

**IN THE ARBITRATION UNDER CHAPTER ELEVEN  
OF THE NORTH AMERICAN FREE TRADE AGREEMENT  
AND THE UNCITRAL ARBITRATION RULES**

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APOTEX INC.

Claimant,

v.

THE GOVERNMENT OF THE UNITED STATES OF AMERICA

Respondent.

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**SUBMISSION OF APOTEX INC.  
IN SUPPORT OF A STAY**

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## **I. Introduction**

1. In accordance with the Tribunal's correspondence, dated October 15, 2010, Apotex hereby respectfully submits the grounds upon which it seeks a stay of arbitration relating to its Notice of Arbitration dated June 4, 2009 (the "second-filed claim" or "Pravastatin Claim"), pending the Tribunal's consideration and resolution of matters relating to Apotex's Notice of Arbitration dated December 10, 2008 (the "first-filed claim" or "Sertraline Claim").

2. As explained in more detail below, Apotex's two NAFTA claims arise from entirely different factual scenarios pertaining to separate investments; involve separate and independent legal issues; and involve wholly separate injuries at the hands of wholly separate Party actors. Apotex's first-filed Sertraline Claim arises from the U.S. federal courts' unlawful refusal to apply the controlling "case or controversy" standard under Article III of the U.S. Constitution in determining whether subject matter jurisdiction existed over Apotex's declaratory judgment action involving certain patents purporting to cover Apotex's generic sertraline drug product. In stark contrast, Apotex's second-filed Pravastatin Claim arises from the U.S. federal courts' unlawful interpretation of the Federal Food, Drug, and Cosmetic Act ("FFDCA") and departure from Congressional intent and controlling federal court precedent in refusing to treat the dismissal of Apotex's patent litigation involving the drug product pravastatin as a so-called "triggering court decision" for purposes of triggering the 180-day generic marketing exclusivity period under the FFDCA.

3. As explained below, Apotex will suffer tremendous prejudice if the two cases proceed concurrently, as both claims involve complex factual and legal issues that bear no relevance to each other, but easily could lead to confusion. In addition, hearing the two claims together could create unnecessary burdens on counsel and the Tribunal, waste time and resources, and create unnecessary accounting problems.

4. As requested, a proposed procedural schedule is provided below in Section V.

## **II. Statutory Background Governing The Review And Approval Of Generic Drugs**

5. As discussed below, Apotex's two NAFTA Claims each arise from a separate nucleus of operative facts and law. Nevertheless, for the Tribunal's convenience, we provide here a brief discussion of the statutory framework applicable to generic drug manufacturers, such as Apotex.

6. 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 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, attached hereto at Tab A, and 35 U.S.C. § 271, attached hereto at Tab B).

7. Under the FFDCA, a company that seeks to sell a new or previously-unapproved drug must file with the U.S. Food and Drug Administration ("FDA") a New Drug Application ("NDA"). The NDA 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* Tab A, 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." (Tab A, 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2).) FDA publishes all such patent information in what is known as the "Orange Book."

8. The FDCA, as amended by Hatch-Waxman and the MMA, provides for an abbreviated approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-priced generic versions of previously-approved NDA drugs on an expedited basis, thereby benefiting the U.S. health-care system and American consumers.

9. A company seeking to market a generic version of an NDA drug, such as Apotex, must submit what is known as an abbreviated new drug application (“ANDA”). An ANDA applicant must establish that its generic drug product is bioequivalent to the 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 NDA drug. (Tab A, 21 U.S.C. § 355(j)(2)(A).)

10. The ANDA must also include a “certification” to any properly-listed Orange Book patents. (See Tab A, 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, unenforceable, and/or not infringed by the proposed ANDA product. (*Id.*)

11. Submitting an ANDA containing a paragraph IV certification has two important consequences. *First*, the first company to submit an ANDA for a drug product containing a paragraph IV certification to any listed patent (“first-filer”) is entitled to a 180-day generic exclusivity period, during which time FDA will not approve any subsequently filed paragraph IV ANDAs. (See Tab A, 21 U.S.C. § 355(j)(5)(B)(iv).) *Second*, the submission of a paragraph IV certification for a listed patent constitutes an act of patent infringement that creates the necessary case or controversy and subject matter jurisdiction to enable a district court to resolve any dispute concerning infringement or validity of the listed patent prior to the actual launch of the

generic drug product. (Tab B, 35 U.S.C. § 271(e)(2)(A); *Id.* § 271(e)(5); Tab A, 21 U.S.C. § 355(j)(5)(B).)

12. For purposes of Apotex's NAFTA claims, the 180-day generic marketing exclusivity period can be "triggered" by the earlier of two events: (1) the first-filer's commercial marketing ("the commercial marketing trigger"); or (2) a final, unappealable court decision that the patent is invalid or not infringed ("the court decision trigger"). (21 U.S.C. § 355(j)(5)(B)(iv) (2002), attached hereto at Tab C.)

13. Both of Apotex's claims require a basic understanding of this statutory framework governing generic drugs. But any similarities between the claims end there. To suggest, as Respondent apparently does, that both claims should proceed together just because they both involve pharmaceuticals or generic drugs is profoundly misguided, and conveniently ignores the entirely different facts and law surrounding and giving rise to each claim. Indeed, Apotex agreed to empanel one Tribunal to hear both of Apotex's claims only for convenience and in the spirit of cooperation. Because of the complicated factual and legal issues singularly relevant to each of Apotex's individual NAFTA claims, however, Apotex did not agree to have its two separate claims heard together under the same procedural schedule.

### **III. Apotex's Sertraline And Pravastatin Claims Lack Commonality Of Fact And Law**

14. As explained in more detail below, Apotex's Sertraline Claim arises from injuries suffered due to certain U.S. district and appellate court decisions in which Apotex was denied the protections and benefits afforded by Article III of the U.S. Constitution. In contrast, Apotex's Pravastatin Claim arises from injuries suffered due to separate U.S. Agency and federal court decisions denying Apotex the protections and benefits of U.S. statutory law. Both claims involve different investments; different responsible Party actors; different types of underlying

disputes; different underlying laws breached; and different ways in which Respondent has violated Articles 1102, 1105 and 1110 of the NAFTA.

**A. Apotex's First-Filed Sertraline Claim**

15. Apotex's First-Filed Claim involves Pfizer Inc.'s antidepressant, Zoloft<sup>®</sup> (sertraline). To protect Zoloft<sup>®</sup> from generic competition, Pfizer listed U.S. Patent No. 5,248,699 ("the '699 patent") in the Orange Book, thus affirmatively representing that a suit for infringement of the '699 patent could reasonably be asserted against any generic ANDA-filer, including Apotex, that attempts to market a generic version of sertraline.

16. Apotex filed an ANDA for generic sertraline tablets containing a paragraph IV certification to the '699 patent, representing that such patent was invalid, unenforceable, or not infringed by Apotex's proposed generic drug products. Apotex was not the first applicant to file an ANDA for generic sertraline tablets containing a paragraph IV certification. Apotex's submission of a paragraph IV ANDA nevertheless constituted an act of infringement sufficient to create subject matter jurisdiction to resolve any questions regarding the infringement and validity of the '699 patent.

17. As noted above, under the FDCA, the filing of a paragraph IV certification to a listed patent constitutes an 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* Tab B, 35 U.S.C. § 271(e)(2)(A); Tab A, 21 U.S.C. § 355(j)(5)(B).)

18. In 2003, Congress amended the FDCA through the MMA to explicitly authorize declaratory judgment actions where the ANDA-filer is not sued by the patentee. 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 45-days have passed since notice of the paragraph IV certification was received and neither the patent owner nor the NDA-holder brought an action for infringement of the patent within that period, and provided that the NDA-holder/patent owner have been granted an Offer of Confidential Access to the ANDA. (Tab A, 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa-cc).) So long as these 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,” and that “the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any [such] action”. (Tab A, 21 U.S.C. § 355(j)(5)(C)(i)(II); Tab B, 35 U.S.C. § 271(e)(5).)

19. Pfizer did not sue Apotex for infringement of the ‘699 patent. Consequently, in order to obtain patent certainty and immediate approval of its product, 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.

20. Pfizer moved to dismiss Apotex’s suit 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. Apotex opposed the motion on grounds that, under U.S. Supreme Court and Federal Circuit precedent, Article III of the Constitution simply requires a redressible injury-in-fact traceable to the declaratory judgment defendant’s conduct. On December 30, 2004, the district court granted Pfizer’s motion under the prudential “reasonable

apprehension” test, and dismissed Apotex’s action for lack of subject matter jurisdiction. (*Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187 (S.D.N.Y. 2005), attached hereto at Tab D.)

21. Apotex appealed the decision of the district court to the U.S. Court of Appeals for the Federal Circuit. On December 12, 2005, the Federal Circuit affirmed the district court’s dismissal of Apotex’s suit without opinion. (*Apotex, Inc. v. Pfizer Inc.*, 159 F. App’x 1013, 2005 WL 3457408 (Fed. Cir. Dec. 12, 2005), attached hereto at Tab E.)

22. Apotex submitted a petition for a writ of certiorari to the U.S. 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), attached hereto at Tab F.)

23. As explained in more detail in Apotex’s December 10, 2008 Notice of Arbitration, the decisions of 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 have deprived Apotex of its constitutional right to a decision on the validity or infringement of the ‘699 patent under Article III of the U.S. Constitution, as interpreted by the U.S. Supreme Court, and as guaranteed by the U.S. Congress through the provisions of the MMA.

24. 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 pursuing its declaratory judgment action for patent noninfringement or invalidity, Apotex was unable to obtain the court decision necessary to trigger the first-filer’s generic exclusivity period, thereby significantly delaying Apotex’s own eligibility for approval. As a result, the first-filer launched its generic sertraline products with exclusivity, causing Apotex considerable delays in securing approval and, in turn, substantial damages.

25. Apotex filed its Notice of Arbitration relating to its Sertraline Claim on December 10, 2008, alleging violations of Articles 1102, 1105 and 1110 of the NAFTA.

26. Apotex's Article 1102 Sertraline Claim alleges, in general, that Respondent unlawfully failed to extend to Apotex the protections and benefits of Article III of the U.S. Constitution afforded to similarly situated U.S. investors, while requiring Apotex to meet a non-constitutional prudential standard for subject matter jurisdiction, in direct contravention of U.S. Supreme Court and Federal Circuit precedent, the FFDCA, as amended by the MMA, and legislative intent.

27. Apotex's Article 1105 Sertraline Claim alleges, in general, that Respondent's federal court decisions are manifestly unjust, and have misapplied constitutional, statutory, and common law in holding Apotex to an unconstitutional justiciability standard.

28. Apotex's Article 1110 Sertraline Claim alleges, in general, that Respondent has interfered with Apotex's property rights stemming from Apotex's sertraline tablet ANDA by preventing Apotex from obtaining federal court jurisdiction over its declaratory judgment action against Pfizer; has unduly delayed Apotex's eligibility for approval; and has unlawfully redistributed the financial benefits to which Apotex was entitled by delaying Apotex's ability to market its sertraline drug products.

**B. Apotex's Second-Filed Pravastatin Claim**

29. Apotex's Second-Filed Claim involves Apotex's ANDA for pravastatin sodium tablets, 10 mg, 20 mg, 40 mg and 80 mg, which Bristol-Myers Squibb ("BMS") sells under the tradename Pravachol<sup>®</sup>.

30. Another company, Teva Pharmaceuticals USA, Inc., 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, Inc. 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 BMS's listed patents, along with a paragraph III certification to listed U.S. Patent No. 4,346,227 ("the '227 patent"), thus indicating that neither applicant 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.

31. Apotex's own ANDA contained paragraph IV certifications to certain patents, and a paragraph III certification to the '227 patent as well. As required by the statute and FDA regulations, Apotex sent notice of its paragraph IV certifications to BMS, but BMS did not initiate litigation against Apotex.

32. Apotex asked BMS for a binding covenant not to sue Apotex for infringement of its listed patents, but BMS refused. Apotex thus 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.

33. BMS moved to dismiss Apotex's declaratory judgment action for lack of subject matter jurisdiction and, in support, filed a sworn declaration that it would not sue Apotex for infringement of the patents-at-issue.

34. 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. (*See* 7/23/04 Stipulation and Order, attached hereto at Tab G.) The district court's dismissal order became final and unappealable on August 22, 2004.

35. 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, consistent with D.C. Circuit precedent holding that the dismissal of a different declaratory judgment action brought by a subsequent-filer (Teva) triggered Apotex's 180-day exclusivity for the drug "ticlopidine" before Apotex was able to enjoy it, because such dismissal sufficed to estop the patentee from suing Teva for patent infringement, which appeared to satisfy the purpose of the statutory court-decision trigger provision.

36. On June 28, 2005, FDA determined that, based on the prior ticlopidine decision, 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. (*See* 6/28/05 FDA Decision, attached hereto at Tab H.) FDA further concluded that Apotex's pravastatin ANDA would be eligible for immediate final approval upon expiration of the '227 patent on April 20, 2006. (*Id.*)

37. After FDA issued its June 28, 2005 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.

38. On October 21, 2005, the District Court for the District of Columbia granted Teva's motion. (*Teva Pharms. USA, Inc. v. FDA*, 398 F. Supp. 2d 176 (D.D.C. 2005), attached hereto at Tab I.) Apotex appealed the district court's order to the U.S. Court of Appeals for the D.C. Circuit and sought to stay the injunction, which the district court denied. (*Teva Pharms. USA, Inc. v. FDA*, 404 F. Supp. 2d 243 (D.D.C. 2005), attached hereto at Tab J.) As a result, Apotex

was prevented from both obtaining final approval for, and marketing, its pravastatin product upon expiration of the '227 patent in April 2006, due to Teva's 180-day exclusivity.

39. On appeal, the D.C. 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. (*Teva Pharms USA, Inc. v. FDA*, 441 F.3d 1 (D.C. Cir. 2006), attached hereto at Tab K.) The Court instructed the district court to vacate FDA's June 28, 2005 decision and remand to the Agency for further proceedings.

40. On April 11, 2006, FDA issued a second administrative decision, in which the Agency 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. (*See* 4/11/06 FDA Decision, attached hereto at Tab L.) 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. Consequently, Teva and Ranbaxy alone were allowed to market their pravastatin products, while Apotex was not.

41. 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. The district court denied Apotex's motion on April 19, 2006. (*Apotex, Inc. v. FDA*, No. Civ.A. 06-0627, 2006 WL 1030151 (D.D.C. Apr. 19, 2006), attached hereto at Tab M.) Apotex appealed.

42. 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 (D.C. Cir. 2006), attached hereto

at Tab N.) 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.

43. Apotex filed its Notice of Arbitration relating to its Pravastatin Claim on June 4, 2009, alleging violations of Articles 1102, 1105 and 1110 of the NAFTA.

44. Apotex's Article 1102 Pravastatin Claim alleges, in general, that Respondent's interpretation and application of the FFDCA against Apotex, and in particular the court-decision trigger provision, is unlawful, and inconsistent with prior Agency and federal court decisions affecting different similarly-situated U.S. investors.

45. Apotex's Article 1105 Pravastatin Claim alleges, in general, that Respondent's Agency and federal court decisions are manifestly unjust, and have missapplied the governing statute and common law governing the triggering of 180-day exclusivity.

46. Apotex's Article 1110 Pravastatin Claim alleges, in general, that Respondent's decisions have interfered with Apotex's property rights in its investment in its pravastatin tablet ANDA; have unduly delayed the approval of Apotex's pravastatin sodium ANDA; and have unlawfully distributed the financial benefits to which Apotex was entitled by delaying Apotex's ability to market its pravastatin sodium drug products.

**C. Significant Factual And Legal Differences Exist Between Apotex's NAFTA Claims**

47. Both of Apotex's claims admittedly involve decisions of at least one U.S. federal court relating to generic drug products, but the similarities end there. While necessarily overly-simplistic for purposes here, in brief, the Sertraline Claim alleges that the U.S. federal courts deprived Apotex of the benefits of Article III of the U.S. Constitution, while the Pravastatin

Claim alleges injuries derived from FDA’s and the U.S. federal court’s unlawful interpretation and application of a U.S. statute – two vastly different claims with vastly different facts and vastly different legal considerations.

48. As noted in the chart below, the underlying factual differences are extensive, and include different investments, different U.S. actors responsible for Apotex’s injuries, different parties involved in the underlying cases, and different types of underlying disputes:

<b><u>Factual Issues</u></b>	<b><u>Sertraline Claim</u></b>	<b><u>Pravastatin Claim</u></b>
<b>Investment at Issue</b>	<ul style="list-style-type: none"> <li>• Apotex’s Sertraline ANDA products</li> </ul>	<ul style="list-style-type: none"> <li>• Apotex’s Pravastatin ANDA products</li> </ul>
<b>U.S. Actors Responsible for Apotex’s Injuries</b>	<ul style="list-style-type: none"> <li>• U.S. District Court for the Southern District of New York</li> <li>• U.S. Court of Appeals for the Federal Circuit</li> <li>• U.S. Supreme Court</li> </ul>	<ul style="list-style-type: none"> <li>• U.S. Food and Drug Administration</li> <li>• U.S. District Court for the District of Columbia</li> <li>• U.S. Court of Appeals for the District of Columbia Circuit</li> </ul>
<b>Parties Involved in Underlying Cases</b>	<ul style="list-style-type: none"> <li>• Bristol Myers Squibb</li> <li>• Apotex</li> </ul>	<ul style="list-style-type: none"> <li>• FDA</li> <li>• Apotex</li> <li>• Teva Pharmaceuticals USA, Inc.</li> </ul>
<b>Type of Underlying Dispute</b>	<ul style="list-style-type: none"> <li>• Declaratory Judgment Action to obtain patent certainty, pursuant to Article III of the U.S. Constitution</li> </ul>	<ul style="list-style-type: none"> <li>• Action for declaratory and injunctive relief challenging final Agency action, pursuant to the Administrative Procedure Act, 5 U.S.C. § 706</li> </ul>

49. Similarly, as noted in the chart below, the two claims involve significantly different legal issues, including different underlying laws, different bases for Apotex’s Article 1102 claims, different bases for Apotex’s Article 1105 claims, and different bases for Apotex’s Article 1110 claims:

<u>Legal Issues</u>	<u>Sertraline Claim</u>	<u>Pravastatin Claim</u>
<b>Underlying Legal Issue</b>	<ul style="list-style-type: none"> <li>• Whether the U.S. federal courts unlawfully denied Apotex subject matter jurisdiction over its declaratory judgment action, under Article III of the U.S. Constitution</li> </ul>	<ul style="list-style-type: none"> <li>• Whether the FDA and U.S. federal courts interpreted and applied the FFDCA in an unlawful manner with respect to Apotex’s pravastatin ANDA</li> </ul>
<b>Laws Interpreted and Applied in the Underlying Actions</b>	<ul style="list-style-type: none"> <li>• Article III of the U.S. Constitution</li> <li>• 35 U.S.C. § 271(e)(5)</li> </ul>	<ul style="list-style-type: none"> <li>• 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002)</li> </ul>
<b>Basis for Article 1102 Claim</b>	<ul style="list-style-type: none"> <li>• Respondent’s failure to extend to Apotex the protections and benefits of Article III of the U.S. Constitution afforded to similarly-situated U.S. investors</li> </ul>	<ul style="list-style-type: none"> <li>• Respondent’s unlawful interpretation and application of the FFDCA against Apotex in a manner inconsistent with prior Agency and federal court decisions affecting different similarly-situated U.S. investors</li> </ul>
<b>Basis for Article 1105 Claim</b>	<ul style="list-style-type: none"> <li>• Respondent’s manifestly unjust federal court decisions, which misapplied constitutional, statutory, and common law in holding Apotex to an unconstitutional justiciability standard</li> </ul>	<ul style="list-style-type: none"> <li>• Respondent’s manifestly unjust Agency and federal court decisions, which misinterpreted and misapplied the FFDCA’s court decision trigger provision</li> </ul>
<b>Basis for Article 1110 Claim</b>	<ul style="list-style-type: none"> <li>• Respondent’s interference with Apotex’s sertraline investment</li> <li>• Respondent’s actions unduly delaying Apotex’s eligibility for approval</li> </ul>	<ul style="list-style-type: none"> <li>• Respondent’s interference with Apotex’s pravastatin investment</li> <li>• Respondent’s decisions, which unduly delayed the approval of Apotex’s pravastatin sodium</li> </ul>

	<ul style="list-style-type: none"> <li>Respondent’s unlawful redistribution of the financial benefits to which Apotex was entitled with respect to its sertraline ANDA</li> </ul>	<p>ANDA</p> <ul style="list-style-type: none"> <li>Respondent’s unlawful distribution of the financial benefits to which Apotex was entitled with respect to its pravastatin sodium ANDA</li> </ul>
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**IV. Apotex Would Be Severely Prejudiced If Its Claims Were To Proceed Concurrently**

50. Respondent has indicated that it is not seeking to consolidate the two arbitrations under NAFTA Article 1126. Instead, Respondent appears to be seeking “*de facto*” consolidation of the two arbitrations – effectively obtaining the exact same result as if undertaking the formal consolidation process without having to undergo the procedural and substantive legal requirements to do so.

51. NAFTA Article 1126 specifically provides the process and procedures for requesting consolidation of multiple arbitrations that have “a question of law or fact in common” in the “interests of fair and efficient resolution of the claims.” Apotex respectfully submits that Respondent would not be able to meet the commonality standard in a formal consolidation proceeding, and cannot do so here, either.

52. In fact, far from raising common questions of law and fact, Apotex’s Sertraline and Pravastatin Claims involve wholly independent and highly complicated facts and legal issues that, if briefed and heard together, will severely prejudice Apotex. Accordingly, the Tribunal should stay the Second-Filed Pravastatin Claim pending resolution of the First-Filed Sertraline Claim.

**A. The Likelihood Of Confusion Of The Issues Will Substantively Prejudice Apotex**

53. Due to the extremely complex nature of the facts and legal issues involved in Apotex's two Claims, there exists great risk of confusion of the issues. The general statutory framework governing the review and approval of Apotex's generic drug products is confusing and dense, and each of Apotex's Claims involves very different and complicated sets of underlying facts and law. Given the complexity of the issues at hand in both Claims, there is a high likelihood of confusion for both counsel and the Tribunal if the parties are forced to argue the two Claims simultaneously.

54. Importantly, this is *not* a case where hearing the two arbitrations together would provide the Tribunal with a more complete set of facts necessary to render its decision. Indeed, as explained above, the opposite is true. The material facts involved in the two claims have nothing to do with each other. The Sertraline Claim involves Apotex's attempt to obtain patent certainty in a declaratory judgment action against an NDA holder, while the Pravastatin Claim involves Apotex's challenge to an FDA decision interpreting and applying the governing federal statute and its court decision trigger provision. Each arbitration stands on its own. Hearing the two separate arbitrations concurrently would all but guarantee that the two separate claims will be co-mingled at some point.

55. By staying the Pravastatin Claim, the Tribunal will limit the number of legal issues it must address at any one time, thereby enhancing the Tribunal's comprehension of the Claim at hand. Without a stay, Apotex will be prejudiced by having to present facts and legal arguments related to both Claims at once, at risk of the Tribunal inadvertently failing to appreciate the significance of a certain fact or legal argument in one Claim due to its focus on the facts or law involved in the other Claim, if not missing an important issue altogether.

56. For instance, certain provisions of the statutes governing the review and approval of generic drugs are critical to the Sertraline Claim while irrelevant to the Pravastatin Claim, and vice versa. Apotex could be greatly prejudiced if counsel or the Tribunal were to gloss over statutory issues highly relevant to one Claim, thinking they were unimportant.

57. In the same vein, Apotex would be similarly prejudiced if key facts or other legal arguments were ignored or overlooked with respect to one Claim, or attributed more significance than they deserved, because either counsel or the Tribunal sought to simplify the issues.

58. Indeed, Respondent has argued that both of Apotex's claims should be briefed and heard concurrently simply because both arbitrations involve decisions of federal courts relating to Apotex's proposed generic drug products. Such an attempt to simplify the extremely independent and complicated facts and legal issues involved in the two Claims exemplifies just how such issues could become confused, and how significant time could be wasted simply trying to clarify the issues. Indeed, Respondent has already misconstrued and mischaracterized the claims and underlying facts and law.

59. Moreover, given the sheer number of underlying court decisions and administrative rulings involved in each individual Claim, the Tribunal, and even counsel for that matter, could have difficulty trying to keep the two arbitrations separate. This very real and imminent risk of confusion can easily be avoided by simply staying the latter Pravastatin Claim until the Sertraline Claim is fully resolved.

60. Simply put, courts do not hear claims together just because they involve pharmaceuticals, and nor should this Tribunal. Indeed, no court at issue here could have heard all of the issues involving Sertraline and Pravastatin in the same action, even if it had wanted to do so. The reasons why are clear and straightforward: the facts and law giving rise to the various claims are

so disparate that any attempt to hear them together would have been disastrous to all parties involved, in particular Apotex. Respondent should not be permitted to inflict that prejudice on Apotex here just because both claims involve generic drugs and U.S. courts.

61. Furthermore, a stay also will assist the Parties and the Tribunal in maintaining a manageable volume of factual evidence and supporting legal documents. This is especially true where, as here, the claims involve entirely different supporting evidence and law.

**B. Hearing Apotex's Claims Concurrently Will Unnecessarily Burden The Parties And The Tribunal**

62. Apotex submits that both counsel and the Tribunal would be best served by focusing its energies and resources on the first arbitration claim (Sertraline) at this time. To begin, briefing and hearing the less complex Sertraline Claim first may potentially simplify certain issues or defenses that may be raised in the later-filed Pravastatin Claim. In contrast, without a stay, Apotex may be prejudiced by having to fully address certain defenses in both arbitrations that could have been resolved in the Sertraline arbitration and potentially carried over to the Pravastatin arbitration without, or with minimal, additional argument.

63. Forcing counsel to argue and the Tribunal to preside over two extremely complicated and vastly different factual patterns, with very different legal considerations, moreover, is an ineffective use of time and resources. Indeed, even if the two Claims were heard concurrently, the parties likely would spend the same amount of time advancing the same positions and defenses, clarifying the issues, and preparing for longer and more complicated hearings. If anything, staying the Pravastatin Claim will narrow the issues relevant solely to the more straight-forward Sertraline Claim, allowing for quicker and more efficient briefing schedules and hearings.

**C. Requiring The Parties To Brief And Argue Both Arbitration Claims Simultaneously Could Create Accounting Problems**

64. Finally, a legitimate concern lingers over the proper apportionment of costs. Under the UNCITRAL rules, “the arbitral tribunal, taking into account the circumstances of the case, shall be free to determine which party shall bear such costs or may apportion such costs between the parties if it determines that apportionment is reasonable.” (UNCITRAL Article 40(2); *see also id.* at Article 40(1).) If the two Claims proceed simultaneously, there is virtually no way to ensure that the costs and expenses for each Claim is kept separate for accounting purposes – both for counsel and for the Tribunal. A proper accounting will be especially important if the Tribunal reaches a different conclusion on each separate Claim, because as noted earlier, the Claims do not rise and fall together but are separate and independent. By staying the second Pravastatin Claim, as Apotex requests, this issue will be altogether avoided.

**V. Apotex’s Proposed Scheduling Order**

65. As requested by the Tribunal, Apotex proposes the following arbitration schedule:

**FIRST-FILED SERTRALINE CLAIM**

EVENT	DATE
Claimant to file a Statement of Claim	December 17, 2010
Respondent to file a Statement of Defense	January 14, 2011
Respondent to file Memorial on Objections to Jurisdiction	January 28, 2011
Claimant to file Counter-Memorial on Objections to Jurisdiction	March 11, 2011

EVENT	DATE
Article 1128 and/or Amicus Submissions	March 11, 2011
Respondent to file Reply on Objections to Jurisdiction	March 25, 2011
Claimant to file Rejoinder on Objections to Jurisdiction	April 5, 2011
Jurisdictional Hearing	April 22, 2011
Award on Jurisdiction	TBD by Tribunal
<i>As agreed by the parties, remainder of schedule to be set at a second procedural hearing following resolution of any jurisdictional issues.</i>	

**SECOND-FILED PRAVASTATIN CLAIM**

EVENT	DATE
<i>To be stayed pending resolution of the Sertraline Claim</i>	

**VI. Conclusion**

66. As noted above, Apotex has not, does not, and will not consent to hearing its Claims concurrently, as Apotex believes that hearing both arbitrations at the same time will substantively prejudice the presentation of its cases. While Apotex fully acknowledges the Tribunal’s authority to order that the arbitrations proceed in parallel under the UNCITRAL Rules, Apotex submits that it should be provided every opportunity to fairly and adequately state its case. NAFTA demands nothing less. Apotex thus respectfully requests that the Tribunal solely focus on the first-filed Sertraline Claim at this time, in the interests of both counsel and the

Tribunal, and enter a schedule substantially in keeping with the schedule proposed in Section V,  
above.

Dated: October 29, 2010

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