

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

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BETWEEN:

**APOTEX INC.**

**Claimant,**

- AND -

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

**Respondent.**

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**STATEMENT OF CLAIMS**

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1. In accordance with Procedural Order No. 1, entered on December 16, 2010, and Article 18 of the Arbitration Rules of the United Nations Commission on International Trade Law (UNCITRAL), Claimant Apotex Inc. hereby respectfully submits its Statement of Claims with respect to both Apotex's Notice of Arbitration dated December 10, 2008 (hereinafter, the "first-filed claim" or the "Sertraline Claim") and Apotex's Notice of Arbitration dated June 4, 2009 (hereinafter, the "second-filed claim" or the "Pravastatin Claim").

**I. NAMES AND ADDRESSES OF THE PARTIES.**

2. Claimant, Apotex Inc., is a corporation duly incorporated and existing under the laws of Canada and having a principal place of business at:

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

3. Respondent, the Government of the United States of America, is a Party to NAFTA:

The Government of the United States of America  
c/o  
Office of the Assistant Legal Adviser  
for International Claims and Investment Disputes (L/CID)  
U.S. Department of State  
2430 E Street, N.W.  
Suite 203, South Building  
Washington, D.C. 20037-2800  
USA.

**II. ARBITRATION CLAUSE OR ARBITRATION AGREEMENT INVOKED.**

4. For both of Apotex's Arbitration Claims, 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.

5. Both of Apotex's Sertraline and Pravastatin Claims relate to the treatment accorded to Apotex by the Government of the United States of America, its Agencies and federal courts, 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.

**A. NAFTA ARTICLE 1102: NATIONAL TREATMENT.**

6. Under Article 1102 of NAFTA, 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. Article 1102, entitled "National Treatment," 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.

\* \* \*

7. "National treatment" is specifically mentioned as an example of the "principles and rules" that must be used to "elaborate[]" the objectives of NAFTA. NAFTA Article 102(1). Among other things, these objectives include the promotion of "conditions of fair competition in the free trade area" and to "provide adequate and effective protection and enforcement of

intellectual property rights in each Party's territory." *Id.* Article 102(2) mandates that any interpretation and application of NAFTA text must be undertaken "in the light of" these objectives. *Id.*

8. National treatment has been deemed a "fundamental obligation" of NAFTA, which bears analogies to its use in other international trade agreements, such as Article III of the General Agreement on Tariffs and Trade (GATT 1947). *Marvin Feldman v. Mexico*, NAFTA/ICSID Case No. ARB(AF)/99/1, Award at ¶ 165 (Dec. 16, 2002).

9. To determine whether a Party has breached its obligations under Article 1102 of NAFTA, the Tribunal should consider:

- (a) Whether the foreign investor has demonstrated that the Party accorded treatment to it with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments;
- (b) Whether the foreign investor or investment is in like circumstances with local investors or investments; and
- (c) Whether the NAFTA Party has treated the foreign investor or investment less favorably than it treats local investors or investments.

*See United Parcel Serv. Of Am., Inc. v. Gov't of Canada*, NAFTA/UNCITRAL, Award at ¶ 83 (May 24, 2007).

10. Moreover, when examining the third factor listed above, the *Feldman* Tribunal recognized that, by its plain terms, a breach under Article 1102 of NAFTA does not require a showing that the Party's treatment of the investor be a result of the investor's nationality, but

merely that the Party accorded “less favorable treatment for the foreign investor than for domestic investors in like circumstances.” Feldman, Award at ¶ 181.

**B. NAFTA ARTICLE 1105: MINIMUM STANDARD OF TREATMENT.**

11. Under Article 1105 of NAFTA, the United States is obligated to accord Apotex’s investments fair and equitable treatment and meet the minimum standard of treatment under international law. 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.

\* \* \*

12. Under settled principles of international law, a manifestly unjust judgment violates international law and is 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 Foreigners*, Art. 9, 23 AM. J. INT’L L. 133, 173 (Special Supp. 1929)); *see also* Loewen Group, Inc. (Can.) v. United States, NAFTA/ICSID Case No. ARB(AF)/98/3, Award at ¶ 129 (June 26, 2003).

13. In determining whether a “denial of justice” has occurred in the context of domestic court decisions, tribunals have considered “whether, at an international level and having regard to generally accepted standards of the administration of justice, a tribunal can conclude in the light of all the available facts that the impugned decision was clearly improper and discreditable, with the result that the investment has been subjected to unfair and inequitable treatment.” *Waste Mgmt., Inc. v. United Mexican States*, NAFTA/ICSID Case No.

ARB(AF)/00/3, Award at ¶ 95 (April 30, 2004) (citing *Mondev Int'l Ltd. v. United States*, NAFTA/ICSID Case No. ARB(AF)/99/2, Award at ¶ 127 (Oct. 11, 2001)).

14. Bad faith or malicious intent is not required for a finding of unfair and inequitable conduct or of a denial of justice amounting to a breach of international justice. *Waste Mgmt.*, Award at ¶ 97 (citing *Loewen*, Award at ¶ 132).

15. When analyzing the “fair and equitable treatment” requirement under Article 1105, Tribunals must consider a number of different components, including at least: 1) protection of the investor’s reasonable and legitimate expectations; 2) transparent and consistent conduct by the Party; and 3) good faith by the parties, though bad faith on behalf of the Party is not required. *See generally* *Biwater Gauff (Tanzania) Ltd. v. United Republic of Tanzania*, ICSID Case No. ARB/05/22, Award at ¶ 602 (July 24, 2008) (citing *Waste Mgmt.*, Award at ¶ 95).

16. Among other things, foreign investors expect, and Article 1105 demands, that the Party must act consistently, *i.e.*, without arbitrarily revoking any preexisting decisions issued by the Party that were relied upon by the investor. *LG&E Energy Corp. et al. v. Argentine Republic*, ICSID Case No. ARB/02/1, Decision on Liability at ¶¶ 127-28 (Oct. 3, 2006). The failure to ensure a transparent and predictable framework and the absence of a clear rule amounts to a failure of the State to ensure the transparency required by NAFTA. *Metalclad Corp. v. United Mexican States*, NAFTA/ICSID Case No. ARB(AF)/97/1, Award at ¶¶ 87-88 (Aug. 30, 2000); *LG&E*, Award at ¶ 128.

17. While the fair and equitable treatment standard generally recognizes that the contracting parties act in good faith, a violation of Article 1105 does not require that the Party’s conduct complained of be outrageous, egregious in bad faith, a willful neglect of duty or

otherwise extraordinary. Waste Mgmt., Award at ¶ 93; *see also* Pope & Talbot, Inc. v. Gov't of Canada, NAFTA/ICSID Award on the Merits of Phase 2 at ¶ 118 (April 10, 2001).

**C. NAFTA ARTICLE 1110: EXPROPRIATION AND COMPENSATION.**

18. Under Article 1110 of NAFTA, the United States is prohibited from expropriating Apotex's investments. 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.

\* \* \*

19. 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, 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.").

20. Expropriation covers a number of situations, including those 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.” *Tecnicas Medioambientales Tecmed S.A. v. United Mexican States*, ICSID Case No. ARB(AF)/00/2, Award at ¶ 113 (May 29, 2003). Indirect *de facto* expropriation may occur through actions or conduct which do not explicitly express the purpose of depriving one of rights or assets, but actually has that effect. *Id.* at ¶ 114. The *effects* of relevant acts, not just the intention behind the acts, are important in the context of indirect expropriation. *Biwater*, Award at ¶ 463.

21. Moreover, “[i]f there is a finding of expropriation, compensation is required, *even if* the taking is for a public purpose, non-discriminatory and in accordance with due process of law and Article 1105(1).” *Feldman*, Award at ¶ 98 (emphasis in original).

### **III. STATUTORY BACKGROUND PERTAINING TO BOTH ARBITRATION CLAIMS.**

22. As an initial matter, as indicated in Procedural Order No. 1, Apotex withdrew its application to stay its second-filed Notice of Arbitration dated June 4, 2009, without prejudice or waiver of its right to reintroduce that application after resolution of any jurisdictional issues. While Apotex maintains that the two arbitrations are in fact comprised of two separate and independent claims that should not be consolidated or heard concurrently for merits purposes, for convenience and to avoid duplication, the following section provides the general background common to both arbitration claims, together with the particular statutory background and provisions relevant to each specific claim. In doing so, Apotex in no way waives its right to reintroduce its application to stay the second-filed Pravastatin Claim after the resolution of any

jurisdictional issues, nor does Apotex otherwise concede that the two arbitration claims should be heard together for merits purposes.

### ***General Statutory Background***

23. Apotex develops and manufactures quality generic drugs, including solid oral dosage forms such as capsules and tablets. In connection therewith, Apotex invests millions of dollars in designing and formulating its proposed drug products, procuring or manufacturing the active pharmaceutical ingredients for such products, preparing and filing applications with the U.S. Food and Drug Administration (“FDA”) seeking approval to market and sell its drug products in the United States, and manufacturing the finished drug products.

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. Under the FFDCA, a company that seeks to sell a new or previously unapproved drug must file with the FDA a New Drug Application (“NDA”). The applicant must include in its NDA, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results establishing its safety and effectiveness, and labeling describing the use for which approval is requested. *See* 21 U.S.C. § 355(b)(1). The NDA applicant also must submit information to FDA with respect to any patent that “claims the drug for which the applicant submitted the application or which claims a method of using such drug and with

respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2).

26. 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.

27. Additionally, prior to 1984, a company seeking to market a generic version of an FDA approved drug had to complete expensive and time-consuming safety and efficacy studies on the drug, even though the NDA-holder had already established the drug’s safety and efficacy through its own studies.

28. Congress simplified the procedure for obtaining approval of lower-priced generic drugs with the Hatch-Waxman Amendments to the FDCA. Congress enacted Hatch-Waxman (and later the MMA), to amend the FDCA to provide 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. These Amendments permit a generic drug

company to file an abbreviated drug new application (“ANDA”) that relies on information from the NDA.

29. A company seeking to market a generic drug product must file an ANDA. Instead of repeating the comprehensive, extensive clinical studies of safety and efficacy conducted for the previously-approved NDA drug, a generic applicant submitting an ANDA is required to establish, among other details, that its proposed generic product is bioequivalent to the already-approved NDA drug and that it has the same active ingredient, dosage form, dosage strength, route of administration, and labeling (with certain exceptions) as the approved NDA drug. 21 U.S.C. § 355(j)(2)(A).

30. In addition to creating a regulatory approval pathway, the Hatch-Waxman Amendments also created a special, expedited mechanism for resolving patent disputes before a generic drug is commercialized to increase generic competition for pharmaceutical drug products. To that end, as part of its NDA, a brand company is required to submit information regarding each patent that claims the drug or a 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”).

31. 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 version of the NDA drug. 21 U.S.C. §§ 355(b)(1), (c)(2).

32. 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.

33. An ANDA applicant is required, *inter alia*, to address each patent listed in the Orange Book in connection with the approved NDA drug. Specifically, the ANDA must include a "certification" to any properly-listed Orange Book patents. *See* 21 U.S.C. § 355(j)(2)(A)(vii). The statute provides four certification options, two of which are relevant here: the so-called "paragraph III" certification, where the applicant certifies that it will not market until after the listed patent has expired, and the so-called "paragraph IV" certification, where the applicant seeks immediate approval because the listed patent is invalid and/or not infringed by the proposed ANDA product. *Id.* Where an ANDA applicant submits a paragraph IV certification, it must notify the patentee and NDA-holder of the factual and legal bases for that certification. *See id.* § 355(j)(2)(B).

34. If the ANDA applicant seeks approval prior to patent expiration, it submits a paragraph IV certification. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The submission of a paragraph IV certification has two important effects.

35. *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 of the generic drug; or (2) a court decision of noninfringement or invalidity by *any* filer in *any* action. 21 U.S.C. § 355(j)(5)(B)(iv) (2002).<sup>1</sup> 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, e.g., 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.

36. *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 Orange Book-listed patent prior to the actual launch and commercialization 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.

#### ***Sertraline Claim: Statutory Background***

37. Relevant specifically to Apotex’s Sertraline Claim are the statutory provisions directed to an ANDA applicant’s ability to file and maintain a declaratory judgment action for patent noninfringement, invalidity, and/or unenforceability. As an incentive for brand companies to bring suit, Hatch-Waxman prohibits FDA from approving a paragraph IV ANDA for 30

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<sup>1</sup> Citations to 21 U.S.C. § 355(j)(5)(B)(iv) refer to Hatch-Waxman as it existed prior to the passage of the MMA, which amended, among others, the exclusivity provisions of the statute. The changes to the 180-day exclusivity provision implemented by the MMA were prospective only and do not apply to either of Apotex’s sertraline and pravastatin ANDAs, both of which were filed before December 8, 2003.

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, the statute 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)(C).

38. Specifically, 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). 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).

39. Congress directed the federal courts to exercise subject matter jurisdiction over such declaratory judgment actions to the maximum extent permitted by the U.S. 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) (emphasis added).

40. 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 (Nov. 25, 2003). 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.*

41. 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)).

### ***Pravastatin Claim: Statutory Background***

42. Relevant specifically to Apotex's Pravastatin Claim is the statutory court-decision trigger for 180-day generic exclusivity. Courts have interpreted the court decision trigger broadly. For instance, the court decision trigger includes *any* court decision on the patent that is the subject of the paragraph IV certification, regardless of whether the first-filer is involved in that particular litigation. *See Granutec, Inc. v. Shalala*, 139 F.3d 889, 1998 WL 153410, at \*5, \*10 (4th Cir. Apr. 3, 1998) (finding exclusivity triggered by a court decision involving a subsequent applicant); *Teva*, 182 F.3d at 1005 n.3 (same).

43. The court decision trigger also encompasses a broad spectrum of decisions, including decisions of patent unenforceability, despite the absence of this ground in the express language of the statute, and the grant of partial summary judgment based on the patentee's admission of noninfringement. *See Teva*, 182 F.3d at 1009; 21 C.F.R. § 314.107(c)(1)(ii); *Granutec*, 1998 WL 153410, at \*5, \*8 n.2.

44. Additionally, and as explained in more detail in Section V.A., below, the U.S. Court of Appeals for the District of Columbia Circuit has held that the dismissal of a declaratory judgment action for lack of subject matter jurisdiction can constitute a "court decision" for purposes of triggering generic exclusivity, if the dismissal estops the patentee from subsequently asserting that the ANDA product infringes the patent-in-suit. *See Teva*, 182 F.3d at 1009-10 (holding that "[t]o start, or trigger, the period of market exclusivity by a 'court decision,' an ANDA applicant need only obtain a judgment that has the effect of rendering the patent invalid or not infringed with respect to itself").

#### **IV. APOTEX'S SERTRALINE CLAIM.**

##### **A. STATEMENT OF FACTS SUPPORTING APOTEX'S SERTRALINE CLAIM.**

45. On October 27, 2003, Apotex submitted an ANDA seeking FDA approval for a generic version of Pfizer Inc.'s popular antidepressant medication, Zoloft<sup>®</sup>, known generically as sertraline hydrochloride. Apotex invested more than \$1,000,000 in formulating and developing a generic version of Zoloft<sup>®</sup> (sertraline hydrochloride) tablets in 25 mg, 50 mg, and 100 mg strengths. As part of its generic drug application, Apotex was statutorily required to address and certify to any patents listed by Pfizer as purporting to claim the approved use of Zoloft<sup>®</sup> Tablets, or the approved product itself.

46. Pfizer submitted information on several patents to FDA for listing in the Orange Book in connection with Zoloft<sup>®</sup>, including U.S. Patent Nos. 4,356,518 ("the '518 patent") and 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 sertraline product prior to the expiration of these patents.

47. Another generic company and competitor, Ivax Corporation ("Ivax"), was the first applicant to file an ANDA for generic sertraline containing a paragraph IV certification to a listed patent—the '699 patent—thus making Ivax eligible for 180-day 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. Ivax submitted a paragraph III certification to the '518 patent, indicating that it would not seek approval until that patent expired in June 2006.

48. 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.

49. Like Ivax, Apotex also filed a paragraph IV certification to the '699 patent and a paragraph III certification to the '518 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. Yet, instead of filing suit against Apotex, as it did with Ivax, Pfizer intentionally delayed suing Apotex (and all other sertraline ANDA filers) to avoid a triggering court decision that would trigger Ivax's exclusivity and relieve the "bottleneck" in the market, thus allowing Apotex to launch its product on the earliest lawful date.

50. Given Pfizer's strategy, Apotex filed a declaratory judgment action against Pfizer on April 1, 2004, in the United States District Court for 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.

51. 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.

52. 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 of the U.S. Constitution.

53. 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). The district court blatantly violated Article III and decades of binding Supreme Court precedent by applying the unlawful “reasonable apprehension” test.

54. 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 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.

55. In fact, the United States 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](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) 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”—*which is also what Apotex required in the case of its own declaratory judgment action against Pfizer. (Id.)*

56. 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, e.g., MedImmune*, 127 S. Ct. at 771. In fact, the Federal Circuit previously has been careful to note that its reasonable apprehension test is merely “useful” in declaratory judgment actions, 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.

57. 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 of the U.S. Constitution.

58. 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 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 due to Pfizer's covenant not to sue.

59. 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<sup>®</sup> tablets.

## **B. PROCEDURAL BACKGROUND**

60. 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.

61. Pursuant to Article 1120 of NAFTA, Apotex filed its Sertraline Notice of Arbitration on December 10, 2008, which Respondent received on December 11, 2008—more

than six months after the events giving rise to Apotex's claim, and not more than three years after 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.

**C. POINTS AT ISSUE: NAFTA ARTICLES BREACHED RELATING TO APOTEX'S SERTRALINE CLAIM**

62. 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.

**Claim 1: Breach Of National Treatment Obligations Under Article 1102**

63. Under Article 1102 of NAFTA, 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. 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.

\* \* \*

64. The United States has breached its obligations to Apotex and its investments under Article 1102(1) and (2).

65. The unlawful, arbitrary and capricious actions of the United States, by way of the U.S. federal courts, including the U.S. District Court for the Southern District of New York, the U.S. Court of Appeals for the Federal Circuit, and the U.S. Supreme Court, wrongfully prevented Apotex from obtaining a declaratory judgment of patent noninfringement or invalidity, which in turn prevented Apotex from promptly bringing its generic sertraline products to the market and caused Apotex substantial damages, in violation of Article 1102 of NAFTA.

66. By preventing Apotex from maintaining its declaratory judgment action, the U.S. federal courts unlawfully, arbitrarily and capriciously acted in a manner that was (1) inconsistent with and violated the constitutional requirement for a justiciable case or controversy as required under Article III of the U.S. Constitution; (2) inconsistent with and violated well-established U.S. Supreme Court precedent interpreting the Article III case or controversy requirement; and (3) inconsistent with and violated Congress's explicit direction that the U.S. federal courts exercise jurisdiction over declaratory judgment actions, such as Apotex's suit against Pfizer, "to the extent consistent with the Constitution." Additionally, the U.S. federal courts acted unlawfully, arbitrarily and capriciously by 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.

67. The actions of the United States, through the U.S. federal courts, breached Article 1102 by, among other things, according treatment to Apotex that was less favorable than that provided to U.S. investors and investments. By way of example only, Apotex's substantial

investment in the development and preparation of its ANDA for generic sertraline products was not treated in the same fashion as the investments of certain other U.S. investors, such as MedImmune, Inc., headquartered in Maryland, U.S.A., who was able to bring and maintain a declaratory judgment action in similar circumstances. *See MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007). The United States failed 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.

68. For these and other reasons, the United States breached its obligations under Article 1102 of NAFTA.

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

69. Under Article 1105 of NAFTA, the United States is obligated to accord Apotex's investments fair and equitable treatment and meet the minimum standard of treatment under international law. 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.

\* \* \*

70. The actions of the United States, through the decisions of U.S. federal courts, breached Article 1105 by rendering manifestly unjust, improper, and unlawful decisions that misapplied constitutional, statutory, and common law relevant to the justiciability of declaratory judgment actions, which denied Apotex fair and equitable treatment and violated the minimum standard of treatment under international law. The U.S. federal court decisions were inconsistent

with and violated the constitutional case or controversy requirement under Article III of the U.S. Constitution and well-established U.S. Supreme Court precedent interpreting the Article III case or controversy requirement, and amount to a denial of justice.

71. The United States, through the decisions of U.S. federal courts, unjustly, arbitrarily, and improperly acted in a way that was inconsistent with and violated 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." The U.S. federal courts unfairly and inequitably required 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, which also amounts to a denial of justice.

72. The United States' actions prevented Apotex from promptly bringing its generic sertraline products to the market and caused Apotex substantial damages, in violation of Article 1105 of NAFTA.

73. For these and other reasons, the United States breached its obligations under Article 1105 of NAFTA.

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

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

\* \* \*

75. The United States, through the actions of the United States federal courts, including the U.S. District Court for the Southern District of New York, the Federal Circuit, and the Supreme Court, interfered with and expropriated Apotex's property rights in its ANDA for generic sertraline tablets, in violation of Article 1110 of NAFTA. Apotex's inability to maintain a declaratory judgment action to assess the validity of Pfizer's '699 patent and Apotex's claims of noninfringement, because of the unlawful, wrongful, and improper actions of the U.S. federal courts, substantially deprived Apotex of the benefits of its investments in its generic sertraline ANDA by unlawfully redistributing the financial benefits of Apotex's investment to the patentee and another sertraline ANDA filer, and by preventing Apotex from obtaining final approval of its generic sertraline tablets immediately upon expiration of the '518 patent.

76. 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.

77. The United 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.

78. 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).

79. Apotex has incurred significant loss and damage as a result of the United States' conduct described herein.

80. For these and other reasons, the United States breached its obligations under Article 1110 of NAFTA.

\* \* \* \* \*

81. Apotex reserves all rights to assert additional bases for its Sertraline Claim against the United States.

**D. RELIEF SOUGHT AND DAMAGES CLAIMED RELATING TO APOTEX'S SERTRALINE CLAIM.**

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

- a. A declaration that the United States has breached its obligations under Chapter 11 of NAFTA and is liable to Apotex therefore;
- b. An award of compensatory damages in an amount not less than \$8,000,000.00 (US);
- c. 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;
- d. An award of pre-award and post-award interest at a rate to be fixed by the Tribunal; and

- e. An award of any such further relief that the Tribunal may deem appropriate.

## **V. APOTEX'S PRAVASTATIN CLAIM.**

### **A. STATEMENT OF FACTS SUPPORTING APOTEX'S PRAVASTATIN CLAIM.**

83. Apotex's Pravastatin Claim involves the prescription heart medication pravastatin sodium tablets, marketed by Bristol Myers Squibb ("BMS") under the brand-name Pravachol<sup>®</sup>.

84. On December 21, 2001, Apotex submitted an ANDA seeking FDA approval for a generic version of Pravachol<sup>®</sup>. At the time Apotex filed its ANDA, BMS had submitted information on four patents for listing in FDA's Orange Book in connection with Pravachol<sup>®</sup>: U.S. Patent Nos. 4,346,227 ("the '227 patent"), 5,030,447 ("the '447 patent"), 5,180,589 ("the '589 patent"), and 5,622,985 ("the '985 patent"). By listing these patents, BMS affirmatively represented that a suit for infringement could reasonably be asserted against any generic pravastatin manufacturer, including Apotex.

85. Teva Pharmaceuticals USA, Inc. ("Teva") purportedly was the first generic applicant to submit a paragraph IV ANDA for generic pravastatin tablets, 10 mg, 20 mg, and 40 mg, and Ranbaxy Laboratories Limited ("Ranbaxy") was purportedly the first generic applicant to submit a paragraph IV ANDA for generic pravastatin tablets in the 80 mg strength. As a result, Teva and Ranbaxy were eligible for 180-day exclusivity for these products. Based on public documents, both Teva and Ranbaxy filed paragraph IV certifications to certain of the patents, along with a paragraph III certification to the '227 patent, thus indicating that neither would seek final FDA approval until the '227 patent and its corresponding period of pediatric exclusivity expired on April 20, 2006. BMS did not sue either company.

86. Apotex's pravastatin sodium ANDA contains paragraph IV certifications to the '447, '589, and '985 patents, and a paragraph III certification to the '227 patent. Consequently, FDA could not approve Apotex's ANDA until April 20, 2006, when the '227 patent and its associated pediatric exclusivity expired.

87. As required under the statute, Apotex provided BMS with notice of its pravastatin sodium ANDA and its paragraph IV certifications. But BMS, without comment or explanation, refrained from suing Apotex for infringement of the '447, '589 and '985 patents.

88. Merely because BMS initially refused to sue Apotex did not mean that Apotex could launch its products without fear from infringement liability. BMS still had the right and ability to sue Apotex when Apotex launched its generic products. Thus, Apotex could not market its products without fear of infringement liability and significant, if not catastrophic, monetary damages—damages far exceeding Apotex's sales—and an injunction prohibiting future marketing.

89. In order to obtain patent certainty without court intervention, Apotex repeatedly tried to obtain assurances from BMS that it would not sue Apotex for infringement of the '447, '589, and '985 patents. When BMS would not sign a binding covenant not to sue Apotex for infringement of these listed patents, Apotex filed a declaratory judgment action in the United States District Court for the Southern District of New York in order to attempt to secure a binding court order that would provide a "perfected" preclusive effect, estopping BMS from suing Apotex upon commercial launch of its generic product.

90. BMS moved to dismiss Apotex's declaratory judgment action for lack of subject matter jurisdiction on the basis that Apotex lacked a reasonable apprehension of suit in light of

BMS's binding representations, contained in filed court papers and a sworn declaration, that it would not sue Apotex for infringement of the '447, '589, and '985 patents.

91. While the district court did not rule on BMS's motion, the court ultimately did enter an Order dismissing Apotex's declaratory judgment action based upon BMS's binding representations that it would not sue Apotex. (Stipulation and Order, *Apotex Inc. v. Bristol-Myers-Squibb Co.*, No. 04-cv-2922 (S.D.N.Y. July 23, 2004)). The district court's dismissal order became final and unappealable on August 22, 2004.

92. On September 7, 2004, Apotex wrote to FDA, seeking confirmation that the dismissal of its declaratory judgment action against BMS triggered any generic exclusivity that would be awarded for pravastatin, such that Apotex's own ANDA would be eligible for full and final approval once the '227 patent expired in April 2006.

93. On June 28, 2005, FDA responded to Apotex's letter, confirming that exclusivity for all strengths of pravastatin expired no later than February 18, 2005, having been triggered by the dismissal of Apotex's declaratory judgment action. (6/28/2005 FDA Ltr., G. Buehler to W. Rakoczy). FDA further concluded that Apotex's pravastatin ANDA would be eligible for immediate final approval on April 20, 2006. (*Id.* at 2).

94. FDA's decision explicitly relied on controlling federal court decisions involving the drug ticlopidine and the same filers for pravastatin—Teva and Apotex—in which the U.S. Court of Appeals for the District of Columbia Circuit found that the dismissal of Teva's declaratory judgment action for lack of subject matter jurisdiction, based on the patent holder's disavowal of an intent to sue, constituted a triggering court decision.

95. In that case, Apotex was the first generic filer for ticlopidine and therefore was eligible for 180-day generic exclusivity. Teva filed a declaratory judgment action against the

patentee (Syntex) in order to obtain patent certainty, and obtained a dismissal that precluded the patentee from suing for infringement damages. FDA subsequently refused to recognize the dismissal of Teva's declaratory judgment action as a triggering court decision, and Teva challenged the Agency's refusal.

96. The district court sided with FDA, holding that the dismissal order did not fall within the plain language of the statute. On appeal, however, the U.S. Court of Appeals for the District of Columbia Circuit reversed and remanded, finding FDA's decision arbitrary and capricious. *Teva*, 182 F.3d at 1012. The Circuit Court explained that "the [Teva-Syntex] dismissal appears to meet the requirements of a triggering 'court decision' because that court had to make a predicate finding with respect to whether Syntex would ever sue Teva for infringement in order to conclude that there was no case or controversy between the parties." *Id.* at 1009. The Court further noted that "[a]lthough the dismissal was not a judgment on the merits after consideration of evidence presented by the parties, there was no need for such a procedure here because the dismissal sufficed to estop Syntex from suing Teva for patent infringement. This is the result that appears to be the purpose of the triggering 'court decision' provision." *Id.* (internal citations omitted). The Court went on to hold that "it is unclear that a triggering 'court decision' need explicitly hold the patent at issue is 'invalid' or is 'not infringed' in order to trigger the 180-day period of market exclusivity," noting that both FDA and the Federal Circuit recognize that a decision that a patent is "unenforceable" also suffices as a "court decision," even though the statute says only if the patent is "invalid" or "will not be infringed." *Id.* The Court also demanded that FDA explain on remand how it could reasonably treat a partial summary judgment ruling differently from a dismissal with estoppel effect "[g]iven that [the dismissal

order] supports estoppel to the same extent as the grant of partial summary judgment at issue in *Granutec* . . . .” *Id.* at 1011.

97. On remand, FDA attempted to justify its disparate treatment of the *Granutec* order and the Teva-Syntex dismissal by arguing that *Granutec* involved a decision on the “actual merits” of patent noninfringement, whereas the dismissal for lack of subject matter jurisdiction did not. The Agency again refused to treat the Teva-Syntex dismissal as a court decision trigger because it “did not state on its face that the underlying patent was not infringed and that refusing to look beyond the face of the order served goals of administrative convenience.” *Teva Pharms. USA, Inc. v. FDA*, 254 F.3d 316, 2000 WL 1838303, at \*1 (D.C. Cir. Nov. 15, 2000).

98. The district court rejected FDA’s explanation, finding that the D.C. Circuit had already squarely rejected this argument, and entered a permanent injunction in favor of Teva, which the D.C. Circuit upheld. *Teva Pharms. USA, Inc. v. FDA*, No. Civ.A. 99-67, 1999 WL 1042743, at \*5-6 (Aug. 19, 1999) (holding that “the purpose of the court decision trigger is to ensure that the patent-holder is estopped from suing the ANDA applicant,” and noting that the D.C. Circuit found that “the significance of a triggering court decision lies in its estoppel effect”), *aff’d by Teva*, 254 F.3d 316, 2000 WL 1838303, at \*1-2 (noting that a dismissal for lack of subject matter jurisdiction based on a patent holder’s disavowal of an intent to sue “supports estoppel to the same extent as the grant of partial summary judgment” (quoting *Teva*, 182 F.3d at 1011)). As a result, Apotex’s 180-day exclusivity period for ticlopidine was triggered and expired without Apotex being able to enjoy it.

99. Applying the *Teva*/ticlopidine decision to the facts at issue in the pravastatin matter, FDA observed that the New York court dismissed Apotex’s suit only after BMS represented that it did not intend to sue Apotex for infringement of the ‘447, ‘589, and ‘985

patents, and further observed that the order, coupled with BMS's representations, precluded a subsequent suit by BMS against Apotex for infringement of these patents. (6/28/2005 FDA Ltr., G. Buehler to W. Rakoczy at 4-5). In light of the controlling legal authorities, FDA concluded that, under the rule established in the ticlopidine matter, the BMS-Apotex dismissal qualified as a court decision under the statute, triggering the 180-day exclusivity period for pravastatin. (*Id.*).

100. After FDA issued its pravastatin decision, Teva challenged the Agency's ruling in the U.S. District Court for the District of Columbia. Teva argued that the BMS-Apotex dismissal did not trigger the 180-day generic exclusivity period for pravastatin, and sought a preliminary injunction and judgment on the merits preventing Apotex and other generic companies from marketing their products. Apotex intervened and opposed Teva's motion.

101. On October 21, 2005, the District Court for the District of Columbia granted Teva's motion. *See Teva Pharms. USA, Inc. v. FDA*, 398 F. Supp. 2d 176, 191-92 (D.D.C. 2005). Apotex sought to stay the injunction pending an appeal of the district court's decision, but the court denied Apotex's motion on December 8, 2005. *See Teva Pharms. USA, Inc. v. FDA*, 404 F. Supp. 2d 243, 246 (D.D.C. 2005). Thus, Apotex was prevented from both obtaining final approval for, and marketing, its pravastatin product upon expiration of the '227 patent in April 2006.

102. On appeal, the U.S. Court of Appeals for the District of Columbia Circuit held that FDA's June 28, 2005 decision was arbitrary and capricious because the Agency had not properly explained the reasoning behind its decision. *See Teva Pharms USA, Inc. v. FDA*, 441 F.3d 1, 5 (D.C. Cir. 2006). While the D.C. Circuit expressed no opinion on what actually constitutes a triggering court decision under the statute, the Court instructed the district court to vacate FDA's June 28, 2005 decision and remand to the Agency for further proceedings. *See id.*

103. On April 11, 2006, FDA issued its second administrative decision pertaining to the issue of 180-day exclusivity for pravastatin sodium tablets. In that decision, FDA reversed itself and, contrary to its prior ticlopidine precedent, determined that the BMS-Apotex dismissal was insufficient to trigger the 180-day exclusivity for pravastatin. (4/11/2006 FDA Ltr., G. Buehler to T. McIntire). FDA determined that only a decision of a court holding on the merits that a particular patent is invalid, not infringed, or unenforceable would suffice to trigger the 180-day exclusivity period, and that such holding must be evidenced by language on the face of the court's decision. (*Id.* at 2, 15). In short, without any reasoned basis, FDA completely flip-flopped from its prior determination and adopted the same statutory interpretation that was previously rejected in the ticlopidine matter. Indeed, the Agency admitted that, under its statutory interpretation, the *Teva/ticlopidine* dismissal would not constitute a court decision trigger. (*Id.* at 12).

104. Apotex challenged FDA's April 11, 2006 decision in the U.S. District Court for the District of Columbia, moving for immediate injunctive relief setting aside the Agency's administrative ruling and enjoining FDA from awarding 180-day exclusivity for pravastatin. Apotex argued that the Agency's decision was contrary to Hatch-Waxman and the FDCA, and conflicted with controlling precedent from the D.C. Circuit in the ticlopidine line of cases, wherein the court previously rejected the Agency's holding-on-the-merits approach and its failed attempt to differentiate between the dismissal for lack of subject matter jurisdiction and the *Granutec* partial summary judgment order, given that both orders have the same preclusive effect. The district court denied Apotex's motion on April 19, 2006. *See Apotex, Inc. v. FDA*, No. Civ.A. 06-0627, 2006 WL 1030151, at \*19 (D.D.C. Apr. 19, 2006).

105. Apotex appealed and Teva moved for summary affirmance of the district court's decision. On June 6, 2006, the U.S. Court of Appeals for the District of Columbia Circuit affirmed the district court's order. *Apotex, Inc. v. FDA*, 449 F.3d 1249, 1254 (D.C. Cir. 2006). Apotex moved for rehearing *en banc*, which was denied on August 17, 2006. *Id.*, *reh'g en banc denied* (Aug. 17, 2006). In light of the D.C. Circuit's order, and the fact that Teva's exclusivity for pravastatin would expire before Apotex's suit could be resolved on the merits, Apotex voluntarily dismissed its claim.

106. As set forth above, the decisions of FDA, the U.S. District Court for the District of Columbia, and the U.S. Court of Appeals for the District of Columbia Circuit have each violated U.S. statutory law and prior controlling precedent. *See, e.g., Teva*, 182 F.3d at 1009-10 (holding that “[t]o start, or trigger, the period of market exclusivity by a ‘court decision,’ an ANDA applicant need only obtain a judgment that has the effect of rendering the patent invalid or not infringed with respect to itself,” and that the dismissal of Teva's declaratory judgment action for lack of subject matter jurisdiction “appear[ed] to meet the requirements of a ‘court decision’ under § 355(j)(5)(B)(iv)(II)”); *Teva*, 254 F.3d 316, 2000 WL 1838303, at \*1-2 (noting that a dismissal for lack of subject matter jurisdiction based on a patent holder's disavowal of an intent to sue “supports estoppel to the same extent as the grant of partial summary judgment at issue in *Granutec*” (quoting *Teva*, 182 F.3d at 1011)); *Teva*, 1999 WL 1042743, at \*5-6 (noting that “the purpose of the court decision trigger is to ensure that the patent-holder is estopped from suing the ANDA applicant,” and that the D.C. Circuit found that “the significance of a triggering court decision lies in its estoppel effect”); *Granutec*, 139 F.3d 889, 1998 WL 153410, at \*5, \*10 (confirming that marketing exclusivity for ranitidine was triggered by a grant of partial summary judgment based on the patent holder's admission of non-infringement).

107. More particularly, FDA and the D.C. district and appellate courts committed *at least* the following legal errors in refusing to find that the BMS-Apotex dismissal triggered any unexpired period of 180-day exclusivity for generic pravastatin tablets: (1) adopting and applying an interpretation of the FDCA that squarely conflicts with and violates Congressional intent, the purpose behind Hatch-Waxman, and controlling federal court precedent; (2) adopting and upholding a statutory interpretation that runs counter to FDA's own regulation implementing the statute in a non-textual manner by permitting a court decision of unenforceability to qualify as a court decision trigger; (3) construing the statute in a manner that nullifies and renders inoperable the declaratory judgment mechanism under Hatch-Waxman; and (4) failing to treat the BMS-Apotex dismissal in a manner similar to those court decisions entered in similar cases, despite the fact that this dismissal supports estoppel to the same extent as the Teva-Syntex dismissal, as well as the grant of partial summary judgment in *Granutec*.

108. Further, because the decisions by the FDA and the D.C. district and appellate courts wrongfully determined that the dismissal of Apotex's declaratory judgment action against BMS failed to constitute a court decision trigger under the FDCA, Apotex was unable to promptly bring its generic pravastatin products to the market as soon as the '227 patent and its associated period of pediatric exclusivity expired, causing Apotex to suffer substantial damages. More specifically, because the Agency and these courts refused to find that the 180-day exclusivity period for generic pravastatin products had been triggered and expired, Teva and Ranbaxy launched their generic pravastatin products with exclusivity, thus securing a stranglehold over the market.

**B. PROCEDURAL BACKGROUND**

109. Pursuant to Article 1119 of NAFTA, on or about March 2, 2009, 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.

110. Pursuant to Article 1120 of NAFTA, Apotex filed its Pravastatin Notice of Arbitration on June 4, 2009, which Respondent received on June 5, 2009—more than six months after the events giving rise to Apotex's claim, and not more than three years after 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.

**C. POINTS AT ISSUE: NAFTA ARTICLES BREACHED RELATING TO APOTEX'S PRAVASTATIN CLAIM**

111. 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.

**Claim 1: Breach Of National Treatment Obligations Under Article 1102**

112. Under Article 1102 of NAFTA, 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. 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.

\* \* \*

113. The United States has breached its obligations to Apotex and its investments under Article 1102(1) and (2).

114. The unlawful, arbitrary and capricious interpretation and application of the court decision trigger by FDA and the U.S. federal courts (1) is clearly inconsistent with Congressional purpose and intent; (2) is contradictory to controlling federal U.S. court precedent interpreting and applying the same federal statutory provisions to other similarly-situated ANDA applicants; (3) is counter to FDA's own implementing regulations; and (4) rendered the statute's declaratory judgment mechanism superfluous and/or inoperative. The actions of FDA and the federal courts prevented Apotex from promptly bringing its generic pravastatin product to market, and thus caused Apotex substantial damages, in violation of Article 1102 of NAFTA.

115. The actions of the United States, through the FDA and the U.S. federal courts, breached Article 1102 by, among other things, according disparate treatment to court decisions and orders having the same estoppel effect entered in suits brought by or against similarly-situated U.S. ANDA applicants, thereby according Apotex treatment that is less favorable than that provided to U.S. investors and investments. By way of example, and as explained more fully above, the identical situation occurred in the *Teva/ticlopidine* matter, in which Teva

Pharmaceuticals USA, Inc. (“Teva”) and Apotex stood in each other’s shoes. In that case, Apotex received 180-day generic exclusivity for ticlopidine, but the federal courts found that the dismissal of Teva’s declaratory judgment action against the patentee (Syntex) triggered Apotex’s 180-day exclusivity period such that it expired before Apotex could benefit from the exclusivity. In the underlying pravastatin matter, however, Teva received 180-day generic exclusivity, but the same federal courts held that the dismissal of Apotex’s declaratory judgment action was not sufficient to trigger Teva’s exclusivity, and thus Teva was able to retain and enjoy its 180-day generic exclusivity while Apotex was excluded from the market during that time period. The United States, by way of the FDA and the U.S. federal courts, accorded treatment to Apotex with respect to its ANDA investment less favorably than it did in like circumstances with local investors, namely, and by way of example only, Teva.

116. For these and other reasons, the United States breached its obligations under NAFTA Article 1102.

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

117. Under Article 1105 of NAFTA, the United States is obligated to accord Apotex’s investments fair and equitable treatment and meet the minimum standard of treatment under international law. 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.

\* \* \*

118. The actions of the United States, by way of the FDA, the U.S. District Court for the District of Columbia, and the U.S. Court of Appeals for the District of Columbia Circuit,

breached Article 1105 by rendering manifestly unjust, improper, and unlawful rulings and decisions that misapplied statutory and common law governing the triggering of 180-day exclusivity and the market entry of competing ANDA filers pursuant to the FFDCA, thereby denying Apotex fair and equitable treatment and violating the minimum standard of treatment under international law. The unfair and inequitable application of the court decision trigger provision of the governing statute, by the United States, was inconsistent with Congressional purpose and intent and controlling federal court precedent interpreting and applying the same statutory provision to other similarly-situated ANDA applicants, and amounts to a denial of justice.

119. The actions of the United States prevented Apotex from promptly launching its pravastatin ANDA product upon patent expiration and caused Apotex substantial damages, in violation of Article 1105 of NAFTA.

120. The rulings and decisions of the FDA, the U.S. District Court for the District of Columbia, and the U.S. Court of Appeals for the District of Columbia Circuit, unlawfully, arbitrarily, and capriciously interpreted and applied the governing statute in a manner that runs counter to FDA's own implementing regulations, are inconsistent with the Agency's and the courts' prior decisions, and effectively rendered the statute's declaratory judgment mechanism superfluous or inoperative.

121. 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 required under Article 1105 of NAFTA.

122. For these and other reasons, the United States breached its obligations under NAFTA Article 1105.

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

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

\* \* \*

124. The conduct of the United States, through the actions of the FDA and the U.S. federal courts, interfered with and expropriated Apotex's property rights in its ANDA for generic pravastatin tablets, in violation of Article 1110 of NAFTA. By unlawfully, arbitrarily and improperly interpreting and applying the court decision trigger provision, other ANDA applicants were permitted to unlawfully enjoy 180-day exclusivity, despite the fact that such exclusivity should have long expired, while Apotex was prohibited from marketing its generic pravastatin product. These actions substantially deprived Apotex of the benefits of its investments in its generic pravastatin ANDA by preventing Apotex's timely entry into the generic pravastatin market, and unlawfully redistributing the financial benefits of Apotex's

investment by preventing Apotex from obtaining final approval of its generic pravastatin tablets immediately upon expiration of the '227 patent and its corresponding period of pediatric exclusivity.

125. The United States has no “public purpose” for interfering with Apotex’s property rights in its pravastatin ANDA or for providing such huge windfalls to other ANDA applicants, as required by Article 1110(1)(a).

126. The United 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 to other similarly-situated generic drug applicants governed by the same statutory approval process.

127. 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).

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

129. For these and other reasons, the United States breached its obligations under NAFTA Article 1110.

\* \* \* \* \*

130. Apotex reserves all rights to assert additional bases for its Pravastatin Claim against the United States.

**D. RELIEF SOUGHT AND DAMAGES CLAIMED RELATING TO APOTEX'S PRAVASTATIN CLAIM.**

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

- a. A declaration that the United States has breached its obligations under Chapter 11 of NAFTA and is liable to Apotex therefore;
- b. An award of compensatory damages in an amount not less than \$8,000,000.00 (US);
- c. 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;
- d. An award of pre-award and post-award interest at a rate to be fixed by the Tribunal; and
- e. An award of any such further relief that the Tribunal may deem appropriate.

Dated: January 17, 2011

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2.	21 U.S.C. § 355 (2002)
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4.	21 C.F.R. § 314.107
	<u>U.S. FEDERAL CASES</u>
5.	<i>Apotex, Inc. v. FDA</i> , No. Civ.A. 06-0627, 2006 WL 1030151 (D.D.C. Apr. 19, 2006)
6.	<i>Apotex, Inc. v. FDA</i> , 449 F.3d 1249 (D.C. Cir. 2006)
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8.	<i>Apotex, Inc. v. Pfizer Inc.</i> , 159 F. App'x 1013, 2005 WL 3457408 (Fed. Cir. Dec. 12, 2005)
9.	<i>Apotex Inc. v. Pfizer, Inc.</i> , 127 S.Ct. 379 (2006)
10.	<i>Fina Oil &amp; Chem. Co. v. Ewen</i> , 123 F.3d 1466 (Fed. Cir. 1997)
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20.	149 CONG. REC. S15,746 (Nov. 24, 2003)
21.	149 CONG. REC. S15,885 (Nov. 25, 2003)
22.	Brief of Amicus Curiae FTC Supporting Appellant, <i>Teva Pharms. USA, Inc. v. Pfizer, Inc.</i> , No. 04-1186 (Fed. Cir. Mar. 31, 2004) (excerpts)
23.	Stipulation and Order <i>Apotex Inc. v. Bristol-Myers-Squibb Co.</i> , No. 04-cv-2922 (S.D.N.Y. July 23, 2004)
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