

# Public Version

**INTERNATIONAL CENTRE FOR SETTLEMENT OF INVESTMENT DISPUTES  
(ICSID Case No. ARB(AF)/12/1)**

**In the Arbitration under Chapter Eleven of the North America Free Trade Agreement  
(NAFTA)**

**Between:**

**(1) APOTEX HOLDINGS INC.**

**(2) APOTEX INC.**

*First and Second Claimants*

and

**UNITED STATES OF AMERICA**

*Respondent*

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## AWARD

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V.V. Veeder, President  
J. William Rowley, Arbitrator  
John R. Crook, Arbitrator

***The Tribunal's Secretary:***

Monty Taylor

*Date of dispatch to the Parties: 25 August 2014*

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## ***GLOSSARY***

Act	US Federal Food, Drug and Cosmetic Act
ANDA	Abbreviated New Drug Application
API	Active Pharmaceutical Ingredients
Apotex	The Claimants
Apotex-Canada	Apotex Inc. (the Second Claimant)
Apotex-Holdings	Apotex Holdings Inc. (the First Claimant)
Apotex-US	Apotex Corp., a corporation organized under the laws of Delaware, USA
Apotex I & II Award	The award on jurisdiction and admissibility dated 14 June 2013 made by the NAFTA tribunal (Toby T. Landau, Clifford M. Davidson, Fern M. Smith) in the UNCITRAL Arbitration between Apotex Inc. and the Respondent
Apotex Costs Submission	The Claimants' first submission on costs filed on 17 January 2014
Apotex Second Costs Submission	The Claimants' second submission on costs filed on 7 February 2014
Arbitration Agreement	The arbitration agreement invoked by the Claimants resulting from their Request, NAFTA Articles 1116(1), 1117(1) and 1120(1)(b) and the ICSID Arbitration AF Rules
BNM	Business Neatness Magnanimity BNM srl
BVL	Ben Venue Laboratories in Bedford, Ohio, USA
[C.] [R.] [number]	Exhibit [Claimant] [Respondent]
CDER	The FDA's Center for Drug Evaluation and Research, Office of Compliance
cGMP	Current Good Manufacturing Practices
Counter-Memorial	The Respondent's Counter-Memorial dated 14 December 2012
DIOP	The FDA's Division of Import Operations and Policy
DWPE	Detention Without Physical Examination
ECJ	European Court of Justice
EIRs	FDA's Establishment Inspection Reports

Etobicoke	The drug production facility operated by Apotex Inc. and located at Etobicoke, Ontario
Etobiocoke warning letter	The warning letter issued by the FDA on 25 June 2009 in respect of Etobicoke
FAA	The US Federal Arbitration Act
FARs	Field Alert Reports
FDA	The US Food and Drug Administration
Form 483	A standard form on which FDA inspectors record their written observations at the conclusion of an inspection of a drug production facility
GAO	The US General Accounting Office
GMP	Good Manufacturing Practices
Guide	FDA's Guide to Inspections of Foreign Pharmaceutical Manufacturers
Hearing	The hearing on jurisdiction and the merits (liability) which took place at the World Bank in Washington DC, USA, from 18 November to 26 November 2013
ICAA	Ontario's International Commercial Arbitration Act
ICJ	The International Court of Justice
ICSID (or the Centre)	The International Centre for Settlement of Investment Disputes
ICSID Arbitration AF Rules	ICSID Arbitration (Additional Facility) Rules in force as of April 2006
ICSID Convention	Convention on the Settlement of Investment Disputes Between States and Nationals of Other States dated 18 March 1965
Import Alert	The FDA's amendment of Import Alert 66-40 on 28 August 2009 to include all products produced by the Etobicoke and Signet facilities
Jamaica-USA BIT	Jamaica-USA bilateral investment treaty of 4 February 1994, which entered into force on 7 March 1997
Medsafe	New Zealand's Medicines and Medical Devices Safety Authority
Memorial	The Claimants' Memorial dated 30 July 2012
NAFTA	North American Free Trade Agreement
NAI	No Action Indicated
NDA	New Drug Application



New York Convention	The 1958 UN Convention on the Recognition and Enforcement of Foreign Arbitral Awards
OAI	Official Action Indicated
OOS	Out-of-specification
PAI	Pre-Approval Inspection
PCIJ	The Permanent Court of International Justice
PQA	Product Quality Assessment
Rejoinder	The Respondent's Rejoinder dated 27 September 2013
Rejoinder on Jurisdiction	The Claimants' Rejoinder on Jurisdiction dated 18 October 2013
Reply	The Claimants' Reply dated 24 May 2013
Reply Supp	The Claimants' Supplement to Reply dated 22 July 2013
Request (for Arbitration)	The Claimants' Request for Arbitration dated 29 February 2012
Sandoz	The Sandoz/Novartis group of companies
Signet	The drug production facility operated by Apotex Inc. and located at Signet Drive in Toronto, Ontario
Signet warning letter	The warning letter issued by the FDA on 29 March 2010 in respect of Signet
TD. [day] [page]	Transcript of the oral hearing from 18 to 26 November 2013, with day and page reference
Teva	The Teva group of companies
TGA	Australia's Therapeutic Goods Administration
UNCITRAL Notes	The UNCITRAL Notes on Organising Arbitral Proceedings
USA Costs Submission	The Respondent's submission on costs filed on 17 January 2014
x	examination-in-chief
xx	cross-examination
xxx	re-direct examination

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## ***PART I – THE ARBITRATION***

### **(1) *The Parties***

- 1.1. *Apotex-Holdings*: The First Claimant is Apotex Holdings Inc. (“Apotex-Holdings”). It is a privately owned corporation organised under the Canada Business Corporations Act, a Canadian federal law. It functions as a holding company, by way of vertical integration, for the investments of the Apotex group of companies, consisting of companies formed and operating in Canada and elsewhere in the world (including the USA). The principal place of business of Apotex-Holdings is 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.
- 1.2. *Apotex Inc.*: The Second Claimant is Apotex Inc. (also called “Apotex-Canada” in these proceedings). It is a company incorporated under the laws of the province of Ontario, Canada. The principal place of business of Apotex Inc. is also 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. Apotex Inc. is indirectly owned and controlled by Apotex-Holdings. It operates several facilities in Canada, two of which are relevant to these arbitration proceedings.
- 1.3. *Apotex-US*: Apotex Corp. is a corporation organized under the laws of Delaware, USA, authorised to transact business in the state of Florida (“Apotex-US”). Its principal place of business is 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326, USA. The First Claimant (Apotex-Holdings) indirectly owns and controls Apotex-US (which is not a named party to this arbitration).
- 1.4. *Apotex*: For ease of reference, the Claimants are collectively described by the Parties and below as “Apotex.”
- 1.5. *The Respondent*: The Respondent is the United States of America, a Party to the North American Free Trade Agreement (“NAFTA”) which entered into force on 1 January 1994.

### **(2) *The Arbitration Agreement***

- 1.6. This arbitration takes place under an arbitration agreement invoked by the Claimants resulting from their Request for Arbitration dated 29 February 2012,

NAFTA Articles 1116(1), 1117(1) and 1120(1)(b) and the ICSID Arbitration (Additional Facility) Rules (the “ICSID Arbitration AF Rules”). For ease of reference, this arbitration agreement is here called the “Arbitration Agreement.”

1.7. The Respondent denies the jurisdiction in this Tribunal asserted by the Claimants for their claims against the Respondent under the Arbitration Agreement.

**(3) *The Arbitral Tribunal***

1.8. The Tribunal is comprised of three arbitrators, appointed pursuant to NAFTA Article 1123, as follows:

1.9. The Claimants appointed Mr. J. William Rowley, a national of Canada and the United Kingdom, of 20 Essex Street Chambers 20 Essex Street, London WC2R 3AL United Kingdom and (at that time) also of McMillan LLP Brookfield Place, 181 Bay Street, Suite 4400, Toronto, Ontario, Canada M5J 2T3.

1.10. The Respondent appointed Mr. John Crook, a national of the United States of America, of 10610 Belfast Place, Potomac, Maryland 2084, USA.

1.11. The Parties agreed on the appointment of Mr. V.V. Veeder, a national of the United Kingdom, as the third and presiding arbitrator, of Essex Court Chambers, 24 Lincoln’s Inn Fields, London WC2 3EG, United Kingdom.

1.12. The Tribunal was constituted on 11 June 2012 in accordance with Article 6(3) of the ICSID Arbitration AF Rules.

1.13. Ms. Eloïse Obadia, ICSID Legal Counsel, was designated to serve as the Secretary of the Tribunal. Ms. Obadia was later replaced as Secretary of the Tribunal by Mr. Monty Taylor, ICSID Legal Counsel, with Ms. Martina Polasek, also ICSID Legal Counsel, acting as Alternate Secretary of the Tribunal.

**(4) *The Arbitral Procedure***

1.14. *Request:* On 6 March 2012, Apotex-Holdings and Apotex Inc. submitted on their own behalf and on behalf of Apotex-US their Request for Arbitration dated 29 February 2012 against the Respondent (“the Request”) pursuant to Article 2 of the ICSID Arbitration AF Rules.

- 1.15. The Request, as supplemented by the Claimants' subsequent letter dated 8 March 2012, was registered by the Secretary-General of ICSID pursuant to Articles 4 and 5 of the ICSID Arbitration AF Rules on 16 March 2012. The Secretary-General notified in writing the Parties of such registration on the same day.
- 1.16. The Tribunal held a first session with the Parties at the World Bank in Washington DC, USA on 24 July 2012. The Parties confirmed that the Tribunal was properly constituted and that no Party had any objection to the appointment of any member of the Tribunal. It was also confirmed (*inter alia*) that the applicable ICSID Arbitration AF Rules would be those in force as of April 2006 and that the procedural language would be English. The agreement of the Parties was eventually embodied in Procedural Order No. 1 of 29 November 2012 signed by the President of the Tribunal and circulated to the Parties.
- 1.17. Also on 24 July 2012, the Tribunal issued a Confidentiality Agreement and Order signed by the President of the Tribunal and the Parties. An Amended Confidentiality Agreement and Order was issued by the Tribunal on 30 October 2013, also signed by the President of the Tribunal and the Parties.
- 1.18. At the first session, the Parties confirmed their disagreement on the legal place of the arbitration, albeit that the Parties agreed that the geographical place of the oral hearing(s) would be the World Bank, Washington DC, USA. As to the legal place of the arbitration, the Claimants proposed Toronto, Canada and the Respondent proposed Washington DC or alternatively New York, USA. The Tribunal decided that it would determine the place of arbitration without a hearing on the issue. After considering the Parties' written submissions, the Tribunal decided upon New York, NY, USA, as the legal place of this arbitration pursuant to Article 20(1) of the ICSID Arbitration AF Rules. The Tribunal communicated this decision to the Parties by letter dated 6 November 2012.
- 1.19. By the same letter, the Tribunal also confirmed the Parties' agreement that the geographical place for all the procedural meetings and oral hearings was the seat of ICSID, at the World Bank's offices in Washington DC, USA.

- 1.20. The reasons for the Tribunal’s decision with respect to the legal place of arbitration are set out in the Tribunal’s “Decision on the Place of Arbitration” attached to this Part I below, as Appendix A.
- 1.21. *Apotex Memorial*: On 30 July 2012, the Claimants filed their Memorial. With the Memorial, the Claimants also filed, in writing: (i) an Expert Report of Mr. Howard M. Rosen dated 30 July 2012; (ii) an Expert Report of Mr. Sheldon T. Bradshaw and Mr. Ron M. Johnson dated 30 July 2012; (iii) a Witness Statement of Mr. Kiran Krishnan dated 27 July 2012; (iv) a Witness Statement of Mr. John Flinn dated 30 July 2012; (v) a Witness Statement of Mr. Gordon Fahner dated 30 July 2012; (vi) a Witness Statement of Dr. Jeremy Desai dated 30 July 2012; (vii) a Witness Statement of Mr. Bruce Clark dated 27 July 2012; (viii) a Witness Statement of Mr. Edmund Carey dated 29 July 2012; (ix) a Witness Statement of Mr. Jeff Watson dated 30 July 2012; and (x) a Witness Statement of Ms. Bernice Tao dated 29 July 2012.
- 1.22. On 29 October 2012, the Tribunal issued a procedural order concerning the procedural timetable for this proceeding.
- 1.23. *USA Counter-Memorial*: On 14 December 2012, the Respondent filed its Counter-Memorial, including its objections to jurisdiction and a request to have the Tribunal address those objections to jurisdiction as a bifurcated preliminary matter. With its Counter-Memorial, the Respondent also filed, in writing: (i) a Witness Statement of Mr. Michael R. Goga dated 12 December 2012; (ii) a Witness Statement of Mr. Lloyd Payne dated 12 December 2012; (iii) a Witness Statement of Commander Debra M. Emerson dated 13 December 2012; and (iv) a Witness Statement of Dr. Carmelo Rosa dated 14 December 2012.
- 1.24. On 28 December 2012, the Claimants filed written observations on the Respondent’s request for bifurcation, to which the Respondent filed a written response on 10 January 2013. On 16 January 2013 the Claimants filed their written observations on that response.
- 1.25. On 25 January 2013, the Tribunal issued its procedural order on the Respondent’s request for bifurcation. The Tribunal dismissed the Respondent’s request and ordered that both the jurisdictional and liability issues in the proceeding be

addressed in the remaining written procedure and heard during the oral procedure at the same hearing, with all quantum issues (including interest) to be addressed in a later phase of this proceeding (if and to the extent relevant).

- 1.26. On 7 February 2013, a non-disputing party, Business Neatness Magnanimity BNM srl (“BNM”), made an application to file a non-disputing party submission in the arbitration. Mr. Barry Appleton, another non-disputing party, also made an application on 8 February 2013. These applications were made in accordance with Procedural Order No. 1, which allowed amicus applications (for permission to file a substantive amicus submission) by 8 February 2013.
- 1.27. *Mexico’s Article 1128 Submission:* On 9 February 2013, the United Mexican States filed a written submission as a non-disputing State Party pursuant to NAFTA Article 1128.
- 1.28. The Claimants filed observations on BNM’s application on 15 February 2013; and the Respondent indicated by letter of the same date that it was taking no position on BNM’s application. With respect to Mr. Appleton’s application, the Respondent filed observations on that application on 15 February 2013; and the Claimants indicated by a letter on the same day that they were taking no position on that application.
- 1.29. On 1 March 2013, the Tribunal informed BNM and Mr. Appleton by separate letters that their respective applications were denied by the Tribunal. These letters indicated that detailed reasons for the decisions would follow; and these were provided in two separate procedural orders dated 4 March 2013, respectively (i) “Procedural Order on the Participation of the Applicant, BNM, as a Non-Disputing Party” and (ii) “Procedural Order on the Participation of the Applicant, Mr. Barry Appleton, as a Non-Disputing Party.”
- 1.30. On 15 March 2013, the Claimants and the Respondent requested the Tribunal to decide on the production of documents disputed between them. To that end, pursuant to Paragraph 14.2.7(v) of Procedural Order No. 1, the Claimants and the Respondent submitted to the Tribunal disputes under their respective schedules for document production for decision by the Tribunal. On 20 March 2013, the Respondent filed observations on the Claimants’ request; and the Claimants made

submissions on 22 and 24 March 2013 regarding the Respondent's observations. On 29 March 2013, the Tribunal issued a "Procedural Order on the Parties' Respective Requests for Document Production."

- 1.31. On 14 May 2013, the Tribunal issued a "Procedural Order on the Schedule Regarding the Parties' Respective Privilege Logs, Further Submissions and Certifications."
- 1.32. *Apotex Reply*: On 24 May 2013, the Claimants filed their Reply, together with, in writing: (i) a Second Expert Report of Mr. Sheldon T. Bradshaw and Mr. Ron M. Johnson dated 24 May 2013; (ii) a Second Witness Statement of Mr. Gordon Fahner dated 24 May 2013; (iii) a Second Witness Statement of Mr. Edmund Carey dated 24 May 2013; (iv) a Second Witness Statement of Ms. Bernice Tao dated 24 May 2013; (v) a Second Witness Statement of Dr. Jeremy Desai dated 23 May 2013; and (vi) a Second Witness Statement of Mr. Kiran Krishnan dated 23 May 2013.
- 1.33. Following written exchanges between the Parties, on 11 June 2013 the Claimants and the Respondent filed further requests for the Tribunal to decide on the production of documents disputed between them. On 5 July 2013, the Tribunal issued a "Procedural Order on Document Production Regarding the Parties' Respective Claims to Privilege and Privilege Logs."
- 1.34. On 22 July 2013, the Claimants filed a Supplement to their Reply of 24 May 2013.
- 1.35. *USA Rejoinder*: On 27 September 2013, the Respondent filed its Rejoinder on Merits and Reply on Objections to Jurisdiction together with, in writing: (i) a supplemental Witness Statement of Dr. Carmelo Rosa dated 27 September 2013; and (ii) an Expert Report of Mr. William W. Vodra dated 20 September 2013.
- 1.36. *Apotex Rejoinder on Jurisdiction*: The Claimants filed their Rejoinder on Jurisdiction on 18 October 2013.
- 1.37. On 31 October 2013, the Tribunal held a pre-hearing organisational meeting with the Parties by telephone conference.
- 1.38. *The Hearing*: A hearing on jurisdiction and the merits took place at the World Bank in Washington DC, USA, from 18 November to 26 November 2013 (the

“Hearing”), recorded by verbatim daily transcript.<sup>1</sup> In addition to the three Members of the Tribunal and the Secretary and Alternate Secretary of the Tribunal, those present at the Hearing were:

For the Claimants:

*Counsel*

Mr. Barton Legum	Salans FMC SNR Denton Europe LLP
Ms. Anne-Sophie Dufêtre	Salans FMC SNR Denton Europe LLP
Ms. Brittany Gordon	Salans FMC SNR Denton Europe LLP
Ms. Lara Elborno	Salans FMC SNR Denton Europe LLP

Mr. John Hay	Dentons US LLP
Ms. Ulyana Bardyn	Dentons US LLP
Ms. Kristen Weil	Dentons US LLP
Mr. Johan Buys	Dentons US LLP

*The Claimants’ Representatives*

Dr. Jeremy Desai	Apotex Inc.
Ms. Roberta Loomar	Apotex Inc.

*Expert Witnesses*

Mr. Sheldon T. Bradshaw	Hunton & Williams LLP
Mr. Ron M. Johnson	Becker & Associates Consulting

For the Respondent:

*Counsel*

Ms. Mary McLeod	U.S. Department of State
Ms. Lisa J. Grosh	U.S. Department of State
Mr. John D. Daley	U.S. Department of State
Mr. Jeremy K. Sharpe	U.S. Department of State
Mr. Neale H. Bergman	U.S. Department of State
Mr. David M. Bigge	U.S. Department of State
Mr. John I. Blanck	U.S. Department of State
Ms. Alicia L. Cate	U.S. Department of State
Ms. Nicole C. Thornton	U.S. Department of State
Ms. Abby Lounsberry	U.S. Department of State

*The Respondent’s Representatives*

Ms. Wendy Vicente	U.S. Food and Drug Administration
Ms. Elizabeth Philpy	U.S. Food and Drug Administration
Mr. Diogo Simas	U.S. Food and Drug Administration
Mr. Maan Abdulda	U.S. Food and Drug Administration

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<sup>1</sup> This transcript was later issued, as corrected and approved by the Parties on 18 February 2014 and as confirmed by the Tribunal on 18 April 2014. The key to this daily transcript, in references below, is: “TD1.05” signifies Day 1 (18 November 2013), at Page 5.



Ms. Hidee Molina	U.S. Food and Drug Administration
Ms. Jennifer Thornton	Office of the United States Trade Representative
Mr. Gary Sampliner	U.S. Department of Treasury
Mr. Zachary Gold	U.S. Department of State
Mr. Daniel Michaeli	U.S. Department of State
Mr. Zachary Stuart	U.S. Department of State
Ms. Lana Ulrich	U.S. Department of State
Mr. Thomas Weatherall	U.S. Department of State

*Factual Witnesses(subject to sequestration)*

Cdr. Debra M. Emerson	U.S. Food and Drug Administration
Mr. Michael R. Goga	U.S. Food and Drug Administration
Mr. Lloyd Payne	U.S. Food and Drug Administration
Dr. Carmelo Rosa	U.S. Food and Drug Administration

*Expert Witness*

Mr. William W. Vodra	Arnold & Porter LLP (retired)
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For the United Mexican States:

Mr. Salvador Behar	The Embassy of Mexico in Washington DC, USA
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1.39. *Oral Testimony:* At the Hearing, the Tribunal heard oral testimony from the following factual and expert witnesses:<sup>2</sup>

(i) Called by the Claimants:

- Mr. Sheldon T. Bradshaw [x TD2.265, xx TD2.277]

(ii) Called by the Respondent:

- Cdr. Debra M. Emerson [x TD3.696, xx TD3.703];  
 - Mr. Lloyd Payne [x TD3.739, xx TD3.744];  
 - Mr. Michael R. Goga [x TD3.808, xx TD3.812];  
 - Dr. Carmelo Rosa [x TD3.824, xx TD3.828, xxx TD4.1023]; and  
 - Mr. William W. Vodra [x TD4.1094, xx TD4.1118, xxx TD4.1161].

1.40. *Costs Submissions:* After the Hearing, the Parties filed their written submission on costs on 17 January 2014. The Respondent filed its written submission on costs together with, in writing: (i) a Witness Statement of Mr. David M. Bigge dated 17 January 2014; (ii) a Witness Statement of Ms. Mary T. Reddy dated 16 January 2014; and (iii) a Witness Statement of Mr. Jeremy K. Sharpe dated 17 January 2014.

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<sup>2</sup> Key: “x” denotes examination-in-chief; “xx” cross-examination; and “xxx” re-direct examination.

- 1.41. The Claimants filed a second costs submission on 7 February 2014. The Respondent did not elect to file a reply costs submission.<sup>3</sup>
- 1.42. *Closing the File:* The proceeding was closed, as regards the issues here expressly decided in the Operative Part, on 1 August 2014, by the Tribunal’s letter dated 1 August 2014 as earlier notified to the Parties by the Tribunal’s letters dated 14 March and 24 July 2014 under or by analogy to Article 44(1) of the ICSID Arbitration AF Rules.
- 1.43. *Redactions:* This award is issued to the Parties in a non-redacted form. The Parties agreed, as regards any wider publication, to a procedure for redacting confidential information in Paragraph 21.2 of the Tribunal’s Procedural Order No.1, as later confirmed by the Parties in their respective email messages to the Tribunal dated 29 July 2014.

**(5) *The Parties’ Dispute (Jurisdiction and Merits)***

- 1.44. *Jurisdiction:* As already indicated above, the Claimants submit that this Tribunal has jurisdiction to decide all their claims advanced in this arbitration under NAFTA and the ICSID Arbitration AF Rules. The Respondent disputes that submission, having made timely objections that the Parties’ dispute is not within the competence of the Tribunal under Article 45(2) of the ICSID Arbitration AF Rules.
- 1.45. *Merits:* The named Claimants (*i.e.* Apotex-Holdings and Apotex Inc.) make claims for breach by the Respondent of several of its obligations under NAFTA and the Treaty Between the United States of America and Jamaica Concerning the Reciprocal Encouragement and Protection of Investment of 4 February 1994 (“Jamaica-USA BIT”) both for themselves and also (by Apotex-Holdings) for Apotex-US. The Claimants also claim interest and costs (the latter under Article 52(1)(j) of the ICSID Arbitration AF Rules). The Respondent, without prejudice to its jurisdictional objections, denies any liability to the Claimants (for themselves and also for Apotex-US); and, in turn, the Respondent claims costs (also under Article 52(1)(j) of the ICSID Arbitration AF Rules).

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<sup>3</sup> See the Respondent’s email message to the Tribunal dated 7 February 2014.

1.46. As indicated above, by its procedural order of 25 January 2013, the Tribunal ordered the bifurcation between (i) the joined jurisdiction and liability issues and (ii) all quantum issues. Hence, the Hearing addressed only the former issues; and the latter issues are not here addressed by the Tribunal.

1.47. The Parties' dispute, as to both jurisdiction and the merits (liability), is further described below in Part II.

**(6) *The Parties' Claims for Relief***

1.48. The Tribunal here records the formal relief sought from the Tribunal by the Parties at successive stages of this arbitration.

1.49. *The Claimants:* The Claimants, by their Request (Paragraph 89), request an award, "on behalf of Apotex-US and on their own behalf" in their favour in the terms there specified pursuant to NAFTA Articles 1116(1) and 1117(1), as re-stated in their Memorial (Paragraph 572), their Reply (Paragraph 532) and their Rejoinder on Jurisdiction (Paragraph 127).

1.50. (i) *The Claimants' Request:* Section V, Paragraph 89 (page 19) states: "As a result of the actions and breaches of the Government of the United States of America described above, the Claimants, on behalf of Apotex-US and on their own behalf, respectfully intend to request an award in their favour:

(a) Finding that the United States of America has breached its obligations under the NAFTA;

(b) Directing the United States of America to pay damages in an amount to be proven at the hearing but which the Claimants presently estimate to be in the hundreds of millions of US dollars;

(c) Directing the United States of America to pay interest on all sums awarded;

(d) Directing the United States of America to pay the Claimants' costs associated with these proceedings, including professional fees and disbursements;

(e) Ordering such other and further relief as the Tribunal deems appropriate in the circumstances."

- 1.51. (ii) *The Claimants' Memorial*: Paragraph 572 (page 171) states: "As a result of the actions and breaches of the Government of the United States of America described above, the Claimants respectfully intend to request an award in their favour:
- (a) Declaring that the United States of America has breached its obligations under Articles 1102, 1103 and 1105 of the NAFTA;
  - (b) Ordering the United States of America to pay damages in an amount to be proven at the hearing but which the Claimants presently estimate to be in the hundreds of millions of US dollars, including pre-award interest;
  - (c) Ordering the United States of America to pay the Claimants' interest and taxes on all sums awarded;
  - (d) Ordering the United States of America to pay the Claimants' costs associated with these proceedings, including professional fees and disbursements;
  - (e) Ordering such other and further relief as the Tribunal deems appropriate in the circumstances."
- 1.52. (iii) *The Claimants' Reply*: Paragraph 532 (page 179) states: "As a result of the actions and breaches of the Government of the United States of America described above, the Claimants respectfully request a decision in their favour:
- (a) Dismissing the US jurisdictional objections;
  - (b) Declaring that the United States of America has breached its obligations under Articles 1102, 1103 and 1105 of the NAFTA;
  - (c) Ordering that the Claimants' claims to damages and interest be addressed in the subsequent phase of this arbitration, and decided in the final award;
  - (d) Reserving decision on Claimants' request for an award of costs, including professional fees and disbursements, until the next phase of this arbitration;
  - (e) Ordering such other and further relief as the Tribunal deems appropriate in the circumstances."

1.53. (iv) *The Claimants' Rejoinder on Jurisdiction*: Paragraph 127 (page 47) relevantly states: "For the foregoing reasons and those set out in its previous submissions, claimants Apotex Holdings and Apotex-Canada respectfully submit that the US objections to jurisdiction should be dismissed .... and a decision entered in accordance with the submissions set out at paragraph 532 of the Apotex Reply."

1.54. *The Respondent*: The Respondent, by its Counter-Memorial (Paragraph 402, page 204), requests an award from the Tribunal:

- (1) Upholding the Respondent's jurisdictional objections; and/or
- (2) Dismissing the Claimants' claims in their entirety and with prejudice; and
- (3) Ordering that the Claimants bear the costs of these proceedings, including the Respondent's costs for legal representation and assistance.

This claim for relief was re-stated in the Respondent's Rejoinder to like effect (Paragraph 378, page 192).

## ***PART I – APPENDIX A***

### ***The Reasons for the Tribunal’s Decision on New York as the Legal Place of the Arbitration under Article 20(1) of the ICSID Arbitration AF Rules***

#### **(1) *Introduction***

- A.1. As described in Part I above, the Tribunal decided that the legal place of this arbitration was New York, New York, USA under Article 20(1) of the ICSID Arbitration AF Rules; and the Tribunal communicated that decision to the Parties by letter dated 6 November 2012. The Tribunal here sets out its reasons for that decision. For practical purposes, the effect of the Tribunal’s decision is relevant only to its award made under the ICSID Arbitration AF Rules. It was not relevant during the arbitration given the Parties’ consensus on the geographical place of this arbitration, namely the seat of ICSID at the World Bank, Washington DC, USA.
- A.2. As also described in Part I, in consultation with the Parties, the Tribunal agreed to hold the first session in person in Washington DC on 24 July 2012. The legal place of arbitration was one of the items listed on the agenda for this first session. Earlier, on 17 July 2012, the Parties had submitted their written observations on the agenda and had indicated that they were unable to reach agreement on the legal place of arbitration. The Claimants were then proposing Toronto, Canada; and the Respondent was then proposing Washington DC, USA, later also proposing New York, New York, USA.
- A.3. It was common ground between the Parties that it was not open to the Tribunal to choose another legal place of arbitration, its choice being limited by NAFTA’s Chapter Eleven, Article 19 of the ICSID Arbitration AF Rules and the Parties’ proposals to one of the three places disputed by the Parties; namely (i) Toronto, (ii) Washington DC or (iii) New York. In other circumstances, the Tribunal might have wished to choose a legal place of arbitration neutral for all Parties; but such a choice was not open to the Tribunal in this arbitration.
- A.4. At the first session, the Parties confirmed their disagreement over the legal place of arbitration; and it was agreed that the Tribunal would determine the issue after

receiving the Parties' written submissions on the issue without any additional oral hearing.

- A.5. As directed by the Tribunal at the first session, the Claimants filed their written submission on the legal place of arbitration on 24 August 2012 (the "Claimants' submission") and the Respondent filed its written submission on the legal place of arbitration on 31 August 2012 (the "Respondent's submission").
- A.6. On 11 September 2012, the Claimants applied for the Tribunal's permission to make a short written reply submission on the issue and for the Respondent to make a short written rejoinder submission to the Claimants' reply.
- A.7. On 12 September 2012, the Tribunal granted the Claimants' application; and it directed the Claimants to file their reply submission by 17 September 2012 and the Respondent to file its rejoinder submission by 26 September 2012.
- A.8. The Parties filed their respective further written submissions, the Claimants on 17 September 2012 (the "Claimants' reply submission") and the Respondent on 26 September 2012 (the "Respondent's rejoinder submission").
- A.9. By Procedural Order of 2 October 2012, the Tribunal confirmed its receipt of the Parties' written submissions as to the respective merits and demerits of the Parties' proposed legal places of arbitration. The Tribunal noted that it had not received submissions from the Claimants as regards New York, which had been suggested (in the alternative) as a possible legal place of the arbitration by the Respondent in its rejoinder submission. Accordingly, the Tribunal invited the Claimants' brief written comments as regards the Respondent's alternative suggestion of New York, to be filed by 10 October 2012. The Claimants filed such submission on that date (the "Claimants' surreply submission").
- A.10. As requested by the Tribunal, on 10 October 2012 the ICSID Secretariat also filed comments on the legal places suggested by the Parties, pursuant to Article 20(1) of the ICSID Arbitration AF Rules.
- A.11. In arriving at its decision on New York as the legal place of arbitration, the Tribunal took into account all the Parties' written submissions and the written comments of

the ICSID Secretariat. For the purposes of stating reasons for the Tribunal's decision, it is not necessary to refer in full to these submissions and comments.

**(2) *The Parties' Relevant Submissions***

- A.12. In summary, the Parties' disagreement on the legal place of the arbitration was between the Claimants in favour of Toronto and the Respondent in favour of Washington DC or, alternatively, New York. The Parties agreed that the Tribunal could be guided, in the exercise of its discretion under Article 20(1) of the ICSID Arbitration AF Rules, by the general considerations set out in Paragraph 22 of the UNCITRAL Notes on Organising Arbitral Proceedings (the "UNCITRAL Notes").<sup>1</sup>
- A.13. In summary, the UNCITRAL Notes' general considerations comprise the following: (i) the suitability of the law on arbitral procedure of the place of arbitration (the *lex loci arbitri*); (ii) whether there is a multilateral or bilateral treaty on the enforcement of arbitral awards between the State where the arbitration takes place and the State or States where the award may have to be enforced; (iii) the convenience of the parties and the arbitrators, including travel distances; (iv) the availability and cost of support services needed for the arbitration; and (v) the location of the subject-matter in dispute and the proximity of evidence.
- A.14. It can be seen that most of these considerations relate to the geographical place of arbitration, as distinct from its legal place. As to the latter, only the first and second considerations (i) and (ii) are potentially material to the legal place of this arbitration. Hence, the considerations (iii), (iv) and (v) here provided no assistance to the Tribunal. In *Mobil Investments Canada Inc. v. Canada*, the tribunal noted that: "the place that is selected to hold any hearings and the place of arbitration raise different considerations. The latter raises considerations of a jurisdictional nature, by bringing the arbitration into the jurisdiction of a particular court in whose geographical ambit the place of arbitration is established."<sup>2</sup>

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<sup>1</sup> The Claimants' submission, at pp. 2-3; and the Respondent's submission, at p. 2. (These Notes are currently being revised by UNCITRAL.)

<sup>2</sup> *Mobil Investments Canada Inc. and Murphy Oil Corporation v. Canada*, ICSID Case No. ARB(AF)/07/4, Procedural Order No. 1, Decision of the Tribunal on the Place of Arbitration (7 October 2009), Para. 36. All legal citations referred to in this Award are provided in full in the 'List of Legal Materials' (see the Award's Table of Contents in this respect). For ease of reference, all subsequent citations in this Award to a case or text



- A.15. As to the second consideration (ii) relating to the existence of an international treaty, the Parties agreed that it is not here a decisive consideration since both Canada and the USA are parties to the 1958 UN Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the “New York Convention”).<sup>3</sup> Moreover, Article 19 of the ICSID Arbitration AF Rules requires this arbitration to be held only in States that are parties to the New York Convention. Hence, the consideration (ii) here provided no assistance to the Tribunal.
- A.16. As to the first consideration (i) relating to the *lex loci arbitri*, in summary, the Claimants submitted that Toronto should be the legal place of this arbitration. Recognising that Toronto was not a neutral place (given the two Claimants’ Canadian nationalities), the Claimants submitted that all three suggested legal places (Toronto, New York and Washington DC) were incapable of being neutral since none of them was a jurisdiction that was neither that of the Claimants nor that of the Respondent.<sup>4</sup> The Claimants, therefore, contended that neutrality was here best addressed by fixing the legal place of the arbitration in Toronto where the Canadian courts would treat all the Parties with equality.<sup>5</sup>
- A.17. In summary, the Respondent submitted that the legal place of every arbitration against the Respondent under NAFTA’s Chapter Eleven has been in the USA, forming a well-founded accepted practice by disputing parties which should be followed by the Tribunal in this arbitration. The Respondent further submitted, with respect to the consideration (i), that Washington DC and New York were equally suitable and found support from the fact that six NAFTA tribunals have found the laws of the USA to be appropriate for arbitrations under NAFTA’s Chapter Eleven.<sup>6</sup> The Respondent therefore pressed for Washington DC or, in the subsidiary alternative, New York.

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already cited in full will be abbreviated (*e.g.* this case will subsequently be referred to as *Mobil Investments Canada Inc. v. Canada*).

<sup>3</sup> The Claimants’ submission, at p. 7; the Respondent’s submission, at p. 13.

<sup>4</sup> The Claimants’ submission, at p. 9.

<sup>5</sup> *Id.*, at p. 10.

<sup>6</sup> The Respondent’s submission, at p. 2.

A.18. The Parties also disagreed on the suitability of their proposed legal places with respect to the law on arbitral immunity and quorum. It is appropriate to consider these two differences in turn.

**(3) *Arbitral Immunity***

A.19. The Claimants submitted that, in Toronto, arbitrators who exercise judicial functions are (as a general rule) immune from claims of negligence or breach of contract. In Washington DC, according to the Claimants, arbitrators are immune from liability to the same extent as a judge of a DC court acting in a judicial capacity, such immunity being governed by common law and subject to various exceptions.<sup>7</sup> The Claimants indicated that, as regards New York, there “may be exceptions” to arbitral immunity.<sup>8</sup>

A.20. The Respondent submitted that arbitrators and arbitral institutions enjoy in the USA the broadest degree of immunity from suit for actions taken within their duties and that the exceptions identified by the Claimants were inapposite.<sup>9</sup>

A.21. The Tribunal does not consider that any difference regarding arbitral immunity between the three proposed legal places, if it exists at all, is materially significant for this case. Accordingly, this factor here provided no assistance to the Tribunal.

**(4) *Quorum***

A.22. The Claimants submitted that Ontario’s International Commercial Arbitration Act (the “ICAA”) does not specifically address the question of quorum but does provide for the number of arbitral votes required for an arbitral decision. In the absence of agreement between the parties to an arbitration (subject to Ontario law), the tribunal may conduct the arbitration as it considers appropriate, subject to the provisions of the ICAA.<sup>10</sup> The Claimants further submitted that with respect to an arbitration, the legal place of which is situated in Washington DC, the United States Federal Arbitration Act (the “FAA”) is silent with respect to quorum requirements while the *lex loci arbitri* in DC (under the DC Arbitration Act) requires the presence of all

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<sup>7</sup> The Claimants’ submission, at p. 18.

<sup>8</sup> The Claimants’ surreply submission, at p. 6.

<sup>9</sup> The Respondent’s submission, at pp. 12-13.

<sup>10</sup> The Claimants’ submission, at p. 17.

arbitrators at the hearings on the merits.<sup>11</sup> The same is true, according to the Claimants, under New York arbitration law.<sup>12</sup>

A.23. The Respondent did not comment on this factor.

A.24. Given the effect of Articles 22(2) and 24(1) of the ICSID Arbitration AF Rules, the Tribunal does not consider that any relevant difference exists as regards quorum between the three proposed legal places. Accordingly, this factor here provided no assistance to the Tribunal.

**(5) *The Lex Loci Arbitri***

A.25. The Claimants submitted that the law applicable to arbitration proceedings with a legal place of arbitration in Washington DC is the DC Arbitration Act, to the extent that it does not conflict with the FAA.<sup>13</sup> As regards setting-aside proceedings in the USA, according to the Claimants, the law applicable is the FAA, including setting-aside proceedings both in Washington DC and New York.<sup>14</sup> The Claimants contended that it was difficult to predict in advance whether the provisions of the DC Arbitration Act or the New York state law would apply or if they would be held to limit or hinder the goals of the FAA.<sup>15</sup>

A.26. In Toronto, the Claimants submitted that the *lex loci arbitri* is contained in the ICAA, which incorporates the UNCITRAL 1985 Model Law on International Commercial Arbitration (with minor variations).<sup>16</sup>

A.27. The Claimants submitted that selecting Washington DC, or New York, as the legal place of this arbitration would create for the Parties an “uneven playing field for post-award proceedings.”<sup>17</sup> The Claimants asserted that the law applicable to arbitration proceedings in Washington DC or New York is not suitable because it

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<sup>11</sup> *Id.*, at p. 17.

<sup>12</sup> The Claimants’ surreply submission, at p. 6.

<sup>13</sup> The Claimants’ submission, at p. 17.

<sup>14</sup> *Id.*, at p. 13; the Claimants’ surreply submission, at p. 4 (the grounds for setting aside an award are provided in Section 10 of the FAA).

<sup>15</sup> The Claimants’ submission, at p. 14; the Claimants’ surreply submission, at p. 5.

<sup>16</sup> The Claimants’ submission, at p. 6 (the grounds for setting aside an award are provided in Article 34 of the ICAA).

<sup>17</sup> *Id.*, at p. 1.

requires US courts to defer to the views of the US Government on the interpretation of treaties, such as NAFTA. Treaty interpretation, as the Claimants submitted, is often the central issue presented before the judicial body responsible to determine an application to set aside an arbitration award made under a treaty.<sup>18</sup> According to the Claimants, this creates a presumption in favour of the US Government's views (albeit rebuttable) which is unfairly disadvantageous to the Claimants.<sup>19</sup>

- A.28. The Claimants also asserted that the courts in Washington DC are more “interventionist” than the courts of Ontario, which have shown due deference for arbitral awards and limited judicial intervention in the arbitral process.<sup>20</sup> To that effect, the Claimants cited the decision in *Mexico v. Cargill, Inc.*<sup>21</sup> of the Ontario Court of Appeals in support of their case that reviewing courts in Ontario take a narrow view when questions of jurisdiction are raised in proceedings to set aside arbitral awards; and that they also carefully limit the issues to be addressed so as to ensure that they are “true questions of jurisdiction.”<sup>22</sup>
- A.29. In contrast, the Claimants cited the decision of the DC Court of Appeals in *Argentina v. BG Group PLC*,<sup>23</sup> which, so they submitted, showed (at that time) that US courts are more interventionist in regard to international arbitration awards. The Claimants noted that even if this were a solitary example (contrary to their submission), this decision was a binding legal precedent in Washington DC.<sup>24</sup> The Claimants contended that while the decision was not similarly binding upon New York courts (including the US Court of Appeals for the Second Circuit), the decision remained potentially persuasive for such New York courts.<sup>25</sup>
- A.30. The Respondent, on the other hand, submitted that the Claimants' contention contradicted their own position in two previous NAFTA cases in which Apotex Inc. had voluntarily consented to New York as the legal place of arbitration and,

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<sup>18</sup> The Claimants' submission, at p. 4.

<sup>19</sup> The Claimants' reply submission, at pp. 1-2.

<sup>20</sup> The Claimants' submission, at p. 6.

<sup>21</sup> *Mexico v. Cargill, Inc.*, 2011 ONCA 622 (Can.) (4 October 2011).

<sup>22</sup> The Claimants' submission, at p. 12.

<sup>23</sup> *Argentina v. BG Group PLC*, 665 F. 3d 1363 (DC Cir. 17 January 2012). This case was decided under the United Kingdom-Argentina bilateral investment treaty of 1990.

<sup>24</sup> The Claimants' reply submission, at p. 3.

<sup>25</sup> The Claimants' surreply submission, at p. 4.

consequently, to US law as the *lex loci arbitri*.<sup>26</sup> To that effect, the Respondent stated in its submission that, subsidiarily, it would now agree to New York as the legal place of arbitration.<sup>27</sup>

- A.31. The Respondent also refuted the idea that US courts provided an unfair advantage to the views of the US Government in US legal proceedings relating to an award. Although the views of the US Government are routinely given great weight, the Respondent submitted that US courts also take into consideration the views of other contracting parties to a treaty (as well as the disputing parties). According to the Respondent, there are also a number of cases in which US courts have disregarded the views of the US Government on treaty interpretation.<sup>28</sup>
- A.32. The Respondent also submitted that the Claimants misread the *BG Group* decision. It asserted that the Claimants should not derive from a single decision (for which the *BG Group* had petitioned, at that time, the US Supreme Court for a writ of *certiorari*) the sweeping conclusion that US courts are unduly interventionist in regard to arbitration awards.<sup>29</sup> The Respondent further submitted that, in any event, the *BG Group* decision was not a legal precedent in the US Court of Appeals for the Second Circuit, which has appellate jurisdiction over federal courts in New York.<sup>30</sup>
- A.33. In addition, the Respondent asserted that there was in the USA longstanding support for international arbitration and that US courts have long recognised that the grounds for judicial review of an award are extremely limited.<sup>31</sup> The Respondent also cast doubts on the allegedly limited interventionist character of the Canadian courts in the international arbitration process. It submitted that, in the *Cargill* decision, the Ontario Court of Appeals did not leave to the arbitral tribunal an entire discretion in deciding upon its own jurisdiction, but determined that it was: “up to the court to determine whether it [the tribunal] was [correct in its assumption of jurisdiction].”<sup>32</sup> The Respondent also referred to the fact that other NAFTA

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<sup>26</sup> The Respondent’s submission, at pp. 3-4.

<sup>27</sup> The Respondent’s submission, at p. 1 (fn 2); the Respondent’s rejoinder submission, at p. 3.

<sup>28</sup> The Respondent’s submission, at p. 5.

<sup>29</sup> *Id.*, at p. 9.

<sup>30</sup> The Respondent’s rejoinder submission, at p. 2.

<sup>31</sup> The Respondent’s submission, at p. 10.

<sup>32</sup> *Id.*, at p. 12.

tribunals have expressed doubts as to the suitability of Canada as the legal place of an arbitration in the light of the standard of review urged by the Canadian Government.<sup>33</sup>

**(6) *The Tribunal's Analysis and Reasons***

- A.34. The Tribunal considers that the choice of legal place lies between Toronto and New York. For this arbitration it discounts Washington DC. Washington DC is the Respondent's capital city; and the two other candidates are only regional centres, albeit significant metropolitan cities in their respective countries. In the Tribunal's view, it would not be appropriate for the Claimants to be required, effectively, to play away in the Respondent's national home stadium.
- A.35. The Tribunal also considers that, given the Parties' limitations imposed upon the Tribunal, considerations of national neutrality are inapplicable to the exercise of the Tribunal's discretion. New York as a legal place of arbitration is as foreign to the Claimants as Toronto is foreign to the Respondent. Whilst national neutrality would ordinarily be an important factor for a tribunal's decision, that factor is not available to be taken into account by the Tribunal in this arbitration.
- A.36. The Tribunal further considers unhelpful the Parties' debate over the relative interventionist (or non-interventionist) tendencies of New York and Toronto courts. In this regard, Toronto and New York represent an invidious choice to make, since both would provide, in the Tribunal's view, suitable legal places for this arbitration within the meaning of the consideration (i), *i.e.* the suitability of the law on arbitral procedure of the place of arbitration. Both places have acceptable laws for international arbitration, including the judicial review of investor-state arbitration awards.
- A.37. Moreover, it is of no material concern to this Tribunal to what extent its jurisdictional decisions can be reviewed under the *lex loci arbitri*, whether to a greater extent in New York or to a lesser extent in Toronto or vice-versa (as the Parties submitted differently). Whilst not here expressing any view on the scope of judicial review, the Tribunal considers that in general such decisions should be

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<sup>33</sup> *Id.*

reviewable, given that consent to arbitration by the Parties is an essential pre-requisite to the Arbitration Agreement from which this Tribunal derives its jurisdiction to decide the Parties' dispute under NAFTA's Chapter Eleven. Moreover, with the subsequent decision of the US Supreme Court in *BG Group*,<sup>34</sup> the Claimants' concerns as to US law may now seem less well-founded, being based (as they then were) upon the decision of the DC Court of Appeals, since reversed by the US Supreme Court. (The Tribunal returns to the Supreme Court's decision below.)

- A.38. In the circumstances, the Tribunal considered (as it does still) the decisive consideration as between Toronto and New York to be the legal level-playing field provided to all Parties equally under the *lex loci arbitri*.
- A.39. Subject to one factor considered below, the Tribunal considered that, by a whisker, New York should be preferred over Toronto as the legal place of arbitration for this arbitration. First, New York is an older and more established place of arbitration, with its courts long familiar with international arbitration (including the United States Court of Appeals for the Second Circuit). New York has a settled legal system regarding arbitration generally, providing for legal certainty and predictability. In contrast, the 1985 UNCITRAL Model Law (upon which the ICAA is based) is of relatively recent creation. Second, New York is a place not unfamiliar to the Parties. Apotex Inc. and the Respondent jointly agreed to New York as the legal place for their recent arbitration leading to the Apotex I & II Award,<sup>35</sup> with no undue legal mishap for any Party (albeit that the Tribunal recognises that the amount at issue in that arbitration was much less than the amount of the Claimants' claims in this arbitration). Third, but only as a minor supporting factor, Toronto is where the two Claimants have their principal places of business; and a choice of Toronto could thus imbalance the Claimants' interests over those of the Respondent.
- A.40. This one factor concerned the Claimants' submission that US Courts favour the US Government over other litigants. As understood by the Tribunal, the Claimants objected to New York (over Toronto) because of the canon of interpretation enunciated by the US Supreme Court in cases such as *Sumitomo Shoji America, Inc.*

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<sup>34</sup> *Argentina v. BG Group PLC*, 572 U.S. -- (Decided 5 March 2014).

<sup>35</sup> *Apotex Inc. v. United States*, UNCITRAL, Award on Jurisdiction and Admissibility (14 June 2013).

*v. Avagliano*,<sup>36</sup> and *Abbott v. Abbott*,<sup>37</sup> to the effect that US courts are to give “great weight” to the views of the US Government in interpreting US treaties.

- A.41. As evidence of this canon’s continued vitality, the Claimants cited the Second Circuit decision, *Lozano v. Alvarez*,<sup>38</sup> applying this canon of interpretation to the Hague Convention on Child Abduction. In the Claimants’ submission, “US judges are required by established US law to defer to the US Government on issues of treaty interpretation.”<sup>39</sup> For the Claimants, this “would create an uneven playing field for post-award proceedings,”<sup>40</sup> as issues of treaty interpretation are likely to be at the centre of any post-award legal proceedings in New York.
- A.42. The Respondent disputed the characterisation of US law as requiring US courts to defer to the US Government’s views, submitting that “U.S. courts ... are not required by U.S. law to – and do not – provide an ‘unfair advantage in post-award proceedings’ to the U.S. government on treaty interpretation issues.”<sup>41</sup> As summarised above, the Respondent acknowledged that “U.S. courts routinely give great weight to the views of the U.S. government on treaty matters.”<sup>42</sup> However, the Respondent also noted that the US Supreme Court also rejects the US Government’s interpretations of treaty provisions, as it did in *Hamdan v. Rumsfeld*<sup>43</sup> and *Gonzales v. O. Centro Espirita Beneficiente Uniao do Vegetal*.<sup>44</sup>
- A.43. For the Respondent, recent cases like *Abbott v. Abbott* show that the contemporary process of treaty interpretation by US Courts begins with the text of the treaty, assigning only a secondary role to any views by the US Government amongst multiple other extra-textual elements. The Respondent highlighted in this regard writings by Professor David Bederman contending that views of the US

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<sup>36</sup> *Sumitomo Shoji America, Inc. v. Avagliano*, 457 U.S. 176, 184-85 (1982). This case concerned the USA-Japan Friendship, Commerce and Navigation Treaty.

<sup>37</sup> *Abbott v. Abbott*, 560 U.S. 1 (2010). This case concerned the Hague Convention on the Civil Aspects of International Child Abduction.

<sup>38</sup> *Lozano v. Alvarez*, No. 11-2224-cv., --- F.3d ---, 2012 WL 44790007 (2d Cir. 1 October 2012).

<sup>39</sup> The Claimants’ submission, at p. 5 (fn 12) (emphasis omitted).

<sup>40</sup> *Id.*, at p. 1; The Claimants’ surreply submission, at p. 1.

<sup>41</sup> The Respondent’s submission, at p. 5 (footnote omitted).

<sup>42</sup> *Id.*, at p. 5.

<sup>43</sup> *Hamdan v. Rumsfeld*, 548 U.S. 557, 630-634 (2006). This case concerned the Hague Conventions.

<sup>44</sup> *Gonzales v. O. Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418 (2006). This case concerned the United Nations Convention on Psychotropic Substances.



Government are only one of several factors the US Supreme Court now weighs in treaty cases, including elements such as other Governments' views and international tribunals' interpretations.<sup>45</sup> In Professor Bederman's view, no single factor necessarily holds a privileged place.

A.44. As a tribunal created by international law under NAFTA's Chapter Eleven, this Tribunal owes no special deference to the views of the Respondent as a NAFTA Party. This Tribunal's task is to interpret NAFTA in accordance with the international law rules governing treaty interpretation, as provided by NAFTA Article 1131(1). Canons of interpretation operating only in US domestic law are not relevant to this Tribunal. The Tribunal considers that its mandate under NAFTA Article 1131(1) is absolute: it would be a violation of that mandate for this Tribunal to interpret and apply NAFTA's Chapter Eleven taking into account any canon of construction under US law unduly favourable to the Respondent and unfavourable to the Claimants. Hence, any award by this Tribunal could not apply the canon so criticised by the Claimants; and accordingly no jurisdictional decision by this Tribunal should be judicially reviewable before any Court by reference to any such canon.

A.45. The Tribunal nonetheless recognises, as the Parties themselves acknowledged, that the Claimants' deference argument is novel in the NAFTA context. So far as this Tribunal was informed, no US court has addressed this argument in regard to an arbitration award, still less any investor-state award. Thus, the Tribunal faces different and unresolved legal theories as to how a domestic US canon of construction might operate in any possible future US litigation to set aside an award by this Tribunal under NAFTA's Chapter Eleven. On one hand, the US Supreme Court does indeed assert that an administration's treaty interpretation "is entitled to great weight."<sup>46</sup> However, the US Supreme Court also maintains that it should "give respectful consideration to the interpretation of an international treaty rendered by an international court with jurisdiction to interpret" it.<sup>47</sup>

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<sup>45</sup> Bederman, David J., *Agora: Medellín: Medellín's New Paradigm for Treaty Interpretation*, 102 Am. J. Int'l L. 529 (2008).

<sup>46</sup> *Medellín v. Texas*, 552 U.S. 491, 492, 513 (2008).

<sup>47</sup> *Breard v. Green*, 523 U.S. 371, 375 (1998) (*per curiam*).

- A.46. This Tribunal is not a US court. It cannot decide how US courts might resolve the tensions in this uncertain and disputed area of domestic US law. However, the possibility that a deference doctrine might be invoked and upheld in future litigation to set aside an award clearly creates an element of legal uncertainty. Is that theoretical uncertainty a bar to New York as a legal place for this arbitration?
- A.47. The Tribunal answers this question in the negative. The Tribunal would regard the invocation of any deference argument by the Respondent in any future litigation between the Parties over an award by this Tribunal as being wholly inconsistent with the Respondent's commitment to international arbitration under NAFTA Articles 1116 and 1117. In the Tribunal's view, consent by the Respondent to a process of international arbitration under a treaty, such as NAFTA's Chapter Eleven, carries with it an obligation in good faith not to seek an escape from an adverse award by invoking a US domestic law doctrine that is not recognised in, and has no authority, in international law, particularly by virtue of NAFTA Article 1131(1). The Tribunal cannot here assume that the Respondent, by its executive or judicial branches, would violate its obligation under international law.
- A.48. As noted above, following this Tribunal's decision on New York as the legal place of this arbitration on 6 November 2012, the US Supreme Court decided the appeal in *BG Group* on 5 March 2014, restoring the decision of the arbitration tribunal. For the majority of the Supreme Court, in addressing the issues of admissibility and jurisdiction, Justice Breyer decided that US courts "presume that the parties intend arbitrators, not courts, to decide disputes about the meaning and application of particular procedural conditions for the use of arbitration."<sup>48</sup> The Supreme Court found nothing in the United Kingdom-Argentina bilateral investment treaty to overcome this presumption. The Court also rejected the position of the US Solicitor-General that the BIT's local litigation provision should be treated differently because it was a condition laid down in a treaty between States, and not a private party.<sup>49</sup> The Supreme Court saw no reason with a treaty to warrant "abandoning, or increasing the complexity of, our ordinary intent-determining framework" for

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<sup>48</sup> *Argentina v. BG Group PLC*, 572 U.S. -- (Decided 5 March 2014), at p. 8 (Scalia, Thomas, Ginsburg, Alito and Kagan JJ joined with Justice Breyer).

<sup>49</sup> *Id.*, at p. 10.

arbitration agreements.<sup>50</sup> In the Tribunal’s view, this majority decision of the US Supreme Court confirms that a US Court (not limited to New York) presented with an application by a party to review an arbitral award must do so under a “highly deferential” standard in favour of the award, which is inconsistent with the deference to the Respondent’s executive branch raised by the Claimants. The Tribunal acknowledges that the Respondent was not a party to the BIT; and it recognises that the Parties have had no opportunity to comment on the US Supreme Court’s decision. Hence, for present purposes, the Tribunal places no reliance on the Supreme Court’s judgment as a reason for its decision on New York as the legal place of this arbitration.

- A.49. *Conclusion:* Having discounted this remaining factor under consideration (i) potentially weighing against New York and in favour of Toronto, the Tribunal (by a majority) confirms for the reasons stated above that New York should be and is the legal place of this arbitration, as decided pursuant to NAFTA Article 20(1) of the ICSID Arbitration AF Rules. As stated, this is a majority decision: Mr. Rowley’s dissent from these reasons is set out in the following two Paragraphs.
- A.50. *Dissent:* Mr. Rowley agrees that the possibility that a deference doctrine might be invoked and upheld in future litigation to set aside an award does not result in a bar, as such, to the choice by the Tribunal of New York as the legal place for this arbitration.
- A.51. However, where, as here, the decisive consideration in a choice between New York and Toronto is the comparative levelness of the legal playing fields provided under the competing *lex loci arbitri*, Mr. Rowley considers that the US Supreme Court’s requirement for New York courts to give “great weight” to the executive branch’s interpretation of a treaty (here, NAFTA) tips the scale in favour of Toronto. With respect to the majority’s view, expressed in Paragraph A.44 above, it is by no means clear to Mr. Rowley that the canon of interpretation enunciated in cases such as *Sumitomo Shoji America, Inc. v. Avagliano*, and *Abbott v. Abbott* (cited above) is inapplicable in a judicial review by the New York courts of a jurisdictional decision by the Tribunal.

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<sup>50</sup> *Id.*, at p. 12.

## ***PART II – THE PARTIES’ DISPUTE***

### **(1) *Introduction***

- 2.1. The Tribunal summarises below the broad scope of the Parties’ jurisdictional and substantive disputes in these arbitration proceedings. These summaries are made solely for later ease of reference and to ensure that what follows may be more readily comprehensible; and none is intended to describe the full scope of the Parties’ respective cases as presented to the Tribunal in thousands of pages, numerous factual and expert witnesses and a lengthy hearing. In particular, the mere fact that a Party’s submission is not expressly recorded below should not be taken as meaning that the Tribunal has overlooked it or, by itself, that the submission has played no part in the Tribunal’s decisions.
- 2.2. It is appropriate to begin these summaries with the Claimants’ case and to follow with the Respondent’s case. It is then appropriate to address the written submission made under NAFTA Article 1128 by the United Mexican States.

### **(2) *The Claimants’ Case***

- 2.3. In summary, the Claimants contend that the Tribunal has jurisdiction under NAFTA to decide the Parties’ dispute and should decide that the Respondent has violated its substantive obligations towards each of the Claimants (for itself and Apotex-US) under NAFTA, requiring the Respondent to pay substantial monetary compensation to the Claimants, with interest and costs.
- 2.4. *Apotex-Holdings*: According to the Claimants, Apotex-Holdings is a Canadian investor in the generic pharmaceutical industry. It has over the past two decades made substantial investments in Apotex-US, a US company that it indirectly owns and controls. Accordingly, within the meaning of NAFTA’s Chapter Eleven, the Claimants submit that Apotex-Holdings is an “investor” with Apotex-US as its “investment.”
- 2.5. *Apotex-US*: According to the Claimants, the business of Apotex-US is the sale within the USA of drugs produced by other Apotex companies, notably by Apotex Inc., a Canadian generic drug manufacturer that Apotex-Holdings also indirectly

owns and controls. Due to the substantial investment of capital, know-how and expertise by Apotex-Holdings, according to the Claimants, Apotex-US at the beginning of 2009 was one of the most successful generic drug companies in the USA measured by sales volume. As at mid-2009, Apotex-US had the sixth-highest sales of any generic drug company in the USA.

- 2.6. *Apotex Inc.:* Apotex Inc. operates several facilities in Canada. Two of its production facilities are located at: (i) Signet Drive in Toronto, Ontario (“Signet”) and (ii) Etobicoke, Ontario (“Etobicoke”). The Signet and Etobicoke facilities produce oral solid-dose medicinal products, such as tablets. Certain of these products were sold by Apotex-US on the US market; and, as at mid-2009, those products accounted for about 80% of sales by Apotex-US in the USA. The Etobicoke facility also performed research and development; and the Signet facility was seeking to produce drug products in injectable form.
- 2.7. According to the Claimants, Apotex Inc. is also an “investor” within the meaning of NAFTA’s Chapter Eleven, having as its “investment” Abbreviated New Drug Applications (“ANDAs”) approved by the US Food and Drug Administration (“FDA”), also called by the Claimants “marketing authorizations.” The Claimants further submit, given that Apotex Inc. is indirectly owned by Apotex-Holdings, that these ANDAs are also an “investment” of Apotex-Holdings. At the time of the FDA’s Import Alert in August 2009 (described below), Apotex Inc. had 153 ANDAs permitting the sale of its drugs in the USA manufactured at its two Canadian facilities (ANDAs being site specific).
- 2.8. *State Regulators:* As a Canadian drug manufacturer, Apotex Inc. was and remains primarily regulated and controlled by Health Canada, an agency of the Canadian State. Apotex Inc.’s facilities have been regularly inspected by Health Canada since the mid-1970s. Because Apotex Inc. also supplies the US drug market, its production sites have also periodically been inspected by the FDA, as an agency of the Respondent.
- 2.9. As acknowledged by the Claimants, inspections by Health Canada and the FDA customarily address a multitude of matters associated with modern pharmaceutical production. These include what are known as current good manufacturing practices

("cGMP"), being standards developed through consultations between industry and regulatory agencies and then codified in regulations. These regulatory standards address, among other topics, the proper design, monitoring and control of drug manufacturing processes at facilities, such as Signet and Etobicoke.

- 2.10. *The Act*: Under the US Federal Food, Drug and Cosmetic Act ("the Act"), the FDA assesses conformity with cGMP in part through on-site inspections of pharmaceutical manufacturing facilities, both within the USA and abroad. Because the FDA's cGMP standards are by their nature general, according to the Claimants, their application to specific processes, equipment and facilities leaves much to the discretion of manufacturers.
- 2.11. At the conclusion of a facility's inspection, FDA inspectors record their written observations on a standard form known as "Form 483." A Form 483 lists inspectional observations; they do not represent the FDA's final determination regarding a manufacturer's compliance with cGMP standards. A manufacturer may provide comments on the FDA inspectors' observations to the FDA; and these observations and comments are reviewed by the FDA.
- 2.12. If the FDA decides that the manufacturer has not responded adequately to significant cGMP violations at the facility, the FDA may issue a "warning letter." According to the Claimants, a manufacturer is afforded an opportunity to comment to the FDA in response to a warning letter; and the FDA typically takes that comment into account in determining whether or not to take enforcement actions against the manufacturer and its facility.
- 2.13. Such enforcement actions could include the seizure of the manufacturer's products or a civil action in the US courts seeking injunctive relief against the manufacturer. Such an injunction (issued by a US court) could preclude the continued marketing of affected products until the FDA confirms the manufacturer's compliance with cGMP.
- 2.14. According to the Claimants, the Act also authorises the Respondent to detain, physically examine and refuse admission of a product into the USA if the product is "adulterated" within the meaning of the Act. Under US legislation, a drug is considered "adulterated" if the methods or facilities used to produce it do not

conform to cGMP so as to ensure the safety, identity, strength, quality and purity of the drug required by the Act.

- 2.15. Based on the Act, according to the Claimants, the FDA has created a measure known as an import alert; *i.e.* a notice by the FDA to US customs officials added to a general import alert that calls for detention without physical examination of a specified category of products. In practice, the result often is not the actual detention of a product; but a refusal at the US border of admission into the USA of all products within the specified category.
- 2.16. *FDA Inspections:* Before 2008, the FDA had inspected Apotex Inc.'s facilities in Signet and Etobicoke on numerous occasions since 2002. Until 2008, according to the Claimants, the FDA had never recorded any cGMP violation at these two facilities (nor at any other Apotex facilities elsewhere).
- 2.17. In April 2002, May 2005 and November 2006, the FDA had inspected the Etobicoke facility; and the FDA had inspected the Signet facility in September 2000, March 2003 and June 2006. During the 2000, 2002 and 2006 inspections, FDA inspectors made certain observations concerning cGMP at these two facilities; but, after receiving Apotex Inc.'s clarifications, the FDA found cGMP compliance at both facilities to be sufficient.
- 2.18. *The 2008 Etobicoke Inspection:* From 10 to 19 December 2008, the FDA inspected Apotex Inc.'s facility at Etobicoke. At the end of this inspection, the FDA inspectors issued three pages of observations on their Form 483, listing 11 alleged deviations from cGMP. According to the Claimants, the FDA inspectors did not suggest that their observations raised any actual concern as to the continued manufacture or distribution in the USA of drugs manufactured at Etobicoke.
- 2.19. Later, on 30 January 2009, Apotex Inc. provided an eight-page written response to the FDA inspectors' observations. As promised in its response, so the Claimants contend, Apotex Inc. enhanced its quality and manufacturing processes and equipment at Etobicoke in the first half of 2009. Apotex Inc. received no further communication from the FDA concerning Etobicoke for several months, until June 2009.

- 2.20. *The Etobicoke Warning Letter:* On 25 June 2009, the FDA issued a warning letter identifying three issues of concern to the FDA (the “Etobicoke warning letter”). The Claimants contend that only two of these issues concerned cGMP. Of these, the first was not identified as an issue by the FDA inspectors on their Form 483 observations; and the second issue was stated as a request for further information, rather than a finding of any violation. The remaining Form 483 observations were either resolved by Apotex Inc.’s response or otherwise not adopted by the FDA.
- 2.21. *The 2009 Signet Inspection:* From 27 July to 14 August 2009, the FDA inspected Apotex Inc.’s facility at Signet. At the close of the inspection, the FDA inspectors issued a list of 17 observations on their Form 483. The FDA inspectors asked Apotex Inc. to schedule a telephone conference call with the FDA to discuss these observations. (This was on Friday, 14 August 2009).
- 2.22. On Monday, 17 August 2009 (*i.e.* one working day later), Apotex Inc. held the required conference call with the FDA. While noting that it was still studying the Form 483 observations, Apotex Inc. undertook voluntarily to recall 675 batches of drug products from the US market as a precautionary measure.
- 2.23. By an internal memorandum dated 20 August 2009, the FDA’s director of compliance for drug products requested that the FDA director of import operations amend the existing Import Alert 66-40 to include all products manufactured at the Etobicoke and Signet facilities. The request was made without the benefit of Apotex Inc.’s written response to the Signet Form 483 (which was only due on 4 September 2009); and the FDA had provided no prior notice to Apotex Inc. of its proposed enforcement action.
- 2.24. *The 2009 Import Alert:* On 28 August 2009, the FDA amended Import Alert 66-40 to include all products produced by the Etobicoke and Signet facilities (the “Import Alert”). The Claimants contend that the FDA provided no notice of this measure to Apotex Inc. or any other Apotex company. The measure prevented Apotex-US from receiving for sale in the USA any product manufactured at the Etobicoke and Signet facilities. In addition, the FDA suspended consideration of any new ANDAs for drugs produced or to be produced by Apotex Inc. at these two facilities. It therefore prohibited Apotex-US from bringing to market any of Apotex Inc.’s new solid dose



generic drugs, effectively eliminating Apotex-US's ability to secure the advantage of statutory marketing exclusivity for new products in the USA.

- 2.25. The Import Alert remained in place for a period of almost two years. The FDA did not lift in full the Import Alert regarding both Etobicoke and Signet facilities until the end of July 2011, belatedly so according to the Claimants.
- 2.26. The Claimants contend that the FDA's actions taken against Apotex Inc. were exceptional, indeed unique, as the FDA itself recognised in public speeches made by its senior officers at the time. According to the Claimants, the FDA had never before rushed to take action against a major pharmaceutical company in the absence of any actual or imminent health hazard and without providing to such company any real opportunity to address the FDA's concerns. The Claimants also complain at the FDA's complete lack of procedural due process: the Import Alert was issued without any notice to the Claimants; no reasons for the notice were made known to the Claimants; no opportunity was granted to the Claimants to dispute the notice or even to present evidence in support of the Claimants' position; and no access was accorded to any court for judicial review or even any review by an impartial decision-maker. The Claimants allege, in particular, that the purpose of the FDA's Signet inspection was "was to identify cGMP deviations to support an Import Alert. FDA's judgment against Apotex had already been made."<sup>1</sup> The Claimants also allege that the FDA's true reason for the Import Alert "was to demonstrate FDA's new tough enforcement policy and to provide an example which FDA could hold out for the world to see" and in its rush to judgment "to make Apotex an example ... even though its treatment of Apotex was completely unjustified."<sup>2</sup>
- 2.27. *Jurisdiction:* The Claimants contend that no jurisdictional issue can arise in regard to Apotex-Holdings and Apotex-US respectively as a qualified "investor" and a covered "investment" under NAFTA Chapter Eleven. As regards the Import Alert, the Claimants submit that it did "relate to" Apotex-US within the meaning of NAFTA Article 1101(1): Apotex-US was established specifically as the marketing and distribution arm of Apotex Inc. (to which the Import Alert was directed); Apotex Inc. sold its products exclusively through Apotex-US in the USA; Apotex-

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<sup>1</sup> TD6.1554.

<sup>2</sup> TD6.1556; TD1.88.

US was the sole commercial importer and distributor of record for drugs manufactured at the Etobicoke and Signet facilities; following the Import Alert, Apotex-US was a named addressee of the Respondent's notices of detention; and the Import Alert directly prevented Apotex-US from carrying on its business for almost two years, causing it to suffer severe financial losses. Hence, so the Claimants argue, the Import Alert "related" both to Apotex-US as an "investment" and also to its "investor", Apotex-Holdings.<sup>3</sup>

- 2.28. As regards Apotex Inc., the Claimants contend that its ANDAs are "intangible property" under NAFTA Article 1139(g). The Claimants further submit that ANDAs are "interests" under NAFTA Article 1139(h). Hence, so the Claimants argue, Apotex Inc. is an "investor" with its ANDAs as "investments" and, further, Apotex-Holdings is an "investor" with the same "investments", given its status as the ultimate (indirect) owner of Apotex Inc.<sup>4</sup>
- 2.29. The Claimants contend that, as a matter of jurisdiction, there can be no jurisdictional objection arising from the Apotex I & II Award made by the NAFTA Tribunal in the "Apotex I & II Arbitration"<sup>5</sup> (to which the Tribunal returns below), as argued by the Respondent.<sup>6</sup>
- 2.30. *Liability*: The Claimants contend that the Import Alert violated NAFTA Article 1102 (National Treatment), Article 1103 (Most-Favoured-Nation Treatment) and Article 1105 (Minimum Standard of Treatment). The Claimants also contend, by virtue of NAFTA Article 1103 and Annex IV, that the Respondent also violated Article II(2) and II(6) of the Jamaica-USA BIT.
- 2.31. Articles 1102 & 1103: During the relevant time period, the Claimants contend that the FDA accorded more favourable treatment to US investors and US owned investments in like circumstances to Apotex-Holdings, Apotex Inc. and Apotex-US in violation of NAFTA Article 1102. The Claimants submit that no such investor or investment was subjected to a measure as severe as the Import Alert imposed on the Apotex companies. The Claimants also contend that investors of other countries and

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<sup>3</sup> Apotex Memorial, Paras. 410-413; Apotex Reply, Paras. 254-259; TD6.1561ff.

<sup>4</sup> Apotex Memorial, Paras. 349ff; Apotex Reply, Paras. 206ff; TD3.544ff; TD6.1569ff.

<sup>5</sup> *Apotex Inc. v. United States, supra*.

<sup>6</sup> Apotex Rejoinder on Jurisdiction, Paras. 95-110; TD3.541ff; TD6.1571ff.

investments owned by such investors in like circumstances also received more favourable treatment than the treatment accorded to the Apotex companies in violation of NAFTA Article 1103. The Claimants refer to a number of such comparators, particularly the Teva group of companies (“Teva”) and the Sandoz/Novartis companies (“Sandoz”).<sup>7</sup>

- 2.32. Article 1105: The Claimants complain at the FDA’s lack of basic procedural due process, amounting to a violation by the Respondent of NAFTA Article 1105 and Article II of the Jamaica-USA BIT.<sup>8</sup> Whilst the Claimants do not agree in this proceeding with the FDA’s determination that Apotex Inc.’s two facilities were not compliant with cGMP, the Claimants do not, however, here seek to impugn the FDA’s substantive decisions: *i.e.* “[w]hether FDA was right or wrong about Apotex’s cGMP compliance ... is not a part of the claims presented in this case.”<sup>9</sup>
- 2.33. The Jamaica-USA BIT: The Claimants submit that, with the FDA’s deficient procedure regarding the Import Alert, the Respondent violated Article II(2)(b) & (6) of the Jamaica-USA BIT.<sup>10</sup>
- 2.34. *Quantum*: Because of the Import Alert, according to the Claimants, Apotex-Holdings, Apotex Inc. and Apotex-US suffered substantial damage. In particular, Apotex-US’s business was decimated, with 80% of its supplies cut-off from Canada; Apotex Inc. and Apotex-US lost sales in excess of US\$ 500 million; Apotex-US dropped from being a market leader for generic drugs in the USA to the bottom ranks; and Apotex Inc. was prevented from bringing any new drugs to the US market. The Claimants estimate that financial losses to the Claimants resulting from the Respondent’s violations of NAFTA amount to between US\$ 1.0 billion to US\$ 1.5 billion (as at early 2013) for which the Respondent is liable to pay compensation to the Claimants, subject to upward revision for continuing losses.<sup>11</sup>

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<sup>7</sup> Apotex Request, Paras. 77-79; Apotex Memorial, Paras. 442-452; Apotex Reply, Paras. 261ff; TD2.321ff; TD6.1580ff.

<sup>8</sup> Apotex Request, Paras. 85-87; Apotex Memorial, Paras. 454-487; Apotex Reply, Paras. 389ff; TD2.457ff; TD6.1602ff.

<sup>9</sup> TD1.13; Apotex Reply, Para. 6.

<sup>10</sup> Apotex Memorial, Paras. 478-487; Apotex Reply, Paras. 515-531; TD2.527ff.

<sup>11</sup> TD6.1615.

2.35. Given that all quantum issues have been bifurcated to another phase of these proceedings (if and to the extent relevant), it is unnecessary to describe the Claimants' case on quantum any further.

2.36. *Relief:* Accordingly, the Claimants seek a decision in their favour, as against the Respondent, on both jurisdiction and liability; namely dismissing the Respondent's jurisdictional objections; holding that the Respondent has breached NAFTA Articles 1102, 1103 and 1105 and the Jamaica-USA BIT; and ordering a further phase of this proceeding on damages in accordance with the formal relief recorded in their written pleadings, as set out in Part I above and confirmed in their closing oral submissions at the Hearing.<sup>12</sup>

**(3) *The Respondent's Case***

2.37. In summary, the Respondent contends that the Tribunal has no jurisdiction to decide the Parties' dispute under NAFTA; and, if the Tribunal were to exercise jurisdiction over any of the Claimants' claims, that the Tribunal should decide that the Respondent has not violated any of its substantive obligations under NAFTA or the Jamaica-USA BIT; and that no compensation is payable to the Claimants. According to the Respondent, the Tribunal should deny all the Claimants' claims concerning the Respondent's lawful and appropriate exercise of its authority to protect the health of its own people in its own territory. The Tribunal should also recognise, according to the Respondent, that the Claimants' complaint is in fact directed at a trade measure, addressed only to Apotex Inc.'s two foreign facilities, and that the Claimants are seeking improperly in these proceedings to convert a possible trade-related claim between NAFTA Contracting States (under NAFTA Chapter Twenty) into an investment claim by a foreign entity (under NAFTA Chapter Eleven).

2.38. The Respondent also contends that, for more than a century, the Respondent has established laws and regulations to prevent the importation of adulterated drugs in order to protect public health in the USA. The FDA's policy on import alerts has been in effect since at least the 1970s. The Respondent did not relinquish this authority and responsibility when it concluded NAFTA. Nor did the Respondent

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<sup>12</sup> TD7.1745; Apotex Reply, Para. 532.

(with its NAFTA Contracting Parties) establish the form of investment arbitration under NAFTA's Chapter Eleven to resolve complaints by foreign entities whose adulterated drugs have been turned away at the US border.

- 2.39. The Respondent contends that the material facts in this case are largely undisputed between the Parties, as listed below (according to the Respondent).
- 2.40. *The 2008 Etobicoke Inspection:* In December 2008, the FDA inspected Apotex Inc.'s manufacturing facilities at Etobicoke following complaints from US patients, doctors and pharmacists about problems with Apotex drugs. The eight-day inspection by the FDA inspectors uncovered significant violations of US laws and regulations, including numerous deviations from cGMP. The FDA inspectors informed Apotex Inc. of their findings at the close of this inspection.
- 2.41. *The 2009 Etobicoke Warning Letter:* The FDA subsequently issued to Apotex Inc. a "warning letter" dated 25 June 2009, apprising Apotex Inc. that drugs from its Etobicoke facility were adulterated under US law and thus could be denied admission to the USA. The FDA further warned Apotex Inc. that the FDA could withhold approval of new drug applications linked to the Etobicoke facility. Apotex Inc. acknowledged serious problems with its manufacturing practices and promised to implement corrective action.
- 2.42. *The 2009 Signet Inspection:* In August 2009, the FDA's inspectors inspected Apotex Inc.'s Signet facilities. This inspection was prompted by the serious cGMP deficiencies found at the Etobicoke facilities and by additional complaints that the FDA had received concerning the quality and efficacy of Apotex's products in the USA.
- 2.43. According to the Respondent, this 14-day inspection by the FDA's inspectors uncovered significant violations of US laws and regulations at the Signet facility, including numerous cGMP deficiencies, several of which mirrored those found at the Etobicoke facility. These violations affected many products and confirmed systemic problems with Apotex Inc.'s entire manufacturing program. The FDA inspectors found that Apotex had distributed products in the US market contaminated with hair, glue, plastic, nylon, metal, rust, acetate fibres, fluorocarbons and PVC-based material. The FDA inspectors also cited Apotex Inc.

for improperly produced and misbranded drug products; poor cleaning practices; a failure to investigate or report manufacturing problems properly; inadequate production procedures; poor recordkeeping; and numerous other serious failings.

- 2.44. *The Import Alert:* The FDA placed Apotex Inc.’s Etobicoke and Signet facilities on “Import Alert” in August 2009, signalling that drugs from those facilities were adulterated and could be detained at the US border without physical examination. Apotex Inc. did not dispute FDA’s cGMP findings or protest at having been placed on Import Alert. Nor did Apotex Inc. exercise its right to challenge the FDA’s actions in US administrative proceedings or in US federal court.
- 2.45. After being placed on Import Alert in August 2009, Apotex Inc. accepted responsibility for systemic problems with its manufacturing practices; recalled adulterated drug products from the US market; hired third-party consultants to help bring its facilities into compliance with US law; and promised to overhaul its operations, management structure, and quality control systems.
- 2.46. Apotex Inc.’s primary regulator, Health Canada, launched its own inspections of the Etobicoke and Signet facilities. Health Canada corroborated the FDA’s findings, recording 37 “major observations” at these two sites. Health Canada discovered, for instance, “a dead insect or insect fragment” in active pharmaceutical ingredients, prompting Apotex Inc. to recall drugs using those ingredients from the Canadian market. Health Canada further faulted Apotex Inc. for using the same material to fabricate cytotoxic and non-cytotoxic materials without taking proper precautions to prevent cross-contamination, being a violation that alone would have warranted stripping Apotex Inc. of its establishment license under Canadian law. Health Canada also discovered that Apotex Inc. had, among other violations, misreported test results; released failed products for sale in Canada; failed to conduct timely investigations of potentially unsafe products; and delayed recalling product until long after learning of health risks to patients. Apotex Inc. also acknowledged problems with its manufacturing practices and pledged to address the “system deficiencies highlighted by them.” Health Canada opted not to shut down Apotex Inc.’s facilities (because Apotex is Canada’s largest supplier of generic drugs); but it placed Apotex under close and continuous on-site supervision for more than a year, so as to ensure that Apotex followed through with its promised corrective actions.

- 2.47. During 2009 and 2010, the FDA communicated continuously with Apotex on how to achieve sustainable compliance with US law, devoting extraordinary agency resources to that task. Apotex Inc. only notified FDA that its facilities would be ready for re-inspection in October 2010, more than a year after the FDA's Import Alert.
- 2.48. The FDA's follow-up re-inspections of the Etobicoke and Signet facilities in January and February 2011 revealed significant and on-going cGMP problems; and accordingly the FDA investigators recommended against the lifting of the Import Alert. Nonetheless, after evaluating Apotex's corrective reactions and its plans for continued improvements, the FDA decided to lift the Import Alert as regards products manufactured at the Etobicoke and Signet facilities. The FDA also resumed its evaluation of whether, from a cGMP perspective, the FDA could approve Apotex's drug applications from the Etobicoke and Signet facilities.
- 2.49. The Respondent contends that the Claimants do not materially dispute any these facts. The Claimants, according to the Respondent, merely belittle and disregard their serious nature. The Respondent contends that the FDA cannot allow a company to market drugs in the USA, in the Claimants' language, that "almost without exception" are safe and effective; or that fail testing "only" 11 per cent of the time; and that when serious manufacturing and quality control problems are identified by the FDA, mere "good will gestures" by Apotex Inc. should suffice for the FDA. As the meningitis outbreak in the USA tragically demonstrated, pharmaceutical products manufactured in violation of cGMP can be deadly for patients. The Respondent submits that all companies, foreign and domestic, must comply with current good manufacturing practice to market their drugs to patients in the USA.
- 2.50. The Respondent submits that the Claimants are wrong to blame the FDA for having prevented Apotex Inc. from exporting adulterated drugs to the USA; and wrong to claim that the Respondent (*i.e.* the US taxpayer) should compensate Apotex Inc. for the costs of bringing its own manufacturing practices into compliance with US law. The Respondent also submits that the Claimants are wrong in asserting their claims as an investment dispute in order to claim significant damages from the Respondent as a foreign investor under NAFTA's

Chapter Eleven. The Respondent accordingly disputes the Claimants' case, both as a matter of jurisdiction and on the merits.

- 2.51. *Jurisdiction:* In regard to the Claimants' claim that Apotex Inc., a Canadian drug manufacturer with facilities only in Canada, is an "investor" that made and sought to make "investments" in the USA, the Respondent submits that the Claimants have failed to establish that Apotex Inc. has made or even sought to make any investments in the USA within the meaning of "investment" and "investor" in NAFTA's Chapter Eleven. The Respondent submits that Apotex Inc. does not claim to manufacture or even test any drugs in the USA; nor does it assert the existence of any offices or employees in the USA; it pays no taxes in the USA on its supposed investments (including its ANDA-related activities); it does not claim to prepare its drug applications to the FDA in the USA; and it does not own or control Apotex-US.<sup>13</sup>
- 2.52. According to the Respondent, the issue of jurisdiction in regard to Apotex Inc. turns decisively upon the character of its ANDAs. The Respondent submits that ANDAs, whether unapproved, tentatively approved or finally approved (in whole or in part) are incapable of being "investments" under NAFTA Article 1139(g) or Article 1139(h). Even after approval, ANDAs remain revocable by the FDA; and, in the Respondent's submission, an ANDA is no more than an application by a foreign drug manufacturer for permission to export its drug products to the USA.<sup>14</sup>
- 2.53. Further, the Respondent relies upon the reasoning to this effect, operating as *res judicata* in this arbitration, contained in the Apotex I & II Award. Although that earlier arbitration decided claims relating to tentatively approved ANDAs (rather, as here, finally approved ANDAs), the Respondent submits that this is a distinction without a difference. The Respondent invites the Tribunal to reject jurisdiction over all claims made by Apotex Inc. and related claims by Apotex-Holdings.<sup>15</sup> (The Respondent does not here contend that the Apotex I & II Award has any preclusive effect on Apotex-Holdings' claim to be an investor by virtue of its

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<sup>13</sup> USA Counter-Memorial, Paras. 220, 233-244; USA Rejoinder, Paras. 95ff.

<sup>14</sup> USA Counter-Memorial, Paras. 222-232; USA Rejoinder, Paras. 111ff; TD5.1248ff; TD6.1681ff.

<sup>15</sup> USA Counter-Memorial, Para. 219; USA Rejoinder, Para. 208; TD4.1177ff; TD5.1211ff; TD6.1642ff.



investment in Apotex-US, being “a jurisdictional issue obviously not arbitrated or determined in the previous proceeding.”)<sup>16</sup>

- 2.54. As regards Apotex-Holdings’ other claims, the Respondent agrees that Apotex-Holdings is an “investor” within the meaning of NAFTA Article 1139(a). The Respondent accepts that Apotex-Holdings committed to establish Apotex-US as a US distributor of generic drugs; hence Apotex-US may be regarded as an investment by Apotex-Holdings; but that is not enough, according to the Respondent, to establish Apotex-Holdings’ investment claim under NAFTA’s Chapter Eleven.<sup>17</sup>
- 2.55. The Respondent submits that NAFTA’s Chapter Eleven also requires that the challenged measure “relate to”, or in other words have a “legally significant connection” to the investor or the investor’s investment. The only measure challenged by the Claimants in this case is the Import Alert; but that Import Alert did not “relate to” Apotex-Holdings as an investor, nor to Apotex-US as an investment which continued to market generic drugs in the USA throughout the period of the Import Alert.<sup>18</sup>
- 2.56. The Respondent also contends that an Import Alert operates under US law only as internal agency guidance: it does not now provide for “automatic detention”;<sup>19</sup> and “[i]t is neither necessary nor sufficient for the detention of drugs.”<sup>20</sup> The Respondent submits that products shipped by Apotex Inc. were detained at the USA-Canadian border because such products were adulterated. The relevant measure, according to the Respondent, was either: (i) the FDA’s determination that Apotex Inc.’s two facilities were not cGMP compliant and its products therefore adulterated under US law; or (ii) the Respondent’s notices of detention addressed to Apotex Inc.’s consignees in the USA, *i.e.* Apotex- US (but equally so any other consignee of products made at these two facilities). The Claimants, however, do not complain about either of these two measures in these proceedings.

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<sup>16</sup> TD4.1194.

<sup>17</sup> USA Counter-Memorial, Para. 15.

<sup>18</sup> USA Counter-Memorial, Paras. 287-319; TD5.1282ff.

<sup>19</sup> TD7.1777.

<sup>20</sup> TD6.1686.

- 2.57. The Respondent acknowledges that Apotex Inc. was effectively prevented from exporting its drugs to any US distributor, including Apotex-US. The Respondent contends that, although the Claimants seek to show that the Import Alert particularly related to Apotex-US because of its relationship with Apotex Inc., the Claimants' arguments directly contradict formal statements previously made by Apotex companies before several US courts to the effect that Apotex Inc. and Apotex-US are separate and independent companies. According to the Respondent, the Claimants cannot here opportunistically argue one thing to establish jurisdiction before this Tribunal; but the opposite when seeking to avoid jurisdiction before US courts.
- 2.58. The Respondent invites the Tribunal to reject jurisdiction over all claims made by Apotex Inc. and Apotex-Holdings.
- 2.59. *Liability*: As to the merits of the Claimants' claims (assuming jurisdiction), the Respondent contends that the Claimants do not dispute that Apotex Inc.'s drugs were adulterated as a matter of US law; nor do the Claimants challenge the underlying legality of import alerts as a policy exercisable by the FDA, given similar policies by Canada and other States.
- 2.60. Articles 1102 & 1103 NAFTA: The Respondent denies any breach of NAFTA Articles 1102 and 1103. It also denies any breach of the Jamaica-USA BIT. In particular, the Respondent contends that the Claimants' claims that the Respondent accorded better treatment to US and foreign companies, in violation of NAFTA Articles 1102 (national treatment) and 1103 (most-favoured-nation treatment), suffer from three major defects.<sup>21</sup>
- 2.61. First, the Claimants cannot establish a national or most-favoured-nation treatment claim because the Import Alert (which applied to Apotex Inc.'s two Canadian manufacturing facilities) had no legally significant connection to Apotex-Holdings as an "investor" or to Apotex-US as its "investment" under NAFTA Article 1101;

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<sup>21</sup> USA Rejoinder, Paras. 211 and 282.

and neither Apotex-Holdings nor Apotex-US received any relevant “treatment” under NAFTA Articles 1102 and 1103.<sup>22</sup>

- 2.62. Second, the Claimants cannot establish a national treatment claim under NAFTA Article 1102, because the Claimants have failed to identify any comparators in “like circumstances.” In particular, the Claimants cite the FDA’s treatment of drug manufacturing facilities in the USA; but these are obviously not subject to import alerts; and thus they cannot be in “like circumstances” with Apotex Inc., with only foreign facilities in Canada.<sup>23</sup>
- 2.63. Third, the Claimants cannot establish a most-favoured-nation treatment claim under NAFTA Article 1103, because the Claimants have failed to identify any third country-owned comparator that received in like circumstances more favourable treatment than the Claimants. Of the comparators cited by the Claimants, for instance, one drug manufacturer shut down the operations of its non-compliant facilities; and another manufacturer had two facilities placed on import alert for more than three years, forfeited dozens of drug applications and set aside US\$ 500 million for potential civil and criminal penalties. The Respondent submits that the Claimants’ allegation that the Respondent discriminated in favour of these foreign manufacturers is factually wrong.<sup>24</sup>
- 2.64. Article 1105 NAFTA: The Respondent submits that the Claimants’ claim under NAFTA Article 1105 claim is baseless on the merits. The Respondent notes that the Claimants contend that the FDA (*i.e.* the Respondent) should have allowed Apotex Inc. to continue exporting adulterated drugs to the USA until it had been afforded six “procedural safeguards”: (i) a hearing; (ii) with advance notice; (iii) before an impartial body; (iv) where the party may present evidence and contest the decision; (v) with a reasoned decision relying on all relevant legal and factual considerations; and (vi) with judicial review of that decision. Failure to provide these, so the Claimants assert, put the Respondent in violation of the customary international law minimum standard of treatment. The Respondent denies that

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<sup>22</sup> USA Counter-Memorial, Paras. 328-329; USA Rejoinder, Paras. 212-214; TD5.1386ff.

<sup>23</sup> USA Counter-Memorial, Paras. 330-333; USA Rejoinder, Paras. 215-248.

<sup>24</sup> USA Counter-Memorial, Paras. 334-343; USA Rejoinder, Paras. 249-281; TD6.1658ff.

these are customary rules of international law that form part of the minimum standard of treatment under NAFTA Article 1105.<sup>25</sup>

- 2.65. The Respondent submits that the Claimants have not established their supposed new standard as rule of customary international law, nor any general and consistent practice of States followed from a sense of legal obligation requiring these generous “safeguards” before blocking the importation of foreign adulterated drugs. The Respondent submits that the Claimants have merely plucked their proposed new rule from soft law sources, law review articles, working papers, and human rights, trade and European Union decisions that have no bearing on this case. The Respondent submits that international law does not require that a State continue to allow the import of adulterated drugs whilst the foreign manufacturer conducts litigation over that State’s decision to bar such imports made on grounds of public health and for the safety of its own people; and that, if it did, the implications of any such rule would be enormous and potentially dangerous for patients.
- 2.66. Currently, the USA imports about 40% of its finished drug products and about 80% of its active pharmaceutical ingredients (“API”) from more than 100 countries around the world. The heparin scandal in 2007, caused by a contaminant in the drug’s API manufactured at a facility in China, demonstrates, according to the Respondent, the “difficult and complicated balancing of risk” required of the FDA.<sup>26</sup>
- 2.67. Moreover, so the Respondent submits, even if the Claimants could demonstrate the existence of such a new rule of customary international law, the evidence shows that the Respondent actually offered the Claimants the “procedural safeguards” they now claim were due to them, both as administrative and judicial processes. But the Claimants chose not to invoke them, for good reasons: Apotex Inc. acknowledged as significant its cGMP violations; its third party consultants confirmed the findings of the FDA’s inspectors; and Apotex Inc. took over a year to prepare itself for the FDA’s re-inspections.

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<sup>25</sup> USA Counter-Memorial, Paras. 344-390; USA Rejoinder, Paras. 283-377; TD6.1674ff.

<sup>26</sup> TD6.1627.

- 2.68. Jamaica-USA BIT: The Respondent submits that the Jamaica-USA BIT does not assist the Claimants' case under NAFTA Article 1105 or at all: its terms add nothing to NAFTA Article 1105 (read with the Free Trade Commission's binding interpretation); and NAFTA Article 1103 cannot expand the substantive scope of NAFTA Article 1105. For all these reasons, the Respondent denies any breach of NAFTA Article 1105 and Article II of the Jamaica-USA BIT.<sup>27</sup>
- 2.69. *Quantum*: As to the quantum of compensation claimed by the Claimants, the Respondent denies the basis on which these claims are made. The Respondent notes that the quantum of the Claimants' claim is [REDACTED] times greater than their claimed sales in the USA, [REDACTED] times greater than their annual worldwide sales (in more than 115 countries) and greater than the value of the entire Apotex group of companies.
- 2.70. As already indicated, given that quantum is not an issue for present purposes, it is unnecessary here to summarise the Respondent's case on quantum any further.
- 2.71. *Relief*: Accordingly, the Respondent submits that the Claimants' claims fall outside the scope and coverage of NAFTA's Chapter Eleven. As a matter of jurisdiction and/or, alternatively, the merits as to liability, the Respondent requests the Tribunal to dismiss the Claimants' claims with prejudice and in either case to award to the Respondent, against the Claimants, the full costs of these arbitration proceedings, in accordance with the formal relief recorded in its written pleadings, as set out above and confirmed in its closing oral submissions at the Hearing.<sup>28</sup>

**(4) *The Submission of the United Mexican States***

- 2.72. In summary, with its written submission of 9 February 2013 under NAFTA Article 1128, the United Mexican States ("Mexico") addresses NAFTA Article 1101(1) and Article 1139(h), recording its concurrence with the written submissions made by the Respondent in its Counter-Memorial (at Paragraphs 245-263).<sup>29</sup> (This submission did not address NAFTA Article 1139(g) separately).

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<sup>27</sup> USA Counter-Memorial, Paras. 344-347; USA Rejoinder, Para. 283; TD5.1451ff and 1522ff.

<sup>28</sup> TD6.1716-1717 and TD7.1778-1779.

<sup>29</sup> Mexico Article 1128 Submission, Para. 3.

- 2.73. Mexico submits that NAFTA Article 1101(1) is the jurisdictional gateway to the dispute resolution and other provisions in NAFTA’s Chapter Eleven,<sup>30</sup> as it establishes and places limits on the scope and coverage of Chapter Eleven.<sup>31</sup> As such, Mexico submits that Article 1101(1) is a necessary component of the context required to interpret Article 1139(h).<sup>32</sup>
- 2.74. Mexico contends that it follows from Article 1101(1) that investments, as defined by Article 1139(h), of an investor of a Party can only fall within the scope and coverage of Chapter Eleven if they are located in the territory of another Party.<sup>33</sup> Mexico submits that an investor of a Party must make a commitment of capital or other resources in the territory of another Party in order to make an “investment” within the meaning of Article 1139(h).<sup>34</sup>
- 2.75. To the extent that a comparison of NAFTA’s three language versions may reveal a difference of meaning in the text of NAFTA Article 1139(h), Mexico submits, by applying Article 33(4) of the Vienna Convention on the Law of Treaties, that any perceived discrepancy between the English and French texts (on the one hand) and the Spanish text (on the other) is best reconciled by upholding the territoriality requirement in Article 1139(h).<sup>35</sup> Mexico bases this submission upon the consistency of the English and French versions of Article 1139(h) with Article 1101(1).<sup>36</sup>

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<sup>30</sup> *Id.*, Para. 4, citing *Methanex Corporation v. United States of America*, UNCITRAL, First Partial Award (7 August 2002), Para. 106.

<sup>31</sup> *Id.*, Para. 4.

<sup>32</sup> *Id.*, Paras. 3-4.

<sup>33</sup> *Id.*, Para. 5.

<sup>34</sup> *Id.*, Para. 6. Mexico further submits that a failure to take into account the territoriality requirement of NAFTA Article 1101(1) as a part of the context in interpreting Article 1139(h) would render the “scope and coverage” limitations in the former provision meaningless (Para. 8).

<sup>35</sup> *Id.*, Para. 7.

<sup>36</sup> *Id.*

## ***PART III – THE PRINCIPAL FACTS***

### **(1) *Introduction***

- 3.1. It is necessary at the outset to summarise the principal facts relevant to the Tribunal's reasons for its several decisions below, many of which are materially fact specific or at least require factual explanations. Whilst there is much common ground between the Parties as regards these principal facts, there remain significant differences, especially in regard to foreign comparators under NAFTA Article 1103. Moreover, the facts are complicated; and their account is necessarily lengthy. Where factual references are made later in this document, these should be read with the fuller account of those facts summarised below, including their respective evidentiary references.
- 3.2. The first chronology relates to the Claimants; and the second and third chronologies relate to two principal foreign comparators invoked by the Claimants (“Teva” and “Sandoz”, also described as “Sandoz/Novartis”). The first chronology is largely, but not completely, undisputed by the Parties. The second and third chronologies are, for the most part, not agreed by the Parties.
- 3.3. The Tribunal emphasises that these factual chronologies are only summaries, as with the Parties' submissions in Part II above. It would burden this document unduly, even if it were possible, for all potentially relevant factual evidence, documents and testimony to be set out here in the fullest detail. Nonetheless, as earlier indicated with the Parties' pleadings, it should be assumed that the Tribunal has considered all relevant factual evidence adduced by the Parties in this arbitration and, further, that no relevant evidence has been overlooked by the Tribunal by reason only of its omission from the three summaries below.

### **(2) *The Apotex Chronology***

- 3.4. The Tribunal has compiled the following factual chronology largely from the documentary exhibits and written testimony cited by the Parties in their written and oral pleadings in this arbitration, save where otherwise indicated.

### *The Apotex Group of Companies*

- 3.5. Apotex-Holdings was founded in 1974 as a Canadian company in Toronto by Dr. Barry Sherman. It functions as a vertically integrated holding company, operating as a privately held corporation under the Canada Business Corporations Act. With its subsidiaries, Apotex-Holdings employs over 7,500 people in research, development, manufacturing and distribution facilities worldwide, becoming a leader in the North American generic pharmaceutical market and distributing its drug products in 115 countries. In addition to the two manufacturing facilities at Signet and Etobicoke, the Apotex group operates facilities in other locations in Canada, Mexico, China and India (which are not relevant to this arbitration). The Apotex group of companies operates no manufacturing facilities in the USA.
- 3.6. Apotex Inc. is a company incorporated under the laws of Ontario, Canada. It is indirectly owned by Apotex-Holdings. As already described above, Apotex Inc. operates the two manufacturing facilities in Canada at issue in this arbitration: (i) Signet and (ii) Etobicoke. These two facilities produce solid-dose medicinal products, such as tablets. Apotex Inc. is the largest Canadian-owned pharmaceutical company in Canada, producing more than 300 kinds of generic drugs in about 4,000 dosages and formats. As a manufacturer of drugs for export to the USA, Apotex Inc.'s drugs are subject to the Act and eligible for Import Alert 66-40. As a large manufacturer with long experience of exporting its products to the USA, the senior management of Apotex Inc. was familiar with the Act and the FDA's functions under US law.
- 3.7. Apotex-US is a corporation organised under the laws of Delaware, USA and authorised to transact business in Florida, USA. It is indirectly owned by Apotex-Holdings. Its principal business activity in the USA is selling drugs produced by other Apotex companies, including Apotex Inc. In August 2009, sales of Apotex Inc.'s solid dose products accounted for about 80% of Apotex-US's sales in the USA.<sup>1</sup> It maintains a storage facility in Indianapolis, Indiana, for products shipped by Apotex Inc. from Canada.

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<sup>1</sup> Apotex Request, Paras. 12-16; Apotex Memorial, Paras. 33ff.



3.8. In summary (as further described below), the FDA in 2006 separately inspected the Signet and Etobicoke facilities, with no sanctions imposed by the FDA upon Apotex Inc. (or any other member of the Apotex group of companies). In December 2008, the FDA inspected the Etobicoke facility with adverse observations on the Form 483, resulting in the FDA's warning letter dated 25 June 2009. In July-August 2009, the FDA inspected the Signet facility with adverse observations on the Form 483. On 28 August 2009, the FDA amended Import Alert 66-40 to include all finished form drug products manufactured by Apotex Inc. at the Signet and Etobicoke facilities. On 29 March 2010, the FDA sent a warning letter to Apotex Inc. regarding the Signet facility. The FDA removed Apotex Inc.'s two facilities from the Import Alert on 15 June 2011 (Etobicoke) and 29 July 2011 (Signet); and on 25 November 2011, the FDA resumed its approval of Apotex Inc.'s pending ANDAs for products produced by its two Canadian facilities.

#### ***The 2006 Inspections of Signet and Etobicoke***

3.9. From 26 June to 13 July 2006, the FDA inspected Apotex Inc.'s Signet facility in Toronto, Canada.<sup>2</sup> This is a large facility located at 150 Signet Drive, comprising of a head office, dry products facility, commercial laboratory, R&D laboratory, raw material warehouse and a regulatory affairs office extending over 575,000 sq. ft.<sup>3</sup> The Form 483 issued by the FDA's inspectors at the conclusion of this inspection listed one "inspectional observation", namely that there was no program to verify that the current procedures were adequate to prevent contamination and cross-contamination.<sup>4</sup> After reviewing Apotex Inc.'s response to the Form 483, the FDA classified the Signet facility as "acceptable."<sup>5</sup>

3.10. From 20 to 24 November 2006, the FDA inspected Apotex Inc.'s Etobicoke facility in Ontario, Canada.<sup>6</sup> This site has a solid dose facility and employs specific technologies, such as wet granulation, flaking, pelletisation and coating.<sup>7</sup> The Form 483 issued by the FDA's inspectors at the conclusion of this inspection noted

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<sup>2</sup> Apotex Memorial, Para. 144; Exhibit C-017.

<sup>3</sup> Exhibit C-320; First Witness Statements of Edmund Carey, Para. 15, and of Gordon Fahner, Paras. 55-58.

<sup>4</sup> Exhibit C-017.

<sup>5</sup> Apotex Memorial, Para. 144; Exhibit C-020, at p. 1.

<sup>6</sup> Apotex Memorial, Para. 145; Exhibit C-021; Exhibit R-141.

<sup>7</sup> First Witness Statement of Edmund Carey, Para. 16.

several deficiencies, including a failure in a timely manner to file field alert reports (“FARs”). From Apotex Inc.’s responses, the FDA confirmed that Apotex Inc. had satisfactorily addressed the FDA’s questions and concerns.<sup>8</sup>

*The 2007 – 2008 Criticism of the FDA’s Foreign Inspection Practices*

- 3.11. On 1 November 2007, the US General Accounting Office (“GAO”), an independent investigative arm of the US Congress,<sup>9</sup> issued a report entitled “Drug Safety: Preliminary Findings Suggest Weaknesses in FDA’s Program for Inspecting Foreign Drug Manufacturers.”<sup>10</sup> This 2007 GAO report noted the FDA’s poor data regarding the number of foreign facilities subject to inspection and the FDA’s small number of foreign inspections.<sup>11</sup> The report also noted the FDA’s difficulties in conducting foreign inspections.<sup>12</sup> At that time, and continuing until recent legislative changes, those inspections took place without financial charge to the foreign facility.
- 3.12. Beginning in 2007, many patients in the USA and elsewhere suffered from the effects of adulterated heparin (a blood thinner).<sup>13</sup> Through its investigations, the FDA identified a contaminant in the drug’s API sourced from China.<sup>14</sup> The contamination, to which 81 fatalities in the USA were attributed,<sup>15</sup> stimulated concern about the adequacy of the FDA’s inspection of foreign facilities, not limited to China.<sup>16</sup>
- 3.13. In April 2008, the GAO issued a second report entitled “Drug Safety: Preliminary Findings Suggest Recent FDA Initiatives Have Potential, but Do Not Fully Address Weaknesses in Its Foreign Drug Inspection Program.”<sup>17</sup> A third report was issued by the GAO in September 2008 entitled “Drug Safety: Better Data Management and

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<sup>8</sup> Apotex Memorial, Para. 145; Exhibit C-025.

<sup>9</sup> USA Counter-Memorial, Para. 62.

<sup>10</sup> Exhibit R-015.

<sup>11</sup> *Id.*, at p. 2.

<sup>12</sup> *Id.*

<sup>13</sup> USA Counter-Memorial, Para. 61.

<sup>14</sup> Exhibit R-057.

<sup>15</sup> Exhibit R-027.

<sup>16</sup> Exhibits R-019 and R-027.

<sup>17</sup> Exhibit R-017.

More Inspections Are Needed to Strengthen FDA’s Foreign Drug Inspection Program.”<sup>18</sup>

***The December 2008 Etobicoke Inspection***

- 3.14. On 4 April 2008, the FDA’s Center for Drug Evaluation and Research, Office of Compliance (“CDER”) requested a “priority inspection” of Apotex Inc.’s Etobicoke facility. CDER is a part of the FDA responsible for drug quality, including drugs produced at foreign facilities. This request was made following a number of complaints in the USA and a US Congressional inquiry regarding an alleged lack of efficacy of the Etobicoke-produced drug carbidopa-levodopa (a drug used to treat Parkinson’s disease).<sup>19</sup> In FDA terminology, this was a priority inspection which was “directed” or “for cause”, given these complaints.<sup>20</sup>
- 3.15. Two FDA investigators, Commander Debra M. Emerson (a pharmacist) and Ms. Rochelle Campbell (a chemist), inspected the Etobicoke facility from 10 to 19 December 2008.<sup>21</sup> The investigators were assigned to conduct a cGMP inspection, as well as a pre-approval inspection (“PAI”) of nine pending ANDAs.<sup>22</sup>
- 3.16. During the inspection, the two FDA investigators interviewed Apotex Inc. personnel, reviewed documents, and investigated the Etobicoke facility. At the close of the inspection on 19 December 2008, the investigators provided the senior management of Apotex Inc. with 11 written “inspectional observations” in their Form 483.<sup>23</sup> This Form 483’s observations included the following:
- a. Apotex Inc. had failed to transfer the methods for testing products between the different Apotex laboratories;

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<sup>18</sup> Exhibit R-018.

<sup>19</sup> USA Counter-Memorial, Para. 72; Exhibit R-020, at p. 1.

<sup>20</sup> Witness Statement of Debra M. Emerson, Para. 5.

<sup>21</sup> Apotex Request, Para. 28; Apotex Memorial, Para. 147; USA Counter-Memorial, Para. 72.

<sup>22</sup> USA Counter-Memorial, Para. 72.

<sup>23</sup> Apotex Memorial, Para. 148; USA Counter-Memorial, Para. 73; Exhibit C-034.

- b. Apotex Inc. had failed to submit timeously to the FDA certain FARs (Field Alert Reports) regarding problems observed in the manufacture of approved drugs;<sup>24</sup>
- c. Apotex Inc. had failed to include complete production and process controls in all approved productions records;
- d. Apotex Inc. had failed to include a copy of all approved labels and labelling in the master batch records; and
- e. Apotex Inc. had changed the expiry date on a certain product without conducting proper stability testing.<sup>25</sup>

3.17. Commander Emerson testified that, as a result of this investigation, she recommended “OAI” [Official Action Indicated] “[b]ecause of the seriousness of the problems we identified .... More specifically, I recommended the recall and an import alert for the combination product: carbidopa-levodopa, due to the lack of stability. I also recommended that FDA withhold approval of several ANDAs [numbers here omitted] because of Apotex’s failure to adequately transfer and verify testing methods. I further recommended that FDA withhold approval of the [REDACTED] because the firm had not investigated or resolved the failed scale-up batches. Finally, I recommended that FDA re-inspect the facility to review Apotex’s scale-up and stability testing for two other ANDAs [numbers here omitted].”<sup>26</sup>

***January – June 2009***

3.18. In January 2009, the FDA received further complaints regarding the size and shape of certain Apotex Inc. drugs. In one complaint, the report related to a round leflunomide pill (a rheumatoid arthritis drug) in a bottle of triangular-shaped pills;<sup>27</sup> and, in another complaint, a pharmacy technician reported a tablet of tramadol

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<sup>24</sup> In particular, the Form 483 referred to a failure by Apotex Inc. to report a problem with “over-thick” tablets of the heart medication [REDACTED]. The complaint was originally recorded in May 2008 but was not reported to the FDA until November 2008 (USA Counter-Memorial, Para. 75; Exhibit C-034, Observation 4).

<sup>25</sup> Exhibit C-034; Apotex Memorial, Para. 148; USA Counter-Memorial, Paras. 73-80; Commander Emerson’s Establishment Inspection Report at Exhibit R-026.

<sup>26</sup> Witness Statement of Debra M. Emerson, Para. 27.

<sup>27</sup> USA Counter-Memorial, Para. 82; Exhibit R-031, at p. 1.

hydrochloride (a synthetic version of codeine used to treat pain) that was “about twice the thickness” of the other pills in the bottle.<sup>28</sup>

- 3.19. In regard to the tramadol complaint, by an email dated 22 January 2009, an FDA consumer products safety officer (a physician) asked FDA officials to obtain the bottle containing the oversized tramadol tablet and conduct lab tests.<sup>29</sup> The officer wrote that “[w]e are concerned that the oversized Tramadol tablet may lead to [REDACTED].”<sup>30</sup> The FDA officer also noted that she had found over [REDACTED] complaints regarding Apotex Inc. in the last three years.<sup>31</sup>
- 3.20. In regard to the leflunomide complaint, an email dated 16 January 2009 from Dr. Carmelo Rosa (then Acting Team Leader of CDER’s International Compliance Branch) to the pharmacy which had discovered the reported defect stated: “[w]e are very concerned with this situation .... an FDA representative [will] visit your pharmacy in the next few days and investigate the situation and collect the necessary samples.”<sup>32</sup> After the FDA informed Apotex Inc. of the complaint, Apotex Inc. described the reported defect as “an extremely isolated incident.”<sup>33</sup>
- 3.21. Apotex Inc. responded to the Etobicoke Form 483 observations on 30 January 2009.<sup>34</sup> The response addressed each of FDA’s 11 observations and undertook to implement certain corrective actions.<sup>35</sup>
- 3.22. On 20 February 2009, Apotex Inc. submitted an FAR to the FDA regarding a pharmacist’s complaint that a [REDACTED] tablet had been found in a bottle of [REDACTED].<sup>36</sup>
- 3.23. In an internal FDA email dated 20 March 2009, Ms. Hidee Molina, a compliance officer at CDER, criticised the FDA’s inspection in December 2008 of the Etobicoke facility. The email stated: “[w]e have received approximately [REDACTED]

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<sup>28</sup> USA Counter-Memorial, Para. 83; Exhibit R-032.

<sup>29</sup> Exhibit R-034.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> Exhibit C-335.

<sup>33</sup> Exhibit C-350.

<sup>34</sup> Exhibit C-037; Apotex Memorial, Para. 149; USA Counter-Memorial, Para. 81.

<sup>35</sup> *Id.*

<sup>36</sup> Exhibit R-142.

consumer complaints and [REDACTED] total Adverse Event Reports ([REDACTED] of which have been coded specifically under ‘Pharmaceutical product complaint’) since December 2006. Many of which have been for [REDACTED], or [REDACTED] [REDACTED], for different products.”<sup>37</sup>

- 3.24. In April 2009, Dr. Rosa became Team Leader of the FDA’s Office of Manufacturing and Product International Compliance Branch.<sup>38</sup> From February 2011 to June 2011 he was the Branch Chief of International Compliance in this Office, reviewing Team Leaders’ recommendations for regulatory actions, later becoming the Division Director of the CDER component responsible for international drug quality.<sup>39</sup> Dr. Rosa was a senior figure within the FDA; but he was not in any sense a political appointment. He testified: “I come from Puerto Rico, and I have no involvement in policies or political interests of commissioners ... I was brought to the Center for Drugs to do a job, and I’ve done it no differently there than what I was doing it for my entire career ....”<sup>40</sup>
- 3.25. By an internal FDA email dated 22 May 2009, Mr. Edwin Rivera-Martinez (Dr. Rosa’s superior) provided Ms. Hidee Molina with an example of an import alert “that you can use as a model for drafting the Apotex IA [Import Alert],”<sup>41</sup> as had earlier been discussed between them. This message was copied to Dr. Rosa.
- 3.26. On 1 June 2009, Dr. Rosa sent an internal FDA email attaching a list of products for shortage assessment on Apotex Inc. drugs in the US market. The subsequent email in the chain from Mr. Michael Smedley to Captain Valerie Jensen and Mr. Jouhayna Saliba (all FDA), also dated 1 June 2009, noted that: “[c]ompliance is considering regulatory action.”<sup>42</sup> This was a reference to a possible import alert. (Captain Jensen was an officer in CDER’s Drug Shortage Program.)

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<sup>37</sup> Exhibit C-486.

<sup>38</sup> First Witness Statement of Dr. Carmelo Rosa, Para. 4.

<sup>39</sup> *Id.*, Paras. 2-3.

<sup>40</sup> TD3.851.

<sup>41</sup> Exhibit C-355.

<sup>42</sup> Exhibit C-357; USA Rejoinder, Para. 82.

*Dr. Hamburg and the FDA's Policies*

3.27. During this period in early June 2009, a new FDA Commissioner appointed by President Obama's administration, Dr. Margaret Hamburg, took office.<sup>43</sup> In an early public speech as Commissioner, delivered on 6 August 2009, Dr. Hamburg described the FDA's new regulatory policy with an emphasis on its strategic, rapid and visible aspects.

3.28. Dr Hamburg's speech included the following passage:<sup>44</sup>

"...the pathways for enforcement action can be too long and arduous when the public's health is in jeopardy. We are fixing these pathways to improve the effectiveness of our enforcement system. Today, the FDA is taking several initial steps in this direction.

First, the FDA will set post-inspection deadlines. When the FDA finds that a firm is significantly out of compliance, we expect a prompt response to our findings. Once the FDA provides inspection findings identifying a serious problem, the firm will generally have no more than fifteen working days in which to respond before the FDA moves ahead with a warning letter or enforcement action. This will help FDA issue warning letters on a timely basis and facilitate prompt corrective action.

Second, the FDA will take responsible steps to speed the issuance of warning letters. I have approved a new policy brought forward by the FDA's Chief Counsel to limit warning letter review to significant legal issues. As a result, most enforcement letters will be able to move forward through a more streamlined process. This approach is consistent with the FDA's longstanding historical practice.

Third, the FDA will seek to work more closely with our regulatory partners to develop effective risk control and enforcement strategies. In many food safety cases, for example, local, state, and international officials have more authority to take action quickly than the FDA. When the public health is at risk, the FDA will reach

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<sup>43</sup> Apotex Memorial, Para. 150. (The change of US administration took place in January 2009, following the US Presidential election held in November 2008.)

<sup>44</sup> Exhibit C-051.

out to our partners to take rapid action while we alert the public and prepare longer-term responses.

Fourth, the FDA will prioritize enforcement follow-up. After a warning letter is issued or a major product recall occurs, we will make it a priority to follow up promptly with appropriate action, such as an inspection or investigation to assess whether or not a company has made required changes in its practices.

Fifth, the FDA will be prepared to act swiftly and aggressively to protect the public. The FDA will no longer issue multiple warning letters to noncompliant firms before taking enforcement action. If we find that we must move quickly to address significant health concerns or egregious violations, we will consider immediate action – even before we have issued a formal warning letter.

These five procedural changes will help to ensure that violations are taken seriously, that warning letters and enforcement actions occur in a timely manner, and that steps are taken to protect consumers in cases where immediate enforcement action is not possible ...”

- 3.29. There is an issue which the Tribunal addresses later, as to whether Dr. Hamburg introduced a “new” enforcement policy which was being used at that time to target Apotex Inc. “pour encourager les autres” (as the Claimants contend) or only returned the FDA to its “historical practice” without any attempt to make Apotex Inc. a public example (as the Respondent contends).<sup>45</sup> There were undoubtedly material changes to the FDA’s policies and practices from mid-2009 onwards. The issue, however, is whether any of these changes were material to the Claimants’ several claims in this arbitration; and that mixed issue of fact and law is considered separately later below.
- 3.30. The relevant statistics for the period from 2003 (before Dr. Hamburg’s appointment) to 2012 (three years after her appointment) show the following as regards Import Alerts 66-40 “GMP Issues for Human Drugs”, affecting foreign facilities (including Apotex’s Import Alert in 2009):<sup>46</sup>

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<sup>45</sup> TD1.8 & 87-88 and TD3.614-615.

<sup>46</sup> Exhibit R-086.



<i>Year</i>	<i>Additions</i>	<i>Removals</i>
2003	0	0
2004	1	6
2005	1	0
2006	0	0
2007	2	1
2008	3	0
2009*	10	0
2010	12	0
2011	19	3
2012	20	7

(\*The Tribunal accepts the explanation for part of this increase from 2009 onwards, as involving foreign facilities in China manufacturing crude heparin during the heparin crisis, as Dr. Rosa testified.)<sup>47</sup>

- 3.31. In addition, the FDA increased its inspections of foreign facilities. During the period from 2000 to 2007, the FDA conducted an average of 282 foreign inspections annually. The figures thereafter were much higher: 2008 – 372; 2009 – 491; 2010 – 525; 2011 – 631; and 2012 – 672.<sup>48</sup>
- 3.32. As regards warning letters, for the period 2002 to 2008, the FDA averaged three letters annually to foreign facilities for cGMP violations. Thereafter, the figures were much higher: 2009 – 13; 2010 – 18; and 2011 – 20. (In total, not limited to foreign facilities, the FDA regularly issued a much greater number of warning letters; for example, it issued 1,720 warning letters in 2011).<sup>49</sup>

***The June 2009 Etobicoke Warning Letter***

- 3.33. On 7 June 2009, Ms. Deborah Autor (Director of CDER’s Office of Compliance) sent a draft warning letter regarding Apotex Inc.’s Etobicoke facility to (among other FDA officers) Dr. Janet Woodcock (Director of CDER).<sup>50</sup> In her reply email of 8 June 2009, Dr. Woodcock wrote: “Obviously this firm [Apotex Inc.] should not be shipping drug [sic] to the US! What are we going to do about it besides WL

<sup>47</sup> TD4.1076-1078 Dr. Rosa xx (T).

<sup>48</sup> USA Counter-Memorial, Para. 65.

<sup>49</sup> *Id.*, Para. 66 (fn 126).

<sup>50</sup> Exhibit C-359.

[warning letter]? ... Their QC [Quality Control] unit has no idea what is going on ...”<sup>51</sup>

- 3.34. Shortly afterwards, Ms. Autor circulated Dr. Woodcock’s email message to other FDA officers and asked: “[c]an we do an import alert sooner rather than later?”<sup>52</sup> In response, Mr. Joseph Famulare (a senior FDA officer) wrote that “[t]he shortage determination will need to be completed.”<sup>53</sup> This was a reference to the pending evaluation within the CDER component responsible for drug shortage issues as to the effect, in the USA, of an import alert on possible shortages of medically necessary drugs produced by Apotex Inc.’s facilities at Signet and Etobicoke.
- 3.35. On 18 and 19 June 2009, FDA officers exchanged emails regarding the possibility of an Apotex Inc. import alert and the attendant possibility of short supply issues.<sup>54</sup> Following an email from Captain Jensen which identified certain products of Apotex Inc. with shortage issues, Dr. Rosa wrote on 19 June 2009: “From what I see below, other companies can ramp up. However, the amount of Apotex product in the market is significant. Meaning that this decision needs to be carefully evaluated.”<sup>55</sup>
- 3.36. Later that same day, Mr. Rivera-Martinez replied to Dr. Rosa’s email: “Based on this information, we may want to hold off on the IA [Import Alert] until after our regulatory meeting with Apotex’s management.”<sup>56</sup>
- 3.37. On 25 June 2009, the FDA sent to Apotex Inc. a seven-page warning letter stating that the FDA’s inspection of the Etobicoke facility in December 2008 had revealed “significant deviations” from cGMP regulations (the “Etobicoke warning letter”).<sup>57</sup> Whilst acknowledging that Apotex Inc. appeared to have completed certain corrections, the warning letter stated that Apotex Inc.’s response of 30 January 2009 to the Etobicoke Form 483 observations “fails to adequately address multiple,

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<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> Exhibit C-502.

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> Exhibit C-041; Apotex Request, Para. 31; Apotex Memorial, Para. 152; USA Counter-Memorial, Para. 84.

serious deficiencies.”<sup>58</sup> The warning letter provided that the cGMP violations included, but were not limited to, the following:

- a. “Failure to thoroughly investigate the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed”;
- b. “Failure to submit NDA<sup>59</sup>/ANDA field alert reports (FARs) in the required timeframe, within 3 working days of becoming aware of information concerning any significant chemical, physical, or other change or deterioration in the distributed drug product”; and
- c. “Failure to include a specimen or copy of each approved label and all other labeling in the master production and control record.”<sup>60</sup>

3.38. The Etobicoke warning letter provided that, until all corrections to cGMP deviations had been completed by Apotex Inc. and confirmed by the FDA, CDER might recommend withholding approval of any new applications or supplements listing Apotex Inc. as a drug product manufacturer.<sup>61</sup> It also provided that a failure to correct these violations might result in the FDA denying entry of products manufactured by Apotex Inc. at the Etobicoke facility.<sup>62</sup> (This was an implicit reference to an import alert.) It further warned that the deficiencies identified in the warning letter and the earlier Form 483 were not all-inclusive; and that it was Apotex Inc.’s responsibility to ensure cGMP compliance.<sup>63</sup>

3.39. By letter dated 17 July 2009, Apotex Inc. provided a 24-page response to the Etobicoke warning letter and the cGMP deficiencies there set out.<sup>64</sup> On 12 August

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<sup>58</sup> Exhibit C-041.

<sup>59</sup> “NDA” signifies “New Drug Application.”

<sup>60</sup> Exhibit C-041. The Etobicoke warning letter also discussed “problems in the quality control unit’s ability to conduct thorough investigations” (Exhibit C-041, at p. 3).

<sup>61</sup> Exhibit C-041; USA Counter-Memorial, Para. 85.

<sup>62</sup> *Id.*

<sup>63</sup> Exhibit C-041, at p. 6.

<sup>64</sup> Exhibit C-044; Apotex Request, Para. 34; Apotex Memorial, Para. 157.

2009, Apotex Inc. requested a meeting with the FDA to address its response to the Etobicoke warning letter.<sup>65</sup>

***The July – August 2009 Signet Inspection***

- 3.40. From 27 July to 14 August 2009, four FDA investigators (Mr. Lloyd Payne, Ms. Kristy Zielny, Mr. Brian Belz and Mr. Brian Lee, a chemist) conducted a 14-day inspection at Apotex Inc.’s Signet facility.<sup>66</sup> Although the inspection was originally scheduled to include both a cGMP inspection and PAI inspections for ■ pending ANDAs and one new drug application, the PAIs were not concluded.<sup>67</sup>
- 3.41. About a week before the inspection, the four FDA inspectors had taken part in a telephone conference-call with a large number of participants from the FDA (about 30 persons), including Mr. Rivera-Martinez. It was a form of general brainstorming with no mention of an import alert, as Mr. Payne testified at the Hearing.<sup>68</sup> During the inspection, there was at least one telephone conference-call between certain of the inspectors and Mr. Rivera-Martinez, during which the possibility of an import alert was mentioned, as Mr. Payne also testified.<sup>69</sup>
- 3.42. On 6 August 2009, while the Signet inspection was taking place, the FDA’s Commissioner, Dr. Hamburg, made the public speech already described above. Apart from what might be inferred from its text, there is no evidence in this arbitration to suggest that Dr. Hamburg was directing her speech with Apotex Inc. specifically in mind.
- 3.43. In an internal summary, an Associate Director of Apotex Inc. (Ms. Carol Austin) described the FDA’s inspection of the Signet facility as “very intense.”<sup>70</sup> There is also evidence that personal relations between certain of the FDA’s inspectors became difficult during the inspection, with Mr. Payne testifying at the Hearing that

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<sup>65</sup> Apotex Memorial, Para. 158; Exhibit C-056.

<sup>66</sup> Apotex Request, Para. 35; Apotex Memorial, Paras. 159-160; USA Counter-Memorial, Para. 86.

<sup>67</sup> Apotex Memorial, Para. 159; USA Counter-Memorial, Para. 86 (fn 183).

<sup>68</sup> TD3.758-759 Mr. Payne xx.

<sup>69</sup> TD3.761-762 and 777 Mr. Payne xx.

<sup>70</sup> Exhibit C-047; Apotex Memorial, Para. 161.

it still left him in a “sizzle.”<sup>71</sup> This difficulty became evident at the time to Apotex Inc.’s senior management, including Dr. Clark, Dr. Desai and Ms. Tao.<sup>72</sup>

3.44. On the final day of the Signet inspection, but before the closeout meeting, Mr. Lance Lovelock (then Vice President of Quality at Apotex Inc.) submitted two affidavits to the FDA inspectors, at their request, regarding the use of drugs in the production of finished products sourced from Mexico and India ( [REDACTED] and [REDACTED] respectively).<sup>73</sup> Apotex’s senior officers viewed the FDA’s inspectors’ insistence upon such affidavits as an unusual procedure, prompted by the inspectors’ apparent concern that Apotex Inc. was seeking to mislead the FDA (a suggestion refuted by Apotex Inc. at the time).<sup>74</sup> Dr. Desai testified that that there was an issue with data integrity regarding a specific product ( [REDACTED] ) raised by one of the FDA investigators, Ms. Zielny, which Apotex Inc. treated very seriously (albeit, as he testified, without seeking any legal advice at that time).<sup>75</sup> Dr. Clark testified that Ms. Zielny was “effectively accusing Apotex of misleading the Agency with respect to the manufacturing processes of this generic drug. We emphasized that while documentation may have been incomplete with respect to changes in the manufacturing process, what was provided was accurate. We categorically rejected any suggestion of any intent to mislead ...”<sup>76</sup> On the other hand, Mr. Payne testified that these affidavits were not an exceptional procedure, being a ‘best practice’ when collecting a documentary sample of a product.<sup>77</sup> Whatever the FDA’s motivation, it made for an unpleasant situation between Apotex’s senior officers and the FDA’s inspectors prior to and during the subsequent closeout meeting.

3.45. At the closeout meeting, taking place after the end of the Signet facility inspection on 14 August 2009 (it was a Friday), the FDA investigators provided Apotex Inc.’s

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<sup>71</sup> TD3.790 and 798-799 Mr. Payne xx.

<sup>72</sup> Witness Statements of Bruce D. Clark, Para. 30; Jeremy B. Desai, Paras. 44-45; and Bernice Tao, Para. 44.

<sup>73</sup> Exhibits C-062 and C-063; Apotex Memorial, Para. 168.

<sup>74</sup> First Witness Statement of Edmund Carey, Para. 35; Witness Statement of Bruce D. Clark, Para. 30; Exhibits C-062 and C-063.

<sup>75</sup> First Witness Statement of Jeremy B. Desai, Para.45.

<sup>76</sup> Witness Statement of Bruce D. Clark, Para. 30.

<sup>77</sup> TD3.772ff Mr. Payne xx.

management with 17 written observations in their Form 483.<sup>78</sup> There were also other concerns raised by the FDA inspectors, each of whom presented observations which he or she had found. Mr. Payne testified that: “Ms. Zielny presented the most observations, because she had reviewed the Quality systems, where most of the cGMP violations were found. As the team leader, I reviewed and approved every observation and concern presented.” Mr. Payne also testified: “On several occasions during the presentation, Apotex Inc. management acknowledged the deficiencies. For example, Apotex Inc.’s President and Chief Operating Officer, Jack Kay, acknowledged the ‘unacceptable sloppiness’ in the firm’s written procedures for assuring correct labeling and packaging materials for drug products. Regarding Apotex Inc.’s failures to follow written procedures for cleaning and maintaining equipment, the firm’s Vice-President for Quality, Lance Lovelock, acknowledged ‘that there needs to be some self-policing in issuing deviations and that this is an opportunity to look at the procedures and processes in place’. In relation to the observed failure to investigate unexplained discrepancies or batch failures, Mr. Lovelock stated that ‘in-process investigations need to be looked at and closed in a timelier manner.’ Our EIR [Establishment Inspection Report] recorded many such acknowledgments and promises of remedial action.”<sup>79</sup>

3.46. The FDA Inspectors’ concerns reflected in their Form 483 observations included the following (here much summarised by the Tribunal):

- a. Apotex Inc. had distributed drugs to the US which were produced from contaminated drug batches;
- b. Apotex Inc. had failed to submit timeously FARs to the FDA regarding problems observed in the manufacture of approved drugs;
- c. Apotex Inc. had failed to follow its written procedures for cleaning and maintaining equipment used in the manufacturing, processing, packing, or holding of drug products; and

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<sup>78</sup> Apotex Request, Para. 35; Apotex Memorial, Para. 169; USA Counter-Memorial, Para. 86; Exhibit C-061.

<sup>79</sup> Witness Statement of Lloyd Payne, Paras. 25-26.

- d. Apotex Inc. had failed sufficiently to investigate and document defective batches.<sup>80</sup>
- 3.47. The FDA investigators directed Apotex Inc. to contact CDER the next business day, *i.e.* the following Monday, 17 August 2009.<sup>81</sup>

***The Telephone Conference-Call of 17 August 2009***

- 3.48. A telephone conference-call between senior representatives of Apotex Inc. and the FDA took place on Monday, 17 August 2009.<sup>82</sup> During this conference, Apotex Inc. undertook voluntarily to recall 675 batches of drug products manufactured at the Etobicoke and Signet facilities and distributed in the US market. Apotex Inc. prepared its own internal notes of the meeting.<sup>83</sup> Apotex Inc. there acknowledged that: “there are significant deficiencies.”<sup>84</sup> In answer to the specific question from Mr. Rivera-Martinez (FDA) “whether Apotex intends to continue distributing products”, these notes record Dr. Desai’s answer: “Apotex does intend to continue distributing. We believe we can deliver safe and efficacious product.” This telephone conference-call was also important for what was not said by its participants.
- 3.49. As regards Apotex Inc., Dr. Desai testified: “... In order to prove to FDA our commitment to placing only the highest quality products in the US market, Mr. Lovelock and I decided to voluntary [sic] recall the batches associated with these black particles [this is a reference to black particles of ██████████]. We thought that if we completely eliminated what appeared to be FDA’s source of concern, the problem would be solved. We also thought that this kind of action would demonstrate to FDA that we were taking their observations seriously and that we were doing our best to cooperate with them. Thus, we told FDA in the call that we would do a recall. Mr. Friedman [FDA Director, Division of Manufacturing and Product Quality] asked whether this would be enough and whether Apotex felt that

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<sup>80</sup> Apotex Memorial, Para. 169; USA Counter-Memorial, Paras. 87-93.

<sup>81</sup> Apotex Memorial, Para. 170; USA Counter-Memorial, Para. 94.

<sup>82</sup> Apotex Request, Para. 36; Apotex Memorial, Para. 171; USA Counter-Memorial, Para. 99 (fn 230); Exhibits C-064 and R-043.

<sup>83</sup> Exhibit R-043.

<sup>84</sup> *Id.*, at p. 2.

it should cease distribution in the US. I explained that we believed the recall was more than sufficient and that we did not need to stop distribution in the US. Mr. Friedman did not disagree or otherwise indicate a different view.”<sup>85</sup> Significantly, Apotex Inc. did not undertake to suspend production at its Signet or Etobicoke facilities; nor would it temporarily cease shipments to the USA.

- 3.50. At this time, the senior management of Apotex Inc., whilst acknowledging regulatory deficiencies found by the FDA, did not consider that there was any problem with the quality and safety of their products; they firmly believed that Apotex products did not pose any imminent risks to public health; that none were in fact adulterated; and that “Apotex drugs were only ‘deemed adulterated’ under the Act”, as Dr. Desai testified.<sup>86</sup> Mr. Clark testified that, apart from regulatory requirements: “... there was absolutely no safety concern with our products and no question as to their quality.”<sup>87</sup>
- 3.51. As regards the FDA, Dr. Rosa testified: “... We expressed concern with Apotex’s decision to continue distributing any drugs in the U.S. market from Etobicoke and Signet, given the firm’s acknowledgment of the serious cGMP deficiencies at those facilities. Apotex told us that it planned to retain a third-party expert to assist its remediation efforts. But that was no substitute for actually fixing the serious cGMP violations *before* shipping additional drugs to the United States. When faced with this level of FDA concern, many other companies have halted distribution, temporarily suspended manufacturing, or slowed production of drug products. Apotex proposed nothing of the sort ... It became clear during the call that Apotex failed to grasp the seriousness of the situation.”<sup>88</sup>
- 3.52. Dr. Rosa was also cross-examined at the Hearing on his account of this important telephone conference-call and, in particular, his conclusion that Apotex Inc. was not in control of its two facilities. He testified that: “FDA had evidence that the firm was not operating in a state of control”;<sup>89</sup> and “It’s about, ‘Do you have the system under control? Can you identify and find the problems that you have in your

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<sup>85</sup> First Witness Statement of Jeremy B. Desai, Para. 48.

<sup>86</sup> *Id.*, Para. 47; Second Witness Statement of Jeremy B. Desai, Paras. 9, 10 and 22.

<sup>87</sup> Witness Statement of Bruce D. Clark, Para. 30.

<sup>88</sup> Supplemental Witness Statement of Dr. Carmelo Rosa, Paras. 23-24.

<sup>89</sup> TD4.912 Dr. Rosa xx.



facility?'; We are focused on the evidence ... to operate in a sustainable state of compliance, ... it's about the controls and the systems that you have to show that you're sustainable";<sup>90</sup> "... when you look at the Signet Drive inspection, you can see that [it was] a facility [that] is not in control";<sup>91</sup> and "Apotex did initiate a recall, and it was a voluntary recall of batches that were in the market. Again, as I mentioned, when you look at the recall of Apotex, you look at the inspections at Apotex, that was certainly out of control in terms of quality."<sup>92</sup>

3.53. In re-examination at the Hearing, Dr. Rosa testified: "When we look and talk about a firm – company being in or not in control, a firm that is capable of identifying the issues, a firm that is capable of predicting the issues, a firm that is capable of implementing Corrective Action Plans that can lead them and can lead them to the point where they can show that they can operate in a sustainable state of control.... When we have a firm that identifies problems, corrects them, and is operating at a level where their investigations are appropriate, when they make – when they decide to reject a batch, it's not rejecting a batch because of trial and error. Let me – if it passes, I release it; if I reject it – if it fails, I'll reject it. That is not operating in a state of control. That is guessing and crossing your fingers that you can have a good test result."<sup>93</sup> Later, Dr. Rosa testified: "Apotex, in the meeting of August 17, we asked them the question, 'What do you intend to do?' And one of the statements in that discussion was, 'We plan to continue manufacturing and distributing products.' That was something that was very concerning to the Agency because it gave a clear indication that Apotex wanted to satisfy FDA's application, but not operate in sustainable compliance with GMPs. Because they continued manufacturing product for the rest of the world. They continued releasing products ...."<sup>94</sup>

3.54. Dr. Rosa testified at the Hearing that the FDA representatives did not mention to Apotex Inc. in the conference call on 17 August 2009 that the FDA was actively considering an import alert in respect of both the Etobicoke and Signet facilities. Thus, the Import Alert was imposed on 28 August 2009 (11 days later) without the

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<sup>90</sup> TD4.965-966 Dr. Rosa xx.

<sup>91</sup> TD4.970. Dr. Rosa xx.

<sup>92</sup> TD4.1006 Dr. Rosa xx.

<sup>93</sup> TD4.1024-1025 Dr. Rosa xxx.

<sup>94</sup> TD4.1037-1038 Dr. Rosa xxx.

FDA issuing any prior warning letter to Apotex Inc. relating to the Signet facility and without giving Apotex Inc. any opportunity to make a considered response to the FDA's concerns relating to the Signet facility (in contrast to the earlier opportunity given to Apotex Inc. in regard to its Etobicoke facility).<sup>95</sup>

3.55. Mr. Vodra (the expert witness called by the Respondent) testified that, in his opinion, this telephone conference-call on 17 August 2009 appears to have been a “turning point” for the FDA: “...The agency had considered adding Apotex to the Import Alert [Import Alert 66-40] as early as April 2009, but not implemented it. The Signet inspection had revealed numerous – and as Apotex conceded ‘significant’ – deficiencies in cGMP compliance across all six systems, some of which were repeat observations and paralleled those made at the Etobicoke site. Apotex volunteered to recall many products made at both facilities, but failed to persuade FDA that it had a rational basis for distinguishing between those to recall and those to leave alone. Moreover, the company told FDA it intended to continue to distribute products into the U.S. market relying on its current quality system – the system that the company and FDA agreed was deficient and needed remediation. In my experience, FDA would have interpreted Apotex’s responses as lacking a real commitment to drug quality ... In my opinion, had Apotex ... told FDA on August 17, 2009, that it would not export any non-medically necessary products to the U.S. pending remediation, it is probable that no Import Alert would have been issued [footnotes omitted].”<sup>96</sup>

3.56. In his oral testimony at the Hearing, Mr. Vodra testified that there was “a complete disconnect” between Apotex Inc. and the FDA: “This is something I’ve seen before. It is not unusual. Companies frequently do not hear FDA clearly until FDA basically hits them alongside the head with a 2 by 4.”<sup>97</sup> He also testified that the FDA’s regulatory action affecting both the Signet and Etobicoke facilities was justified because the quality control system was under the same management.<sup>98</sup>

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<sup>95</sup> TD4.1082 Dr. Rosa xx (T).

<sup>96</sup> Expert Report of William W. Vodra, Paras. 75-76.

<sup>97</sup> TD4.1174-1175 Mr. Vodra (T).

<sup>98</sup> TD4.1146 Mr. Vodra xx.

### *The 28 August 2009 Import Alert*

- 3.57. On 19 August 2009, Captain Jensen (of the CDER Drug Shortage Program) confirmed in an internal FDA email that the placement of an Import Alert on the drugs produced at the Etobicoke and Signet facilities would not create significant, prolonged shortages in the USA.<sup>99</sup> The email stated: “[b]ased on responses from the alternate firms at this time, there are not any significant, prolonged shortages anticipated as a result of Apotex products on the lists we were provided being unavailable.”<sup>100</sup>
- 3.58. Three days after the telephone conference-call with Apotex Inc., an internal FDA memorandum dated 20 August 2009 from CDER to the Division of Import Operations and Policy (“DIOP”) commented: “[Apotex Inc.] have not committed to cease US distribution of all drug products manufactured at [the Etobicoke and Signet sites]. Our office is concerned about the firm’s rationale and decision to only recall 675 batches and not address all products on the US market.”<sup>101</sup> The FDA memorandum recorded that the significant cGMP violations discovered at the Etobicoke and Signet sites “demonstrate a lack of adequate process controls and raises serious concerns regarding the firm’s quality and production systems.”<sup>102</sup> The memorandum recommended that, as the methods and controls used in manufacture did not appear to conform to cGMP, all finished pharmaceutical products manufactured by Apotex Inc. at the Etobicoke and Signet facilities should be refused admission to the US.<sup>103</sup> It recommended that Import Alert 66-40 be amended to include these products.<sup>104</sup>
- 3.59. This recommendation was accepted by the FDA’s DIOP; and, on 28 August 2009, the FDA amended the existing Import Alert 66-40 to include all finished form drug products produced by Apotex Inc. at its Etobicoke and Signet facilities.<sup>105</sup> This Import Alert addressed “detention without physical examination of drugs

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<sup>99</sup> USA Rejoinder, Para. 273; Exhibit R-154, at p. 2.

<sup>100</sup> Exhibit R-154, at p. 2.

<sup>101</sup> Exhibit C-064, at p. 2.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*, at pp. 2-3.

<sup>104</sup> *Id.*

<sup>105</sup> Apotex Request, Para. 38; Apotex Memorial, Para. 185; USA Counter-Memorial, Para. 101.

["DWPE"] from firms which have not met drug GMPs."<sup>106</sup> The FDA did not immediately inform Apotex Inc. of its decision to place its products on Import Alert, although the information was published on the FDA's website. Apotex Inc. only learnt of the Import Alert accidentally on 2 September 2009.<sup>107</sup> There was no legal obligation under the Act requiring the FDA to notify Apotex Inc. of the Import Alert (whether in advance or contemporaneously); but its failure to do either in the circumstances of this case, requires explanation.

- 3.60. As a matter of policy, as Dr. Rosa testified, the FDA does not provide advance notice of an import alert so as to ensure that companies do not flood the US market with adulterated drugs before the FDA can alert its district offices; and firms "typically learn of Import Alerts when they receive notice that a shipment has been detained without physical examination" at the US border.<sup>108</sup> In the present case, given the Signet facility's recent inspection and their subsequent telephone conference-call only three days old, it remains surprising that the FDA did not notify Apotex Inc.'s senior management immediately after issuing the Import Alert, at least informally. Given the FDA's practices hitherto, there was no reason for Apotex Inc. to suspect that any import alert was imminent.
- 3.61. In a public speech delivered later at a conference in March 2010, Mr. Rivera-Martinez referred to Apotex Inc. and the Import Alert: "... That import alert was implemented 10 days after the completion of an inspection. We've never done that before. Generally, we place companies on an import alert after a warning letter. This inspection was completed on Friday. On Monday the FDA Office of Compliance International Alert Branch was on the phone with the executive officer and asked them what they intended to do with respect to the violations. They didn't take us too seriously .... Things are changing folks, and you need to react a lot faster because FDA is moving a lot faster."<sup>109</sup>
- 3.62. It is important to record that, whilst Apotex's drug products were considered "adulterated" within the legislative meaning of the Act under US law for the

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<sup>106</sup> Exhibit C-067.

<sup>107</sup> First Witness Statement of Jeremy B. Desai, Para. 56.

<sup>108</sup> First Witness Statement of Dr. Carmelo Rosa, Para. 23.

<sup>109</sup> Exhibit C-141.

purpose of the Import Alert, the Tribunal received no firm evidence that any such drug caused any actual harm to any patient in the USA or that the FDA ever expressed to Apotex Inc. that its products constituted an actual health hazard to patients in the USA.

- 3.63. For Apotex Inc., Mr. Carey testified that, apart from the Import Alert, the FDA did not take any contemporaneous action that would show that the FDA had concerns over the safety of Apotex's products; and, to the contrary, that the FDA classified Apotex's recall of the 675 batches as a "Class II" recall only (thereby acknowledging that the probability of serious adverse consequences was "remote"); that the FDA did not request Apotex Inc. to recall all of its products from the US market; and that the FDA did not issue any public advisories concerning alleged safety issues regarding Apotex Inc.'s products.<sup>110</sup> For the Respondent, Dr. Rosa testified at the Hearing: "... I cannot say that Apotex's products were not safe and were not effective or were safe or effective. I'm focusing on Apotex's GMP violations that made the drug adulterated."<sup>111</sup> The Tribunal understands that Dr. Rosa's use of the term "adulterated" here referred (as elsewhere) to its legal definition under the Act and not to its more colloquial meaning.
- 3.64. On the same day, by letter dated 28 August 2009, Apotex Inc. informed CDER of its intention to develop a "continuous improvement action plan" to address the FDA's concerns regarding cGMP compliance at the Etobicoke and Signet facilities.<sup>112</sup> The letter reiterated Apotex Inc.'s earlier commitment voluntarily to recall certain drug batches from US distribution and confirmed its engagement of a third party cGMP consultant to evaluate Apotex Inc.'s quality systems and ensure its cGMP compliance.<sup>113</sup> This letter also notified the FDA that Apotex Inc. had retained an outside consultant (Jeff Yuen & Associates) "to augment existing quality systems" at its two facilities.
- 3.65. On 30 August 2009, two days after the Import Alert was issued (albeit still unknown to Apotex Inc.), two shipments of products originating from the Etobicoke and

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<sup>110</sup> Second Witness Statement of Edmund Carey, Paras. 9-10.

<sup>111</sup> TD4.913 Dr. Rosa xx

<sup>112</sup> Apotex Memorial, Paras. 182-183; USA Counter-Memorial, Paras. 95-98.

<sup>113</sup> Exhibit C-066.

Signet facilities arrived at the Canada-USA border. Both shipments were held by the US border authorities pending the FDA's review and then detained without physical examination.<sup>114</sup> Further shipments were put on hold at the border; and by 1 September 2009, seven shipments from the Etobicoke and Signet facilities had been put on hold,<sup>115</sup> with several notifications sent to Apotex Inc. (as the importer of record), Apotex US (as the consignee), and Apotex Inc.'s customs broker.<sup>116</sup>

- 3.66. Following up on its earlier commitment, on 2 September 2009 Apotex Inc. issued a "Voluntary Drug Recall" of 659 drug batches from the US market.<sup>117</sup> On 3 September 2009, Apotex Inc. provided a 42-page response to the Form 483 observations regarding the FDA's Signet inspection, after the Import Alert.<sup>118</sup>

#### ***The Telephone Conference-Call of 3 September 2009***

- 3.67. On 3 September 2009, Apotex Inc. and FDA representatives held a telephone conference-call to discuss the Import Alert and the corrective action required of Apotex Inc.<sup>119</sup> Apotex Inc. contemporaneously prepared internal notes of this telephone call: these record that the FDA "explained that the FDA would like details regarding Apotex's global corrective actions to ensure GMP compliance at all of its locations and that the current voluntary recall plan by Apotex does not meet with the FDA's expectations given the significance of the documented GMP violations."<sup>120</sup>
- 3.68. Dr. Desai testified that the FDA informed him during this conference-call that Apotex Inc. had "an opportunity for a hearing on [the] detention and that re-inspection of our facilities had to take place before the Import Alert could be lifted. FDA also stated that they wanted to see a *global* corrective action plan for all Apotex sites, as opposed to site-specific changes. I requested a meeting and it was decided that Apotex should present its corrective action plan at the September 11,

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<sup>114</sup> Apotex Request, Para. 38; Apotex Memorial, Paras. 187-192; USA Counter-Memorial, Paras. 102-104.

<sup>115</sup> Apotex Memorial, Para. 192; USA Rejoinder, Para. 56.

<sup>116</sup> See for example Exhibits R-044, C-068-C-073, C-078-C-080.

<sup>117</sup> Apotex Memorial, Para. 193; USA Counter-Memorial, Para. 7; USA Rejoinder Para. 37; Exhibit C-074, at p. 1.

<sup>118</sup> Apotex Request, Para. 40; Apotex Memorial, Para. 195; USA Counter-Memorial, Para. 105.

<sup>119</sup> Apotex Memorial, Para. 194; USA Counter-Memorial, Para. 106.

<sup>120</sup> Exhibit R-045.

2009 meeting – that had already been scheduled before the Import Alert was adopted.”<sup>121</sup> (Apotex Inc. did not initiate, then or later, an application for a hearing on the detention of its drug shipments at the US-Canadian border.)

*New Zealand, Australia and the European Union*

- 3.69. In early September 2009, the New Zealand drugs regulator, Medsafe, indicated that it was “leaning toward” banning imports into New Zealand of drugs produced at the Etobicoke and Signet facilities.<sup>122</sup> Apotex NZ Limited subsequently signed a voluntary (and temporary) import restriction to the effect that it would not import into New Zealand drugs manufactured at the two facilities.<sup>123</sup> Import suspensions or bans were also requested or imposed by health regulators in Australia and the European Union, pending Health Canada’s inspection of the Signet and Etobicoke facilities.<sup>124</sup>

*The September 2009 Meetings*

- 3.70. On 11 September 2009, the planned meeting between Apotex Inc. and FDA representatives took place at the FDA’s headquarters in Washington DC, USA.<sup>125</sup> The meeting was attended by Apotex Inc.’s senior management with its consultants and legal advisers, including Mr. Kay, Dr. Desai, Mr. Lovelock and Dr. Clark; and the FDA’s representatives included Mr. Friedman, Mr. Rivera-Martinez, Dr. Rosa and two of the recent Signet inspectors on the telephone (Mr. Belz and Ms. Zielny). Both Apotex Inc. and the FDA gave slide presentations at this meeting.
- 3.71. The FDA’s presentation noted that “[s]imilar significant CGMP deficiencies” had been found at both the Signet and Etobicoke facilities, stating the following under the heading “FDA’s Current Concerns”:
- a. “Deficiencies found at both Etobicoke and Signet Campus facilities include...[c]orporate culture of reprocessing and retesting products into specification...[p]oor, inadequate, or incomplete OOS [out-of-specification]

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<sup>121</sup> First Witness Statement of Jeremy B. Desai, Para. 59 (original emphasis).

<sup>122</sup> Exhibit C-091; USA Counter-Memorial, Paras. 136-137.

<sup>123</sup> Apotex Memorial, Para. 210; USA Counter-Memorial, Para. 139 (fn 333); Exhibits C-102 and C-113.

<sup>124</sup> For Australia, Exhibit C-095; for the European Union, Exhibit C-114.

<sup>125</sup> Apotex Request, Para. 44; Apotex Memorial, Paras. 216-222; USA Counter-Memorial, Paras. 107-110.

and process deviations investigations...[n]on-timely submission of Field Alert Reports (FARS)”; and

- b. “Failure to have an appropriate global quality culture and system...[d]eficiencies were found in all six systems for the manufacture of drugs/drug products...[l]ack of root cause determinations and effective corrective actions to ensure reliable and reproducible manufacturing processes are in place.”<sup>126</sup>
- 3.72. Apotex Inc.’s presentation set out the immediate actions which had been taken at the Etobicoke and Signet facilities. The presentation also outlined Apotex Inc.’s several improvement plans and commitments, including an undertaking that independent consultants would conduct a product quality assessment (“PQA”) on all its products currently on the US market, or in the Etobicoke and Signet warehouses, in order to verify that Apotex Inc. products met appropriate standards and specifications at release until expiry.<sup>127</sup> Apotex Inc. also voluntarily agreed to suspend distribution of Etobicoke and Signet products from Apotex-US’s warehouse in Indianapolis, USA, until the completion of the PQA.<sup>128</sup>
- 3.73. Apotex Inc. requested that, based on a satisfactory completion of the product quality assessments and verification audits, FDA should promptly lift the Import Alert for the Etobicoke and Signet facilities following FDA re-inspection or sign-off by independent consultants.<sup>129</sup> Apotex Inc. further requested prompt PAIs for its pending ANDAs.<sup>130</sup>
- 3.74. The FDA informed Apotex Inc. that it would only recommend lifting the Import Alert after its own re-inspection of the two facilities;<sup>131</sup> and the FDA’s readiness for re-inspection would be contingent on assurances of sustainable cGMP conformance and the evaluation and resolution of deficiencies throughout all quality systems.<sup>132</sup>

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<sup>126</sup> Exhibits C-093 and C-094.

<sup>127</sup> Apotex Memorial, Para. 217; Exhibit C-092.

<sup>128</sup> Apotex Reply, Para. 46 (fn 30); Exhibit C-092, at p. 5; First Witness Statement of Jeremy B. Desai, Para. 63.

<sup>129</sup> Exhibit C-092.

<sup>130</sup> *Id.*

<sup>131</sup> USA Counter-Memorial, Para. 109; Exhibit C-094, at p. 2.

<sup>132</sup> Apotex Memorial, Para. 219; Exhibit C-093.



Mr. Rivera-Martinez closed the meeting by saying that “the ball is now in Apotex’s court.”<sup>133</sup>

- 3.75. On 17 September 2009, Apotex Inc. and the FDA held a telephone conference-call regarding the supply to the US market of two drugs (deferiprone and ██████████) for emergency or IND (investigational new drugs) treatment, so as to avoid a shortage of these drugs.<sup>134</sup> During the telephone call, Apotex Inc. agreed to FDA’s conditions that each batch shipped to the US would be subject to PQA (Product Quality Assessment) by an independent third party, and that each batch would be subject to retesting.<sup>135</sup> On 24 September 2009, subject to Apotex Inc.’s agreement to these conditions, the FDA allowed Apotex Inc. to ship a small quantity of deferiprone to the US to treat 47 gravely ill patients under the “Compassionate Use Program.”<sup>136</sup>
- 3.76. Following the Import Alert, as indicated to the FDA, Apotex Inc. retained an independent cGMP expert (Lachman Consultant Services, Inc.) to conduct the PQA.<sup>137</sup> On 24 September 2009, Lachman Consultant Services, Inc. submitted a PQA protocol for products in Apotex US’s Indianapolis warehouse.<sup>138</sup> Apotex Inc. also pursued a corrective action plan and a global quality systems enhancement program.<sup>139</sup> The Q6 Program, otherwise entitled “Apotex Global Quality Systems Revitalization Corrective Action Plan,”<sup>140</sup> was initiated by Apotex Inc. in November-December 2009.<sup>141</sup>

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<sup>133</sup> Exhibit C-094, at p. 9.

<sup>134</sup> Apotex Memorial, Para. 223; Exhibit C-103.

<sup>135</sup> Apotex Memorial, Para. 223 (fn 317); Exhibit C-103.

<sup>136</sup> Apotex Memorial, Para. 223; Exhibit C-107.

<sup>137</sup> Apotex Memorial, Para. 224; First Witness Statement of Edmund Carey, Paras. 46-48.

<sup>138</sup> Exhibits R-163, C-148.

<sup>139</sup> Apotex Memorial, Para. 228; First Witness Statement of Edmund Carey, Paras. 49-52; Exhibits C-132 and C-133.

<sup>140</sup> Apotex Inc. referred to the program as “Q6” internally because the plan was developed with the FDA’s “six quality systems” model originally set out in its “Guidance for Industry – Quality Systems Approach to Pharmaceutical CGMP Regulations” of September 2006 (First Witness Statement of Jeremy B. Desai, Para. 62; First Witness Statement of Edmund Carey, Para. 49).

<sup>141</sup> First Witness Statement of Jeremy B. Desai, Para. 68.

***Health Canada's Inspections October – November 2009***

- 3.77. Following a multi-week inspection of Apotex Inc.'s Etobicoke and Signet facilities, Health Canada issued "Inspection Exit Notices" for Signet on 14 October 2009 and for Etobicoke on 4 November 2009.<sup>142</sup> Although these notices gave the two facilities a "C" rating (*i.e.* "recommended for the continuation or issuance of the Establishment Licence"<sup>143</sup>), the Signet notice listed 26 observations, including 18 "Risk 2" observations (*i.e.* "major" observations<sup>144</sup>) and eight "Risk 3" observations (*i.e.* "other" observations<sup>145</sup>); and the Etobicoke notice listed 26 observations, including 19 "Risk 2" observations and seven "Risk 3" observations. Both notices provided that, in respect of four Signet observations and three Etobicoke observations, similar observations and issues had been made and reported during past inspections of Apotex Inc. by Health Canada.<sup>146</sup>
- 3.78. Health Canada subsequently carried out numerous follow-up inspections of the two facilities.<sup>147</sup>

***January – March 2010***

- 3.79. On 27 January 2010, Apotex Inc. and the FDA held a telephone conference which addressed issues with several of the firm's recent FARs. During the meeting, FDA noted that "[i]t appears that serious issues have not been resolved yet (FARs issued in December 2008, July and August 2009) as new concerns are still ongoing (recently filed FARs)."<sup>148</sup>
- 3.80. On 17 March 2010, the various independent experts retained by Apotex Inc. submitted their respective reports, including Lachman Consultant Services, Inc.'s PQA, and the independent review of Apotex Inc.'s quality structures and processes by Jeff Yuen & Associates (a GMP compliance consultancy firm).<sup>149</sup> The latter report's executive summary stated: "Recent quality systems assessments confirmed

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<sup>142</sup> Exhibits C-112 and C-116.

<sup>143</sup> Exhibit C-112, at p. 3, Exhibit C-116, at p. 3.

<sup>144</sup> Exhibit R-097, at p. 6.

<sup>145</sup> *Id.*; Exhibit C-112; USA Counter-Memorial, Para. 116.

<sup>146</sup> Exhibits C-112 and C-116.

<sup>147</sup> Apotex Memorial, Para. 208.

<sup>148</sup> Exhibit R-051, at p. 1; USA Counter-Memorial, Para. 157.

<sup>149</sup> Apotex Memorial, Para. 228; Exhibits C-120 and C-137.

that system level improvements were needed for all six systems. The [Jeff Yuen & Associates] quality system assessment was consistent with recent FDA inspectional observations and the recent warning letter citations with respect to three systems in particular: Quality Systems, Laboratory Systems, and Production/Packaging & Labeling Control Systems ...”<sup>150</sup>

- 3.81. Apotex Inc.’s “Q6” action plan was also launched also on 17 March 2010, along with the “Quality Systems Revitalization Program & Project Management Manual.”<sup>151</sup> These programs were produced with the assistance of Paul Vogel Consulting Services LLC.<sup>152</sup>

***The March 2010 Signet Warning Letter***

- 3.82. On 29 March 2010, the FDA sent to Apotex Inc. a warning letter with respect to the Signet facility (the “Signet warning letter”).<sup>153</sup> The Signet warning letter provided that FDA investigators had identified “significant violations” of cGMP regulations during their inspection of the Signet facility in July-August 2009.<sup>154</sup> The letter stated that it was being issued because of “serious and repeat violations from the 2008 and 2009 inspections” of the Etobicoke and Signet facilities, and because Apotex Inc.’s response to the Signet Form 483 (of 3 September 2009) was “inadequate and lacks sufficient corrective actions.”<sup>155</sup> The letter highlighted several cGMP violations observed during the 2009 inspection at Signet, including contamination, a failure thoroughly to investigate batch failures or unexplained batch discrepancies, and a failure to implement adequate equipment cleaning and maintenance procedures/programs to prevent contamination.<sup>156</sup> The letter also cited Apotex Inc. for its violations of the requirements for FARs.<sup>157</sup>
- 3.83. The Signet warning letter provided that, until all corrections had been completed by Apotex Inc. and confirmed by the FDA, the FDA would continue to deny entry of

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<sup>150</sup> Exhibit C-137, at p. 2.

<sup>151</sup> Apotex Memorial, Para. 228 (fn 326); Exhibits C-132 and C-133.

<sup>152</sup> Apotex Memorial, Para. 228.

<sup>153</sup> Apotex Request, Para. 46; Apotex Memorial, Para. 229; USA Counter-Memorial, Paras. 158-160.

<sup>154</sup> Exhibit C-138, at p. 1.

<sup>155</sup> *Id.*

<sup>156</sup> Exhibit C-138.

<sup>157</sup> *Id.*

products manufactured at the Signet facility and that CDER would recommend withholding approval of any new applications or supplements listing Apotex Inc. as a drug product manufacturer.<sup>158</sup>

- 3.84. On 31 March 2010, senior representatives of Apotex Inc. and the FDA met to discuss the Etobicoke and Signet facilities.<sup>159</sup> This meeting had been requested by Apotex Inc. in February 2010.<sup>160</sup>
- 3.85. At this meeting, both Apotex Inc. and the FDA made presentations. In opening the Apotex Inc. presentation, Mr. Kay (then Apotex Inc.’s President and Chief Operating Officer) stated that Apotex Inc. “gets” the FDA’s concerns.<sup>161</sup> Dr. Desai (then Executive Vice President Global Research and Development and Quality of Apotex Inc.) acknowledged that “Apotex needs to look at their Quality System. Apotex has hired 250 FTEs [full time equivalents] to address their quality issues...”<sup>162</sup> Apotex Inc.’s presentation included preliminary comments on the Signet warning letter, adding that Apotex would respond formally within 15 days.<sup>163</sup> Apotex Inc. then reported on its corrective actions and its product quality assessment.<sup>164</sup>
- 3.86. The FDA observed that “[w]e are not confident that all sites have a clear understanding of FDA requirements, including CGMPs.”<sup>165</sup> The FDA’s presentation noted that readiness for re-inspection and the removal of the Import Alert would be contingent on both the assurance of sustainable cGMP conformance and the evaluation and resolution of potential data integrity issues.<sup>166</sup> The FDA noted that “[t]hese pervasive issues can only be remedied through systemic and transformational changes at your firm.”<sup>167</sup>

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<sup>158</sup> *Id.*

<sup>159</sup> Apotex Request, Para. 47; Apotex Memorial, Paras. 232-238; USA Counter-Memorial, Paras. 162-168.

<sup>160</sup> Apotex Request, Para. 45; Apotex Memorial, Para. 225; USA Counter-Memorial, Para. 161.

<sup>161</sup> Exhibit C-140, at p. 2; Exhibit R-054, at p. 2.

<sup>162</sup> *Id.*

<sup>163</sup> Exhibit R-053.

<sup>164</sup> *Id.*; Apotex Memorial, Para. 233; USA Counter-Memorial, Para. 162.

<sup>165</sup> Exhibit R-055, at p. 12.

<sup>166</sup> *Id.*, at p. 13.

<sup>167</sup> *Id.*

- 3.87. At the end of the meeting, Apotex Inc. stated that it was confident that “Apotex is on the right track, even though the touchdown hasn’t been scored yet.”<sup>168</sup> There is no record that the FDA’s representatives agreed with this statement.
- 3.88. Apotex Inc. submitted its full written response to the Signet warning letter on 17 April 2010.<sup>169</sup> It had earlier suggested a follow-up by telephone conference-call with “Carmelo [Rosa] and his team” by email message dated 1 April 2010.<sup>170</sup>
- 3.89. On 14 June 2010, Apotex Inc. and FDA representatives (including Dr. Rosa) held a telephone conference-call which addressed multiple recent FARs received from Apotex Inc. regarding product contamination at its third facility in Richmond Hill, Ontario. The FDA’s minutes of this meeting recorded the following under the heading “Background”: “[t]he FARs are still under evaluation by Apotex, but the firm continues to release these products without initiating a product recall, which is concerning to [FDA Division of Manufacturing and Product Quality’s] International Compliance Branch.”<sup>171</sup>
- 3.90. On 14 June 2010, Dr. Rosa sent an internal FDA email summarising the FDA’s history of inspections of Apotex Inc. with an update regarding its Richmond Hill facility.<sup>172</sup> Dr. Rosa wrote that: “Apotex’s response of July 17, 2009, to the Etobicoke WL [warning letter], along with the additional corrective actions implemented throughout 2009 and 2010 ... appear to adequately address our concerns and will be verified during the next FDA GMP inspection ... The firm’s response of April 17, 2010 [to the Signet warning letter], including the decision to recall affected products, appears to adequately address our concerns...[a] follow up inspection is needed to verify the corrective and preventative actions.”<sup>173</sup>
- 3.91. On 25 June 2010, Apotex Inc. sought the FDA’s approval to export certain “shortage” drug products from the Etobicoke facility to the USA prior to the FDA’s

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<sup>168</sup> Exhibit C-140, at p. 7; USA Counter-Memorial, Para. 167.

<sup>169</sup> Apotex Memorial, Paras. 239-241; USA Counter-Memorial, Para. 163 (fn 394).

<sup>170</sup> Exhibit R-056.

<sup>171</sup> USA Counter-Memorial, Para. 170; Exhibit R-061.

<sup>172</sup> Exhibit R-185, at pp. 2-6.

<sup>173</sup> *Id.*, at p. 3.

re-inspection of that facility.<sup>174</sup> According to this request, the shipping (if approved) would occur under the supervision of a third party consultant who would certify the facility's compliance with cGMP, pending re-inspection by the FDA.<sup>175</sup> The FDA rejected this request, except for deferiprone which the FDA had previously authorised Apotex Inc. to export under direct oversight of a third party consultant.<sup>176</sup>

***Apotex Inc. Requests Re-Inspections: August – December 2010***

- 3.92. On 27 August 2010, Apotex Inc. requested the FDA to re-inspect its Etobicoke facility in early October 2010.<sup>177</sup> The request noted, among other matters, that Jeff Yuen & Associates, Inc. had informed Apotex Inc. in June 2010 that it was prepared to certify that the Etobicoke facility and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs were in compliance with cGMP.<sup>178</sup>
- 3.93. Within the FDA, Dr. Rosa requested a “priority inspection” of the Etobicoke facility on 22 September 2010, identifying the priority as “High.”<sup>179</sup>
- 3.94. On 29 September 2010, Apotex Inc. requested the FDA to re-inspect its Signet facility.<sup>180</sup> As with the Etobicoke facility, within the FDA, Dr. Rosa requested a “priority inspection” of that facility on 14 October 2010, again identifying the priority as “High.”<sup>181</sup>
- 3.95. On 21 October 2010, the FDA notified Apotex Inc. that the FDA was planning to conduct GMP inspections at the Etobicoke and Signet sites “sometimes between November 29 – December 17, 2010.”<sup>182</sup> However, on 22 November 2010, the FDA

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<sup>174</sup> Apotex Memorial, Para. 245; USA Counter-Memorial, Para. 171.

<sup>175</sup> Apotex Memorial, Para. 245.

<sup>176</sup> Apotex Memorial, Para. 246; Exhibit C-156; Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 36; *infra* Para. 3.75.

<sup>177</sup> Apotex Request, Para. 48; Apotex Memorial, Para. 250; USA Counter-Memorial, Para. 172.

<sup>178</sup> Exhibit C-166.

<sup>179</sup> USA Counter-Memorial, Para. 173; Exhibit R-062.

<sup>180</sup> Apotex Request, Para. 48; Apotex Memorial, Para. 251; USA Counter-Memorial, Para. 172.

<sup>181</sup> USA Counter-Memorial Para. 173; Exhibit R-063.

<sup>182</sup> Apotex Memorial, Para. 255; Exhibit C-172.

postponed the re-inspections until 24 January – 24 February 2011.<sup>183</sup> The notice from the FDA to Apotex Inc. stated: “This inspection will be postponed until 1/24 – 2/24/11 to be able to get an inspectional team of investigators and chemist together, review the [REDACTED] plus pending applications as well as evaluate corrections made by the firm to correct both Warning Letters.”<sup>184</sup> Apotex Inc. understood that the inspections were delayed by the FDA because a larger team was necessary to complete both a GMP inspection and a PAI inspection.<sup>185</sup>

- 3.96. Apotex Inc. requested the FDA to expedite the re-inspections on numerous occasions, but without success until January 2011.<sup>186</sup>

***FDA Re-inspections: January – February 2011***

- 3.97. The FDA re-inspected the Signet facility between 24 January and 11 February 2011 and the Etobicoke facility between 3 and 11 February 2011.<sup>187</sup> The same team of four FDA investigators conducted the re-inspection at both sites: Mr. Michael Goga, Mr. Francis Guidry, Mr. Steven Weinman and Ms. Sarah McMullen.<sup>188</sup>
- 3.98. Mr. Goga testified, as regards the GMP re-inspections, that: “Apotex had not remedied several of the cGMP violations that led to the firm’s addition to the import alert list”, in addition to new violations at both sites.<sup>189</sup> As regards the PAI inspections, Mr. Goga also testified that: “Due to the vast number of cGMP issues that were observed and the time it took to investigate them, we were not able to complete all of the PAIs ....”<sup>190</sup>
- 3.99. At the conclusion of the re-inspections, at the closeout meeting, the FDA’s inspectors provided Apotex Inc. with their Form 483 for the Signet facility and their Form 483 for the Etobicoke facility.<sup>191</sup> The Etobicoke Form 483 listed five inspectional observations regarding cGMP compliance; and the Signet Form 483

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<sup>183</sup> Apotex Request, Para. 52; Apotex Memorial, Para. 257; USA Counter-Memorial, Para. 177.

<sup>184</sup> Exhibit R-065.

<sup>185</sup> First Witness Statement of Edmund Carey, Para. 57.

<sup>186</sup> Apotex Memorial, Paras. 258-260.

<sup>187</sup> Exhibits C-193 and C-194; Apotex Memorial, Para. 262; USA Counter-Memorial, Para. 182.

<sup>188</sup> *Id.*

<sup>189</sup> Witness Statement of Michael R. Goga, Paras. 19-21.

<sup>190</sup> *Id.*, Para. 24.

<sup>191</sup> Exhibits C-193 and C-194; Apotex Memorial, Para. 263; USA Counter-Memorial, Paras. 188, 190.

listed 22 such observations.<sup>192</sup> At this meeting, as Mr. Goga testified, Dr. Desai acknowledged that Apotex Inc. was not satisfying the FDA’s expectations, adding: “Dr. Desai did tell us that he thought the inspection was fair and balanced. The Health Canada compliance officers who were present for the inspections told us that they agreed with our assessment that Apotex was not ready for re-inspection.”<sup>193</sup>

- 3.100. The FDA’s Establishment Inspection Reports (“EIRs”) for both re-inspections recommended the continuation of the Import Alert and the non-approval of pending applications for continuing GMP deviations.<sup>194</sup> The Etobicoke EIR provided that: “[the] [c]urrent inspection uncovered significant systematic and on-going objectionable conditions. Corrective action has not been fully implemented to every objectionable condition cited during the December 2008 inspection.”<sup>195</sup> With respect to the Signet re-inspection, the EIR provided that: “[t]he inspection identified twenty-two new or on-going deficiencies that were cited on an FDA 483 ...”<sup>196</sup> The Signet EIR also recorded that Dr. Desai (of Apotex Inc.) had commented that “the inspection was fair and balanced.”<sup>197</sup>
- 3.101. Following these two re-inspections, Apotex Inc. prepared a “US Re-Entry Product Assessment Protocol” on 24 February 2011.<sup>198</sup> The protocol was designed to assess all commercial ANDA products in order to assure product robustness, quality and regulatory compliance.<sup>199</sup> Each product was to be reintroduced into the US market only after meeting the protocol’s requirements.<sup>200</sup>
- 3.102. On 1 March 2011, Apotex Inc. submitted to the FDA its written response to the two Forms 483.<sup>201</sup> Apotex Inc. there outlined the overhaul of its quality systems and

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<sup>192</sup> Exhibits C-193 and C-194.

<sup>193</sup> Witness Statement of Michael R. Goga, Para. 26.

<sup>194</sup> Exhibit R-070, at pp. 1, 6 (Signet); Exhibit R-073, at pp. 1, 6 (Etobicoke).

<sup>195</sup> Exhibit R-072, at p. 1; Exhibit R-073, at p. 1.

<sup>196</sup> Exhibit R-070, at p. 1; Exhibit R-071, at p. 2.

<sup>197</sup> Exhibit R-070, at p. 1; Exhibit R-071, at p. 2. For Dr. Desai’s 1 March 2011 response to the two Forms 483 (“I felt that the inspection was extremely thorough and was well led, by Michael Goga”: Exhibit C-197, at p. 1).

<sup>198</sup> Apotex Memorial, Para. 264; Exhibit C-196.

<sup>199</sup> Apotex Memorial, Para. 264.

<sup>200</sup> *Id.*; First Witness Statement of Edmund Carey, Para. 64; First Witness Statement of Jeremy B. Desai, Para. 92.

<sup>201</sup> Apotex Memorial, Para. 265; USA Counter-Memorial, Paras. 195-197.



noted its intention to begin manufacturing for the US market as soon as possible.<sup>202</sup> Apotex Inc. also requested approval from the FDA to release new products from Etobicoke and Signet upon regulatory approval (with third party oversight for the Signet facility).<sup>203</sup>

***Lifting of the Import Alert: May – July 2011***

- 3.103. After reviewing the FDA’s EIR for the Etobicoke inspection and Apotex Inc.’s responses to the Forms 483, the FDA informed Apotex Inc. on 6 May 2011 that it would classify the Etobicoke facility as “acceptable.”<sup>204</sup>
- 3.104. An internal FDA memorandum dated 9 May 2011 from CDER to DIOP recommended that the Etobicoke facility be removed from Import Alert 66-40.<sup>205</sup> The memorandum provided: “The firm appears to be manufacturing in compliance with cGMPs and therefore, should be allowed to import their products into the United States or any of its territories.”<sup>206</sup> The recommendation was accepted within the FDA; and the Import Alert lifted with respect to the Etobicoke facility on 15 June 2011.<sup>207</sup> The Import Alert remained as regards the Signet facility.
- 3.105. From 16 May to 11 June 2011, Health Canada conducted GMP re-inspections of the Etobicoke and Signet facilities.<sup>208</sup> An internal Health Canada memorandum provided that the inspection findings would result in a “Compliant” rating under Canadian standards.<sup>209</sup> It also observed that: “[i]n general, the inspection team felt that Apotex has demonstrated significant improvement in its quality systems when compared with 2009/2010.”<sup>210</sup>

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<sup>202</sup> Exhibit C-197, at p. 10.

<sup>203</sup> *Id.*

<sup>204</sup> Apotex Memorial, Para. 266; USA Counter-Memorial, Para. 198; Exhibit C-233, at p. 1.

<sup>205</sup> Apotex Memorial, Para. 267; USA Counter-Memorial, Para. 199.

<sup>206</sup> Exhibit C-234.

<sup>207</sup> Apotex Request, Para. 54; Apotex Memorial, Para. 269; USA Counter-Memorial, Para. 199.

<sup>208</sup> Exhibit R-076.

<sup>209</sup> *Id.*, at p. 2.

<sup>210</sup> *Id.*, at p. 3. Also, in relation to the ‘black particles’ issue dating back to July 2009, the memorandum noted that “Apotex’s handling of the issue demonstrates some of its systemic weaknesses in 2009 and improvements that it has since implemented to its quality systems” (at p. 3).

- 3.106. The FDA requested additional information from Apotex Inc. on 20 May 2011 concerning four of the 22 observations in the Signet Form 483 issued on 11 February 2011.<sup>211</sup> Apotex Inc. responded to the FDA’s request on 10 June 2011.<sup>212</sup>
- 3.107. After reviewing the Signet EIR and Apotex Inc.’s responses dated 1 March and 10 June 2011, the FDA informed Apotex Inc. on 1 July 2011 that it was classifying Apotex Inc.’s Signet facility as “acceptable.”<sup>213</sup> In addition to the Signet EIR and Apotex Inc.’s responses, the FDA had also reviewed the findings made by Health Canada in its cGMP inspection of the Signet facility conducted in May and June 2011.<sup>214</sup>
- 3.108. On the same day, CDER recommended to DIOP that the Signet facility be removed from the Import Alert.<sup>215</sup> The recommendation was subsequently accepted by DIOP; and the Signet facility was removed from the Import Alert on 29 July 2011.<sup>216</sup>

***Etobicoke PAI: May – November 2011***

- 3.109. On 9 May 2011 (three days after FDA informed Apotex Inc. of Etobicoke’s “acceptable” classification), Apotex Inc. requested approval of its seven pending applications for new drugs produced at Etobicoke.<sup>217</sup> The FDA, however, informed Apotex Inc. on 29 June 2011 that “the limited pre-approval coverage [during the 2011 re-inspection] will not allow us to recommend approval of the pending applications for the Etobicoke site.”<sup>218</sup> The FDA told Apotex Inc. that a PAI would still be required in respect of the Etobicoke facility, and that “an effort will be made to prioritized [sic] a PAI inspection” for Etobicoke.<sup>219</sup>

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<sup>211</sup> Apotex Memorial, Para. 270; USA Counter-Memorial, Para. 200.

<sup>212</sup> Apotex Memorial, Para. 271; USA Counter-Memorial, Para. 200.

<sup>213</sup> Apotex Memorial, Para. 273; USA Counter-Memorial, Para. 202; Exhibit C-247, at p. 1.

<sup>214</sup> Apotex Memorial, Para. 272; USA Counter-Memorial, Paras. 201-202.

<sup>215</sup> Apotex Memorial, Para. 273; USA Counter-Memorial, Para. 202.

<sup>216</sup> Apotex Request, Para. 54; Apotex Memorial, Paras. 275-76; USA Counter-Memorial, Para. 202.

<sup>217</sup> Apotex Request, Para. 55; Apotex Memorial, Para. 278.

<sup>218</sup> Exhibit C-246, at p. 1. *See also* Exhibits C-236 and C-240.

<sup>219</sup> Exhibit C-246.

- 3.110. On 23 August 2011, the FDA issued a notice stating that FDA would conduct a pre-approval inspection of Apotex Inc.'s ANDAs at the Etobicoke facility on 18 to 30 September 2011.<sup>220</sup>
- 3.111. FDA conducted the pre-approval inspection at Etobicoke from 19 to 28 September 2011.<sup>221</sup> At the conclusion of the inspection, the FDA provided Apotex Inc. with a two-item Form 483.<sup>222</sup>
- 3.112. By letter dated 12 October 2011, Apotex responded to the FDA inspectors' observations in their Form 483.<sup>223</sup> The letter (signed by Apotex Inc.'s Chief Operating Officer) began: "Firstly, I would like to recognize the efforts of the FDA Inspection Team and thank them. The inspection was thorough and was well led, by CSO Marie Fadden, CSO Kevin Foley and Chemist Sneha Patel. Throughout the course of the inspection, the investigators were found to be cordial, competent and professional. The Inspection Team made every effort to ensure that we were informed as to their requirements and they made all reasonable efforts to engage Apotex staff during the inspection. I very much appreciated the effort expended and the forthright approach that the investigators took in dealing with observations that they made. Our goal is to always meet, or exceed where possible, the requirements of all laws and regulations administered by the FDA as well as those of all other regulatory bodies that oversee the international markets we serve. We do not believe that there is anything trivial in the observations provided and we accept them as part of our ongoing journey of continuous improvement ..."<sup>224</sup>
- 3.113. On 30 October 2011, the FDA informed Apotex Inc. that "[w]e will be entering an approval recommendation for the applications specifically covered during the inspection, by NLT [not later than] Monday (if not done already)."<sup>225</sup>

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<sup>220</sup> Exhibit C-254.

<sup>221</sup> Apotex Request, Para. 56; Apotex Memorial, Para. 282; USA Counter-Memorial, Para. 205; Exhibit R-081.

<sup>222</sup> Apotex Memorial, Para. 282; USA Counter-Memorial, Para. 205.

<sup>223</sup> *Id.*

<sup>224</sup> Exhibit C-268, at p. 1.

<sup>225</sup> Exhibit C-270, at p. 1; First Witness Statement of Bernice Tao, Para. 79.

3.114. On 25 November 2011, the FDA approved the first pending ANDA at Etobicoke, followed by further approvals on 7 and 30 December 2011 and 3 February 2012.<sup>226</sup> (Two Etobicoke ANDAs were not yet approved by the FDA).<sup>227</sup>

### *Conclusion*

3.115. In conclusion, the period from the FDA's warning letter regarding the Etobicoke facility in June 2009 to the lifting of the Import Alert in June-July 2011 for both the Etobicoke and Signet facilities was 24/25 months, with 23 of these months spent under the Import Alert. The FDA took a "global" or "corporate" approach to Apotex Inc. and its Etobicoke and Signet Facilities.

3.116. For the Claimants, Apotex Inc. did not materially challenge the FDA decisions to treat deficiencies found at its two facilities as violations of cGMP, rendering their products "adulterated" under the Act, neither during the telephone conference-call of 17 August 2009 nor thereafter. In this arbitration, Apotex Inc. claims only in regard to the FDA's Import Alert and not the Form 483s or the warning letters. For present purposes, the losses sustained by Apotex Inc. resulting from the Import Alert can be assumed to be very considerable, as also its remedial expenses incurred at both facilities. (These losses are the subject of the claims advanced by Apotex Inc. against the Respondent in this arbitration, with quantum much in issue and, as already indicated, bifurcated.)

3.117. For the Respondent, Dr. Rosa testified at the Hearing that during this period the FDA's resources spent on Apotex Inc. were "countless", adding: "This is one of the cases where we spent most of – most time reviewing, and I've been involved in injunctions, consent decrees, and prosecutions. This one certainly is one of the top ones in terms of resources consumed for evaluating."<sup>228</sup> Dr. Rosa also testified: "... The extraordinary time and effort devoted to Apotex Inc. during this time represented a tremendous drain on Agency resources, and far exceeded the time we spent on nearly every other drug manufacturing facility during that period. Hundreds of inspections of other firms were still pending, yet Apotex Inc. continued

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<sup>226</sup> Apotex Memorial, Para. 285; USA Counter-Memorial, Para. 207.

<sup>227</sup> Apotex Memorial, Para. 285.

<sup>228</sup> TD4.1085 Dr. Rosa xx (T).

to demand that FDA inspect and re-inspect its facilities until it came into compliance. In fact, Apotex was reinspected sooner than other firms with cGMP violations, and, as we learned during those reinspections, the firm was not ready for the reinspections.”<sup>229</sup> As already noted, the FDA’s resources were expended without financial charge to Apotex Inc. and do not form the basis of any claim by the Respondent against Apotex Inc. in this arbitration.

**(3) *The Teva Chronology***

3.118. The Tribunal has compiled the following factual chronology principally from: (i) the list of evidentiary references to contemporary documentation which was supplied by the Parties to the Tribunal in regard to Teva (including those in response to Question B2 in the Tribunal’s email message of 23 November 2013); and (ii) other documentary exhibits and testimony cited by the Parties in their written and oral pleadings in this arbitration. The Tribunal heard no witness from Teva in this arbitration; and, accordingly it is necessary to cite at some length contemporary materials relating to Teva that is relevant to this chronology.

3.119. The Teva group of companies are engaged in the development, production, and marketing of generic pharmaceuticals (as well as proprietary branded pharmaceuticals and active pharmaceutical ingredients) and operate 56 manufacturing facilities around the world, with a total revenue in 2010 of US \$16.21 billion.<sup>230</sup> Teva is the world’s leading generic pharmaceutical company and the leading provider of generics to the US market. For the USA, Teva has over 600 ANDAs.<sup>231</sup> (For ease of reference below, the Tribunal does not distinguish between these different legal entities, referring to them all as “Teva”.)

3.120. Teva operated a facility at Irvine, California and also a facility in Jerusalem, Israel. As regards the Irvine facility, the FDA conducted an inspection in 2009, finding numerous cGMP violations. As regards the Jerusalem facility, the FDA conducted

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<sup>229</sup> First Witness Statement of Dr. Carmelo Rosa, Para. 77.

<sup>230</sup> First Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 142.

<sup>231</sup> Exhibit C-283.

three inspections in 2006, 2008 and 2010 “with 483s issued.”<sup>232</sup> These inspections and their consequences are described below.

- 3.121. Although Teva has a facility within the USA making it subject to other sanctions, Teva’s manufacture in Jerusalem of drugs for export to the US market makes those drugs subject to the Act and eligible for Import Alert 66-40.

### **2009**

- 3.122. *11 December 2009*: The FDA issued a warning letter to Teva Parenteral Medicines, Inc.<sup>233</sup> This letter referred to FDA’s inspection on 13-24 July 2009 of Teva’s Irvine, California facility.
- 3.123. The Irvine warning letter stated: “The inspection identified significant violations of the Current Good Manufacturing Practice (CGMP) Regulations for Finished Pharmaceuticals ... These violations cause your drug products to be adulterated within the meaning of Section of 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 351(a)(2)(B)] in that the methods used in, or the facility or controls used for, their manufacturing, processing, packing, or holding do not conform to or are operated or administered in conformity with, CGMP. We have received your firm’s responses of August 10, September 4 and 8, October 27 and 29, and November 13, 2009, and note these Responses lack sufficient corrective actions. Specific violations observed during the inspection include, but are not limited to: [here follow 13 numbered violations].”<sup>234</sup>
- 3.124. Following the formal warning, the Irvine warning letter concluded: “Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step taken to prevent the recurrence of violations and copies of supporting documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the date by which you will have completed the correction. Additionally, your response should state if you no longer

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<sup>232</sup> Exhibit C-424a.

<sup>233</sup> Exhibit C-124.

<sup>234</sup> *Id.*, at p. 1.

manufacture Propofol Sterile Emulsion for Injection, and provide the date(s) and reason(s) you ceased production.”<sup>235</sup>

## **2010**

- 3.125. *22 February 2010*: Teva Pharmaceutical Industries Limited filed its Annual Report (SEC Form 20-F) with the US Securities and Exchange Commission.<sup>236</sup>
- 3.126. Under “Risk Factors”, the following risk was described: “Recently there has been increasing regulatory scrutiny of pharmaceutical manufacturers. We must register our facilities, whether located in the U.S. or elsewhere, with the FDA and similar regulators and our products must be made in a manner consistent with current good manufacturing practices (“cGMP”), or similar standards in each territory in which we manufacture. In addition, the FDA and other agencies periodically inspect our manufacturing facilities. Following an inspection, an agency may issue a notice listing conditions that are believed to violate cGMP or other regulations, or a warning letter for violations of ‘regulatory significance’ that may result in enforcement action if not promptly and adequately corrected. Compliance with production and quality control regulations requires substantial expenditure of resources. If any regulatory body were to require one of our manufacturing facilities to cease or limit production, our business could be adversely affected. In addition, because regulatory approval to manufacture a drug is site-specific, the delay and cost of obtaining approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations.”<sup>237</sup>
- 3.127. *16 April 2010*: Teva voluntarily suspended manufacturing operations at the Irvine facility.<sup>238</sup> Teva also recalled a number of drugs due to impurities.<sup>239</sup>
- 3.128. *28 October 2010*: FDA officials met with Teva executives regarding the Irvine facility. According to the FDA’s minutes of that meeting:<sup>240</sup> “Mr. Gall [Teva Vice-

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<sup>235</sup> *Id.*, at p. 7.

<sup>236</sup> Exhibit C-129.

<sup>237</sup> *Id.*, at p. 8.

<sup>238</sup> Exhibit C-424a.

<sup>239</sup> First Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 143.

<sup>240</sup> Exhibit C-424.

President of Operations at the Irvine facility] provided an example of the new maintenance plan on water systems. Ms. Sakers [Teva Executive Vice-President, Corporate Quality] informed FDA of changes in the QA reporting structure as well as QA's new involvement in all levels of the drug manufacturing including on the floor. She assured FDA that QA will be involved in all deviation investigations and QA will review and document any changes to the system. Mr. Friedman [FDA Director, Division of Manufacturing and Product Quality], once again, stressed the importance of thinking globally and applying corrective actions to all facilities and not just to the Irvine site.”

- 3.129. Later in the meeting: “Mr. Cruse [FDA Los Angeles District Director] recognized Teva’s summary of their corrective actions and applaud[ed] Teva’s attempt to put the right systems in place to ensure compliance. He cautioned that no matter how big the system is or how great the innovation is, implementation, training, and accountability will produce success. He also cautioned Teva for putting too much onus on the consultant and stressed the importance of Teva’s leadership to sustain the momentum of compliance when the consultant is no longer there. Mr. Cruse mentioned that although the findings from the Irvine facility ultimately resulted in this meeting, the correction actions provided during this meeting should be global and Teva should take a proactive approach in ensuring all facilities are in compliance. Mr. Cruse acknowledged that the shut down of the Irvine facility is the type of corporate reaction FDA is looking for when the firm is not in substantial compliance and asked if Teva plans to take the same strategy for other facilities when they are found to be non-compliant.”
- 3.130. The Tribunal notes that, at this meeting of 28 October 2010, the FDA welcomed Teva’s voluntary ‘shut-down’ of the Irvine facility in response to the FDA’s warning letter and called for Teva to take a “global” and “proactive” approach. This meeting was attended by (*inter alios*) Dr. Rosa.
- 3.131. At this same meeting on 28 October 2010, Teva presented a slide presentation to the FDA listing as a voluntary action (*inter alia*) Teva’s “moratorium” on production and release at the Irvine facility.<sup>241</sup> The FDA likewise presented a slide presentation

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<sup>241</sup> Exhibit C-424a.



to Teva. The shut-down of the Irvine facility effected in April 2010 was to continue until April 2011, a period of 12 months.

- 3.132. *24 November 2010*: An FDA Enforcement Report described Teva's nationwide "ongoing" recall (by letter dated 22 September 2010) of tamoxifen citrate tablets.<sup>242</sup>

## **2011**

- 3.133. *31 January 2011*: The FDA issued a warning letter to Teva Pharmaceutical Industries Ltd regarding cGMP non-compliance at its facility in Jerusalem.<sup>243</sup>

- 3.134. This Jerusalem warning letter stated: "During our September 12-16, 2010 inspection of your pharmaceutical manufacturing facility, Teva Pharmaceutical Industries, Ltd., located at 24 Professor Hartum Street, Har Hozvim, Jerusalem, Israel, investigators from the Food and Drug Administration (FDA) identified significant violations of Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals .... These violations cause your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act .... in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP. We have reviewed your firm's response of October 7, 2010, and note that it lacks sufficient corrective actions. Specific violations observed during the inspection include, but are not limited, to the following: [here follows two numbered violations]." After the formal warning, the letter concluded: "Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations and copies of supporting documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the date by which you will have completed the correction ..."

- 3.135. Dr. Rosa testified that, in response to the Jerusalem warning letter, Teva volunteered to cease production until its resolution of the cGMP violations and that it committed to correct them swiftly. He also described later actions by Teva and the FDA:

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<sup>242</sup> Exhibit C-566.

<sup>243</sup> Exhibit C-191.

“Because the [Jerusalem] facility makes numerous medically necessary drugs, FDA requested that Teva Pharmaceuticals continue producing those drugs, while simultaneously implementing proposed corrective actions. FDA determined that the medical necessity of Teva Pharmaceutical’s drugs and the quality of Teva Pharmaceutical’s retrospective evaluation and ongoing corrective action weighed against adding the firm to the Import Alert.”<sup>244</sup>

- 3.136. *23 February 2011*: Teva announced a recall of several products manufactured at its Jerusalem facility on or about 23 February 2011.<sup>245</sup>
- 3.137. On 23 February 2011, an FDA internal email chain addressed an internal request to assess the possibility of drug shortages following a possible suspension of production at Teva’s Jerusalem facility.<sup>246</sup> It revealed serious concerns within the FDA about shortages and impacts on patients in the USA resulting from such a suspension; and it foreshadowed an urgent telephone conference-call between the FDA and Teva.
- 3.138. At the Hearing, Dr. Rosa testified about his telephone conversation with Teva’s corporate quality officer (Ms. Fran Zipp) in which Ms. Zipp indicated to him that “... their intentions were to stop production, to stop distribution of drugs. That’s why you will see a chain of e-mails going back and forth because the Agency was extremely concerned with that possibility.”<sup>247</sup> He added later: “... she was definitely very concerned with the inspectional findings and was speaking about that Teva [sic] will be taking all and any necessary action to remove product from the market that could be affected, and they were ready to cease and stop. She actually ordered – her statement was she ordered that that [Jerusalem] facility stop producing, stop the distribution ... And that certainly was a concern because of the medical [sic] necessary drugs that they manufactured or drugs that ... are in shortage and produced at that facility.”<sup>248</sup> The precise date of this conversation is not known: it was clearly after the Jerusalem warning letter; and Dr. Rosa thought it was close to

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<sup>244</sup> Supplemental Witness Statement of Dr. Carmelo Rosa, Para. 31.

<sup>245</sup> Exhibit R-131.

<sup>246</sup> *Id.*

<sup>247</sup> TD4.973 Dr. Rosa xx.

<sup>248</sup> TD4.1032-1034 Dr. Rosa xxx.

the issuance of that warning letter, but probably before the email messages summarised below.<sup>249</sup>

- 3.139. *24 February 2011*: In an FDA internal email,<sup>250</sup> Captain Jensen, a senior FDA official dealing with drug shortage issues, stated: “Firm [Teva] has made the decision to recall 30 lots involving 21 different drug products made at the Jerusalem facility. There is a real concern about patient impact - these are chronic medications that patients won’t have when they go to get their medications from the pharmacy (including common blood pressure drugs, cholesterol lowering drugs, diabetes drugs, arthritis drugs, antidepressants and other widely used medications). We see the need for a teleconference with Teva as soon as possible to let them know the medical need for these and to work with them to keep manufacturing medically necessary drugs at the supply levels needed to meet patient needs while fixing their problems (as long as benefit outweighs any potential risks). We don’t see any products on the list that would not be impacting patients and we are worried about the impact of any supply disruption at the Jerusalem facility. Teva has a very large market share for these products and acquired additional market share when CGMP issues occurred in recent years at other manufacturers making these drugs (Caraco, Ranbaxy, Apotex, Actavis, and KV).”
- 3.140. *16 March 2011*: An FDA internal email chain recorded concerns within the FDA at a hold put on imports of Teva’s products by US officials at the port of entry into the USA.<sup>251</sup> Captain Jensen’s email message of 21 March 2011 advised her FDA colleagues: “ ... Teva is still reporting multiple entries of lots made at the Teva Jerusalem facility are on hold and are reporting shortages will occur (again these are common prescription medications and patients will have difficulty filling their everyday prescriptions at the pharmacy without these - the Jerusalem facility supplies large portion of the US market for medications needed for blood pressure, seizures, Parkinson’s, diabetes and other chronic diseases.”

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<sup>249</sup> TD4.1002-1004 Dr. Rosa xx.

<sup>250</sup> Exhibit R-131, at p. 2.

<sup>251</sup> Exhibit R-192.

- 3.141. *26 April 2011*: The Wall Street Journal reported:<sup>252</sup> “Teva Pharmaceutical Industries Ltd. ... resumed production at an Irvine, Calif., facility that was on voluntary hold for a year following quality control issues and regulatory intervention. The site, which makes injectable products for the Israel generic drug company, received a Food and Drug Administration warning letter in December 2009 that detailed ‘significant’ manufacturing violations and fixing the problems took longer than the company initially expected. The company had said in February [2011] that manufacturing problems at the site had cut sales by \$230 million in 2010. Teva reported full-year sales of \$16.1 billion. At the time, Teva said ramping up production at the plant would be a slow process that would take most of the year. On Tuesday, Teva said restarting the operation - after an April 2010 manufacturing and distribution hold - was a ‘significant step for improving its product availability for the U.S. injectable market.’ The anesthetic propofol was manufactured at the site and some product was recalled in 2009 after elevated levels of toxins were discovered at the Irvine site. Teva has since stopped making the drug. In a regulatory filing Tuesday, Teva said it also submitted a response to a January [2011] warning letter relating to a Jerusalem pill-making facility, noting that it had implemented ‘corrective actions.’ The FDA had cited deficiencies related to laboratory reporting and quality control systems, and deemed a response to an earlier inspection as insufficient ...”
- 3.142. *29 April 2011*: FDA officials drafted a briefing note in preparation for a telephone conference between Dr. Janet Woodcock, Director of CDER, and Teva’s CEO:<sup>253</sup> “This briefing is to prepare Dr. Woodcock for telephone conference with Teva’s CEO. The purpose of the call is to express FDA’s continuing concern regarding the CGMP problems that the firm has had at several facilities, reinforce FDA’s concern about the detrimental impact that Teva’s problems have had on market supply of medically necessary drugs and seek commitment from the firm to notify FDA before they take any action such as recall, plant/line shutdown, suspension of distribution, and any other action that may result in shortage of medically necessary drug.”

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<sup>252</sup> Thomas Gryta, “Teva Resumes Manufacturing at Irvine, Calif. Plant”, Wall Street Journal MarketWatch”, Exhibit R-075.

<sup>253</sup> Exhibit C-572.

- 3.143. As regards the first item on the proposed agenda (“The Medical Needs for Teva’s Products”), the FDA briefing note states: “Teva manufactures a significant number of medically necessary drugs that can result in market shortage when they discontinue or cut back production of these products. In 2010, the firm decided to simply shut down production at the Teva Parenteral Medicines facility in Irvine, CA, causing massive shortages and market supply disruptions of products that are medically necessary for patients. Recently, the firm has recalled 30 lots involving 21 different drug products made at the Jerusalem facility. There is a real concern about patient impact – these are medications that patients rely on for chronic diseases. The products involved are blood pressure drugs, cholesterol lowering drugs, diabetes drugs, arthritis drugs, antidepressants and other widely used medications. We are worried about the impact of any supply disruption that might occur at the Jerusalem facility. Teva has a very large market share for these products described above and acquired additional market share when cGMP issues occurred in recent years at other manufacturers making these drugs (Caraco, Ranbaxy Apotex, Actavis and KV).” The agenda’s second item described Teva’s efforts to address the cGMP issues at its facilities at Irvine and Jerusalem.
- 3.144. *26 May 2011*: In an FDA internal memorandum, Dr. Rosa requested a “priority inspection” to be conducted by the FDA at Teva’s facility in Jerusalem.<sup>254</sup> This inspection was completed on 19 June 2011 “with an NAI” [No Action Indicated].<sup>255</sup>
- 3.145. *24 August 2011*: An FDA internal email chain recorded concerns at the unanticipated holding at a US port of entry of Teva’s products regarded by the FDA as medically necessary drugs.<sup>256</sup> Dr. Rosa’s concluding message stated: “... A T-CON with Teva has been scheduled for tomorrow at 4 pm. We do not know why the product is being held up at the port, unless its [sic] due to routine import verification as part of the import entry process. All the profiles are acceptable and an approval recommendation has been enter[ed] for their pending applications, pertaining to the Jerusalem facility. CDER OC is not the cause of the import hold up. We are aware that the administrative/review record must be closed sooner than later. However they needed to provide information about the[ir] global corrective action plan and

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<sup>254</sup> Exhibit C-573.

<sup>255</sup> Exhibit C-574.

<sup>256</sup> *Id.*

their FARs investigation into glass found in the API produced at their Jerusalem site. We now have the information, and hope to resolved [sic] all outstanding issues tomorrow ...”

- 3.146. *9 September 2011*: The FDA issued a close out letter regarding Teva’s Jerusalem facility,<sup>257</sup> stating: “The Food and Drug Administration has completed an evaluation of your firm’s corrective actions in response to our warning letter 320-11-08 dated January 31, 2011. Based on our evaluation, it appears that you have addressed the violation(s) contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections. This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.”
- 3.147. Prior to this close out letter, the FDA had approved ANDAs by Teva: ANDA #090289 on 3 June 2011, ANDA #076361 on 20 June 2011 and ANDA #090199 on 22 August 2011.<sup>258</sup>

## **2012**

- 3.148. *23 July 2012*: The FDA’s Assistant Commissioner for Legislation sent to The Honorable Elijah E. Cummings, Ranking Member of the Committee on Oversight and Government Reform of the US House of Representatives, a long and detailed letter addressing the Committee’s staff report on drug shortages in the USA.<sup>259</sup>
- 3.149. It suffices here to cite only the opening paragraphs: “Thank you for your letter of July 9, 2012, regarding the report entitled ‘FDA’s Contribution to the Drug Shortage Crisis’ (the Report). We appreciate the opportunity to provide clarification about the issues raised in the Report. Preventing drug shortages is a top priority for

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<sup>257</sup> Exhibit C-256.

<sup>258</sup> First Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 147.

<sup>259</sup> Exhibit C-452.

the Food and Drug Administration (FDA or the Agency). The number of drug shortages has risen steadily since 2005 to hit an all-time high of 251 drug shortages in 2011. This is a very troubling situation that FDA takes very seriously. The root causes of drug shortages, however, lie largely outside of FDA's purview. Contrary to the conclusion reached in the Report, FDA is not the root cause of this serious public health problem. In recent years, more than half of all drug shortages were related to manufacturing production problems, including quality-related issues and delays. The remainder of the shortages was caused by business decisions to discontinue certain products, difficulty obtaining raw materials, loss of manufacturing sites, increased demand, and component problems. Patients expect and deserve high-quality drugs. It is the manufacturer's responsibility to ensure that its products are safe, effective, and of high quality. FDA is committed to working with industry to resolve quality or manufacturing problems that arise, to ensure continued patient access to vital safe and effective medicines. In fact, in appropriate cases, FDA may exercise regulatory flexibility to prevent or mitigate a drug shortage, such as by expediting inspections or review of manufacturing supplements to facilitate production changes ..." [footnotes omitted]. The letter also addressed the closure of Teva's facility at Irvine.

- 3.150. *18 October 2012*: A Knight Ridder/Tribune Brief reported:<sup>260</sup> "The Orange County Business Journal' reports that Teva Pharmaceutical Industries Ltd. .... is firing 65 employees at its plant in Irvine, California, according to a state filing. The newspaper added that cuts will take effect on October 29 and scientists, chemists, and inspectors [sic]. Teva had an estimated 500 workers in Irvine before the filing. It cut 156 workers in Irvine last year as a result of an earlier year-long halt to production after it stopped making propofol, a sedative that gained notoriety in the death of Michael Jackson. Teva acquired the Irvine plant in 2003 through the acquisition of generic drug maker Sicor Inc. 'The New York Times' reported today that, in 2009, the US Food and Drug Administration (FDA) cited Teva for several violations at its injectable drug plant in Irvine, including for the failure to catch bacterial contamination of propofol, before it left the factory. The citation was part of a crackdown after Margaret Hamburg became FDA commissioner. Teva said it

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<sup>260</sup> "Teva Fires 65 Employees at California Plant", Business Week, Exhibit R-100.

spent \$375 million for improvements and reopened its factory in Irvine, but it that [sic] has not yet resumed full production.”

- 3.151. *2008-2012*: A ranking of major participants in the US generics drug market placed Teva as the first in total sales on US Annual IMS Data. (Apotex is not listed).<sup>261</sup>

### **2013**

- 3.152. *4 June 2013*: In-Pharma Technologist reported:<sup>262</sup> “... Last July [2012], the Food and Drug Administration Safety and Innovation Act (FDASIA) - aimed to tighten the grip on the global supply chain - was signed into law and included the requirement for pharmaceutical companies to notify the US Food and Drug Administration (FDA) of any anticipated shortages. FDA spokesperson Lisa Kubaska told this publication that ‘since FDASIA was enacted, the FDA has been receiving daily calls and emails from manufacturers about potential problems.’ Though the legislation has led to closer cooperation between manufacturers and the FDA, Kubaska told us shortages are still an issue and ‘about 75 per cent of drug shortages are caused by manufacturing issues’ and breakdowns in quality. ‘Such breakdowns have occurred most often with manufacturers of sterile injectable drugs, including oncology drugs. These quality issues have included compromised sterility and the presence of glass, metal and other material inside drug vials’ ... Propofol Off Shortage List: One drug that has sat on the FDA’s drug shortage list for the past few years was propofol, the anaesthesia infamously associated with the death of Michael Jackson. The shortage had been caused by manufacturing issues first at Teva’s Irvine, California facility and then at Hospira’s Clayton, North Carolina plant, yet following the recent re-entry into propofol manufacturing by these two players, supply levels are, according to Kubaska, ‘anticipated by the firms to be more than adequate to meet demand.’ Last summer the only company manufacturing the drug was Fresenius Kabi, who worked with the FDA in order to ramp up capacity from two of its European sites ....”

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<sup>261</sup> IMS Medical, Comparators’ Ranking & Sales Data based on the US Generic Drug Market, FY2008-FY2012, Exhibit C-327.

<sup>262</sup> “Propofol Off FDA List but Manufacturing Issues Case 75% of Shortages”, Exhibit R-228.



### *Conclusion*

- 3.153. In conclusion, the FDA issued its warning letter regarding Teva’s Jerusalem facility on 31 January 2011; it was site-specific (as with Teva’s Irvine facility); and the FDA did not take in its warning letters a “corporate” view of Teva’s violations in its two facilities. Beyond the Jerusalem warning letter, the FDA did not implement against Teva’s Jerusalem facility any import alert; and the FDA did not initiate any further administrative or enforcement action against Teva in regard to its Jerusalem facility.<sup>263</sup> Following the Jerusalem warning letter, Teva proposed immediately to close down production at its Jerusalem facility (as it had earlier with its Irvine facility); and this proposal provoked sustained attempts by the FDA to ensure Teva’s continued production and shipment to the USA of medically necessary drugs. For Teva’s Jerusalem facility, the period from the warning letter in January 2011 to the FDA’s close out letter in September 2011 (following the FDA’s re-inspection in June 2011) was nine months.
- 3.154. As a matter of fact, on the evidence adduced in this arbitration, the Tribunal concludes that Apotex Inc.’s two facilities at Signet and Etobicoke were regulated differently by the FDA during 2009-2011 from Teva’s Jerusalem facility in 2011, based on the imposition of an import alert in one case and not in the other. The material question is why?
- 3.155. Mr. Bradshaw and Mr. Johnson (the expert witnesses called by the Claimants) testified that, in their view, Apotex was not “riskier” than Teva in a way that would justify the FDA treating Apotex less favourably than Teva.<sup>264</sup> In contrast, Mr. Vodra (the expert witness called by the Respondent) testified that the FDA “was extremely worried about the impact of the Teva recall on U.S. patients in a way that it was not with the Apotex recall two years before ...” Mr. Vodra also testified that, had the cGMP problems with Teva emerged in 2009 and those with Apotex in 2011, “FDA’s drug shortage analysis might well have led to a different regulatory action vis-à-vis Apotex ...”<sup>265</sup> Apart from drug shortages and timing, Dr. Rosa testified

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<sup>263</sup> First Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Paras. 145 and 146.

<sup>264</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 47.

<sup>265</sup> Expert Report of William W. Vodra, Paras. 79 and 80.

that Teva at its Jerusalem facility, in contrast with Apotex Inc. at its two facilities, was not operating “out of control.”<sup>266</sup>

3.156. The Tribunal returns to other factual and legal issues later below.

**(4) *The Sandoz Chronology***

3.157. The Tribunal has taken the following factual chronology principally from: (i) the list of evidentiary references to contemporary documentation which was supplied by the Parties to the Tribunal in regard to Sandoz/Novartis (namely, in response to its Question B2); and (ii) documentary exhibits and testimony cited by the Parties in their written and oral pleadings in this arbitration. The Tribunal did not hear any witness from Sandoz/Novartis in this arbitration. For reasons explained later below, the contemporary public documentary evidence assumed particular significance in this case; and hence it is necessary here to cite much of it verbatim.

3.158. Novartis AG, a Swiss company, owns a group of companies engaged in the research, development, manufacture and marketing of branded drugs, generic pharmaceutical products, preventive vaccines, diagnostic tools, and consumer health products. Novartis operates through different divisions: Sandoz International GmbH, a German company, is its generic business division which owns subsidiary companies in several countries, including Canada and the USA. Novartis/Sandoz is the second largest generic manufacturer (in terms of revenues) in the world, being engaged in the development, manufacture and marketing of generic medicines (as well as pharmaceutical and biotechnological active ingredients). It has global operations in more than 130 countries; and its revenues in 2011 were US\$ 8.5 billion.<sup>267</sup> For the USA, it has in excess of 600 ANDAs.<sup>268</sup> (For ease of reference below, the Tribunal does not seek to distinguish between the different members of the Novartis group of companies, referring to them as “Sandoz” or “Novartis.”)

3.159. Sandoz operates three manufacturing facilities at (i) Wilson, North Carolina USA, (ii) Boucherville, Quebec, Canada and (iii) Broomfield, Colorado, USA. The FDA inspected the Broomfield facility in April-May 2011, the Wilson facility in March

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<sup>266</sup> TD4.970 Dr. Rosa xx (with TD4.1032 xxx).

<sup>267</sup> First Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 135.

<sup>268</sup> Apotex Memorial, Para. 323; Exhibits C-284 and C-387.

2008 and June 2011 and the Boucherville facility in July-August 2011.<sup>269</sup> These inspections and their consequences are described in further detail below. Sandoz operates a fourth facility at Lincoln, Nebraska, USA.

- 3.160. Like Teva, although the Sandoz facilities within the USA make Sandoz subject to other sanctions, its manufacture in Boucherville, Canada, of drugs for export to the US market makes those drugs subject to the Act and eligible for Import Alert 66-40.

### **2008**

- 3.161. *12 August 2008*: The FDA sent a warning letter to Sandoz in regard to its Wilson facility:<sup>270</sup> “On March 17 through March 31, 2008, the Food and Drug Administration (FDA) conducted an inspection of your manufacturing facility located at 4700 Sandoz Drive, Wilson, North Carolina. The inspection revealed significant deviations from the Current Good Manufacturing Practice (CGMP) regulations ... in the manufacturing of your drug products, which include Metoprolol Succinate ER tablets. These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 351 (a)(2)(B)]. The violations include, but are not limited to, the following ... [Here follow seven numbered violations].” After the formal warning, the letter concluded: “We acknowledge that some corrections were initiated by your firm during the course of this inspection. We also acknowledge receipt of your initial response to the FDA 483, dated April 9, 2008, as well as your follow-up responses dated April 29, 2008 and June 27, 2008.”
- 3.162. This Wilson warning letter continued: “In your responses, you committed to implementing a quality improvement plan for your facility after you complete your analysis of the existing quality system and the revision of all control records, which will be completed by [redacted by the Respondent] and [redacted by the Respondent] respectively. You also agreed that the Metoprolol products were not validated, and you have committed to revalidate both strengths (25 and 50 mg). Our concerns with these responses were discussed with Sandoz representatives at the meeting held at the Atlanta District office on July 10. We are in receipt of a follow

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<sup>269</sup> First Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 136.

<sup>270</sup> Exhibit C-032.

up response dated August 10 [2008] to that meeting. This latest response is currently under review. You originally decided to temporarily suspend distribution of Metoprolol 25 and 50 mg tablets until the available pre-compression and dissolution data was reviewed. However, you have decided to resume distribution of these products based on your rationale that successful, routine, finished-product testing of manufactured lots is sufficient proof that the product is of acceptable quality. We question the continued distribution of this product until better process controls are implemented and process validation is completed. We are also concerned that the problems noted in the Metoprolol validations could be indicative of problems and poor decisions made with other product validations. In addition to the deficiencies listed above, we are also concerned that you may not be utilizing a global approach to the implementation of manufacturing controls. For example, one proposed corrective action at the Wilson site is to implement an automated investigation management tracking system ([redacted by the Respondent]) which is already in use at other Sandoz sites. It is our expectation that all Sandoz sites intended to be used for the manufacture of drugs have a comprehensive evaluation to assure compliance with all laws and regulations governing the manufacture of drugs. We request that you provide documentation describing the specific steps you will take to perform these evaluations and to implement the necessary corrective actions at all Sandoz' sites ...”

- 3.163. Given the paucity of evidence regarding subsequent events in 2008, the Tribunal assumes that the violations in this Wilson warning letter were somehow resolved by Sandoz to the FDA's ultimate satisfaction. Nonetheless, these violations are relevant to subsequent events in 2011 onwards, with repeat violations later cited by the FDA regarding Sandoz's facility at Wilson.

### ***2011***

- 3.164. *18 November 2011*: The FDA sent a warning letter to Novartis in Basel, regarding the three Sandoz facilities at Boucherville, Broomfield and Wilson.<sup>271</sup>
- 3.165. This Novartis warning letter stated: "... During our April 19 to May 6, 2011, June 6 to 22, 2011, and July 26 to August 4, 2011 inspections of your pharmaceutical

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<sup>271</sup> Exhibit C-273.

manufacturing facilities, Sandoz Inc., located at 2555 W. Midway Blvd, Broomfield, Colorado; Sandoz Inc., located at 4700 Sandoz Dr., Wilson, North Carolina; and Sandoz Canada Inc., located at 145 Jules-Leger Street, Boucherville, Quebec, Canada, investigators from the Food and Drug Administration (FDA) identified significant violations of the Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals ... These violations cause your drug products to be adulterated within the meaning of section 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act ... in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP. The August 2011 inspection also revealed that Sandoz Canada Inc. failed to submit NDA Field Alert Reports (FARs) to FDA in compliance with 21 CFR § 314.81(b)(1)(ii), as required by section 505(k) of the Act [21 U.S.C. § 355(k)]. An applicant is required to submit, within three working days of receipt, information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of drug product to meet the specifications established for it in the application. We have reviewed your firm's responses of May 31, 2011, July 13, 2011, and August 25, 2011, and note that they lack sufficient corrective action. Specific violations observed during the inspections include, but are not limited to, the following: [here follow several numbered and unnumbered violations]"; and, after the formal warning, the letter continued: "Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations and copies of supporting documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the date by which you will have completed the correction ..."

- 3.166. The Novartis warning letter concluded: "If, as a result of receiving this Warning Letter or in general, you are considering making a decision that will result in a decreased number of finished drug products or bulk drug substances produced by your manufacturing facility, FDA requests that you contact CDER's Drug Shortages Program immediately, as you begin your internal discussions, at

drugshortages@fda.hhs.gov in order to ensure that your action(s) does not adversely affect the public health.”

- 3.167. The Tribunal notes that these three inspections of different facilities at similar times, involving two FDA offices and the FDA’s international office were co-ordinated by the FDA in a manner which suggests that the FDA already suspected that Sandoz/Novartis as a corporate entity was not providing sufficient oversight and control of the state of compliance at its facilities, *i.e.* the FDA was taking a “corporate view” even before the inspections leading to this Novartis warning letter.<sup>272</sup> As regards the quotation from the warning letter in the paragraph immediately above, the Tribunal notes that this reference in 2011 to CDER’s Drug Shortages Program did not appear in the FDA’s earlier warning letters regarding Apotex’s two facilities in 2009 and 2010.
- 3.168. The Novartis warning letter of 18 November 2011 was addressed to Novartis’ Chief Executive Officer as a “corporate” letter addressing all three facilities collectively and placing full responsibility on the upper management of Novartis/Sandoz, as the following passage makes clear: “We note that CGMP violations listed in this letter include multiple repeated violations from those cited in the August 2008 Warning Letter issued to Sandoz Inc.’s Wilson, North Carolina facility and repeated observations from previous inspections at your Sandoz Canada Inc. facility in Boucherville, Quebec, Canada. It is apparent that Novartis International AG (Novartis) is not implementing global and sustainable corrective actions. We remind you that you are responsible for ensuring that your firm’s drug manufacturing operations comply with applicable requirements, including the CGMP regulations. FDA expects Novartis to undertake a comprehensive and global assessment of your manufacturing operations to ensure that drug products conform to FDA requirements. Finally, the Agency is concerned about the response of Novartis to this matter. Corporate management has the responsibility to ensure the quality, safety, and integrity of its products. Neither upper management at Novartis nor at Sandoz Inc., nor at Sandoz Canada Inc., ensured global, adequate, or timely resolution of the issues at these sites.”

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<sup>272</sup> First Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 137.

- 3.169. Dr. Rosa testified that Sandoz voluntarily responded to the cGMP violations found by the FDA at the Boucherville facility by temporarily suspending and slowing production at that facility, adding: “Although Sandoz Canada was focused on remediation efforts and supplying critical injectable drugs to the Canadian market, it supplied certain medically necessary injectable drugs for the U.S. market. FDA determined that the medical necessity of these drugs and Sandoz Canada’s remediation commitments weighed against adding the facility to the Import Alert. As a result, Sandoz Canada continued to market life-sustaining, single source drugs with the concurrence of FDA’s Drug Shortage Office. The firm voluntarily stopped shipping other products to the United States. FDA’s investigation of this facility remains ongoing.”<sup>273</sup>
- 3.170. At the Hearing, Dr. Rosa was asked for the sources of his information summarised in the paragraph immediately above, to which he replied: “They [Sandoz Canada] submitted the information in writing to us that was going to be the action. They also, during conversations, said that they were going to be eliminating, ceasing production, specifically ceasing, not moving products out that were not – they were not continuing manufacturing products that were not essential products. In terms of slow production, that is actually one of the documents that they submitted. So that’s where the information is coming from, and from conversations and meetings held with the Center for Drugs.”<sup>274</sup> Earlier during his testimony at the Hearing, Dr. Rosa had acknowledged that he was not personally involved in the FDA’s decisions about drug shortages, but rather: “I’m involved in sending the consult [sic], having the discussion in terms of their assessment, and moving forward based on an agency decision.”<sup>275</sup> The Tribunal accepts that Dr. Rosa was generally involved in the Novartis warning letter and its consequences, based on his testimony at the Hearing: “I would have to see exactly if I reviewed the exact [Novartis] Warning Letter [of 18 November 2011] and the details of the case. But I do recall having discussions and looking at and being involved, to the extent – if I sign off on [sic] ... I was one of the reviewers, I would have to say – meaning one of the senior officers reviewing

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<sup>273</sup> Supplemental Witness Statement of Dr. Carmelo Rosa, Para. 31.

<sup>274</sup> TD4.1043 Dr. Rosa xxx.

<sup>275</sup> TD4.993 Dr. Rosa xx.

the case, I would have to refer to the record and see if I was.”<sup>276</sup> The Tribunal was not shown this “record” by the Respondent nor the written “information” from Sandoz described by Dr. Rosa, for reasons explained below.

## **2012**

- 3.171. *2008 – 2012*: Sandoz was ranked second (after Teva) based on US Annual IMS Data for Total Sales.<sup>277</sup>
- 3.172. *25 January 2012*: The Novartis Annual Report (SEC Form 20-F) cited the FDA’s warning letter of 18 November 2011.<sup>278</sup> It advised, under the heading “Forward Looking Statements” of “unexpected product manufacturing issues, including the potential outcomes of the Warning Letter issued to us with respect to three Sandoz manufacturing facilities, and the potential outcome of the shutdown of the OTC manufacturing facility at Lincoln, Nebraska ... “ (p. 2); and “Like our competitors, we have faced, and continue to face, significant manufacturing issues. For example, in November 2011, we received a Warning Letter from the FDA with respect to three of our Sandoz Division’s facilities - in Broomfield, Colorado, Wilson, North Carolina, and Boucherville, Canada - which remains unresolved. The Warning Letter raised concerns regarding these facilities’ compliance with FDA cGMP regulations. It states that until the FDA confirms that the deficiencies have been corrected, the FDA can recommend disapproval of any pending applications or supplements listing Novartis affiliates as a drug manufacturer. In addition, FDA may refuse requests to issue export certificates to our Sandoz US affiliate, or import certificates to our Sandoz Canada affiliates. The letter further states that other federal agencies may take the Warning Letter into account when considering the award of contracts. Sandoz is collaborating with the FDA to promptly correct all concerns raised in the Warning Letter, and to ensure that our products are safe and effective and meet highest quality standards. However, if we fail to fully resolve the issues raised in the Warning Letter then we could be subject to legal action without further notice including, without limitation, seizure and injunction.” (p. 10).

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<sup>276</sup> TD4.991 Dr. Rosa xx.

<sup>277</sup> Exhibit C-327.

<sup>278</sup> Exhibit C-288.



- 3.173. *19 February 2012: The Globe and Mail*, Canada’s national newspaper, reported:<sup>279</sup> “... Today, Sandoz Canada’s reputation lies in tatters after chronic problems at its state-of-the-art plant on Montreal’s south shore caught the eye of U.S. regulators [*i.e.* the Boucherville facility]. Much of its production is halted as it tries to fix the problems, leaving pharmacists and health-care providers alarmed at what could be months of shortages of injectable medications that treat everything from nausea among cancer patients and abnormal heart rhythms to endometriosis. Last week, Sandoz told Canadian health-care providers it would discontinue certain products and temporarily suspend production on the heels of a scathing ‘warning letter’ from the U.S. Food and Drug Administration three months ago that criticized the plant’s ‘ineffective quality system’. ‘As we progress with our remediation activities, all production processes will be affected, significantly reducing output from our Boucherville plant and likely resulting in temporary supply disruptions,’ Sandoz Canada president Michel Robidoux said in a Feb. 16 [2012] letter to pharmacists, obtained by *The Globe and Mail*. He didn’t specify how long the disruption would last, but that Sandoz Canada would focus on ‘optimizing’ supplies of medically necessary drugs to the Canadian market and had halted production of ointments, ophthalmics, suppositories and all non-medically necessary drugs. ... In a statement to *The Globe and Mail*, Sandoz Canada said it was intensifying efforts ‘to ensure high quality standards’... It said the decision to halt production was voluntary and related to efforts to restore ‘high quality standards in manufacturing operations’... In total, Sandoz said it had committed a total of over \$170-million (U.S.) to improve quality at the Boucherville plant as well as two other plants in Colorado and North Carolina that were also cited in the FDA letter ...”
- 3.174. *20 February 2012: CBC News* (of the Canadian Broadcasting Corporation) reported:<sup>280</sup> “The revelation that a major drugmaker is cutting production at its Quebec plant has ramped up fears among doctors and patients about a critical shortage of injectable medicines nationwide. Supplies have already dried up for some pharmacies seeking to stock up after Sandoz Canada – one of the country’s leading suppliers of generic cancer and heart medications – announced Sunday it

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<sup>279</sup> “Sandoz Canada’s Production Slows to a Crawl After Harsh Criticism from U.S. Regulators”, Exhibit R-091.

<sup>280</sup> “Drug Shortage Feared as Quebec Plant Retools: Leading Maker of Generic Medications Halts Some Production after U.S. Inspections”, Exhibit R-092.

was temporarily suspending production at its Boucherville Que., facility. ... The company said it was expecting ‘a significant reduction in output’ and was halting production lines to upgrade operations after quality-control assessments by the U.S. Food and Drug Administration warned the factory fell short of FDA standards ... Some products will be discontinued, while others will resume production once the suspension is lifted, although Sandoz has not clarified which drugs will go out of production. The company said in a statement it would prioritize production of its most critical drugs ... ‘We will focus all available capacity on the supply of life-saving and acute care injectable medicines to ensure that Canadian patients with critical medical conditions continue receiving adequate treatment,’ the statement read. In the meantime, physicians are scrambling to find replacement therapies to treat certain ailments. Response from Sandoz Canada: ‘In light of the November 2011 FDA Warning Letter, Sandoz Canada has further intensified its ongoing efforts to ensure high quality standards across its manufacturing operations. As part of these efforts, we will temporarily suspend or discontinue the production of certain products at our Boucherville site, most of which have alternatives in the marketplace, to prioritize production of most medically necessary products, and focus on the supply of critical medicines to the Canadian market.’ ...”

- 3.175. The CBC report continued, as regards drug shortages in Canada: “ ... Feldman [Larissa Feldman, operating a Montreal drugstore] said pharmacists will have to consult closely with doctors to ensure they prescribe alternative medications, if they're available. ‘We call the hospital, we call other pharmacist colleagues, and we try to find the medication,’ she said. The latest slowdown comes amid a global shortage hitting the pharmaceutical industry, but health-care providers have complained they often receive little warning ahead of major production trims from drugmakers. Early warning system urged: Dianne Lamarre, president of the Quebec Order of Pharmacists, said that kind of timely information could be used to seek out backup drugs and alternatives in the marketplace. She has called for the creation of an early warning system to signal when a specific drug is in short supply. Such a system would require unprecedented co-operation among competing drug companies. ‘We need a special agency which will ensure a follow-up with industries, which will make Health Canada react more quickly when essential drugs are not available,’ Lamarre said. She told The Globe and Mail newspaper she

expects some production lines will be running at half capacity. The Canadian Pharmacists Association is also urging Health Canada to force pharmaceuticals companies to provide notice of changes to production and inform doctors long before they discontinue certain drugs.”

3.176. *Mid-February 2012*: In a media release (of 16 May 2012),<sup>281</sup> Sandoz Canada reported that it had set up an allocation system in mid-February 2012. The system was set up “to handle the temporary decrease in injectable drug production and to ensure all customers received fair supply of products.”<sup>282</sup> (This allocation system continued until 8 May 2013: see below.)

3.177. *29 February 2012*: A Sandoz Canada media release stated:<sup>283</sup> “Sandoz Canada is continuing its efforts to maintain reliable supply of essential medicines following a temporary slow-down of production, resulting from increased investment in strengthening manufacturing compliance at its Boucherville, Quebec, site. In light of the November 2011 Warning Letter from the US Food and Drug Administration, Sandoz Canada has intensified its ongoing efforts to ensure high quality standards at this manufacturing plant. As production continues, the company is focusing its efforts on essential medicines and prioritizing resources to ensure normal supply is restored as quickly as possible. As part of this prioritization, the company has discontinued production of some non-essential drugs, including ointments, ophthalmics, suppositories and certain injectable drugs, for most of which it has already identified potential alternative supply from within Sandoz/Novartis or other qualified third-party suppliers. ... ‘Our objective is to restore normal levels of supply as soon as possible, and we will make every effort to meet patient needs ...’ said Sandoz Canada President Michel Robidoux. ‘We will focus all available capacity on the supply of medically necessary injectable medicines to try to ensure that patients with critical medical conditions continue receiving adequate treatment ...’”

3.178. *4 March 2012*: According to a Sandoz press statement: “A fire broke out on Sunday, 4 March, shortly after 12:30pm, in the ceiling above the boiler room in one section

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<sup>281</sup> Sandoz Canada Media Release (of 16 May 2012) “Sandoz Canada Makes Strong Progress in Supply of Critical Medicine”, Exhibit C-447.

<sup>282</sup> Exhibit C-446.

<sup>283</sup> Exhibit C-441.

of the Sandoz Canada production plant in Boucherville ... Production has been temporarily suspended and will partially resume during the week of 12 March ...”<sup>284</sup>

- 3.179. *10 March 2012*: A CBC News website reported:<sup>285</sup> “Patients, pharmacies and hospitals in New Brunswick are feeling the ripple effects of a temporary stop in production by one of the country’s largest medical drug producers, Sandoz Canada in Quebec. In Dieppe, pharmacist Dennis Abud said that he is running out of several medications, including injectable painkillers like morphine. The shortage has been affecting his patients ... Sandoz Canada – one of the country’s leading suppliers of generic cancer and heart medications – announced in late February that it was temporarily suspending production at its Boucherville, Que., facility. Sandoz has scaled back production of certain drugs – mostly painkillers, antibiotics and anaesthetics – to upgrade operations after quality-control assessments by the FDA warned the factory fell short of its standards. To exacerbate supply concerns, a fire Sunday in the ceiling above the boiler room of Sandoz’s Boucherville plant has halted all production until at least Monday, and the company says it is assessing any impact to product supply ... Last week, Dr. Robert Cushman, director general biologic and genetic therapies at Health Canada, told CBC News that Health Canada is in constant dialogue with Sandoz and other manufacturers ...”
- 3.180. *6 and 12 March 2012*: Short items on the Sandoz Canada Website reporting on (i) the fire of 4 March at the Boucherville facility<sup>286</sup> and (ii) the partial re-start of production at Boucherville:<sup>287</sup> “Sandoz Canada has resumed production over the weekend in the portion of the plant that was not directly affected by the incident which took place on March 4th ... Production at the site is prioritized around essential products to help ensure continued supply of critical drugs to patients ...”
- 3.181. *12 March 2012*: *The Globe and Mail* reported:<sup>288</sup> “The company that produces most of Canada’s generic injectable drugs says it has partly resumed production at its facility in Boucherville, Que. Sandoz Canada slowed production last month after

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<sup>284</sup> Exhibits C-442. *See also* Exhibits C-443 and C-444.

<sup>285</sup> “Drug Shortage Hits Hospitals, Pharmacists, Patients: Supplier Scaling Back Production While It Upgrades to FDA Standards”, Exhibit C-443.

<sup>286</sup> Exhibit C-442.

<sup>287</sup> Exhibit C-444.

<sup>288</sup> “Sandoz Factory Resumes Production of In-Demand Drugs”, Exhibit C-445.

receiving a letter from the U.S. Food and Drug Administration raising concerns about the level of sanitation at the factory. Last week, a fire forced the company to halt production entirely, further squeezing the supply of vital painkillers, anesthetics and antibiotics across the country. In the face of widespread shortages, hospitals have been scrambling to conserve their supplies ... But the current shortage is particularly acute, [doctors and pharmacists] say. Sandoz supplies about 90 per cent of the generic injectable drugs in Canada, so the slowdown was a major blow for health-care facilities ...”

- 3.182. *20 March 2012*: A Sandoz News Flash reported:<sup>289</sup> “Sandoz and Novartis do not view the current supply situation in Canada as an opportunity to increase our profits. Our objective is to ensure that patients have access to critical, high-quality medicines they need, and we will honor our pricing for existing hospital contracts, including supply we secure to service these agreements. Patients remain our priority. We are also investing significantly into the enhancement of quality procedures and systems at the Boucherville site for the benefit of all patients treated with our medicines. Sandoz Canada has been continuing its efforts started in late 2011 to maintain reliable supply of essential medicines following the temporary slow-down in production at its Boucherville, Quebec, site. As part of these efforts, we have identified alternative supply from other reliable third-party suppliers ...”
- 3.183. *27 March 2012*: According to a Sandoz News Flash:<sup>290</sup> “Sandoz Canada is pleased to announce that production has fully resumed as of March 23rd, following the fire that broke out earlier this month. All necessary actions have now been completed, and all capacity is again fully focused on the production and supply of critical medicines.”
- 3.184. *16 May 2012*: A Sandoz Canada Press Release reported:<sup>291</sup> “Sandoz Canada continues to make strong progress in its efforts to maintain a reliable supply of essential medicines following the temporary slow-down in production announced at its Boucherville plant earlier this year. While Sandoz continues to work on site

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<sup>289</sup> “Sandoz and Novartis Do Not View the Current Supply Situation in Canada as an Opportunity to Increase our Profits”, Exhibit C-446.

<sup>290</sup> “Production Resumed at Boucherville Plant”, Exhibit C-446.

<sup>291</sup> “Sandoz Canada Makes Strong Progress in Supply of Critical Medicines”, Exhibit C-447.

remediation efforts and strengthen manufacturing compliance at the Boucherville site, production output has been optimized, allowing Sandoz to meet the vast majority of Canadian market needs for its entire injectable portfolio. At present, Sandoz is supplying more than 80% of market needs for its entire injectable portfolio, and more than 90% for the products currently in production. In mid-February [2012], Sandoz introduced an allocation system based on 2011 demand which ensures that each customer receives a fair share of available medicines. Further improvements in output are expected which should increase allocation levels for all products in production to at least 100% of forecasted market needs by November 2012. Sandoz will nevertheless maintain its allocation system through the first quarter of 2013, in order to avoid unnecessary stockpiling and potential backorder. ‘I am very proud of our team’s unwavering commitment to patients. Since the beginning of the year, we have worked day and night to meet medical needs and have partnered with pharmacists and other healthcare professionals, as well as with provincial governments and Health Canada, to optimally manage the supply situation’ said Sandoz Canada President and General Manager Michel Robidoux. ‘We have provided on-going transparency on our supply status, optimized production for most medically necessary products, and continue to explore all available options to ensure we meet demand as best we can.’ ...”

- 3.185. *18 May 2012:* Sandoz wrote to US medical practitioners regarding the FDA’s approval of importation into USA of an unapproved formulation of injectable phentolamine mesylate manufactured by Sandoz Canada “[d]ue to the current critical shortage” of the drug in USA,<sup>292</sup> stating: “ ... At this time, FDA’s exercise of enforcement discretion for the importation of Sandoz’ phentolamine mesylate injection product is limited to Sandoz during the critical shortage of phentolamine mesylate injection. Importation or distribution of this product in the United States by any other entity is outside the scope of FDA’s regulatory discretion, and FDA has not approved Sandoz’ phentolamine mesylate injection product for marketing in the United States ...”

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<sup>292</sup> Exhibit C-448.

- 3.186. The Tribunal notes that Sandoz’s export of phentolamine mesylate injectables to the USA was the subject of an exceptional permission by the FDA, not extended to non-medically necessary drugs. In his written testimony, Dr. Rosa described this “exercise of enforcement discretion” by the FDA as follows: “Although Sandoz Canada was focused on remediation efforts and supplying critical injectable drugs to the Canadian market, it supplied certain medically necessary injectable drugs for the U.S. market. FDA determined that the medical necessity of these drugs and Sandoz Canada’s remediation commitments weighed against adding the facility to the Import Alert. As a result, Sandoz Canada continued to market life-sustaining, single source drugs with the concurrence of FDA’s Drug Shortage Office. The firm voluntarily stopped shipping other products to the United States.”<sup>293</sup> (The Tribunal also notes that, much later on 22 March 2013, the American Society of Health-System Pharmacists announced, on its website, *Phentolamine Mesylate for Injection*, that Sandoz Canada’s phentolamine injection was no longer required because Bedford (a US manufacturer) had supplies of this drug.<sup>294</sup>)
- 3.187. *June 2012*: A Report of Canada’s House of Commons Standing Committee on Health, Drug Supply in Canada addressed the short supply issues brought on by the interruption of production at the Boucherville facility.<sup>295</sup> The Tribunal attaches significant evidential importance to this official study issued by Canada’s legislature, after taking evidence from several sources (not including Sandoz Canada). The Report includes several passages regarding Sandoz.
- 3.188. First, the Canadian Report described the Canadian legislature’s several resolutions in March 2012: “... On 13 March 2012, the House of Commons Standing Committee on Health (the Committee) adopted a motion to undertake a short study on drug supply in Canada. The motion requested that, over the course of three meetings, the Committee: ‘[E]xamine the role of government and industry in determining drug supply in Canada, how the provinces and territories determine what drugs are required in their jurisdiction, how the industry responds to them, and the impact this has on stakeholders.’ During meetings on 27 and 29 March, as well

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<sup>293</sup> Supplemental Witness Statement of Dr. Carmelo Rosa, Para. 31.

<sup>294</sup> Exhibit C-463.

<sup>295</sup> “Drug Supply in Canada: A Multi-Stakeholder Responsibility – Report of the Standing Committee on Health”, Exhibit C-450.

as 3 April 2012, the Committee heard from Health Canada officials, representatives of the pharmaceutical industry, healthcare professionals, pharmaceutical wholesalers and bulk purchasers, and patient advocates. This report outlines the role played by these stakeholders, summarizes the concerns that were expressed and offers recommendations that may mitigate future disruptions in the drug supply. ... On 14 March 2012 the following motion was passed unanimously in the House of Commons: ‘That, in the opinion of this House, the government should: (a) in cooperation with provinces, territories and industry, develop a nationwide strategy to anticipate, identify, and manage shortages of essential medications; (b) require drug manufacturers to report promptly to Health Canada, the provinces and the territories any planned disruption or discontinuation in production; and (c) expedite the review of regulatory submissions in order to make safe and effective medications available to the Canadian public.’”

- 3.189. Next, the Canadian Report described the reason for the Canadian legislature’s study, namely events at Sandoz’s Boucherville facility: “This motion was prompted by recent events at Sandoz, a major manufacturer of generic medicines in Canada, which brought about significant shortages of critical medicines. Its manufacturing facility in Boucherville, Quebec produces 50% of generic injectable drugs used in Canadian hospitals. Sandoz received a warning letter on 18 November 2011 from the United States’ Food and Drug Administration (FDA) explaining that the facility was non-compliant with U.S. drug regulations. After receiving the FDA’s letter, the company slowed down production in order to address the compliance issues. The Committee heard that, in December 2011, Health Canada saw on the FDA’s Web site the warning letter to Sandoz and that the Department followed up with Sandoz to ask what their remediation plans were. Sandoz initially planned to suspend production of several non-essential products in order to focus their available production capacity on medically necessary products. Nevertheless, the Committee was told that Sandoz announced on 17 February 2012 an immediate reduction in available supply of essential medications. The Committee was not told why Sandoz’s plan to focus on essential medicines was not successful. On 2 March 2012, the Minister of Health wrote a letter to Sandoz concerned about the company’s failure to voluntarily provide publicly available, clear, precise and timely information regarding supply disruptions as this was contrary to an agreement it had



signed onto the previous fall [footnote omitted]. A fire broke out in the boiler room of the Sandoz facility in Boucherville on 4 March 2012. As a result, production was stopped completely for a week before resuming partially ...”

- 3.190. *19 July 2012:* A Novartis press release, with the company’s 2Q 2012 Financial Report, reported:<sup>296</sup> “Sandoz also continued to strengthen quality operations across its manufacturing network. This includes its three North American sites where the division is on track to meet its remediation commitments. Sandoz has upgraded senior leadership in quality and manufacturing operations, both globally and at the site level. ... While Sandoz slowed down production to implement remediation activities at its three North American sites, delivery performance across all sites has improved. Further improvements in service levels and output are expected as remediation progresses.”
- 3.191. *23 July 2012:* The Tribunal has already summarised above (as regards Teva) the letter from the Assistant Commissioner for Legislation to The Hon. Elijah E. Cummings, a Ranking Member of US House of Representatives Committee on Oversight and Government Reform.<sup>297</sup> As regards Sandoz, this letter stated: “Sandoz/Novartis: Sandoz, owned by Novartis, has a site in Canada that makes sterile injectable products for the U.S. market. FDA inspection of that site led to the issuance of a Warning Letter in November 2011, citing concerns with unusual crystal formation in some batches of sterile drug products distributed to the United States. ... Sandoz voluntarily suspended some production of these products to correct the quality concern. In December 2011, Novartis announced a voluntary shutdown to address widespread quality defects and manufacturing failures, identified after more than 1,360 complaints of foreign, stray, and broken tablets found in opiate products. FDA issued Form 483s to Novartis in July 2011 and January 2012, after inspections of Novartis’ [Lincoln] Nebraska facility revealed a failure to investigate consumer complaints in an adequate fashion. FDA also issued a Public Health Advisory to alert health care professionals and patients of the possible contamination of the opiate products manufactured by Novartis. The manufacturing issues Sandoz and Novartis experienced also compromised the

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<sup>296</sup> Exhibit R-208.

<sup>297</sup> Exhibit C-452.

sterility of the products and could result in contaminated products that would severely injure patients if administered.” (The Tribunal notes that the FDA treated the Lincoln facility separately from the Boucherville facility; and the former was not the subject of the FDA’s Novartis warning letter of November 2011 regarding the Wilson, Broomfield and Boucherville facilities).

3.192. *6 September 2012*: A Sandoz News Flash reported:<sup>298</sup> “... At present, Sandoz Canada is supplying 90.2% of market demand for the products currently in production and 90.3% demand for the top 8 medically necessary injectables identified by Health Canada and the provinces and priorities for the Canadian market. During the routine shutdown, good progress was also made in our site remediation efforts according to schedule ...”

3.193. *13 November 2012*: According to the “FiercePharmaManufacturing” newsletter:<sup>299</sup> “The FDA has removed a Novartis ... plant in Colorado [Broomfield] from its warning letter watch list, a development that Novartis CEO Joseph Jimenez says shows the company is getting its manufacturing act together. In an emailed statement, a Novartis spokeswoman explained. ‘The FDA confirmed on November 7, 2012 that our Sandoz manufacturing site in Broomfield, Colorado, one of three sites referenced in the November 2011 Warning Letter, has achieved positive compliance status following a re-inspection in August [2012]. We welcome this development, which we see as a significant milestone in our remediation efforts across all three sites. Wilson and Boucherville are currently pending FDA re-inspection and all commitments to FDA and Health Canada are on track.’ Jimenez, in an interview with a German newspaper, said, ‘This development makes me confident. We are on the right track but must not stop,’ Reuters reports.”

### **2013**

3.194. *23 January 2013*: The Novartis Annual Report (SEC Form 20-F) recorded:<sup>300</sup> “In November 2011, we received a Warning Letter from the FDA with respect to three of our Sandoz Division’s facility - in Broomfield, Colorado, Wilson, North

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<sup>298</sup> “Boucherville Plant Resumes Production Following Regularly Required Summer Maintenance”, Exhibit C-446.

<sup>299</sup> “FDA Confirms Novartis Plant, Renewing CEO’s Confidence”, Exhibit C-454.

<sup>300</sup> Exhibit C-458.

Carolina, and Boucherville, Canada. The letter followed inspections at all three sites in the course of 2011, and raised concerns regarding these facilities' compliance with FDA cGMP regulations. The FDA observations in the letter related primarily to general documentation, validation and investigation practices. It states that until the FDA confirms that the deficiencies have been corrected, the FDA can recommend disapproval of any pending applications or supplements listing Novartis affiliates as a drug manufacturer. In addition, FDA may refuse requests to issue export certificates to our Sandoz US affiliate, or import certificates to our Sandoz Canada affiliates. The letter further states that other federal agencies may take the Warning Letter into account when considering the award of contracts. Sandoz is collaborating with the FDA to promptly correct all concerns raised in the Warning Letter, and to ensure that our products are safe and effective and meet highest quality standards. In the fourth quarter of 2012, Sandoz announced that the FDA upgraded the compliance status of its Broomfield, Colorado site. Nonetheless, if we fail to fully resolve the issues raised in the Warning Letter then we could be subject to legal action without further notice including, without limitation, seizure and injunction..." (p. 79).

3.195. *26/27 March 2013*: According to the *Wall Street Journal*:<sup>301</sup> "The injectables market has been dominated by a handful of companies, because making the sterile medicines is costly but returns are generally low ... Unable to make a profit, several companies fled the market, and some drugs had just one supplier. Then manufacturing problems, supply constraints and government scrutiny of aging plants in recent years forced remaining firms, such as market leaders Hospira Inc., Boehringer Ingelheim GmbH's Ben Venue Laboratories business and Novartis AG's Sandoz unit, to shut down facilities or scale back production. The result was that the number of sterile injectables experiencing shortages jumped to 183 in 2011, from 23 five years earlier. The number of shortages fell to 84 last year, according to the U.S. Food and Drug Administration ..."

3.196. *8 May 2013*: A Sandoz news flash announced:<sup>302</sup> "Sandoz Canada ... is discontinuing the allocation program for injectable drugs and reverting to a regular

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<sup>301</sup> "Drug Makers' Push into Injectables Could Ease Shortages", Exhibit R-219.

<sup>302</sup> "End of Allocation System for Sandoz Canada Injectable Drugs", Exhibit C-446.

ordering system. This is due to continued progress in the remediation plan at our Boucherville plant. The allocation system was set up in mid-February 2012 to handle the temporary decrease in injectable drug production and to ensure all customers received fair supply of products. ...”

### ***Conclusion***

- 3.197. In conclusion, Sandoz received two warning letters in 2008 (as regards its Wilson facility) and in November 2011 (as regards its Wilson, Broomfield and Boucherville facilities). In both warning letters, the FDA took a “corporate” approach to Sandoz’s non-compliance with cGMP regulations. As a foreign facility, the FDA did not subject the Boucherville facility to any import alert. It is not clear on the evidence whether the FDA has yet confirmed that the Boucherville facility is in a state of compliance, although the Broomfield facility was so confirmed on 7 November 2012 (after a re-inspection by the FDA in August 2012). As described below, there seems to be continued regulatory or other action by the FDA against Sandoz and the Boucherville facility (albeit still without any import alert).
- 3.198. As a matter of fact, on the evidence adduced in this arbitration, the Tribunal concludes that Apotex Inc.’s two facilities at Signet and Etobicoke were regulated differently by the FDA in 2009-2011 from Sandoz’s Boucherville facility in 2011-2012, based on the imposition of an import alert in one case and not in the other. The material question, again, is why?
- 3.199. Mr. Bradshaw and Mr. Johnson (the expert witnesses called by the Claimants) testified: “... FDA did not take any enforcement action against Sandoz. There was no ban on sales of Sandoz drugs in the US; FDA had no way to ensure that drugs from Boucherville did not enter the US; and there was no requirement for re-inspection prior to resumption of sales in the US (and, accordingly, without any delays associated with such re-inspection). In contrast with the treatment accorded Sandoz, Apotex was placed on the Import Alert on August 28, 2009, just weeks

after the Signet inspection ... Apotex was not removed from the Import Alert for almost two years.”<sup>303</sup>

3.200. In contrast, Mr. Vodra (the expert witness called by the Respondent) testified: “... [i]n response to a critical FDA inspection of its Canadian facility, Sandoz Inc., temporarily suspended production at the facility of all but some medically necessary drugs, as well as critical medicines that were only to be distributed within Canada, FDA did not add that facility to the Import Alert ... the company told FDA it would not ship any non-medically necessary products to the U.S. while it remedied its cGMP issues, thereby making an Import Alert unnecessary. In my opinion, had Apotex similarly told FDA on August 17, 2009, that it would not export any non-medically necessary products to the U.S. pending remediation, it is probable that no Import Alert would have been issued” [Footnotes omitted].<sup>304</sup>

3.201. At the Hearing, Dr. Rosa was asked why the FDA did not impose an import alert on the Boucherville facility, to which he answered: “Because - for several reasons. We did not place them on Import Alert – one of them we’ve discussed today because of the drug shortage situation. That was one of them. Number 2, Sandoz’s ... actions and approach were the appropriate corrective actions. Ceasing production, reducing the manufacturing of nonessential drugs was another action. They stopped the manufacturing of drugs, not only for the U.S., but for the rest of the world. That’s – those are some of the primary reasons. The other reason is because the history of that facility gave us no indication that that facility was operating outside or out of control. When you compare with Apotex, Apotex was clearly operating outside a state of control ...”<sup>305</sup> Dr. Rosa’s reference to the earlier ‘discussion’ included his previous oral testimony regarding medically necessary drugs for the US market produced at the Boucherville facility: “... Drug Shortage [FDA] was extremely, extremely concerned for this firm – for affecting the availability of product that [was] manufactured by this facility.”<sup>306</sup>

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<sup>303</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Paras. 43 and 44 (*see also* their First Expert Report, Para. 141).

<sup>304</sup> Expert Report of William W. Vodra, Para. 76.

<sup>305</sup> TD4.1037 Dr. Rosa xxx.

<sup>306</sup> TD4.992 Dr. Rosa xx.

- 3.202. The Tribunal notes that the temporary effect of the fire at the Boucherville facility in March 2012 was not regarded by these three witnesses as material to the FDA's treatment of Sandoz. The Tribunal accepts this factual conclusion from the available evidence in this arbitration.
- 3.203. The Tribunal returns to other factual and legal issues later below. At this stage, the Tribunal briefly records the evidential difficulties encountered in this arbitration regarding contemporary non-public documentation held by the FDA regarding Sandoz and the Boucherville facility.
- 3.204. As regards the Claimants, by its procedural order dated 29 March 2013, the Tribunal denied the Claimants' request for certain document production relating to Novartis/Sandoz on the ground of (*inter alia*) the Respondent's "legal impediment" because the Boucherville facility was still under investigation by the FDA (pursuant to Article 9 of the IBA Rules on the Taking of Evidence in International Arbitration 2010).
- 3.205. As regards the Respondent, its counsel confirmed to the Tribunal at the Hearing that the FDA was and remained precluded by US law from disclosing even to counsel from the Respondent's own State Department certain third-party information relating to the Boucherville facility, still less to the Claimants (even on a confidential basis protected by order of the Tribunal).<sup>307</sup> This impediment was disputed by the Claimants at the Hearing.<sup>308</sup>
- 3.206. The Tribunal notes that, at least as at 27 September 2013, the FDA's investigation of Boucherville facility, was still "ongoing";<sup>309</sup> and the Tribunal assumes from what was stated by the Respondent's counsel that this investigation remained materially incomplete at the time of the Hearing. For these reasons, as with its earlier procedural order, the Tribunal accepts, as a fact, the explanation tendered by the Respondent for the paucity of material evidence and documentation from within the

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<sup>307</sup> TD6.1662, 1678-1679 and TD7.1761-1765, citing Section 301 of the Food and Drug Administration Act, the US Freedom of Information Act; 21 US Code Section 331(j); 21 CFR Section 20.61; 5 USC, Section 552(b)(4); and 21 CFR Section 20.85.

<sup>308</sup> TD7.1735-1738.

<sup>309</sup> Supplemental Witness Statement of Dr. Carmelo Rosa, Para. 31.

FDA regarding Sandoz/Novartis. The Tribunal addresses the legal consequences of this explanation later below.

## ***PART IV – THE PRINCIPAL LEGAL TEXTS***

4.1. It is convenient, for ease of reference later, to cite here in full the relevant parts of the principal legal texts considered below, from: NAFTA, the Jamaica-USA BIT, the ICSID Arbitration AF Rules and the UNCITRAL Arbitration Rules 1976.

(1) ***The North American Free Trade Agreement (NAFTA)***

4.2. *Article 1101 NAFTA*: Article 1101(1) provides (in relevant part) as follows:

This Chapter [Eleven] applies to measures adopted or maintained by a Party relating to:

- (a) investors of another Party;
- (b) investments of investors of another Party in the territory of the Party; ...

4.3. *Article 1102 NAFTA*: Article 1102 provides (in relevant part) as follows:

- (1) Each Party shall accord to investors of another Party treatment no less favorable than that it accords, in like circumstances, to its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.
- (2) Each Party shall accord to investments of investors of another Party treatment no less favorable than that it accords, in like circumstances, to investments of its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments. ...

4.4. *Article 1103 NAFTA*: Article 1103 provides as follows:

- (1) Each Party shall accord to investors of another Party treatment no less favorable than that it accords, in like circumstances, to investors of any other Party or of a non-Party with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.



- (2) Each Party shall accord to investments of investors of another Party treatment no less favorable than that it accords, in like circumstances, to investments of investors of any other Party or of a non-Party with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.

4.5. *Article 1105(1) NAFTA*: Article 1105(1) provides as follows:

Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security.

4.6. *NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter 11 Provisions (31 July 2001)*: Clause 2 of the Commission's Notes of Interpretation provides as follows, under the heading 'Minimum Standard of Treatment in Accordance with International Law':

- (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).

4.7. *Article 1116 NAFTA*: Article 1116(1) provides as follows:

- (1) An investor of a Party may submit to arbitration under this Section a claim that another Party has breached an obligation under:
  - (a) Section A or Article 1503(2) (State Enterprises),  
or

- (b) Article 1502(3)(a) (Monopolies and State Enterprises) where the monopoly has acted in a manner inconsistent with the Party's obligations under Section A,

and that the investor has incurred loss or damage by reason of, or arising out of, that breach.

4.8. *Article 1117 NAFTA*: Article 1117(1) provides as follows:

- (1) An investor of a Party, on behalf of an enterprise of another Party that is a juridical person that the investor owns or controls directly or indirectly, may submit to arbitration under this Section a claim that the other Party has breached an obligation under:
  - (a) Section A or Article 1503(2) (State Enterprises), or
  - (b) Article 1502(3)(a) (Monopolies and State Enterprises) where the monopoly has acted in a manner inconsistent with the Party's obligations under Section A, and that the enterprise has incurred loss or damage by reason of, or arising out of, that breach.

4.9. *Article 1120 NAFTA*: Article 1120 provides (in relevant part) as follows:

- (1) Except as provided in Annex 1120.1, and provided that six months have elapsed since the events giving rise to a claim, a disputing investor may submit the claim to arbitration under:
  - (a) the ICSID Convention, provided that both the disputing Party and the Party of the investor are parties to the Convention;
  - (b) the Additional Facility Rules of ICSID, provided that either the disputing Party or the Party of the investor, but not both, is a party to the ICSID Convention; or
  - (c) the UNCITRAL Arbitration Rules.
- (2) The applicable arbitration rules shall govern the arbitration except to the extent modified by this Section.

4.10. *Article 1122 NAFTA*: Article 1122 provides as follows:

- (1) Each Party consents to the submission of a claim to arbitration in accordance with the procedures set out in this Agreement.
- (2) The consent given by paragraph 1 and the submission by a disputing investor of a claim to arbitration shall satisfy the requirement of:
  - (a) Chapter II of the ICSID Convention (Jurisdiction of the Centre) and the Additional Facility Rules for written consent of the parties;
  - (b) Article II of the New York Convention for an agreement in writing; and
  - (c) Article I of the InterAmerican Convention for an agreement.

4.11. *Article 1131 NAFTA*: Article 1131 provides as follows:

- (1) A Tribunal established under this Section shall decide the issues in dispute in accordance with this Agreement and applicable rules of international law.
- (2) An interpretation by the Commission of a provision of this Agreement shall be binding on a Tribunal established under this Section.

4.12. *Article 1136(1) NAFTA*: Article 1136(1) provides as follows:

An award made by a Tribunal shall have no binding force except between the disputing parties and in respect of the particular case.

4.13. *Article 1139(g) NAFTA*: Article 1139 provides (in relevant part) as follows:

‘investment’ means: ...

- (g) real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes; ...

4.14. *Article 1139(h) NAFTA*: Article 1139 provides (in relevant part) as follows:

‘investment’ means: ...

- (h) interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory, such as under
  - (i) contracts involving the presence of an investor’s property in the territory of the Party, including turnkey or construction contracts, or concessions, or
  - (ii) contracts where remuneration depends substantially on the production, revenues or profits of an enterprise;

but investment does not mean,

- (i) claims to money that arise solely from
  - (i) commercial contracts for the sale of goods or services by a national or enterprise in the territory of a Party to an enterprise in the territory of another Party, or
  - (ii) the extension of credit in connection with a commercial transaction, such as trade financing, other than a loan covered by subparagraph (d);
- ...

4.15. *Annex IV NAFTA*: The Schedule to NAFTA’s Annex IV provides (in relevant part) as follows:

The United States takes an exception to Article 1103 for treatment accorded under all bilateral or multilateral international agreements in force or signed prior to the date of entry into force of this Agreement [*i.e.*, 1 January 1994].

(2) ***The Jamaica-USA BIT***

4.16. The Jamaica-USA BIT was signed on 4 February 1994 and entered into force on 7 March 1997.

4.17. Articles II(2)(b) and II(6) of this BIT provide (in relevant part) as follows:

(2)(b) Neither Party shall in any way impair, by unreasonable or discriminatory measures the management, operation, maintenance, use, enjoyment, acquisition, expansion, or disposal of investments.

...

(6) Each Party shall provide effective means of asserting claims and enforcing rights with respect to investments ...

**(3) *The ICSID Arbitration (Additional Facility) Rules***

4.18. *Article 52(1)*: Article 52(1) of the ICSID Arbitration AF Rules provides (in relevant part) as follows:

The award shall be made in writing and shall contain: ...

(i) the decision of the Tribunal on every question submitted to it, together with the reasons upon which the decision is based; ...

4.19. *Article 52(4)*: Article 52(4) of the ICSID Arbitration AF Rules provides (in relevant part) as follows:

The award shall be final and binding on the parties. ...

4.20. *Article 20*: Article 20 of the ICSID Arbitration AF Rules provides (in relevant part) as follows:

(1) Subject to Article 19 of these Rules the place of arbitration shall be determined by the Arbitral Tribunal after consultation with the parties and the Secretariat.

(2) ...

(3) The award shall be made at the place of arbitration.

4.21. *Article 58: Article 58 of the ICSID Arbitration AF Rules provides as follows:*

- (1) Unless the parties otherwise agree, the Tribunal shall decide how and by whom the fees and expenses of the members of the Tribunal, the expenses and charges of the Secretariat and the expenses incurred by the parties in connection with the proceeding shall be borne. The Tribunal may, to that end, call on the Secretariat and the parties to provide it with the information it needs in order to formulate the division of the cost of the proceeding between the parties,
- (2) The decision of the Tribunal pursuant to paragraph (1) of this Article shall form part of the award.

**(4) *The UNCITRAL Arbitration Rules 1976***

4.22. *Article 32(2) UNCITRAL Rules: Article 32(2) provides as follows:*

The award shall be made in writing and shall be final and binding on the parties. The parties undertake to carry out the award without delay.

4.23. *Article 32(3) UNCITRAL Rules: Article 32(3) provides as follows:*

The arbitral tribunal shall state the reasons upon which the award is based, unless the parties have agreed that no reasons are to be given.

## ***PART V – THE PRINCIPAL ISSUES***

### **(1) *Introduction***

5.1. The Tribunal addresses the Parties' disputes as to jurisdiction and the merits (liability) under five distinct principal issues. These issues are listed below and subsequently decided *seriatim* by the Tribunal.

### **(2) *The Principal Issues***

5.2. *Jurisdiction – NAFTA Article 1101(1)*: This issue addresses the Respondent's jurisdictional objections in regard to the claims made by Apotex Inc. and by Apotex-Holdings (for itself and for Apotex-US). This issue is decided in Part VI below.

5.3. *Jurisdiction – Res Judicata and NAFTA Article 1139*: This issue addresses the Respondent's jurisdictional objections in regard to the claims made by Apotex Inc. and by Apotex-Holdings in regard to Apotex Inc.'s ANDAs. This issue is decided in Part VII below.

5.4. *Merits – NAFTA Articles 1102 & 1103*: This issue addresses the merits of the claims made by Apotex-Holdings (for itself and for Apotex-US) under NAFTA Articles 1102 and 1103. This issue is decided in Part VIII below.

5.5. *Merits – NAFTA Article 1105*: This issue addresses the merits of the claims made by Apotex-Holdings (for itself and for Apotex-US) under NAFTA Article 1105 and the Jamaica-USA BIT. This issue is decided in Part IX below.

5.6. *Legal and Arbitration Costs*: This issue addresses the Parties' respective claims in regard to legal and arbitration costs under the ICSID Arbitration AF Rules. This issue is decided in Part X below.

5.7. In Part XI below, the Tribunal summarises the effect of its decisions on the several claims for relief made by the Parties respectively, as set out in Part I above.

5.8. In Part XII, the Tribunal sets out the formal operative part of its decisions.

## ***PART VI – JURISDICTION: NAFTA ARTICLE 1101(1)***

### **(1) *Introduction***

- 6.1. This first principal issue addresses the Respondent’s jurisdictional objections under NAFTA Article 1101(1) in regard to the claims made by Apotex-Holdings (for itself and for Apotex-US) and by Apotex Inc. (subject to the assumption described below).
- 6.2. NAFTA Article 1101(1) limits, as a matter of jurisdiction, the substantive protections of NAFTA’s Chapter Eleven to a measure “adopted or maintained by a Party relating to: (a) investors of another Party; (b) investments of investors of another Party in the territory of the Party.” (The relevant text of NAFTA Article 1101(1) is set out in Part IV above).
- 6.3. It is necessary to address this jurisdictional provision within the context of NAFTA’s Chapter Eleven and the Claimants’ substantive claims in this arbitration. As recorded elsewhere, the only measure impugned by the Claimants in this arbitration is the Import Alert of 28 August 2009. Accordingly, the Import Alert (as adopted and maintained by the Respondent) must relate to the Claimants as investors or to their investments in the territory of the USA within the meaning of NAFTA Article 1101(1).

### **(2) *NAFTA Article 1101(1)***

- 6.4. *NAFTA Articles 1120 & 1121*: It is common ground between the Parties that, as a matter of jurisdiction, the Claimants have met the temporal and formal elements required for their claims in this arbitration under NAFTA’s Chapter Eleven for their substantive claims under NAFTA Articles 1120(1)(b) and 1121.
- 6.5. *NAFTA Articles 1116 and 1117*: It is also common ground between the Parties, on the admitted facts of this case (namely, that Apotex-Holdings indirectly owns and controls Apotex-US via a wholly owned intermediary Canadian company, Aposhern Inc.), that Apotex-Holdings (as a Canadian enterprise) is an “investor” within the meaning of NAFTA Article 1116(1) in regard to Apotex-US; that Apotex-US is an



“investment” of Apotex-Holdings within the meaning of NAFTA Article 1139; and that, as such, Apotex-US qualifies as an “investment of an investor of a Party” (*i.e.* of Apotex-Holdings of Canada) within the meaning of NAFTA Article 1117(1).

6.6. It is disputed between the Parties whether Apotex Inc. (albeit also a Canadian enterprise) is an “investor” under NAFTA Article 1116(1) with any “investment” under NAFTA Article 1139. It is also disputed whether Apotex-Holdings is an “investor” with any “investment” in Apotex Inc. under NAFTA Articles 1116(1) and 1139. These disputes, regarding the legal significance of Apotex Inc.’s ANDAs, are addressed separately in Part VII below. However, for present purposes in regard to this issue under NAFTA Articles 1101(1) and 1139, it is convenient to assume in regard to the ANDAs that Apotex Inc. is an “investor” with an “investment” in the ANDAs and also that Apotex-Holdings is an “investor” with an indirect “investment” in the ANDAs, both investments being “in the territory of” the USA. This assumption is subject to the Tribunal’s decisions in Part VII below.

(In earlier stages of this arbitration, Apotex Inc. appeared to assert other activities in the USA which it contended were “investments” independent of its ANDAs;<sup>1</sup> but these were superseded by the Claimants’ further pleaded case;<sup>2</sup> and it is now clear that none of these other activities forms part of the Claimants’ case, if they ever did. In any event, in the Tribunal’s view, none of those other activities can qualify, separately or collectively, as an “investment” of Apotex Inc. under NAFTA Article 1139(h) independently of the ANDAs.)

6.7. Accordingly, the Tribunal concludes that the present jurisdictional issue in this Part VI turns upon the subject matter of the Parties’ dispute, namely the Respondent’s Import Alert of 28 August 2009 under NAFTA Article 1101(1). As the Parties asserting the Tribunal’s jurisdiction to decide their substantive claims, it is for the Claimants to establish a positive answer to this issue.

6.8. *NAFTA Article 1101(1)*: The Respondent objects to the jurisdiction of this Tribunal to determine claims made by Apotex-Holdings (for itself and for Apotex-US) and by Apotex Inc. on the ground that NAFTA Article 1101(1), with its phrase “relating

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<sup>1</sup> Apotex Memorial, Paras. 398-401.

<sup>2</sup> Apotex Reply, Para. 240 (“...it has never been Apotex’s case that these activities constitute an investment”).

to”, requires as a threshold jurisdictional matter a legally significant connection between the disputed measure and the investor and/or its investment. The Respondent submits that the Import Alert did not relate to Apotex-Holdings or Apotex Inc. as “investors” or to any “investments” in the territory of the USA. (There is no dispute that the Import Alert was a “measure” adopted or maintained by the Respondent.)

- 6.9. The Respondent relies upon the NAFTA first partial award in *Methanex v USA* in support of its case that it is insufficient that the disputed measure somehow “affects” the investor or its investment. In that arbitration, the disputed measure restricted the use of MTBE as a gasoline additive; and the Canadian investor made methanol as a component of MTBE, but it did not manufacture or sell MTBE itself. The tribunal decided that Article 1101(1) required something more than the mere effect of a measure and required a legally significant connection between the measure and the investor and its alleged loss, an interpretation supported in that arbitration by the three NAFTA Parties. The tribunal held: “If the threshold provided by Article 110(1) was merely one of ‘affecting’, as Methanex contends, it would be satisfied wherever any economic impact was felt by an investor or an investment ... A threshold which could be surmounted by an indeterminate class of investors making a claim alleging loss is no threshold at all ...”<sup>3</sup>
- 6.10. This approach was subsequently followed in the NAFTA award in *Bayview v Mexico*. That tribunal held: “The simple fact that an enterprise in one NAFTA State is affected by measures taken in another NAFTA State is not sufficient to establish the right of that enterprise to protection under NAFTA Chapter Eleven: it is the relationship, the legally significant connection, with the State taking those measures that establishes the right to protection, not the bare fact that the enterprise is affected by the measures.”<sup>4</sup>
- 6.11. In response, the Claimants rely upon the NAFTA award in *Cargill v Mexico*, where the NAFTA tribunal concluded that the disputed measure, a Mexican legal requirement for an import permit, prevented the US claimant investor’s goods from

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<sup>3</sup> *Methanex v. United States of America*, *supra*, Paras. 137 and 147.

<sup>4</sup> *Bayview Irrigation District et al. v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award (19 June 2007), Para. 101.

crossing the border into Mexico and thereby directly affected (adversely) its investment in Mexico, namely the business of its Mexican subsidiary. This tribunal found: “The import permit requirement not only had an immediate and direct effect on the business of Cargill de Mexico [*i.e.* the claimant’s investment] but also constituted a legal impediment to carrying on the business of Cargill de Mexico in sourcing HFCS [high fructose corn syrup] in the United States and re-selling it in Mexico.”<sup>5</sup>

6.12. The Respondent disputes the application to the present case of the decision in *Cargill*. In particular, it points to the *Cargill* tribunal’s finding that the import permit requirement constituted a legal impediment to the Mexican subsidiary’s operations; whereas there was no such legal impediment for Apotex-US from the Import Alert: Apotex-US could still sell and did sell generic drugs in the USA, obtained from other manufacturers (including Hisamitsu Pharmaceutical of Japan and GSK).<sup>6</sup>

6.13. The Tribunal does not consider that the *Cargill* tribunal was seeking to apply a different legal interpretation of NAFTA Article 1101(1) from the two tribunals in *Methanex* and *Bayview*. Moreover, in the Tribunal’s view, there is in the present case no material difference between the Parties in their legal interpretation of the relevant wording in NAFTA Article 1101(1), applying the customary rules of interpretation codified in Article 31 of the Vienna Convention on the Law of Treaties. The Parties jointly agree that something more than a mere “effect” from the measure is required to overcome the jurisdictional threshold in NAFTA Article 1101(1). Their dispute derives from their different applications of that interpretation to the relevant facts and circumstances of this case, as regards Apotex-US, Apotex Inc. and Apotex-Holdings. It is convenient to consider each of these in turn.

**(3) *Apotex-US***

6.14. As to the facts relevant to Apotex-US, the Claimants submit that the Import Alert clearly related to Apotex-US: it was the named consignee of the products detained at the Canada-US border as a result of the Import Alert; the FDA district office that

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<sup>5</sup> *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award (18 September 2009), Para. 175.

<sup>6</sup> USA Counter-Memorial, Paras. 293-298.

intercepted these products expressly identified Apotex-US as the named party prevented from receiving those products, again as a result of the Import Alert; and Apotex-US was directly impacted by the Import Alert, losing sales and market shares because Apotex-US could no longer supply products manufactured by Apotex Inc. at its two facilities which Apotex-US was marketing for sale and was also contractually obliged to sell in the USA.<sup>7</sup>

- 6.15. As to the relevant facts, the Respondent makes four principal points. First, the Import Alert concerned products manufactured by Apotex Inc. and not Apotex-US; and there is no relationship of ownership or control between Apotex Inc. and Apotex-US. Second, the Import Alert was not applied to Apotex-US: the Import Alert named Apotex Inc. as the affected party; and its products from its two facilities were subject to detention upon export to the USA (*i.e.* not Apotex-US). Third, the Import Alert affected all US distributors of Apotex Inc.'s products from its two facilities, said to number 82 distributors and 113 wholesale dealers (*i.e.* not limited to Apotex-US). Fourth, the Import Alert did not affect the business of Apotex-US in marketing and selling generic drugs obtained from suppliers other than products manufactured at Apotex Inc.'s two facilities.<sup>8</sup>
- 6.16. The Respondent further submits that the Import Alert had only a single function: to apprise the FDA's district offices, as a matter of information and guidance, that Apotex Inc.'s Etobicoke and Signet facilities were not cGMP compliant and that products from these two facilities could therefore be detained without physical examination (DWPE) at the US border. Under US law, so the Respondent submits, the authority of an FDA district office to detain products offered for import does not depend upon any import alert.<sup>9</sup>
- 6.17. To rebut this submission, the Claimants relied upon the US Federal Court judgment in *Bellarno v FDA* (1988).<sup>10</sup> The Claimants submitted that the Court there decided that import alerts constituted an automatic detention of the specified products offered for import into the USA, legally effective on both the FDA and the importer; and that the Court rejected the FDA's argument that import alerts were a mere

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<sup>7</sup> Apotex Memorial, Para. 411.

<sup>8</sup> USA Counter-Memorial, Paras. 290ff.

<sup>9</sup> USA Counter-Memorial, Paras. 46 and 274.

<sup>10</sup> *Bellarno International Ltd v. FDA*, 678 F. Supp. 410 (E.D.N.Y. 1988), at 412ff.

interpretative rule or a general statement of policy, leaving US border officers to decide for themselves whether or not to detain shipments.<sup>11</sup> In turn, the Respondent demonstrated that, after this decision, the FDA had materially amended the wording of its import alerts to make clear that these did not call for automatic detention, as is apparent from the Import Alert here at issue with its revisions dating from 17 August 2007 (with no reference to “automatic detention”).<sup>12</sup> The Claimants dismissed this change in wording as mere “window-dressing.”<sup>13</sup>

- 6.18. The Tribunal notes that the wording of the import alert considered in *Bellarno* was only one of several factors that led the Court to its conclusion. The Tribunal is not persuaded that this judgment can be so easily distinguished as the Respondent submitted as regards the Import Alert in this case. However, it is unnecessary to decide the point. What matters for present purposes is not the status of the Import Alert under US law, but its factual significance for the application of the phrase “relating to” in NAFTA Article 1101(1).
- 6.19. Whatever the precise legal effect of the Import Alert’s wording under US law, it is a fact that the detention of Apotex Inc.’s products began on 30 August 2009, only two days after the Import Alert of 28 August 2009; and that such detention did not begin earlier with the FDA inspectors’ determinations that the Etobicoke and Signet facilities were non-cGMP compliant (on 19 December 2008 and 14 August 2009) or with the FDA’s Etobicoke warning letter of 25 June 2009. There is therefore a strong temporal relationship between the Import Alert and its effect upon Apotex-US. Further, within the FDA itself, it is clear that the Import Alert was intended to prevent products from Apotex Inc.’s two facilities being imported into the USA, not achievable with the FDA’s earlier determinations and warning letter: see the FDA’s internal memorandum dated 20 August 2009 considered in Part III above. There is therefore at least a strong subjective relationship between the Import Alert and the detention at the US border of shipments consigned by Apotex Inc. to Apotex-US.
- 6.20. However, as explained further below, the Tribunal thinks it inappropriate to introduce within NAFTA Article 1101(1) a legal test of causation applicable under

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<sup>11</sup> TD6.1568-1569.

<sup>12</sup> TD6.1690 and TD7.1774-1778.

<sup>13</sup> TD7.1741.

Chapter Eleven's substantive provisions for the merits of the Claimants' claims. For jurisdictional purposes, the threshold is necessarily different under NAFTA Article 1101(1), given the ordinary meaning of the connecting phrase "relating to."

- 6.21. For the reasons set out below, the Tribunal decides that the Import Alert did relate to Apotex-US within the meaning of NAFTA Article 1101(1).
- 6.22. The Tribunal considers that the Import Alert applied, as a fact, to Apotex-US as the consignee of Apotex Inc.'s products and as Apotex Inc.'s co-contracting party. The direct and immediate effect of the Import Alert was imposed not only upon Apotex Inc. but also upon Apotex-US, as seller/shipper and buyer/consignee respectively. Section 801 of the Act (from which the practice of import alerts derives) specifically refers to both "owner or consignee", as do the related provisions (relating to notices of detention) in the FDA Imports and Exports Rules (21 CFR § 1.94) and the FDA's Regulatory Procedures Manual (2011, at 9-8). Further, the FDA's sample Notice of FDA Action in this case, regarding the "hold" on Apotex Inc.'s products, expressly named Apotex-US with its Florida address as "Consignee."<sup>14</sup> (This factual analysis does not depend upon the location of sales made between Apotex Inc. and Apotex-US, nor the place where legal title passed in products sold between them).
- 6.23. In the Tribunal's view, the relevant circumstances of the present case, whilst not identical, are materially similar to those in *Cargill* but materially different from those in *Methanex* (as considered in the first partial award). The immediate effect of the Import Alert made it impossible for Apotex-US legally to receive contracted products from Apotex Inc.'s two facilities at Etobicoke and Signet; and, as a direct result, Apotex-US was prevented from carrying on that major part of its business of sourcing those products from Apotex Inc.'s two facilities for re-sale in the USA. In *Cargill*, the tribunal held that the requirement for an import permit had an immediate and direct effect on the business of the Mexican company and constituted a legal impediment to the carrying on of that company's business in sourcing HFCS in the USA for re-sale in Mexico, with the result that the threshold gateway in NAFTA Article 1101(1) was there met by the claimant investor. Further, the commercial relationship between Apotex Inc. and Apotex-US was not fleeting or minimal as at August 2009: the Import Alert interrupted an established long term

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<sup>14</sup> For example, see the FDA Notice 1 at p. 5, dated 2 September 2009 (Exhibit R-044).

relationship with Apotex Inc. on which Apotex-US depended for a significant proportion of its sales in the USA.

- 6.24. All these circumstances distinguish *Methanex*, where the potential class of investors indirectly affected by the dispute measure was indeterminate and unknown. In the present case, the Import Alert more than affected, uniquely, both Apotex Inc. and Apotex-US; and of all US recipients of Apotex Inc.'s products, Apotex-US was by far the enterprise most immediately, most directly and most adversely affected by the Import Alert. In the Tribunal's view, that suffices to satisfy the Claimant's relationship with the Import Alert within the meaning of NAFTA Article 1101(1).
- 6.25. In the Tribunal's view, it is therefore no answer for the Respondent to point to other shipments by Apotex Inc. which, by virtue of the Import Alert, also could not be made to consignees or buyers other than Apotex-US. Compared to Apotex-US, the effect on such other consignees and buyers was minimal. It is also no answer for the Respondent to show (as was indeed the fact) that Apotex-US could source and resell products from other manufacturers and suppliers during the two-year period in question. The latter could, of course, affect issues of liability and would affect questions of quantum; but none of these answers provides any warrant for interpreting NAFTA Article 1101(1) so narrowly as to require Apotex-US to be the exclusive purchaser of all Apotex Inc.'s products for the USA or Apotex Inc. to be Apotex-US's sole supplier in the USA.
- 6.26. Equally, in the Tribunal's view, it is no answer for the Respondent to invoke different theories as to the legal cause of loss to Apotex-US, other than the Import Alert. That issue may likewise affect issues of liability and quantum; but, again, there is no reason for requiring NAFTA Article 1101(1) to be so narrowly interpreted as to require only a claimant with a successful case on causation to pass through its threshold gateway; or to establish that the disputed measure is the only relevant possible measure.
- 6.27. Lastly, as submitted by the Claimants, there is a practical problem in seeking to interpret and apply the phrase "relating to" as a narrow threshold jurisdictional issue without any regard to the substantive NAFTA provisions invoked by a claimant investor in the particular case. The Claimants contend that, if the connection

between the measure and the investment that is required to establish a breach of a substantive provision in a particular case is present, it is difficult to conclude that such connection could have no legal significance under NAFTA Article 1101(1) as a jurisdictional matter. Here, in this case, so the Claimants contend, the Import Alert has a sufficient connection with the alleged breaches of NAFTA Articles 1102, 1103 and 1105 and, hence, a sufficient legal connection has been established by the Claimants under NAFTA Article 1101(1) for jurisdictional purposes.<sup>15</sup>

6.28. The Tribunal accepts the result of the Claimants' analysis for this case; but it may go too far for other cases where there is no sufficient connection between the disputed measure and the investment. In this case, there is clearly more than a sufficient connection. Were the result otherwise (as the Claimants contended), it could mean that a claimant investor might have a legitimate claim for breach of a substantive NAFTA provision, made in good faith and upon reasonable grounds, without any remedy under NAFTA's Chapter Eleven. In the Tribunal's view, there is no reason to interpret or apply NAFTA Article 1101(1) as an unduly narrow gateway to arbitral justice under NAFTA's substantive provisions under Chapter Eleven. None of the legal materials cited by the Parties support such a restrictive interpretation of the phrase "relating to" in NAFTA Article 1101(1). Accordingly, if and to the extent that the Respondent was arguing otherwise in this arbitration,<sup>16</sup> the Tribunal would reject such argument.

**(4) *Apotex Inc.***

6.29. *Apotex Inc.*: The Claimants contend that the Import Alert specifically named Apotex Inc. as the affected party; and that the Import Alert had the direct effect of rendering Apotex Inc.'s ANDAs useless, during a period of almost two years, for the purpose for which Apotex Inc. had acquired them: *i.e.* for marketing its products covered by the ANDAs in the USA.<sup>17</sup>

6.30. The Tribunal repeats its decisions above relating to the factual significance and effect of the Import Alert.

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<sup>15</sup> Apotex Reply, Paras. 96-97; TD1.130-131.

<sup>16</sup> TD5.1285-1286.

<sup>17</sup> Apotex Memorial, Para. 412.



6.31. Accordingly, subject to the assumption made above, the Tribunal accepts that the Import Alert “related to” Apotex Inc. and its ANDAs within the meaning of NAFTA Article 1101(1). This is, of course, insufficient for Apotex Inc. to prevail as a matter of jurisdiction, being also dependent on the issue next considered in Part VII below.

**(5) *Apotex-Holdings***

6.32. *Apotex-Holdings*: The Claimants submit that, because Apotex-Holdings is the ultimate owner of Apotex-US and Apotex Inc. and their investments, the Import Alert relates also to Apotex-Holdings and its indirect investments.<sup>18</sup>

6.33. It is possible to address this submission succinctly, given that jurisdiction over all claims made by Apotex-Holdings necessarily depends upon the issues relating to Apotex-US and Apotex Inc. respectively.

6.34. Accordingly, for the reasons set out above, the Tribunal decides that it has jurisdiction over the claims made by Apotex-Holdings under NAFTA Articles 1116 and 1117 (for itself and for Apotex-US). As regards jurisdiction over Apotex-Holdings’ claims under NAFTA Article 1116 relating to Apotex Inc.’s ANDAs, the Tribunal’s decision depends the issue next addressed in Part VII below.

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<sup>18</sup> Apotex Memorial, Para. 413.

**PART VII – RES JUDICATA: JURISDICTION AND NAFTA ARTICLE 1139**

**(1) Introduction**

- 7.1. The Tribunal here addresses the second principal issue, namely the Respondent’s jurisdictional objections in regard to the claims made by Apotex Inc. and Apotex-Holdings as investors in regard to the ANDAs as investments. As already indicated, this issue depends upon the interpretation of the ANDAs as an “investment” under NAFTA Article 1139 raising in turn the issue of Apotex Inc. and Apotex-Holdings as investors with investments, forming part of the threshold requirements as to jurisdiction contained in NAFTA Article 1101(1) (with Article 1116).
- 7.2. However, this issue first raises the question whether and to what extent the Respondent can invoke the doctrine of *res judicata* to preclude the Claimants from providing any positive answer to this issue as a matter of jurisdiction, given the Apotex I & II Award made between Apotex Inc. and the Respondent. Although that Award identifies the Respondent as “the Government of the United States of America”, it is common ground between the Parties that the Respondent is a party or “privy” to the Award.<sup>1</sup> It is also common ground that Apotex-Holdings is not a named party to that Award or the arbitration in which that Award was made. The position of Apotex-Holdings must therefore be considered separately from Apotex Inc., on the basis of the limited concession made by Apotex-Holdings as a “privy”, which is described later below.
- 7.3. The Apotex I & II Award was made under NAFTA’s Chapter Eleven and the UNCITRAL Arbitration Rules 1976, with its place of arbitration stated to be New York, New York, USA. The Tribunal has only been shown the redacted version of this Award; but nothing material to this arbitration has been withheld from the Tribunal by Apotex Inc. or the Respondent. Indeed, only a part of the Apotex I & II Award is relevant to the Parties’ submissions on *res judicata*; and, for ease of reference below, the relevant (redacted) passages of the Award are set out as an Annex to this Part VII.

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<sup>1</sup> In answer to the Tribunal’s Question A3 at the Hearing, TD6.1578 for the Claimants and TD6.1646 for the Respondent.

(2) *NAFTA Article 1136(1)*

- 7.4. The Parties' respective submissions begin with NAFTA Article 1136(1). It provides: "An award made by a Tribunal shall have no binding force except between the disputing parties and in respect of the particular case." The Claimants interpret this provision to mean that the legal effects of the Apotex I & II Award are wholly confined to that particular arbitration and can have no binding force in this different arbitration. Thus, according to the Claimants, there can be no possible *res judicata* effect upon the Claimants' claims in the present case. The Respondent disagrees.
- 7.5. The Tribunal does not share the Claimants' interpretation of NAFTA Article 1136(1).
- 7.6. In the Tribunal's view, NAFTA Article 1136(1) closely parallels, and appears to be based upon, Article 59 of the Statute of the International Court of Justice ("ICJ"). Article 59 provides that: "The decision of the Court has no binding force except between the parties and in respect of that particular case." This text repeats verbatim Article 59 of the earlier Statute of the Permanent Court of International Justice ("PCIJ"). For both international courts (the ICJ and the PCIJ), the text consistently has been understood to mean that the court has no rule of *stare decisis*. Neither international court has interpreted the provision to bar the operation of *res judicata*. Moreover, as described below, both international courts have applied the doctrine of *res judicata*.
- 7.7. Professor Rosenne writes that, for the ICJ, "[t]he effect of Article 59 is that the Statute itself excludes the doctrine of *stare decisis*, the binding force of a judicial decision as a law-creating precedent."<sup>2</sup> Addressing Article 59's role in the PCIJ's Statute, Judge Hudson similarly observes that "Article 59 ... clearly precludes the Court from adopting any doctrine similar to the Anglo-American doctrine of *stare decisis*."<sup>3</sup> However, "[t]he elimination of the possibility of the Court's developing a doctrine of *stare decisis* does not preclude it from applying the general principle of *res judicata*. Indeed, the application of that principle seems to be required by Article

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<sup>2</sup> Rosenne, Shabtai, III *The Law and Practice of The International Court, 1920-1995* (2006), at p. 1571.

<sup>3</sup> Hudson, Manley O., *The Permanent Court of International Justice* (1934), at p. 536, §522.

59 of the Statute, for otherwise a decision of the Court would not be binding on the parties.”<sup>4</sup>

7.8. Other learned commentators have also understood NAFTA Article 1136(1) in the same sense as Article 59 of the ICJ and PCIJ Statutes, as precluding a rule of binding precedent. In the scholarly work edited by Ms. Kinnear (et al), it is observed: “Article 1136(1) makes clear that the rule of *stare decisis* does not apply to awards rendered under Chapter 11.”<sup>5</sup>

7.9. Accordingly, the Tribunal decides that NAFTA Article 1136(1) does not bar the Respondent in this arbitration from invoking the doctrine of *res judicata* on the basis of the Apotex I & II Award, where applicable. If the position were otherwise, the Claimants’ submission would effectively mean that it could re-litigate the same claims over and over again in different arbitrations against the same party, which would be an absurd result for an arbitral procedure intended to produce finality with a legally binding decision.

### (3) *Res Judicata in International Law*

7.10. The Parties agree that the Tribunal, under NAFTA Article 1131, “shall decide the issues in dispute in accordance with this Agreement [NAFTA] and applicable rules of international law.”

7.11. In the Tribunal’s view, the doctrine of *res judicata* is a general principle of law and is thus an applicable rule of international law within the meaning of NAFTA Article 1131. In its Advisory Opinion of 13 July 1954, the ICJ affirmed that “[a]ccording to a well-established and generally recognized principle of law, a judgment rendered by ... a judicial body [such as the U.N. Administrative Tribunal] is *res judicata* and has binding force between the parties to the dispute.”<sup>6</sup> Accordingly, Professor Bin Cheng writes, “[t]here seems little, if indeed any, question as to *res judicata* being a general principle of law or as to its applicability in international judicial

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<sup>4</sup> *Id.*, at p. 537, §523.

<sup>5</sup> Kinnear, Meg N., Bjorkland, Andrea K., and Hannaford, John F. G., *Investment Disputes Under NAFTA: An Annotated Guide to NAFTA Chapter 11* (2006, updated March 2008), at p. 1136-3.

<sup>6</sup> *Effect of Awards of Compensation Made by the U.N. Administrative Tribunal, Advisory Opinion of 13 July 1954*, I.C.J. Reports 1954, p. 47, p. 53.

proceedings.”<sup>7</sup> As later confirmed in the *Amco* award, “The principle of *res judicata* is a general principle of law.”<sup>8</sup>

- 7.12. The doctrine of *res judicata* defines the binding effect of a prior final determination made by a competent tribunal. In *Amco*, the tribunal decided: “The general principle, announced in numerous cases is that a right, question, or fact *distinctly put in issue and distinctly determined* by a court of competent jurisdiction as a ground of recovery, cannot be disputed.”<sup>9</sup> Thus, according to Professor Bin Cheng, “[o]nce a case has been decided by a valid and final judgment, the same issue may not be disputed again between the same parties, as long as that judgment stands.”<sup>10</sup>
- 7.13. The doctrine of *res judicata* is often described as operating in international proceedings where three conditions establish the congruence of the matters previously determined and those currently at issue. Legal scholars often refer to Judge Anzilotti’s formulation of this triple identity test in his dissent in the PCIJ case of *Chorzów Factory (Interpretation)*. Judge Anzilotti there referred to: “the three traditional elements for identification, *persona, petitum, causa petendi*, for it is clear that ‘that particular case’ (*le cas qui a été décidé*) covers both the object and the grounds of the claim.”<sup>11</sup> The judgment of the majority had there accorded *res judicata* to the passage in the Court’s earlier declaratory judgment setting out the grounds or ‘essential conditions’ on which that decision was based.<sup>12</sup>
- 7.14. No issue arises in the present case regarding *persona*: Apotex Inc. and the Respondent are named parties to the Apotex I & II Award (the position of Apotex-Holdings as a privy, albeit not a named party, is considered separately below). Professors Schreuer and Reinisch explain the Latin legal terms *petitum* and *causa petendi*, as follows: “[i]dential ‘object’ (*petitum*) means that the same type of relief

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<sup>7</sup> Cheng, Bin, *General Principles of Law as Applied by International Courts and Tribunals* (1953), at p. 336.

<sup>8</sup> *Amco Asia Corp. v. Republic of Indonesia*, ICSID Case No. ARB/81/1, Resubmitted Case, Decision on Jurisdiction (10 May 1988), 27 ILM 1281 (1988).

<sup>9</sup> *Id.*, Para. 30 (quoting expert report of Professor Reisman) (emphasis in original).

<sup>10</sup> Cheng, *supra*, at p. 337.

<sup>11</sup> *Interpretation of Judgments Nos. 7 & 8 Concerning the Case of the Factory at Chorzow*, 1927 P.C.I.J. (ser. A) no. 13 (16 December 1927) (dissenting opinion of Judge Anzilotti) at p. 23. Judge Anzilotti’s Latin terms were translated by the tribunal in *Trail Smelter Case (United States of America v. Canada)*, 3 R.I.A.A. 1938 (11 March 1941) to mean “parties, object, and cause.”

<sup>12</sup> *Interpretation of Judgments Nos. 7 & 8 Concerning the Case of the Factory at Chorzow*, *supra*, at p. 20.

is sought in different proceedings. Identical ‘ground’ (*causa petendi*) means that the same legal arguments are relied upon in different proceedings.”<sup>13</sup>

- 7.15. Whilst the triple identity test is often referred to in describing the requirements for *res judicata* to operate,<sup>14</sup> certain international tribunals and scholars have questioned its division between *petitum* and *causa petendi*; and many cases have used a simpler analysis.<sup>15</sup> The British-U.S. Claims Arbitral Tribunal saw the doctrine as involving only two elements: “res judicata applies only where there is identity of the parties and of the question at issue.”<sup>16</sup> The *Pious Fund* tribunal (applying *res judicata* in the Permanent Court of Arbitration’s first case and viewed as “[t]he leading early case”<sup>17</sup>) also applied a two-part test, emphasising that “there are not only the same parties to the suit, but also the same subject-matter that was judged” in a prior arbitral award.<sup>18</sup>
- 7.16. Professor Cheng questions the division between *petitum* and *causa petendi*, observing that “an examination of international decisions ... throws some doubt about the accuracy of this sub-division, especially in border-line cases.”<sup>19</sup> Professors Schreuer and Reinisch point out that “[i]nternational tribunals have ... been aware of the risk that if they use too restrictive criteria of ‘object’ and ‘grounds’, the doctrine of *res judicata* would rarely apply: if only an exactly identical relief sought (object) based on exactly the same legal arguments (grounds) in a second case would be precluded as a result of *res judicata*, then litigants could easily evade this by slightly modifying either the relief requested or the grounds

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<sup>13</sup> Schreuer, Christoph and Reinisch, August, Legal Opinion, *CME Czech Republic B.V. v. Czech Republic*, UNCITRAL (20 June 2002), at p. 16, Para. 43 (“Schreuer & Reinisch”). See also Amerasinghe, Chittharanjan F, *International Arbitral Jurisdiction* (2011), at p. 169; and Lowe, Vaughan, *Res Judicata and the Rule in International Arbitration*, 8 RADIC 38 (1996), at pp. 40-41. Professors Schreuer and Reinisch discuss the use by contemporary tribunals of an “economic approach” in assessing identity; but that is not relevant to the present case (see Paras. 21-40).

<sup>14</sup> International Law Association, *Interim Report, “Res Judicata” and Arbitration*, International Law Association, Berlin Conference on International Arbitration (2004), at p. 2. (“ILA Interim Report”). The Tribunal notes that the ILA’s Final Report on “Res Judicata” was expressly limited to international commercial arbitration: hence its citation here is of limited relevance, as submitted by the Claimants [TD1.158].

<sup>15</sup> See the cases cited by Schreuer and Reinisch, *supra*, at p. 8, Para. 15.

<sup>16</sup> *British-U.S. Claims Arbitration* (1910), cited in Cheng, *supra*, at pp. 339-340.

<sup>17</sup> Schreuer & Reinisch, *supra*, at p. 3, Para. 6.

<sup>18</sup> *The Pious Fund of the Californias*, Permanent Court of Arbitration, Award (14 October 1902), at p. 3 (unofficial English translation).

<sup>19</sup> Cheng, *supra*, at p. 343.

relied upon.”<sup>20</sup> Professor Dodge voices a similar concern, although he indicates (as do Professors Schreuer and Reinisch) that tribunals have not allowed “claim splitting” by claimants seeking to avoid the preclusive effects of prior awards.<sup>21</sup>

- 7.17. The Claimants and the Respondent disagree on the scope of *res judicata*'s effect in international law. The Parties agree that the provisions of the *dispositif*, or operative part, of a prior judgment or award have *res judicata* effect. They disagree whether *res judicata* in international law includes the broader concept of or akin to issue estoppel, the principle that a party in subsequent proceedings cannot contradict an issue of fact or law not reflected in the *dispositif* if it has already been distinctly raised and finally decided in earlier proceedings between the same parties (or their privies). The Claimants submit it does not; whereas the Respondent says it does.
- 7.18. It is clear that past international tribunals have applied forms of issue estoppel, without necessarily using the term. Umpire Plumley's award in *Orinoco Steamship* found that “every matter and point distinctly in issue ... and which was directly passed upon and determined in said decree, and which was its ground and basis, is confirmed by said judgment, and the claimants ... are forever estopped from asserting any right or claim based in any part upon any fact actually and directly involved in the said decree.”<sup>22</sup> In Professor Lowe's opinion, the tribunal in the resubmitted *Amco* case<sup>23</sup> “clearly applied the principle of issue estoppel to the determination of specific facts and of the legal characterisations of facts by the previous tribunal.”<sup>24</sup> Most recently, the ICSID tribunal in *Grynberg v. Grenada*<sup>25</sup> applied issue estoppel (albeit describing it as “collateral estoppel”<sup>26</sup>) to foreclose the

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<sup>20</sup> Schreuer & Reinisch, *supra*, at p. 17, Para. 45.

<sup>21</sup> Dodge, William, *National Courts and International Arbitration: Exhaustion of Remedies and Res Judicata Under Chapter Eleven of NAFTA*, 23 *Hastings Int'l & Comp. L.* (2000), at p. 366; Schreuer & Reinisch, *supra*, at pp. 17-18, Paras. 46-48.

<sup>22</sup> *Claim of Company General of the Orinoco Case*, Report of French-Venezuelan Mixed Claims Commission of 1902 (1906, Ralston, Jackson H., ed.) at p. 355.

<sup>23</sup> *Amco v. Indonesia*, *supra*.

<sup>24</sup> Lowe, *supra*, at p. 42.

<sup>25</sup> *Rachel S. Grynberg, Stephen M. Grynberg, Miriam Z. Grynberg and RSM Production Corporation v. Grenada*, ICSID Case No. ARB/10/6, Award (10 December 2010).

<sup>26</sup> Although the *Grynberg* Award referred to the principle as “collateral estoppel”, the US legal concept of “collateral estoppel” is broader, permitting non-parties (or privies) to a prior litigation to invoke the doctrine to preclude re-litigation of an issue previously decided. That broader principle is not an issue in the present case, as the Respondent recognised [TD4.1190].

claimants' efforts to re-open issues decided in an award made in a prior ICSID arbitration.<sup>27</sup>

- 7.19. In *Grynberg v. Grenada*, the award in the first ICSID arbitration had dismissed the claims against Grenada as the respondent made by a Texan company (RSM) alleging contractual breaches of a concession agreement. In the second ICSID arbitration, RSM and its three shareholders alleged breaches by the same respondent of the bilateral investment treaty between the USA and Grenada. On the face of it, the triple identity test was not satisfied as regards these three shareholders as *persona*, nor the *petitum* or *causa petendi* as regards both RSM and the shareholders. Yet, the second arbitration tribunal summarily dismissed all claims made by these four claimants as being “manifestly without legal merit” under ICSID Arbitration Rule 41(5), together with costs orders adverse to the claimants.
- 7.20. In so doing, the second tribunal accepted the respondent’s submission of issue estoppel arising from the first award, to the effect that the legal and factual contentions on which the new claims depended had already been fully litigated in the first ICSID arbitration.<sup>28</sup> Applying the doctrine to all four claimants as “privies” as a general principle of law recognised in *Amco v Indonesia*<sup>29</sup> and the *Orinoco* case, the second ICSID tribunal accepted that “a finding concerning a right, question or fact may not be re-litigated (and, thus, is binding on a subsequent tribunal), if, in a prior proceeding: (a) it was distinctly put in issue; (b) the court or tribunal actually decided it; and (c) the resolution of the question was necessary to resolving the claims before that court or tribunal.”<sup>30</sup> Applying these principles, the tribunal concluded: “that an essential predicate to the success of each of Claimants’ claims is an ability for the Tribunal to re-litigate and decide in Claimants’ favour conclusions of fact or law concerning the parties’ contractual rights that have already distinctly been put in issue and distinctly determined by the Prior Tribunal”;

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<sup>27</sup> *Grynberg v. Grenada*, *supra*, Para. 7.1.8.

<sup>28</sup> *Id.*, Para. 4.1.1.

<sup>29</sup> *Amco v. Indonesia*, *supra*, quoting the expert report of Professor Reisman at Para. 30: “[A] right, question or fact distinctly put in issue and distinctly determined by a court of competent jurisdiction as a ground of recovery, cannot be disputed.”

<sup>30</sup> *Grynberg v. Grenada*, *supra*, Para. 7.1.1.



and having determined that ability adversely to the claimants, the tribunal decided that each of their claims was manifestly without legal merit.<sup>31</sup>

- 7.21. The Claimants denied the relevance of the *Grynberg* award to the present case, contending that the parties there had agreed to the application of collateral estoppel (issue estoppel) under the governing law.<sup>32</sup> In the Tribunal’s view, this submission is incorrect.<sup>33</sup> The parties strongly disputed its application to their case; but, significantly, there was no dispute as its requirements as a general principle of international law.
- 7.22. The Claimants also contend that *Orinoco Steamship* (and presumably other like authorities<sup>34</sup>) do not correctly reflect *res judicata* under international law. In their submission, the case reflected Umpire Plumley’s common law orientation, as evidenced by his reliance on a decision of the US Supreme Court decision as legal authority for the cited principle.<sup>35</sup> The Claimants contend that notions of issue estoppel found in common law systems are not found in civil law systems, which typically (so the Claimants submit) limit *res judicata* effects to matters addressed in the *dispositif* of an award or judgment.<sup>36</sup> Given this significant difference in approach between two major systems of law, the Claimants contend that issue estoppel cannot be said to be an aspect of *res judicata* as a general principle of law “recognised by civilized nations.”
- 7.23. The Tribunal recognises that historical differences as to issue estoppel have existed and, to a lesser extent, still exist in national laws between certain common law and certain civil law systems. As the ILA Interim Report makes clear, however, there is no sharp divide between these two legal systems.<sup>37</sup> It is also clear that international courts and tribunals have regularly examined under international law a prior tribunal’s reasoning, and the arguments it considered, in determining the scope, and thus the preclusive effect, of the prior award’s operative part. The first international

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<sup>31</sup> *Id.*, Para. 7.2.1.

<sup>32</sup> TD3.542.

<sup>33</sup> *Grynberg v. Grenada, supra, see (inter alia)* Paras. 5.3.5 and 5.3.6.

<sup>34</sup> *See, e.g., Cheng, supra, at p. 337; Amco v. Indonesia, supra, Para. 30.*

<sup>35</sup> *Southern Pacific R.R. Co. v. United States*, 168 U.S. 1 (1897).

<sup>36</sup> *See* ILA Interim Report, *supra*, at p. 14.

<sup>37</sup> *Id.*, at p. 15.

tribunal's analysis and reasoning thus often play a significant role before the second international tribunal in determining the *res judicata* effect of the earlier award.

- 7.24. This is illustrated in the *Pious Fund* arbitration, where the tribunal held that an umpire's award in a prior mixed claims commission proceeding had *res judicata* effect, and obliged Mexico to pay certain annuities to the USA on behalf of the Archbishop of San Francisco and the Bishop of Monterey. The tribunal rejected Mexico's contention that only the amount specified in the prior award had *res judicata* effect, instead considering that it must consider the earlier award in its entirety to determine the *res judicata* effect of its *dispositif*: "Considering that all the parts of a judgment or a decree concerning the points debated in the dispute enlighten and mutually supplement each other, and that they all serve to render precise the meaning and bearing of the *dispositif* (the decisory part of the judgment), to determine the points upon which there is *res judicata* and which therefore cannot be put in question."<sup>38</sup>
- 7.25. The Permanent Court of International Justice was of like mind in *Advisory Opinion No. 11*: "It is perfectly true that all the parts of a judgment concerning the points in dispute explain and complete each other and are to be taken into account in order to determine the precise meaning and scope of the operative portion. This is clearly stated in the award of the Permanent Court of Arbitration of October 14th, 1902, concerning the Pious Fund of the Californias ... The Court agrees with this statement."<sup>39</sup>
- 7.26. In his dissent in *Chorzów Factory*, Judge Anzilotti was of the view that "the binding effect attaches only to the operative part of the judgment and not to the statement of reasons." However, he added: "[w]hen I say that only the terms of a judgment are binding, I do not mean that only what is actually written in the operative part constitutes the Court's decision. On the contrary, it is certain that it is almost always necessary to refer to the statement of reasons to understand clearly the operative part and above all to ascertain the *causa petendi*."<sup>40</sup>

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<sup>38</sup> *Pious Fund*, *supra*, at p. 2.

<sup>39</sup> *Polish Postal Service in Danzig, Advisory Opinion*, 1925 P.C.I.J. (Ser. B) No. 11 (May 16), Para. 86.

<sup>40</sup> *Interpretation of Judgments Nos. 7 & 8 Concerning the Case of the Factory at Chorzow, supra*, at p. 24.

- 7.27. The *Channel Arbitration* tribunal similarly observed that while *res judicata* “attaches in principle only to the provisions of” the *dispositif*, “it is equally clear that, having regard to the close links that exist between the reasoning of a decision and the provisions of its *dispositif*, recourse may in principle be had to the reasoning in order to elucidate the meaning and scope of the *dispositif*.”<sup>41</sup>
- 7.28. The International Court of Justice also looks to the parties’ arguments and submissions to determine the legal effect of prior judgments. As Professor Rosenne observes, “[t]he relevance of whether a question was argued between the parties might arise ... if it is necessary to determine the scope of the *res judicata* ... In the *Asylum* case ... the problem was ... of the scope of the binding force of the decision. The *res judicata* does not derive from the operative clause of the judgment, which confined itself to stating which submissions of the parties were rejected or accepted and to what extent, but from the reasons in point of law given by the Court.”<sup>42</sup> Accordingly, cases such as *Asylum*<sup>43</sup> and *Corfu Channel*<sup>44</sup> “bring into sharp relief the delayed-action effect attaching to the written and oral pleadings. In the last analysis the scope of *res judicata* can only be determined by reference to the pleadings in general, and to the parties’ submissions in particular.”<sup>45</sup>
- 7.29. The jurisprudence of the European Court of Justice (ECJ) is to like effect. For the ECJ (applying the laws of the European Union and international law), the legal effect of a decision by the ECJ and other EU institutions is not to be limited to the wording of the operative part. In *Asteris & Greece v. Commission*, the ECJ noted that the EU institution was required to have regard not only to the operative part of the decision but also to the *motifs* which led to that decision in order to determine the former’s exact meaning.<sup>46</sup> In *Commission v. BASF*,<sup>47</sup> the ECJ noted that: “the operative part of such a decision can be understood, and its full effect ascertained, only in the light of the statement of reasons”; and that a decision’s *dispositif* and

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<sup>41</sup> *Case Concerning the Delimitation of the Continental Shelf (U.K. v. France)*, 18 R.I.A.A. 272 (14 March 1978), 295 (Para. 28).

<sup>42</sup> Rosenne, *supra*, at p. 1603.

<sup>43</sup> *Request for Interpretation of the Judgment of 20 November 1950, in the Asylum Case (Colombia v. Peru)*, *Judgment of 27 November 1950*, I.C.J. Reports 1950, p. 395.

<sup>44</sup> *Corfu Channel case, Judgment of 9 April 1949*, I.C.J. Reports 1949, p. 4.

<sup>45</sup> Rosenne, *supra*, at p. 1603.

<sup>46</sup> *Asteris & Greece v Commission*, [1988] ECR 2181, Para. 27.

<sup>47</sup> *Commission of the European Communities v. BASF AG & Others*, [1994] ECR I-2555, Para. 67.

*motifs* constituted “an indivisible whole.” In *Deggendorf v. Commission*, the ECJ held that: “the operative part of an act is indissociably linked to the statement of reasons for it, so that, when it has to be interpreted, account must be taken of the reasons which led to its adoption.”<sup>48</sup>

7.30. Thus, where there is a question regarding the extent of a prior decision or award’s *res judicata* effect, international tribunals regularly look to the prior tribunal’s reasons and indeed also to the parties’ arguments, in order to determine the scope of what was finally decided in that earlier proceeding.

7.31. In Professor Rosenne’s opinion, in examining a prior tribunal’s reasoning and the arguments it considered, international tribunals have not drawn the distinctions between *ratio decidendi* and *obiter dicta* “which is an essential element of the common-law rule of the binding force of judicial precedents (*stare decisis*).”<sup>49</sup> For the International Court of Justice, Professor Rosenne observes, “ [t]he reasons in point of law of Article 95 ... of the Rules of Court do not contemplate such a finely drawn distinction.”<sup>50</sup> As in the *Pious Fund* arbitration, tribunals have considered that “all the parts of the judgment or the decree concerning the points debated in the litigation enlighten and mutually supplement each other.”<sup>51</sup>

7.32. It would be possible to cite many further legal materials in support of the legal analysis made above; but it would serve no purpose here to prolong what is already a lengthy analysis. However, the Tribunal is comforted to see its approach above confirmed by the ICJ’s recent Judgment of 11 November 2013 in *Cambodia v Thailand*.<sup>52</sup> In that Judgment, albeit not directly concerned with the doctrine of *res judicata*, the ICJ considered in regard to an earlier judgment of 1962 the scope of Article 60 of the ICJ’s Statute, which provides: “The judgment is final and without appeal. In the event of dispute as to the meaning or scope of the judgment, the Court shall construe it upon the request of any party.” In accordance with the ICJ’s jurisprudence, a dispute under Article 60 must relate to the operative part of the

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<sup>48</sup> *Textilwerke Deggendorf GmbH (TWD) v Commission*, [1997] ECR I-2549, Para. 21.

<sup>49</sup> Rosenne, *supra*, at p. 1556.

<sup>50</sup> *Id.*

<sup>51</sup> *Pious Fund, supra.*

<sup>52</sup> *Request for Interpretation of the Judgment of 15 June 1962 in the Case Concerning the Temple of Preah Vihear (Cambodia v. Thailand)*, Judgment of 11 November 2013 (ICJ).

judgment in question and cannot concern the reasons for the judgment except in so far as these are inseparable from the operative part.<sup>53</sup> The ICJ nonetheless held under Article 60 that the “scope of the operative part of a judgment of the Court is necessarily bound up with the scope of the dispute before the Court.”<sup>54</sup> The Tribunal concludes from this Judgment that even with the restrictive language of Article 60, the ICJ is not barred from interpreting the operative part of a judgment by reference to its reasons for that judgment.

**(4) *Res Judicata under the UNCITRAL Arbitration Rules***

7.33. The Apotex I & II Award was made under the UNCITRAL Arbitration Rules 1976 forming part of the arbitration agreement between the parties to that arbitration. Under Article 32(2) of the UNCITRAL Rules, an award “shall be final and binding on the parties”, including an award made in the exercise of the tribunal’s power to decide upon its own jurisdiction. Under Article 32(3) of the UNCITRAL Rules, an award “shall state the reasons upon which the award is based.” Accordingly, as an award containing reasons under Article 32 of the UNCITRAL Rules, the Apotex I & II Award (with its reasons) was and remains final and binding upon Apotex Inc. and the Respondent, as agreed by those Parties.

7.34. The Respondent submitted at the Hearing that the combined effect of Articles 32(2) and 32(3) means that the reasons in the Apotex I and II Award have effect as *res judicata* as between the Parties to this arbitration, just as much as its operative part: “... This is because the purpose of an Award is to decide the Parties’ dispute for all time, both as to the whole and as to its constituent parts.”<sup>55</sup>

7.35. The Tribunal is minded to accept this submission as a matter of legal logic; but, for the purpose of deciding this issue, it is unnecessary to apply it here in full. Given the status of both the operative part and the reasons in the Apotex I & II Award under Article 32 of the UNCITRAL Arbitration Rules, the Tribunal concludes that those relevant reasons can be read together with the operative part for the purpose of applying the doctrine of *res judicata* in this arbitration, similarly to the position under international law. It is not necessary in this case to read the reasons

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<sup>53</sup> *Id.*, Para. 34.

<sup>54</sup> *Id.*, Para. 101.

<sup>55</sup> TD6.1653-1654.

independently from the operative part (as the Respondent submits); but it would clearly be impermissible for this Tribunal to read the operative part independently in isolation from its relevant reasons under the UNCITRAL Arbitration Rules.

7.36. The Tribunal has not addressed separately the legal status under New York law (as the *lex loci arbitri*) of the reasons or the operative part of the Apotex I & II Award. In the Tribunal's view, if and to the extent relevant, the effect of New York law does not materially change or add to the analysis made above. It is not disputed that the Apotex I & II Award (with its reasons) is final and binding under New York law; nor has Apotex Inc. sought to challenge that Award before the New York courts (or elsewhere).

**(5) Summary as to the Res Judicata Doctrine**

7.37. Applying NAFTA Article 1131(1), the rules of international law and the UNCITRAL Arbitration Rules, the Tribunal concludes that the Apotex I & II Award, with its relevant reasons, operates in this arbitration as *res judicata* as regards both named parties to that arbitration, namely Apotex Inc. and the Respondent. It remains to be considered in what manner it operates in regard to the specific claims made by Apotex Inc. in this arbitration.

7.38. As regards Apotex-Holdings, the Claimants agreed at the Hearing that Apotex-Holdings, for the purpose of *res judicata*, should be identified as a "privy" to the Apotex I and II Award: "... having reviewed the RSM versus Grenada decision, the second one, Apotex would agree that privies are bound to the same extent as the Party with which they stand in privity. So we would accept that Apotex Holdings could not bring the claim asserted and decided in the Apotex [I and ] II case ..."<sup>56</sup> In other words, the two named Claimants in this arbitration stand in similar shoes, as regards the effect of *res judicata* resulting from the Apotex I and II Award, notwithstanding the fact that only one of them was a named party to the Apotex I and II Award.

7.39. However, Apotex-Holding's shoes are only similar and not the same. As the Claimants made clear towards the end of the Hearing, in answer to the Tribunal's Question A2: "... there is a distinction between derivative claims made on behalf of

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<sup>56</sup> TD3.542. See also TD3.544.

a company and claims made directly by a shareholder on its own behalf. In this arbitration, Apotex Holdings brings a claim in its own right and in its own name. It is different from the claim made by Apotex-Canada [Apotex Inc.]. Apotex Holdings is bound by the Apotex I and II Award only to the extent that it addresses Apotex-Canada as the investor and holder of the two tentatively approved ANDAs at issue.”<sup>57</sup>

7.40. In the Tribunal’s view, independently from the concession (rightly) made by Apotex-Holdings at the Hearing, Apotex-Holdings is a “privy” with Apotex-US, albeit not a named party in the Apotex I & II arbitration. Its relevant claims in this arbitration, albeit made in its own right and in its own name, depend upon Apotex Inc.’s ANDAs as investments under NAFTA Articles 1116 and 1139; and if these are not investments, Apotex-Holdings cannot bring such claims before this Tribunal as a matter of jurisdiction.

**(6) *The Application of Res Judicata***

7.41. It is self-evident that the “Operative Order” in Paragraph 358 of the Apotex I & II Award (pages 118-119) does not, read strictly in isolation by itself, address the Claimants’ specific claims in this arbitration. That operative part merely records, in Paragraph 358(a), that Apotex Inc. “does not qualify as an ‘investor’, who has made an ‘investment’ in the U.S., for the purposes of NAFTA Articles 1116 and 1139, and accordingly both the Sertraline and Pravastatin Claims are hereby dismissed in their entirety, on the basis that the Tribunal lacks jurisdiction in relation thereto.” The Claimants in this arbitration make no similar claims regarding Sertraline and Pravastatin.

7.42. However, in this Tribunal’s view, that operative part as a “*dispositif*” can and should be read with the relevant “*motifs*” or reasons for that operative part, as decided above. Hence, the Tribunal concludes, for the purpose of *res judicata*, that Paragraph 358(a) of the operative part is to be applied together with the reasons applicable to that paragraph, namely the relevant passages in Paragraphs 177 to 246 of the Apotex I & II Award (pages 55 to 78). As indicated above, for ease of reference and given their significance, these paragraphs are reproduced in full from

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<sup>57</sup> TD6.1577.

the redacted public version of the Apotex I & II Award in the Annex to this Part VII. It is nonetheless useful briefly to summarise the tribunal's approach in these parts of the Apotex I & II Award.

- 7.43. First, the tribunal addresses the issue whether activities surrounding ANDAs qualify as 'investments' under NAFTA Article 1139, as there submitted by Apotex Inc. and there disputed by the Respondent: see Paragraphs 177ff. For several reasons, the tribunal rejects Apotex Inc.'s submissions: see Paragraphs 178, 186ff & 225.
- 7.44. Second, the tribunal addresses the issue whether ANDAs qualify as 'intangible property' under NAFTA Article 1139(g) in Paragraphs 196ff. For several reasons, the tribunal rejects Apotex Inc.'s submissions: see Paragraphs 178, 206ff & 225. In Paragraphs 206 and 208, the tribunal equates Apotex Inc. to "a mere exporter of goods into the United States" and decides that "... property is not an 'investment' if, as here, it merely supports cross-border sales." In Paragraph 217, the tribunal states (*inter alia*): "... The ANDA was thus a requirement in order to conduct an export business. If there had been no ANDA process, the underlying business could not be said to be an 'investment' in the U.S. The fact that an ANDA was required does not change the nature of the business." The tribunal concludes, in Paragraph 225: "Thus, neither Apotex's ANDAs, nor its activities in Canada, nor the costs incurred there in meeting the requirements of the U.S. regulatory regime for exporting its goods, are 'investments' in the United States."
- 7.45. Third, the tribunal addresses the issue whether Apotex Inc.'s commitment of capital and resources towards ANDAs could constitute an 'investment' under NAFTA Article 1139(h) in Paragraphs 226ff. The tribunal notes that Apotex Inc. "made clear that its submissions under NAFTA Article 1139(h) were to be treated as part of its submissions under NAFTA Article 1139(g), and not as independent grounds": see Paragraph 229. The tribunal rejects Apotex Inc.'s submissions under Article 1139(h): see paragraph 230ff. In Paragraph 233, the tribunal decides that NAFTA Article 1139(h) "... excludes simple cross-border trade interests. Something more permanent is necessary"; and, in Paragraph 235, that "each of the specific activities and expenses relied upon by Apotex [*i.e.* Apotex Inc.] simply supported and facilitated its Canadian-based manufacturing and export operations."



- 7.46. In Paragraphs 241-246, the tribunal concludes overall that Apotex Inc. had made no “investment” in the territory of the USA within the meaning of NAFTA Article 1139; that, as a necessary consequence, Apotex Inc. does not qualify as an “investor” under NAFTA Article 1116; and that, accordingly, the tribunal has no jurisdiction over the claims there made by Apotex Inc. as the claimant.
- 7.47. Lastly, in the first part of the operative part, in Paragraph 358(a), the Tribunal unanimously orders and awards: “[Lines 1-2] Apotex does not qualify as an ‘investor’, who has made an ‘investment’ in the U.S., for the purposes of NAFTA Articles 1116 and 1139, [Lines 2-4] and accordingly both the Sertraline and Pravastatin Claims are hereby dismissed in their entirety, on the basis that the Tribunal lacks jurisdiction in relation thereto.”
- 7.48. This Tribunal accepts that there are several factors in the Apotex I & II Award which qualify the application of its passages for the purpose of *res judicata* in this arbitration.
- 7.49. The specific claims pleaded by Apotex-Canada in the Apotex I & II arbitration, as recited and decided in the Apotex I & II Award, are different from the specific claims made by the Claimants in this arbitration. The former claims related to “tentatively approved” ANDAs. This is not the specific case pleaded by the Claimants in this arbitration where the ANDAs were “finally approved” and where no claim as to “tentatively approved” ANDAs is advanced by the Claimants.<sup>58</sup> Hence, the operative part, read by itself and in strict isolation from the preceding reasons, could not form the basis of *res judicata* in this arbitration.
- 7.50. However, as decided above, it is necessary to read the first two lines of Paragraph 358(a) of the operative part in the Apotex I & II Award with the tribunal’s earlier relevant reasons for this part of the paragraph. It is clear from those reasons that the parties put distinctively in issue ANDAs generally, not limited to tentatively approved ANDAs but also including finally approved ANDAs; that the tribunal actually decided that issue; and that, as that tribunal saw it, that decision, amongst others, was necessary to resolve the parties’ dispute before it. In the Tribunal’s

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<sup>58</sup> The complaints made in the Request (Paras. 55-56) and the Apotex Memorial (Paras. 530-538) as regards “pending ANDAs” were subsequently abandoned by the Claimants: see the Claimants’ letter to the Tribunal dated 7 February 2013.

view, it is not required for the application of the *res judicata* doctrine that there should be a single reason necessary for the tribunal's decision: there can be two or more reasons of equal relevance for the application of the doctrine, particularly when the parties advance more than one argument in support of their respective cases (as the parties clearly did in the Apotex I & II arbitration).

- 7.51. Nevertheless, several reasons in the Apotex I & II Award are inapplicable to this arbitration for the purpose of *res judicata*, being expressly limited to tentatively approved ANDAs.<sup>59</sup> Accordingly, the Tribunal here takes no account of these reasons in applying *res judicata* in this case. On the other hand, other passages clearly do refer to or necessarily include finally approved ANDAs.<sup>60</sup> It is therefore not possible to conclude that the tribunal's reasons are limited to tentatively approved ANDAs.
- 7.52. Whilst addressing whether ANDAs were "property" under NAFTA Article 1139(g), the tribunal did not independently address ANDAs as "interests" under NAFTA Article 1139(h). In Paragraph 229 of the Apotex I and II Award, as noted above, the tribunal records Apotex Inc.'s confirmation that its submissions under NAFTA Article 1139(h) "were to be treated as part of its submissions under NAFTA Article 1139(g), and not as independent grounds." It is not entirely clear what these "submissions" were as part of Apotex Inc.'s submissions under Article 1139(g); but it is any event clear that both parties made submissions regarding Article 1139(h) and that the tribunal did address and decide upon ANDAs as investments under Article 1139(h).<sup>61</sup>
- 7.53. Lastly, it is necessary to record that this is not a case which raises any issue of bad faith or abuse of process by the Claimants. Indeed, the contrary was not suggested by the Respondent; and, although the Claimants' Request in this arbitration originally included a claim relating to non-approved ANDAs, that claim was

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<sup>59</sup> Apart from its summaries of the parties' respective arguments, see in Paras. 200, 209, 210 (in part), 211, 212-215, 220-221 (in part) and 223 (in part) of the Apotex I & II Award.

<sup>60</sup> See, in particular, Paras. 196-199, 202-205, 207-208, 210-211 (in part), 216-219, 220-221 (in part), 222, 223 (in part), 224-225, 226 and 229-240 of the Apotex I & II Award.

<sup>61</sup> See the Apotex I & II Award, Paras. 226ff and 235. (Apotex Inc. was represented by different Counsel in the Apotex I & II arbitration than Counsel for the Claimants in this arbitration).

abandoned before the publication of the Apotex I & II Award, as already indicated above.

- 7.54. For the reasons set out below, as regards the claims made by Apotex Inc. in this arbitration, the Tribunal decides that the Apotex I & II Award, applying the doctrine of *res judicata*, precludes Apotex Inc. from contending that its finally approved ANDAs, within the meaning of NAFTA Article 1139(g), are “property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes.”
- 7.55. In the Tribunal’s view, the operative part (first two lines) and its relevant reasons in the Apotex I & II Award apply equally to all ANDAs, whether tentatively approved or finally approved. As part of their essential character, as distinctly decided in the Apotex I & II Award, Apotex Inc.’s ANDAs are no more than applications operating as quasi-import licences which support cross-border sales by Apotex Inc. to its consignees in the USA of products manufactured at its Canadian facilities. The possibilities of Apotex Inc. selling or transferring ANDAs (albeit revocable and remaining site-specific to the designated manufacturing facility) do not change the inherent nature of these ANDAs, as decided in the Apotex I & II Award. ANDAs are not commodities in the territory of the USA.
- 7.56. As regards Apotex Inc., the Tribunal comes to the same conclusion in regard to NAFTA Article 1139(h). Applying the doctrine of *res judicata*, the Tribunal decides that Apotex Inc. is precluded from contending that its finally approved ANDAs, within the meaning of NAFTA Article 1139(h), are “interests arising from the capital or other resources in the territory of a Party [the USA] to economic activity in such territory ...” As decided in the Apotex I & II Award, an ANDA operates only as a quasi-import licence supporting cross-border trade interests falling outside the definition of this provision. Whilst the tribunal in the Apotex I & II Award did not independently apply NAFTA Article 1139(h), as noted above, the tribunal nonetheless distinctly addressed this provision. The tribunal rejected the case advanced by Apotex Inc.<sup>62</sup>

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<sup>62</sup> See the Apotex I & II Award, Paras. 230-235.

- 7.57. Shorn of all semantic technicalities, it is worth asking the simple question after reading the relevant passages from the Apotex I & II Award in the Annex to this Part VII: how would that tribunal respond to the specific claims made by Apotex Inc. in this arbitration under NAFTA Article 1139? In this Tribunal's view, that question admits of only one answer: the Apotex I & II tribunal would say that it had already decided the essential issues relating to these claims in its award; and, applying the same two lines of its operative part with its same supporting reasons, that these claims failed to meet the requirements of NAFTA Article 1139 for jurisdiction under NAFTA's Chapter Eleven.
- 7.58. In the Tribunal's view, it is impossible to dismiss those reasons as mere 'obiter dicta' or to read one passage in isolation from those reasons as a whole. Those reasons under both NAFTA Articles 1139(g) and 1139(h) were essential to the operative part and thereby distinctly determined matters distinctly in issue in the Apotex I & II arbitration. It is also impermissible to parse the two sets of claims in the two arbitrations, so as artificially to distinguish one case from the other. The purpose of the *res judicata* doctrine under international law is to put an end to litigation; and it would thwart that purpose if a party could so easily escape the doctrine by 'claim-splitting' in successive proceedings.
- 7.59. Thus, the Claimants did not argue (nor could they) that simply because the Apotex I & II Award addressed specific claims relating to Sertraline and Pravastatin, the Claimants could still bring the same claims relating to other drug products. Similarly, in the Tribunal's view, the Claimants cannot now distinguish tentatively approved ANDAs from finally approved ANDAs so as to frustrate the application of *res judicata* to issues decided in the Apotex I & II Award. That is an impermissible attempt to re-argue and overturn the final and binding decisions in the Apotex I & II Award. The Tribunal notes that, in *Grynberg v. Grenada*, that tribunal likewise rejected an analogous attempt based upon a new allegation of corruption.<sup>63</sup> Indeed, were it so easy to side-step the application of *res judicata*, the doctrine would be largely meaningless under international law, a risk recognised by

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<sup>63</sup> *Grynberg v. Grenada, supra*, Para. 7.3.6 ("It is true that Claimants style the present arbitration as Treaty claim based [the first arbitration was contract-based upon a concession agreement]. But the difficulty with this is that, as pleaded and argued, the present case is no more than an attempt to re-litigate and overturn the findings of another ICSID tribunal, based on allegations of corruption that were either known at the time or which ought to have been raised by way of a revision application and over which the Prior Tribunal had jurisdiction").

several scholars, including Professors Dodge, Schreuer and Reinisch in the works cited earlier in this Part. The costs and time required for investor-state arbitrations, already not inconsiderable, would be multiplied several times over if unsuccessful claimants could persuade later tribunals to restrict the effect of earlier awards by simply reformulating their claims and arguments. As already described, there is a strong interest, both public and private, in bringing an end to a dispute by one final and binding arbitration award.

7.60. In regard to Apotex-Holdings, the Tribunal decides that same result must follow, albeit for additional reasons. Given that Apotex Inc.'s ANDAs are not "investments" under NAFTA Article 1139, it follows that Apotex-Holdings cannot make any claim in respect of its indirect interest in such ANDAs because Apotex-Holdings is not, for that purpose, an investor with a relevant "investment" under NAFTA Article 1139.

**(7) Conclusion**

7.61. Accordingly, for these reasons, the Tribunal (by a majority) decides this second issue in favour of the Respondent and against Apotex Inc. and Apotex-Holdings. Thus, the Tribunal (by a majority) upholds the Respondent's jurisdictional objections to the claims made by the Claimants in regard to the ANDAs under NAFTA Articles 1101(1), 1116 and 1139. (This decision does not apply, of course, to the other claims made by Apotex-Holdings for itself and for Apotex-US which are considered in the Parts which follow).

7.62. Whilst this conclusion disposes of the Claimants' claims under the doctrine of *res judicata*, it should not be assumed that the Tribunal (by a majority) would have reached any different decision on the Claimants' other submissions under NAFTA Article 1139. Notwithstanding a well-researched argument by Counsel for the Claimants as regards the correct interpretation of Article 1139 (to which the Tribunal here pays tribute), the Tribunal remains attracted to the succinct submissions of the Respondent and Mexico to the effect that the definition of an "investment" under both Article 1139(g) and 1139(h) must be read with Article NAFTA 1101(1), collectively requiring such investment to be "in the territory" of the host State. Although Apotex Inc.'s ANDAs were originally submitted and approved in the USA, this Tribunal (by a majority) considers that such ANDAs

cannot meet that particular requirement, particularly when Apotex Inc. has never had any presence, activity or other investment in the territory of the USA, including the non-payment of any relevant US taxes. (This is not inconsistent with the approach taken in the Apotex I & II Award.)<sup>64</sup>

7.63. *Dissent:* As noted above, the decision on this issue is not made by the Tribunal unanimously. What follows in the next three paragraphs is the dissent on this issue by Mr. Rowley.

7.64. Had he been sitting alone, Mr. Rowley would have reached a different conclusion on this issue. For him, the essence of *res judicata* is that a right, question or fact has distinctly been put in issue and distinctly determined by a court or tribunal of competent jurisdiction in an earlier proceeding between the same parties. He considers that the Apotex I & II tribunal neither decided, nor needed to decide the question which is now before the Tribunal, *i.e.*, whether Apotex Inc.’s finally approved ANDAs plus associated products are to be characterised as “property” for the purposes of NAFTA Article 1139(g). The Apotex I & II tribunal stated clearly that: “The jurisdictional issue here turns upon the inherent nature of the relevant ANDAs ...” (Paragraph 224, emphasis added). The relevant ANDAs were understood to be Apotex Inc.’s Sertraline and Pravastatin ANDA filings which had only been tentatively approved by the FDA. The Apotex I & II tribunal well understood the difference between tentatively approved and finally approved ANDAs, and made the point that “ ... it remains entirely unclear whether a tentatively-approved ANDA (*i.e.* as distinct from (i) a finally-approved ANDA, and (ii) a finally-approved ANDA plus associated products) has value.” (Paragraph 220, emphasis added). Because the ANDAs before the Apotex I & II tribunal had only been tentatively approved, the tribunal reasoned that “ ... at the relevant time, (a) Apotex’s [*i.e.* Apotex Inc.’s] ANDAs could not (yet) be characterised as ‘*property*’ for the purposes of NAFTA Article 1139(g), and (b), even if they did constitute “*property*”, Apotex’s [*i.e.* Apotex Inc.’s] ANDAs were not yet ‘acquired in the expectation or used for the purpose of economic benefit or other business purposes’ ...” (Paragraph 209, emphasis added/italics in the original).

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<sup>64</sup> See Paras. 186, 192, 196 and 225 of the Apotex I & II Award.

- 7.65. For Mr. Rowley, it was plain that the Apotex I & II tribunal simply did not determine whether the relevant ANDAs here in issue (*i.e.* finally approved ANDAs plus associated products) constitute an “investment” under the terms of NAFTA Article 1139(g). Indeed, as it addressed the character of tentatively approved ANDAs, it was at pains to point out how they differed from finally approved ANDAs. How the Apotex I & II tribunal would have decided the claims made by Apotex in this proceeding is not relevant to the question as to what was “distinctly in issue” before it, and what it “distinctly determined”, except to the extent that if the question needs to be asked, it points strongly to the conclusion that the Apotex I & II tribunal did not decide the question here in issue.
- 7.66. As to whether Apotex Inc.’s finally approved ANDAs are properly characterised as an “investment” for the purposes of NAFTA Article 1139(g), Mr. Rowley considers the uncontroverted evidence that: (i) Apotex’s finally approved ANDAs were being used for the purposes of economic benefit at the time of the Import Alert; (ii) such ANDAs are regularly bought and sold in the US (often for substantial amounts); (iii) FDA regulations explicitly recognise that ANDAs are “owned” by the applicant; and (iv) US tax law treats ANDAs as franchises or intangibles for the purposes of the US tax code, is sufficient proof that Apotex’s ANDAs here in issue constitute intangible property for the purposes of NAFTA Article 1139(g).

## **PART VII – ANNEX**

***Relevant Extracts from the Apotex I & II Award:  
Paragraphs 177 to 246 & 358(a) (pp.55-78 & 118)  
(taken from the public redacted version of the document)***

### **V. *The Jurisdiction and Admissibility Objections***

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177. *Apotex’s second characterisation of its alleged “investment” focuses upon the actual ANDA submissions themselves. Properly analysed, this submission has two distinct elements:*
- (a) the activity of preparing each ANDA for filing in the United States, and*
  - (b) the actual ANDA itself, as an item of “property”.*
178. *In the Tribunal’s view, neither element qualifies for the purposes of NAFTA Chapter Eleven.*
179. *The Activity of Preparing ANDAs: Apotex has made detailed submissions as to the substantial nature of ANDAs, and the huge effort and expenditure required to compile them.*
180. *In particular, Apotex points to the statutory and regulatory requirements for ANDA approval, which are not only extensive, but specific to the United States (i.e. different to the requirements for other countries). By way of example, in order to sell a product in the United States, an ANDA applicant must meet the FDA’s so-called “Current Good Manufacturing Practice for Finished Pharmaceuticals”, which imposes strict requirements governing the testing, manufacturing and labelling of the ANDA products.<sup>1</sup> These include, inter alia:*
- (a) Particular laboratory controls; stability testing programs; batch production and process controls; in-process controls for sampling; and procedures for identifying; storing; handling; sampling; testing and approving drug products, components and containers<sup>2</sup>;*
  - (b) Strict requirements governing the documentation of such testing, sampling, and manufacturing, and the controls for each<sup>3</sup>;*
  - (c) Specific requirements relating to the design; size; location; construction and maintenance of the facilities and equipment used in manufacturing, processing, packaging, testing, or storage of its drug products, regardless of where such*

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<sup>1</sup> 21 C.F.R. § 211 *et seq.* [C43].

<sup>2</sup> *Id.* at §§ 211.80-211.188.

<sup>3</sup> *Id.* at §§ 211.180-211.198.



*facilities and equipment are located.<sup>4</sup> Indeed, as Apotex noted, the FDA inspects each applicant's manufacturing facilities, whether domestic or foreign, to ensure that the establishment is capable of manufacturing the proposed drug product in accordance with the FDA's requirements, and that the submitted data is accurate and complete.<sup>5</sup>*

181. *According to Apotex, the FDA's approval requirements differ significantly from those in other countries.<sup>6</sup> This means that when Apotex invests its financial and other resources towards designing, formulating, and manufacturing an ANDA product, and preparing the ANDA itself, it does so with the expectation of marketing such product solely in the United States.<sup>7</sup>*

182. *Further, Apotex emphasises that the efforts it made to comply with the FDA's processing, manufacturing, testing, sampling, packaging, and storage requirements were product specific.<sup>8</sup> For example:*

(a) *Formulation and development work on Apotex's sertraline tablets obviously does not carry over to Apotex's pravastatin tablets, or indeed any other product;*

(b) *Testing conducted to show that Apotex's sertraline tablets are bio-equivalent to Zoloft® cannot be used to demonstrate bio-equivalence of Apotex's pravastatin tablets to Pravachol®, and vice versa.<sup>9</sup>*

(c) *Apotex's in-process and manufacturing controls are specific to each product.<sup>10</sup>*

(d) *Apotex obviously cannot reuse labels designed for either its sertraline or pravastatin products in the sale of another product.<sup>11</sup>*

183. *On the basis of all these points, it is Apotex's case that the costs it has incurred in meeting the specific FDA requirements for approval of its sertraline and pravastatin ANDAs are "investments" under Article 1139.<sup>12</sup> Apotex would never have incurred these expenses if it had not been required to do so under U.S. statutory and federal regulatory requirements.<sup>13</sup> Likewise, the only reason Apotex undertook the enormous expense and effort to comply with these U.S.-specific requirements was to obtain approval for, and to market and sell, its sertraline and pravastatin ANDA products in the United States.<sup>14</sup>*

184. *Apotex placed heavy reliance here upon the statement in Grand River Enterprises Six Nations, Ltd. et. al. v. United States that:*

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<sup>4</sup> *Id.* at §§211.42-211.72.

<sup>5</sup> Witness Statement of Bernice Tao, paras. 9, 10 [C39]; FDA, Compliance Program Guidance Manual, Ch. 46 New Drug Evaluation § 2.1 (Prog. 7346.832) [C46].

<sup>6</sup> Witness Statement of Bernice Tao, para. 6 [C39].

<sup>7</sup> Witness Statement of Shashank Upadhye, Esq. para. 8 [C40].

<sup>8</sup> Witness Statement of Bernice Tao, paras. 16, 26 [C39].

<sup>9</sup> *Id.* at paras. 17, 27.

<sup>10</sup> *Id.* at paras. 18, 28.

<sup>11</sup> *Id.* at paras. 19, 29.

<sup>12</sup> *E.g.* Counter-Memorial, para. 44.

<sup>13</sup> Witness Statement of Shashank Upadhye, Esq., para. 10 [C40].

<sup>14</sup> Witness Statement of Bernice Tao, paras. 11-12 [C39]; Witness Statement of Shashank Upadhye, Esq., paras. 6-19 [C40].

*“a salient characteristic of an investment covered by the protection of NAFTA Chapter Eleven would be that the investment is primarily regulated by the law of a state other than the state of the investor’s nationality, and that this law is created and applied by that state which is not the state of the investor’s nationality”.*<sup>15</sup>

185. Further, Apotex argues that all this activity should be persuasive evidence that it had an investment in the territory of the United States. For this, Apotex relies upon the statement of the Tribunal in *SGS v. Philippines* that:

*“SGS’s inspections abroad were not carried out for their own sake but in order to enable it to provide, in the Philippines, an inspection certificate on which [the Philippines] could rely to enter goods ...”*<sup>16</sup>

186. The Tribunal is unpersuaded that the costs and effort expended in preparing ANDAs either constitutes or evidences an “investment” in the United States, for the purposes of NAFTA Chapter Eleven. This is for a number of reasons.

187. First, whilst ANDAs are of course filed within the territory of the United States, the actual activity in question (the preparation of each submission) is evidently conducted by Apotex outside of the United States. Specifically, it is reported that at the Signet Campus:

*“operations focus on product development activities, which include product formulation and process development, production and evaluation of clinical batches, analytical development and assessment as well as the creation and submission of generic drug approvals”.*<sup>17</sup>

188. Second, it is common ground that an ANDA must be submitted by any manufacturer of generic drugs that seeks to have its products sold in the United States. This is so regardless of whether the manufacturer is investing in, or merely exporting to, the United States. Consequently, the preparation of the filing, in and of itself, does not establish that a generic drug manufacturer is investing in, rather than exporting products to, the United States.

189. Notably in this case, whilst Apotex describes itself as a Canadian manufacturer and exporter of:

*“approved generic pharmaceutical products for sale in the United States and throughout the world”,*<sup>18</sup>

*and whilst, in its ANDAs, Apotex sought approval for the sale of its sertraline and pravastatin products in the United States, it is clear that the actual sale of these products in the United States was always to be conducted by parties other than Apotex itself. Hence in each of its Notices of Arbitration, Apotex states (at para. 13) that:*

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<sup>15</sup> *Grand River*, Award, para. 88, citing *Bayview*, Award on Jurisdiction, paras. 98-99.

<sup>16</sup> *SGS Société Générale de Surveillance S.A. v. Republic of Philippines*, ICSID Case No. ARB/02/6, Decision of the Tribunal on Objections to Jurisdiction, para. 101 (29 Jan. 2004).

<sup>17</sup> GlobalData - Business Description, Apotex, Inc. (3 Jan. 2001) [R53] (emphasis added).

<sup>18</sup> Statement of Claims, paras. 62, 111.

*“[b]efore one of Apotex’s generic drugs can be sold by others in the United States, Apotex must obtain approval from the [FDA]”.*

*[emphasis added].*<sup>19</sup>

190. *Third, Apotex’s reliance on the Grand River and Bayview awards to suggest that costs incurred outside the United States in compliance with a U.S. regulatory regime can constitute “investments” in the United States is misplaced. As noted, Apotex relies in particular on the observation that “a salient characteristic of an investment” is:*

*“regulation by the law of a state other than the state of the investor’s nationality.”*<sup>20</sup>

*But both the Grand River and Bayview tribunals made clear that the law of the host State is only one “salient” factor in determining whether expenditures qualify as an “investment” under NAFTA Article 1139.<sup>21</sup> It is not, in itself, a sufficient factor. Hence, the Bayview tribunal declined jurisdiction over all of the claimants’ claims, because the claimants had not made an investment in the territory of the respondent State, stating:*

*“In the opinion of the Tribunal, it is quite plain that NAFTA Chapter Eleven was not intended to provide substantive protections or rights of action to investors whose investments are wholly confined to their own national States, in circumstances where those investments may be affected by measures taken by another NAFTA State Party. The NAFTA should not be interpreted so as to bring about this unintended result”.*<sup>22</sup>

191. *The Grand River tribunal similarly declined jurisdiction over most of the claimants’ claims, concluding that it did not have jurisdiction:*

*“ ... over claims that are based on injury to investments located in one NAFTA Party on account of actions taken by authorities in another”.*<sup>23</sup>

192. *Thus, as the Respondent has argued, the mere regulation of Apotex’s foreign products (however extensive) cannot transform the costs incurred in developing those products into investments in the United States.*

193. *Fourth, even if Apotex had incurred these regulatory costs in the United States, the expenditures incurred in the preparation and filing of an ANDA submission, being no more than an exercise in securing regulatory clearance, do not fall within the scope of NAFTA Article 1139. Nor do they change the inherent nature of the activity for which clearance is sought.*

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<sup>19</sup> Also [deleted in original]

<sup>20</sup> Counter-Memorial, para. 39, fn.37 (citing *Grand River*, Award. Para. 88).

<sup>21</sup> *Grand River*, Award. para.88 (citing with approval *Bayview*, Award paras. 98-99).

<sup>22</sup> *Bayview*, Award, para.103.

<sup>23</sup> *Grand River*, Award, para. 87. See similarly paras. 5-6, where the tribunal held that it did “... not have jurisdiction over the claims of Kenneth Hill, Jerry Montour and Grand River, because they did not have an investment in the United States”, but that it did “ ... have jurisdiction over Arthur Montour’s claim”, because “he created a substantial business in the United States, importing cigarettes manufactured by Grand River and distributing them ... in the United States”).

194. As the Grand River tribunal made clear, where a company must meet “regulatory requirements” to sell its products in the United States, the costs of such compliance themselves are not “investments”.<sup>24</sup> Rather, those costs are:

“incident to ‘commercial contracts for the sale of goods or services,’ which fall outside of Article 1139’s definition of investment”.<sup>25</sup>

195. Indeed, as the Respondent has pointed out, if preparing an ANDA could constitute an “investment” under Article 1139, then any Canadian or Mexican exporter requiring U.S. regulatory clearance to have its goods sold by third parties in the United States could potentially bring an investment claim under NAFTA Chapter Eleven, whenever such clearance, in the exporter’s view, was wrongly denied or delayed. This would be so regardless of whether the exporter made or sought to make an investment in the United States. The Tribunal is persuaded by the Respondent’s submission that allowing a mere application for regulatory clearance to export goods into the United States to give rise to an “investment” claim under Chapter Eleven would be inconsistent with the core objectives of NAFTA’s investment chapter.

196. The ANDA Submissions as “Property”: *The second way in which this submission was put by Apotex was to characterise the actual ANDA filing itself as “property ... acquired in the expectation or used for the purpose of economic benefit or other business purposes” in the United States, for the purposes of NAFTA Article 1139(g).*

197. *This argument proceeded in a number of stages.*

198. *First, Apotex asserted that for the purposes of NAFTA Article 1139(g), it had to identify two separate elements: (a) “property”, (b) that was “acquired in the expectation or used for the purpose of economic benefit or other business purposes”.*

199. *Second, and with respect to element (a), it was asserted that an ANDA filing, and the confidential data and information contained therein, constitutes the “property” of the ANDA applicant. According to Apotex, once filed in the United States with the FDA, only the “applicant may transfer ownership of its application”.<sup>26</sup> Further, an ANDA can be bought and sold like all other property,<sup>27</sup> and (bearing in mind the general definition of “property” in Black’s Law Dictionary), the ANDA applicant has the exclusive right to possess, use and enjoy the ANDA, as well as the products approved thereunder.<sup>28</sup>*

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<sup>24</sup> *Grand River*, Award, para. 115. It may be recalled that Grand River claimed to have spent approximately US\$ 29 million dollars complying with U.S. statutory and regulatory requirements for the purposes of marketing its generic cigarettes in the United States.

<sup>25</sup> *Grand River*, Award, para. 115.

<sup>26</sup> 21 C.F.R. §314.72(a).

<sup>27</sup> Hence, the MMA requires that certain agreements between two ANDA applicants, or between ANDA applicants and brand name drug manufacturers, regarding an ANDA be submitted to the Federal Trade Commission and the United States Assistant Attorney General (MMA § 1112).

<sup>28</sup> Citing Black’s Law Dictionary 1232, “property” (9th ed. 2009). According to Apotex, whether an ANDA, and the data and information contained therein, is considered *tangible* or *intangible* property makes no difference, since the United States Supreme Court has stated that the intangible nature of certain business information does not make it any less “property” (citing *McNally v. United States*, 483 U.S. 350, 356 (1987)).

200. Hence, the FDA is obligated to maintain confidential all information in unapproved ANDAs and is not even permitted to confirm the existence of an unapproved ANDA unless the ANDA sponsor itself has already done so.<sup>29</sup>
201. Third, with respect to the second element in NAFTA Article 1139(g), all investments in each ANDA were effected "... in the expectation or used for the purpose of economic benefit or other business purposes" in the United States.
202. Apotex submitted that while an ANDA, and the products approved thereunder, unquestionably are property of the applicant, the value of an ANDA is intrinsically tied to FDA approval in the United States (or the promise of future approval in the United States). If an ANDA is never approved and the product can never be sold, the ANDA in question is then essentially worthless.<sup>30</sup>
203. Further, as already noted, an ANDA is an extremely substantial document. It generally comprises thousands, if not tens of thousands, of pages containing confidential and proprietary information pertaining to the formulation, development, manufacture, processing, testing, packaging, labelling, and storage of the proposed generic drug product.
204. On the basis of these points, Apotex then contended that it is therefore more than simply an "exporter". It cannot export and commercialise anything in the United States without an approved ANDA, and without undertaking the investment and development that goes into that ANDA. An ANDA is therefore a uniquely United States investment. It is also of no use anywhere else.
205. According to Apotex, unlike a mere import permit or certificate, it is the pharmaceutical product and investment itself that is necessary not only to get a product into the United States, but also to make and ultimately realise the commercial value of that investment. In other words, without the ANDA, there is no product to commercialise in the United States.
206. The Tribunal has carefully considered all aspects of this submission, and all evidence on which it is based. But in the Tribunal's view, neither of Apotex's sertraline and pravastatin ANDAs are properly characterised as "property acquired in the expectation or used for the purpose of economic benefit or other business purposes," within the meaning of NAFTA Article 1139(g), and none of Apotex's submissions are sufficient to distinguish itself from a mere exporter of goods into the United States.
207. First, whilst an ANDA may be characterised for certain purposes as "property",<sup>31</sup> the Tribunal does not consider that the nature of an ANDA is such as to fall within the contemplated scope of NAFTA Article 1139(g), as that provision must be understood as a whole, by reference to the objects and purposes of NAFTA Chapter Eleven.

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<sup>29</sup> Citing 18 U.S.C. § 1905; 21 U.S.C. § 331(j); 21 C.F.R. § 314.430.

<sup>30</sup> Witness Statement of Shashank Upadhye, Esq., paras. 6-9 [C40].

<sup>31</sup> The Tribunal accepts Apotex's submission that U.S. law is informative in defining "property", because it is the law of the host State. See e.g., Rosalyn Higgins, *The Taking of Property by the State: Recent Developments in International Law*, 176 *Recueil des Cours* 263, 270 (1982) (for a definition of "property ...[w]e necessarily draw on municipal law sources and on general principles of law"); *Glamis Gold Ltd. v. United States*, NAFTA/UNCITRAL, Award, para. 37 (8 June 2009) examining U.S. law to determine whether an "unpatented mining claim" constituted "property".

*Notwithstanding its very substantial nature, and the time and cost required for its compilation, an ANDA, ultimately, remains simply an application for revocable permission to (in this case) export a product for sale (by others) in the United States. Even if, as a technical matter, the application may be “owned”, unlike Apotex’s approach, the Tribunal does not consider that NAFTA Article 1139(g) can be approached by divorcing the concept of “property” from its context, and applying it in the abstract.*

208. *As observed by the Respondent, property is not an “investment” if, as here, it merely supports cross-border sales.*
209. *Second, this is all the more so here because (as the Respondent has emphasised) on the date of the alleged NAFTA breaches, the sertraline and pravastatin ANDAs were only tentatively approved by the FDA. It follows that at the relevant time, (a) Apotex’s ANDAs could not (yet) be characterised as “property” for the purposes of NAFTA Article 1139(g), and (b), even if they did constitute “property”, Apotex’s ANDAs were not yet “acquired in the expectation or used for the purpose of economic benefit or other business purposes,” given that the only economic benefit or other business purpose Apotex claims is the right to sell drugs in the U.S., and given that this right was neither acquired nor enjoyed by virtue of tentatively approved ANDAs.*
210. *The FDA grants “tentative approval” to an ANDA when all scientific and procedural conditions for approval have been met. But the FDA does not finally approve an ANDA until various other barriers to approval no longer apply,<sup>32</sup> and an application with a tentative approval will not become finally approved until the FDA issues a final approval letter.<sup>33</sup> Even then, final approval of a tentatively-approved ANDA is not automatic, because the FDA still “has an ongoing health and safety responsibility to perform”.<sup>34</sup> The FDA may revoke tentative approval, or even final approval, of ANDAs for a variety of reasons related to the new products’ safety and effectiveness, including (inter alia) a finding that there is an imminent hazard to public health; that clinical or other tests or scientific data indicate any lack of safety; or a lack of substantial evidence from adequate and well controlled investigations that the drug will have the effect it is reported or represented to have. The regulations expressly afford the FDA a broad discretion in this regard.*
211. *In this case, the FDA informed Apotex in terms that its tentatively-approved ANDAs for sertraline and pravastatin were “subject to change on the basis of new information that may come to [FDA’s] attention”.<sup>35</sup> The same letters instructed Apotex to apply for final approval of its ANDAs, and noted that the tentative approval could be rescinded.*
212. *As part of the application process, Apotex received several notices of deficiency for both sertraline and pravastatin, including at least one notice following the tentative approval. These notices required Apotex to supplement its ANDAs with additional*

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<sup>32</sup> 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA) [R3]; 21 C.F.R § 314.107(b) [R89].

<sup>33</sup> 21 C.F.R. §314.107(b)(3)(v) [R89].

<sup>34</sup> *Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 15, 19, 21 (D.D.C. 2004) [R114].

<sup>35</sup> FDA Tentative Approval for Sertraline Hydrochloride Tablets (25, 50, and 100 mgs) (27 Sept. 2006) [R96]; FDA Tentative Approval for Pravastatin Sodium Tablets (10, 20, and 40 mgs) (30 Sept. 2003) [R98]; FDA Tentative Approval for Pravastatin Sodium Tablets (10, 20, 40, and 80 mgs) (25 Apr. 2006) [R99]; FDA Final Approval for Pravastatin Sodium Tablets (10, 20, and 40 mgs) and Tentative Approval for Pravastatin Sodium Tablets (80 mg) (23 Oct. 2006) [R100].

information before they could be finally approved, and before permission could be granted to export its generic drugs to the United States.<sup>36</sup>

213. Apotex alleges that the sertraline-related NAFTA breaches occurred no later than October 2006.<sup>37</sup> This was prior to the FDA's final approval or Apotex's sertraline ANDA.<sup>38</sup>
214. Similarly, Apotex alleges that the pravastatin-related NAFTA breaches occurred no later than August 2006.<sup>39</sup> This was prior to the FDA's final approval of Apotex's pravastatin ANDA.<sup>40</sup>
215. Apotex responded to this by asserting that but for the Respondent's alleged breach of its legal obligations, Apotex would have been granted final, not tentative, approval because no other impediments to approval existed at that time. The Tribunal is unpersuaded by this submission. Whether or not each of Apotex's ANDAs would have been granted final approval is by no means certain on the evidence. But in any event, the critical enquiry must be as to the nature of the alleged "property" as at the date of the alleged breach – not at some future point.
216. Third, Apotex's argument that an ANDA cannot be equated with an application for an export or import licence is unconvincing, Apotex submits that ANDAs are never treated as export or import licences in the relevant U.S. statutes and regulations, and that:

*"Anyone who wants to engage in the pharmaceutical market in the United States, whether domestic or foreign, regardless of what borders that drug or product may have to cross, they have to do an ANDA. There is no exception. So, it's not an import or export permit".<sup>41</sup>*

217. But the fact that domestic U.S. companies are also required to submit ANDAs appears to miss the point. Whilst an ANDA itself may not be, in strict technical terms, an export or import licence, it operated - in this case - in precisely the same way. As already noted, all Apotex's operations were outside of the U.S. Apotex wanted to export its goods to the U.S., to be marketed and sold there by other entities. In order to do this, Apotex was required to obtain permission, which was to be secured by the submission of an ANDA. The ANDA was thus a requirement in order to conduct an export business. If there had been no ANDA process, the underlying business could not be said

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<sup>36</sup> Pre-Tentative Approval FDA Deficiency Letters for Sertraline Tablets (25, 50, and 100 mgs) dated 9 Apr. 2004 [R102]; 26 Nov. 2004 [R103]; 23 Aug. 2005 [R104]; 7 Aug. 2006 [R105]; Post-Tentative Approval Letter for Sertraline Tablets (25, 50, and 100 mgs) from Apotex Inc. to FDA (1 Dec. 2006) [R106]; Pre-Tentative Approval FDA Deficiency Letters for Pravastatin Sodium Tablets (10, 20, and 40 mgs), dated 9 July 2002) [R107]; 7 Nov. 2002 [R108]; Post-Tentative Approval FDA Deficiency Letter for Pravastatin Sodium Tablets (10, 20, 40, and 80mgs) 27 Oct. 2004 [R109].

<sup>37</sup> Sertraline Notice of Arbitration, paras. 55-56.

<sup>38</sup> FDA Tentative Approval for Sertraline Hydrochloride Tablets (25, 50, and 100 mgs) dated 27 Sept. 2006 [R96]; FDA Final Approval for Sertraline Hydrochloric Tablets (25, 50, and 100 mgs) dated 6 Feb. 2007 [R97].

<sup>39</sup> Pravastatin Notice of Arbitration, para. 31.

<sup>40</sup> FDA Tentative Approval for Pravastatin Sodium Tablets (10, 20, and 40 mgs) dated 30 Sept. 2003 [R98]; FDA Tentative Approval for Pravastatin Sodium Tablets (10, 20, 40, and 80 mgs) dated 25 Apr. 2006 [R99]; FDA Final Approval for Pravastatin Sodium Tablets (10, 20, and 40 mgs) and Tentative Approval for Pravastatin Sodium Tablets (80 mg) dated 23 Oct. 2006 [R100]; FDA Final Approval for Pravastatin Sodium Tablets (80 mg) dated 28 Dec. 2007 [R101].

<sup>41</sup> Transcript, Day 1, page 223.

to be an “investment” in the U.S. The fact that an ANDA was required does not change the nature of the business.

218. Further, the fact that the ANDA process is governed exclusively by U.S. law and regulations does not change the nature of the process: it remains an application to permit the sale of goods which in this case are to be produced entirely outside of the U.S., and to be exported for sale by others.
219. Fourth, the Tribunal is not persuaded that an ANDA must be characterised as “property” for the purposes of NAFTA Article 1139(g) because it contains “confidential data and information”.<sup>42</sup> As the Respondent has observed, Apotex may have a right under U.S. law to have its disclosures to the FDA kept confidential, but there is no basis for this to transform the inherent nature of the ANDA itself, from an application for permission to export goods into the United States, into some form of investment within the scope of NAFTA Article 1139(g).
220. Fifth, Apotex’s asserts that ANDAs “can be bought and sold like all other property”,<sup>43</sup> but it remains entirely unclear whether a tentatively-approved ANDA (i.e. as distinct from (i) a finally-approved ANDA, and (ii) a finally-approved ANDA plus associated products) has value. It is to be recalled that a tentatively-approved ANDA provides no permission to export generic drugs into the United States for sale. Further, as Apotex itself made clear: “[i]f an ANDA is never approved and the product can never be sold, such ANDA is essentially worthless”.<sup>44</sup> And yet Apotex has insisted that:
- “Apotex’s investment in its ANDAs, and its property rights therein, are actualized the moment such ANDAs are filed with the FDA”.*
221. The Tribunal acknowledges Apotex’s argument that companies do, nevertheless buy, sell, and calculate the estimated value of ANDAs that have not yet received approval (albeit most examples given were in the context of broader purchases /rearrangements of pharmaceutical businesses, rather than individual unapproved ANDAs). But even if an ANDA may be bought and sold as Apotex argues, this would still not change its essential character, which is an application to (in this case) export generic drugs into the United States. As such, the Tribunal considers that it would still not qualify for the purposes of NAFTA Article 1139(g).
222. Sixth, Apotex’s assertion that an ANDA applicant has “the exclusive right to possess, use and enjoy the ANDA and the products approved thereunder”,<sup>45</sup> takes the matter no further. Even if Apotex has exclusive rights over the ANDA, this cannot change the inherent nature of the ANDA itself. In other words, an application to export generic drugs into the United States is not transformed into an “investment” for the purposes of NAFTA Chapter Eleven, because the holder of the application has exclusive rights thereto.
223. Indeed, it may be noted that Apotex’s asserted “exclusivity” is open to question in any event. As already noted, no products could be sold until the ANDAs had been finally approved. All that Apotex held at the relevant time were tentatively-approved

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<sup>42</sup> E.g. Counter-Memorial, para. 37.

<sup>43</sup> E.g. Counter-Memorial, para. 37.

<sup>44</sup> E.g. Counter-Memorial, para. 38.

<sup>45</sup> E.g. Counter-Memorial, para. 37.



*applications for revocable permission, which were subject to continual regulatory oversight and monitoring in the public interest. And even when finally approved, Apotex was not protected from changes to, or revocation of, its ANDAs.*

224. *For all these reasons, the Tribunal concludes that Apotex’s submissions as to the notion and general characteristics of “property” (based upon Black’s Law Dictionary) are of only limited assistance in delimiting NAFTA Article 1139(g). The jurisdictional issue here turns upon the inherent nature of the relevant ANDAs, not the nature of Apotex’s rights over them. As set out above, even assuming that the ANDAs were Apotex’s exclusive “property”, they remained no more than applications for permission to (in this case) export, and as such neither fell within NAFTA Article 1139(g), nor constituted “investments” as contemplated more generally by NAFTA Chapter Eleven.*
225. *Thus, neither Apotex’s ANDAs, nor its activities in Canada, nor the costs incurred there in meeting the requirements of the U.S. regulatory regime for exporting its goods, are “investments” in the United States.*

**iii. Other Investments Made In the U.S.**

226. *Apotex’s third characterisation of its alleged “investment” focuses upon “other significant” investments said to have been made in the territory of the United States, within the scope of NAFTA Article 1139(h).*
227. *In its written submissions, Apotex asserted that it has committed significant capital and resources towards the preparation, filing and maintenance of its sertraline and pravastatin ANDAs and products in the United States, as well as towards U.S. patent litigation arising as a result of these ANDAs. In particular:<sup>46</sup>*
- (a) *Because Apotex does not reside or have a place of business in the United States, in accordance with FDA’s regulations, Apotex has utilised its U.S. affiliate, Apotex Corp., (a Delaware corporation with a place of business in Florida) as its U.S. Agent for all correspondence and submissions to the FDA for its pravastatin and sertraline ANDAs.<sup>47</sup>*
  - (b) *Apotex Corp. also acts as the distributor for both of Apotex’s pravastatin and sertraline ANDA products.<sup>48</sup> According to Apotex, the sale of its ANDA products in the United States qualifies as “economic activity in [the] territory”, the proceeds of which go directly, and in full, to it and its affiliates. Further, Apotex’s relationship with its U.S. affiliate, agent and distributor (Apotex Corp.) also independently qualifies as “an interest in an enterprise that entitles the owner to share in income or profits of the enterprise” for the purposes of NAFTA Art 1139(e), and so qualifies as an “investment”.*
  - (c) *Apotex has also committed significant capital in the United States towards the purchase of raw materials and ingredients used in its sertraline and pravastatin ANDA products, which again are sold solely in the United States. Apotex emphasises that:*

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<sup>46</sup> E.g. Counter-Memorial, paras. 48-62.

<sup>47</sup> Witness Statement of Bernice Tao, paras. 14, 25 [C39].

<sup>48</sup> Witness Statement of Bernice Tao, paras. 23, 32 [C39].

- *it purchased all but one of the inactive ingredients used in the manufacture of its pravastatin sodium tablets (10 mg, 20 mg and 50 mg) from U.S. manufacturers,<sup>49</sup> and it spent over [deleted in original\*] on these ingredients;<sup>50</sup>*
  - *it purchased all but two of the inactive ingredients used in the manufacture of its sertraline hydrochloride tablets (25 mg, 50 mg and 100 mg), from U.S. manufacturers,<sup>51</sup> and spent nearly [deleted in original] on these ingredients;<sup>52</sup>*
  - *each of these ingredients is essential to the formulation and manufacture of both sertraline and pravastatin products, and is a substantial and non-severable aspect of Apotex's overall investment in each ANDA.*
- (d) *As a consequence of filing a paragraph IV certification in connection with both its sertraline and pravastatin ANDAs, Apotex was required by the FDA regulation to designate a U.S. Agent to accept service of process for any patent litigation initiated in response to its sertraline and pravastatin ANDAs.<sup>53</sup> In doing so, Apotex notes that it consented to jurisdiction and suit in the United States, thus exposing itself to patent litigation in U.S. federal courts, and the potential for incurring substantial sums in legal fees in connection with this U.S. litigation.<sup>54</sup> And in this regard, Apotex has spent in excess of [deleted in original] in legal fees in connection with its sertraline ANDA litigation, and in excess of [deleted in original] in legal fees in connection with its pravastatin ANDA litigation, all such expenses having been incurred in the United States.<sup>55</sup> Apotex emphasises that this expenditure was made for the sole purpose of “securing an economic benefit from the sale of its sertraline and pravastatin ANDA products in the United States”.*

228. *Apotex emphasised that other tribunals (under other treaties) have recognised that claimants need not have incurred all, or even most, of their expenses inside the territory of the host State citing, inter alia, SGS v. Philippines, at para. 106:*

*“The fact that the bulk of the cost of providing the service was incurred outside the Philippines is not decisive”.*

*And SGS v. Pakistan,<sup>56</sup> at para. 136:*

*“While the expenditures [in Pakistan related to SGS's extraterritorial customs inspection] may be relatively small ... they involved the injection*

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<sup>49</sup> Pravastatin ANDA § 8(2)(d) at 5262-63 [C55].

\* This bracketed text has been inserted by the *Apotex Holdings Inc. and Apotex Inc. v. United States of America* (ICSID Case No. ARB(AF)/12/1) Tribunal and does not appear in the public redacted version of the Apotex I & II Award.

<sup>50</sup> Witness Statement of Bernice Tao, para. 31 [C39].

<sup>51</sup> Sertraline ANDA § 8(2)(d) at 4222-23 [C54].

<sup>52</sup> Witness Statement of Bernice Tao, para. 21 [C39].

<sup>53</sup> 21 C.F.R. § 314.95(c)(7) [C45].

<sup>54</sup> Witness Statement of Shashank Upadhye, Esq. paras. 13, 18 [C40].

<sup>55</sup> *Id.* at paras. 14, 19.

<sup>56</sup> *SGS Société Générale de Surveillance S.A. v. Islamic Republic of Pakistan*, ICSID Case No. ARB/01/13, Decision of the Tribunal on Objections to Jurisdiction (6 Aug. 2003).

*of funds into the territory of Pakistan for carrying out SDS's engagements under the PSI Agreement”.*

229. *In the course of its oral submissions, Apotex then made clear that its submissions under NAFTA Article 1139(h) were to be treated as part of its submissions under NAFTA Article 1139(g), and not as independent grounds. This was specifically confirmed to the Tribunal:*

*“PRESIDENT LANDAU: ... The other point I just wanted to ask is, just for clarity, the exact positioning of your Article 1139(h) case ... that actually the 1139(h) argument, it doesn't stand by itself; is that right? Is it dependent upon us making a finding that the ANDA itself is an investment?”*

*MR. RAKOCZY: Yes. Our basic argument is it's part and parcel of the ANDA investment because the commitments that had been made, the commitments of capital, that's why - and I apologize, Mr. President, it goes back to some of your earlier questions. It's hard to parcel out all the elements that go into this investment, but all these things go into it: The costs of development, the amount spent in the United States on the raw materials all go into the ANDA investment itself, and then obviously the substantial costs incurred in the litigation, the causes of action, obviously are all part and parcel of the ANDA. We would not be able to separate those.*

*PRESIDENT LANDAU: So, is it right to summarise the argument that 1139(h) is part of your 1139(g) argument? And if not you're not asking us to find 1139(h) by itself?*

*MR. RAKOCZY: Would you just give me one moment.*

*PRESIDENT LANDAU: Yes, of course.*

*(Pause.)*

*MR. RAKOCZY: Mr. President, we wouldn't dispute that, yes, the sub (h) claim basically relies on as part and parcel of the (g) claim, which is our primary contention”.*

230. *In the Tribunal's view, none of the items identified under NAFTA Article 1139(h) amounts to an “investment” within NAFTA Chapter eleven, and whether considered separately or together, none changes the analysis under NAFTA Article 1139(g).*

231. *As set out earlier, NAFTA Article 1139(h) includes:*

*“(h) interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory, such as under*

*(i) contracts involving the presence of an investor's property in the territory of the Party, including turnkey or construction contracts, or concessions, or*

*(ii) contracts where remuneration depends substantially on the production, revenues or profits of an enterprise[.]”*

232. *But this article must be read with NAFTA Articles 1139(i) and (j), which clarify that “investment does not mean”:*

“(i) claims to money that arise solely from

(i) commercial contracts for the sale of goods or services by a national or enterprise in the territory of a Party to an enterprise in the territory of another Party, or

(ii) the extension of credit in connection with a commercial transaction, such as trade financing, other than a loan covered by subparagraph (d); or

(j) any other claims to money,

that do not involve the kinds of interests set out in subparagraphs (a) through (h)”.

233. Hence, as the Respondent has stressed, NAFTA Article 1139(h)’s focus on interests arising from the commitment of capital in the host State to economic activity in such territory - excludes simple cross-border trade interests. Something more permanent is necessary.

234. By way of example, in *Mondev v. United States*, the Canadian claimant alleged that through its wholly owned U.S. limited partnership, it obtained interests arising from contractual rights to develop large parcels of property in downtown Boston. The tribunal thus concluded that, through the rights acquired in these construction contracts:

“*Mondev’s* claims involved interests arising from the commitment of capital or other resources in the territory of the United States”

which fell squarely within the definition of “investment” under NAFTA Article 1139(h).

235. On being challenged to identify precisely what investment “interests” arose from its designation of a U.S. agent and distributor; the purchase of U.S. raw materials; or the incurring of U.S. legal fees,<sup>57</sup> Apotex stated as follows in its Rejoinder:

“Apotex’s investment “interests” lie in the submission, maintenance and utilization of its sertraline and pravastatin ANDAs and in achieving an economic benefit from the marketing and sale of the products subject to such ANDAs in the United States”.<sup>58</sup>

In the Tribunal’s considered view, this is inadequate to meet the requirements of NAFTA Article 1139. The “interests” so identified amount to no more than the ordinary conduct of a business for the export and sale of goods. And as set out below, each of the specific activities and expenses relied upon by Apotex simply supported and facilitated its Canadian-based manufacturing and export operations.

236. Designation of Apotex Corp. as U.S. Agent: Apotex’s designation of its U.S. affiliate as its agent for correspondence and submissions to the FDA with respect to its ANDAs cannot, on any view, amount to an “investment”. In the Respondent’s words, it was

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<sup>57</sup> Respondent’s Reply Memorial on Jurisdiction, dated 17 Oct. 2011, para. 35.

<sup>58</sup> Rejoinder Memorial On Respondent’s Reply On Objections To Jurisdiction, dated 16 Dec. 2011, para. 33.

simply a “commercial contract for the sale of ... services” incident to the regulatory requirements of the U.S. market. It did not involve the kinds of interests that Article 1139 contemplated as arising from the “commitment of capital or other resources in the territory of a Party”. On a fair reading of NAFTA, it is excluded as an “investment” by Article 1139(i).

237. Utilisation of Apotex Corp as U.S. Distributor: *Similarly, the fact that Apotex Corp acts as Apotex’s distributor of pravastatin and sertraline ANDA products in the United States does not transform Apotex’s activity from one of export to one of investment. On the contrary, it is simply the mechanism by which the export and sale is conducted. It is to be noted that the Grand River tribunal found expressly that the appointment of a separate company to distribute the claimants’ products did not transform the distributor into an “investment” under NAFTA.*<sup>59</sup>
238. *Apotex’s reliance on SGS v. Philippines and SGS v. Pakistan is of no assistance here. Apart from the fact that neither case involved an interpretation of the NAFTA, which provides its own definition of “investment”, in both cases the claimant had established “liaison offices” in the respondent States.*<sup>60</sup> *Apotex has not alleged any such investments in the United States, but instead conceded that it “does not reside or have a place of business in the United States”.*<sup>61</sup>
239. Purchase of Raw Materials in the U.S.: *The Tribunal has no reason to doubt that Apotex has committed significant capital in the United States towards the purchase of raw materials and ingredients used in its sertraline and pravastatin ANDA products. But this activity was evidently undertaken for the purposes of manufacturing in Canada products intended for export to the United States (and subsequent sale by others). These were no more than purchases from U.S. suppliers by way of a “commercial contract, for the sale of goods” which are generally excluded by NAFTA Article 1139(i). In the words of the Bayview tribunal (applying NAFTA Article 1139(i)):*
- “[t]he economic dependence of an enterprise upon supplies of goods ... from another State is not sufficient to make the dependent enterprise an ‘investor’ in that other State”.*<sup>62</sup>
240. Consent to US. Jurisdiction / Legal Fees: *Apotex’s submission to U.S. jurisdiction; its engagement of U.S. attorneys; and its expenditure on legal fees again neither amount to “investments”, nor change the nature of Apotex’s activity. Each is, again, no more*

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<sup>59</sup> *Grand River*, Award, para. 85 (“The other distributor – Tobaccoville - is an independent U.S. corporation that purchases Grand River’s cigarettes and distributes them off reservation under the terms of a contract with Grand River. It is a U.S. owned and controlled entity. It is not, and could not be, claimed as part of the Claimants’ investment”)

<sup>60</sup> *SGS v. Pakistan*, Decision, paras. 137, 140 (expenditures incurred in establishing and operating a liaison office in the host State constituted an investment); *SGS v. Philippines*, Decision, paras. 101, 103 (expenditures incurred in establishing and operating “a substantial office, employing a significant number of people”, in the host State constituted an investment).

<sup>61</sup> Counter-Memorial, para. 50. Apotex did suggest at one point in its written submissions that its relationship with its U.S. affiliate, agent and distributor (Apotex Corp.) also independently qualified as “an interest in an enterprise that entitles the owner to share in income or profits of the enterprise” for the purposes of NAFTA Art 1139(e), and so qualified as an “investment”. This point, however, was neither developed in writing, nor mentioned in oral submissions, and the Tribunal is unpersuaded by it. There was no evidence that Apotex Corp was an “investment” of Apotex, or that Apotex had an interest in it, such as to satisfy NAFTA Chapter Eleven.

<sup>62</sup> *Bayview*, Award, para. 104.

than an incident of the regulatory requirements of the U.S. market, and a step Apotex took in order to facilitate its export business. NAFTA Article 1139(i) once again applies.

241. Overall Conclusion on “Investment”: *It follows from the Tribunal’s conclusions above that no “investment” has been made by Apotex in the territory of the United States, within the scope of NAFTA Chapter Eleven.*

**(b) “Investor”**

242. *Having concluded that Apotex has made no “investment” in the territory of the United States within the scope of NAFTA Chapter Eleven, it necessarily follows that Apotex itself does not qualify as an “investor” for these purposes. As noted above, the scope and coverage of the protections of NAFTA Chapter Eleven extend to “investors” only to the extent that they have made, or have sought to make, “investments” in the territory of another NAFTA Party.*

**v. Conclusions**

243. *Apotex has failed to establish that it made or sought to make an “investment” in the United States. It therefore does not qualify as an “investor” under NAFTA Article 1116.*

244. *Apotex’s activities with respect to the contemplated sales of its sertraline and pravastatin products in the United States are those of an exporter, not an investor. As such, the position is analogous to that in Grand River Enterprises, Inc. v. United States, where the tribunal found that:*

*“claimants activities centered on the manufacture of cigarettes at Grand River’s manufacturing plant in Canada for export to the United States,”*

*and, as a result, determined that:*

*“such activities and investments by investors in the territory of one NAFTA party do not satisfy the jurisdictional requirements for a claim against another NAFTA party”.<sup>63</sup>*

245. *Apotex, like any company that intends to export generic drug products to the United States for sale in the U.S. market, sought regulatory approval from the FDA through the submission of ANDAs. But this process cannot change the nature of the underlying activity, or constitute an “investment” in and of itself, within the meaning and scope of NAFTA Article 1139.*

246. *It follows that the Tribunal lacks jurisdiction over Apotex’s claims, which must be dismissed in their entirety.*

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<sup>63</sup> *Grand River*, Award, para. 5.

**VII. Operative Order**

358. *In light of the above considerations the Tribunal hereby unanimously Orders and Awards as follows:*

- (a) *Apotex does not qualify as an “investor”, who has made an “investment” in the U.S., for the purposes of NAFTA Articles 1116 and 1139, and accordingly both the Sertraline and Pravastatin Claims are hereby dismissed in their entirety, on the basis that the Tribunal lacks jurisdiction in relation thereto.*

## ***PART VIII – NAFTA ARTICLES 1102 & 1103***

### **(1) *Introduction***

- 8.1. The Tribunal here addresses the third principal issue regarding the merits of the claims made by Apotex-Holdings (for itself and for Apotex-US) under NAFTA Articles 1102 and 1103. Whilst the Tribunal has upheld the Respondent’s jurisdictional objections to Apotex Inc.’s claims under NAFTA Articles 1102 and 1103, it is nonetheless necessary to consider the factual position of Apotex Inc. as part of this issue, hence the collective references below to “the Claimants.” As decided in Part VI above, there is a close commercial relationship between Apotex Inc. and Apotex-US (with the latter as the former’s principal US distributor and with Apotex-Holdings as their parent company) to warrant such collective consideration here.
- 8.2. In summary, the Claimants contend that, by adopting and maintaining the Import Alert, the Respondent accorded to Apotex-Holdings and Apotex-US treatment that was less favourable than the Respondent’s treatment of comparable investors and investments in like circumstances; and in so doing, that the Respondent breached NAFTA Articles 1102 and 1103, on national treatment and most-favoured-nation treatment respectively.
- 8.3. In summary, the Respondent contends that the Claimants have failed to establish the required elements of either a national treatment claim under NAFTA Article 1102 or a most-favoured-nation treatment claim under NAFTA Article 1103. The Respondent submits that the Claimants have not shown that they are in “like circumstances” with any US-based (domestic) comparator; and thus the Claimants cannot establish a national treatment claim. Further, so the Respondent submits, the Claimants have failed to establish that any non US-based (foreign) comparator in like circumstances received better treatment; and thus the Claimants cannot establish a most-favoured-nation claim.



**(2) *Legal Standard for NAFTA Articles 1102 & 1103***

8.4. Although the Parties approached the matter slightly differently, it was common ground that establishing a violation of NAFTA Article 1102 involves an inherently fact-specific analysis of whether the Claimants, or their alleged investments: (i) were accorded *treatment* by the Respondent with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments; (ii) were *in like circumstances* with the identified *domestic* investors or investments; and (iii) received treatment *less favourable* than that accorded to the identified domestic investors or investments. The Respondent also asserted (but the Claimants denied) that the less favourable treatment invoked by the Claimants must be shown to have been accorded on the basis of the Claimants' Canadian nationalities.<sup>1</sup>

8.5. It is not in issue that the requirements for establishing a violation of NAFTA Article 1103 are the same as establishing a violation of NAFTA Article 1102, except that the applicable comparator in step (ii) above is a *foreign* (non-US based) investor or its investments. It is also not suggested that either NAFTA Article 1102 or Article 1103 prohibits discrimination with respect to investments in the territory of another Party. The Respondent, therefore, is not obliged to accord national or most-favoured-nation treatment to the Claimants' investments in Canada.

**(3) *Legal and Evidential Burdens of Proof***

8.6. Relying on the decisions of the *UPS* tribunal, the Respondent contends that a failure by the Claimants to establish any of the three required elements under NAFTA Articles 1102 and 1103 is fatal to the merits of the Claimants' claims. The Respondent submits that: "This is a legal burden that rests squarely with the Claimant" and "[t]hat burden never shifts to the [other] Party."<sup>2</sup> The Respondent points to the *Rompetrol* award which is said to confirm that a claimant's "burden of

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<sup>1</sup> USA Counter-Memorial, Para. 324(3).

<sup>2</sup> *United Parcel Service of America Inc. v. The Government of Canada*, UNCITRAL, Award on the Merits (24 May 2007), Para. 84.

proof” is “absolute”, never shifting to the respondent<sup>3</sup> which bears no “burden of proof” of its own.<sup>4</sup>

- 8.7. For their part, the Claimants do not dispute that they carry such a *legal burden* of proof, but point to the distinction between the legal burden of proof, which defines which party has to prove what in order for its case to prevail, and the *evidential burden* that may rest upon a party alleging a fact on which it relies in support of its case or defence. This distinction is relevant, according to the Claimants, when the Tribunal is required (as here) to consider whether the Respondent has established with sufficient evidence those facts alleged in its defence.
- 8.8. The Tribunal considers such a distinction exists between the legal burden of proof (which never shifts) and the evidential burden of proof (which can shift from one party to another, depending upon the state of the evidence). In the *Pulp Mills* case, the ICJ noted that: “...in accordance with the well-established principle of *onus probandi incumbit actori*, it is the duty of the party which asserts certain facts to establish the existence of such facts. This principle which has been consistently upheld by the Court applies to the assertions of fact both by the Applicant and the Respondent.”<sup>5</sup>
- 8.9. It is thus for a claimant to prove its positive case and for a respondent to prove its positive defence, if it has a case to meet. In the wording of the *Feldman* award: “[V]arious international tribunals, including the International Court of Justice, have generally and consistently accepted and applied the rule that the party who asserts a fact, whether the claimant or respondent, is responsible for providing proof thereof. Also, it is a generally accepted canon of evidence in civil law, common law and, in

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<sup>3</sup> *Rompetrol Group N.V. v. Romania*, ICSID Case No. ARB/06/3, Award (6 May 2013), Para. 178 (“[T]he burden of proof defines which party has to prove what, in order for its case to prevail; the standard of proof defines how much evidence is needed to establish either an individual issue or the party’s case as a whole. As soon as the distinction is stated in that way, it becomes evident that the burden of proof is absolute, whereas the standard of proof is relative. By this the Tribunal means (again, in simple terms) that if, according to basic principle, it is for the one party, or for the other, to establish a particular factual assertion, that will remain the position throughout the forensic process, starting from when the assertion is first put forward and all the way through to the end. Operating within an international system characterised by principle rather than procedural formality, the Tribunal is not enamoured of arguments setting out to show that a burden of proof can under certain circumstances shift from the party that originally bore it to the other party, and then perhaps in appropriate circumstances shift back again to the original party.”).

<sup>4</sup> *Id.*, Para. 179.

<sup>5</sup> *Pulp Mills on the River Uruguay (Argentina v. Uruguay)*, 2010 I.C.J. Reports, p. 14 (20 April 2010), Para. 162 (citations omitted).

fact, most jurisdictions, that the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a claim or defence. *If that party adduces evidence sufficient to raise a presumption that what is claimed is true, the burden then shifts to the other party, who will fail unless it adduces sufficient evidence to rebut the presumption.*”<sup>6</sup>

8.10. Accordingly, the Tribunal decides that, whilst the legal burden of proof rests always on the Claimants to prove their claims under NAFTA Articles 1102 & 1103, the question whether the evidential burden shifts to the Respondent is relevant to the Tribunal’s analysis of whether either Sandoz or Teva was “in like circumstances” to the Claimants under Article 1103. As considered below, in regard to both Sandoz and Teva, the Tribunal decides that the evidential burden of proof does shift to the Respondent.

**(4) “Treatment”**

8.11. NAFTA Articles 1102 and 1103 require the Respondent to afford no less favourable “treatment” with respect to “the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.”

8.12. The Claimants point out that NAFTA tribunals have noted the “broad scope of application”<sup>7</sup> of these provisions, and have found that “treatment” “includes almost any conceivable measure that can be with respect to the beginning, development, management and end of an investor’s business activity.”<sup>8</sup> The Claimants refer (*inter alia*) to the decision by the *Merrill & Ring* tribunal that: “treatment is no different than the aggregate of all the regulatory measures applied to that business.”<sup>9</sup>

8.13. The Respondent does not contest the Claimants’ submission on the scope of the word “treatment” in NAFTA Articles 1102 and 1103. Rather, the Respondent contends that because the Import Alert (as the only measure here at issue) did not

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<sup>6</sup> *Marvin Feldman v. United Mexican States*, ICSID Case No. ARB(AF)/99/1, Award (16 December 2002), Para. 177 (quoting Appellate Body Report, *United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/AB/R at 14 (23 May 1997)) (emphasis added by the *Feldman* tribunal).

<sup>7</sup> *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Award (9 January 2003), Paras. 152-53 (referring to “the breadth of the definitional scope of the critical term ‘investment,’” to the definition of “investment” in Article 1139 and of “enterprise” in Article 201, and to the “range of the ‘treatment’ which must be accorded to the beneficiary ‘investor’ and ‘investment’: that is, ‘treatment’ ‘with respect to the establishment, acquisition, expansion, management, conduct, operation and sale or other disposition of investments.’”).

<sup>8</sup> *Merrill & Ring Forestry L. P. v. The Government of Canada*, UNCITRAL, Award (31 March 2010), Para. 79.

<sup>9</sup> *Id.*

“relate to” the Claimants or their investments, the measure cannot be said to have accorded the Claimants or their investments any “treatment” under Articles 1102 and 1103.

8.14. Having regard to the Tribunal’s decision in Part VI above under NAFTA Article 1101(1) to the effect that the Import Alert “related to” Apotex-Holdings and Apotex-US, the Tribunal concludes that the Import Alert qualifies as “treatment” for the purposes of NAFTA Articles 1102 and 1103.

**(5) “Like Circumstances”**

8.15. The Parties accept that the determination of whether NAFTA claimants are in “like circumstances” with the relevant investors or investments (as “comparators”) involves a highly fact-specific inquiry.<sup>10</sup> The Parties also accept that it is appropriate in the identification of comparators which are in “like circumstances” to look at, *inter alia*, whether those which are said to be comparators: (i) are in the same economic or business sector; (ii) have invested in, or are businesses that compete with the investor or its investments in terms of goods or services; or (iii) are subject to a comparable legal regime or regulatory requirements,<sup>11</sup> as the Claimants and their investments.

8.16. The principal points of disagreement between the Parties on this point concern the Respondent’s submissions that none of the domestic comparators identified by the Claimants for the purpose of NAFTA Article 1102 are subject to the same legal and regulatory regime (particularly import alerts). The Respondent contends that the products of the identified domestic comparators are not regulated under Section 801(a) of the Act; and that, as such, they are not appropriate comparators “in like circumstances.”<sup>12</sup> As regards NAFTA Article 1103, the Respondent submits that the foreign comparators identified by Claimants cannot be considered to have been “in like circumstances” when regard is had to the FDA’s analysis of the different factors associated with the FDA’s decision to issue the Import Alert for foreign products manufactured at the Etobicoke and Signet facilities.

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<sup>10</sup> Apotex Memorial, Para. 432; USA Counter-Memorial, Para. 330.

<sup>11</sup> Apotex Memorial, Paras. 434-438; USA Counter-Memorial, Para. 330.

<sup>12</sup> USA Counter-Memorial, Para. 333; USA Rejoinder, Para. 218.

8.17. The Parties' competing positions are set out more fully and analysed by the Tribunal below.

**(6) “Less Favorable”**

8.18. The Claimants submit that NAFTA tribunals have decided that the term “no less favorable” means equivalent to, not better or worse than, the best treatment accorded to the comparator.”<sup>13</sup> For this term’s application, the Claimants contend that NAFTA tribunals have focused on the practical impact of the disputed measure.<sup>14</sup>

8.19. The Claimants submit that an investor establishes a violation of NAFTA Articles 1102 and 1103 by demonstrating like circumstances and less favourable treatment in relation to a single eligible comparator. The Claimants argue that NAFTA Articles 1102 and 1103 do not require a showing of class-based discrimination;<sup>15</sup> nor do they require any showing of discriminatory intention.<sup>16</sup>

8.20. The Respondent does not take issue with the Claimants’ interpretation of the term “no less favorable”, or what a claimant must show to establish breach. Instead, the

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<sup>13</sup> *Pope & Talbot Inc v. The Government of Canada*, UNCITRAL, Award on the Merits of Phase 2 (10 April 2001), Para. 42 ; Para. 41 (“ ... like states and provinces, national governments cannot comply with NAFTA by according foreign investments less than the most favourable treatment they accord their own investments.”); *Archer Daniels Midland Company and Tate & Lyle Ingredients Americas, Inc. v. The United Mexican States*, ICSID Case No. ARB(AF)/04/5, Award (21 November 2007), Para. 205 (“Accordingly, Claimants and their investment are entitled to the best level of treatment available to any other domestic investor or investment operating in like circumstances ...”).

<sup>14</sup> *S.D. Myers, Inc. v. The Government of Canada*, UNCITRAL, Partial Award (13 November 2000), Para. 254 (“The word ‘treatment’ suggests that *practical impact* is required to produce a breach of Article 1102, not merely a motive or intent that is in violation of Chapter 11.” (emphasis added)).

<sup>15</sup> Apotex Memorial, Para. 429; *Pope & Talbot v. Canada*, *supra*, Para. 36 (dismissing Canada’s argument that the use of “investments” and “investors” in Articles 1102 and 1103 required a showing concerning multiple comparators: “The Tribunal also rejects the contention that that plural form requires, as a matter of semantics, comparison of the treatment provided to the foreign investor with that accorded to more than one domestically owned investment.”); *See, e.g., Marvin Feldman v. Mexico*, *supra*, Para. 187 (finding violation of Article 1102 based on showing of more favourable treatment of a single comparator).

<sup>16</sup> Apotex Memorial, Para. 429; *Marvin Feldman v. Mexico*, *supra*, Para. 183 (rejecting Mexico’s argument that a showing of intent to discriminate was required, finding that “ ...requiring a foreign investor to prove that discrimination is based on his nationality could be an insurmountable burden to the Claimant, as that information may only be available to the government”). *See also International Thunderbird Gaming Corporation v. United Mexican States*, UNCITRAL, Award (26 January 2006), Paras. 176-77 (“ ...Thunderbird must show that its investment received treatment less favourable than Mexico has accorded, in like circumstances, to investments of Mexican nationals. It is not expected from Thunderbird that it shows separately that the less favourable treatment was motivated because of nationality.” (emphasis in original)); *Grand River Enterprises Six Nations, Ltd., et al v. United States of America*, UNCITRAL, Rejoinder of the United States (13 May 2009), at p. 67 (“ ... the requirement to show discrimination on the basis of nationality under Article 1102 does *not* require a showing of discriminatory intent. Rather, a Claimant must establish that a measure either on its face, or as applied, favors nationals over non-nationals.” (emphasis in original)).

Respondent concentrates its arguments on: (i) whether the Claimants, for the purposes of NAFTA Article 1102, have identified domestic comparators based in the USA which were in like circumstances with the Claimants and their investments (it asserts they have not); and (ii) whether, for the purposes of NAFTA Article 1103, the Respondent, as a factual matter, accorded to the Claimants or their investments less favourable treatment than the US accorded to any foreign-based comparator in like circumstances (it asserts it did not).<sup>17</sup>

8.21. The Tribunal addresses these questions below. In doing so, the Tribunal proceeds on the basis that for the Claimants (Apotex-Holdings for itself and for Apotex-US) to succeed, they are required to prove, on the balance of the evidential record, that the Respondent treated them or their investment less favourably, *i.e.* worse than, their comparators who were in like circumstances. In this regard, the Tribunal considers that the treatment complained of must have some not-insignificant practical negative impact in order to lead to a breach of NAFTA Articles 1102 or 1103.

**(7) Comparators**

8.22. For the purposes of the Claimants' national treatment and most-favoured-nation claims, the Claimants and their expert witnesses proposed a number of comparators which were said to be in like circumstances to the Claimants and their investments. The Claimants based their cases under NAFTA Articles 1102 and 1103 on the treatment accorded to five comparators. Each of these five maintained generic drug manufacturing facilities in the USA; three were domestic-based in the USA (on which the Claimants relied for Article 1102) and two were foreign-based (on which the Claimants relied for Article 1103). These two foreign-based comparators had manufacturing facilities from which finished form drugs for human consumption were exported to the USA subject to the Act.

8.23. The five comparators proposed by the Claimants were:

- (a) Baxter Healthcare Corporation (USA-based, with facilities in Puerto Rico);
- (b) L. Perrigo Company (USA-based, with facilities in Michigan);
- (c) Hospira, Inc. (USA-based, with facilities in North Carolina);

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<sup>17</sup> USA Counter-Memorial, Para. 327; USA Rejoinder, Paras. 215, 216 and 249.

- (d) Novartis/Sandoz (Canada-based, with facilities in Boucherville, Quebec); and
- (e) Teva (Israel-based, with facilities in Jerusalem).

8.24. These comparators were selected by the Claimants' expert witnesses, Mr. Sheldon T. Bradshaw and Mr. Ron M. Johnson, based on a review which they had conducted of FDA warning letters and enforcement actions for cGMP issues with finished drug products during the period from 2008 to 2011.

8.25. Mr. Bradshaw and Mr. Johnson testified that: "...comparable companies (or, put another way, companies that are 'in like circumstances') are large generic drug manufacturers of finished dosage forms (as opposed to Active Pharmaceutical Ingredients) that have received an FDA Warning Letter during the 2008 – 2011 time period citing violations of the drug cGMPs. Companies having violations that FDA has, in fact, concluded are significant and serious, provide for like comparisons, *i.e.* 'in like circumstances.' While FDA does not consider issuance of a Warning Letter a final agency action, a Warning Letter does represent an institutional FDA position, *i.e.* that violations are significant and if uncorrected may lead to enforcement action. All of the companies identified for comparison, and discussed below, received Warning Letters from FDA for cGMP violations. Companies meeting the above criteria were further evaluated to assess the comparability of treatment to that of Apotex. The FDA website was searched to detect previous Warning Letters or other FDA communications, adverse inspectional findings, public health advisories or notifications, import alerts and/or notices of detention, and product recalls. Company websites and government filings were also searched for this information."<sup>18</sup>

8.26. For the purposes of NAFTA Article 1102, the Claimants relied on the treatment that the Respondent accorded to the three domestic USA-based comparators: Baxter, L. Perrigo and Hospira – each being a company that was subject to one or more warning letters issued by the FDA in connection with their domestic facilities based in the USA.

8.27. For the purposes of NAFTA Article 1103, the Claimants relied on the treatment the Respondent accorded to the two foreign comparators: Sandoz and Teva – each

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<sup>18</sup> First Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Paras. 107 and 108.

being recipients of one or more warning letters issued in connection with their foreign facilities based outside the USA.

8.28. Mr. Bradshaw and Mr. Johnson testified that the FDA had inspected the facilities of these five comparators and found cGMP violations similar in significance (although, in their opinion, more serious) to those that the FDA inspectors had found at Apotex Inc.'s facilities at Etobicoke and Signet. However, Mr. Bradshaw and Mr. Johnson considered that the subsequent enforcement actions taken by the FDA in each of these five cases differed materially from the treatment accorded to the Claimants and their investments and were not remotely as severe as the Import Alert. Based on their examination of the violations that had been identified by the FDA and the treatment that resulted, Mr. Bradshaw and Mr. Johnson concluded that the "FDA's treatment of those companies was very different, i.e., significantly more favourable, than the treatment afforded Apotex."<sup>19</sup>

**(8) *Domestic Comparators***

8.29. As stated above, in its defence to the Claimants' claims under Article 1102, the Respondent contends that the Claimants have failed to prove that the Claimants or their investments were in "like circumstances" with any of their three domestic comparators, being one of the essential elements required to establish any breach of NAFTA Article 1102.

8.30. The Respondent submits that none of these three domestic comparators manufactures products at foreign facilities for export to the USA; and that each manufactured products for sale in the USA only from its US-based facilities.

8.31. The Respondent notes that drug products manufactured at domestic facilities within the USA cannot be subject to Section 801(a) of the Act, import alerts or detentions at the US border (without physical examination) unless these products are exported and re-imported into the USA. The Respondent contends that the fact that products from domestic facilities are never subject to such import alerts or detentions or, even more generally, subject to the same legal and regulatory regime, shows clearly that US manufacturers with US facilities are not in "like circumstances" with

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<sup>19</sup> First Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 109 (emphasis omitted).



foreign manufacturers with foreign facilities, such as Apotex Inc.'s two facilities in Canada.

- 8.32. The Respondent submits that this territorial distinction which US law makes between products produced at facilities outside the USA and those within the USA is a critical part of the FDA's ability to protect US consumers from foreign adulterated products. According to the Respondent, the principal dissimilarity, between the legal regimes applicable to drug products manufactured at domestic facilities and those manufactured at foreign facilities, is that the FDA has the administrative authority to refuse to admit foreign products into the USA if such products appear to be adulterated, but for drugs manufactured domestically, the FDA must first establish adulteration through judicial action in order to bar such drugs from the US marketplace.
- 8.33. For the purpose of likeness of circumstance under NAFTA Article 1102, the Claimants accept the requirement of a foreign investor and its domestic comparators being subject to the same legal and regulatory regime. However, the Claimants contend that the Respondent is wrong to reduce that regime to only one form of enforcement measure, namely an import alert. The Claimants submit that the legal and regulatory regime here constitutes the cGMP regulations; that, because US-based and foreign facilities which manufacture drug products for the US market must conform their operations to the same cGMP regulations, US-based and foreign drug manufacturers are subject to the same regime.
- 8.34. The Claimants also contend that the Respondent improperly merges the separate concepts of "treatment" and "circumstances" under NAFTA Article 1102. The Claimants submit that the according of "treatment" by the host State is the active verb and the central element in both NAFTA Articles 1102 and 1103; that the ordinary meaning of treatment is conduct, behaviour or action towards a person; and that the phrase "in like circumstances" directly qualifies the verb "accord."
- 8.35. The Claimants submit that the term "circumstances" denotes conditions or facts that accompany or surround an action. Accordingly, so the Claimants submit, the "action" in NAFTA Articles 1102 and 1103 is the according of treatment; the circumstances are not the action, but the facts that accompany or determine the

action; and “treatment” and “circumstances”, as used in these provisions, cannot be the same thing. Thus, the Claimants contend that the regulatory action (in this case, the Import Alert) constitutes the treatment received; and it is not a circumstance to be considered when assessing likeness of circumstances. The fact that Apotex Inc. received differential, less favourable, treatment does not alter the conclusion that Apotex Inc. or the Claimants were in like circumstances to domestic investors with drug manufacturing facilities in the USA.

8.36. The Claimants further submit that the regulatory actions that the FDA can adopt against non-cGMP-compliant drug manufacturers can take different forms. As Mr. Bradshaw and Mr. Johnson testified: “FDA’s primary enforcement tools for facilities located within the United States are Warning Letters, seizures, and injunctions. FDA’s primary enforcement tools for facilities located outside the United States are Warning Letters, detentions without physical examination, and import alerts”,<sup>20</sup> and “FDA could also use seizures and injunctions for products produced at foreign facilities, but as a matter of practice it does so infrequently, likely because it is easier for FDA to issue an import alert than obtain an injunction or seizure.”<sup>21</sup>

8.37. It follows, so the Claimants argue, that an import alert is just one enforcement measure within the FDA’s arsenal to ensure cGMP compliance. It is true that import alerts can be applied only to *foreign* manufacturers that offer drug products for import into the USA. However, if a *domestic* drug manufacturer fails to comply with cGMP requirements, the FDA can adopt alternative enforcement measures, such as an injunction or seizure. Injunctions and seizures have the same effect as an import alert: they prevent by law pharmaceutical drugs from being sold to patients in the USA.

8.38. The Claimants assert that the legal regime in this case did not require the FDA to issue the Import Alert in respect of Apotex Inc.’s two facilities. Rather, the FDA had a discretion whether to bar Apotex Inc.’s products from the US market by imposing an import alert or to achieve the same result by seeking an injunction or seizure (subject to establishing jurisdiction). By placing products from Etobicoke

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<sup>20</sup> First Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 41.

<sup>21</sup> *Id.*, Para. 41 (fn 5).

and Signet on import alert, the Respondent afforded the Claimants less favourable treatment compared to Baxter, L. Perrigo and Hospira. Because of the Import Alert, the Claimants were prevented from selling any products manufactured at Etobicoke and Signet during a period of almost two years. By contrast, the FDA did not prevent Baxter, L. Perrigo or Hospira, from selling their products in the USA, even though these products were manufactured at US-based facilities that failed to comply with cGMP regulations.

8.39. In the result, the Claimants contend that they received less favourable treatment than these three domestic comparators and that the Respondent thus breached the national treatment standard under NAFTA Article 1102.

**(9) *The Tribunal’s Analysis as to NAFTA Article 1102***

8.40. For the reasons set out below, the Tribunal decides that none of the three domestic comparators proposed by the Claimants is “in like circumstances” to the Claimants or their investments for the purposes of NAFTA Article 1102.

8.41. The Respondent’s defence to the Claimants’ case under Article 1102 (on the merits) is that the three domestic comparators proposed by the Claimants were not in like circumstances to the Claimants and their investments.<sup>22</sup> As already summarised above, this defence is based on the different legal and regulatory regimes applicable to domestic and foreign facilities, including the fact that drug products manufactured by domestic comparators could not be subject to import alerts or detentions (without physical examination) under the Act unless they were exported and re-imported into the USA.

8.42. The Parties did not take issue with the concept expressed by the *Pope & Talbot* tribunal, that “‘circumstances’ are context dependent and have no unalterable meaning across the spectrum of fact situations.”<sup>23</sup> In addition, the Parties accepted,

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<sup>22</sup> Mr. Bradshaw and Mr. Johnson testified that these comparators were selected because they “...were unable to uncover any instance of an FDA warning letter or enforcement action concerning cGMP violations at any manufacturing facilities outside of US territory of a US-owned company manufacturing finished dosage forms for human consumption.” First Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 111. In its Rejoinder, the Respondent identified a US company, Pfizer Inc., whose foreign subsidiaries supplied Pfizer’s US subsidiaries and which received a warning letter dated 27 March 2013, post-dating Mr. Bradshaw’s and Mr. Johnson’s first report.

<sup>23</sup> *Pope & Talbot v. Canada, supra*, Para. 75 (discussing the meaning of “like circumstances” and stating that “[i]t goes without saying that the meaning of the term will vary according to the facts of a given case. By their

as the *Archer Daniels* tribunal put it, that “all ‘circumstances’ in which the treatment was accorded are to be taken into account in order to identify the appropriate comparator.”<sup>24</sup> These obviously include the legal and regulatory regime that governs parties that are being compared for the purposes of NAFTA Article 1102.

- 8.43. It is common ground that all of the three domestic comparators proposed by the Claimants were in the same sector as the Claimants, sold like drug products to those sold by Apotex Inc., and were direct competitors in the US market. In these circumstances, in the Tribunal’s view, the question of whether the Claimants and their investments were subject to the same legal regime or regulatory requirements (to those to which the identified US-comparators were subject) becomes an important potential differentiator.
- 8.44. As a Canadian drug manufacturer, Apotex Inc. is primarily regulated and controlled by Health Canada and not the FDA.<sup>25</sup> Its Canadian facilities have been inspected regularly by Health Canada since the mid-1970’s. Canadian manufacturers such as Apotex Inc. are obliged to comply with what are known in Canada as good manufacturing practices.<sup>26</sup> Foreign firms (*i.e.* non-US firms), such as Apotex Inc. are, generally speaking, under no obligation to comply with US regulations. Such compliance is militated only by their desire to market their products in the USA and by commitments they may have made in applications filed with the FDA.<sup>27</sup> Because Apotex Inc. supplies the US market, *inter alia*, it needs to ensure that its systems address the Respondent’s requirements for the proper design, manufacturing and control of manufacturing processes of its facilities which supply the US market, such as the FDA’s cGMP.
- 8.45. Unsurprisingly, the relevant law and practice recognise and provide for differences between domestic and foreign facilities as regards the inspection by the FDA of

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very nature, ‘circumstances’ are context dependent and have no unalterable meaning across the spectrum of fact situations”); Apotex Memorial, Para. 432 (quoting same).

<sup>24</sup> *Archer Daniels v. Mexico*, *supra*, Para. 197.

<sup>25</sup> “FDA’s Foreign Drug Inspection Program”, Statement of FDA Commissioner Andrew C. von Eschenbach (1 November 2007), Exhibit C-027, at p. 1.

<sup>26</sup> Apotex Memorial, Para. 89; Canadian Food and Drug Regulations, Division 2, Good Manufacturing Practices (in effect from 23 April 2009 to 30 September 2009 and from 1 October 2009 to 22 February 2010).

<sup>27</sup> FDA, *Guide to Inspections of Foreign Pharmaceutical Manufacturers* (May 1996).

such facilities, and the tools available to the FDA for the enforcement of the cGMP standard.

8.46. Section 704(a)(1) of the Act authorises the FDA to:

- (a) “enter, at reasonable times, any factory, warehouse, or establishment in which ... drugs ... are manufactured, processed, packed, or held, for introduction in interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such ... products”; and
- (b) “inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.”<sup>28</sup>

8.47. The FDA’s statutory inspection authority extends to: “records, files, papers, processes, controls, and facilities” bearing on whether drugs are adulterated or misbranded, or are otherwise in violation of the Act.<sup>29</sup> In addition, companies that hold FDA-approved NDAs and ANDAs are required to maintain certain records; and FDA investigators are authorised “to have access to and copy and verify such records.”<sup>30</sup> The Act requires the FDA to inspect drug manufacturing establishments at least once every two years.<sup>31</sup> However, due to limited resources and the significant increase in foreign drug products imported into the USA, the FDA has experienced difficulties in meeting this statutory requirement. The FDA’s program for inspecting foreign drug manufacturers differs in a number of respects from that for inspecting domestic drug manufacturers, and the FDA “strives to ensure that it ... informs the prospective inspection staff of the differences in the foreign vs. domestic drug inspection programs.”<sup>32</sup>

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<sup>28</sup> Act § 704(a)(1); 21 U.S.C. § 374(a)(1).

<sup>29</sup> *Id.*

<sup>30</sup> Act § 505(k)(2); 21 U.S.C. § 355(k)(2).

<sup>31</sup> Act § 510(h); 21 U.S.C. § 360(h). The Food and Drug Administration Safety and Innovation Act, which was signed by President Obama on 9 July 2012, amended section 510(h) of the Act by replacing the biennial inspection schedule for drug establishments with a “risk-based” inspection schedule (Pub. L. No. 112-144, § 705, 126 Stat. 993 (2012)).

<sup>32</sup> FDA, *Guide to Inspections of Foreign Pharmaceutical Manufacturers*, *supra*.

- 8.48. An important distinction between drug manufacturers located in the territory of the USA and those located abroad is that the former are directly subject to the jurisdiction of the FDA. Thus, under the terms of Section 704(a)(1) of the Act, the FDA has authority to enter US drug manufacturing facilities, at reasonable times, without the need for agreeing and scheduling such an inspection in advance. By comparison, the FDA, being a US regulator, obviously has no unilateral authority to enter and carry out an inspection of premises located on foreign territory.
- 8.49. As the FDA observes in its *Guide to Inspections of Foreign Pharmaceutical Manufacturers* (the “Guide”), its ability to inspect foreign drug facilities does not come from Section 704 of the Act (which confers jurisdiction over domestic facilities), but from the FDA’s ability to invoke Section 801 of the Act and also from commitments made by sponsors or holders of NDAs and ANDAs. For that reason, “...the agency is not required to provide stringent documentary evidence to establish violations of the Act.”<sup>33</sup> Section 801(a) of the Act states that a drug offered for import into the United States “shall be refused admission” by the Agency if it “appears” that such drug, among other things, “is adulterated, misbranded, or in violation of section 355” of the Act.<sup>34</sup>
- 8.50. As a result, the FDA’s Guide instructs FDA inspectors, as follows: “During the inspection of a foreign drug manufacturer, it is not necessary to obtain the same level of documentation expected from a domestic inspection to establish evidence of GMP violations or data integrity problems. The agency has the authority under [the Act] to administratively restrict the importation of a product without demonstrating the adulteration of the product. The burden of proof is placed on the importing party.”<sup>35</sup> Similarly, the FDA’s *Guide to International Inspections and Travel* instructs FDA inspectors that: “[i]n general, fewer exhibits are usually required for international EIs [*i.e.* Establishment Inspections] than for domestic EIs.”<sup>36</sup>
- 8.51. In the Tribunal’s view, the decisive difference in the legal and regulatory regime that governs foreign products manufactured outside the USA and those that are

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<sup>33</sup> *Id.*

<sup>34</sup> Act § 801(a); 21 U.S.C. § 381(a).

<sup>35</sup> FDA, *Guide to Inspections of Foreign Pharmaceutical Manufacturers*, *supra*; *accord id.* (“[T]he agency is not required to provide stringent documentary evidence to establish violations of the Act” when inspecting foreign drug facilities).

<sup>36</sup> FDA, *Guide to International Inspections and Travel*, § 322.

manufactured at USA-based facilities is that Section 801(a) does not apply to domestic products that are manufactured in the USA, regardless of whether the manufacturing facilities are US-owned or foreign-owned (unless the products are exported and then re-imported into the USA). Import Alert 66-40 operates in conjunction with Section 801(a) of the Act, which authorises FDA district offices to detain at the US border, without physical examination, foreign drug products that “appear” to be adulterated because they were not manufactured in conformity with current good manufacturing practice.

- 8.52. It is evident that the FDA’s ability to restrict access to the US markets of products manufactured at foreign facilities that appear to be adulterated is more easily achieved through the use of an Import Alert 66-40 in conjunction with Section 801(a) of the Act, than under Section 704 of the Act. It is quite a different thing for the FDA to form an impression of adulteration as a result of an inspection than to establish that adulteration through a formal adjudicative process in the US courts, as it must for domestically manufactured products.
- 8.53. To the Tribunal’s mind, the differences in the FDA’s ability to deny access to the US market as between foreign and domestically manufactured drugs are substantial; and that these constitute a material distinction between the legal and regulatory regimes applicable to foreign and domestic manufacturing facilities. These differences go to “like circumstances”, rather than to “treatment” and the Import Alert of 28 August 2009 itself.
- 8.54. The observations of the *Grand River* tribunal concerning “like circumstances” for the purposes of NAFTA Articles 1102 and 1103 are here helpful and apposite. The *Grand River* tribunal confirmed that the appropriate comparators under NAFTA Article 1102 (and Article 1103) are those that are subject to like legal requirements.<sup>37</sup> After canvassing several NAFTA Chapter Eleven decisions, the *Grand River* tribunal decided: “While each case involved its own facts, tribunals have assigned important weight to ‘like legal requirements’ in determining whether there were ‘like circumstances.’ The *ADF* tribunal thus emphasized that both the claimant and its U.S. competitors were subject to the same U.S. ‘Buy America’

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<sup>37</sup> *Grand River v. USA*, *supra*, Para. 166.

provisions. *Pope & Talbot* found that the relevant comparators were lumber exporters subject to the same restrictive legal regime as the claimant, so there was no denial of national treatment if exporters in other unregulated provinces were not so limited. *Feldman v. Mexico* found the relevant comparators for purposes of MFN analysis to be a limited group of cigarette exporters subject to the same legal requirements as the claimant. The *Methanex* tribunal (citing *Pope & Talbot*) emphasized the importance of assuring that purported comparators face similar regulatory requirements. Looking at the question from the other direction, *UPS v. Canada* found a key difference between the parties there to be that Canada Post was subject to legal requirements under national law and international postal agreements that did not affect UPS.”<sup>38</sup>

- 8.55. The *Pope & Talbot* tribunal formulated a test, in the context of its analysis of “like circumstances”, that: “[d]ifferences in treatment will presumptively violate Article 1102(2), unless they have a reasonable nexus to rational government policies that (1) do not distinguish, on their face or *de facto*, between foreign-owned and domestic companies, and (2) do not otherwise unduly undermine the investment liberalizing objectives of NAFTA.”<sup>39</sup>
- 8.56. The Tribunal considers that Section 801(a) of the Act (with the guidance as to import alerts thereunder) passes this test. Both protect the public health of US residents and patients, do not distinguish between companies or facilities on the basis of nationality and are consistent with the investment objectives of NAFTA’s Chapter Eleven. Indeed, as the Claimants acknowledge, the FDA is not the primary regulator outside of the territory of the USA; and the FDA does not have the resources to examine every drug product made abroad that is offered for import into the USA.
- 8.57. In this arbitration, the only measure challenged by the Claimants is the Import Alert of 28 August 2009, namely the FDA’s decision to place Apotex Inc.’s Etobicoke and Signet facilities on Import Alert 66-40. When, as here, the only domestic comparators proposed by the Claimants could never have been subject to any

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<sup>38</sup> *Id.* (footnotes omitted).

<sup>39</sup> *Pope & Talbot, supra*, Para. 78 (footnote omitted).



similar measure, the Tribunal considers it to be impermissible to contend that such comparators are in “like circumstances” to the Claimants and their investments.

8.58. Accordingly, the Tribunal decides that there is no basis to accept the Claimants’ case that placing the Import Alert on Apotex Inc.’s Etobicoke and Signet facilities constituted a breach by the Respondent of NAFTA Article 1102’s national treatment standard. The Tribunal therefore dismisses all claims made under NAFTA Article 1102 in this arbitration by Apotex-Holdings (for itself and for Apotex-US).

**(10) *Foreign Comparators and the Tribunal’s Analysis as to NAFTA Article 1103***

8.59. In its Counter-Memorial, the Respondent accepted that Sandoz (Canada) and Teva (Jerusalem) are “...potential comparators for Apotex’s most-favored-nation treatment claim under Article 1103...”<sup>40</sup> In its Rejoinder, however, the Respondent contended that these foreign facilities were not in like circumstances to the Claimants and their Canadian facilities.<sup>41</sup> At the Hearing, the Tribunal understood that the Respondent did not accept that Teva or Sandoz, or their respective foreign-based facilities, were appropriate comparators for the purposes of NAFTA Article 1103.

8.60. It is possible here to address this part of the Parties’ respective cases succinctly, given the Tribunal’s factual summaries regarding Teva and Sandoz in Part III and also the Tribunal’s legal analysis regarding NAFTA Article 1102 above which applies, *mutatis mutandis*, to NAFTA Article 1103.

8.61. In short, the Tribunal decides that both Teva and Sandoz are *prima facie* appropriate comparators for the purposes of NAFTA Article 1103. In the Tribunal’s view, the US legal and regulatory regime, as to import alerts and detention (without physical examination) to which these foreign manufacturers, their foreign-based facilities and their foreign products were exposed, was materially the same regime to which the Claimants (Apotex Inc.) were subject in Canada as regards the Etobicoke and Signet facilities and their products.

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<sup>40</sup> USA Counter-Memorial, Para. 334.

<sup>41</sup> USA Rejoinder, Para. 267.

- 8.62. As regards “treatment”, the Tribunal has already decided that both Teva and Sandoz were treated more favourably than the Claimants (Apotex Inc.) as regards Import Alert 66-40: see the Tribunal’s conclusions stated for each of these comparators in Part III Above.
- 8.63. Accordingly, the remaining questions under NAFTA Article 1103 are whether either Teva or Sandoz or their respective foreign facilities were indeed “in like circumstances” to the Claimants (Apotex Inc.) and the Etobicoke and Signet facilities within the meaning of NAFTA Article 1103 and, if so, whether the Respondent breached its obligations under NAFTA Article 1103.
- 8.64. It is necessary here to return to the legal and evidential standards of proof considered earlier in this Part VIII, applied to the evidence adduced in this arbitration and its probative value assessed by the Tribunal under Article 41(1) of the ICSID Arbitration AF Rules.
- 8.65. In the Tribunal’s view, the Claimants as regards these remaining questions have sufficiently discharged their evidential burden of proof so as to place the evidential burden of rebutting their case upon the Respondent. In other words, in the absence of such rebuttal, the Tribunal considers that Apotex-Holdings (for itself and for Apotex-US) would succeed, as to liability, on their claims against the Respondent under NAFTA Article 1103.
- 8.66. This results from the totality of the evidence on these questions adduced by the Claimants in this arbitration; but it also accords with a procedural aspect inherent in this form of investor-state arbitration. Whilst Articles 40 and 41(2) of the ICSID Arbitration AF Rules permit an investor-claimant to request documentation from a respondent State, there is no Anglo-Saxon form of automatic discovery of all potentially relevant documentation. Where crucial documents are properly withheld by a respondent State on grounds of strict confidentiality or other like privilege and not ordered for production by a tribunal (on those grounds), how then can the claimant investor discharge the legal burden of proving its positive case under NAFTA Article 1103 in regard to factual matters essentially within the exclusive domain of the respondent State?

- 8.67. For example, the Respondent submitted that Mr. Bradshaw and Mr. Johnson (as expert witnesses called by the Claimants) were wrong to suggest that the FDA applied its discretion in an arbitrary manner: “It is always easy to second-guess, to draw inferences from incomplete facts, to see the world in black and white. But FDA does not have the luxury to choose black and white, to always prioritize drug safety over drug availability. FDA has to make difficult choices, and it is not always clear to those outside looking in to understand what factors tilted the scale in one direction or the other.”<sup>42</sup> In the absence of Anglo-Saxon discovery, how does investor-state arbitration under NAFTA’s Chapter Eleven provide a fair procedure for a claimant, as an outsider with incomplete facts, to discharge the legal burden of proving its case?
- 8.68. In the Tribunal’s view, the answer must be that at some stage the evidential burden of proof shifts towards the respondent State and requires it to rebut the evidence adduced by the claimant. Otherwise, the claimant would be left to prove its case from whatever incomplete documentary evidence and witness testimony the respondent State may choose to present. That burden would be, invariably, an almost impossible task. Accordingly, the Tribunal considers, as regards the Respondent’s remaining defences under NAFTA Article 1103 and given the procedural history of this arbitration, that such stage has here been reached.
- 8.69. The Respondent first emphasises the great responsibilities entrusted to the FDA and exercised in its discretion as a specialist and skilled regulator of long-standing and great repute. The Respondent submits that the FDA is required necessarily to exercise a difficult regulatory discretion lying at the heart of its important mandate on public health; and that this discretion as to enforcement actions is never a binary choice, but depends on many factors particular to the specific situation. The Respondent submits that the Claimants’ case would effectively require, whenever the FDA found significant cGMP violations with respect to a facility, to take the same enforcement action that it has taken against another company with cGMP violations “regardless of the specific nature of the violations and any factors weighing for and against such action with respect to the particular facility and drugs concerned. Either it [the FDA] has to bar all products from noncompliant facilities,

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<sup>42</sup> TD6.1710-1711.

or it can bar none of them.”<sup>43</sup> According to the Respondent, this would mean that the FDA would have to ignore the many factors it routinely considers when exercising that discretion; that it would radically alter the way that the FDA operates; and that it would also have serious implications for the import and sale of drug products in the USA and public health.

- 8.70. The FDA’s discretionary exercise in regard to import alerts was described by Dr. Rosa in his testimony. He described the FDA’s use of a “risk-based approach” when determining whether to take enforcement action, where the relevant factors included: the seriousness of the violations; the public health risks of those violations; the company’s prior history of and responses to violations (including voluntary corrective actions); and whether drug products may be medically necessary or in short supply.<sup>44</sup> It is this last factor which, in the Tribunal’s view plays a decisive role in this case.
- 8.71. As summarised in Part III above, the Tribunal concludes that the evidence adduced in this arbitration proves that the FDA’s different treatment of Teva was materially influenced by the FDA’s genuine concerns over shortages of essential drugs manufactured at Teva’s Jerusalem facility intended for shipment and sale in the USA. The Tribunal has also there referred to the testimony of Dr. Rosa; and it suffices only to add here that the Tribunal found him to be an impressive and reliable witness, both in his written testimony and during his oral evidence at the Hearing. The Tribunal accepts this evidence.
- 8.72. The evidence in regard to Sandoz is less straightforward, for reasons already described by the Tribunal in Part III. The Tribunal rejects the Claimants’ submission that adverse inferences should be drawn against the Respondent for the paucity of the evidence tendered in support of its case. The Respondent considered itself under a legal impediment which prevented it from adducing relevant evidence in this arbitration. Conversely, however, in such circumstances the Tribunal does not consider that it should draw any positive inference in favour of the Respondent in discharging its evidential burden of proof. To the contrary, whilst the Respondent is not to be blamed for these missing evidential pieces in its jigsaw defence, the fact

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<sup>43</sup> TD1.42-43.

<sup>44</sup> Supplemental Witness Statement of Dr. Carmelo Rosa, Paras. 28 and 31.

remains that its jigsaw is materially incomplete with a likely mass of documentation and numerous factual witnesses unavailable to be heard by the Tribunal in this arbitration, as to which the Respondent must accept the legal consequence.

- 8.73. Apart from the publicly available materials relating to Sandoz/Novartis, there was, however, one factual witness from the FDA who did testify before the Tribunal: Dr. Rosa. As summarised in Part III above, Dr. Rosa could testify of his own knowledge that the FDA's different treatment of Sandoz/Novartis was materially influenced by the FDA's genuine concerns over shortages of essential drugs manufactured at Sandoz's Boucherville facility intended for shipment and sale in the USA. The Tribunal accepts this evidence.
- 8.74. The Claimants have much criticised the FDA for its "rush to judgment", at times bordering on allegations of malign bad faith. The Tribunal readily understands the strong sense of grievance felt by the Claimants in regard to the period from 17 August to 28 August 2009. The Tribunal nonetheless does not accept this criticism. From the FDA's perspective, its discretionary process began no later than December 2008 with the Etobicoke inspection and the FDA inspectors' findings of serious cGMP violations. As Dr. Rosa testified, the FDA had considered an import alert in early 2009 but did not do so because it wished to inspect the Signet facility and complete a drug-shortage analysis in regard to products manufactured by Apotex Inc. (which confirmed no relevant drug-shortage).<sup>45</sup>
- 8.75. The Tribunal also rejects any suggestion that the FDA especially targeted or sought to discriminate against the Claimants, based on the public speeches of its senior officers described in Part III. In the Tribunal's view, there was a change of policy in early 2009 under the Respondent's new political administration intended to resume stricter and swifter enforcement practices by the FDA, not limited to the Claimants. Under NAFTA Article 1103, there is no general bar to such a change in policy in regulatory practice made in good faith and in a non-arbitrary manner (as this was). In any event, based on Dr. Rosa's evidence, the Tribunal does not consider that the

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<sup>45</sup> Supplemental Witness Statement of Dr. Carmelo Rosa, Para. 20.

FDA's exercise of discretion towards the Claimants was materially influenced by this policy change, although it was not of course inconsistent with that new policy.<sup>46</sup>

8.76. The Tribunal accepts that the FDA was also influenced, to a lesser extent, by the failure of the Claimants (Apotex Inc.) to take more extensive voluntary action during the telephone conference-call with the FDA on 17 August 2019 and, as Dr. Rosa described Apotex Inc., for being "out of control." This also materially distinguishes Apotex Inc. from Teva and Sandoz. However, as with the legal term "adulterated" drugs, the Tribunal infers that Dr. Rosa was here using an FDA term of art and not literally suggesting that Apotex Inc. was actually out of control. In the Tribunal's view, Dr. Rosa was only describing the failure of Apotex Inc.'s senior management to understand by mid-August 2009 the gravity of what the FDA inspectors had found at both the Etobicoke and Signet facilities, requiring a much stronger and immediate voluntary response from Apotex Inc. towards the FDA.

8.77. For all these reasons, the Tribunal determines that the Respondent has proven that Teva and Sandoz (with their respective foreign-based facilities and foreign products) were not in like circumstances to the Claimants and the Etobicoke and Signet facilities and their products, within the meaning of NAFTA Article 1103. The Tribunal therefore rejects all claims against the Respondent under NAFTA Article 1103 by Apotex-Holdings (for itself and for Apotex-US).

**(11) Conclusion**

8.78. Accordingly, the Tribunal dismisses, on the merits, all claims made by Apotex-Holdings (for itself and for Apotex-US) under both NAFTA Articles 1102 and 1103. It follows that, if the Tribunal had accepted jurisdiction over the claims made by Apotex Inc. in this arbitration, the Tribunal would also have dismissed all its claims, on the merits, under both NAFTA Articles 1102 and 1103.

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<sup>46</sup> Dr. Rosa denied any "rush to judgment": *Id.*, Para. 20.

## ***PART IX – NAFTA ARTICLE 1105***

### **(1) *Introduction***

- 9.1. The Tribunal here addresses the fourth principal issue relating to NAFTA Article 1105(1), NAFTA Article 1103 and Article II(2) and II(6) of the Jamaica-USA BIT. As earlier with Part VIII, although the Tribunal has upheld the Respondent’s jurisdictional objections to all claims made by Apotex Inc. in Part VII, it nonetheless remains convenient here to refer to the claims made by Apotex-Holdings (for itself and for Apotex-US) as the Claimants’ claims. The Tribunal considers first NAFTA Article 1105(1) and, in the light of its analysis and decisions, turns to NAFTA Article 1103 and the Jamaica-USA BIT at the end of this Part IX.
- 9.2. *NAFTA Article 1105(1)*: NAFTA Article 1105(1) requires that: “Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security.”
- 9.3. On 31 July 2001, the NAFTA Free Trade Commission adopted the following Note of Interpretation regarding the minimum standard of treatment under Article 1105(1), entitled “Minimum Standard of Treatment in Accordance with International Law”: “(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).”
- 9.4. Under NAFTA Article 1131(2), an interpretation by the Free Trade Commission of a NAFTA provision “shall be binding on a Tribunal established under this Section.” The Tribunal, of course, accepts in this proceeding the binding effect of this Note of Interpretation.

9.5. *Jamaica-USA BIT*: The Tribunal refers to the text of Article II(2)(b) and Article II(6) of the BIT set out in Part IV above, together with the text of NAFTA Article 1103.

9.6. The Tribunal considers that Apotex-Holdings, as the party alleging a breach of NAFTA Article 1105(1) and Article II of the BIT, bears the legal burden of proving its case.

**(2) *The Claimants' Case***

9.7. In summary, as regards NAFTA Article 1105(1), the Claimants allege that the Respondent breached its minimum standard of treatment “by adopting the import alert with no prior notice to Apotex [the Claimants], no possibility for Apotex to prepare a defense, no opportunity for Apotex to present its position and no decision by an impartial administrative authority.”<sup>1</sup>

9.8. The Claimants contend that customary international law requires “that administrative authorities must afford certain procedural safeguards in deciding the rights and interests of individual parties. Recent State practice further reinforces this conclusion.”<sup>2</sup> Thus, in the Claimants’ submission, “the rule of law translates today into certain procedural requirements for the deployment of legal process that include the right to a hearing before a decision is made, the right to have the decision made in an unbiased and impartial fashion, the right to know the basis of the decision so that it can be contested, the right to reasons for the official’s decision, and the right to a decision that is reasonably justified by all relevant legal and factual considerations. And in order to make these rights effective one must add the right to have the validity of the decision tested in a court of law.”<sup>3</sup>

9.9. The Claimants contend that each of these procedural requirements is required by the customary international law minimum standard of treatment of aliens;<sup>4</sup> and that the Import Alert was adopted by the Respondent in disregard of these requirements. The Claimants maintain that they were not given prior notice<sup>5</sup> and had no opportunity to

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<sup>1</sup> Apotex Memorial, Para. 13.

<sup>2</sup> *Id.*, Para. 458.

<sup>3</sup> *Id.*, Para. 466 (footnote omitted).

<sup>4</sup> TD6.1604-1605.

<sup>5</sup> Apotex Memorial, Para. 472.



present evidence and witnesses before being placed on Import Alert;<sup>6</sup> the decision to adopt the Import Alert was made by partial FDA officers and not by any impartial decision-maker;<sup>7</sup> no reasons were given by the Respondent for adopting the Import Alert;<sup>8</sup> the administrative remedies available to the Claimants were ineffectual;<sup>9</sup> and the Claimants could not dispute the FDA's decision in the US courts.<sup>10</sup>

9.10. In support of their case that these procedural requirements are part of customary international law, the Claimants rely heavily upon the provisions of Section 181 of the American Law Institute's Restatement (Second) of Foreign Relations Law of the United States ("the Second Restatement"). In the Claimants' submission, Section 181 sets out rules of customary international law regarding the treatment of aliens that govern their claim.

9.11. As excerpted by the Claimants, Section 181 of the Second Restatement provides: "[A] trial or other proceeding to determine the rights or liabilities of an alien must be fair. In determining whether the proceeding is fair, it is relevant to consider, among other factors whether the alien has had the benefit of

- (a) An impartial ... administrative authority,
- (b) Adequate information with respect to the nature of the proceedings so as to permit the alien to present his claim or defense,
- ...
- (d) Reasonable opportunity to contest evidence against him,
- (e) Reasonable opportunity to obtain and present witnesses and evidence in his own behalf, ..."<sup>11</sup>

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<sup>6</sup> *Id.*, Para. 473.

<sup>7</sup> *Id.*, Para. 471. ("The same organ that proposed the measure decided to adopt it.")

<sup>8</sup> *Id.*, Para. 475.

<sup>9</sup> *Id.*, Para. 474.

<sup>10</sup> *Id.*, Para. 476.

<sup>11</sup> *Id.*, Para. 460.

### (3) *The Respondent's Case*

9.12. In summary, the Respondent raises three principal arguments as regards NAFTA Article 1105(1). First, the Respondent contends that the relevant rules of customary international law do not require States to give prior notice and a hearing to a foreign drug manufacturer before blocking imports of its products that they consider to be adulterated. In the Respondent's submission, there is no legal authority for the existence of the Claimants' asserted rules of customary international law, contending that the Claimants did not present any state practice or *opinio juris* supporting their asserted customary rules,<sup>12</sup> as the Claimants were bound to do as the proponent of these alleged rules.<sup>13</sup> The Respondent also maintains that the Claimants failed to address past decisions and awards made under NAFTA's Chapter Eleven which contradict the Claimants' case; and that Article 1105(1) embraces only the treatment of investments (not investors), so that "only those rules of State responsibility that relate to a foreign investor's economic stake or property interests in the host State inform the minimum standard of treatment obligation in Article 1105(1)."<sup>14</sup>

9.13. Second, the Respondent contends that the Claimants incorrectly seek to import rights available to aliens under international law for trials and other formal adjudicative proceedings into "general administrative decision-making outside of adjudication."<sup>15</sup> In this regard, the Respondent maintains that the provisions of the Second Restatement (as invoked by the Claimants) address trials and other adjudicatory proceedings, but not administrative decision-making. The Respondent also referred to several prior NAFTA and ICSID awards indicating that deference should be given by international tribunals to States in their exercise of regulatory decision-making.<sup>16</sup>

9.14. Finally, the Respondent maintains, on the facts, that the Claimants were accorded or had available extensive procedural safeguards. In the Respondent's contention, the

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<sup>12</sup> USA Counter-Memorial, Para. 345; USA Rejoinder, Para. 301.

<sup>13</sup> USA Counter-Memorial, Para. 354.

<sup>14</sup> *Id.*, Para. 351 (footnote omitted); *see also* USA Rejoinder, Para. 284. (For the Claimants' responses, see TD6.1602ff; Apotex Memorial, Paras. 453ff and Apotex Reply, Paras. 389ff).

<sup>15</sup> USA Counter-Memorial, Para. 346.

<sup>16</sup> USA Counter-Memorial, Paras. 356-363 (citing, *inter alia*, *S.D. Myers v. Canada*, *supra*, *Thunderbird v. Mexico*, *supra*, *Gami Investments, Inc. v. The Government of the United Mexican States*, UNCITRAL, Award (15 November 2004), and *Genin v. Republic of Estonia*, ICSID Case No. ARB/99/2, Award (25 June 2001)).

Claimants had sufficient opportunities to ascertain the reasons for the Import Alert and to contest the FDA's decision to impose it; but the Claimants chose not to utilise the means available to contest this decision.<sup>17</sup> In the Respondent's submission, it is an inherent contradiction for the Claimants to claim in this proceeding that they could not contest the decision, when at the time the Claimants had not even attempted to utilise any of the remedies available to them to do so.<sup>18</sup>

**(4) *The Tribunal's Analysis and Decision***

- 9.15. The Tribunal initially considers whether the specific procedural rights invoked by the Claimants are part of any evolving "customary international law minimum standard of treatment of aliens" that a NAFTA Party must accord to the investments of another Party's investors as required by NAFTA Article 1105(1).
- 9.16. The Parties agree that the prohibition on denial of justice has acquired the status of customary international law and is among the protections embraced within the required minimum standard of treatment of aliens.<sup>19</sup> However, the claim here is not framed as being for denial of justice under international law. Instead, it is that customary international law requires a State to accord to aliens several specific types of procedural protections in connection with that State's regulatory action affecting imports of drug products manufactured in aliens' facilities located in a foreign country. The Claimants maintain that customary international law, forming part of NAFTA Article 1105(1), guarantees such aliens the right to "effective means" of redress "different from, and less demanding than, denial of justice under customary international law."<sup>20</sup>
- 9.17. In support of their case, the Claimants cite extensive scholarly commentaries urging in general terms that due process is required by customary international law. The Claimants also identify a number of countries that have adopted laws regulating administrative procedure as part of their national laws. However, the Tribunal considers that the Claimants have not presented sufficient evidence of state practice or *opinio juris* indicating that States recognise an obligation to extend the specific

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<sup>17</sup> USA Counter-Memorial, Paras. 376ff; USA Rejoinder, Paras. 321ff.

<sup>18</sup> USA Rejoinder, Para. 365.

<sup>19</sup> USA Counter-Memorial, Para. 353.

<sup>20</sup> Apotex Memorial, Para. 483.

procedural rights claimed here to aliens in connection with regulators' decisions affecting the importation of drug products manufactured abroad in the aliens' foreign facilities. Nor have the Claimants, in the Tribunal's view, identified any prior decisions of NAFTA and other international tribunals recognising the asserted principles of customary international law in circumstances comparable to those presented in the present case.

9.18. The Claimants nonetheless contend that several procedural rights listed in Section 181 of the Second Restatement are required by customary international law. In the Claimants' submission "these requirements are part of the 'international standard of justice' resulting from the 'applicable principles of international law'" and reflect "established customary international law as it existed in 1965."<sup>21</sup> In the Claimants' submission, because the cited elements of Section 181 then reflected accepted principles of customary international law defining the rights of aliens, no further evidence of state practice and *opinio juris* is now necessary to confirm their status: "[T]he U.S. errs in suggesting that Apotex must demonstrate State practice and *opinio juris* in the specific context of the due process safeguards for drug importation Measures. This is not the way that customary international law works. No showing at such a level of granularity is required. The existence of the general rule recognized by the Restatement is sufficient. That rule is, as Apotex has already demonstrated, sufficiently flexible to apply to a wide variety of contexts, including this one."<sup>22</sup> Thus, the Claimants' claims under NAFTA Article 1105(1) rest heavily on the contention that the cited elements of Section 181 of the Second Restatement reflect generally accepted rules of customary international law binding upon the FDA's decisions to impose import alerts affecting the drug products of foreign manufacturers.

9.19. The Tribunal considers that this to be an incorrect understanding of Section 181. Section 181 draws heavily on the provisions of Article 7 of the 1961 revision by Professors Sohn and Baxter of the 1929 Harvard Draft Convention on Responsibility of States for Damage Done on Their Territory to the Person or

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<sup>21</sup> *Id.*, Para. 461.

<sup>22</sup> TD6.1607.

Property of Aliens<sup>23</sup> addressing aliens' rights in proceedings before tribunals and administrative authorities. Article 6 of the 1961 draft, captioned "Denial of Access to a Tribunal or an Administrative Tribunal," provides that denial of an alien's "right to initiate, or to participate in, proceedings in a tribunal or an administrative authority to determine his civil rights or obligations is wrongful" if certain conditions are met. Article 7, captioned "Denial of a Fair Hearing" then lists "relevant" factors to consider in determining whether a hearing is fair. These include such factors as the availability of compulsory process to obtain witnesses and evidence, free or assisted legal representation on the same basis as provided to nationals, services of an interpreter if the alien cannot "fully understand or speak the language used in the tribunal," and the presence of a representative of the alien's government "at any judicial or administrative proceeding."

9.20. Section 181 mirrors Article 7 of the Sohn/Baxter draft in emphasising procedures involving formal adjudication of an alien's rights. The section appears in a chapter of the Second Restatement entitled "Inadequate Administration of Law" that contains two topics: "Denial of Procedural Justice" (Sections 178-182) and "Failure to Protect from Private Injury" (Section 183). Section 178 defines denial of procedural justice as relating to "enforcement of the state's law as it affects the alien in criminal, civil, or administrative proceedings ...". Section 179 deals with arrest and detention, indicating (*inter alia*) that there is denial of procedural justice if an arrested alien is not granted a trial without unreasonable delay. Section 180(1) provides that "[f]ailure to afford to an alien an appropriate trial or other legal proceeding for the determination of his rights or liabilities is a denial of procedural justice." Section 182 concludes that "[a]n adverse determination that is manifestly unjust in a proceeding determining criminal charges against an alien, or determining his rights and liabilities of a civil nature, is a denial of procedural justice."

9.21. As cited above, the first sentence of Section 181 directs that "a trial or other proceeding to determine the rights of liabilities of an alien must be fair." The second sentence then sets out several factors "relevant to consider" in assessing whether a given proceeding is fair, which merit reciting again: "In determining whether the

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<sup>23</sup> Sohn, Louis B. and Baxter, R. R., *Responsibility of States for Injuries to the Economic Interests of Aliens*, 55 Am. J. Int'l L. 545 (1961). Professor Sohn was a member of the Advisory Committee for the Second Restatement.

proceeding is fair, it is relevant to consider, among other factors whether the alien has had the benefit of

- (a) An impartial tribunal or administrative authority,
- (b) Adequate information with respect to the nature of the proceedings so as to permit the alien to present his claim or defense,
- (c) Adequate interpretation and translation into his own language at all stages of the proceeding,
- (d) Reasonable opportunity to contest evidence against him,
- (e) Reasonable opportunity to obtain and present witnesses and evidence in his own behalf,
- (f) Reasonable opportunity to communicate with a representative of his government with respect to the proceedings,
- (g) Reasonable opportunity to consult counsel and time to prepare for the proceeding, and
- (h) Reasonable dispatch by the tribunal or administrative authority in reaching a determination.”

9.22. In the Tribunal’s view, these inter-connected provisions of the Second Restatement indicate two things. First, the wording throughout emphasises criminal, civil or administrative proceedings of a formal adjudicative character. The alien is to be given information “with respect to the nature of the proceedings,” given “reasonable opportunity to obtain and present witnesses” and the like, all wording conveying the sense of adjudicatory proceedings. Indeed, the provisions requiring interpretation and translation into the alien’s language “at all stages of the proceeding” and the opportunity for the alien to meet a representative of the alien’s government “with respect to the proceedings” only make sense in the context of such proceedings. They do not make sense in the context of the regulatory decision-making at issue in this case.

- 9.23. Second, more importantly, it is clear that the eight elements listed in Section 181 are not free-standing rules of customary international law. Rather, these are only “factors” that are “relevant” “in determining whether the proceeding is fair.” This is far short of showing that each factor reflects an existing rule of customary international law.
- 9.24. Moreover, the Reporters’ Notes to Section 181 make clear that not every factor applies to every situation; and that their application varies significantly, depending upon context: “[I]t is clear that they [the factors] are not all required in all types of proceedings. The extent to which the specific safeguards indicated in this Section [181] may be requisite for a fair trial or other proceeding will depend primarily on (1) the seriousness of the consequences to the alien, and (2) the extent to which the exercise of administrative discretion is reasonably involved in the determination of the case. In a criminal trial involving a severe penalty or in a civil trial involving a substantial claim, each of the safeguards is normally essential. In an administrative proceeding to determine, for example, the issuance or revocation of a license to engage in a particular occupation, the specific safeguards may not all be necessary or practicable. Other examples of administrative proceedings in which the circumstances may not call for each of the specific safeguards are the granting or denying of a variance under a zoning ordinance, the granting and termination of parole to a convicted criminal, the exercise of executive clemency, the waiver or assessment of a penalty for overdue taxes, the granting of a permit to travel in a restricted area, and the granting of a public utility franchise.”<sup>24</sup>
- 9.25. Thus, the Tribunal concludes that the specific elements of Section 181 of the Second Restatement are not free-standing rules of customary international law that constitute part of the international law minimum standard of treatment of aliens. As already noted above, the Claimants contend that they do not need to adduce evidence of state practice and *opinio juris* to show the existence of a rule of customary international law, because Section 181 offered a sufficient statement of settled customary principles. However, Section 181 involves factors for assessing “fairness,” not rules of customary international law. It does not therefore assist the

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<sup>24</sup> American Law Institute, Restatement (Second) Foreign Relations Law Of The United States, Reporters’ Comment B, at p. 545.

Claimants' case; and indeed, for a text dating from almost 50 years ago, it might be thought by many to be surprising if it did. Thus, it is next necessary for the Tribunal to consider whether there is support in state practice and *opinio juris* for ascribing greater legal weight to any of the elements invoked by the Claimants.

- 9.26. The Claimants cite scholarly commentaries contending, generally at a high level of abstraction, that customary international law requires due process. The Claimants also cite the administrative procedure laws adopted by certain countries, the practice of European multi-national institutions and the domestic and treaty practice of the USA, in support of their proposition that States provide protections for due process.
- 9.27. However, the issues before the Tribunal are not whether the abstract notion of due process has acquired sufficient status in customary international law, but whether the specific procedural protections claimed by the Claimants in this case are required by customary international law, particularly whether those protections are part of the customary international law minimum standard of treatment of aliens required by NAFTA Article 1105(1). In the Tribunal's view, the state practice available to the Tribunal in the specific context presented here, namely the regulation of imported drug products, weighs heavily against the assertion that the claimed protections are required by customary international law.
- 9.28. For example, in August 2011, Health Canada announced that it had limited imports to Canada of certain drugs manufactured by Ben Venue Laboratories in Bedford, Ohio, USA ("BVL"), on account of "deficiencies in the area of Good Manufacturing Practices (GMP)" at the BVL manufacturing facility. "In light of these deficiencies, Health Canada is allowing only the importation of drugs deemed medically necessary."<sup>25</sup> In November 2011, the European Medicines Agency's Committee on Medicinal Products for Human Use also called for limits and recalls of drug products supplied by BVL, except for medicines "absolutely essential to meet patients' needs ... and which are currently not available from another

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<sup>25</sup> Health Canada, "Notice to Hospitals, Health Canada Important Safety Information on Certain Drug Products Imported into Canada from Ben Venue Laboratories Inc.", 17 August 2011 (Exhibit R-079); Carly Weeks, "Cancer Drug Shortage Will Get Worse", *Globe and Mail*, 19 August, 2011 (Health Canada has "clamped down on importations from Ben Venue's plant in Bedford, Ohio.") (Exhibit R-080).



source.”<sup>26</sup> Thus, as the Claimants’ legal experts point out “other regulators (in Canada and the EU) imposed a ban [sic] on Ben Venue’s products.”<sup>27</sup> The Tribunal’s attention was not drawn to anything in the evidential record to indicate that these regulatory actions were preceded by notice to BVL or to any other specific procedures of the kind the Claimants contend are required by customary international law.

9.29. The evidence adduced in this proceeding also shows that, following the FDA’s Import Alert on 28 August 2009, at least three other important national and regional regulatory agencies took actions effectively ending imports of the Claimants’ products into their territories for varying periods. Again, there is no indication that any of these regulators delayed action until they had completed the prior notice, hearing or any other procedural elements said by the Claimants to be required by customary international law.

9.30. Thus, in September 2009, the Claimants’ internal e-mail regarding conversations with New Zealand’s Medicines and Medical Devices Safety Authority (Medsafe)<sup>28</sup> quotes senior Medsafe officials as saying they were leaning toward prohibiting further imports of Apotex drug products into New Zealand under Section 37 of New Zealand’s Medicines Act.<sup>29</sup> In lieu of a prohibition on imports of its products under Section 37, the Claimants promptly entered into a “voluntary import restriction” barring imports into New Zealand of drug products manufactured at the Signet and Etobicoke facilities. Medsafe agreed that the voluntary ban on imports from the

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<sup>26</sup> European Medicines Agency Press Release, “European Medicines Agency Gives Interim Recommendations to Deal with Shortcomings in Quality Assurance at Ben Venue Laboratories”, 22 November 2011 (Exhibit R-083).

<sup>27</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, Para. 57.

<sup>28</sup> Exhibits C-091 and C-099.

<sup>29</sup> Article 37 of the New Zealand Medicines Act 1981 provides in relevant part: Powers of Minister to prohibit import, etc, of medicines: “(1) The Minister may from time to time, by notice in the *Gazette*, prohibit the import ... of medicines of any specified description or medical devices of any specified kind, either absolutely or subject to such conditions as he thinks fit, for any specified period not exceeding 1 year; but he shall not exercise this power more than once in respect of medicines or medical devices so specified. (2) Where the Minister gives a notice under subsection (1), he shall, on the written request of any person, state his reasons for doing so.”

Signet facility could be lifted on 20 October 2009;<sup>30</sup> and the ban on products from the Etobicoke facility was lifted on 24 November 2009.<sup>31</sup>

- 9.31. Also in September 2009, another of the Claimants' internal e-mails reveals a similar sequence of events with regulators from Australia's Therapeutic Goods Administration ("TGA"). According to the report from the Claimants' officer in Australia, reporting discussions with TGA to senior Apotex officers in Toronto: "These are the actions that we have to take – *Non negotiable*. (1) We must initiate a voluntary recall of Meloxicam batches identified as potentially problematic as per the details sent by Lance earlier this week ... (2) We are to suspend all shipments of products manufactured by the Signet and Etobicoke site for Australia with immediate effect. The suspension is to remain in place until Health Canada has completed its review of the Signet site ... The 'voluntary suspension' of shipments is confidential ... For the avoidance of doubt, the suspension is to remain in place until Health Canada has completed its review of the Signet site. If Health Canada is OK with the plans that Apotex HQ has put in place then we will be allowed to ship again."<sup>32</sup>
- 9.32. From the evidence, it is apparent that the European Union's drug regulators took similar action, again with no indication that the Claimants were given the prior notice, hearing or other procedures said by the Claimants to be required by customary international law.
- 9.33. According to an EU press release of 26 October 2009: "The European Medicines Agency (EMA), the Medicines Evaluation Board (MEB) and the Netherlands Health Care Inspectorate (IGZ) have been made aware of Good Manufacturing Practices (GMP) problems with two manufacturing sites in Canada, belonging to the company Apotex. As a precautionary measure IGZ has requested that Apotex temporarily cease the import and distribution of all products imported into the European Economic Area (EEA) that were manufactured at one of the manufacturing sites, with the exception of Ferriprox (deferiprone). Apotex has complied with this request. This manufacturing site is currently being inspected.

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<sup>30</sup> Exhibit C-113.

<sup>31</sup> Exhibit C-121.

<sup>32</sup> Exhibit C-095 (emphasis in original).

The other manufacturing site has already been inspected and found to be GMP compliant ... The suspension of import and distribution is a precautionary measure that will be lifted once the manufacturing site is found to be GMP compliant. Ferriprox is excluded from the suspension of import and distribution, because it is considered to be an essential product by some European Union (EU) Member States. After careful review of the manufacture of this product, the IGZ, in collaboration with the EMEA, has decided to allow the supply of this product onto the EU market to continue.”<sup>33</sup>

9.34. At the Hearing, the Claimants submitted that these three responses do not show state practice, because in each case the Claimants voluntarily suspended imports of their drug products: “A private Party’s voluntary act cannot constitute state practice. Because Apotex acted voluntarily, there was no legal process and there is no evidence of the legal processes that these States provided to Apotex.”<sup>34</sup>

9.35. The Tribunal rejects this explanation. Certain of the New Zealand, Australian and EU drug regulators’ requirements were indeed couched as “requests”, but in each case these requests rested upon a clear expectation of rapid and mandatory regulatory action if the Claimants did not comply. The Claimants’ “voluntary import restriction” on imports into New Zealand remained in effect until Medsafe said it could be lifted; TGA’s requirements to initiate a recall and to “suspend all shipments of products” from Signet and Etobicoke were (as the Apotex officer recognised at the time) “non-negotiable”; and EU regulators “decided to allow” the drug Ferriprox to be imported because some EU countries considered it an essential pharmaceutical product. Indeed, the Claimants’ own witness describes the actions of New Zealand’s regulators and of the Netherlands Health Care Inspectorate as an “import ban.”<sup>35</sup> The relatively temperate language of foreign drug regulators towards the Claimants may reflect a difference in regional culture; but their acts were not materially different from the FDA’s Import Alert.

9.36. In the Tribunal’s view, these actions by several state regulators, from countries with legal systems sensitive to due process, cast still further doubt on the Claimants’

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<sup>33</sup> Exhibit C-114.

<sup>34</sup> TD6.1608.

<sup>35</sup> Witness Statement of Bruce D. Clark, Para. 45.

contention that customary international law bars a State's regulatory decisions that block imports of adulterated foreign drug products, unless that State's regulator accords to the alien prior notice, a hearing and other procedural safeguards.

- 9.37. The Tribunal also recalls in this regard the decisions by NAFTA and other international tribunals emphasising the need for international tribunals to recognise the special roles and responsibilities of regulatory bodies charged with protecting public health and other important public interests. These are of course not binding on this Tribunal, which must make its own determinations regarding the facts and the law relevant to this case; and, moreover, the Tribunal here addresses under NAFTA Article 1105(1) a "minimum" standard of treatment, with no permissible margin of appreciation below such minimum. Nevertheless, these other decisions indicate the need for international tribunals to exercise caution in cases involving a state regulator's exercise of discretion, particularly in sensitive areas involving protection of public health and the well-being of patients.
- 9.38. As the NAFTA *Thunderbird* tribunal observed in a different context, the role of NAFTA's Chapter Eleven is "to measure the conduct of Mexico towards Thunderbird against the international law standards set up by Chapter Eleven of the NAFTA. Mexico has in this context a wide regulatory 'space' for regulation; in the regulation of the gambling industry, governments have a particularly wide scope of regulation reflecting national views on public morals."<sup>36</sup> In the Tribunal's view, what is true for regulating gambling (however expressed) must be no less true with respect to regulating drug imports to protect the public health of its citizens and residents.
- 9.39. In a similar vein, the NAFTA *Chemtura* tribunal stated that: "the rule [sic: role] of a Chapter 11 Tribunal is not to second-guess the correctness of a science-based decision-making of highly specialized national regulatory agencies";<sup>37</sup> and in *S.D. Myers v. Canada*, the NAFTA tribunal stated: "When interpreting and applying the 'minimum standard', a Chapter 11 tribunal does not have an open-ended mandate to second-guess government decision making."<sup>38</sup> This Tribunal agrees with these

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<sup>36</sup> *Thunderbird Gaming v. Mexico*, *supra*, Para. 127.

<sup>37</sup> *Chemtura Corporation v. Government of Canada*, UNCITRAL, Award (2 August 2010), Para. 134.

<sup>38</sup> *S.D. Myers v. Canada*, *supra*, Para. 261.

statements. Otherwise, NAFTA tribunals would be required in cases such as the present case, as the Respondent submitted at the Hearing, to “step into the shoes of FDA and evaluate how those factors [*i.e.* all the specialist factors relevant to the FDA’s regulatory discretion] were applied to Apotex and other companies.”<sup>39</sup> This Tribunal, by inclination, qualification and training, cannot possibly act as a drug regulator; and, indeed, the Claimants do not suggest that it could.

9.40. For all these reasons, the Tribunal concludes that the Claimants have not established the existence of the specific procedural rights required by customary international law in the context of the FDA’s regulatory decision here challenged, namely the Import Alert.<sup>40</sup> As the Party bearing the legal burden of establishing its case, this determination would suffice to dismiss the Claimants’ case under NAFTA Article 1105(1).

9.41. However, it is necessary to consider the Claimants’ case further. Because of the Claimants’ emphasis on the specific procedural protections listed in Section 181 of the Second Restatement, the Parties did not clearly address two broader questions. First, is an obligation to accord some form of due process appropriate to a particular context one of the elements making up the customary international law minimum standard?<sup>41</sup> In this regard, the Tribunal recalls that past NAFTA tribunals generally have interpreted the minimum standard in NAFTA Article 1105 as being comprised of a limited number of defined elements (denial of justice, failure to accord full protection and security, etc.). These international tribunals have rejected conceptions equating this minimum standard with broader and more abstract notions such as “justice” or “the rule of law.”<sup>42</sup>

9.42. Second, if an obligation to accord due process is one of the elements of the minimum standard (or is an aspect of denial of justice, as some scholars and decisions suggest), by what standard should an international tribunal assess whether that obligation has not been met? The Claimants argued forcibly that some form of due process is required by customary international law, but they did not directly

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<sup>39</sup> TD1.43.

<sup>40</sup> Apotex Memorial, Para. 13.

<sup>41</sup> Both Parties agree that the nature of the process that is due depends on the context, as the Reporters’ Note to Section 181 indicates (USA Rejoinder, Para. 299; Apotex Reply, Para. 421; and the Claimants at TD2.476).

<sup>42</sup> Dumberry, Patrick, *The Fair And Equitable Treatment Standard: A Guide To NAFTA Case Law On Article 1105* (2013), at p. 262.

address in what manner this constitutes one of the elements of the minimum standard for purposes of NAFTA Article 1105(1). The Respondent's position was that, while the Respondent provided substantial due process protections to the Claimants, this was "not based on a rule of customary international law."<sup>43</sup>

- 9.43. The Tribunal observes that NAFTA tribunals have treated the relationship between due process and Article 1105's minimum standard in greatly varying ways. The *Glamis Gold* tribunal concluded that the customary international law minimum standard remains as apparently articulated in the 1926 *Neer* award:<sup>44</sup> "to violate the customary international law minimum standard of treatment codified in Article 1105 of the NAFTA, an act must be 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 ..." (emphasis added by this Tribunal).<sup>45</sup>
- 9.44. The *Waste Management* tribunal gave more, but circumscribed, weight to the element of due process in Article 1105's minimum standard. That tribunal understood earlier NAFTA cases to indicate that the minimum standard was infringed by "*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 or a complete lack of transparency and candour in an administrative process" (emphasis added by this Tribunal).<sup>46</sup>
- 9.45. For its part, the *Thunderbird* tribunal saw denial of due process as an aspect of denial of justice and therefore part of the customary international standard.<sup>47</sup> That tribunal inquired whether "there was a failure to provide due process, constituting an administrative denial of justice."<sup>48</sup> The tribunal rejected the claimant's contention that it was denied due process because an administrative hearing (a

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<sup>43</sup> USA Rejoinder, Para. 321.

<sup>44</sup> *L.F.H. Neer and Pauline Neer (U.S.A.) v. United Mexican States*, 4 R.I.A.A. 60 (2006) (15 October 1926).

<sup>45</sup> *Glamis Gold, Ltd. v. The United States of America*, UNCITRAL, Award (8 June 2009), Para. 22.

<sup>46</sup> *Waste Management, Inc. v. United Mexican States*, ICSID Case No. AB(AF)00/3, Award (30 April 2004), Para. 98.

<sup>47</sup> The *Genin* tribunal, under the Estonia-USA BIT, also treated allegations of denial of due process as an aspect of denial of justice, concluding "[n]ot without some hesitation" that "the actions of the Bank of Estonia did not amount to a denial of justice." *Genin v. Estonia*, *supra*, Para. 357.

<sup>48</sup> *Thunderbird Gaming v. Mexico*, *supra*, Para. 85.

formal adversarial proceeding of the sort Section 181 of the Second Restatement primarily addresses) did not satisfy the requirements of NAFTA Article 1105. The tribunal found that the evidence did not show that the proceedings “were arbitrary or unfair, let alone so manifestly arbitrary or unfair as to violate the minimum standard of treatment.”<sup>49</sup> It further observed that the administrative proceedings at issue “should be tested against the standards of due process and procedural fairness applicable to administrative officials. The administrative due process requirement is lower than that of a judicial process.”<sup>50</sup>

9.46. The *Chemtura* tribunal took yet another approach, evidently assuming (although without discussion) that due process is part of the minimum standard under NAFTA Article 1105.<sup>51</sup> The case involved allegations that Canada violated Article 1105 by conducting a flawed review of the registration of lindane, a pesticide. The tribunal rejected claims that Canada’s procedures failed to satisfy Article 1105, observing that it “should not limit its inquiry to a specific portion of such arrangements [the lindane review process]. It must appraise any procedural deficiency in the light of the mechanisms provided by the Respondent [to conduct the review].”<sup>52</sup> Further, the tribunal emphasised the context in which the claim arose: “In assessing whether the treatment afforded to the Claimant’s investment was in accordance with the international minimum standard, the Tribunal must take into account all the circumstances, including the fact that certain agencies manage highly specialized domains involving scientific and public policy determinations.”<sup>53</sup> However, the *Chemtura* tribunal did not posit a standard for assessing claims of deprivation of due process, finding instead that it found no facts “that would even come close to the type of treatment required for a breach of the FET standard.”<sup>54</sup>

9.47. Despite their varying approaches regarding this element of due process, Professor Dumberry concludes in his well-known work that all of these past NAFTA tribunals “have emphasized that a high threshold of severity and gravity is required in order to conclude that the host state has breached any of the elements contained within the

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<sup>49</sup> *Id.*, Para. 197.

<sup>50</sup> *Id.*, Para. 200.

<sup>51</sup> *Chemtura v. Canada, supra*, Para. 145.

<sup>52</sup> *Id.*, Para. 145.

<sup>53</sup> *Id.*, Para. 123.

<sup>54</sup> *Id.*, Para. 236.

FET standard under Article 1105.”<sup>55</sup> The Tribunal agrees with this scholarly conclusion. It does not support the Claimants’ case.

- 9.48. Further, as prior international tribunals have decided, whatever process may be due depends on the particular context or circumstances of the claim. The evidence in the present case shows that the regulation of cross-border trade in drug products is intended primarily to ensure the safety of domestic patients and that it is inherently a complex and specialised process involving professional judgments as to public health for which there are no mechanical rules. Regulation can involve the balancing of conflicting discretionary factors, such as cases where a foreign company experiencing grave manufacturing difficulties may be the sole or primary producer of drugs medically necessary for treating serious medical conditions for domestic patients in the regulator’s country.
- 9.49. This proceeding has not addressed the diversity in NAFTA jurisprudence on the relationship between due process and the minimum standard of treatment under NAFTA Article 1105. However, assuming (without here deciding) that some element of due process figures in Article 1105’s customary minimum standard, the Tribunal finds, on the facts of this case, that the Respondent’s conduct impugned by the Claimants does not approach the “high threshold of severity and gravity” required to establish a violation of Article 1105(1).
- 9.50. The Claimants first contend that they were denied due process because they were not given prior notice that an import alert was being considered by the FDA;<sup>56</sup> and that they had no opportunity to present evidence and witnesses before being placed on import alert.<sup>57</sup> As already described in Part III above, the Respondent indicates that the FDA’s practice is not to give prior notice and hearings to a foreign firm being considered for import alert for cGMP deficiencies, lest that firm (or others) take advantage of the notice and ensuing delay to surge its adulterated product into the US market. The Respondent submits that, in addition to direct communication with the FDA both before and after a decision to impose an import alert, affected entities have several administrative procedures available to contest adverse FDA

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<sup>55</sup> Dumberry, *supra*, at p. 262.

<sup>56</sup> Apotex Memorial, Para. 472.

<sup>57</sup> *Id.*, Para. 473.



actions. The Tribunal does not see this FDA practice as unreasonable or abusive in the particular regulatory context, involving imports of drug products potentially bearing serious risks to public health and originating from a wide variety of manufacturers of varying quality (and even integrity) in numerous foreign jurisdictions.

9.51. The Claimants next maintain that the FDA gave no reasons for imposing the Import Alert of 28 August 2009,<sup>58</sup> but this criticism is not supported on the evidence adduced in this proceeding.<sup>59</sup> The evidential record shows that officers from the Claimants (Apotex Inc.) were constantly present during the FDA inspections of the Etobicoke and Signet facilities and met with the FDA's inspectors following these inspections on 19 December 2008 and 14 August 2009 respectively. The Claimants had copies of the FDA Form 483s recording the FDA's inspectors' observations. The Claimants had the Etobicoke warning letter of 25 June 2009. After the Import Alert was imposed, the record shows numerous face-to-face meetings, telephone conferences, telephone calls and e-mail communications between FDA officers and Apotex personnel regarding the Claimants' efforts to improve the quality control systems at the Etobicoke and Signet facilities, during which Apotex personnel and their consultants expressed an understanding of what was expected of the Claimants. The evidence does not show that Apotex personnel did not understand the FDA's concerns regarding the Claimants' non-compliance with cGMP regulations at the Etobicoke and Signet facilities.

9.52. The Claimants also complained that the decision to adopt the Import Alert was made by partial FDA officers and not by an impartial decision-maker.<sup>60</sup> The Tribunal rejects this allegation of partiality, based particularly on the character of Dr. Rosa, who appeared to the Tribunal as a thoroughly professional and highly responsible person, as well as an impressive witness (to which the Tribunal has already referred in Parts III and VIII). However, the evidential record also shows that Dr. Rosa and other CDER officers did not have the sole power to impose the Import Alert, which was imposed by the FDA's senior officials following formal coordination and concurrence by officers in several parts of the FDA. The Tribunal

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<sup>58</sup> *Id.*, Para. 475.

<sup>59</sup> For the Respondent's response, see USA Rejoinder, Para. 332.

<sup>60</sup> Apotex Memorial, Para. 471.

notes in this regard that the FDA's multi-layered decision-making worked to the benefit of the Claimants when senior FDA officials rejected the FDA inspectors' recommendations to maintain the Import Alert after the unsuccessful re-inspections of the Signet and Etobicoke facilities in January-February 2011 (see the findings of fact in Part III above).

9.53. Significantly, as the Respondent asserts, the Claimants did not pursue any of the administrative remedies potentially available to them under the FDA's regulations and US law. The Claimants maintain that these were ineffectual and could not provide effective means to contest the FDA's action and secure redress against the Import Alert.<sup>61</sup> In the Tribunal's view, the evidence shows that under the FDA's regulations, the Claimants could have requested an administrative hearing to contest the detention of products before the FDA's responsible district officer detaining those products; they could have requested reconsideration of the findings of cGMP violations or the decision to impose the Import Alert under 21 CFR Section 10.75; and they could have lodged a citizen petition under 21 CFR Section 10.25, 10.30. To gain fully effective relief, it is likely that the Claimants would have had to seek modification of the FDA's findings of cGMP violations because even if the Import Alert were withdrawn or suspended, these findings would leave products manufactured at the Signet and Etobicoke facilities subject to refusal of entry into the USA even without any import alert. However, this factor does not assist the Claimants' case because the Claimants do not impugn these findings as a "measure" by the Respondent in this proceeding.

9.54. The Claimants did not utilise any of these remedies, maintaining in this proceeding that it was the Respondent's legal burden to prove that they could give the Claimants effective relief against the Import Alert.<sup>62</sup> In this connection, the Claimants also contended: "at the time the Import Alert was imposed, FDA repeatedly made clear that the only way Apotex could seek relief from the Import Alert was through re-inspection."<sup>63</sup>

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<sup>61</sup> *Id.*, Para. 474.

<sup>62</sup> Apotex Reply, Para. 461.

<sup>63</sup> *Id.*, Para. 462.

- 9.55. The Tribunal heard detailed and sharply conflicting expert testimony from the Parties' legal experts (Mr. Bradshaw and Mr. Vodra), both highly qualified and prominent US lawyers with extensive experience in FDA matters, regarding the Claimants' ability to gain relief through the administrative procedures set out in the FDA's regulations. The Respondent's legal expert (Mr. Vodra) contended that these procedures provided credible avenues for the Claimants to seek relief had there been legally improper or unjustified agency action. The Claimants' expert (Mr. Bradshaw) argued that the Claimants could not secure relief because it lay in the FDA's discretion or because the reviewing party would not be independent but would instead be the official making the original decision or that official's supervisor.
- 9.56. At the Hearing, the Claimants also urged that an administrative appeal to the FDA would not be an effective remedy under the International Court of Justice's judgment in *Diallo*, which was said to show that an appeal to the agency that made a contested administrative decision cannot be an effective remedy in international law.<sup>64</sup> The Tribunal considers this misapprehends the ICJ's decision. *Diallo* found that an appeal to a decision maker to reverse a decision "as an act of grace" is not a local remedy that must be exhausted under international law. However, administrative remedies must be pursued for purposes of the exhaustion of remedies rule "if they are aimed at vindicating a right and not at obtaining a favour."<sup>65</sup> The Claimants' pursuit of administrative remedies under the FDA's regulations would not be to seek the agency's "grace", but because they would seek to show that the FDA's action was legally or factually incorrect.
- 9.57. *Diallo* involved whether Guinea satisfied the customary law requirement of exhaustion of remedies for its exercise of diplomatic protection, not the international law minimum standard. While the context is different, the case is instructive here. In *Diallo*, the ICJ found it "incumbent on the applicant to prove that local remedies were indeed exhausted or to establish that exceptional circumstances relieved the allegedly injured person ... of the obligation to exhaust available local remedies. ... It is for the respondent to convince the Court that there

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<sup>64</sup> *Id.*, Para. 459 (at the Hearing, see for the Claimants, TD2.508-509; and for the Respondent, see TD5.1508).

<sup>65</sup> *Ahmadou Sadio Diallo (Republic of Guinea v. Democratic Republic of the Congo)*, 2007 I.C.J. Reports, p. 582 (24 May 2007), Para. 47.

were effective remedies in its domestic legal system that were not exhausted.”<sup>66</sup> (The ICJ found that the Democratic Republic of the Congo did not prove that it offered an effective remedy where its law expressly provided that refusals of entry into the country “shall not be subject to appeal.”<sup>67</sup>)

9.58. The Tribunal has carefully weighed the Parties’ conflicting assessments of the administrative remedies available to the Claimants in regard to the Import Alert. It finds that the evidence sufficiently establishes that remedies were available to the Claimants (particularly Apotex Inc. and Apotex-US) to challenge a legally or factually unwarranted regulatory decision by the FDA. The evidence does not establish that there were any “exceptional circumstances” justifying a decision by the Claimants not to pursue those remedies. The evidence shows that the Claimants were (and remain) a sophisticated international corporate organisation that makes vigorous use of legal proceedings (with specialist legal and other advisers) as part of its business model.<sup>68</sup> Yet, the Claimants made no effort to utilise any of the FDA’s administrative procedures to contest the FDA’s findings of cGMP deficiencies, as they could have done had they believed that those findings involved factual or legal error. The Tribunal concludes from the evidence that, at the time, the Claimants held no such belief.

9.59. In this connection, the Tribunal notes that the evidential record indicates that the Claimants were at the time well aware of shortcomings in their manufacturing facilities and processes at the Signet and Etobicoke facilities. The Tribunal also notes that the Claimants’ Request states that: “Apotex-Canada [Apotex Inc.] rejected FDA’s suggestion that its facilities were not compliant with cGMP.”<sup>69</sup> Likewise, certain of the Claimants’ written witness statements prepared for purposes of this arbitration maintain that the FDA’s action was not justified. However, no contemporaneous evidence to this effect was identified to the Tribunal.

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<sup>66</sup> *Id.*, Para. 44.

<sup>67</sup> *Id.*, Para. 48.

<sup>68</sup> Apotex Memorial, Para. 41. (“Apotex-US operates under a specific business model, designed to identify new business opportunities and open up the US market of generic drugs through litigation in the US. To that end, Apotex spends USD 50 million every year in attorney’s fees in the US” (footnote omitted)).

<sup>69</sup> Apotex Request, Para. 43.

9.60. To the contrary, there is substantial evidence indicating that at the time of the Import Alert, the Claimants recognised material deficiencies at both the Signet and Etobicoke facilities. Apotex Inc.'s own minutes of the conference-call with the FDA on 17 August 2009 (after the Signet inspection) record that Apotex Inc.'s Vice President for Quality twice acknowledged "deficiencies."<sup>70</sup> Perhaps most telling, the executive summary of the Claimants' quality consultants' report presented to the FDA at the meeting in March 2010 confirmed the correctness of key FDA findings and the need for the Claimants to improve their quality systems.<sup>71</sup> The FDA's minutes of that meeting record Apotex Inc.'s president and chief operating officer as saying that Apotex "knows their current state of operations and will rectify the issues of concern to get the company on the right track." At the same meeting, a senior Apotex officer "stated that Apotex needs to look at their Quality System. Apotex has hired 250 [full-time equivalents] to address their quality issues."<sup>72</sup> The Claimants adopted extensive remedial measures and spent millions of US dollars to improve their quality control systems at the Signet and Etobicoke facilities, taking almost a year before even requesting re-inspection of these two facilities by the FDA.<sup>73</sup> Health Canada did not find Apotex's corrective action plan acceptable until December 2010.<sup>74</sup> Last but not least, the Claimants do not formally dispute the correctness of the FDA's findings of cGMP violations in this arbitration. According to the Claimants, their claims "do not put into issue whether or not FDA erred in its observations and conclusions regarding cGMP."<sup>75</sup>

9.61. This record cannot be reconciled with the proposition that the Claimants in fact rejected the FDA's findings of cGMP violations at the time. It is only consistent with the conclusion that the Claimants did not pursue administrative relief because they decided that doing so would be unavailing because there was a sufficient

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<sup>70</sup> Meeting Minutes – FDA Conference Call, 17 August 2009 (Exhibit R-043).

<sup>71</sup> Executive Summary, Jeff Yuen & Associates Inc. Report (Exhibit C-137). ("Recent quality systems assessments confirmed that system level improvements were needed for all six systems. The [consultants'] quality system assessment was consistent with recent FDA inspectional observations and the recent Warning Letter citations with respect to three systems in particular: Quality Systems, Laboratory Systems, and Production/Packaging & Labeling Control Systems.")

<sup>72</sup> FDA minutes of 31 March 2010 Apotex-FDA meeting (Exhibit R-054).

<sup>73</sup> Witness Statement of Bruce D. Clark, Para. 53.

<sup>74</sup> Exhibit C-184.

<sup>75</sup> Apotex Reply, Para. 40.

factual and legal basis for the FDA’s action, and not because the available remedies were ineffectual.

9.62. Finally, the Claimants did not contest the FDA’s actions in the US courts. They submit that they could not do so,<sup>76</sup> citing the position taken by the FDA in domestic litigation that imposing an import alert is not a final agency action subject to judicial review. The Respondent submits that the Claimants could have brought suit against the FDA for unreasonable delay (in lifting the Import Alert), pointing out that the Claimants had previously filed such a suit against the FDA in another setting.<sup>77</sup> Further, the Respondent submits that the Claimants could have brought suit to challenge the Import Alert itself, observing that while the FDA believes that decisions to impose an Import Alert are not judicially reviewable, US courts are not bound to this view and that some US courts have rejected the FDA’s position in analogous settings.<sup>78</sup>

9.63. The Tribunal notes that in *Bellarno*,<sup>79</sup> the US District Court ruled that the FDA acted unlawfully in imposing an import alert barring the plaintiff’s reimport into the USA of certain pharmaceuticals, rejecting the FDA’s argument that imposing the Import Alert was not judicially reviewable. While the FDA subsequently modified the terms of its import alerts (as described in Part VIII above), *Bellarno* and other like US cases<sup>80</sup> indicate that US courts do not feel bound to defer to the FDA’s views that its actions involving imports are not judicially reviewable. The Tribunal also notes that whilst the Import Alert was in effect, the Claimants’ lawyers twice threatened to bring suit against the FDA in the USA, suggesting that they saw recourse to US courts as an available avenue of relief.<sup>81</sup>

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<sup>76</sup> Apotex Memorial, Para. 476.

<sup>77</sup> USA Rejoinder, Para. 363 (fn 827).

<sup>78</sup> *Id.*, Para. 364.

<sup>79</sup> *Bellarno International Ltd v. FDA*, *supra*.

<sup>80</sup> *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62 (D.D.C. 2010) (14 January 2010), 69 (n.8). (“FDA might well be entitled to *Chevron* deference on this threshold legal question, but it is certainly not entitled to *unreviewable* discretion.” (emphasis in original)); *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010) (2011) (7 December 2010). (US District Court enjoined FDA from prohibiting imports of electronic cigarettes, rejecting FDA’s claim that import decisions are committed to its discretion and are not judicially reviewable.); *Cook v. FDA*, No. 12-5176, 2013 U.S. App. LEXIS 14883 (D.C. Cir.) (23 July 2013), rejecting the FDA’s argument that its decision not to take enforcement action to bar imports of drugs used by states for lethal inspections was not subject to judicial review.

<sup>81</sup> Exhibits R-194 and R-201; *see also* USA Rejoinder, Para. 365.

9.64. In light of all the evidence, the Tribunal cannot conclude, as the Claimants assert, that it would have been futile for the Claimants to seek relief in the US courts to contest the FDA's actions if the FDA had indeed been acting improperly and that the Claimants were justified in not pursuing any such legal remedy.

9.65. Given the overall record, including the Claimants' decisions not to pursue either administrative or judicial remedies to contest the FDA's allegedly improper action in imposing the Import Alert, the Tribunal decides that the Claimants have failed to establish that the Respondent's conduct rose to the threshold of severity and gravity required to establish a violation of NAFTA Article 1105, even assuming that such protection extends beyond an investment to the treatment of an investor.

**(5) *The Jamaica-USA BIT***

9.66. In the Tribunal's view, the Jamaica-USA BIT does not assist the Claimants' case. This part of the Claimants' claim raises many of the same matters already addressed by the Tribunal under NAFTA Article 1105(1) above; and, in the circumstances, it suffices here to address only other relevant matters. Accordingly, the Tribunal addresses below the Claimants' principal argument based on "effective means" under Article II(6) of the BIT. Given its earlier decisions, the Claimants' subsidiary argument based on impairment under Article II(2)(b) of the BIT fails on the facts found by the Tribunal. There was in this case no unreasonable or discriminatory wrongdoing by the Respondent in regard to any the Claimants' actual or alleged investments from the "violation of the most elementary due process rules" (as alleged by the Claimants);<sup>82</sup> and accordingly the Tribunal rejects this subsidiary argument.

9.67. In summary, the Claimants contend that Article II(6) of the BIT provides more favourable treatment for both investors and investments than NAFTA Article 1105(1) because this provision establishes (via the MFN wording in NAFTA Article 1103 and independently from customary international law) an obligation upon the Respondent towards the Claimants to provide "effective means" for asserting claims and enforcing rights; and the Claimants further contend that such means are not limited to judicial or adjudicatory proceedings but include also (because these are

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<sup>82</sup> Apotex Memorial, Para. 486.

not excluded) administrative decision-making by the Respondent, such as the FDA's decision to impose the Import Alert on products manufactured at the Signet and Etobicoke facilities.<sup>83</sup> The Claimants submit that the evidence proves that the Claimants were not accorded effective means by the Respondent because "Apotex had no way to challenge the Import Alert."<sup>84</sup>

- 9.68. In summary, the Respondent contends the Claimants cannot establish that they would have received, nor would any comparator, better treatment under Article II(6) of the BIT than under NAFTA Article 1105(1). Further, according to the Respondent, Article II(6) of the BIT on "effective means" does not import the procedural rights here asserted by the Claimants because this provision is limited to adjudicatory proceedings "where claims can be asserted and rights can be enforced."<sup>85</sup>
- 9.69. The Respondent submits that this interpretation is supported both by the plain meaning of the provision's wording and by its drafting history, as recounted by Professor Vandavelde. As to the former, the Respondent submits that the text speaks for itself; and that no decision or award supports the Claimants' interpretation. As to the latter, Professor Vandavelde states that this "effective means" provision in US bilateral investment treaties derives originally from judicial access provisions in the Respondent's Friendship, Commerce and Navigation Treaties.<sup>86</sup> Hence, so the Respondent concludes, the wording cannot bear the much broader interpretation here asserted by the Claimants.
- 9.70. In the Tribunal's view, this part of the Claimants' case can be decided shortly. The Tribunal determines that the plain meaning of Article II(6) of Jamaica-USA BIT, interpreted under international law (as codified in Article 31 of the Vienna Convention on the Law of Treaties) does not apply to non-adjudicatory proceedings, such as the administrative decision of the FDA as a regulator on the Import Alert of

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<sup>83</sup> TD2.529; *see also* Apotex Memorial, Paras. 482-483; and Apotex Reply, Paras. 518ff.

<sup>84</sup> TD2.530. The Claimants also refer to *Chevron Corporation (USA) and Texaco Petroleum Company (USA) v. The Republic of Ecuador*, UNCITRAL, PCA Case No. 34877, Partial Award (30 March 2010), Para. 242; and *White Industries Australia Limited v. Republic of India*, UNCITRAL, Award (30 November 2011), Para. 11.3.3.

<sup>85</sup> TD5.1524; *see also* USA Counter-Memorial, Paras. 383ff and USA Rejoinder, Paras. 368ff.

<sup>86</sup> Vandavelde, Kenneth, *U.S. International Investment Agreements* (2009), at pp. 411-412. The Respondent also refers to *Duke Energy Electroquil Partners and Electroquil, S.A. v. Republic of Ecuador*, ICSID Case No. ARB/04/19, Award (18 August 2008), Para. 391.



28 August 2009. The wording “asserting claims and enforcing rights” is the language of adjudicatory proceedings. It is not the language of non-adjudicatory administrative decision-making, such as the FDA’s decision regarding the Import Alert; and if it had been intended by the BIT’s Contracting Parties to bear this broader meaning, it would have been necessary to add further unambiguous wording.

9.71. In the circumstances, the Tribunal does not decide whether or not the MFN provision in NAFTA Article 1103 can modify the content of NAFTA Article 1105(1). The Respondent submitted that all three NAFTA Parties are unanimously agreed that it cannot;<sup>87</sup> but whether the NAFTA Parties are correct will have to await the decision of another NAFTA tribunal.

**(6) *Conclusion***

9.72. Accordingly, for these reasons, the Tribunal dismisses, on the merits as to liability all claims under NAFTA Article 1105(1), NAFTA Article 1103 and Article II(2)(b) and (6) of the Jamaica-USA BIT made in this proceeding by Apotex-Holdings (for itself and for Apotex-US). Although the Tribunal has upheld the Respondent’s jurisdictional objections against Apotex Inc. in Part VII above, it can be assumed that the same result on the merits would have followed for Apotex Inc. if the Tribunal had assumed jurisdiction over its separate claims under these provisions. Moreover, this overall result avoids a potential issue with regard to the Claimants’ different claims, namely whether a violation based upon any want of due process (as argued by the Claimants) could succeed collectively if only one and not all of the three claiming entities was affected by any relevant procedural deficiency.

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<sup>87</sup> USA Counter-Memorial, Para. 389.

## ***PART X – LEGAL AND ARBITRATION COSTS***

### **(1) *Introduction***

- 10.1. The Tribunal here addresses the fifth and last principal issue, namely the Parties' respective claims for legal and arbitration costs under Article 58(1) of the ICSID Arbitration AF Rules, to be considered in the current phase of this arbitration together with Paragraph 12 of the Tribunal's Procedural Order deciding Bifurcation and Non-Bifurcation dated 25 January 2013 (the "Order").
- 10.2. Article 58(1) of the ICSID Arbitration AF Rules provides: "Unless the parties otherwise agree, the Tribunal shall decide how and by whom the fees and expenses of the members of the Tribunal, the expenses and charges of the Secretariat and the expenses incurred by the parties in connection with the proceeding shall be borne. The Tribunal may, to that end, call on the Secretariat and the parties to provide it with the information it needs in order to formulate the division of the cost of the proceeding between the parties."
- 10.3. Paragraph 12 of the Order provides: "As to additional costs borne by the Respondent in addressing liability issues (when it could succeed on the jurisdictional issues), the Tribunal here confirms that it would be minded to apply in this case the 'loser pays' principle in allocating legal and arbitration costs to reflect that event and not leave costs where they lay under Article 58 of the ICSID Arbitration (Additional Facility) Rules. It is also assumed that the Claimants would honour such an award for costs in favour of the Respondent pursuant to Article 52(4) of the ICSID Arbitration (Additional Facility) Rules."
- 10.4. From the Parties' respective submissions on costs (summarised below), the Tribunal understands that it is common ground between the Parties that the Tribunal should exercise its discretion under Article 58(1) as to legal and arbitration costs by reference to this "loser pays" principle.
- 10.5. The Tribunal recognises that this issue concerns significant amounts: (i) for the Claimants: US\$ 774,931 and EUR 5,088,387; and (ii) for the Respondent: US\$ 1,572,584.

(2) *The Claimants' Submissions*

- 10.6. In accordance with the Tribunal's procedural orders made at the Hearing, the Claimants filed their first submission on costs on 17 January 2014 (the "Apotex Costs Submission"). In summary, the Claimants submit that, in the event that they are successful on jurisdiction and liability, the Tribunal should either (i) reserve its decision on costs for the eventual award in this arbitration; or (ii) determine costs in favour of the Claimants for this first bifurcated phase of the arbitration, with that determination to be recorded in the eventual award issued at the end of the next and final phase of the arbitration.<sup>1</sup>
- 10.7. As to (i), the Claimants record that they had previously requested that the Tribunal follow this course and to reserve its decision on costs until the next and final phase of the arbitration.<sup>2</sup> The Claimants confirm that they remain content with this approach.<sup>3</sup>
- 10.8. As to (ii), the Claimants contend that, should the Claimants be held successful on jurisdiction and liability (thereby requiring a further phase), the Tribunal cannot issue an award on costs at this first stage of the arbitration.<sup>4</sup> The Claimants recognise that costs decisions of the Tribunal must form a part of its eventual award ending the arbitration (which would necessarily occur at a later date should the Tribunal now decide in favour of the Claimants regarding jurisdiction and liability). Under the ICSID Arbitration AF Rules (as the Tribunal also recognises), there can be only one award; and there can be no interim or partial awards.<sup>5</sup> However, the Claimants also submit that nothing prevents the Tribunal (should it be so inclined at this first stage) from now assessing what legal costs have been incurred and how the Tribunal is inclined to allocate such costs in its eventual award.<sup>6</sup>
- 10.9. As to the relevant principles to be applied in allocating costs under Article 58(1) of the ICSID Arbitration AF Rules, the Claimants refer to the statement made by the Tribunal in its Order rejecting the Respondent's Request for Bifurcation: "... the

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<sup>1</sup> Apotex Costs Submission, Paras. 1 and 12.

<sup>2</sup> *Id.*, Para. 2, citing the Apotex Reply and certain demonstrative exhibits referred to at the Hearing.

<sup>3</sup> *Id.*, Para. 3.

<sup>4</sup> *Id.*, Para. 7.

<sup>5</sup> *Id.*, Para. 6, citing Article 58(2) of the ICSID Arbitration AF Rules.

<sup>6</sup> *Id.*, Para. 7.

Tribunal ... confirms that it would be minded to apply in this case the ‘loser pays’ principle in allocating legal and arbitration costs to reflect that event and not leave costs where they lay under Article 58 of the ICSID Arbitration (Additional Facility) Rules.”<sup>7</sup> (The Tribunal cites this Order more fully above). In the event that they are successful, the Claimants submit that the Tribunal should adopt this approach.<sup>8</sup>

10.10. The Claimants claim the following arbitration and legal costs for this first phase of the arbitration: (i) the charges for the use of the facilities and expenses of the ICSID Secretariat and the Tribunal’s fees and expenses (this item is here called by the Tribunal “Arbitration Costs”); (ii) the cost of external legal representation; (iii) fees paid by the Claimants to their expert witnesses in relation to this first phase; and (iv) the expenses incurred by the Claimants in connection with the arbitration, including travel and accommodation expenses in relation to the Hearing (these last three items are here collectively called by the Tribunal “Legal Costs”).<sup>9</sup>

10.11. The Arbitration and Legal Costs originally claimed by the Claimants are as follows:<sup>10</sup>

ICSID Lodging Fee	US\$ 25,000
Advances on Arbitration Costs	US\$ 350,000
Dentons’ legal fees and disbursements	EUR 5,064,491
Fees paid to their expert witness, Mr. Bradshaw	US\$ 250,450
Fees paid to their expert witness, Mr. Johnson	US\$ 112,205
Costs paid for accommodation for the Hearing	US\$ 37,276
Totals	US\$ 774,931 and EUR 5,064,491

10.12. The Claimants submit that the amounts of their Legal Costs are reasonable and proportionate to the issues in dispute, the claims made by the Claimants, the

<sup>7</sup> *Id.*, Para. 8, citing the Tribunal’s Order Para. 12.

<sup>8</sup> *Id.*, Para. 8. The Claimants record that an increasing number of ICSID tribunals have taken this same approach (Apotex Costs Submission, Para. 8, at fn 9).

<sup>9</sup> *Id.*, Para. 9. The Claimants note that, as damages will be heard in a subsequent phase of the arbitration should the Claimants prove successful at this stage, they have not included the fees and expenses of damages expert Howard N. Rosen in their submission. These will be included in their costs submission in the next phase (Apotex Costs Submission, Para. 4).

<sup>10</sup> The Claimants submit that the claimed costs are supported by the evidential record and the certified spreadsheets attached to their submission (Apotex Costs Submission, Para. 11).

Respondent's jurisdictional objections and the defences raised by the Respondent on the merits of the Claimants' claims (as to liability).<sup>11</sup> The Claimants note that their costs amount to less than one per cent of the quantum of compensation in dispute between the Parties in this arbitration.<sup>12</sup>

10.13. In accordance with the Tribunal's procedural orders at the Hearing, the Claimants filed a second costs submission on 7 February 2014 (the "Apotex Second Costs Submission").

10.14. In summary, in this second submission the Claimants do not object to the reasonableness of the costs claimed by the Respondent in its costs submission or to the method of their calculation (summarised below).<sup>13</sup> The Claimants also note that the Parties are in agreement that the 'loser pays' principle should be applied in this arbitration.<sup>14</sup> However, the Claimants disagree with the Respondent's suggestion that the Respondent's jurisdictional suggestions are meritorious and that a full bifurcated arbitration, as between jurisdiction and all merits, would have been more efficient.<sup>15</sup> The Claimants also contend that it is beside the point whether a bifurcated arbitration would have been more efficient, as should the Respondent's jurisdictional objections succeed in this arbitration, the Respondent would in any event be entitled to its costs under the 'loser pays' principle.<sup>16</sup>

10.15. As to the inefficiencies suggested by the Respondent of a combined hearing on jurisdiction and the merits (as to liability), the Claimants submit that much of the testimony heard at the Hearing was relevant both to liability and jurisdiction.<sup>17</sup> The Claimants also submit that the Respondent declined to call any of the eight witnesses tendered by the Claimants, a possibility which had not been raised by the Respondent at the time when the Parties were considering bifurcation with the

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<sup>11</sup> *Id.*, Para. 10. (As explained below, these amounts were subsequently revised upwards by the Claimants).

<sup>12</sup> *Id.*, Para. 10.

<sup>13</sup> Apotex Second Costs Submission, Paras. 1, 9.

<sup>14</sup> *Id.*, Paras. 1-2.

<sup>15</sup> *Id.*, Paras. 1, 3-8.

<sup>16</sup> *Id.*, Para. 4.

<sup>17</sup> *Id.*, Para. 7.

Tribunal.<sup>18</sup> The Claimants further contend that the bulk of the Respondent’s extensive document requests of the Claimants concerned jurisdictional issues.<sup>19</sup>

10.16. The Claimants revised their costs calculation to reflect their additional costs incurred in January 2014.<sup>20</sup> The only item affected by the revision is that of Dentons’ legal fees and disbursements.<sup>21</sup>

10.17. Accordingly, the total Legal and Arbitration Costs now claimed by the Claimants, as revised, are as follows:

ICSID Lodging Fee	US\$ 25,000
Advances on Arbitration Costs	US\$ 350,000
Dentons’ legal fees and disbursements	EUR 5,088,387
Fees paid to Mr. Bradshaw	US\$ 250,450
Fees paid to Mr. Johnson	US\$ 112,205
Costs paid for accommodation for the Hearing	US\$ 37,276
Revised Totals	US\$ 774,931 and EUR 5,088,387

10.18. As with their first costs submission, the Claimants again request that the Tribunal should either (i) reserve for the eventual award its decisions on costs for this first phase or (ii) determine the amount of costs in favour of the Claimants as regards this phase as US\$ 774,931 and EUR 5,088,387, with those amounts to be recorded in that eventual award.<sup>22</sup>

**(3) *The Respondent’s Submission***

10.19. The Respondent filed its submission on costs on 17 January 2014 (the “USA Costs Submission”). The Respondent submits that its Legal and Arbitration Costs should

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<sup>18</sup> *Id.*, Para. 6.

<sup>19</sup> *Id.*, Para. 8.

<sup>20</sup> *Id.*, Para. 10. In so doing, the Claimants refer to the discussion at the Hearing on this subject [TD7.1785-87].

<sup>21</sup> *Id.*, Para. 10. To support the Claimants’ revised costs claim, an updated certification of the spreadsheet for Dentons is attached to the Apotex Second Costs Submission as Annex C *bis*.

<sup>22</sup> *Id.*, Para. 12.

be borne in full by the Claimants, namely US\$ 1,572,584 in total (to be adjusted to account for the Tribunal's final assessment of Arbitration Costs).<sup>23</sup>

- 10.20. The Respondent submits that Article 58(1) of the ICSID Arbitration AF Rules confers a broad discretion on the Tribunal as to the allocation of Legal and Arbitration costs.<sup>24</sup> Like the Claimants, the Respondent submits that the Tribunal should apply the 'loser pays' principle.<sup>25</sup> The Respondent also contends that a costs award is especially warranted in this arbitration to compensate a respondent for having to defend a claim without any jurisdictional basis (assuming the Respondent's jurisdictional objections prevail before the Tribunal).<sup>26</sup>
- 10.21. The Respondent refers to two further reasons in submitting that the Tribunal should award costs in favour of the Respondent, namely: (i) the Respondent should never have been involved in this arbitration given the manifest lack of jurisdiction over the Claimants' claims and the lack of any merits in those claims;<sup>27</sup> and (ii) the Claimants required the Respondent to incur costs unnecessarily by refusing to agree to bifurcate the case in full, as between jurisdiction and all merits.<sup>28</sup>
- 10.22. In submitting that the Claimants' arguments against full bifurcation were not borne out at the Hearing (the Respondent in particular refers to the Claimants' argument that full bifurcation, instead of saving time or costs, would rather increase the cost of the proceedings<sup>29</sup>), the Respondent refers to the following factors: (i) witness testimony presented at the Hearing related solely to issues of liability; (ii) oral arguments on jurisdiction took "mere hours"; and (iii) the "vast bulk" of document production, witness statements and expert reports addressed issues of liability, not

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<sup>23</sup> USA Costs Submission, Paras. 1 and 25. In submitting that the Claimants should reimburse the Respondent in the claimed amount, the Respondent refers both to its reasons provided in its costs submission, and also those set out in previous submissions in the arbitration (USA Costs Submission, Paras. 1 and 25).

<sup>24</sup> *Id.*, Para. 5, citing *Gemplus S.A. et al. v. United Mexican States*, ICSID Cases No. ARB(AF)/04/3 & ARB(AF)/04/4, Award (16 June 2010), Paras. 17-21.

<sup>25</sup> *Id.*, Para. 4, relevantly citing *Gemplus v. Mexico*, *supra*, Paras. 17-22.

<sup>26</sup> *Id.*, Para. 4, citing *Europe Cement Investment and Trade S.A. v. Republic of Turkey*, ICSID Case No. ARB(AF)/07/2, Award (13 August 2009), Paras. 185-86.

<sup>27</sup> *Id.*, Para. 5, citing the *Apotex I & II Award*, Para. 342.

<sup>28</sup> *Id.*, Para. 5. At Paras. 5-8, the Respondent refers to its request of 21 September 2012 to the Tribunal to bifurcate the arbitration (as reiterated in its Counter-Memorial at Para. 401) and the Claimants' opposition to that request.

<sup>29</sup> *Id.*, Para. 7.

jurisdiction.<sup>30</sup> In light of these factors, the Respondent submits that significant procedural efficiencies and cost savings could have been obtained had the Claimants agreed to bifurcate the arbitration in full.<sup>31</sup>

10.23. The Respondent also refers to the Tribunal's statement in its Order that the Tribunal would be minded to apply the 'loser pays' principle in this case.<sup>32</sup> The Respondent submits that nothing has occurred since January 2013 that should alter the Tribunal's assumption that such principle should apply here.<sup>33</sup>

10.24. In accordance with Article 58(1) of the ICSID Arbitration AF Rules, the Respondent claims the following amounts as costs: (i) fees and expenses of the Members of the Tribunal and the expenses and charges of the ICSID Secretariat; and (ii) expenses incurred by the Respondent in connection with the arbitration. Those costs, totalling US\$ 1,572,584, are broken down as follows:<sup>34</sup>

1. *Arbitration Costs*: US\$ 350,000 in fees and expenses of the Members of the Tribunal and expenses and charges of the ICSID Secretariat; and
2. *Legal Costs*: US\$ 1,222,584.38 in other expenses incurred by the Respondent in connection with the arbitration, comprising:
  - i. US\$ 881,978 for attorney and paralegal costs, excluding travel;
  - ii. US\$ 333,366.80 for fees for expert consultants;<sup>35</sup> and
  - iii. US\$ 7,239.58 for attorney and witness travel.

10.25. The Respondent contends that the amounts claimed as Legal Costs are reasonable, considering the size and shifting nature of the Claimants' claims, the expansiveness

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<sup>30</sup> *Id.*, Para. 9.

<sup>31</sup> *Id.* In so submitting, the Respondent notes that Apotex Inc. had agreed to bifurcate in the Apotex I & II Arbitration.

<sup>32</sup> *Id.*, Para. 10.

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*, Para. 24. The amounts claimed by the Respondent are addressed in the following signed written witness statements filed together with the USA Costs Submission: (i) the Witness Statement of Mr. David M. Bigge dated 17 January 2014; (ii) the Witness Statement of Ms. Mary T. Reddy dated 16 January 2014; and (iii) the Witness Statement of Mr. Jeremy K. Sharpe dated 17 January 2014.

<sup>35</sup> The expert consultant fees comprise the fees paid by the Respondent for engaging the services of Navigant Consulting, Mr. William W. Vodra, and IEDiscovery (USA Costs Submission, Paras. 18-22).



of the Claimants' document production requests and the large number of submissions required from the Respondent.<sup>36</sup>

- 10.26. With respect to attorney and paralegal costs, the Respondent notes the established (and accepted<sup>37</sup>) method by which those costs are claimed by the Respondent in NAFTA Chapter Eleven disputes: namely, the relevant individuals' salaries are multiplied by the estimated percentage of attorney and paralegal time expended in the arbitration on an annual basis.<sup>38</sup> The Respondent submits that the resulting costs are conservative in three respects, namely: (a) the estimate does not include the time that a number of other US government attorneys, paralegals and other personnel devoted to this arbitration;<sup>39</sup> (b) the estimate does not include the time spent by administrative personnel on the arbitration;<sup>40</sup> and (c) the Respondent only claims for out-of-pocket costs for attorney and paralegal time, rather than the market value of such services.<sup>41</sup>
- 10.27. As already indicated in Part 1 above, the Respondent did not elect to file a second costs submission.

**(4) *The Tribunal's Analysis and Decisions***

- 10.28. In here deciding the issue between the Parties regarding Legal and Arbitration Costs, the Tribunal exercises its discretionary powers under ICSID Article 58(1) of the ICSID Arbitration AF Rules, together with the indication recorded in the Order on the "loser pays principle" (both fully cited above). Before addressing these costs, it is necessary to record several relevant circumstances.
- 10.29. First, by its Order, the Tribunal ordered bifurcation as between (i) a first phase on jurisdiction and liability and (ii) subject to a decision on jurisdiction and liability, a second and final phase on the remaining part of the Parties' dispute (principally

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<sup>36</sup> USA Costs Submission, Para. 1.

<sup>37</sup> In support, the Respondent cites the Apotex I & II Award, Para. 348.

<sup>38</sup> USA Costs Submission, Para. 13. This estimation and salary information is provided, respectively, in the Witness Statement of Mr. Sharpe, Para. 5 and the Witness Statement of Ms. Reddy, Para. 5. The calculation of estimated percentage of annual time expended multiplied by salary is provided in Mr. Sharpe's Witness Statement dated 17 January 2014, Para. 6.

<sup>39</sup> USA Costs Submission, Para. 15; Witness Statement of Mr. Sharpe, Paras. 7-9.

<sup>40</sup> USA Costs Submission, Para. 16; Witness Statement of Mr. Sharpe, Para. 10.

<sup>41</sup> USA Costs Submission, Para. 17; Witness Statement of Mr. Sharpe, Para. 11; Witness Statement of Ms. Reddy, Para. 2.

quantum). In the Tribunal's view, that mixed approach was justified during the conduct of this first phase (including the Hearing), as a matter of efficiency, cost-saving and overall procedural fairness for all Parties. Accordingly, the Tribunal does not accept the criticisms made by the Respondent of the Claimants in regard to their objection to the Respondent's request for full bifurcation (as between jurisdiction and all merits). Full bifurcation would have required at least two successive written and oral phases, with the second addressing the merits of the claims made by Apotex-Holdings (for itself and for Apotex-US) falling within the jurisdiction of this Tribunal, as the Tribunal has here decided. Full bifurcation would therefore have been less efficient, more costly and a much longer proceeding.

- 10.30. Second, whilst the overall end-result of this arbitration's bifurcated first phase may be regarded as favourable to the Respondent and unfavourable to the Claimants, the position is mixed regarding separate issues on jurisdiction and liability. As decided above, the Respondent prevailed on its jurisdictional objections to all claims regarding ANDAs based on its introduction into this arbitration of the Apotex I & II Award with the Respondent's Rejoinder (six months after the Tribunal's Order); but the Respondent did not prevail on its jurisdictional objections regarding other claims made by Apotex-Holdings (for itself or for Apotex-US). On the other hand, as to liability on the merits, the Respondent prevailed on all such claims made by Apotex-Holdings (for itself and for Apotex-US).
- 10.31. Third, the Parties have treated the Claimants, as regards costs, as one entity without distinguishing between the First and Second Claimants as claiming or responding parties. Given the Claimants' joint legal representation and joint conduct of the arbitration, the Tribunal is content to adopt the same approach in deciding the issue of Legal and Arbitration Costs.
- 10.32. Fourth, for what was always a complicated and difficult arbitration with very large amounts at stake and significant issues of general importance, the Tribunal decides that the amounts claimed by the Parties respectively as Legal Costs are reasonable in amount and were reasonably incurred by the Parties for this arbitration.

- 10.33. Lastly, the Tribunal recognises that its discretion regarding costs falls into two distinct parts regarding Legal Costs and Arbitration Costs respectively. It is therefore appropriate to address these costs separately, in turn.
- 10.34. *Legal Costs*: In the circumstances, with regard to the principle “loser pays” and taking into account its decision as to Arbitration Costs below, the Tribunal orders the Claimants to bear and pay to the Respondent its Legal Costs in the total amount of US\$ 1,222,584.38.
- 10.35. *Arbitration Costs*: In the circumstances, with regard also to the principle “loser pays” and taking into account its decisions to different effect as to jurisdiction, the Tribunal orders the Claimants (as between the Claimants and the Respondent) to bear and pay 75% of the Arbitration Costs with 25% to be borne and paid by the Respondent. The final amount of such Arbitration Costs (to which these percentages are applicable) shall be calculated by the ICSID Secretariat as soon as practicable and notified in writing to the Parties pursuant to Article 58(1), last sentence, of the ICSID Arbitration AF Rules.

## ***PART XI – THE TRIBUNAL’S SUMMARY***

- 11.1. *Introduction:* The Tribunal here summarises its several decisions in Parts III to X by specific reference to the Parties’ respective formal claims for relief set out earlier in Part I above.
- 11.2. *The Claimants’ Claims:* The First and Second Claimants, Apotex-Holdings and Apotex Inc., by their Request (paragraph 89), request an award in their favour, for themselves and (as regards the First Claimant) also on behalf of Apotex-US, in the terms there specified pursuant to NAFTA Articles 1116(1) and 1117(1), as re-stated in their Memorial (paragraph 572), their Reply (paragraph 532) and their Rejoinder on Jurisdiction (paragraph 127).
- 11.3. *The Tribunal’s Summary:* By virtue of the Apotex I & II Award operating as *res judicata* between the Claimants and the Respondent, the Tribunal (by a majority) dismisses for want of jurisdiction all Claims by Apotex Inc. and all Claims made by Apotex-Holdings as regards ANDAs under Article 45 of the ICSID Arbitration AF Rules. The Tribunal otherwise dismisses all other jurisdictional objections made by the Respondent.
- 11.4. As regards claims within its jurisdiction, the Tribunal dismisses on their merits (as to liability) all other Claims made by Apotex-Holdings (for itself and on behalf of Apotex-US) under NAFTA Articles 1116(1) and 1117(1).
- 11.5. (i) *The Claimants’ Request:* Section V, Para. 89 (pages 19-20) states: “As a result of the actions and breaches of the Government of the United States of America described above, the Claimants, on behalf of Apotex-US and on their own behalf, respectfully intend to request an award in their favour:
- (a) Finding that the United States of America has breached its obligations under the NAFTA;
  - (b) Directing the United States of America to pay damages in an amount to be proven at the hearing but which the Claimants presently estimate to be in the hundreds of millions of US dollars;

- (c) Directing the United States of America to pay interest on all sums awarded;
- (d) Directing the United States of America to pay the Claimants' costs associated with these proceedings, including professional fees and disbursements;
- (e) Ordering such other and further relief as the Tribunal deems appropriate in the circumstances."

11.6. *The Tribunal's Summary:* As summarised above, the Tribunal dismisses these Claims (a) to (c) as to jurisdiction (based on ANDAs) and otherwise on the merits (as to liability), as summarised above. The Tribunal dismisses Claims (d) and (e).

11.7. (ii) *The Claimants' Memorial:* Paragraph 572 (page 171) states: "As a result of the actions and breaches of the Government of the United States of America described above, the Claimants respectfully intend to request an award in their favour:

- (a) Declaring that the United States of America has breached its obligations under Articles 1102, 1103 and 1105 of the NAFTA;
- (b) Ordering the United States of America to pay damages in an amount to be proven at the hearing but which the Claimants presently estimate to be in the hundreds of millions of US dollars, including pre-award interest;
- (c) Ordering the United States of America to pay the Claimants' interest and taxes on all sums awarded;
- (d) Ordering the United States of America to pay the Claimants' costs associated with these proceedings, including professional fees and disbursements;
- (e) Ordering such other and further relief as the Tribunal deems appropriate in the circumstances."

11.8. *The Tribunal's Summary:* As summarised above, the Tribunal dismisses these Claims (a) to (c), as to jurisdiction (based on ANDAs) and otherwise on the merits (as to liability). The Tribunal dismisses Claims (d) and (e).

- 11.9. (iii) *The Claimants' Reply*: Paragraph 532 (page 179) states: "As a result of the actions and breaches of the Government of the United States of America described above, the Claimants respectfully request a decision in their favour:
- (a) Dismissing the US jurisdictional objections;
  - (b) Declaring that the United States of America has breached its obligations under Articles 1102, 1103 and 1105 of the NAFTA;
  - (c) Ordering that the Claimants' claims to damages and interest be addressed in the subsequent phase of this arbitration, and decided in the final award;
  - (d) Reserving decision on Claimants' request for an award of costs, including professional fees and disbursements, until the next phase of this arbitration;
  - (e) Ordering such other and further relief as the Tribunal deems appropriate in the circumstances."
- 11.10. *The Tribunal's Summary*: As to Claim (a), as summarised above, the Tribunal dismisses the Respondent's jurisdictional objections to the claims made by Apotex-Holdings (for itself and for Apotex-US) in regard to Claims not based on ANDAs; but the Tribunal otherwise dismisses the Claimants' Claim (a). As to Claim (b), on the merits as to liability, the Tribunal dismisses these Claims by Apotex-Holdings (for itself and for Apotex-US). The Tribunal dismisses Claims (c), (d) and (e).
- 11.11. (iv) *The Claimants' Rejoinder on Jurisdiction*: Paragraph 127 (page 47) states: "For the foregoing reasons and those set out in its previous submissions, claimants [Apotex-Holdings] and [Apotex Inc.] respectfully submit that the US objections to jurisdiction should be dismissed ... and a decision entered in accordance with the submissions set out at paragraph 532 of the Apotex Reply."
- 11.12. *The Tribunal's Summary*: As summarised above, the Tribunal dismisses the Respondent's jurisdictional objections to the Claims made by Apotex-Holdings for itself and for Apotex-US in regard to Claims not based on ANDAs. To that extent, the Tribunal accepts the Claimants' Claim; but otherwise this Claim is dismissed.

11.13. *The Respondent*: The Respondent, by its Counter-Memorial (Paragraph 402, page 204), requests an award from the Tribunal:

- (1) Upholding the Respondent's jurisdictional objections; and/or
- (2) Dismissing the Claimants' claims in their entirety and with prejudice; and
- (3) Ordering that the Claimants bear the costs of these proceedings, including the Respondent's costs for legal representation and assistance.

This claim for relief was re-stated in the Respondent's Rejoinder to like effect (Paragraph 378, page 192).

11.14. *The Tribunal's Summary*: As regards Claim (1), as summarised above, the Tribunal upholds the Respondent's jurisdictional objections to all Claims made by Apotex Inc.; but the Tribunal dismisses the Respondent's jurisdictional objections to the Claims made by Apotex-Holdings (for itself and for Apotex-US) not based on ANDAs.

11.15. As regards Claim (2), the Tribunal dismisses on their merits, as to liability, all Claims not based on ANDAs made by Apotex-Holdings (for itself and on behalf of Apotex-US) under NAFTA Articles 1116(1) and 1117(1).

11.16. As regards Claim (3), the Tribunal orders the Claimants to pay the Respondent's Legal Costs in the total sum of US\$ 1,222,584.38; and as regards Arbitration Costs, the Tribunal orders the Respondent to bear and pay 25% and the Claimants to bear and pay 75% of such Arbitration Costs, as calculated by the ICSID Secretariat.

11.17. *Operative Part*: These summaries should be read with the other Parts of this Award and, in particular, the Operative Part XII below.

## ***PART XII – THE OPERATIVE PART***

12.1. For the reasons set out above, the Tribunal finally decides and awards as follows:

- (1) *Jurisdiction and Res Judicata*: The Tribunal upholds the Respondent’s jurisdictional objections against all claims made by the First and Second Claimants under NAFTA’s Chapter Eleven as regards approved abbreviated new drug applications (“ANDAs”), pursuant to Article 45 of the ICSID Arbitration (Additional Facility) Rules, on the grounds that, by reason of the Apotex I & II Award of 14 June 2013 operating as *res judicata* between the Respondent and the Claimants, such claims are not within the jurisdiction (“competence”) of the Tribunal in this arbitration;
- (2) *Other Jurisdictional Objections*: Save as ordered in the preceding paragraph, the Tribunal dismisses all other jurisdictional objections made by the Respondent in this arbitration and assumes jurisdiction to decide all other claims made by the First Claimant (for itself and Apotex Corp.), *i.e.* all claims other than ANDAs;
- (3) *Merits (Liability)*: The Tribunal dismisses on their merits as to liability all claims (other than ANDAs) made against the Respondent by the First Claimant (both for itself and for Apotex Corp.) under NAFTA’s Chapter Eleven and the Jamaica-USA bilateral investment treaty;
- (4) *Arbitration Costs*: The First and Second Claimants shall bear under Article 58(1) of the ICSID Arbitration (Additional Facility) Rules, 75% of all arbitration costs of this arbitration and the Respondent shall bear 25% of such arbitration costs (namely the fees and expenses of the members of the Tribunal and the expenses and charges of the Secretariat), in amounts to be separately confirmed by letter to the Parties from the ICSID Secretariat; and to the extent necessary, the Claimants shall reimburse the Respondent for any arbitration costs paid by the Respondent exceeding its said percentage share;



- (5) *Legal Costs*: The First and Second Claimants shall pay to the Respondent, under Article 58(1) of the ICSID Arbitration (Additional Facility) Rules, the total amount of US\$ 1,222,584.38 for the Respondent's legal costs (namely, the expenses incurred by the Respondent in connection with the arbitration); and
- (6) Save as ordered above, all other claims made the Parties in this arbitration are dismissed.

**LEGAL PLACE OF ARBITRATION:**

**New York, New York, United States of America.**

**SIGNED BY THE TRIBUNAL:**

[Signed]

**J. William Rowley:**

**(dissenting, as indicated, from Appendix A to Part I, Part VII and Paragraph 12.1(1) of this Award)**

**Date: 25 August 2014**

[Signed]

**John Crook:**

**Date: 25 August 2014**

[Signed]

**V.V.Veeder:**

**Date: 25 August 2014**