*CONTAINS CONFIDENTIAL MATERIAL*

**IN THE ARBITRATION UNDER
CHAPTER 11 OF THE
NORTH AMERICAN FREE TRADE AGREEMENT
AND THE
UNCITRAL ARBITRATION RULES (1976)**

BETWEEN:

**APOTEX INC.**

**Claimant,**

- AND -

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

**Respondent.**

# CLAIMANT APOTEX INC.'S COUNTER-MEMORIAL ON RESPONDENT'S OBJECTIONS TO JURISDICTION

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August 1, 2011

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1. In accordance with Procedural Order No. 1, entered on December 16, 2010, Claimant Apotex Inc. hereby respectfully submits its Counter-Memorial On Respondent's Objections To Jurisdiction.

## I. INTRODUCTION.

2. Apotex's arbitration claims under Chapter Eleven of NAFTA arise directly from Respondent's violations of Apotex's reasonable and legitimate expectations regarding its investments in its Abbreviated New Drug Applications ("ANDAs") for Sertraline Hydrochloride Tablets and Pravastatin Sodium Tablets, and Respondent's breach of its obligations under NAFTA. More specifically, with respect to each of Apotex's two arbitration claims (*i.e.*, the "Sertraline Claim"—subject of Apotex's Notice of Arbitration dated December 10, 2008, and the "Pravastatin Claim"—subject of Apotex's Notice of Arbitration dated June 4, 2009), the actions of Respondent United States of America ("Respondent" or "United States") violated at least its obligation to: (1) accord to Apotex treatment no less favorable than it accords its own investors in like circumstances under NAFTA Article 1102; (2) accord to Apotex treatment in accordance with international law, including fair and equitable treatment, under NAFTA Article 1105; and (3) refrain from directly or indirectly nationalizing or expropriating Apotex's investment under NAFTA Article 1110.

3. Prior to resolving Apotex's arbitration claims on their merits, Respondent urges this Tribunal to dismiss Apotex's claims, alleging that Apotex's claims somehow fall outside the scope of NAFTA. In particular, Respondent argues, without foundation, that somehow Apotex is not an "investor" that made or sought to make an "investment" under NAFTA; that a portion of Apotex's claims are somehow untimely; and that Apotex somehow failed to satisfy the finality requirement for its Pravastatin arbitration claim. For the reasons stated herein, each of

Respondent's purported jurisdictional challenges fail and should (and indeed must) be rejected in their entirety.

4. To begin, under the plain terms of NAFTA, Apotex is an "investor" that made "investments . . . in the territory of the Party," thus bestowing this Tribunal with the necessary jurisdiction to hear Apotex's arbitration claims on their full merits. As explained herein, Apotex invested millions of dollars in developing its products and preparing and filing its ANDAs with the U.S. Food and Drug Administration ("FDA") in the United States, in accordance with U.S. statutory and regulatory requirements, in order to attain an economic benefit in the United States. Indeed, the sole purpose of Apotex's development and submission of its ANDAs was to obtain FDA approval to commercialize its ANDA products in the United States. 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.***" No more is required for—and indeed it is hard to imagine a clearer case of—an investment under NAFTA.

5. If that were not enough (and it certainly is), 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. 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. And on top of that, 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 commercialization of its investments in the United

States. For these reasons too, Apotex is clearly an "investor" with an "investment" in the United States.

6. Finally, both of Apotex's arbitration claims were timely submitted, and Apotex has unquestionably satisfied the requirement of finality for its Pravastatin arbitration claim, even under the standard advocated by the Respondent.

7. For all these reasons, Apotex's arbitration claims satisfy all jurisdictional requirements for an action pursuant to Chapter Eleven of NAFTA. Accordingly, this Tribunal should reject and deny Respondent's baseless jurisdictional challenges, and allow the parties to move forward and present evidence on the merits of Apotex's arbitration claims.

## II. BACKGROUND.

### A. General Statutory Background.

8. The approval of new and generic drugs is governed by the applicable provisions of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by 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 the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended in relevant part at 21 U.S.C. § 355 [C1][1] and 35 U.S.C. § 271 [C3]). Under the FFDCA, a company that seeks to sell a new or previously unapproved drug must file with the FDA a New Drug Application ("NDA"), which includes, among other things, expensive and time-consuming safety and efficacy studies on the drug. In 1984, the United States Congress simplified the procedure for

[1] References to C1-C38 are to exhibits submitted in connection with Apotex's Statement of Claims, dated January 17, 2011.

obtaining approval of lower-priced generic drugs in the United States by creating a separate regulatory approval pathway by enacting the Hatch-Waxman Amendments.

9. Under Hatch-Waxman, a company seeking to market a generic drug product in the United States must file an ANDA. By filing an ANDA, instead of repeating the comprehensive, extensive clinical studies of safety and efficacy conducted for the previously-approved NDA drug, a generic applicant submitting an ANDA is required to establish, among other details, that its proposed generic product is bioequivalent to the already-approved NDA drug and that it has the same active ingredient, dosage form, dosage strength, route of administration, and labeling (with certain exceptions) as the approved NDA drug.[2] While certainly less extensive than full safety and efficacy studies, ANDA applicants must demonstrate the required bioequivalence through costly and time-consuming scientific testing, including clinical studies evaluating the pharmacokinetics of the ANDA product, such as the rate of absorption, or bioavailability, of the ANDA product in the bloodstream of human subjects.

10. FDA's approval requirements differ significantly from those in other countries.[3] Thus, when Apotex invests its financial and other resources toward 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.[4] In fact, that is the singular purpose of an ANDA, namely, investing in and developing a United States pharmaceutical drug product.

11. In addition to creating a regulatory approval pathway, the Hatch-Waxman Amendments also created a special, expedited mechanism for resolving patent disputes before a generic drug is commercialized to increase generic competition for pharmaceutical drug

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[2] 21 U.S.C. § 355(j)(2)(A) [C1].
[3] Witness Statement of Bernice Tao ¶ 6 (hereinafter "Tao Stmt.") [C39].
[4] Witness Statement of Shashank Upadhye, Esq. ¶ 8 (hereinafter "Upadhye Stmt.") [C40].

products. As explained more fully in Apotex's Statement of Claims[5], as part of the NDA approval process, a brand company is required to list each patent for which a claim of infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product.[6] FDA publishes the patent information submitted by an NDA-holder in what is commonly known as the "Orange Book," thus putting all prospective generic ANDA applicants on notice that a suit for infringement can and will be asserted against any ANDA applicant that attempts to seek approval for and market a generic version of the NDA drug.

12. As part of the ANDA process, an ANDA applicant is required, *inter alia*, to include one of four "certification" options to any properly-listed Orange Book patents.[7] One such option is 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.[8]

13. If the ANDA applicant seeks approval prior to patent expiration, it submits a paragraph IV certification.[9] The submission of a paragraph IV certification has two important effects.

14. *First*, as an incentive for generic companies to challenge brand patents, the first company to file a paragraph IV ANDA is granted a 180-day period of generic market exclusivity during which time FDA will not approve other ANDAs.[10] This exclusivity is "triggered" by the earlier of two events: (1) the first-filer's commercial marketing of the generic drug; or (2) a

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[5] *See* Apotex's Statement of Claims ¶¶ 22-44 (Jan. 17, 2011).
[6] 21 U.S.C. §§ 355(b)(1), (c)(2) [C1].
[7] *See* 21 U.S.C. § 355(j)(2)(A)(vii) [C1].
[8] 21 U.S.C. § 355(j)(2)(A)(vii)(IV) [C1].
[9] *Id.*
[10] 21 U.S.C. § 355(j)(5)(B)(iv)(I) [C1].

court decision of noninfringement or invalidity by *any* filer in *any* action.[11] By including the so-called "court decision trigger," a subsequent ANDA applicant may trigger the first-filer's exclusivity by way of obtaining such a decision, even if the first-filer is not in a position to benefit from it.

15. *Second*, the submission of a paragraph IV certification for a listed patent constitutes an act of infringement that creates the necessary jurisdiction for a court to resolve any action regarding the approval of the generic drug, prior to the actual launch and commercialization of the generic product.

**B. Apotex's Sertraline Claim.**

16. On October 27, 2003, Apotex submitted an ANDA seeking FDA approval for a generic version of Pfizer Inc.'s popular antidepressant medication, Zoloft®, known generically as sertraline hydrochloride. To prepare its ANDA, Apotex invested more than $1,000,000 in formulating and developing a generic version of Zoloft® (sertraline hydrochloride) tablets in 25 mg, 50 mg, and 100 mg strengths.[12] As part of its ANDA, Apotex was statutorily required to address and certify to any Orange Book-listed patents.

17. Pfizer submitted information on several patents to FDA for listing in the Orange Book in connection with Zoloft®, including U.S. Patent Nos. 4,356,518 ("the '518 patent") and 5,248,699 ("the '699 patent"). 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—thus making Ivax eligible for 180-day

[11] 21 U.S.C. § 355(j)(5)(B)(iv) (2002) [C2]. 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 provision implemented by the MMA were prospective only and do not apply to either of Apotex's sertraline and pravastatin ANDAs, both of which were filed before December 8, 2003.

[12] Tao Stmt. ¶ 15 [C39].

exclusivity, which is "triggered" by the earlier of first commercial marketing or a favorable court decision.

18. On April 1, 2004, Apotex filed a declaratory judgment action against Pfizer in the United States District Court for the Southern District of New York ("New York District Court"), in order to "trigger" Ivax's 180-day exclusivity. Initiating this action was the only way for Apotex to obtain patent certainty and immediate approval of its product in 2006, as intended by Congress under Hatch-Waxman.

19. On December 30, 2004, the New York District Court dismissed Apotex's action for lack of subject matter jurisdiction on the grounds that Apotex did not have a "reasonable apprehension" that it would be sued by Pfizer over its generic sertraline ANDA.[13] The New York District Court specifically rejected Apotex's argument that application of the United States Court of Appeals for the Federal Circuit's ("Federal Circuit") "reasonable apprehension" standard was unlawful and conflicted with both United States Supreme Court ("Supreme Court") precedent and Article III of the U.S. Constitution.[14] The "reasonable apprehension" test applied by the New York District Court is not, however, the controlling law for determining whether there is subject matter jurisdiction for a declaratory judgment action. As the Supreme Court and Federal Circuit have both since acknowledged, the controlling test is the case or controversy standard under Article III of the Constitution, which the New York District Court steadfastly refused to apply.[15]

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[13] *See Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187, 191-94 (S.D.N.Y. 2005) [C7].
[14] *Id.* at 191-92.
[15] *See MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764, 771 (2007) (holding that the reasonable apprehension test for subject matter jurisdiction is *not* and has never been the proper test) [C12].

20. Apotex appealed the decision of the New York District Court to the Federal Circuit. On December 12, 2005, the Federal Circuit affirmed the New York District Court's dismissal of Apotex's suit without opinion.[16]

21. Thereafter, Apotex submitted a petition for a writ of *certiorari* to the Supreme Court, seeking review of the Federal Circuit's decision. On October 10, 2006, the Supreme Court denied Apotex's petition without comment.[17]

**C. Apotex's Pravastatin Claim.**

22. On December 21, 2001, Apotex submitted an ANDA seeking FDA approval for a generic version of the prescription heart medication pravastatin sodium tablets, marketed by Bristol Myers Squibb ("BMS") under the brand-name Pravachol®. At the time Apotex filed its ANDA, BMS had submitted information on four patents for listing in FDA's Orange Book in connection with Pravachol®: 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").

23. Teva Pharmaceuticals USA, Inc. ("Teva") purportedly was the first generic applicant to submit a paragraph IV ANDA for generic pravastatin tablets, 10 mg, 20 mg, and 40 mg, strengths. As a result, Teva was eligible for 180-day exclusivity for these products. Because Teva did not challenge the '227 patent, however, it was unable to obtain final FDA approval and commercially launch until after the '227 patent effectively expired on April 20, 2006.

24. Apotex's pravastatin sodium ANDA contains paragraph IV certifications to the '447, '589, and '985 patents, and Apotex also chose not to challenge the '227 patent. BMS nevertheless refrained from suing Apotex for infringement of the '447, '589 and '985 patents.

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[16] *See Apotex, Inc. v. Pfizer Inc.*, 159 F. App'x 1013, 2005 WL 3457408 (Fed. Cir. Dec. 12, 2005) [C8].
[17] *Apotex Inc. v. Pfizer, Inc.*, 127 S.Ct. 379 (2006) [C9].

As a result, Apotex filed a declaratory judgment action in the New York District Court in order to obtain patent certainty by securing a binding court order that would preclude BMS from suing Apotex upon commercial launch of its generic product.

25. The New York District Court ultimately entered an Order dismissing Apotex's declaratory judgment action based upon BMS's binding representations that it would not sue Apotex.[18]

26. On September 7, 2004, Apotex wrote to 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.

27. On June 28, 2005, FDA responded to Apotex's letter, confirming that exclusivity for all strengths of pravastatin expired no later than February 18, 2005, having been triggered by the dismissal of Apotex's declaratory judgment action.[19] FDA further concluded that Apotex's pravastatin ANDA would be eligible for immediate final approval on April 20, 2006.[20] In doing so, FDA's decision explicitly relied on controlling federal court decisions involving the drug ticlopidine and the same filers for pravastatin—Teva and Apotex—in which the U.S. Court of Appeals for the District of Columbia Circuit ("D.C. Circuit") 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.

28. After FDA issued its pravastatin decision, Teva challenged the Agency's ruling in the U.S. District Court for the District of Columbia ("D.C. District Court"). Teva argued that the

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[18] *Apotex Inc. v. Bristol-Myers-Squibb Co.*, No. 04-cv-2922, Dkt. No. 16, Stipulation and Order (S.D.N.Y. July 23, 2004) [C23].
[19] June 28, 2005 FDA letter from G. Buehler to W. Rakoczy [C24].
[20] *Id.*

BMS-Apotex dismissal did not trigger the 180-day generic exclusivity period for pravastatin, 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.

29. On October 21, 2005, the D.C. District Court granted Teva's motion.[21] On appeal, the D.C. Circuit held that in FDA's June 28, 2005 decision, the Agency had not properly explained the reasoning behind its decision.[22] The D.C. Circuit instructed the D.C. District Court to vacate FDA's June 28, 2005 decision and remand to the Agency for further proceedings.[23]

30. On April 11, 2006, FDA issued its second administrative decision pertaining to the issue of 180-day exclusivity for pravastatin sodium tablets. In that decision, FDA reversed itself and, contrary to its prior ticlopidine precedent, determined that the BMS-Apotex dismissal was insufficient to trigger the 180-day exclusivity period for pravastatin.[24]

31. Apotex challenged FDA's April 11, 2006 decision in the D.C. District Court, moving for immediate injunctive relief setting aside the Agency's administrative ruling and enjoining FDA from awarding 180-day exclusivity for pravastatin. The D.C. District Court denied Apotex's motion on April 19, 2006.[25]

32. Apotex appealed and Teva moved for summary affirmance of the D.C. District Court's decision. On June 6, 2006, the D.C. Circuit affirmed the district court's order.[26] Apotex then moved for rehearing *en banc*, which was denied on August 17, 2006.[27] 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 voluntarily dismissed its claim.

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[21] *See Teva Pharm. USA, Inc. v. FDA*, 398 F. Supp. 2d 176, 190-92 (D.D.C. 2005) [C16].
[22] *See Teva Pharm. USA, Inc. v. FDA*, 441 F.3d 1, 5 (D.C. Cir. 2006) [C18].
[23] *See id.*
[24] April 11, 2006 FDA letter from G. Buehler to T. McIntire [C25].
[25] *See Apotex, Inc. v. FDA*, No. 06-0627, 2006 WL 1030151, at *19 (D.D.C. Apr. 19, 2006) [C5].
[26] *Apotex, Inc. v. FDA*, 449 F.3d 1249, 1254 (D.C. Cir. 2006) [C6].
[27] *Id., reh'g en banc denied* (Aug. 17, 2006).

## III. APOTEX IS AN "INVESTOR" AND HAS MADE "INVESTMENTS" IN THE UNITED STATES UNDER NAFTA CHAPTER ELEVEN.

33. Respondent's first jurisdictional argument challenges Apotex's status as an "investor" in the United States for purposes of NAFTA. Respondent seems to argue that, because certain of Apotex's financial investments made in the preparation of its ANDAs, including certain formulation, development and manufacturing activities, were undertaken in Canada, Apotex is merely an "exporter" of goods into the United States rather than an "investor" in an "investment" in the United States. Respondent is wrong on all counts.

34. Article 1139 of NAFTA defines "investment" broadly:[28]

> **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;

[28] 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.") [R82].

> **(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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> **(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[.]"[29]

35. As explained in more detail below, Apotex's ANDA is "property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes" and thus an "investment" under Article 1139(g).[30] Apotex also has made other significant investments 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]" that qualify as "investments" under Article 1139(h).[31] Apotex is thus a proper Claimant in this NAFTA arbitration.

**A. Apotex ANDAs Are "Investments" In The United States.**

36. Both of Apotex's sertraline and pravastatin ANDAs are "investments" in the United States. More specifically, Apotex's ANDAs are "property . . . acquired in the expectation

[29] NAFTA, art. 1139 (emphasis added).
[30] *Id.* at "investment" sub(g).
[31] *Id.* at "investment" sub(h).

or used for the purpose of economic benefit or other business purposes" in the United States.[32] For this reason alone, Apotex is an "investor" under Article 1116.

37. An ANDA, and the confidential data and information contained therein, unquestionably is "property" of the ANDA applicant. An ANDA can be bought and sold like all other property.[33] The ANDA applicant, moreover, has the *exclusive* right to possess, use and enjoy the ANDA and the products approved thereunder.[34] Indeed, FDA is obligated to maintain confidential all information in unapproved ANDAs and, in fact, is not even permitted to confirm the existence of an unapproved ANDA unless the ANDA sponsor itself has already done so.[35]

38. While an ANDA, and the products approved thereunder, unquestionably is 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, such ANDA is essentially worthless.[36] For this reason, Respondent's argument that Apotex is nothing more than an "exporter" is gravely mistaken. Apotex cannot export and commercialize 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.

39. Prior NAFTA Tribunals have held 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

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[32] *Id.* at "investment" sub(g).
[33] Indeed, 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 [C48].
[34] *See* BLACK'S LAW DICTIONARY 1232, "property" (9th ed. 2009) [C60].
[35] *See* 18 U.S.C. § 1905 [C41]; 21 U.S.C. § 331(j) [C42]; 21 C.F.R. § 314.430 [C44].
[36] Upadhye Stmt. ¶¶ 6-9 [C40].

is created and applied by that state which is not the state of the investor's nationality."[37] That is certainly the case here with respect to Apotex's ANDAs, which are regulated solely by the FDA and the United States.

40. As Respondent concedes, Apotex may not lawfully sell its generic pharmaceutical products in the United States unless such products are the subject of an FDA-approved ANDA.[38] An ANDA is not some ethereal concept—it is an actual submission to FDA, in the United States, that amounts to thousands, if not tens of thousands, of pages containing extremely confidential and proprietary information pertaining to the formulation, development, manufacture, processing, testing, packaging, labeling, and storage of the proposed generic drug product.[39] Until FDA approves the ANDA, the applicant may not lawfully market the proposed generic product in the United States. Unlike a mere import permit or certificate, an ANDA is not only a gateway to the United States. Rather, an ANDA 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 realize the commercial value of that investment. In other words, without the ANDA, there is no product to commercialize in the United States.

41. As explained in Section II, above, the statutory and regulatory requirements for ANDA approval are extensive. By way of example only, as FDA explained:

> [An] ANDA applicant must show, among other things, that its proposed generic product is the same as the pioneer drug with respect to the active ingredient, dosage form, strength, route of administration, and with certain narrow

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[37] *Grand River Enterprises Six Nations, Ltd. et al. v. United States*, NAFTA/UNCITRAL, Award ¶ 88 (Jan. 12, 2011) (citing *Bayview Irrigation District v. Mexico*, ICSID Case No. ARB(AF)/05/1, Award on Jurisdiction ¶¶ 98-99 (June 19, 2007) [R69]) [R76].

[38] *See* Memorial on Objections to Jurisdiction of Respondent United States of America ¶ 8 (May 16, 2011) (hereinafter "U.S. M.O.J.").

[39] Whether an ANDA, and the data and information contained therein, is considered tangible or intangible property makes no difference. The United States Supreme Court has stated that the intangible nature of certain business information does not make it any less "property." *McNally v. United States*, 483 U.S. 350, 356 (1987) [C53]; *see also* Tao Stmt. ¶¶ 5-33 [C39].

> exceptions, labeling. The ANDA applicant must also show that its product is bioequivalent to the pioneer drug [and] . . . must include in its application detailed information about the research undertaken to establish bioequivalence . . . ."[40]

42. In order to sell a product in the United States, an ANDA applicant also must meet FDA's so-called "Current Good Manufacturing Practice for Finished Pharmaceuticals," which impose strict requirements governing the testing, manufacturing and labeling of the ANDA products.[41] These include, but are not limited to, the imposition of 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, just to name a few.[42] ANDA applicants such as Apotex must also follow strict requirements governing the documentation of such testing, sampling, and manufacturing, and the controls for each.[43]

43. An ANDA applicant further must meet 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.*[44] FDA, in fact, inspects each applicant's manufacturing facilities, *whether domestic or foreign*, to ensure that the establishment is capable of manufacturing the proposed drug product in accordance with FDA requirements, and that the submitted data is accurate and complete.[45]

44. Without question, the costs Apotex has incurred in meeting the specific FDA requirements for approval of its sertraline and pravastatin ANDAs are investments under Article

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[40] U.S. M.O.J. ¶ 9.
[41] 21 C.F.R. § 211 *et seq.* [C43].
[42] *Id.* at §§ 211.80 – 211.188.
[43] *Id.* at §§ 211.180 – 211.198.
[44] *Id.* at §§ 211.42 – 211.72.
[45] Tao Stmt. ¶¶ 9, 10 [C39]; *see also* FDA, COMPLIANCE PROGRAM GUIDANCE MANUAL, Ch. 46 New Drug Evaluation § 2.1 (Prog. 7346.832) [C46].

1139. Apotex would never have incurred these expenses if it had not been required to do so under U.S. statutory and federal regulatory requirements.[46] 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*.[47] Other Tribunals have considered such activity persuasive evidence of having an investment in the territory at issue.[48]

45. In sum, if Apotex wishes to sell a generic pharmaceutical product in the United States, it cannot simply "export" such product to the United States and offer it for sale. The product may only be lawfully sold if Apotex has met *all* of the statutory and regulatory requirements for FDA approval, has complied with *all* of FDA's CGMP requirements, and has passed inspection, regardless of where the facilities are located. Apotex's sertraline and pravastatin ANDAs met all of these U.S. requirements prior to approval.

46. The efforts Apotex made to comply with FDA's processing, manufacturing, testing, sampling, packaging, and storage requirements, moreover, are not only expensive, most are product-specific.[49] For instance, formulation and development work on Apotex's sertraline tablets obviously does not carry over to Apotex's pravastatin tablets, or any other product for that matter. Similarly, testing conducted to show that Apotex's sertraline tablets are bioequivalent to Zoloft® cannot be used to demonstrate bioequivalence of Apotex's pravastatin tablets to Pravachol®, and vice versa.[50] Apotex's in-process and manufacturing controls are specific to

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[46] Upadhye Stmt. ¶ 10 [C40].
[47] Tao Stmt. ¶¶ 11-12 [C39]; Upadhye Stmt. ¶¶ 6-19 [C40].
[48] *See 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 ¶ 101 (Jan. 29, 2004) ("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 . . . .") [C68].
[49] Tao Stmt. ¶¶ 16, 26 [C39].
[50] *Id.* at ¶¶ 17, 27.

each product.[51] And Apotex obviously cannot reuse labels designed for either its sertraline or pravastatin products in the sale of another product.[52] In other words, Apotex's investments in its sertraline and pravastatin ANDAs are not transferable—they are investments in those ANDAs alone, made solely for the purpose of obtaining FDA approval to sell Apotex's sertraline and pravastatin ANDA products in the United States.[53]

47. For these reasons, each of Apotex's sertraline and pravastatin ANDAs are property of Apotex "acquired in the expectation or used for the purpose of economic benefit or other business purposes," and constitute an "investment" in the United States under Article 1139 of NAFTA.[54]

**B. Apotex Has Made Other Significant "Investments" In The United States, Under Article 1139(h).**

48. While Apotex's sertraline and pravastatin ANDAs constitute "investments" under Article 1139(g) and thus are sufficient in and of themselves to give this Tribunal jurisdiction over Apotex's claims, Apotex has made other "investments" in the United States under Article 1139(h) in connection with each of its ANDAs.

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[51] *Id.* at ¶¶ 18, 28.
[52] *Id.* at ¶¶ 19, 29.
[53] *Id.* at ¶¶ 22, 32.
[54] The NAFTA Chapter Eleven Tribunal awards cited by the United States in their Memorial on Objections to Jurisdiction—*Bayview*, *Grand River*, and *Canadian Cattlemen*—fail to address jurisdictional issues remotely similar to those at issue here. For example, in *Bayview*, U.S. Claimants alleged that Mexico had seized and diverted river water in Mexico that the Claimants were somehow entitled to use in Texas in connection with their investment in Texas property. *Bayview*, Award on Jurisdiction ¶¶ 91, 109 [R69]. The *Bayview* Tribunal found that the Claimants did not own the river water in Mexico. *Id.* at ¶ 117. The *Grand River* Tribunal found that the Claimants' evidence of investments was severely lacking and, furthermore, was not proportionate to their claim for hundreds of millions of dollars. *Grand River*, Award ¶ 122 [R76]. The *Canadian Cattlemen* Tribunal, moreover, did not even address the factual circumstances because the Claimants conceded that they had not made, were not seeking to make, and did not make an investment in the territory of another Party. *Canadian Cattlemen for Fair Trade v. United States*, NAFTA/UNCITRAL, Award on Jurisdiction ¶¶ 31, 41, 95 (Jan. 28, 2008) [R70]. The Tribunal only addressed the narrow legal issue of whether "investors of another party" includes persons who have not made, are not seeking to make, and are not making, investments in the territory of another NAFTA Party. *Id.* at ¶¶ 31, 120.

49. Article 1139 states that "investment" also includes "interests arising from the commitment of capital or other resources in the territory of a party to economic activity in such territory."[55] Apotex 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.

50. First, because Apotex does not reside or have a place of business in the United States, in accordance with FDA's regulations, Apotex must utilize 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 FDA for its pravastatin and sertraline ANDAs.[56]

51. Apotex's U.S. affiliate and Agent Apotex Corp. also acts as the distributor for both of Apotex's pravastatin and sertraline ANDA products.[57] The sale of Apotex's ANDA products in the United States unquestionably qualifies as "economic activity in [the] territory," the proceeds of which go directly, and in full, to Apotex and its affiliates.[58]

52. Apotex also has 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. Indeed, nearly all of these raw materials and inactive ingredients used in these products are purchased by Apotex directly from U.S. manufacturers.

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[55] NAFTA, art. 1139, "investment" sub(h).
[56] Tao Stmt. ¶¶ 14, 25 [C39]; *see also* Apotex's sertraline and pravastatin ANDAs [R44, R45].
[57] Tao Stmt. ¶¶ 23, 32 [C39].
[58] *Id.* Indeed, 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." NAFTA, art. 1139, "investment" sub(e). This, too, easily qualifies as an "investment."

53. For instance, Apotex purchased all but one of the inactive ingredients used in the manufacture of Apotex's pravastatin sodium tablets, 10 mg, 20 mg and 50 mg, from the following U.S. manufacturers:[59]

| Inactive Ingredient | Manufacturer |
|---|---|
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |

54. Apotex has spent over [redacted] on these ingredients for use in the manufacture of its pravastatin tablets sold in the United States pursuant to its approved ANDA.[60]

55. Similarly, Apotex purchased all but two of the inactive ingredients used in the manufacture of Apotex's sertraline hydrochloride tablets, 25 mg, 50 mg and 100 mg, from the following U.S. manufacturers:[61]

[59] Pravastatin ANDA § 8(2)(d) at 5262-63 [C55].
[60] Tao Stmt. ¶ 31 [C39].

| Inactive Ingredient | Manufacturer |
| --- | --- |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |

[61] Sertraline ANDA § 8(2)(d) at 4222-23 [C54].

| Inactive Ingredient | Manufacturer |
| --- | --- |
| [redacted] | [redacted] |
| [redacted] | [redacted] |

56. Apotex has spent nearly [redacted] on these ingredients for use in the manufacture of its sertraline tablets sold in the United States pursuant to its approved ANDA.[62]

57. Each of these ingredients is essential to the formulation and manufacture of Apotex's sertraline and pravastatin products, and is a substantial and non-severable aspect of Apotex's overall investment in its sertraline and pravastatin ANDAs. As other tribunals have recognized in disputes involving other treaties, a claimant such as Apotex need not have incurred all, or even most, of its expenses relating to the filing of its ANDAs inside the United States.[63]

58. For example, in *SGS v. Philippines*, Claimant SGS provided customs certification services for the Philippines based on pre-shipment inspections carried out in the exporting country.[64] Though "the bulk of the costs of providing the service was incurred outside of the Philippines," SGS's inspection operations abroad were organized through an office located in the

[62] Tao Stmt. ¶ 21 [C39].
[63] *SGS v. Philippines* ¶ 106 ("The fact that the bulk of the cost of providing the service was incurred outside the Philippines is not decisive.") [C68]; *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 ¶ 136 (Aug. 6, 2003) ("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.") [C67]. While these tribunals were not held under NAFTA Chapter Eleven, there is no reason why Apotex's ANDA investments should be evaluated any differently here.
[64] *SGS v. Philippines* ¶ 12 [C68].

Philippines.[65] The Tribunal, considering the totality of the circumstances, concluded that SGS was an "investor" with an "investment" in the territory of the Philippines.[66]

59. Similarly, the Tribunal in *SGS v. Pakistan* found that the Claimant SGS was an "investor" with an "investment" in Pakistan.[67] There, SGS provided pre-shipment inspection services for Pakistan.[68] The pre-shipment inspections occurred outside of Pakistan, but were processed at a liaison office located in Pakistan.[69] Here, again, even though SGS's expenditures within Pakistan were "relatively small," the Tribunal held that the expenditures constituted an investment.[70]

60. Simply put, the amount of expenses incurred in the United States need not meet some arbitrary threshold for this Tribunal to treat Apotex as an "investor" under NAFTA. Apotex's purchase of the necessary ANDA product ingredients from the United States, along with Apotex's investment in capital and resources in preparing and filing its pravastatin and sertraline ANDAs in accordance with U.S. statutory and regulatory requirements for FDA approval, were done for the sole purpose of securing an economic benefit from the sale of its sertraline and pravastatin ANDA products *in the United States*. These activities alone are sufficient to qualify Apotex as an "investor" with an "investment" in the United States.[71]

61. Even if more evidence of Apotex's investment in the United States were necessary (it is not), as a consequence of filing a paragraph IV certification in connection with both its sertraline and pravastatin ANDAs, Apotex was required by FDA regulation to designate a U.S. Agent to accept service of process for any patent litigation initiated in response to its

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[65] *Id.* at ¶¶ 101, 106.
[66] *Id.* at ¶¶ 103, 106.
[67] *SGS v. Pakistan* ¶ 140 [C67].
[68] *Id.* at ¶ 11.
[69] *Id.* at ¶ 13.
[70] *Id.* at ¶¶ 136, 140.
[71] *See SGS v. Philippines* ¶¶ 103, 112 [C68].

sertraline and pravastatin ANDAs.[72] In doing so, Apotex consented to jurisdiction and suit in the United States, thus exposing itself to patent litigation in U.S. federal court and the potential for incurring substantial sums in legal fees in connection with this U.S. litigation.[73] In fact, one of the primary and indeed unique purposes of Hatch-Waxman was to encourage early resolution of United States patent disputes in order to expedite the market entry of lower-priced generic drugs—both by obtaining patent certainty and triggering 180-day exclusivity, as Apotex sought to do here.

62. To that end, Apotex invested in excess of [redacted] in legal fees in connection with its sertraline ANDA litigation, and invested in excess of [redacted] in legal fees in connection with its pravastatin ANDA litigation, in the United States.[74] Apotex's expenditures towards U.S. litigation over its pravastatin and sertraline ANDAs were also made for the sole purpose of securing an economic benefit from the sale of its sertraline and pravastatin ANDA products *in the United States.*

63. Considering the totality of Apotex's activities in the United States, Apotex has made a number of investments with respect to its ANDAs in the United States and is an investor under Article 1139.[75] Apotex's commitment of money and other resources to the development and manufacture of its ANDA products and the preparation and submission of its ANDAs—including the purchase of raw materials and ingredients used therein, Apotex's commitment of money and other resources to the filing and maintenance of its paragraph IV certifications in connection with its ANDAs, and Apotex's commitment of money and other resources to ANDA-

[72] 21 C.F.R. § 314.95(c)(7) [C45].
[73] Upadhye Stmt. ¶¶ 13, 18 [C40].
[74] *Id.* at ¶¶ 14, 19.
[75] *See Grand River* ¶ 122 ("[T]he Tribunal should consider the totality of [Claimants'] activities and not weigh each element in isolation.") [R76]; *see also SGS v. Philippines* ¶ 103 (SGS's pre-shipment inspection services and office in the Philippines "taken together are sufficient to qualify the service as one provided in the Philippines.") [C68].

related litigation in the United States—individually and collectively—constitutes an "investment" under Article 1139. For these additional reasons, Apotex is an "investor" under Article 1116 of NAFTA.

## IV. APOTEX'S ARBITRATION CLAIMS WERE TIMELY SUBMITTED.

64. Respondent argues that "many of Apotex's claims" contained in the two Notices of Arbitration are time-barred.[76] Specifically, with respect to Apotex's Sertraline Claim, Respondent argues that any claims arising from the decision of the New York District Court should be dismissed, as that decision was rendered more than three years before the date Apotex filed its Sertraline Notice of Arbitration; and, with respect to Apotex's Pravastatin Claim, Respondent argues that any claims arising from either FDA's exclusivity decision or the decision of the D.C. District Court similarly should be dismissed, as those decisions were rendered more than three years before Apotex filed its Pravastatin Notice of Arbitration. Respondent is wrong on both counts.

65. To the extent Respondent is arguing that a hard-and-fast cut-off date exists under NAFTA, under which any issues that arose prior to that date must be completely ignored, Respondent is incorrect as a matter of law. Not only is this untenable in light of the requirement regarding the exhaustion of local remedies (as explained in more detail below), but it also is incompatible with the plain text of NAFTA and controlling principles of international law.

66. Under NAFTA Article 1116(2), "[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." This limitation includes two separate and distinct components: (1) knowledge of the

[76] U.S. M.O.J. ¶ 3.

breach; and (2) knowledge that the investor has incurred loss or damage. The three year period thus begins to run only after *both* of these requirements have been met.[77]

67. Moreover, as Respondent concedes, under international law, "[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."[78]

68. As an initial matter, it appears that Respondent fails to comprehend the nature of Apotex's two arbitration claims and more specifically, when, exactly, Apotex's "knowledge of the alleged breach" arose in each case.[79] As explained in more detail below, Apotex's Sertraline Claim and Apotex's Pravastatin Claim each consist of a single, continuous set of underlying factual bases leading to Respondent's breach. First, Apotex's Sertraline Claim is based on the actions of at least three U.S. federal courts, including the New York District Court, the Federal Circuit, and the Supreme Court, all of which refused to allow Apotex to rightfully maintain its declaratory judgment action in violation of, *inter alia*, Article III of the United States Constitution.[80] Second, Apotex's Pravastatin Claim is based on the unlawful, arbitrary and capricious ruling by FDA finding that the dismissal of Apotex's declaratory judgment action against the patent owner failed to constitute a court decision trigger under the FFDCA, and the subsequent actions by the D.C. District Court and the D.C. Circuit in wrongfully denying

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[77] 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.") [C65]; *see also* U.S. M.O.J. ¶ 32 & n.63 (*citing* 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 [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]).

[78] U.S. M.O.J. ¶ 61.

[79] NAFTA, art. 1116(2).

[80] *See* Apotex Statement of Claims ¶¶ 59, 63-80.

Apotex's federal court challenge to that ruling.[81] The underlying factual bases for these two Claims, including the respective decisions made by the administrative and judicial bodies of the United States challenged therein, simply cannot be parsed into separate, unrelated events or "claims," as the United States seems to suggest.

69. Further, Respondent flat-out ignores 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. Only after such remedies are exhausted has a breach occurred, let alone "knowledge of the alleged breach," as required under NAFTA Article 1116(2).

70. As explained below, the breaches serving as the bases for Apotex's Pravastatin and Sertraline Claims, and Apotex's awareness of each breach, occurred well within the three-year limitations period.

### A. State Responsibility Under NAFTA And International Law: The Finality Or Futility Requirement.

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."[82] 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

[81] *See* Apotex Statement of Claims ¶¶ 107-08, 112-29.

[82] NAFTA, art. 1101 ("This Chapter applies to measures adopted and maintained by a Party . . . ."); *see also Loewen Group v. United States*, ICSID Case No. ARB(AF)/98/3, Award ¶¶ 142-57 (June 26, 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.) [R78].

responsible for the [conduct of a judicial office] when no attempt . . . has been made to obtain justice from a higher court."[83]

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.[84] 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 there was available an *effective and adequate appeal* within the State's legal system.[85]

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.[86] 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."[87]

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[83] 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].
[84] *Loewen*, Award ¶ 143 (emphasis added) [R78]; U.S. M.O.J. ¶ 61 (emphasis added).
[85] *Loewen*, Award ¶ 154 (emphasis added) [R78].
[86] *See* C.F. Amerasinghe, LOCAL REMEDIES IN INT'L LAW 3-4 (2d ed. 2004) [C61]; *Interhandel Case (Switz. v. U.S.)*, 1959 I.C.J. 6, 27 (Mar. 21, 1959) [C63].
[87] *See Loewen*, Award ¶ 156 [R78].

74. Stated otherwise, the requirement to exhaust "local remedies" "afford[s] the host State the opportunity of remedying the default in the court below, by taking the matter to a higher court, . . . subject to reasonable practical limitations."[88] As the *Loewen* Tribunal found, however, this requirement makes allowances for practical limitations, and obligates claimants only to exhaust local remedies "which are effective and adequate and are reasonably available to the complainant in the circumstances in which it is situated."[89] Respondent even concedes this exception in its Memorial.[90]

### B. Apotex's Sertraline Claim Was Timely Submitted Under NAFTA Article 1116(2).

75. Turning first to Apotex's Sertraline Claim, Respondent argues that certain of Apotex's "claims" allege breach and loss occurring prior to December 11, 2005, or more than three years before Apotex filed its notice of arbitration, and therefore should be dismissed. Given the principles of judicial finality under international law, and in light of the position Respondent has taken both before prior NAFTA Tribunals[91] and in its opening Memorial on Objections to Jurisdiction,[92] Respondent's argument goes nowhere.

76. As indicated in Apotex's Statement of Claims, Apotex's Sertraline Claim lies in the unlawful, arbitrary and capricious decisions of the United States federal courts, including the December 30, 2004 decision of the New York District Court, the affirmance of that decision by the Federal Circuit on December 12, 2005, and the denial of *certiorari* by the Supreme Court on October 10, 2006.

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[88] *Id.* ¶ 167 [R78].
[89] *Id.* ¶ 168 [R78].
[90] U.S. M.O.J. ¶ 61.
[91] *See, e.g., Loewen*, Award ¶ 77 [R78]; *Glamis Gold, Ltd. v. United States*, NAFTA/UNCITRAL, Procedural Order No. 2 at ¶ 19 (May 31, 2005) (recognizing Respondent United States' view that claimant, "of course, may refer to facts that predate [the three-year limitations period] as background for its claims. . . .") [C62].
[92] *See, e.g.*, U.S. M.O.J. ¶ 61.

77. Respondent seemingly argues that, because the New York District Court rendered its decision more than three years before Apotex submitted its Notice of Arbitration, any claims of breach and loss stemming from this decision are time-barred. This simply is not so. Apotex's Sertraline Claim was commenced well within three years from the date that Apotex's obtained "knowledge of the alleged breach and knowledge that the investor has incurred loss or damage"[93]—namely, after exhaustion of its appeal.

78. A similar issue was raised in the *Mondev* arbitration, also under Chapter Eleven of NAFTA, where the Claimant there alleged, *inter alia*, a NAFTA violation based upon wrongful U.S. court decisions.[94] In *Mondev*, the Respondent challenged jurisdiction on grounds that the claimant had failed to bring its claim within the three-year limitations period, where the notice of arbitration was filed on September 20, 1999, while the original trial court decision from which the dispute stemmed issued on August 17, 1995.[95] Despite the fact that more than three years had passed since the initial trial court decision, the Tribunal found that the May 20, 1998 decision of the Supreme Judicial Court of Massachusetts (the highest court in Massachusetts) and the denial of *certiorari* by the United States Supreme Court on March 1, 1999 were well within the three year time period.[96] The Tribunal dismissed the Respondent's argument in a single paragraph, noting that "[t]he present proceedings were commenced within three years from the final court decisions."[97]

79. Likewise, as noted above, before the *Loewen* Tribunal, Respondent successfully argued that a court decision made by a lower level trial court lacks the necessary finality and that

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[93] NAFTA, art. 1116(2).
[94] *Mondev Int'l Ltd. v. United States*, ICSID Case No. ARB(AF)/99/2, Award (Oct. 11, 2002) [R81].
[95] *See Mondev*, ICSID Case No. ARB(AF)/99/2, Notice of Arbitration ¶ 15 (Sept. 1, 1999) [C66]; *Mondev*, Award ¶¶ 12-13 [R81].
[96] *See Mondev*, Notice of Arbitration ¶¶ 15-22 [C66]; *Mondev*, Award ¶ 87 [R81].
[97] *Mondev*, Award ¶ 87 [R81].

such a decision is insufficient to attribute responsibility to the State under NAFTA, unless the claimant exhausts its local remedies or such remedies were deemed futile.

80. Accordingly, given the arguments made by Respondent before this and other Tribunals, the New York District Court decision in Apotex's Sertraline Claim is only one part of a single, continuous action, and, alone, lacks the necessary finality required under international law to hold the State accountable. Apotex could, and did, appeal that decision, and both the appellate court decision and denial of *certiorari* unquestionably fall within the three-year limitations period. For this reason, Respondent's jurisdictional challenge on this ground must be denied, and the Tribunal may consider the December 30, 2004 district court decision as part of the underlying basis for Apotex's Sertraline Claim.[98]

### C. Apotex's Pravastatin Claim Was Timely Submitted Under NAFTA Article 1116(2).

81. Turning next to Apotex's Pravastatin Claim, Respondent again argues that certain of Apotex's "claims" are time barred, as they occurred more than three years before Apotex submitted its Notice of Arbitration on June 5, 2009. For the same reasons that Respondent's Article 1116(2) arguments fail with respect to Apotex's Sertraline Claim, Respondent's jurisdictional objections here, too, fail. Because international law requires a claimant, such as Apotex, to first pursue any "available and effective" remedies, Apotex's Pravastatin Claim was timely filed and may be considered on the merits.

[98] In footnote 91 of its Memorial, Respondent argues that "Apotex, as Claimant, must specify with particularity the applicable date of breach for its claims." While Respondent points to no authority to support such a claim, for purpose of avoiding any unnecessary issues, Apotex submits that no earlier than December 12, 2005, the date on which the United States Court of Appeals for the Federal Circuit rendered its decision denying Apotex's request for relief, could Apotex have acquired "knowledge of the alleged breach and knowledge that the investor has incurred loss or damage," pursuant to NAFTA Article 1116(2).

82. As indicated in Apotex's Statement of Claims, Apotex's Pravastatin Claim stems from the unlawful, arbitrary and capricious decision of the FDA on April 11, 2006; the subsequent denial of emergency injunctive relief seeking to overturn that decision by the D.C. District Court on April 19, 2006; and the June 6, 2006 affirmance by the D.C. Circuit denying Apotex's request for emergency relief.[99]

83. In its Memorial, Respondent first argues that "any claims based on the FDA letter decision of April 11, 2006 are time-barred [and] should be dismissed."[100] This argument, however, completely ignores the fact that the Agency's decisions gave way to the litigation and court decisions at issue in Apotex's Pravastatin Claim, and therefore cannot be considered as a separate breach.

84. Rather, as Respondent previously acknowledged in the *Loewen* arbitration, "*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.[101]

85. Put differently, there simply is no way to divorce FDA's decisions from the ultimate decision of the D.C. Circuit rejecting Apotex's request to overturn the Agency's April 11, 2006 decision, as Respondent urges the Tribunal to do. Accordingly, this Tribunal may not simply "dismiss" all claims based on the April 11, 2006 FDA decision.

86. Likewise, the Tribunal also must reject Respondent's jurisdictional challenge to the April 19, 2006 decision of the D.C. District Court. Respondent argues that "any claims based on the District Court decision alone, to the extent that Apotex alleges that breach and loss

[99] Apotex Statement of Claims ¶¶ 83-129.
[100] U.S. M.O.J. ¶ 51.
[101] *Loewen*, Award ¶ 143 (emphasis added) [R78]; U.S. M.O.J. ¶ 61 (emphasis added).

occurred at that time, should also be dismissed."[102] Yet, because local remedies still existed (indeed Apotex could and did appeal that decision), for the same reasons discussed above with respect to the timeliness of Apotex's Sertraline Claim, the D.C. District Court's April 19, 2006 decision, along with FDA's administrative decision, are simply part of the same single, continuous action that in this case only became ripe for a NAFTA challenge after Apotex's later appeals were exhausted (which occurred well within the three-year limitation period), and that such further action was, at that time, futile.

87. For these reasons, the Tribunal may consider the April 11, 2006 FDA decision and the April 19, 2006 district court decision as additional bases for Apotex's Pravastatin Claim.

## V. APOTEX'S PRAVASTATIN CLAIM SATISFIES THE FINALITY REQUIREMENT.

88. Finally, even though Respondent concedes that certain "parts" of Apotex's Pravastatin Claim satisfy the three-year limitations period, Respondent argues that because "none of these judicial acts were final, they cannot be the basis for claims under Chapter Eleven of the NAFTA."[103] Specifically, Respondent argues that, after the appellate court granted summary affirmance rejecting Apotex's request for injunctive relief on June 6, 2006, and subsequently denied Apotex's petition for rehearing *en banc* on August 17, 2006, Apotex was required to: (1) petition the Supreme Court for a writ of *certiorari*; and/or (2) continue to proceed in litigating the case at the district court level (on a non-expedited basis) instead of voluntarily dismissing its claim upon remand.[104] According to Respondent, because Apotex failed to undertake these actions, the judicial acts on which Apotex's claim is based lack the requisite finality. Respondent is wrong again.

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[102] U.S. M.O.J. ¶ 51.
[103] *Id.* ¶ 54.
[104] *Id.* ¶ 59.

89. Quite simply, due to 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.[105] Apotex originally brought its declaratory judgment action against BMS in order to obtain patent certainty, and later sought to use the dismissal of that action to trigger the 180-day exclusivity period for first-filer Teva.

90. As explained above, the 180-day generic exclusivity period for pravastatin could be triggered by the earlier of: (1) the first commercial marketing of the drug; or (2) a decision of a court holding the patent invalid, unenforceable, or not infringed.[106] Teva, however, was not eligible for final FDA approval until at least April 20, 2006 (when the '227 patent effectively expired), thus it could not commercially market its product until after that date.

91. After FDA issued its unreasoned and wholly unsupportable April 11, 2006 decision 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, FDA approved Teva's ANDA on April 24, 2011.[107] Teva immediately launched its respective ANDA products, thereby triggering the 180-day exclusivity period, which would expire on October 23, 2006. Apotex immediately appealed the district court's decision and Teva moved for summary affirmance.

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

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[105] Respondent concedes that an exception to the finality requirement exists if such "recourse is obviously futile." *Id.* ¶ 61.
[106] 21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II) (2002) [C2].
[107] Drugs@FDA, Teva ANDA No. 076056 (pravastatin sodium) [C56].

93. What Respondent fails to explain is that, once Apotex's petition for rehearing *en banc* was denied, only 67 days remained of Teva's 180-day exclusivity period. After such period expired (*i.e.*, on October 23, 2006), Apotex would be eligible for final approval regardless of the outcome of its case.[108] Moreover, even if Apotex had eventually succeeded on the merits on or after that date, Apotex would not be entitled to damages from the Agency, 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 effective relief from either FDA or the courts.

94. Given these facts, the notion that Apotex was required to petition for *certiorari* requesting expedited relief to overturn the D.C. Circuit's summary affirmance is absurd, 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. Suggesting, as the Respondent does here, that the Supreme Court would not only grant the petition, but could schedule argument and render an opinion in Apotex's favor within 67 days is more than unrealistic (to say the least), and any efforts to achieve such a result undeniably would have been "objectively futile."[109] Indeed, even had Apotex immediately petitioned the Supreme Court for *certiorari*, under the relevant U.S. Supreme Court rules, FDA had 30 days from the date the case was docketed to submit a response, after which Apotex had an additional 10 days to reply.[110] Thus, the Supreme Court Clerk could not have even have distributed Apotex's petition to the Supreme

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[108] Apotex's Pravastatin ANDA was approved by FDA on October 23, 2006. *See* Drugs@FDA, Apotex ANDA No. 076341 (pravastatin sodium) [C57].

[109] According to the U.S. Supreme Court's website, "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, *available at* http://www.supremecourt.gov/faq.aspx (last visited July 30, 2011) [C58]. Further, it is known that "[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." *See* Aaron-Andrew P. Bruhl, *The Supreme Court's Controversial GVRS – And An Alternative*, 107 MICH. L. REV. 711, 745 (Mar. 2009) [C59].

[110] SUP. CT. R. 15.3, 15.5 [C49].

Court until less than a month was left in Teva's exclusivity period.[111] It is unfathomable to suggest that the Court would have granted the petition, ordered briefing and a hearing, and decided the matter at any time before October 23, 2006, when the relief requested would be rendered moot.

95. Further, Respondent's argument that Apotex should have pressed onward with its claim at the district court level is just as absurd. 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. On remand, the district court scheduled a status hearing to be held on October 6, 2006.[112] On October 3, 2006, a mere 20 days before Teva's exclusivity period expired, Apotex voluntarily dismissed its suit.[113] At that time, no motions had been filed, and, again, expedited relief was no longer an option. Indeed, even had Apotex immediately filed a summary judgment motion after the October 6, 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 October 23, 2006.[114]

96. Accordingly, by any standard, Apotex had effectively exhausted all of its remedies after the D.C. Circuit rejected its expedited appeal seeking emergency injunctive

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[111] SUP. CT. R. 15.6 [C49].

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

[113] *Id.* at Dkt. No. 42, Stipulation of Dismissal (D.D.C. Oct. 3, 2006).

[114] Under the version of Local Civil Rule 7 of the United States District Court for the District of Columbia that was in effect in 2006, 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. *See* United States District Court for the District of Columbia, Local Civil Rule 7 (effective as of March 2010) [C50]; United States District Court for the District of Columbia, Amendments to Local Civil Rule 7 (Nov. 30, 2009) [C51]; FED. R. CIV. P. 6 (2008) [C47]. Accordingly, pursuant to the local rules of the D.C. District Court, the time permitted for the matter to have been fully briefed would have been after October 23, 2006—the date which Apotex had obtained FDA approval and the relief requested by Apotex became moot. Apotex, of course, not only needed the matter briefed, but further needed the D.C. District Court to rule in its favor before this date.

relief.[115] At such point in time, Apotex no longer could have obtained any meaningful effective relief, even had it eventually succeeded on the merits. Pursuing the options suggested by Respondent would thus have been necessarily futile given the factual circumstances here. Accordingly, the Tribunal should reject Respondent's jurisdictional objection to the finality of Apotex's Pravastatin Claim, and allow this arbitration to move forward on the merits.

## VI. CONCLUSION AND RELIEF REQUESTED.

97. For the foregoing reasons, Claimant Apotex Inc., respectfully requests that the Tribunal dismiss Respondent United States' objections to jurisdiction; deny in its entirety the relief sought in the United States' Memorial on Objections to Jurisdiction; proceed with the scheduling of a hearing on the merits of Apotex's arbitration claims; and award Apotex any further relief the Tribunal may deem appropriate, including but not limited to an award of costs and fees for defending against Respondent's jurisdictional objections.

Dated: August 1, 2011

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[115] *See Loewen*, Award ¶ 170 ("If a State attaches conditions to a right of appeal which render exercise of the right impractical, the exercise of the right is neither available nor effective nor adequate. . . . The scope of the need to exhaust local remedies must be considered in the light of these considerations."). [R78].