

IN THE ARBITRATION UNDER CHAPTER ELEVEN
OF THE NORTH AMERICAN FREE TRADE AGREEMENT
AND THE UNCITRAL ARBITRATION RULES (1976)
BETWEEN

APOTEX INC.,

Claimant/Investor,

-and-

UNITED STATES OF AMERICA,

Respondent/Party.

**MEMORIAL ON OBJECTIONS TO JURISDICTION OF
RESPONDENT UNITED STATES OF AMERICA**

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Washington, D.C. 20520

May 16, 2011

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Pursuant to Article 21 of the UNCITRAL Arbitration Rules (1976) and in accordance with the Tribunal's Procedural Order No. 1, dated December 16, 2010, the United States of America respectfully submits its Memorial on Objections to Jurisdiction.

PRELIMINARY STATEMENT

1. NAFTA Chapter Eleven accords protections to "investors" from one NAFTA Party to the extent they have made or have sought to make "investments" located in the territory of another NAFTA Party. According to the Claimant, Apotex Inc. ("Apotex") is a corporation registered in the province of Ontario, Canada that has made such "investments," specifically through expenditures "in preparing ANDAs for filing in the United States" and in "formulating,

developing, and manufacturing approved generic pharmaceutical products for sale in the United States.”

2. As discussed below, Apotex has failed to establish that it meets the basic elements of a Chapter Eleven claim—that it is an “investor” that has made or is seeking to make an “investment” in the United States. Any company that intends to have a generic drug product marketed in the United States must file an abbreviated new drug application (“ANDA”), which is an application for approval to sell generic pharmaceutical products in the United States. That regulatory requirement applies to any company whose products will be sold in the United States, regardless of whether the company is investing in the United States or merely exporting goods to the United States. Apotex’s own ANDA filings and submissions in this arbitration make clear that the company is an exporter that intended to export its sertraline hydrochloride (“sertraline”) and pravastatin sodium (“pravastatin”) products to the United States, where those products would be sold by “others.” Apotex makes no attempt to articulate how expenditures made in preparing an application for regulatory approval to have its products sold by distributors in the United States constitute an “investment” as defined under NAFTA Article 1139. In addition, the formulation, development, and manufacture of those products occur outside the United States, and thus do not constitute an investment within the United States. Given Apotex’s failure to support its allegation that the company made an “investment” in the United States, Apotex cannot be considered an “investor” under Article 1116. As such, Apotex’s claims should be dismissed in their entirety.

3. In addition, many of Apotex’s claims are time-barred. NAFTA Chapter Eleven sets out a clear limitations period, which requires a notice of arbitration to be submitted within three years of the date on which the claimant first acquired knowledge of an alleged breach and of loss or

damage. In its sertraline and pravastatin claims, Apotex alleges breach and loss occurring outside the applicable three-year limitations period. Those occurrences of breach and loss, according to Apotex, arose from a federal court decision that was issued prior to December 11, 2005 (for the sertraline claim) and certain U.S. Food and Drug Administration (“FDA”) and federal court decisions that were issued prior to June 5, 2006 (for the pravastatin claim). Those claims are time-barred and should be dismissed.

4. Finally, Apotex’s pravastatin claim, to the extent that it also alleges breach and loss occurring on or after June 5, 2006 arising from judicial acts, should be dismissed because those acts lack the requisite judicial finality. Judicial acts that remain subject to appeal lack the requisite finality to give rise to state responsibility, unless such recourse is obviously futile. With respect to Apotex’s request for a preliminary injunction related to its pravastatin claim, Apotex failed to appeal to the U.S. Supreme Court the relevant decision of the U.S. Court of Appeals for the District of Columbia Circuit, which had remanded Apotex’s action to the District Court for further proceedings. Furthermore, Apotex failed to pursue its claim on the merits in the District Court on remand, opting instead to stipulate to the dismissal of the claim. Thus, the pravastatin claims based on the non-final judicial acts of federal courts in the District of Columbia, such as the pravastatin-related denial of justice claim, lack the requisite judicial finality and should be dismissed.

5. For the above reasons, which are discussed in detail below, Apotex’s claims should be dismissed in their entirety, with costs awarded to the United States.

I. FACTS

A. Apotex's Global Export Operations

6. Apotex is a pharmaceutical company that develops pharmaceutical products in Canada for the domestic Canadian market and for export to dozens of other countries, including the United States.¹ According to business data sources, Apotex began business operations on May 24, 1974, and is a wholly-owned subsidiary of Apotex Pharmaceutical Holdings, Inc., located in North York, Ontario.² Business data sources also indicate that Apotex was registered as a corporation under Ontario law on April 1, 2004.³

7. According to Apotex's website, "[t]he company's pharmaceuticals . . . are exported to over 115 countries around the globe," and "[e]xport markets represent an ever growing portion of the total sales."⁴ For exports to the U.S. market, Apotex's website indicates that Apotex has built three "extensive" facilities in Ontario, Canada: (1) Etobicoke (2) Richmond Hill, and (3) the

¹ Apotex states that it "is 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 M9L 1T9." Statement of Claims ¶ 2 (Jan. 17, 2011) ("Apotex SOC"). See also Notice of Intent related to sertraline claim at 1 (Sept. 21, 2007) ("Sertraline NOI"); Notice of Arbitration related to sertraline claim ¶ 4 (Dec. 10, 2008) ("Sertraline NOA"); Notice of Intent related to pravastatin claim at 2 (Mar. 2, 2009) ("Pravastatin NOI"); Notice of Arbitration related to pravastatin claim ¶ 4 (June 4, 2009) ("Pravastatin NOA"); Apotex Website, About Apotex at <http://www.apotex.com/global/about/default.asp> (last visited Apr. 12, 2011) (noting that "[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") [R46]. Although Apotex has not submitted any documentation in this proceeding to demonstrate that it is incorporated in Canada, it has done so in its ANDAs, and publicly available sources suggest that it is a Canadian corporation. See ANDA – Sertraline (excerpts) (Oct. 27, 2003) at 0001-3 (FDA Form 356h), 0113 (distributor), 0154-55 (example of proposed container label), 4070 (bioavailability/bioequivalence), 4335 (description of manufacturing facility), 5597 (letter designating authorized representative) [R44]; ANDA – Pravastatin (excerpts) (Dec. 21, 2001) at cover letter, 0001-3 (FDA Form 356h), 0100 (distributor), 0117-18 (example of proposed container label), 0273 (bioavailability/bioequivalence), 5370 (description of manufacturing facility), 6803 (letter designating authorized representative) [R45].

² See Dun & Bradstreet Report re: Apotex Inc. (Apr. 14, 2011) at 7-8 [R50]; see also GlobalData – History, Apotex, Inc. (Jan. 3, 2011) [R52]. In turn, Apotex Pharmaceuticals Holdings Inc., located at 150 Signet Drive, North York, Ontario M9L 1T9, Canada is a subsidiary of Apotex Holdings, Inc., located in North York, Ontario, Canada. See Dun & Bradstreet Report, Apotex Pharmaceuticals Holding Inc. (Apr. 18, 2011) at 1, 7 [R51].

³ Dun & Bradstreet Report re Apotex Inc. (Apr. 14, 2011) at 8 [R50]. "In 2004, the company announced that is re-branding all companies in the Apotex Group of Companies (Apotex, Novex Pharma, TorPharm and Brantford Chemicals) under the Apotex name." GlobalData – History, Apotex, Inc. (Jan. 3, 2011) [R52].

⁴ Apotex Website, About Apotex at <http://www.apotex.com/global/about/default.asp> (last visited Apr. 12, 2011) [R46].

Signet Campus.⁵ Business data sources indicate that “the company carries out drug development and manufacturing activities from [these] three campuses.”⁶ The same source notes 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.*”⁷ As such, available sources indicate that Apotex’s development and manufacture of generic drugs for export to the United States, including the preparation of ANDAs for submission to FDA, occur outside of the United States.

B. The Abbreviated New Drug Application Process

8. For its new generic drugs to be sold in the United States, Apotex, like all generic drug manufacturers, whether foreign or domestic, must seek regulatory approval through the submission of an ANDA to FDA.⁸ Generic drugs usually are non-patented (and often less expensive) versions of brand-name pioneer drugs that are, may be, or were previously protected by patents. The purpose of the ANDA process, through which generic pharmaceutical manufacturers file an “abbreviated” application for FDA approval of generic drugs for marketing

⁵ Apotex Website at <http://www.apotex.com/us/en/about/video.asp> (last visited May 3, 2011) [R47].

⁶ GlobalData – Business Description, Apotex, Inc. (Jan. 3, 2001) [R53].

⁷ *Id.* (emphasis added) [R53].

⁸ As noted in the Statement of Defense of Respondent United States of America (Mar. 15, 2011) (“U.S. Statement of Defense), Apotex’s ANDAs for both sertraline and pravastatin were governed by the same law, primarily the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (“Section 355”), as amended in 1984 by the Drug Price Competition and Patent Term Restoration Act (the “Hatch-Waxman Amendments”), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the “MMA”). The MMA amended not only Section 355, which governs the approval of new drug applications (“NDAs”) and ANDAs submitted to FDA, but also Title 35 of the U.S. Code, which governs patents more generally, specifically 35 U.S.C. § 271 (“Section 271”). Finally, Apotex’s ANDAs are governed by federal regulations maintained by FDA, 21 C.F.R. § 314, as well as other relevant federal law.

in the United States, 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.”⁹

9. The ANDA process is “abbreviated” in that it shortens the time and expense needed for FDA approval by, among other things, allowing an ANDA applicant to rely on FDA’s previous finding of safety and effectiveness for a pioneer drug rather than requiring the ANDA applicant to repeat the clinical studies that were the basis of that approval. To rely on a previous finding of safety and effectiveness by FDA, the ANDA applicant must show, among other things, that its proposed generic drug product is the same as the pioneer drug with respect to the active ingredient, dosage form, strength, route of administration, and with certain narrow exceptions, labeling. The ANDA applicant must also show that its product is bioequivalent to the pioneer drug.¹⁰ The ANDA applicant must include in its application detailed information about the research undertaken to establish bioequivalence, including the address of the facility or facilities conducting the bioequivalence study. The ANDA must also contain a description, including a full address, of the facility for manufacturing, processing, testing, and packaging of the proposed product, and sample labeling for the proposed product with the address of the manufacturer of the product. Apotex’s ANDAs for its sertraline and pravastatin products indicate that these activities occurred outside the United States.¹¹

⁹ *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].

¹⁰ 21 U.S.C. § 355(j)(2) [R3].

¹¹ See ANDA – Sertraline (excerpts) (Oct. 27, 2003) at 0001-3 (FDA Form 356h), 0113 (distributor), 0154-55 (example of proposed container label), 4070 (bioavailability/bioequivalence), 4335 (description of manufacturing facility), 5597 (letter designating authorized representative) [R44]; ANDA – Pravastatin (excerpts) (Dec. 21, 2001) at cover letter, 0001-3 (FDA Form 356h), 0100 (distributor), 0117-18 (example of proposed container label), 0273 (bioavailability/bioequivalence), 5370 (description of manufacturing facility), 6803 (letter designating authorized representative) [R45].

10. All ANDAs are reviewed for approval or disapproval by FDA's Office of Generic Drugs, which maintains a staff of review scientists, physicians, and pharmacists.¹² FDA may disapprove an ANDA for any one of a number of reasons related to public health and safety listed in the governing statute and regulations.¹³ FDA grants "tentative approval" to an ANDA when all scientific and procedural conditions for approval have been met. However, the ANDA cannot be finally approved until various other barriers to approval related to applicable patents no longer apply.¹⁴ The statutes and regulations governing the submission of ANDAs further provide that final ANDA approvals are revocable by FDA for a variety of reasons.¹⁵

11. As discussed in more detail in the U.S. Statement of Defense,¹⁶ ANDA applicants are required to submit certifications with respect to any patent listed in the FDA-published "Orange Book" for the pioneer drug.¹⁷ The ANDA applicant files a "paragraph III" certification to indicate that it will wait until an identified patent expires before going to market with the generic drug, and the ANDA will not be approved until that patent expiration date. A "paragraph IV" certification, on the other hand, indicates the ANDA applicant's view that an identified patent would *not* be infringed by the generic drug or is invalid, and thus the ANDA can be approved and the generic drug can be sold before the patent expires. The relevant statute provides that the first ANDA applicant to make a paragraph IV certification with respect to a pioneer drug's patent may be entitled to 180 days of market exclusivity for its generic drug.¹⁸

¹² See FDA, *Welcome from the Director, Office of Generic Drugs*, available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm119433.htm> (last visited May 3, 2011) [R55].

¹³ 21 U.S.C. § 355(j)(4) [R3]; 21 C.F.R. § 314.125(b) [R39].

¹⁴ 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA) [R3].

¹⁵ See 21 U.S.C. § 355(e) [R3]; 21 U.S.C. § 355(j)(6) [R3]; 21 C.F.R. § 314.150 [R40]; 21 C.F.R. § 314.151 [R41].

¹⁶ U.S. Statement of Defense ¶¶ 4-10.

¹⁷ U.S. Statement of Defense ¶ 5.

¹⁸ 21 U.S.C. § 355(j)(5)(B)(iv) (2002) [R4].

12. For the sertraline and pravastatin products, the first ANDA applicant and later applicants filed both paragraph III and paragraph IV certifications. Therefore the later-in-time applicant could, 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, waited for the patent subject to the paragraph III certification to expire before they could get FDA approval to market their respective drugs.¹⁹ As discussed more fully below, Apotex, which was not the first ANDA applicant with a paragraph IV certification for either sertraline or pravastatin, attempted unsuccessfully to obtain a court decision that would trigger the first paragraph IV applicants' 180-day exclusivity period prior to the expiration of the patents governing the pioneer drugs. Had it succeeded, Apotex would have circumscribed or eliminated the first paragraph IV applicants' 180-day exclusivity period by causing the 180 days of exclusivity to run prior to the expiration of the paragraph III patent.²⁰

C. Apotex Developed And Manufactured Its Sertraline And Pravastatin Products In Canada

13. Apotex's claims against the United States concern ANDAs for two of its exported products: sertraline and pravastatin.²¹ As the following information from each of the ANDAs indicates, these products were developed and manufactured in Canada for export to the United States.

1. The Development And Manufacture For Export Of Sertraline Hydrochloride

¹⁹ For sertraline and pravastatin, the first paragraph IV applicants' 180-day exclusivity period could have been triggered by the earlier of two events: (1) the first commercial marketing of the drug, which could not occur until the patents subject to paragraph III certifications expired; or (2) a court decision that the patent subject to paragraph IV is invalid, not infringed, or unenforceable. 21 U.S.C. § 355(j)(5)(B)(iv) (2002) [R4]. See U.S. Statement of Defense ¶ 9.

²⁰ U.S. Statement of Defense ¶ 8.

²¹ See Apotex SOC ¶¶ 45, 83.

14. Sertraline is the generic form of the drug Zoloft, an antidepressant first developed by Pfizer, Inc. On October 27, 2003, Apotex²² submitted to FDA an ANDA for sertraline oral tablets.²³ In the ANDA submission for sertraline, Apotex's [REDACTED] facility is listed as performing [REDACTED]

[REDACTED]²⁴ One business data source indicates that Apotex prepares its ANDA submissions at its Signet Campus in Ontario, Canada.²⁵

15. Apotex, which is not incorporated in the United States, designated Apotex Corp. in its sertraline ANDA as its "Authorized U.S. Agent."²⁶ Apotex Corp. is not listed anywhere in the sertraline ANDA submissions as developing, manufacturing, or testing Apotex products; rather, Apotex Corp. is identified as a U.S.-based distributor.²⁷ In its pleadings in this arbitration, Apotex does not identify the U.S.-based distributors for its sertraline products; instead, Apotex states that its sertraline products are sold by "others" in the United States.²⁸ The proposed container label for sertraline tablets submitted with Apotex's sertraline ANDA indicates that

²² The ANDA was submitted by TorPharm Inc., which changed its name to Apotex Inc. in 2004. *See* Datamonitor Company Profiles – History, Apotex, Inc. (June 25, 2010) (TorPharm was "established in 1993 for supplying products to the U.S. oral solid dosage market," and in 2004, TorPharm was rebranded under the Apotex name.) [R49]. Apotex Inc. was formed on April 1, 2004 by amalgamation of Apotex Inc. and TorPharm Inc. *See* Dun & Bradstreet Report re: Apotex Inc (Apr. 14, 2011) at 8 [R50].

²³ *See* ANDA – Sertraline (excerpts) (Oct. 27, 2003) at 0001-3 (FDA Form 356h), 0113 (distributor), 0154-55, (example of proposed container label), 4070 (bioavailability/bioequivalence), 4335 (description of manufacturing facility), 5597 (letter designating authorized representative) [R44].

²⁴ ANDA – Sertraline (excerpts) (Oct. 27, 2003) at 4335 (description of manufacturing facility); *see also id.* at 0003 (Form FDA 356h) (noting that "TorPharm[, the former name of Apotex Inc.,] [REDACTED] for the finished product at [REDACTED]") [R44].

²⁵ GlobalData – Business Description, Apotex, Inc. (Jan. 3, 2001) (noting that "creation and submission of generic drug approvals" occurs at Apotex's Signet Campus) [R53].

²⁶ *See* ANDA – Sertraline (excerpts) (Oct. 27, 2003) at 0001 (Form FDA 356h), 5597 (letter designating authorized representative) (designating Apotex Corp., located in Illinois, as the "Authorized U.S. Agent") [R44].

²⁷ *See* ANDA – Sertraline (excerpts) (Oct. 27, 2003) at 0113 (distributor) (stating that "Apotex Corp. is the distributor for TorPharm[, the former name of Apotex Inc.])" [R44].

²⁸ Sertraline NOA ¶ 13 (stating 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]").

manufacturing of Apotex's sertraline products occurs in Canada for export to and sale by Apotex Corp.:

Manufactured by:

[REDACTED]

Manufactured for:

[REDACTED]

16. Thus, as Apotex's own regulatory filings indicate, the company's sertraline products are developed, manufactured, and tested outside the United States, and would be exported by Apotex to U.S.-based distributors.

2. The Development And Manufacture For Export Of Pravastatin Sodium

17. Pravastatin is the generic form of the drug Pravachol, a cholesterol-lowering medication first developed by Bristol-Myers Squibb. On December 21, 2001, Apotex³¹ submitted to FDA an ANDA for pravastatin oral tablets.³² In the ANDA submission for pravastatin, Apotex's [REDACTED] facility is listed as performing [REDACTED]

²⁹ See *supra* note 24.

³⁰ See ANDA – Sertraline (excerpts) (Oct. 27, 2003) at 0154-55 (example of proposed container label) (noting that the sertraline is “Manufactured by” [REDACTED] in Canada, which later changed its name to Apotex Inc., and “Manufactured for” [REDACTED] in the United States) [R44].

³¹ The ANDA was submitted by TorPharm Inc., which changed its name to Apotex Inc. in 2004. See Datamonitor Company Profiles – History, Apotex, Inc. (June 25, 2010) (TorPharm was “established in 1993 for supplying products to the U.S. oral solid dosage market,” and in 2004, TorPharm was rebranded under the Apotex name.) [R49]. Apotex Inc. was formed on April 1, 2004 by amalgamation of Apotex Inc. and TorPharm Inc. See Dun & Bradstreet Report re: Apotex Inc (Apr. 14, 2011) at 8 [R50].

³² See ANDA – Pravastatin (excerpts) (Dec. 21, 2001) at cover letter, 0001-3 (FDA Form 356h), 0100 (distributor), 0117-18 (example of proposed container label), 0273 (bioavailability/bioequivalence), 5370 (description of manufacturing facility), 6803 (letter designating authorized representative) [R45].

[REDACTED]³³ One business data source indicates that Apotex's ANDA submissions were prepared at its Signet Campus in Ontario, Canada.³⁴

18. Apotex Corp. is designated as Apotex's "Authorized U.S. Agent" in the pravastatin ANDA submission.³⁵ Apotex Corp. is not listed anywhere in the pravastatin ANDA submission as developing, manufacturing, or testing Apotex products; rather, Apotex Corp. is identified as a U.S.-based distributor.³⁶ In its pleadings in this arbitration, Apotex does not identify the U.S.-based distributors of its pravastatin products; instead, Apotex states that its pravastatin products are sold by "others" in the United States.³⁷ The proposed container label for pravastatin tablets submitted with Apotex's pravastatin ANDA indicates that the manufacturing of Apotex's pravastatin products occurs in Canada for export to and sale by Apotex Corp.:

Manufactured by:

[REDACTED]

Manufactured for:

[REDACTED]

³³ ANDA – Pravastatin (excerpts) (Dec. 21, 2001) at 5370. *See id.* at p. 0003 (FDA Form 356h) (noting that "TorPharm [, the former name of Apotex Inc.,] [REDACTED] for the finished product at [REDACTED]") [R45].

³⁴ GlobalData – Business Description, Apotex, Inc. (Jan. 3, 2001) (noting that "creation and submission of generic drug approvals" occurs at Apotex's Signet Campus) [R53].

³⁵ *See* ANDA – Pravastatin (excerpts) (Dec. 21, 2001) at 0001 (FDA Form 356h), 6803 (letter designating authorized representative) (designating Apotex Corp., located in Illinois, as the "Authorized U.S. Agent") [R45].

³⁶ *See* ANDA – Pravastatin (excerpts) (Dec. 21, 2001) at 0100 (distributor) (stating that "Apotex Corp. is the distributor for TorPharm [, the former name of Apotex, Inc.]") [R45].

³⁷ *See* Pravastatin NOA ¶ 13 (stating 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]").

³⁸ *See supra* note 24.

³⁹ *See* ANDA – Pravastatin (excerpts) (Dec. 21, 2001) at 0117-18 (example of proposed container label) [R45].

19. Thus, as Apotex's own regulatory filings indicate, the company's pravastatin product, like its sertraline product, is developed, manufactured, and tested outside the United States, and would be exported by Apotex to U.S.-based distributors.

D. Legal Proceedings Before U.S. Courts

20. In its Statement of Claims, Apotex challenges, as violations of NAFTA Chapter Eleven, several decisions of U.S. federal courts related to the two ANDAs that Apotex submitted to FDA concerning its sertraline and pravastatin products. As noted above, for both ANDAs, Apotex was not the first applicant to submit a paragraph IV certification for the proposed generic drug. For sertraline, Ivax Pharmaceuticals submitted the first ANDA with a paragraph IV certification in 1999.⁴⁰ Apotex did not submit its ANDA with a paragraph IV certification for sertraline until October 27, 2003.⁴¹ Likewise, for pravastatin, Teva Pharmaceuticals USA ("Teva") submitted the first ANDA with a paragraph IV certification on December 20, 2000.⁴² Apotex did not submit its ANDA with a paragraph IV certification for pravastatin until December 21, 2001.⁴³

21. With respect to sertraline and pravastatin, each of the applicants eligible for 180-day exclusivity, as well as Apotex (which was not eligible), included both paragraph III and paragraph IV certifications in their ANDAs. In each instance, Apotex brought suit against the patent holder seeking to obtain a court decision that would trigger the applicable 180-day exclusivity period prior to the expiration of the paragraph III patent, in order to eliminate or circumscribe the first applicant's 180-day exclusivity.

⁴⁰ See *Apotex Inc. & Apotex Corp. v. Pfizer Inc.*, 385 F. Supp. 2d 187, 190 (S.D.N.Y. 2005) [R16].

⁴¹ Apotex SOC ¶ 45.

⁴² *Teva Pharmaceuticals USA, Inc. v. FDA*, 398 F. Supp. 2d 176, 179 (D.D.C. 2005) [R28].

⁴³ Apotex SOC ¶ 84.

1. Legal Proceedings Related To Sertraline

22. In Apotex's first claim, concerning its ANDA for generic sertraline products, Apotex challenges a decision of the U.S. District Court for the Southern District of New York that dismissed Apotex's declaratory judgment action against Pfizer for lack of subject matter jurisdiction because Apotex failed to establish the existence of an actual controversy under applicable law.⁴⁴ In that decision, the U.S. District Court for the Southern District of New York applied a common law standard known as the "reasonable apprehension of suit" standard to determine whether there was a "case or controversy" for purposes of jurisdiction, and, finding none, accordingly dismissed the action. As discussed at length in the U.S. Statement of Defense, at the time, the reasonable apprehension of suit standard had been applied in hundreds of cases by federal courts throughout the United States over the course of several decades in declaratory judgment actions involving intellectual property.⁴⁵

23. Apotex asserts that the reasonable apprehension of suit standard applied by the U.S. District Court for the Southern District of New York,⁴⁶ and subsequently affirmed by the U.S. Court of Appeals for the Federal Circuit,⁴⁷ was in error because it incorrectly interpreted Article III of the U.S. Constitution. Apotex petitioned the U.S. Supreme Court for a writ of certiorari on this question, which the U.S. Supreme Court denied.⁴⁸

2. Legal Proceedings Related To Pravastatin

24. In Apotex's second claim, concerning its ANDA for generic pravastatin products, Apotex challenges decisions by the U.S. District Court for the District of Columbia and the U.S. Court of

⁴⁴ See *Apotex Inc. & Apotex Corp. v. Pfizer Inc.*, 385 F. Supp. 2d 187, 194 (S.D.N.Y. 2005) [R16].

⁴⁵ U.S. Statement of Defense ¶¶ 14-15.

⁴⁶ *Apotex Inc. & Apotex Corp. v. Pfizer Inc.* 385 F. Supp. 2d 187 (S.D.N.Y. 2005) [R16].

⁴⁷ *Apotex Inc. & Apotex Corp. v. Pfizer, Inc.*, 159 Fed. Appx. 1013 (Fed. Cir. 2005) [R17].

⁴⁸ See *Apotex Inc., et al. v. Pfizer, Inc.*, 549 U.S. 970 (2006) [R18].

Appeals for the District of Columbia Circuit. Apotex initially brought a declaratory judgment action against Bristol-Myers Squibb (“BMS”) in the U.S. District Court for the Southern District of New York seeking an order that BMS’s patents were invalid. The case was voluntarily dismissed on July 23, 2004, when the U.S. District Court for the Southern District of New York entered a stipulated dismissal order as submitted by Apotex and BMS.⁴⁹ The stipulated order noted only that BMS “had no intention to bring suit against Apotex . . . with respect to Apotex’s generic pravastatin sodium products that are the subject of [its] ANDA[.]”⁵⁰ Upon receiving the dismissal order, Apotex sought a determination from FDA that this dismissal had successfully triggered Teva’s 180-day exclusivity with regard to Teva’s first-submitted paragraph IV certification.

25. On June 28, 2005, FDA informed Teva by letter that, according to what it considered controlling legal precedent, the dismissal of Apotex’s lawsuit in the U.S. District Court for the Southern District of New York constituted a court decision trigger. FDA further informed Teva that the 180-day exclusivity period that would have been awarded to Teva, subject to final approval by FDA, therefore had already run.⁵¹ With the expiry of Teva’s exclusivity period Apotex would have been permitted to market its own generic pravastatin drug simultaneously with Teva as soon as (i) Apotex received final approval of its ANDA, and (ii) another patent, subject to a paragraph III certification, expired in April 2006.

26. Shortly after being informed about FDA’s decision with regard to the 180-day exclusivity for generic pravastatin, Teva sued FDA in the U.S. District Court for the District of Columbia seeking to reverse FDA’s decision. The U.S. District Court for the District of Columbia ruled

⁴⁹ Stipulation of Dismissal, *Apotex Inc. & Apotex Corp. v. Bristol-Myers-Squibb Co.*, No. 04-cv-2922 (S.D.N.Y. 2004) (Dkt. No. 16) [R10].

⁵⁰ *Id.* at 3 [R10].

⁵¹ Letter from G. Buehler to P. Erickson (June 28, 2005) [R7].

that FDA was in error and that the voluntary dismissal of the declaratory judgment patent infringement action between Apotex and BMS did not qualify as a court decision trigger under Section 355(j)(5)(B)(iv)(II).⁵² On appeal, the U.S. Court of Appeals for the District of Columbia Circuit remanded the case to FDA to reconsider its decision, noting that its previous rulings, upon which FDA relied in its June 28, 2005 letter decision to Teva, were not binding precedent as to the scope of the court decision trigger, and directing FDA to reexamine whether the Apotex/BMS voluntary dismissal qualified as a court decision trigger under the statute.⁵³ The U.S. Court of Appeals for the District of Columbia Circuit wrote that “[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.”⁵⁴

27. In response to this decision and drawing on its experience and expertise, FDA issued a new letter decision on April 11, 2006, interpreting the statute to require a court decision holding on the merits that the patents at issue were invalid, not infringed, or unenforceable in order to constitute a trigger. Because the U.S. District Court for the Southern District of New York did not make a finding on the merits, FDA determined that the Apotex/BMS voluntary dismissal order did not trigger Teva’s 180-day exclusivity period. Apotex unsuccessfully challenged FDA’s new letter decision by bringing suit against FDA seeking a temporary restraining order and preliminary injunction. The U.S. District Court for the District of Columbia denied the

⁵² *Teva Pharmaceuticals USA v. FDA*, 398 F. Supp. 2d 176, 192 (D.D.C. 2005) [R28].

⁵³ *Teva Pharmaceuticals USA, Inc. v. FDA*, 441 F.3d 1, 5 (D.C. Cir. 2006) [R29].

⁵⁴ *Id.* (internal citations and quotations omitted) [R29].

request.⁵⁵ Apotex appealed that denial of injunctive relief to the U.S. Court of Appeals for the District of Columbia Circuit, which affirmed the U.S. District Court for the District of Columbia's decision and remanded to that court for further proceedings on the merits.⁵⁶ Apotex sought, and was denied, rehearing en banc by the U.S. Court of Appeals for the District of Columbia Circuit, but Apotex did not petition for a writ of certiorari for review by the U.S. Supreme Court.⁵⁷ Finally, rather than litigating the merits of its case after losing its bid for preliminary injunctive relief, Apotex stipulated to the dismissal of its claims with prejudice for certain strengths of the drug, and without prejudice for another strength.⁵⁸

II. APOTEX'S CLAIMS FALL OUTSIDE OF THE SCOPE AND COVERAGE OF NAFTA CHAPTER ELEVEN

28. NAFTA Chapter Eleven provisions and cases interpreting those provisions confirm that claims against the United States under Chapter Eleven can be brought only by claimants that have made, or have sought to make, an "investment" in the territory of the United States. 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."⁵⁹ As discussed below, Apotex has failed to establish that it made

⁵⁵ *Apotex Inc. v. FDA*, 2006 WL 1030151 (D.D.C., Apr. 19, 2006) [R11].

⁵⁶ *Apotex Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006) [R13].

⁵⁷ Petition for Rehearing *en banc* of Plaintiff-Appellant *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir., July 21, 2006) (Dkt. No. 982546-1) [R14]; Per Curiam Order, *en banc*, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir., Aug. 17, 2006) (Dkt. No. 986687) [R15].

⁵⁸ Stipulation of Dismissal at 2, *Apotex Inc. v. FDA*, No. 06-627 (D.D.C. Oct. 3, 2006) (Dkt. No. 42) [R12].

⁵⁹ UNCITRAL Arbitration Rules (1976), Art. 24(1) ("Each party shall have the burden of proving the facts relied on to support his claim or defence") [R84]; *see also Feldman v. United Mexican States*, ICSID Case No. ARB(AF)/99/1, Award ¶ 177 (Dec. 16, 2002) ("[I]t is a generally accepted canon of evidence in civil law, common law and, in fact, most jurisdictions, that the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a claim or defense.") [R74]; *Phoenix Action, Ltd. v. Czech Republic*, ICSID Case No. ARB/06/5, Award ¶¶ 58-64 (Apr. 15, 2009) (summarizing relevant investment treaty arbitral awards and concluding

or sought to make an “investment” as defined under NAFTA Article 1139 in the United States, and thus Apotex does not qualify as an “investor” under NAFTA Chapter Eleven. The Tribunal therefore does not have jurisdiction over Apotex’s claims.

A. To Qualify As An “Investor” Under NAFTA Chapter Eleven, A Claimant Must Make Or Seek To Make An “Investment” In The Territory Of Another NAFTA Party

29. Apotex submitted both of its claims to arbitration pursuant to NAFTA Article 1116.

Under that provision, the United States consented to arbitration only if a claimant qualifies as an “investor” of another NAFTA Party alleging that it “has incurred loss or damage by reason of, or arising out of” a breach by the United States of one or more Chapter Eleven, Section A obligations.⁶⁰ “Investor of a Party” is defined in Article 1139 as “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.” Thus, under Article 1116, the United States’ consent to arbitrate in this matter is limited to claims for loss or damage incurred by Apotex in seeking to make, making, or having made an “investment,” as that term is defined in Article 1139.

30. Furthermore, under Article 1101(1)(b), measures relating to “investments” of investors fall within the scope and coverage of Chapter Eleven only to the extent such investments are located “in the territory” of another NAFTA Party. Article 1101 has been described as the

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” [R83].

⁶⁰ A claim can also be brought by an investor under Chapter Eleven with respect to certain Chapter Fifteen obligations not relevant to this case. *See* Article 1116(1)(b) (permitting claim to be submitted to arbitration for alleged breaches of Article 1503(2) (referring to the manner in which private and state-owned monopolies may exercise regulatory, administrative or other governmental authority) and Article 1502(3)(a) (ensuring that any state-owned enterprises acts in a manner not inconsistent with Chapter Eleven)).

“gateway leading to the dispute resolution provisions of Chapter 11,” whose requirements limit the powers of a Chapter Eleven arbitral tribunal.⁶¹

31. Accordingly, Article 1101, read together with Article 1139, make clear that the scope and coverage of the protections of NAFTA Chapter Eleven, including Article 1116, extend to “investors” only to the extent that they have made, or have sought to make, “investments” in the territory of another NAFTA Party.⁶²

32. This interpretation of Articles 1116, 1101, and 1139 is confirmed by reading the ordinary meaning of those articles in their context and in light of the object and purpose of the treaty.⁶³

The NAFTA as a whole indicates the NAFTA Parties’ recognition that businesses can and do engage in different types of economic activity, and the NAFTA provides different remedies depending on the type of activity carried out by the person or entity. For example, a company’s activities undertaken in its capacity as a foreign exporter of goods into the United States, like those alleged by Apotex, are not addressed by Chapter Eleven but rather by Chapter Three. With the exception of the investment provisions of Chapter Eleven (and two provisions of Chapter

⁶¹ *Methanex Corp. v. United States*, NAFTA/UNCITRAL, First Partial Award ¶ 106 (Aug. 7, 2002) [R80]; *see also Bayview Irrigation District et al. v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award on Jurisdiction ¶ 85 (June 19, 2007) (Article 1101 “defines the ‘scope and coverage’ of the entirety of Chapter Eleven.”) [R69].

⁶² *See Bayview*, Award on Jurisdiction ¶ 105 (“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.”) [R69]; *Canadian Cattlemen for Fair Trade v. United States*, NAFTA/UNCITRAL, Award on Jurisdiction ¶ 126 (Jan. 28, 2008) (“‘investors’ are inextricably linked to ‘investments,’ which Article 1101 limits to ‘foreign investments,’ that is to say, investments of a party in the territory of another Party whose measure is at issue.”) [R70]; *Grand River Enterprises Six Nations Ltd. v. United States*, NAFTA/UNCITRAL, Award ¶ 87 (Jan. 12, 2011) (holding that 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.”) [R76].

⁶³ *See Vienna Convention on the Law of Treaties (“VCLT”),* May 23, 1969, 1155 U.N.T.S. 331, 8 I.L.M. 679 (1969), art. 31 (“[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”) [R85]. While the United States is not a party to the VCLT, it has recognized since at least 1971 that the Convention is the “authoritative guide” to treaty law and practice. *See Letter from Secretary of State Rogers to President Nixon Transmitting the Vienna Convention on the Law of Treaties*, Oct. 18, 1971, *reprinted in* 65 DEP’T OF ST. BULL. 684, 685 (1971) [R77]. The International Court of Justice has determined that VCLT Article 31 is reflective of customary international law. *See, e.g., Case Concerning Kasikili/Sedudu Island (Bots. v. Namib.)*, 1999 I.C.J. 1045, 1059 (Judgment of Dec. 13, 1999) [R71].

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 delineated in Chapter Twenty.⁶⁴ 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.

33. Furthermore, NAFTA Article 102(1)(c) states that one of the NAFTA's objects and purposes is to "increase substantially investment opportunities in the territories of the Parties." This article is understood to mean that the Parties intend to promote opportunities for investment by investors of one Party in the territory of another Party.⁶⁵

34. Thus, the ordinary meaning of the text of Articles 1116, 1101, and 1139, read in context and in light of the object and purpose of the NAFTA, confirms that the scope and coverage of 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. As discussed below, Apotex has not demonstrated that it is an "investor" with an "investment" in the United States, and its claims should therefore be dismissed in their entirety.

⁶⁴ See *Canadian Cattlemen*, Award on Jurisdiction ¶ 193 (stating that 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.") [R70].

⁶⁵ See *Bayview*, Award on Jurisdiction ¶ 100 (stating that the "clear and ordinary meaning that is borne by the text of NAFTA Chapter Eleven" is that NAFTA Article 102(1)(c) "refers to, and can only sensibly be considered as referring to, opportunities for *foreign* investment in the territory of each Party made by investors of another Party.") [R69]; *Metalclad Corp. v. United Mexican States*, ICSID Case No. ARB(AF)/97/1, Award ¶ 75 (Aug. 30, 2000) (Article 102(1)(c) evidences the Parties' intent "to promote and increase cross-border investment opportunities . . .") [R79]. The United States Statement of Administrative Action confirms that Chapter Eleven "applies where such firms or nationals make or seek to make investments in another NAFTA country." 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 (1993) [R82]. Likewise, in the Canadian Statement on Implementation of the NAFTA, the Government of Canada explained that Chapter Eleven built upon Canada's prior experience with "investment agreements both to protect the interests of Canadian investors abroad and to provide a rules-based approach to the resolution of disputes involving foreign investors in Canada or Canadian investors abroad." Department of External Affairs, *North American Free Trade Agreement: Canadian Statement on Implementation*, in CANADA GAZETTE 68, 147 (Jan. 1, 1994) [R72].

B. Apotex Fails To Establish That It Made Or Sought To Make An “Investment” As Defined Under Article 1139

35. As alleged by Apotex in this arbitration, Apotex is a Canadian manufacturer of generic pharmaceuticals that were intended to be sold in the United States by “others.”⁶⁶ Apotex alleges that damages arose from its inability to “promptly bring” to market or to “promptly launch” its sertraline and pravastatin products in the United States.⁶⁷

36. Recognizing that NAFTA Chapter Eleven requires an “investor” to make or seek to make an “investment” in the territory of another NAFTA Party, Apotex asserts that it has an “investment” in the United States. However, Apotex offers only two bases for this alleged investment: first, “the expenditure of millions of dollars each year in preparing ANDAs for filing in the United States,” and second, “formulating, developing, and manufacturing approved generic pharmaceutical products for sale in the United States and throughout the world.”⁶⁸ Apotex fails to address how either set of activities meets the definition of “investment” under Article 1139, which is an “exclusive list of elements or activities that constitute an investment for purposes of NAFTA,”⁶⁹ and whether these activities took place in the United States.

37. With respect to Apotex’s first alleged “investment”—“the expenditure of millions of dollars each year in preparing ANDAs for filing in the United States”—an ANDA must be submitted by any generic drug manufacturer that seeks to have its products sold in the United

⁶⁶ Sertraline/Pravastatin NOAs ¶ 13.

⁶⁷ Apotex SOC ¶¶ 72, 119.

⁶⁸ Apotex SOC ¶¶ 62, 111. *See also* Apotex SOC ¶ 23: “Apotex 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.”

⁶⁹ *Grand River Enterprises*, Award ¶ 82 [R76].

States,⁷⁰ regardless of whether the manufacturer is investing in, or merely exporting to, the United States. The preparation of an ANDA for filing does not establish that a generic drug manufacturer is investing in, rather than exporting products to, the United States. Moreover, Apotex itself admits in this arbitration that its sertraline and pravastatin products would be “sold by others” in the United States.⁷¹

38. Apotex has made no attempt to explain how its ANDA expenditures fall within Article 1139’s exclusive list of qualifying “investments.” Indeed, 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, regardless of whether the exporter made or sought to make an investment in the United States. Allowing 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 the investment chapter of the NAFTA, specifically to promote an increase in opportunities for, and protection of, investments in the territory of another NAFTA Party.

39. Apotex similarly fails to articulate how its second alleged investment—“formulating, developing, and manufacturing” the pharmaceuticals at issue—constitutes an “investment” under Article 1139. As discussed above, the formulation, development, and manufacture of Apotex’s sertraline and pravastatin products (including the preparation of its ANDAs)⁷² occur in Canada,

⁷⁰ There is no dispute between the parties on this point. *See* Apotex SOC ¶ 29 (“A company seeking to market a generic drug product must file an ANDA.”)

⁷¹ Sertraline/Pravastatin NOAs ¶ 13.

⁷² GlobalData – Business Description, Apotex, Inc. (Jan. 3, 2011) (noting that “creation and submission of generic drug approvals” occurs at Apotex’s Signet Campus) [R53].

not the United States. Such activity by an exporter in its own country does not constitute an “investment” under Article 1139.⁷³

40. For the above reasons, Apotex has failed to establish that it made or sought to make an “investment” as that term is defined under NAFTA Article 1139.

C. Apotex Does Not Qualify As An “Investor” As Required By Article 1116

41. As discussed 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. Because Apotex has failed to establish that it made or sought to make an “investment” in the United States, Apotex does not qualify as an “investor” under Article 1116, and therefore the Tribunal lacks jurisdiction over its claims.⁷⁴

42. Apotex developed and manufactured its sertraline and pravastatin products entirely outside the territory of the United States,⁷⁵ and submitted its ANDAs for those products in order to obtain the regulatory approval that was required before Apotex’s exported goods could be sold in the United States.

⁷³ See *Grand River Enterprises*, Award ¶¶ 85-89 (finding that investment in a Canadian factory did not constitute an “investment” supporting a Chapter Eleven arbitration by Canadian claimants against the United States) [R76]; *Bayview*, Award on Jurisdiction ¶¶ 93-98 (finding that a qualifying “investment” under Article 1139’s definition must be a “foreign investment”) [R69].

⁷⁴ See *Canadian Cattlemen*, Award on Jurisdiction ¶ 137 (stating that “both Article 1116 and 1117 focus on investors; . . . [b]oth rely on the Article 1139 definition of ‘investor.’ . . . [T]his definition makes it clear that investors do not exist in isolation from their investments.”) [R70].

⁷⁵ Apotex could have invested in U.S.-based manufacturing, development, or testing facilities, but opted instead to create and manufacture its generic pharmaceuticals in Canadian factories. In its U.S. federal court filings related to pravastatin, Apotex made clear that it invested in a factory for the development and production of the active pharmaceutical ingredient, pravastatin sodium. Apotex chose to make that investment not in the United States, but in Winnipeg, Canada. See Declaration of Dr. Bernard C. Sherman ¶ 6, *Apotex Inc. v. FDA*, Case No. 1:06-cv-00627 (JDB) (D.D.C. Apr. 14, 2006) (Dkt. No. 17-4) (identifying a \$100 million investment in a fermentation facility for the development and production of pravastatin) [R58]; see also Apotex Fermentation Website, <http://apoferm.com/contactus/contactus.html> (last visited May 3, 2011) (stating that the location of Apotex Fermentation is in Winnipeg, Manitoba, Canada) [R48].

43. As noted above, for exports to the U.S. market, Apotex has three facilities in Ontario, Canada: (1) Etobicoke, (2) Richmond Hill, and (3) Signet.⁷⁶ In addition, as Apotex's ANDA submissions make clear, Apotex manufactures its generic drugs entirely in Canada, i.e., outside the territory of the United States,⁷⁷ and according to one business data source, Apotex creates its generic drug approval submissions at the Signet campus, located in Weston, Ontario.⁷⁸ Apotex has not asserted any U.S.-based activities related to its sertraline and pravastatin products apart from the filing of its ANDAs with FDA and related litigation.

44. 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.⁷⁹ Apotex's statements on its website emphasize the importance of its export operations to the company:

The Apotex Group and our facilities are recognized by the world as among the best. This has resulted in approvals by the Food and Drug Administration in the U.S.; the Canadian Therapeutics Products Directorate, the European Medicines Evaluation Agency and the Australian Therapeutics Goods Administration. These approvals have opened the doors for export to over 115 countries.⁸⁰

45. In sum, the development and production of Apotex's sertraline and pravastatin products occur outside the United States, and, as contemplated by Apotex, sales of those products in the United States would be made by U.S.-based distributors.⁸¹ Apotex, like any company that

⁷⁶ Apotex Website at <http://www.apotex.com/us/en/about/video.asp> (last visited May 3, 2011) [R47].

⁷⁷ See ANDA – Sertraline (excerpts) (Oct. 27, 2003) at 0003 (FDA Form 356h), 4335 (description of manufacturing facility) [R44]; see also ANDA – Pravastatin (excerpts) (Dec. 21, 2001) at 0003 (FDA Form 356h), 5370 (description of manufacturing facility) [R45].

⁷⁸ GlobalData – Business Description, Apotex, Inc (Jan. 3, 2011) [R53].

⁷⁹ Apotex's exporter status is similar to that found 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.” *Grand River Enterprises*, Award ¶ 5 [R76].

⁸⁰ See Apotex Website at <http://www.apotex.com/us/en/about/video.asp> (last visited May 3, 2011) [R47].

⁸¹ See ANDA – Sertraline (excerpts) (Oct. 27, 2003) at 0113 (distributor) (stating that “Apotex Corp. is the distributor for TorPharm [, the former name of Apotex Inc.]”) [R44]. See ANDA – Pravastatin (excerpts) (Dec. 21,

intends to export generic drug products to the United States for sale in the U.S. market, sought regulatory approval from FDA through the submission of ANDAs. Apotex has made no attempt to articulate how the mere submission of an ANDA to FDA constitutes an “investment” under Article 1139. In any event, as discussed above, because an enterprise “must make an investment in another NAFTA State, and not in its own,”⁸² to qualify as an “investor” under NAFTA Chapter Eleven, Apotex fails to qualify as an “investor” in this arbitration. Accordingly, the Tribunal lacks jurisdiction over Apotex’s claims, which should be dismissed in their entirety.

III. APOTEX HAS FAILED TO ESTABLISH THAT IT HAS SUBMITTED TIMELY CLAIMS AS REQUIRED BY NAFTA ARTICLE 1116(2)

46. To the extent that Apotex alleges breach and loss that occurred outside the applicable three-year limitations period, those claims are time-barred under Article 1116,⁸³ the article under which Apotex submitted both of its claims.⁸⁴ Article 1116(2) provides that “[a]n 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.”⁸⁵

2001) at 0100 (distributor) (stating that “Apotex Corp. is the distributor for TorPharm [, the former name of Apotex, Inc.]”) [R45].

⁸² *Bayview*, Award on Jurisdiction ¶ 101[R69]. See also *Canadian Cattlemen*, Award on Jurisdiction ¶ 126 (“‘[i]nvestors’ are inextricably linked to ‘investments,’ which Article 1101 limits to ‘foreign investments,’ – that is to say, investments of a party in the territory of another Party whose measure is at issue.”) [R70]; *id.* ¶ 147 (“Chapter Eleven is not intended to apply to interests arising merely from cross-border trade activities”); *Grand River Enterprises*, Award ¶ 5 (finding, where the claimants manufactured products in Canada for export to the United States, that the claimants’ investments in Canada did not satisfy jurisdictional requirements for a NAFTA Chapter Eleven claim against the United States) [R76].

⁸³ As discussed in paragraphs 54–61 *infra*, the judicial acts at issue in Apotex’s pravastatin claim lack finality and thus could not give rise to a breach of the NAFTA. Nevertheless, even if those judicial acts were found to have the requisite judicial finality, claims alleging breach and loss occurring outside the applicable limitations period that are based on such acts would be time-barred under NAFTA Article 1116(2).

⁸⁴ Sertraline/Pravastatin NOAs ¶ 6.

⁸⁵ NAFTA, art. 1116(2).

47. As the NAFTA Chapter Eleven tribunal in *Feldman v. United Mexican States* explained, the term “making a claim” “is used to denote the definitive activation of an arbitration procedure.”⁸⁶ For a claim brought under the UNCITRAL Arbitration Rules, Article 1137(1)(c) defines that time as the date on which the NOA “is received by the disputing Party.”⁸⁷

48. Accordingly, Article 1116(2) requires a claimant to submit, and for the NAFTA Party to receive, a NOA within three years of the date on which the claimant first acquired knowledge, either actual or constructive, of the alleged breach and of supposed loss or damage. Under this article, an investor first acquires knowledge of an alleged breach and loss on a particular date.⁸⁸

49. Both the *Grand River v. United States* and the *Feldman v. United Mexican States* NAFTA Chapter Eleven tribunals described the three-year limitations period as a “clear and rigid” defense, adding that the time limitation is “not subject to any suspension, prolongation or other qualification.”⁸⁹

A. Any Sertraline Claims That Allege Breach And Loss Occurring Prior To December 11, 2005 Are Time-Barred

50. In its Sertraline NOA, Apotex alleges that the January 3, 2005 decision by 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.”⁹⁰ Thus, Apotex appears to allege that the January 2005 court decision

⁸⁶ *Feldman v. United Mexican States*, ICSID Case No. ARB(AF)/99/1, Interim Decision on Preliminary Jurisdictional Issues ¶ 44 (Dec. 6, 2000) [R73].

⁸⁷ NAFTA, art. 1137(1)(c).

⁸⁸ Knowledge of loss or damage incurred by the investor under Article 1116(2) does not require knowledge of the extent of loss or damage. See *Mondev Int’l Ltd. v. United States*, ICSID Case No. ARB(AF)/99/2, Award ¶ 87 (Oct. 11, 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.”) [R81]; *Grand River Enterprises Six Nations, Ltd. et al. v. United States*, NAFTA/UNCITRAL, Decision on Objections to Jurisdiction ¶ 78 (July 20, 2006) (quoting same) [R75].

⁸⁹ *Grand River*, Decision on Jurisdiction ¶ 29 [R75]; *Feldman*, Award ¶ 63 [R74].

⁹⁰ Sertraline NOA ¶ 50; see also Sertraline NOI at 5 (stating same).

breached obligations under Article 1105 (minimum standard of treatment) and Article 1110 (expropriation) of the NAFTA. However, the United States received Apotex's NOA for the sertraline claim on December 11, 2008. Accordingly, under Article 1116(2), any Article 1105 and Article 1110 claims made by Apotex based on the January 3, 2005 decision of the District Court alone, to the extent that Apotex alleges that a breach and loss occurred at that time, are time-barred and should be dismissed because they are outside the three-year limitations period.⁹¹

B. Any Pravastatin Claims That Allege Breach And Loss Occurring Prior To June 5, 2006 Are Also Time-Barred

51. In its Pravastatin NOA, Apotex alleges that FDA's letter decision of April 11, 2006—determining that the 180-day exclusivity period had not been triggered—and the U.S. District Court for the District of Columbia's decision of April 19, 2006, in *Apotex, Inc. v. FDA*—denying Apotex's motion for a temporary restraining order and preliminary injunction—“each” constitute a violation of Article 1102, Article 1105, and Article 1110 of the NAFTA.⁹² However, the United States received Apotex's Pravastatin NOA on June 5, 2009. Therefore, any claims based on the FDA letter decision of April 11, 2006 are time-barred should be dismissed. Moreover, any claims based on the District Court decision alone, to the extent that Apotex alleges that breach and loss occurred at that time, should also be dismissed.

52. Apotex's own allegations in this arbitration confirm that it had knowledge of alleged breach and loss with respect to its pravastatin claim in April 2006. As alleged in the Pravastatin NOA, Apotex's inability to bring its pravastatin products to market in April 2006 (by which

⁹¹ In its Statement of Claims, Apotex also states more generally that the “actions of the United States, by way of the U.S. federal courts, including the U.S. District Court for the Southern District of New York, the U.S. Court of Appeals for the Federal Circuit, and the U.S. Supreme Court” violated Articles 1102, 1105, and 1110 of the NAFTA. See Apotex SOC ¶ 65 (Article 1102); see also *id.* ¶ 70 (Article 1105) and ¶ 75 (Article 1110). Apotex, as Claimant, must specify with particularity the applicable date of breach for its claims. Any claim of breach and loss that allegedly occurred prior to December 11, 2005 would be time-barred.

⁹² Pravastatin NOA ¶ 67.

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."⁹³ 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."⁹⁴

53. Thus, given its stated knowledge of alleged breach and loss in April 2006, Apotex's claim that the April 11, 2006 FDA letter decision breached Article 1102, Article 1105, and Article 1110 is time-barred and should be dismissed. Additionally, to the extent that Apotex is alleging that the April 19, 2006 decision of the U.S. District Court breached those same articles, those claims are also time-barred and should be dismissed.⁹⁵

IV. EVEN IF NOT TIME-BARRED, APOTEX'S PRAVASTATIN CLAIMS RELATED TO JUDICIAL ACTS LACK THE REQUISITE JUDICIAL FINALITY

54. In addition to asserting claims related to pravastatin based on judicial and administrative decisions occurring prior to June 5, 2006, Apotex's pravastatin claim also refers generally to acts of U.S. federal courts occurring after that date.⁹⁶ However, given that none of these judicial acts were final, they cannot be the basis for claims under Chapter Eleven of the NAFTA.⁹⁷

Specifically, Apotex never sought review in the U.S. Supreme Court of the pravastatin-related

⁹³ Pravastatin NOA ¶¶ 50, 67; *see also* ¶ 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.").

⁹⁴ Apotex SOC ¶ 108.

⁹⁵ In its Statement of Claims, Apotex also states more generally that the "actions of the United States, by way 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" violated Articles 1102, 1105, and 1110 of the NAFTA. *See* Apotex SOC ¶ 118 (Article 1105); *see also id.* ¶ 115 (Article 1102) and ¶ 124 (Article 1110). Any claim of breach and loss that allegedly occurred prior to June 5, 2006, such as a claim of breach and loss arising from the decisions in *Teva v. FDA*, would be time-barred.

⁹⁶ *See* Apotex SOC ¶¶ 115, 118, 124.

⁹⁷ *See infra* note 113 and accompanying text.

decisions by the U.S. Court of Appeals. Moreover, Apotex voluntarily agreed to the dismissal of its entire pravastatin claim, most of which was dismissed with prejudice.

55. None of the pravastatin-related judicial acts cited by Apotex as breaching U.S. obligations under the NAFTA was finally reviewed within the U.S. judicial system. 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 FDA's first pravastatin letter decision of June 28, 2005.⁹⁸ 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 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, on April 5, 2006.⁹⁹

56. After FDA issued its April 11, 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 FDA to set aside its April 11, 2006 letter decision and temporarily enjoining the award of any 180-day exclusivity for pravastatin ANDAs. The proposed injunction also would have prevented 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.¹⁰⁰

57. Following the denial of Apotex's motion by the District Court for the District of Columbia,¹⁰¹ Apotex filed an emergency motion for reconsideration, which was rejected.¹⁰²

⁹⁸ *Teva 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)).

⁹⁹ Complaint, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. Apr. 5, 2006) (Dkt. No. 1) [R56].

¹⁰⁰ Motion for Temporary Restraining Order and/or Preliminary Injunction, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. Apr. 14, 2006) (Dkt. No. 17) [R57].

¹⁰¹ *Apotex Inc. v. FDA*, 2006 WL 1030151, *1, *19 (Apr. 19, 2006) [R11].

¹⁰² Order, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. Apr. 20, 2006) (Dkt. No. 33) [R59].

Apotex also appealed to the Court of Appeals for the District of Columbia Circuit and filed an emergency motion for injunctive relief pending appeal.¹⁰³ Teva opposed Apotex's emergency motion and filed a cross-motion for summary affirmance of the District Court's decision.¹⁰⁴ On April 20, 2006, the Court of Appeals enjoined FDA "from granting final approval of any ANDA for generic pravastatin pending further order of the court . . . to give the court sufficient opportunity to consider the merits of the motion for injunctive relief pending appeal."¹⁰⁵ On April 24, 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."¹⁰⁶ On May 18, 2006, Apotex filed a motion to expedite consideration of its appeal.¹⁰⁷ On June 6, 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.¹⁰⁸

58. Apotex filed a petition to the Court of Appeals for rehearing en banc on July 21, 2006, which was denied on August 17, 2006.¹⁰⁹ Following the denial of its en banc petition, Apotex again did not seek review by the U.S. Supreme Court.

¹⁰³ Notice of Appeal and Emergency Motion, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. Apr. 19, 2006) (Dkt. Nos. 963396-1 and 963398-1) [R60][R61].

¹⁰⁴ Combined Opposition and Cross-Motion, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. Apr. 20, 2006) (Dkt. Nos. 963590-1 and 963950-2) [R62].

¹⁰⁵ Order, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. Apr. 20, 2006) (Dkt. No. 963810) [R63].

¹⁰⁶ Order, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. Apr. 24, 2006) (Dkt. No. 964341) [R64].

¹⁰⁷ Motion of Plaintiff-Appellant Apotex Inc. to Expedite Consideration of this Appeal, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. May 18, 2006) (Dkt. No. 969469) [R65].

¹⁰⁸ *Apotex Inc. v. FDA*, 449 F.3d 1249, 1253-54 (D.C. Cir. June 6, 2006) [R13]; Order, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. June 6, 2006) (Dkt. No. 971806) [R66]. Apotex's motion for expedited consideration was thus dismissed as moot. Clerk's Order, *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. June 6, 2006) (Dkt. No. 971810) [R67].

¹⁰⁹ Petition for Rehearing en banc of Plaintiff-Appellant Apotex Inc., *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir. July 21, 2006) (Dkt. No. 982546-1) [R14]; Per Curiam Order, *en banc, Apotex v. FDA*, No. 06-5105 (D.C. Cir. Aug. 17, 2006) (Dkt. No. 986687) [R15].

59. 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 FDA, Apotex agreed to the dismissal of “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.”¹¹⁰

60. Unlike 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—Apotex did not seek certiorari in *Apotex v. FDA*. Apotex thus failed to seek U.S. Supreme Court review of the Court of Appeals decision on injunctive relief in its pravastatin claim. Indeed, pursuant to 28 U.S.C. § 1254(1), Apotex could have sought U.S. Supreme Court review on an expedited basis in the matter.¹¹¹ Also unlike the sertraline claim, Apotex subsequently failed to pursue its claim even in the District Court, opting instead to agree to the dismissal of the claim.¹¹²

61. 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.¹¹³ Thus, the judicial acts challenged by Apotex in its pravastatin claim were not

¹¹⁰ Stipulation of Dismissal at 2, *Apotex Inc. v. FDA*, No. Civ. A.06-0627 (D.D.C. Oct. 3, 2006) (Dkt. No. 42) [R12].

¹¹¹ 28 U.S.C. § 1254 (“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.”) [R42].

¹¹² Apotex’s voluntary dismissal of all claims against FDA regarding pravastatin sodium tablets 10 mg, 20 mg, and 40 mg with prejudice precludes any international claims against the United States with respect to those dosages. See Louis B. Sohn & R.R. Baxter, *Responsibility of States for Injuries for Injuries to the Economic Interest of Aliens*, 55 AM. J. INT’L L. 545, 578 (1961) (stating that, in Article 22(4) of the Draft Convention on the International Responsibility of States for Injuries to Aliens, “[n]o claim may be presented by a claimant if, after the injury and without duress, the claimant himself or the person through whom he derived his claim waived, compromised or settled the claim.”) [R88].

¹¹³ See EDWIN M. BORCHARD, *THE DIPLOMATIC PROTECTION OF CITIZENS ABROAD* 198 (1915) (“It is a fundamental principle that [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.”) [R86]; 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

final manifestations of justice within the U.S. judicial system. To the extent that Apotex's pravastatin claim alleges breach and loss occurring on or after June 5, 2006 arising from judicial acts, the claim should be dismissed because those acts lack the requisite judicial finality.¹¹⁴

RELIEF SOUGHT

62. For the foregoing reasons, the United States respectfully requests that this Tribunal render an award: (A) in favor of the United States and against Apotex, dismissing all claims in their entirety and with prejudice; and (B) pursuant to paragraphs 1 and 2 of Article 40 of the UNCITRAL Arbitration Rules, ordering that Apotex bear the costs of this arbitration, including the United States' costs for legal representation and assistance.

involve the State in responsibility, but the judicial decision with which it is confronted must be final and without appeal." [R87]; and *Loewen Group v. United States*, ICSID Case No. ARB(AF)/98/3, Award ¶ 165 (June 26, 2003) (explaining that "the obligation to pursue local remedies in a case in which the alleged violation of international law is founded upon a judicial act" requires "that the complainant is bound to exhaust any remedy which is adequate and effective . . . so long as the remedy is not 'obviously futile.'" [R78] (quoting *The Finnish Ships Arbitration Award*, 3 R. INT'L ARB. AWARDS 1480, 1495, 1503-05 (May 9, 1934) [R36] and *Nielsen v. Denmark* [1958-1959] Y.B. EUR. COMM'N H.R. 412 at 436, 438, 440, 444) [R35]).

¹¹⁴ See *Loewen*, Award ¶ 156 ("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. The requirement has application to breaches of Articles 1102 and 1110 as well as Article 1105.") [R78]. See also 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.") [R38].

Dated: May 16, 2011

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