RAKOCZY MOLINO MAZZOCHI SIWIK LLP

6 WEST HUBBARD STREET
SUITE 500
CHICAGO, IL 60654
www.rmmslegal.com

312-527-2157 main phone
312-527-4205 main fax

L/EX
2009 JUN -5 P 2:45
DEPARTMENT OF STATE

L/EX
2009 JUN -5 P 2:45
DEPARTMENT OF STATE

William A. Rakoczy
312.222.6301 telephone
312.222.6321 facsimile
wrakoczy@rmmslegal.com

June 4, 2009

VIA FEDEX

SERVICE ACCEPTED IN
OFFICIAL CAPACITY ONLY
Alicia Frechette
EXECUTIVE DIRECTOR 06/05/09
OFFICE OF THE LEGAL ADVISER

Alicia A. Frechette
Executive Director (L/EX)
Office of the Legal Adviser
United States Department of State
Room 5519
2201 C Street N.W.
Washington, D.C. 20520

Re: Notice of Arbitration under Chapter 11 of the North American Free Trade Agreement

Dear Ms. Frechette:

On behalf of Apotex Inc., please find enclosed a Notice of Arbitration, submitted under Chapter 11 of the North American Free Trade Agreement and the UNCITRAL Arbitration Rules. A courtesy copy of the enclosed Notice of Arbitration also has been to sent Mr. Mark Feldman.

If you have any questions, please call me at (312) 222-6301.

Very truly yours,

RAKOCZY MOLINO MAZZOCHI SIWIK LLP

William A Rakoczy/cg

William A. Rakoczy

Enclosure

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

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 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, which, accordingly, was more than ninety days before the submission of this claim. In a letter dated March 13, 2009, 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
Lara E. FitzSimmons
Bob M. Teigen
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. This 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 the 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. This matter involves the prescription heart medication pravastatin sodium tablets, marketed by Bristol Myers Squibb ("BMS") under the brand-name Pravachol®.

15. Apotex submitted an abbreviated new drug application ("ANDA") seeking FDA approval for a generic version of Pravachol®, as did several other applicants, including Teva Pharmaceuticals, USA, Inc. ("Teva") and Ranbaxy Laboratories Limited ("Ranbaxy").

16. At the time Apotex filed its ANDA, BMS had listed four patents with FDA in connection with Pravachol®: U.S. Patent Nos. 4,346,227 ("the '227 patent"), 5,030,447 ("the '447 patent"), 5,180,589 ("the '589 patent"), and 5,622,985 ("the '985 patent"). By listing these patents, BMS affirmatively represented that a suit for infringement could reasonably be asserted against any generic manufacturer, including Apotex, which attempted to market a generic version of pravastatin prior to the expiration of these patents.

17. In its application to FDA, Apotex represented that it would not begin selling its pravastatin drug products until after the '227 patent (and the pediatric exclusivity associated with it) expired in April 2006. With respect to the '447, '589, and '985 patents, however, Apotex submitted a so-called "paragraph IV certification," indicating that Apotex sought final FDA approval prior to the expiration of these patents.

18. Teva and Ranbaxy were purportedly the first applicants to submit ANDAs containing paragraph IV certifications for generic pravastatin tablets. Like Apotex, Teva and Ranbaxy indicated that they would not launch until the '227 patent expired.

19. As a result of being the first applicants to challenge one of BMS's patents, Teva and Ranbaxy were eligible for 180 days of generic market exclusivity that would be triggered by the earlier of either a court decision finding BMS's patents invalid or not infringed, or the first commercial marketing of their generic products.

20. BMS chose not to sue Apotex over its pravastatin ANDA, and similarly refused to sue any other generic pravastatin applicant as well. As a result, the lack of a court

decision on BMS's patents preserved Teva's and Ranbaxy's 180-day market exclusivity period for pravastatin, which could not be triggered until the first commercial marketing of the generic pravastatin products, which could not occur until after the '227 patent expired in April 2006.

21. In order to obtain patent certainty, and to obtain timely approval of its application in April 2006, Apotex sued BMS in the U.S. District Court for the Southern District of New York. In response, BMS moved to dismiss for lack of subject matter jurisdiction on the ground that it had no intention of suing Apotex for infringement of the '447, '589, and '985 patents.

22. While the district court did not rule on BMS's motion, the court signed and entered a stipulated order dismissing Apotex's declaratory judgment action for lack of subject matter jurisdiction based upon BMS's disavowal of any intent to sue Apotex. The dismissal order became final and unappealable on August 22, 2004.

23. Apotex subsequently submitted the dismissal order and underlying documents to FDA seeking confirmation that the order constituted a court decision that triggered any exclusivity for pravastatin.

24. On June 28, 2005, FDA issued an administrative ruling confirming that the BMS-Apotex dismissal order triggered Teva's and Ranbaxy's exclusivity for pravastatin; that such exclusivity expired no later than February 18, 2005; and that Apotex's ANDA would be eligible for final approval in April 2006.

25. FDA's decision explicitly relied on controlling federal court decisions involving the drug ticlopidine and the same parties involved here (Teva, Apotex, and FDA), in which the U.S. Court of Appeals for the District of Columbia 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. In that case, Teva consequently triggered Apotex's exclusivity for ticlopidine before Apotex ever got to enjoy it. Relying on that controlling precedent, FDA explained in its June 28, 2005 decision that the BMS-Apotex dismissal based on BMS's representations that it would not sue Apotex similarly constituted a decision of a court for purposes of triggering any 180-day exclusivity for pravastatin.

26. On July 26, 2005, Teva sued FDA in the U.S. District Court for the District of Columbia, challenging the Agency's pravastatin decision. Teva argued that the BMS-Apotex dismissal was distinguishable from the dismissal in the ticlopidine matter, and did not constitute a "court decision" because it involved a stipulation between the parties. On October 21, 2005, the district court issued its decision adopting Teva's argument and granting Teva permanent injunctive relief preventing Apotex from both obtaining final approval for, and marketing, its pravastatin products.

27. 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, but expressed no opinion on whether a voluntary dismissal could serve as a court decision trigger. The court thus vacated FDA's decision, and remanded to the Agency for further proceedings.

28. On April 11, 2006, FDA issued a second administrative decision concerning the 180-day exclusivity for generic pravastatin tablets, this time denying that 180-day exclusivity had been triggered and expired; refusing to recognize the BMS-Apotex dismissal order as a court decision trigger, despite its preclusive effect; and refusing to approve Apotex's pravastatin ANDA in April 2006. FDA defended its new position by concluding 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.

29. Apotex challenged FDA's April 11, 2006 decision in the U.S. District Court for the District of Columbia, arguing that the Agency's decision was contrary to governing statutory law and conflicted with prior precedent from the D.C. Circuit and the Agency itself. The district court denied Apotex's motion for injunctive relief, which the U.S. Court of Appeals for the District of Columbia Circuit summarily affirmed. The appellate court also denied Apotex's motion for rehearing *en banc*.

30. As a direct result of the FDA's and the U.S. federal courts' unlawful application of the statute and sheer disregard for binding court precedent, Apotex was prevented from obtaining approval and timely bringing its pravastatin tablets to market in April 2006, thus causing Apotex substantial injury including, but not limited to, significant lost sales and lost market share.

31. 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, (1) FDA's April 11, 2006 administrative decision, which misapplied U.S. statutory law, the Agency's own precedent, and controlling decisions of the D.C. Circuit; (2) the April 19, 2006 decision by the U.S. District Court for the District of Columbia in *Apotex, Inc. v. FDA*, No. Civ.A. 06-0627 JDB, 2006 WL 1030151 (D.D.C. Apr. 19, 2006), which improperly affirmed FDA's administrative decision; (3) the June 6, 2006 decision by the U.S. Court of Appeals for the District of Columbia Circuit in *Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006), which improperly affirmed the district court's decision; and, (4) the August 17, 2006 decision by the U.S. Court of Appeals for

the District of Columbia Circuit refusing to grant Apotex's petition for rehearing *en banc*, *see Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006), *reh'g en banc denied* (Aug. 17, 2006).

RELEVANT NAFTA OBLIGATIONS BREACHED

32. 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

33. 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).

34. A company that seeks to sell a new drug must file with 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 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). FDA publishes all such patent information in the "Orange Book." *See* 21 C.F.R. § 314.53(e).

35. Before 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. In 1984, Congress simplified the procedure for obtaining approval of

generic drugs with the Hatch-Waxman Amendments to the FFDCA. These Amendments permit a generic drug company to file an ANDA that relies on information from the NDA.

36. An ANDA applicant must establish that its generic drug product is bioequivalent to the NDA drug. *See* 21 U.S.C. § 355(j)(2)(A). The ANDA also includes 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).

37. Submitting an ANDA containing a paragraph IV certification has two important consequences. *First*, it constitutes a technical act of infringement, vesting the district courts with subject matter jurisdiction over either a patent infringement lawsuit brought by the patent owner, or a declaratory judgment action brought by the ANDA applicant to obtain patent certainty and to remove any barriers to approval, such as another applicant's 180-day exclusivity. *See* 35 U.S.C. § 271(e)(2)(A); 21 U.S.C. § 355(j)(5)(B). *Second*, the first company to submit an ANDA for a drug product containing a paragraph IV certification to any listed patent is entitled to a 180-day generic exclusivity period, during which time FDA will not approve any subsequently filed paragraph IV ANDAs. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

38. At all times relevant to this dispute, the 180-day generic marketing exclusivity period could be "triggered" by the earlier of two events: (1) the first-filer's

commercial marketing ("the commercial marketing trigger"); or (2) relevant to this case, a final, unappealable court decision that the patent is invalid or not infringed ("the court decision trigger"). *Id.* (2002).[1]

39. 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. *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002). FDA and the courts have both recognized that 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 Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1009-11 (D.C. Cir. 1999). In fact, the ability of a later-filer to bring a declaratory judgment action for purposes of triggering exclusivity is so crucial that, in 2003, Congress amended Hatch-Waxman 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 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer).) These statutory changes apply retroactively to all ANDAs (including pravastatin ANDAs).

40. Courts have interpreted the court decision trigger broadly. *See Minn. Mining & Mfg. Co.*, 289 F.3d at 786 (Gajarsa, J., concurring). 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. *Id.*; *see also 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).

[1] Under Title XI of the MMA, which in relevant part amended the FFDCA for all pending ANDAs, a triggering "court decision" is a final decision from which no appeal has been or can be taken. *See* Pub. L. No. 108-173, § 1102(b)(3), 117 Stat. 2066, 2460 (2003).

41. 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.

42. Additionally, in the *Teva*/ticlopidine matter mentioned above, the D.C. Circuit 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", 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)").

43. In the *Teva*/ticlopidine matter, Teva and Apotex stood in each other's shoes. There, it was Apotex who was the first generic filer and had received 180-day generic exclusivity for ticlopidine. 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.

44. 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.

45. 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).

46. 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 (CKK), 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.

47. Here, however, FDA and the U.S. federal courts, and in particular the U.S. District Court for the District of Columbia and the U.S. Court of Appeals for the District of Columbia Circuit, improperly refused to apply the statute as intended by Congress—ignoring the clear preclusive effect of the BMS-Apotex dismissal, and denied Apotex minimum standards of justice and effectively expropriated Apotex's investment in its generic pravastatin products.

FACTUAL BACKGROUND

48. BMS sells pravastatin sodium tablets under the brand-name Pravachol® for the treatment of, among other things, hyperlipidemia and the primary prevention of coronary events. At all times relevant to this action, four patents were listed in FDA's Orange Book in

connection with Pravachol® Tablets: the '227 patent, the '447 patent, the '589 patent, and the '985 patent.

49. 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 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.

50. On December 21, 2001, Apotex submitted its own ANDA seeking approval to market generic pravastatin sodium tablets. 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 associated pediatric exclusivity expired.

51. 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.

52. 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.

53. 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 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 launch.

54. 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.

55. 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. The district court's dismissal order became final and unappealable on August 22, 2004.

56. After obtaining patent certainty, Apotex sought to remove the regulatory barrier to obtaining approval on April 20, 2006, upon expiration of the '227 patent and its corresponding pediatric exclusivity. 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.

57. 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. FDA further concluded that Apotex's pravastatin ANDA would be eligible for immediate final approval on April 20, 2006.

58. In reaching its decision, FDA carefully and thoroughly examined BMS's unequivocal and binding representations, the statute, and the dismissal order, and correctly applied the reasoning articulated in the D.C. Circuit's *Teva*/ticlopidine decision, 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." *Teva*, 182 F.3d at 1010. FDA correctly 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. 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.

59. 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. *See Teva Pharms. USA, Inc. v. FDA*, No. 05-1469 (D.D.C.). Apotex intervened and opposed Teva's motion.

60. 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.

61. On appeal, the 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.*

62. 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. 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. 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 as a court decision trigger.

63. 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 FFDCA, 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 (JDB), 2006 WL 1030151, at *19 (D.D.C. Apr. 19, 2006).

64. 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.

65. 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 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); *see also Indep. Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1258 (D.C. Cir. 1996) (citation omitted) (holding that an "agency must treat similar cases in a similar manner unless it can provide a legitimate reason for failing to do so"); *Freeman Eng'g Assocs., Inc. v. FCC*, 103 F.3d 169, 178 (D.C. Cir. 1997) ("[A]n agency may not 'treat like cases differently.'" (citation omitted)); *El Rio Santa Cruz Neighborhood Health Ctr., Inc. v. HHS*, 300 F. Supp. 2d 32, 42 (D.D.C. 2004) (same).

66. 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 FFDCA that squarely conflicts with 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*.

67. 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 FFDCA, 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 strangle-hold over the market. 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, FDA's April 11, 2006 administrative ruling, the D.C. district court's April 19, 2006 decision (*Apotex, Inc. v. FDA*, No. Civ.A. 06-0627 JDB, 2006 WL 1030151 (D.D.C. April 19, 2006)), the D.C. Circuit's June 6, 2006 decision (*Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006)), and the D.C. Circuit's August 17, 2006 decision refusing to grant Apotex's petition for rehearing *en banc* (*Id.*, *reh'g en banc denied* (Aug. 17, 2006)), each 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

68. 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.

* * *

69. 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.

70. 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 interpreting and applying the court decision trigger provision of the governing statute in a way that is inconsistent with Congressional purpose and intent;

b. Unlawfully, arbitrarily, and capriciously interpreting and applying the governing statute in a way that is inconsistent with controlling federal court precedent interpreting and applying the same statutory provision to other similarly-situated ANDA applicants;

c. Unlawfully, arbitrarily, and capriciously interpreting and applying the governing statute in a way that runs counter to FDA's own implementing regulations;

d. Unlawfully, arbitrarily, and capriciously interpreting and applying the governing statute in a way that renders the statute's declaratory judgment mechanism superfluous or inoperative;

e. Failing to treat Apotex in the same fashion as U.S. investors and according disparate treatment to court decisions and orders having the same estoppel effect entered in suits brought by or against similarly-situated ANDA applicants; and,

f. Failing to treat Apotex's substantial investment in the development and preparation of its ANDA for generic pravastatin 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

71. 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.

* * *

72. 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) ("customary international law imposes on States an obligation 'to maintain and make available to aliens, a fair and effective system of justice'") (citation omitted).

73. The FDA, the U.S. District Court for the District of Columbia, and the U.S. Court of Appeals for the District of Columbia Circuit violated Article 1105 by, among other things:

a. Rendering manifestly unjust decisions by misapplying statutory and common law governing the triggering of 180-day exclusivity and the market entry of competing ANDA filers pursuant to the FFDCA;

b. Unlawfully, arbitrarily, and capriciously interpreting and applying the court decision trigger provision of the governing statute in a way that is inconsistent with Congressional purpose and intent;

c. Unlawfully, arbitrarily, and capriciously interpreting and applying the governing statute in a way that is inconsistent with controlling federal court precedent interpreting and applying the same statutory provision to other similarly-situated ANDA applicants;

d. Unlawfully, arbitrarily, and capriciously interpreting and applying the governing statute in a way that runs counter to FDA's own implementing regulations; and,

e. Unlawfully, arbitrarily, and capriciously interpreting and applying the governing statute in a way that renders the statute's declaratory judgment mechanism superfluous or inoperative.

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

74. 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.

* * *

75. Under international law, expropriation occurs where government action unreasonably interferes with, or unduly delays, 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.").

76. 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).

77. 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 pravastatin tablets by interpreting and applying the governing statute in a way that unlawfully awarded Teva and Ranbaxy 180-day exclusivity for pravastatin, despite such exclusivity having long-since expired;

b. Substantially depriving Apotex of the benefits of its investments in its generic pravastatin ANDA by delaying Apotex's eligibility for final approval and timely entry into the generic pravastatin market; and,

c. 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.

78. 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 Teva and Ranbaxy, as required by Article 1110(1)(a).

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

80. 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).

81. 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

82. 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

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

Dated: June 4, 2009

William A. Rakoczy
Christine J. Siwik
Lara E. FitzSimmons
Bob M. Teigen
RAKOCZY MOLINO MAZZOCHI SIWIK LLP

6 West Hubbard Street, Suite 500
Chicago, Illinois 60654
312-222-6301 (telephone)
312-222-6321 (facsimile)

Counsel for Claimant/Investor Apotex Inc.

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

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 4th day of June, 2009.

APOTEX INC.

By: Shashank Upadhye / with permission by Anna St Ginna

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

CERTIFICATE OF SERVICE

I, Lara E. FitzSimmons, 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 4th day of June, 2009:

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

Lara FitzSimmons
Attorney for Claimant/Investor
Apotex Inc.