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.

STATEMENT OF DEFENSE
RESPONDENT UNITED STATES OF AMERICA

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CONTENTS

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STATEMENT OF DEFENSE
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Pursuant to Article 19 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 this Statement of Defense.

PRELIMINARY STATEMENT

1. This arbitration includes two claims by Apotex Inc. ("Apotex") against the United States of America under NAFTA Chapter Eleven, one brought in a Notice of Arbitration ("NOA") dated December 10, 2008 (the "sertraline claim") and received by the Respondent on December 11, 2008, and the other in a NOA dated June 4, 2009 (the "pravastatin claim") and received by the Respondent on June 5, 2009. Both claims arise from Apotex's efforts to bring new generic drugs to market in a commercially advantageous manner in the United States through its export

operations in Canada, and its disappointment with the outcome of litigation brought to further this marketing strategy. In both claims, Apotex seeks damages allegedly resulting from its inability to trigger other companies' 180-day market exclusivity period. These other generic manufacturers were eligible for this 180-day exclusivity period under the governing statute because, in their applications to market these drugs, they had filed the first challenges (known as "paragraph IV certifications") to certain patents listed for those drugs. Specifically, Apotex alleges that federal courts in New York and the District of Columbia, including the Supreme Court of the United States, as well as the U.S. Food and Drug Administration ("FDA"), made legal errors and that such legal errors give rise to violations of NAFTA Chapter Eleven obligations.

2. Apotex's claims amount to nothing more than an attempt to seek review by this Tribunal of the decisions of U.S. courts and agencies made under U.S. law. Apotex's plan to export drugs from Canada for sale in the United States is not an "investment" under NAFTA Chapter Eleven, and in any event, its disappointment with the outcome of litigation related to its sertraline and pravastatin products does not give rise to violations of NAFTA Chapter Eleven.

3. In Section I, the United States sets forth the relevant facts and U.S. legal proceedings related to this case. In Section II, the United States delineates the points at issue in this case, including why this Tribunal has no jurisdiction to hear Apotex's claims and why, in any event, Apotex's claims are wholly without merit. In Section III, the United States requests that this Tribunal dismiss Apotex's claims with prejudice and award all costs, both for this arbitration and for legal representation and assistance, to the United States.

I. STATEMENT OF FACTS

A. Regulatory Context For Abbreviated New Drug Applications

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

5. The ANDA process is "abbreviated" because 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 for approval of the pioneer drug. 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. 21 U.S.C. § 355(j)(2) [R3]. Prior to submitting an ANDA for FDA approval, the generic manufacturer must review an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, known as the "Orange Book," in which all drugs approved by FDA under Section 355 are listed. Pioneer drug manufacturers must list in the Orange Book certain patents (with patent expiration dates) for drugs with approved NDAs. In the ANDA, the generic manufacturer must make one or more of the following certifications for each patent that is listed for the brand drug:

(I) No patent information has been filed;

(II) The patent has expired;

(III) The generic manufacturer is not seeking ANDA approval until after the patent expires; and/or

(IV) The patent is invalid, not infringed by the generic drug, or otherwise not enforceable against the generic manufacturer.

21 U.S.C. § 355(j)(2)(A)(vii) [R3]; 21 C.F.R. § 314.94(a)(12)(i)(A) [R1]. A so-called paragraph I or II certification indicates that the applicant believes that no patent bars immediate approval of the ANDA. A paragraph III certification indicates that the applicant is not challenging the validity or applicability of a non-expired patent and that the applicant is seeking final ANDA approval only after the patent expires. A paragraph IV certification indicates that the ANDA applicant disputes the applicability, validity, or enforceability of a patent. Apotex asserts that only paragraph III and IV certifications are at issue in this case. Apotex Statement of Claims ("Apotex SOC") ¶ 33.

6. An ANDA applicant making a paragraph IV certification must provide notice to the NDA holder and patent owner indicating that it submitted an ANDA and why in the ANDA applicant's

view the patent is invalid, not infringed, or unenforceable. 21 U.S.C. § 355(j)(2)(B) [R3]; 21 C.F.R. § 314.94(a)(12)(i)(A) [R1]. If the NDA holder or patent owner believes that the paragraph IV certification is improper (that is, that its patent is valid and enforceable), it may bring suit against the ANDA applicant within 45 days, and FDA must stay approval of the ANDA for 30 months from the date that notice was received unless a final court decision is reached earlier in which a court orders a longer or shorter period. 21 U.S.C. § 355(j)(5)(B)(iii) [R3]. If no action is brought within the requisite 45-day period, FDA may approve an ANDA with a paragraph IV certification effective immediately, provided that other conditions for approval have been met. 21 U.S.C. § 355(j)(5)(B)(iii) [R3]; 21 C.F.R. § 314.107(f)(2) [R2].

7. If approved, an ANDA with a paragraph IV certification provides potential exclusive market benefits for the ANDA applicant. The first ANDA applicant to submit a paragraph IV certification for a particular patent for a drug may be eligible for 180 days of market exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv) (2002) [R4]. Section 355 provides would-be market entrants an incentive to be the first to challenge patents through a paragraph IV certification, by requiring FDA to delay approval, under certain circumstances, of later-submitted ANDAs with the same paragraph IV certification until the expiration of the 180-day exclusivity period.

8. Because ANDA applicants may include both paragraph III and paragraph IV certifications in one application to market a new generic drug, the validity period of a patent that is the subject of a paragraph III certification can influence market timing related to a patent that is the subject of a paragraph IV certification. For example, ANDA applicants may admit that one of the patents listed in the Orange Book for a pioneer drug is valid, enforceable, and unexpired, and thus subject to paragraph III certification, while also arguing that other patents related to the same drug, such as a particular formulation of the drug or the use of a drug for

treating a particular disease, are invalid, not infringed, or unenforceable, and thus subject to paragraph IV certification. Where an ANDA applicant includes both a paragraph III and a paragraph IV certification, the applicant must wait until the patent subject to the paragraph III certification expires before its ANDA is approved. A later applicant, which was not the first to make a paragraph IV certification, and which is therefore not eligible for 180-day exclusivity, may seek to trigger the start of the 180-day exclusivity period before the first applicant can bring its product to market. In other words, the later-in-time applicant may, in such circumstances, seek to eliminate or shorten the 180-day exclusivity period by causing the 180 days to run while all of the ANDA applicants, including the ANDA applicant eligible for exclusivity, wait for the patent subject to the paragraph III certification to expire before they may get FDA approval to market their respective drugs.

9. There are two possible events to trigger the 180-day exclusivity period: (1) the first commercial marketing of the generic drug under an approved ANDA, or (2) "a decision of a court . . . holding the patent which is subject of the certification to be invalid or not infringed." 21 U.S.C. § 355 (j)(5)(B)(iv) (2002) [R4]. The latter possibility is commonly referred to as the "court decision trigger." *See, e.g., Apotex Inc. v. FDA*, 449 F.3d 1249, *passim* (D.C. Cir. 2006) [R13] (referring throughout to the "court decision trigger"); *see also* David E. Korn, Erika Lietzan, Shaw W. Scott, *A New History and Discussion of 180-Day Exclusivity*, 64 Food & Drug L. J. 335, 349-358 (2009) (discussing application of the "court decision trigger") [R37]. If the patent holder fails to bring suit against the ANDA applicant with a paragraph IV certification within 45 days of receiving notice, that ANDA applicant, or any subsequent applicant with the same paragraph IV certification, may, to the extent permitted by law, bring a declaratory judgment action against the patent holder in U.S. federal court and seek an order that the patent

listed in the paragraph IV certification is invalid, not infringed, or unenforceable. 21 U.S.C. § 355(j)(5)(C)(i)(II) [R3].

10. Pursuant to Section 355, declaratory judgment actions must be brought by ANDA applicants "in accordance with section 2201 of Title 28," i.e., the Declaratory Judgment Act. 21 U.S.C. § 355(j)(5)(C)(i)(II) [R3]. The Declaratory Judgment Act specifies that courts have jurisdiction to issue a declaratory judgment "in a case of actual controversy,"[1] which is generally understood as a reference to the "case or controversy" requirement for jurisdiction in the federal courts under Article III of the U.S. Constitution. Section 271, which as noted above governs patents generally, confirms that federal courts have subject matter jurisdiction over declaratory judgment actions brought by ANDA applicants "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5) [R6].[2] Under the U.S. Constitution, the power of the federal courts is limited to "cases" and to "controversies" arising under federal law. U.S. CONST. art. III, § 2 [R9]. Therefore, an ANDA applicant that wishes to bring a declaratory judgment action under

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[1] 28 U.S.C. § 2201 [R5] states:

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

[2] The statute provides that:

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

Section 355, Section 271 and the Declaratory Judgment Act must meet the "case or controversy" requirement of Article III of the U.S. Constitution.

B. Legal Proceedings Before U.S. Courts

11. In its Statement of Claims, Apotex challenges, as violations of NAFTA Chapter Eleven, several decisions of U.S. federal courts related to two ANDAs that Apotex submitted to FDA. In both instances, Apotex was not the first applicant to submit a paragraph IV certification for the proposed generic drug. For sertraline hydrochloride ("sertraline"), which was marketed under the brand name "Zoloft" by the patent holder, Pfizer Inc., Ivax Pharmaceuticals submitted the first ANDA with a paragraph IV certification in 1999. *See Apotex Inc. & Apotex Corp. v. Pfizer Inc.* 385 F. Supp. 2d 187, 190 (S.D.N.Y. 2005) [R16]. Apotex did not submit its ANDA with a paragraph IV certification for sertraline until October 27, 2003. Apotex SOC ¶ 45. Likewise, for pravastatin sodium ("pravastatin"), which was marketed under the brand name "Pravachol" by the patent holder, Bristol-Myers Squibb, Inc., Teva Pharmaceuticals USA ("Teva") submitted the first ANDA with a paragraph IV certification on December 20, 2000. *Teva Pharmaceuticals USA, Inc. v. FDA*, 398 F. Supp. 2d 176, 179 (D.D.C. 2005) [R28]. Apotex did not submit its ANDA with a paragraph IV certification for pravastatin until December 21, 2001. Apotex SOC ¶ 84.

12. 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 180-day exclusivity periods prior to the expiration of the paragraph III patent.

13. 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, which 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. *See Apotex Inc. & Apotex Corp. v. Pfizer Inc.* 385 F. Supp. 2d 187, 194 (S.D.N.Y. 2005) [R16]. 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 or not there was a "case or controversy" for purposes of jurisdiction. 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.

14. Apotex's challenge to the standard applied by the U.S. District Court for the Southern District of New York in determining the existence of a "case or controversy" was rejected by the Court of Appeals for the Federal Circuit, which described the reasonable apprehension of suit standard applied by the U.S. District Court for the Southern District of New York as the "traditional test" for determining whether there is an actual controversy for purposes of Article III standing. *See Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1340 (Fed. Cir. 2005) [R30]; *accord Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1326 (Fed. Cir. 1998) (holding that the reasonable apprehension test is used to determine whether the case presented a "constitutional controversy, which is judicially cognizable under the Declaratory Judgment Act") [R23]. In the Southern District of New York, where Apotex brought its declaratory judgment action against Pfizer, the standard had been applied dozens of times in a variety of intellectual property contexts to assess Article III standing. *See, e.g., O Zon Inc. v.*

Charles, 272 F. Supp. 2d 307 (S.D.N.Y. 2003) [R27]; *Lonza Inc. v. Rohm & Haas, Inc.*, 951 F. Supp. 46 (S.D.N.Y. 1997) [R24]; *Evans Med. Ltd. v. American Cyanamid Co.*, 980 F. Supp. 132 (S.D.N.Y. 1997) [R22]; *B.V. Optische Industrie De Oude Delft v. Hologic, Inc.*, 909 F. Supp. 162 (S.D.N.Y. 1995) [R20].

15. In cases involving pharmaceutical patents in particular, the reasonable apprehension of suit standard often was applied to decide motions to dismiss declaratory judgment actions. *See, e.g., Teva Pharm. USA, v. Pfizer*, 395 F. 3d 1324, 1340 (Fed. Cir. 2005) [R30]; *Mut. Pharm. Co., Inc. v. Pfizer, Inc.*, 307 F. Supp. 2d 88 (D.D.C. 2004) [R26]; *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 101 F. Supp. 2d 1139 (S.D. Ind. 2000) [R21]; *Bristol-Myers Squibb Co. v. IVAX Corp.*, 77 F. Supp. 2d 606 (D.N.J. 2000) [R19]. While the U.S. Supreme Court cast some doubt on this standard in its 2007 decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) [R25], the reasonable apprehension of suit standard was the accepted standard for Article III standing in intellectual property declaratory judgment cases when the court decisions about which Apotex complains were decided.

16. Apotex asserts that the reasonable apprehension of suit standard applied by the U.S. District Court for the Southern District of New York in *Apotex Inc. & Apotex Corp. v. Pfizer Inc.* 385 F. Supp. 2d 187 (S.D.N.Y. 2005) [R16] and affirmed by the U.S. Court of Appeals for the Federal Circuit in *Apotex Inc. & Apotex Corp. v. Pfizer, Inc.*,159 Fed. Appx. 1013 (Dec. 12, 2005) [R17] was in error because it incorrectly interpreted Article III of the U.S. Constitution. Apotex sought leave to appeal to the U.S. Supreme Court, i.e. a petition for writ of certiorari, which was denied. *See Apotex Inc., et al. v. Pfizer, Inc*, 549 U.S. 970 (2006) [R18]. Apotex asserts that these decisions were "blatant legal errors" that violated Articles 1102, 1105 and 1110 of the NAFTA. Sertraline NOA ¶ 54.

17. 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 Appeals for the District of Columbia Circuit. Apotex initially brought a declaratory judgment action against patent holder Bristol-Myers Squibb ("BMS") in the U.S. District Court for the Southern District of New York seeking an order that BMS's patent was 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. *Apotex Inc. & Apotex Corp. v. Bristol-Myers-Squibb Co*., No. 04-cv-2922 (S.D.N.Y. 2004) (Dkt. No. 16, Stipulation of Dismissal) [R10]. 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[.]" *Id*. at 3 [R10]. Upon receiving the dismissal order of the U.S. District Court for the Southern District of New York, Apotex sought a determination from FDA that this dismissal had successfully triggered Teva's 180-day exclusivity with regard to its first-submitted paragraph IV certification.

18. 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 generic exclusivity period that would have been awarded to Teva, subject to final approval by FDA, therefore had already run. Letter from G. Buehler to P. Erickson (June 28, 2005) [R7]. As such, Apotex potentially would have been permitted, pending full and final approval of its ANDA, to market its own generic pravastatin drug simultaneously with Teva once another patent, subject to a paragraph III certification, expired in April 2006.

19. 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 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). *Teva Pharmaceuticals USA v. FDA*, 398 F. Supp. 2d 176, 192 (Oct. 21, 2005) [R28]. 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 to Teva, were not binding precedent as to the scope of the court decision trigger, and directing FDA to reexamine whether the voluntary dismissal qualified as a court decision trigger under the statute. *Teva Pharmaceuticals USA, Inc. v. FDA*, 441 F.3d 1, 5 (D.C. Cir. 2006) [R29]. 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." *Id.* (internal citations and quotations omitted) [R29].

20. In response to this decision and drawing on its experience and expertise, FDA issued a new decision, interpreting the statute to require a court decision holding on the merits that the patents at issue were invalid, not infringed, or unenforceable. 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 decision by bringing suit against FDA and

seeking a temporary restraining order and preliminary injunction. The U.S. District Court for the District of Columbia denied the request. *Apotex Inc. v. FDA*, 2006 WL 1030151 (D.D.C., April 19, 2006) [R11]. 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. *Apotex Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006) [R13]. 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 of the Court of Appeals' ruling. *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir., July 21, 2006) (Dkt. No. 982546-1, Petition for Rehearing *en banc* of Plaintiff-Appellant Apotex Inc.) [R14]; *Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir., Aug. 17, 2006) (Dkt. No. 986687, Per Curiam order, *en banc*) [R15]. 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. *Apotex Inc. v. FDA*, No. 06-627 (D.D.C. Oct. 3, 2006) (Dkt. No. 42, Stipulation of Dismissal) [R12]. Apotex now challenges the decisions of the U.S. courts in this proceeding, alleging that they are in violation of NAFTA Chapter Eleven.

21. Taken together, Apotex's two claims in this arbitration raise one core allegation, specifically, that federal courts in New York and the District of Columbia, the U.S. Supreme Court, and the federal agency charged with interpreting the relevant statute, made legal errors in applying U.S. federal law, and that such legal errors: (i) accorded treatment less favorable than that accorded to U.S. investors or their investments in like circumstances in violation of Article 1102 of the NAFTA; (ii) constitute a denial of justice in violation of Article 1105 of the NAFTA; and finally, (iii) amount to an expropriation in violation of Article 1110 of the NAFTA.

However, Apotex makes no effort to establish the basis – other than legal error – on which these decisions violated the NAFTA. This Tribunal does not sit as a court of appeals for the courts of the United States, and in any event "legal error" by a court when applying U.S. law does not give rise to a violation of the NAFTA. Apotex's meritless claims should be dismissed.

II. POINTS AT ISSUE

22. Below, the United States first presents the grounds on which the Tribunal should dismiss both claims without reaching the merits. The United States then sets forth its defenses on the merits of the claims under each of the relevant provisions of NAFTA Chapter Eleven.

A. The Tribunal Should Not Hear Apotex's Claims

23. Apotex alleges that errors of law by U.S. courts and FDA negatively impacted its ability to export products from Canada for sale in the United States, in violation of NAFTA Chapter Eleven obligations. However, Apotex does not articulate how its actions or operations constitute an "investment" under NAFTA Article 1139, or how they qualify Apotex as an "investor" under NAFTA Article 1116. For the reasons set forth below, these claims are not properly before the Tribunal.

1. Apotex's Claims Fall Outside Of The Scope And Coverage Of NAFTA Chapter Eleven

24. The United States objects to the jurisdiction of the Tribunal on the grounds that Apotex has not made an "investment" as defined under NAFTA Article 1139 and does not qualify as an "investor" under NAFTA Article 1116.

25. Under Article 1116, the provision under which Apotex brought its arbitration claims, the NAFTA Parties consented to arbitration only where a claimant is 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 respondent Party of one or more Chapter Eleven, Section A obligations.[3] "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." Reading Articles 1116 and 1139 together, for claims submitted under Article 1116 an "investor" may recover only for "loss or damage" incurred in seeking to make, making, or having made an "investment" as defined under Article 1139.

26. NAFTA Article 1101, which establishes the scope and coverage of the entire investment chapter of the NAFTA, expressly limits the "scope and coverage" of Chapter Eleven to those "measures" adopted or maintained by a Party "relating to" "investors of another Party" (NAFTA Article 1101(1)(a)) and to "investments of investors of another Party in the territory of the Party" (NAFTA Article 1101(1)(b)).[4] Given that Article 1139 defines "investor of a Party" as one "that seeks to make, is making or has made an investment," Article 1101 makes clear that the scope and coverage of the protections of NAFTA Chapter Eleven, including Article 1116, extends to "investors" only to the extent that they have made, were making, or sought to make "investments" in the territory of another NAFTA Party. *See Bayview Irrigation District et al. v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award (on Jurisdiction) ¶ 105 (June 19, 2007) (stating that, "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.") [R31].

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

[4] NAFTA Article 1101(1)(c) also provides, in instances not relevant here, for application of Chapter Eleven to investments with respect to NAFTA Articles 1106 and 1114.

i. Apotex Does Not Have An "Investment" As Defined Under Article 1139

27. Apotex has failed to meet its burden of identifying an "investment" as defined under NAFTA Article 1139, and both of its claims should be dismissed for this reason alone. With respect to its investment, Apotex stated in its Statement of Claims that it:

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

Apotex SOC ¶¶ 62, 111.

In its submission in support of a stay, Apotex also stated that the "investment at issue" was "Apotex's [Sertraline/Pravastatin] ANDA products." Submission of Apotex, Inc. in Support of Stay ¶ 48. In none of these submissions, however, does Apotex articulate how an ANDA or "ANDA products" constitute an "investment" within the definition of Article 1139. Apotex has therefore not met Chapter Eleven jurisdictional requirements.

ii. Apotex Does Not Qualify As An "Investor"

28. Apotex describes itself as a Canadian manufacturer and exporter of "approved generic pharmaceutical products for sale in the United States and throughout the world," but does not describe how it is an "investor" for purposes of the NAFTA. Apotex SOC ¶¶ 62, 111. The NAFTA does not provide jurisdiction for tribunals to hear claims of foreign manufacturers and exporters that do not qualify as "investors" who may bring their claims under Chapter Eleven. *See Grand River Enterprises Six Nations, Ltd. et al. v. United States*, NAFTA/UNCITRAL, Award ¶ 5 (Jan. 12, 2011) [R32]. Apotex's application for approval to export sertraline and pravastatin drugs from Canada to the United States does not itself constitute an "investment" by an "investor" in the United States. In its ANDAs, Apotex sought approval for the sale of

Apotex's sertraline and pravastatin products in the United States. But the actual sale of those products in the United States, Apotex has made clear, would have been made by parties other than Apotex. Specifically, in each of its NOAs, Apotex states 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]." Sertraline/Pravastatin NOAs ¶ 13 (emphasis added). Seeking approval for the export of products to the United States does not constitute an "investment" under Article 1139.

29. Apotex has failed to establish both that it is an "investor" and that it has made, was making, or sought to make an "investment," as those terms are defined by NAFTA Chapter Eleven. The Tribunal therefore does not have jurisdiction over Apotex's claims, which do not fall within the scope and coverage of NAFTA Chapter Eleven.

2. Apotex Has Failed To Establish That It Has Submitted Timely Claims As Required By NAFTA Article 1116(2)

30. According to NAFTA Article 1116(2), Apotex may not submit its claims "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." (Emphasis added).

31. Under NAFTA Article 1137, the date that the NOA is received by the NAFTA Party is the date that the claim is submitted. NAFTA 1137(1) ("A claim is submitted to arbitration . . . when . . . (c) the [NOA] given under the UNCITRAL Arbitration Rules is received by the disputing party."). The United States received Apotex's NOA for the sertraline claim, dated December 10, 2008, on December 11, 2008. The United States received Apotex's NOA for the pravastatin claim, dated June 4, 2009, on June 5, 2009.

32. Apotex's claims refer to acts that occurred both within, and outside of, the applicable three-year limitations period for each claim. Apotex does not specify, however, on which of

these acts each claim is based. To the extent that Apotex's allegations of breach are based on acts that occurred before December 11, 2005, for the sertraline claim, and June 5, 2006, for the pravastatin claim, its claims are time-barred.

3. Apotex's Pravastatin Claim Lacks The Requisite Judicial Finality

33. Apotex alleges that it suffered harm as a result of certain acts of U.S. federal courts in both its sertraline and pravastatin claims, but it failed to pursue all potentially available avenues of relief related to the pravastatin claim. Claims based on judicial acts, such as Apotex's denial of justice claim, cannot arise until all available challenges to the underlying action have reached judicial finality in the Party's domestic courts unless such recourse is obviously futile.[5] A denial of justice cannot represent mere legal error, but must instead amount to a systemic failure of the judiciary. A claimant cannot raise a denial of justice claim without first proceeding through the judicial system that it purports to challenge.[6] Apotex sought, and was denied, review from the U.S. Supreme Court with regard to the lower court decisions rejecting its declaratory judgment action related to its sertraline claim. However, Apotex did not seek U.S. Supreme Court review with regard to its disagreement with court decisions rejecting its efforts to enjoin application of

[5] *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.'") [R33] (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].

[6] 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]. *See Loewen Group v. United States*, 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.") [R33].

the FDA decision related to its pravastatin claim. With respect to its pravastatin claim, Apotex voluntarily dismissed with prejudice most of its claims in the U.S. District Court for the District of Columbia after it lost its bid for preliminary injunctive relief and has not brought any remaining claims in court. *See Apotex Inc. v. FDA*, No. Civ. A. 06-027 (D.D.C., Oct. 3, 2006) (Dkt. No. 42, Stipulation of Dismissal) [R12]. Apotex therefore failed to pursue available remedies at the trial court level – let alone reach judicial finality with regard to its domestic court remedies on appeal.

34. For the reasons stated above, where Apotex failed to reach judicial finality with respect to its domestic court remedies, this Tribunal cannot consider claims based on the acts of U.S. federal courts, such as the alleged denial of justice in the pravastatin claim.

B. There Is No State Responsibility For The Acts Alleged

35. To the extent these claims are not rejected at a preliminary stage on the basis that they are not properly before the Tribunal, the claims should be dismissed on the merits.

1. Apotex's Claims Under NAFTA Article 1102 (National Treatment) Are Without Merit

36. Apotex's claims under NAFTA Article 1102 fail because Apotex does not allege how the company or any of its investments have been accorded treatment less favorable than that accorded to U.S. investors or their investments in like circumstances.

37. Article 1102 provides that a NAFTA Party must accord to investors of another Party and their investments "treatment no less favorable" than that it accords, in like circumstances, to its own investors and their investments "with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments." Article 1102 prohibits discriminatory treatment on the basis of nationality. Apotex points to nothing in the

law or the decisions about which Apotex complains that suggest that Apotex was provided less favorable treatment than an American comparator because of its Canadian nationality. Both U.S.-owned and foreign-owned generic pharmaceutical manufacturers are treated identically under the relevant statutory and regulatory framework and before U.S. federal courts. Furthermore, Apotex has not identified any U.S. comparator in like circumstances that received treatment more favorable than that accorded to it with regard to the application of the law implicated in its claims. Accordingly, Apotex's Article 1102 claims are without merit and must be dismissed.

2. Apotex's Claims Under NAFTA Article 1105 (Minimum Standard of Treatment) Are Without Merit

38. Apotex's claims under the minimum standard of treatment obligation of NAFTA Article 1105(1) are meritless because Apotex has not identified any customary international law obligation that has been violated by the challenged actions. Article 1105(1) establishes a "minimum standard of treatment" for covered investments, providing that "[e]ach Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security." The NAFTA Free Trade Commission's July 31, 2001 Notes of Interpretation of Certain Chapter Eleven Provisions ("FTC Interpretation") [R34], confirms that Article 1105(1) prescribes the customary international law minimum standard of treatment to be afforded to investments of investors of another Party. The FTC Interpretation further provides that the concepts of fair and equitable treatment and full protection and security do not require treatment in addition to or beyond that which is required by the customary international law minimum standard of treatment of aliens, and that a determination that there has been a breach of another provision of the NAFTA or of a

separate international agreement does not establish that there has been a breach of Article 1105(1). *Id*. [R34]. Under NAFTA Article 1131, this interpretation by the FTC of Article 1105 is binding on NAFTA Chapter Eleven tribunals.

39. With respect to its Article 1105(1) claims related to sertraline, Apotex argues that the reasonable apprehension of suit standard employed by courts in declaratory judgment actions involving intellectual property "violates Article III and binding Supreme Court precedent" and that such "blatant legal errors . . . constitute a denial of justice as defined by international law and an expropriation of Apotex's investment." Sertraline NOA ¶¶ 21, 54. Specifically, Apotex argues that the courts' decisions "unlawfully, arbitrarily and capriciously" required Apotex to meet a "non-constitutional prudential standard for subject matter jurisdiction" and resulted in a "manifestly unjust judgment" that "violates international law and may be described as a substantive 'denial of justice.'" Apotex SOC ¶ 12.

40. As an initial matter, Apotex's contention that the U.S. federal courts were violating binding U.S. Supreme Court precedent in applying the reasonable apprehension of suit standard is factually and legally wrong. In any event, to establish a denial of justice it is not sufficient merely to show that a U.S. federal appeals court, having full participation of all interested parties, interprets established law in a manner that results in an unfavorable outcome to one of the parties and favorable to the other. A measure can breach Article 1105(1) only if it fails to accord the investment of an investor treatment in accordance with customary international law. Indeed, Apotex has not identified, because none exists, any support for its contention that the challenged U.S. federal court decisions interpreting domestic law — in reasoned decisions citing established precedent — violate any standard of customary international law incorporated into

Article 1105(1). It is not the function of tribunals under NAFTA Chapter Eleven to act as courts of appeal.

41. In addition, Apotex argues, without support, that the "actions of the United States prevented Apotex from promptly launching its pravastatin ANDA product . . . in violation of Article 1105 of NAFTA." Apotex SOC ¶ 119. Specifically, Apotex argues that the "actions of the United States violated Apotex's reasonable and legitimate expectations regarding its investment in its pravastatin ANDA based on prior agency and court decisions in like circumstances, and denied Apotex the minimum standard of treatment under Article 1105 of NAFTA." Apotex SOC ¶ 121. Apotex does not articulate any basis in international law for its assertion that it had a legally protected legitimate expectation that it would be successful in triggering the 180-day exclusivity period of the first applicant with a paragraph IV certification for pravastatin with its voluntary dismissal of the Apotex-BMS litigation. For the reasons above, Apotex's claims under NAFTA Article 1105 are without merit and must be dismissed.

3. Apotex's Claims Under NAFTA Article 1110 (Expropriation) Are Without Merit

42. Apotex's expropriation claims under NAFTA Article 1110 are meritless. Article 1110 provides that "[n]o Party may directly or indirectly nationalize or expropriate an investment of an investor of another Party in its territory or take a measure tantamount to nationalization or expropriation of such an investment" except where certain conditions are met, including payment of compensation.

43. Specifically, Apotex asserts on the basis only of substantive legal error that the U.S. federal courts and FDA allegedly denied it the "protections and benefits afforded by the U.S. Constitution," and "failed to provide Apotex with due process of law and treatment" and therefore unlawfully expropriated its investment in violation of Article 1110. Apotex also asserts

that the U.S. federal courts and FDA "unlawfully, arbitrarily and improperly interpret[ed] and appli[ed] the court decision trigger provision" and that these decisions "deprived Apotex of the benefits of its investments" which according to Apotex is tantamount to an expropriation. Apotex SOC ¶¶ 67, 77, 124.

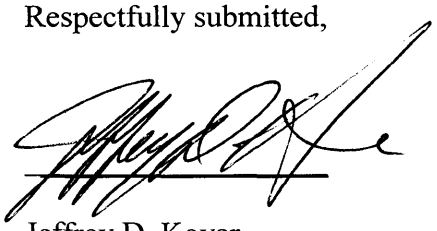
44. In order to constitute a violation of Article 1110, the challenged measure must amount to an expropriation of "an investment of an investor of another Party in its territory." Apotex has not articulated how its ANDAs, which are applications for approval to market generic drugs exported from Canada, constitute an "investment" as defined under Article 1139. Moreover, Apotex has not offered any support for its assertion that any of the various administrative and judicial decisions taken by U.S. federal courts and FDA were tantamount to an expropriation. Accordingly, Apotex's Article 1110 claims are without merit and must be dismissed.

III. RELIEF SOUGHT

45. 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.

Dated: March 15, 2011

Respectfully submitted,



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APPENDIX TO
STATEMENT OF DEFENSE OF
RESPONDENT UNITED STATES OF AMERICA

STATUTES, REGULATIONS, AND FDA LETTERS

R1	21 C.F.R. § 314.94
R2	21 C.F.R. § 314.107
R3	21 U.S.C. § 355
R4	21 U.S.C. § 355 (2002)
R5	28 U.S.C. § 2201
R6	35 U.S.C. § 271
R7	Letter from Gary Buehler, Director, FDA Office of Generic Drugs, to Philip Erickson, Teva Pharmaceuticals USA (June 28, 2005)
R8	Letter from Gary Buehler, Director, FDA Office of Generic Drugs, to Tammy McIntire, Apotex Corp. (Apr. 11, 2006)
R9	U.S. Const. art. III, § 2

U.S. COURT FILINGS AND JUDGMENTS

R10	*Apotex Inc. & Apotex Corp. v. Bristol-Myers-Squibb Co*., No. 04-cv-2922 (S.D.N.Y. 2004) (Dkt. No. 16, Stipulation of Dismissal)
R11	*Apotex Inc. v. FDA*, No. Civ.A. 06-0627, 2006 WL 1030151 (D.D.C., April 19, 2006)
R12	*Apotex Inc. v. FDA*, No. Civ.A. 06-0627 (D.D.C., Oct. 3, 2006) (Dkt. No. 42, Stipulation of Dismissal)
R13	*Apotex Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006)
R14	*Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir., July 21, 2006) (Dkt. No. 982546-1, Petition for Rehearing *en banc* of Plaintiff-Appellant Apotex Inc.)

R15	*Apotex Inc. v. FDA*, No. 06-5105 (D.C. Cir., Aug. 17, 2006) (Dkt. No. 986687, Per Curiam Order, *en banc*)
R16	*Apotex Inc. & Apotex Corp. v. Pfizer, Inc.*, 385 F. Supp. 2d 187 (S.D.N.Y. 2005)
R17	*Apotex Inc. & Apotex Corp. v. Pfizer, Inc.*, 159 Fed. Appx. 1013, 2005 WL 3457408 (Fed. Cir. Dec. 12, 2005)
R18	*Apotex Inc., et al. v. Pfizer, Inc.*, 549 U.S. 970 (2006)
R19	*Bristol-Myers Squibb Co. v. IVAX Corp.*, 77 F. Supp. 2d 606 (D.N.J. 2000)
R20	*B.V. Optische Industrie De Oude Delft v. Hologic, Inc.*, 909 F. Supp. 162 (S.D.N.Y. 1995)
R21	*Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 101 F. Supp. 2d 1139 (S.D. Ind. 2000)
R22	*Evans Med. Ltd. v. American Cyanamid Co.*, 980 F. Supp. 132 (S.D.N.Y. 1997)
R23	*Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318 (Fed. Cir. 1998)
R24	*Lonza Inc. v. Rohm & Haas, Inc.*, 951 F. Supp. 46 (S.D.N.Y. 1997)
R25	*MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007)
R26	*Mut. Pharm. Co., Inc. v. Pfizer, Inc.*, 307 F. Supp. 2d 88 (D.D.C. 2004)
R27	*O Zon Inc. v. Charles*, 272 F. Supp. 2d 307 (S.D.N.Y. 2003)
R28	*Teva Pharmaceuticals USA, Inc. v. FDA*, 398 F. Supp. 2d 176 (D.D.C. 2005)
R29	*Teva Pharmaceuticals USA, Inc. v. FDA*, 441 F.3d 1 (D.C. Cir. 2006)
R30	*Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir. 2005)

INTERNATIONAL CASES AND MATERIALS

R31	*Bayview Irrigation District et al. v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award (on Jurisdiction) ¶ 105 (June 19, 2007)

R32	*Grand River Enterprises Six Nations Ltd. et al.*, v. *United* States, NAFTA/UNCITRAL, Award ¶ 5 (Jan. 12, 2011)
R33	*Loewen Group v. United States*, ICSID Case No. ARB(AF)/98/3, Award ¶¶ 156, 165 (June 26, 2003)
R34	NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter 11 Provisions (July 31, 2001)
R35	*Nielsen v. Denmark* [1958-1959] Y.B. EUR. COMM'N H.R. 412 at 436, 438, 440, 444
R36	*The Finnish Ships Arbitration Award*, 3 R. INT'L ARB. AWARDS 1480, 1495, 1503-5 (May 9, 1934)

TREATISES AND SCHOLARLY ARTICLES

R37	David E. Korn, Erika Lietzan, Shaw W. Scott, *A New History and Discussion of 180-Day Exclusivity*, 64 Food & Drug L. J. 335, 349-358 (2009)
R38	JAN PAULSSON, DENIAL OF JUSTICE IN INTERNATIONAL LAW 108 (2005)