

# Public Version

**In The Matter Of Two Arbitrations Under Chapter 11 Of The NAFTA  
And The UNCITRAL Arbitration Rules (1976)**

**B e t w e e n:**

**APOTEX INC.**

**Claimant**

**– and –**

**THE GOVERNMENT OF THE UNITED STATES OF AMERICA**

**Respondent**

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**AWARD ON JURISDICTION AND ADMISSIBILITY**

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**The Arbitral Tribunal:**

Hon. Fern M. Smith

Mr. Clifford M. Davidson

Mr. Toby T. Landau QC (*Presiding Arbitrator*)

*Secretary to the Tribunal:* Ms. Aurélie Antonietti

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## Frequently Used Abbreviations and Acronyms

<b>ANDA</b>	Abbreviated New Drug Application
<b>Counter-Memorial</b>	Apotex's Counter-Memorial On Respondent's Objections To Jurisdiction, dated 1 August 2011
<b>FDA</b>	The U.S. Food and Drug Administration
<b>FFDCA</b>	Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 <i>et seq.</i>
<b>Hatch-Waxman Amendments / Hatch-Waxman</b>	Amendments to the FFDCA by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984)
<b>MMA</b>	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271)
<b>NAFTA</b>	The North American Free Trade Agreement
<b>NDA</b>	New Drug Application

<b>Orange Book</b>	FDA's publication, <i>Approved Drug Products with Therapeutic Equivalence Evaluations</i> (which contains a "Patent and Exclusivity Information Addendum", containing patent information submitted by NDA-holders).
<b>Reply</b>	Respondent's Reply on Objections to Jurisdiction, dated 17 October 2011
<b>Rejoinder</b>	Apotex's Rejoinder Memorial On Respondent's Reply On Objections To Jurisdiction, dated 16 December 2011
<b>Statement of Claims</b>	Apotex's Statement of Claims, dated 17 January 2011
<b>Statement of Defense</b>	Respondent's Statement of Defense, dated 15 March 2011
<b>Transcript Day [1 / 2]</b>	Condensed version of the transcript of the oral hearing held in Washington, D.C., on 15 & 16 February 2012
<b>UNCITRAL Rules</b>	Arbitration Rules of the United Nations Commission on International Trade Law, 1976
<b>U.S. Memorial</b>	Respondent's Memorial on Objections to Jurisdiction, dated 16 May 2011

## I. INTRODUCTION

1. This is an Award on Jurisdiction and Admissibility in two arbitrations conducted pursuant to Chapter 11 of the North American Free Trade Agreement (“**NAFTA**”), and the Arbitration Rules of the United Nations Commission on International Trade Law, 1976 (the “**UNCITRAL Rules**”).
2. The first arbitration was commenced by a Notice dated 10 December 2008 (the “**Sertraline Claim**”).
3. The second arbitration was commenced by a Notice dated 4 June 2009 (the “**Pravastatin Claim**”).
4. By agreement of the Parties, the jurisdiction / admissibility phase in each arbitration has been held concurrently, albeit not consolidated, and determinations on these preliminary issues in both arbitrations are set out in this single Award.

### (A) THE PARTIES

5. *The Claimant:* The Claimant in both arbitrations is Apotex, Inc. (“**Apotex**” or the “**Claimant**”), a company incorporated and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Weston, Ontario, Canada M91 1T9.
6. *The Respondent:* The Respondent in both arbitrations is the Government of the United States of America (the “**USA**” or the “**Respondent**”), represented by its Department of State.
7. The Claimant and the Respondent are referred to collectively as “**the Parties**”.

**(B) THE ARBITRATION AGREEMENTS**

8. Both arbitrations have been conducted pursuant to Section B of Chapter 11 of NAFTA, and specifically Articles 1116, 1120 and 1122, which provide as follows:

**“Article 1116: Claim by an Investor of a Party on Its Own Behalf**

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.

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

**“Article 1120: Submission of a Claim to Arbitration**

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.”

**“Article 1122: Consent to Arbitration**

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 Inter-American Convention for an agreement.”
9. Apotex’s consent to arbitration, pursuant to Article 1121 of NAFTA, and in accordance with the procedures set out in NAFTA, is recorded in each of its two Notices of Arbitration. Concurrently with the filing of each of its Notices of Arbitration, Apotex submitted an executed waiver in the form required by NAFTA Article 1121.
10. Subject to its jurisdictional / admissibility objections, the Respondent has consented to arbitration by virtue of Article 1122 of NAFTA.
11. In each arbitration, Apotex has elected to proceed under the UNCITRAL Arbitration Rules (1976), as is its option under NAFTA Article 1120.

**(C) GENERAL NATURE OF THE DISPUTE**

12. Apotex develops and manufactures generic drugs, including solid oral dosage forms such as capsules and tablets. Generic drugs are usually non-patented (and often less expensive) versions of brand-name pioneer drugs that are, may be, or were previously protected by patents.
13. Apotex’s activities in this regard include, in particular, the design and formulation of proposed drug products; the procuring or manufacturing of active pharmaceutical

ingredients; the preparation and filing of applications with the U.S. Food and Drug Administration (“FDA”); the seeking of approval to market and sell its drug products in the United States; and the manufacture of the finished drug products.

14. Both of Apotex’s claims relate to the treatment said to have been accorded it by the USA, its agencies and Federal Courts, in the course of its efforts to bring new generic drugs to market in the United States.
15. The Sertraline Claim arises out of three decisions of the US Federal Courts in relation to Apotex’s application seeking FDA approval for a generic version of a drug manufactured by Pfizer Inc., called “Zoloft<sup>®</sup>”, which is used to treat depression; obsessive-compulsive disorders; panic attacks; and post-traumatic stress disorder.
16. The Pravastatin Claim arises out of a decision of the FDA, and three decisions of the US Federal Courts, in relation to Apotex’s new drug application seeking FDA approval for a generic version of a drug manufactured by Bristol Myers Squibb, called “Pravachol<sup>®</sup>”, which is commonly used for lowering cholesterol and preventing cardiovascular disease.
17. In each case, Apotex alleges that the USA has breached its obligations under Section A of Chapter 11 of the NAFTA, including: (i) Article 1102 – National Treatment; (ii) Article 1105 – Minimum Standard of Treatment; and (iii) Article 1110 – Expropriation.

**(D) NATURE OF THE PRELIMINARY OBJECTIONS**

18. This Award addresses three preliminary objections that have been raised by the Respondent. The first objection (whether there was an “investment” and an “investor” within the scope of NAFTA Chapter Eleven) applies to both arbitrations. The second objection (whether the judicial acts complained of were “final”) and the third objection (the NAFTA time bar) apply only to the Pravastatin Claim.

(E) **STRUCTURE OF THIS AWARD**

19. The remaining sections of this Award are structured as follows:

**Section II:** sets out a brief account of the procedural history of the two arbitrations, from their commencement to the rendering of this Award.

**Section III:** describes the U.S. statutory background against which both the Sertraline and Pravastatin Claims arise.

**Section IV:** briefly describes the nature of Apotex's claims in each arbitration, in so far as needed to put the Respondent's jurisdictional and admissibility objections into context.

**Section VII:** analyses each of the Respondent's jurisdictional and admissibility objections.

**Section VIII:** assesses and allocates the costs of the proceedings to date.

**Section IX:** comprises the Award's operative order.

## II. PROCEDURAL HISTORY

### (A) INITIATION OF PROCEEDINGS

20. *The Sertraline Claim:* On or about 21 September 2007, Apotex served a Notice of Intent to Submit a Claim to Arbitration upon the USA, in accordance with NAFTA Article 1119.
21. This was followed, on 10 December 2008, by a Notice of Arbitration, served pursuant to Article 3 of the UNCITRAL Rules, and NAFTA Articles 1116 and 1120. This Notice was received by the USA on 11 December 2008.
22. *The Pravastatin Claim:* On or about 2 March 2009, Apotex served a second Notice of Intent to Submit a Claim to Arbitration upon the USA, in accordance with NAFTA Article 1119.
23. This was followed, on 4 June 2009, by a second Notice of Arbitration, served pursuant to Article 3 of the UNCITRAL Rules, and NAFTA Articles 1116 and 1120. This Notice was received by the USA on 5 June 2009.
24. *Application for a Stay / Co-Ordination of Proceedings:* On 29 October 2010, Apotex submitted a Submission in Support of a Stay of the proceedings in relation to the Notice of Arbitration of 4 June 2009 pending the resolution of its first Notice of Arbitration by the Tribunal.
25. On 12 November 2010, the USA filed a Submission in Opposition to a Stay.

26. By subsequent agreement of the Parties, Apotex's application to stay its Notice of Arbitration dated 4 June 2009 was withdrawn, without waiving its right to reintroduce the same after resolution of the Respondent's preliminary objections.

**(B) CONSTITUTION OF THE ARBITRAL TRIBUNAL**

27. Pursuant to NAFTA Article 1123, the Arbitral Tribunal comprises three arbitrators, with one arbitrator appointed by each of the disputing Parties and the third, presiding arbitrator, appointed by agreement of the disputing Parties.

28. On 23 October 2009, Apotex appointed Mr. Clifford M. Davidson, and on 20 August 2009, the USA appointed The Honorable Fern M. Smith. The Parties agreed to appoint Mr. Toby T. Landau QC as Presiding Arbitrator, and the Arbitral Tribunal was deemed constituted as of 17 July 2010. A declaration of independence and impartiality pursuant to Article 9 of the UNCITRAL Rules was duly completed by each Member of the Tribunal.

**(C) FIRST PROCEDURAL MEETING**

29. The Parties agreed on certain initial procedural matters, as reflected in a joint letter of 10 August 2010 addressed to the Members of the Tribunal. The agreement included that the Secretariat of ICSID render full administrative services in relation to the arbitration similar to those rendered in arbitrations under the ICSID Additional Facility Rules, and that the cost of ICSID's services be included in the costs of the arbitration.

30. A first procedural meeting was convened in Washington, D.C. on 30 November 2010.

31. At the procedural meeting, the Parties confirmed that the Arbitral Tribunal had been duly constituted in accordance with NAFTA Article 1123. They also agreed that the place of arbitration (seat) would be New York, NY, USA, but that the hearings would be held in Washington, D.C.

32. It was also agreed that, until resolution of the Respondent's preliminary objections, and without prejudice to any future application, the two claims would be heard concurrently, but not consolidated.
33. The Parties agreed on a timetable for the exchange of written submissions.
34. It was also agreed that Ms. Aurélie Antonietti, Senior Counsel, ICSID, be appointed as Secretary to the Tribunal.
35. On 16 December 2010, the ICSID Secretariat issued a detailed **Procedural Order No. 1**, on instructions from the Arbitral Tribunal.

**(D) WRITTEN SUBMISSIONS**

36. In accordance with paragraphs 62 of Procedural Order No. 1, Apotex submitted its Statements of Claims in both arbitrations (pursuant to Art 18 of the UNCITRAL Rules) on 17 January 2011, and the USA submitted its Statement of Defense in both arbitrations (pursuant to Art 19 of the UNCITRAL Rules) on 15 March 2011.
37. Thereafter, as directed by Procedural Order No 1, and pursuant to Art. 21 of the UNCITRAL Rules, the USA filed its Memorial on Objections to Jurisdiction with respect to both claims on 16 May 2011; on 1 August 2011, Apotex filed a Counter-Memorial on Objections to Jurisdiction; on 17 October 2011, the USA filed a Reply on Objections to Jurisdiction, and on 16 December 2011, Apotex filed a Rejoinder on Objections to Jurisdiction.

**(E) PARTICIPATION OF NON-DISPUTING PARTIES**

38. Section XV of Procedural Order No. 1 provided that:

“The parties agree that the Arbitral Tribunal shall consider any application for leave to file a submission in this arbitration by an intending amicus, and any notice by a non-party pursuant to Article 1128 of the NAFTA, taking

into account the recommendations of the FTC on non-disputing party participation, issued on 7 October 2003.

The parties shall have the opportunity to make submissions on any application for leave to file a submission in this arbitration by an intending amicus and any notice by a non-party.

The Arbitral Tribunal shall issue a ruling on any amicus application for leave to file a submission, taking into account the recommendations of the FTC on amicus participation.”

39. On 25 August 2011, the Centre received an “*Application For Leave To File A Non-Disputing Party Submission*” filed by the Study Centre for Sustainable Finance, “the research and development arm of the Business Neatness Magnanimity BNM srl”, a per profit non-governmental organisation incorporated in Rome, Italy. Attached to the application was a “*Statement of Non-Disputing Party*”.
40. After having heard both Parties, on 15 September 2011, the Tribunal informed the Parties of its decision to refuse the application, on the basis that the proposed amicus brief did not satisfy the relevant criteria as set out in the Statement of the Free Trade Commission on Non-Disputing Party Participation of 7 October 2003. The applicant was also informed of the Tribunal’s decision.
41. The reasoning of the Tribunal was set out in detail in its **Procedural Order No. 2** dated 11 October 2012.

**(F) HEARING ON PRELIMINARY OBJECTIONS**

42. As agreed at the first procedural meeting, the Parties and the President of the Tribunal held a pre-hearing conference by telephone on 24 January 2012.
43. The hearing on preliminary objections took place at the World Bank offices in Washington, D.C., from 15 February 2012 to 16 February 2012. The hearing was open to the public, although some limited business information was treated as confidential at

Apotex's request, and the hearing moved into closed session for a short while on the first day to accommodate this.

44. Apotex was represented at the hearing by Mr. William A. Rakoczy; Ms. Lara Fitzsimmons; and Mr. Robert M. Teigen, all of Rakoczy Molino Mazzochi Siwik, LLP. The Respondent was represented at the hearing by Ms. Mary Mcleod (Principal Deputy Legal Adviser); Mr. Jeffrey D. Kovar (Assistant Legal Adviser); Mr. Jeremy Sharpe; Mr. Neale H. Bergman; Mr. David M. Bigge; Mr. Patrick W. Pearsall; Ms. Abby L. Lounsberry; and Ms. Karin Kizer (Attorney-Advisers, Office of International Claims and Investment Disputes, Office of the Legal Adviser). Mr. Salvador Behar and Ms. Joanna Holguin appeared on behalf of the Government of Mexico, and Ms. Megan Clifford and Ms. Fatima Nakhuda appeared on behalf of the Government of Canada. The Tribunal was assisted by its Secretary, Ms. Aurélia Antonietti.
45. At the conclusion of the oral hearing, each Party confirmed:
  - (a) that the requirements of the UNCITRAL Rules had been met, and that it had been given a full opportunity of presenting its case; and
  - (b) that the hearing was to be declared closed for the purposes of Article 29(1) of the UNCITRAL Rules.
46. Following the hearing, each Party submitted suggested corrections to the transcript, and a finalised version was then circulated.

**(G) POST-HEARING SUBMISSIONS**

47. By agreement of the Parties, as recorded at the end of the oral hearing, and subsequently embodied in **Procedural Order No. 3**, dated 17 February 2012:
  - (a) there were no post-hearing briefs;

- (b) for the purposes of NAFTA Article 1128, the non-disputing parties to NAFTA (Canada and Mexico) were given a period of one month within which to make any written observations that they may have, with each Party thereafter having a period of two weeks to respond to any such submissions so filed.

48. In the event, no submissions were filed by Canada or Mexico.

**(H) COSTS SUBMISSIONS**

49. Pursuant to paragraph 2(b) of Procedural Order No. 3, costs submissions were filed by each Party six weeks after the closure of the oral hearing.

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### III. RELEVANT U.S. STATUTORY BACKGROUND

#### (A) INTRODUCTION

50. This section describes the U.S. statutory background that gives rise to each of Apotex's claims.

#### (B) GENERAL STATUTORY BACKGROUND

51. In the United States, the approval of new and generic drugs is governed by the Federal Food, Drug, and Cosmetic Act (“**FFDCA**”), 21 U.S.C. §§ 301 *et seq.*, as amended by:

(a) the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the “**Hatch-Waxman Amendments**” or “**Hatch-Waxman**”); and

(b) the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“**MMA**”).<sup>1</sup>

52. *New Drug Applications:* Under the FFDCA, a company that seeks to sell a new or previously unapproved drug must file a “New Drug Application” (“**NDA**”) with the FDA.

53. NDAs are very substantial filings. They must include, *inter alia*, technical data on the composition of the drug; the means for manufacturing it; clinical trial results establishing its safety and effectiveness; and labelling describing the use for which approval is requested (21 U.S.C. § 355(b)(1)).

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<sup>1</sup> The MMA also amended Title 35 of the U.S. Code, which governs patents more generally, specifically 35 U.S.C. § 271 (“**Section 271**”).

54. *Generic Drug Applications / ANDAs:* Before the 1984 Hatch-Waxman Amendments, a generic drug company was obliged to wait until the patent protecting a drug product expired, before it could begin the lengthy process of preparing its application for submission to the FDA. Because such testing often takes years, the brand company continued to monopolise the particular drug market years *after* patent expiration, for the time it took the generic drug company to complete the necessary tests and for the FDA to issue its approval. This unintended period of extended market exclusivity constituted, in effect, a *de facto* extension of the patent term.
55. Additionally, prior to 1984, a company seeking to market a generic version of an FDA approved drug had to complete expensive and time-consuming safety and efficacy studies on the drug, even though the NDA-holder had already established the drug's safety and efficacy through its own studies.
56. By the Hatch-Waxman and MMA amendments to the FDCA, the US Congress simplified the procedure for obtaining approval of lower-priced generic drugs. An abbreviated approval process was introduced, that enables generic pharmaceutical manufacturers to obtain regulatory approval of generic versions of previously-approved NDA drugs on an expedited basis. The process is now a streamlined version of the full NDA procedure, and results in a generic drug product that is normally marketed under the chemical name of the active drug ingredient.
57. The amendments permit a generic drug company to file an "Abbreviated New Drug Application" ("ANDA"), which relies on information contained in the NDA, instead of repeating the same comprehensive, extensive clinical studies of safety and efficacy.
58. The purpose of the ANDA process is to:

“strike a balance between incentives, on the one hand, for innovation, and on the other, for quickly getting lower-cost generic drugs to market.”<sup>2</sup>

59. An applicant submitting an ANDA is required to establish, among other matters, that its proposed generic product is bio-equivalent to the already-approved NDA drug, and that it has the same active ingredient, dosage form, dosage strength, route of administration, and labelling (with certain exceptions) (21 U.S.C. § 355(j)(2)(A)).
60. In addition to creating a simplified regulatory approval pathway, the Hatch-Waxman Amendments also created a special, expedited mechanism for resolving patent disputes, before a generic drug is commercialised. To this end, as part of its NDA, a brand company is required to submit information regarding each patent that:

“claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”

(21 U.S.C. § 355(b)(1); § 355(c)(2)).

61. The FDA publishes patent information submitted by NDA-holders in the Patent and Exclusivity Information Addendum of its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “**Orange Book**”).
62. By submitting a patent for listing in the Orange Book, the NDA-holder necessarily puts all prospective generic ANDA applicants on notice that a suit for infringement could be asserted against any ANDA applicant that attempts to seek approval for and market a generic version of the NDA drug.

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<sup>2</sup> *Teva Pharms. Indus. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005) [R68]; see also H.R. Rep. No. 98-857 pt. 1 at 30 (Judiciary Committee), noting that the goal of the Hatch-Waxman Amendments was to “*balance the need to stimulate innovation against the goal of furthering the public interest*” [R43].

63. An ANDA applicant is required, *inter alia*, to address each patent listed in the Orange Book in connection with the approved NDA drug. Specifically, the ANDA must include a so-called “certification” to any properly-listed Orange Book patents (21 U.S.C. § 355(j)(2)(A)(vii)).
64. The statute provides four certification options, two of which are relevant in this case:
- (a) the so-called “**paragraph III**” certification, where the applicant certifies that it will not market until after the listed patent has expired (21 U.S.C. § 355(j)(2)(A)(vii)(III)); and
  - (b) the so-called “**paragraph IV**” certification, where the applicant seeks immediate approval because the listed patent is invalid and/or not infringed by the proposed ANDA product, or otherwise not enforceable against the generic manufacturer (21 U.S.C. § 355(j)(2)(A)(vii)(IV)).<sup>3</sup>
65. *Paragraph IV Certification:* A paragraph IV certification allows an ANDA applicant to seek approval prior to patent expiration. In so doing, it must notify the patentee and NDA-holder of the factual and legal bases for the certification, and in particular why, in the ANDA applicant’s view, the patent is invalid, not infringed, or unenforceable (21 U.S.C. § 355(j)(2)(B)).
66. The submission of a paragraph IV certification has two important effects:
- (a) *First*, as an incentive for generic companies to challenge brand patents, Congress granted the first company to file a paragraph IV ANDA, in limited circumstances, a 180-day period of generic market exclusivity, during which time the FDA will

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<sup>3</sup> The other certification options are: paragraph I, where the applicant certifies that no patent information has been filed, and paragraph II, where the applicant certifies that the patent has expired.

not approve other ANDAs (21 U.S.C. § 355(j)(5)(B)(iv)). This exclusivity is triggered by the earlier of two events:

- i. the first-filer’s commercial marketing of the generic drug; or
- ii. “a decision of a court . . . holding the patent which is subject of the certification to be invalid or not infringed” - the so-called “**court decision trigger**” (21 U.S.C. § 355(j)(5)(B)(iv) (2002)).<sup>4</sup>

It is Apotex’s case that the court decision trigger includes any decision of non-infringement by, or invalidity with respect to, *any* filer in *any* action. In particular, that Congress intended for a court decision to trigger the first-filer’s exclusivity even if the latter was not in a position to benefit from it (citing *e.g.*, *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1009-11 (D.C. Cir. 1999)). Further, by including the court decision trigger, Congress sought to ensure that the 180-day exclusivity period did not indefinitely delay generic competition from subsequent ANDA-filers.

- (b) *Second*, the submission of a paragraph IV certification for a listed patent constitutes an act of infringement that creates the necessary case or controversy and subject-matter jurisdiction to enable a US District Court to resolve any dispute concerning infringement or validity of the patent, prior to the actual launch and commercialisation of the generic drug product (35 U.S.C. § 271(e)(2)(A)).

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<sup>4</sup> See, *e.g.*, *Apotex Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006); David E. Korn, Erika Lietzan, Shaw W. Scott, *A New History and Discussion of 180-Day Exclusivity*, 64 Food & Drug L. J. 335, 349-358 (2009).

Citations to 21 U.S.C. § 355(j)(5)(B)(iv) refer to Hatch-Waxman as it existed prior to the passage of the MMA, which amended, among others, the exclusivity provisions of the statute. The changes to the 180-day exclusivity period that were implemented by the MMA were prospective only, and do not apply to either of the Sertraline or Pravastatin ANDAs, both of which were filed before 8 December 2003.

67. *Certifications Under Multiple Paragraphs:* ANDA applicants may include both paragraph III and paragraph IV certifications in one application to market a new generic drug. If this occurs, the validity period of a patent that is the subject of a paragraph III certification can influence market timing related to a patent that is the subject of a paragraph IV certification.
68. For example, ANDA applicants may admit that one of the patents listed in the Orange Book for a pioneer drug is valid, enforceable, and unexpired, and thus subject to paragraph III certification, whilst also arguing that other patents related to the same drug, such as a particular formulation of the drug or the use of a drug for treating a particular disease, are invalid, not infringed, or unenforceable, and thus subject to paragraph IV certification.
69. Where an ANDA applicant includes both a paragraph III and a paragraph IV certification, the applicant must wait until the patent subject to the paragraph III certification expires before its ANDA is approved.
70. A later applicant, which was not the first to make a paragraph IV certification, and which is therefore not eligible for 180-day exclusivity, may seek to trigger the start of the 180-day exclusivity period before the first applicant can bring its product to market. In other words, the later-in-time applicant may, in such circumstances, seek to eliminate or shorten the 180-day exclusivity period by causing the 180 days to run while all of the ANDA applicants, including the ANDA applicant eligible for exclusivity, wait for the patent subject to the paragraph III certification to expire before they may get FDA approval to market their respective drugs.

**(C) RELEVANT STATUTORY BACKGROUND TO THE SERTRALINE CLAIM**

71. Apotex's Sertraline Claim involves statutory provisions governing an ANDA applicant's ability to file and maintain a declaratory judgment action for patent non-infringement, invalidity, and/or unenforceability.

72. As a means of safeguarding brand companies, Hatch-Waxman prohibits the FDA from approving a paragraph IV ANDA for 30 months, if the brand company brings suit within 45 days of learning of the paragraph IV filing (21 U.S.C. § 355(j)(5)(B)(iii)).

73. However, under the MMA, if the NDA-holder/patent owner does not file such a suit within the 45-day period, the statute allows an ANDA applicant to file and maintain a suit for a declaratory judgment against the NDA-holder/patent owner, both to obtain patent certainty and to remove any barriers to approval, such as another applicant's 180-day exclusivity. Specifically, this applies if:

- (a) the 45-day period has passed since notice of the paragraph IV certification was received;
- (b) neither the patent owner nor the NDA-holder has brought an action for infringement of the patent within the 45-day period; and
- (c) the NDA-holder/patent owner has been granted an Offer of Confidential Access to the ANDA

(21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa-cc).

74. Once these three conditions are met, the MMA provides that an ANDA applicant:

“may, in accordance with section 2201 of Title 28 [*i.e.* the Declaratory Judgment Act], bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . .”

(21 U.S.C. § 355(j)(5)(C)(i)(II)).

75. According to the MMA, in such circumstances:

“the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of Title 28 for a declaratory judgment that such patent is invalid or not infringed.”

(35 U.S.C. § 271(e)(5)).

76. As emphasised by Apotex, Congress enacted these declaratory judgment provisions, *inter alia*, to:

“ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition.”

(149 Cong. Rec. S15,746 (24 Nov. 2003)).

Congress was concerned that:

“when generic applicants are blocked by a first generic applicant’s 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the ‘failure to market’ provision and force the first generic to market.”

And Congress expected that:

“in almost all situations where a generic applicant has . . . not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable ‘case or controversy’ under the Constitution.”

(149 Cong. Rec. S15,885 (25 Nov. 2003)).

77. The Respondent, on the other hand, emphasises that the Declaratory Judgment Act specifies that courts have jurisdiction to issue a declaratory judgment “in a case of actual controversy,”<sup>5</sup> which (according to the Respondent) is generally understood as a reference

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<sup>5</sup> 28 U.S.C. § 2201 provides:

to the “case or controversy” requirement for jurisdiction in the federal courts under Article III of the U.S. Constitution. 35 U.S.C. § 271(e)(5) (“Section 271”), which governs patents generally, states that Federal Courts have subject matter jurisdiction over declaratory judgment actions brought by ANDA applicants “to the extent consistent with the Constitution.”<sup>6</sup> Under the U.S. Constitution, the power of the federal courts is limited to “cases” and to “controversies” arising under federal law (U.S. Const. art. III, § 2). On the Respondent’s analysis, therefore, an ANDA applicant that wishes to bring a declaratory judgment action under Section 355, Section 271 and the Declaratory Judgment Act must meet the “case or controversy” requirement of Article III of the U.S. Constitution.

**(D) RELEVANT STATUTORY BACKGROUND TO THE PRAVASTATIN CLAIM**

78. Apotex’s Pravastatin Claim concerns the statutory “court-decision trigger” for the 180-day generic exclusivity.
79. According to Apotex, US Courts have interpreted this trigger broadly. In particular, Apotex submits that the trigger includes any court decision on the patent that is the subject of the paragraph IV certification, regardless of whether the first-filer is involved in that particular litigation (citing *e.g.*, **Granutec, Inc. v. Shalala**, 139 F.3d 889, 1998 WL 153410, at \*5, \*10 (4th Cir. Apr. 3, 1998), and **Teva**, 182 F.3d at 1005 n.3, both of which

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*“In a case of actual controversy within its jurisdiction, except with respect to Federal taxes . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.”*

<sup>6</sup> The provision, in full, is as follows:

*“Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.”*

held that exclusivity had been triggered by a court decision involving a subsequent applicant).

80. According to Apotex, this trigger also encompasses a broad spectrum of decisions, including decisions of patent unenforceability, despite the absence of this ground in the express language of the statute, and the grant of partial summary judgment based on the patentee's admission of non-infringement (citing *e.g.*, **Teva**, 182 F.3d at 1009; 21 C.F.R. § 314.107(c)(1)(ii); **Granutec**, 1998 WL 153410, at \*5, \*8 n.2).
81. Additionally, Apotex points to the finding in **Teva** (*supra*) that the dismissal of a declaratory judgment action for lack of subject-matter jurisdiction can constitute a “*court decision*” for the purposes of triggering generic exclusivity, if the dismissal estops the patentee from subsequently asserting that the ANDA product infringes the patent-in-suit (the Court holding that: “[t]o start, or trigger, the period of market exclusivity by a ‘court decision,’ an ANDA applicant need only obtain a judgment that has the effect of rendering the patent invalid or not infringed with respect to itself”).

#### IV. OUTLINE OF APOTEX'S CLAIMS

##### (A) INTRODUCTION

82. This section provides an outline of the nature of Apotex's claims against the USA, as set out in its various pleadings and submissions. This is simply by way of broad context for the jurisdiction and admissibility issues analysed in **Section V** below, and without any findings or conclusions by the Tribunal.

83. It is to be noted that each of Apotex's claims is denied by the USA, which asserts that there has been no violation of NAFTA Chapter 11, and which has set out a detailed defence on each issue. Since this Award deals only with issues of jurisdiction and admissibility, however, there is no need to elaborate on the USA's position on the merits.

##### (B) THE SERTRALINE CLAIM

84. On 27 October 2003, Apotex submitted an ANDA seeking FDA approval for a generic version of Pfizer Inc.'s popular anti-depressant medication, Zoloft<sup>®</sup>, known generically as sertraline hydrochloride. Apotex states that it invested more than ██████████ in formulating and developing a generic version of this drug, in the form of tablets in 25 mg, 50 mg, and 100 mg strengths.<sup>7</sup> As part of its generic drug application, Apotex was statutorily required to address and certify to any patents listed by Pfizer as purporting to claim the approved use of Zoloft<sup>®</sup> Tablets, or the approved product itself.

85. Pfizer submitted information on several patents to the FDA for listing in the Orange Book in connection with Zoloft<sup>®</sup>, including U.S. Patent Nos. 4,356,518 (the "**518 patent**") and

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<sup>7</sup> Witness Statement of Bernice Tao, para. 15 [C39].

5,248,699 (the “**699 patent**”). On Apotex’s case, by listing these patents, Pfizer affirmatively represented that a suit for infringement could reasonably be asserted against any generic manufacturer (such as Apotex) that attempted to market a generic sertraline product prior to the expiration of these patents.

86. Another generic company and competitor, Ivax Corporation (“**Ivax**”), was the first applicant to file an ANDA for generic sertraline containing a paragraph IV certification to a listed patent (the ‘699 patent). This was done in 1999,<sup>8</sup> and made Ivax eligible for 180-day exclusivity, which would be triggered by the earlier of (i) first commercial marketing or (ii) a favourable Court decision.
87. Further, Ivax’s ANDA filing was an act of infringement that created the necessary subject-matter jurisdiction for Pfizer to sue Ivax for infringement of the ‘699 patent. This Pfizer did in January 2000.
88. Ivax submitted a paragraph III certification to the ‘518 patent, indicating that it would not seek approval until that patent expired in June 2006.
89. In May 2002, Pfizer and Ivax settled their litigation, with Ivax effectively conceding validity and infringement of the ‘699 patent, in exchange for a royalty-bearing licence. The settlement thus preserved Ivax’s exclusivity and, consequently, acted to block approval of all other sertraline ANDAs, including Apotex’s ANDA.
90. In the same way as Ivax, Apotex also filed a paragraph IV certification to the ‘699 patent, and a paragraph III certification to the ‘518 patent. This was done on 27 October 2003.<sup>9</sup>
91. Apotex’s submission of a paragraph IV certification constituted an act of infringement sufficient to create subject-matter jurisdiction to resolve any questions regarding the

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<sup>8</sup> See *Apotex Inc. & Apotex Corp. v. Pfizer Inc.*, 385 F. Supp. 2d 187, 190 (S.D.N.Y. 2005) [R16].

<sup>9</sup> Apotex’s Statement of Claims, para. 45.

infringement and validity of the '699 patent. But, instead of filing suit against Apotex, as it did with Ivax, Apotex claims that Pfizer intentionally delayed suing it (and all other sertraline ANDA filers) so as to avoid a triggering court decision, which would trigger Ivax's exclusivity and relieve the "bottleneck" in the market.

92. Given Pfizer's strategy, Apotex filed an action for a declaratory judgment against Pfizer on 1 April 2004 in the United States District Court for the Southern District of New York, pursuant to the MMA. According to Apotex, this suit was the only way for it to obtain patent certainty and immediate approval of its product in 2006.
93. Pfizer moved to dismiss Apotex's suit for lack of subject-matter jurisdiction.
94. On 30 December 2004, the District Court granted Pfizer's motion, and dismissed Apotex's action for lack of subject-matter jurisdiction on the ground that Apotex did not have a "*reasonable apprehension*" that it would be sued by Pfizer over its generic sertraline ANDA.<sup>10</sup> The District Court specifically rejected Apotex's argument that application of the Federal Circuit's "*reasonable apprehension*" standard was unlawful because it conflicts with controlling Supreme Court precedent, and that the MMA required that the Court:

"employ the Article III case or controversy analysis applied in non-patent cases and in patent cases involving allegations of actual (as opposed to potential) infringement, requiring that '*there is (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision.*'"

(*Id.* at 192 (citations omitted)).

95. Applying this test, Apotex had argued that there was subject-matter jurisdiction because Pfizer had listed the '699 patent, thus asserting that a claim of patent infringement could reasonably be asserted against any unlicensed generic ANDA-filer like Apotex; that

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<sup>10</sup> *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187, 192-94 (S.D.N.Y. 2005).

Apotex had challenged the '699 patent in its ANDA, thereby subjecting itself to suit; that Apotex was at risk of substantial financial losses having spent considerable sums preparing and filing its ANDA—an investment that could be lost if Pfizer were to mount a successful infringement action; that such losses would be even more substantial if Apotex's sertraline products were found to infringe the patent *after* Apotex had launched its products; and that, absent a declaratory judgment, Apotex could be delayed from obtaining final FDA approval indefinitely, and at the very least by 180 days after Ivax's marketing of its own sertraline products.

96. As set out in detail in its Statement of Claims, it is Apotex's case that the District Court erred as a matter of law in failing to find subject-matter jurisdiction over Apotex's claims for declaratory relief, and proceeded on a basis that (1) ignored the MMA; (2) failed to consider whether Apotex satisfied the actual controversy requirement of Article III of the U.S. Constitution, regardless of any reasonable apprehension of suit;<sup>11</sup> (3) in any event misapplied the Federal Circuit's reasonable apprehension test; and (4) misapplied controlling Supreme Court precedent regarding Article III of the U.S. Constitution.
97. Apotex appealed this decision to the Federal Circuit. On 12 December 2005, the Federal Circuit affirmed the District Court's dismissal of Apotex's suit, without opinion.<sup>12</sup>
98. Apotex then submitted a petition for a writ of certiorari to the United States Supreme Court, seeking review of the Federal Circuit's decision. On 10 October 2006, the Supreme Court denied Apotex's petition, without comment.<sup>13</sup>

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<sup>11</sup> In particular, Apotex states the Supreme Court and Federal Circuit have both since acknowledged that the controlling test is the case or controversy standard under Article III of the Constitution, which the New York District Court refused to apply. Apotex cites, *inter alia*, **MedImmune, Inc. v. Genentech, Inc.**, 127 S.Ct. 764, 771 (2007) for the proposition that the reasonable apprehension test for subject matter jurisdiction is not and has never been the proper test.

<sup>12</sup> **Apotex, Inc. v. Pfizer Inc.**, 159 F. App'x 1013, 2005 WL 3457408 (Fed. Cir. 12 Dec. 2005).

<sup>13</sup> **Apotex Inc. v. Pfizer, Inc.**, 127 S.Ct. 379 (2006).

99. By way of broad outline only, it is the Respondent’s case that, at the time, the “reasonable apprehension of suit” standard as applied by the District Court had been applied in hundreds of cases by Federal Courts throughout the U.S. over the course of several decades in declaratory judgment actions involving intellectual property.
100. In the course of its pleading, Apotex, on the other hand, has applied a variety of epithets to the conduct of each of these Courts, including “*unlawful*”; “*wrongful*”; “*improper*”; “*arbitrary*”; “*capricious*”; and “*unjust*”.
101. At the core of Apotex’s complaint is the assertion that the Courts permitted and enabled Pfizer to continue to “*bottleneck*” the generic market, and delay approval of Apotex’s ANDA.
102. Further, because the decisions by the U.S. District Court for the Southern District of New York, the Federal Circuit, and the Supreme Court prevented Apotex from obtaining a declaratory judgment of patent non-infringement or invalidity, Apotex was unable to bring its generic sertraline products to the US market promptly, causing Apotex (on its case) substantial damages. More specifically, because these Courts refused to hear Apotex’s declaratory judgment action, Apotex was unable to obtain the Court decision necessary to trigger Ivax’s generic exclusivity period prior to the expiration of the ‘518 patent. As a result, Ivax launched its generic sertraline products with exclusivity, thereby obtaining—at Apotex’s expense—the majority of the generic sertraline market share and a financial windfall by virtue of offering the sole generic alternative to Pfizer’s Zoloft<sup>®</sup> tablets.
103. It is Apotex’s case, in broad summary, that in preventing it from obtaining a declaratory judgment of patent non-infringement or invalidity, which in turn prevented it from promptly bringing its generic sertraline products to the U.S. market, the USA, through its Federal Courts, has:
- (a) acted in breach of its National Treatment obligations under NAFTA Article 1102;

- (b) acted in breach of its obligation to accord Apotex's investments fair and equitable treatment, and to meet the minimum standard of treatment under international law, under NAFTA Article 1105 (including an alleged denial of justice);
  - (c) interfered with and expropriated Apotex's property rights in its ANDA for generic sertraline tablets, in violation of NAFTA Article 1110 (in particular, by unlawfully redistributing the financial benefits of Apotex's investment to the patentee and another sertraline ANDA filer, and by preventing Apotex from obtaining final approval of its generic sertraline tablets immediately upon expiration of the '518 patent).
104. Apotex claims that it has incurred significant loss and damage as a result of the USA's conduct, and claims declaratory and monetary relief (not less than US\$ 8,000,000) in this regard.

**(C) THE PRAVASTATIN CLAIM**

105. Apotex's Pravastatin Claim involves the prescription heart medication pravastatin sodium tablets, marketed by Bristol Myers Squibb ("**BMS**") under the brand-name Pravachol<sup>®</sup>.
106. On 21 December 2001, Apotex submitted an ANDA seeking FDA approval for a generic version of Pravachol<sup>®</sup>. At the time Apotex filed its ANDA, BMS had submitted information on four patents for listing in FDA's Orange Book in connection with this drug: U.S. Patent Nos. 4,346,227 (the "**227 patent**"); 5,030,447 (the "**447 patent**"); 5,180,589 (the "**589 patent**"); and 5,622,985 (the "**985 patent**").
107. On Apotex's case, by listing these patents, BMS affirmatively represented that a suit for infringement could reasonably be asserted against any generic pravastatin manufacturer, including Apotex.

108. Teva Pharmaceuticals USA, Inc. (“**Teva**”) purportedly was the first generic applicant to submit a paragraph IV ANDA for generic pravastatin tablets in 10 mg, 20 mg, and 40 mg strengths, and Ranbaxy Laboratories Limited (“**Ranbaxy**”) was purportedly the first generic applicant to submit a paragraph IV ANDA for these generic tablets in the 80 mg strength. As a result, Teva and Ranbaxy were eligible for 180-day exclusivity for these products.
109. Both Teva and Ranbaxy filed paragraph III certifications to the ‘227 patent, thus indicating that neither would seek final FDA approval until this patent expired (on 20 April 2006).
110. BMS did not sue either company.
111. Apotex’s pravastatin sodium ANDA contained paragraph IV certifications to the ‘447, ‘589, and ‘985 patents, and a paragraph III certification to the ‘227 patent. Consequently, the FDA could not approve Apotex’s ANDA until 20 April 2006, when the ‘227 patent expired.
112. As required under the statute, Apotex provided BMS with notice of its pravastatin sodium ANDA and its paragraph IV certifications. However, BMS, without comment or explanation, refrained from suing Apotex for infringement of the ‘447, ‘589 and ‘985 patents.
113. But the fact that BMS initially refused to sue Apotex did not mean that Apotex could launch its products without fear from infringement liability. BMS still had the right and ability to sue Apotex when Apotex launched its generic products. Thus, Apotex could not market its products without fear of infringement liability and (on Apotex’s case) significant, if not catastrophic, monetary damages—damages far exceeding Apotex’s sales—and an injunction prohibiting future marketing.
114. In order to obtain patent certainty without Court intervention, Apotex repeatedly tried to obtain assurances from BMS that it would not sue Apotex for infringement of the ‘447,

‘589, and ‘985 patents. When BMS would not sign a binding covenant not to sue Apotex for infringement of these patents, Apotex filed a declaratory judgment action in the United States District Court for the Southern District of New York in order to attempt to secure a binding Court order that would provide a “perfected” preclusive effect, estopping BMS from suing Apotex upon commercial launch of its generic product.

115. BMS moved to dismiss Apotex’s declaratory judgment action for lack of subject-matter jurisdiction on the basis that Apotex lacked a “reasonable apprehension” of suit in light of BMS’s binding representations, contained in filed Court papers and a sworn declaration, that it would not sue Apotex for infringement of the ‘447, ‘589, and ‘985 patents.
116. Whilst the District Court did not rule on BMS’s motion, it ultimately entered an Order dismissing Apotex’s declaratory judgment action based upon BMS’s binding representations that it would not sue Apotex.<sup>14</sup> The District Court’s dismissal order became final and unappealable on 22 August 2004.
117. On 7 September 2004, Apotex wrote to the FDA, seeking confirmation that the dismissal of its declaratory judgment action against BMS triggered any generic exclusivity that would be awarded for pravastatin, such that Apotex’s own ANDA would be eligible for full and final approval once the ‘227 patent expired in April 2006.
118. On 28 June 2005, the FDA responded to Apotex’s letter, confirming that exclusivity for all strengths of pravastatin expired no later than 18 February 2005, having been triggered by the dismissal of Apotex’s declaratory judgment action.<sup>15</sup> The FDA further concluded that Apotex’s pravastatin ANDA would be eligible for immediate final approval on 20 April 2006.

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<sup>14</sup> Stipulation and Order, *Apotex Inc. v. Bristol-Myers-Squibb Co.*, No. 04-cv-2922 (S.D.N.Y. 23 July 2004).

<sup>15</sup> 28 June 2005 FDA letter from G. Buehler to W. Rakoczy [C24].

119. The FDA's decision explicitly relied on controlling Federal Court decisions involving the drug "ticlopidine" and the same filers as for pravastatin - Teva and Apotex - in which the U.S. Court of Appeals for the District of Columbia Circuit had found that the dismissal of Teva's declaratory judgment action for lack of subject-matter jurisdiction, based on the patent holder's disavowal of an intent to sue, constituted a triggering court decision.
120. After the FDA issued its pravastatin decision, Teva challenged the Agency's ruling in the U.S. District Court for the District of Columbia. Teva argued that the BMS-Apotex dismissal did not trigger the 180-day generic exclusivity period for pravastatin (*i.e.* it did not qualify as a court decision trigger under Section 355(j)(5)(B)(iv)(II)), and sought a preliminary injunction and judgment on the merits preventing Apotex and other generic companies from marketing their products. Apotex intervened and opposed Teva's motion.
121. On 21 October 2005, the District Court for the District of Columbia granted Teva's motion.<sup>16</sup>
122. Apotex sought to stay the injunction pending an appeal but, on 8 December 2005, the Court denied Apotex's motion.<sup>17</sup> Thus, Apotex was prevented from both obtaining final approval for, and marketing, its pravastatin product upon expiration of the '227 patent in April 2006.
123. On appeal, the U.S. Court of Appeals for the District of Columbia Circuit held that the FDA's 28 June 2005 decision was arbitrary and capricious, because the Agency had not properly explained the reasoning behind its decision.<sup>18</sup> Whilst the D.C. Circuit expressed no opinion on what actually constitutes a triggering court decision under the statute, the

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<sup>16</sup> *Teva Pharms. USA, Inc. v. FDA*, 398 F. Supp. 2d 176, 191-92 (D.D.C. 2005).

<sup>17</sup> *Teva Pharms. USA, Inc. v. FDA*, 404 F. Supp. 2d 243, 246 (D.D.C. 2005).

<sup>18</sup> *Teva Pharms USA, Inc. v. FDA*, 441 F.3d 1, 5 (D.C. Cir. 2006).

Court instructed the District Court to vacate the FDA's 28 June 2005 decision, and remand the matter to the Agency for further proceedings. The Court stated:

“[w]hile the statute may preclude treating voluntary dismissals (or, for that matter [involuntary] dismissals . . . ) as triggering events, we express no opinion on the matter. It is up to the agency to bring its expertise to bear in light of competing interests at stake and make a reasonable policy choice. The FDA has not yet done so.”

124. On 11 April 2006, the FDA issued its second administrative decision pertaining to the issue of 180-day exclusivity for pravastatin sodium tablets.<sup>19</sup> In that decision, the FDA reversed itself and, contrary to its prior ticlopidine ruling, determined that the BMS-Apotex dismissal was insufficient to trigger the 180-day exclusivity for pravastatin. The FDA determined that only a decision of a court, holding on the merits that a particular patent is invalid, not infringed, or unenforceable, would suffice to trigger the 180-day exclusivity period, and that such holding must be evidenced by language on the face of the court's decision.
125. Apotex challenged this 11 April 2006 decision in the U.S. District Court for the District of Columbia, moving for immediate injunctive relief setting aside the FDA's administrative ruling and enjoining it from awarding 180-day exclusivity for pravastatin. Apotex argued that the FDA's decision was contrary to Hatch-Waxman and the FFDCA, and conflicted with controlling precedent from the D.C. Circuit in the ticlopidine line of cases.
126. On 19 April 2006, the District Court denied Apotex's motion.<sup>20</sup>
127. Apotex appealed, and Teva moved for summary affirmation of the District Court's decision.

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<sup>19</sup> 11 April 2006 FDA letter from G. Buehler to T. McIntire [C25].

<sup>20</sup> *Apotex, Inc. v. FDA*, No. Civ.A. 06-0627, 2006 WL 1030151, at \*19 (D.D.C. 19 Apr. 2006).

128. On 6 June 2006, the U.S. Court of Appeals for the District of Columbia Circuit affirmed the District Court's order.<sup>21</sup>
129. Apotex moved for rehearing *en banc*, which was denied on 17 August 2006. In light of the D.C. Circuit's order, and the fact that Teva's exclusivity for pravastatin would expire before Apotex's suit could be resolved on the merits, Apotex voluntarily dismissed its claim. It elected not to petition for a writ of certiorari for review by the U.S. Supreme Court of the Court of Appeals' ruling, and, rather than litigating the merits of its case after losing its bid for preliminary injunctive relief, it stipulated to the dismissal of its claims with prejudice for certain strengths of the drug, and without prejudice for another strength (*Apotex Inc. v. FDA*, No. 06-627 (D.D.C. 3 Oct. 2006) (Dkt. No. 42, Stipulation of Dismissal)).
130. It is Apotex's case that the decisions of the FDA, the U.S. District Court for the District of Columbia, and the U.S. Court of Appeals for the District of Columbia Circuit were "*unlawful*", "*unjust*", "*improper*", "*arbitrary*" and "*capricious*", and have each violated U.S. statutory law and prior controlling precedent. In particular, it is alleged that the FDA and the D.C. district and appellate courts: (1) adopted and applied an interpretation of the FFDCRA that squarely conflicts with and violates Congressional intent, the purpose behind Hatch-Waxman, and controlling Federal Court precedent; (2) adopted and upheld a statutory interpretation that runs counter to the FDA's own regulation implementing the statute in a non-textual manner, by permitting a court decision of unenforceability to qualify as a court decision trigger; (3) construed the statute in a manner that nullifies and renders inoperable the declaratory judgment mechanism under Hatch-Waxman; and (4) failed to treat the BMS-Apotex dismissal in a manner similar to those court decisions entered in similar cases, despite the fact that this dismissal supports estoppel to the same extent as the Teva-Syntex dismissal, as well as the grant of partial summary judgment in *Granutec*.

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<sup>21</sup> *Apotex, Inc. v. FDA*, 449 F.3d 1249, 1254 (D.C. Cir. 2006).

131. According to Apotex, the FDA and the D.C. district and appellate courts' refusals to deem the dismissal of its declaratory judgment action against BMS as a trigger under the FDCA, meant that Apotex was unable to bring its generic pravastatin products to the market promptly, and as soon as the '227 patent and its associated period of paediatric exclusivity expired. This, so Apotex claims, caused it substantial damages. More specifically, because there was a refusal to find that the 180-day exclusivity period for generic pravastatin products had been triggered and expired, Teva and Ranbaxy launched their generic pravastatin products with exclusivity, thus securing a strangle-hold over the market.
132. It is Apotex's case, in broad summary, that by reason of these matters, the USA, through the FDA and its Federal Courts, has:
- (a) acted in breach of its National Treatment obligations under NAFTA Article 1102;
  - (b) acted in breach of its obligation to accord Apotex's investments fair and equitable treatment, and to meet the minimum standard of treatment under international law, under NAFTA Article 1105 (including an alleged denial of justice);
  - (c) interfered with and expropriated Apotex's property rights in its ANDA for generic pravastatin tablets, in violation of NAFTA Article 1110 (in particular, by unlawfully redistributing the financial benefits of Apotex's investment to other pravastatin ANDA filers, and by preventing Apotex from obtaining final approval of its generic pravastatin tablets immediately upon expiration of the '227 patent and its corresponding period of paediatric exclusivity).
133. Apotex claims that it has incurred significant loss and damage as a result of the USA's conduct, and claims declaratory and monetary relief (not less than US\$ 8,000,000) in this regard.

134. Again by way of broad outline only, it is the Respondent's case that Apotex's two claims in this arbitration raise one core allegation, specifically, that Federal Courts in New York and the District of Columbia, the U.S. Supreme Court, and the federal agency charged with interpreting the relevant statute, made legal errors in applying U.S. federal law. Alongside detailed responses to each of Apotex's individual claims under the provisions of NAFTA Chapter Eleven, the Respondent emphasises the general point that this Tribunal does not sit as a court of appeals for the courts of the United States, and in any event "legal error" by a court when applying U.S. law does not give rise to a violation of the NAFTA.

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## V. THE JURISDICTION AND ADMISSIBILITY OBJECTIONS

### (A) INTRODUCTION

135. It is the Respondent's case that Apotex's claims are not properly before this Tribunal, and that this Tribunal lacks jurisdiction to entertain them, on the following grounds:

- (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;
- (b) Apotex failed to pursue available remedies within the U.S. Court system with respect to its Pravastatin Claim, such that the judicial acts now complained of lack sufficient finality to form the basis of claims under NAFTA Chapter Eleven;
- (c) the time bar in NAFTA Article 1116(2) precludes Apotex's allegation in its Pravastatin Notice of Arbitration that the FDA's letter decision of 11 April 2006 (determining that the 180-day exclusivity period had not been triggered) itself constituted a violation of Articles 1102, 1105, and 1110 of the NAFTA.

136. Each objection is considered in turn below.

(B) NO “*INVESTMENT*” OR “*INVESTOR*”

i. Relevant Provisions of NAFTA

137. NAFTA Article 1101 establishes the scope and coverage of the entire investment chapter (Chapter Eleven) of the NAFTA, and expressly limits this to those “measures” adopted or maintained by a Party “relating to”:

(a) “*investors of another Party*” (NAFTA Article 1101(1)(a)) and to

(b) “*investments of investors of another Party in the territory of the Party*” (NAFTA Article 1101(1)(b)).<sup>22</sup>

138. Accordingly, NAFTA Article 1116 requires that claimants submitting claims to arbitration pursuant to this section be “*investors*” of a NAFTA Party.

139. The term “*investor of a Party*” is defined in NAFTA Article 1139 as follows:

“a Party or state enterprise thereof, or a national or enterprise of such Party, that seeks to make, is making or has made an investment.”

140. As noted in *Bayview Irrigation District et al. v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award (on Jurisdiction) para. 105 (19 June 2007) – if indeed any authority is needed for this proposition:

“in order to be an ‘investor’ under Article 1139 one must make an investment in the territory of another NAFTA State, not in one’s own.”<sup>23</sup>

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<sup>22</sup> Article 1101 has been described as the “*gateway leading to the dispute resolution provisions of Chapter 11*,” whose requirements limit the powers of a Chapter Eleven arbitral tribunal. *See e.g., Methanex Corp. v. United States*, NAFTA/UNCITRAL, First Partial Award, para. 106 (7 Aug. 2002); *Bayview Irrigation District and others v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award on Jurisdiction, para. 85 (19 June 2007). For the sake of completeness, NAFTA Article 1101(1)(c) also provides for the application of Chapter Eleven to investments with respect to NAFTA Articles 1106 and 1114 (which are of no relevance here).

141. The term “*investment*” is defined in NAFTA Article 1139 as follows:

“**investment** means:

- (a) an enterprise;
- (b) an equity security of an enterprise;
- (c) a debt security of an enterprise
  - (i) where the enterprise is an affiliate of the investor, or
  - (ii) where the original maturity of the debt security is at least three years,

but does not include a debt security, regardless of original maturity, of a state enterprise;

- (d) a loan to an enterprise
  - (i) where the enterprise is an affiliate of the investor, or
  - (ii) where the original maturity of the loan is at least three years,

but does not include a loan, regardless of original maturity, to a state enterprise;

- (e) an interest in an enterprise that entitles the owner to share in income or profits of the enterprise;
- (f) an interest in an enterprise that entitles the owner to share in the assets of that enterprise on dissolution, other than a debt security or a loan excluded from subparagraph (c) or (d);
- (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; and

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<sup>23</sup> See similarly: *Canadian Cattlemen for Fair Trade v. United States*, NAFTA/UNCITRAL, Award on Jurisdiction, para. 126 (28 Jan. 2008); *Grand River Enterprises Six Nations Ltd. v. United States*, NAFTA/UNCITRAL, Award, para. 87 (12 Jan. 2011) (NAFTA Chapter Eleven is applicable “*only to investors of one NAFTA Party who seek to make, are making, or have made an investment in another NAFTA Party: absent those conditions, both the substantive protection of Section A and the remedies provided in Section B of Chapter Eleven are unavailable to an investor*”).

- (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); or
- (j) any other claims to money,

that do not involve the kinds of interests set out in subparagraphs (a) through (h).”

142. Apotex has emphasised that Article 1139 is drawn broadly.<sup>24</sup> But as stated in *Grand River*:

“[In contrast to the] ICSID Convention or other regional and bilateral treaties ... containing broad and sometimes open-textured definitions of investment ... NAFTA’s Article 1139 is neither broad nor open-textured,”

but

“prescribes an exclusive list of elements or activities that constitute an investment for purposes of NAFTA”<sup>25</sup>

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<sup>24</sup> Citing *e.g.*, North American Free Trade Agreement, Implementation Act, Statement of Administrative Action, H.R. Doc. No. 103-159, Vol. 1, 103d Cong. 1st Sess., at 140 (“‘Investment’ is broadly defined in Article 1139, and both existing and future investments are covered”).

143. As observed by the Respondent, the NAFTA as a whole recognises that businesses can and do engage in different types of economic activity, and thus different remedies are provided for, depending on the type of activity in question. For example (and of particular note here), a company’s activities undertaken in its capacity as a foreign exporter of goods into the territory of a NAFTA Party are not addressed by Chapter Eleven, but rather by Chapter Three.
144. With the exception of the investment provisions of Chapter Eleven (and two provisions of Chapter Fifteen), the Parties to the NAFTA limited dispute resolution for alleged violations of most of the treaty, including Chapter Three, to the state-to-state dispute resolution mechanisms set out in Chapter Twenty.<sup>26</sup> Only Chapter Eleven, which addresses foreign investments, includes the NAFTA Parties’ consent to arbitration brought by an individual claimant directly against a NAFTA Party for breach of that Chapter.

**ii. The Respondent’s Position**

145. According to the Respondent, the Tribunal does not have jurisdiction over Apotex’s claims, which fall outwith the scope and coverage of NAFTA Chapter Eleven.
146. In outline,<sup>27</sup> the Respondent contends that:
- (a) As Claimant, Apotex bears the burden of proving at the jurisdictional stage the factual elements necessary to establish the Tribunal’s jurisdiction, including its claims that it was an “investor” with a qualifying “investment”. Apotex has failed to discharge this burden.

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<sup>25</sup> *Grand River*, Award, para. 82.

<sup>26</sup> See e.g., *Canadian Cattlemen*, Award on Jurisdiction, para. 193 (the “remedy” for claimant’s “trade dispute” “lies not in the investor-state dispute resolution mechanism of Chapter Eleven, but in the state-to-state dispute resolution mechanism of Chapter 20 of the NAFTA”).

<sup>27</sup> Further detail of the Respondent’s submissions is set out in the course of the Tribunal’s analysis below.

- (b) Apotex is a Canadian entity with no relevant presence or activity in the United States;
- (c) With respect to Apotex's actual development and manufacture of generic drugs, all its activities in relation to both its sertraline and pravastatin products take place outside of the United States (including, *inter alia*, the development, manufacture; processing; testing; packaging; and labelling of each drug);
- (d) Apotex's products, once manufactured outside the United States, are then exported by Apotex to United States-based distributors;
- (e) With respect to Apotex's preparation of ANDA submissions, this activity also takes place outside the United States;
- (f) Ultimately, therefore, Apotex is no more than an exporter of goods into the United States, for which, as with all other exporters of the same goods, it was required to secure regulatory clearance by the filing of ANDAs. None of this amounts to "*investment*" activity as contemplated by NAFTA Chapter Eleven.
- (g) Accordingly, Apotex's claims must be dismissed in their entirety.

**iii. Apotex's Position**

147. It is Apotex's case that both its Sertraline and Pravastatin Claims satisfy all jurisdictional requirements for an action pursuant to Chapter Eleven of NAFTA.

148. In outline,<sup>28</sup> Apotex contends that:

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<sup>28</sup> Further detail of Apotex's submissions is set out in the course of the Tribunal's analysis below.

- (a) Article 1139 of NAFTA defines “*investment*” broadly.
- (b) Apotex invested millions of dollars in developing its products and preparing and filing its ANDAs with the FDA, in accordance with U.S. statutory and regulatory requirements, in order to attain an economic benefit in the United States.
- (c) The sole purpose of Apotex’s development and submission of its ANDAs was to obtain FDA approval to commercialise its ANDA products in the United States.
- (d) These ANDAs (and everything that went into their development and submission) were and are manifestly a United States investment—that is, “*property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes.*”
- (e) Further, Apotex made substantial commitments of capital and other resources in the United States towards this economic activity (namely, the approval and sale of its ANDA products) in the United States. Such commitments included the purchase of raw materials for its ANDA products from suppliers in the United States.
- (f) Apotex also designated its U.S. affiliate and distributor (Apotex Corp.) as its U.S. Agent for FDA regulatory purposes and submissions, as required by U.S. law.
- (g) Further still, Apotex designated an agent for service of process in the United States, thus consenting to jurisdiction and suit there, and committed substantial resources litigating its ANDA products in the United States—all necessary for the commercialisation of its investments in the United States.
- (h) Under the plain terms of NAFTA, Apotex is therefore an “*investor*” that made “*investments . . . in the territory of the Party,*” thus bestowing this Tribunal with the necessary jurisdiction to hear its claims on their merits.

iv. The Tribunal's Analysis

(a) *“Investment”*

149. This issue obviously turns upon the precise (i) location and (ii) nature of each of the activities / property relied upon by Apotex as an *“investment”* for the purposes of NAFTA Article 1139.
150. Apotex (as Claimant) bears the burden of proof with respect to the factual elements necessary to establish the Tribunal's jurisdiction in this regard.<sup>29</sup>
151. *The Alleged “Investment”*: The exercise of identifying a precise *“investment”* for the purposes of NAFTA Article 1139 evidently caused Apotex some difficulty in this case. Indeed, this proved something of a moving target in the course of the proceedings.
152. In its Statement of Claims (paras. 62, 111), Apotex did not identify any specific subparagraphs of NAFTA Article 1139, but stated that it:

“has made substantial ‘investments,’ including, but not limited to, the expenditure of millions of dollars each year in preparing ANDAs for filing in the United States, and formulating, developing, and manufacturing approved generic pharmaceutical products for sale in the United States and throughout the world.”

153. Similarly, in para. 23 of its Statement of Claims, Apotex stated that it:

“... invests millions of dollars in designing and formulating its proposed drug products, procuring or manufacturing the active pharmaceutical ingredients for such products, preparing and filing applications with the U.S. Food and Drug Administration (“FDA”) seeking approval to market and sell its drug products in the United States, and manufacturing the finished drug products.”

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<sup>29</sup> See e.g., *Phoenix Action, Ltd. v. Czech Republic*, ICSID Case No. ARB/06/5, Award, paras. 58-64 (15 Apr. 2009) (summarising previous decisions, and concluding that “if jurisdiction rests on the existence of certain facts, they have to be proven [rather than merely established prima facie] at the jurisdictional phase”).

154. In its submission in support of a stay (para. 48), Apotex identified its “*investment at issue*” simply as:

“Apotex’s [Sertraline/Pravastatin] ANDA products.”

155. Thereafter, in its Counter-Memorial on Respondent’s Objections to Jurisdiction, dated 1 August 2011, Apotex characterised its “*investment*” in the following ways:

- (a) in terms of the actual ANDA filings themselves, which were said to constitute “*property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes*” (NAFTA Article 1139(g)); and
- (b) in terms of other significant investments made by Apotex in the United States that involve “*the commitment of capital or other resources in the [United States] to economic activity in such territory,*” including “*contracts involving the presence of [Apotex’s] property in the [United States]*” (NAFTA Article 1139(h)).

156. These points were again set out in Apotex’s Rejoinder, dated 16 December 2011, but with the clarification that, for the purposes of NAFTA Article 1139(h), Apotex’s

“investment interests lie in its ANDAs, not merely in claims for money arising from its supply contracts or relationships with its U.S. agent or U.S. attorneys.”<sup>30</sup>

157. Overall, it would appear that - across all its submissions - Apotex has advanced three distinct alleged “*investments*”:

- (a) the formulation, development and manufacture of approved generic pharmaceutical products for sale in the United States;

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<sup>30</sup> Rejoinder, para. 6.

- (b) the preparation of ANDAs for filing in the United States, including all the effort and expenditure that this entails, and the resulting ANDAs themselves;
- (c) other significant investments made in the territory of the United States, including (*inter alia*) utilisation of its US affiliate, Apotex Corp.; the purchase of raw materials and ingredients in the United States; and expenditure on US litigation.

158. *Analysis:* Having carefully considered the entire record in this case, the Tribunal is clear that none of Apotex's characterisations of its alleged "*investment*" meet the requirements of NAFTA Article 1139, whether considered separately or together.

159. Each of Apotex's characterisations is addressed in turn below.

*i. Development and Manufacture of Products*

160. Apotex's first characterisation of its alleged "*investment*" focuses upon the "*formulating, developing, and manufacturing*" of the pharmaceuticals in issue. This cannot qualify for the purposes of NAFTA Chapter Eleven, for the simple reason that all the activities relied upon in relation to both sertraline and pravastatin products occur in Canada, not in the territory of the United States.

161. As noted above, activity by an exporter in the latter's own country does not constitute an "*investment*" under Article 1139.

162. The position with respect to Apotex and its activities is as follows.

163. *The Company Apotex:* In paragraph 2 of its Statement of Claim of 17 January 2011, Apotex describes itself as:

“a corporation duly incorporated and existing under the laws of Canada and having a principal place of business at: Apotex Inc. 150 Signet Drive Weston, Ontario, Canada M91 1T9.”

164. Apotex began business operations on 24 May 1974, and is a wholly-owned subsidiary of Apotex Pharmaceutical Holdings, Inc., located in North York, Ontario.<sup>31</sup> It appears that Apotex was registered as a corporation under Ontario law on 1 April 2004.<sup>32</sup>
165. By its own admission, it does not reside or have a place of business in the United States.<sup>33</sup>
166. It is to be noted that Apotex has not brought its claims under NAFTA Article 1117, which is entitled “*Claim by an Investor of a Party on behalf of an enterprise.*” In other words, it has brought its claims on its own behalf and not on behalf of any enterprise established in the U.S. - because Apotex does not claim to have established an enterprise there.
167. Similarly, Apotex has not claimed to have an equity or a debt interest in any U.S. company. It has not claimed to have purchased property or to have built facilities or to have hired a workforce in the U.S. And it has not claimed to have developed, tested, or manufactured its drugs in the United States.
168. *Apotex’s Operations:* Apotex develops pharmaceutical products in Canada for the domestic Canadian market, as well as for export to a large number of other countries, including the United States. Indeed, according to its website, as cited by the Respondent:

“[t]he company’s pharmaceuticals can be found in virtually every pharmacy and healthcare facility in Canada and are exported to over 115 countries around the globe”

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<sup>31</sup> Dun & Bradstreet Report on Apotex Inc. (14 April 2011) at 7-8 [R50]; GlobalData – History, Apotex, Inc. (3 Jan. 2011) [R52].

<sup>32</sup> Dun & Bradstreet Report on Apotex Inc. (14 April 2011) at 8 [R50]; GlobalData – History, Apotex, Inc. (3 Jan. 2011) [R52].

<sup>33</sup> Counter-Memorial, para. 50 & fn. 56 (citing Witness Statement of Bernice Tao, paras. 14, 25 (1 Aug. 2011) [C39]).

and

“[e]xport markets represent an ever growing portion of the total sales.”<sup>34</sup>

169. For exports to the U.S. market, Apotex’s website indicates that Apotex has built three “extensive” facilities in Ontario, Canada, at:

- (a) Etobicoke
- (b) Richmond Hill, and
- (c) the Signet Campus.<sup>35</sup>

170. Apotex carries out drug development and manufacturing activities from these three campuses.<sup>36</sup>

171. *Development and Manufacture of Sertraline Products:* As noted in **Section III** above, ANDA applicants must include in their application (*inter alia*):

- detailed information about the research undertaken to establish bio-equivalence, including the address of the facility or facilities conducting the relevant bio-equivalence study;
- a description, including a full address, of the facility for manufacturing, processing, testing, and packaging of the proposed product, and sample labelling for the proposed product with the address of the manufacturer of the product.

172. Notably, in its ANDA submission for sertraline oral tablets, dated 27 October 2003:

- (a) Apotex’s facility at [REDACTED], is listed as performing:

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<sup>34</sup> <http://www.apotex.com/global/about/default.asp> - [R46].

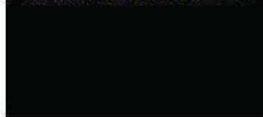
<sup>35</sup> [R47].

<sup>36</sup> GlobalData – Business Description, Apotex, Inc. (3 Jan. 2001) [R53].



- (b) Apotex Corp. (an Illinois entity) is designated as Apotex’s “Authorized U.S. Agent.”<sup>38</sup> Apotex Corp. is identified as a United States-based distributor, but there is no indication that this entity has any role in the development, manufacture, or testing of Apotex’s products.<sup>39</sup>
- (c) The proposed container label for sertraline tablets (submitted with the ANDA) indicates that manufacturing of Apotex’s sertraline products occurs in Canada, for export to, and sale by, Apotex Corp., as follows:<sup>40</sup>

“Manufactured by:



Manufactured for:



173. *Development and Manufacture of Pravastatin Products:* Similarly, in its ANDA submission for pravastatin oral tablets, dated 21 December 2001:

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<sup>37</sup> ANDA – Sertraline (27 Oct. 2003) at: 4335 (description of manufacturing facility). *See also id.* at 0003 (Form FDA 356h): “*TorPharm* [Apotex Inc.’s former name] [REDACTED] for the finished product [REDACTED]” [R44].

<sup>38</sup> ANDA – Sertraline (27 Oct. 2003) at: 0001 (Form FDA 356h); 5597 (letter designating authorised representative) [R44].

<sup>39</sup> ANDA – Sertraline (27 Oct. 2003) at: 0113 (distributor) [R44].

<sup>40</sup> ANDA – Sertraline (27 Oct. 2003) at 0154-55 (example of proposed container label) [R44].

<sup>41</sup> Apotex’s previous name.

(a) Apotex's facility at [REDACTED] is listed as performing:

[REDACTED]

(b) Apotex Corp. is designated as Apotex's "Authorized U.S. Agent".<sup>43</sup> Once again, Apotex Corp. is not listed anywhere as developing, manufacturing, or testing Apotex products, but is simply described as a U.S.-based distributor.<sup>44</sup>

(c) As with its sertraline products, the proposed container label for pravastatin tablets (submitted with its ANDA) indicates that manufacturing occurs in Canada for export to, and sale by, Apotex Corp., as follows:<sup>45</sup>

"Manufactured by:

[REDACTED]

Manufactured for:

[REDACTED]

174. Thus, on the basis of Apotex's own regulatory filings, it is clear that both its sertraline and pravastatin products are formulated, developed, manufactured, tested and labelled outside the United States, and then exported by Apotex to (separate) U.S.-based distributors.

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<sup>42</sup> ANDA – Pravastatin (21 Dec. 2001) at 5370, and at p. 0003 (FDA Form 356h) noting that "TorPharm [*i.e.* Apotex] [REDACTED] for the finished product [REDACTED] [R45].

<sup>43</sup> ANDA – Pravastatin (21 Dec. 2001) at 0001 (FDA Form 356h); 6803 (letter designating authorized representative) [R45].

<sup>44</sup> ANDA – Pravastatin (21 Dec. 2001) at 0100 (distributor) [R45].

<sup>45</sup> ANDA – Pravastatin (21 Dec. 21) at 0117-18 (example of proposed container label) [R45].

<sup>46</sup> Apotex's previous name.

175. Apotex could, of course, have invested in U.S.-based manufacturing, development, or testing facilities, but opted instead to create and manufacture its generic pharmaceuticals in Canadian factories. Indeed, in its U.S. federal court filings related to pravastatin, Apotex made clear that it invested in a factory in Winnipeg, Canada, for the development and production of the active pharmaceutical ingredient, pravastatin sodium.<sup>47</sup>

176. It follows that Apotex's formulation, development, and manufacture of the pharmaceuticals in issue does not qualify for the purposes of NAFTA Chapter Eleven, since these are all activities conducted outside of the United States.

*ii. The ANDA Submissions Themselves*

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.

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<sup>47</sup> See Declaration of Dr. Bernard C. Sherman, para. 6, *Apotex Inc. v. FDA*, Case No. 1:06-cv-00627 (JDB) (D.D.C. 14 Apr. 2006) (Dkt. No. 17-4) (identifying a US\$100 million investment in a fermentation facility for the development and production of pravastatin) [R58].

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>48</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>49</sup>
- (b) Strict requirements governing the documentation of such testing, sampling, and manufacturing, and the controls for each;<sup>50</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 facilities and equipment are located.<sup>51</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

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<sup>48</sup> 21 C.F.R. § 211 *et seq.* [C43].

<sup>49</sup> *Id.* at §§ 211.80 – 211.188.

<sup>50</sup> *Id.* at §§ 211.180 – 211.198.

<sup>51</sup> *Id.* at §§ 211.42 – 211.72.

accordance with the FDA's requirements, and that the submitted data is accurate and complete.<sup>52</sup>

181. According to Apotex, the FDA's approval requirements differ significantly from those in other countries.<sup>53</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>54</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>55</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<sup>®</sup> cannot be used to demonstrate bio-equivalence of Apotex's pravastatin tablets to Pravachol<sup>®</sup>, and vice versa.<sup>56</sup>
- (c) Apotex's in-process and manufacturing controls are specific to each product.<sup>57</sup>

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<sup>52</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>53</sup> Witness Statement of Bernice Tao, para. 6 [C39].

<sup>54</sup> Witness Statement of Shashank Upadhye, Esq. para. 8 [C40].

<sup>55</sup> Witness Statement of Bernice Tao, paras. 16, 26 [C39].

<sup>56</sup> *Id.* at paras. 17, 27.

<sup>57</sup> *Id.* at paras. 18, 28.

(d) Apotex obviously cannot reuse labels designed for either its sertraline or pravastatin products in the sale of another product.<sup>58</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>59</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>60</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>61</sup>

184. Apotex placed heavy reliance here upon the statement in *Grand River Enterprises Six Nations, Ltd. et al. v. United States* that:

“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>62</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:

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<sup>58</sup> *Id.* at paras. 19, 29.

<sup>59</sup> *E.g.* Counter-Memorial, para. 44.

<sup>60</sup> Witness Statement of Shashank Upadhye, Esq., para. 10 [C40].

<sup>61</sup> Witness Statement of Bernice Tao, paras. 11-12 [C39]; Witness Statement of Shashank Upadhye, Esq., paras. 6-19 [C40].

<sup>62</sup> *Grand River*, Award, para. 88, citing *Bayview*, Award on Jurisdiction, paras. 98-99.

“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>63</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>64</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>65</sup>

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<sup>63</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>64</sup> GlobalData – Business Description, Apotex, Inc. (3 Jan. 2001) [R53] (emphasis added).

<sup>65</sup> Statement of Claims, paras. 62, 111.

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:

“[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>66</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>67</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>68</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

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<sup>66</sup> Also: [REDACTED] [R113].

<sup>67</sup> Counter-Memorial, para. 39, fn. 37 (citing *Grand River*, Award, para. 88).

<sup>68</sup> *Grand River*, Award, para. 88 (citing with approval *Bayview*, Award, paras. 98-99).

measures taken by another NAFTA State Party. The NAFTA should not be interpreted so as to bring about this unintended result.”<sup>69</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>70</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.

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>71</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>72</sup>

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<sup>69</sup> *Bayview*, Award, para. 103.

<sup>70</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”).

<sup>71</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.

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>73</sup> Further, an ANDA can be

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<sup>72</sup> *Grand River*, Award, para. 115.

<sup>73</sup> 21 C.F.R. § 314.72(a).

bought and sold like all other property,<sup>74</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>75</sup>

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>76</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>77</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.

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<sup>74</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>75</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)).

<sup>76</sup> Citing 18 U.S.C. § 1905; 21 U.S.C. § 331(j); 21 C.F.R. § 314.430.

<sup>77</sup> Witness Statement of Shashank Upadhye, Esq., paras. 6-9 [C40].

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>78</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. 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

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<sup>78</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*”.

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>79</sup> and an application with a tentative approval will not become finally approved until the FDA issues a final approval letter.<sup>80</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>81</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

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<sup>79</sup> 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA) [R3]; 21 C.F.R. § 314.107(b) [R89].

<sup>80</sup> 21 C.F.R. § 314.107(b)(3)(v) [R89].

<sup>81</sup> *Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 15, 19, 21 (D.D.C. 2004) [R114].

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>82</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 information before they could be finally approved, and before permission could be granted to export its generic drugs to the United States.<sup>83</sup>
213. Apotex alleges that the sertraline-related NAFTA breaches occurred no later than October 2006.<sup>84</sup> This was prior to the FDA’s final approval of Apotex’s sertraline ANDA.<sup>85</sup>

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<sup>82</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].

<sup>83</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 80 mgs) 27 Oct. 2004 [R109].

<sup>84</sup> Sertraline Notice of Arbitration, paras. 55-56.

<sup>85</sup> FDA Tentative Approval for Sertraline Hydrochloride Tablets (25, 50, and 100 mgs) dated 27 Sept. 2006 [R96]; FDA Final Approval for Sertraline Hydrochloride Tablets (25, 50, and 100 mgs) dated 6 Feb. 2007 [R97].

214. Similarly, Apotex alleges that the pravastatin-related NAFTA breaches occurred no later than August 2006.<sup>86</sup> This was prior to the FDA’s final approval of Apotex’s pravastatin ANDA.<sup>87</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>88</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

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<sup>86</sup> Pravastatin Notice of Arbitration, para. 31.

<sup>87</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>88</sup> Transcript, Day 1, page 223.

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 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>89</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>90</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>91</sup> And yet Apotex has insisted that:

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<sup>89</sup> *E.g.* Counter-Memorial, para. 37.

<sup>90</sup> *E.g.* Counter-Memorial, para. 37.

“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>92</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 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

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<sup>91</sup> Counter-Memorial, para. 38.

<sup>92</sup> Counter-Memorial, para. 37.

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>93</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>94</sup>

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<sup>93</sup> Counter-Memorial, paras. 48-62.

<sup>94</sup> Witness Statement of Bernice Tao, paras. 14, 25 [C39].

- (b) Apotex Corp. also acts as the distributor for both of Apotex’s pravastatin and sertraline ANDA products.<sup>95</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:
- 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>96</sup> and it spent over [REDACTED] on these ingredients;<sup>97</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>98</sup> and spent nearly [REDACTED] on these ingredients;<sup>99</sup>

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<sup>95</sup> Witness Statement of Bernice Tao, paras. 23, 32 [C39].

<sup>96</sup> Pravastatin ANDA § 8(2)(d) at 5262-63 [C55].

<sup>97</sup> Witness Statement of Bernice Tao, para. 31 [C39].

<sup>98</sup> Sertraline ANDA § 8(2)(d) at 4222-23 [C54].

<sup>99</sup> Witness Statement of Bernice Tao, para. 21 [C39].

-- 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>100</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>101</sup> And in this regard, Apotex has spent in excess of [REDACTED] in legal fees in connection with its sertraline ANDA litigation, and in excess of [REDACTED] in legal fees in connection with its pravastatin ANDA litigation, all such expenses having been incurred in the United States.<sup>102</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.”

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<sup>100</sup> 21 C.F.R. § 314.95(c)(7) [C45].

<sup>101</sup> Witness Statement of Shashank Upadhye, Esq. paras. 13, 18 [C40].

<sup>102</sup> *Id.* at paras. 14, 19.

and *SGS v. Pakistan*,<sup>103</sup> at para. 136:

“While the expenditures [in Pakistan related to SGS’s extraterritorial customs inspection] may be relatively small ... they involved the injection 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.”

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<sup>103</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).

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>104</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>105</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 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).

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<sup>104</sup> Respondent’s Reply Memorial on Jurisdiction, dated 17 Oct. 2011, para. 35.

<sup>105</sup> Rejoinder Memorial On Respondent’s Reply On Objections To Jurisdiction, dated 16 Dec. 2011, para. 33.

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>106</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>107</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>108</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

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<sup>106</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>107</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>108</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.

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>109</sup>

240. *Consent to U.S. 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 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.

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<sup>109</sup> *Bayview*, Award, para. 104.

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>110</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.

247. This is a complete answer to all of Apotex’s claims in both cases before this Arbitral Tribunal, such that, strictly, there is no need for the Arbitral Tribunal to consider the Respondent’s two remaining objections. However, since each of the remaining objections

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<sup>110</sup> *Grand River*, Award, para. 5.

was the subject of detailed written and oral argument, the Arbitral Tribunal considers it appropriate to address them.

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(C) **JUDICIAL FINALITY WITH RESPECT TO THE PRAVASTATIN CLAIM**

i. **Respondent's Position**

248. As summarised in **Section IV** above, in both its Sertraline and Pravastatin Claims, Apotex alleges that it suffered harm as a result of certain acts of (*inter alia*) U.S. Federal Courts.

249. With respect to its Sertraline Claim, Apotex sought, and was denied, review from the U.S. Supreme Court with regard to the lower court decisions rejecting its declaratory judgment action. All avenues of recourse within the U.S. court system were thereby exhausted.

250. With respect to its Pravastatin Claim, however, Apotex elected not to pursue all potentially available avenues before the U.S. Courts. In particular, it did not seek U.S. Supreme Court review of the court decisions rejecting its efforts to enjoin application of the FDA decision. On the contrary, Apotex voluntarily dismissed with prejudice most of its claims in the U.S. District Court for the District of Columbia, after it lost its bid for preliminary injunctive relief, and has not brought any remaining claims in court (See *Apotex Inc. v. FDA*, No. Civ. A. 06-027 (D.D.C., 3 Oct. 2006) (Dkt. No. 42, Stipulation of Dismissal)).

251. In outline,<sup>111</sup> the Respondent argues that Apotex therefore failed to pursue available remedies at the trial court level – let alone reach judicial finality with regard to its domestic court remedies on appeal.

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<sup>111</sup> Further detail of the Respondent's submissions is set out in the course of the Tribunal's analysis below.

252. Given that the judicial acts which are now the subject of complaint in the Pravastatin Claim are not final, the Respondent submits that none can be the basis for claims under NAFTA Chapter Eleven.

**ii. Apotex's Position**

253. It is Apotex's case that it has satisfied the requirement of finality for its Pravastatin Claim, even under the standard advocated by the Respondent.

254. The Respondent argues that, after the appellate court granted summary affirmance rejecting Apotex's request for injunctive relief on 6 June 2006, and subsequently denied Apotex's petition for rehearing *en banc* on 17 August 2006, Apotex should have:

(a) petitioned the Supreme Court for a writ of *certiorari*; and/or

(b) continued to proceed in litigating the case at the District Court level (on a non-expedited basis) instead of voluntarily dismissing its claim upon remand.

255. According to Apotex, however, and in outline only,<sup>112</sup> given the timing of the D.C. Circuit's order denying Apotex's petition for rehearing *en banc*, it would have been "obviously futile" for Apotex to pursue either one of these actions.

256. Apotex's application for rehearing *en banc* was denied on 17 August 2006. In light of the D.C. Circuit's order, and the fact that Teva's exclusivity for pravastatin would expire well before Apotex's suit could be resolved on the merits, Apotex was justified in voluntarily dismissing its claim.

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<sup>112</sup> Further detail of Apotex's submissions is set out in the course of the Tribunal's analysis in the following section.

### iii. The Tribunal's Analysis

257. *The Nature of this Objection:* As explained in more detail below, this objection has been argued by both Parties on the basis of an agreed basic principle, namely that any claim under NAFTA which is based upon a judicial act, is subject to a requirement that all judicial remedies within the host State first be exhausted. In other words, both sides have proceeded upon a common assumption (a) that “judicial finality” must first be reached in the host State’s domestic courts, (b) unless such recourse is “obviously futile”.<sup>113</sup> The Parties have differed, however, on the precise calibration of the “obviously futile” exception.

258. At the outset of the oral hearing, the Tribunal questioned the proper characterisation of this objection, and in particular whether it raised an issue of jurisdiction or admissibility, or whether it might also be viewed as a preliminary substantive objection.<sup>114</sup> This is a debate with a long heritage as a matter of international law, and long-divided views.<sup>115</sup>

259. However, from the inception of these proceedings, both Parties have treated this objection as one of jurisdiction. This was then clarified in oral submissions by Counsel for the Respondent, as the objecting Party, as follows:

“First, the United States agrees that the principle of finality in this case is distinct from the general international law rule of the exhaustion of local remedies, which the President has characterized as a procedural rule. The exhaustion rule does not apply as a precondition to bringing a claim under Chapter Eleven where the claim is based on a final Government act. In other

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<sup>113</sup> This is an assumption that has been challenged by some commentators. *See e.g.*, McLachlan Shore & Weiniger, *International Investment Arbitration* (OUP 2007), at paras. 7.87 - 7.98, who criticise the reasoning in *Loewen*, and argue that the customary international law rule on the exhaustion of local remedies has no role to play in the different / hybrid context of investor-State arbitration. Given both Parties’ approach in this case, and both Parties’ heavy reliance on *Loewen* (see below), this wider debate was not engaged here.

<sup>114</sup> Transcript, Day 1, pages 9-14.

<sup>115</sup> *See e.g.*, Crawford, Pellet & Olleson (Eds) *The Law of International Responsibility* (OUP 2010), at pp.1066-7.

words, a ‘*measure*’ that has been, ‘*adopted or maintained*’ pursuant to Article 1101.

Second, as we explained yesterday, the United States position is that under Article 1101, the act of a domestic court cannot constitute a measure that has been adopted or maintained by the State, unless the Claimant has exhausted all his judicial appeals. This interpretation derives from the rule of finality in international law under which, ‘*an act of a domestic court that remains subject to appeal has not ripened into the type of final act that is sufficiently definite to implicate State responsibility unless such recourse is obviously futile.*’ I quote from the Parties’ submissions.

Thus, it is the United States’ position that Apotex has no basis in the NAFTA for challenging non-final judicial acts as breaches of Articles 1102, 1105, and 1110, unless they can show that final appeal would have been obviously futile. To support a Chapter Eleven claim, the judicial acts complained of must be final. In our view, this is a question of jurisdiction *ratione materiae*, a question of subject-matter jurisdiction, because it goes to whether the Tribunal may consider a claim based on a non-final judicial act. But, whether the Tribunal chooses to characterize it as a question of ripeness, of admissibility, or of jurisdiction, the outcome in this case is the same: The claim should be dismissed because Claimants failed to seek appeal to the Supreme Court. In the United States’ view, if the Tribunal characterizes the finality requirement as an issue of admissibility, this does not compel it to defer decision on it, as Claimant suggested yesterday. Even an authority such as Judge Fitzmaurice who considers finality a question related to the merits treats it as a ‘*preliminary objection.*’ Thus, it is entirely proper to consider finality as ‘*a preliminary question,*’ under Article 21(4) of the UNCITRAL Rules, along with the issues of investment and time bar. We believe there is no dispute about the nature of investment in time bar as jurisdictional questions.

In other words, whether characterized as admissibility or ripeness or jurisdiction, the question whether Apotex can properly state a claim that non-final judicial acts violated the NAFTA is a threshold issue. It should be decided by the Tribunal as a matter of sound judicial economy. Both Apotex and the United States have presented rounds of briefs and evidence on the matter and have argued it before the Tribunal. The question is now ready for decision by the Tribunal.”<sup>116</sup>

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<sup>116</sup> Transcript, Day 2, pages 322-325.

260. In line with both Parties' approach, the Tribunal proceeds on the basis that this objection concerns the Tribunal's jurisdiction *ratione materiae*. In the alternative, the Tribunal has also considered the matter in terms of the admissibility of claims.

261. *Relevant Chronology:* It is clear, as a matter of fact, that two further avenues of recourse within the U.S. judicial system were available to Apotex, and that Apotex elected not to pursue them.

262. First, Apotex never sought review in the U.S. Supreme Court of the pravastatin-related decisions by the U.S. Court of Appeals. In fact, none of the pravastatin-related judicial acts now relied upon by Apotex as breaching U.S. obligations under the NAFTA was finally reviewed within the U.S. judicial system.

263. Second, Apotex voluntarily agreed to the dismissal of its entire pravastatin claim in the U.S. courts, most of which was dismissed with prejudice, instead of proceeding at the District Court level.

264. It is useful here to re-cap the (somewhat complex) procedural history behind the Pravastatin Claim, as set out in **Section IV** above:

- (a) In *Teva v. FDA*, the Court of Appeals for the District of Columbia Circuit remanded the case to the District Court of the District of Columbia to vacate the FDA's first pravastatin letter decision of 28 June 2005.<sup>117</sup> Apotex, which was a party to the *Teva v. FDA* matter, did not file a petition for certiorari with the U.S. Supreme Court in that case, opting instead to file (on 5 April 2006) its own complaint in *Apotex v. FDA* in the District Court for the District of Columbia, along with a motion for a temporary restraining order.<sup>118</sup>

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<sup>117</sup> *Teva Pharms. USA, Inc. v. FDA*, 441 F.3d 1, 5 (D.C. Cir. 2006) [R29] (quoting *PDK Labs., Inc. v. DEA*, 362 F.3d 786, 797-98 (D.C. Cir. 2004)).

<sup>118</sup> Complaint, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. 5 Apr. 2006) (Dkt. No. 1) [R56].

- (b) After the FDA issued its 11 April 2006 letter decision (which found that the Apotex / BMS voluntary dismissal did not trigger the 180-day exclusivity period), Apotex re-filed its motion seeking a preliminary injunction as well as a temporary restraining order. Specifically, Apotex sought an order requiring the FDA to set aside its 11 April 2006 letter decision and temporarily enjoining the award of any 180-day exclusivity for pravastatin ANDAs. The proposed injunction also would have prevented the FDA from granting final approval of any pravastatin ANDAs pending final approval of Apotex’s ANDA or resolution of Apotex’s challenge to the FDA decision.<sup>119</sup>
- (c) Following the denial of Apotex’s motion by the District Court for the District of Columbia,<sup>120</sup> Apotex filed an emergency motion for reconsideration, which was rejected.<sup>121</sup> Apotex also appealed to the Court of Appeals for the District of Columbia Circuit and filed an emergency motion for injunctive relief pending appeal.<sup>122</sup> Teva opposed Apotex’s emergency motion and filed a cross-motion for summary affirmance of the District Court’s decision.<sup>123</sup>
- (d) On 20 April 2006, the Court of Appeals enjoined the FDA:

“from granting final approval of any ANDA for generic pravastatin pending further order of the court . . . to give the court sufficient

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<sup>119</sup> Motion for Temporary Restraining Order and/or Preliminary Injunction, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. 14 Apr. 2006) (Dkt. No. 17) [R57].

<sup>120</sup> *Apotex Inc. v. FDA*, 2006 WL 1030151, \*1, \*19 (19 Apr. 2006) [R11].

<sup>121</sup> Order, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. 20 Apr. 2006) (Dkt. No. 33) [R59].

<sup>122</sup> Notice of Appeal and Emergency Motion, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. 19 Apr. 2006) (Dkt. Nos. 963396-1 and 963398-1) [R60][R61].

<sup>123</sup> Combined Opposition and Cross-Motion, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. 20 Apr. 2006) (Dkt. Nos. 963590-1 and 963950-2) [R62].

opportunity to consider the merits of the motion for injunctive relief pending appeal.”<sup>124</sup>

- (e) On 24 April 2006, the Court of Appeals dissolved the administrative injunction and denied Apotex’s motion for injunctive relief pending appeal for failure to “*satisf[y] the stringent standards for an injunction pending appeal.*”<sup>125</sup>
- (f) On 18 May 2006, Apotex filed a motion to expedite consideration of its appeal.<sup>126</sup>
- (g) On 6 June 2006, the Court of Appeals granted Teva’s motion for summary affirmance, finding that Apotex had “*little likelihood of succeeding on the merits of its claims*” and remanding to the District Court for further proceedings.<sup>127</sup>
- (h) Apotex then filed a petition to the Court of Appeals for rehearing *en banc* on 21 July 2006, which was denied on 17 August 2006.<sup>128</sup>
- (i) Following the denial of its *en banc* petition, Apotex did not seek review by the U.S. Supreme Court.
- (j) Furthermore, following the remand of its case to the District Court, rather than pursuing a decision on the merits in court, Apotex stipulated to the dismissal of the claim. By stipulation with the FDA, Apotex agreed to the dismissal of:

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<sup>124</sup> Order, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. 20 Apr. 2006) (Dkt. No. 963810) [R63].

<sup>125</sup> Order, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. 24 Apr. 2006) (Dkt. No. 964341) [R64].

<sup>126</sup> Motion of Plaintiff-Appellant Apotex Inc. to Expedite Consideration of this Appeal, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. 18 May 2006) (Dkt. No. 969469) [R65].

<sup>127</sup> *Apotex Inc. v. FDA*, 449 F.3d 1249, 1253-54 (D.C. Cir. 6 June 2006) [R13]; Order, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. 6 June 2006) (Dkt. No. 971806) [R66].

<sup>128</sup> Petition for Rehearing *en banc* of Plaintiff-Appellant Apotex Inc., *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. 21 July 2006) (Dkt. No. 982546-1) [R14]; Per Curiam Order, *en banc*, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. 17 Aug. 2006) (Dkt. No. 986687) [R15].

“all claims regarding pravastatin sodium tablets 10 mg, 20 mg, and 40 mg with prejudice, without costs to any party”

and

“all claims regarding pravastatin sodium tablets 80 mg without prejudice, without costs to any party.”<sup>129</sup>

265. This was therefore a different situation to the Sertraline Claim—where Apotex sought, and was denied, a writ of certiorari by the U.S. Supreme Court with regard to the lower court decisions dismissing its declaratory judgment action.

266. Also unlike the Sertraline Claim, Apotex subsequently failed to pursue its claim even in the District Court, opting instead to agree to its dismissal.

267. Stated thus, the judicial acts now challenged by Apotex in its Pravastatin Claim do not appear as “final” manifestations of justice within the U.S. judicial system such as to allow for international law claims – because Apotex still had other options to pursue.

268. The key issue is therefore the basis upon which Apotex elected not to exhaust all available remedies, and whether such remedies were (according to the Parties’ common test) “*obviously futile*”.

269. *Application to the U.S. Supreme Court:* Apotex explains that after the FDA issued its letter decision on 11 April 2006 (refusing to treat the BMS - Apotex dismissal as a triggering court decision), Apotex promptly sought injunctive relief from the District Court. After the D.C. District Court denied Apotex’s motion, the FDA then approved Teva’s ANDA on 24 April 2006.<sup>130</sup> Teva immediately launched its respective ANDA

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<sup>129</sup> Stipulation of Dismissal at 2, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. 3 Oct. 2006) (Dkt. No. 42) [R12].

<sup>130</sup> Drugs@FDA, Teva ANDA No. 076056 (pravastatin sodium) [C56].

products, thereby triggering the 180-day exclusivity period, which would expire on 23 October 2006. Apotex immediately appealed the District Court's decision and Teva moved for summary affirmance.

270. As already noted, on 6 June 2006, the D.C. Circuit summarily affirmed the District Court's decision on Apotex's motion for a preliminary injunction. Apotex petitioned for rehearing of that decision, which the D.C. Circuit denied on 17 August 2006. At that point, the case returned to the D.C. District Court for further proceedings on the merits, on a non-expedited basis.

271. The core point, as far as Apotex is concerned, is that once its petition for rehearing *en banc* was denied, only 67 days remained of Teva's 180-day exclusivity period. After this period expired (*i.e.*, on 23 October 2006), Apotex would then be eligible for final approval of its pravastatin ANDA - regardless of the outcome of its case.<sup>131</sup>

272. Moreover, even if Apotex had eventually succeeded on the merits on or after that date, Apotex would not have been entitled to damages from the FDA, or any other party for that matter. Thus, once the 180-day exclusivity period had expired, Apotex would no longer be able to obtain any meaningful or effective relief from either the FDA or the Courts.

273. Therefore, against these facts, Apotex submits that it should not have been required to petition for *certiorari* requesting expedited relief to overturn the D.C. Circuit's summary affirmance – particularly given that the decision by the D.C. Circuit Court related solely to Apotex's request for injunctive relief, and was not a full decision on the merits.

274. Further, Apotex submits that it is wholly unrealistic to suppose that the Supreme Court would not only have granted the petition, but could have scheduled argument and render an

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<sup>131</sup> Apotex's pravastatin ANDA was in fact approved by the FDA on 23 October 2006, as *per* Drugs@FDA, Apotex ANDA No. 076341 (pravastatin sodium) [C57].

opinion in Apotex's favour within 67 days. Any efforts to achieve such a result would have been "*objectively futile*".<sup>132</sup>

275. Had Apotex immediately petitioned the Supreme Court for *certiorari*, under the relevant U.S. Supreme Court rules, the FDA would have had 30 days from the date the case was docketed to submit a response, after which Apotex would have had an additional 10 days to reply.<sup>133</sup> Thus, Apotex argues that the Supreme Court Clerk could not even have distributed Apotex's petition to the Supreme Court until less than a month was left in Teva's exclusivity period.<sup>134</sup> Thus, the Court would not have granted the petition, ordered briefing and a hearing, and decided the matter at any time before 23 October 2006, when the relief requested would have been rendered moot.

276. The Tribunal has sympathy for Apotex's position, and can readily appreciate that a judgment call was taken at the time that petitioning the U.S. Supreme Court was unlikely to secure the desired relief. However, as the Respondent has observed, under established principles, the question whether the failure to obtain judicial finality may be excused for "*obvious futility*" turns on the unavailability of relief by a higher judicial authority, not on measuring the likelihood that the higher judicial authority would have granted the desired relief. In this case, and on balance, the Tribunal is not satisfied that finality was achieved, such as to allow for a claim under NAFTA in respect of the particular judicial decisions in question.

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<sup>132</sup> According to the U.S. Supreme Court's website, as cited by Apotex, "*The Court receives approximately 10,000 petitions for a writ of certiorari each year. The Court grants and hears oral argument in about 75-80 cases.*" Supreme Court of the United States, Frequently Asked Questions, taken from <http://www.supremecourt.gov/faq.aspx> [C58]. Further, Apotex cites Aaron-Andrew P. Bruhl, *The Supreme Court's Controversial GVRs – And An Alternative*, 107 Mich. L. Rev. 711, 745 (Mar. 2009) [C59]: "[t]he average time between a grant of certiorari and the Supreme Court's decision is on the order of nine months, depending on the time of year."

<sup>133</sup> Sup. Ct. R. 15.3, 15.5 [C49].

<sup>134</sup> Sup. Ct. R. 15.6 [C49].

277. The starting point is to recall the very serious nature of the allegations against the U.S. judicial system in Apotex’s Pravastatin Claim. Apotex asserts that the U.S. District Court for the District of Columbia, and the U.S. Court of Appeals for the D.C. Circuit, administered justice so deficiently as to violate Apotex’s rights under the U.S. Constitution, and to put the United States in breach of its international law obligations under the NAFTA. Yet, at the same time (and notwithstanding the gravity of the alleged breaches), Apotex elected not to allow the U.S. Supreme Court all possible opportunities to correct the alleged errors and transgressions. Instead, Apotex now requests that this Tribunal – in effect – substitute itself for the U.S. Supreme Court, and sit as a supranational appellate court, to review the judicial decisions of lower U.S. courts. The Tribunal declines to do so, for three reasons.

278. First, as a general proposition, it is not the proper role of an international tribunal established under NAFTA Chapter Eleven to substitute itself for the U.S. Supreme Court, or to act as a supranational appellate court. This has been repeatedly emphasised in previous decisions. For example:

(a) *Mondev* Award, at paragraph 126:<sup>135</sup>

“Under NAFTA, parties have the option to seek local remedies. If they do so and lose on the merits, it is not the function of NAFTA tribunals to act as courts of appeal.”

(b) *Azinian* Award, at paragraph 99:<sup>136</sup>

“The possibility of holding a State internationally liable for judicial decisions does not, however, entitle a claimant to seek international review of the national court decisions as though the international jurisdiction seised has plenary appellate jurisdiction. This is not true generally, and it is not true for NAFTA.”

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<sup>135</sup> *Mondev Int’l Ltd. v. United States*, NAFTA/ICSID Case No. ARB(AF)/99/2, Award (11 Oct. 2002).

<sup>136</sup> *Azinian v. United Mexican States*, NAFTA/ICSID Case No. ARB(AF)/97/2, Award (1 Nov. 1999).

(c) *Waste Management* Award, at paragraph 129.<sup>137</sup>

“Turning to the actual reasons given by the federal courts, the Tribunal would observe that it is not a further court of appeal, nor is Chapter 11 of NAFTA a novel form of amparo in respect of the decisions of the federal courts of NAFTA parties.”

279. Second, and related to this, the “obvious futility” threshold is a high one. This necessarily follows from the nature of the rule to which it is an exception.

280. The requirement that local judicial remedies be exhausted before judicial acts may found an international complaint was said by both Parties to flow from two sources: (a) NAFTA Article 1101, by which any impugned act must be a “*measure adopted or maintained*” by the host State (and the proposition that a judicial act is not a measure adopted or maintained by the State unless “final”); and (b) customary international law, as applicable by virtue of NAFTA Article 1131, which provides that:

“A tribunal established under this section shall decide the issues in dispute in accordance with this agreement and applicable rules of international law.”

281. As a matter of customary international law, both Parties asserted that an act of a domestic court that remains subject to appeal has not ripened into the type of final act that is sufficiently definite to implicate State responsibility - unless such recourse is obviously futile. As summarised on behalf of the Respondent:

“The finality requirement is fundamental to claims that may result in holding a State’s Judiciary in violation of international law. National judicial systems including those of the three NAFTA Parties, provide for higher courts to correct errors below. Decisions by higher courts harmonise the interpretation and application of the law by lower courts. A finding by an International Tribunal such as this one, that national courts violated

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<sup>137</sup> *Waste Management Inc. v. United Mexican States*, NAFTA/ICSID Case No. ARB(AF)/00/3, Award (30 Apr. 2004).

international law implicates a systemic failure of the national judiciary. International law recognises, therefore, that the national court system must be given a chance to correct errors.”<sup>138</sup>

282. Although both Parties asserted that this rule applies to all causes of action premised upon judicial acts, both Parties primarily invoked authorities concerning denial of justice claims.<sup>139</sup> Such claims depend upon the demonstration of a systemic failure in the judicial system. Hence, a claimant cannot raise a claim that a judicial act constitutes a breach of international law, without first proceeding through the judicial system that it purports to challenge, and thereby allowing the system an opportunity to correct itself. In the words of Jan Paulsson, *Denial of Justice in International Law* 108 (2005):

“For a foreigner’s international grievance to proceed as a claim of denial of justice, the national system must have been tested. Its perceived failings cannot constitute an international wrong unless it has been given a chance to correct itself.”

And as stated in *Loewen Group v. United States*:

“The purpose of the requirement that a decision of a lower court be challenged through the judicial process before the State is responsible for a breach of international law constituted by judicial decision is to afford the State the opportunity of redressing through its legal system the inchoate breach of international law occasioned by the lower court decision.”<sup>140</sup>

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<sup>138</sup> Transcript, Day 1, pages 162-3.

<sup>139</sup> There is a live issue in the context of NAFTA as to whether the “finality” rule, or the requirement that local judicial remedies be exhausted, applies to any claim arising out of a judicial act, or merely “denial of justice” claims (or claims within the category of FET). This issue, however, was not pursued by the Parties in this case. Instead, both Parties relied upon the analysis in *The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Award (26 June 2003), in which the obligation to exhaust local remedies in a case in which the alleged violation of international law is founded upon a judicial act was applied to claims under NAFTA Articles 1102 and 1110 as well as Article 1105 (see *Loewen*, Award, para. 165, by reference, *inter alia*, to *The Finnish Ships Arbitration Award*, 3 R. INT’L ARB. AWARDS 1480, 1495, 1503-05 (9 May 1934) and *Nielsen v. Denmark* [1958-1959] Y.B. EUR. COMM’N H.R. 412 at 436, 438, 440, 444).

<sup>140</sup> *Loewen*, Award, para. 156. The same basic principle has a long and broader heritage. See e.g., Edwin M. Borchard, *The Diplomatic Protection of Citizens Abroad* 198 (1915) (“It is a fundamental principle that

283. Importantly, this principle was emphasised and relied upon in terms by Apotex in this case (to support its argument that none of its claims are time barred under NAFTA Article 1116(2) - see **Section V(d)** below). In Apotex’s own words:<sup>141</sup>

“71. Under Chapter Eleven of NAFTA, before an action by an agent of a State may be elevated to a breach that implicates State responsibility, it must be considered a ‘measure[ ] adopted and maintained by a Party.’<sup>142</sup> In other words, as explained over a century ago in the decisions of the United States-Mexican Claims Tribunal, a Respondent may not ‘be made responsible for the [conduct of a judicial office] when no attempt . . . has been made to obtain justice from a higher court.’<sup>143</sup>

72. Respondent has consistently maintained, and indeed prevailed on, this very position in other NAFTA Chapter Eleven proceedings. For example, before the *Loewen* Tribunal, where the Respondent United States also attempted to dismiss a NAFTA arbitration claim based upon alleged jurisdictional deficiencies, the Respondent argued that, under NAFTA and well-recognized principles of international law, ‘*judicial action is a single action from beginning to end so that the State has not spoken (and therefore no liability arises) until all appeals have been exhausted,*’ or any such appeals would be obviously futile.<sup>144</sup> The *Loewen* Tribunal agreed, stating:

No instance has been drawn to our attention in which an international tribunal has held a State responsible for a breach of international law constituted by a lower court decision when

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[with respect to acts of the judiciary] . . . only the highest court to which a case is appealable may be considered an authority involving the responsibility of the state.”); League of Nations Publications, Bases of Discussion, Vol. III Responsibility of States 41-51 (1920) (“It is not disputed that the courts are able to involve the State in responsibility, but the judicial decision with which it is confronted must be final and without appeal.”)

<sup>141</sup> Counter-Memorial on Jurisdiction, 1 Aug. 2011, paras. 71-74.

<sup>142</sup> Citing: NAFTA Art. 1101 (“This Chapter applies to measures adopted and maintained by a Party . . .”); and *Loewen*, Award, paras. 142-57 (26 June 2003) (“NAFTA Tribunal Award agreeing with the Respondent United States’ position that a finality requirement exists under NAFTA prior to an action being attributable to the state for which it bears responsibility”).

<sup>143</sup> Citing: John Bassett Moore, *Jennings, Laughland & Co. v. Mexico*, Case No. 374, in 3 History & Digest of The Int’l Arbs. to Which The U.S. Has Been a Party 3135, 3136 (1898) [C64].

<sup>144</sup> Citing *Loewen*, Award, para. 143.

there was available *an effective and adequate appeal* within the State's legal system.<sup>145</sup>

73. The principles under international law mandate that a claimant must exhaust its 'local remedies' prior to holding the State accountable for a breach of its obligations.<sup>146</sup> As the *Loewen* Tribunal aptly noted, the reason claimants are required to exhaust local remedies before a State can be held responsible under international law 'is to afford the State the opportunity of redressing through its legal system the inchoate breach of international law occasioned by the lower court decision. The requirement has application to breaches of [NAFTA] Articles 1102 and 1110 as well as Article 1105.'"<sup>147</sup>

284. Because each judicial system must be allowed to correct itself, the "obvious finality" exception must be construed narrowly. It requires an actual unavailability of recourse, or recourse that is proven to be "*manifestly ineffective*"<sup>148</sup> – which, in turn, requires more than one side simply proffering its best estimate or prediction as to its likely prospects of success, if available recourse had been pursued.<sup>149</sup>

285. It is not enough, therefore, to allege the "*absence of a reasonable prospect of success or the improbability of success, which are both less strict tests.*"<sup>150</sup> In the (frequently quoted) words of Professor Borchard, a claimant is not:

"relieved from exhausting his local remedies by alleging ... a pretended impossibility or uselessness of action before the local courts."<sup>151</sup>

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<sup>145</sup> Citing *Loewen*, Award, para. 154 (emphasis added by Apotex).

<sup>146</sup> Citing C.F. Amerasinghe, *Local Remedies in Int'l Law* 3-4 (2<sup>nd</sup> Ed. 2004); *Interhandel Case* (*Switz. v. U.S.*), 1959 I.C.J. 6, 27 (21 Mar. 1959).

<sup>147</sup> Citing *Loewen*, Award, para. 156.

<sup>148</sup> *Per* C.F. Amerasinghe, *Local Remedies in International Law* 206 (2nd. ed. 2004).

<sup>149</sup> It may be noted that of various formulations, the ILC, in Art 15 of its Draft Articles on Diplomatic Protection, did not adopt the stringent language of the "*obvious futility*" test, and instead settled upon: "*no reasonable possibility of an effective redress*" – but this was still described as imposing a heavy burden on claimants (*see* ILC Commentary to art 15, para. 3). This, of course, was in the context of the general principle as to exhaustion of local remedies in customary international law, as opposed to the more specific rule regarding judicial acts and "finality" in issue here.

<sup>150</sup> *Per* C.F. Amerasinghe, *Local Remedies in International Law* 206 (2nd. ed. 2004).

286. To give some flavour to the threshold, the Respondent has emphasised that where international tribunals have found “obvious futility”, they have tended to do so because there “*was no justice to exhaust.*” By way of example (as relied upon by the Respondent):

(a) ***The Finnish Ships Arbitration Award (Finland v. U.K.)*** (9 May 1934): rule excusing failure to appeal where reversal was “hopeless” is “*most strictly construed, and if substantial right of appeal existed, failure to prosecute an appeal operated as a bar to relief*”;<sup>152</sup>

(b) ***Robert E. Brown Case (U.S. v. U.K.)*** (23 Nov. 1923): excusing claimant’s failure to exhaust because there was “*no justice to exhaust*” where “[*a*]ll three branches of the Government conspired to ruin [*claimant’s*] enterprise”.<sup>153</sup>

287. Third, on the facts of this case, even if the chance of the U.S. Supreme Court agreeing to hear Apotex’s case was remote, the availability of a remedy was certain. Pursuant to 28 U.S.C. § 1254(1), Apotex could have sought U.S. Supreme Court review on an expedited basis of the Court of Appeals decision on injunctive relief, even after its petition for rehearing *en banc* was denied.<sup>154</sup>

288. As against this, Apotex submits that because the chances of a successful outcome were “*unrealistic*”, a petition to the U.S. Supreme Court was “*objectively futile*”,<sup>155</sup> or to be treated as if unavailable. In effect, the Tribunal is being asked to determine the likelihood of a successful result before the U.S. Supreme Court – which the Tribunal does not

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<sup>151</sup> E. Borchard, *The Diplomatic Protection of Citizens Abroad* 824 (1916).

<sup>152</sup> ***Finnish Ships Arbitration Award (Finland v. U.K.)***, R. Int’l Arb. Awards 1480, 1495, 1503-5 (9 May 1934), (quoting Professor Borchard, at 823).

<sup>153</sup> ***Robert E. Brown Case (U.S. v. U.K.)***, R. Int’l Arb. Awards 120, 129 (23 Nov. 1923).

<sup>154</sup> 28 U.S.C. § 1254 provides: “*Cases in the courts of appeal may be reviewed by the Supreme Court by the following methods: (1) By writ of certiorari granted upon the petition of any party to any civil or criminal case before or after rendition of judgment or decree.*”

<sup>155</sup> Counter-Memorial, para. 94.

consider is its proper task, or indeed the correct enquiry. In the words of Judge Lauterpacht, in *Norwegian Loans* case:<sup>156</sup>

“[H]owever contingent and theoretical these remedies may be, an attempt ought to have been made to exhaust them.”

289. Equally, the consequence of Apotex’s submission as to its chances of success before the U.S. Supreme Court (based in part on the small number of cases that this Court entertains each year) would be, in effect, to write the U.S. Supreme Court out of the exhaustion of remedies rule in almost all cases. This cannot be correct.

290. Even if (for the sake of completeness) the Tribunal was to embark on a prediction as to the likely ruling of the U.S. Supreme Court, had it been asked to rule, there are number of factors that undermine Apotex’s position:

- (a) Apotex asserts that seeking *certiorari* on its pravastatin claim would have been “*absurd*”, because the D.C. Circuit’s decision “*related solely to Apotex’s request for injunctive relief, and was not a decision on the merits.*”<sup>157</sup> In so far as this is intended to imply that the U.S. Supreme Court does not hear cases relating only to procedural matters, this is obviously not so: the U.S. Supreme Court has the power to hear cases that relate only to preliminary procedural issues,<sup>158</sup> and (importantly) to issue stays.<sup>159</sup> Apotex simply failed to seek any such relief here.

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<sup>156</sup> *Norwegian Loans (France v. Norway)*, 1957 I.C.J. 9, 39, Separate Opinion of Judge Lauterpacht.

<sup>157</sup> Counter-Memorial, para. 94.

<sup>158</sup> Federal Practice & Procedure § 4036 (2011) (stating that, with regard to 28 U.S.C. § 1254(1), “[e]ven more dramatic illustration of the lack of technical restrictions is provided by contrasting certiorari to the courts of appeals with certiorari to state courts. The greatest opportunity for imposing technicalistic difficulties is presented by the statutory requirement that the case be “in” the court of appeals, but no genuine obstacle has in fact resulted. *Beyond that starting point, there is no requirement that there be a ‘final’ decision; once a case has come to be in a court of appeals, the Supreme Court may grant certiorari to review interlocutory decisions or procedural rulings, and may even grant review before the court of appeals has taken any action at all.*”) (Emphasis added) [R90].

<sup>159</sup> Rules 22 and 23 of the Rules of the Supreme Court provide that the Court can issue stays, for example, to maintain the status quo. U.S. Sup. Ct. R. 22, 23 (2006) [R91].

(b) Apotex appears to have (in the Respondent’s words) “*run out the litigation clock*”. As such, it cannot now claim insufficient time to pursue further remedies. Apotex claims to have “*promptly*” sought injunctive relief from the District Court on its pravastatin claim,<sup>160</sup> and to have “*immediately*” appealed the District Court’s decision denying that relief.<sup>161</sup> But (as the Respondent has pointed out) when the D.C. Circuit, on 24 April 2006, dissolved the administrative injunction temporarily staying the FDA’s approval of any pravastatin ANDAs, Apotex then waited 24 days before seeking expedited consideration (a simple 14-page motion).<sup>162</sup> The D.C. Circuit rendered its decision in just under three weeks (6 June 2006) – well ahead of Apotex’s proposed schedule.<sup>163</sup> Apotex could then have immediately petitioned the U.S. Supreme Court (*i.e.* as of 7 June 2006, 138 days before the end of Teva’s exclusivity period). Apotex elected not to do so, but instead chose to petition the D.C. Circuit for *en banc* rehearing.<sup>164</sup> And yet Apotex then took 44 of 45 allotted days to file a 15-page petition for rehearing *en banc*<sup>165</sup>—a motion that, according to the Respondent, was not required in any event in order to seek review by the U.S. Supreme Court (or, indeed, to pursue claims on the merits in the District Court.) After the D.C. Circuit denied Apotex’s *en banc* petition, Apotex still had 67 days to seek *certiorari* (or, indeed, other relief, such as a stay), before the 180-day market exclusivity expired. Overall, as the Respondent has noted, Apotex spent a total of 135 days of the 180-day exclusivity period “*not advancing its claim in court*”. The timing difficulty,

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<sup>160</sup> Counter-Memorial, para. 91.

<sup>161</sup> *Id.*

<sup>162</sup> Motion of Plaintiff-Appellant Apotex, Inc. to Expedite Consideration of this Appeal, *Apotex, Inc. v. FDA*, No. 06-5105 (D.C. Cir. 18 May 2006) [R65].

<sup>163</sup> *Id.* at 1.

<sup>164</sup> Petition for Rehearing *en banc* of Plaintiff-Appellant Apotex Inc., *Apotex, Inc. v. FDA*, No. 06-5105 (D.C. Cir. 21 July 2006) [R14].

<sup>165</sup> D.C. Cir. R. 35(a) (2006) (“In all cases in which the United States or an agency or officer thereof is a party, the time within which any party may seek panel rehearing or rehearing *en banc* is 45 days after entry of judgment or other form of decision.”) [R92].

therefore, was in large part a consequence of Apotex's own litigation strategy. As stated in the *Ambatielos Case (Greece v. U.K.)*, at 122 (6 Mar 1956):

“It would be wrong to hold that a party who, by failing to exhaust his opportunities in the Court of first instance, has caused an appeal to become futile should be allowed to rely on this fact in order to rid himself of the rule of exhaustion of local remedies.”<sup>166</sup>

291. *Pursuing the Claim at District Court Level:* As to the Respondent's argument that Apotex should have pressed onward with its claim at the District Court level, Apotex submits that the D.C. District Court had already denied Apotex's request for emergency relief, which the D.C. Circuit affirmed on appeal. Thus, at the District Court level, Apotex would have been forced to proceed at the standard litigation pace, as expedited relief was no longer an option.

292. On remand, the District Court scheduled a status hearing to be held on 6 October 2006.<sup>167</sup> On 3 October 2006, a mere 20 days before Teva's exclusivity period expired, Apotex voluntarily dismissed its suit.<sup>168</sup> According to Apotex, even if it had immediately filed a summary judgment motion after the 6 October 2006 status conference, under the local rules of that District Court, the time permitted to fully brief the matter would have extended beyond the date the issue became moot on 23 October 2006.<sup>169</sup>

293. Once again, however, the Tribunal does not consider that Apotex has met the “*obvious futility*” exception here.

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<sup>166</sup> *Ambatielos Case (Greece v. U.K.)*, 12 R. Int'l Arb. Awards 83 (6 Mar. 1956).

<sup>167</sup> See *Apotex Inc. v. FDA*, No. 06-627, Text-only Order (D.D.C. 20 Sept. 2006) [C52].

<sup>168</sup> *Id.* at Dkt. No. 42, Stipulation of Dismissal (D.D.C. 3 Oct. 2006).

<sup>169</sup> Apotex cites Local Civil Rule 7 of the United States District Court for the District of Columbia (as in effect in 2006), by which a party opposing a motion had 11 days to file an opposition brief, and Apotex would then have had five days (excluding weekends) to file a reply [C50] & [C51]; Fed. R. Civ. P. 6 (2008) [C47].

294. The Tribunal is not persuaded that pursuing substantive relief on remand would have been “*absurd*”, because Apotex “*would have been forced to proceed at standard litigation pace, as expedited relief was no longer an option.*”<sup>170</sup> Just as Apotex had sought expedited consideration of its appeal (on the interlocutory issue) before the D.C. Circuit, it remains unclear why it could not have sought expedited consideration of its claim on the merits before the D.C. District Court.<sup>171</sup> On any view, it made no attempt to do so.
295. Further, after the D.C. Circuit rejected Apotex’s petition for rehearing *en banc* on 17 August 2006, Apotex waited 47 days (until 3 October 2006) before voluntarily dismissing all of its claims against the FDA.<sup>172</sup>
296. Further still, as is clear from its Stipulation of Dismissal, Apotex dismissed all claims “with prejudice” for 10, 20, and 40 mg strengths, but “without prejudice” for the 80 mg strength. As the Respondent notes, the 180-day exclusivity period for 80 mg generic pravastatin had not yet begun to run, because Ranbaxy (the company that had been awarded the 180-day exclusivity for 80 mg generic pravastatin) had not yet launched that strength.<sup>173</sup> Ranbaxy did not in fact do so until 25 June 2007.<sup>174</sup> Importantly, Apotex preserved its ability to continue litigating before the District Court with respect to 80 mg pravastatin – but it never did.

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<sup>170</sup> Counter-Memorial, para. 95.

<sup>171</sup> 28 U.S.C. § 1657(a) (“Notwithstanding any other provision of law, each court of the United States shall determine the order in which civil actions are heard and determined, except that the court shall expedite the consideration of any action brought under chapter 153 or section 1826 of this title, any action for temporary or preliminary injunctive relief, or any other action if good cause therefor is shown. For purposes of this subsection, ‘good cause’ is shown if a right under the Constitution of the United States or a Federal Statute . . . would be maintained in a factual context that indicates that a request for expedited consideration has merit.”) As the Respondent notes, under the Local Civil Rules of the D.C. District Court, Rule 16.1(a) permits the judge assigned to the case to determine the schedule accordingly [R94].

<sup>172</sup> Stipulation of Dismissal, at 2, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. 3 Oct. 2006) [R12].

<sup>173</sup> Hence, Apotex’s petition for rehearing *en banc* made clear that “*the public ha[d] no access to a generic 80mg pravastatin product*” at that time: Petition for Rehearing *en banc* of Plaintiff-Appellant Apotex Inc. at 15, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. 21 July 2006) [R14].

<sup>174</sup> News Release, “*Ranbaxy Launches Pravastatin Sodium 80 Mg Tablets*” (25 June 2007) [R112].

297. Apotex has sought to rebut this point, on the basis that once Teva’s exclusivity period had expired for all other strengths, Apotex’s ability to obtain effective relief expired with it, and that “*the damage to the generic pravastatin market had been done*”. The Tribunal, however, remains unpersuaded on Apotex’s reply, which was neither properly developed as a submission, nor supported by any evidence.

**iv. Conclusion**

298. It follows that, even if Apotex did qualify as an “*investor*”, who has made an “*investment*” in the U.S. for the purposes of NAFTA Articles 1116 and 1139, all claims within Apotex’s Pravastatin Claim that the judicial acts of the D.C. District Court and the D.C. Circuit breached Articles 1102, 1105, and 1110 of the NAFTA would fall to be dismissed in any event, on the additional basis that Apotex has failed to exhaust all local judicial remedies, and the Tribunal therefore lacks jurisdiction *ratione materiae*.

299. In the alternative, and for the same reasons, all such claims would be inadmissible in any event.

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**(D) THE NAFTA TIME BAR**

**i. Relevant Provisions of NAFTA**

300. NAFTA Article 1116(2) provides that:

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

301. As explained by the Tribunal in *Feldman v. United Mexican States*, the term “making a claim” refers to the “definitive activation of an arbitration procedure.”<sup>175</sup> For a claim brought under the UNCITRAL Arbitration Rules, NAFTA Article 1137(1)(c) defines the relevant time as the date on which the Notice of Arbitration “is received by the disputing Party.”
302. Accordingly, Article 1116(2) requires a claimant to submit, and for the NAFTA Party to receive, a Notice of Arbitration within three years of the date on which the claimant first acquired knowledge, either actual or constructive, of the alleged breach and of the alleged loss or damage.
303. Knowledge of loss or damage incurred by the investor under Article 1116(2) does not, however, require knowledge of the extent of loss or damage.<sup>176</sup>
304. In both *Grand River v. United States* and *Feldman v. United Mexican States*, NAFTA Chapter Eleven tribunals described the three-year limitation period as a “clear and rigid” defence, and noted that the time limitation is “not subject to any suspension, prolongation or other qualification.”<sup>177</sup>

ii. **Respondent’s Position**

305. The Respondent received Apotex’s Notice of Arbitration in the Sertraline Claim, dated 10 December 2008, on 11 December 2008, and Apotex’s Notice of Arbitration in the Pravastatin claim, dated 4 June 2009, on 5 June 2009.

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<sup>175</sup> *Marvin Roy Feldman Karpa v. United Mexican States*, ICSID Case No. ARB(AF)/99/1, Interim Decision on Preliminary Jurisdictional Issues, para. 44 (6 Dec. 2000).

<sup>176</sup> See *Mondev*, Award, para. 87 (11 Oct. 2002) (“A claimant may know that it has suffered loss or damage even if the extent or quantification of the loss or damage is still unclear.”); *Grand River Enterprises Six Nations, Ltd. et al. v. United States*, NAFTA/UNCITRAL, Decision on Objections to Jurisdiction, para. 78 (20 July 2006).

<sup>177</sup> *Grand River*, Decision on Jurisdiction, para. 29; *Feldman*, Award, para. 63.

306. The Respondent initially raised time bar objections to both the Sertraline and Pravastatin Claims.
307. In relation to the Sertraline Claim, the Respondent objected to Apotex's allegation in its Sertraline Notice of Arbitration<sup>178</sup> that the 3 January 2005 decision of the U.S. District Court for the Southern District of New York in *Apotex, Inc. v. Pfizer Inc.* was “tantamount to a denial of justice as defined by international law and constitutes an expropriation of Apotex's investment” (to the extent that it was alleged that a breach and loss occurred at that time).
308. However, in the course of its written submissions, this objection was dropped, and the Respondent then focused exclusively upon the Pravastatin Claim.<sup>179</sup>
309. In outline,<sup>180</sup> the Respondent submits, that the time bar precludes Apotex's allegation in its Pravastatin Notice of Arbitration that the FDA's letter decision of 11 April 2006 (determining that the 180-day exclusivity period had not been triggered) itself constituted a violation of Articles 1102, 1105, and 1110 of the NAFTA.<sup>181</sup>
310. The FDA decision was administrative in nature, and so not subject to any duty to exhaust judicial remedies. Critically, it occurred more than three years before Apotex brought its Pravastatin Claim under the NAFTA, and it is therefore time-barred.
311. Although Apotex seeks to toll the limitation period by linking the FDA measure to later court actions, NAFTA Chapter Eleven tribunals have consistently rejected such efforts as

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<sup>178</sup> Sertraline Notice of Arbitration, para. 50.

<sup>179</sup> See Respondent's Reply on Objections to Jurisdiction of Respondent United States of America, dated 17 Oct. 2011, at paras. 8 & 40-54. The Respondent ultimately accepted that Apotex's Sertraline Claim was not time-barred, given Apotex's clarification in its Counter-Memorial (para. 68) that its denial of justice claim did not rest on the 3 Jan. 2005 District Court decision alone, but rather “. . . the actions of at least three U.S. federal courts, including the New York District Court, the Federal Circuit, and the Supreme Court[.]”

<sup>180</sup> Further detail of the Respondent's submissions is set out in the course of the Tribunal's analysis below.

<sup>181</sup> Pravastatin Notice of Arbitration, para. 67.

contrary to the plain language of the agreement. The FDA measure thus falls outside the Tribunal's jurisdiction.

**iii. Apotex's Position**

312. It is Apotex's case that all elements of its Pravastatin Claim were timely submitted.

313. In outline,<sup>182</sup> Apotex argues that:

- (a) Contrary to the Respondent's analysis, there is no "hard-and-fast" cut-off date under NAFTA, such that any issues that arose prior thereto must be completely ignored.
- (b) The limitation rule in NAFTA Article 1116(2) includes two separate and distinct components: (1) knowledge of the breach; and (2) knowledge that the investor has incurred loss or damage. The three year period begins to run only after *both* of these requirements have been met.<sup>183</sup>
- (c) Under international law, as the Respondent itself asserts:

“[a]n act of a domestic court that remains subject to appeal has not ripened into the type of final act that is sufficiently definite to implicate state responsibility, unless such recourse is obviously futile.”<sup>184</sup>

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<sup>182</sup> Further detail of Apotex's submissions is set out in the course of the Tribunal's analysis below.

<sup>183</sup> Citing, *inter alia*, Kinnear, Bjorklund & Hannaford, *Investment Disputes Under NAFTA: An Annotated Guide to NAFTA Chapter 11* at 1116-36b (July 2009) (“*The investor must, however, acquire knowledge of both the breach and the ensuing damage. The three-year limitation period presumably runs from the later of these events to occur in the event that the knowledge of both events is not simultaneous*”).

<sup>184</sup> U.S. Memorial, para. 61.

- (d) Apotex’s Pravastatin Claim consists of a “single, continuous set” of underlying factual bases leading to the Respondent’s breach. It is based on the ruling by the FDA that the dismissal of Apotex’s declaratory judgment action against the patent owner failed to constitute a court decision trigger under the FFDCFA, and the subsequent actions by the D.C. District Court and the D.C. Circuit in denying Apotex’s federal court challenge to that ruling.<sup>185</sup> The underlying factual basis for the claim, including the respective decisions made by the administrative and judicial bodies of the United States challenged therein, cannot be parsed into separate, unrelated events or “claims”, as the Respondent suggests.
- (e) Further, the well-established “*finality or futility*” requirement, under which a complainant must exhaust its local remedies (unless obviously futile) prior to an action being attributable to the State under international law, means that only after such remedies are exhausted has a breach occurred, let alone “*knowledge of the alleged breach*” as required under NAFTA Article 1116(2).
- (f) The breaches serving as the basis for Apotex’s Pravastatin Claim, and Apotex’s awareness of each breach, therefore occurred well within the three-year limitation period.

**iv. The Tribunal’s Analysis**

314. *The Nature of this Objection:* As with the previous issue, there is an initial question as to the precise nature of this objection, and whether it is properly characterised as one of “jurisdiction” or merits / substance. The objection was treated by both Parties as a “jurisdictional” issue. The Respondent, as the objecting Party, explained its position as follows:

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<sup>185</sup> Apotex’s Statement of Claims, paras. 107-08, 112-29.

“The Tribunal has asked whether the time-bar objection was an objection to the jurisdiction of the Tribunal. We submit that it is. As stated in NAFTA Article 1122, the United States consented to investor-State arbitration under Chapter Eleven in accordance with the procedures set out in this agreement. The scope of the three NAFTA Parties’ consent is thus limited by the procedures contained within Chapter Eleven. In that regard and as discussed at length yesterday, Article 1116(2) prohibits an investor from making and the Tribunal from hearing, ‘*a claim if more than three years have elapsed from the date on which the investor first acquired or should have first acquired knowledge of the alleged breach and knowledge that the investor has incurred loss or damage.*’ Article 1116(2), thus, contains a temporal requirement for jurisdiction over the investor’s claim. It’s a jurisdictional objection *ratione temporis*. Just as the United States does not consent to be bound by obligations and treaties which are not in force, also an objection *ratione temporis*, the United States did not consent to arbitrate NAFTA Chapter Eleven claims that arise outside of the applicable three-year limitations period. We believe the plain language of Article 1116(2) makes this clear.

As further confirmation, the U.S. Statement of Administrative Action in briefly discussing Articles 1116 and Article 1117 states simply that those Articles require that, ‘*all claims must be brought within three years.*’<sup>186</sup>

315. *Analysis:* In relation to the Pravastatin Claim, the relevant cut-off date is 5 June 2006 (*i.e.* three years before Apotex filed its Notice of Arbitration).
316. As set out in its Statement of Claims (and summarised in **Section IV** above), Apotex’s Pravastatin Claim arises out of:
- (a) the decision of the FDA on 11 April 2006;
  - (b) the subsequent denial of emergency injunctive relief seeking to overturn that decision by the D.C. District Court on 19 April 2006;
  - (c) the 6 June 2006 affirmation by the D.C. Circuit denying Apotex’s request for emergency relief; and

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<sup>186</sup> Transcript, Day 2, pages 313-315.

(d) the 17 August 2006 denial of rehearing *en banc* by the same D.C. Court.

317. In the Tribunal's view, a distinction must be drawn between:

(a) claims based upon the FDA decision itself; and

(b) claims based upon the 6 June 2006 and 17 August 2006 decisions of the D.C. Circuit, which may entail reference to the earlier FDA and District Court decisions.

318. *Claims Based on the FDA Decision Itself:* In so far as Apotex seeks to advance any claim based exclusively on the FDA decision of 11 April 2006, this clearly falls outside of the NAFTA three-year limitation period, and is therefore time-barred. In other words, Apotex cannot now assert that the FDA decision constituted – in and of itself – a breach of NAFTA Articles 1102, 1105, and 1110.

319. Contrary to Apotex's subsequent submissions, this is a claim that was in fact pleaded in terms in the Pravastatin Notice of Arbitration.<sup>187</sup>

320. It is clear that in April 2006 Apotex already had knowledge of the FDA measure and knowledge of any resulting loss or damage allegedly arising from it. According to its own pleading, Apotex's inability to bring its pravastatin products to market in April 2006 (by which time, in Apotex's view, the market exclusivity period held by the first paragraph IV applicants should have expired) caused Apotex "*to suffer substantial damages.*"<sup>188</sup>

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<sup>187</sup> Pravastatin Notice of Arbitration, para. 67.

<sup>188</sup> Pravastatin Notice of Arbitration, paras. 50, 67; also para. 30: "*Apotex was prevented from obtaining approval and timely bringing its pravastatin tablets to market in April 2006, thus causing Apotex substantial injury including, but not limited to, significant lost sales and lost market share.*"

321. Apotex further alleges in its Statement of Claims that the ability of the first paragraph IV applicants to launch their generic pravastatin products while enjoying market exclusivity in April 2006 enabled those companies to “*secur[e] a stranglehold over the market.*”<sup>189</sup>
322. Apotex even pre-emptively challenged the FDA measure in court on 5 April 2006, claiming that Apotex had been “*adversely affected by final agency action and/or agency action unlawfully withheld.*”<sup>190</sup>
323. And yet Apotex delayed submitting its Pravastatin Notice of Arbitration until 5 June 2009. There is no obvious reason why Apotex could not have made its claims regarding the FDA measure in a timely manner. The FDA decision was taken in April 2006. All U.S. litigation over the measure ended in August 2006, and Apotex voluntarily dismissed all claims relating to the measure in October 2006. Apotex then had ample time to bring its NAFTA claim challenging the FDA decision. Indeed, Apotex brought its Sertraline Claim on 11 December 2008, which, had it included the Pravastatin Claim, would have been within the required time limit.
324. Accordingly, the Tribunal accepts the Respondent’s submission that by reason of NAFTA Article 1116(2), all claims based exclusively upon the FDA decision of 11 April 2006 are time-barred, and so must be dismissed.
325. Apotex cannot avoid this conclusion by asserting that the FDA measure is part of a “*continuing breach*” by the United States, or “*part of the same single, continuous action,*” in so far as this is intended as a mechanism to use later court proceedings to toll the limitation period for the earlier FDA measure.

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<sup>189</sup> Apotex’s Statement of Claims, para. 108.

<sup>190</sup> Complaint, para. 10, in *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. 5 Apr. 2006) (“*Apotex has standing to maintain this action, pursuant to the [Administrative Procedure Act], as a legal entity that has suffered a legal wrong and has been adversely affected by final agency action and/or agency action unlawfully withheld.*”) [R56].

326. As the Respondent has forcefully argued, nothing in the text or jurisprudence of NAFTA Chapter Eleven suggests that a party can evade NAFTA’s limitation period in this way.

327. On the contrary, the rule in NAFTA Article 1116(2) has been described as a:

“clear and rigid limitation defense, which . . . is not subject to any suspension, prolongation or other qualification.”<sup>191</sup>

328. Further, there is support in previous NAFTA decisions for the proposition that the limitation period applicable to a discrete government or administrative measure (such as the FDA decision of 11 April 2006) is not tolled by litigation, or court decisions relating to the measure. For example:

- (a) In *Mondev*, the tribunal rejected an attempt by the claimant to toll the limitation period through a court action against the underlying measures.<sup>192</sup> At issue in that case were actions of the City of Boston and the Boston Redevelopment Agency (“BRA”) concerning the development of commercial real estate in Boston, as well as subsequent litigation involving those actions. The tribunal declined to consider actions of the City of Boston and the BRA, as those actions had arisen before 1 January 1994, when the NAFTA entered into force. Relevantly for present purposes, the tribunal noted that:

“if *Mondev*’s claims concerning the conduct of the City and BRA had been continuing NAFTA claims as at 1 January 1994, they would now be time-barred.”

The *Mondev* tribunal thus limited its jurisdiction to claims concerning the decisions of U.S. courts, as those claims:

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<sup>191</sup> *Grand River*, Decision on Jurisdiction, para. 29.

<sup>192</sup> *Mondev*, Award, para. 87 (11 Oct. 2002).

“were commenced within three years from the *final* court decisions.”<sup>193</sup>

- (b) In *Grand River*, the claimants argued that the NAFTA’s limitation period applied differently depending on when each U.S. state implemented an underlying measure.<sup>194</sup> The tribunal found that claimants’ approach would:

“render the limitations provisions ineffective in any situation involving a series of similar and related actions by a respondent state, since a claimant would be free to base its claim on the most recent transgression, even if it had knowledge of earlier breaches and injuries.”

and that:

“[T]he Tribunal’s views parallel those of the NAFTA Tribunal in *Mondev*. The claimant there also faced difficulties arising from the time limitations of Articles 1116(2) and 1117(2). The claimant sought to surmount these with the argument that it could have certain knowledge that it had incurred injury from events prior to the limitations period only after it knew the outcome of subsequent litigation that stood to quantify the extent of loss was known. The Tribunal did not agree, finding that ‘a Claimant may know that it has suffered loss or damage even if the extent of quantification of the loss or damage is still unclear.’”<sup>195</sup>

329. Apotex places much reliance upon the *Loewen* tribunal’s statement (quoting the U.S. as respondent in that case) that:

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<sup>193</sup> *Id.* (emphasis added).

<sup>194</sup> *Grand River Enterprises Six Nations, Ltd. v. United States*, NAFTA/UNCITRAL, Decision on Jurisdiction para. 81 (20 July 006) (Claimants “maintained that there is not one limitations period, but many”).

<sup>195</sup> *Id.* para. 78 (quoting *Mondev*, Award, para. 87).

“judicial action is a single action from beginning to end so that the State has not spoken (and therefore no liability arises) until all appeals have been exhausted.”<sup>196</sup>

330. But this is of no application here, for the simple reason – as Apotex itself asserts elsewhere – that the FDA measure in question is an “*administrative decision*”, not a “*judicial action*”;<sup>197</sup> that the FDA measure could have been the subject of a separate complaint under the NAFTA<sup>198</sup>; and that the NAFTA does not require claimants to exhaust all available remedies before challenging non-judicial decisions.<sup>199</sup>
331. The position, therefore, is that any challenge to the FDA decision itself had to be brought within three years, and could not be delayed by resort to court action. Any conclusion otherwise would provide a very easy means to evade the clear rule in NAFTA Article 1116(2) in most cases (*i.e.* by filing any court action, however hopeless).
332. Whilst this provides the certainty and finality intended by NAFTA Article 1116(2), and forces parties to initiate proceedings with respect to (as here) administrative decisions, it obviously does not preclude the exercise of discretion on the part of NAFTA tribunals, once constituted, to stay arbitral proceedings pending court proceedings, in appropriate cases.
333. *Claims Based on the 6 June & 17 August 2006 D.C. Decisions:* Having so ruled, it must be made clear that there is no time-bar difficulty with respect to Apotex’s claims based upon the 6 June 2006 and 17 August 2006 decisions of the D.C. Circuit. And

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<sup>196</sup> *Loewen*, Award, para. 143 (26 June 2003). *Also*: U.S. Memorial, para. 61.

<sup>197</sup> Pravastatin Notice of Arbitration, para. 62; Counter-Memorial, para. 86.

<sup>198</sup> As Apotex accepted in the course of its oral submissions – *e.g.*, Transcript Day 2, pages 381 – 385.

<sup>199</sup> *E.g.*, *Loewen*, Award, paras. 158-64.

clearly, any claim that these judicial decisions constituted a breach of the NAFTA would require at least some consideration of the prior administrative and judicial decisions.<sup>200</sup>

334. But the two types of claim are clearly analytically distinct. One is a claim that a breach occurred, and loss was incurred, as at 11 April 2006, by reason of the FDA's (administrative) ruling that the dismissal of Apotex's declaratory judgment action against the patent owner did not constitute a "court decision trigger". The other is a claim that a breach occurred, and loss was incurred, as at 6 June 2006, or alternatively 17 August 2006, by reason of the (judicial) decisions of the Court of Appeals for the D.C. Circuit.

#### v. Conclusions

335. It follows that, even if Apotex qualified as an "investor", who has made an "investment" in the U.S. for the purposes of NAFTA Articles 1116 and 1139, the Tribunal would have no jurisdiction *ratione temporis* with respect to Apotex's allegation in its Pravastatin Notice of Arbitration that the FDA's letter decision of 11 April 2006 (determining that the 180-day exclusivity period had not been triggered) itself constituted a violation of NAFTA Articles 1102, 1105, and 1110. This particular claim would therefore fall to be dismissed on this basis in any event.

#### (E) **OVERALL CONCLUSION ON PRELIMINARY OBJECTIONS**

336. It follows that both the Sertraline and Pravastatin Claims must be dismissed in their entirety, on the basis that 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 the Tribunal therefore lacks jurisdiction.

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<sup>200</sup> See e.g., *Glamis Gold, Ltd. v. United States*, NAFTA/UNCITRAL, Procedural Order No. 2, para. 19 (31 May 2005), recognising the United States' view that claimant "of course, may refer to facts that predate [the three-year limitations period] as background for its claims. . . ."

337. Even if Apotex did qualify as an “investor”, who has made an “investment” in the U.S. for the purposes of NAFTA Articles 1116 and 1139:

- (a) all claims within Apotex’s Pravastatin Claim that the judicial acts of the D.C. District Court and the D.C. Circuit breached Articles 1102, 1105, and 1110 of the NAFTA would have to be dismissed in any event, on the basis that Apotex has failed to exhaust all local judicial remedies, and the Tribunal therefore lacks jurisdiction *ratione materiae* in relation thereto, or alternatively the said claims are inadmissible; and
- (b) Apotex’s claim in its Pravastatin Notice of Arbitration that the FDA’s letter decision of 11 April 2006 itself constituted a violation of Articles 1102, 1105, and 1110 of the NAFTA would have to be dismissed in any event, on the basis that the Tribunal lacks jurisdiction *ratione temporis* in relation thereto.

## VI. COSTS

### (A) ALLOCATION OF COSTS

338. Article 40 of the UNCITRAL Rules provides in part as follows:

“1. Except as provided in paragraph 2, the costs of arbitration shall in principle be borne by the unsuccessful party. However, the arbitral tribunal may apportion each of such costs between the parties if it determines that apportionment is reasonable, taking into account the circumstances of the case.

2. With respect to the costs of legal representation and assistance referred to in article 38, paragraph (e), the arbitral tribunal, taking into account the circumstances of the case, shall be free to determine which party shall bear such costs or may apportion such costs between the parties if it determines that apportionment is reasonable.

[. . .]”

339. The Respondent is clearly the successful party in both arbitrations before this Tribunal. It has established each of its three preliminary objections, and secured the dismissal of both the Sertraline and Pravastatin Claims in their entirety.

340. In the circumstances, pursuant to the general principle in Article 40(1) of the UNCITRAL Rules, the Tribunal considers that the costs of both arbitrations, including the Respondent’s costs of legal representation and assistance, must be borne by Apotex.

341. In its written submission on costs, Apotex has argued that should the Tribunal dismiss its Sertraline and Pravastatin Claims at the jurisdictional stage, it should order that the costs of arbitration associated with the Respondent’s Objections to Jurisdiction (excluding costs of legal representation) be equally allocated amongst the Parties, and refuse to apportion any legal fees – thereby leaving the Parties as they currently stand with respect to costs, fees

and expenses. This was justified by reference (*inter alia*) to the disposition on costs in the *Loewen* arbitration,<sup>201</sup> and on the basis that leaving costs where they lie here:

“ . . . would be entirely reasonable, particularly given the purportedly ‘novel questions of far-reaching importance,’ as asserted by the Respondent, raised in Apotex’s Claims, and the efficient and professional manner in which Apotex conducted the arbitration at all times. Such an Award also eliminates the risk of discouraging future investors by avoiding placing additional constraints on their access to justice under NAFTA.”

342. The issues in this case, however, were less complex, and less novel, than those in *Loewen*. Apotex conducted both arbitrations in an efficient and professional manner, but the fact remains that it initiated two sets of proceedings against the Respondent, and thereby caused the Respondent to incur costs, in circumstances where neither proceeding was within the scope of NAFTA Chapter Eleven, and no claim was properly before this Tribunal. The Respondent has raised entirely appropriate objections, and on the basis of the Tribunal’s findings, ought never to have been embroiled in this process. In all the circumstances, the Tribunal sees no justification for the Respondent to bear any of the costs it has (reasonably) incurred.

**(B) ASSESSMENT OF COSTS**

343. Article 38 of the UNCITRAL Rules provides in part as follows:

“The arbitral tribunal shall fix the costs of arbitration in its award. The term ‘costs’ includes only:

- (a) The fees of the arbitral tribunal to be stated separately as to each arbitrator and to be fixed by the tribunal itself in accordance with article 39;
- (b) The travel and other expenses incurred by the arbitrators;

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<sup>201</sup> *Loewen*, Award, para. 240 (26 June 2003): “[T]he Tribunal is of the view that the dispute raised difficult and novel questions of far-reaching importance for each party, and the Tribunal therefore makes no award of costs.”

- (c) The costs of expert advice and of other assistance required by the arbitral tribunal;
- (d) The travel and other expenses of witnesses to the extent such expenses are approved by the arbitral tribunal;
- (e) The costs for legal representation and assistance of the successful party if such costs were claimed during the arbitral proceedings, and only to the extent that the arbitral tribunal determines that the amount of such costs is reasonable;
- (f) Any fees and expenses of the appointing authority . . .”

**i. The Respondent’s Costs of Legal Representation and Assistance**

344. The Respondent has claimed costs in relation to these two arbitrations in the total amount of US\$ 705,814, which it describes as an “*exceptionally conservative*” quantification.

345. This figure includes US\$ 180,000 in respect of the Respondent’s half share of the total advances to cover the Tribunal’s fees and reimbursable expenses (as to which, see below). Aside from this amount, the balance of US\$ 525,814 comprises the following elements:

- (a) US\$ 498,575 in respect of attorney and paralegal time;
- (b) US\$ 13,750 in respect of expert consultant advice; and
- (c) US\$ 13,489 in respect of contractor paralegal services.

346. The Tribunal has carefully considered this claim, together with the detailed evidence and statements filed in support, and concludes that each element is reasonable, and ought to be reimbursed in full by Apotex.

347. *Attorney and Paralegal Time:* As explained by the Respondent in its written submissions on costs, unlike their counterparts in the private sector, attorneys and paralegals in the U.S. State Department’s Office of International Claims and Investment Disputes do not bill for their time by matter or hour (given that there is only one client).

The Respondent has therefore estimated the amount of time devoted to these two arbitrations. This has been done by way of a careful exercise, as explained in detail in a written statement by Mr. Patrick Pearsall (an Attorney-Adviser who played a major role in the Respondent's team throughout the proceedings) and a written statement by Ms Mary Reddy of the Office of the Executive Director in the U.S. State Department's Office of the Legal Adviser (detailing annual salary and benefits information for all individuals concerned). By way of summary, the Respondent has multiplied the cost of each individual's salary and benefits for a given year by the estimated percentage of time that individual spent on both arbitrations in that year.

348. The Tribunal is satisfied that this is an appropriate methodology, and satisfied that the exercise has been conducted properly. In particular, given the nature of the issues that needed to be addressed in the course of these proceedings; the division of responsibility between different members of the Respondent's legal team; and the procedural steps involved between the inception of each case in 2009, and the hearing in 2012, the Tribunal considers that the overall amount of time spent by the Respondent's team, and the rates that have been applied to each individual, are reasonable.
349. The Tribunal notes in this regard, as pointed out by the Respondent, that the total claimed excludes (a) the time of several senior attorneys within the U.S. State Department's Office of the Legal Adviser who reviewed drafts and participated in meetings for this matter; (b) the time of attorneys at the FDA and other federal agencies such as the Office of the U.S. Trade Representative, the Department of Commerce, the Department of Commerce, the Department of Justice, and the Department of the Treasury; (c) the time of various administrative personnel. Further, the Respondent has claimed only for its out-of-pocket cost for attorney and paralegal time, as opposed to the market value of such services.
350. *Expert Consultant Advice:* The Respondent retained Prof. C. Scott Hemphill (a consultant in U.S. pharmaceutical law, then of Columbia Law School) to assist it in this matter. The Tribunal considers that the costs claimed in this regard are reasonable.

351. *Contractor Paralegal Services:* The Respondent contracted with IE Discovery, Inc., to provide paralegal services for the February 2012 hearing (because the Respondent's own internal paralegal assigned to these arbitrations left in 2011). The Tribunal considers that the costs claimed in this regard are reasonable.

352. *Conclusion:* It follows that Apotex must reimburse the Respondent in the total amount of US\$ 525,814 in respect of the latter's costs for legal representation and assistance.

**ii. The Tribunal's Fees and Expenses / ICSID Administration Costs**

353. Article 39 of the UNCITRAL Rules provides in part as follows:

"1. The fees of the arbitral tribunal shall be reasonable in amount, taking into account the amount in dispute, the complexity of the subject-matter, the time spent by the arbitrators and any other relevant circumstances of the case.

[. . .]"

354. Paragraphs 13 and 14 of Procedural Order No. 1 provided as follows (by agreement of all Parties):

**"V. FEES AND EXPENSES OF THE ARBITRAL TRIBUNAL**

(ARTS 38 AND 41 OF THE UNCITRAL RULES)

13. The arbitrators will be remunerated in accordance with the ICSID Schedule of Fees.

14. The arbitrators' disbursements shall be reimbursed in accordance with ICSID practice . . ."

355. Pursuant to Article 40(3) of the UNCITRAL Rules, the Tribunal hereby fixes the following amounts in respect of its fees and expenses, and ICSID's charges and expenses for the administration of both arbitrations:

Total Tribunal's fees and expenses: US\$ 233,658.94

comprising:

<b>Mr. Toby Landau QC:</b>	Fees:	US\$ 113,298.75
	Expenses:	US\$ 23,594.40
<b>Mr. Clifford Davidson:</b>	Fees:	US\$ 63,990.00
	Expenses:	US\$ 2,411.04
<b>Judge Fern Smith:</b>	Fees:	US\$ 25,875.00
	Expenses:	US\$ 4,489.75
Total ICSID charges and expenses: <sup>202</sup>		US\$ 44,204.68
<b><u>Total:</u></b>		<b><u>US\$ 277,863.62</u></b>

(C) SUMMARY

356. Pursuant to two requests made by ICSID on behalf of the Tribunal (dated 15 October 2010 and 24 August 2011 respectively), each Party deposited a total of US\$ 180,000 with ICSID on account of the fees and reimbursable expenses of the Tribunal. The unused balance will be refunded to the Parties by ICSID in equal shares (reflecting the proportion in which the advances were received).

357. Apotex must therefore reimburse the Respondent as follows:

- (a) US\$ 525,814 in respect of the Respondent's costs of legal representation and assistance; and
- (b) 50% (*i.e.* the Respondent's share) of the Tribunal's and ICSID's total fees, charges and expenses, as notified by ICSID to the Parties within 90 days of the dispatch of this Award.

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<sup>202</sup> The total costs of the proceeding provided by ICSID include an estimate of the courier services expenses for sending the certified copies of the Award as well as estimates for the printing and binding costs of the Award. Therefore, the total amount of the actual final costs will likely be subject to a slight variation. A financial statement will be provided by ICSID when the account for this case is financially closed and notified to the Parties within a maximum of 90 days from the dispatch of the Award to the Parties.

## VII. OPERATIVE ORDER

358. In the 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.
  
- (b) Even if Apotex did qualify as an “*investor*”, who has made an “*investment*” in the U.S. for the purposes of NAFTA Articles 1116 and 1139:
  - i. Apotex has failed to exhaust all local judicial remedies with respect to all claims within its Pravastatin Claim that the judicial acts of the D.C. District Court and the D.C. Circuit breached NAFTA Articles 1102, 1105, and 1110, and the said claims would therefore have to be dismissed in any event on the basis that the Tribunal lacks jurisdiction *ratione materiae* in relation thereto, or alternatively that the said claims are inadmissible; and
  
  - ii. Apotex’s claim in its Pravastatin Notice of Arbitration that the FDA’s letter decision of 11 April 2006 itself constituted a violation of Articles 1102, 1105, and 1110 of the NAFTA would have to be dismissed in any event, on the basis that the Tribunal lacks jurisdiction *ratione temporis* in relation thereto.

- (c) Pursuant to Article 40(1) and (2) of the UNCITRAL Rules, Apotex shall bear the costs of these arbitrations, and shall reimburse the Respondent in the following amounts:
- i. US\$ 525,814 in respect of the Respondent's costs of legal representation and assistance; and
  - ii. 50% (*i.e.* the Respondent's share) of the Tribunal's and ICSID's total fees, charges and expenses, as notified by ICSID to the Parties within 90 days of the dispatch of this Award.



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**Clifford M. Davidson**  
*Arbitrator*



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**Hon. Fern M. Smith**  
*Arbitrator*



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**Toby T. Landau QC**  
*Presiding Arbitrator*

**Dated:** 14 June 2013

**Place of Arbitration:** New York, NY, USA.