

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

APOTEX INC.,

*Claimant/Investor,*

*-and-*

UNITED STATES OF AMERICA,

*Respondent/Party.*

**SUBMISSION OF  
RESPONDENT UNITED STATES OF AMERICA  
IN OPPOSITION TO A STAY**

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UNITED STATES DEPARTMENT OF STATE

Washington, D.C. 20520

November 12, 2010

## **I. Introduction**

1. This arbitration includes two claims by Apotex, Inc. (“Apotex”) against the United States of America under NAFTA Chapter 11, one brought in a Notice of Arbitration (“NOA”) dated December 10, 2008 (the “Sertraline claim”) and the other in a NOA dated June 4, 2009 (the “Pravastatin claim”). Both claims arise from Apotex’s efforts to bring new generic drugs to market in a commercially advantageous manner in the United States and its disappointment with the outcome of litigation brought in U.S. courts in connection with this marketing strategy. The disputing parties agreed to have the same Tribunal hear both claims but have not agreed on how to organize the proceedings.

2. Apotex has asked the Tribunal to stay the Pravastatin claim in favor of the Sertraline claim, alleging that to do so would avoid “confusion” and “unnecessary burdens.”<sup>1</sup> By contrast, the United States objects to a stay, and seeks to have the Tribunal hear both claims concurrently in a fashion that will ensure that common issues of fact, law, and procedure are briefed, heard, and considered at the same time and are therefore dealt with in the fairest, most consistent, and most efficient manner.

3. On October 15, 2010, the Tribunal directed Apotex to “file a submission explaining in detail the precise grounds upon which it seeks such a stay; detailing the differences between the two cases; [and] detailing the prejudice it will suffer if the two cases proceed concurrently[.]”<sup>2</sup>

4. Apotex filed its submission in response to the Tribunal’s request on October 29, 2010. Despite the Tribunal’s direction that Apotex provide “precise grounds” for seeking a stay of the Pravastatin claim, Apotex offered no basis in the NAFTA, the UNCITRAL Rules, or in arbitral practice for its request. Instead, Apotex focuses only on what it asserts are differences in the two

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<sup>1</sup> Submission of Apotex in Support of a Stay ¶ 3 (“Apotex Stay Submission”).

<sup>2</sup> See Letter from the Tribunal to the Parties (Oct. 15, 2010).

claims and the prejudice it believes it would suffer if a stay of the Pravastatin claim were not granted. Apotex alleges in broad terms that its “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.”<sup>3</sup> Moreover, Apotex states that were the claims to be heard together, counsel and the Tribunal would be “unnecessarily burden[ed],” that the concurrent proceeding would “waste time and resources,” and that a divergent result could produce “unnecessary accounting problems,” all of which would result in “tremendous prejudice.”<sup>4</sup> Apotex states repeatedly that the claims are so “complicated” that “there exists great risk of confusion” by the Tribunal if it were to hear them concurrently.<sup>5</sup> In the view of the United States, these concerns are profoundly overstated and without merit.

5. First, the Tribunal has broad power under Article 15(1) of the UNCITRAL Rules to organize these proceedings. In relevant part the UNCITRAL Rules authorize the Tribunal to “conduct the arbitration in such manner as it considers appropriate, provided that the parties are treated with equality and that at any stage of the proceedings each party is given a full opportunity of presenting his case.”

6. Second, contrary to Apotex’s assertions that its claims are “wholly” different from one another, the Sertraline claim and the Pravastatin claim are remarkably similar. As discussed below, both claims allege the same type of investment, by the same alleged investor. That investor is alleged to have sustained the same type of injury and incurred the same amount of damages, arising from measures that are alleged to have breached the same provisions of the

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<sup>3</sup> Apotex Stay Submission ¶ 2.

<sup>4</sup> *Id.* ¶ 3.

<sup>5</sup> *Id.* ¶¶ 3, 53.

NAFTA. Furthermore, both claims involve the same statutory framework, arbitration rules, and legal place of arbitration.

7. Finally, rather than “detailing the prejudice it will suffer if the two cases proceed concurrently,” as directed by the Tribunal, Apotex offers only that the Tribunal would be confused by the complexity of the two claims and might fail “to appreciate the significance of a certain fact or legal argument . . . if not missing an important issue altogether” or that it will be unable to manage the “volume of factual evidence and supporting legal documents.”<sup>6</sup>

8. Apotex’s concerns are baseless. The Tribunal will not have any difficulty in understanding the claims involved in this arbitration if they are heard concurrently. Even if the Tribunal were to accept Apotex’s characterization of the claims as “extremely complex,”<sup>7</sup> the United States is nevertheless confident that this Tribunal is particularly well-suited to decide any and all issues arising out of these claims in one proceeding.

9. Moreover, hearing the claims concurrently will result in substantial savings of time and costs by ensuring common issues are presented, heard, and decided together. In contrast to the obvious advantages of concurrent proceedings, Apotex’s inchoate fear of the Tribunal “missing an important issue” is not a sufficient showing of prejudice to support its request for a stay of the Pravastatin claim.

## **II. Apotex’s Claims Have Substantial Commonalities Of Fact And Law And Should Be Heard At The Same Time**

10. Apotex asserts in its submission that “both claims involve complex factual and legal issues that bear no relevance to each other.”<sup>8</sup> Nonetheless, Apotex’s own description of the claims belies this assertion. Apotex sets out in each claim, in both NOAs, and its submission

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<sup>6</sup> *Id.* ¶¶ 55, 61.

<sup>7</sup> *Id.* ¶ 53.

<sup>8</sup> *Id.* ¶ 3.

requesting a stay, nearly identical “Statutory Background” sections. Moreover, it concedes in its stay submission that “[b]oth of Apotex’s claims” involve decisions of the U.S. courts relating to its generic products.<sup>9</sup> However, the similarities do not end there. In point of fact, both the Sertraline claim and the Pravastatin claim concern the same legal framework and will require the Tribunal to understand the same process and authorizations necessary to bring a generic drug to market under an Abbreviated New Drug Application (“ANDA”) and a Paragraph IV certification pursuant to the applicable statutes. Moreover, both claims are brought under the same three provisions of the NAFTA and therefore present the Tribunal with a single applicable law framework for resolving the claims.

**A. Apotex’s NAFTA Claims Have Substantial Commonalities**

11. In each of its NOAs, Apotex uses the same language to allege violations of the same NAFTA provisions (Articles 1102, 1105, and 1110).

12. Apotex’s first claim is for a breach of national treatment under Article 1102. In its Sertraline and Pravastatin NOAs, Apotex uses identical language to present its claim under Article 1102 at paragraphs 58 and 68 respectively. *Compare* Sertraline NOA ¶ 58 *with* Pravastatin NOA ¶ 68.

13. Apotex’s second claim is for breach of the minimum standard of treatment under Article 1105. Here again in its Sertraline and Pravastatin NOAs, Apotex uses identical language to present its claim under Article 1105 at paragraphs 61 and 71 respectively. *Compare* Sertraline NOA ¶ 61 *with* Pravastatin NOA ¶ 71. Moreover, Apotex’s legal support for its allegations under Article 1105 is also identical in both the Sertraline and Pravastatin NOAs. *Compare* Sertraline NOA ¶ 62 *with* Pravastatin NOA ¶ 72. Apotex cites three sources to support its

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<sup>9</sup>*Id.* ¶ 47.

Sertraline claim under Article 1105 and the same three sources to support its Pravastatin claim under Article 1105. *Id.*<sup>10</sup>

14. Apotex's third claim is for expropriation under Article 1110. Again, in its Sertraline and Pravastatin NOAs, Apotex uses identical language to present its claim under Article 1110 at paragraphs 64-66 and paragraphs 74-76 respectively. Compare Sertraline NOA ¶¶ 64-66 with Pravastatin NOA ¶¶ 74-76. Apotex's attempt to distinguish the two claims in the chart on pages 14-15 of its submission is unconvincing. Using the words "action" and "redistribution" for the Sertraline claim as opposed to the words "decision" and "distribution" in the Pravastatin claim does not establish that the claims are "wholly" independent. See Apotex Stay Submission at 14-15 (compare "Respondent's *actions* unduly delaying Apotex's eligibility for approval" for the Sertraline claim with "Respondent's *decisions*, which unduly delayed the approval" for the Pravastatin claim and compare "Respondent's unlawful *redistribution* of the financial benefits to which Apotex was entitled" for the Sertraline claim with "Respondent's unlawful *distribution* of the financial benefits to which Apotex was entitled") (emphasis added).

15. Moreover, Apotex's Sertraline claim and Pravastatin claim both allege breaches of the NAFTA with regard to the same type of investment, the same investor, the same type of injury, and the same alleged damages. It is beyond dispute that Apotex's Sertraline claim and Pravastatin claim are identical in these respects. Indeed, throughout the respective NOAs, sentences and even entire paragraphs are nearly, and in some instances actually, word-for-word identical.<sup>11</sup> Several examples illustrate how the two claims share many commonalities:

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<sup>10</sup> The single difference between these paragraphs is Apotex's inclusion in the Pravastatin NOA of an additional parenthetical quotation from the Award in *Loewen Group, Inc. v. United States*, ICSID ARB(AF)/98/3 (June 26, 2003).

<sup>11</sup> See, e.g., Sertraline NOA ¶ 60.g; Pravastatin NOA ¶ 70.f ("Failing to treat Apotex's substantial investment in the development and preparation of its ANDA for generic [sertraline/pravastatin] products in the same fashion as the investments of U.S. investors."); Sertraline NOA ¶ 67.c; Pravastatin NOA ¶ 77.c ("Unlawfully redistributing the

- Both the Sertraline claim and the Pravastatin claim involve the same alleged investor: “Apotex, Inc.”<sup>12</sup>
- Both the Sertraline claim and the Pravastatin claim use identical language with regard to NAFTA Article 1139: “Apotex, a privately-owned generic pharmaceutical company . . . manufacturing approved generic pharmaceutical products for sale in the United States and throughout the world.”<sup>13</sup>
- Both the Sertraline claim and the Pravastatin claim involve the same alleged type of investment: “ANDA products.”<sup>14</sup>
- Both the Sertraline claim and the Pravastatin claim involve the same alleged injury: “Apotex was unable to promptly bring its generic [sertraline/pravastatin] products to market.”<sup>15</sup>
- Both the Sertraline claim and the Pravastatin claim involve the same alleged damages: Apotex “suffered lost sales and a loss in market share worth a total of at least \$8,000,000 (US).”<sup>16</sup>

16. In sum, Apotex presents two claims, alleging identical breaches under the NAFTA, both involving the same investor, the same type of investment, the same theory of injury, and the

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financial benefits of Apotex’s investment by preventing Apotex from obtaining final approval of its generic [sertraline/pravastatin] tablets immediately upon expiration of the [‘518/‘227] patent”); Sertraline NOA ¶ 67.b; Pravastatin NOA ¶ 77.b (“Substantially depriving Apotex of the benefits of its investments in its generic [sertraline/pravastatin] ANDA by delaying Apotex’s eligibility for final approval”). Moreover, whole sections of the Sertraline NOA and the Pravastatin NOA are copied nearly verbatim from one another. *Compare* Sertraline NOA ¶¶ 68-73 *with* Pravastatin NOA ¶¶ 78-83 (using identical language in describing claims under the NAFTA).

<sup>12</sup> Sertraline NOA ¶¶ 1, 4; Pravastatin NOA ¶¶ 1, 4.

<sup>13</sup> Sertraline NOA ¶ 59; Pravastatin NOA ¶ 69.

<sup>14</sup> Apotex Stay Submission at 13.

<sup>15</sup> Sertraline NOA ¶ 57; Pravastatin NOA ¶ 67.

<sup>16</sup> *Id.*

same sum of damages. In the interest of efficiency and cost-effectiveness, these claims should be briefed, heard, and decided together.

**B. Apotex's NAFTA Claims Concern The Same Domestic Statutory Framework**

17. Apotex's NAFTA claims challenge the application of the same U.S. law. Both claims concern action under the Federal Food, Drug, and Cosmetic Act of 1938 ("FFDCA"), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). *Compare* Sertraline NOA ¶ 24 *with* Pravastatin NOA ¶ 33.<sup>17</sup>

18. Pursuant to the FFDCA, a company may submit an ANDA for the approval of a new generic drug. Apotex submitted a Sertraline ANDA and a Pravastatin ANDA so that these "generic drugs [could] be sold by others in the United States." *Compare* Sertraline NOA ¶ 13 *with* Pravastatin NOA ¶ 13. Both ANDAs were thus subject to the same Food and Drug Administration ("FDA") ANDA approval process.

19. Both ANDAs contained Paragraph IV certifications. *Compare* Sertraline NOA ¶ 46 *with* Pravastatin NOA ¶ 50. For both ANDAs, Apotex filed its Paragraph IV certifications after another ANDA applicant had already filed Paragraph IV certifications to the applicable patents. As a result, Apotex was not eligible for the statutorily prescribed 180 days of marketing exclusivity for either of those drugs. *Compare* Sertraline NOA ¶ 44 *with* Pravastatin NOA ¶ 49.

20. Similarly, in both claims, Apotex initiated a declaratory judgment action, seeking to obtain "a court decision finding [the applicable patents] invalid or not infringed" in order "to obtain patent certainty" and to trigger the 180-day generic exclusivity period belonging to the first ANDA applicant who had filed Paragraph IV certifications to those patents. *Compare*

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<sup>17</sup> FFDCA, 21 U.S.C. § 1 *et seq.*; Hatch-Waxman Amendments, Pub. L. No. 98-417, 98 Stat. 1585 (1984); MMA, Pub. L. No. 108-173, 117 Stat. 2066 (2003).



Sertraline NOA ¶¶ 18-19 *with* Pravastatin NOA ¶¶ 19, 21. Both actions were dismissed for lack of subject matter jurisdiction. *Compare* Sertraline NOA ¶ 20 *with* Pravastatin NOA ¶ 22. Thus, although Apotex seeks to characterize the claims as “entirely different,” both claims concern the conduct of the U.S. federal courts in applying U.S. federal law that, as alleged by Apotex, resulted in a delay in marketing of its generic Sertraline/Pravastatin tablets in violation of NAFTA Articles 1102, 1105, and 1110.

21. While the two claims arise at different points in Apotex’s respective attempts to bring Sertraline and Pravastatin generics to market, and reflect other differences related to the fact that they involve different drugs, that does not mean that they are “very different,” too “complex,” or that briefing and hearing them at the same time would be too “confusing.”<sup>18</sup>

### **III. Apotex’s Allegation That It Will Be Prejudiced Is Unfounded**

22. Contrary to Apotex’s rhetoric, hearing the claims together “will not severely prejudice” Apotex or be “disastrous to all parties involved.”<sup>19</sup> Nor will hearing the claims together “unnecessarily burden” the disputing parties or the Tribunal.<sup>20</sup> Indeed, Apotex does not, because it cannot, detail what prejudice or burdens would flow from hearing the claims together. In fact, given the substantial overlap in basic aspects of the claims, hearing the claims together will result in considerable savings in time and expense by the parties and the Tribunal. At base, Apotex fails to support its bare allegations that hearing the two claims together may “confuse” the Tribunal and “burden” the parties, and thus its unfounded claims of prejudice fail.

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<sup>18</sup> Apotex Stay Submission ¶ 53.

<sup>19</sup> *Id.* ¶¶ 52, 60.

<sup>20</sup> *Id.* ¶¶ 62, 63.

**A. Hearing The Claims Together Will Not “Confuse” The Tribunal**

23. As an initial matter, Apotex has not provided the Tribunal with any basis to conclude that the claims are “extremely independent and complicated.”<sup>21</sup> For example, while asserting that it will be “severely prejudice[d],” and decrying its fear that the Tribunal might “gloss over statutory issues,” Apotex does not identify which “provisions of the statutes governing the review and approval of generic drugs are critical to the Sertraline Claim while irrelevant to the Pravastatin Claim.”<sup>22</sup> In fact, Apotex’s stated concern about the differences in the domestic law origins of the claims contradicts its other statement that “[b]oth of Apotex’s claims require a basic understanding of this statutory framework”<sup>23</sup> and is further belied by Apotex’s use of the same seven paragraphs laying out the statutory framework common to both claims.<sup>24</sup>

24. Apotex offers no explanation for why it would be less confusing for the claims to proceed separately. Instead, Apotex offers the conclusory assertion that, if the claims are heard concurrently, the Tribunal will not be able to understand the “extremely complicated and vastly different factual patterns, with very different legal considerations.”<sup>25</sup> Apotex asserts that its two claims concern separate provisions of domestic “statutes governing the review and approval of generic drugs,” without acknowledging that this arbitration is governed by international, not domestic, law. Under the governing law of this arbitration, Apotex’s two claims raise the identical issues, namely whether the application of those domestic statutes by U.S. courts violated Article 1102, Article 1105, and Article 1110 of the NAFTA.

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<sup>21</sup> *Id.* ¶ 58.

<sup>22</sup> *Id.* ¶¶ 52, 56.

<sup>23</sup> *Id.* ¶ 13.

<sup>24</sup> *Id.* ¶¶ 6-12.

<sup>25</sup> *Id.* ¶ 63.

25. In any case, despite Apotex's allegations to the contrary, the complexity of a case is not a sufficient reason to conclude that the Tribunal will not be able to understand the alleged issues in the arbitration and apply the proper factual and legal analysis to the two claims, and that therefore the claimant will be prejudiced. Respondent is fully confident in the Tribunal's ability to understand the facts and law at issue in this arbitration.

**B. Hearing The Claims Together Will Not Result In An Unnecessary Burden**

26. Apotex's assertion that the same Tribunal hearing its two claims together at the same time will place "unnecessary burdens"<sup>26</sup> on the disputing parties is similarly without foundation. Apotex offers no basis for its contention that hearing the claims concurrently would be burdensome, instead offering only the same generalized concerns of "complexity" that it invoked in its argument that it would "suffer tremendous prejudice" if the claims were heard together.<sup>27</sup>

27. Apotex itself recognizes that the claims are so similar that "certain defenses in both arbitrations" would be "potentially carried over . . . without, or with minimal, additional argument."<sup>28</sup> Thus, even were the Tribunal to accept that the facts and law are "extremely complicated," which Respondent rejects, Apotex concedes in its own submission that there is substantial overlap in the alleged legal issues presented for decision. Indeed, Apotex asserts that an advantage of hearing the Sertraline claim first is that the Tribunal's rulings in that matter could be "carried over" to foreclose issues otherwise presented in the Pravastatin claim. In the view of Respondent, however, this is an argument for hearing the claims concurrently because they present certain identical issues of fact and law.

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<sup>26</sup> *Id.* ¶ 3.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* ¶ 62.

### C. Hearing The Claims Together Will Not Result In Accounting Problems

28. Finally, Apotex argues that combining the claims is inappropriate because it could create accounting difficulties when calculating a final award of costs.<sup>29</sup> But this is putting the cart before the horse. It is entirely inappropriate to base a decision on the fairest and most efficient way to organize arbitral proceedings on speculation about potential cost orders, when such orders are made at the discretion of the Tribunal. Indeed, Article 40 of the UNCITRAL Rules creates a presumption that an “unsuccessful party” shall “in principle” bear the costs of Arbitration, and grants the Tribunal authority to apportion the costs of arbitration “between the parties if it determines that apportionment is reasonable, taking into account the circumstances of the case.” Article 40(2) contains a similar provision granting the Tribunal discretionary authority to apportion the costs of legal representation and assistance.

29. Apotex asserts that if the claims proceed together and the Tribunal finds in favor of Apotex on one, but not the other, there would be “no way to ensure that the costs and expenses for each Claim is kept separate” and that hearing the claims separately would avoid this “legitimate concern.”<sup>30</sup> Again, Respondent does not share Claimant’s concern about the Tribunal’s ability to make distinctions where necessary based on the applicable facts and circumstances of the claim. Indeed, the ability of other NAFTA Chapter 11 Tribunals to do what Apotex fears cannot be done demonstrates that such a concern is unwarranted. For example, in *Pope & Talbot, Inc. v. Canada*, the tribunal considered a reasonable apportionment of costs and fees after Pope & Talbot prevailed on one claim under Article 1105, but failed to sustain its claims under Articles 1102, 1106, and 1110.<sup>31</sup> The *Pope & Talbot* tribunal concluded that

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<sup>29</sup> *Id.* ¶ 64.

<sup>30</sup> *Id.*

<sup>31</sup> *Pope & Talbot, Inc. v. Canada*, NAFTA/UNCITRAL, Award on Costs ¶ 8 (Nov. 26, 2002).

because the result was mixed, an equitable apportionment would be for Canada to pay more than half of the arbitral costs and for both parties to pay their own legal representation costs.<sup>32</sup>

Because this Tribunal has the authority to apportion costs in the manner that it determines reasonable, and because previous tribunals have apportioned costs equally when a “prevailing party” cannot be determined, Apotex’s accounting concerns are baseless.

#### **IV. In The Interest Of Efficiency And Cost-Effectiveness, Apotex’s Claims Should Be Heard Together**

30. Briefing, hearing, and deciding the claims together will result in substantial advantages. Concurrent proceedings will avoid duplication and save the disputing parties time and costs. All of the relevant facts and legal arguments can be formulated and presented at the same time both in written submissions and during hearings. Questions raised by the Tribunal that address similar issues in both claims can be answered once. Given the substantial overlap in fact and law, fact witnesses and experts need not be called upon to present evidence in two separate proceedings potentially separated by years. The Tribunal itself will save on travel and hearing time and realize efficiencies in deliberations and drafting of awards. All of the above advantages flow naturally from the agreement to have both claims heard by the same Tribunal. In sum, while Apotex provides the Tribunal with no compelling justification for hearing these claims separately, it is clear that there are significant advantages and efficiencies that concurrent proceedings would provide for all involved.

#### **V. The United States’ Proposed Scheduling Order**

31. As requested by the Tribunal, the Respondent proposes the following schedule, which apportions equal time to both disputing parties, for both the Sertraline claim and the Pravastatin claim:

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<sup>32</sup> *Id.* ¶¶ 17-18.

<b>Event</b>	<b>Date</b>
Claimant to file a Statement of Claim	December 17, 2010
Respondent to file a Statement of Defense	February 15, 2011
Respondent to file Memorial on Objections to Jurisdiction	April 16, 2011
Claimant to file Counter-Memorial on Objections to Jurisdiction	June 15, 2011
Article 1128 and/or Amicus Submissions	July 15, 2011
Respondent to file Reply on Objections to Jurisdiction	August 14, 2011
Claimant to file Rejoinder on Objections to Jurisdiction	October 13, 2011
Jurisdictional Hearing	December 12, 2011
Award on Jurisdiction	TBD by Tribunal

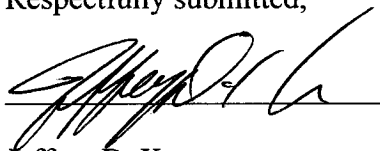
## **VI. Conclusion**

32. The issue for the Tribunal to decide – upon which the parties have been unable to reach agreement – is the best manner in which to proceed to hear these two claims in one arbitration. The claims relate to the same statutory framework, involve many of the same facts, involve similar, if not identical, claims under the NAFTA, and assert identical claims for relief. In the interest of efficiency and cost-effectiveness, these claims should be briefed, heard, and decided together. Creating separate procedural paths for each claim and staying one claim in favor of the other because of Apotex's baseless and inchoate fears that the Tribunal will be confused by the complexity of the claims is not only without merit, but would be remarkably inefficient and costly. Respondent is confident that the Tribunal has the ability to hear these claims together

and, for the reasons set forth above, asks that it enter a scheduling order in keeping with Section V.

Dated: November 12, 2010

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Jeffrey D. Kovar', is written over a horizontal line.

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