Public Version

IN THE ARBITRATION UNDER CHAPTER ELEVEN
OF THE NORTH AMERICAN FREE TRADE AGREEMENT
AND THE ICSID ARBITRATION (ADDITIONAL FACILITY) RULES
BETWEEN

APOTEX HOLDINGS INC. *and* APOTEX INC.,

Claimants/Investors,

-and-

THE UNITED STATES OF AMERICA,

Respondent/Party.

Case No. ARB(AF)/12/1

REPLY OF RESPONDENT UNITED STATES OF AMERICA ON BIFURCATION

Lisa J. Grosh
Assistant Legal Adviser
Jeremy K. Sharpe
Chief, Investment Arbitration
Neale H. Bergman
David M. Bigge
John I. Blanck
Alicia L. Cate
Nicole C. Thornton
Attorney-Advisers
Office of the Legal Adviser
UNITED STATES DEPARTMENT OF STATE
Washington, D.C. 20520

TABLE OF CONTENTS

I. INTRODUCTION

1. In accordance with the Tribunal's First Procedural Order and its Order of October 29, 2012, the United States respectfully submits this Reply to Claimants' Opposition to Bifurcation of December 28, 2012.

2. The U.S. Counter-Memorial on Merits and Objections to Jurisdiction established that bifurcating these proceedings is not only permitted by the applicable arbitration rules, but also compelled by reasons of economy, efficiency, and fairness. The United States has presented credible, well-founded jurisdictional objections that are separate from the merits and, if accepted, will eliminate or substantially reduce the scope of Apotex's claims. Bifurcation thus is expected to save the parties the significant expense of (1) further briefing the merits; (2) preparing for and presenting argument and witness testimony at a lengthy merits hearing; and (3) gathering, reviewing, redacting, and producing documents. We thus ask that the Tribunal grant the United States' request to decide the U.S. jurisdictional objections as a preliminary matter, in accordance with Article 45 of the ICSID Additional Facility Rules.

3. We further request that the Tribunal reject Apotex's proposed pleading schedule on issues of quantum. The Tribunal has reserved to itself the prerogative of fixing that schedule, if necessary, "at a later date."[1] And yet Apotex has sought, unilaterally, to join the scheduling of those issues to the United States' bifurcation request. Apotex's proposal is not only untimely, but also highly prejudicial, as it would require the United States to file an expert report on valuation and brief quantum issues a mere *nine weeks* after receiving Apotex's "supplemental" damages report and evidence. The United States should not be penalized for Apotex's own failure to submit a complete damages claim and complete evidence. It would be inefficient,

[1] Letter from Eloïse Obadia to the Parties, at 2 (Oct. 29, 2012).

moreover, for the United States to incur the enormous expense of pleading issues of quantum before the Tribunal first has adjudicated the United States' well-founded jurisdictional objections, which we anticipate will eliminate Apotex's entire case.

4. Finally, we note that Apotex's 48-page submission contains extensive arguments on the substance of the United States' jurisdictional objections, which we believe are inappropriate for a submission on bifurcation. Although compelled to provide some response, we recognize that briefing on those issues has been reserved for the parties' submissions on jurisdiction, as set forth in the First Procedural Order. The United States thus will provide a fuller response to Apotex's arguments in a later substantive submission.

II. ARGUMENT

A. Apotex Misstates the U.S. Jurisdictional Objections, the Facts, and the Law

5. Apotex has made extensive arguments and introduced new evidence in an attempt to demonstrate that (1) the challenged measure "relates to" Apotex Holdings and Apotex Inc. as "investors" and their alleged U.S. "investments"; and (2) Apotex Inc. is an "investor" that made or sought to make an "investment" in United States. Apotex's new arguments, however, misconstrue the United States' jurisdictional objections, the facts, and the law.

1. Apotex Mistakenly Claims that the United States' Jurisdictional Objections Are "Partial" and "Mutually Exclusive"

6. Apotex argues that the United States' jurisdictional objections are "partial" and "mutually exclusive," and that "[f]or the US to achieve the premise for its bifurcation request and 'eliminate Apotex's entire claim,' the Tribunal would need to accept *both* categories of objections."[2] Apotex is mistaken. The United States has raised two main jurisdictional

[2] Claimants' Opposition to Bifurcation ¶¶ 15, 18 (emphasis added).

objections, each of which independently justifies bifurcating these proceedings. *First*, the sole challenged measure in this case – the FDA Import Alert – did not "relate to" either Apotex Holdings or Apotex Inc. as "investors" or their alleged U.S. "investments."[3] Because Apotex cannot show that the Import Alert "related to" (*i.e.*, had a "legally significant connection to") either Claimant as an "investor" or any alleged "investment," Apotex's entire case fails for lack of jurisdiction.[4]

7. *Second*, Apotex also must prove that Apotex Inc. is an investor that made, or sought to make, an investment in the United States. If Apotex fails to do so, the case will be greatly simplified, and Apotex's damages claim will be substantially reduced. Apotex's latest submission has made it even more difficult for Apotex to clear this jurisdictional hurdle. There is no dispute between the parties that Apotex Inc. is a Canadian company whose "facilities, offices, real estate and employees are located solely in Canada."[5] Nor is there any dispute that Apotex Inc. does not own or control any U.S. company; does not share in the income or profits of any U.S. company; does not have an equity or debt interest in any U.S. company; does not develop or manufacture its products in the United States; and does not prepare or hold its drug applications in the United States. Apotex's latest submission acknowledges, moreover, that Apotex Inc. sells its products *exclusively in Canada*.[6] Apotex has even argued in U.S. court that

[3] *See* U.S. Counter-Memorial at 135 ("The Import Alert Did Not Relate to Apotex Inc. as an Alleged Investor or to its Alleged Investments"); *id.* at 140 ("The Import Alert Did Not Relate to Apotex Holdings as an Investor or to Its U.S. Investment, Apotex Corp.").

[4] *See id.* ¶¶ 267-71 (discussing authority); Claimants' Memorial ¶ 410 (acknowledging standard).

[5] *Shire LLC v. Apotex Inc., Apotex Corp. and Apotex Pharmaceutical Holdings Inc.*, No. 2:08-cv-265 (E.D. Tex.), Apotex Inc.'s and Apotex Pharmaceutical Holding Inc.'s Reply in Support of Their Rule 12(b)(2) Motion to Dismiss for Lack of Personal Jurisdiction, at 2 (Sept. 11, 2008) [RLA-184].

[6] *See* Claimants' Opposition to Bifurcation ¶ 31.

"*Apotex Inc. has put nothing into the stream of commerce*" in the United States.[7] And yet Apotex Inc. nonetheless claims to be an "investor" with "investments" in the United States for purposes of NAFTA Chapter Eleven. It is Apotex, not the United States, that is making "brave" arguments in this arbitration.[8]

2. Apotex Continues to Misunderstand, and Hence Misrepresent, the Legal Effect of the Import Alert

8. Apotex argues that the Import Alert "relates to" Apotex Corp. because the Import Alert (1) was "specifically addressed to the Apotex group"; (2) "interrupted the transactions on which Apotex [Corp.] depended for 80 percent of its sales"; (3) "applied directly" to Apotex Corp.; and (4) uniquely affected Apotex Corp. because of its "special relationship" with Apotex Inc.[9] Apotex is wrong in all four respects.

9. *First*, the Import Alert was not "specifically addressed to the Apotex group."[10] Rather, the Import Alert was specifically addressed to drug products from *Apotex Inc.'s* manufacturing facilities at "150 Signet Drive, North York, Ontario" and "50 Steinway Blvd., Etobicoke,

[7] *Abbott Laboratories Inc. and Abbott GMBH & Co. KG v. Apotex Inc. and Apotex Corp.*, No. 1:09-cv-00990-JJF (D. Del.), Defendant Apotex Inc.'s Brief in Support of its Motion to Dismiss for Lack of Personal Jurisdiction Pursuant to Fed. R. Civ. P. 12(b)(2), at 10-11 (Jan. 13, 2010) (emphasis added) (denying that "Apotex Inc. sells various products unrelated to this case in the United States," and affirming that "Apotex Inc. has put nothing into the stream of commerce") [RLA-175].

[8] *See* Claimants' Opposition to Bifurcation ¶ 8.

[9] *Id.* ¶¶ 8, 23, 67.

[10] *Id.* ¶ 8. *But see* Claimants' Memorial ¶ 412 ("The Import Alert specifically named Apotex [Inc.] as the affected party."); Claimants' Request for Arbitration ¶ 2 (Feb. 29, 2012) ("On August 28, 2009, the US Food and Drug Administration . . . adopted a measure with respect to two Canadian facilities operated by Apotex [Inc.].").

Ontario."[11] The Import Alert nowhere mentions, directly or indirectly, any other company in the Apotex group, including Apotex Corp.[12]

10. *Second*, the Import Alert did not interrupt any "transactions" between Apotex Inc. and Apotex Corp. or make it "legally impossible for these transactions to be carried out."[13] Apotex's latest submission, in fact, confirms that *all* transactions between Apotex Corp. and Apotex Inc. occurred *in Canada*, with title and risk of loss passing to Apotex Corp. when Apotex Inc. "handed over its products" to a carrier "at the facilities in Etobicoke and Signet."[14] Apotex has emphasized in U.S. court, moreover, that "*Apotex Inc. does not directly sell any products of any kind in the United States*."[15] Apotex has failed to explain how the FDA Import Alert could have interrupted sales transactions that occurred entirely in Canada.

11. Apotex's real complaint is that the Import Alert affected Apotex Corp.'s ability to *import* into the United States drug products manufactured at Apotex Inc.'s Etobicoke and Signet facilities. But as the United States demonstrated in its Counter-Memorial, the Import Alert was not the underlying measure that prevented Apotex Corp. (or any other company) from importing

[11] Import Alert 66-40, *Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug GMPs* (Oct. 2, 2009) ("2009 Import Alert 66-40") [C-110].

[12] *See id*. Apotex asserts that the U.S. argument that the challenged measure was addressed to a Canadian company's manufacturing facilities in Canada is "diametrically opposite" to what the United States argued in its submissions on place of arbitration. Claimants' Opposition to Bifurcation ¶ 35 n.23. There is no inconsistency, however, between the fact that the challenged measure specifically addressed two of Apotex Inc.'s manufacturing facilities *in Canada* and the argument that, because "Apotex purports to have brought an *investment* dispute against the United States," the "subject matter" of Apotex's claim necessarily falls within the *United States*. *See* U.S. Submission on Place of Arbitration, at 16-17 (Aug. 31, 2012); U.S. Rejoinder Submission on Place of Arbitration, at 3 (Sept. 26, 2012).

[13] Claimants' Opposition to Bifurcation ¶¶ 23-24.

[14] *Id.* ¶ 31.

[15] *See, e.g.*, *Shire LLC v. Apotex Inc., Apotex Corp. and Apotex Pharmaceutical Holdings Inc.*, No. 2:08-cv-265 (E.D. Tex.), Declaration of Bernice Tao ¶ 12 (Aug. 6, 2008) (emphasis added) [RLA-183]; *Cephalon, Inc. et al. v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS (D. Del.), Declaration of Bernice Tao ¶ 11 (stating same) (Oct. 12, 2010) [RLA-178].

into the United States products from those facilities.[16] Under U.S. law, drug products manufactured at facilities that fail to comply with current good manufacturing practice (cGMP) are deemed to be "adulterated" and thus may be detained and refused admission into the United States.[17] This is true *regardless of whether the drug products are from facilities listed on an Import Alert*. By contrast, an Import Alert constitutes "compliance guidance information" for FDA field offices when determining whether goods offered for import appear to be adulterated.[18] As such, the underlying "legal impediment" that prevented Apotex Corp. (and every other company that purchased Apotex Inc. drugs)[19] from importing drugs into the United States from the Etobicoke and Signet facilities was FDA's determination that those facilities were not cGMP-compliant and thus drugs from those facilities were deemed to be adulterated.[20] Apotex,

[16] *See* U.S. Counter-Memorial ¶¶ 49-53 (citing authority).

[17] *See id.* ¶ 46 (citing authority).

[18] *See id.* (quoting definition of "Import Alert").

[19] Apotex contends that, during the period of the Import Alert, "Apotex [Corp.] was the only company denied the *ability* to import products made at Etobicoke and Signet for commercial sale in the United States." Claimants' Opposition to Bifurcation ¶ 116 (emphasis altered). This is wrong. Once FDA determined that Apotex's Etobicoke and Signet facilities failed to comply with current good manufacturing practice, U.S. law authorized FDA field offices to detain without physical examination all finished form drug products from those facilities, *regardless of the owner or consignee*. *See* U.S. Counter-Memorial ¶ 49 (citing U.S. law). Apotex calculates that, during the period of the Import Alert, companies in the United States other than Apotex Corp. were permitted to receive 98% of "hundreds of shipments" of Etobicoke and Signet products. Claimants' Opposition to Bifurcation ¶ 59. As noted in the Counter-Memorial, however, FDA officials retain discretion to determine whether to detain products listed on an Import Alert. *See* Counter-Memorial ¶ 46 (citing authority). At Apotex's request, for example, some drug product shipments from these facilities were permitted, including for compassionate use of [redacted] manufactured at Apotex Inc.'s Etobicoke facility and for an urgent medical need for an investigational use drug. *See id.* ¶¶ 155-56; FDA, *Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009)*, at 1 [R-119]. Had Apotex Inc., for instance, shipped [redacted] to Apotex Corp. for distribution, instead of shipping it directly to a commercial pharmacy or hospital, then *Apotex Corp.* also would have received that shipment. It is thus wrong and disingenuous for Apotex to cite its 98% figure as suggesting that the Import Alert uniquely affected Apotex Corp.

[20] Apotex's reliance on *Cargill* is misplaced. There, the challenged Mexican measure imposed a "legal impediment" to business operations in Mexico of the claimant's wholly owned Mexican subsidiary. *See* U.S. Counter-Memorial ¶¶ 293-94 (citing *Cargill Inc. v. United Mexican States*, NAFTA/ICSID Case No. ARB(AF)/05/2, Award (Sept. 18, 2009) [CLA-23]). Apotex does not and cannot argue that the Import Alert prevented Apotex Corp. (which is not a subsidiary of Apotex Inc.) from continuing to operate in the United States, including by obtaining drugs from (1) other Apotex Inc. facilities; (2) other facilities within the Apotex group; and (3) non-Apotex facilities. *See* U.S. Counter-Memorial ¶¶ 293-98 (citing authority).

however, does not challenge that underlying determination. Apotex's entire case thus rests on its misunderstanding – and hence misrepresentation – of U.S. law.

12. *Third,* Apotex argues that the Import Alert was "applied to" Apotex Corp., citing a Notice of FDA Action that listed Apotex Corp. as the "consignee" of products shipped from Apotex Inc.'s Etobicoke facility. Apotex contends that the Notice of FDA Action: (1) is "the only contemporaneous official evidence of the adoption of the Import Alert"; and (2) demonstrates that the Import Alert was "specifically addressed to Apotex [Corp.]," as the consignee of products being shipped from Apotex Inc.[21] Again, Apotex is wrong on both counts.

13. The "contemporaneous official evidence of the adoption of the Import Alert" is the Import Alert itself. FDA published Import Alert 66-40 on its website, which, as noted, specifically identified Apotex Inc.'s Etobicoke and Signet facilities, not Apotex Corp.[22]

14. The Notice of FDA Action, moreover, merely informed Apotex Corp. (as the consignee of a particular shipment of drugs from Apotex Inc.'s non-cGMP-compliant facility being imported into the United States) that: (1) the product appeared to be adulterated and thus was being detained; and (2) Apotex Corp. could introduce testimony regarding the admission of that shipment into the United States. These points are clearly stated in the very statute, regulation, and FDA manual Apotex cites.[23]

15. *Fourth*, Apotex Corp. argues that it was uniquely affected by the Import Alert because Apotex Corp. (1) was specifically identified in FDA Notices of Action; (2) was the sole

[21] Claimants' Opposition to Bifurcation ¶ 25.

[22] 2009 Import Alert 66-40 [C-110].

[23] *See* Claimants' Opposition to Bifurcation ¶¶ 27-29 (citing 21 U.S.C. § 381 [CLA-239], 21 C.F.R. § 1.94 [CLA-245]; FDA Regulatory Procedures Manual § 9.1 [CLA-310].

distributor of Apotex Inc. products in the United States; and (3) is part of the Apotex "group of companies."[24] Again, each of these assertions is incorrect.

16. Apotex Corp. was not the only consignee to receive such notices or the only commercial company whose shipments were denied admission to the United States during the relevant period. Other consignees – such as [redacted] – similarly had shipments of Apotex Inc. products interrupted.[25] There can be no argument, then, that Apotex Corp. "was *the* consignee of the shipments of product interrupted by the Import Alert."[26]

17. Apotex nonetheless insists that Apotex Corp. is different from the many other U.S. importers of Apotex Inc. products, contending:

> Apotex [Corp.] was the only US company that Apotex [Inc.] supplied with drugs for commercial sale from Apotex [Inc.'s] plants in Etobicoke and Signet. Apotex [Corp.] was the source of supply of all Apotex products imported from those facilities and sold in the US.[27]

This argument is flawed in four respects. *First*, Apotex has submitted no evidence establishing that Apotex Corp. is the "source of supply of all Apotex products imported from those facilities and sold in the US."

18. *Second*, Apotex's unsupported claim contradicts existing evidence in the record. FDA's import database (the information in which Apotex does not dispute[28]) shows that Apotex Corp. is *not* the only company that imports drugs from Apotex Inc.'s Etobicoke and Signet facilities for

[24] Claimants' Opposition to Bifurcation ¶¶ 23, 51, 67.

[25] *See, e.g.*, Notice of FDA Action re: Entry No. 334-2761279-2 [redacted] [R-120]; FDA, *Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011)*, at 1 [R-115] (showing other consignees, including [redacted], whose shipments of Apotex Inc. drug products were interrupted).

[26] Claimants' Memorial ¶ 411 (emphasis added).

[27] Claimants' Opposition to Bifurcation ¶ 60.

[28] If Apotex wishes to dispute this information, the United States is pleased to authenticate it.

sale in the United States.[29] On the contrary, the database identified other companies – including [redacted] – that imported drugs into the United States from these two facilities for sale in the United States.[30]

19. *Third*, Apotex's claim contradicts representations it has made in U.S. court. When seeking to avoid jurisdiction in U.S. court, Apotex confirmed that Apotex Corp. was *not* the sole seller of Apotex Inc.'s drugs in the United States, stating: "Because Apotex Inc. does not directly sell any products in the U.S. it must rely on the products [being] sold by *others, such as* Apotex Corp.[.]"[31]

20. *Fourth*, Apotex's claim, even if true and admissible, is legally irrelevant. Apotex attempts to create a category of one – namely U.S. companies that (1) purchased drugs directly from Apotex Inc.'s Etobicoke and Signet facilities, (2) imported those drugs into the United States directly from Apotex Inc., and (3) resold those drugs in the United States.[32] Apotex suggests that other U.S. importers of Apotex drugs used "an unrelated third party as the shipper,"

---

[29] *See, e.g.*, FDA, *Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009)* [R-118]; FDA, *Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009)* [R-119].

[30] *See, e.g.*, FDA, *Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011)*, at 1 [R-115]; FDA, *Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009)*, at 2, 23, 56, 67, 85 [R-118]; FDA, *Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009)*, at 4 [R-119]. Had all of these entries occurred during the period of the Import Alert, such as those for [redacted] and [redacted], then those shipments also could have been detained.

[31] *Cephalon, Inc. et al. v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS (D. Del.), Reply Brief in Support of Motion to Dismiss Complaint by Apotex Inc. and Apotex Corp. or in the Alternative to Transfer, at 7 (Nov. 15, 2010) (emphasis added) [RLA-179].

[32] Apotex previously argued, however, that "the Import Alert addressed the sale of products from the two Ontario facilities only on the *US market*." Apotex Submission on Place of Arbitration, at 8 (Aug. 24, 2012) (emphasis added). Apotex thus recognized that, in its view, the Import Alert affected any company in the United States that distributed and sold (but could not receive) Apotex Inc. drugs from those facilities. *See also* Claimants' Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven ¶ 2 (Nov. 23, 2011) ("This measure, called an import alert, prevented Apotex Corp. from *receiving any drugs produced at these two facilities* [Etobicoke and Signet].") (emphasis added); Claimants' Request for Arbitration ¶ 2 (Feb. 29, 2012) (same).

or declined to use the drugs for "commercial *sale*" in the United States.[33] But Apotex has offered no plausible explanation why other companies that imported Apotex products into the United States for non-exempted[34] commercial purposes were not similarly affected, legally, by the FDA actions. Because the Etobicoke and Signet facilities failed to comply with cGMP, drug products from those facilities imported into the United States *by any company* were subject to detention and refusal of admission.

21. Finally, Apotex argues that Apotex Corp. has a "special relationship" with Apotex Inc. because "it is part of the same group of companies," all of which "coordinate and collaborate closely to ensure that customers in the US have access to the medical products they need in a timely, efficient and seamless manner."[35] This statement is belied by representations Apotex has made in U.S. court. When seeking to avoid jurisdiction, Apotex characterized the relationship between Apotex Inc. and Apotex Corp. as "*purportedly tangential corporate relatives*," adding that Apotex Corp. is "entirely separate and independent" from Apotex Inc.[36] Apotex has flatly denied the existence of "*any facts* showing a corporate relationship between Apotex Corp. and Apotex Inc."[37] Far from acting in concert to "coordinate and collaborate closely," Apotex has stated that Apotex Corp. and Apotex Inc. operate strictly at arm's length, making clear that the:

> conclusory assertion that Apotex Inc. and Apotex Corp. are two arms of the same business group that act in concert with respect to drug sales and conduct nearer-

[33] Claimants' Opposition to Bifurcation ¶ 55 (emphasis added).

[34] *See supra* note 19 (discussing exemptions, such as compassionate use).

[35] Claimants' Opposition to Bifurcation ¶¶ 64, 67.

[36] *Shire LLC v. Apotex Inc., Apotex Corp. and Apotex Pharmaceutical Holdings Inc.*, No. 2:08-cv-265 (E.D. Tex.), Defendants Apotex Corp.'s and Apotex Pharmaceutical Holdings Inc.'s Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(1) and/or 12(b)(6), at 2, 13 n.7 (Aug. 6, 2008) ("Apotex Corp. and [Apotex Inc. parent Apotex Pharmaceutical Holdings Inc.] are purportedly *tangential* corporate relatives of Apotex Inc." and "Apotex Corp. is not a subsidiary of APHI, but rather is wholly owned by an *entirely separate and independent foreign entity*.") (emphasis added) [RLA-182].

[37] *Id.* at 14-15 (emphasis in original).

> than-arm's-length transactions is unsupported by the facts in this case. As described above, Apotex Inc. and Apotex Corp. are separate and distinct entities. Apotex Corp. independently decides which of Apotex Inc.'s products it will market and generates its own revenue, with which it purchases the products it sells. These facts directly contradict Cephalon's assertions that Apotex Inc. and Apotex Corp. are two arms of the same business group that act in concert with respect to generic drug sales.[38]

22. Apotex dismisses its countless contradictory statements in this case as "beside the point," arguing that its business dealings reflect "how sophisticated companies operate throughout the world today."[39] But Apotex has failed to explain why "sophisticated companies" should be permitted, opportunistically, to argue one set of "facts" when seeking to avoid jurisdiction in U.S. court and precisely the opposite when seeking to establish jurisdiction before an international tribunal in a case against the United States.

23. In sum, Apotex has failed to establish that the Import Alert affected Apotex Corp. differently, in any legally relevant sense, from other U.S. companies that distributed and sold in the United States Apotex Inc. products from the Etobicoke and Signet facilities during the relevant period.

3. Apotex's Argument that the Import Alert "Related to" Apotex's Drug Applications Misstates U.S. Law and Contradicts Apotex's Admissions

24. The Import Alert also had no legally significant connection to Apotex Inc.'s abbreviated new drug applications (ANDAs).[40] For its *approved* ANDAs, Apotex asserts that "the drug products in question could not be sold in the US due to the Import Alert," but that is simply

[38] *Cephalon, Inc. et al. v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS (D. Del.), Reply Brief in Support of Motion to Dismiss Complaint by Apotex Inc. and Apotex Corp. or in the Alternative to Transfer, at 4-5 (Nov. 15, 2010) [RLA-179]; *see also Cephalon, Inc. et al. v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-22997-UU (S.D. Fla.), Answer, Defenses and Counterclaims of Defendants Apotex Inc. and Apotex Corp. ¶ 18 (Sept. 15, 2010) (denying that "Apotex Corp. and Apotex Inc. are two arms of the same business group, operate in concert with each other, and enter into agreements with each other that are nearer than arms length.") [RLA-177].

[39] Claimants' Opposition to Bifurcation ¶¶ 63-64.

[40] *See* U.S. Counter-Memorial ¶¶ 284-286.

untrue.[41] Apotex itself has acknowledged in U.S. litigation that it could have continued to sell products under the approved ANDAs by transferring the necessary technology from its Etobicoke and Signet facilities to one of its many "plants throughout the world."[42] Contrary to Apotex's assertion, moreover, Apotex's ability to utilize its approved ANDAs relates to far more than just mitigation.[43] Rather, the possibility that Apotex could continue to sell approved drugs in the United States during the period of the Import Alert demonstrates that the Import Alert had no legally significant connection to Apotex's approved ANDAs.

25. Similarly, the Import Alert had no connection to Apotex Inc.'s *unapproved* ANDAs pending with FDA.[44] Rather, in accordance with relevant statutes and regulations, FDA's refusal to approve the pending ANDAs was solely due to Apotex's cGMP violations.[45] Indeed, as a result of the cGMP failures observed during the Etobicoke inspection in 2008, FDA refused to approve ANDAs from that facility long before the issuance of the Import Alert.[46]

26. The Import Alert, therefore, clearly did not "relate to" the "investments" that Apotex Inc. claims to have made, or sought to make, in the United States.

4. Apotex's Argument that Its Drug Applications Constitute "Property" in the United States Misinterprets the NAFTA

27. The U.S. Counter-Memorial established that, under U.S. law, Apotex's ANDAs are contingent interests that may be revoked without payment of compensation for any number of

[41] Claimants' Opposition to Bifurcation ¶ 94.

[42] U.S. Counter-Memorial ¶ 282 (quoting *Apotex Inc. v. Cephalon, Inc.*, No. 06-cv-02768 (E.D. Pa.), Response of Apotex to Cephalon's Request for Conference, at 2 (Apr. 21, 2010) [RLA-70]).

[43] *See* Claimants' Opposition to Bifurcation ¶ 95.

[44] *See* U.S. Counter-Memorial ¶¶ 275-283.

[45] *See id.* ¶ 276 (citing 21 C.F.R. § 314.127(a)(1) (2012) [CLA-277]; 21 U.S.C. § 355(j)(4)(A) (2012) [CLA-234]).

[46] *See id.* ¶¶ 277-280.

reasons provided by law.[47] Apotex's additional arguments that these applications constitute "property" within the meaning of Article 1139(g) are without merit.

28. Apotex seeks support in NAFTA Article 1110(7), which states that Chapter Eleven's expropriation provision (Article 1110) "does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights to the extent that such issuance, revocation, limitation or creation is consistent with [NAFTA] Chapter Seventeen (Intellectual Property)." According to Apotex, Article 1110(7) "reflects the NAFTA Parties' clear understanding that revocable intangible rights are investments" pursuant to Article 1139.[48] Apotex is mistaken.

29. As Apotex acknowledges, the exception in Article 1110(7) "is limited to those revocations authorized by Chapter Seventeen of the NAFTA."[49] Chapter Seventeen discusses the revocation of intellectual property rights only in connection with patents.[50] Apotex does not claim that its drug applications constitute patents, nor could it.[51] Thus, Apotex's reliance on Article 1110(7) cannot advance its argument that its ANDAs constitute the sort of intangible property that may be considered an "investment" under Article 1139(g).

30. Curiously, Apotex interprets an Internal Revenue Service memorandum as supporting its view that "US tax law considers ANDAs to be assets the sale of which is subject to taxation like

[47] *See id.* ¶ 226 (citing authority).

[48] Claimants' Opposition to Bifurcation ¶ 77 (emphasis omitted).

[49] *Id.* ¶ 76.

[50] Article 1709(8) provides that "[a] Party may revoke a *patent* only when: (a) grounds exist that would have justified a refusal to grant the patent; or (b) the grant of a compulsory license has not remedied the lack of exploitation of the patent" (emphasis added).

[51] U.S. Counter-Memorial ¶¶ 223-25 (citing authority).

the sale of other property."[52] And yet Apotex declined to affirm that it ever paid U.S. taxes on sales of its putative U.S. "property."

31. Apotex also takes issue with the United States' position that Apotex's ANDAs are not property "in the United States," while acknowledging that its ANDAs are prepared and held by Apotex Inc. *in Canada*.[53] Apotex suggests that the United States' position would exclude from the scope of Chapter Eleven "a long-term loan by a Canadian bank to a U.S. debtor . . . if the bank prepared the loan documentation [in Canada]."[54] Long-term loans to an enterprise, however, can be "investments" under the express language of Article 1139(d). But even if they could not, Apotex's analogy is inapt: Apotex Inc. (the owner and holder of the ANDAs) does not "lend" its applications to Apotex Corp. (which is not a subsidiary of Apotex Inc.[55]). Unlike a long-term loan of money, moreover, Apotex's ANDAs do not constitute a flow of capital from a foreign investor to its U.S. investment.

5. Apotex's Argument that Article 1139(h) Protects Interests Arising From the Commitment of Capital *Outside* of the Host State Misinterprets the NAFTA and Conflicts with Apotex's Representations in U.S. Court

32. It is clear that Apotex has expended funds preparing and filing its drug applications. But it is equally clear that those funds were expended in Canada, not in the United States. As Ms. Tao testified in U.S. court:

[52] Claimants' Opposition to Bifurcation ¶ 71 & n.60.

[53] *Id.* ¶ 79.

[54] *Id.*

[55] *See Abbott Laboratories, Inc., and Abbott GMBH & Co. KG v. Apotex Inc. and Apotex Corp.*, No. 1:09-cv-00990-JJF (D. Del.), Declaration of Bernice Tao ¶ 28 (Jan. 13, 2010) ("Apotex Corp. is not a subsidiary of, or otherwise controlled by Apotex Inc.") [RLA-176]; *Pfizer Inc. v. Apotex Inc. and Apotex Corp.*, No. 1:08-cv-00948 (LDD) (D. Del.), Declaration of Bernice Tao ¶ 28 (Feb. 10, 2009) (same) [RLA-92].

> None of the relevant work regarding Apotex Inc.'s ANDA product, the preparation of the ANDA, or the filing of the ANDA occurred or was otherwise performed in Texas. *All such work occurred in Canada*.[56]

Apotex thus does not (and cannot) claim that Apotex Inc.'s ANDAs constitute "interests arising from the commitment of capital or other resources" *in the United States*, as required by Article 1139(h).

33. Instead, Apotex argues that "nothing in Article 1139(h) requires that the same entity within a corporate group both own the interest and contribute the resources; all that is required is that the interests arise from a commitment of such resources to economic activity in the territory of the Party."[57] But Apotex still has failed to establish that its alleged investment interests (its ANDAs) arose from the commitment of capital by either entity *in the United States*, as required by Article 1139(h).[58]

34. Additionally, even if Apotex had incurred these regulatory costs in the United States, they would not constitute "investments" under NAFTA Article 1139. As the *Grand River* tribunal made clear, where a company must meet "regulatory requirements" to sell its products in the United States, the costs of such compliance themselves are not "investments."[59] Rather,

---

[56] *Shire LLC v. Apotex Inc., Apotex Corp. and Apotex Pharmaceutical Holdings Inc.*, No. 2:08-cv-265 (E.D. Tex.), Declaration of Bernice Tao ¶ 31 (Aug. 6, 2008) (emphasis added) [RLA-183]; *accord Pfizer Inc. v. Apotex Inc. and Apotex Corp*., No. 1:08-cv-00948 (LDD) (D. Del.), Declaration of Bernice Tao ¶ 17 (Feb. 10, 2009) ("Apotex Inc. conducted all of the research, development and manufacturing of the generic . . . products that are the subject of its ANDA. All of this work was performed in Canada[.]") [RLA-92]; *see also id*. ¶ 25 ("None of the relevant work regarding Apotex Inc.'s ANDA product, the preparation of the ANDA, or the filing of the ANDA occurred or was otherwise performed in Delaware. *All such work occurred in Canada*.") (emphasis added).

[57] Claimants' Opposition to Bifurcation ¶ 85.

[58] *See* U.S. Counter-Memorial ¶¶ 245-47.

[59] *Grand River Enterprises Six Nations Ltd. et al. v. United States of America*, NAFTA/UNCITRAL, Award ¶ 87 (Jan. 12, 2011) [CLA-29].

those costs are "incident to 'commercial contracts for the sale of goods or services,' which fall outside of Article 1139's definition of investment."[60]

35. Apotex's argument, moreover, is directly contrary to representations Apotex has made in U.S. court. For example, when Apotex Inc. and its parent (Apotex Pharmaceutical Holdings Inc.) were seeking to avoid domestic jurisdiction, Apotex argued that a plaintiff could "not use an independent corporate affiliate [Apotex Corp.] as a surrogate for jurisdiction over Apotex Inc. and APHI."[61] And yet Apotex now seeks to use another entity within its corporate group as a surrogate to establish jurisdiction in this case. The Tribunal should not countenance such opportunism.

B. Considerations of Economy, Efficiency, and Fairness Compel Bifurcation

36. Apotex insists that "bifurcation can result in no time efficiency," and that any "economies in presentation of evidence" are limited and "depend upon a gamble that both US jurisdictional objections will succeed."[62] Apotex is mistaken. As the *Glamis* tribunal recognized, a tribunal should decide jurisdictional objections by preliminary decision where: (1) the jurisdictional objections are substantial and not frivolous; (2) the jurisdictional issues are not unduly entwined with the merits; and (3) the objections, if successful, would materially reduce the proceedings on the merits.[63] The United States' objections satisfy all three criteria.

---

[60] *Id.* ¶ 115.

[61] *Shire LLC v. Apotex Inc., Apotex Corp. and Apotex Pharmaceutical Holdings Inc.*, No. 2:08-cv-265 (E.D. Tex.), Defendants Apotex Inc.'s and Apotex Pharmaceutical Holdings Inc.'s Reply in Support of Their Rule 12(b)(2) Motion to Dismiss for Lack of Personal Jurisdiction, at 1 (Sept. 11, 2008) (emphasis added) [RLA-184].

[62] Claimants' Opposition to Bifurcation ¶ 12.

[63] *Glamis Gold, Ltd. v. United States of America*, NAFTA/UNCITRAL, Procedural Order No. 2 (Revised) ¶ 12(c) (May 31, 2005) [CLA-444].

1. The United States' Jurisdictional Objections Are Well Founded

37. Apotex does not dispute that the United States has presented substantive, non-frivolous jurisdictional objections.[64] Apotex simply disagrees with those objections.

38. The United States' "relating to" argument is a straightforward jurisdictional objection grounded in the express language of Article 1101(1)[65] – "the gateway leading to the dispute resolution provisions of Chapter 11"[66] – and established case law.[67]

39. In addition, the United States' argument that Apotex Inc. is not an "investor" that made, or sought to make, an "investment" in the United States is equally straightforward and grounded in the text of NAFTA Chapter Eleven.[68] Indeed, the question of whether a claimant is a qualifying investor with covered investments is at the heart of the investment chapter's jurisdictional ambit. It is unsurprising, therefore, that Apotex Inc. itself *agreed* to bifurcated proceedings on this very question in the two NAFTA Chapter Eleven claims it previously

---

[64] *See* GARY B. BORN, INTERNATIONAL COMMERCIAL ARBITRATION 993 (2009) ("Although no absolute rules can be prescribed, the more appropriate course for the arbitral tribunal is generally to conduct a preliminary proceeding on credible good faith jurisdictional challenges," permitting the parties to avoid "the expense of presenting the case on the merits" if jurisdiction is lacking) (citations omitted) [RLA-64].

[65] Although disputed by Apotex, Article 1101(1) clearly limits the scope and coverage of NAFTA Chapter Eleven to "*measures* adopted or maintained by a Party *relating to*: (a) *investors* of another Party; [and] (b) *investments* of investors of another Party[.]" NAFTA art. 1101(1) (emphasis added) [CLA-1]. *See* Claimants' Opposition to Bifurcation ¶¶ 10, 39-43 (arguing that NAFTA "regulates measures not at all addressed to a given investment or investor," and that a breach may be "established by the absence of a measure") (emphasis omitted). *But see* M. KINNEAR, A. BJORKLUND & J. HANNAFORD, INVESTMENT DISPUTES UNDER NAFTA: AN ANNOTATED GUIDE TO NAFTA CHAPTER ELEVEN 1101-30 (Mar. 2008) ("In short, the presence of a measure is a precondition to a permissible claim under Chapter 11 of the NAFTA.") [RLA-147]. As discussed in the Counter-Memorial, and as the United States will develop in a subsequent substantive submission, a measure that is not addressed, directly or indirectly, to an "investor" or its "investment" does not "relate to" that investor or investment within the meaning of NAFTA Article 1101(1).

[66] *Methanex Corp. v. United States of America*, NAFTA/UNCITRAL, First Partial Award ¶ 106 (Aug. 7, 2002) [CLA-36].

[67] *See id.* ¶ 147.

[68] *See, e.g.*, NAFTA arts. 1101(1) (scope and coverage); 1116 (claims made directly by an "investor of a Party"); and 1139 (defining "investor of a Party" and "investment").

brought against the United States, thereby implicitly recognizing the efficiency and appropriateness of resolving this fundamental threshold question by preliminary decision.[69]

40. In any event, a tribunal need not definitively determine the factual and legal merit of a respondent's jurisdictional objections in order to decide whether bifurcation is appropriate. Rather, a tribunal must satisfy itself that the jurisdictional objections are "substantial" and not "frivolous."[70] The U.S. jurisdictional objections far exceed that low threshold.

2. There Is No "Substantial Overlap" Between Issues of Jurisdiction and the Merits

41. Contrary to Apotex's suggestion, there is no "substantial overlap" between issues of jurisdiction and merits in the case.[71] Apotex highlights the U.S. argument that the Import Alert did not relate to Apotex Corp. because, among other reasons, the Import Alert accorded other distributors of Apotex Inc. products the same "treatment" accorded to Apotex Corp. Apotex contends that this argument is simply the "MFN argument on the element of 'less favorable treatment' packaged as a jurisdictional objection."[72] This is plainly false.

42. The United States has argued that the Tribunal lacks jurisdiction over any of Apotex's claims because the Import Alert did not relate to Apotex as an "investor" or its alleged U.S. "investments." The United States also has argued, and Apotex previously accepted,[73] that national and most-favored-nation treatment claims require that the claimant satisfy a three-prong test: (1) treatment; (2) "like circumstances"; and (3) "less favorable" treatment. Because the

[69] *See Apotex Inc. v. United States*, NAFTA/UNCITRAL, Transcript, First Session, at 47:3-6 (Nov. 30, 2010) [R-2].

[70] *Glamis Gold, Ltd. v. United States of America*, NAFTA/UNCITRAL, Procedural Order No. 2 (Revised) ¶ 12(c) (May 31, 2005) [CLA-444].

[71] Claimants' Opposition to Bifurcation ¶¶ 5, 103.

[72] *See id.* ¶ 5.

[73] *Apotex Inc. v. United States*, NAFTA/UNCITRAL, Statement of Claims ¶ 9 (Jan. 17, 2011) (adopting three-part test) [RLA-101].

Import Alert did not relate to Apotex as an "investor" or to any U.S. "investments," the United States necessarily accorded Apotex no "treatment" for purposes of Chapter Eleven. The "relating to" issue can be decided as a preliminary matter on the evidence already in the record. But even if Apotex could overcome this jurisdictional hurdle, it still would have to establish two other, discrete prongs of its national treatment and most-favored-nation treatment claims: "like circumstances," and "less favorable" treatment.[74] These two issues have no overlap with the jurisdictional issues in this case.

3. Acceptance of the United States' Jurisdictional Objections Will Either Eliminate or Materially Reduce the Scope of Apotex's Claims

43. Apotex suggests that holding a single hearing always is more efficient than holding two hearings.[75] That argument, however, assumes that a preliminary hearing on jurisdiction would never terminate a case or substantially reduce its scope. But clearly that is not correct. The United States' objections, if accepted, would eliminate Apotex's claim or substantially reduce the scope of any subsequent merits hearing, saving both parties significant time and costs.

[74] Apotex's reliance on *Methanex* in this regard is misplaced. Apotex claims that the *Methanex* tribunal recognized that the presence of a "connection of legal significance . . . cannot be decided without reference to the substantive NAFTA provisions at issue." Claimants' Opposition to Bifurcation ¶ 11. That is not correct. Rather, the *Methanex* tribunal determined that, in materially different circumstances, evidence demonstrating a violation of Article 1102 "could *conceivably*" support the United States' 1101(1) argument, given the "potentially asymmetrical connection" between the two provisions. *Methanex Corp. v. United States of America*, NAFTA/UNCITRAL, Final Award, Part IV, Chapter B ¶ 1 (Aug. 3, 2005) (emphasis added) [CLA-34]. Those circumstances involved Methanex's inferential claim based on allegations of malign intent to penalize foreign producers of methanol (and MTBE) and benefit the U.S. ethanol industry. *See Methanex*, First Partial Award ¶¶ 151, 158 (Aug. 7, 2002) [CLA-36]. Accordingly, the tribunal followed the "exceptional procedure" of not bifurcating the preliminary jurisdictional issue and ordered Methanex to submit a fresh pleading with additional evidence, so that it could evaluate Methanex's allegations based on a fuller record. *See id.* ¶¶ 160-61, 163, 167, 169. Here, by contrast, Apotex asserts that the "Import Alert applied *directly* to Apotex [Corp.]" as a consignee and "related to" Apotex Inc.'s U.S. investments (*i.e.*, its ANDAs), by preventing the importation of approved generic drugs and the approval of pending applications. Claimants' Opposition to Bifurcation ¶¶ 8, 93-98 (emphasis added). Thus, in contrast with *Methanex*, the Tribunal here need not analyze Apotex's merits claims when deciding the U.S. jurisdictional objections concerning Article 1101(1).

[75] *See* Claimants' Opposition to Bifurcation ¶¶ 110-18.

44. Apotex argues that "[i]f a single objection fails, a hearing must be held on the merits, with no change in the scope of the issues to be considered."[76] As discussed above, however, Apotex is mistaken.[77] If Apotex fails to prove that the Import Alert "related to" either Apotex Inc. or Apotex Holdings as "investors" or to their alleged U.S. "investments," Apotex's entire case will be dismissed. If Apotex fails to prove that Apotex Inc. is an "investor" that made or sought to make an "investment" in the United States, the scope of the issues on the merits and, if necessary, on damages will be greatly reduced.

45. Both parties anticipate that a jurisdictional hearing would be shorter, less intense, and less expensive than a merits hearing. As Apotex acknowledged at the First Session:

> Obviously, if there is a request for bifurcation and if the Tribunal grants that request for bifurcation, then *the issues that will be presented I do not think will require that intense of a hearing*. So, I would imagine that that will be shorter[.][78]

46. The Tribunal President similarly acknowledged that bifurcation would likely result in "a two-day or so [jurisdictional] hearing," as opposed to the eight days scheduled for a possible November 2013 hearing on jurisdiction and the merits.[79]

47. Contrary to Apotex's argument, moreover, a "hearing on all issues" is not merely "marginally more expensive than a hearing limited to jurisdiction."[80] As a leading commentator observed, leaving the management and determination of all issues to a "single, final hearing often ensures wasted effort, for both the tribunal and the parties[.]"[81] Here, briefing and arguing

[76] *Id.* ¶ 3.

[77] *See supra* Section II.A.1.

[78] Transcript, First Session, at 19:8-13 (emphasis added) (statement by Apotex's counsel).

[79] *Id.* at 58:20-59:1.

[80] Claimants' Opposition to Bifurcation ¶ 114.

[81] GARY B. BORN, INTERNATIONAL COMMERCIAL ARBITRATION 1815 (2009) [RLA-180].

the merits could cost each party additional hundreds of thousands of dollars in legal fees, expert fees, travel expenses, arbitrator fees, administrative fees, and so forth.[82] Bifurcating the jurisdictional issues, by contrast, would spare the parties the majority of these expenses by substantially reducing the scope of the issues and the involvement of fact and expert witnesses, including FDA fact witnesses who would otherwise be performing their duties to protect public health by inspecting facilities and ensuring compliance with U.S. laws and regulations.

48. Finally, bifurcation will prevent the parties from having to engage in unnecessary document production. Under the First Procedural Order, no document requests or production are contemplated if the proceedings are bifurcated.[83] The fact that Apotex agreed to this schedule undercuts its current claim that a fuller record is somehow required to decide the United States' jurisdictional objections. If the case is not bifurcated, by contrast, the parties will request documents from each other within a week of the Tribunal's decision on bifurcation.[84] The Tribunal will be required to resolve any objections to document requests within two weeks of any such objections.[85] Although the United States hopes for a smooth document production process, experience demonstrates that document review and production can be time-consuming and costly, and that document request disputes can be arduous for the parties and the Tribunal. In light of the United States' legitimate jurisdictional objections (which the parties have agreed can be resolved without document production), it would be more efficient to bifurcate the case

[82] The estimated cost of a hearing at the World Bank (without interpretation) is $5,208 per day. Letter from Eloïse Obadia to the Tribunal, at 2 (Oct. 10, 2012). Reducing the hearing from eight days to two would save over $31,000 in hearing costs alone.

[83] First Procedural Order ¶ 14.2.8.

[84] *Id.* ¶ 14.2.7(i).

[85] *Id.* ¶ 14.2.7(vi).

and rule on those objections, instead of ordering the parties to engage in a premature and ultimately unnecessary document production process.

4. Bifurcation Is Fair and in No Way Requires the Tribunal to Prejudge the United States' Jurisdictional Objections

49. Apotex suggests that deciding jurisdictional issues by preliminary decision would be unfair because doing so necessarily "prejudges" the merits of those issues. Apotex thus states:

> [I]t would be fairer for the Tribunal to assess the US objections to jurisdiction after all parties have had an opportunity to fully brief the issues raised. Prejudging the merit of those objections now, on the basis of a less than ample record and under hurried conditions, would be less fair than at a November hearing on all issues.[86]

This argument is difficult to credit. It was Apotex, not the United States, that insisted on the current "hurried" pleading schedule.[87] When the United States initially proposed bifurcating these proceedings, Apotex objected, urging that only after the United States had filed its Counter-Memorial and Objections on Jurisdiction would the Tribunal have "a clear understanding of the support, or lack thereof, for the US position . . . based on a record," including "the full cases-in-chief presented by the Parties' initial round of memorials."[88] The parties have now presented their cases-in-chief through an initial round of memorials, and yet Apotex nonetheless complains that the Tribunal is being asked to "prejudge" the U.S. jurisdictional objections based on a "less than ample record."[89] Apotex cannot continuously move the goalposts to defeat bifurcation. Indeed, by Apotex's reasoning, a tribunal could never adjudicate jurisdictional objections without first receiving a full presentation of the merits, thus

[86] Claimants' Opposition to Bifurcation ¶ 7.

[87] Apotex, in fact, sought to submit, and did submit, its Memorial a mere six days after the First Session.

[88] Letter from Barton Legum to the Tribunal, at 2 (Oct. 5, 2012).

[89] Claimants' Opposition to Bifurcation ¶ 7.

obviating Article 45(5) of the ICSID Additional Facility Rules[90] and overturning decades of settled arbitration practice.[91]

C. Requiring the United States to Brief Damages in Nine Weeks Would Be Inconsistent with the Tribunal's Order, Unfair, and Inefficient

50. Apotex proposes that the November hearing include issues of quantum, urging a separate briefing stream in advance of the hearing. Apotex thus proposes that its valuation expert submit a supplemental damages report in February, and that the United States respond *nine weeks later*.[92] This proposal is inconsistent with the Tribunal's Order, prejudicial to the United States, and inefficient.

51. The Tribunal explicitly reserved to itself the prerogative of addressing "at a later date the schedule for written pleadings regarding quantum issues, including the Claimants' pending offer to submit further materials regarding the quantum of their claims."[93] The Tribunal thus should reject Apotex's unilateral attempt to join this issue to the United States' request for bifurcation.

52. Apotex's proposal, moreover, is unfair and prejudicial. Apotex failed to submit a full statement of its case with its Memorial, and it now proposes submitting next month "a supplemental damages expert report limited to the two issues that Mr. Rosen did not quantify in July 2012 due to limited available information at that time."[94] To this date, however, Apotex still has not provided (1) financial statements for either of the claimed investors, Apotex Inc. and Apotex Holdings; (2) audited financial statements for either of the claimed investors *or* Apotex

[90] ICSID Additional Facility Rules, art. 45(5) (authorizing the tribunal to deal with jurisdictional objections "as a preliminary question or join it to the merits of the dispute").

[91] *See* U.S. Counter-Memorial ¶¶ 394-96 and accompanying notes (addressing applicable arbitration rules and practice, including the presumption favoring bifurcation in multiple arbitration rules involving States).

[92] *See* Claimants' Opposition to Bifurcation ¶¶ 131-32.

[93] Letter from Eloïse Obadia to the Parties, at 2 (Oct. 29, 2012).

[94] Claimants' Opposition to Bifurcation ¶ 132 (emphasis deleted).

Holding's U.S. investment, Apotex Corp.; or (3) other fundamental information required for a U.S. submission on damages. Apotex presumably intends to furnish missing sales information, but it has not pledged to produce this other crucial information. Apotex nonetheless proposes that the United States prepare an expert damages report and a damages submission in nine weeks, solely to satisfy Apotex's desire to hold a hearing on all issues in November. The United States should not be penalized for Apotex's own failure to submit a complete damages claim and complete evidence. Nor should the United States be deprived of its right to adequate time to present its case fully and fairly.

53. Finally, briefing issues of quantum, in addition to issues of jurisdiction and liability, would be hugely expensive. In addition to legal costs, the United States would have to expend substantial sums on a valuation expert. In a recent NAFTA Chapter Eleven case, for example, the valuation expert's fees exceeded the costs of all U.S. government lawyers who had worked on the case over a seven-year period, even though issues of quantum proved irrelevant in the final award.[95] Here, it would be a tremendous waste of taxpayer dollars to require pleading and expert testimony on damages before the Tribunal has adjudicated the United States' well-founded jurisdictional arguments.

54. For all of these reasons, the question of when to address issues of quantum should be briefed and decided, if necessary, after the Tribunal has resolved the United States' pending bifurcation request.

* * *

[95] *See Grand River Enterprises Six Nations Ltd. v. United States*, NAFTA/UNCITRAL, Submission on Costs of Respondent United States of America (Mar. 31, 2010) (noting expert fees exceeding $1 million) [RLA-181].

55. In requesting bifurcation, the United States is not "gambling" on the success of its jurisdictional objections.[96] It is the Claimants that bear the burden of proving that their claims fall within the Tribunal's jurisdiction. The United States simply asks for a decision on its legitimate, good-faith objections to jurisdiction before it is required to incur the substantial expense of further pleading the merits of claims that, in its view, clearly fall outside the Tribunal's jurisdiction. The U.S. request is fully consistent with the applicable arbitration rules, decades of arbitral practice, and considerations of economy, efficiency, and fairness.

III. CONCLUSION

56. For the foregoing reasons, and those set out in the U.S. Counter-Memorial on Merits and Objections to Jurisdiction, the United States respectfully requests that the Tribunal (1) decide the U.S. jurisdictional objections as a preliminary matter, in accordance with Article 45 of the ICSID Additional Facility Rules; and (2) adopt the pleading schedule set out in Paragraph 14.2.8 ("scenario 2") of the Tribunal's First Procedural Order.

Dated: January 10, 2013

Respectfully submitted,

Lisa J. Grosh
Assistant Legal Adviser
Jeremy K. Sharpe
Chief, Investment Arbitration
Neale H. Bergman
David M. Bigge
John I. Blanck
Alicia L. Cate
Nicole C. Thornton
Attorney-Advisers
Office of the Legal Adviser
UNITED STATES DEPARTMENT OF STATE
Washington, D.C. 20520

[96] *See* Claimants' Opposition to Bifurcation ¶ 7.