.K. filed Canadian Patent Application No. 2,041,113 in relation to olanzapine, as a selection from the genus of the ‘687 Patent (the “**Zyprexa Patent**” or “**113 Patent**”).<sup>24</sup> The patent application mentions the invention as a novel organic compound, to be used as a pharmaceutical in the context of the “category known as antipsychotics for treating serious mental conditions such as schizophrenia and schizophreniform illnesses”.<sup>25</sup>

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<sup>17</sup> Dimock First Report ¶¶43, 154.

<sup>18</sup> Dimock First Report ¶¶43, 154. In such a suit, the generic manufacturer may allege that the patent is invalid on any ground, including utility.

<sup>19</sup> See, e.g., **R-250**, *President and Fellows of Harvard College v. Canada (Commissioner of Patents)*, [2000] 4 FC 528, ¶14.

<sup>20</sup> **C-050/R-001**, Patent Act, RSC, 1985, c. P-4, §60(1). (“A patent or any claim in a patent may be declared invalid or void by the Federal Court at the instance of the Attorney General of Canada or at the instance of any interested person”.)

<sup>21</sup> **C-145/R-033**, *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 1018, ¶23.

<sup>22</sup> **R-292**, Patent Specification CA 1,075,687.

<sup>23</sup> Memorial ¶84; citing Postlethwait Statement ¶13.

<sup>24</sup> **C-126**, Canadian Patent Application No. 2,041,113 (published 24 April 1991).

<sup>25</sup> **C-126**, Canadian Patent Application No. 2,041,113 (published 24 April 1991), p. 1.

74. On 13 October 1995, Lilly Canada requested examination of the Zyprexa Patent by the Canadian Intellectual Property Office (“**CIPO**”).<sup>26</sup>
75. On 28 October 1996, Health Canada issued an NOC with the relevant requirements of the Food and Drug Regulations in relation to “Zyprexa Tablets”, in which the active ingredient was olanzapine.<sup>27</sup> Zyprexa was approved for the treatment of the symptoms of psychotic disorders.<sup>28</sup>
76. Claimant states that it launched Zyprexa in Canada in 1996.<sup>29</sup>
77. Following the patent examination process, on 17 March 1998, CIPO gave notice that the Zyprexa Patent application would be accepted.<sup>30</sup>
78. On 14 July 1998, the Zyprexa Patent was issued.<sup>31</sup> According to Claimant, it obtained patents for olanzapine in 81 jurisdictions, including Mexico and the United States.<sup>32</sup>
79. On 6 June 2007, Canadian drug manufacturer Novopharm Limited (“**Novopharm**”, now Teva Canada Limited) obtained regulatory approval from Health Canada to market a generic version of Zyprexa.<sup>33</sup> Lilly Canada had attempted to obtain an order prohibiting the Minister of Health from issuing that NOC to Novopharm, but its action was dismissed by the Federal Court on 5 June 2007.<sup>34</sup> Lilly Canada’s appeal in relation to the NOC was dismissed as moot, given that the NOC had already been issued.<sup>35</sup>

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<sup>26</sup> **C-131**, Request for Examination (Canadian Patent Application 2,041,113) (Zyprexa/Olanzapine).

<sup>27</sup> **C-133**, Notice of Compliance DIN(s) 02229250, 02229269, 02229277, 02229285 (28 October 1996).

<sup>28</sup> **C-137**, Centerwatch, *Zyprexa*.

<sup>29</sup> Memorial ¶92.

<sup>30</sup> **C-065**, Notice of Allowance re Canadian Patent Application No. 2,041,113 (Zyprexa/Olanzapine) (5 September 1997).

<sup>31</sup> **C-132**, Canadian Patent No. 2,041,113 (14 July 1998).

<sup>32</sup> Memorial ¶85; *citing* Armitage First Statement ¶11; **C-096**, Mexican Zyprexa file wrapper; C-426, File History for Mexican Patent No. 173791 (Zyprexa/olanzapine) (Partial Translation for C-096); **C-128**, U.S. Patent Application No. 07/890,348 (22 May 1992).

<sup>33</sup> **C-151**, Health Canada, Notice of Compliance Database, Search Results for “Olanzapine”.

<sup>34</sup> **C-144/R-032**, *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596.

<sup>35</sup> **C-512/R-208**, *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359.

80. Lilly Canada filed suit against Novopharm for patent infringement. On 5 October 2009, the Federal Court dismissed the action. In the same judgment, Justice James W. O'Reilly invalidated the Zyprexa Patent on the basis that it “is not a valid selection patent”, holding that it “does not describe an invention over and above what was disclosed in the ‘687 patent”.<sup>36</sup> The judgment held further that:

One does not have to discredit a product or those who make it in order to invalidate its patent. I am satisfied that olanzapine is a useful drug for the treatment of schizophrenia. However, Lilly had a patent for it that lasted from 1980 to 1997. It sought a separate and supplementary patent for it, no doubt, to try to recuperate some of its corporate investment in its neuroleptic programme. . . . But as the sun began to set on the '687 patent, it became important to try to extend the patent protection for olanzapine. The '113 patent was clearly drafted with a view of justifying a fresh patent. But the evidence just was not there, yet. Accordingly, I must conclude that the '113 is not a valid selection patent. The claims set out above are invalid. Novopharm is entitled to relief under s. 8 of the *Patented Medicines (Notice of Compliance) Regulations*, to be determined in a separate proceeding, and to its costs.<sup>37</sup>

81. Lilly Canada appealed this judgment. The appeal was allowed, and the Federal Court of Appeal set aside the Federal Court's decision on 21 July 2010. The Federal Court of Appeal found that Justice O'Reilly had erroneously treated the conditions for a valid selection patent as “an independent basis upon which to attack the validity of a patent”.<sup>38</sup> The Federal Court of Appeal remanded the issues of “utility” and “sufficiency of disclosure” to the Federal Court for re-determination.<sup>39</sup>
82. Justice O'Reilly reconsidered the case on the basis of the directions of the Federal Court of Appeal. By judgment dated 10 November 2011 (the “**Zyprexa Decision**”), he found the Zyprexa Patent to be invalid for lack of utility, noting that:

Novopharm has established that the patent's promise had not been demonstrated and could not have been soundly predicted on the

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<sup>36</sup> C-145/R-033, *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 1018, ¶139.

<sup>37</sup> *Id.*, ¶154.

<sup>38</sup> C-046/R-015, *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, ¶4.

<sup>39</sup> *Id.*, ¶124.

basis of the evidence available to the inventors in 1991. Accordingly, I must conclude that the '113 is not a valid selection patent. The claims set out above are invalid. Lilly's action for patent infringement is dismissed, with costs.<sup>40</sup>

83. Lilly Canada appealed the Zyprexa Decision to the Federal Court of Appeal. On 10 September 2012, the appeal was dismissed.<sup>41</sup>

84. On 16 May 2013, the Supreme Court of Canada refused leave to appeal the decision of the Federal Court of Appeal of 10 September 2012.<sup>42</sup>

### C. **Strattera Patent (Atomoxetine)**

85. In 1979, Claimant obtained a Canadian patent for a genus group of compounds including atomoxetine (Canadian Patent No. 1,051,034). The patent specification mentions compounds "useful as psychotropic agents, particularly as anti-depressants".<sup>43</sup>

86. In 1985, Claimant filed for a second patent relating only to atomoxetine, stating that "[t]he compound of this invention is used as an antidepressant in the method of this invention, which comprises administering to a human suffering from depression an effective antidepressant dose of the compound".<sup>44</sup>

87. According to Claimant, it approached doctors at the Massachusetts General Hospital ("MGH") in the United States, with a proposal for a joint human clinical trial to test the efficacy of atomoxetine in treating attention-deficit/hyperactivity disorder ("ADHD"). The trial was carried out from January to April 1995, and a report was subsequently published in the *American Journal of Psychiatry*.<sup>45</sup>

88. On 4 January 1996, Claimant filed a "new use" patent application for atomoxetine under the PCT, requesting entry into the Canadian national phase on 7 July 1997 (the "**Strattera**

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<sup>40</sup> C-146/R-016, *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, ¶273.

<sup>41</sup> C-147/R-035 *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2012 FCA 232.

<sup>42</sup> R-002, *Eli Lilly Canada Inc., et al. v. Novopharm Limited*, 2013 CanLII 26762 (SCC).

<sup>43</sup> R-247, Patent Specification CA 1,051,034, p. 1.

<sup>44</sup> R-269, Patent Specification CA 1,181,430, p. 20.

<sup>45</sup> Memorial ¶119; citing C-152, Thomas Spencer, et al, *Effectiveness and Tolerability of Tomoxetine in Adults with Attention Deficit Hyperactivity Disorder*, 155 *Am. J. Psychiatry* 693 (May 1998).

**Patent**” or “**735 Patent**”).<sup>46</sup> The patent claims the use of atomoxetine for a “method of treatment of the psychiatric disorder known as attention-deficit/hyperactivity disorder”.<sup>47</sup>

89. On 27 February 2001, Claimant requested examination of the Strattera Patent by CIPO.<sup>48</sup> On 21 January 2002, it requested expedited examination on the basis that “[t]he invention described and claimed in the present application has become of great commercial importance to the Applicant”.<sup>49</sup>
90. On 21 March 2002, CIPO gave notice that the Strattera Patent would be accepted.<sup>50</sup>
91. On 1 October 2002, the Strattera Patent was issued.<sup>51</sup> According to Claimant, it also obtained patents for atomoxetine in dozens of other jurisdictions.<sup>52</sup>
92. On 24 December 2004, Health Canada issued an NOC with respect to Strattera and it was launched on the market thereafter.<sup>53</sup>
93. Novopharm challenged the validity of the Strattera Patent in the Federal Court. On 14 September 2010, Justice R.L. Barnes issued a judgment finding the Strattera Patent to be “invalid on the basis of inutility” (the “**Strattera Decision**”).<sup>54</sup> Justice Barnes held that:

to the extent that the ‘735 Patent is based on a sound prediction from the MGH Study that atomoxetine is useful in the treatment of ADHD, the patent fails for want of disclosure before some reference to those findings was required to be set out in the patent.<sup>55</sup>

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<sup>46</sup> **C-154**, Canadian Patent Application No. 2,209,735 (published 18 July 1996).

<sup>47</sup> *Id.*, p. 1. *See also* **R-026**, Patent Specification CA 2,209,735.

<sup>48</sup> **C-066**, Request for Examination re Canadian Patent Application No. 2,209,735 (Strattera/Atomoxetine).

<sup>49</sup> **C-157**, Request to Advance Examination (Canadian Patent Application 2,209,735) (Strattera).

<sup>50</sup> **C-069**, Notice of Allowance re Canadian Patent Application No. 2,209,735 (Strattera/Atomoxetine) (21 March 2002).

<sup>51</sup> **C-067**, Canadian Patent No. 2,209,735 (Strattera) (1 December 2002).

<sup>52</sup> Memorial ¶124; *citing* Armitage First Statement ¶19 and Appendix B.

<sup>53</sup> **C-159**, Notice of Compliance DIN(s) 02262800, 02262819, 02262827, 02262835, 02262843.

<sup>54</sup> **C-160/R-027**, *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, ¶122.

<sup>55</sup> *Id.*, ¶120.

94. Claimant appealed the Strattera Decision. On 5 July 2011, the Federal Court of Appeal dismissed the appeal.<sup>56</sup> On 8 December 2011, Claimant was denied leave to appeal to the Supreme Court of Canada.<sup>57</sup>

#### **IV. REQUESTS FOR RELIEF**

##### **A. Relief Sought by Claimant**

95. In the SoC, Claimant requests the following relief:

- (i) damages for the full measure of direct losses and consequential damages sustained as a consequence of Respondent's breach of its obligations under NAFTA Chapter 11, estimated in an amount not less than CDN \$500 million plus any payments Lilly or its enterprise is required to make arising from the improvident loss of its Zyprexa and Strattera Patents or its inability to enforce its Zyprexa and Strattera Patents;
- (ii) the full costs associated with these proceedings, including all professional fees and disbursements, as well as the fees of the arbitral tribunal;
- (iii) pre-award and post-award interest;
- (iv) payment of a sum of compensation equal to any tax consequences of the award, in order to maintain the award's integrity; and
- (v) such further relief as the arbitral tribunal may deem just and appropriate.<sup>58</sup>

96. Claimant confirms this request for relief in the Memorial and the Reply and its Post-Hearing Memorial.<sup>59</sup>

97. In the Opposition on Jurisdiction, Claimant requests that the Tribunal:

- (i) reject Canada's jurisdictional objection as untimely under UNCITRAL Article 21(3) or, in the alternative, reject Canada's

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<sup>56</sup> **C-163/R-028**, *Eli Lilly & Co. v. Teva Canada Ltd.*, 2011 FCA 220.

<sup>57</sup> **R-003**, *Eli Lilly and Company v. Teva Canada Limited*, 2011 CanLII 79177 (SCC).

<sup>58</sup> SoC ¶85.

<sup>59</sup> Memorial ¶295; Reply ¶371; C-PHM ¶323.

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.<sup>60</sup>

## **B. Relief Sought by Respondent**

98. In the SoD, Respondent requests the Tribunal to issue an Award:

- dismissing Claimant's claim in its entirety;
- awarding Respondent its costs, with applicable interest, pursuant to Article 1135(1) of the NAFTA and Article 40 of the UNCITRAL Rules; and
- granting any other relief that may seem just.<sup>61</sup>

99. Respondent confirms this request in the Counter-Memorial, the Rejoinder and its Post-Hearing Memorial.<sup>62</sup>

## **V. INTRODUCTION TO THE TRIBUNAL'S ANALYSIS**

### **A. The Jurisdiction of the Tribunal and Questions of Applicable Law**

100. The jurisdiction of the Tribunal is rooted in Section B of Chapter Eleven of NAFTA. In this regard, insofar as may be material for purposes of these proceedings,<sup>63</sup> NAFTA Article 1116(1) provides that a Party may submit to arbitration under Section B of Chapter Eleven a claim that another Party has breached an obligation under Section A of Chapter Eleven. This provision is echoed in Article 1117(1) in respect of claims on behalf an enterprise.

101. It follows from these provisions that the Tribunal's jurisdiction is limited, in the circumstances of this case, to claims of a breach of obligations under Section A of NAFTA

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<sup>60</sup> Opposition on Jurisdiction ¶50.

<sup>61</sup> SoD ¶120.

<sup>62</sup> Counter-Memorial ¶421; Rejoinder ¶283; R-PHM ¶273.

<sup>63</sup> The Tribunal notes for completeness the reference in NAFTA Articles 1116(1) and 1117(1) to claims under NAFTA Articles 1503(2) and 1502(3)(a) falling within the jurisdiction of a tribunal established under Section B of NAFTA Chapter Eleven.

Chapter Eleven. A NAFTA Chapter Eleven tribunal is not a tribunal of general jurisdiction with competence to adjudicate claims of a breach of other provisions of NAFTA.

102. Without prejudice to this appreciation, the Tribunal notes, as will be evident from the discussion that follows on the question of applicable law, that the proper limitation of the Tribunal's jurisdiction to alleged breaches of Section A of NAFTA Chapter Eleven does not require the Tribunal to ignore other provisions of the NAFTA, other agreements between the NAFTA Parties, or other relevant and applicable rules of international law, for purposes of assessing the claims before it.
103. As regards applicable law, NAFTA Article 1131(1), under the heading "Governing Law", provides: "A Tribunal established under this Section shall decide the issues in dispute in accordance with this Agreement and applicable rules of international law". This reflects, for purposes of proceedings under NAFTA Chapter Eleven, the requirement in NAFTA Article 102(2), addressing the objectives of the NAFTA, that "The Parties shall interpret and apply the provisions of this Agreement in the light of its objectives set out in paragraph 1 and in accordance with applicable rules of international law". Having regard also to the terms of Article 33(1) of the UNCITRAL Rules,<sup>64</sup> the Tribunal accordingly observes that the applicable law for purposes of these proceedings is the NAFTA and applicable rules of international law.
104. The Tribunal notes also the terms of NAFTA Article 1112(1) and Article 103(2), which provide further clarity on the relevant applicable law in the event of any inconsistency, first, between NAFTA Chapter Eleven and other chapters of the NAFTA, and, second, between the NAFTA and other agreements. Thus, Article 1112(1) provides: "In the event of any inconsistency between this Chapter and another Chapter, the other Chapter shall prevail to the extent of the inconsistency". Article 103(2) provides: "In the event of any inconsistency between this Agreement and such other agreements [to which the Parties to

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<sup>64</sup> Article 33(1) of the UNCITRAL Arbitration Rules 1976 provides: "The arbitral tribunal shall apply the law designated by the parties as applicable to the substance of the dispute. Failing such designation by the parties, the arbitral tribunal shall apply the law determined by the conflict of laws rules which it considers applicable".

the NAFTA are party], this Agreement shall prevail to the extent of the inconsistency, except as otherwise provided in this Agreement”.

105. The Tribunal notes, additionally, the terms of NAFTA Article 1131(2), which provides: “An interpretation by the [NAFTA Free Trade] Commission of a provision of this Agreement shall be binding on a Tribunal established under this Section”. In this regard, the Tribunal notes that the Commission adopted interpretations of, *inter alia*, NAFTA Article 1105(1), on 31 July 2001 (“**FTC Note**”).<sup>65</sup>
106. As will be evident from the FTC Note interpretation of Article 1105(1), a tribunal seised of a dispute concerning, *inter alia*, the interpretation and application of this provision is required to have regard at the very least to customary international law to determine the content, under customary international law, of the minimum standard of treatment requirement for purposes, *inter alia*, of interpreting and applying the concepts of “fair and equitable treatment” and “full protection and security”. It follows, and in the Tribunal’s view this accords with a plain reading of both NAFTA Article 1131(1) and Article 102(2), that the phrase “applicable rules of international law” addresses not simply, for example, rules of interpretation of treaties, such as those reflected in Articles 31 and 32 of the Vienna Convention on the Law of Treaties (“**VCLT**”), but also any other applicable rules of international law that may be relevant to the case before it. This would include, for example, relevant and applicable rules on State responsibility, such as go to questions of attribution of conduct, as well as other relevant and applicable rules of international law that inform the interpretation and application of the provisions, *inter alia*, of Section A of NAFTA Chapter Eleven that are in issue in the proceedings. It will be a matter for each tribunal constituted under Section B of NAFTA Chapter Eleven to evaluate, with the

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<sup>65</sup> Under the heading “Minimum Standard of Treatment in Accordance with International Law”, the Commission adopted the following interpretations: “1. Article 1105(1) prescribes the customary international law minimum standard of treatment of aliens as the minimum standard of treatment to be afforded to investments of investors of another Party. 2. The concepts of ‘fair and equitable treatment’ and ‘full protection and security’ do not require treatment in addition to or beyond that which is required by the customary international law minimum standard of treatment of aliens. 3. 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 Article 1105(1)”.

assistance of submissions of the parties on the matter, the precise scope of the phrase “applicable rules of international law” in the circumstances of the case of which it is seised.

107. As regards the interpretation of the NAFTA, the Tribunal will proceed by reference to the commonly accepted customary international law rules of interpretation of treaties reflected in Articles 31 and 32 of the VCLT.

## **B. Burden of Proof**

108. The Tribunal shall be guided by Article 24(1) of the UNCITRAL Arbitration Rules, which provides that “[e]ach party shall have the burden of proving the facts relied on to support his claim or defence”.

109. The Tribunal shall apply the well-established principle that the party alleging a violation of international law giving rise to international responsibility has the burden of proving it. If that party adduces evidence that *prima facie* supports its allegation, the burden of proof may shift to the other party when the circumstances so justify.

## **C. Roadmap to the Tribunal’s Analysis**

110. During the Hearing, each Party proposed a decision tree setting forth what it considered to be the issues to be addressed by the Tribunal, and the order in which those issues should be addressed.<sup>66</sup> The Parties agree on the fundamental issues to be decided, although they disagree on the order of the analysis. Having considered the decision tree of each side, the Tribunal will approach the issues in the following order:

- (i) What is the scope of the Tribunal’s jurisdiction, if any? (Section VI)
- (ii) Is denial of justice the only basis of liability for judicial measures under NAFTA Chapter Eleven? (Section VII)
- (iii) Has there been a dramatic change in the utility requirement in Canadian patent law? (Section VIII)

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<sup>66</sup> Respondent’s Opening Statement, slide 7; Claimant’s Closing Presentation, slide 140; R-PHB ¶5.

- (iv) Is the utility requirement in Canadian patent law, as applied to the Zyprexa and Strattera Patents, arbitrary and/or discriminatory?<sup>67</sup> (Section IX)
- (v) If (iii) and/or (iv) is answered in the affirmative, did the invalidations of the Zyprexa and Strattera Patents breach Respondent's obligations under NAFTA Article 1110 and/or Article 1105?

## **VI. JURISDICTION**

### **A. Applicable Law**

111. Article 21(3) of the UNCITRAL Rules states that "A plea that the arbitral tribunal does not have jurisdiction shall be raised not later than in the statement of defence ...".

112. NAFTA Article 1116(2) provides:

An investor may not make a claim if more than three years have elapsed from the date on which the investor first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the investor has incurred loss or damage.

113. NAFTA Article 1117(2) provides:

An investor may not make a claim on behalf of an enterprise ... if more than three years have elapsed from the date on which the enterprise first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the enterprise has incurred loss or damage.

### **B. The Parties' Positions**

114. In the Rejoinder, Respondent raised for the first time an objection to the Tribunal's jurisdiction *ratione temporis*. Respondent's position is that Claimant recast its claim in the Reply in a way that brought it outside of the three-year limitation period set forth in NAFTA Articles 1116(2) and 1117(2). In response, Claimant argues that this jurisdictional objection should be rejected as untimely and, in any event, fails as a matter of law.

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<sup>67</sup> Although not listed as a fundamental issue on the Parties' decision trees, the Tribunal finds it appropriate to address Claimant's allegations of arbitrariness and discrimination in a separate section, as explained further below at ¶389.

**(1) Respondent's Position**

***a. Timeliness of Respondent's Jurisdictional Objection***

115. Respondent contends that its jurisdictional objection is timely because (i) it was raised as early as possible; (ii) Claimant was not prejudiced by the timing of this objection; and (iii) an objection to jurisdiction pursuant to NAFTA Articles 1116(2) and 1117(2) cannot be waived.<sup>68</sup>
116. According to Respondent, Article 21(3) of the UNCITRAL Rules applies only to the extent that a respondent knew or should have known of the jurisdictional objection at the filing of the statement of defence.<sup>69</sup> When a claimant is permitted to make additional written submissions after the statement of claim and reorients its claim therein, Article 21(3) cannot be used to bar a jurisdictional objection arising from the new version of the claim.<sup>70</sup>
117. Respondent argues that in this case, prior to the Reply, Claimant's claims were seemingly based on the invalidation of the Zyprexa and Strattera Patents, and Respondent therefore did not raise an objection under NAFTA Articles 1116(2) and 1117(2). Then, when Claimant began to reorient its claim during the document production phase, Respondent immediately objected.<sup>71</sup> According to Respondent, it became clear only in the Reply that the measure Claimant was challenging was the promise utility doctrine itself, creating the basis for Respondent's jurisdictional objection. Respondent asserts that it made this objection to the Tribunal as soon as possible—in its next written submission, the Rejoinder.
118. In any event, according to Respondent, even if the Tribunal were to find that Respondent should have brought the objection sooner, Article 21(3) cannot be interpreted to bar its

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<sup>68</sup> R-PHB §III.A.

<sup>69</sup> R-PHB ¶78.

<sup>70</sup> R-PHB ¶79. Respondent points out that under Article 22 of the UNCITRAL Rules, a claimant does not have a presumptive right to make another written submission following the statement of claim.

<sup>71</sup> R-PHB ¶81, *citing* Procedural Order No. 2, Annex B, in which Respondent stated: "In order to establish jurisdiction in this matter, Claimant stated the measures to be the invalidation of two of its patents by the Federal Court. Having asked the Tribunal to assert jurisdiction on the basis of these two specific measures, Claimant cannot now recast the measure as 'Canada's development of a new utility doctrine'. This goes beyond the Tribunal's jurisdiction, extending to an undefined time period and cases involving unspecified patents that did not form any part of Claimant's investment."

objection in the present circumstances, because Claimant suffered no prejudice from the timing of the objection. Respondent argues that the purpose of Article 21(3) “is to prevent surprise and prejudice to a claimant at the hearing”.<sup>72</sup> This is not a concern in this case, as Respondent raised its jurisdictional objection six months before the Hearing, and Claimant had the opportunity to respond in writing.<sup>73</sup>

119. Finally, Respondent argues that the Tribunal must address its jurisdictional objection in any event, because an objection made pursuant to NAFTA Articles 1116(2) and 1117(2) cannot be waived by a disputing party.<sup>74</sup> These provisions set a temporal limit on a tribunal’s jurisdiction that forms part of the NAFTA Parties’ consent to arbitration. According to Respondent:

variation of the terms of a State Party’s consent to arbitration in the context of any particular dispute is not possible, unless allowed for in the treaty, because it would amount to an amendment of the terms of the underlying treaty itself. Therefore, in a treaty-based investor-State arbitration, in order to ascertain the limits of its jurisdiction, the Tribunal must look not to the conduct or agreement of the particular disputing parties before it, but rather to the terms of the treaty by which it is governed and the agreement of the States that are Parties to it.<sup>75</sup>

120. Respondent’s view is that the UNCITRAL Rules do not change this required approach; they cannot expand the jurisdiction of a Chapter Eleven tribunal.<sup>76</sup> To support its position, Respondent points to the following provisions: Article 1(2) of the UNCITRAL Rules,<sup>77</sup> NAFTA Article 1120(2)<sup>78</sup> and NAFTA Article 1122(1).<sup>79</sup>

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<sup>72</sup> R-PHB ¶82.

<sup>73</sup> R-PHB ¶¶82-83.

<sup>74</sup> R-PHB ¶¶84-88.

<sup>75</sup> R-PHB ¶86.

<sup>76</sup> R-PHB ¶88.

<sup>77</sup> Article 1(2) of the UNCITRAL Rules states: “These Rules shall govern the arbitration except that where any of these Rules is in conflict with a provision of the law applicable to the arbitration from which the parties cannot derogate, that provision shall prevail”.

<sup>78</sup> NAFTA Article 1120(2) states that the “applicable arbitration rules shall govern the arbitration except to the extent modified by this Section.”

<sup>79</sup> NAFTA Article 1122(1) states “Each Party consents to the submission of a claim to arbitration in accordance with the procedures set out in this Agreement” (emphasis added by Respondent).

***b. Claimant's Compliance with NAFTA Articles 1116(2) and 1117(2)***

121. Respondent submits that the Tribunal lacks jurisdiction *ratione temporis* because Claimant failed to satisfy the temporal limit on Respondent's consent to arbitrate found in NAFTA Articles 1116(2) and 1117(2). According to Respondent, Claimant's claim is fundamentally a challenge to the promise utility doctrine. On Claimant's own case, this doctrine crystallized when it was applied to Claimant's patent for raloxifene (the "**Raloxifene Patent**") by the Federal Court on 5 February 2008 (the "**Raloxifene Decision**").<sup>80</sup> Although Claimant suffered a loss as a result of the Raloxifene Decision, it chose not to submit its claim within three years of the alleged measures and loss.
122. Respondent interprets the three-year limitation period set out in NAFTA Articles 1116(2) and 1117(2) as a strict precondition to its consent to arbitration, such that a tribunal lacks jurisdiction *ratione temporis* over claims falling outside that time period.<sup>81</sup> It notes that a number of NAFTA Chapter Eleven tribunals have declined jurisdiction on this basis.<sup>82</sup>
123. For Respondent, the inclusion of the word "first" in Articles 1116(2) and 1117(2) is critical "because it identifies the precise moment at which the three-year time limitation begins to run": the instant when the investor or enterprise acquired knowledge of the alleged breach and a loss, as opposed to the middle or the end of such a breach.<sup>83</sup> Thus, the time-bar clock does not stop or restart even if a measure is alleged to have a continuing effect or to have been applied many times after original adoption.<sup>84</sup>

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<sup>80</sup> In the Raloxifene case, Claimant applied to the Federal Court for an order barring the Minister of Health from allowing the generic pharmaceutical company Apotex to market a generic version of Raloxifene before the expiration of Claimant's patent for the drug. The court held against Claimant on the ground that Claimant had failed to demonstrate or soundly predict utility as of the filing date of its Raloxifene Patent. **C-115/R-200**, *Eli Lilly Canada Inc. v. Apotex Inc. et al.*, 2008 FC 142. The Federal Court of Appeal affirmed the trial court's decision on March 25, 2009. **C-119/R-354**, *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97. Claimant sought leave to appeal the decision to the Supreme Court of Canada but the Supreme Court denied on October 22, 2009. **R-447**, *Eli Lilly Canada Inc. v. Apotex Inc.*, [2009] SCCA No. 219.

<sup>81</sup> Rejoinder ¶¶66-71.

<sup>82</sup> Rejoinder ¶¶70-71, citing, *inter alia*, **RL-090**, *Grand River Enterprises Six Nations, Ltd., et al. v. United States of America*, UNCITRAL, Decision on Objections to Jurisdiction, 20 July 2006 ("*Grand River v. United States*, Dec. on Juris."), ¶38; **RL-016**, *Apotex Holdings Inc., Apotex Inc. v. United States of America*, ICSID Case No. ARB(AF)/12/1, Award, 25 August 2014 ("*Apotex v. United States*"), ¶¶314-335.

<sup>83</sup> Rejoinder ¶72. See R-PHB ¶93.

<sup>84</sup> Rejoinder ¶72.

124. Respondent submits that all three NAFTA Parties have repeatedly expressed their view that this is the proper interpretation of Articles 1116(2) and 1117(2).<sup>85</sup> According to Respondent, such a clear, consistent position constitutes “a ‘subsequent agreement between the parties regarding the interpretation of the treaty’ and/or ‘subsequent practice’ which ‘shall be taken into account’ when interpreting NAFTA” under the VCLT.<sup>86</sup>
125. Similarly, Respondent asserts that tribunals interpreting Articles 1116(2) and 1117(2) have found that the limitation period is not subject to suspension or extension on account of subsequent actions of the respondent State.<sup>87</sup> Only the tribunal in *UPS v. Canada* held differently, deciding that a continuing breach tolls the limitations period. According to Respondent, the *UPS* approach, which has been rejected by the NAFTA Parties and endorsed by no other tribunal, fails to give meaning to the word “first” and is therefore contrary to the principle of *effet utile*.<sup>88</sup>
126. Applying this interpretation to the present case, Respondent asserts that Claimant failed to submit its claim within the prescribed three-year period. According to Respondent, Claimant’s claim as stated in the Reply is actually a challenge to the judiciary’s alleged adoption of the promise utility doctrine, not to the invalidation of the Zyprexa and Strattera Patents. On Claimant’s own case, this doctrine was developed through Canadian federal court decisions issued between 2002 and 2008.<sup>89</sup>
127. Respondent considers one of those court decisions, the Raloxifene Decision, particularly significant because it concerned Claimant’s own patent, and “[a]ll three aspects of Canadian patent law that Claimant now challenges in this arbitration as a violation of

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<sup>85</sup> Rejoinder ¶¶73-75. Respondent cites, for example, **RL-091**, *Merrill & Ring Forestry L.P. v. Canada*, UNCITRAL, 1128 Submission of the United States, 14 July 2008 (“*Merrill & Ring v. Canada*”), ¶5 (“An investor *first* acquires knowledge of an alleged breach and loss at a particular moment in time: under Article 1116(2), that knowledge is acquired on a particular ‘date’. Such knowledge cannot *first* be acquired on multiple dates, nor can such knowledge *first* be acquired on a recurring basis”).

<sup>86</sup> Rejoinder ¶75, quoting **RL-072**, VCLT Art. 31(3).

<sup>87</sup> Rejoinder ¶77, citing **CL-109/RL-058**, *Marvin Feldman Karpa v. United Mexican States*, ICSID Case No. ARB(AF)/99/1, Award, 16 December 2002 (“*Marvin Feldman v. Mexico*”), ¶63; **RL-090**, *Grand River v. United States*, ¶¶29, 81.

<sup>88</sup> Rejoinder ¶79, citing **RL-091**, *Merrill & Ring v. Canada*. See **RL-103**, *United Parcel Service v. Government of Canada*, UNCITRAL, Award on the Merits, 24 May 2007.

<sup>89</sup> Rejoinder ¶¶87-90.

Canada's obligations under Chapter Eleven were applied to Claimant" in that case.<sup>90</sup> Further, according to Respondent, Claimant suffered a loss as a result of the Raloxifene Decision on 30 March 2009, when the Minister of Health issued an NOC to the generic pharmaceutical company Apotex, which allowed Apotex to market a generic raloxifene product.<sup>91</sup>

128. Therefore, Respondent submits that "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 denied Claimant's application for leave to appeal the Raloxifene Decision on 22 October 2009.<sup>92</sup> Accordingly, the three-year limitation period started to run no later than that date.<sup>93</sup>
129. According to Respondent, by waiting nearly four years after that critical date to submit its claim to arbitration, Claimant has run afoul of NAFTA Articles 1116(2) and 1117(2).<sup>94</sup> In Respondent's view, the only claim on which Claimant could rely would be a denial of justice in the specific court proceedings concerning the Zyprexa and Strattera Patents, but Claimant has conceded that there was no such denial of justice.<sup>95</sup>
130. Respondent considers it irrelevant that the Raloxifene Decision was rendered in a PM(NOC) proceeding that did not result in an invalidation of the Raloxifene Patent (unlike the proceedings concerning the Zyprexa and Strattera Patents). According to Respondent, the important fact is that Claimant undeniably suffered a loss as a result of the Raloxifene Decision, which was based on the same judicial doctrine that Claimant now challenges.<sup>96</sup>

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<sup>90</sup> Rejoinder ¶94; *see id.* ¶¶95-103 and R-PHM ¶95.

<sup>91</sup> Rejoinder ¶¶104-108; R-PHM ¶95; **R-473**, Health Canada, Drugs and Health Products, Notice of Compliance Information, "Apo-Raloxifene".

<sup>92</sup> Rejoinder ¶110; **R-447**, *Eli Lilly Canada Inc. v. Apotex Inc.*, [2009] SCCA No. 219.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> Rejoinder ¶111, *citing* Reply ¶17.

<sup>96</sup> Rejoinder ¶107.

131. Respondent also finds it insignificant that the Raloxifene Decision does not relate to the Zyprexa or Strattera Patents, which are at issue in this case. In this regard, Respondent argues:

Claimant cannot have first acquired knowledge of the alleged NAFTA breach in the raloxifene proceedings with respect solely to its raloxifene patent, and then again first acquired knowledge of the alleged breach years later with respect to its atomoxetine and olanzapine patents. The fact that the impugned “promise utility doctrine” continued to affect Claimant’s other investments is irrelevant for the purpose of the limitations period imposed by NAFTA.<sup>97</sup>

132. Citing the award in *Grand River v. United States*, Respondent argues that finding jurisdiction in this case “would allow Claimant to base its claim on the most recent transgression, even if it had knowledge of earlier breaches and injuries”.<sup>98</sup> It would also erase the temporal limitation with respect to judicial doctrines, as court decisions are always limited to a specific dispute.<sup>99</sup>
133. In its Post-Hearing Memorial, Respondent argues in the alternative that Claimant’s claim would be barred by NAFTA Articles 1116(2) and 1117(2) even if the Tribunal were to consider the promise utility doctrine solely with respect to the Zyprexa and Strattera Patents.<sup>100</sup> According to Respondent, “given the lack of data supporting those patents when they were filed, Claimant knew of at least some loss of value after the decision in raloxifene”.<sup>101</sup>

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<sup>97</sup> Rejoinder ¶109; R-PHM ¶102.

<sup>98</sup> R-PHM ¶101, quoting **RL-090**, *Grand River v. United States*, Dec. on Juris., ¶81.

<sup>99</sup> R-PHM ¶101.

<sup>100</sup> R-PHM ¶¶103-105.

<sup>101</sup> R-PHM ¶105. Respondent argues that Claimant employed many Canadian patent attorneys, who would have understood the consequences of the promise utility doctrine on the Zyprexa and Strattera Patents. *Id.*, citing Armitage, Tr. 344:14-19 (“If there had been material developments in the Canadian law on utility, there would have been any number of communications back and forth between Lilly’s in-house patent attorneys and its Canadian patent agents”).

## (2) Claimant's Position

### *a. Timeliness of Respondent's Jurisdictional Objection*

134. Claimant submits that Respondent's jurisdictional objection is untimely and therefore should not be considered.<sup>102</sup> Under Article 21(3) of the UNCITRAL Rules, any objection to the Tribunal's jurisdiction must be raised no later than in the statement of defence. According to Claimant, Respondent has violated this provision by failing to raise its objection to the Tribunal's jurisdiction *ratione temporis* until the filing of the Rejoinder. Prior to that submission, Respondent had expressly declined to object to the Tribunal's jurisdiction on several occasions: during the First Procedural Hearing, in the Statement of Defence and in the Counter-Memorial.<sup>103</sup>
135. Claimant further argues that the timing of Respondent's objection is prejudicial, as highlighted by Respondent's attempt to deny Claimant an opportunity to respond.<sup>104</sup> In addition, it is not responsive to the Reply and thereby conflicts with Section 10.2 of Procedural Order No. 1<sup>105</sup> governing the scope of written submissions.<sup>106</sup> Moreover, in Claimant's view, the late objection has increased costs and compromised the efficiency of this proceeding.<sup>107</sup>
136. According to Claimant, tribunals have consistently found untimely jurisdictional objections to be procedurally improper and declined to entertain them on that basis, even where a party had attempted to reserve its right to raise an objection later than the statement of defence.<sup>108</sup>

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<sup>102</sup> Opposition on Jurisdiction §I.

<sup>103</sup> Opposition on Jurisdiction ¶8, *citing* Recording of First Procedural Hearing, 3:13-3:15, SoD ¶83, and Counter-Memorial ¶209 (stating that "Canada is not seeking dismissal of the claim on the basis of lack of jurisdiction").

<sup>104</sup> Opposition on Jurisdiction ¶9, *citing* Letter of Mr. Shane Spelliscy to Ms. Marney Cheek of 18 December 2015, p. 2.

<sup>105</sup> PO 1 §10.2 ("The Disputing Parties may 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 documents produced by that other Disputing Party with, or in the period following, that submission").

<sup>106</sup> Opposition on Jurisdiction ¶12.

<sup>107</sup> Opposition on Jurisdiction ¶9.

<sup>108</sup> Opposition on Jurisdiction ¶¶10-11, *citing* **CL-174**, *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,

137. Claimant submits that Respondent’s justification for delay—that Claimant “recast” its case in the Reply—is untenable and directly contradicted by the record.<sup>109</sup> According to Claimant, it has consistently argued that the measures at issue are the invalidations of the Zyprexa and Strattera Patents, not the promise utility doctrine itself or any action taken in respect of its Raloxifene Patent.<sup>110</sup> Claimant argues that it discussed the content and operation of the promise utility doctrine in the factual background section of the Reply only to provide the factual context for its case and to respond to arguments advanced in Respondent’s Counter-Memorial.<sup>111</sup>
138. According to Claimant, Respondent’s interpretation of UNCITRAL Rule 21(3) is flawed. In particular, Respondent provides no valid reason why this Rule should not be enforced in complex cases with multiple rounds of briefing.<sup>112</sup>
139. Claimant also rejects Respondent’s position that UNCITRAL Rule 21(3) is pre-empted by NAFTA. Claimant considers this argument “nonsensical” because NAFTA itself specifies that Chapter Eleven proceedings may be governed by the UNCITRAL Rules.<sup>113</sup> Although NAFTA can modify the UNCITRAL Rules,<sup>114</sup> “there is nothing in Articles 1116 and 1117 that indicates an intent to modify Rule 21(3). Instead, without any conflict between them, Rule 21(3) and Articles 1116 and 1117 operate together in a coherent fashion”.<sup>115</sup> Indeed, in set-aside proceedings concerning the award in *S.D. Myers v. Canada*, the Canadian Federal Court recognized that a NAFTA Party can waive a jurisdictional objection by failing to timely raise it.<sup>116</sup>

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¶52; **CL-175**, *Canfor Corporation v. United States of America*, UNCITRAL, Decision on the Place of Arbitration, Filing of a Statement of Defence and Bifurcation of the Proceedings, 23 January 2004, ¶48.

<sup>109</sup> Opposition on Jurisdiction §I.B.

<sup>110</sup> Opposition on Jurisdiction ¶¶25-27.

<sup>111</sup> Opposition on Jurisdiction ¶28.

<sup>112</sup> C-PHM ¶¶34-35.

<sup>113</sup> C-PHM ¶37, *citing* NAFTA Art. 1120(1).

<sup>114</sup> *See* NAFTA Article 1126(1).

<sup>115</sup> C-PHB ¶37.

<sup>116</sup> C-PHB ¶38, *citing* **C-001**, *Attorney Gen. of Can. v. S.D. Myers, Inc.*, 2004 FC 38, ¶¶46-53. The court found that Canada had failed to object to the Tribunal’s jurisdiction during the arbitration; therefore, its jurisdictional objection in the set-aside proceeding was untimely under UNCITRAL Rule 21(3).

***b. Claimant's Compliance with NAFTA Articles 1116(2) and 1117(2)***

140. Claimant submits that it filed the NoA squarely within the three-year limitation period set forth in NAFTA Articles 1116(2) and 1117(2), and that Respondent has failed to meet its burden of showing otherwise.<sup>117</sup> In this regard, Claimant stresses that its case concerns just two of its patents: the Zyprexa and Strattera Patents. Therefore, the facts relevant to Articles 1116(2) and 1117(2) are that: (i) the Supreme Court rejected Claimant's application to appeal the invalidation of the Strattera Patent on 8 December 2011; (ii) the Supreme Court rejected its application relating to the Zyprexa Patent on 16 May 2013; and (iii) Claimant filed its NoA on 12 September 2013, within three years after the dates of these final judgments.<sup>118</sup> Thus, Claimant concludes that its claims are timely.
141. According to Claimant, Respondent's jurisdictional objection mistakenly focuses on the treatment of Claimant's Raloxifene Patent, which is not being challenged in this arbitration.<sup>119</sup> This approach is contrary to the principle that a claimant's case is defined by its own submissions.<sup>120</sup> Further, Respondent fails to show how the treatment of this patent can trigger the limitations clock for claims concerning two other investments, which are legally and factually distinct.<sup>121</sup> For Claimant, it is unclear how it could have acquired "knowledge [of] loss or damage" to the Zyprexa and Strattera Patents in 2009, before the courts had issued any decision invalidating them.<sup>122</sup>
142. Claimant argues that Respondent has not cited a single case that supports its position.<sup>123</sup> Rather, it contends, NAFTA tribunals have consistently held that acts occurring more than three years before a claimant's claim "may provide necessary and vital context for the

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<sup>117</sup> Opposition on Jurisdiction §II.

<sup>118</sup> Opposition on Jurisdiction ¶36.

<sup>119</sup> Opposition on Jurisdiction ¶37.

<sup>120</sup> Opposition on Jurisdiction ¶38, citing **CL-116/RL-006**, *Glamis Gold, Ltd. v. United States*, UNCITRAL, Award, 8 June 2009 ("*Glamis Gold v. United States*"), ¶349 ("The basis of the claim is to be determined with reference to the submissions of [the] [c]laimant").

<sup>121</sup> Opposition on Jurisdiction §I(b).

<sup>122</sup> Opposition on Jurisdiction ¶35.

<sup>123</sup> Opposition on Jurisdiction §II(b); C-PHM ¶40.

evaluation of host state actions that take place within the limitation period”.<sup>124</sup> For example, in *Bilcon v. Canada*, the tribunal stated:

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.<sup>125</sup>

143. Thus, Claimant argues, its references to earlier Canadian court decisions are appropriate and do not have the effect of shortening the limitation period. They instead serve only as a factual predicate to the challenged measures and the development of the promise utility doctrine.<sup>126</sup>
144. According to Claimant, NAFTA tribunals have not taken issue with references to acts outside of the limitation period, even if those prior acts could themselves have been the basis of a NAFTA claim.<sup>127</sup> In this regard, Claimant cites *Apotex* and *Bilcon*, cases in which the tribunal was asked to consider a series of interrelated but distinct government acts.<sup>128</sup> In both cases the tribunal found certain of the claimant’s claims to be time-barred, but found no time-bar difficulty for later, related acts that took place within the limitation period.<sup>129</sup>
145. Claimant also considers Respondent’s reliance on past submissions by NAFTA Parties regarding Article 1128 unavailing. While these submissions may support the proposition that an allegation of a continuing breach does not stop the time-bar clock, that point is

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<sup>124</sup> Opposition on Jurisdiction ¶35; C-PHM ¶39.

<sup>125</sup> **CL-166**, *William Ralph Clayton, William Richard Clayton, Douglas Clayton, Daniel Clayton and Bilcon of Delaware Inc. v. Government of Canada*, UNCITRAL, PCA Case No. 2009-04, Award on Jurisdiction and Liability, 17 March 2015 (“*Bilcon v. Canada*”), ¶282. See also **CL-116/RL-006**, *Glamis Gold. v. United States*, ¶¶348-350.

<sup>126</sup> Opposition on Jurisdiction ¶¶41-44.

<sup>127</sup> Opposition on Jurisdiction ¶¶44-46.

<sup>128</sup> **CL-176/RL-119**, *Apotex Inc. v. Government of the United States of America*, UNCITRAL, Award, 14 August 2013, ¶¶330-333; **CL-166**, *Bilcon v. Canada*, ¶¶266, 740.

<sup>129</sup> *Ibid.*

irrelevant because Claimant has neither alleged a continuing breach nor advanced any claim for its Raloxifene Patent.<sup>130</sup>

146. Finally, Claimant submits as a factual matter that, given the unpredictable and inconsistent application of the promise utility doctrine, Claimant had no way of predicting a loss in connection with the Zyprexa and Strattera Patents as a consequence of the prior invalidation of the Raloxifene Patent.<sup>131</sup>

### **C. NAFTA Party Article 1128 Submissions**

#### **(1) Mexico**

147. In its NAFTA Article 1128 Submission, Mexico also offers its views on the interpretation of NAFTA Articles 1116(2) and 1117(2).
148. Mexico agrees with Respondent’s submissions in paragraphs 66 to 80 of the Rejoinder, which fall under the headings: “Articles 1116(2) and 1117(2) Establish a Strict Three-Year Time Limit to Submit a Claim to Arbitration” and “The Time Limit in NAFTA Articles 1116(2) and 1117(2) Begins to Run from the First Date a Claimant Acquires Knowledge of the Alleged Breach and a Loss”.<sup>132</sup>
149. Mexico states that the jurisdiction *ratione temporis* of a tribunal established under NAFTA Chapter Eleven depends on a claimant’s compliance with Articles 1116(2) and 1117(2).<sup>133</sup>
150. In addition, according to Mexico, Tribunals have recognized that noncompliance with Article 1116(2) or 1117(2) is a “clear and rigid limitation defense—not subject to any suspension, prolongation or other qualification”.<sup>134</sup> Thus, “neither a continuing course of conduct nor the occurrence of subsequent acts or omissions can renew or interrupt the three-year limitation period once it has commenced to run”.<sup>135</sup>

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<sup>130</sup> Opposition on Jurisdiction ¶47.

<sup>131</sup> C-PHM ¶42.

<sup>132</sup> Mexico Article 1128 Submission ¶4.

<sup>133</sup> Mexico Article 1128 Submission ¶5.

<sup>134</sup> Mexico Article 1128 Submission ¶6, quoting **RL-090**, *Grand River v. United States*, Dec. on Juris., ¶29.

<sup>135</sup> Mexico Article 1128 Submission ¶7.

## **(2) United States**

151. In its NAFTA Article 1128 Submission, the United States offers two main observations on the interpretation of NAFTA Articles 1116(2) and 1117(2).
152. First, the United States observes that these provisions apply to claims by an “investor of a Party”, which is defined in Article 1139 as a national or an enterprise of a NAFTA Party “that seeks to make, is making or has made an investment”. According to the United States, the limitation period “must therefore relate to the particular investment for which the investor seeks a remedy for the breach and loss” and begins to run “when the investor first acquires knowledge of the alleged breach and loss in connection with that particular investment”.<sup>136</sup>
153. Second, the United States submits that knowledge of an alleged breach and loss is “first acquired” on a particular date, not on multiple dates or on a recurring basis. Therefore, once an investor “first acquires” the relevant knowledge, the limitation period begins to run and cannot be renewed by subsequent acts of the State Party arising from a continuing course of conduct.<sup>137</sup>

## **D. The Parties’ Observations on the NAFTA Party Article 1128 Submissions**

### **(1) Claimant’s Observations**

154. In its observations on the NAFTA Party Article 1128 Submissions, Claimant first discusses generally the role and nature of Article 1128 submissions, before turning to the specific comments offered by the United States and Mexico.<sup>138</sup> Specifically, Claimant challenges Respondent’s argument that the Tribunal should afford such submissions special weight in interpreting NAFTA. According to Claimant, the only entity granted authority to issue

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<sup>136</sup> United States Article 1128 Submission ¶3.

<sup>137</sup> United States Article 1128 Submission ¶4, citing **RL-090**, *Grand River v. United States*, Dec. on Juris., ¶29.

<sup>138</sup> Claimant’s Observations on 1128 and *Amicus* Submissions §I.A.

interpretations of NAFTA is the NAFTA Free Trade Commission; Article 1128 submissions have no such status.<sup>139</sup>

155. Further, Claimant submits that “Article 1128 submissions are inextricably linked to NAFTA Parties’ litigation positions when they act as respondents”.<sup>140</sup> Thus, the arguments presented in those submissions are not entitled to special deference, but rather must be “afforded weight solely in proportion to their persuasive merit”.<sup>141</sup>
156. While maintaining that Respondent’s jurisdictional objection is not properly before the Tribunal, Claimant nevertheless offers a number of observations regarding the specific Article 1128 submissions relating to that objection.<sup>142</sup> According to Claimant, the United States’ interpretation of the limitation period in NAFTA Articles 1116 and 1117 confirms that Respondent’s objection has no merit.<sup>143</sup> In particular, Claimant cites the United States’ statement 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”.<sup>144</sup> In Claimant’s view, “Canada’s proposed dates for the commencement of the

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<sup>139</sup> Claimant’s Observations on 1128 and *Amicus* Submissions ¶3, citing NAFTA Article 2001.

<sup>140</sup> Claimant’s Observations on 1128 and *Amicus* Submissions ¶4, citing **CL-181**, 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 International Investment Law & Policy* 2013-2014 (Oxford 2015), p. 371 (“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”); 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 (2000), p. 338.

<sup>141</sup> Claimant’s Observations on 1128 and *Amicus* Submissions ¶5, citing **CL-184**, *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, ¶47 and fn 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-185**, *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; **CL-180**, 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 Review* 142 (2015), p. 166.

<sup>142</sup> Claimant’s Observations on 1128 and *Amicus* Submissions ¶8.

<sup>143</sup> Claimant’s Observations on 1128 and *Amicus* Submissions ¶¶9-10.

<sup>144</sup> Claimant’s Observations on 1128 and *Amicus* Submissions ¶9, quoting United States Article 1128 Submission ¶3 (emphasis added by Claimant).

limitations period simply do not relate to ‘the particular investment[s]’ at issue in this arbitration—the Zyprexa and Strattera patents”.<sup>145</sup>

157. In addition, Claimant raises no objection to the United States’ submission that “a continuing course of conduct ... does not renew the limitations period”, but argues that this principle is irrelevant in the present case. According to Claimant, its claim relates to the invalidation of its Zyprexa and Strattera Patents, which occurred within the three-year limitation period, and its references to earlier Federal Court decisions are appropriate to provide factual context for this claim.<sup>146</sup>

## **(2) Respondent’s Observations**

158. Like Claimant, Respondent makes observations concerning Article 1128 submissions generally before addressing the specific submissions of the United States and Mexico.<sup>147</sup> In particular, Respondent asserts that the submissions of the NAFTA Parties in this and other proceedings reflect a common interpretation of NAFTA Articles 1105, 1110, 1116 and 1117.<sup>148</sup> In accordance with VCLT Article 31(3), the Tribunal must give “considerable weight” to this agreement of the NAFTA Parties.<sup>149</sup>

159. Referring to the specific submissions of the United States and Mexico on Articles 1116 and 1117, Respondent argues that the NAFTA Parties have a shared understanding of the NAFTA limitation period. For Respondent, three points of agreement are particularly relevant: (i) the limitation period is “not subject to any suspension, prolongation, or other qualification”;<sup>150</sup> (ii) it begins to run when the investor first acquires knowledge of the

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<sup>145</sup> Claimant’s Observations on 1128 and *Amicus* Submissions ¶9.

<sup>146</sup> Claimant’s Observations on 1128 Submissions ¶10, *citing* Opposition on Jurisdiction ¶¶41-42, 47.

<sup>147</sup> Respondent’s Observations on 1128 Submissions §§II and IV.

<sup>148</sup> Respondent’s Observations on 1128 Submissions ¶5.

<sup>149</sup> Respondent’s Observations on 1128 Submissions ¶4, *citing* **CL-066**, VCLT Article 31(3) (“There shall be taken into account, together with the context: (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation”).

<sup>150</sup> Respondent’s Observations on 1128 Submissions ¶7, *citing, inter alia*, Mexico Article 1128 Submission ¶6 (stating that NAFTA tribunals “have recognized that there is a ‘clear and rigid limitation defense – not subject to any suspension, prolongation or other qualification’”.); United States Article 1128 Submission ¶2 (“The claims litigation period has been described as ‘clear and rigid’ and not subject to any ‘suspension’, ‘prolongation’ or ‘other qualification’”).

breach and loss, which can occur only at a single point in time;<sup>151</sup> and (iii) a continuing course of conduct cannot stop or renew the time-bar clock.<sup>152</sup> For Respondent, the result of applying this common interpretation to the present case is that “Claimant’s recast challenge to the ‘promise utility doctrine’ *per se* is time-barred”.<sup>153</sup>

## **E. The Tribunal’s Analysis**

### **(1) Timeliness of Respondent’s Jurisdictional Objection**

160. The Parties disagree as to whether Respondent’s jurisdictional objection should be barred as untimely under Article 21(3) of the UNCITRAL Rules. The Tribunal need not decide this issue, as Respondent’s objection must be dismissed in any event for the reasons set forth below.

### **(2) Claimant’s Compliance with NAFTA Articles 1116(2) and 1117(2)**

161. The three-year limitation period set forth in NAFTA Articles 1116(2) and 1117(2) begins to run on “the date on which the investor first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the investor has incurred loss or damage”. As a consequence, the merits of Respondent’s objection to the Tribunal’s jurisdiction *ratione temporis* turn on the identity of the “alleged breach”.

162. Respondent has endeavored to show that the basis of Claimant’s claim is the alleged promise utility doctrine, adopted by the Canadian judiciary in decisions issued from 2002 to 2008.

163. However, as Claimant is the Party asserting the Tribunal’s jurisdiction to decide its substantive claim, the “alleged breach” must, in the first instance, be identified by reference

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<sup>151</sup> Respondent’s Observations on 1128 Submissions ¶8, *citing, inter alia*, Mexico Article 1128 Submission ¶4 (“once the investor first acquires knowledge of the alleged breach and that it has suffered damage, the limitation period for filing a claim commences and will end at the three-year mark regardless of whether the impugned measure continues thereafter”); United States Article 1128 Submission ¶4 (“An investor or enterprise *first* acquires knowledge of an alleged breach and loss at a particular moment in time ... Such knowledge cannot *first* be acquired at multiple points in time or on a recurring basis”).

<sup>152</sup> Respondent’s Observations on 1128 Submissions ¶9, *citing* United States Article 1128 Submission ¶4; Mexico Article 1128 Submission ¶7.

<sup>153</sup> Respondent’s Observations on 1128 Submissions ¶10.

to Claimant's submissions.<sup>154</sup> Claimant has repeatedly asserted that the measure at issue is the Canadian courts' invalidation of the Zyprexa and Strattera Patents by application of the promise utility doctrine; Claimant denies that it is challenging the promise doctrine in the abstract or the doctrine's application to the Raloxifene Patent.

164. The Tribunal has carefully examined Claimant's written and oral submissions to evaluate whether Claimant's characterization of its claim for the purpose of jurisdiction is supported by its position on the merits. In light of Respondent's argument that Claimant "recast" its claim in the Reply, the Tribunal has paid particular attention to this pleading. An overall reading of the Reply confirms that Claimant's challenge is aimed solely at the invalidation of the Zyprexa and Strattera Patents.<sup>155</sup> Indeed, this is clear even if one focuses specifically on the paragraphs of the Reply cited by Respondent for its portrayal of the claim.<sup>156</sup> Claimant does not allege that the promise utility doctrine itself in the abstract is a violation of NAFTA Chapter Eleven.
165. Therefore, Respondent's attempt to re-characterize Claimant's case cannot be accepted. The Tribunal finds that the "alleged breach" for purposes of NAFTA Articles 1116(2) and 1117(2) is the invalidation by the Canadian judiciary of the Zyprexa and Strattera Patents through application of the promise utility doctrine.
166. This finding of the Tribunal about the nature of the case has repercussions both for Respondent's jurisdictional objection and for the Tribunal's ability to have regard to developments that occurred more than three years before this arbitration was initiated.

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<sup>154</sup> **CL-116/RL-006**, *Glamis Gold v. United States*, ¶349.

<sup>155</sup> See, e.g., Reply ¶3 (asserting that the promise utility doctrine violates NAFTA Chapter 17 and then alleging that "[w]hen Canada applied this doctrine to revoke Lilly's Zyprexa and Strattera patents, it effected an uncompensated expropriation in violation of Article 1110 of NAFTA and a violation of Canada's obligation to afford 'fair and equitable treatment' to Lilly's investments under Article 1105 of NAFTA"); Reply §IV ("Canada's Revocation of the Zyprexa and Strattera Patents Constituted a Wrongful Expropriation Under Article 1110"); Reply §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)"); Reply ¶371 (confirming its request for relief set forth in the SoC, which includes damages "arising from the improvident loss of its Zyprexa and Strattera Patents or its inability to enforce its Zyprexa and Strattera Patents").

<sup>156</sup> Rejoinder ¶87, citing, Reply ¶¶70, 173, 211; see also Reply ¶¶88-90, citing, Reply ¶¶48, 72, 73, 92-93, 104.

167. With respect to jurisdiction, the critical question is obviously: when did Claimant first acquire knowledge, or constructive knowledge, of the alleged breach and the ensuing loss? Given the Tribunal’s finding on the identity of the alleged breach, the Tribunal sees no way in which Claimant could have acquired the requisite knowledge before the court invalidated the Zyprexa and Strattera Patents. An investor cannot be obliged or deemed to know of a breach before it occurs. Further, any loss suffered by Claimant *before* the date of the alleged breach with respect to a different investment (the Raloxifene Patent) is irrelevant to the application of NAFTA Articles 1116(2) and 1117(2) to the investments at issue in this arbitration (the Zyprexa and Strattera Patents).
168. In its Post-Hearing Memorial, Respondent appears to offer an alternative argument, that, after the Raloxifene Decision, Claimant knew that the Zyprexa and Strattera Patents themselves had suffered “at least some loss of value”.<sup>157</sup> Aside from the fact that Respondent does not fully explain the loss that it purports here to identify, its argument fails as a consequence of the Tribunal’s finding of the content of Claimant’s claim. Quite simply, Claimant did not suffer, and could not have suffered, the loss of which it complains here (i.e., invalidation of the Zyprexa and Strattera Patents) before those patents were invalidated.
169. This remains true even assuming that the Raloxifene Decision increased the risk that the Zyprexa and Strattera Patents would one day be invalidated. Articles 1116(2) and 1117(2) do not require investors to bring claims for possible future breaches on the basis of potential (and therefore necessarily hypothetical) losses to their investments or the increased risks of such losses. Thus, the Tribunal declines to impute knowledge of a future breach and loss to Claimant.
170. For these reasons, the Tribunal finds the relevant dates for the commencement of the limitation period to be 8 December 2011 and 16 May 2013, when the Supreme Court denied Claimant leave to appeal the invalidation of the Strattera Patent and the Zyprexa Patent, respectively.<sup>158</sup> Claimant submitted its NoA on 12 September 2013, within the three-year

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<sup>157</sup> R-PHM ¶105.

<sup>158</sup> **R-003**, *Eli Lilly and Company v. Teva Canada Limited*, 2011 CanLII 79177 (S.C.C.); **R-003**, *Eli Lilly Canada Inc., et al. v. Novopharm Limited*, 2013 CanLII 26762 (S.C.C.). The original Federal Court decisions invalidating the

limitation period set forth in NAFTA Articles 1116(2) and 1117(2).<sup>159</sup> Therefore, Respondent's objection to the Tribunal's jurisdiction *ratione temporis* is denied.

171. A remaining issue concerns the Tribunal's treatment of those events that did occur more than three years before this arbitration was initiated. Although the alleged promise utility doctrine is not the substantive basis of Claimant's claim, it plays a prominent role in Claimant's submissions. Indeed, one critical element of Claimant's case is establishing that judicial decisions issued from 2002 to 2008 effected a dramatic change in the Canadian utility requirement.
172. In this context, many previous NAFTA tribunals that have found it appropriate to consider earlier events that provide the factual background to a timely claim. As stated by the tribunal in *Glamis Gold v. United States*, a claimant is permitted to cite "factual predicates" occurring outside the limitation period, even though they are not necessarily the legal basis for its claim.<sup>160</sup> The tribunal in *Grand River v. United States* reached the same conclusion, drawing on past decisions:

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,

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Strattera and Zyprexa Patents on the ground of inutility were issued on 14 September 2010 and 10 November 2011, both within the three-year limitations period. **C-160/R-027**, *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915; **C-146/R-016**, *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 F.C. 1288.

<sup>159</sup> The Tribunal notes the submissions of Respondent, Mexico and the United States stating that the limitation period under Articles 1116(2) and 1117(2) is not subject to suspension, prolongation or other qualification, and that in particular, a continuing course of State conduct cannot stop or renew the time-bar clock. In the present case, Claimant has not advanced a theory of continued breach or otherwise advocated the suspension or extension of the limitation period. Nor does the Tribunal adopt any such approach in reaching its decision. This case is simpler: the alleged breach for each investment—the invalidation of the patent—occurred at a single point in time within the three-year period.

<sup>160</sup> **CL-116/RL-006**, *Glamis Gold v. United States*, ¶348.

but its analysis of this and other claims again required consideration of earlier events.<sup>161</sup>

173. The Tribunal also adopts this well accepted approach. The following analysis of the merits of Claimant’s claim will be informed where appropriate by reference to earlier relevant events, including the Canadian judiciary’s interpretation of the utility requirement over time. NAFTA Articles 1116(2) and 1117(2) in no way limit or preclude such consideration.

## **VII. LIABILITY FOR JUDICIAL MEASURES UNDER NAFTA CHAPTER ELEVEN**

### **A. The Parties’ Positions**

#### **(1) Claimant’s Position**

174. Claimant rejects Respondent’s position that under international law, the only possible theory of liability for judicial measures is a denial of justice.
175. In this regard, Claimant highlights Respondent’s acknowledgment that “a State is responsible in international law for the conduct of its organs, including the judiciary”.<sup>162</sup> As stated in Article 4 of the ILC Draft Articles on State Responsibility: “[t]he conduct of any State organ shall be considered an act of that State under international law, whether the organ exercises legislative, executive, judicial or any other functions”.<sup>163</sup>
176. Further, Claimant argues that NAFTA Chapter Eleven does not distinguish among executive, legislative, or judicial actions.<sup>164</sup> To the contrary, under NAFTA Article 201, a “measure” includes “any law, regulation, procedure, requirement or practice”, and

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<sup>161</sup> **RL-090**, *Grand River v. United States*, Dec. on Juris., ¶86. See **CL-007/RL-004**, *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Award, 11 October 2002 (“*Mondev v. United States*”), ¶70 (“events or conduct prior to the entry into force of an obligation for the respondent State may be relevant in determining whether the State has subsequently committed a breach of the obligation. But it must still be possible to point to conduct of the State after that date which is itself a breach”); **CL-109/RL-058**, *Marvin Feldman v. Mexico*.

<sup>162</sup> Reply ¶242, quoting Counter-Memorial ¶230 and fn 416.

<sup>163</sup> **CL-057**, Responsibility of States for Internationally Wrongful Acts, Article 4(1).

<sup>164</sup> Reply ¶239.

tribunals have found the terms “procedure” and “requirement” to be sufficiently broad to encompass judicial actions involving private parties.<sup>165</sup>

177. In Claimant’s view, Respondent has failed to explain why the creation of a new legal rule by courts should be treated differently from the creation of the same legal rule by another branch of government.<sup>166</sup> The result of Respondent’s position would be to exempt all judge-made law from the requirements of international law.<sup>167</sup>
178. In addition, Claimant considers Respondent’s approach to be inconsistent with the principle that a State’s internal political system cannot alter its obligations under customary international law. To the extent that judges serve a greater law-making function in common law jurisdictions, those countries would be advantaged over others by a heightened standard for judicial measures.<sup>168</sup>
179. According to Claimant, when a national court violates a *procedural* norm of international law, the State may be liable for a denial of justice, but when a court violates a *substantive* rule of international law, it is “a freestanding basis of liability”.<sup>169</sup> Professor Jan Paulsson states in his treatise on denial of justice: “[a] national court’s breach of other [non-procedural] rules of international law, or of treaties, is not a denial of justice, but a direct violation of the relevant obligation imputable to the state like any acts or omissions by its agents”.<sup>170</sup>

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<sup>165</sup> Reply ¶¶239 and 325; citing **CL-061/RL-002**, *Robert Azinian et al. v. United Mexican States*, ICSID Case No. ARB(AF)/97/2, Award, 1 November 1999 (“*Azinian v. Mexico*”), ¶98; **CL-008**, *The Loewen Group, Inc. & Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Decision on Hearing on Respondent’s Objection to Competence and Jurisdiction, 5 January 2001, ¶60 (“We reject therefore the Respondent’s objection that the Mississippi Court judgments are not ‘measures adopted or maintained by a Party’ because they resolved a dispute between private parties”).

<sup>166</sup> C-PHM ¶199.

<sup>167</sup> Reply ¶331; see also Reply §§II-III.

<sup>168</sup> Claimant gives the example of the Mexican Patent Act, which is principally interpreted by an administrative agency rather than its courts. In that case, Respondent’s approach would allow a Canadian investor to challenge an arbitrary interpretation of the Mexican Patent Act by the administrative agency but not to challenge a patent revocation by a Canadian court. Reply ¶332 and fn 671, citing **CL-158**, *The Oxford Handbook of International Investment Law*, p. 555 (2008); **CL-159**, John Henry Merryman and Rogelio Pérez-Perdomo, *The Civil Law Tradition* (2007), p. 37; González First Report ¶15.

<sup>169</sup> Reply ¶244.

<sup>170</sup> Reply ¶244, quoting **CL-147**, Jan Paulsson, *Denial of Justice in International Law* (2010), p. 98.

180. Claimant also cites the tribunal in *Azinian v. Mexico*, which quoted former ICJ President Eduardo Jiménez de Aréchaga’s statement that:

The responsibility of the State for acts of judicial authorities may result from three different types of judicial decision. The first is a decision of a municipal court *clearly incompatible with a rule of international law*. The second is what is known traditionally as a ‘denial of justice.’ The third occurs when, in certain exceptional and well-defined circumstances, a State is responsible for a judicial decision contrary to municipal law.<sup>171</sup>

**a. NAFTA Article 1110**

181. In the context of its expropriation claim, Claimant argues that “tribunals have concluded that judicial measures qualify as indirect expropriations when they result in a substantial deprivation and violate a rule of international law”.<sup>172</sup> For example, in *Saipem v. Bangladesh*, the tribunal found the annulment of a commercial arbitration award by the Bangladeshi courts to be an indirect expropriation under the Italy-Bangladesh BIT. In its analysis, the tribunal looked at two factors: (i) the impact of the court’s action, finding a “substantial deprivation”; and (ii) whether that action was unlawful under international law, finding that it violated, *inter alia*, Bangladesh’s obligations under the New York Convention.<sup>173</sup> Claimant cites in particular the *Saipem* tribunal’s statement that:

While the Tribunal concurs with the parties that expropriation by the courts presupposes that the courts’ intervention was illegal, this does not mean that expropriation by a court necessarily presupposes a denial of justice.<sup>174</sup>

182. Claimant argues that other tribunals have similarly recognized that when judicial measures violate an international obligation, they may constitute an expropriation, even in the absence of a denial of justice. These include the tribunals in: (i) *ATA v. Jordan*, which

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<sup>171</sup> Memorial ¶178, quoting **CL-061/RL-002**, *Azinian v. Mexico*, ¶98 (quoting Eduardo Jiménez de Aréchaga, *International Law in the past Third of a Century*, Recueil des cours (1978) 159-1) (emphasis added in *Azinian*).

<sup>172</sup> Memorial ¶180; see Reply ¶246.

<sup>173</sup> Memorial ¶180, citing **CL-062/RL-064**, *Saipem S.p.A. v. People’s Republic of Bangladesh*, ICSID Case No. ARB/05/7, Award, 30 June 2009 (“*Saipem v. Bangladesh*”), ¶133.

<sup>174</sup> Memorial ¶182, quoting **CL-062/RL-064**, *Saipem v. Bangladesh*, ¶181. Claimant dismisses Respondent’s view that *Saipem* was a “results oriented decision”; even if true, this would not undermine the fact that the tribunal’s “logic is well-grounded in international law and relevant to the case at hand”. Reply ¶247.

found an expropriation based on a Jordanian court’s retroactive application of a law;<sup>175</sup> (ii) *Rumeli Telekom v. Kazakhstan*, which held that a judicial decision constituted an unlawful expropriation even though there was no evidence of a violation of due process;<sup>176</sup> and (iii) *Oil Field of Texas v. Iran*, stating that “[i]t is well established in international law that the decision of a court in fact depriving an owner of the use and benefit of his property may amount to an expropriation of such property that is attributable to the state of that court”.<sup>177</sup>

***b. NAFTA Article 1105***

183. In the context of its claim under NAFTA Article 1105, Claimant argues that multiple arbitral awards have confirmed that denial of justice is not the only protection against judicial action offered by the minimum standard of treatment. In particular, Claimant relies upon:
- a. *Liman Caspian Oil v. Kazakhstan*, in which the tribunal observed that denial of justice is just one example of the standard of fair and equitable treatment, and that the standards of fair and equitable treatment and denial of justice “are not synonymous” with respect to acts of courts;<sup>178</sup>
  - b. *White Industries v. India*, in which the tribunal analysed the acts of India’s courts under three distinct aspects (denial of justice, protection of legitimate expectations and transparency);<sup>179</sup> and

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<sup>175</sup> C-PHM ¶186, citing **CL-063/RL-068**,

*ATA Construction, Industrial and Trading Company v. Hashemite Kingdom of Jordan*, ICSID Case No. ARB/08/2, Award, 18 May 2010, ¶¶125-128.

<sup>176</sup> Reply ¶249; C-PHM ¶186, citing *Rumeli Telekom A.S., Telsim Mobil Telekomikasyon Hizmetleri A.S. v. Republic of Kazakhstan*, ICSID Case No. ARB/05/16, Award, 29 July 2008, ¶¶705-706.

<sup>177</sup> C-PHM ¶186, quoting **CL-059**, *Oil Field of Texas, Inc. v. Iran*, 12 Iran-U.S. C.T.R. 308, 318 (1986), ¶42.

<sup>178</sup> Reply ¶327; quoting **RL-027**, *Liman Caspian Oil BV and NCL Dutch Investment BV v. Republic of Kazakhstan*, ICSID Case No. ARB/07/14, Award, 22 June 2010 (“*Liman v. Kazakhstan*”), ¶268.

<sup>179</sup> Reply ¶327; citing **CL-157**, *White Industries Australia Ltd. v. Republic of India*, UNCITRAL, Award, 30 November 2011, (“*White Industries v. India*”) ¶10.1.1.

c. *Frontier Petroleum v. Czech Republic*, in which the tribunal considered whether a court decision was arbitrary or discriminatory, in addition to examining procedural propriety and due process.<sup>180</sup>

184. Claimant also points to *Mondev v. United States*. Although the tribunal in that case found no violation of Article 1105, it considered whether the court decision at issue was based on a retroactive application of new law, suggesting that if this could be shown, the claimant would not have been confined to arguing a denial of justice.<sup>181</sup>

185. According to Claimant, Respondent cannot identify a single arbitral decision supporting its position that a denial of justice is the only basis of liability for court decisions.<sup>182</sup> *Waste Management v. Mexico*, *Azinian v. Mexico* and *Loewen v. United States* cannot help Respondent, because in the specific circumstances of each of those cases, denial of justice was the only relevant theory of liability before the tribunal.<sup>183</sup>

## (2) Respondent's Position

186. As its primary defence, Respondent asserts that "Claimant has failed to state a claim under Articles 1116(1) and 1117(1) for a breach of Articles 1110 and 1105 because it admits that there has been no denial of justice".<sup>184</sup> Respondent accepts that a State is responsible under international law for the conduct of all of its organs, including the judiciary, but contends that different State functions attract different types of liability. According to Respondent, the only substantive obligation under NAFTA Chapter Eleven with respect to judicial measures is to ensure that the investments of an investor from another NAFTA Party are

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<sup>180</sup> Reply ¶327; citing **RL-067**, *Frontier Petroleum Services Ltd. v. Czech Republic*, UNCITRAL, Award, 12 November 2010 ("*Frontier Petroleum v. Czech Republic*"), ¶¶284, 525.

<sup>181</sup> C-PHM ¶190, citing **CL-007/RL-004**, *Mondev v. United States*, ¶¶133-134

<sup>182</sup> Reply ¶¶250-252.

<sup>183</sup> Reply ¶¶250-252 and 328; citing **RL-013**,

*The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Award, 26 June 2003 ("*Loewen v. United States*"), ¶¶44, 141; **CL-007/RL-004**, *Mondev v. United States*, ¶134; **CL-061/RL-002**, *Azinian v. Mexico*, ¶¶100-102 (noting that the claimants "raised no complaints against the Mexican courts" and did "not allege a denial of justice"); **RL-013**, *Loewen v. United States*, ¶¶39, 141.

<sup>184</sup> R-PHM §II.

not denied justice.<sup>185</sup> As Claimant has not claimed a denial of justice, the Tribunal need make no further inquiries.<sup>186</sup>

187. Respondent denies that this rule advantages common law jurisdictions over civil law jurisdictions, where the role of the courts is more limited. According to Respondent, the adjudicative function in both systems is protected by the same rule of denial of justice.<sup>187</sup>

**a. NAFTA Article 1110**

188. Focusing specifically on Claimant’s claim under Article 1110, Respondent argues that denial of justice is the only basis on which a domestic court judgment on the validity of a property right could constitute an expropriation.<sup>188</sup>

189. To support this position, Respondent cites the tribunal’s statement in *Loewen v. United States* that: “[i]n the circumstances of this case, a claim alleging an appropriation in violation of Article 1110 can succeed only if *Loewen* establishes a denial of justice under Article 1105”.<sup>189</sup> Similarly, Respondent points to *Azinian v. Mexico*, which involved a contract found to be invalid by the Mexican court. The tribunal determined that in the absence of a denial of justice, the domestic court’s ruling must stand.<sup>190</sup>

190. Respondent rejects Claimant’s main submission that domestic court decisions can be expropriatory if they violate a rule of international law. According to Respondent, if Claimant’s position is accepted, “NAFTA Chapter Eleven tribunals will be transformed both into tribunals with plenary jurisdiction over all international treaties and supranational courts of appeal in domestic property law issues”.<sup>191</sup>

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<sup>185</sup> R-PHM ¶19. See Counter-Memorial ¶¶230-245, 318-325 and 331-343; Rejoinder ¶¶213-222, 236-237 and 244-255; Respondent’s Observations on 1128 Submissions, ¶¶12-14, 19-21 and 30-33.

<sup>186</sup> Reply ¶¶17, 334, fn 433; Rejoinder ¶255; R-PHM ¶20.

<sup>187</sup> Rejoinder ¶255, fn 489.

<sup>188</sup> Counter-Memorial ¶¶318-325; Rejoinder ¶¶120-123.

<sup>189</sup> Counter-Memorial ¶320, quoting **RL-013**, *Loewen v. United States*, ¶141.

<sup>190</sup> Counter-Memorial ¶321, citing **CL-061/RL-002**, *Azinian v. Mexico*, ¶103. According to Respondent, this principle has also been applied by tribunals in more recent cases under bilateral investment treaties. Counter-Memorial ¶¶323-325 (discussing **RL-063**, *Frank Charles Arif v. Republic of Moldova*, ICSID Case No. ARB/11/23, Award, 8 April 2013 (“*Arif v. Moldova*”), ¶¶415-416; **RL-027**, *Liman v. Kazakhstan*, ¶431).

<sup>191</sup> Counter-Memorial ¶334; see Rejoinder ¶216.

191. According to Respondent, Claimant’s approach confuses distinct international law obligations. The international law on expropriation requires first establishing the existence of a property right under domestic law, and an investor “cannot circumvent an adverse determination of its rights at domestic law simply by pointing to an alleged inconsistency with some other, independent international obligation owed between States”.<sup>192</sup>
192. In Respondent’s view, Claimant bases its proposed rule on a mischaracterisation of past arbitral decisions, beginning with the speech of Judge Aréchaga that was quoted by the *Azinian* tribunal. Respondent contends that this speech concerned State responsibility generally, not the international rules governing expropriation or the possibility of judicial expropriation. It stands for nothing more than the proposition that States are responsible for the acts of their courts.<sup>193</sup> Thus, the *Azinian* tribunal, after quoting Judge Aréchaga on that point, proceeded to hold that there was no expropriation because the claimant had not proven a denial of justice.<sup>194</sup>
193. Respondent also denies that *Saipem v. Bangladesh* supports Claimant’s position, arguing that (i) “the asserted right at issue in *Saipem* was an international arbitral award, not a right purely derived from domestic law”; and (ii) the tribunal based its holding of expropriation on its finding that the Bangladeshi courts’ conduct was so irregular that it amounted to abuse of right.<sup>195</sup> Respondent points to commentary suggesting that *Saipem* was in fact about judicial conduct amounting to a denial of justice, but the tribunal was prevented from reaching that outcome.<sup>196</sup>
194. In addition, Respondent opposes Claimant’s reliance on Professor Paulsson’s statement that when “national courts disregard or misapply international law, they are subject to international censure like any other organ of a state”.<sup>197</sup> According to Respondent, given

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<sup>192</sup> Counter-Memorial ¶332.

<sup>193</sup> Counter-Memorial ¶335.

<sup>194</sup> Counter-Memorial ¶335, citing **CL-061/RL-002**, *Azinian v. Mexico*, ¶98.

<sup>195</sup> Counter-Memorial ¶336, citing **CL-062/RL-064**, *Saipem v. Bangladesh*, ¶¶159-160, 167.

<sup>196</sup> Counter-Memorial ¶338, citing, *inter alia*, **R-339**, Mavluda Sattorova, “Denial of Justice Disguised? Investment Arbitration and the Protection of Foreign Investors from Judicial Misconduct”, ICLQ 2012, p. 12. In *Saipem*, the tribunal’s jurisdiction did not extend to denial-of-justice claims, as the claimant had not exhausted all local remedies.

<sup>197</sup> Rejoinder ¶¶121-122, citing Reply ¶245.

that the first step of the expropriation analysis—identifying the property right—is purely a question of domestic law, the most apt quotation from Professor Paulsson, which Claimant also cites, is: “[t]o the extent that national courts disregard or misapply national law, their errors do not generate international responsibility unless [there is] technical or procedural denial of justice”.<sup>198</sup>

195. Respondent argues that Claimant cannot point to any (i) examples of a judicial expropriation in the absence of a denial of justice; (ii) instances where a judicial determination that a property right was invalid under domestic law was found to be an expropriation under international law; or (iii) evidence of state practice.<sup>199</sup>

***b. NAFTA Article 1105***

196. In the context of NAFTA Article 1105, Respondent points to the FTC Note, which makes clear that the only source of obligations in Article 1105 is the customary international law minimum standard of treatment of aliens. Respondent argues that denial of justice is the only rule of customary international law applicable to State organs exercising an adjudicative function.<sup>200</sup> Thus, Claimant has not stated a claim under Article 1105.
197. Respondent points to the statement of the tribunal in *Waste Management II* that to establish a breach of Article 1105, the conduct must have either been “arbitrary, grossly unfair, unjust or idiosyncratic” or “involve[d] a lack of due process leading to an outcome which offends judicial propriety—as might be the case with a manifest failure of natural justice in judicial proceedings...”.<sup>201</sup> According to Respondent, this requirement is confirmed by

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<sup>198</sup> Rejoinder ¶122, quoting **CL-147**, Jan Paulsson, *Denial of Justice in International Law* (2010), p. 5 (emphasis added by Respondent).

<sup>199</sup> Rejoinder ¶¶125, 214.

<sup>200</sup> Counter-Memorial ¶231; Rejoinder ¶245; citing **CL-061/RL-002**, *Azinian v. Mexico*, ¶¶102-103; **CL-007/RL-004**, *Mondev v. United States*, ¶126; **RL-024**, *The Loewen Group, Inc. & Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Response of United States of America to the November 9, 2001 Submissions of the Governments of Canada and Mexico Pursuant to NAFTA Article 1128, 7 December 2001, pp. 6-7; **RL-023**, *The Loewen Group, Inc. & Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Second Submission of the United Mexican States, 9 November 2001, pp. 5-6.

<sup>201</sup> Counter-Memorial ¶224; quoting **CL-065/RL-014**,

*Waste Management, Inc. v. United Mexican States*, ICSID Case No. ARB(AF)/00/3, Award, 30 April 2004 (“*Waste Management I*”), ¶98; also citing **RL-076**, *S.D. Myers, Inc. v. Government of Canada*, UNCITRAL, Partial Award, 13 November 2000, ¶263; **CL-007/RL-004**, *Mondev v. United States*, ¶127; **RL-005**, *ADF Group Inc. v. United States*

the decisions in *Glamis Gold v. United States*, *Cargill v. Mexico*, *Mobil and Murphy v. Canada*, and *International Thunderbird v. Mexico*.<sup>202</sup>

198. According to Respondent, the *Mondev v. United States* tribunal recognized that domestic courts are to be afforded substantial deference, and that NAFTA tribunals cannot “second-guess the reasoned decisions of the highest courts of a State”.<sup>203</sup> Respondent relies upon the finding of the *Mondev* tribunal that even if a domestic court were to elaborate a new interpretation of the law, as Claimant alleges in this case, this is not unexpected in a common law jurisdiction. In the absence of a denial of justice, there would be no violation of Article 1105.<sup>204</sup>
199. To the extent that Claimant argues that the minimum standard of treatment prohibits conduct other than a denial of justice, Respondent argues that Claimant bears the burden of establishing the existence of such rules and has failed to do so.<sup>205</sup> In its view, arbitral decisions can elucidate but not create state practice and *opinio juris*. Thus, reliance on such decisions does not help Claimant meet its evidentiary burden.<sup>206</sup>
200. In any event, Respondent argues that the arbitral decisions cited by Claimant do not support its position. First, the tribunal in *Liman Caspian v. Kazakhstan* found that the Energy Charter Treaty’s fair and equitable treatment provision provides protection beyond the

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of America, ICSID Case No. ARB(AF)/00/1, Award, 9 January 2003, ¶184; **RL-013**, *Loewen v. United States*, ¶¶132-134.

<sup>202</sup> Counter-Memorial ¶¶225-226; quoting **CL-102/RL-015**,

*Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, 18 September 2009 (“*Cargill v. Mexico*”), ¶296; also citing **CL-116/RL-006**, *Glamis Gold v. United States*, ¶627; **CL-112/RL-007**, *Mobil Investments Canada Inc. and Murphy Oil Corporation v. Canada*, ICSID Case No. ARB(AF)/07/4, Decision on Liability and on Principles of Quantum, 22 May 2012 (“*Mobil v. Canada*”), ¶¶138-153; **RL-016**, *Apotex v. United States*, ¶9.47.

<sup>203</sup> Rejoinder ¶¶246-247; quoting **CL-007/RL-004**, *Mondev v. United States*, ¶126; also citing **CL-061/RL-002**, *Azinian v. Mexico*, ¶99; **RL-013**, *Loewen v. United States*, ¶51; **RL-063**, *Arif v. Moldova*, ¶¶398, 416, 440-441; **R-327**, Rudolf Dolzer and Christoph Schreuer, *Principles of International Law* (2008), pp.165-166; **RL-025**, *The Loewen Group, Inc. & Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, *Opinion of Christopher Greenwood*, 26 March 2001, ¶64.

<sup>204</sup> Counter-Memorial ¶238; citing **CL-007/RL-004**, *Mondev v. United States*, ¶126.

<sup>205</sup> Rejoinder ¶256.

<sup>206</sup> Rejoinder ¶¶248, 259; citing Reply ¶¶326-327. Respondent’s position is that the autonomous fair and equitable treatment provisions in other treaties do not form a rule of customary international law, and are not relevant for determining the content of Article 1105(1).

minimum standard of treatment in international law. Thus, the tribunal’s conclusion that this higher standard was not synonymous with denial of justice is unsurprising.<sup>207</sup> Similarly, Respondent contends that in *White Industries v. India*, the relevant fair and equitable treatment provision was autonomous from the minimum standard of treatment.<sup>208</sup> Third, in *Frontier Petroleum Services v. Czech Republic*, the tribunal essentially found that there had been no denial of justice.<sup>209</sup> Furthermore, Respondent highlights that no breach of the fair and equitable treatment standard was found in these three cases, demonstrating the high threshold for court actions to constitute a breach.<sup>210</sup>

## **B. NAFTA Party Article 1128 Submissions**

### **(1) Mexico**

201. Mexico agrees with the statement by the United States in the context of other NAFTA proceedings that customary international law has crystallized a minimum standard of treatment in only a few areas, one of which is fair and equitable treatment.<sup>211</sup> In the particular case of judicial acts of a State, Mexico’s view is that there are

fundamental distinctions that international law has made and continues to make between acts of the judiciary and the acts of other organs of the State. International tribunals defer to the acts of municipal courts not only because the courts are recognized as being expert in matters of a State’s domestic law, but also because of the judiciary’s role in the organisation of the State.<sup>212</sup>

202. On that basis, Mexico agrees with Respondent that with respect to judicial acts, denial of justice is the only rule of customary international law clearly identified and established so far as part of the minimum standard of treatment of aliens.

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<sup>207</sup> Rejoinder ¶249; citing Reply ¶327; **RL-027**, *Liman v. Kazakhstan*, ¶¶263, 268.

<sup>208</sup> Rejoinder ¶250; citing Reply ¶327; **CL-157**, *White Industries v. India*, ¶¶4.3.1, 10.2.3, 10.3.9, 10.3.16, 10.3.19, 10.3.21.

<sup>209</sup> Rejoinder ¶251; citing Reply ¶327; **RL-067**, *Frontier Petroleum v. Czech Republic*, ¶529.

<sup>210</sup> Rejoinder ¶252.

<sup>211</sup> Mexico Article 1128 Submission ¶12; quoting *Mesa Power LLC v. Government of Canada*, PCA Case No. 2012-17, Second Article 1128 Submission of the United States, 12 June 2015 (“*Mesa v. Canada*”), ¶12.

<sup>212</sup> Mexico Article 1128 Submission ¶13; quoting *The Loewen Group, Inc. & Raymond Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Second Article 1128 Submission of the United Mexican States, p. 5.

203. If a claimant asserts a breach of Article 1105 based on a different rule, it has the burden of establishing the existence of that rule based on State practice and *opinio juris*. Mexico does not consider decisions of international tribunals, particularly those which interpret autonomous standalone fair and equitable treatment, to constitute State practice.<sup>213</sup>

## (2) United States

204. According to the United States, under international law, the actions of domestic courts are accorded a greater presumption of regularity than legislative or administrative acts are. Foreign nationals have no cause for complaint at international law about a domestic system of law if it conforms to a “reasonable standard of civilized justice” and is fairly administered.<sup>214</sup> Thus, unless there is a denial of justice, international tribunals will defer to domestic courts interpreting matters of domestic law.<sup>215</sup>

205. The United States provides examples of instances where a denial of justice may exist.<sup>216</sup> In its view, there is a high threshold required for judicial measures to rise to the level of a denial of justice in customary international law.

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<sup>213</sup> Mexico Article 1128 Submission ¶14; citing Counter-Memorial ¶¶231-245, 271; **CL-102/RL-015**, *Cargill v. Mexico*, ¶273; *Mesa v. Canada*, ¶14; *Mercer International Inc. v. Government of Canada*, ICSID Case No. ARB(AF)/12/3, Submission of Mexico pursuant to Article 1128 of NAFTA, 8 May 2015, ¶18.

<sup>214</sup> United States Article 1128 Submission ¶20; quoting Edwin Borchard, *The Diplomatic Protection of Citizens Abroad or the Law of International Claims* (1925), p. 198.

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United States Article 1128 Submission ¶22; citing *Barcelona Traction, Light and Power Co., Ltd. (Belgium v. Spain)*, ICJ, Separate Opinion of Judge Tanaka, 5 February 1970, p. 154; **R-323**, Zachary Douglas, *International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed*, *International and Comparative Law Quarterly*, September 2014, pp. 10-11(); *The Loewen Group, Inc. & Raymond Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Response of the United States of America to the Submissions of Claimants Concerning Matters of Jurisdiction and Competence, 7 July 2000, p. 8; Edwin Borchard, *The Diplomatic Protection of Citizens Abroad or the Law of International Claims* (1925), pp. 195-196; Alwyn V. Freeman, *International Responsibility of States for Denial of Justice* (1938), p. 33; **CL-061/RL-002**, *Azinian v. Mexico*, ¶99; *Mohammad Ammar Al Bahloul v. Republic of Tajikistan*, SCC Case No. V(064/2008), Partial Award on Jurisdiction and Liability, 2 September 2009, ¶237.

<sup>216</sup> United States Article 1128 Submission ¶21. The United States gives the following examples of circumstances that might amount to a denial of justice: an obstruction of access to courts, failure to provide guarantees which are generally considered indispensable to the proper administration of justice, a manifestly unjust judgment, corruption in judicial proceedings, and executive or legislative interference with the judicial process. *Id.* ¶28.

206. With respect to NAFTA Article 1110, the United States submits that a State’s obligation forms part of the minimum standard of treatment under customary international law.<sup>217</sup> Accordingly, “decisions of domestic courts acting in the role of neutral and independent arbiters of the legal rights of litigants do not give rise to a claim for expropriation under Article 1110(1).”<sup>218</sup> For the United States, the “dearth” of international precedents examining whether judicial acts may be expropriatory is not surprising.<sup>219</sup>
207. Further, the United States observes that the concept of “judicial takings” is not recognized in U.S. law.<sup>220</sup> According to the United States, there is one exception: a judicial measure may constitute an expropriation absent a denial of justice where the “judiciary is not separate from other organs of the State [which] direct or otherwise interfere with a domestic court decision so as to cause an effective expropriation”.<sup>221</sup>
208. With respect to NAFTA Article 1105, the United States’ position is that judicial measures may form the basis of claim only if (i) they are final, and (ii) a denial of justice is proven. Otherwise, Chapter Eleven tribunals would become supranational appellate courts on the application of substantive domestic law.<sup>222</sup>

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<sup>217</sup> United States Article 1128 Submission ¶28.

<sup>218</sup> United States Article 1128 Submission ¶29.

<sup>219</sup> United States Article 1128 Submission ¶29, *citing, inter alia*, Parvan P. Parvanov & Mark Kantor, “Comparing U.S. Law and Recent U.S. Investment Agreements: Much more similar than you might expect”, in *Yearbook on International Investment Law & Policy* 2010-2011, p. 801 (Sauvant, ed. 2012) (“Judicial improprieties may in theory form the basis for a claim under international law for expropriation. However, it is far more common for an investor to pursue that claim under the customary international law principle of ‘denial of justice,’ which is often considered part of the international minimum standard of treatment ... Given the dearth of precedents, our analysis of judicial expropriations under international law could end right here”).

<sup>220</sup> United States Article 1128 Submission ¶29, *discussing* **RL-046**, *Stop the Beach Renourishment, Inc. v. Florida Department of Environmental Protection*, 560 U.S. 702 (2010) (“*Stop the Beach v. Florida*”).

<sup>221</sup> United States Article 1128 Submission ¶30.

<sup>222</sup> United States Article 1128 Submission ¶24; *citing* **R-322**, Christopher Greenwood, “State Responsibility for the Decisions of National Courts” in *Issues of State Responsibility before International Judicial Institutions* 61 (2004), p. 64; **R-323**, Zachary Douglas, *International Responsibility for Domestic Adjudication: Denial of Justice Deconstructed*, *International and Comparative Law Quarterly*, September 2014, p. 33; *see also* United States Article 1128 Submission ¶22.

## C. The Parties' Observations on the NAFTA Party Article 1128 Submissions

### (1) Claimant's Observations

209. Claimant argues that the United States' position ignores the rule that the "conduct of *any* State organ shall be considered an act of that State under international law".<sup>223</sup> In this way, the United States' approach would create an unworkable distinction among the functions of government branches, and such a distinction "may provide common law jurisdictions with an advantage over jurisdictions where judge-made law is less prevalent".<sup>224</sup> International tribunals cannot favor some forms of State organization over others.<sup>225</sup>
210. Regarding the United States' view that investment tribunals will defer to domestic courts interpreting domestic law, Claimant does not consider this proposition to be implicated in this arbitration. Claimant emphasizes that it alleges that Respondent's conduct is at odds with its international commitments, not that the courts have misapplied Canadian law.<sup>226</sup> Claimant submits that the United States has recognized in other contexts that a State's judiciary may violate substantive international norms to the same extent that any other branch of government may.<sup>227</sup>
211. Claimant specifically challenges the United States' submission that a denial of justice is required for judicial acts to result in an expropriation under Article 1110.<sup>228</sup> Claimant argues that the United States has offered no authority to support this view, and that it has

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<sup>223</sup> Claimant's Observations on 1128 and *Amicus* Submissions ¶23, quoting **CL-188**, Draft Articles on State Responsibility, Article 4 (emphasis added by Claimant).

<sup>224</sup> Claimant's Observations on 1128 and *Amicus* Submissions ¶23.

<sup>225</sup> Claimant notes the exception proposed by the United States: a judicial measure may constitute an expropriation without a denial of justice where the "judiciary is not separate from other organs of the State". According to Claimant, "[t]his 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". Claimant's Observations on 1128 and *Amicus* Submissions ¶24.

<sup>226</sup> Claimant Comments on Article 1128 Submissions and *Amicus* Submissions ¶19; citing United States Article 1128 Submission ¶¶22, 24; Reply ¶334.

<sup>227</sup> Claimant Comments on Article 1128 Submissions and *Amicus* Submissions ¶20; citing **CL-196**, Request for Consultations by the United States, 'China-Measures Affecting the Protection and Enforcement of Intellectual Property Rights'; **CL-197**, First Submission of the United States, 'China-Measures Affecting the Protection and Enforcement of Intellectual Property Rights', ¶¶23-24; **R-404**, Panel Report, 'China-Measures Affecting the Protection and Enforcement of Intellectual Property Rights'.

<sup>228</sup> Claimant's Observations on 1128 and *Amicus* Submissions ¶21, citing United States Article 1128 Submission ¶¶28-29.

ignored the decisions presented by Claimant, in which tribunals have found “judicial measures to be expropriatory based on violations of substantive norms of international law”.<sup>229</sup> Thus, there is no “dearth” of such precedents as the United States suggests.<sup>230</sup>

212. Claimant points to the U.S. Supreme Court decision in *Stop the Beach Renourishment v. Florida Department of Environmental Protection* to counter the United States’ assertion that the concept of “judicial takings” is not recognized in US law.<sup>231</sup> According to Claimant, a plurality of the Court found that judicial measures can constitute takings under the Fifth Amendment.<sup>232</sup>
213. With regard to Article 1105, Claimant disagrees that judicial measures may form the basis of a claim only if denial of justice is proven.<sup>233</sup> According to Claimant, tribunals and scholars have repeatedly recognized that a national judiciary may contravene substantive norms protected under Article 1105, and not only procedural standards under international law.<sup>234</sup> Claimant sees the United States’ submission on this point as lacking authoritative support. In this regard, Claimant rejects the United States’ reliance upon the article of Professor Zachary Douglas, which in its view is not supported by authority.<sup>235</sup>

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<sup>229</sup> Claimant’s Observations on 1128 and *Amicus* Submissions ¶21, *citing* Reply ¶¶243-253.

<sup>230</sup> Claimant’s Observations on 1128 and *Amicus* Submissions fn 51, *citing* United States Article 1128 Submission ¶29.

<sup>231</sup> Claimant’s Observations on 1128 and *Amicus* Submissions ¶22, *citing* **RL-046**, *Stop the Beach v. Florida*.

<sup>232</sup> Claimant’s Observations on 1128 and *Amicus* Submissions ¶22, *citing* **RL-046**, *Stop the Beach v. Florida*, at 714 (“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 fiat”). Claimant notes that, “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”.

<sup>233</sup> Claimant Comments on Article 1128 Submissions and *Amicus* Submissions ¶18; *citing* United States Article 1128 Submission ¶24.

<sup>234</sup> Claimant Comments on Article 1128 Submissions and *Amicus* Submissions ¶17; *citing* Reply ¶325-334.

<sup>235</sup> Claimant Comments on Article 1128 Submissions and *Amicus* Submissions ¶18; *citing* United States Article 1128 Submission ¶¶21, 23-24; Reply ¶¶ 327 fns 657, 330.

## (2) Respondent's Observations

214. Respondent cites the United States' statement that "as a matter of customary international law, international tribunals will defer to domestic courts interpreting matters of domestic law unless there is a denial of justice".<sup>236</sup>
215. According to Respondent, "[a]ll three NAFTA Parties agree that where a neutral and independent domestic court determines legal rights, there can be no expropriation under Article 1110".<sup>237</sup> In this regard, Respondent highlights the United States' observations that the concept of judicial takings is not recognized under U.S. law, and that in the international context, there is a "dearth" of precedents.<sup>238</sup>
216. With respect to Article 1105, Respondent points out that the NAFTA Parties' agree that denial of justice is the only basis on which judicial measures can breach the minimum standard of treatment.<sup>239</sup>
217. For Respondent, this agreed interpretation of Articles 1110 and 1105 is fatal to Claimant's claim, as there is no allegation that the Federal Courts that invalidated the Zyprexa and Strattera Patents were not acting as neutral and independent arbiters.<sup>240</sup>

## D. The Tribunal's Analysis

218. The issue of a respondent State's liability, in proceedings such as this, for the decisions and actions of its courts is much disputed. The debate about whether such liability is restricted to conduct that amounts to a denial of justice turns on how denial of justice is defined. There was considerable discussion of this issue in the Hearing, including whether there is a distinction to be drawn between a substantive denial of justice and the requirements of procedural due process, and whether the concept of denial of justice encompasses notions

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<sup>236</sup> Respondent's Observations on 1128 Submissions ¶29, *citing* United States Article 1128 Submission ¶22.

<sup>237</sup> Respondent's Observations on 1128 Submissions ¶30, *citing inter alia* United States Article 1128 Submission ¶29; Mexico Article 1128 Submission ¶19.

<sup>238</sup> Respondent's Observations on 1128 Submissions ¶29, *citing* United States Article 1128 Submission ¶29.

<sup>239</sup> Respondent Comments on Article 1128 Submissions ¶¶19-20; *quoting* Counter-Memorial ¶14; Mexico Article 1128 Submission ¶14; United States Article 1128 Submission ¶24.

<sup>240</sup> Respondent's Observations on 1128 Submissions ¶33.

of egregious irrationality or manifest unreasonableness. At bottom, Respondent's position appears to be that, as long as it is possible to say that a court acted on a reasoned and rational basis, no question of liability could arise, whether, for present purposes, under either NAFTA Article 1105 or Article 1110.

219. This acknowledges the possibility that a decision of a court, or other judicial conduct, that falls so far below accepted minimum standards—in the words of counsel for Respondent, that “had a result that was so surprising that propriety and competence had to be questioned”—might engage the liability of the respondent State. The Tribunal agrees with this acknowledgment by Respondent. The question that follows is whether conduct that does not constitute a denial of justice may nonetheless be capable of qualifying as a violation of NAFTA Articles 1105 or 1110.
220. For the reasons and conclusions set out in the section that follows on the utility requirement under Canadian law, the Tribunal does not need to reach a decision on the Parties' submissions on these issues, and judicial economy dictates that it should not do so. Having regard to the Parties' submissions, the Tribunal accordingly limits itself to the following brief observations on these points.
221. First, the judiciary is an organ of the State. Judicial acts will therefore in principle be attributable to the State by reference to uncontroversial principles of attribution under the law of State responsibility. As a matter of broad proposition, therefore, it is possible to contemplate circumstances in which a judicial act (or omission) may engage questions of expropriation under NAFTA Article 1110, such as, perhaps, in circumstances in which a judicial decision crystallizes a taking alleged to be contrary to NAFTA Article 1110. This said, the Tribunal emphasizes the point made below in respect of NAFTA Article 1105(1) that a NAFTA Chapter Eleven tribunal is not an appellate tier in respect of the decisions of national judiciaries.
222. Second, as regards NAFTA Article 1105(1), the Tribunal accepts in principle the analysis and conclusions of the NAFTA Chapter Eleven tribunal in *Glamis Gold* on the content of the customary international law minimum standard of treatment addressed in NAFTA Article 1105(1) and, in particular, its conclusion as follows:

The Tribunal therefore holds that a violation of the customary international law minimum standard of treatment, as codified in Article 1105 of the NAFTA, requires an act that is sufficiently egregious and shocking—a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons—so as to fall below accepted international standards and constitute a breach of Article 1105. Such a breach may be exhibited by a “gross denial of justice or manifest arbitrariness falling below acceptable international standards;” or the creation by the State of objective expectations *in order to induce* investment and the subsequent repudiation of those expectations. The Tribunal emphasizes that, although bad faith may often be present in such a determination and its presence certainly will be determinative of a violation, a finding of bad faith is not a requirement for a breach of Article 1105(1).<sup>241</sup>

223. Third, adopting this analysis, it is evident that there are distinctions to be made between conduct that may amount to a denial (or gross denial) of justice and other conduct that may also be sufficiently egregious and shocking, such as manifest arbitrariness or blatant unfairness. It is also apparent, in the Tribunal’s view, that concepts of manifest arbitrariness and blatant unfairness are capable, as a matter of hypothesis, of attaching to the conduct or decisions of courts. It follows, in the Tribunal’s view, that a claimed breach of the customary international law minimum standard of treatment requirement of NAFTA Article 1105(1) may be properly a basis for a claim under NAFTA Article 1105 notwithstanding that it is not cast in denial of justice terms. As noted above, the conduct of the judiciary will in principle be attributable to the State by reference to uncontroversial principles of State responsibility. As a matter of principle, therefore, having regard to the content of the customary international law minimum standard of treatment, the Tribunal is unwilling to shut the door to the possibility that judicial conduct characterized other than as a denial of justice may engage a respondent’s obligations under NAFTA Article 1105, within the standard articulated in the award in *Glamis*. The Tribunal considers that this assessment is consistent with the approach, *inter alia*, of the NAFTA Chapter Eleven tribunal in *Mondev*, with which it is content to agree.

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<sup>241</sup> CL-116/RL-006, *Glamis Gold v. United States*, ¶627 (footnotes omitted).

224. Fourth, this said, as has also already been noted, the Tribunal emphasizes that a NAFTA Chapter Eleven tribunal is not an appellate tier in respect of the decisions of the national judiciary. It is not the task of a NAFTA Chapter Eleven tribunal to review the findings of national courts and considerable deference is to be accorded to the conduct and decisions of such courts. It will accordingly only be in very exceptional circumstances, in which there is clear evidence of egregious and shocking conduct, that it will be appropriate for a NAFTA Chapter Eleven tribunal to assess such conduct against the obligations of the respondent State under NAFTA Article 1105(1).
225. Fifth, the Tribunal notes that NAFTA Article 1110(1)(c) includes the requirement that, to be concordant with NAFTA Article 1110(1), the nationalization or expropriation of an investment must be “in accordance with due process of law and Article 1105(1)”. As regards decisions of the national judiciary, the interplay between obligations under NAFTA Articles 1105(1) and 1110 will be a matter for careful assessment in any given case, subject to the controlling appreciation that a NAFTA Chapter Eleven tribunal is not an appellate tier with a mandate to review the decisions of the national judiciary
226. Sixth, as will emerge from the discussion and conclusion in the section that follows, the Tribunal has concluded that the factual predicate, in this case, that would be necessary to sustain Claimant’s case of a breach of Article 1105(1) and/or Article 1110 has not been established. Regardless of the debate about the denial of justice limits of liability of a respondent State, therefore, the Tribunal concludes that Claimant’s case does not meet the threshold requirement to proceed under this head.

## **VIII. THE ALLEGED DRAMATIC CHANGE IN THE UTILITY REQUIREMENT UNDER CANADIAN LAW**

### **A. The Parties’ Positions**

#### **(1) Claimant’s Position**

227. Claimant argues that the promise utility doctrine is a radical departure from Canada’s traditional utility standard and the utility standards applied by Canada’s NAFTA partners,

the United States and Mexico.<sup>242</sup> It claims that for decades Canada applied the traditional utility test for which a “mere scintilla” of utility sufficed, and under that test, pharmaceutical patents were never found to lack utility until the advent of the promise utility doctrine in the mid-2000s.<sup>243</sup>

***a. The Traditional Utility Test***

228. According to Claimant, in the mid-1990s when NAFTA entered into force *and* when the Zyprexa and Strattera patents were granted, the utility requirement enshrined in the Patent Act had “a well-established meaning that was applied by the Federal Courts, the Patent Office, and inventors”.<sup>244</sup> It was a “mere scintilla” test, under which “very little” or a “slight amount” of utility satisfied the low threshold of utility required.<sup>245</sup> Patents that were held to lack utility under this standard were wholly inoperable.<sup>246</sup> Claimant’s expert Professor Siebrasse points to two classic examples of inoperable inventions: a “death ray” and a “perpetual motion machine”.<sup>247</sup> In other words, so long as an invention was capable of being put to a specific use, even if that use had no commercial value, then it was “useful” under the Patent Act.<sup>248</sup>
229. As evidence of the low threshold for utility, Claimant asserts that from 1980 to 2004 there were only 28 utility challenges in Canadian trial courts.<sup>249</sup> Four of the challenges related to pharmaceutical patents, all of which eventually were found to be useful under the Patent Act.<sup>250</sup> Claimant contends that this “point bears emphasis: for a quarter of a century – from

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<sup>242</sup> Memorial ¶36.

<sup>243</sup> Memorial ¶¶56, 222.

<sup>244</sup> Memorial ¶45.

<sup>245</sup> Siebrasse First Report ¶20 (citing **C-207**, *Prentice v. Dominion Rubber Co.*, [1928] Ex CR 196, at 199 (Ex Ct); **C-208**, *Asten-Hill Ltd v. Ayers Ltd.*, [1939] 2 DLR 234, at 246 (Ex Ct)).

<sup>246</sup> Siebrasse First Report ¶¶ 20-21; *see also* Wilson First Report ¶27.

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Siebrasse First Report ¶23 (citing **C-210**, *X v. Commissioner of Patents*, [1981], 59 C.P.R. 7 (F.C.A.) (death ray); **C-211**, *Otta v. Canada (Patent Commissioner)*, [1979] 51 C.P.R. 2d 134 (P.A.B.) *aff’d* 51 C.P.R. 2d 139 (F.C.A.) (perpetual motion machine).

<sup>248</sup> *See, e.g.*, **C-042**, *Wandscheer et al. v. Sicard Ltd.*, [1948] S.C.R. 1, at 4; Siebrasse First Report ¶79.

<sup>248</sup> **C-305**; Chronological List of Canadian Utility Decisions from 1980 to Present.

<sup>249</sup> **C-305**; Chronological List of Canadian Utility Decisions from 1980 to Present.

<sup>250</sup> Memorial ¶46.

1980 to 2004 – not a single pharmaceutical patent was found to lack utility in any Canadian court”.<sup>251</sup>

230. Claimant also points to the Manual of Patent Office Practice (“**MOPOP**”), which it characterizes as “guidelines relied upon by patent examiners as a practical summary of applicable patent law in Canada”.<sup>252</sup> According to Claimant, Section 12 of the 1990 MOPOP restated the application of the “mere scintilla” to pharmaceutical patents.<sup>253</sup>

231. Claimant’s expert, Mr. Wilson, explained that patent examiner practice under the traditional utility test was in keeping with MOPOP guidance and the “mere scintilla” test:

Unless the examiner had reason to doubt that the invention worked, the inquiry [into utility] ended there . . . . [I]t was neither required nor typical for applicants to provide much, if any, data derived from real world use, whether through clinical data of pharmaceuticals, or through road testing of machines.<sup>254</sup>

232. According to Claimant, if a utility challenge arose during this era, then “testing or other evidence that had been generated *after* the date of the patent application” could be used to show utility.<sup>255</sup> Such evidence took two forms, according to Claimant’s expert. First, commercial success of a patent “was considered good evidence of utility on the view that a useless invention could not be commercially successful”.<sup>256</sup> Second, evidence of post-filing testing could prove utility on the assumption that “if a process works today, it must also have worked yesterday. The fact that it was not *tested* yesterday does not mean it did not *work* yesterday”.<sup>257</sup>

233. According to Claimant, the traditional utility test requiring a “mere scintilla” of utility was consistent with the requirement in NAFTA Chapter 17 that patents be made available for,

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<sup>251</sup> *Id.*

<sup>252</sup> Memorial ¶47.

<sup>253</sup> **C-54**, MOPOP §§ 12.02, 12.03 (January 1990).

<sup>254</sup> Wilson First Report ¶30.

<sup>255</sup> Memorial ¶52.

<sup>256</sup> Siebrasse First Report ¶30 nn.40, 41 (collecting cases).

<sup>257</sup> Siebrasse First Report ¶34; *see also* Memorial ¶53, *citing C-044/R-190, Ciba-Geigy AG v. Canada (Commissioner of Patents)*, [1982] 65 C.P.R. 2d 73 (F.C.A.) (“*Ciba-Geigy*”), at 78.

*inter alia*, inventions that are “capable of industrial application”.<sup>258</sup> It was also consistent with a low threshold for utility required in the United States and Mexico.<sup>259</sup>

***b. Creation of the Promise Utility Doctrine***

234. Claimant argues that a decade later, in the mid-2000s, after the patents for Zyprexa and Strattera were granted but before they were invalidated by the courts, Canada’s utility requirement “underwent a dramatic transformation” as the promise utility doctrine emerged.<sup>260</sup>
235. Claimant submits that the promise utility standard imposes three elements that drastically depart from the traditional utility test. In practice, the three elements operate as an integrated, single, heightened utility requirement.<sup>261</sup> First, patent examiners and judges seek to identify a “promise” in the patent disclosure, and this promise becomes the measuring stick for utility. Second, evidence submitted with the patent application to show fulfilment of any promise in the patent description is subject to heightened scrutiny, and post-filing evidence such as commercial use may not be relied upon. Third, pre-filing evidence may not be considered to support a sound prediction unless that pre-filing evidence was referenced in the patent application itself.<sup>262</sup>

***c. Promise Standard***

236. Claimant asserts that, since 2005, “the Canadian courts have identified or inferred additional promises of utility from the disclosure that go beyond the utility of the claimed invention, imposing an elevated requirement for utility”.<sup>263</sup> Thus, identifying the patent’s “promise” is “inherently arbitrary and unpredictable”, and a promise may be found even if

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<sup>258</sup> CL-044, NAFTA Art. 1709.1.

<sup>259</sup> Memorial §V(C); Reply §II(C).

<sup>260</sup> Memorial ¶56; Reply ¶¶70-71.

<sup>261</sup> C-PHM ¶74.

<sup>262</sup> Memorial ¶57; Reply ¶70.

<sup>263</sup> C-PHM ¶84; *see also* Testimony of Siebrasse Tr. 520:10-15 (stating that Canadian courts are imposing an “elevated” utility standard). Testimony of Reddon Tr. 827:9-16 (“Courts now derive, and sometimes using considerable lengths and expert evidence imply, promises into the disclosure of patents,... but it’s now done without reference to the utility of the claimed invention.”).

not intended as such.<sup>264</sup> Claimant cites the statement of the Federal Court of Appeal in *Sanofi-Aventis* that “[a]n inventor whose invention is described in a patent which would otherwise be valid can nonetheless promise more for his invention than required by the Act so as to render his patent invalid”.<sup>265</sup>

237. Claimant’s expert, Professor Siebrasse, opines that the “standard against which utility is assessed now has two branches. The first branch corresponds to the long standing requirement of a mere scintilla of utility, while the second branch sets an elevated standard according to the ‘promise of the patent’”.<sup>266</sup> Essentially, according to Claimant, a patentee can now invalidate its own patent—one which would have easily satisfied the mere scintilla test—if it inadvertently over-promised what the invention could do.
238. Claimant disagrees with Respondent’s contention that the promise utility doctrine has been long “recognized as an integral part of Canadian law”.<sup>267</sup> In particular, it argues that *Consolboard*, a Supreme Court case from 1981, which Respondent claims is the seminal decision on the utility standard, actually has nothing to do with the promise utility doctrine at all. In *Consolboard*, the Supreme Court of Canada, quoting with approval *Halsbury’s Laws of England*, a comprehensive narrative statement of English law, stated that an invention lacks utility if “the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises to do”.<sup>268</sup> According to Claimant, the use of the word “promise” in *Consolboard* is not akin to its meaning within the promise utility doctrine; it is simply “shorthand for the invention’s intended use”.<sup>269</sup> Thus, the holding of *Consolboard* actually reaffirms the low bar for utility and the “mere scintilla test”.<sup>270</sup> In any event, Professor Siebrasse opines that Canadian

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<sup>264</sup> Memorial ¶61.

<sup>265</sup> C-047, *Sanofi-Aventis v. Apotex, Inc.*, 2013 FCA 186, at ¶54.

<sup>266</sup> Siebrasse First Report ¶41.

<sup>267</sup> Reply ¶35, quoting Counter-Memorial ¶93.

<sup>268</sup> C-118/R-011, *Consolboard Inc. v. MacMillan Bloedel (Sask) Ltd.*, [1981] 1 S.C.R. 504 (“*Consolboard*”), at 525.

<sup>269</sup> Reply ¶79.

<sup>269</sup> Reply ¶79.

<sup>270</sup> Siebrasse First Report ¶73, citing C-118/R-011, *Consolboard*, at 525.

courts never cited or relied upon *Consolboard* as supporting any elevated utility standard or the promise utility doctrine until 2005.<sup>271</sup>

239. Claimant argues that there is no other pre-2005 authority for the promise utility doctrine. In particular, none of the cases presented in Mr. Dimock’s “Selected History” supports Respondent’s position.<sup>272</sup> According to Claimant: (i) in several of these cases, including the *Consolboard* trial decision and *New Process Screw*, the court found the claimed invention was inoperable;<sup>273</sup> (ii) in other cases, the inventions at issue were held to have utility because they worked—the “mere scintilla test”;<sup>274</sup> (iii) in two other cases, the court *rejected* the argument that utility could be assessed by reference to the patent’s disclosure; and (iv) two other cases did not involve utility findings at all.<sup>275</sup>
240. Claimant also refutes the legal commentaries on which Respondent relies for pre-2005 evidence of the promise utility doctrine,<sup>276</sup> as none of the underlying Canadian cases cited in these writings supports the proposition that promises of utility can be found in the disclosure.<sup>277</sup>

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<sup>271</sup> Reply ¶83; Siebrasse First Report ¶73 (collecting cases citing *Consolboard* for precedent for other issues, not for utility); Testimony of Siebrasse, Tr. 522:8-15, 526:3-527:7.

<sup>272</sup> C-PHM ¶92, citing Dimock Presentation, slide 15 (“Promise of Utility: Selected History of Case Law and Legal Commentary”); see also Claimant’s Closing Statement, slide 56.

<sup>273</sup> Reply ¶85; **R-162**, *New Process Screw Corp. v. PL Robertson Mfg. Co. Ltd.*, [1961] 39 C.P.R. 31 (Ex. Ct.), at 32. C-PHM ¶94 (citing **C-042**, *Wandscheer et al. v. Sicard Ltd.*, [1948] S.C.R. 1; **R-195**, *Hoescht Pharmaceuticals of Canada Limited et al. v. Gilbert & Company et al.*, [1964], Fox Pat. 28 (Ex. Ct.); **R-360**, *Feherguard Products Ltd. v. Rocky’s of BC Leisure Ltd.*, [1994], 53 P.C.R. 3d417 (F.C.T.D.); **R-376**, *TRW Inc. v. Walbar of Canada Inc.*, [1991], 39 C.P.R. 3d.) 176 (F.C.A.)); see also Claimant’s Closing Statement, slide 58 (summarizing Siebrasse’s expert testimony on these cases).

<sup>274</sup> C-PHM ¶94, citing **R-008**, *Rodi & Weinenberger Aktiengesellschaft v. Metalliflex Ltd.*, [1959], 32 C.P.R. 102 (Q.A.C.); **R-375**, *Corning Glass Works v. Canada Wire & Cable Ltd.*, [1984], 81 C.P.R. 2d 39 (F.C.T.D.); **R-401**, *Wellcome Foundation Ltd v. Apotex Inc.*, [1995] F.C.J. No. 226, 60 C.P.R. 3d 135 (F.C.A.); **C-230**, *Almecon Industries Ltd. v. Anchortek Ltd.*, [2001], 17 C.P.R. 4th 74 (F.C.T.D.); **R-187**, *Goldfarb v. W.L. Gore & Associates Inc.*, [2001], 11 C.P.R. 4th 1290; **R-168**, *Amfac Foods, Inc. v. Irving Pulp & Paper, Ltd.*, [1986], 12 C.P.R. 3d 193 (F.C.A.). See also Claimant’s Closing Statement, slide 57 (summarizing Siebrasse’s expert testimony on these cases).

<sup>275</sup> C-PHM ¶97, citing **C-118/R-011**, *Consolboard*; **R-173**, *American Cyanamid Company v. Ethicon Limited*, [1979] R.P.C. 215; see also Claimant’s Closing Statement, slide 57 (summarizing Siebrasse’s expert testimony on *Consolboard*).

<sup>276</sup> See Dimock Presentation, slide 15.

<sup>277</sup> C-PHM ¶98.

***d. Post-Filing Evidence***

241. Claimant asserts that a second major change in Canadian patent law raised the evidentiary burden on patentees to prove any “promises” of utility. Claimant’s position is that this change occurred in 2002, when the Canadian Supreme Court ruled in *AZT* that evidence of utility such as scientific effectiveness and commercial use is inadmissible if it was generated after the filing date of the patent.<sup>278</sup> According to Claimant, *AZT* reversed a contrary Federal Court of Appeal ruling below and overturned the prior ruling of the Federal Court of Appeal in *Ciba-Geigy*.<sup>279</sup> In *Ciba-Geigy*, the court held:

if indeed what is in the patent specification was mere speculation or prediction, the speculation or prediction having turned out to be true, ought to be considered to have been well founded at the time it was made.<sup>280</sup>

242. Claimant rejects Respondent’s position that the ban on post-filing evidence predates *AZT*.<sup>281</sup> Claimant contends that there is “voluminous case law allowing post-filing evidence of utility” prior to that case.<sup>282</sup> Respondent’s argument that these cases relate to operability is misplaced, given that operability is the core of the utility requirement.<sup>283</sup>

243. Claimant argues that Respondent cannot point to a single utility case before *AZT* excluding post-filing evidence.<sup>284</sup> Respondent’s reliance on inventorship disputes is unavailing

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<sup>278</sup> See **C-213/R-004**, *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, at ¶46, 80-85. According to Claimant, this new requirement is especially problematic for pharmaceutical patents. Memorial ¶66; Reply ¶94; Siebrasse First Report ¶59

<sup>279</sup> C-PHM ¶104. See **C-044/R-190**, *Ciba-Geigy*, at 77.

<sup>280</sup> C-PHM ¶107, quoting **C-044/R-190**, *Ciba-Geigy*, at 77.

<sup>281</sup> See R-PHM ¶142.

<sup>282</sup> C-PHM ¶106; Reply ¶98, citing **C-220**, *McPhar Engineering Co. of Canada v. Sharpe Instruments Ltd.*, [1960] 35 C.P.R. 105, at 147-48; **C-228**, *Cochlear Corp. v. Cosem Neurostim Ltée*, [1995] 64 C.P.R. 3d 10, at 16, 35; Siebrasse Second Report ¶ 58, fn. 90 (discussing *Hoechst Pharmaceuticals of Canada Ltd. v. Gilbert & Co.*, [1965] Ex. C.R. 710, at 714).

<sup>283</sup> C-PHM ¶106, citing Testimony of Siebrasse, Tr. 518:9-12 (noting that under Canada’s traditional utility test, only “inoperable inventions failed).

<sup>284</sup> Reply ¶99.

because as such disputes do not require any proof of utility; they concern who filed for a patent first.<sup>285</sup>

244. Claimant also points to testimony from the Hearing to show the novelty of AZT. Professor Siebrasse testified that, prior to AZT, no commercially successful product was ever held to lack utility.<sup>286</sup> Indeed, Respondent's expert, Mr. Dimock, could not identify a single such case.<sup>287</sup> Nor could Mr. Dimock cite any case before 2002 in which a court expressly disallowed a patentee to rely on post-filing evidence to prove utility.<sup>288</sup>

*e. Disclosure for Sound Prediction*

245. Claimant submits that another heightened evidentiary burden was imposed beginning with the 2008 Raloxifene Decision. This was the first time a Canadian court declined to consider pre-filing evidence of soundly predicted utility that was not disclosed in the patent.<sup>289</sup> Now, when utility is based on a sound prediction, the patent must contain the factual basis for that prediction, including the evidence and line of reasoning that supports the prediction.
246. Again, Claimant rejects Respondent's argument that this is a long standing rule in Canadian law. According to Claimant, Respondent primarily relies on *Monsanto*, a 1979 decision of the Supreme Court of Canada, which does not support its position.<sup>290</sup> Rather, "*Monsanto* reversed a decision of the CIPO Patent Appeal Board that effectively required disclosure of the factual basis for sound prediction".<sup>291</sup> Further, the court held that the burden is on the patent office to disprove utility, not on the applicant to prove it.<sup>292</sup> Indeed, at the Hearing, Respondent's expert, Mr. Dimock, conceded that *Monsanto* did not expressly

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<sup>285</sup> Respondent's Closing Statement, Tr. 2264:23-2266:11; C-PHM ¶108 (citing Testimony of Dimock, Tr. at 1136:16-1137:22).

<sup>286</sup> Testimony of Siebrasse, Tr. 519:24-520:3.

<sup>287</sup> Testimony of Dimock, Tr. 1169:25-1170:6.

<sup>288</sup> Testimony of Dimock, Tr. 1170:10-23.

<sup>289</sup> C-PHM ¶113; *see also* C-115/R-200, *Raloxifene*.

<sup>290</sup> *See* C-061/R-023, *Monsanto*.

<sup>291</sup> Reply ¶109.

<sup>292</sup> Siebrasse Second Report ¶69.

require disclosure of the factual basis for sound prediction.<sup>293</sup> Claimant accepts Respondent's point that *Monsanto* draws upon a 1969 English decision, *Olin Mathieson*.<sup>294</sup> However, in Claimant's view, *Olin Mathieson* actually stands for the proposition that that evidence supporting sound prediction does not need to be in the patent.<sup>295</sup>

247. Claimant also accepts that the court in the Raloxifene Decision applied language from *AZT* regarding disclosure, but according to Claimant, the “*AZT* ruling itself expressly declined to decide what would be considered ‘proper disclosure’ where utility is based on a sound prediction”.<sup>296</sup>

248. Claimant asserts that the testimony of Respondent's witness and expert at the hearing demonstrates the novelty of the rule. For example, Dr. Gillen explained that it was only after the Raloxifene Decision that Patent Office examiners were instructed to require the factual basis and line of reasoning for sound prediction to be in the patent itself.<sup>297</sup> Mr. Dimock conceded that: (i) there were no cases between the 2002 *AZT* decision and the Raloxifene Decision that imposed an additional disclosure requirement for sound prediction;<sup>298</sup> (ii) during that same period, the Federal Court of Appeal considered evidence from outside the patent in a sound prediction case;<sup>299</sup> and (iii) the scope of this evidentiary rule is still in dispute.<sup>300</sup>

#### ***f. MOPOP Amendments and CIPO Practice***

249. Claimant submits that MOPOP amendments in 2009 and 2010 incorporated all three elements of the promise utility doctrine and demonstrate the sea-change in the law on utility.<sup>301</sup> For example, Chapter 12 of MOPOP was revised in 2009 to include for the first

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<sup>293</sup> Dimock Testimony, Tr. 1086:6-10 (“Agree or disagree. Monsanto made no finding that the factual basis had to be disclosed? MR. DIMOCK: It didn't make that explicit finding. Yes, it did not.”).

<sup>294</sup> See C-461, *Olin Mathieson Chemical Corp. v Biorex Laboratories Ltd.*, [1970] R.P.C. 157 (Ch D).

<sup>295</sup> Siebrasse Second Report ¶ 67.

<sup>296</sup> C-PHM ¶115, citing oSiebrasse Testimony, Tr. 683:21-684:3.

<sup>297</sup> Gillen Testimony, Tr. 992:12-25.

<sup>298</sup> Dimock Testimony, Tr. 1112:21-1113:3.

<sup>299</sup> *Id.* at 1127:9-1129:17.

<sup>300</sup> *Id.* at 1117:14-20.

<sup>301</sup> C-PHM §II.A.

time a utility requirement that an inventor had to meet every “promise” made in the patent application.<sup>302</sup>

250. In addition, the 2010 MOPOP included the requirement that the factual basis for a sound prediction be disclosed in the description.<sup>303</sup> It also included a new section entitled “Office Actions on Utility,” which would have been useless before 2005 when rejections on the ground of utility were rare.<sup>304</sup>
251. Claimant submits that “MOPOP is a reliable restatement of Canadian patent law”, reflecting the Canadian Patent Office’s interpretation of the Patent Act.<sup>305</sup> It follows that the 1990s MOPOPs represented the Canadian utility requirement when the Zyprexa and Strattera patents were issued, and that the 2009 and 2010 MOPOPs show the dramatic change that occurred thereafter.<sup>306</sup> According to Claimant, neither of these points is rebutted by Respondent’s characterization of MOPOP as a “high-level summary”.<sup>307</sup>
252. For Claimant, there is no question that the MOPOP amendments were based on changes in Canadian law. The new MOPOP sections on utility and sound prediction contain citations to new cases, including *AZT* and the *Raloxifene Decision*, as acknowledged by Dr. Gillen.<sup>308</sup> Claimant asserts that MOPOP did not cite the “promise” language in *Consolboard* until the 2000s.<sup>309</sup>
253. Claimant further argues that the “dramatic changes to the MOPOP were accompanied by parallel changes in Patent Office practice”.<sup>310</sup> According to Claimant, utility objections were raised for the first time in Office Actions in the mid-2000s.<sup>311</sup> Indeed, Respondent’s

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<sup>302</sup> C-59, MOPOP §12.08.01 (December 2009).

<sup>303</sup> C-60, MOPOP §9.04.01 (December 2010).

<sup>304</sup> C-59, MOPOP §12.09 (December 2009); Reply ¶125.

<sup>305</sup> Reply ¶¶143-146; C-PHM ¶51.

<sup>306</sup> C-PHM ¶52.

<sup>307</sup> C-PHM ¶53, quoting Respondent’s Opening Statement, Tr. 193:20-194:8.

<sup>308</sup> Gillen Testimony, Tr. 935:20-936:4, 963:7-970:8.

<sup>309</sup> C-PHM ¶54.

<sup>310</sup> C-PHM ¶59.

<sup>311</sup> Reply ¶¶140-142.

experts were unable to identify any example of a patent application rejected on the basis of the promise utility doctrine prior to the 2000s.

254. Finally, Claimant asserts that the reactions of several CIPO examiners, who expressed concerns and confusion about how to implement the new MOPOP sections on utility, serve as contemporaneous evidence of the dramatic change in the law on utility.<sup>312</sup>

***g. Statistical Evidence***

255. Claimant also puts forth statistical evidence on the number of patents that were invalidated by Canadian courts for inutility, arguing that this data reflects the dramatic change in the law. Claimant asserts that since 2005, there has been a “sudden and unprecedented spike” in patent invalidations by courts for lack of utility, and that this change is exclusively in the pharmaceutical sector.<sup>313</sup> Claimant updated its statistical evidence at the Hearing to show that:

In the early period utility was rarely challenged in that sector and never successfully but, since 2005, given the change in Canada’s test, utility challenges have spiked and 28 cases (41 percent) have been successful.<sup>314</sup>

256. Claimant argues that Respondent has given no plausible alternate explanation for the spike in invalidations based on inutility. In particular, Claimant challenges Respondent’s position that the spike is somehow due to the end of compulsory licensing and the introduction of the PM(NOC) regulations in 1993.<sup>315</sup> Not only did those changes take place more than 10 years before the spike in 2005, but the increased *volume* of litigation does not account for the increase in the *rate* of invalidations.<sup>316</sup> Further, according to Claimant, Respondent’s

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<sup>312</sup> C-PHM ¶¶61-68. Claimant relies on examiner comments on early drafts of the 2009 and 2010 MOPOPs, emails and an internal CIPO study. *See e.g.* C-357, “Chapter 17 Working draft (July 2007) comments from C9,” Comments of Daniel Begin and Marsha Black [Canada Doc. No. 1065, at 066681], C-361, “MOPOP Chapter 12 feedback C14 - part 2,” Comments of Nancy Trus (Examiner) (17 March 2008) [Canada Doc. No. 921, at 065459] ; C-491, *Let’s Talk About Literal Assertions*, Canada Doc. No. 39.

<sup>313</sup> Claimant’s Opening Statement, Tr. 95:8-23; C-PHM ¶121.

<sup>314</sup> Claimant’s Opening Statement, Tr. 95:12-16.

<sup>315</sup> Respondent’s Closing Statement, Tr. 2249:22-24.

<sup>316</sup> C-PHM ¶124.

attempt to rely on case-specific factors (such as experience of the fact finder and the evidence presented) fails to explain the overall increase in invalidations.<sup>317</sup>

257. Finally, Claimant does not accept that changing the cut-off date between pre- and post-2005 invalidations (from 1 January to 2 September 2005), as Respondent suggests, would diminish the evidence of a dramatic change; the jump in invalidations would still be significant, from 2 to 26 (rather than 0 to 28).<sup>318</sup> Claimant accepts that the rate of invalidities in the pre-2005 category would increase but argues that this is due to the small data set.<sup>319</sup>

#### ***h. Comparison with Other Jurisdictions***

258. Claimant argues that the dramatic change in Canadian law is also evident from the “recent divergence” between the utility requirement in Canada and in the other NAFTA Parties.<sup>320</sup> According to Claimant, the utility requirement remains a low bar in both the United States and Mexico.<sup>321</sup> This difference in law is reflected in “a stark divergence in outcomes”; while invalidations based on utility have become frequent in Canada, utility “is a non-issue in the rest of North America”.<sup>322</sup> In this regard, Claimant’s expert, Professor Merges, cited a survey of 239 cases in the United States over several years in which only one patent was found invalid for lack utility.<sup>323</sup> Claimant also points to the testimony of Respondent’s expert on Mexican law, Ms. Lindner, confirming that no Mexican patent has ever been invalidated for lack of “industrial application” (the utility standard in Mexico).<sup>324</sup>

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<sup>317</sup> *Id.*

<sup>318</sup> C-PHM ¶126. Claimant denies that it is appropriate to move both of those cases to the pre-2005 period, as one of them involved the application of the new utility requirement. *Id.*, citing C C-354, *Merck & Co., Inc. et al v. Apotex Inc. et al.*, [2005] F.C. 755, at 73-74.

<sup>319</sup> C-PHM ¶126. Claimant’s statistical expert Professor Levin warns that it is inappropriate to draw conclusions from the pre-2005 period due to the small number of cases. Testimony of Bruce Levin, Tr. at 1277:2-12.

<sup>320</sup> C-PHM ¶137. *See* Memorial §V.

<sup>321</sup> C-PHM §II.E.1, citing, e.g., testimony of Canada’s expert Professor Holbrook, Tr. 1475:4-12 (“[Y]ou, Professor Merges and Mr. Kunin notably agree . . . [t]hat the utility requirement is a low bar in the United States . . . . PROFESSOR HOLBROOK: That’s correct”).

<sup>322</sup> C-PHM ¶144.

<sup>323</sup> Testimony of Robert Merges, Tr. 1299:2-6.

<sup>324</sup> Testimony of Hedwig Lindner, Tr. 1970:17-21.

259. According to Claimant, in comparing the utility requirement across the NAFTA jurisdictions, it is inappropriate to consider other, distinct patentability requirements (e.g., enablement), as Respondent attempts to do. In any event, even comparing patent law as a whole across NAFTA jurisdictions, Canada remains an “outlier”, as demonstrated by the difference in invalidations.<sup>325</sup> For Claimant, this explains why the Office of the U.S. Trade Representative (“**USTR**”), in its “Special 301” report, has expressed “serious concerns” regarding Canada’s heightened patent utility standards since 2013.<sup>326</sup>
260. Claimant also points to negotiating documents of the World Intellectual Property Organization (“**WIPO**”) to show a broader global consensus on the meaning of utility. Claimant states that this evidence “confirms that Canada’s promise utility doctrine constitutes a new and radical departure from the traditional patent law concept of utility, as reflected in the laws of many countries”.<sup>327</sup>

*i. Legitimate Expectations*

261. Claimant submits that it had “legitimate expectations that its Zyprexa and Strattera patents would not be invalidated on the basis of a radically new utility requirement.”<sup>328</sup> According to Claimant, this expectation was reasonably grounded in (i) Canadian patent law, (ii) Respondent’s grant of the Strattera and Zyprexa Patents, and (iii) Respondent’s international commitments under NAFTA and the PCT.<sup>329</sup>
262. Claimant argues that multiple NAFTA Chapter Eleven tribunals have held that NAFTA Article 1105 protects expectations that are reasonable in light of the respondent’s conduct, including its established legal and regulatory framework.<sup>330</sup>

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<sup>325</sup> C-PHM ¶¶154-155.

<sup>326</sup> Reply ¶52, C-PHM ¶155. See **C-331**, Office of the United States Trade Representative, *Special 301 Report* (2014), pp. 49-50.

<sup>327</sup> C-PHM ¶158.

<sup>328</sup> Claimant’s Closing Statement, Tr. 2135:12-15; see Reply ¶349. Claimant has developed this argument primarily in the context of its submissions on the alleged breach of NAFTA Article 1105. However, as explained below, the Tribunal finds it appropriate to consider Claimant’s factual allegations here. See §VIII.B(6) below.

<sup>329</sup> Memorial §VII.B.3; Reply §V.B.2; C-PHM §IV.C.2.(a).

<sup>330</sup> Reply ¶356; C-PHM ¶278. Claimant cites, *inter alia*, **CL-107**, *Grand River Enterprises Six Nations, Ltd., et al. v. United States of America*, UNCITRAL, Award, 12 January 2011, ¶140 and **CL-166**, *Bilcon v. Canada*, ¶572.

263. In this regard, Claimant alleges that it reasonably relied upon the traditional utility requirement in Canadian patent law throughout the process of developing Zyprexa and Strattera, and continued to do so as it brought the drugs to market.<sup>331</sup> For support, Claimant offers the testimony of Eli Lilly’s former General Counsel, Mr. Armitage, and the executives who oversaw the launch of the two products.<sup>332</sup> These witnesses testify that confidence in the ability to secure patent protection was critical to the decision to proceed with launch of the drugs in Canada.<sup>333</sup>
264. Claimant further submits that its legitimate expectations were also based on Respondent’s specific commitments to Claimant with respect to the patent protection of Strattera and Zyprexa.<sup>334</sup> First, Respondent’s traditional utility requirement was a specific commitment to Claimant because patentability standards are technical regulations aimed at, and relied upon, by a discrete identifiable group.<sup>335</sup> Second, Respondent made a commitment to Claimant in the form of the grant of the Zyprexa and Strattera Patents themselves.<sup>336</sup> According to Claimant, the patents specifically assured Claimant that it would have exclusive rights to make, use, and sell its invention until the expiry of the patents. Thus, in Claimant’s view, the patents were more than mere representations; they were bundles of legally enforceable rights.<sup>337</sup>
265. According to Claimant, it relied upon the Strattera and Zyprexa Patents when making significant investment decisions in relation to the drugs, such as investing in regulatory approvals and marketing.<sup>338</sup> In this context, Claimant cites the testimony of Mr.

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<sup>331</sup> Memorial ¶¶275-278.

<sup>332</sup> Armitage First and Second Statements; Postlethwait Statement; Nobles Statement; Stringer Statement.

<sup>333</sup> See, e.g., Postlethwait Statement ¶29 (“we were very focused on patent protection, and our patent attorneys had not flagged any issues with our Canadian patent application. The fact that no issues were raised gave us confidence that we would receive a patent, which in turn was a key consideration in our decision to proceed with the Canadian launch”).

<sup>334</sup> As a legal matter, Claimant rejects Respondent’s position that legitimate expectations must be based on a State’s specific commitments to an investor, but as a factual matter, Claimant states that Respondent did in fact make such commitments.

<sup>335</sup> Memorial ¶284.

<sup>336</sup> Memorial ¶285; Reply ¶360; C-PHM ¶281.

<sup>337</sup> Memorial ¶286.

<sup>338</sup> Memorial ¶287; Reply ¶360; Nobles Statement ¶23; Postlethwait Statement ¶30.

Postlethwait and Ms. Nobles, who state that patent protection was critical to the market success of both products.<sup>339</sup>

266. In response to Respondent’s argument that patents are subject to judicial invalidation and therefore cannot be the basis of legitimate expectations, Claimant contends that the normal risk of invalidation is different from the unacceptable risk that a patent will be tested against a new patentability requirement that could not have been foreseen at the time the patent was granted.<sup>340</sup>
267. Claimant also relies on Respondent’s international obligations. According to Claimant, its “legitimate expectations were reinforced by NAFTA Chapter 17, under which Canada was obligated not to develop and retroactively apply a doctrine like the promise utility doctrine”.<sup>341</sup> Specifically with regard to the Strattera Patent, Claimant asserts that it had a legitimate expectation that its application, which was valid under the PCT, would be sufficient to meet Canadian requirements. For Claimant, this follows from the fact that the PCT (i) does not require evidence of the utility of an invention to be disclosed, and (ii) prohibits member countries from imposing additional or different form and content requirements.<sup>342</sup>
268. Claimant contends that its expectations of patent protection were objectively reasonable. In this regard, Claimant rejects Respondent’s argument that Claimant’s expectations were insufficiently informed.<sup>343</sup> According to Claimant, it has a network of qualified patent agents and attorneys to advise management and ensure compliance with Canadian patent law.<sup>344</sup> For Claimant, the reason that none of these experts gave specific advice on the

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<sup>339</sup> Nobles Statement ¶23; Postlethwait Statement ¶30.

<sup>340</sup> Reply ¶361; *citing* Counter-Memorial ¶294.

<sup>341</sup> C-PHM ¶280; *see* Memorial ¶279; Reply ¶330.

<sup>342</sup> Memorial ¶280-283; Reply ¶355; *citing* Erstling First Report ¶¶16, 24-28, 33-34; **C-186**, An Act to Amend the Patent Act and To Provide for Certain Matters in Relation Thereto, Ch. 41; **C-187**, ‘Regulations for Carrying Into Effect the Terms of the Patent Cooperation Treaty Done at Washington on June 19, 1970 and accompanying Regulatory Impact Analysis Statement; **CL-073/R-037**, PCT, Article 27(1); **C-188**, Regulations Under the Patent Cooperation Treaty, Rule 5.1(a)(vi); **C-050/R-001**, Patent Act, RSC, 1985, c. P-4, §38.2(2).

<sup>343</sup> C-PHM ¶286.

<sup>344</sup> C-PHM ¶286, *citing inter alia* Testimony of Robert Armitage, Tr. 343:18-344:1 (“Lilly maintained a network of patent agents whose responsibility it was to provide advice on matters of patent law and practice to keep Lilly abreast of those developments. That global network included patent agents in each of the countries in which Lilly sought

utility requirement in relation to the filing of the Strattera and Zyprexa Patents is precisely because the traditional utility test was well understood to be a low bar, and analysis was not required.<sup>345</sup> Thus, Claimant contends that its expectations were reasonably rooted in Canadian patent law as it existed at the time of its investments, before the law underwent a dramatic change.

269. Claimant’s position is that the dramatic change in the Canadian utility requirement was outside the “acceptable margin of change” that investors must anticipate.<sup>346</sup> Therefore, in its view, the invalidation of the Strattera and Zyprexa Patents through application of the promise utility doctrine violated its legitimate expectations. In this regard, Claimant draws “a distinction between measured change in the law or clarification of previously unsettled law, on the one hand, and the adoption of a completely new doctrine in a well-settled area, on the other”.<sup>347</sup> According to Claimant, it could not reasonably have expected that Canadian courts would create and then retroactively apply a new utility requirement.<sup>348</sup> Furthermore, for Claimant, “it is not just the extent of the change that is striking. It is also the inconsistency between Canada’s new promise utility doctrine and relevant international treaties and practices.”<sup>349</sup>

## (2) Respondent’s Position

270. Respondent rejects Claimant’s allegation of a recent sea-change in the Canadian law on utility. According to Respondent, the term “useful” is not defined in the Patent Act, and its meaning has therefore necessarily evolved through jurisprudence. Respondent argues that

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patents around the world, and in the case of Canada included highly competent Canadian patent agents located in Canada who routinely provided that kind of advice to Lilly”).

<sup>345</sup> C-PHM ¶289, *citing inter alia* Testimony of Robert Armitage, Tr. 344:18-25 (stating that he would have been “shocked if there were evidence that advice on Canadian utility law had been given during that time frame, since it was so well understood that the threshold for meeting the Canadian utility requirement for pharmaceutical inventions was so low”).

<sup>346</sup> Memorial ¶279; C-PHM ¶279, *quoting* CL-050, Rudolf Dolzer and Christoph Schreuer, *Principles of International Investment Law* (2012), p. 148.

<sup>347</sup> C-PHM ¶279. *See* C-PHM ¶282 (“there is a categorical difference between a challenge based on the law as it stood at the time of grant and a challenge based on entirely new law”).

<sup>348</sup> Memorial ¶279; Reply ¶364.

<sup>349</sup> C-PHM ¶280. *See* Memorial ¶279, *citing* C-184, North American Free Trade Agreement Implementation Act, S.C. 1993, c. 44 and C-039, Honorable John Manley, Canadian Minister of Industry, Speaking Notes for Address to the Standing Committee on Industry, Review of Bill C-91, 17 February 1997; *see also* Reply ¶364.

what Claimant presents as a unitary “promise utility doctrine” is in reality three distinct long-standing patent law rules, discussed below.

**a. Promise Standard**

271. According to Respondent, the first long-standing rule is that a patentee will be held to any promises contained in the patent. Utility has long been a bifurcated standard.<sup>350</sup>
272. Respondent observes that Claimant has narrowed its allegation regarding the promise standard, such that the “dramatic change that it now alleges occurred in 2005 is not holding patentees to promises of utility *per se*, but holding them to promises found in the disclosure portion of the patent”.<sup>351</sup> Respondent finds this to be a confusing aspect of Claimant’s case, as Claimant continues to rely on cases where the promise was found in the language of the claims (rather than the disclosure) as examples of the promise utility doctrine.<sup>352</sup>
273. In any event, Respondent argues that even Claimant’s narrowed allegation is incorrect. Indeed, Respondent points out that Claimant itself acknowledged that the promise standard was an established principle of patent law in submissions to the Supreme Court.<sup>353</sup> Claimant’s expert, Professor Siebrasse, in his academic writing, also recognized the place of the promise doctrine in earlier Canadian law.<sup>354</sup>

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<sup>350</sup> Counter-Memorial ¶92, quoting **R-050**, E. Richard Gold and Michael Shortt, “The Promise of the Patent in Canada and Around the World”, 30:1 Canadian Intellectual Property Review 35, 54 June 2014 (“First, where the patent document itself makes no promise of utility, a ‘mere scintilla of utility’ will suffice; this requirement has normally been interpreted as requiring that the invention produce some minimally useful result. Second, where the inventor makes a promise, the patent will have utility only if it fulfils that promise, regardless of whether it possesses a scintilla of utility”).

<sup>351</sup> R-PHM ¶113. See Tr. 911:4-19 (“MR. REDDON: In my report, and I think I’m very clear, it’s not so much suddenly we’re going to take promises. It’s we’re going to stop looking in the claims for promises and start pulling them out of the disclosure ... it really arose when we changed from the claims to the disclosure ...”); Tr. 555:19-24 (“MR. JOHNSTON: As we’ve been discussing, on your view for a case to be an example of the promise utility doctrine, the promise must be derived from the disclosure, not from the claims. PROFESSOR SIEBRASSE: That’s right. That’s correct.”).

<sup>352</sup> R-PHM ¶114.

<sup>353</sup> R-PHM ¶115, citing **R-034**, *Novopharm Limited v. Eli Lilly and Company*, Supreme Court of Canada Case No. 33870, Memorandum of Argument of the Respondent, Application for Leave to Appeal, 26 October 2010, ¶2.

<sup>354</sup> See, e.g., **C-206**, Norman V. Siebrasse, *Must the Factual Basis for Sound Prediction Be Disclosed in the Patent?* (2012)28 Can IP Rev 39, p. 11, fn. 30 (“[The promise standard] has a long, but sporadic, history in Anglo-Canadian patent law ... but it has recently become a much more important feature of Canadian patent law...”).

274. Respondent points to what it considers “extensive historical evidence demonstrating the existence of the promise standard in Canadian law long before Claimant filed its patents or NAFTA entered into force”.<sup>355</sup>
275. Respondent relies in particular on the 1981 Supreme Court decision in *Consolboard*, which holds that that “not useful” means an invention “will not do what the specification promises that it will do”.<sup>356</sup> Contrary to Claimant’s position, Respondent argues that there are numerous pre-2005 cases that cite *Consolboard* for the promise standard.<sup>357</sup>
276. For example, Respondent points to the Federal Court of Appeal in the 1995 *Wellcome Foundation Ltd. v. Apotex* decision, which stated that “[s]ince the utility of a patent must ultimately be judged against its promise, the exercise requires that the specification be carefully construed to determine exactly what the promise is”.<sup>358</sup> Indeed, Professor Siebrasse characterized the holding in *Wellcome* as the “clearest support for the promise of the patent doctrine”.<sup>359</sup> The Canadian government also referred to the bifurcated test in submissions to WIPO in 2001 and 2003.<sup>360</sup>

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<sup>355</sup> R-PHM ¶117; see Counter-Memorial ¶¶88-107; Rejoinder ¶¶152-156; Dimock First Report ¶¶53-91; Dimock Second Report ¶10, Annex B.

<sup>356</sup> **C-118/R-011**, *Consolboard*, at ¶¶36-37.

<sup>357</sup> R-PHM ¶121 n.27 (citing **R-187**, *Goldfarb v. W.L. Gore & Associates Inc.*, [2001] 11 C.P.R. 4th 129, para. 109; **R-360**, *Feherguard Products Ltd. v. Rocky's of B.C. Leisure Ltd.*, [1994] 53 P.C.R. 3d 417 (F.C.T.D.), para. 23; **C-230**, *Almecon Industries Ltd. v. Anchortek Ltd.*, [2001] 17 C.P.R. 4th 74 (F.C.T.D.), ¶¶45-46).

<sup>358</sup> **R-401**, *Wellcome Foundation Ltd v. Apotex Inc.*, [1995] F.C.J. No. 226, 60 C.P.R. 3d 135 (F.C.A.), p. 154. As confirmed by Professor Siebrasse, “specification” in this context refers to the disclosure portion of the patent. Tr. 621:14-17.

<sup>359</sup> **C-205**, Norman V. Siebrasse, *The False Doctrine of False Promise*, (2013) 29 Can IP Rev 3, p. 22, fn. 91; see also Testimony of Siebrasse, Tr. 621:18-22 (“MR. JOHNSTON: Just to be clear, is this the case we discussed earlier that you described as the clearest support for the promise of the patent doctrine? PROFESSOR SIEBRASSE: Yes”).

<sup>360</sup> **R-407**, WIPO, *The Practical Application Of Industrial Applicability/Utility Requirements Under National And Regional Laws*, April 2001, ¶13 (“An invention lacks utility if it is not operable or it will not do what the specification promised it will do (‘false promise’)); **R-230**, WIPO, *Industrial Applicability” and “Utility” Requirements: Commonalities and Difference*, document SCP/9/5, 17 March 2003, ¶41 (“A finding that the alleged invention is not useful may be expressed in a way that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promised it would do (‘false promise’).

277. Respondent also cites other commentary, including a 1960 article by leading Canadian patent lawyer Mr. Donald Hill and the 1969 treatise of Dr. Harold G. Fox, both of which refer to promises in the specification.<sup>361</sup>
278. Finally, according to Respondent, Claimant overlooks that patentees have always been held to promises under other doctrines such as overbreadth. Respondent states that the “doctrine of overbreadth has for decades held patentees to promises of utility by prohibiting claims that are broader than the invention made or disclosed”.<sup>362</sup>

***b. Post-Filing Evidence***

279. Respondent also rejects Claimant’s assertion that the 2002 Canadian Supreme Court decision in *AZT* changed the law by disallowing post-filing evidence of utility. Respondent argues that Claimant’s characterization of *AZT* is inaccurate for four main reasons.
280. First, according to Respondent, the principle that utility must be established before filing is enshrined in the Patent Act and early cases. Claimant’s “file now, pay later approach” has no basis in Canadian jurisprudence; post-filing evidence was never permissible to prove utility in Canadian law.<sup>363</sup> For Respondent, this is confirmed by the Supreme Court’s adoption of the doctrine of sound prediction in 1979 in *Monsanto*.<sup>364</sup> The sound prediction doctrine would be unnecessary if a patent could be granted based on speculations of utility that would only be confirmed with *post hoc* testing.<sup>365</sup>
281. Second, Respondent argues that nothing in Justice Binnie’s decision in *AZT* suggests the Supreme Court was changing or making new law. Instead, the Court interpreted various provisions of the Patent Act and concluded that it required that utility be proven at the time of the patent application. It also interpreted jurisprudence such as the 1930 Supreme Court decision in *Rice v. Cristiani* and the 1979 case *Procter & Gamble*, in which the Supreme

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<sup>361</sup> **R-160**, Donald Hill, “Claim Inutility” (1960), 35 CPR 185, 188; **R-163**, Harold G. Fox, Canadian Patent Law and Practice, 4<sup>th</sup> ed. (1969), pp. 152-153.

<sup>362</sup> R-PHM ¶131.

<sup>363</sup> Counter-Memorial ¶120.

<sup>364</sup> Dimock First Report ¶¶98-101, 103.

<sup>365</sup> R-PHM ¶139.

Court stated, “Knowing a new process without knowing its utility is not in my view knowledge of an ‘invention’”.<sup>366</sup>

282. Respondent disagrees with Claimant’s position that cases prior to *AZT* allowed post-filing evidence to prove utility. In particular, Respondent argues that Claimant misreads *Ciba-Geigy*. According to Respondent, the Federal Court of Appeal in *Ciba-Geigy* determined that there was enough pre-filing evidence to soundly predict utility.<sup>367</sup> Respondent argues that the other cases cited by Claimant as allowing post-filing evidence are off point, as those cases allowed post-filing evidence to prove obviousness and operability, elements of patent law that are separate from utility.<sup>368</sup>
283. Third, Respondent asserts that the legal community did not regard *AZT* as a dramatic change in the law.<sup>369</sup> Respondent offers as an example commentary by a leading Canadian intellectual property law firm that published a contemporaneous comment on *AZT* stating that it “reaffirmed a long-standing position” on post-filing evidence and “confirmed” the disallowance of post-filing evidence.<sup>370</sup> Respondent argues that Claimant has offered no evidence to the contrary. Claimant misreads the two cases which it interprets as confirming the *AZT* changed the law.<sup>371</sup> Further, Claimant’s expert, Mr. Reddon, offered no documentary evidence to support his claim that other practitioners regarded *AZT* as a change in the law.<sup>372</sup>
284. Fourth, Respondent argues that there is no other heightened evidentiary standard for utility as a result of *AZT*. Here, Respondent addresses Claimant’s allegation that pharmaceutical companies would now be required to conduct and finalize human clinical trials in order to

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<sup>366</sup> **C-213/R-004**, *AZT* (quoting *Procter & Gamble Co. v. Bristol-Myers Canada Ltd.*, [1979] 42 C.P.R. 2d 33).

<sup>367</sup> **R-190**, see *Ceiba-Geigy AG v. Canada (Commissioner of Patents)*, (1982), 65 CPR (2d) 73 (FCA).

<sup>368</sup> See Counter-Memorial ¶115.

<sup>369</sup> R-PHM ¶¶144-146.

<sup>370</sup> **R-191**, *Supreme Court of Canada Reaffirms the Doctrine of Sound Prediction in Canadian Law*, *IP Perspectives Intellectual Property & Technology Newsletter*, Smart & Biggar/Fetherstnhaugh, February 2003, pp 2-3.

<sup>371</sup> R-PHM ¶146 (citing **C-532**, *Bristol-Myers Squibb Company v. Apotex Inc.*, [2010] F.C. 1304, at ¶¶ 30-31; **C-209**, *Aventis Pharma Inc. v. Apotex Inc.*, [2005] F.C. 1283, at ¶157).

<sup>372</sup> Testimony of Reddon, Tr. 912:12-18.

prove or soundly predict the utility of a drug for human use.<sup>373</sup> Respondent points to *AZT* itself, in which *in vitro* tests were sufficient to prove or soundly predict utility.<sup>374</sup> Respondent also suggests that Claimant’s perception of a heightened evidentiary standard may be the result of a strengthened adversarial process in which litigants rigorously seek to validate or invalidate a patent.<sup>375</sup>

***c. Disclosure for Sound Prediction***

285. According to Respondent, Claimant is also wrong to assert that the requirement to disclose the factual basis and reasoning for a sound prediction of utility in the patent is new. Respondent offers three main reasons to reject Claimant’s position.
286. First, Respondent argues that the need to disclose the basis for a sound prediction in the patent has been recognized in Canadian law since the 1979 *Monsanto* decision, the seminal case on sound prediction in Canada.<sup>376</sup> In *Monsanto*, the Supreme Court allowed a claim for a group of compounds whose utility was soundly predicted, based only on three examples disclosed in the patent and affidavit evidence of the common general knowledge.<sup>377</sup> Both types of evidence are still used today.<sup>378</sup> Thus, *Monsanto* established the need to substantiate the basis for a sound prediction at the time of filing.
287. In addition, Respondent argues that Patent Office practice in the 1990s confirms that the disclosure requirement for the basis of a sound prediction existed long before the Raloxifene Decision. According to Dr. Gillen, in that era “the examiner would determine whether or not the prediction appeared to be sound based on the type of research disclosed

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<sup>373</sup> Memorial ¶66; Reply ¶94. Claimant alleges for example that *in vitro* testing would not be sufficient under the alleged heightened standard to prove utility.

<sup>374</sup> R-PHM ¶149 (citing **C-213/R-004**, *AZT*).

<sup>375</sup> R-PHM ¶150.

<sup>376</sup> R-PHM ¶153.

<sup>377</sup> **C-061/R-023**, *Monsanto*. According to Respondent, Professor Siebrasse concedes this point. *See, e.g.*, Testimony of Siebrasse, Tr. 699:24-700:4.

<sup>378</sup> R-PHM ¶153.

in the application, the results obtained, and the explanation provided in the specification as to how those results could predict the utility of a subject compound”.<sup>379</sup>

288. Second, Respondent argues that *AZT* affirmed *Monsanto* and the need to disclose the basis for a sound prediction. In *AZT*, the Supreme Court explained that “the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly”.<sup>380</sup> It follows that a patentee must substantiate the basis for a sound prediction before obtaining the patent, as did the patentee in *AZT*.<sup>381</sup> Respondent asserts that practitioners, including Claimant’s law firm Gowlings, interpreted *AZT* as requiring disclosure of the basis for a sound prediction.<sup>382</sup> Indeed, the Federal Court in the *Strattera* Decision specifically cites *AZT* for the disclosure rule.<sup>383</sup>
289. For Respondent, Claimant cannot claim that it did not know of the requirement to disclose the basis for a sound prediction in the patent. Before the *Raloxifene* Decision, Claimant had received CIPO Office Actions that called for disclosure of the basis for a sound prediction and cited *AZT* for the requirement.<sup>384</sup>

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<sup>379</sup> Gillen First Statement ¶44.

<sup>380</sup> R-PHM ¶¶155-158.

<sup>381</sup> **C-213/R-004**, *AZT*, ¶¶3, 70, 75 (The trial judge found that “the inventors possessed and disclosed in the patent both the factual data on which to base a prediction, and a line of reasoning ... to enable them to make a sound prediction at the time they applied for the patent”).

<sup>382</sup> R-PHM ¶¶157, citing **R-191**, *Supreme Court of Canada Reaffirms the Doctrine of Sound Prediction in Canadian Law*, *IP Perspectives Intellectual Property & Technology Newsletter*, Smart & Biggar/Fetherstnhaugh, February 2003, pp 2-3); **R-494**, *Gowling Lafleur Henderson LLP, Pharmacapsules @ Gowlings*, 4 May 2009, p. 5 (“The Court [in the *Raloxifene* Decision] reiterated the test articulated by the Supreme Court in *AZT* namely that when an invention had not yet been reduced to practice, the disclosure must give both the underlying facts and the sound line of reasoning to justify the prediction.”)

<sup>383</sup> **C-160/R-027**, *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, ¶117.

<sup>384</sup> Gillen Second Statement ¶¶ 26-27, citing **R-382**, CIPO Office Action dated 23 October 2003, Application No. CA2304567 (“Claims 1 to 20 do not comply with Section 84 of the Patent Rules. The description fails to provide a sound line of reasoning for the utility claimed.”); **R-383**, CIPO Office Action dated 7 October 2004, Application No. CA2248873 (“Claim 6 does not comply with section 2 of the *Patent Act*. The description fails to provide a sound line of reasoning for the utility of olanzapine for treating inflammation.”).

290. Third, Respondent argues that there is no precedent in Canadian law that would have supported finding a sound prediction in relation to the Strattera Patent, which disclosed no information at all to evidence of sound prediction.<sup>385</sup>

*d. MOPOP Amendments and CIPO Practice*

291. According to Respondent, MOPOP is neither an authoritative statement of the law nor a comprehensive summary of Canadian patent law or Patent Office practice. Respondent quotes the Foreword to eleven versions of MOPOP from 1989 to 2014, which states that it “is to be considered solely as a guide, and should not be quoted as an authority. Authority must be found in the Patent Act, the Patent Rules, and in decisions of the Courts interpreting them”.<sup>386</sup> Further, Respondent argues that conclusions about the state of the law cannot be drawn from MOPOP because revisions come about slowly and are incomplete.<sup>387</sup> As an illustration, Respondent highlights that the 1990 MOPOP does not include the doctrine of sound prediction, which was adopted in Canadian law in 1979.

292. In any event, Respondent rejects Claimant’s argument that MOPOP and Patent Office practice reflect the creation of the promise utility doctrine in the mid-2000s. In particular, Respondent notes that the 1990 MOPOP did not exclude the promise standard, and it reflected a longstanding requirement to establish utility before filing.<sup>388</sup>

293. Further, according to Respondent’s witness Dr. Gillen, “The only situation in which an examiner would accept evidence of utility after filing was one in which the examiner had doubts about the credibility of an allegedly demonstrated (not predicted) utility. However,

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<sup>385</sup> See **C-160/R-027**, *Novopharm Ltd. v. Eli Lilly and Co.*, [2010] F.C. 915, at ¶36 (“...the [Strattera] Patent offers no information about the nature or sources of the evidence relied upon by the inventors to support the promise of atomoxetine’s utility to treat ADHD by demonstration or by sound prediction”).

<sup>386</sup> **R-025**, MOPOP, Foreword (August 1989, January 1990, March 1998, September 2004, February 2005, April 2006, January 2009, December 2009, November 2013, December 2013 and May 2014).

<sup>387</sup> Gillen First Statement ¶20 (“An inherent weakness of the MOPOP ... is that it cannot be relied upon to be completely up to date.”).

<sup>388</sup> **R-PHM** ¶140; **R-309**, 1990 MOPOP §18.20.02 (“An invention, such as that related to a new substance, may not be said to be invented until such date as the utility for it is known”).

even then the evidence would be required to have pre-dated the filing of the application in question”.<sup>389</sup>

***e. Statistical Evidence***

294. Respondent characterizes Claimant’s statistical evidence as “anecdotal” and detached from Claimant’s own theory of the case. Claimant’s statistics are not keyed to the events in 2002, 2005, and 2008 that Claimant claims to have caused a dramatic change in the law on utility.<sup>390</sup> The date selected by Claimant for the introduction of the promise utility doctrine (1 January 2005) is nine months before Claimant alleges the promise standard was adopted, and correcting the date materially changes Claimant’s results.<sup>391</sup>
295. While Respondent acknowledges that there has been an uptick in pharmaceutical patent litigation on the issue of utility, it insists that the increase is due to “developments in the patent regime that *strengthened* intellectual property protection for pharmaceuticals”.<sup>392</sup> Respondent points specifically to the introduction of PM(NOC) proceedings in 1993, which allowed pharmaceutical patent holders to pre-emptively block generic manufacturers from entering the market.<sup>393</sup>
296. Respondent’s witness, Dr. Brisebois, identifies a number of methodological errors in Claimant’s statistics. For example, he argues that Claimant’s expert, Professor Levin, inappropriately includes in his 2005-2014 data set pharmaceutical cases in which the patent was successfully challenged on other grounds, in addition to utility.<sup>394</sup> Also, Claimant includes PM(NOC) proceedings that do not result in true “invalidations”. Correcting for these flaws shows that only three, not 23, pharmaceutical patents were invalidated for a lack of utility alone during this period.<sup>395</sup> In addition, Claimant counts all utility-based

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<sup>389</sup> Gillen First Statement ¶41.

<sup>390</sup> R-PHM ¶162.

<sup>391</sup> R-PHM ¶164.

<sup>392</sup> Counter-Memorial ¶138 (emphasis in original).

<sup>393</sup> Counter-Memorial ¶¶138-141.

<sup>394</sup> Brisebois First Statement ¶37.

<sup>395</sup> Counter-Memorial ¶¶144-148.

invalidations as examples of the promise utility doctrine, whether or not the promise standard was actually applied in the case.<sup>396</sup>

*f. Comparison With Other Jurisdictions*

297. Like Claimant, Respondent has submitted extensive evidence relating to the patent law regimes in the United States and Mexico. According to Respondent, the other NAFTA Parties' laws on utility are not in discord with Canada's bifurcated standard.<sup>397</sup> Of particular relevance in the current context, Respondent argues that U.S. and Mexican patent law has evolved since NAFTA. For example, the U.S. enablement and written description doctrines are similar to Canada's law on utility,<sup>398</sup> and the enablement requirement has become more rigorous since the passage of NAFTA.<sup>399</sup> Similarly, Respondent contends that Mexico's industrial applicability requirement requires a rigorous showing of claimed utility as of the filing date.<sup>400</sup> In any event, Respondent finds any differences in patent law regimes across jurisdictions irrelevant, as it contends that international patent law is not harmonized by NAFTA or otherwise.<sup>401</sup>
298. Respondent further argues that no other State or international organization voiced any concern over Canada's law on utility prior to this arbitration, confirming that there has been no dramatic change in the law.<sup>402</sup> Respondent challenges the reliability of the 2014 and 2015 editions of the USTR Special 301 Report cited by Claimant, in which the United States expresses "serious concerns" over Canada's utility requirement.<sup>403</sup> According to Respondent, "the Special 301 Report is based not on empirical evidence and analysis, but on industry allegations made to USTR, including representations made by the Claimant

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<sup>396</sup> R-PHM ¶165.

<sup>397</sup> See, e.g., Counter-Memorial §II(G)-(H).

<sup>398</sup> Counter-Memorial ¶¶171-172; Holbrook First Report ¶¶21-33.. According to Respondent, These doctrines, particularly as applied to pharmaceutical compounds, require that claims of utility be substantiated with credible test results in the patent description as of the filing date.

<sup>399</sup> Holbrook First Report ¶67.

<sup>400</sup> Counter-Memorial ¶¶176-177 (citing Lindner First Report ¶¶12, 42-44).

<sup>401</sup> Counter-Memorial § II(I-J).

<sup>402</sup> R-PHM §IV.F.

<sup>403</sup> R-PHM ¶173. See C-331, Office of the United States Trade Representative, *Special 301 Report* (2014); C-332, Office of the United States Trade Representative, *Special 301 Report* (2015).

and its industry associations”.<sup>404</sup> In addition, these reports were not issued contemporaneously with the changes in the law that Claimant alleges, but rather at the time of the commencement of this arbitration. Thus, Respondent supposes that the reports were the result of Claimant’s own lobbying efforts to bolster its claims in this arbitration.<sup>405</sup>

299. Respondent confirms that it knows of no other complaint or comment received by Canada in the PCT, WIPO, or WTO context relating to its utility requirement during the relevant period.<sup>406</sup>

***g. Legitimate Expectations***

300. In response to Claimant’s submissions regarding its alleged legitimate expectations, Respondent argues that a mere failure to fulfil an investor’s expectations does not breach the minimum standard of treatment in NAFTA Article 1105(1), although it may be relevant to the analysis of whether a measure was sufficiently egregious to breach customary international law.<sup>407</sup>

301. In any event, even if Claimant’s legal arguments were accepted, Respondent submits that Claimant has failed to establish its alleged legitimate expectations. For Respondent, a legitimate expectation must: (i) be objective, not subjective;<sup>408</sup> (ii) involve a specific assurance or promise by the State to induce the investment, which was relied upon by the investor;<sup>409</sup> (iii) exist at the time the investor decided to make the investment;<sup>410</sup> and (iv)

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<sup>404</sup> R-PHM ¶173.

<sup>405</sup> *Id.*

<sup>406</sup> R-PHM ¶174.

<sup>407</sup> Counter-Memorial ¶¶276, 283; citing **CL-065/RL-014**, *Waste Management II*, ¶98; **CL-104/RL-003**, *International Thunderbird Gaming Corporation v. United Mexican States*, UNCITRAL/NAFTA, Award, 26 January 2006, ¶¶147, 194; **CL-116/RL-006**, *Glamis Gold v. United States*, ¶¶620, 627.

<sup>408</sup> Counter-Memorial ¶282; citing **CL-112/RL-007**, *Mobil v. Canada*, ¶152; **CL-116/RL-006**, *Glamis Gold v. United States*, ¶627.

<sup>409</sup> Counter-Memorial ¶282; citing **CL-112/RL-007**, *Mobil v. Canada*, ¶152; **CL-116/RL-006**, *Glamis Gold v. United States*, ¶620; **CL-065/RL-014**, *Waste Management II*, ¶98; **RL-008**, *EDF (Services) Limited v. Romania*, ICSID Case No. ARB/05/13, Award, 8 October 2009, ¶217.

<sup>410</sup> Counter-Memorial ¶282, citing **RL-054**, *Bayindir Insaat Turizm Ticaret Ve Sanayi A.Ş. v. Islamic Republic of Pakistan*, ICSID Case No. ARB/03/29, Award, 27 August 2009, ¶¶190-191; **CL-094/RL-048**, *Duke Energy Electroquil Partners & Electroquil S.A. v. Republic of Ecuador*, ICSID Case No. ARB/04/19, Award, 18 August 2008 (“*Duke Energy v. Ecuador*”), ¶340.

be reasonable in the circumstances, including the political, socioeconomic, cultural and historical conditions prevailing in the host State.<sup>411</sup>

302. According to Respondent, Claimant’s alleged expectations do not satisfy these criteria. In particular, Respondent contends that it made no specific assurances to Claimant regarding the Strattera and Zyprexa Patents. Respondent argues that Claimant cannot rely on the grant of the patents as a basis for its alleged legitimate expectations because patents issued by the Patent Office are only presumptively valid, subject to challenge and to final determination by the judiciary.<sup>412</sup> In this regard, Respondent cites Claimant’s annual public filings, which state that “there is no assurance that ... patents we have been granted would be found valid if challenged”.<sup>413</sup>
303. Moreover, Respondent argues that Claimant’s alleged expectations were not reasonable. In Respondent’s view, the record shows that the decision-makers within the company were not sufficiently informed about Canadian patent law.<sup>414</sup> Claimant’s employees testified that they did not know of any reason why their patents would be invalidated for lack of utility.<sup>415</sup> Yet, according to Respondent, “the record is full of Canadian patent law publications ... warning about including promises in your patent, and of disclosing a sufficient basis for a sound prediction long before Claimant filed its patent applications”.<sup>416</sup> More generally, Respondent argues that when Claimant filed the Strattera and Zyprexa Patents, it knew, or should have known, that its patents could be invalidated if they did not satisfy the applicable patentability requirements, and that the legal meaning of patentability requirements is constantly being clarified and elaborated through court decisions.<sup>417</sup>

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<sup>411</sup> Counter-Memorial ¶282, citing **CL-094/RL-048**, *Duke Energy v. Ecuador*, ¶340.

<sup>412</sup> Counter-Memorial ¶294; R-PHM ¶268.

<sup>413</sup> **R-303**, Eli Lilly Annual Report, Fiscal Year 1999, p. 4.

<sup>414</sup> R-PHM ¶269.

<sup>415</sup> Stringer Statement ¶25; Armitage First Statement ¶¶8, 12, 16; Noble Statement ¶23; Postlethwait Statement ¶¶22, 29. Respondent points out that none of Claimant’s witnesses testified in support of the patents before the Federal Court. Counter-Memorial ¶293.

<sup>416</sup> R-PHM ¶269, citing **R-163**, Harold G. Fox, *Canadian Patent Law and Practice*, 4<sup>th</sup> ed. (1969), p. 153; **R-164**, William L. Hayhurst, Q.C., *Disclosure Drafting*, [1971], 28 P.T.I.C. Bull 7th 64, at 78; **R-199**, William L. Hayhurst, Q.C., “The Art of Claiming and Reading a Claim”, in Gordon F. Henderson, *Patent Law of Canada* (1994), p. 217.

<sup>417</sup> Counter-Memorial ¶298, citing Dimock First Report ¶¶147-152.

304. Respondent dismisses Claimant’s specific argument that its expectations relating to the Strattera Patent were grounded on the PCT. Respondent contends that Claimant could not have expected that mere compliance with the PCT’s form and contents requirements would meet Canada’s substantive disclosure requirements.<sup>418</sup> For Respondent, this is obvious because (i) the PCT is a strictly procedural treaty that says nothing about the substantive conditions of patentability, (ii) Claimant did not make an appropriate attempt to comply with country-specific validity requirements,<sup>419</sup> and (iii) Respondent’s actions were consistent with the PCT’s form and contents requirements, as evidenced by the lack of evidence of any complaints being lodged by its treaty partners.<sup>420</sup>
305. According to Respondent, the only legitimate expectation Claimant could have had was to receive a fair hearing from the Federal Court in the event of a challenge to its patents.<sup>421</sup> Respondent contends that Claimant did in fact receive one; the application of the rules to Claimant’s patents revealed that they were latently defective at the time of filing.<sup>422</sup>
306. Respondent rejects Claimant’s position that its legitimate expectations were violated as a result of a dramatic change in the law. As summarized above, Respondent denies that the law dramatically changed after the Strattera and Zyprexa Patents were granted. In its response to Claimant’s position on legitimate expectations, Respondent further argues that:

[e]ven if such a change had occurred, it is trite to say that the common law evolves over time. Any sophisticated investor expects developments in the law, particularly in the area of patent law. It simply cannot be that every time a court overrules a precedent, it violates customary international law.<sup>423</sup>

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<sup>418</sup> Counter-Memorial ¶297, *citing* Reed First Report ¶¶33, 44-45; Gillen First Statement ¶56; **CL-073/R-037**, PCT, Article 3; **R-042**, WIPO PCT Applicant’s Guide, ¶¶5.094-5.095.

<sup>419</sup> Counter-Memorial ¶297; *citing* **CL-073/R-037**, PCT, Article 27(5) (“Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires...”).

<sup>420</sup> C-PHM ¶272, *citing* Tr. 1601:13-17 (“MR. SPELLISCY: So the answer is no, none of Canada’s Treaty partners under the PCT have brought a dispute complaining that Canada is violating the PCT, correct? PROFESSOR ERSTLING: That is correct”).

<sup>421</sup> Counter-Memorial ¶299.

<sup>422</sup> Counter-Memorial ¶292.

<sup>423</sup> R-PHM ¶267.

## **B. The Tribunal's Analysis**

307. The Canadian courts' interpretation of the utility requirement under Canadian patent law, and in particular their adoption of the promise utility doctrine in the mid-2000s, allegedly departing dramatically from prior Canadian patent law, is the factual premise for Claimant's case.<sup>424</sup> The Parties agree that a fundamental question before this Tribunal is whether there was a "dramatic" change in the utility requirement in Canada.<sup>425</sup> Claimant has confirmed that it must succeed on this issue to prevail in this arbitration.<sup>426</sup>
308. Claimant bears the burden of establishing the facts on which it relies for this aspect of its claim. Therefore, the Tribunal will analyse in this section whether Claimant adduced sufficient evidence to prove its allegation that "[i]n the mid-2000s, after the patents for Zyprexa and Strattera had been examined and granted, but prior to their invalidation by the courts, Canada's patent utility law underwent a dramatic transformation".<sup>427</sup> As discussed below, the Tribunal finds that Claimant has not met its burden in relation to this allegation.

### **(1) Preliminary Observations**

309. Claimant has asserted that the promise utility doctrine is a unitary doctrine that crystalized with the 2008 Raloxifene Decision, contending that this transformed the utility requirement in Canadian law. As a preliminary observation, the Tribunal considers that it is difficult for Claimant to establish that there has been a dramatic change in Canada's patent utility law where the relevant Canadian judicial decisions were handed down over a period of more than six years, encompassing a range of cases from first instance to appellate tier. Nevertheless, the Tribunal will examine more closely the evidence put forward by Claimant with regard to each of the three alleged elements of the promise utility doctrine and the doctrine as a whole.

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<sup>424</sup> See §VI.E(2) above.

<sup>425</sup> Claimant's Closing Statement, slide 140, "The Tribunal's Decision Tree" ("2. Whether there has been a dramatic change in the utility requirement in Canada"); R-PHM ¶5.

<sup>426</sup> Claimant's Closing Statement, slide 140, "The Tribunal's Decision Tree" ("2. Whether there has been a dramatic change in the utility requirement in Canada"); Tr. 2144:6-9 ("SIR DANIEL BETHLEHEM: You have to succeed on each one. MS. CHEEK: Yes, the Claimant would need to succeed on each of these").

<sup>427</sup> Memorial ¶56.

310. In undertaking this analysis, the Tribunal is mindful of the role of the judiciary in common law jurisdictions. Claimant’s position in this proceeding rests on an implicit premise that common law decisions must follow in a reasonably foreseeable and predictable channel, without significant or material changes. Yet evolution of the law through court decisions is natural, and departures from precedent are to be expected.<sup>428</sup>
311. Finally, the Tribunal observes that the present case is one in which the facts are the law. Thus, this analysis necessarily touches upon aspects of Canadian patent law previously unfamiliar to the Members of the Tribunal. The Tribunal has been greatly assisted by the Parties’ submissions and the testimony of their experts and witnesses, and thereby reaches its conclusions with confidence.

## **(2) The Utility Requirement in Canadian Jurisprudence**

312. The Patent Act defines an invention as follows:

“invention” means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter<sup>429</sup>

313. As summarized above, Claimant alleges that Canadian courts dramatically changed the application of this provision through a series of cases adopting the promise utility doctrine. To recall, the doctrine comprises three elements: (i) the identification of a “promise” in the patent disclosure, against which utility is measured; (ii) the prohibition on the use of post-filing evidence to prove utility; and (iii) the requirement that pre-filing evidence to support a sound prediction of utility must be included in the patent.

### ***a. The Promise Standard***

314. The Tribunal understands Claimant’s specific allegation regarding the promise standard to be that courts now look beyond the *claims* in the patent to the *disclosure* in order to construe

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<sup>428</sup> See **CL-007/RL-004**, *Mondev v. United States* (finding that even if one were to accept the claimant’s argument that the Massachusetts Supreme Judicial Court had made new law, “its decision would have fallen within the limits of common law adjudication”).

<sup>429</sup> **C-050/R-001**, *Patent Act*, RSC 1985, c P-4, §2.

the “promise” against which utility is assessed.<sup>430</sup> Claimant asserts that this practice was adopted by the Canadian judiciary in the mid-2000s without any basis in prior jurisprudence.<sup>431</sup>

315. The Tribunal further understands that Claimant is *not* arguing that the promise standard replaced the traditional “mere-scintilla” test, but rather that the two tests co-exist today.<sup>432</sup> This is one point on which the Parties agree.

316. In determining whether Claimant has established that the promise standard is new law, the Tribunal must begin by considering the much discussed 1981 Canadian Supreme Court decision in *Consolboard*, in which Justice Dickson wrote:

There is a helpful discussion in Halsbury’s Laws of England, (3rd ed.), vol. 29, at p.59, on the meaning of “not useful” in patent law. It means “that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do ... the practical usefulness of the invention does not matter, nor does commercial utility, unless the specification promises commercial utility” ... Canadian law is to the same effect.<sup>433</sup>

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<sup>430</sup> See, e.g., C-PHM §II.C.a. (“Finding Elevated ‘Promises’ Beyond the Claimed Invention’s Use Is New”); *id.* ¶89 (“It is common ground that under Canada’s traditional test, the invention *as claimed* must work and be operable, such that specific assertions of utility in the claims (which is part of the specification) must be fulfilled”).

<sup>431</sup> Reply ¶73; Siebrasse Second Report ¶72. In light of Claimant’s assertion that this was a dramatic change in the law, it is striking that nowhere in its Memorial or Reply does Claimant identify the name or date of the first court decisions adopting this standard. One has to look to a footnote in Professor Siebrasse’s expert report to find the citations to two trial court decisions in 2005 and a 2008 Court of Appeal decision, which he identifies as the first cases applying the promise standard. Siebrasse First Report fn. 98. (“The original Federal Court cases were *Bristol-Myers Squibb Co v. Apotex Inc*, 2005 FC 1348 [C-520], *Pfizer Canada Inc v Apotex Inc*, 2005 FC 1205 (C-250) and *Aventis Pharma Inc v Apotex Inc*, 2005 FC 1283 (C-209)”). The first Court of Appeal decision affirming the promise of the patent analysis was *Atorvastatin* 2008 FCA 108, *supra* note 51 [C-235]”). During the Hearing, a typographical error in this footnote was corrected. The reference to C-190 was replaced with C-520. Tr. 1194:3-1195:20. The Tribunal notes that it also misidentified C-235 as C-234.

<sup>432</sup> See, e.g., Memorial ¶57; Siebrasse First Report ¶41 (“The standard against which utility is assessed now has two branches. The first branch corresponds to the long standing requirement of a mere scintilla of utility, while the second branch sets an elevated standard according to the “promise of the patent”); Claimant’s Opening Statement, Tr. 21:4-12.

<sup>433</sup> C-118/R-011, *Consolboard*, at ¶¶36-37.

317. The Tribunal notes that “specification” in this context refers to both the claims and the disclosure of the patent.<sup>434</sup> Thus, the utility test articulated by Justice Dickson, at least in its language, is strikingly similar to Claimant’s presentation of the co-existing “mere scintilla” and promise standards.
318. Claimant has argued that *Consolboard* was never cited for the promise standard before 2005. The record contradicts this position. Respondent has submitted a number of pre-2005 cases that rely on *Consolboard* for the proposition that “not useful” means “the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do”.<sup>435</sup> Like *Consolboard*, these decisions do not appear to have applied the promise standard (in the sense of looking to the patent disclosure for a promise of utility), but the citations cannot be ignored as indications of similar analysis and policy considerations to that of the promise doctrine.
319. For the Tribunal, it is also relevant that Canadian courts have cited *Consolboard* for the promise standard *after* 2005, a fact which Claimant does not contest. Notably, when the promise standard was applied to Claimant’s patents, the courts relied on *Consolboard*. The Strattera Decision includes a section titled “Utility – Legal Principles” in which the “promise” language of *Consolboard* is quoted, followed by citations to authorities from the 1960s.<sup>436</sup> The 2010 Court of Appeals decision in the Zyprexa Patent litigation also cited *Consolboard*, together with a 2008 Court of Appeals case.<sup>437</sup>

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<sup>434</sup> See Tr. 621:14-17, where Professor Siebrasse confirms that “specification” as used by the court includes the disclosure portion of the patent.

<sup>435</sup> **R-187**, *Goldfarb v. W.L. Gore & Associates Inc.* (2001), 11 CPR (4th) 129 ¶109 (emphasis added) (“The Supreme Court of Canada in [*Consolboard*], discussed this concept. Dickson J., as he then was, explored, at page 525, the meaning of ‘not useful’ in patent law. He said, quoting from Halsbury’s Laws of England, (3rd ed.), vol. 29, at page 59: It means ‘that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do’”); **R-360**, *Feherguard Products Ltd. v. Rocky’s of B.C. Leisure Ltd.* (1994), 53 PCR (3d) 417 (FCTD), ¶23 (citing *Consolboard* for the proposition that “In patent law, a patent is “not useful” if the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do”); **C-230**, *Almecon Industries Ltd. v. Anchartek Ltd.* (2001), 17 CPR(4th) 74 (FCTD), ¶46.

<sup>436</sup> **C-160/R-027**, *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, ¶91.

<sup>437</sup> **C-046/R-015**, *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, ¶74-76. In the Zyprexa Decision, the Federal Court recalled this part of the Court of Appeals decision. **C-146/R-016**, *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, ¶84.

320. As highlighted by Respondent, when Novopharm sought leave to appeal the 2010 Court of Appeals decision in the Zyprexa case, Claimant opposed it. In its submission to the Supreme Court, Claimant did not seek revision of the utility standard set out by the Court of Appeals. Rather, it stated that the court had done “nothing more than follow established principles of patent law and the jurisprudence of this Court”.<sup>438</sup>
321. Faced with all of this evidence, the Tribunal is not persuaded to dismiss *Consolboard* as an authority on the basis of Claimant’s nuanced argument that the case does not in fact stand for the promise standard, or Mr. Reddon’s view that practitioners thought the Supreme Court was talking about promises in the claims.<sup>439</sup> Fundamentally, the Tribunal sees no basis for questioning the Canadian judiciary’s interpretation of its own Supreme Court precedent.
322. In addition, the Tribunal has taken note of other pre-2005 Canadian authorities for the promise standard in the record. Most notably, the Federal Court of Appeal in 1995 in *Wellcome* reasoned:

Since the utility of a patent must ultimately be judged against its promise, the exercise requires that the specification be carefully construed to determine exactly what that promise is. The question is then to decide whether the number of possible results, with or without other evidence, leads to the inference that the process lacks utility.<sup>440</sup>

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<sup>438</sup> **R-034**, *Novopharm Limited v. Eli Lilly and Company*, Supreme Court of Canada Case No. 33870, Memorandum of Argument of the Respondent, Application for Leave to Appeal, 26 October 2010, ¶2 (emphasis added) (“While Novopharm suggests that the Federal Court of Appeal has changed established law, a review of the Reasons for Judgment of the Federal Court of Appeal shows that it did nothing more than follow established principles of patent law and the jurisprudence of this Court. It certainly did not lower the threshold for the validity of patents in Canada as alleged by Novopharm”). The Tribunal acknowledges that Novopharm was not arguing that the Court of Appeal had changed law by adopting the promise standard, and that Claimant’s statement was therefore not specifically aimed at that rule.

<sup>439</sup> Testimony of Reddon, Tr. at 910:16-20 (“As a practitioner you have to contend with the words after the ‘or’ and be ready to deal with them if it ever is applied, and what practitioners thought was that you needed to show some promise in the claims”).

<sup>440</sup> *Wellcome Foundation Ltd v. Apotex Inc.*, [1995] F.C.J. No. 226, 60 C.P.R. 3d 135 (F.C.A.), at 154.

323. Before this arbitration, Claimant’s expert, Professor Siebrasse, opined that the holding in *Wellcome* was the “clearest support for the promise of the patent doctrine”.<sup>441</sup> The Tribunal also finds Professor Siebrasse’s explanation of the jurisprudence in this article helpful:

The promise of the patent doctrine played no significant role in Canadian patent law until 2005. There were only two cases of which I am aware that considered a heightened utility requirement based on the promise of the specification [*Wellcome* and *Corning Glass Works*],<sup>442</sup> and one more which arguably did so [*Mobile*].<sup>443</sup> In all three cases the promise was modestly construed and the claimed invention was held to be useful. A fourth case implicitly rejected the doctrine [*Unilever*].<sup>444</sup> A few more cases used “promise” language in discussing the utility of the patent, but only in the uncontroversial senses as a synonym for utility,<sup>445</sup> or as referring to the claim as construed.<sup>446</sup>

324. This reading of the case law offers a realistic summary of the record before the Tribunal. While the promise standard may not have played a *significant* role in the Canadian jurisprudence before 2005, and courts looked to the disclosure for the promise in relatively few cases, the rule was clearly “out there”, to be ignored at a patentee’s peril.<sup>447</sup> Furthermore, the rule has a strong foundation in the language of *Consolboard*, which Canadian courts still cite for the promise standard today, as already discussed.

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<sup>441</sup> **C-205**, Norman Siebrasse, *The False Doctrine of False Promise*, (2013) 29 Can IP Rev 3, p. 22, fn. 91.

<sup>442</sup> **R-375**, *Corning Glass Works v. Canada Wire & Cable Ltd.* (1984), 81 CPR (2d) 39 (FCTD), p. 18 (finding the patent useful and stating that “neither in the disclosures nor in the claims” does the patent “promise any particular result”).

<sup>443</sup> **C-347**, *Mobil Oil Corp. v. Hercules Canada Inc.*, (1994), 57 C.P.R. (3d) 488 (FC), p. 23.

<sup>444</sup> **R-172**, *Unilever PLC. v. Procter & Gamble Inc.*, (1995) 61 C.P.R. (3d) 499 (FCA).

<sup>445</sup> **R-162**, *New Process Screw Corp. v. PL Robertson Mfg. Co. Ltd.*, (1961) 39 C.P.R. 31; **R-360**, *Feherguard Products Ltd. v. Rocky’s of BC Leisure Ltd.* (1994), 53 PCR (3d) 417 (FCTD); **R-376**, *TRW Inc. v. Walbar of Canada Inc.* (1991), 39 CPR (3d) 176 (FCA). Professor Siebrasse states that in *TRW* “the Court of Appeal used language which strongly suggests the application of the promise of the patent doctrine, but on my reading, the case really turns on claim construction and traditional inoperability”.

<sup>446</sup> **C-205**, Norman Siebrasse, *The False Doctrine of False Promise*, (2013) 29 Can IP Rev 3, p. 22 (internal citations to cases maintained but adjusted to cite the record).

<sup>447</sup> As Claimant points out, there were very few utility cases before 2005. See Section VIII.B(4) below. While many cases appear to have applied the “mere scintilla” standard, this alone does not support Claimant’s position, given its acknowledgement that this lower standard still exists in parallel with the promise standard.

325. Therefore, Claimant’s argument that the promise standard constitutes a dramatic change in the law fails.

***b. Post-Filing Evidence***

326. In respect of the second element of the promise utility doctrine, Claimant alleges that in the 2002 *AZT* decision, the Supreme Court changed prior law and imposed a new ban on post-filing evidence to prove utility. The Tribunal notes the Parties’ agreement that, under the Patent Act, the date on which utility is assessed is the date of the patent application.<sup>448</sup> The question is whether *AZT* changed prior law that allowed patentees to offer post-filing evidence to show the claimed invention possessed utility.

327. In examining Claimant’s allegation, the Tribunal begins by reviewing the *AZT* decision. In doing so, the Tribunal recalls that the sole purpose of this analysis is to assess the factual basis of Claimant’s case, not to judge the Supreme Court’s ruling against any legal standard, in NAFTA or elsewhere.

328. In *AZT*, the Supreme Court reversed a Federal Court of Appeal decision admitting post-filing evidence of utility. The most relevant portions of Justice Binnie’s judgment, delivering the Judgment of the Court, are reproduced here:

Nor, in my view, is it enough for a patent owner to be able to buttress speculation with post-patent proof, and thereby to turn dross into gold. Utility is an essential part of the definition of an “invention” (Patent Act, s. 2). A policy of patent first and litigate later unfairly puts the onus of proof on the attackers to prove *invalidity*, without the patent owner’s ever being put in a position to establish validity. Unless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either demonstration or sound prediction, the Commissioner “by law” is required to refuse the patent (Patent Act, s. 40). [...]

The Patent Act defines an “invention” as, amongst other criteria, “new and useful” (s. 2). If it is not useful, it is not an invention within the meaning of the Act. [...]

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<sup>448</sup> See Reply ¶98.

The question was whether AZT did the job against HIV that was claimed; in other words, whether on February 6, 1985, there was *any* invention at all within the meaning of s. 2 of the *Patent Act*. Canadian case law dealing with inventorship has to be read keeping the particular factual context in mind. In *Christiani v. Rice*, [1930] S.C.R. 443, this Court held, *per* Rinfret J. (as he then was), at p. 454:

... for the purpose of section 7 [now s. 27], “it is not enough for a man to say that an idea floated through his brain; he must at least have reduced it to a definite and practical shape before he can be said to have invented a process”. [Emphasis added.]<sup>449</sup>

329. Justice Binnie recognized that the Court of Appeal’s reasoning in its 1981 *Ciba-Geigy* decision offered some support for the argument that post-filing evidence could be used to support a finding of utility.<sup>450</sup> In that case, the Court of Appeal stated that:

if indeed what is in the patent specification was mere speculation or prediction, the speculation or prediction having turned out to be true, ought to be considered to have been well founded at the time it was made. Even at the time it was made it is not improbable that it would have been considered well founded.<sup>451</sup>

330. Considering this language, Justice Binnie explains that (i) reading *Ciba-Geigy* as endorsing post-filing validation of “bare speculation” would be inconsistent with the 1979 *Monsanto* decision, and (ii) on the facts of *Ciba-Geigy*, the Court of Appeal had determined that it was probable that the invention’s utility would have been considered well-founded at the time of filing (suggesting that the language was *obiter dicta*).<sup>452</sup> He then reasoned that:

In the broader context of the *Patent Act*, as well, there is good reason to reject the proposition that bare speculation, even if it afterwards turns out to be correct, is sufficient. ... Accordingly, to the extent *Ciba-Geigy* stands for a contrary position, I do not think it should be followed.<sup>453</sup>

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<sup>449</sup> C-213/R-004, AZT, ¶¶46 *et seq.* (interpreting the Patent Act).

<sup>450</sup> C-213/R-004, AZT, ¶84.

<sup>451</sup> C-044/R-190, *Ciba-Geigy*, at 77. The Court of Appeals cited the *Monsanto* decision for this proposition.

<sup>452</sup> C-213/R-004, AZT, ¶84 (“on the facts of *Ciba-Geigy* itself, Thurlow C.J. says, as quoted above, that ‘[e]ven at the time it was made it is not improbable [i.e., it is probable] that it [the invention] would have been considered well founded [i.e., a sound prediction]’”).

<sup>453</sup> C-213/R-004, AZT, ¶84-85.

331. A number of observations are in order. First, contrary to Claimant’s arguments, the fact that the Supreme Court’s *AZT* decision reversed the lower court decision on appeal is not evidence of a change in the law; reversal serves various critical functions in a tiered judicial system. Second, the *AZT* decision is expressly and satisfactorily based on the Patent Act, jurisprudence and policy considerations. Third, although the contrast between the language of *Ciba-Geigy* and *AZT* is apparent, Justice Binnie is able to read *Ciba-Geigy* in a way that is not entirely inconsistent with the court’s ruling in *AZT*.<sup>454</sup> Claimant would have the Tribunal dismiss the court’s analysis of *Ciba-Geigy* in *AZT* on the basis that it is “unpersuasive”.<sup>455</sup> That is not the Tribunal’s role. Rather, its role is to determine whether there was a dramatic change in Canadian patent law in this respect, a conclusion which it is unable to reach on the record before it.
332. In light of these observations, the Tribunal finds that the *AZT* decision, on its face and as it relates to *Monsanto* and *Ciba-Geigy*, cannot be considered a “complete and surprising reversal from prior law”, as alleged by Claimant.<sup>456</sup> For completeness, the Tribunal will also look beyond the decision to consider the entire record on this issue.
333. Professor Siebrasse has presented several court decisions handed down before *AZT* in which courts allowed post-filing evidence of utility.<sup>457</sup> Respondent’s expert Mr. Dimock has asserted, *inter alia*, that these cases relate not to utility but to “operability”, which is relevant because post-filing evidence of operability is still admissible today.<sup>458</sup> In response, Professor Siebrasse has argued that (i) operability and utility are indistinguishable, and (ii) Mr. Dimock misreads the cases. The Tribunal found both of these experts credible and competent, and considers that each has made a reasoned case. The only appropriate

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<sup>454</sup> **C-213/R-004**, *AZT*, ¶84.

<sup>455</sup> Reply fn. 170 (“Canada suggests that Claimant ‘over-reads’ *Ciba-Geigy*, but its arguments rest on the Supreme Court’s entirely understandable, yet unpersuasive, attempts to distinguish *Ciba-Geigy* in the *AZT* decision itself.”).

<sup>456</sup> C-PHM, Answer to Tribunal Question 29.

<sup>457</sup> Siebrasse First Report ¶30; Siebrasse Second Report ¶¶56-59, *citing inter alia* **C-218**, *Reliable Plastics Ltd. v. Louis Marx & Co.*, [1958] 29 C.P.R. 113, at 126; **C-221**, *CH Boehringer Sohn v. Bell-Craig Ltd.*, [1962] Ex. C.R. 201, at 245; **C-228**, *Cochlear Corp. v. Cosem Neurostim Ltée*, [1995] 64 C.P.R. 3d 10, at 35 (F.C.T.D.); **C-301**, *Hoechst Pharmaceuticals of Canada Ltd. v. Gilbert & Co.*, [1965] 1 Ex. C.R. 710, at 714, 28 Fox Pat. C. 120, 50 C.P.R. 26, aff’d [1966] S.C.R. 189, at 191, 50 C.P.R. 26.

<sup>458</sup> Dimock First Report ¶105; Dimock Second Report ¶105. In this regard, the Tribunal notes that Claimant has not specifically contested Respondent’s assertion that post-filing evidence is still today admitted to demonstrate operability. *See* Reply fn. 168.

conclusion, then, in the Tribunal's view, is that reasonable minds may differ in the interpretation of the cases.<sup>459</sup>

334. Similarly, the record shows that after *AZT* was handed down, there was divergence among Canadian judges and practitioners regarding the case's relationship with prior law. For example, as Claimant points out, in 2002, Apotex sought to amend its pleadings in a Federal Court case on the basis that *AZT* had changed the law, and the trial judge expressly accepted that position.<sup>460</sup> On review, however, the Federal Court of Appeal took no view on whether there had been a change.<sup>461</sup>
335. From the practitioner perspective, Mr. Reddon explained that *AZT* was a surprising, dramatic change.<sup>462</sup> On the other hand, a 2003 article in the newsletter of the patent law firm Smart & Biggar referred to the relevant portion of *AZT* as a confirmation of an existing principle:

#### After-the-fact-Validation

The Court confirmed that bare speculation, even if it afterwards turns out to be correct, will not amount to sound prediction. It rejected the suggestion, arising from earlier Canadian Federal Court of Appeal decisions, that mere speculation which later turned out to be true would be considered a sound prediction.<sup>463</sup>

336. Taking a broader perspective, the Tribunal accepts Claimant's point that before *AZT*, no commercially successful products were found to lack utility, whereas now this is not

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<sup>459</sup> As recognized by both experts, the courts in these decisions generally do not distinguish between pre- and post-filing evidence, so this has to be determined based on the facts of the case.

<sup>460</sup> **C-532**, *Bristol-Myers Squibb Company v. Apotex Inc.*, 2010 FC 1304, ¶31 (“While I agree that it would have been preferable if Apotex had formally withdrawn its statement in light of the change of law, I find that the amendments made by Apotex to paragraph 21 in July of 2004 sufficiently demonstrated that lack of sound prediction with respect to nefazodone and nefazodone hydrochloride was a live issue. The amendment to paragraph 21 paralleled the change of law with respect to sound prediction: it alleged that even if one of the compounds of the ‘436 Patent had eventually been shown to have the utility promised, there was a lack of sound prediction at the time of filing.”)

<sup>461</sup> **C-545**, *Apotex Inc. v. Bristol-Myers Squibb Company*, 2011 FCA 34, ¶23 (“Today, Apotex tells us that the decision of the Supreme Court in *Apotex Inc. v. Wellcome Foundation Ltd*, 2002 SCC 77, [2002] 4 S.C.R. 153 changed the law and, therefore, necessitated the 2004 amendments to its pleadings. If that was the case, it could have addressed *Wellcome* with specific and well-particularized amendments, but did not do so.”).

<sup>462</sup> *See, e.g.*, Tr. 874:22-875:8

<sup>463</sup> **R-191**, “Supreme Court of Canada Reaffirms the Doctrine of Sound Prediction in Canadian Patent Law”, *IP Perspectives Intellectual property & Technology Newsletter*, Smart & Biggar /Fetherstonhaugh, February 2003, p. 3.

uncommon.<sup>464</sup> This is a notable fact, but Claimant has not established this to be the result of changed law.<sup>465</sup>

337. In sum, the Tribunal recognizes that the outcome in *AZT* was unexpected for some practitioners and even judges who had understood the language of the Court of Appeal in *Ciba-Geigy* to mean that utility could be demonstrated through post-filing evidence (most notably commercial success). Still, having considered all of the evidence, the Tribunal cannot conclude that the Supreme Court effected a dramatic change from previously well-established law when it clarified this rule in *AZT*.

***c. Disclosure for Sound Prediction***

338. The Tribunal now turns to Claimant’s allegation that the judiciary changed the law in the 2008 Raloxifene Decision by requiring the basis of sound prediction to be disclosed in the patent.

339. As discussed above, the Raloxifene Decision concerned one of Claimant’s own Canadian patents. In this litigation, Claimant appealed the trial court decision, arguing that the court erred in holding that the Raloxifene Patent lacked adequate disclosure. In its decision dismissing this appeal, the Court of Appeal stated:

The importance of the disclosure obligation in applying for a patent has been emphasized by the Supreme Court of Canada on a number of occasions in recent years (*Pioneer Hi Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at paragraph 23; *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142 at paragraph 46; *Free World Trust v. Électro Santé Inc.* 2000 SCC 66, [2000] 2 S.C.R. 1024 at paragraph 13; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at paragraph 37 (commonly referred to as *AZT* and hereinafter referred to as such)).

The decision of the Supreme Court in *AZT* is particularly significant to the disposition of this appeal. According to *AZT*, the requirements

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<sup>464</sup> Courts cite *AZT* as the authority for disallowing evidence of commercial success. See **C-209**, *Aventis Pharma Inc v. Apotex Inc*, 2005 FC 1283, ¶157 (“There is no question that the ‘206 patent turned out to be a very useful invention. However, this sort of ‘after the fact validation’ was specifically rejected by the Supreme Court of Canada in *Wellcome*”). Such citations do not suggest one way or the other whether *AZT* was a departure from prior law.

<sup>465</sup> See subsection VIII.B(4) below, discussing Claimant’s quantitative data on litigation outcomes.

of sound prediction are three-fold: there must be a factual basis for the prediction; the inventor must have at the date of the patent application an articulable and sound line of reasoning from which the derived result can be inferred from the factual basis; and third, there must be proper disclosure (*AZT, supra*, at paragraph 70). As was said in that case (para. 70): “the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly”. In sound prediction cases there is a heightened obligation to disclose the underlying facts and the line of reasoning for inventions that comprise the prediction. [...]

The appellant argues that in requiring the complete disclosure of the factual basis underlying the sound prediction (i.e. requiring data to substantiate the invention), the Federal Court Judge has changed the disclosure requirements as set out in subsection 27(3) of the Patent Act, R.S.C. 1985, c. P-4. I respectfully disagree. In *AZT*, the Supreme Court, with obvious reference to subsection 34(1) of the Patent Act (the predecessor to subsection 27(3)), held that where the claimed invention had not yet actually been reduced to practice, the patent must provide a disclosure such that a person skilled in the art, given that disclosure, could have as the inventors did, soundly predicted that the invention would work once reduced to practice. Significantly, in *AZT*, the Court went on to state that the disclosure requirements had been met given that both the underlying facts (the test data) and the sound line of reasoning (the chain terminator effect) were in fact disclosed (*AZT*, para. 70).<sup>466</sup>

340. The Tribunal finds this analysis highly instructive. It shows that Claimant raised the “new requirement” argument in the Raloxifene proceeding, and the Court of Appeal rejected it on the basis of Supreme Court precedent. This evidence weighs heavily against Claimant’s position. Again, however, as part of its factual analysis, the Tribunal has carefully reviewed the full record on this issue to assess whether Claimant is able to rebut this evidence.
341. The Parties and their experts have debated at length the implication of the Supreme Court’s 1979 *Monsanto* decision. On one side, Respondent asserts that *Monsanto* “emphasized that a sound prediction must not go beyond the consideration provided by the disclosure”.<sup>467</sup> On the other, Claimant finds nothing in the case to imply that the factual basis of sound

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<sup>466</sup> **C-119/R-354**, *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97, ¶¶13-14, 18. Professor Siebrasse notes that Justice Hughes, the trial judge who authored the Raloxifene Decision, “was a patent practitioner with decades of experience before being appointed to the bench”. Siebrasse Second Report ¶76.

<sup>467</sup> Counter-Memorial ¶131.

prediction must be disclosed. During the Hearing, it became clear to the Tribunal that (i) *Monsanto* does not expressly hold one way or the other on this issue;<sup>468</sup> (ii) the court in *Monsanto* did not admit any undisclosed evidence of sound prediction that would not be admitted in Canadian courts today;<sup>469</sup> and (iii) *Monsanto* draws upon a 1969 English decision, *Olin Mathieson*, in which the court did admit evidence from outside the patent.<sup>470</sup> Therefore, *Monsanto* does not offer a specific answer to the question of disclosure for sound prediction.

342. There is some evidence that after *Monsanto* the Patent Office understood that applicants should disclose the basis of a sound prediction. Dr. Gillen highlights a 1995 Commissioner's Decision which concluded that the patent at issue did not contain anything in its disclosure upon which to base a sound prediction.<sup>471</sup> The Tribunal finds the language of this decision instructive but notes that the refusal to grant the patent was based on a provision of the Patent Act that does not concern utility (disclosure).
343. The Parties have also discussed *AZT* extensively in this context. The Tribunal has before it numerous sources indicating that *AZT* was understood to set out the disclosure requirement for sound prediction. As Claimant's counsel stated at the Hearing, "the *AZT* decision basically stated an additional disclosure rule, or what might have looked like an additional disclosure rule, but didn't actually apply it in that case because it wasn't at issue".<sup>472</sup> Professor Siebrasse also conceded that the language of *AZT* could be interpreted to support the disclosure rule.<sup>473</sup>

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<sup>468</sup> See, e.g., Tr. 1083:2-17.

<sup>469</sup> Tr. 699: 24-700:4 ("MR. JOHNSTON: But in *Monsanto* the court did not admit any evidence that would not still be admissible under Canadian law to justify a sound prediction. PROFESSOR SIEBRASSE: Well, yes, that's right.").

<sup>470</sup> **C-461**, *Olin Mathieson Chemical Corp. v Biorex Laboratories Ltd.*, [1970] R.P.C. 157 (Ch D); Tr. 1098:13-18 ("We have reference [in *Olin Mathieson*], sir, without a doubt to post-filing evidence and evidence that's not in the disclosure, correct? MR. DIMOCK: Yes, I've agreed with you on that.").

<sup>471</sup> **R-381**, Commissioner's Decision 1206, relating to Application No. 529,362, 11 December 1995, p. 10. The decision cites *Monsanto* and *Olin Mathieson* in relation to sound prediction.

<sup>472</sup> Claimant's Opening Statement, Tr. 49:1-5. See also Tr. 68:15-20 ("MS. WAGNER:...the disregarding of post-filing evidence, does absolutely date to *AZT* 2002. It's the extra disclosure requirement that's uncertain because the court alluded to it but then never applied it, and then it wasn't until 2008 that it actually was applied.")

<sup>473</sup> Tr. 684:11-685:2 ("PROFESSOR SIEBRASSE: It made some statements that certainly could be interpreted as supporting this disclosure ... those words are amenable to that interpretation, although they're amenable to other interpretations as well.").

344. Notably, the judges in both the Raloxifene Decision, discussed above, and the Strattera Decision, traced the disclosure rule to *AZT*. The Strattera Decision states:

In a case involving a claimed sound prediction of utility, it is ... beyond debate that an additional disclosure obligation arises. According to Justice Binnie in *AZT*, above, this obligation is met by disclosing *in the patent* both the factual data on which the prediction is based and the line of reasoning followed to enable the prediction to be made.<sup>474</sup>

345. In fact, Claimant was aware of this interpretation of *AZT* many years earlier. In 2003, Claimant received an Office Action regarding one of its patent applications for the use of atomoxetine (active ingredient of Strattera), stating that:

The description fails to provide a sound line of reasoning for the utility claimed. The factual support described does not lead to the conclusion that the subject matter of these claims would have the predicted utility. ([citing *AZT*])<sup>475</sup>

346. One year later, Claimant received a similar notice with respect to one of its applications for a use of olanzapine (active ingredient of Zyprexa).<sup>476</sup>

347. Canadian patent law firms also noted that the disclosure requirement was set forth in *AZT*.<sup>477</sup> Indeed, after the Raloxifene Decision was handed down, Claimant's law firm, Gowlings, wrote that the Supreme Court had "reiterated the test articulated by the Supreme Court in *AZT*".<sup>478</sup>

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<sup>474</sup> **C-160/R-027**, *Novopharm Ltd. v. Eli Lilly & Co.*, [2010] F.C. 915, at ¶117 (emphasis in original).

<sup>475</sup> **R-443**, CIPO Office Action, Application No. 2,304,657, 23 October 2003. An Office Action is a formal letter from a patent examiner at CIPO.

<sup>476</sup> **R-444**, CIPO Office Action, Application No. 2,248,873, 7 October 2004.

<sup>477</sup> **R-191**, "Supreme Court of Canada Reaffirms the Doctrine of Sound Prediction in Canadian Patent Law," *IP Perspectives Intellectual property & Technology Newsletter*, Smart & Biggar /Fetherstonhaugh, February 2003, pp. 2-3 ("The Court identified a three-component requirement of the doctrine: 1. There must be a factual basis for the prediction; 2. The inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis; and 3. There must be proper disclosure of the foregoing.").

<sup>478</sup> **R-494**, *Gowling Lafleur Henderson LLP, Pharmacapsules @ Gowlings*, May 4, 2009, p. 5 ("The Court reiterated the test articulated by the Supreme Court in *AZT* namely that when an invention had not yet been reduced to practice, the disclosure must give both the underlying facts and the sound line of reasoning to justify the prediction").

348. On the other hand, another law firm considered the Raloxifene Decision to be a “watershed decision that is particularly relevant to the filing of patent applications henceforth”.<sup>479</sup> Moreover, Claimant has presented cases decided in the period between *AZT* and the Raloxifene Decision, in which the courts appear to have relied on evidence not disclosed in the patent to assess whether utility could be soundly predicted.<sup>480</sup>
349. Taking together all of the documents and testimony, the Tribunal cannot accept Claimant’s position that the Raloxifene Decision radically changed a well-settled rule of Canadian law. Instead, the Tribunal sees the progressive development of the doctrine of sound prediction over decades, specifically in relation to the required disclosure. When the Supreme Court first adopted the doctrine in *Monsanto*, it did not set a clear disclosure rule. Over the following years, during which there was little litigation over utility, the law was not significantly clarified. Then, the 2002 *AZT* decision set out the requirements for a sound prediction, identifying proper disclosure as one of those requirements. As proper disclosure was not at issue on the facts of *AZT*, it was not until the 2008 Raloxifene Decision that the requirement was applied by a court (although the Patent Office began applying it much earlier, including in relation to Claimant’s patents).<sup>481</sup> Indeed, the doctrine may develop further. According to Professor Siebrasse, the details of the disclosure requirement for sound prediction are still being debated in the courts, with some judges opining that it should apply only to new use patents.<sup>482</sup>
350. This process has of course involved some elements of change, but based on the record, that change is more incremental and evolutionary than dramatic.

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<sup>479</sup> **C-485**, McCarthy Tétrault Case Alert (*Eli Lilly v. Apotex Inc.*) (17 September 2009) (“The Court of Appeal held that when a patent is based on sound prediction, *the disclosure must include* the underlying factual basis for the prediction *and* the sound line of reasoning that grounded the inventors’ prediction”) (emphasis in original).

<sup>480</sup> Siebrasse Second Report ¶71, citing **C-215**, *Pfizer Canada Inc v. Apotex Inc*, 2007 FCA 209; **C-209**, *Aventis Pharma. Inc. v. Apotex Inc.*, 2005 FC 1283, *aff’d* 2006 FCA 64. See Tr. 1127:9-1129:17 (Mr. Dimock reasoning that if the patentee was “trying to rely on the priority date, then that would be added matter, and you’d have some debate as to whether or not you could rely on the priority date. So my inference from what you’ve told me is that [the rat studies] were likely not in the Canadian patent as filed”).

<sup>481</sup> See ¶¶345-346 above.

<sup>482</sup> Siebrasse Second Report ¶77.

351. The Tribunal concludes that the facts surrounding each of the three elements of the alleged promise utility doctrine do not demonstrate a dramatic transformation of the utility requirement in Canadian law. In this regard, the Tribunal is cognizant of Claimant's position that these three elements are part of a unitary, cohesive doctrine and must be considered together. Therefore, in the following sections, the Tribunal examines the evidence Claimant has produced in relation to the promise utility doctrine as a whole.

### **(3) MOPOP Amendments and CIPO Practice**

352. Claimant submits that all three elements of the promise utility doctrine were included in MOPOP for the first time in the 2009 and 2010 versions, which stand in stark contrast to the 1990 MOPOP that was in place at the time the Zyprexa and Strattera patents were granted, and which reflected the traditional "mere scintilla" test.

353. The Tribunal will first address the authoritative weight of MOPOP, which has been a matter of contention in this case. The introductory language of MOPOP speaks to this point:

The manual has been prepared by the Patent Office to instruct patent examiners in Office policy relating to the examination of applications for patents. [...] This manual is to be considered solely as a guide, and should not be quoted as an authority. Authority must be found in the Patent Act, the Patent Rules, and in decisions of the Courts interpreting them.<sup>483</sup>

354. The Tribunal notes this caveat and yet also agrees with Claimant that MOPOP *could* be a reliable statement of Canadian patent law even if it lacks the force of law. Indeed, it is common ground that MOPOP is relied upon by Canadian patent examiners in reviewing applications, as stated in the text above.

355. The question of whether MOPOP is in fact reliable in the present context, as evidence of a change in the law, turns on whether it is reasonably comprehensive and current. In this regard, the Tribunal tends to agree with Respondent that MOPOP provides high level internal guidance but cannot be considered a complete summation of Canadian patent

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<sup>483</sup> C-054, Canadian Intellectual Property Office – Patent Office, Manual of Patent Office Practice (January 1990), Foreword.

law.<sup>484</sup> Further, it would be unreasonable to expect MOPOP to reflect all relevant jurisprudence at any specific point in time, as understood by anyone tasked with keeping a legal treatise up to date.

356. Notably, Chapter 12 of the 1990 MOPOP, covering subject matter and utility, was relatively sparse at just five pages (English and French), compared to the 38-page Chapter 12 in the 2009 MOPOP (English only). Claimant’s expert Mr. Wilson tried to explain that this was because “utility was so basic” in the 1990s.<sup>485</sup> But that is not the whole story. Mr. Wilson had to accept that the 1990 MOPOP included no reference to *Monsanto*, the 1979 Supreme Court decision that established the principle of sound prediction of utility.<sup>486</sup> Indeed, there is no mention of “sound prediction” at all.<sup>487</sup> Yet it is undisputed that *Monsanto* was a seminal utility case, and that patent examiners were accepting sound predictions of utility in 1990.<sup>488</sup> MOPOP’s evolution over time has not necessarily always precisely tracked the case law or determined Patent Office practice.<sup>489</sup>
357. Therefore, the Tribunal finds MOPOP to be relevant as a general guide to Canadian patent law but proceeds with caution in drawing any conclusion from specific amendments.
358. Claimant cites, *inter alia*, the following sections of the 1990 MOPOP as a statement of the traditional “mere scintilla” test:

12.02.01 An invention must be useful:

Section 2 of the Act requires utility as an essential feature of invention. If an invention is totally useless, the purposes and objects

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<sup>484</sup> Gillen First Statement ¶24 (“I am unaware of any examiner, patent applicant, or patent agent who would consider the MOPOP to be a complete and authoritative guide on Patent Office practice or patent law in Canada at any given point in time.”); Tr. 791:5-8 (“MR. WILSON: [MOPOP] doesn’t provide instructions on how to examine each specific application, no, but it gives principles on how to examine all applications.”).

<sup>485</sup> Tr. 794:10-19 (“MR. WILSON: Utility was so basic, it didn’t need pages to describe it. Utility was “not totally useless”. You can describe it in three or four words, not five pages.”).

<sup>486</sup> Tr. 794:14-24. See **R-023**, *Monsanto Co. v. Canada*, [1979] 2 S.C.R. 1108 (SCC), ¶¶24-25.

<sup>487</sup> Tr. 794:14-24. See **C-061/R-023**, *Monsanto*, ¶¶24-25.

<sup>488</sup> See, e.g., Tr. 793:18-22 (“MS. ZEMAN: But you agree that examiners were accepting sound predictions of utility in 1990, right? MR. WILSON: I’m pretty sure they were, yes.”).

<sup>489</sup> More generally, it is reasonable to accept that the Patent Office may expand and clarify MOPOP even when there has been no change in the law, as suggested by the modernization of MOPOP between 1990 and 2009. See Gillen Second Statement ¶31 (discussing the addition to Chapter 9 (Description) in 2010 that discusses in detail the person of ordinary skill in the art (POSITA), although the POSITA analysis did not change in the 1990s or 2000s).

of the grant [of a patent] would fail and such grant would consequently be void on the grounds of false suggestion, failure of consideration and having tendency to hinder progress.

12.02.02 Utility must be disclosed:

An application for patent must not only describe the invention, but also its operation or use (Section 34(1)). The operation or use of the invention must, of course, show the purpose for which the invention was intended. An invention may have several uses, but it must always have at least one.

The claims must be drafted to an invention having the utility disclosed. If the claims cover only things that have utility other than that disclosed or if they included inoperable and therefore useless embodiments, they are bad.<sup>490</sup>

359. Claimant then points to the following portion of the 2009 MOPOP:

12.08.01 Operability

Where, however, the inventors promise that their invention will provide particular advantages (e.g. will do something better or more efficiently or will be useful for a previously unrecognized purpose) it is this utility that the invention must in fact have.<sup>491</sup>

360. Claimant is correct that the promise standard set forth in the 2009 MOPOP does not appear in the 1990 MOPOP, and this new language appears to have signalled a change in practice to at least some patent examiners.<sup>492</sup> Indeed, Claimant's expert Mr. Wilson explains that the first Commissioner's Decision dealing with the issue of promised utility was issued in 2010.<sup>493</sup>

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<sup>490</sup> Memorial ¶47 quoting **C-054**, MOPOP §§ 12.02, 12.03 (January 1990) (emphasis added by Claimant).

<sup>491</sup> Counter-Memorial ¶124, quoting **C-059**, MOPOP §12.08.01 (December 2009). The section continues: "Although an invention need only have one use in order to be patentable, where several uses are promised the applicant must be in a position to establish each of them. For example, if a composition is promised to be useful as a drug, the applicant must be in a position to show that it is useful in the therapy of at least once disease. If, however, it is promised to be useful as a drug for treaty many diseases, the applicant must be in a position to establish its utility . . . in treating each of the diseases".

<sup>492</sup> As summarized above, Claimant has submitted emails and comments of patent examiners stating that application of this provision would be a change in examination practice. See, e.g., **C-358**, Comments on MOPOP Chapter 12 Compiled from Section C5 Biotech," Comments of Linda Brewer, (17 March 2008) [Canada Doc. No. 910, at 065407] (commenting that Section 12.8.01 of the draft 2009 MOPOP "does not appear to be in line with our practice").

<sup>493</sup> Wilson Second Report ¶35; **C-412**, Application No. 592,567 (Patent No. 1,341,621), Decision of the Commissioner of Patents number 1303 (June 4, 2010) , ¶28 ("What we need to determine then is whether the compositions defined

361. However, as noted above, the Tribunal must be cautious in drawing conclusions from additions to MOPOP's text. The obvious inquiry is whether MOPOP itself indicates that this promise standard is derived from new jurisprudence. It does not. None of the cases cited by Professor Siebrasse for the promise standard is referenced. Instead, MOPOP cites *Consolboard*:

The Supreme Court affirmed in *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* that, for the purposes of Canadian law, a lack of utility exists if "the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do" and that "[i]f and when used in accordance with the directions contained in the specification, the promised results are obtained, the invention is useful in the sense in which that term is used in the patent law". This was merely the reiteration of a long-accepted and extant standard.<sup>494</sup>

362. Accepting Claimant's position would require the Tribunal to dismiss this clear statement of the Patent Office regarding the source of the promise standard in MOPOP. The Tribunal is not prepared to do so.

363. With respect to the other elements of the promise utility doctrine (prohibition on pre-filing evidence and disclosure of the factual basis for sound prediction), Claimant cites the following provisions:

12.08.05      Relevant date

The applicant must be in a position to establish the utility of their invention no later than at their filing date. Consequently, the factual basis upon which either the demonstration or sound prediction are based must necessarily exist as of the filing date. Similarly, if a sound prediction is to be relied upon, the articulable and sound line of reasoning referred to in 12.08.04 must also exist as of the filing date. As put by Binnie J. in *Apotex*, "[n]or, in my view, is it enough

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in these claims could be soundly predicted to have the promised utility; viz. to be superconductive at a temperature of 77 K or higher. This determination is based on the disclosure, the state of the art and the common general knowledge available to a person skilled in the art").

<sup>494</sup> C-059, MOPOP §12.08.01 (December 2009).

for a patent owner to be able to buttress speculation with post-patent proof, and thereby to turn dross into gold”.<sup>495</sup>

9.04.01a Disclosure of the factual basis

The factual basis needed to render the line of reasoning sound must be disclosed. If some or all of the facts being relied on are found in another publicly available document, this document must be properly identified. Any necessary facts that are not otherwise publicly available must be included in the description.<sup>496</sup>

364. The Tribunal has discussed above the prohibition on post-filing evidence and found that the Supreme Court clarified this rule in the 2002 *AZT* decision. This is reflected in the citation to Justice Binnie’s decision in Section 12.08.05. In the present context, the Tribunal observes that (i) nothing in the 1990 MOPOP suggests that post-filing evidence of utility would be admitted, and (ii) the rule set out in *AZT* finds support in the 1990 MOPOP requirement that “Utility must be disclosed”.<sup>497</sup>
365. Regarding the requirement that the factual basis for sound prediction be disclosed, the Tribunal does not see how MOPOP assists Claimant, given that sound prediction was not addressed at all in the 1990 MOPOP.
366. On the basis of this analysis, the Tribunal concludes that Claimant’s evidence relating to MOPOP and Patent Office practice does not support its allegation of a dramatic change in the law.

**(4) Statistical Evidence**

367. Setting aside the details of patent law jurisprudence and CIPO practice, Claimant argues that the stark effect of the promise utility doctrine on litigation outcomes speaks for itself. In this context, Claimant puts forward quantitative evidence (through its expert, Professor Levin) to illustrate a spike in (i) the number of successful utility challenges, and (ii) the

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<sup>495</sup> C-059, MOPOP §12.08.01 (December 2009).

<sup>496</sup> C-060, MOPOP §9.04.01 (December 2010).

<sup>497</sup> C-054, MOPOP §§ 12.02, 12.03 (January 1990).

rate of success of such challenges since 2005. Claimants’ data is summarized in Table 1 below.

**Table 1: Utility Outcomes Before and After 1 January 2005 (Pharmaceutical Patents)<sup>498</sup>**

Period	Cases invalidating patent for lack of utility	Cases upholding patent on utility grounds	Total	Rate of Invalidity
<b>1980 to 2004</b>	0	3	3	0%
<b>2005 to 2016</b>	28	41	69	41%

368. At the outset, the Tribunal notes its doubts regarding Claimant’s selection of 1 January 2005 to serve as the dividing line between “before” and “after” the promise utility doctrine. First, on Claimant’s case, the final element of this allegedly *unitary* doctrine did not come into existence until 2008.<sup>499</sup> Second, this date does not correspond to any of the court decisions cited by Claimant, or for that matter, any other event that is apparently relevant to Claimant’s case. Professor Levin explained that he was not the one who selected this date, describing it as a “legal decision”.<sup>500</sup> However, the legal significance of this date is questionable, and Claimant has failed to adequately explain the basis of its instruction to Professor Levin.

369. The difficulty for Claimant is that, given the small number of cases before 2005, changing the cut-off date, even just slightly, erases any increase in the *rate* of utility-based invalidations of pharmaceutical patents, thereby undermining the conclusions Claimant seeks to draw from the statistical evidence. Respondent illustrated this during the Hearing by moving the cut-off date to 2 September 2005, the date of the first decision cited by Professor Siebrasse for the promise standard. The results are shown in Table 2 below, showing a decrease in the rate of invalidities after the alleged adoption of the promise standard.

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<sup>498</sup> Claimant’s Opening Presentation, slide 68; C-PHM ¶121.

<sup>499</sup> **C-115/R-200**, *Raloxifene*.

<sup>500</sup> Day 5, 1255:12-15.

**Table 2: Utility Outcomes Before and After 2 September 2005 (Pharmaceutical Patents)<sup>501</sup>**

Period	Cases invalidating patent for lack of utility	Cases upholding patent on utility grounds	Total	Rate of Invalidity
1980 to 1 Sep 2005	2	3	5	40%
2 Sep 2005 to 2016	26	41	67	39%

370. Similarly, if the cut-off date is set at the date of the Raloxifene Decision (5 February 2008), when the court adopted the final element of the promise utility doctrine, the increase in the rate of invalidations of pharmaceutical patents for lack of utility becomes barely apparent.<sup>502</sup>
371. The small data set poses a more fundamental problem for Claimant, even when 1 January 2005 is applied as the cut-off date. Professor Levin did not identify any statistically significant difference between the rate of invalidations pre- and post-2005, as there are simply too few pre-2005 cases.<sup>503</sup> As Professor Levin explained, it cannot be concluded from the data whether there was a significant increase in invalidity rates or not.<sup>504</sup>
372. Clearly, the *number* of utility-based invalidations of pharmaceutical patents has increased sharply. There were essentially no such court decisions until 2005, compared to almost 30 over the last decade.<sup>505</sup> The Tribunal understands that Claimant would be concerned by this development. However, it is undisputed that at the same time there has been a spike in

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<sup>501</sup> Respondent's Opening Presentation, slide 85; R-PHM ¶164.

<sup>502</sup> See Brisebois First Statement, Table 11, p. 13. Mr. Brisebois counts patents rather than court judgments, which Professor Levin called into question.

<sup>503</sup> C-PHM ¶126; Tr. 1276:23 – 1277:8 (“THE PRESIDENT: Is that because the sheer number you have is not too sensitive to make actually a meaningful – you say statistically significant analysis here? PROFESSOR LEVIN: The point you're raising is exactly the point I drew as an important caveat when I testified about table 2. If you recall, I said I draw no conclusion from the lack of significance between pre and post, and the reason is precisely that. The number of cases pre-2005 challenged on utility was too small.”).

<sup>504</sup> *Id.* The main focus of Professor Levin's report was showing the difference between the proportion of pharmaceutical and non-pharmaceutical patents held invalid on grounds of utility in the post-2005 period, not showing the difference in invalidity rates over time.

<sup>505</sup> Respondent's Opening Presentation, slide 85; R-PHM ¶164.

utility challenges in the pharmaceutical sector.<sup>506</sup> Absent evidence of a corresponding increase in the *rate* of invalidations, there is nothing striking about an increase in invalidations as more patents are challenged.<sup>507</sup>

373. Notably, around the same time in the mid-2000s, validity challenges of pharmaceutical patents on other grounds (such as obviousness and anticipation) also increased, as did the number of invalidations, to varying degrees.<sup>508</sup> This suggests a broader trend of increasing pharmaceutical patent litigation and greater numbers of invalidations.
374. The increase in utility litigation could plausibly be motivated by developments in the law that make success more likely for generic manufacturers, but again there is nothing on the record to demonstrate a greater rate of success (much less any causal connection). And there are other plausible causes for an escalation in litigation relating to a particular sector or statutory provision. Respondent has offered some explanations of its own, such as the introduction of PM(NOC) proceedings and the growing prevalence of secondary patents.<sup>509</sup>
375. Without having been presented with any strong indication toward a single factor, the Tribunal considers it most likely that a combination of developments, including those in patent litigation procedures, the application of substantive patent law, and the pharmaceutical sector, has led to a rise in challenges directed at pharmaceutical patents and more invalidations.
376. In sum, Claimant's quantitative data provides insufficient evidentiary support for its allegation of a dramatic change in the law.

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<sup>506</sup> See Claimant's Opening Statement, Tr. 95:12-16 ("In the early period utility was rarely challenged in that sector and never successfully but, since 2005, given the change in Canada's test, utility challenges have spiked and 28 cases (41 percent) have been successful.").

<sup>507</sup> The Tribunal accepts the logic of Claimant's statement that "the mere fact that there was a higher *absolute incidence* of pharmaceutical patent litigation after 1993 cannot explain the higher *rate (or proportion) of invalidity findings* under the utility doctrine". Reply ¶196. However, as discussed, no significant increase in the rate of invalidations has been shown.

<sup>508</sup> See Brisebois Second Statement, Figure 1, p. 15 and Figure 2, p. 16.

<sup>509</sup> R-PHM ¶167. The Tribunal notes that PM(NOC) proceedings were introduced in 1993 and have not been shown to have sparked the increase in litigation in 2005. However, many of the post-2005 cases cited by Claimant are PM(NOC) proceedings, suggesting that the availability of this process has played a role during this period.

## (5) Comparison with Other Jurisdictions

377. In its Post-Hearing Memorial and Reply Post-Hearing Memorial, Claimant submits that the dramatic change in Canadian law is confirmed by the utility requirement in United States and Mexican law, as well as by discussions among the members of WIPO and the WTO.<sup>510</sup> Although it is difficult to see how a comparison across jurisdictions can demonstrate a change over time within a single jurisdiction, the Tribunal has carefully considered the Parties' extensive submissions and evidence on these issues.
378. The Tribunal has paid particular attention to the 2014 and 2015 editions of the Special 301 Report of the USTR. In these documents, USTR notes that the United States "has serious concerns about the lack of clarity and the impact of the heightened utility requirements for patents that Canadian courts have applied *recently*".<sup>511</sup> This comment cannot be dismissed outright as a lobbying effort by Claimant, as suggested by Respondent. However, the Special 301 Report stands alone in the record as a complaint regarding Canada's utility doctrine from any other State, including Mexico, in the decade since the promise utility doctrine was allegedly adopted.<sup>512</sup> For the Tribunal, that silence speaks louder than the single, brief criticism contained in the USTR's Special 301 Report.
379. Ultimately, the Tribunal is not persuaded that Claimant's comparative analyses alters our findings above.

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<sup>510</sup> Claimant has argued throughout this arbitration that Canada's utility requirement is unlike that of its NAFTA partners or other countries, but in its Post-Hearing Memorial, it tied this issue directly to its allegation of a change in the law.

<sup>511</sup> **C C-331**, Office of the United States Trade Representative, *Special 301 Report* (2014), pp. 49-50 (April 2014) ("The United States also has serious concerns about the lack of clarity and the impact of the heightened utility requirements for patents that Canadian courts have applied *recently*. Under this amorphous and evolving standard, courts can invalidate a patent on utility grounds by construing the "promise of a patent" years after the patent has been granted, leading to uncertainty for patent holders and applicants and undermining incentives for investment in the pharmaceutical sector. In applying this standard, courts have invalidated a number of patents held by U.S. pharmaceutical companies, finding now that those products lack utility (*i.e.*, not capable of industrial application), even though such products have been in the market and benefiting patients for years."). (emphasis added); **C-332**, Office of the United States Trade Representative, *Special 301 Report* (2014), pp. (April 2015) (same language).

<sup>512</sup> In addition, Respondent has confirmed that "Canada is not aware of any complaints regarding its utility requirement from any State or international organization prior to Claimant's initiation of this arbitration". R-PHM ¶174.

## **(6) Legitimate Expectations**

380. Claimant alleges that the Canadian courts' application of the alleged promise utility doctrine to invalidate the Strattera and Zyprexa Patents contravened its legitimate expectations. The Tribunal notes that this allegation, made primarily in the context of Claimant's claim under NAFTA Article 1105, depends on Claimant establishing a dramatic change in the Canadian law on utility.<sup>513</sup> Therefore, Claimant's allegation of a violation of its legitimate expectations must be dismissed on the basis of the Tribunal's findings above.
381. The Tribunal has considered whether there is any other factual basis on which Claimant could establish a violation of any legitimate expectation. For this limited purpose, the Tribunal need not, and does not, determine the contentious legal question of whether a violation of an investor's legitimate expectations can constitute a breach of NAFTA Article 1105.
382. As summarized above, Claimant argues that its asserted expectations were reasonably based on the traditional utility requirement in Canadian patent law, as well as the grant of the Strattera and Zyprexa Patents. In this regard, the Tribunal notes that all patentees, including Claimant, understand that their patents are subject to challenge before the courts on the ground that the invention does not satisfy one or more patentability requirements.
383. The record shows that at the time Claimant made its investments, it was aware that Canadian patent law required patented inventions to be useful. Eli Lilly executives testified that they understood the Canadian utility requirement to be a low threshold.<sup>514</sup> In fact, it appears that the utility of Strattera and Zyprexa in Canada was taken for granted within the company. Claimant expected its patents would not be invalidated for lack of utility.
384. However, this perception cannot amount to a legitimate expectation. For the reasons stated above, the Tribunal has found that each of the three elements of the alleged promise utility doctrine had a foundation in Canadian law when Claimant's patents were filed. At that

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<sup>513</sup> See Claimant's Closing Presentation, slide 140.

<sup>514</sup> For example, Claimant's former General Counsel, Mr. Armitage, stated that he would have been "shocked if there were evidence that advice on Canadian utility law had been given during that time frame, since it was so well understood that the threshold for meeting the Canadian utility requirement for pharmaceutical inventions was so low". Tr. 344:20-25.

time, although Claimant may not have been able to predict the precise trajectory of the law on utility, it should have, and could have, anticipated that the law would change over time as a function of judicial decision-making. The record in this case shows that the law did in fact undergo a reasonable measure of change and development.

385. Therefore, for these reasons, the Tribunal finds that Claimant has not met its burden of proving a violation of its legitimate expectations.<sup>515</sup>

## **(7) Conclusion**

386. Taken as a whole, the evidence before the Tribunal shows that Canada's utility requirement underwent incremental and evolutionary changes between the time that the Zyprexa and Strattera Patents were granted and then invalidated, in particular during the six-year period that Claimant highlights (2002-2008). Over those years, there was an increase in the number of utility-based challenges of pharmaceutical patents, which appears to have increased the pace of the development of the law most relevant to that sector. The Tribunal also sees that each of the three rules that Claimant considers part of the promise utility doctrine has a reasonably solid foundation in prior authority, even if there is a question about the extent to which that prior authority was applied in practice.

387. For all of the reasons in subsections (1) to (5) above, the Tribunal finds that, on the record in this arbitration, Claimant has not demonstrated a fundamental or dramatic change in Canadian patent law. For the interrelated reasons in subsection (6) above, the Tribunal finds that Claimant has not demonstrated, as a factual matter, that its legitimate expectations were violated by the application of Canadian patent law to the Zyprexa and Strattera Patents.

388. As noted above, Claimant has acknowledged that it must demonstrate a dramatic change in the law to succeed on its claims under NAFTA Articles 1105 and/or 1110.<sup>516</sup> The

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<sup>515</sup> Claimant has also alleged that its legitimate expectations were grounded in, or at least reinforced by, Respondent's obligations under NAFTA Chapter 17 and the form and contents requirement of the PCT. The Parties have exchanged extensive submissions on these international instruments, all of which the Tribunal has considered. However, nothing therein alters the Tribunal's analysis. For all of the reasons stated above, Claimant has failed to establish, as a matter of fact, that Respondent breached any international obligations by invalidating the Strattera and Zyprexa Patents.

<sup>516</sup> See ¶307 above.

Tribunal agrees that this is what Claimant is required to show to establish a breach of Article 1105 or 1110 in the circumstances of this case.

389. Having failed to demonstrate a fundamental or dramatic change in Canadian patent law, the Tribunal would properly dismiss the claims without further inquiry. Without detracting from this, for completeness and the avoidance of doubt, the Tribunal notes that in the course of the proceedings Claimant alleged that the promise utility doctrine is both arbitrary and discriminatory.<sup>517</sup> Given that an arbitrary or discriminatory measure could, as a matter of hypothesis, violate NAFTA Articles 1105 and/or 1110 in the absence of a fundamental or dramatic change in the relevant area of law, the Tribunal considers it appropriate to address Claimant's allegations in the following section.

## **IX. THE ALLEGED ARBITRARY AND DISCRIMINATORY NATURE OF THE UTILITY REQUIREMENT UNDER CANADIAN LAW**

### **A. The Parties' Positions**

#### **(1) Claimant's Position**

##### ***a. Arbitrariness***

390. Claimant alleges that the promise utility doctrine is arbitrary because it (i) "is unpredictable and incoherent", and (ii) "serves no legitimate public purpose".<sup>518</sup>

391. According to Claimant, all three elements of the promise utility doctrine contribute to its arbitrariness. First, as stated by Professor Siebrasse, the subjective process of construing the promise of a patent is "inherently arbitrary" in that it allows courts to ignore the distinction between the claims and the disclosure.<sup>519</sup> Claimant argues that the process differs from court to court and that even the same court can reach conflicting conclusions

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<sup>517</sup> Memorial ¶¶248-249, 261, 266, 347-348; Reply ¶¶339, 348; C-PHM ¶219, 226-227; 293-321.

<sup>518</sup> C-PHM § IV.C.B.2(a).

<sup>519</sup> Memorial ¶263, citing **C-146/R-016**, *Eli Lilly Canada Inc. v. Novopharm Ltd.*, [2011] F.C. 1288, at ¶209; Reply ¶339; C-PHM ¶296, quoting Tr. 633:3-634:25.

as to the promised utility of a patent in two different cases.<sup>520</sup> According to Claimant, generic drug companies—the principal beneficiaries of the promise doctrine—have acknowledged that it is “a hopeless tangle of contradictory approaches” in which the “outcome of cases depends upon the particular judge or panel hearing the dispute, rather than legal authority”.<sup>521</sup>

392. Second, Claimant submits that the heightened evidentiary burden is arbitrary and unpredictable because it bars post-filing evidence that validates earlier tests showing a drug’s likely effectiveness.<sup>522</sup> In Claimant’s view, patent applicants currently have no way of knowing how much, and what type, of evidence a judge will require to demonstrate or soundly predict a patent’s utility.<sup>523</sup> Claimant argues that the rule leaves pharmaceutical companies caught, because if they invest in extensive clinical trials (which may or may not be required by the court) before filing a patent application, the drug may no longer meet the obviousness and novelty conditions of patentability.<sup>524</sup> In addition, Claimant finds the application of the bar on post-filing evidence arbitrary; while the use of such evidence is prohibited to establish utility, it is permitted to demonstrate other patentability criteria and to attack utility.<sup>525</sup>
393. Third, Claimant contends that the heightened disclosure obligation for sound prediction is “unprincipled and unfair”.<sup>526</sup> According to Claimant, this rule introduces an unjustified distinction whereby Canadian courts rely on evidence outside of the patent application to determine whether utility was *demonstrated* at the date of filing, but that same evidence cannot be relied upon to establish whether utility was *soundly predicted*. The resulting

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<sup>520</sup> Claimant refers to the Canadian patent for Latanoprost, a glaucoma drug, arguing that it was construed differently by two Federal Court of Appeal panels, resulting in one determination of validity and one determination of invalidity for inutility. Claimant argues that Latanoprost is not an isolated or extreme case. Memorial ¶¶64, 68, 263; Reply ¶¶341-342; C-PHM ¶¶298-300.

<sup>521</sup> Reply ¶343; C-PHM ¶297, *quoting* C-375, Notice of Application for Leave to Appeal of Apotex Inc. et al, *Apotex Inc. v. Sanofi-Aventis*, S.C.C. File No. 35562 (30 September 2013), ¶14.

<sup>522</sup> C-PHM ¶301.

<sup>523</sup> Memorial ¶265; Reply ¶339; *see also* Reply §II.A.2.

<sup>524</sup> Memorial ¶266; Reply ¶¶192-194; Claimant’s Observations on 1128 and Amicus Submissions ¶¶50-51; C-PHM ¶303. Claimant contends that it faced this situation with respect to the Strattera and Zyprexa Patents, and could have missed its chance to patent them if it had waited until comprehensive clinical testing had been completed.

<sup>525</sup> Memorial ¶268; Siebrasse First Report ¶¶55-56; C-PHM ¶302.

<sup>526</sup> Memorial ¶¶269-270; Siebrasse First Report ¶¶67-68; C-PHM ¶304.

unpredictability is compounded by the fact that the disclosure obligation's scope of application remains unclear.<sup>527</sup> Claimant also argues that the disclosure rule is unfair because it is used to invalidate patents that were filed when rule did not exist.<sup>528</sup>

394. According to Claimant, the unpredictable and incoherent nature of the promise utility doctrine as a whole is illustrated by the invalidation of the Zyprexa and Strattera Patents: the Canadian courts implied a promise of long-term effectiveness without any basis in the patents, discounted pre-filing scientific studies, and applied the heightened disclosure requirement.<sup>529</sup> As a result, the courts determined that these revolutionary, successful drugs were not useful.<sup>530</sup>
395. Claimant submits that the promise utility doctrine serves no legitimate policy purpose. Citing *Occidental v. Ecuador*, Claimant asserts that an incoherent rule of law such as the promise utility doctrine cannot support a policy objective because it leads to inconsistent results and does not promote compliance.<sup>531</sup>
396. In any event, Claimant argues that Respondent has failed to identify any credible policy objective advanced by the promise utility doctrine.<sup>532</sup> Specifically, Claimant rejects Respondent's position that the doctrine is meant to enforce the patent bargain in relation to new use and selection patents. According to Claimant, there is no legal basis for applying special rules to such patents, and in fact, the promise utility doctrine has been applied to invalidate all types of pharmaceutical patents.<sup>533</sup> Similarly, Claimant argues that no evidence supports Respondent's assertion that the doctrine addresses speculative patenting.<sup>534</sup>

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<sup>527</sup> Memorial ¶269; Reply ¶339; Siebrasse First Report ¶67; C-PHM ¶304.

<sup>528</sup> C-PHM ¶304.

<sup>529</sup> Claimant acknowledges that the disclosure rule for sound prediction of utility was applied in the Strattera case but not in the Zyprexa case.

<sup>530</sup> C-PHM ¶307. Claimant also points to confusion among Canadian patent examiners as an illustration of the doctrine's arbitrary nature. See Reply ¶192; Claimant's Closing Statement, slides 9-13; C-PHM ¶305.

<sup>531</sup> C-PHM, citing **CL-097/RL-033**, *Occidental Exploration and Production Co. v. Republic of Ecuador*, UNCITRAL, LCIA Case No. UN 3467, Award, 1 July 2004.

<sup>532</sup> Reply ¶348; C-PHM ¶¶310 *et seq.*

<sup>533</sup> C-PHM ¶311.

<sup>534</sup> Reply ¶345; citing Counter-Memorial §II.E; see also Reply §II.D.3.

***b. Discrimination***

397. Additionally, in the context of its claims under both NAFTA Articles 1105 and 1110, Claimant submits that the promise utility doctrine discriminates against pharmaceutical patents as a field of technology, which NAFTA Article 1709(7) expressly prohibits.<sup>535</sup>
398. According to Claimant, although the promise utility doctrine is facially neutral, it has “differentially disadvantageous effects” on the pharmaceutical sector.<sup>536</sup> As evidence of these effects, Claimant refers to statistical data presented by Professor Levin showing that:
- a. Before 2005 (when the Federal Courts began to apply the doctrine), no pharmaceutical patents were invalidated for lack of utility.<sup>537</sup>
  - b. Since 2005, courts have found that more than two dozen pharmaceutical patents lack utility, but have not reached this conclusion with respect to a patent in any other technological field. This constitutes a statistically significant difference between utility-based invalidity rates for pharmaceutical and non-pharmaceutical patents.<sup>538</sup>
  - c. Also since 2005, 41 percent of utility decisions concerning pharmaceutical patents have found a lack of utility, compared to zero percent in all other sectors.<sup>539</sup>
399. Claimant asserts that Respondent’s counter-arguments fail in light of these undisputed facts.<sup>540</sup>

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<sup>535</sup> Memorial ¶¶216-226; Reply ¶¶291-300; C-PHM ¶¶318-321.

<sup>536</sup> C-PHM ¶257.

<sup>537</sup> Reply ¶294 and Figure 1; C-342, “Annual Number of Canadian Inutility Decisions, 1980 – present”.

<sup>538</sup> Memorial ¶221 and Figure 2; C-PHM ¶258; C-305, “Chronological List of Canadian Utility Decisions from 1980 to Present”.

<sup>539</sup> Memorial ¶222 and Figure 3; Claimant’s Opening Statement, Tr. 2114:19-24; C-PHM ¶258.

<sup>540</sup> For example, Claimant contends that Respondent is wrong to argue that there cannot be discrimination against the pharmaceutical sector since most pharmaceutical patents challenged on the basis of utility are found to be valid. This argument ignores that the relevant comparison is between sectors, not within the pharmaceutical sector. Reply ¶298; Levin Report ¶9.

400. Further, Claimant argues that although evidence of discriminatory intent is not required, such intent on the part of Respondent can be inferred.<sup>541</sup> In this context, Claimant makes the following allegations:
- a. The promise utility doctrine was adopted by the courts in litigation over pharmaceutical patents.
  - b. The Federal Court has expressly acknowledged the gap between treatment of pharmaceuticals and other sectors, holding that the “basis for sound prediction, *at least in respect of a pharmaceutical*, must be disclosed in the descriptive part of the patent”.<sup>542</sup>
  - c. There appears to be an elevated evidentiary standard for pharmaceutical inventions, given that the utility of mechanical inventions can be shown by a model without testing.<sup>543</sup>
  - d. The doctrine’s requirements “conflict, and would objectively be known to conflict, with the reality of innovative drug development”.<sup>544</sup>
401. Claimant further submits that “[a]nother, less prominent aspect of discrimination, relating to nationality, is also present in the application of the promise utility doctrine by Canadian courts”.<sup>545</sup> In support of this position, Claimant points out that only patents held by foreign firms have been invalidated pursuant to this doctrine, despite its facially neutral character. According to Claimant, the main beneficiary is the prominent Canadian generic drug industry.<sup>546</sup>

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<sup>541</sup> Memorial ¶¶223-225; C-PHM, Appendix, pp. 9-10, Answer to Tribunal Question 18.

<sup>542</sup> Memorial ¶224, *quoting C-180, Pfizer Canada Inc. v. Pharmascience Inc.*, [2013] F.C. 120 (Can. Fed. Ct.), ¶¶157-158 (emphasis added by Claimant).

<sup>543</sup> Memorial ¶224, *citing* Siebrasse First Report ¶59.

<sup>544</sup> Memorial ¶225.

<sup>545</sup> Memorial ¶226; *see* Reply ¶368.

<sup>546</sup> Memorial ¶226; Reply ¶368; C-PHM ¶321. Claimant identifies the following groups that have been affected: Merck, Abbott Laboratories, Sanofi (through Sanofi-Aventis and Aventis Pharma), Pfizer, Eli Lilly and Company, Shire Biochem., GlaxoSmithKline, Lundbeck, AstraZeneca, and Novartis (including through its affiliate Alcon). Memorial, fn. 539, citing **C-191**, *The World’s Biggest Public Companies*, FORBES, 2014, filtered for the pharmaceutical industry.

## (2) Respondent's Position

### *a. Arbitrariness*

402. In response to Claimant's allegations of arbitrariness, Respondent again contends that the promise utility doctrine is not a unitary doctrine, but rather several distinct rules of Canadian patent law. In Respondent's view, Claimant's attempt to show that this fictional doctrine is arbitrary fails as a matter of principle and fact.<sup>547</sup>
403. In any event, Respondent denies that any of the elements of the alleged promise utility doctrine are arbitrary. First, Respondent rejects Claimant's assertion that identifying the promises contained in a patent is inherently unpredictable.<sup>548</sup> Respondent argues that the interpretation of a patent is based on sound principles of construction, as confirmed by Claimant's expert.<sup>549</sup> This includes the longstanding principle that the patent is construed as a whole (*i.e.* both disclosure and claims).<sup>550</sup> For Respondent, the interpretation of the patent is therefore not "arbitrary", but rather what judges are called upon to do every day.<sup>551</sup>
404. In this context, Respondent also disagrees with Claimant's argument that judges "scour" patent applications to find promises; in fact, judges decide on the basis of competing evidence presented by patent litigants and their lawyers.<sup>552</sup> In response to Claimant's assertion that this exercise results in inconsistent outcomes, Respondent contends that different outcomes are a product of the highly fact-dependent circumstances of each case.<sup>553</sup>

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<sup>547</sup> R-PHM ¶240.

<sup>548</sup> R-PHM ¶243-251.

<sup>549</sup> R-PHM ¶245, *citing* Tr. 633:21-634:12 ("PROFESSOR SIEBRASSE: Yes, yes. The principles are sound principles. I mean, they're applying the same principles that are applied to claim construction."); Dimock First Report, ¶¶85-88.

<sup>550</sup> R-PHM ¶243.

<sup>551</sup> Counter-Memorial ¶255, *citing* Dimock First Report ¶85; R-PHM ¶245.

<sup>552</sup> Rejoinder ¶271; Dimock First Report ¶75.

<sup>553</sup> Rejoinder ¶270. In relation to the two cases involving Latanoprost, Respondent explains that the legal standard in the two cases was the same, but the expert testimony before the two panels was different. Rejoinder ¶272, *quoting* Dimock Second Report ¶82. *See also* Rejoinder fn. 532.

405. As a policy matter, Respondent argues that there is nothing arbitrary about holding patentees to the promises they make in their patents. Respondent points out that patentees are not required to include any promise in the patent; they do so to satisfy other patent law requirements, such as showing the advantages of a selection over a genus or the specified new use of a known compound.<sup>554</sup>
406. Second, in response to Claimant’s criticism of the ban on post-filing evidence, Respondent argues that it is not arbitrary to require inventors to demonstrate or soundly predict the utility of an invention at the time of filing a patent.<sup>555</sup> In Respondent’s view, this is necessary to prevent patents on the basis of “bare speculation”, which is reasonable even where the speculation later turns out to be correct.<sup>556</sup> Respondent points to the testimony of Claimant’s expert Professor Siebrasse, who acknowledged that the ban on post-filing evidence is “rationally connected” to the goal of preventing patenting too far upstream.<sup>557</sup> According to Respondent, Claimant’s argument that the ban leaves pharmaceutical companies caught in relation to the timing of the patentability requirements is untenable because (i) Canadian law does not require the clinical trials to which Claimant refers, and pharmaceutical patents are routinely granted on the basis of animal studies; and (ii) the number of pharmaceutical patents granted in Canada has increased each year since 2005.<sup>558</sup>
407. Third, Respondent contends that requiring patentees to disclose the basis of their sound predictions in the patent is not arbitrary, but rather “an essential part of the patent bargain”.<sup>559</sup> The Supreme Court of Canada set out the rationale for this rule clearly in *AZT*.<sup>560</sup> According to Respondent, sound prediction is a permissive doctrine allowing

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<sup>554</sup> R-PHM ¶246.

<sup>555</sup> R-PHM ¶¶252-262.

<sup>556</sup> R-PHM ¶252.

<sup>557</sup> R-PHM ¶254, *citing* Tr. 665:24-666:5 (“MR. JOHNSTON: And you would say that the court’s statement that utility must be demonstrated or soundly predicted at the time of filing is rationally connected to the objective of patenting too far upstream? PROFESSOR SIEBRASSE: I would say it’s rationally connected, yes.”); **R-476**, Norman Siebrasse, *Sufficient Description Blog Excerpts*, p. 54 (“The principle that a patent may be granted for a speculative invention is sound, and it may be that Lilly patented too soon.”).

<sup>558</sup> R-PHM ¶¶260-261; *see* Counter-Memorial ¶258, *citing* Dimock First Report ¶100.

<sup>559</sup> R-PHM ¶263, *citing* Dimock Report ¶¶99-100.

<sup>560</sup> **C-213/R-004**, *AZT*, ¶70 (“In this sort of case ... the sound prediction is to some extent the quid pro quo the applicant offers in exchange for the patent monopoly.”).

inventors to obtain a patent before utility can be demonstrated; in return, the patentee must explain to the public what makes its prediction sound.<sup>561</sup>

408. In sum, Respondent’s position is that all three of these elements of the alleged promise utility doctrine serve important policy objectives, and while Claimant may disagree with these policies, it has failed to show any evidence of arbitrariness. In the same way, Respondent asserts that the application of the various rules of Canadian patent law to the Strattera and Zyprexa patents “was well-reasoned and grounded in findings of fact rendered after careful consideration of extensive adversarial records”; there is no indication that the courts acted arbitrarily.<sup>562</sup>

***b. Discrimination***

409. Respondent submits that Claimant has also failed to establish that any aspect of the Canadian courts’ interpretation and application of the utility requirement is discriminatory.<sup>563</sup> Respondent highlights Claimant’s acknowledgment that the alleged promise utility doctrine does not on its face discriminate against the pharmaceutical field.<sup>564</sup>

410. According to Respondent, there is also no evidence of *de facto* discrimination against pharmaceutical patents, as Claimant alleges. Respondent finds the evidence that Claimant puts forward in an attempt to show *de facto* discrimination to be flawed in several ways.<sup>565</sup>

411. With respect to Claimant’s statistical evidence, Respondent alleges several errors in the data set Claimant provided to Professor Levin, including the following:

a. In cases involving findings of both utility and inutility, Claimant used inconsistent coding rules to support its arguments.<sup>566</sup>

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<sup>561</sup> Rejoinder ¶275, *quoting* Dimock First Report ¶¶99-100; R-PHM ¶264.

<sup>562</sup> R-PHM ¶242.

<sup>563</sup> Counter-Memorial ¶¶186-203; Rejoinder ¶¶383-388; R-PHM ¶238.

<sup>564</sup> Rejoinder ¶187, *citing* Memorial ¶214.

<sup>565</sup> *See, e.g.*, Rejoinder ¶188.

<sup>566</sup> R-PHM ¶224 (“In pharmaceutical cases such as *Novartis*, where there were findings of both utility and inutility in a single case, Claimant applied its rule to select the ‘not useful’ outcome to code the case. Conversely, in the non-

- b. Claimant’s inclusion of PM(NOC) proceedings in its data set is inappropriate for a comparison between pharmaceutical and non-pharmaceutical sectors, given that PM(NOC) proceedings are the most prevalent type of patent proceeding and are available *only* with respect to pharmaceutical patents.<sup>567</sup>
- c. The data set double-counts inutility findings when the same patent was challenged multiple times by different generic manufacturers under the PM(NOC) regime.<sup>568</sup>
412. According to Respondent’s witness Dr. Brisebois, once these errors are corrected, the data show no statistically significant difference in utility-based invalidation rates between the pharmaceutical sector and other sectors.<sup>569</sup>
413. In any event, Respondent argues that Claimant’s data analysis, even if done correctly, “cannot possibly tell the whole story” because it focuses on litigation outcomes.<sup>570</sup> Respondent points out that of the 25,760 pharmaceutical patents granted from 1980 to 2013, only 134 validity challenges were decided.<sup>571</sup> For Respondent, to fully understand the application of Canadian patent law to pharmaceuticals, one must consider the wider universe of patents.<sup>572</sup> In addition, Respondent asserts that Claimant has failed to account for the many factors that influence litigation outcomes, such as facts and the skill of counsel.<sup>573</sup>

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pharmaceutical cases of *Eurocopter* and *Uponor*, where there were again findings of both utility and inutility in a single case, Claimant applied its rule to select the ‘useful’ outcome to code the case.”) (internal citations omitted); **C-244**, *Novartis Pharmaceuticals Canada Inc. v. Teva Canada Ltd.*, 2013 FC 283 (aff’d 2013 FCA 244) (finding allegations of lack of utility justified for one patent at issue, but not for the other). See Levin First Report, Appendix C, p. 1 (“Where rulings were split by claim within a patent, such that some claims were found valid and others invalid, a coding of ‘Y’ was applied for the relevant ground. ... Where a case involved multiple patents challenged on the same ground, and at least one patent was invalidated on a given ground, a coding of ‘N’ was applied for the relevant ground.”).

<sup>567</sup> Rejoinder ¶¶197-198; Brisebois Second Statement ¶21; Dimock Second Report ¶144.

<sup>568</sup> Rejoinder ¶¶199-200; Brisebois Second Statement ¶¶14-15 and 23-24.

<sup>569</sup> Brisebois Second Statement ¶¶4, 12; R-PHM ¶225.

<sup>570</sup> R-PHM ¶228.

<sup>571</sup> Rejoinder ¶190, *citing* **R-436**, WIPO Database, Patent Grants by Technology – Pharmaceuticals, Total Count by Filing Office – Canada (1980-2013); Brisebois Second Statement, Annex F.

<sup>572</sup> Rejoinder ¶190. Respondent points out that “even within the limited universe identified by Claimant”, many of the cases involve patents that were invalidated for other reasons in addition to inutility.

<sup>573</sup> R-PHM ¶228.

414. More fundamentally, Respondent argues that Claimant has failed to demonstrate any causal connection between Professor Levin’s findings and the alleged promise utility doctrine. Respondent highlights Professor Levin’s testimony acknowledging that he was “not opining on causality”.<sup>574</sup> For Respondent, this problem in Claimant’s case is illustrated by the fact that Claimant improperly counted every inutility finding as an application of the promise utility doctrine.<sup>575</sup> Thus, the most that can be concluded from Claimant’s data is that the utility requirement has more relevance in the pharmaceutical field than other sectors.<sup>576</sup> In Respondent’s view, this greater relevance is not surprising given pharmaceutical patenting practice, and it in no way amounts to discrimination.<sup>577</sup>
415. Finally, in response to Claimant’s assertion that the principal beneficiaries of inutility decisions are domestic generic drug makers,<sup>578</sup> Respondent highlights that half of the top 18 generic drug makers (based on sales) are not Canadian-owned. In addition, contrary to Claimant’s argument that foreign brand-name drug makers face discrimination, Respondent submits that Canadian biopharmaceutical companies are subject to the same rules as Claimant.

## **B. The Tribunal’s Analysis**

### **(1) Preliminary Observations**

416. As noted above, notwithstanding the Tribunal’s rejection of Claimant’s contention that there was a fundamental or dramatic change in Canadian patent law, it is appropriate to address Claimant’s allegations of arbitrariness and discrimination for the reason that, as a matter of hypothesis, an arbitrary or discriminatory measure could violate NAFTA Article 1105 and/or Article 1110 in the absence of a fundamental or dramatic change in the law.
417. For purposes of framing the discussion that follows, the Tribunal observes that, although NAFTA Articles 1105 and 1110 address distinct issues and impose discrete obligations,

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<sup>574</sup> R-PHM ¶227, *citing* Tr. 1266:24-1267:6.

<sup>575</sup> R-PHM ¶165.

<sup>576</sup> R-PHM ¶229.

<sup>577</sup> *Id.*

<sup>578</sup> Memorial ¶291.

they are closely related. This relationship is illuminated by the reference to the requirement, in NAFTA Article 1110(1)(c), that, to be concordant with NAFTA Article 1110(1), the nationalization or expropriation of an investment must “be in accordance with due process of law and Article 1105(1)”. The relationship between these provisions is engaged most acutely in circumstances in which the allegations at issue go to acts of the judiciary, *inter alia*, for the reason that an alleged breach of the minimum standard of treatment requirement of Article 1105(1) informs an alleged breach of Article 1110(1).

418. Nonetheless, as noted above, NAFTA Articles 1105 and 1110 are separate provisions, imposing distinct obligations. It is however unnecessary for present purposes to explore the different standards applicable under Articles 1105(1) and 1110(1) in the present case. That is because the Tribunal is satisfied that, under any plausible standard, the challenged decisions of the Canadian courts are neither arbitrary nor discriminatory, nor can it be said that the judicial measures taken were expropriatory within the meaning of Article 1110 in the present case. The patent grants to Claimant were made in a legal system that historically has, and necessarily, evolves, and this evolution resulted in later decisions, rationally and not unforeseeably, that concluded the initial patent grants were invalid, just as the Canadian statutory patent regime envisions. As such, the challenged decisions of the Canadian courts cannot constitute either a breach of NAFTA Articles 1105 or 1110.

## **(2) Arbitrariness**

419. Claimant alleges that the promise utility doctrine applied by Canadian courts is arbitrary because it is “unpredictable and incoherent” and lacks a legitimate public purpose.<sup>579</sup> The Tribunal has examined the record to determine whether there is evidence to support this allegation with respect to the three elements of the doctrine identified by Claimant, taken individually or together.

420. First, regarding Canadian courts’ process of construing the promise of the patent, Claimant relies primarily on (i) its own description of the subjective nature of the process, (ii) examples of inconsistent judicial decisions, and (iii) statements made by a generic drug

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<sup>579</sup> C-PHM § IV.C.2(a).

company in the context of patent litigation.<sup>580</sup> Through these submissions, Claimant clearly sets out its disagreement with the practice of looking to the disclosure for the promise of a patent, but it has not shown that the exercise is unpredictable or incoherent. Rather, the interpretive process undertaken by Canadian courts, as described by Claimant, falls well within the scope of duties that courts are asked to perform every day. Claimant's own expert, Professor Siebrasse, agreed that in interpreting the disclosure, Canadian courts apply sound principles of construction consistent with principles of statutory construction.<sup>581</sup>

421. The Tribunal is unpersuaded by examples of courts (or a single court) reaching inconsistent determinations of a patent's promise. Some level of unpredictability is present in the application of all law. In the Tribunal's view, inconsistency in judicial interpretation at this limited scale is to be expected, especially in an adversarial system in which courts are presented with different evidence and expert testimony across cases.
422. The Tribunal is also unwilling to put significant weight on Apotex's isolated statements about the unpredictable nature of the promise doctrine.<sup>582</sup> Claimant finds these statements notable because it considers generic drug manufactures like Apotex to be the principle beneficiaries of the promise doctrine. The Tribunal notes, however, that Apotex made this statement in an application for leave to appeal to the Canadian Supreme Court a lower court decision with which it was presumably unhappy.<sup>583</sup> In this context, such criticism is unexceptional.
423. Furthermore, the Tribunal finds that Respondent has asserted a legitimate public policy justification for the promise doctrine. In particular, Respondent has explained that enforcing promises contained in the disclosure helps ensure that "the public receives its end of the patent bargain" (particularly but not solely in connection with "new use" and "selection" patents) and that it "encourages accuracy while discouraging overstatement in

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<sup>580</sup> See ¶¶390-396 above for a more detailed summary of Claimant's position.

<sup>581</sup> Tr. 633:21-634:25.

<sup>582</sup> **C-375**, Notice of Application for Leave to Appeal of Apotex Inc. et al, *Apotex Inc. v. Sanofi-Aventis*, S.C.C. File No. 35562 (30 September 2013), ¶14.

<sup>583</sup> *Id.*

patent disclosures”.<sup>584</sup> The Tribunal need not opine on whether the promise doctrine is the only, or the best, means of achieving these objectives. The relevant point is that, in the Tribunal’s view, the promise doctrine is rationally connected to these legitimate policy goals.

424. Second, the Tribunal has considered Claimant’s submissions concerning the alleged arbitrary nature of the ban on post-filing evidence of utility.<sup>585</sup> The Tribunal finds that Claimant provided no persuasive evidence showing that this rule is unpredictable or incoherent. To the contrary, it is a bright line rule that sets a clear date by which patentees must prove utility.
425. Respondent states that it has chosen to set that deadline as the patent application’s filing date to prevent patents from being granted on the basis of speculation. In the Tribunal’s view, there is a rational connection between the rule and this stated goal, as Claimant’s own expert has acknowledged.<sup>586</sup> All patent regimes must determine the line between speculation and invention, and as Respondent highlights, there is no perfect place to draw this line. However, the Tribunal does not find anything arbitrary about selecting the patent application’s filing date.
426. The Tribunal understands the difficulty for companies in innovative industries described by Claimant, in terms of timing investments and patentability requirements.<sup>587</sup> With many potential products, it may be challenging to identify when all patentability requirements can be met and thereby when to file a patent application. However, this is the consequence of a rational policy approach in Canada, not an indication of arbitrariness in the law. In

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<sup>584</sup> R-PHM ¶244, *citing* Dimock First Report ¶¶72-74, 219.

<sup>585</sup> In this context, Claimant has also stated that patentees have no way of knowing how much evidence will be required by the courts to prove utility. This is not supported by the record. Claimant has not attempted to show, for example, that courts have systematically applied different evidentiary rules in similar utility cases, or that they have required evidence on the basis of personal preference.

<sup>586</sup> Tr. 665:24-666:5 (“MR. JOHNSTON: And you would say that the court’s statement that utility must be demonstrated or soundly predicted at the time of filing is rationally connected to the objective of patenting too far upstream? PROFESSOR SIEBRASSE: I would say it’s rationally connected, yes.”).

<sup>587</sup> *See* ¶392 above.

such circumstances, it is not the role of a NAFTA Chapter Eleven tribunal to question the policy choices of a NAFTA Party.

427. Third, the Tribunal has reviewed the record in relation to Claimant's allegation that it is arbitrary for Canadian courts to require patent applicants to disclose the basis of a sound prediction of utility in the patent. Claimant's submissions on this point focus primarily on the fact that the disclosure rule applies in cases of sound prediction but not in cases of demonstrated utility.<sup>588</sup>
428. In the Tribunal's view, Respondent has advanced a legitimate justification for this distinction: the sound prediction doctrine allows inventors to obtain a patent before they can demonstrate that the invention is useful. In exchange for the monopoly granted, the patentee must disclose to the public the basis of its prediction of utility and what makes it sound. Whether or not this is the preferred approach, it is plainly not an irrational one.
429. With regard to Claimant's argument that the scope of this disclosure rule remains unclear, the Tribunal finds nothing unusual about this level of potential uncertainty. Questions about the precise scope of application of legal rules abound in nearly all legal regimes. If that were to render a legal rule arbitrary, the concept of arbitrariness would lose all meaning.
430. For the above reasons, the Tribunal finds, based on the record before it, that none of the three elements of the promise utility doctrine identified by Claimant is arbitrary. Even if the Tribunal were to accept Claimant's position regarding the legal standards applicable, i.e., that a measure is arbitrary: (i) when it is unpredictable and incoherent, even if it is not motivated by bad faith; and (ii) when it has no legitimate purpose,<sup>589</sup> Claimant would not succeed in its allegation of arbitrariness. Furthermore, Claimant has not demonstrated arbitrariness in the Canadian courts' application of these rules in any combination. Notably, this conclusion is supported by the decisions rendered in the *Strattera* and *Zyprexa* litigations. As discussed above, these decisions have a foundation in Canadian law.<sup>590</sup> They

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<sup>588</sup> The Tribunal need not analyse Claimant's argument that the disclosure rule is unfair because it is used to invalidate patents that were filed when the rule did not exist. This allegation is dismissed for the reasons stated in Section VIII.B(2)c above.

<sup>589</sup> C-PHM ¶294.

<sup>590</sup> See ¶384 above.

are also coherent and consistent with the policy justifications stated by Respondent. It is worth stating again that in these circumstances, the Tribunal will not question the correctness of the policies or the courts' decisions.

### (3) Discrimination

431. Claimant's principal submission under the heading of discrimination is that the promise utility doctrine discriminates against pharmaceutical patents as a field of technology.<sup>591</sup> Claimant acknowledges that the doctrine is facially neutral but alleges that it has "differentially disadvantageous effects" on the pharmaceutical sector, amounting to *de facto* discrimination. As summarised above, Claimant's primary support for this allegation is Professor Levin's statistical analysis of the outcomes of utility cases.<sup>592</sup> Professor Levin concludes that there is a statistical difference between utility-based invalidity rates for pharmaceutical and non-pharmaceutical patents since 2005.
432. As a preliminary point, for the reasons set out in Section VIII above, the Tribunal does not accept Claimant's attempt to artificially divide utility cases into "before" and "after" the creation of the promise utility doctrine.<sup>593</sup> In addition, the Tribunal finds some of Claimant's coding choices questionable. But the critical deficiency of the evidence is not found in these methodological issues. Even if the Tribunal were to fully embrace Professor's Levin's statistical determination, the Tribunal could not reach Claimant's conclusion that the promise utility doctrine has "differentially disadvantageous *effects*" on the pharmaceutical sector.<sup>594</sup>
433. Throughout this proceeding, Claimant has asserted a causal relationship between the promise utility doctrine and higher invalidity rates in the pharmaceutical sector. Yet this is unsupported by the record.<sup>595</sup> Professor Levin explained:

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<sup>591</sup> Memorial ¶¶216-226; Reply ¶¶291-300; C-PHM ¶¶318-321.

<sup>592</sup> See ¶398 above.

<sup>593</sup> See Reply ¶196 ("[I]t is only after 2005 that a disproportionate impact on pharmaceutical patents is observed").

<sup>594</sup> Memorial ¶217 (emphasis added); see Reply ¶293; C-PHM ¶127.

<sup>595</sup> See, e.g., Memorial ¶220 ("A review of all patent utility decisions by the Federal Courts shows the striking, disparate impact of the promise utility doctrine across different fields of technology."); Reply ¶367 ("As explained by Professor Levin, a statistical analysis of all Canadian patent validity cases decided between 1980 and the present

I am not opining on causality. I was not asked to do that; I am not qualified to offer an opinion. I offered a statistical opinion which is the rejection of the null hypothesis was consistent with a causal hypothesis, that of Claimants. I agree there could be other causes; I'm not here to say one way or the other.<sup>596</sup>

434. When the Tribunal posed a question to Claimant on this point, counsel acknowledged that Professor Levin “does not provide an opinion on causation. He provides an opinion on whether the dramatically disproportionate numbers would be due to chance or due to something else. And he says they’re not due to chance”.<sup>597</sup>
435. Thus, setting aside methodological issues, the Tribunal can conclude from Professor Levin’s analysis only that the higher proportion of inutility findings in the pharmaceutical sector is not by chance. Claimant has not presented evidence establishing the crucial link between that fact and the alleged promise utility doctrine. Based on the record, the Tribunal cannot rule out the possibility that alternative factors may give rise or contribute to the difference in rates of inutility finding. To offer just one example, Respondent has proposed that the patenting practices of pharmaceutical companies result in patents more susceptible to utility challenges. The Tribunal cannot determine on the basis of the record whether this proposal is sound, but simply notes that it is one plausible alternative explanation for Professor Levin’s conclusion.
436. In this context, it is worthwhile to identify another methodological issue because it both illustrates and exacerbates the limitations of Claimant’s statistical analysis. Although Claimant has acknowledged that, today, Canadian courts do not apply the promise utility doctrine in all utility cases, Claimant did not attempt to isolate “promise cases” for the purpose of its data set.<sup>598</sup>

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reveals a statistically significant ‘disproportionate impact’ on pharmaceutical patents – one that appears to be ‘attributable to the ground of utility alone.’”); Claimant’s Closing Statement, Tr. 2120:21-2121:3 (“40 percent invalidity decisions only in the pharmaceutical sector, we would posit are discrimination as to field of technology, because no other sector is experiencing the invalidation rates of their patents under Canada’s promise utility doctrine standard, other than the pharmaceutical sector. So yes, we would posit that there’s causation.”).

<sup>596</sup> Tr. 1266:24-1267:6.

<sup>597</sup> Claimant’s Closing Statement, Tr. 2120:13-17.

<sup>598</sup> Tr. 1248:14-1250:13 (“MS. ZEMAN: The dataset provided to you does not make any distinction between utility and promise utility outcomes. Is that right? PROFESSOR LEVIN: Not to my knowledge. MS. ZEMAN: So you also

437. In sum, Claimant asks the Tribunal to find a causal link between the alleged promise utility doctrine and higher rates of inutility decisions in the pharmaceutical sector on the basis of mere assumptions. The Tribunal will not do so.
438. Claimant also asks the Tribunal to infer discriminatory intent for the reasons set out in paragraph 400 above. Claimant’s first allegation—that the Canadian courts adopted the doctrine in pharmaceutical litigation—must be dismissed for the reasons stated in Section VIII above.<sup>599</sup> The Tribunal is also unpersuaded by Claimant’s reliance on the Federal Court’s statement that “[t]he basis for sound prediction, at least in respect of a pharmaceutical, must be disclosed in the descriptive part of the patent”.<sup>600</sup> Claimant does not allege that the disclosure rule for sound prediction applies only to pharmaceutical patents, and has expressly acknowledged that the promise utility doctrine is facially neutral. Therefore, the Tribunal does not see how the court’s reference to pharmaceuticals, in a pharmaceutical patent case, expresses discrimination. Claimant’s remaining criticisms of the doctrine simply do not speak to discriminatory intent.
439. For all of these reasons, the Tribunal concludes that Claimant has not proven its allegation that the promise utility doctrine discriminates against pharmaceutical patents. Even if the Tribunal were to accept Claimant’s position regarding the legal standards applicable, i.e., that a measure is discriminatory where there is (i) “any differential treatment of a foreign investor. . . based on unreasonable distinctions and demands”,<sup>601</sup> and (ii) “facially neutral measures that in practice produce differentially disadvantageous effects on a particular field of technology”,<sup>602</sup> Claimant would not succeed in its allegation of discrimination.
440. The Tribunal notes that Claimant has advanced another allegation of discrimination, “relating to nationality”.<sup>603</sup> Specifically, Claimant’s position is that “the promise utility doctrine discriminates in favor of a prominent domestic industry at the expense of foreign

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did not make any distinction between utility and promise utility outcomes in your analysis. Is that right? PROFESSOR LEVIN: I did not, no.”).

<sup>599</sup> See **C-118/R-011**, *Consolboard*, at ¶¶36-37.

<sup>600</sup> **C-180**, *Pfizer Canada Inc. v. Pharmascience Inc.*, [2013] F.C. 120 (Can. Fed. Ct.), ¶¶157-158

<sup>601</sup> C-PHM ¶¶319-320.

<sup>602</sup> C-PHM ¶257.

<sup>603</sup> Memorial ¶226.

patent holders”.<sup>604</sup> Claimant does not allege that the promise utility doctrine discriminates against foreign patent holders on its face, or that Canadian courts have shown any intent to discriminate against foreign patent holders. Rather, Claimant argues that, in practice, the application of the promise utility doctrine has resulted in the invalidation of patents held by foreign firms only, and that the primary beneficiaries have been domestic generic drug manufacturers.<sup>605</sup>

441. It appears to the Tribunal that Claimant has not made much effort to fully develop this theory of *de facto* nationality-based discrimination. The only facts Claimant has come close to establishing are that (i) since 1 January 2005, the pharmaceutical patents invalidated on the ground of inutility (whether through the application of the promise utility doctrine or not) have been held by foreign pharmaceutical companies, and (ii) the largest pharmaceutical companies in the world are not Canadian.<sup>606</sup> The Tribunal will not infer discrimination from such a bare record. Claimant has wholly failed to demonstrate that the promise utility doctrine discriminates against foreign patent holders.

#### **(4) Conclusion**

442. For the above reasons, the Tribunal holds that even if it were to accept Claimant’s position regarding the legal standards applicable to its allegations of arbitrariness and discrimination, Claimant has failed to establish the factual premise on which its allegations of arbitrariness and discrimination are based. The Tribunal has already concluded that there was no fundamental or dramatic change in Canadian patent law. In the circumstances presented in these proceedings, the evolution of the Canadian legal framework relating to Claimant’s patents cannot sustain a claim of arbitrariness or discrimination going to a violation of NAFTA Articles 1105(1) or 1110(1).

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<sup>604</sup> C-PHM ¶321.

<sup>605</sup> Memorial ¶226; Reply ¶368; C-PHM ¶321.

<sup>606</sup> Memorial, fn. 539, citing C-191, *The World’s Biggest Public Companies*, FORBES, 2014, filtered for the pharmaceutical industry.

## **X. COSTS**

### **A. Applicable Law**

443. NAFTA Article 1135 states that “[a] tribunal may ... award costs in accordance with the applicable arbitration rules”.

444. Article 40 of the UNCITRAL Rules provides:

1. Except as provided in paragraph 2, the costs of arbitration shall in principle be borne by the unsuccessful party. However, the arbitral tribunal may apportion each of such costs between the parties if it determines that apportionment is reasonable, taking into account the circumstances of the case.
2. With respect to the costs of legal representation and assistance referred to in article 38, paragraph (e), the arbitral tribunal, taking into account the circumstances of the case, shall be free to determine which party shall bear such costs or may apportion such costs between the parties if it determines that apportionment is reasonable.

### **B. Claimant’s Submission on Costs**

445. Claimant submits that it should be awarded its costs of the arbitration under UNCITRAL Article 40(1) and its costs of legal representation under Article 40(2) because: (i) Claimant is the proper prevailing party in this arbitration, and (ii) Respondent introduced a number of inefficiencies into the proceeding.<sup>607</sup>

446. In particular, Claimant identifies three ways in which Respondent’s conduct was inefficient. First, Respondent raised an untimely, unfounded jurisdictional objection, which delayed briefing on the *amicus* and Article 1128 submissions and forced Claimant to prepare an additional written pleading. The way in which Respondent then pursued its objection increased Claimant’s burden of defending against it.<sup>608</sup> Second, Respondent, through the testimony of Dr. Marcel Brisebois, introduced evidence on 68 patents related to raloxifene and 27 patents for certain uses of olanzapine and atomoxetine, none of which

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<sup>607</sup> C-CS §I.A.

<sup>608</sup> C-CS ¶5.

was at issue in this case.<sup>609</sup> Third, Respondent’s expert, Professor Daniel Gervais, introduced extensive documentary evidence concerning the substantive patent law obligations of non-NAFTA States, which is entirely irrelevant.<sup>610</sup>

447. In contrast, Claimant asserts that it “consistently presented reasonable and focused evidence” throughout the proceeding, and its costs are therefore reasonable.<sup>611</sup>

448. In these circumstances, Claimant argues that even if Respondent were to prevail, Tribunal could reasonably order the Parties to bear their own costs. In this regard, Claimant notes that:

Tribunals have recognized that claimants in investment arbitration must often present “novel issues of international law, the resolution of which cannot be easily predicted.” Moreover, arbitrators have noted that awards of costs against claimants may deter investors from seeking to enforce the rights accorded under investment treaties.<sup>612</sup>

449. Claimant’s costs are set forth in the following two tables:<sup>613</sup>

**Table 1: Costs of Legal Representation and Assistance**

Fees	
Covington & Burling LLP	US\$ 6,287,745
Gowling WLG (Canada) LLP	US\$ 1,577,017
Subtotal	US\$ 7,864,762
Disbursements	
Printing and Graphics (incl. Hearing Graphics)	US\$ 128,546
Research and Publications	US\$ 36,584
Travel	US\$ 83,694
Other	US\$ 14,858
Subtotal	US\$ 263,682
Total	US\$ 8,128,444

<sup>609</sup> C-CS ¶6.

<sup>610</sup> C-CS ¶7.

<sup>611</sup> C-CS ¶¶8-10.

<sup>612</sup> C-CS ¶11, quoting CL-200, David D. Caron & Lee M. Caplan, *The UNCITRAL Arbitration Rules: A Commentary* (2013) § 27.4.B(2).

<sup>613</sup> Reproduced from C-CS, ¶¶12-13.

**Table 2: Other Costs**

<b>Experts and Witnesses</b>	
Professor Jay Erstling	US\$ 27,952
Ms. Gilda Gonzalez-Carmona	US\$ 70,821
Mr. Steven G. Kunin	US\$ 120,089
Professor Bruce Levin	US\$ 55,768
Professor Robert P. Merges	US\$ 146,285
Mr. Andrew J. Reddon	US\$ 47,362
Mr. Fabián Ramón Salazar	US\$ 46,114
Professor Norman V. Siebrasse	US\$ 213,692
Mr. Philip Thomas	US\$ 29,504
Mr. Murray Wilson	US\$ 39,615
Fact Witnesses	US\$ 42,360
<b>Subtotal</b>	<b>US\$ 839,562</b>
<b>ICSID &amp; Tribunal Fees</b>	
ICSID & Tribunal Fees	US\$ 460,000
<b>Subtotal</b>	<b>US\$ 460,000</b>
<b>Total</b>	<b>US\$ 1,299,562</b>

**C. Respondent’s Submission on Costs**

450. Respondent argues that it should be awarded all of its costs in this arbitration under UNCITRAL Rules Article 40, including both its share of the Tribunal’s fees and expenses and the reasonable costs of its legal representation and assistance.<sup>614</sup> According to Respondent, Canadian taxpayers should not be forced to pay the cost of Respondent’s defence in this arbitration, which Claimant should never have initiated.<sup>615</sup>
451. Respondent asserts that each of the factors that tribunals normally consider in determining the apportionment of costs (the relative success of the parties, quality of the claims, complexity of the issues, and the reasonableness of the parties’ incurred expenses) weighs in favor of awarding Respondent all of its costs.<sup>616</sup> First, Respondent should prevail in this arbitration because it has demonstrated that Claimant’s claim is manifestly without legal merit for several independent reasons.<sup>617</sup> Further, “[t]he lack of quality in Claimant’s claims goes beyond a typical unsuccessful claim” because Claimant is seeking from the

<sup>614</sup> R-CS §II.

<sup>615</sup> R-CS ¶1, 6.

<sup>616</sup> R-CS ¶4.

<sup>617</sup> R-CS ¶¶1, 5.

Tribunal appellate review of Canadian court decisions, which all three NAFTA Parties agree to be outside the jurisdiction of a NAFTA Chapter Eleven tribunal.<sup>618</sup>

452. In addition, Respondent argues that Claimant's conduct in this proceeding introduced unnecessary complexity into the proceeding. For instance, Claimant has (i) failed to clearly articulate the nature and scope of its claim, (ii) taken inconsistent positions on certain issues, (iii) changed its claim in the Reply, (iv) submitted extensive expert evidence that was of limited relevance to its claims and (v) unreasonably insisted on reserving 11 full days for the Hearing.<sup>619</sup>
453. Finally, Respondent submits that all of its costs are reasonable.<sup>620</sup> Respondent's costs are as follows:
- a. *Arbitration costs*: As of the date of its Cost Submission, Respondent had contributed CAD 601,785.00 towards arbitration fees and expenses.<sup>621</sup>
  - b. *Legal fees*: The total amount of Respondent's legal fees is CAD 4,579,260.92.<sup>622</sup>
  - c. *Witness costs and additional disbursements*: These costs are detailed in the table below.<sup>623</sup>

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<sup>618</sup> R-CS ¶6.

<sup>619</sup> R-CS ¶¶7-9.

<sup>620</sup> R-CS §III.

<sup>621</sup> R-CS ¶12.

<sup>622</sup> R-CS ¶14. Respondent highlights that it was represented by lawyers and paralegals of the Government of Canada's Trade Law Bureau, which charges hourly rates that are substantially lower than those charged in the private sector.

<sup>623</sup> Reproduced from R-CS, Annex II.

<b>Disbursement</b>	<b>Total (\$ CDN)</b>
Dimock Stratton	\$492,438.29
Professor Gervais	\$171,786.17
Arochi Lindner	\$157,365.55
Professor Holbrook	\$107,793.79
Micheal Gillen	\$7,845.45
David Reed	\$56,416.44
Marcel Brisebois <sup>15</sup>	\$4,099.55
SRW Trial Consulting (Trial Technology & Graphic Consultants)	\$159,571.17
Strut Legal (Hyperlinking of Documents)	\$27,682.69
Printing	\$20,173.60
Courier	\$2,572.96
Hotel Boardroom Rentals (Hearing)	\$27,783.29
Materials & Supplies	\$649.65
Travel Costs	\$116,060.90
<b>TOTAL DISBURSEMENTS</b>	<b>\$1,352,239.50</b>

#### **D. The Tribunal’s Decision on Costs**

454. Article 40(1) of the UNCITRAL Rules adopts the “loser pays” principle in relation to the “costs of arbitration”, unless the circumstances of the case weigh in favor of a different apportionment. In respect of the “costs of legal representation and assistance”, Article 40(2) confers broad discretion on the Tribunal to determine any reasonable apportionment of such costs in light of the circumstances of the case.
455. Although the UNCITRAL Rules do not elaborate upon the relevant “circumstances of the case” to be considered, Article 40 has been interpreted and applied by numerous tribunals. In the Tribunal’s view, Respondent has correctly identified four of the circumstances most commonly examined in this context: (i) the relative success of the parties, (ii) quality of the claims, (iii) complexity of the issues, and (iv) the reasonableness of the parties’ incurred expenses. The Tribunal will consider each of these factors.
- a. *The relative success of the parties*: Respondent is the successful Party, except in relation to its objection to the Tribunal’s jurisdiction.
  - b. *Quality of the claims*: Although Claimant has not succeeded in this arbitration, its claims were not in any sense frivolous, and Claimant pursued them in good faith.

Indeed, it must be noted that both Parties displayed the highest level of professionalism, efficiency and courtesy in presenting their cases.

- c. *Complexity of the issues*: This arbitration involved many complex issues of fact and law, some of them before a NAFTA Chapter Eleven tribunal for the first time. The complexity of the case is evidenced not only by the Parties' submissions, but also by the *amicus* and Article 1128 submissions.
- d. *Reasonableness of the parties' expenses*: In light of the complexity of the case, the Tribunal does not consider the Parties' expenses to be unreasonable.

456. Taking into account these factors and all of the surrounding circumstances, the Tribunal does not see any reason to depart from the "loser pays" principle reflected in Article 40(1) in relation to the costs of the arbitration. In this regard, the Tribunal notes that both Parties have referred to the "loser pays" principle in their submissions on costs.

457. Therefore, Claimant shall bear the costs of this arbitration, including the Tribunal Members' fees (at USD 375/hour) and expenses, ICSID's administrative fees and direct expenses, amounting to (in USD):<sup>624</sup>

Arbitrators' fees and expenses	
Professor Albert Jan van den Berg	259,734.75
Sir Daniel Bethlehem	114,359.20
Mr. Gary Born	138,872.07
ICSID's administrative fees	96,000.00
Direct expenses (estimated) <sup>625</sup>	140,731.95
<b>Total</b>	<b><u>749,697.97</u></b>

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<sup>624</sup> The ICSID Secretariat will provide the parties with a detailed Financial Statement of the case account once all invoices are received and the account is final.

<sup>625</sup> This amount includes estimated charges (courier, printing and copying) incurred in connection with the dispatch of this Award.

458. The above costs have been paid out of the advances made by the Parties in equal parts.<sup>626</sup> As a result, each Party's share of the costs of arbitration amounts to USD 374,848.99, and Claimant shall reimburse Respondent's share of the costs.
459. Regarding the costs of legal representation and assistance, in the exercise of its discretion under Article 40(2), and considering that Respondent prevailed on the merits but not on jurisdiction, the Tribunal has concluded that it is appropriate for Claimant to bear its own costs and to reimburse Respondent for 75 percent of Respondent's costs.
460. Therefore, Claimant shall pay to Respondent the amount of CAD 4,448,625.32, representing 75 percent of the *sum* of (i) Respondent's legal fees amounting to CAD 4,579,260.92 *plus* (ii) Respondent's additional disbursements of CAD 1,352,239.50.

## **XI. CONCLUSIONS**

461. In this Section the Tribunal sets forth its conclusions reached in this Award with respect to (i) jurisdiction; (ii) the merits; and (iii) costs, fees and expenses.

### **A. Jurisdiction**

462. Respondent submits that Claimant's claim is time-barred.<sup>627</sup> In its view, Claimant's claim falls outside the Tribunal's jurisdiction *ratione temporis*.<sup>628</sup>
463. As set out at ¶97 above, Claimant on the other hand requests that the 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[...]<sup>629</sup>
464. In Section VI.E above, the Tribunal determines that Claimant's NoA was timely, and that Claimant's claims fall within the Tribunal's jurisdiction *ratione temporis*.<sup>630</sup>

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<sup>626</sup> The remaining balance will be reimbursed to the parties in proportion to the payments that they advanced to ICSID.

<sup>627</sup> See R-PHM §III.

<sup>628</sup> Rejoinder ¶91.

<sup>629</sup> Opposition on Jurisdiction ¶50.

<sup>630</sup> See ¶170 above.

465. The Tribunal therefore dismisses Respondent’s objection to the Tribunal’s jurisdiction *ratione temporis* and finds that it has jurisdiction to hear Claimant’s claims as submitted to it in this arbitration. Claimant’s request to reject Respondent’s objection on the merits is granted.

466. In light of the foregoing, the Tribunal does not consider it necessary to decide whether Respondent’s jurisdictional objection should be barred as untimely under Article 21(3) of the UNCITRAL Rules.<sup>631</sup>

**B. Merits**

467. In relation to the merits of its claim, Claimant seeks the following relief, as set out at ¶95 above:

- (i) damages for the full measure of direct losses and consequential damages sustained as a consequence of Respondent’s breach of its obligations under Chapter 11 of the NAFTA, estimated in an amount not less than CDN \$500 million plus any payments Claimant or its enterprise is required to make arising from the improvident loss of its Zyprexa and Strattera Patents or its inability to enforce its Zyprexa and Strattera Patents;

[...]

- (iii) pre-award and post-award interest;

- (iv) payment of a sum of compensation equal to any tax consequences of the award, in order to maintain the award’s integrity[...]<sup>632</sup>

468. Respondent, on the other hand, requests an award “dismissing Claimant’s claim in its entirety”.<sup>633</sup>

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<sup>631</sup> See ¶160 above.

<sup>632</sup> SoC ¶85.

<sup>633</sup> See ¶98 above; SoD ¶120.

469. As a consequence of the findings set forth in Sections VIII and IX above, the Tribunal concludes that Claimant has failed to establish the factual premise of its claims. Specifically, the Tribunal holds that, based on the record of this case, the challenged measures—the invalidation of the Zyprexa and Strattera Patents through application of the legal rules that Claimant refers to as the promise utility doctrine—cannot form the basis of an expropriation claim under NAFTA Article 1110 or a claim for a violation of the minimum standard of treatment under NAFTA Article 1105. The Tribunal also finds that there was not an arbitrary or discriminatory measure in violation of NAFTA Article 1110 or NAFTA Article 1105.<sup>634</sup> The Tribunal must dismiss Claimant’s claims without further inquiry.
470. Since there has been no breach of Respondent’s obligations under Chapter Eleven of NAFTA, the Tribunal denies Claimant’s primary relief sought in the form of damages. Claimant’s further requests for (i) pre-award and post-award interest, and (ii) a “sum of compensation equal to any tax consequences of the award”, therefore fall away.
471. Accordingly, the Tribunal grants Respondent’s request for an award dismissing Claimant’s claim in its entirety.
472. In light of the Tribunal’s conclusions in relation to liability, there will be no second phase of this arbitration in relation to damages.
473. The Tribunal does not deem it necessary or appropriate to give further consideration to the Parties’ respective requests for “such further relief as the Arbitral Tribunal may deem just and appropriate”<sup>635</sup> and “any other relief that may seem just”.<sup>636</sup> No argument or particularized request has been made in relation to these requests. The Tribunal considers that it would violate its mandate if it were to grant relief outside the pleaded cases of the Parties. In the absence of further substantiation, these requests for relief are in the Tribunal’s view meaningless legal recitations.

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<sup>634</sup> See ¶¶416 and 442 above.

<sup>635</sup> SoC ¶85(e).

<sup>636</sup> SoD ¶120.

### C. Costs

474. Claimant seeks the following relief in relation to costs, as set out at ¶95 above:

the full costs associated with these proceedings, including all professional fees and disbursements, as well as the fees of the Arbitral Tribunal.<sup>637</sup>

475. Claimant also seeks its costs specifically in connection with Canada’s jurisdictional objection.<sup>638</sup>

476. As set out at ¶98 above, Respondent requests an award “awarding Respondent its costs, with applicable interest, pursuant to Article 1135(1) of the NAFTA and Article 40 of the UNCITRAL Rules”.<sup>639</sup>

477. As the Tribunal determines in Section X above, in accordance with the “loser pays” principle, Claimant shall bear the costs of this arbitration, including the Tribunal Members’ fees and expenses, ICSID’s administrative fees and direct expenses.<sup>640</sup>

478. With respect to the costs of legal representation and assistance, in the exercise of its discretion under Article 40(2) of the UNCITRAL Rules, and considering that Respondent prevailed on the merits but not on jurisdiction, the Tribunal concludes that it is appropriate for Claimant to bear its own costs and to reimburse Respondent for 75 percent of Respondent’s costs.<sup>641</sup>

479. The Tribunal therefore rejects Claimant’s requests for relief in relation to costs. Respondent’s request for its costs is granted in full in relation to the arbitration costs, and partially to the extent of 75 percent of its costs of legal representation and assistance.

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<sup>637</sup> SoC ¶85.

<sup>638</sup> Opposition on Jurisdiction ¶50.

<sup>639</sup> SoD ¶120.

<sup>640</sup> See ¶457 above. The ICSID Secretariat will provide the parties with a detailed Financial Statement of the case account once all invoices are received and the account is final.

<sup>641</sup> See ¶459 above.

## **XII. AWARD**

480. For the reasons set forth above, the Tribunal decides as follows:

- (1) Respondent's objection to the Tribunal's jurisdiction *ratione temporis* is dismissed. The Tribunal has jurisdiction to hear the claims submitted to it in this arbitration.
- (2) Claimant's claim is dismissed in its entirety.
- (3) Claimant shall bear the costs of the arbitration, amounting to USD 749,697.97. Consequently, Claimant shall pay to Respondent USD 374,848.99 with appropriate expedition.
- (4) Claimant shall cover 75 percent of Respondent's costs of legal representation and assistance. Consequently, Claimant shall pay to Respondent CAD 4,448,625.32 with appropriate expedition.
- (5) All other claims and requests are dismissed.

[signed]

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Sir Daniel Bethlehem QC  
Arbitrator

Date: 28 February 2017

[signed]

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Mr. Gary Born  
Arbitrator

Date: 6 March 2017

[signed]

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Professor Albert Jan van den Berg  
President of the Tribunal

Date: 8 MARCH 2017