NOTICE OF ARBITRATION
UNDER THE ARBITRATION RULES
OF THE
UNITED NATIONS COMMISSION ON INTERNATIONAL TRADE LAW
AND
THE NORTH AMERICAN FREE TRADE AGREEMENT

APOTEX INC.

Claimant/Investor,

v.

THE GOVERNMENT OF THE UNITED STATES OF AMERICA

Respondent/Party.

NOTICE OF ARBITRATION

SERVICE ACCEPTED IN
OFFICIAL CAPACITY ONLY
EXECUTIVE DIRECTOR 12-16-08
OFFICE OF THE LEGAL ADVISER

Pursuant to Article 3 of the United Nations Commission on International Trade Law ("UNCITRAL") Rules of Arbitration (Resolution 31/98 adopted by the General Assembly on December 15, 1976) and Articles 1116 and 1120 of the North American Free Trade Agreement ("NAFTA"), the Claimant initiates recourse to arbitration.

A. DEMAND THAT THE DISPUTE BE REFERRED TO ARBITRATION

1. Pursuant to Article 1120(1)(c) of NAFTA and Article 3 of UNCITRAL, Claimant Apotex Inc. ("Apotex" or "Claimant") hereby demands that the dispute between it and the Respondent be referred to arbitration under the UNCITRAL Arbitration Rules.

2. Pursuant to Article 1119 of NAFTA, on or about September 21, 2007, Apotex served written notice on the Respondent of Apotex's intent to submit a claim to arbitration under Section B of Chapter Eleven of NAFTA, which, accordingly, was more than ninety days before the submission of this claim. In a letter dated October 30, 2007, Respondent confirmed receipt of this notice.

3. As detailed below, more than six months have passed since the events giving rise to Apotex's claim, and not more than three years have passed since the date on which Apotex first acquired or should have acquired knowledge of the Respondent's breach of the obligations set out in Section A of Chapter 11 of NAFTA and knowledge that Apotex incurred loss and damages by reason of or arising out of those breaches.

B. NAMES AND ADDRESSES OF THE PARTIES

4. The Claimant/Investor is:

Apotex Inc.
150 Signet Drive
Weston, Ontario, Canada
M91 1T9

The Claimant/Investor is represented in these proceedings by:

William A. Rakoczy
Christine J. Siwik
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60654, USA
312-222-6301 (telephone)
312-222-6321 (facsimile)

5. The Respondent/Party is:

Government of the United States of America
Executive Director
Office of the Legal Adviser
United States Department of State
Room 5519
2201 C Street N.W.
Washington, D.C. 20520, USA

C. ARBITRATION CLAUSE OR ARBITRATION AGREEMENT INVOKED

6. Apotex invokes Section B of Chapter 11 of NAFTA, and specifically Articles 1116, 1120 and 1122 as authority for the arbitration. Section B of Chapter 11 of NAFTA sets out the provisions agreed to concerning the settlement of disputes between a Party and an Investor of another Party.

D. CONTRACT OUT OF OR IN RELATION TO WHICH THE DISPUTE ARISES

7. The dispute relates to the treatment accorded to Apotex by the Government of the United States of America, and the damages arising out of the United States' breach of its obligations under Chapter 11 of NAFTA and, in particular, Articles 1102, 1105, and 1110.

E. CONSENT TO ARBITRATION

8. Pursuant to Article 1121 of NAFTA, Apotex consents to arbitration in accordance with the procedures set out in NAFTA and the UNCITRAL Arbitration Rules. Apotex hereby waives its right to initiate or continue before any administrative tribunal or court, or other dispute settlement procedures, any proceedings with respect to the measures outlined herein and alleged to be breaches of United States obligations under NAFTA, except for proceedings for injunctive, declaratory or other extraordinary relief, not involving the payment of damages, before an administrative tribunal or court under federal or state laws of the United

States of America. Concurrently with the filing of this Notice of Arbitration, Apotex has submitted the executed waiver in the form required by Article 1121.

9. Pursuant to Article 1122 of NAFTA, the United States has consented to arbitrate this claim.

10. Apotex has elected to proceed under UNCITRAL Arbitration Rules, as is its option under NAFTA Article 1120.

F. GENERAL NATURE OF THE CLAIM AND AN INDICATION OF THE AMOUNT INVOLVED

INTRODUCTION

11. Apotex Inc. is a corporation duly incorporated and existing under the laws of Canada and having a principal place of business at 150 Signet Drive, Weston, Ontario, Canada M9L 1T9.

12. Respondent, the Government of the United States of America, is a Party to NAFTA, an agreement entered into between the Governments of Canada, the United States, and the United Mexican States, effective January 1, 1994.

13. Apotex develops and manufactures quality generic drugs, including solid oral dosage forms such as capsules and tablets. Before one of Apotex's generic drugs can be sold by others in the United States, Apotex must obtain approval from the U.S. Food and Drug Administration ("FDA").

14. In 2003, Apotex submitted an application seeking FDA approval for a generic version of Pfizer Inc.'s popular antidepressant medication, Zoloft®, known generically as sertraline hydrochloride. As part of its generic drug application, Apotex was statutorily required to address and certify to any patents listed by Pfizer as purporting to claim the approved use of Zoloft® Tablets, or the approved product itself.

15. Pfizer listed several patents with FDA in connection with Zoloft®, including U.S. Patent Nos. 4,356,518 ("the '518 patent") and 5,248,699 ("the '699 patent"). By listing these patents, Pfizer affirmatively represented that a suit for infringement could reasonably be asserted against any generic manufacturer, including Apotex, that attempted to market a generic version of sertraline prior to the expiration of these patents.

16. In its application to FDA, Apotex represented that it would not begin selling its sertraline drug products until after the '518 patent expired in June 2006. With respect to the '699 patent, however, Apotex submitted a so-called "paragraph IV certification" indicating that Apotex sought final FDA approval prior to the patent's expiration.

17. Under the applicable statutory authority, Apotex's paragraph IV certification constituted an artificial act of patent infringement that created the necessary case or controversy for Pfizer to file an action for patent infringement before Apotex's generic sertraline tablets were made, used or sold in the United States.

18. Pfizer did not sue Apotex for infringement of the '699 patent, or any other patent listed in connection with Zoloft®. Pfizer did, however, sue another applicant for generic sertraline tablets, Ivax Pharmaceuticals ("Ivax"). Like Apotex, Ivax indicated that it would not launch until the '518 patent expired and also filed a paragraph IV certification to the '699 patent. As a result of being the first applicant to challenge one of Pfizer's patents, Ivax was eligible for 180 days of generic market exclusivity that would be triggered by the earlier of either a court decision finding the '699 patent invalid or not infringed, or Ivax's first commercial marketing of its generic products. Ivax and Pfizer settled their litigation in 2002. The lack of a court decision on the '699 patent preserved Ivax's 180-day exclusivity, which could not be triggered until at

least June 2006, upon expiration of the '518 patent, given Pfizer's refusal to sue any other applicant on the '699 patent.

19. Pfizer's failure to sue Apotex created a substantial cloud of uncertainty over Apotex's ability to enter the marketplace because Apotex faced potentially crippling patent liability with respect to the '699 patent. Apotex also was precluded from obtaining timely approval of its application immediately upon expiration of the '518 patent due to Ivax's exclusivity on the '699 patent. Thus, in order to obtain patent certainty and be eligible for final FDA approval of its product immediately upon expiration of the '518 patent, Apotex filed a declaratory judgment action against Pfizer in the United States District Court for the Southern District of New York.

20. Despite the fact that Apotex's declaratory judgment suit met the case or controversy requirement under Article III of the U.S. Constitution, and despite the fact that the district court did not doubt that Apotex was injured by its inability to enter the marketplace based upon the failure to resolve its patent controversy against Pfizer, the court dismissed Apotex's suit for lack of subject matter jurisdiction solely because Apotex allegedly did not face a "reasonable apprehension of suit" by Pfizer. The United States Court of Appeals for the Federal Circuit ("Federal Circuit") affirmed the district court's decision without opinion and the U.S. Supreme Court denied Apotex's petition for a writ of certiorari.

21. As a direct result of the U.S. federal courts' unlawful application of the Federal Circuit's prudential jurisdictional doctrine (the so-called "reasonable apprehension" requirement), which violates Article III and binding Supreme Court precedent, Apotex was prevented from obtaining approval and bringing its sertraline tablets to market in June 2006, thus

causing Apotex substantial injury including, but not limited to, significant lost sales and lost market share.

22. In sum, Apotex's claim to recover damages for the breach by the United States of certain obligations under Chapter 11 of NAFTA arises from, among other things, the following three decisions by the U.S. Federal courts: (1) the December 30, 2004, decision by the United States District Court for the Southern District of New York in the federal court case *Apotex, Inc. v. Pfizer Inc.*, Case No. 04CV2539 (S.D.N.Y.), which misapplied the applicable law and dismissed Apotex's declaratory judgment action for lack of subject matter jurisdiction, *see Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187 (S.D.N.Y. 2005); (2) the December 12, 2005, decision by the Federal Circuit improperly affirming the decision of the Southern District of New York, *see Apotex, Inc. v. Pfizer Inc.*, 159 F. App'x 1013, 2005 WL 3457408 (Fed. Cir. Dec. 12, 2005); and (3) the October 10, 2006 refusal by the Supreme Court of the United States to grant Apotex's petition for writ of certiorari and reverse the blatant legal errors committed by the Federal Circuit and the district court, *see Apotex Inc. v. Pfizer Inc.*, 127 S. Ct. 379 (2006).

RELEVANT NAFTA OBLIGATIONS BREACHED

23. Apotex alleges that the United States has breached its obligations under at least the following provisions of Section A of Chapter 11 of NAFTA:

Article 1102 – National Treatment

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

2. *Each Party shall accord to investments of investors of another Party treatment no less favorable than that it accords, in like circumstances, to its investments of its own investors with respect*

to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.

Article 1105 – Minimum Standard of Treatment

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

Article 1110 – Expropriation and Compensation

1. *No 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 ("expropriation"), except:*

   (a) for a public purpose;

   (b) on a non-discriminatory basis;

   (c) in accordance with due process of law and Article 1105(1); and

   (d) on payment of compensation in accordance with paragraphs 2 through 6.

Apotex reserves all rights to assert additional bases for its claims against the United States.

PHARMACEUTICAL STATUTORY BACKGROUND

24. 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 more recently as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271).

25. Before the 1984 Hatch-Waxman Amendments, a generic company had to wait until the patent protecting a drug product expired before it could begin the lengthy process

of preparing its application for submission to the FDA. And because such testing can, and often does, take years, the brand company continued to monopolize that particular drug market years *after* patent expiration as the generic company worked to complete the necessary tests and waited for FDA approval. This unintended period of extended market exclusivity often was referred to as a *de facto* patent term extension.

New drugs and patent listing requirements

26. To increase generic competition for pharmaceutical drug products, the Hatch-Waxman Amendments created a special, expedited mechanism for resolving patent disputes before a generic drug is commercialized. To that end, as part of its new drug application ("NDA"), a brand company is required to submit information regarding each patent that claims the drug or method of using the drug that is the subject of the NDA and for which a claim of patent 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. 21 U.S.C. §§ 355(b)(1), (c)(2). FDA publishes patent information submitted by an NDA-holder in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

27. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder, by law, necessarily maintains that the listed patent claims the approved NDA drug and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use, or sale of the drug, and in particular against any company that is seeking to make a generic bioequivalent of the NDA drug. 21 U.S.C. §§ 355(b)(1), (c)(2).

28. Consequently, the NDA-holder necessarily puts 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. Such conduct by the NDA-holder gives rise to a reasonable apprehension on the generic applicant's part that it will face an infringement suit or the threat of one if it attempts to seek approval for or to market a generic version of the NDA drug.

Generic drugs and patent certification requirements

29. The FFDCA, as amended by Hatch-Waxman and the MMA, provides for an abbreviated approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-priced generic versions of previously-approved NDA drugs on an expedited basis, thereby benefiting the U.S. health-care system and American consumers. This process is a streamlined version of the full NDA procedure and results in a generic drug product that is normally marketed under the chemical name of the active drug ingredient.

30. A company seeking to market a generic drug product must file an abbreviated drug new application ("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. 21 U.S.C. § 355(j)(2)(A).

31. An ANDA applicant also is required to address each patent listed in the Orange Book in connection with the approved NDA drug. If the ANDA applicant seeks approval prior to patent expiration, it submits a so-called "paragraph IV" certification. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The submission of a paragraph IV certification has two important effects.

32. *First*, as an incentive for generic companies to challenge brand patents, Congress granted the first company to file a paragraph IV ANDA, in limited circumstances, a 180-day period of generic market exclusivity during which time FDA will not approve other ANDAs. 21 U.S.C. § 355(j)(5)(B)(iv). This exclusivity is "triggered" by the earlier of two events: (1) the first-filer's commercial marketing; or (2) a court decision of noninfringement or invalidity by *any* filer in *any* action. *Id.*[1] Congress intended for a court decision to trigger the first-filer's exclusivity even if it is not in a position to benefit from it. *See Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002); *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1009-11 (D.C. Cir. 1999). Indeed, by including the so-called "court decision trigger," Congress sought to ensure that the 180-day exclusivity period did not indefinitely delay generic competition from subsequent ANDA-filers.

33. *Second*, the submission of a paragraph IV certification for a listed patent constitutes an act of infringement that creates the necessary case or controversy and subject matter jurisdiction to enable a district court to resolve any dispute concerning infringement or validity of the listed patent prior to the actual launch of the generic drug product. 35 U.S.C. § 271(e)(2)(A). This provision creates the necessary jurisdiction for a court to resolve any action regarding the approval of the generic drug.

34. As an incentive for brand companies to bring suit, Hatch-Waxman prohibits FDA from approving a paragraph IV ANDA for 30 months if the brand company brings suit within 45 days of learning of the paragraph IV filing. 21 U.S.C. § 355(j)(5)(B)(iii). If the NDA-holder/patent owner does not file such a suit within the 45-day period, however, Hatch-Waxman

[1] 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 Ivax's and Apotex's sertraline ANDAs that were filed before December 8, 2003. *See* MMA § 1102(b)(1).

allows and authorizes an ANDA applicant to file and maintain a suit for declaratory judgment against the NDA-holder/patent owner both to obtain patent certainty and to remove any barriers to approval, such as another applicant's 180-day exclusivity. 21 U.S.C. § 355(j)(5)(B) (2002).

35. Congress enacted Hatch-Waxman and the ANDA approval process in order to expedite the marketing of lower-priced generic drug products. Over the years, however, brand companies learned to "game the system" in a way that delayed, rather than expedited, generic market entry. One of those delay tactics involved refusing to bring suit immediately upon learning of the paragraph IV filing. When generic companies fought back by bringing declaratory judgment actions for patent invalidity and/or noninfringement, the U.S. courts—albeit improperly—refused to hear the cases. In 2003, Congress stepped in to fix the problem.

36. In the MMA, Congress amended Hatch-Waxman to explicitly authorize declaratory judgment actions where, as in Apotex's case, the ANDA-filer is not sued by the patentee. The new declaratory judgment provision contained in the MMA applies to all ANDAs pending on or after December 8, 2003, which includes Apotex's sertraline ANDA.

37. Under the MMA, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain an action for declaratory judgment against an NDA-holder/patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder brought an action for infringement of the patent within the 45-day period; and, (3) the NDA-holder/patent owner have been granted an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa-cc), as amended. Once these three conditions are met, the MMA specifically and unequivocally provides that an ANDA applicant "may, in accordance with section 2201 of title 28 [United States Code], bring a civil action under such section against the

owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II), as amended.

38. Congress directed the federal courts to exercise subject matter jurisdiction over such declaratory judgment actions to the maximum extent permitted by the Constitution. Specifically, the MMA amended the patent laws such that, if the NDA-holder/patent owner does not file suit within the 45-day period, the ANDA applicant can file and maintain a suit for declaratory judgment to obtain patent certainty and that "the courts of the United States shall, *to the extent consistent with the Constitution*, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5), as amended (emphasis added).

39. As the legislative history makes clear, Congress enacted the declaratory judgment provisions, *inter alia*, to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." 149 CONG. REC. S15,746 (Nov. 24, 2003). Congress was concerned that "when generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the 'failure to market' provision and force the first generic to market." 149 CONG. REC. S15,885 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy). Indeed, consistent with Article III, Congress expected that "in almost all situations where a generic applicant has . . . not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable 'case or controversy' under the Constitution." *Id.*

40. Through Hatch-Waxman and the MMA, Congress thus sought to expedite the resolution of patent disputes and generic market entry by providing that: (a) an NDA-holder's submission of a patent to FDA constitutes a representation that "a claim of patent infringement could reasonably be asserted" (21 U.S.C. § 355(b)(1)); (b) the filing of an ANDA claiming patent noninfringement or invalidity constitutes a statutory act of patent infringement (35 U.S.C. § 271(e)(2)(A)); (c) federal courts have jurisdiction over such a declaratory judgment action by a generic manufacturer (21 U.S.C. § 355(j)(5)(C)(i)(II); 35 U.S.C. § 271(e)(5)); and (d) such suits should be adjudicated to the fullest "extent consistent with the Constitution" (35 U.S.C. § 271(e)(5)).

41. In this case, however, the U.S. federal courts, and in particular the U.S. Supreme Court, the Federal Circuit, and the U.S. District Court for the Southern District of New York, improperly refused to apply the law as written and as intended by Congress, and denied Apotex minimum standards of justice and effectively expropriated Apotex's investment in its generic sertraline products.

FACTUAL BACKGROUND

42. 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. On October 27, 2003 Apotex filed its sertraline ANDA, referencing Pfizer's Zoloft® NDA.

43. To protect Zoloft® from generic competition, Pfizer had listed the '699 patent in the Orange Book, thus affirmatively representing that a suit for infringement of the '699 patent could reasonably be asserted against any generic ANDA-filer, including Apotex, that attempted to market a generic version of sertraline.

44. Another generic company and competitor, Ivax, was the first to file an ANDA for generic sertraline and challenge the '699 patent—thus making Ivax eligible for 180-day exclusivity, which is "triggered" by the earlier of first commercial marketing or a favorable court decision. Ivax's ANDA filing was an act of infringement that created the necessary subject matter jurisdiction for Pfizer to sue Ivax for infringement of the '699 patent, which Pfizer did in January 2000.

45. In May 2002, Pfizer and Ivax settled their litigation, with Ivax effectively conceding validity and infringement of the '699 patent in exchange for a royalty-bearing license. The settlement thus preserved Ivax's exclusivity and, consequently, acted to block approval of all other sertraline ANDAs, including Apotex's ANDA. As a result, by delaying suit against later ANDA applicants, again including Apotex, and bottlenecking the market with Ivax's exclusivity, Pfizer effectively extended its sertraline monopoly to the detriment to the public.

46. Like Ivax, Apotex also challenged and certified to the '699 patent. Apotex's submission of a paragraph IV certification constituted an act of infringement sufficient to create subject matter jurisdiction to resolve any questions regarding the infringement and validity of the '699 patent. Instead, Pfizer intentionally delayed suing Apotex to avoid a triggering court decision that would relieve the "bottleneck" in the market and allow Apotex to launch its product on the earliest lawful date.

47. Given Pfizer's strategy, Apotex filed a declaratory judgment action against Pfizer on April 1, 2004, in the Southern District of New York, pursuant to the MMA. This suit was the only way for Apotex to obtain patent certainty and immediate approval of its product in 2006, as Congress intended.

48. Pfizer moved to dismiss Apotex's suit for lack of subject matter jurisdiction. On December 30, 2004, the district court granted the motion, dismissing 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. *See Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187, 192-94 (S.D.N.Y. 2005). The district court specifically rejected Apotex's argument that application of the Federal Circuit's "reasonable apprehension" standard was unlawful (at least because it conflicts with controlling Supreme Court precedent) and that the MMA required that the court "employ the Article III case or controversy analysis applied in non-patent cases and in patent cases involving allegations of actual (as opposed to potential) infringement, requiring that 'there is (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision.'" *Id.* at 192 (citations omitted). Under this correct analysis, Apotex argued that Article III was satisfied because Pfizer had listed the '699 patent, thus asserting that a claim of patent infringement could reasonably be asserted against any unlicensed generic ANDA-filer like Apotex; that Apotex had challenged the '699 patent in its ANDA, thereby subjecting itself to suit; that Apotex was at risk of substantial financial losses having spent considerable sums preparing and filing its ANDA—an investment that could be lost if Pfizer were to mount a successful infringement action; that such losses would be even more substantial if Apotex's sertraline products were found to infringe *after* Apotex had launched its products; and that, absent a declaratory judgment, Apotex could be delayed from obtaining final FDA approval indefinitely, and at the very least by 180 days after Ivax were to market its own sertraline products.

49. The district court erred as a matter of law in failing to find subject matter jurisdiction over Apotex's claims for declaratory relief. Specifically, the district court committed *at least* the following legal errors: (1) the district court ignored the MMA and applied the Federal Circuit's judicially-created "reasonable apprehension" test as the sole standard for determining whether subject matter jurisdiction exists; (2) the district court erred by failing to consider whether Apotex satisfied the actual controversy requirement of Article III of the U.S. Constitution, regardless of any reasonable apprehension of suit; (3) the district court misapplied the Federal Circuit's reasonable apprehension test for determining the existence of subject matter jurisdiction; and (4) the district court misapplied controlling Supreme Court precedent regarding the actual controversy requirement of Article III.

50. The "reasonable apprehension" test applied by the district court was not then, is not now, and has never been, the controlling law for determining whether there is subject matter jurisdiction for a declaratory judgment action. As Congress intended, and 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 district court steadfastly refused to apply. There is no "reasonable apprehension" test in Article III, or in any Supreme Court precedent interpreting Article III. Indeed, in a recent Supreme Court decision interpreting the Article III case and controversy requirement in the context of a declaratory judgment suit involving another pharmaceutical patent, the Court held that, under its decades-old precedent, the *only* relevant inquiry is "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment"—*just as Apotex argued before the district court.* *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007) (internal

quotation marks and citation omitted) (holding that the reasonable apprehension test for subject matter jurisdiction is *not* and has never been the proper test); *see also Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1337 (Fed. Cir. 2007) (acknowledging that the reasonable apprehension of suit test violates prior Supreme Court precedent) (hereinafter, "*Novartis*"); *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1290 (Fed. Cir. 2008) (same) (citing *Novartis*). The district court blatantly violated Article III and decades of binding Supreme Court precedent by applying the unlawful "reasonable apprehension" test. The district court's multiple legal errors and unlawful decision is tantamount to a denial of justice as defined by international law and constitutes an expropriation of Apotex's investment.

51. Apotex duly appealed the decision of the district court to the Federal Circuit. On December 12, 2005, the Federal Circuit affirmed the district court's dismissal of Apotex's suit without opinion, presumably based on its prior decision in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005), which involved the same drug and virtually identical facts as Apotex's declaratory judgment suit, and which also applied the wrong justiciability standard. *See Apotex, Inc. v. Pfizer Inc.*, 159 F. App'x 1013, 2005 WL 3457408 (Fed. Cir. Dec. 12, 2005). In the *Teva* sertraline decision, the Federal Circuit held that a court may adjudicate a declaratory judgment action only if the generic competitor faces a reasonable apprehension of "imminent" suit by a brand-name manufacturer. *Teva*, 395 F.3d at 1333. The Federal Circuit's decision, moreover, explicitly and unlawfully elevated the reasonable apprehension test to a constitutional requirement. *Id.* at 1335. The Federal Circuit's decision nullified the statutory scheme of the MMA, and effectively and unlawfully re-wrote Article III of the U.S. Constitution.

52. In fact, the Government previously conceded as much in an *amicus* brief submitted to the Federal Circuit by the United States Federal Trade Commission ("FTC"), an administrative agency of the United States Government charged with promoting the efficient functioning of the marketplace and protecting consumer interests. The FTC filed a brief in the *Teva* sertraline case conceding and arguing, among other things, that the district court improperly applied the "reasonable apprehension" test, and that the district court had jurisdiction under Article III under facts identical to the *Apotex* case. Indeed, in its brief, the FTC argued that "it would be contrary to the purpose of the [MMA] to delay market entry by later applicants where the brand-name manufacturer and first ANDA applicant . . . have settled their litigation without resolving the issues of validity or infringement"—*exactly the facts as they stood in Apotex's case*. (Br. of Amicus Curiae FTC Supporting Appellant at 12, *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, No. 04-1186 (Fed. Cir.), available at http://www.ftc.gov/ogc/briefs/teva_v._pfizer.pdf.) The FTC argued that the district court erred in "fail[ing] to consider Teva's injury (as a subsequent ANDA applicant [like Apotex]) and Pfizer's conduct (as a brand-name manufacturer) within the context of Hatch-Waxman." (*Id.*) The FTC further stressed that the reasonable apprehension test applied by the district court "is ill-suited to evaluate an action brought by a subsequent ANDA applicant when that applicant *requires* a court decision so that it can get FDA approval to bring its product to market"—again, *exactly what Apotex required in the case of its own declaratory judgment action against Pfizer*. (*Id.*)

53. As noted both by Apotex and the FTC, the "reasonable apprehension of imminent suit" standard applied by the Federal Circuit cannot be reconciled with Supreme Court precedent, which holds that Article III requires no more than a redressible injury-in-fact traceable to the declaratory judgment defendant's conduct. *See MedImmune*, 127 S. Ct. at 771; *Novartis*,

482 F.3d at 1339. In fact, the Federal Circuit previously has been careful to note that its reasonable apprehension test is merely "useful" in declaratory judgment actions, *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988), and that "[s]atisfaction of this traditional two-part test is ***not*** . . . a prerequisite to jurisdiction in every possible patent declaratory judgment action" *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997) (emphasis added). Of course, the court unlawfully ignored all of this, here.

54. The Federal Circuit committed *at least* the following legal errors in affirming the dismissal of Apotex's declaratory judgment action against Pfizer: (1) ignoring the MMA and elevating its judicially-created "reasonable apprehension" test to a constitutional requirement for determining whether subject matter jurisdiction exists; (2) failing to consider whether Apotex satisfied the actual controversy requirement of Article III, regardless of any reasonable apprehension of suit; (3) misapplying prior Federal Circuit case law regarding the reasonable apprehension test for determining the existence of subject matter jurisdiction; and (4) ignoring controlling Supreme Court precedent regarding the actual controversy requirement of Article III. The blatant legal errors committed by the Federal Circuit also constitute a denial of justice as defined by international law and an expropriation of Apotex's investment.

55. Having been unsuccessful at the trial and appellate levels, Apotex submitted a petition for a writ of certiorari to the United States Supreme Court, seeking review of the Federal Circuit's decision. On October 10, 2006, the Supreme Court denied Apotex's petition for a writ of certiorari without comment. *Apotex Inc. v. Pfizer, Inc.*, 127 S.Ct. 379 (2006). The Supreme Court's refusal to even hear Apotex's appeal and remedy the grave legal errors committed by the district court and the Federal Circuit is tantamount to a denial of justice as defined by international law and constitutes an expropriation of Apotex's investment. This is

particularly so given the clear Supreme Court precedent in existence at the time the Court denied Apotex's petition establishing that the proper standard for determining whether a declaratory judgment action satisfies the Article III case or controversy requirement demands only that "there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). Moreover, the Supreme Court's denial of Apotex's petition permitted and enabled Pfizer to continue to bottleneck the generic market and delay approval of Apotex's ANDA based on a patent that was no longer enforceable against Apotex in any event, based on an unsolicited covenant not to sue provided by Pfizer in response to Apotex's petition.

56. As set forth above, the decisions of the United States District Court for the Southern District of New York, the Federal Circuit, and the Supreme Court have each violated the law and denied Apotex justice in violation of the controlling provisions of NAFTA. Each of these courts plainly misapplied statutory and constitutional law of the United States, as well as various decisions of the U.S. Supreme Court and the Federal Circuit. Indeed, the law and standards applied by the courts here against Apotex directly violate the MMA, Article III of the U.S. Constitution, and prior controlling Supreme Court precedent. *See, e.g., MedImmune,* 127 S. Ct. at 770-777 (holding that the so-called reasonable apprehension test for subject matter jurisdiction is *not* and has never been the proper test, that such test conflicts with prior controlling Supreme Court precedent in, among others, *Altvater v. Freeman*, 319 U.S. 359 (1943), and that a declaratory plaintiff need only demonstrate an "actual controversy" under Article III); *Md. Cas. Co.,* 312 U.S. at 273 (finding jurisdiction even though the declaratory judgment defendant could not have sued the declaratory-judgment plaintiff-insurer without first

obtaining a judgment against the insured); *Aetna Life Ins. Co. v. Haworth,* 300 U.S. 227, 239 (1937) (finding jurisdiction even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit); *Cardinal Chem. Co. v. Morton Int'l, Inc.,* 508 U.S. 83, 98 (1993) (holding that appellate affirmance of a judgment of noninfringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity); *see also Novartis*, 482 F.3d at 1337 (acknowledging that reasonable apprehension of suit test violates prior Supreme Court precedent and holding that the declaratory plaintiff need only satisfy Article III, which merely requires "[a] plaintiff [to] allege injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief"); *Caraco*, 527 F.3d at 1290 (noting that the Federal Circuit's "reasonable apprehension" test was overruled by *MedImmune* and finding declaratory judgment jurisdiction even in view of the NDA-holder's covenant not to sue); *Apotex, Inc. v. Novartis AG*, No. 3:06-cv-698, 2007 WL 5493499 at *3-*5 (E.D. Va. Sept. 4, 2007) (finding declaratory judgment jurisdiction in view of covenant not to sue because, among other things, the MMA was designed to relieve generic "bottleneck[s]"; that a declaratory plaintiff need only satisfy Article III, which requires only a "substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment"; and a generic applicant's inability to enter the market because of such bottlenecks "creates a justiciable case of actual controversy that fits squarely within this Court's original jurisdiction").

57. Further, because the decisions by the U.S. District Court for the Southern District of New York, the Federal Circuit, and the Supreme Court wrongfully prevented Apotex from obtaining a declaratory judgment of patent noninfringement or invalidity, Apotex was unable to promptly bring its generic sertraline products to the market, causing Apotex substantial

damages. More specifically, because these courts refused to hear Apotex's declaratory judgment action, Apotex was unable to obtain the court decision necessary to trigger Ivax's generic exclusivity period prior to the expiration of the '518 patent. As a result, Ivax launched its generic sertraline products with exclusivity, thereby obtaining—at Apotex's expense—the majority of the generic sertraline market share and a financial windfall by virtue of offering the sole generic alternative to Pfizer's Zoloft® tablets. Apotex estimates that it has consequently suffered lost sales and a loss in market share worth a total of at least $8,000,000 (US). For this additional reason, each of these court decisions constitutes a violation of at least Articles 1102, 1105, and 1110 of NAFTA.

CLAIMS FOR BREACHES OF NAFTA

Claim 1: Breach Of National Treatment Obligations Under Article 1102

58. Under NAFTA Article 1102, the United States is obligated to treat Apotex and its investments in a manner no less favorable than the treatment the United States accords to its own investors. NAFTA Article 1102 states:

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

59. Apotex, a privately-owned generic pharmaceutical company based in Canada, is an "investor of another Party," as defined in Article 1139, and 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.

60. The United States has breached its obligations to Apotex and its investments under Article 1102(1) and (2) by, among other things:

a. Unlawfully, arbitrarily and capriciously acting in a way that is inconsistent with the constitutional requirement for a justiciable case or controversy as required under Article III of the U.S. Constitution;

b. Unlawfully, arbitrarily and capriciously acting in a way that is inconsistent with well-established U.S. Supreme Court precedent interpreting the Article III case or controversy requirement;

c. Unlawfully, arbitrarily and capriciously acting in a way that is inconsistent with Congress's explicit direction that U.S. federal courts exercise jurisdiction over declaratory judgment actions, such as Apotex's suit against Pfizer, "to the extent consistent with the Constitution";

d. Unlawfully, arbitrarily and capriciously requiring Apotex to meet a *non*-constitutional prudential standard for subject matter jurisdiction, namely, the "reasonable apprehension of suit" test adopted by the Federal Circuit, as a matter of federal common law;

e. Unlawfully, arbitrarily and capriciously acting in a way that is inconsistent with the distinctions made by the Federal Circuit between a constitutional requirement and a prudential rule of subject matter jurisdiction;

f. Failing to treat Apotex in the same fashion as U.S. investors and failing to extend Apotex the protections and benefits afforded by Article III of the U.S. Constitution, despite the fact that the MMA applies equally to Canadian pharmaceutical drug companies seeking FDA approval to market a drug within the United States as it does to U.S. pharmaceutical drug companies; and

g. Failing to treat Apotex's substantial investment in the development and preparation of its ANDA for generic sertraline products in the same fashion as the investments of U.S. investors.

Claim 2: Breach Of Obligations of Minimum Standard of Treatment In Accordance With International Law Under Article 1105

61. Under NAFTA Article 1105, the United States is obligated to accord Apotex's investments the minimum standard of treatment under international law. NAFTA Article 1105 states:

> 1. Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security.
>
> * * *

62. Under settled principles of international law, a manifestly unjust judgment violates international law and may be described as a substantive "denial of justice." *See* Patrick M. McFadden, *Provincialism in United States Courts*, 81 CORNELL L. REV. 4, 31-32 & n.141 (1995) (citing Harvard Research in International Law, *The Law of Responsibility of States for Damage Done in Their Territory to the Person or Property of Foreignors*, Art. 9, 23 AM. J. INT'L L. 133 (Special Supp. 1929)); *see also* Loewen Group, Inc. (Can.) v. United States, ICSID (W. Bank) ARB(AF)/98/3 (June 26, 2003) (Award at ¶ 129).

63. The U.S. District Court for the Southern District of New York, the U.S. Court of Appeals for the Federal Circuit, and the U.S. Supreme Court violated Article 1105 by, among other things,

a. Rendering manifestly unjust decisions by misapplying constitutional, statutory, and common law relevant to the justiciability of declaratory judgment actions brought pursuant to the MMA;

b. Unlawfully, arbitrarily and capriciously acting in a way that is inconsistent with the constitutional requirement for a justiciable case or controversy as required under Article III of the U.S. Constitution;

c. Unlawfully, arbitrarily and capriciously acting in a way that is inconsistent with well-established U.S. Supreme Court precedent interpreting the Article III case or controversy requirement;

d. Unlawfully, arbitrarily and capriciously acting in a way that is inconsistent with Congress's explicit direction that U.S. federal courts exercise jurisdiction over declaratory judgment actions, such as that brought by Apotex against Pfizer, "to the extent consistent with the Constitution";

e. Unlawfully, arbitrarily and capriciously requiring Apotex to meet a *non*-constitutional prudential standard for subject matter jurisdiction, namely, the "reasonable apprehension of suit" test, adopted by the Federal Circuit, as a matter of federal common law; and

f. Unlawfully, arbitrarily and capriciously acting in a way that is inconsistent with the distinctions made by the Federal Circuit between a constitutional requirement and a prudential rule of subject matter jurisdiction.

Claim 3: Breach Of Obligations Prohibiting Expropriation Of Investment Under Article 1110

64. Under NAFTA Article 1110, the United States is prohibited from expropriating Apotex's investments under the circumstances at issue here. NAFTA Article 1110 states:

> 1. No 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 ("expropriation"), except:
>
> (a) for a public purpose;
>
> (b) on a non-discriminatory basis;
>
> (c) in accordance with due process of law and Article 1105(1); and

(d) on payment of compensation in accordance with paragraphs 2 through 6.

* * *

65. Under international law, expropriation occurs where government action unreasonably interferes with an alien's effective use or enjoyment of property. *See, e.g.,* RESTATEMENT (THIRD) FOREIGN RELATIONS LAW OF THE UNITED STATES § 712, cmt. g (1987); Metalclad Corp. v. United Mexican States, ICSID Case No. ARB(AF)/97/1 (Aug. 30, 2000) (Award at ¶ 103) ("[E]xpropriation under NAFTA includes not only open, deliberate and acknowledged takings of property . . . but also covert or incidental interference with the use of property which has the effect of depriving the owner, in whole or in significant part, of the use or reasonably-to-be-expected economic benefit of property even if not necessarily to the obvious benefit of the host State.").

66. Expropriation can occur where the State itself acquires nothing of value, but "at least has been the instrument of redistribution." A. MOURI, THE INTERNATIONAL LAW OF EXPROPRIATION AS REFLECTED IN THE WORK OF THE IRAN-U.S. CLAIMS TRIBUNAL 66 (1994) (citation omitted); *see also* Tecnicas Medioambientales Tecmed S.A. v. United Mexican States, ICSID Case No. ARB(AF)/00/2 (May 29, 2003) (Award at ¶ 113) ("the term [expropriation] also covers a number of situations defined as *de facto* expropriation, where such actions or laws transfer assets to third parties different from the expropriating State or where such laws or actions deprive persons of their ownership over such assets, without allocating such assets to third parties or to the Government") (citing Metalclad Award at ¶ 103).

67. The United States' conduct has violated Article 1110 for several reasons, including by:

a. Interfering with Apotex's property rights in its ANDA for generic sertraline tablets by unlawfully preventing Apotex from obtaining a federal court decision assessing the validity of Pfizer's '699 patent and Apotex's claims of noninfringement;

b. Substantially depriving Apotex of the benefits of its investments in its generic sertraline ANDA by delaying Apotex's eligibility for final approval; and

c. Unlawfully redistributing the financial benefits of Apotex's investment by preventing Apotex from obtaining final approval of its generic sertraline tablets immediately upon expiration of the '518 patent.

68. The United States has no "public purpose" for interfering with Apotex's property rights in its sertraline ANDA or for providing such huge windfalls to Ivax and Pfizer, as required by Article 1110(1)(a).

69. The Unites States, moreover, failed to provide Apotex with due process of law and treatment in accordance with Article 1105(1), as required by Article 1110(1)(c), by failing to extend Apotex the protections and benefits afforded by the U.S. Constitution and, in particular Article III, and by imposing upon Apotex a non-constitutional prudential requirement for subject matter jurisdiction in contradiction of well-established Supreme Court precedent.

70. In addition, Apotex has not been compensated for the damages it has suffered as a result of the United States' actions, as required by Article 1110(1)(d).

71. Apotex has incurred significant loss and damage as a result of the United States' conduct described herein, for which Apotex seeks compensation.

G. RELIEF SOUGHT AND DAMAGES CLAIMED

72. The aforementioned breaches of Section A of Chapter 11 of NAFTA have caused, and will continue to cause significant loss and damage to Apotex and its investments, for which Apotex requests the following relief:

(i) A declaration that the United States has breached its obligations under Chapter 11 of NAFTA and is liable to Apotex therefore;

(ii) An award of compensatory damages in an amount not less than $8,000,000.00 (US);

(iii) An award of any costs associated with these proceedings, including all professional fees and disbursements, and fees and expenses incurred to oppose the infringing measures;

(iv) An award of pre-award and post-award interest at a rate to be fixed by the Tribunal; and

(v) An award of any such further relief that the Tribunal may deem appropriate.

H. APPOINTMENT OF ARBITRATORS

73. Apotex proposes that this matter be adjudicated by three arbitrators, appointed in the manner set out in Article 1123 of NAFTA.

Dated: December 10, 2008

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United States Department of State
Room 5519
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CONSENT AND WAIVER

Apotex Inc. ("Apotex"), pursuant to Article 1121(1)(a) of the North American Free Trade Agreement ("NAFTA"), hereby consents to arbitration in accordance with the procedures set out in NAFTA and under the UNCITRAL Arbitration Rules.

Pursuant to Article 1121(1)(b) of NAFTA, Apotex hereby waives its right to initiate or continue before any administrative tribunal or court under the laws of any Party, or other dispute settlement procedures, any proceedings with respect to the measures of the Government of the United States which Apotex alleges to be breaches of NAFTA obligations referred to in Article 1116, except for proceedings for injunctive, declaratory, or other extraordinary relief, not involving the payment of damages, before an administrative tribunal or court under the laws of the United States.

Dated this 10th day of December, 2008.

APOTEX INC.

By: Shashank Upadhye / w/ permission by

Shashank Upadhye, Esq.
Vice President - Global Head of Intellectual Property
Apotex Inc.

CERTIFICATE OF SERVICE

I, William A. Rakoczy, hereby certify that I caused a copy of the foregoing APOTEX INC.'S NOTICE OF ARBITRATION to be served via FEDEX® (overnight delivery) upon the following this 10th day of December, 2008:

Government of the United States of America
Executive Director
Office of the Legal Advisor
United States Department of State
Room 5519
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Washington, D.C. 20520, USA

Attorney for Claimant/Investor
Apotex Inc.