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June 4, 2009

VIA FEDEX

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

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

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 sent to 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

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 FDCA. 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 FDCA 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