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IN THE ARBITRATION UNDER CHAPTER ELEVEN OF THE NAFTA  
AND THE ICSID ARBITRATION (ADDITIONAL FACILITY) RULES

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APOTEX HOLDINGS INC. AND APOTEX INC.,

*Claimants,*

*– and –*

THE GOVERNMENT OF THE UNITED STATES OF AMERICA,

*Respondent.*

ICSID CASE No. ARB(AF)/12/1

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## **CLAIMANTS' REJOINDER ON BIFURCATION**

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ARBITRAL TRIBUNAL:

V.V. Veeder  
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January 16, 2013



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In accordance with paragraph 14.2.5 of the Tribunal’s First Procedural Order and its order of October 29, 2012, claimants Apotex Holdings Inc. (“Apotex Holdings”) and Apotex Inc. (“Apotex-Canada”) (collectively, “Apotex”) respectfully submit this rejoinder to the US Reply to Claimants’ Opposition to Bifurcation.<sup>1</sup>

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<sup>1</sup> US Reply to Claimants’ Opposition to Bifurcation (Jan. 10, 2013) (hereinafter “US Reply on Bifurcation” or “US Reply”).

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## INTRODUCTION

1. The US Reply on Bifurcation serves to confirm that economy, efficiency and fairness favor a single hearing on all issues over a hearing limited to the jurisdictional objections presented by the US.
2. *First*, the US does not dispute that bifurcation can only delay the date on which this case will be resolved. The hearing will take place in November 2013 whether the case is bifurcated or not. The issue presented by the US request is whether that hearing will with certainty put the Tribunal in a position to issue an award disposing of the case (as Apotex proposes) or whether following that same hearing the Tribunal will be significantly limited in its ability to resolve the case (as the US proposes).
3. *Second*, the US Reply acknowledges that the economies and efficiencies it posits depend upon its jurisdictional objections succeeding both as to Apotex Holdings and as to Apotex-Canada. It does not dispute that the failure of its objections as to Apotex Holdings will require a full hearing on the merits. Nor does it deny that the failure of its objections as to Apotex-Canada will also require a full hearing on the merits. It does not attempt to support or even explain its assertion that the scope of a hearing on the merits would be limited in the event it succeeded on its objection as to Apotex-Canada.
4. *Third*, the US does not deny the substantial inefficiencies and costs that would result from bifurcation if the Tribunal rejects one or more of the US jurisdictional objections. It does not dispute that at least 18 months of additional delay would result from a failed preliminary phase. It does not contest that the passage of time results in faded memories, unavailable witnesses and documents that are more difficult to locate. It does not deny that the efficiencies of scale that come with a single hearing and a single set of pleadings are lost in the event of a failed preliminary phase.
5. *Fourth*, the US concedes that there is complete overlap between its “relating to” objection and the merits. Instead, it erroneously contends that the overlap is not “substantial” because it is limited to the first of three elements of the national treatment and MFN treatment claims. In a footnote, the US Reply attempts to distinguish

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*Methanex*'s reasoning that a claimant's showing under Articles 1102, 1105 and 1110 informed whether it established a "legally significant connection" under Article 1101(1).

6. The US contentions are without merit. No authority on bifurcation requires complete identity between every legal element of the merits and the jurisdictional objection. Instead, the question is whether "the facts on which the objection is based are closely connected with the merits and a decision on the objection might prejudice the decision on the latter."<sup>2</sup> Here, all Parties acknowledge that the facts on which the "relating to" objection is based are intimately connected with the merits.
7. Moreover, the US attempt to write off *Methanex*'s reasoning is both without merit and beside the point. It is without merit because *Methanex* plainly recognizes the pertinence of the connection between measure and investment contemplated by the substantive provisions of the NAFTA to whether a "legally significant connection" under Article 1101(1) is established. It is beside the point because Apotex has the right to present a full defense to the US objections to jurisdiction. Its case will include a showing that precisely the connection between the Import Alert and the pertinent investors and investments required by Articles 1102, 1103 and 1105 of the NAFTA is present. Apotex will show that, because the specific connection required by the NAFTA is established, it cannot be denied that that connection is "legally significant" for purposes of Article 1101(1). The hearing in November will, in short, include substantial presentations on Articles 1102, 1103 and 1105 – whether it is limited to jurisdiction or whether it addresses all issues.
8. *Fifth*, the US errs in suggesting that the hearing will be significantly shorter and no document disclosure will be required if bifurcation is granted. Much of the same evidence pertinent to the Article 1102, 1103 and 1105 claims will be pertinent to the US "relating to" objection. Apotex currently estimates that at least a week will be required

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<sup>2</sup> **Legal Authority CLA-459**, Note E to Rule 41, ICSID Arbitration Rules (1968), *reprinted in* 1 ICSID Rep. 63, 102 (1993).

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to address the US arguments on jurisdiction and the question of whether a connection legally significant under the NAFTA is present. Given the fact-intensive nature of the US objections, which was not anticipated at the time of the First Session in July, Apotex intends to request document disclosure of the US whether the case is bifurcated or not. Proceedings on jurisdiction, in short, would closely resemble those on the merits. Bifurcation cannot promote efficiency here.

9. *Finally*, the US errs in arguing that a preliminary phase must be ordered if its jurisdictional objections exceed the “low threshold” of being “substantial” and “not frivolous.” The sole authority it cites was decided under 1976 UNCITRAL rules providing a presumption in favor of bifurcation. Those rules do not apply in these proceedings. The US does not dispute that the ICSID rules years ago rejected any presumption in favor of bifurcation and adopted a more flexible approach. The rules applicable to this proceeding contemplate no “low threshold” in favor of bifurcation.
10. The US errs in any event in suggesting that Apotex accepts that the objections have substance. This case does not remotely resemble *Methanex*, where the measure addressed no product made or sold by the claimant. The Import Alert here undisputedly and specifically targeted products made by Apotex-Canada and sold by Apotex-US in the United States. Unlike *Methanex*, this measure on its face “relates to” Apotex-Canada and Apotex-US.
11. The US submissions state no legal standard that could justify finding an absence of a legally significant connection between measure and investor and investment here. Indeed, the US submissions contain no legal argument on “relating to” at all. Instead, they set out only factual arguments, unconnected by any guiding principle. The variation of this amorphous, changing argument presented in the US Reply does not improve on the version addressed in Apotex’s Opposition to Bifurcation. Neither it, nor the arguments presented by the US as concerns Apotex-Canada’s investments, withstand scrutiny.

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**ARGUMENT**

**I. BECAUSE ISSUES OF JURISDICTION AND MERITS ARE CLOSELY ENTWINED, BIFURCATION WOULD NOT REDUCE THE SCOPE OF THE HEARING OR FOSTER EFFICIENCY**

12. It is common ground that bifurcation should be denied where the jurisdictional issues are entwined with the merits and a preliminary phase cannot materially reduce the proceedings on the merits.<sup>3</sup>

13. As demonstrated below, the arguments presented in the US Reply are without merit. Jurisdiction and the merits substantially overlap in this case. A preliminary phase here would look very much like the proceedings on the merits. Bifurcation cannot increase efficiency given the nature of the objections. And, should the Tribunal preliminarily assess the US objections at this stage, it will find that they lack substance.

**A. Jurisdiction and Merits Overlap in the Present Case**

14. Contrary to the US assertion, the issues of jurisdiction and merits closely overlap in the present arbitration.<sup>4</sup> *First*, as pointed out in Apotex’s Opposition to Bifurcation, and as will be further elaborated in the Reply and at the hearing, what constitutes a “legally significant connection” for purposes of Article 1101(1) in a given case must be informed by the substantive provisions at issue, as recognized by the *Methanex* tribunal.<sup>5</sup>

15. The US does not deny that the connection between measure and investment or investor contemplated by Articles 1102, 1103 and 1105 is necessarily one of legal significance. Instead, the US relegates *Methanex* to a footnote and attempts to distinguish it on its

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<sup>3</sup> US Reply on Bifurcation, para. 36 (citing **Legal Authority CLA-444**, *Glamis Gold, Ltd. v. United States of America*, UNCITRAL, Procedural Order No. 2 (Revised), para. 12(c) (May 31, 2005)).

<sup>4</sup> *Id.* at para. 41.

<sup>5</sup> Opposition to Bifurcation, paras. 44-46 (discussing **Legal Authority CLA-34**, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award, Part IV, Chapter B, at 1, para. 1 and at 19, para. 38 (Aug. 3, 2005); *id.* at Part IV, Chapter C, at 1, para. 1 and at 12, para. 27; Part IV, Chapter D, at 1, para. 1 and at 8, para. 18)).

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facts.<sup>6</sup> The US footnote insists on Methanex’s inferential argument, which sought to show that an MTBE ban “related to” methanol producers such as Methanex based on allegations of malign intent against foreign producers of methanol (and MTBE) and in favor of US producers of ethanol. However, the tribunal made clear that its consideration of Article 1102 had nothing to do with Methanex’s malign intent theory: “[A]n affirmative finding under NAFTA Article 1102, which *does not* require the demonstration of the malign intent alleged by Methanex, could conceivably provide evidence relevant to a determination as to whether the ‘relation’ required by NAFTA Article 1101 exists in this case.”<sup>7</sup> It was precisely because Article 1102 could establish a legally significant connection independent of the malign intent theory that the tribunal considered it.

16. *Second*, the US Reply concedes that its “relating to” argument goes both to jurisdiction and the merits.<sup>8</sup> According to the US argument, Apotex’s national treatment and MFN treatment claims fail for lack of “treatment.” There is no treatment, the argument goes, because the Import Alert related to other importers of Apotex-Canada products just as much as it did to Apotex-US.<sup>9</sup> The US contends that this is only the first prong of the national/MFN treatment claims and that, even if Apotex could succeed on the “relating to”/“treatment” issue – thus, meeting the first criterion of the substantive test – Apotex could not establish “like circumstances” and “differential treatment” on the merits.<sup>10</sup>
17. However, no authority requires complete overlap between every element of a merits claim and a jurisdictional objection. It is enough that all Parties here agree that there is complete overlap between the US “relating to” objection and one of the elements of the merits claims.

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<sup>6</sup> US Reply on Bifurcation, at 19 n.74.

<sup>7</sup> **Legal Authority CLA-34**, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award, Part IV, Chapter B, p. 1, para. 1 (Aug. 3, 2005) (emphasis added).

<sup>8</sup> Opposition to Bifurcation, para. 105.

<sup>9</sup> US Counter-Memorial, para. 327.

<sup>10</sup> US Reply on Bifurcation, para. 42.

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18. Moreover, the US Reply on Bifurcation merely confirms Apotex’s observation that the “relating to” objection here is just a “like circumstances” argument repackaged as a jurisdiction argument.<sup>11</sup> The US claims that there were other importers of Apotex products that were impacted by the Import Alert,<sup>12</sup> and argues that Apotex has not demonstrated why these other importers “were not similarly affected, legally, by the FDA actions.”<sup>13</sup> This is an argument that investments in like circumstances did not receive differential treatment. This is a merits argument – a baseless one, but not one going to jurisdiction.<sup>14</sup>
19. In sum, the US jurisdictional objections are entwined with the merits. This case presents precisely the scenario contemplated by the drafters of the ICSID arbitration rules when joinder to the merits is called for: “where the facts on which the objection is based are closely connected with the merits and a decision on the objection might prejudice the decision on the latter.”<sup>15</sup>

**B. The US Objections Cannot Eliminate or Reduce the Scope of Apotex’s Claims**

20. Initially, the US argued that its objections, if sustained, would eliminate Apotex’s “entire” claim.<sup>16</sup> Now, the US claims that the same objections, if accepted, would “eliminate or materially reduce” the scope of Apotex’s claim.<sup>17</sup> Both statements are wrong. Apotex demonstrated in its Opposition to Bifurcation that for Apotex’s entire

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<sup>11</sup> Opposition to Bifurcation, para. 5.

<sup>12</sup> US Reply on Bifurcation, para. 18.

<sup>13</sup> *Id.* at para. 20.

<sup>14</sup> In addition, the US reiterates that Apotex “itself agreed to bifurcate proceedings on this very question [of Apotex-Canada as investor] in the two NAFTA Chapter Eleven claims that it previously brought against the United States[.]” *See* US Reply on Bifurcation, para. 39. These NAFTA arbitrations concern Apotex-Canada’s tentatively-approved ANDAs, as opposed to finally-approved ANDAs, and the legal arguments on NAFTA Article 1139 and the factual record were not developed in a manner similar to that presented here. *See* Memorial, at 118 n.584. In addition, there is no issue in these other arbitrations of Apotex-US as an investment. What Apotex agreed to do in other arbitrations is irrelevant to the present case.

<sup>15</sup> **Legal Authority CLA-459**, Note E to Rule 41, ICSID Arbitration Rules (1968), *reprinted in* 1 ICSID Rep. 63, 102 (1993).

<sup>16</sup> US Counter-Memorial, para. 392.

<sup>17</sup> US Reply on Bifurcation, heading II.B.3 and para. 43.

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claim to be eliminated, both objections would have to be sustained. Contrary to the US new assertion,<sup>18</sup> if one but not all objections is accepted, it will not reduce the scope of the dispute.

21. Assuming for the sake of argument that the Tribunal were to conclude that Apotex-Canada's marketing authorizations (ANDAs) were not a protected investment, but that the Import Alert related to Apotex-US – or vice versa – the case would proceed to the merits and the same issues would have to be addressed. Each of the comparators identified by Apotex for purposes of its national and MFN treatment claims holds comparable investments in the form of *both* ANDAs *and* a US company that markets and distributes its products like Apotex-US.<sup>19</sup> The merits claims under Articles 1102 and 1103 will proceed on the same basis whether the comparable investments are ANDAs or US subsidiaries like Apotex-US. Similarly, the due process implications of the Import Alert are presented whether the affected party is the importer of record or the consignee – as the FDA notices of action and the authorizing statute acknowledge.<sup>20</sup>
22. Whether the investment is deemed to be Apotex-US or Apotex-Canada's ANDAs (or both), the same issues are in play. In other words, the US jurisdictional objections will not reduce the scope of the dispute, unless they are both accepted – a result which, Apotex submits, cannot come to pass consistent with the record. The scope of the dispute will not be reduced if the case is bifurcated.

**C. Bifurcation Can Only Decrease Efficiency**

23. *First*, bifurcation can only delay the resolution of this case. The hearing will take place in November 2013, irrespective of bifurcation. As mentioned in the Opposition, this

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<sup>18</sup> *Id.* at para. 44.

<sup>19</sup> *See* Memorial, para. 302 (“[Baxter’s] wholly owned subsidiary Baxter Healthcare Corporation is a company incorporated in the United States. Like Apotex-US, Baxter Healthcare Corporation sells finished drug products for human use, notably those related to blood-related therapies, medication delivery, and renal therapy. Baxter Healthcare Corporation and its divisions own in excess of 100 ANDAs.”) (footnotes omitted); *id.* paras. 309, 315, 322, 323 & 329 (same for other comparators).

<sup>20</sup> *See* Apotex Opposition to Bifurcation, paras. 25-30.

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date is the same under either alternative schedule agreed by the parties.<sup>21</sup> As a result, bifurcating the proceedings would not achieve faster resolution of the dispute. The US does not challenge this point.<sup>22</sup>

24. *Second*, the US does not dispute that if the case were bifurcated, a failed preliminary phase will result in several years intervening between the decision on jurisdiction and the award on the merits.<sup>23</sup> Nor does the US deny the collateral prejudice resulting from the passage of time in the form of witnesses who are less available, evidence more difficult to locate, memories that fade and case preparation efforts that must begin anew.
25. *Third*, the US errs in asserting that “bifurcation will prevent the parties from having to engage in unnecessary document production.”<sup>24</sup> It is not the case that “the parties have agreed [that the jurisdictional objections] can be resolved without document production[.]”<sup>25</sup> The First Procedural Order does not reflect an agreed document production schedule in the event of bifurcation because in July there was no reason to believe that any jurisdictional objections would present significant factual issues. Each Party, however, expressly reserved its right to request the Tribunal to exercise its discretion to order document disclosure not contemplated by the schedule.<sup>26</sup>
26. Given the fact-intensive nature of the US objections and their extensive overlap with merits issues, Apotex will request production of documents whether or not the case is bifurcated. Strong cause will support such a request.
27. By way of illustration, the US Reply on Bifurcation emphasizes two of the only three interrupted shipments to consignees other than Apotex-US during the Import Alert:

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<sup>21</sup> *Id.* at para. 111.

<sup>22</sup> *See* US Reply on Bifurcation, paras. 43-48.

<sup>23</sup> *See* Opposition to Bifurcation, para. 113. *See also* US Reply on Bifurcation, paras. 43-48.

<sup>24</sup> US Reply on Bifurcation, para. 48.

<sup>25</sup> *Id.*

<sup>26</sup> *See* First Procedural Order, para. 15.9 (“Further requests for the production of documents sought by either Party, if any, shall be permitted only at the discretion of the Tribunal.”).

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those to [REDACTED].<sup>27</sup> The only information provided by the US concerning these supposedly key shipments is reflected in a notice of FDA action addressed to [REDACTED] [REDACTED]<sup>28</sup> – but no similar notice to [REDACTED] – and unexplained and unauthenticated entries on a spreadsheet allegedly taken from “FDA’s import database.”<sup>29</sup>

28. Apotex did not make, receive or otherwise participate in the shipments that the US relies upon. It has no information concerning them. In order to prepare its defense, Apotex will need the US to provide additional documents concerning them.
29. For example, the US has not supplied any notice of action or other document concerning the shipment to [REDACTED]. The FDA spreadsheets indicate that the shipper was [REDACTED], a pharmacy in Quebec.<sup>30</sup> A retail [REDACTED] drugstore in Phoenix, Arizona was the consignee.<sup>31</sup> This shipment concerned the drug [REDACTED], a product that Apotex sells in Canada but which is not authorized in the US in this strength.<sup>32</sup> The US refused to admit the shipment on the ground that the product was unapproved in the US, and also on the ground of “DRUG GMPS.”<sup>33</sup> The limited information provided is consistent with a shipment by request of a retail customer of [REDACTED] Pharmacy who was in Arizona for the winter and needed a refill of his medication. Apotex believes that the notices of action concerning this shipment and other information held by the US will confirm that this is what this shipment represents. Apotex-US, quite obviously, is not in

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<sup>27</sup> US Reply on Bifurcation, para. 16.

<sup>28</sup> **Exhibit R-120**, Notices of FDA Action re: Entry No. 334-2761279-2, dated September 4-October 5, 2009 [REDACTED].

<sup>29</sup> US Reply on Bifurcation, para. 18. See **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated); **Exhibit R-118**, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated); **Exhibit R-119**, FDA, Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated).

<sup>30</sup> **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated), at 1, lines 3 and 4 (entry number 112-5302968-4/1/1).

<sup>31</sup> *Id.*

<sup>32</sup> Apotex is only authorized for the 100 and 300 mg dosages. See **Exhibit C-275**, Excerpts from 2012 Orange Book, ANDAs held by Apotex-Canada as of August 28, 2009, at 3-15.

<sup>33</sup> **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated), at 1, lines 3 and 4 (entry number 112-5302968-4/1/1).

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circumstances resembling those of a Quebecois retired person seeking the Arizona sun who runs out of his prescription.

30. The other shipment was one from [REDACTED], a Canadian wholesaler, to [REDACTED]. [REDACTED] is a company that sources drugs for clinical trials.<sup>34</sup> The shipment to [REDACTED] concerned the product [REDACTED]. Again, Apotex sells [REDACTED] in Canada but it is not authorized to sell that product in the United States. The documentation supplied by the US is unclear as to whether the lack of approval for the product motivated the decision to refuse entry for the shipment. The description for the shipment was “[REDACTED] AS COMPARATOR TO [REDACTED] SPONSOR: [REDACTED].”<sup>35</sup> [REDACTED] is the producer of an anti-inflammatory drug, [REDACTED], which according to a presentation to FDA was tested against [REDACTED] around the time of the Import Alert.<sup>36</sup> The description of the shipment, as well as the business line of the consignee, is consistent with the supply of product for a clinical trial in the United States. FDA documents will shed light on this and whether the unapproved nature of the product was a basis for the exclusion of this shipment.
31. Given the issues raised by the US, Apotex would be able amply to support a request for leave from the Tribunal for document disclosure if the case were bifurcated. The US thus errs in asserting that “it would be more efficient to bifurcate the case and rule on those objections, instead of ordering the parties to engage in a premature and ultimately unnecessary document production process.”<sup>37</sup> Document requests will be a feature regardless of whether the case is bifurcated or not.

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<sup>34</sup> See [REDACTED] website, page on “[REDACTED]”, available at [REDACTED] (last visited on Jan. 16, 2013) (“[REDACTED]”).

<sup>35</sup> See **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated), page 1, line 2 (shipment number 334-2761279-2/1/1).

<sup>36</sup> See FDA, Presentation on [REDACTED], dated May 12, 2010, slide CE-19, available at [REDACTED] (last visited on Jan. 16, 2013) (“Similar Efficacy of [REDACTED] vs [REDACTED]”).

<sup>37</sup> US Reply on Bifurcation, para. 48.

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32. *Fourth*, the US further errs in stating that “[b]oth parties anticipate that a jurisdictional hearing would be shorter, less intense, and less expensive than a merits hearing.”<sup>38</sup> This is not what Apotex anticipates in light of the US objections. As noted, these objections substantially overlap with the merits and raise the same complex and fact-intensive issues that the merits do. Because of this, Apotex now anticipates that a jurisdiction hearing will replicate the merits hearing in many respects, both in terms of the factual issues addressed and the witnesses who would be heard.
33. Apotex notes that, in its Counter-Memorial and again in its Reply on Bifurcation, the US repeatedly suggests that Apotex witnesses have given statements in this proceeding that contradict sworn declarations in US courts. For instance, in its Reply on Bifurcation, the US relies on declarations of Bernice Tao to argue that sales between Apotex-Canada and Apotex-US allegedly “occurred entirely in Canada” and could not have been interrupted by the Import Alert.<sup>39</sup> Likewise, in the Counter-Memorial, the US references other declarations made by Bernice Tao,<sup>40</sup> or US court documents that addressed declarations (or depositions) of other Apotex’s witnesses, including Gord Fahner and Kiran Krishnan.<sup>41</sup> Apotex will demonstrate in its Reply that the US repeatedly and consistently distorts the prior statements and there is no inconsistency. However, if the US intends to pursue this line of argumentation, basic fairness requires that it “put the question” to these witnesses at a hearing and allow them to respond.
34. Apotex presently estimates that a hearing on jurisdiction would require at least five hearing days and would differ from the hearing on the merits principally in the absence

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<sup>38</sup> *Id.* at para. 45.

<sup>39</sup> *Id.* at para. 10 n.15. *See also id.* at para. 31 n.55 (quoting **Legal Authority RLA-176**, *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, para. 28 (Jan. 13, 2010) (on corporate relationship between Apotex-Canada and Apotex-US)); *id.* at para. 32 n.56 (quoting **Legal Authority RLA-183**, *Shire LLC v. Apotex Inc., Apotex Corp. and Apotex Pharmaceutical Holdings Inc.*, No. 2:08-cv-265 (E.D. Tex.), Declaration of Bernice Tao, para. 31 (Aug. 6, 2008) and **Legal Authority RLA-92**, *Pfizer Inc. v. Apotex Inc. Apotex Corp.*, No. 1:08-cv-00948 (LDD) (D. Del.), Declaration of Bernice Tao, para. 17 (Feb. 10, 2009) (on preparation of Apotex’s ANDAs)).

<sup>40</sup> *See* US Counter-Memorial, at 108 n.546; *id.* at 157 nn.767, 772.

<sup>41</sup> *See, e.g.*, **Legal Authority RLA-80**, *In re: Rosuvastatin Calcium Patent Litigation*, 719 F.Supp.2d 388, 397 (D. Del. 2010) (citing to Fahner Dep.; Krishnan Dep.; Tao Dep.).

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of treatment of the quantum of damages. It currently estimates that a hearing on jurisdiction and the merits would require about eight hearing days.

35. Apotex thus rejects the US assertion that bifurcation would spare the parties “the majority” of their expenses “by substantially reducing the scope of the issues and the involvement of fact [] witnesses[.]”<sup>42</sup> Bifurcating jurisdiction and the merits here would not increase procedural efficiency. Given the overlap in issues and the fact-intensive nature of the US objections, it makes no sense to bifurcate this arbitration from a case-management perspective.

#### **D. The US Objections Are Without Substance**

36. The US Reply on Bifurcation errs in relying on *Glamis Gold* to establish a “low threshold” whereby a tribunal need only “satisfy itself that the jurisdictional objections are ‘substantial’ and not ‘frivolous’” to order bifurcation.<sup>43</sup> *Glamis Gold* offers the US no support.
37. *First*, the *Glamis* tribunal operated under the 1976 UNCITRAL Rules, which contained a presumption in favor of addressing jurisdictional objections as a preliminary matter.<sup>44</sup> As Apotex noted previously and the US does not dispute, the ICSID (Additional Facility) Arbitration Rules have eliminated any such presumption.<sup>45</sup> If *Glamis* reflected a “low threshold” as the US suggests, it was a reflection of the presumption established by the rules governing *Glamis* – a presumption with no application to these proceedings.

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<sup>42</sup> US Reply on Bifurcation, para. 47.

<sup>43</sup> *Id.* at para. 40 (citing and quoting **Legal Authority CLA-444**, *Glamis Gold, Ltd. v. United States of America*, UNCITRAL, Procedural Order No. 2 (Revised), para. 12(c) (May 31, 2005)).

<sup>44</sup> **Legal Authority RLA-41**, UNCITRAL Arbitration Rules, art. 21(4) (1976) (“In general, the arbitral tribunal should rule on a plea concerning its jurisdiction as a preliminary question.”). See **Legal Authority CLA-444**, *Glamis Gold, Ltd. v. United States of America*, UNCITRAL, Procedural Order No. 2 (Revised), para. 10 (May 31, 2005) (“Parties direct the Tribunal’s attention to a significant number of arbitral awards and commentary ... these sources often do not involve rules with a presumption in favor of the preliminary consideration of pleas as to jurisdiction and are not relevant to the tribunal’s considerations.”).

<sup>45</sup> Opposition to Bifurcation, paras. 121-22. See also **Legal Authority CLA-461**, ICSID Arbitration (Additional Facility) Rules, art. 45(4) (2006) (“Upon the formal raising of an objection relating to the dispute, the Tribunal may decide to suspend the proceeding on the merits.”).

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38. *Second*, the *Glamis* tribunal in any event rejected the US request for bifurcation, holding that bifurcating jurisdiction and merits in that case “would not ultimately avoid expense for the Parties, contribute to the Tribunal efficiency, or be practical.”<sup>46</sup> The tribunal’s decision was based on practical considerations, not its assessment of whether the US objections were “frivolous” or passed some unstated “low threshold.”
39. Apotex submits that, for the practical reasons stated previously, a preliminary phase on jurisdiction is not warranted here. Should, however, the Tribunal wish to consider the substance of the US objections, it will find them wanting.

1. *The US Contention that the Measure Did Not “Relate to” Apotex-US Is Baseless*

40. In its Opposition to Bifurcation, Apotex previewed the defense that it will mount in its Reply to the US objections to jurisdiction. It showed that the record amply met the legal standard that the US appeared to propound in a heading in the Counter-Memorial.<sup>47</sup> It demonstrated that the Import Alert directly applied to Apotex-US, notices implementing the Import Alert were addressed explicitly to Apotex-US and the statutory regime authorizing import measures recognized the application of these measures to consignees such as Apotex-US.<sup>48</sup> It further showed that the US position was irreconcilable with the NAFTA, which expressly incorporates substantive obligations that do not contemplate a measure directly applying in the sense suggested by the US – obligations such as national treatment, full protection and security and indirect expropriation.<sup>49</sup> It set forth Apotex’s position, based on the reasoning in *Methanex*: if a claimant proves the connection between measure and investment or investor required to establish a violation of a substantive provision such as Articles 1102, 1103 or 1105, that connection must necessarily be “legally significant” under

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<sup>46</sup> **Legal Authority CLA-444**, *Glamis Gold, Ltd. v. United States of America*, UNCITRAL, Procedural Order No. 2 (Revised), para. 16 (May 31, 2005).

<sup>47</sup> Opposition to Bifurcation, para. 9.

<sup>48</sup> *Id.* at paras. 22-30.

<sup>49</sup> *Id.* at paras. 39-43.

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Article 1101(1).<sup>50</sup> It showed that Apotex-US was the sole commercial importer from Apotex-Canada in the United States and that, far from supporting the US, the documents introduced with the Counter-Memorial demonstrated that during the Import Alert the US permitted over 98 percent of the shipments to consignees other than Apotex-US to enter US territory, but blocked all those to Apotex-US.<sup>51</sup>

41. The US Reply scrupulously avoids any affirmative statement of what legal standard informs a “legally significant connection” under Article 1101(1). Instead, it erroneously attempts to attribute the “directly applies” and “legal impediment” standards to Apotex. The US Reply acknowledges that the notices implementing the Import Alert were specifically addressed to Apotex-US and that the statutory regime authorizing import measures recognizes that such measures apply to consignees such as Apotex-US. It does not deny that its approach to Article 1101(1) would create a “gateway” to the NAFTA investment chapter that would be too narrow to allow in the substantive obligations contemplated by the treaty’s drafters, such as national treatment, full protection and security and indirect expropriation. It makes no attempt to reconcile its position with the terms of the NAFTA. It does not deny that the connection between measure and investment or investor specifically contemplated by the NAFTA’s substantive provisions is necessarily a “legally significant” one under Article 1101(1). It does not contest that during the Import Alert the FDA allowed no shipments from Etobicoke or Signet to Apotex-US, but allowed over 98 percent of the shipments to other consignees to enter the US.
42. Instead, the US Reply engages in an exercise of reimagining the record. It imagines that there was contemporaneous official evidence of the adoption of the Import Alert on August 28, 2009, when the exhibit it references recites that the Import Alert was published only on September 30, 2009.<sup>52</sup> It imagines that purchase and sale transactions

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<sup>50</sup> *Id.* at paras. 44-48.

<sup>51</sup> *Id.* at paras. 50-60.

<sup>52</sup> *Compare* US Reply on Bifurcation, para. 13 (“The contemporaneous official evidence of the adoption of the Import Alert is the Import Alert itself.”) (internal quotation omitted; citing **Exhibit C-110**) *with*

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between Apotex-Canada and Apotex-US occurred entirely in Canada, when the record shows purchase orders for shipments from Apotex-Canada in Ontario to Apotex-US in Indiana and that the Import Alert prevented those transactions from being consummated.<sup>53</sup> The US defies logic and argues in the space of two paragraphs both that the Import Alert applied only to Apotex-Canada and that the Import Alert prevented only Apotex-US from bringing goods into US territory.<sup>54</sup> And the US invents a new measure nowhere reflected in the record or mentioned by any witness: “FDA’s determination that ... facilities were not cGMP-compliant and thus drugs from those facilities were deemed to be adulterated.”<sup>55</sup> The US imagines that this previously unmentioned measure, and not the Import Alert, was the “underlying ‘legal impediment’ that prevented Apotex[-US] ... from importing drugs into the United

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**Exhibit C-110**, FDA’s website, Import Alert 66-40, dated October 2, 2009, at 2 (stating for each entry concerning Apotex-Canada: “Date Published: 09/30/2009”).

<sup>53</sup> Compare US Reply on Bifurcation, para. 10, with **Exhibit C-68**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009, at 10:20 am, attaching Notice of FDA Action re: Entry No. EG6-1768658-9, dated August 31, 2009 and commercial invoice; **Exhibit C-69**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009, at 10:21 am, attaching Notice of FDA Action re: Entry No. EG6-1768659-7, dated August 31, 2009 and commercial invoice; **Exhibit C-71**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009, at 12:36 pm, attaching Notice of FDA Action re: Entry No. EG6-1767503-8, dated September 1, 2009 and commercial invoice. Apotex noted in its Opposition that under the UN Convention on the International Sale of Goods, Apotex-US bore the risk of loss when the goods were delivered to the carrier. Apotex Opposition to Bifurcation, para. 31. The Convention, however, does not address when title passes. See **Legal Authority CLA-441**, United Nations Convention on Contracts for the International Sale of Goods, Apr. 11, 1980, 1489 U.N.T.S. 3, art. 4(b) (1980). Contrary to the US contention, Apotex has never suggested that title passed to Apotex-US on delivery of the goods to the carrier.

<sup>54</sup> Compare US Reply on Bifurcation, para. 9 (“the Import Alert was specifically addressed to drug products from *Apotex[-Canada]*...”) (emphasis in original), with *id.* at paras. 10-11 (transactions between Apotex-Canada and Apotex-US “occurred *in Canada*” and only Apotex-US’s “ability to import” was affected by the Import Alert) (emphasis in original).

<sup>55</sup> *Id.* at para. 11. But see, e.g., Witness Statement of Carmelo Rosa, paras. 21-23 (describing “toolbox” of “regulatory actions” but nowhere mentioning such a determination as one such measure); **Legal Authority CLA-280**, Review of Post-Inspection Responses, 74 Fed. Reg. 40211-03, 2009 WL 2430727 (F.R.), at 1 (Aug. 11, 2009) (“[FDA Form 483] lists observations made by FDA representative(s) during the inspection of your facility. They are inspectional observations; and do not represent a final agency determination regarding your compliance. ...”); **Legal Authority CLA-306**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action, subchapter 4-1-1 “Warning Letters Procedures” at 4-3 (2012) (warning letters are only “informal and advisory” and “do[] not commit FDA to taking enforcement action”); **Legal Authority CLA-157**, *Holistic Candles & Consumers Ass’n v. FDA*, 664 F.3d 940 (D.C. Cir. 2012) (“FDA’s warning letters ... neither marked the consummation of FDA’s decision making process nor determined the manufacturers’ legal rights or obligations.”).

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States from the Etobicoke and Signet facilities ...”,<sup>56</sup> when the record shows that it was immediately following adoption of the Import Alert on August 28, 2009 that the US began turning back Apotex-Canada shipments to Apotex-US.<sup>57</sup>

43. The record supports none of the new arguments advanced by the US. There is no substance to them.
44. Nor is there any foundation in fact or law for the US argument that the Import Alert accorded Apotex-US the same treatment as other distributors. The US, as noted, does not dispute that, while the Import Alert prevented all shipments of Etobicoke and Signet products from Apotex-Canada to Apotex-US during the two years it was in effect, the FDA records it introduced as exhibits show the US allowed over 98 percent of shipments of such products to other consignees to proceed into the US. Instead, the US points to two of the three shipments to other consignees that were refused admission during the time of the Import Alert, and argues that the refusal of admission of these shipments shows that Apotex-US received the same treatment as these consignees.<sup>58</sup>
45. The US argument is untenable as a matter of law. First, even if it were correct that the measure applied to more than one consignee, it certainly would not follow that the measure related to *none of them*. The jurisprudence is replete with instances of the same measure applying to multiple parties – the Mexican high-fructose corn syrup and Argentine emergency measure arbitrations being only two of many such examples.<sup>59</sup>

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<sup>56</sup> US Reply on Bifurcation, para. 11.

<sup>57</sup> See **Exhibit C-68**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009, at 10:20 am, attaching Notice of FDA Action re: Entry No. EG6-1768658-9, dated August 31, 2009, and commercial invoices; **Exhibit C-69**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009, at 10:21 am, attaching Notice of FDA Action re: Entry No. EG6-1768659-7, dated August 31, 2009, and commercial invoices.

<sup>58</sup> US Reply on Bifurcation, para. 16 (discussing one interrupted shipment to [REDACTED] and one interrupted shipment to [REDACTED]).

<sup>59</sup> See **Legal Authority CLA-474**, *Corn Products International, Inc. v. United Mexican States* (ICSID Case No. ARB(AF)/04/1) and *Archer Daniels Midland Company and Tate & Lyle Ingredients Americas, Inc. v. United Mexican States* (ICSID Case No. ARB(AF)/04/5), Order of the Consolidation Tribunal, para. 1 (May 20, 2005) (three different companies submitted similar NAFTA claims against Mexico “based on the same tax measure”); **Legal Authority CLA-475**, Marie Christine Hoelck Thjoernelund, *State of Necessity as an Exemption from State Responsibility for Investments*, 13 Max Planck UNYB 423, 440-41 (2009) (“Among

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The fact that a measure applies to more than one party does not mean that an investment claim (including a NAFTA claim) is precluded. There is no requirement in the NAFTA or anywhere else that a measure must “uniquely affect[]” an investment, as the US suggests.<sup>60</sup>

46. Second, the NAFTA does require, for national treatment and MFN claims, that the measure accord less favorable treatment to national or foreign investors or investments “in like circumstances” with the claimant and its investment. Apotex agrees that, in this context, the question is posed of whether Apotex-US is in “like circumstances” with [REDACTED], a company engaged in clinical trials, and [REDACTED], a pharmacy. But this is a classic merits question – it has nothing to do with the power of this Tribunal to hear this case.
47. Apotex welcomes the opportunity to respond to the US suggestion that Apotex-US is in like circumstances with [REDACTED] and [REDACTED]. In its Reply, Apotex will show that in the first 8 months of 2009 alone, Apotex-Canada effected [REDACTED] of shipments containing [REDACTED] of doses of product from Etobicoke and Signet to Apotex-US and that, but for the Import Alert, Apotex-Canada would have made many [REDACTED] more. It will show that, because of the Import Alert, Apotex-Canada made no such shipments. It will show that the three consignees identified by the US had one shipment each interdicted during the entire two-year period of the Import Alert.<sup>61</sup> Apotex will show that none of these three consignees are in the same business as Apotex-US. It will show that none of the three shipments concerned products that Apotex-Canada was authorized

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others, [Argentina] enacted the Public Emergency and Exchange Regime Reform Act .... That situation led investors to initiate arbitration procedures under the ICSID requesting reparation.”).

<sup>60</sup> US Reply on Bifurcation, para. 15.

<sup>61</sup> The three interrupted shipments in question were to [REDACTED], [REDACTED] and [REDACTED]. See **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) at 1 (undated); **Exhibit R-118**, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009) at 2, 23 (undated) (same entry numbers as on Exhibit R-115).

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to sell in the US or that Apotex-US sold.<sup>62</sup> Apotex will demonstrate, in sum, that none of the three consignees is in any respect in like circumstances with Apotex-US.

48. Apotex will further show in its Reply that the US was well aware that Apotex-US was the distributor of record of products made at Etobicoke and Signet. The label on every Apotex product commercially sold in the US, and every medication guide, identifies Apotex-US as the distributor of record and states as follows: “Manufactured by: Apotex Inc., Toronto, Ontario M9L 1T9; Manufactured for: Apotex Corp., Weston, Florida, 33326.”<sup>63</sup> The FDA approved every label and every medication guide for every product as part of its ANDA review process.
49. Finally, the Reply will show that no evidence supports the US argument that the occasional shipments reflected in the FDA spreadsheets to [REDACTED], [REDACTED], [REDACTED], [REDACTED] and [REDACTED] were commercial sales by Apotex-Canada in the United States.<sup>64</sup> Contrary to the US suggestion, the spreadsheets say nothing about the purpose of these shipments. These consignees are not remotely in like circumstances with Apotex-US. The US contention is without support.

2. *A Measure Preventing Marketing of Apotex-Canada Products in the US Relates to Apotex-Canada’s Authorizations to Market those Products*

50. The Reply will show that the record does not support the assertion in the US Reply on Bifurcation that Apotex “could have continued to sell products under the approved ANDAs by transferring the necessary technology from its Etobicoke and Signet

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<sup>62</sup> For the reasons discussed above, the shipments to [REDACTED] and [REDACTED] were of Apotex products unapproved for sale in the US. The third shipment, to the [REDACTED], also was refused admission into the US as “UNAPPROVED.” See **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated), at 1, line 6. The summary description provided by the US, however, does not indicate the dosage, so it is not possible without document disclosure to corroborate that it was unapproved.

<sup>63</sup> See, e.g., **Exhibit C-267**, CBE-30 for Change in Label for Paroxetine Hydrochloride Tablets USP, dated October 5, 2011, at 88, 94.

<sup>64</sup> US Reply on Bifurcation, para. 18.

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facilities to one of its many ‘plants throughout the world.’”<sup>65</sup> The legal authority referenced by the US supports no such statement. Instead, that document makes clear that the FDA would have to approve a change to the single application under discussion there in order to authorize a product to be produced at a location other than the approved one.<sup>66</sup>

51. As the US is well aware, drug marketing authorizations are specific to a given production site – this is why the FDA conducts pre-approval inspections, to assess the site’s capability to produce the product in question.<sup>67</sup> The marketing authorizations for Etobicoke and Signet held by Apotex-Canada in 2009 did not permit manufacture of products anywhere but those facilities. Apotex could not have “continued to sell products under the approved ANDAs” while the Import Alert was in effect, as the US suggests.
52. There is thus no support for the US assertion that the Import Alert did not prevent marketing in the US of products Apotex-Canada was authorized to market under its approved ANDAs. It indisputably did. Apotex-Canada could theoretically have applied for amended ANDAs that would permit production at a different Apotex site. But this was not a viable option given the quantity of molecules banned by the Import Alert.<sup>68</sup> And this question is a classic one of mitigation of damages – not one of whether the measure relates to the investment.

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<sup>65</sup> *Id.* at para. 24 (citing and quoting **Legal Authority RLA-70**, *Apotex Inc. v. Cephalon, Inc.*, No. 06-cv-02768 MSG (E.D. Pa.), Response of Apotex to Cephalon’s Request for Conference, at 2 (Apr. 21, 2010)).

<sup>66</sup> *See Legal Authority RLA-70*, *Apotex Inc. v. Cephalon, Inc.*, No. 06-cv-02768 MSG (E.D. Pa.), Response of Apotex to Cephalon’s Request for Conference, at 2 (Apr. 21, 2010) (“Apotex can file appropriate technology transfer documents with the FDA that would allow manufacture at another FDA approved Apotex manufacturing site. See 21 CFR 314.70(a)”).

<sup>67</sup> Witness Statement of Carmelo Rosa, para. 14, third bullet.

<sup>68</sup> *See* Witness Statement of Jeremy Desai, paras. 89-90.

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3. *The US Arguments that Marketing Authorizations Are Not Property in the US Are Insubstantial*

53. In its Opposition to Bifurcation, Apotex showed that the NAFTA refuted the US argument, which defined “intangible property” under Article 1139(g) by reference to lower court readings of “private property” in the Takings Clause as excluding intangible rights revocable by the Government.<sup>69</sup> Apotex observed that intellectual property rights are covered in the NAFTA only through Article 1139(g)’s reference to “intangible property.”<sup>70</sup> It demonstrated that, contrary to the US argument, revocable interests plainly qualified as “intangible property” and therefore investments under Article 1139(g) because Article 1110(7) explicitly covered revocable intangible interests.<sup>71</sup> The US argument therefore was irreconcilable with the NAFTA. And in any event, the US did not attempt to justify its reliance on the meaning of “private property” in the Takings Clause as opposed to “property” in the Due Process Clause – a significant omission given its acknowledgment that there was no deprivation at issue here.<sup>72</sup>
54. The US Reply does not dispute that its reading of “intangible property” to exclude revocable interests is irreconcilable with Article 1110(7)’s explicit coverage of such interests. Instead, it suggests (erroneously) that Article 1110(7)’s exception to expropriation for revocations consistent with Chapter Seventeen is limited to patents.<sup>73</sup> It concludes, apparently on the strength of its lower-court Takings Clause jurisprudence, that the only revocable intangible interests qualifying as investments under Article 1139(g)’s reference to “intangible property” are patents.
55. To state the US argument is to reveal its lack of weight.

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<sup>69</sup> Opposition to Bifurcation, paras. 72-78.

<sup>70</sup> *Id.* at para. 74.

<sup>71</sup> *Id.* at paras. 75-77.

<sup>72</sup> *Id.* at para. 72, n.61.

<sup>73</sup> US Reply on Bifurcation, para. 29. *But see, e.g., Legal Authority CLA-1*, NAFTA, art. 1708(4)(e) (Parties must provide a “reasonable opportunity for interested persons to petition to cancel the registration of a trademark”); *id.* at art. 1708(8) (trademark “registration may be canceled for the reason of non-use only after an uninterrupted period of at least two years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner.”).

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56. The US Reply's only response to Apotex's observation that "US tax law considers ANDAs to be assets the sale of which is subject to taxation like the sale of other property" is to purport to draw significance from Apotex's failure "to affirm that it ever paid U.S. taxes on sales."<sup>74</sup> The record, however, reflects only a purchase of ANDAs by Apotex, not a sale.<sup>75</sup> There is no foundation for the US argument.
57. Finally, the US again has no answer to Apotex's observation that an investment plainly may be "in the territory of a Party" even though it is held by an investor in another Party's territory. In its Opposition, Apotex pointed to the example of a loan prepared and held by a Canadian bank in its territory but made to a debtor in US territory. The only US response is that loans are "investments."<sup>76</sup> But this in no way addresses the point that the territorial situs of the loan is the country of the debtor even if the bank preparing the documentation and holding the interest is in another NAFTA country.

4. *The US Has No Response to Apotex's Arguments under Article 1139(h)*

58. In its Opposition, Apotex noted that the US did not contest that marketing authorizations were "interests" within the meaning of Article 1139(h).<sup>77</sup> It observed that the US did not dispute that the staff of Apotex-US in Florida devoted to filing and maintaining the ANDAs represented "'resources' committed to economic activity in US territory."<sup>78</sup> Under even the US reading of Article 1139(h), Apotex clearly has established that the marketing authorizations constitute interests arising from the commitment of resources in US territory to economic activity in the US. Apotex further noted that the US offered no response to Apotex's detailed exposition in its Memorial of why Article 1139(h) must be read to encompass the commitment of foreign capital and resources to economic activity in the host State.<sup>79</sup>

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<sup>74</sup> US Reply on Bifurcation, para. 30.

<sup>75</sup> See Memorial, para. 370.

<sup>76</sup> US Reply on Bifurcation, para. 31.

<sup>77</sup> Opposition to Bifurcation, para. 81.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.* at para. 91.

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59. The US Reply offers no response on any of the points reviewed above. It offers only an inapposite reference to the *Grand River Enterprises* award, where the tribunal considered only whether regulatory compliance costs independently qualified as an investment, not whether they constituted resources committed to economic activity that gave rise to an interest in the territory of a Party.<sup>80</sup> The US Reply, again, is without substance.

## II. DAMAGES SHOULD BE HEARD WITH THE MERITS

60. Finally, hearing damages with the merits would in no way be “unfair and prejudicial” to the United States.<sup>81</sup> The US received Apotex’s Memorial, including its 20-page presentation of Apotex’s case-in-chief on damages, on July 30, 2012.<sup>82</sup> On that same date, the US also received Howard Rosen’s damages expert report, accompanied by 695 megabytes of data in 169 files.<sup>83</sup> As noted in the Memorial, Mr. Rosen fully quantified Apotex’s damages in July, except with respect to two variables for which he lacked sufficient data at that point in time because the products had so recently entered the market.<sup>84</sup> It is only for these two variables that Mr. Rosen indicated a range in his July 2012 report and explained that he would finalize his calculations with respect to these two variables with the Reply in May 2013.

61. In other words, the US has had almost six months to review and analyze Apotex’s damages submissions, with the exception of only two variables. The US plainly can address a supplemental damages expert report *limited to these two variables* in nine weeks.

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<sup>80</sup> US Reply on Bifurcation, at para. 34.

<sup>81</sup> *Id.* at para. 52.

<sup>82</sup> Memorial, paras. 488-571.

<sup>83</sup> *See* Apotex’s Letter to the Tribunal, dated October 5, 2012, at 4; Apotex’s Letter to the Tribunal, dated October 25, 2012 at 3.

<sup>84</sup> *See* Memorial, paras. 524-25, 529, 535, 557, 572.

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62. The US complaints about “missing sales information,” or other “crucial information” should be the object of documents requests.<sup>85</sup> In this regard, Apotex notes that under the original procedural schedule agreed by the parties, the US would have had to submit its Counter-Memorial, including its damages submissions, before the document production phase.<sup>86</sup> Apotex notes that its proposal advantages the US by allowing it to make document requests before putting in its responsive case on damages.
63. The US also claims that it “would have to expend substantial sums on a valuation expert.”<sup>87</sup> However, the US does not suggest that it did no work on damages in the three months between receipt of the Memorial and the Tribunal’s October 29, 2012 order. The incremental cost of a damages expert to complete the work is *de minimis* compared to the overall costs in this case.
64. Lastly, the US criticizes “Apotex’s unilateral attempt to join this issue to the United States’s request for bifurcation.”<sup>88</sup> However, as early as October 5, 2012, Apotex proposed that Mr. Rosen submit a supplemental report limited to the two issues that he was not in a position to quantify in July 2012.<sup>89</sup> There is no cause for surprise now.
65. For these reasons, the Tribunal should address the issues on quantum together with those on jurisdiction and liability, so as to be in a position to decide the entire case after the November 2013 hearing.

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<sup>85</sup> US Reply on Bifurcation, para. 52. The US again wrongly asserts that it has not received Apotex’s financial statements. *Id.* As noted in Apotex’s letter to the Tribunal dated October 5, 2012, Mr. Rosen produced 695 megabytes of source data that he relied upon for his report, including the pertinent financial statements for Apotex-US.

<sup>86</sup> First Procedural Order, paras. 14.2.2 and 14.2.7(i).

<sup>87</sup> US Reply on Bifurcation, para. 53.

<sup>88</sup> *Id.* at para. 51.

<sup>89</sup> Apotex’s Letter to the Tribunal, dated October 5, 2012 at 4 (“Apotex thus proposes that Mr. Rosen submit a supplemental report limited to that calculation in January 2013, with the US submitting a supplemental report of its damages expert in response in April 2013. Apotex will then address the US position on damages in its Reply in May 2013 as scheduled, and the US will have a second opportunity to address damages in its Rejoinder.”).

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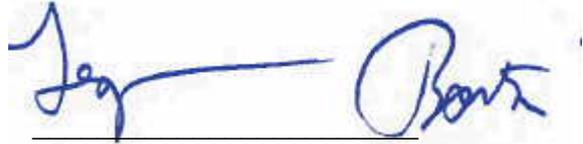
**SUBMISSIONS**

66. For the foregoing reasons, claimants Apotex Holdings and Apotex-Canada respectfully submit that the Tribunal should deny the US request for bifurcation and order the parties to address issues of damages in accordance with the schedule proposed at paragraph 132 of Apotex's Opposition to Bifurcation, or as the Tribunal deems appropriate in order to have all issues in this case presented at the November 2013 hearing.

Date: January 16, 2013

*Respectfully submitted,*

SALANS LLP

A handwritten signature in blue ink, appearing to read 'Jay Legum', is written over a horizontal line. To the right of the signature is a circular stamp or mark.

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