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

APOTEX HOLDINGS INC. AND APOTEX INC.,

Claimants,

– and –

THE GOVERNMENT OF THE UNITED STATES OF AMERICA,

Respondent.

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

CLAIMANTS' OPPOSITION TO BIFURCATION

ARBITRAL TRIBUNAL:

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December 28, 2012



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Apotex Holdings Inc. and
Apotex Inc.*

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In accordance with paragraph 14.2.3 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 memorandum in opposition to the request for bifurcation of respondent United States of America as stated in its counter-memorial of December 14, 2012.¹

¹ Counter-Memorial on Merits and Objections to Jurisdiction of Respondent United States of America (Dec. 14, 2012) (hereinafter "US Counter-Memorial").

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INTRODUCTION

1. The considerations of “economy, efficiency, and fairness” that the United States relies upon compel dismissal of its request for bifurcation.² Economy and efficiency favor a single hearing in November 2013 on all issues. That approach ensures that this Tribunal will bring this case to conclusion based on the evidence adduced at that hearing.
2. *First*, no efficiency in terms of time can be gained from bifurcation here. Under the schedule agreed by the Parties and ordered by the Tribunal, the hearing will take place in November 2013 whether the case is bifurcated or not. Bifurcation cannot advance the resolution of this case.
3. *Second*, the economies and efficiencies that the US posits depend upon a gamble that both of its jurisdictional objections will succeed. Each of the objections presented by the US goes only to a portion of the case put by Apotex. If a single objection fails, a hearing must be held on the merits, with no change in the scope of the issues to be considered.
4. *Third*, the inefficiencies and additional costs resulting from bifurcation if the Tribunal rejects one or more of the US jurisdictional objections are substantial and evident. A failed preliminary phase will result in at least 18 months of additional delay. With the passage of time, memories fade, witnesses become unavailable and documents more difficult to locate. Case preparation must begin anew. The efficiencies of scale that come with a single hearing and a single set of pleadings are lost. The cost of bifurcation in time and expense is high.
5. *Fourth*, there is substantial overlap between the issues the Tribunal will have to address on jurisdiction and on the merits. As the tribunal in *Methanex* observed, whether the “relating to” element of Article 1101(1) is satisfied depends on the existence of a legally

² *Id.* at para. 392.

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significant connection between measure and investor or investment. As that tribunal repeatedly observed in its final award, facts establishing a violation of a substantive provision of Chapter Eleven are highly relevant to whether such a connection is present. Apotex's showing that the US violated the national-treatment, most-favored-nation-treatment and fair-and-equitable-treatment standards is equally pertinent to the US "relating to" objection. The US itself expressly acknowledges that its "relating to" argument goes not only to jurisdiction but also to the merits of the national and MFN treatment claims. And the primary US factual contention supporting its "relating to" argument – that the Import Alert supposedly accorded the same treatment to alleged distributors of Apotex-Canada products that it accorded to Apotex-US – is merely a MFN argument on the element of "less favorable treatment" packaged as a jurisdictional objection. Contrary to the US contention, this objection to jurisdiction substantially overlaps with the merits. No material economy in the presentation of issues or evidence can be realized here.

6. *Fifth*, fairness favors denial of bifurcation. 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."³
7. Moreover, as noted above, the US arguments on efficiency and economy depend upon its gamble that all jurisdictional objections will succeed. The US argument for bifurcation therefore implies an assessment of the merit of its jurisdictional objections based on the record presently before this Tribunal. Apotex respectfully submits that it 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.

³ **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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8. *Finally*, should the Tribunal decide preliminarily to assess jurisdiction at this stage, it will find the US arguments wanting. The objection that a measure specifically addressed to the Apotex group does not “relate to” any Apotex company is a brave one. As Apotex will demonstrate in its Reply, that objection is also hopeless. Contrary to the US assertion, the record clearly shows that the Import Alert applied directly to Apotex-US. The FDA notices of action make this plain by specifically referring to Apotex-US. The US law authorizing import alerts explicitly recognizes that the measure applies to consignees like Apotex-US. The US objection can be reconciled neither with the measure nor with the applicable national legal regime.
9. The record also does not support the US assertion that distributors of Apotex products in the US other than Apotex-US were equally impacted by the measure. Apotex-US was the only US company Apotex-Canada supplied with products made at the Etobicoke and Signet facilities for commercial sale, and the sole US supplier of those products. The evidence submitted by the US shows that 98 percent of shipments of Apotex products to consignees other than Apotex-US during the Import Alert were allowed to reach their destination. Apotex-US, by contrast, received none. Far from supporting the US, the evidence it submitted confirms that the measure relates to Apotex-US.
10. Nor does the NAFTA support the US argument that a measure must apply on its face to an investment or impose a legal impediment to the investment’s business to be covered. The NAFTA repeatedly makes clear that it regulates measures *not at all addressed* to a given investment or investor: measures effecting an indirect expropriation or granting more favorable treatment to investments owned by nationals without mentioning foreign investments – or in the case of a denial of full protection and security, where the breach is established by the *absence* of a measure. A legally significant connection may be established for purposes of Article 1101 regardless of whether the measure purports to be directed at the investor or investment.

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11. As *Methanex* recognized, whether a connection of legal significance is present cannot be decided without reference to the substantive NAFTA provisions at issue. Apotex demonstrated in its Memorial that the FDA accorded Apotex-US treatment less favorable than that accorded to US- and third-country-owned investments in like circumstances. It further showed that the Import Alert was adopted without the barest trappings of due process. Apotex will demonstrate in its Reply that the connection between measure and investment prescribed by Articles 1102, 1103 and 1105 is present on this record, and the US arguments to the contrary are baseless.
12. *In sum*, bifurcation can result in no time efficiency here. The economies in presentation of evidence posited by the US are limited at best and depend upon a gamble that both US jurisdictional objections will succeed. The objections are fact-intensive and largely overlap with the merits. The fairest approach under the circumstances would be for the Tribunal not to make a preliminary assessment of the US objections at this stage, but to give those objections full consideration along with all other issues in the case at the hearing in November. However, should the Tribunal wish preliminarily to consider the US objections at this stage, it will find that they are without factual or legal merit and cannot justify bifurcation.
13. In the discussion that follows, Apotex first provides a preliminary statement of the case that it will put on in opposition to the US objections to jurisdiction. The choice before the Tribunal is between a hearing on all issues and a hearing limited to jurisdiction. Either hearing will include both an affirmative case and a defense. The preliminary statement of Apotex's case on jurisdiction is intended to provide the Tribunal a clear understanding of what issues a hearing on jurisdiction would cover. Apotex then addresses why, in the specific circumstances of this case, it would make no sense to bifurcate the proceedings and conduct two hearings when the whole case can be decided after a single one. Apotex submits that, because bifurcation is a discretionary decision that depends upon case-specific considerations, the general arguments on bifurcation presented by the US are beside the point. Apotex nonetheless demonstrates that the US argument for a presumption in favor of bifurcation relies on decisions under procedural

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rules that provided such a presumption. It further shows that in recent years arbitration rules – including the ICSID rules applicable here – have been modified to remove any such presumption. Finally, Apotex requests that damages issues be addressed at the hearing in November, together with jurisdiction and liability, rather than in a separate phase. It presents its proposal for achieving this result.

14. This is not the place to debate the merits. Nonetheless, for the avoidance of doubt, Apotex notes that it categorically rejects the merits arguments presented in the US Counter-Memorial. Apotex looks forward to the opportunity to present its responsive case.

STATEMENT OF PROCEDURAL FACTS

15. The US jurisdictional objections fall into two categories, each addressing jurisdiction with respect to one claimant. The bases for these two categories of objections are different. For the US to achieve the premise for its bifurcation request and “eliminate Apotex’s entire claim,”⁴ the Tribunal would need to accept both categories of objections.
16. The first category of objections addresses Apotex Holdings. The US does not dispute that Apotex Holdings is an investor. It does not contest that Apotex-US is an investment within the meaning of NAFTA Article 1139.⁵ Its sole objection is that the Import Alert does not relate to Apotex-US under Article 1101.⁶
17. The second category of objections addresses Apotex-Canada. The US argues here that Apotex-Canada has no investment in the United States because its marketing

⁴ US Counter-Memorial, para. 392.

⁵ *See id.* at para. 288; *see also* Memorial, para. 352 (“There can be no dispute that Apotex-US is an investment indirectly owned and controlled by Apotex Holdings. The Tribunal’s jurisdiction *rationae materiae* is clearly established, independent of the marketing authorizations of Apotex-Canada[.]”).

⁶ US Counter-Memorial, para. 289 (“The Import Alert does not ‘relate to’ Apotex Holdings in its capacity as an investor or to its claimed U.S. investment, [Apotex-US], within the meaning of Article 1101(1).”).

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authorizations (or ANDAs) do not fall within the definition of investment in Article 1139(g) and (h).⁷ The US does not dispute that the Import Alert “relates to” Apotex-Canada. However, the US claims that the Import Alert did not “relate to” Apotex-Canada’s investments within the meaning of Article 1101(1).⁸

18. As noted, each category of objections is partial, independent and mutually exclusive. A finding that the measure relates to Apotex-US (or the contrary) would not imply that the measure does not relate to the marketing authorizations. A finding that Apotex-Canada’s marketing authorizations are investments (or the contrary) would not imply that Apotex-US is not an investment. For the US arguments on efficiency from bifurcation to have any merit, the US would have to prevail on *both* of its objections.
19. Apotex will demonstrate in its Reply and at the hearing that the US objections are devoid of substance. It will show that the objections are plainly contrary to the record, that the text of the NAFTA flatly contradicts the US position and that the US does not address the showing on jurisdiction Apotex made in its Memorial.
20. In the preliminary statement that follows, Apotex first addresses the category of objections concerning jurisdiction over Apotex Holdings and then addresses the category concerning Apotex-Canada.

I. THE IMPORT ALERT RELATES TO APOTEX-US AND APOTEX HOLDINGS

21. In its Reply, Apotex will demonstrate the error in the US suggestion that no legally significant connection exists between the Import Alert and Apotex-US or its indirect owner, Apotex Holdings. Curiously, the US states *positively* what connection it thinks Article 1101(1) requires only in a heading in the Counter-Memorial: for the US, the Import Alert must have “[a]ppplied to Apotex Corp., [d]irectly or [i]ndirectly” or

⁷ *Id.* at para. 221 (“Apotex[] nonetheless claims to hold two kinds of ‘investments’ in the United States for purposes of NAFTA Chapter Eleven: (1) ‘intangible property,’ through its abbreviated new drug applications, and; (2) ‘interests arising from the commitment of capital’ made ‘in and into’ the United States. Apotex has failed to substantiate either claim.”).

⁸ *Id.* at para. 274 (“The Import Alert had no legally significant connection to Apotex’s ANDAs.”).

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imposed a legal impediment to its business operations.⁹ The US provides no explanation of how it arrives at this test based on the text of the NAFTA. Instead, it offers only fact-specific arguments based on erroneous suppositions as to distributorship arrangements and contentions concerning the relationship between Apotex-Canada and Apotex-US.

22. Apotex will demonstrate in its Reply that these arguments are without support in fact or in law. First, the Import Alert did apply directly to Apotex-US and certainly was a legal impediment to its business operations. Under even the US's unexplained positive test, the measure plainly related to Apotex-US and Apotex Holdings. Second, the NAFTA does not support the test advocated by the US in any event. Third, the US arguments based on distributorship arrangements and the relationship between Apotex-Canada and Apotex-US are without legal or factual merit. To the contrary, the evidence submitted by the US confirms that the Import Alert related to Apotex-US.

A. The Import Alert Directly Applied to Apotex-US

23. Apotex's Reply will show that the Import Alert applied directly to Apotex-US. The Import Alert interrupted the transactions on which Apotex-US depended for 80 percent of its sales. The transactions that the Import Alert interrupted had two parties. Apotex-Canada was on one side as the seller and importer of record into the United States. Apotex-US was the purchaser and consignee of record on the other side.
24. The Import Alert made it legally impossible for these transactions to be carried out. To use the alternative expression posited by the US, the Import Alert was a legal impediment to the conduct of these transactions. The Import Alert applied equally to both parties to the transactions.
25. Perhaps the best illustration of this observation is the only contemporaneous official evidence of the adoption of the Import Alert: the FDA notices of action concerning

⁹ *Id.* (heading II.E.1.).

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specific transactions that the US interrupted in the days immediately following adoption of the Import Alert.¹⁰ The notices specifically identified Apotex-US as the “consignee” in the interrupted transactions and, according to the US, were specifically addressed to Apotex-US, as the excerpt from the following US exhibit illustrates:

United States Food and Drug Administration
Detroit District Office
Notice of FDA Action

Entry Number: EG6-1768425-3 Notice Number: 1
September 2, 2009

Consignee:
Apotex Corp.
2400 N Commerce Pkwy Ste 400
Weston, FL 33326-3253

> <

Port of Entry: 3801, Detroit, MI
Carrier: LIONS GATE TRANSPORT INC;
Date Received: September 1, 2009
Arrival Date: September 1, 2009

Filer of Record: Affiliated Customs Brokers, Detroit, MI 48216-2063
Importer of Record: Apotex, Inc., Etobicoke, Ontario, Canada M9W 6Y3

HOLD DESIGNATED
Summary of Current Status of Individual Lines

Figure 1, Exhibit R-44¹¹

¹⁰ See **Exhibit R-44**, Notices of FDA Action re: Entry No EG6-1768425-3, dated September 2-28, 2009; **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; **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; **Exhibit C-71**, Email from Customs Broker (Juanita Zaziksi) 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; **Exhibit C-72**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009, at 12:52 pm, attaching Notice of Action re: Entry No. EG6-1768378-4, dated September 1, 2009; **Exhibit C-78**, Notice of FDA Action re; Entry No. EG6-1768425-3, Notice Number 1, dated September 2, 2009; **Exhibit C-79**, Notice of FDA Action re: Entry No. EG6-1768429-5, Notice Number 1, dated September 2, 2009; **Exhibit C-80**, Notice of FDA Action re: Entry No-EG6-1768454-3, Notice Number 1, dated September 2, 2009.

¹¹ **Exhibit R-44**, Notices of FDA Action re: Entry No EG6-1768425-3, p. 5, dated September 2, 2009 (highlighting added).

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26. The record thus establishes that the US’s “relating to” argument is baseless. The only contemporaneous, official manifestation of the Import Alert not only recognized that the measure applied to Apotex-US, it *was specifically addressed to Apotex-US*.
27. The statute relied upon by the US to authorize import alerts further confirms that import measures such as these apply to both the importer and the consignee. Section 801 of the federal Food, Drug and Cosmetic Act (the “Act”) states in relevant part:

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of ... drugs ... which are being imported or offered for import into the United States, giving notice thereof to the *owner or consignee*, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. ... If it appears from the examination of such samples or otherwise that ... (3) such article is adulterated ..., then such article shall be refused admission¹²

28. Similarly, the Code of Federal Regulations provides as follows:

If it appears that the article may be subject to refusal of admission, the district director shall give the *owner or consignee* a written notice to that effect, stating the reasons thereof. The notice shall specify a place and a period of time during which the *owner or consignee* shall have an opportunity to introduce testimony. ...¹³

29. FDA’s Regulatory Procedures Manual (RPM) also states that:

The *owner or consignee* is entitled to an informal hearing before FDA, in order to provide testimony in support of admissibility of the article[s].¹⁴

¹² **Legal Authority CLA-239**, Federal Food, Drug, and Cosmetic Act, 21 USC § 381(a) (Jan. 4, 2011) (emphasis added).

¹³ **Legal Authority CLA-245**, FDA Imports and Exports Rule, 21 CFR § 1.94 (Feb. 2, 2012) (emphasis added).

¹⁴ **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, subchapter “9-1 Import Procedures”, under the heading “Procedures When Violation Is Found,” under the sub-heading “Notice of Detention & Hearing,” at 9-8 (2011) (emphasis added).

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30. The relevant national law and regulations, as well as FDA's guidance documents, concord in recognizing that the import measures "apply to" and "relate to" the consignee, such that that person must be provided notice and an opportunity to be heard. Against this background, it is difficult to understand how the United States can argue that the measure did not relate to Apotex-US.
31. In addition, as the FDA notices of action observe, Lions Gate Transport Inc. was the "carrier" of Apotex's products.¹⁵ According to Apotex's commercial invoices, Apotex-Canada was the "shipper," Apotex-US was the "buyer," and the products were to be shipped to Apotex-US's warehouse in Indianapolis (as indicated under the box "ship to").¹⁶ Pursuant to Article 67(1) of the United Nations Convention on Contracts for the International Sale of Goods (CISG), to which both Canada and the USA are parties, the risk of loss or damage to the goods passes to the buyer when the goods are handed over to the carrier for transmission to the buyer.¹⁷ Here, the risk of loss passed to Apotex-US when Apotex-Canada handed over its products to Lions Gate Transport Inc. at the facilities in Etobicoke and Signet. The US errs in arguing that the Import Alert did not

¹⁵ See, e.g., **Exhibit R-44**, Notices of FDA Action re; Entry No EG6-1768425-3, dated September 2, 2009. See also **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; **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; **Exhibit C-71**, Email from Customs Broker (Juanita Zaziksi) 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; **Exhibit C-72**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009, at 12:52 pm, attaching Notice of Action re: Entry No. EG6-1768378-4, dated September 1, 2009; **Exhibit C-78**, Notice of FDA Action re; Entry No. EG6-1768425-3, Notice Number 1, dated September 2, 2009; **Exhibit C-80**, Notice of FDA Action re: Entry No-EG6-1768454-3, Notice Number 1, dated September 2, 2009.

¹⁶ See, e.g., **Exhibit C-71**, Email from Customs Broker (Juanita Zaziksi) to Apotex, dated September 1, 2009, at 12:36 pm, attaching Commercial Invoice from Apotex-Canada to Apotex-US re: Shipment No. EG6-1767503-8.

¹⁷ **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. 67(1) (1980) ("If the contract of sale involves carriage of the goods and the seller is not bound to hand them over at a particular place, the risk passes to the buyer when the goods are handed over to the first carrier for transmission to the buyer in accordance with the contract of sale. If the seller is bound to hand the goods over to a carrier at a particular place, the risk does not pass to the buyer until the goods are handed over to the carrier at that place. The fact that the seller is authorized to retain documents controlling the disposition of the goods does not affect the passage of the risk.").

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“relate to” Apotex-US, when Apotex-US bore the risk of loss or damage to the products at the time of their detention pursuant to the Import Alert.

32. Finally, contrary to the US suggestion, *Cargill v. Mexico* is directly on point and confirms that the measure here relates to Apotex-US.¹⁸ In *Cargill*, the tribunal addressed an import permit requirement that prevented sales of goods between the US parent company and its subsidiary/investment in Mexico. The tribunal found that the measure thereby “directly affected the business” of the investment in Mexico, which consisted, among others, in “reselling the goods sourced from the United States.”¹⁹ The tribunal held that a legally significant connection was established:

Regardless of whether or not the test espoused in *Methanex* is too restrictive, it is satisfied in this case. The import permit requirement not only had an immediate and direct effect on the business of Cargill de Mexico but also constituted a legal impediment to carrying on the business of Cargill de Mexico in sourcing HFCS [high fructose corn syrup] in the United States and re-selling it in Mexico.²⁰

33. Just as in *Cargill*, the measure here made it impossible for Apotex-US legally to receive the drugs produced by Apotex-Canada at Etobicoke and Signet. Just as the import permit requirement prevented Cargill de Mexico from “carrying on the business of ... sourcing HFCS in the United States and re-selling it in Mexico,”²¹ the Import Alert prevented Apotex-US from carrying on the business of sourcing product from Apotex-Canada in Canada and re-selling it in the United States.
34. The US misleadingly mixes into its discussion of *Cargill*'s analysis on “relating to” a quotation of a different part of the decision, where the tribunal in addressing the claim under Article 1105 considered whether the import permit requirement targeted a

¹⁸ US Counter-Memorial, para. 293.

¹⁹ **Legal Authority CLA-23**, *Cargill Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 173 (Sept. 18, 2009).

²⁰ *Id.* at para. 175.

²¹ *Id.*

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specific class of companies in Mexico.²² That discussion, however, formed no part of the *Cargill* tribunal’s reasoning on “relating to” under Article 1101. The US’s attempt to rewrite the *Cargill* award is without merit.

35. Indeed, *Cargill*’s pertinence to these facts illustrates the error in the US characterization of the alleged “extraordinary nature of Apotex’s ‘investment’ claim” which, the US argument goes, “relates to a measure concerning a Canadian company’s manufacturing facilities in Canada.”²³
36. There is nothing “extraordinary” about Apotex’s claim. Chapter Eleven explicitly addresses measures directed to imports and exports in connection with an investment.²⁴ The purpose of the NAFTA “is to eliminate barriers to trade and increase investment opportunities within the NAFTA Parties.”²⁵ In the context of Chapter Eleven, trade measures and investment measures are not necessarily mutually exclusive.
37. As was held in *Pope & Talbot*, “[t]here is no provision to the express effect that investment and trade in goods are to be treated as wholly divorced from each other.”²⁶

²² See US Counter-Memorial, para. 294, n.702 and accompanying text (quoting *Cargill*, para. 300).

²³ *Id.* at para. 398 (emphasis in original). This characterization is difficult to credit in any event given that, in its submissions on place of arbitration, the US took a diametrically opposite view, arguing that the subject-matter of the dispute had nothing to do with Canada but was located in the United States. See US Submission on Place of Arbitration, 16-17 (Aug. 31, 2012); US Rejoinder Submission on Place of Arbitration, 3 (Sept. 26, 2012) (“The ‘subject-matter’ of Apotex’s claim thus plainly falls within the United States.”).

²⁴ See, e.g., **Legal Authority CLA-1**, North American Free Trade Agreement, U.S.-Can.-Mex., December 17, 1992, 32 I.L.M. 289, art. 1106(1) (1993) (“No party may impose or enforce any of the following requirements, or enforce any commitment or undertaking, in connection with the establishment, acquisition, expansion, management, conduct or operation of an investment of an investor of a Party or of a non-Party in its territory: (a) to export a given level or percentage of goods or services; ... (d) to relate in any way the volume or value of imports to the volume or value of exports or to the amount of foreign exchange inflows associated with such investment; (e) to restrict sales of goods or services in its territory that such investment produces or provides by relating such sales in any way to the volume or value of its exports or foreign exchange earnings[.]”) (hereinafter “NAFTA”).

²⁵ See, e.g., **Legal Authority CLA-446**, *Mobil Investments Inc. and Murphy Oil Corporation v. Canada*, ICSID Case No. ARB(AF)/07/4, Decision on Liability and on Principles of Quantum, para. 225 (May 22, 2012) (citing NAFTA art. 102).

²⁶ **Legal Authority CLA-447**, *Pope & Talbot, Inc. v. The Government of Canada*, UNCITRAL, Award in Relation to Preliminary Motion by Government of Canada, para. 26 (Jan. 26, 2000). See also **Legal**

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As such, “the fact that a measure may primarily be concerned with trade of goods does not necessarily mean that it does not also relate to investment or investors.”²⁷ In *S.D. Myers*, the export ban on PCB wastes imposed by Canada was deemed to be “in relation” to the US investor and its investment in Canada.²⁸ In *Cargill*, as just noted, the import permit requirement imposed by Mexico for the import of high fructose corn syrup in the country “related to” Cargill and its investment in Mexico. Therefore, an import ban such as the Import Alert in no way excludes Apotex’s claim from the scope and coverage of Chapter Eleven.

38. Apotex in its Reply will establish that the Import Alert directly applied to and constituted a legal impediment to the conduct of Apotex-US’s business. Under even the test suggested by the United States, the measure clearly “relates to” Apotex-US and therefore to its indirect owner, Apotex Holdings. The Reply will show that the record rules out any merit to the US objection.

B. The NAFTA Does Not Support the US’s Supposed Requirement That the Measure “Apply to” the Investment

39. In its Reply, Apotex will demonstrate that there is a good reason why the US scrupulously avoids any justification or explanation of the positive test that it puts

Authority CLA-32, *Merrill & Ring Forestry L.P. v. The Government of Canada*, UNCITRAL, Award, para. 87 (March 31, 2010) (emphasizing that it was “necessary to understand [Chapter Eleven] in a broader sense that will allow for the comparison of other relevant elements, not excluding trade where appropriate.”).

²⁷ **Legal Authority CLA-447**, *Pope & Talbot, Inc. v. The Government of Canada*, UNCITRAL, Award in Relation to Preliminary Motion by Government of Canada, para. 33 (Jan. 26, 2000). Similarly, in *Ethyl v. Canada*, the tribunal refused to dismiss the claim at the jurisdictional phase simply because the measure, excluding MMT (a fuel additive used for unleaded gasoline) from importation into Canada, could be viewed as affecting trade in goods. See **Legal Authority CLA-26**, *Ethyl Corporation v. The Government of Canada*, UNCITRAL, Award on Jurisdiction, paras. 62-64 (June 24, 1998). The case settled before it reached the merits phase.

²⁸ **Legal Authority CLA-43**, *S.D. Myers, Inc. v. The Government of Canada*, UNCITRAL, Partial Award, para. 234 (Nov. 13, 2000) (“In this case, the requirement that the export ban be ‘in relation’ to SDMI and its investment in Canada is easily satisfied. It was the prospect that SDMI would carry through with its plans to expand its Canadian operations that was the specific inspiration for the export ban. It was raised to address specifically the operations of SDMI and its investment.”).

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forward for Article 1101(1): there is no explanation or justification that accords with the text, context, object and purpose of the NAFTA.

40. For example, it is well established that Article 1102's requirement of national treatment addresses the situation where a State measure does nothing more than grant favorable treatment to investments owned by nationals.²⁹ In such a situation, there is no measure that "applies" to the foreign-owned investments or which "constitutes a legal impediment" to those investments' conducting business. The measure does not address the foreigners' investments. The measure "applies" only to the investments owned by nationals and makes their business easier. Under the US approach, however, Article 1101(1) would exclude Article 1102 from addressing this scenario. The US approach cannot be reconciled with the clear text of the treaty.
41. Similarly, it is accepted that breaches of the obligation of full protection and security result only from the *failure* of the State to take a protective measure.³⁰ Again, in this scenario there is no measure that "applies" to the affected investment. There is no measure. Nor is there any "legal impediment" to carrying out the business of the investment. A mob may cause property damage that provides a practical impediment to business, but there is no *legal* impediment. Again, the US test would write out of the NAFTA the obligation of full protection and security mentioned in Article 1105(1).

²⁹ See, e.g., **Legal Authority CLA-31**, *Marvin Feldman v. United Mexican States*, ICSID Case No. ARB(AF)/99/1, Award, para. 187 (Dec. 16, 2002) (holding that "Mexico has violated the Claimant's rights to non-discrimination under Article 1102 of NAFTA" because "the Claimant has been effectively denied IEPS rebates for the April 1996 through November 1997 period, while domestic export trading companies have been given rebates not only for much of that period but through at least May 2000, suggesting that Article 4(III) of the law has been *de facto* waived for some if not all domestic firms. While the Claimant has also been effectively precluded from exporting cigarettes from 1998 to 2000, there is evidence that the Poblano Group companies have apparently been allowed to do so, notwithstanding Article 11 of the IEPS law. Finally, the Claimant has not been permitted to register as an exporting trading company, while the Poblano Group firms have been granted this registration.").

³⁰ See, e.g., **Legal Authority CLA-50**, *The Loewen Group, Inc. and Raymond L. Loewen v. United States*, ICSID Case No. ARB(AF)/98/3, Counter-Memorial of the United States of America, 179 (Mar. 30, 2001) (noting that tribunals have found a breach of the full protection and security obligation under customary international law when "a State *failed* to provide reasonable police protection against acts of a criminal nature that physically invaded the person or property of an alien.") (emphasis added).

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42. Finally, it also is well established that an indirect expropriation can result from measures that do not purport to apply to the specific investment at issue or impose any legal impediment as to that investment. For example, in *Biloune v. Ghana*, there was no measure that “applied” to or imposed a legal impediment as concerned the hotel concession contract that was the investment.³¹ Instead, the State adopted other measures, such as issuing stop-work orders, denying a building permit, demolition of works, and arresting and deporting the president of the investor.³² Although these measures did not apply to the contract, which remained in force, they amounted to a constructive expropriation of those contract rights.³³ Again, the US interpretation cannot be reconciled with the coverage of indirect expropriation in Article 1110(1).
43. The US approach to Article 1101(1) resembles the argument long ago rejected in *Pope & Talbot* “that a measure can only relate to an investment if it is primarily directed at that investment.”³⁴ The US in *Methanex* expressly declined any reliance on this argument.³⁵ The US’s attempt here to resurrect this long-discredited argument is baseless, as Apotex will show in its Reply.

³¹ **Legal Authority CLA-455**, *Antoine Biloune (Syria) and Marine Drive Complex Ltd. (Ghana) v. Ghana Investments Centre and the Government of Ghana*, UNCITRAL, 19 Y.B. Comm. Arb. 11 (1994).

³² *Id.* at 13-14 (summarizing the facts).

³³ *Id.* at 20-21, para. 26 (“What is clear is that the conjunction of the stop work order, the demolition, the summons, the arrest, the detention, the requirement of filing assets declaration forms, and the deportation of Mr. Biloune without possibility of re-entry had the effect of causing the irreparable cessation of work on the project. Given the central role of Mr. Biloune in promoting, financing and managing MDCL, his expulsion from the country effectively prevented MDCL from further pursuing the project. In the view of the Tribunal, such prevention of MDCL from pursuing its approved project would constitute constructive expropriation of MDCL’s contractual rights in the project and, accordingly, the expropriation of Mr. Biloune’s interest in MDCL, unless the respondents can establish by persuasive evidence sufficient for these events [sic].”); *id.* at 21, para. 30 (“The Tribunal therefore holds that the Government of Ghana, by its actions and omissions culminating with Mr. Biloune’s deportation, constructively expropriated MDCL’s assets, and Mr. Biloune’s interest therein[.]”).

³⁴ **Legal Authority CLA-447**, *Pope & Talbot Inc. v. The Government of Canada*, UNCITRAL, Award in Relation to Preliminary Motion by Government of Canada, para. 34 (Jan. 26, 2000).

³⁵ *See Legal Authority CLA-445*, *Methanex Corp. v. United States of America*, UNCITRAL, Reply Memorial of Respondent United States of America on Jurisdiction, Admissibility and the Proposed Amendments, 44 (Apr. 12, 2001) (noting that *Pope & Talbot* “rejected the test proffered by Canada ‘that a measure can only

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C. The Connection Prescribed by the NAFTA's Substantive Provisions Is Legally Significant

44. In its Reply, Apotex will demonstrate that what constitutes a “legally significant connection” for purposes of Article 1101(1) in a given case must be informed by the substantive NAFTA provisions at issue. If the connection between measure and investment that is required to establish a breach of a substantive provision is present, it is difficult to conclude that that connection is not of legal significance. Apotex will demonstrate that it has established the requisite legally significant connection because the record shows that the Import Alert breached Articles 1102, 1103 and 1105 as concerns the investors and investments in question here.
45. In its final award, the *Methanex* tribunal repeatedly recognized the relevance of its assessment of the claims under the substantive provisions to the “relating to” question under Article 1101(1). The award stated as follows:

An affirmative finding of the requisite “relation” under NAFTA Article 1101, as decided in the Partial Award for the purposes of this case, does not necessarily establish that there has been a corresponding violation of NAFTA Article 1102 by the USA. But an 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.³⁶

relate to an investment if it is primarily directed at that investment,’ a test that the United States is not advancing here.”) (citation omitted).

³⁶ **Legal Authority CLA-34**, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award of the Tribunal on Jurisdiction and Merits, Part IV, Chapter B, p. 1, para. 1 (Aug. 3, 2005); *see also id.* at Part IV, Chapter C, p. 1, para. 1 (“[A]n affirmative finding of a malign intent under NAFTA Article 1101 might satisfy the requirement of a showing of the requisite ‘relation’ under NAFTA Article 1105. But a failure to find a malign intent under Article 1101 might yet be repaired by an affirmative finding that an investor had not been accorded treatment in accordance with international law.”) (emphasis added); *id.* at Part IV, Chapter D, p. 1, para. 1 (“[T]he Tribunal has considered it appropriate to examine Methanex’s claim arising under Article 1110 in order to determine if Methanex could thereby satisfy the threshold requirements of the required ‘relation’ under Article 1101 NAFTA.”).

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46. The tribunal then systematically considered whether the evidence of breach of each substantive provision established the connection contemplated by that provision. The tribunal found that Methanex had not proven a national treatment violation. It followed that “Methanex’s case under Article 1101 [was] not assisted by its argument under Article 1102.”³⁷ The tribunal also concluded that the US did not breach the minimum standard of treatment under international law and, as a result, “Methanex’s case under Article 1101 [was] not assisted by its arguments under Article 1105.”³⁸ The tribunal held that there was no expropriation and that “Methanex’s case under Article 1101 [was] not assisted by its arguments under Article 1110.”³⁹ There was thus no breach of any substantive provisions of Chapter Eleven that could have established the “legally significant connection” required by Article 1101.
47. Consistent with the tribunal’s approach in *Methanex*, Apotex in its Reply will systematically review the evidence of record establishing breaches of Articles 1102 and 1103. It will show that, contrary to the US contentions, the FDA repeatedly accorded more favorable treatment to US-owned and foreign-owned investors and investments in like circumstances to Apotex. It will prove that the US arguments in the Counter-Memorial are without basis through rebuttal expert reports, rebuttal witness statements and responsive documentary evidence. It will show that precisely the connection between measure and investor and investment contemplated by Articles 1102 and 1103 is established here, and that connection is legally significant.
48. Apotex will also demonstrate that, contrary to the US arguments, the Import Alert was adopted and enforced against Apotex without even the barest trappings of due process required by customary international law. It will show that procedural requirements for administrative decision-making have long been part of the minimum standard of treatment afforded to aliens and that the United States’ actions did not satisfy such

³⁷ *Id.* at Part IV, Chapter B, p. 19, para. 38.

³⁸ *Id.* at Part IV, Chapter C, p. 12, para. 27.

³⁹ *Id.* at Part IV, Chapter D, p. 8, para. 18.

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requirement. Apotex will demonstrate that the avenues indicated by the US to contest FDA's decisions are illusory and could not have afforded effective means of redress in this case.⁴⁰ It will show, again, that precisely the connection between measure and investment contemplated by Article 1105(1) is present on this record and that connection is one of legal significance.

D. There Is No Substance to the US Arguments Based on Distributorship Arrangements and Apotex-US's Relationship with Apotex-Canada

49. Apotex will demonstrate in its Reply that the US arguments concerning other distributors and consignees of Apotex-Canada products, as well as its arguments concerning the relationship between Apotex-US and Apotex-Canada, are without legal or factual merit.

1. Apotex-US Is the Sole Commercial Importer from Apotex-Canada in the United States

50. The US errs in suggesting that “[t]he impact that the Import Alert had on Apotex[-US] was no different, legally, from that felt by any of the many other U.S. companies that imported drugs from Apotex[-Canada]’s Etobicoke and Signet facilities.”⁴¹ This statement is demonstrably false.

51. Apotex will demonstrate in its Reply that Apotex-US was the *only* US company that imported drugs from those two facilities for commercial sale in the United States. Apotex-Canada sold Apotex products produced at those facilities only to Apotex-US. Apotex-US then sold those products to a large number of customers of different types within the United States. This is why IMS data showed Apotex-US, not Apotex-Canada, to be the sixth largest generic seller on the US market in 2009.⁴²

⁴⁰ See US Counter-Memorial, para. 381.

⁴¹ *Id.* at para. 298.

⁴² **Exhibit C-181**, Top 25 Generic Manufacturers per IMS Medical Data, Q2 2009.

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52. Apotex will show that the US misunderstands the evidence it has submitted. That evidence, far from supporting the US, demonstrates the opposite of what the US attempts to prove. That evidence falls into two categories.
53. The first category is a listing of customers from which Apotex product was recalled in September 2009.⁴³ This, however, is a listing of customers of *Apotex-US* that bought recalled product from it. The listing does not purport to describe companies that purchased and imported product from Apotex-Canada. These documents in no way support the US's position.
54. The second category consists of unauthenticated and unexplained spreadsheets, purportedly prepared by FDA from its import action databases.⁴⁴ The spreadsheets purport to list all shipments that identified Apotex-Canada in Etobicoke or Signet as the "manufacturer" and identified a "consignee" other than Apotex-US.
55. However, most of the entries on these documents show an unrelated third party as the shipper. For example, Exhibit R-119 shows that on November 3, 2009 [REDACTED] of [REDACTED], Ukraine shipped [REDACTED] to Apotex's competitor [REDACTED] in Whitehouse Station, New Jersey, and identified Apotex Etobicoke as the manufacturer of the tablets.⁴⁵ It is likely, since [REDACTED] is a company that specializes in clinical trials and the product shipped was a placebo with no active substance, that this shipment had to do with a clinical trial being conducted for [REDACTED]. However, Apotex had nothing to do with this shipment and nothing suggests that it was for commercial sale. Notably, although the shipment

⁴³ **Exhibit C-83**, Letter from Apotex to FDA enclosing recall information package, dated September 4, 2009; **Exhibit R-5**, Apotex, Distribution List for Recall Products ("5-Consignees.xls" in Recall Report Questionnaire), dated September 4, 2009.

⁴⁴ **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).

⁴⁵ **Exhibit R-119**, FDA, Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009), at 1, 7th entry (undated).

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occurred during the Import Alert, the final admissibility activity description column states that “MPro Issued” two days later on November 5, 2009 – indicating that the US authorities decided the shipment “may proceed” into the US.⁴⁶

56. The unrelated shippers such as [REDACTED] apparently bought Apotex-manufactured products on the market in whatever country they were located and ultimately shipped them to the United States for purposes unknown to Apotex. In its Reply, Apotex will show that most if not all of these shipments were by companies, like [REDACTED], involved in clinical trials or testing of pharmaceutical products. These shippers and the consignees of these shipments did not, however, “import[] drugs from Apotex[-Canada]’s Etobicoke and Signet facilities,”⁴⁷ as the US contends.
57. A smaller number of entries on these documents show Apotex-Canada as the shipper.⁴⁸ However, these shipments were not for commercial sale of products, but rather for uses other than commercial sales, such as clinical trials, stability or other testing, or other purposes. For example, many of the entries with Apotex-Canada as the shipper concern Deferiprone, the generic version of Ferriprox, the drug that FDA allowed Apotex to ship to the United States during the Import Alert not for commercial exploitation but for compassionate use.⁴⁹ There were no commercial shipments of Etobicoke and Signet products, however, from Apotex-Canada to consignees other than Apotex-US during the Import Alert.
58. Moreover, the documents submitted by the US affirmatively refute the US hypothesis that other consignees received the same treatment as Apotex-US. The final

⁴⁶ *Id.*

⁴⁷ US Counter-Memorial, para. 298.

⁴⁸ **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).

⁴⁹ **Exhibit R-119**, FDA, Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009) at 1 (undated); *see also* Memorial, paras. 223, 246.

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admissibility activity description column in these documents shows that, of the 328 shipments to other consignees during the Import Alert reflected, *every single shipment* was allowed into the United States – with only seven, unexplained exceptions.⁵⁰

59. Thus, during the Import Alert period, Apotex-US was permitted to receive no shipment of product made by Apotex-Canada in Etobicoke or Signet. By contrast, the US evidence shows that other consignees were permitted to receive hundreds of shipments of such products – 98 percent of these shipments were allowed into the US. Far from supporting the US, the evidence it has submitted confirms that the Import Alert related to Apotex-US.
60. While the US may be correct that “[u]nder Chapter Eleven, a measure affecting a foreign supplier cannot be said to affect, legally, every domestic company which that supplier supplies,”⁵¹ this statement is inapposite to the facts of this case: Apotex-US was the only US company that Apotex-Canada supplied with drugs for commercial sale from Apotex-Canada’s plants in Etobicoke and Signet. Apotex-US was the source of supply of all Apotex products imported from those facilities and sold in the US. Whether the Import Alert “relates to” Apotex-US’s customers, and the customers of those customers, is an interesting question. But it is not a question that is posed in this case. The US’s contention is without merit.

2. *The US Arguments as to Apotex-Canada’s Relationship with Apotex-US Are Without Substance*

61. In its Reply, Apotex will demonstrate that the US errs in its lengthy arguments concerning supposedly conflicting statements about the relationship between Apotex-

⁵⁰ 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). The seven exceptions appear on page 1 of Exhibit R-115 and pages 2 and 23 of Exhibit R-118. With the exception of these seven, all of the shipments listed during the Import Alert period received either a “May Proceed” (MPro), “Released”, “Released with Comment”, or “IB Release” (Rel/IB) determination.

⁵¹ US Counter-Memorial, para. 298.

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Canada and Apotex-US. The Reply will provide a point-by-point response to the US contentions, and show that each is without merit.

62. For present purposes, Apotex limits itself to three observations. The first is that Apotex did not suggest in its Memorial that the relationship between Apotex-Canada and Apotex-US was pertinent to the “relating to” issue.⁵² Instead, it posited that that relationship was relevant to establishing a “commitment of capital or other resources” within the meaning of NAFTA Article 1139(h).⁵³
63. It is not clear why the US has decided to reclassify this issue as concerning “relating to” rather than a “commitment of capital or other resources.” What is clear, however, is that the US argument is beside the point.
64. The second observation is that the US argument reflects a fundamental misunderstanding of how multinational companies operate in the world today. Apotex-Canada and Apotex-US are separate and distinct companies whose officers and directors scrupulously respect the corporate form. And yet they coordinate and collaborate closely to ensure that customers in the US have access to the medicinal products they need in a timely, efficient and seamless manner. Contrary to the US suggestion, there is nothing incompatible in these two statements – and in fact, this is how sophisticated companies operate throughout the world today.
65. The third observation is that NAFTA tribunals have rejected, for good reason, previous efforts to avoid the obligations of the investment chapter through arguments addressed to the form rather than substance of a corporate group’s organization. In *S.D. Myers*, the tribunal rejected a jurisdictional objection concerning an alleged lack of control by the US investor (SDMI) of the Canadian investment (Myers Canada) – the shares of the latter being held by four members of the Myers family rather than by SDMI:

⁵² See Memorial, paras. 410-15.

⁵³ See *id.* at paras. 339-400.

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Taking into account the objectives of the NAFTA, the obligation of the Parties to interpret and apply its provisions in light of those objectives, the Tribunal does not accept that an otherwise meritorious claim should fail solely by reason of the corporate structure adopted by a claimant in order to organise the way in which it conducts its business affairs.⁵⁴

66. The *S.D. Myers* tribunal concluded that SDMI was an investor and Myers Canada an investment.⁵⁵
67. In sum, the US errs in contending that “Apotex’s own evidence and statements in U.S. courts undermine Apotex’s claim in this arbitration that [Apotex-US] has some special relationship with [Apotex-Canada]”⁵⁶ Apotex-US does have a special relationship with Apotex-Canada – it is part of the same group of companies and is the sole importer from Apotex-Canada’s facilities in Etobicoke and Signet for commercial sale in the US. Apotex-US’s relationship with Apotex-Canada respects the separate corporate personality of each of the two companies, but it is nonetheless a special one in the sense described. As Apotex will show in its Reply, the US arguments are without merit.

II. APOTEX-CANADA’S ANDAS ARE PROTECTED INVESTMENTS

68. The second jurisdictional objection of the United States concerns Apotex-Canada’s authorizations to market specific generic drugs in the United States. In the industry, these marketing authorizations are often referred to by the abbreviation for the application for such authorizations: ANDAs. Apotex demonstrated at some length in the Memorial that these authorizations constituted both “intangible property” within Article 1139(g) and “interests arising from a commitment of capital or other resources” within Article 1139(h) of the NAFTA.⁵⁷

⁵⁴ **Legal Authority CLA-43**, *S.D. Myers, Inc. v. The Governmnet of Canada*, UNCITRAL, Partial Award, para. 229 (Nov. 13, 2000).

⁵⁵ *Id.* at para. 231.

⁵⁶ US Counter-Memorial, para. 319.

⁵⁷ Memorial, paras. 353-403.

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69. In its Reply, Apotex will demonstrate that the US devotes most of its argument under this heading in the Counter-Memorial to points not made by Apotex and not presented on this record. The US arguments that do meet Apotex's case are internally inconsistent and irreconcilable with the relevant text, context and object and purpose of the NAFTA. Apotex will show that the US contentions as to Apotex-Canada, including its argument that the Import Alert does not "relate to" Apotex-Canada's ANDAs, are without merit.

A. Apotex-Canada's ANDAs Are "Investments" Under Chapter Eleven

70. As demonstrated in the Memorial, Apotex-Canada's ANDAs fall within the definition of investment in Article 1139(g) (intangible property) and Article 1139(h) ("interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory").⁵⁸ For the reasons set out below, the US arguments concerning Article 1139 must fail.

1. Apotex-Canada's ANDAs Are "Intangible Property" Within the Meaning of Article 1139(g)

71. The US Counter-Memorial does not dispute that FDA regulations explicitly recognize that ANDAs are "owned" by the applicant. It does not contest that the ANDA owner can sell the ANDA like any other property and that, as the record reflects, sales of ANDAs are commonplace in the US market and often ascribe a high value to these rights.⁵⁹ Nor does the Counter-Memorial dispute that US tax law considers ANDAs to be assets the sale of which is subject to taxation like the sale of other property.⁶⁰

72. Instead, the US relies exclusively on national court decisions addressing whether, for purposes of the Takings Clause of the US Constitution, *other types of authorizations*

⁵⁸ *Id.*

⁵⁹ See US Counter-Memorial, paras. 222-32; see also Memorial, paras. 368-73.

⁶⁰ See US Counter-Memorial, para. 229. Contrary to the US assertion at note 577 of its Counter-Memorial, Apotex demonstrated that ANDAs are intangible assets for the purpose of the US tax code. See Memorial, para. 374. See also **Exhibit CLA-312A**, Internal Revenue Service, Office of Chief Counsel, Memorandum, at 8 (Sept. 27, 2011) (concluding that "[a]n ANDA granted by the FDA is a franchise for purposes of the [Treasury] regulations. For the same reasons, an ANDA is also [an] intangible [under the tax code].").

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can be considered “property” for purposes of this 18th Century provision. Its reliance on Takings Clause jurisprudence is puzzling, since it acknowledges that “deprivation of Apotex’s ANDAs is not at issue here.”⁶¹

73. As Apotex will demonstrate in its Reply and contrary to the US argument, governmental ability to revoke a right under limited circumstances in no way removes the “exclusivity” required for a right to constitute property. Most important, the issue presented here is not what “property” means in the Takings Clause of the US Constitution, but what it means in NAFTA Chapter Eleven.
74. Apotex will show that the US argument that revocable intangible rights are not “intangible property” cannot be reconciled with the NAFTA.⁶² The NAFTA is clear that its prohibition of expropriation without compensation extends to revocable intangible interests. As the US observes, “[t]he NAFTA, in contrast with other treaties, does not list intellectual property rights or licenses, authorizations, permits, and similar rights as among investments covered under Article 1139.”⁶³ The NAFTA covers these assets through Article 1139(g)’s definition of “investment” as including “intangible property.”
75. Article 1110 of the NAFTA, which sets out the obligation to refrain from expropriation without compensation, refutes the US contention that revocable rights cannot qualify as

⁶¹ US Counter-Memorial, para. 226, n.561. The word “property” appears twice in the Fifth Amendment to the United States Constitution, once in connection with due process and once in connection with governmental takings. US jurisprudence has given a more restrictive reading of property for purposes of the Takings Clause than for the Due Process Clause. *See, e.g., Legal Authority RLA-72, Arctic King Fisheries, Inc. v. United States*, 59 Fed. Cl. 2360, 372, n.27 (Ct. Fed. Cl. 2004) (noting dissimilar concepts of “property” for purposes of the Takings Clause and “property interest” under the Due Process Clause). While the US acknowledges that this is so, it does not attempt to explain why Takings Clause jurisprudence could be relevant given that there is no claim of a taking here.

⁶² US Counter-Memorial, para. 224 (arguing that ANDAs are not intangible property because “FDA has significant discretion to withhold or refuse approval of the applications – and even when finally approved, the ANDAs are allegedly revocable by the government.”).

⁶³ *Id.* at para. 223 (internal quotation omitted).

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“intangible property” and therefore “investments.” Paragraph 7 of that Article provides as follows:

This Article 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 Chapter Seventeen (Intellectual Property).⁶⁴

76. This provision recognizes that intellectual property rights are revocable. It acknowledges that States have a role in determining whether to grant (or create) or limit such rights. The provision establishes an exception to the obligation to compensate for expropriation. The exception is limited to those revocations authorized by Chapter Seventeen of the NAFTA.⁶⁵ The provision makes clear, *a contrario*, that a revocation of intellectual property rights *inconsistent* with Chapter Seventeen is subject to Article 1110’s prohibition of expropriation without compensation.
77. Article 1110(7) would have no reason to exist, however, if the US argument were correct. If *revocable* intangible property rights were not “investments” within the meaning of Article 1139, the investment chapter and Article 1110 would have no application to them. Article 1110(7) reflects the NAFTA Parties’ clear understanding that revocable intangible rights *are investments* that give rise to obligations under the NAFTA investment chapter. The US argument that rights such as these cannot be

⁶⁴ **Legal Authority CLA-1**, NAFTA, art. 1110(7) (emphasis added). Chapter Seventeen defines intellectual property rights “[f]or purposes of this Agreement” to mean “copyright and related rights, trademark rights, patent rights, rights in layout designs of semiconductor integrated circuits, trade secret rights, plant breeders’ rights, rights in geographical indications and industrial design rights.” *Id.*, art. 1721(2).

⁶⁵ *See, e.g., id.*, art. 1709(8) (“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.”).

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investments would render Article 1110(7) ineffective and thus breach a primary principle of treaty interpretation.⁶⁶

78. In sum, the fact that a right or authorization may be revoked by the State does not mean that the right or authorization cannot constitute a property interest protected under the NAFTA. Notably, in the present case, the US does not claim that there were grounds for revoking Apotex-Canada's ANDAs.⁶⁷

79. Finally, Apotex will show in its Reply that there is no merit to the US terse suggestion that Apotex's ANDAs are not property "*in the United States*."⁶⁸ The sole reasoning provided by the US for this suggestion is that "Apotex acknowledges that its ANDAs are prepared and held by Apotex[-Canada] *in Canada*."⁶⁹ The US does not explain how an authorization granted by a US agency that permits economic activity *only* in the United States and nowhere else in the world could possibly be considered to be an investment in Canada. Under the US's reasoning, a long-term loan by a Canadian bank to a US debtor would fall outside the scope of Chapter Eleven if the bank prepared the loan documentation (as is customary). This is plainly wrong.⁷⁰ The US argument, again, cannot be squared with the plain text of the treaty or the record.

⁶⁶ See, e.g., **Legal Authority CLA-88**, *Territorial Dispute (Libya/Chad)*, Judgment of Feb. 3, 1994, I.C.J. Reports 1994, at 6, para. 51 (collecting authorities supporting "one of the fundamental principles of interpretation of treaties, consistently upheld by international jurisprudence, namely that of effectiveness" (citations omitted)); **Legal Authority CLA-87**, *Corfu Channel*, Judgment of Apr. 9, 1949, I.C.J. Reports 1949, at 4, 24 ("It would indeed be incompatible with the generally accepted rules of interpretation to admit that a provision of this sort occurring in a special agreement should be devoid of purport or effect.").

⁶⁷ See US Counter-Memorial, paras. 222-32.

⁶⁸ *Id.* at para. 231 (emphasis in original).

⁶⁹ *Id.* (emphasis in original).

⁷⁰ See **Legal Authority CLA-1**, NAFTA, art. 1139 ("investment means ... (d) a loan to an enterprise (i) where the enterprise is an affiliate of the investor, or (ii) where the original maturity of the loan is at least three years, ...").

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2. *Apotex-Canada's ANDAs Consitute "Interests Arising From the Commitment of Capital or Other Resources" Within Article 1139(h)*

80. In its Memorial, Apotex demonstrated at some length that its ANDAs also constitute investments under Article 1139(h).⁷¹ The provision includes within the definition of "investment" "interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory[.]" As Apotex showed, investments falling under this provision need not meet the criteria for "property" under Article 1139(g), but may instead take the form of "interests."⁷² Under this provision, the "interest" is the "investment." But to qualify, that interest must "*aris[e]* from the commitment of capital or other resources" to economic activity in the territory of the Party. Apotex showed in its Memorial that its marketing authorizations qualified as interests arising from the commitment of resources both within and without the United States to economic activity in the United States.
81. In its Reply, Apotex will show that the US Counter-Memorial does not so much respond to the Memorial's showing as studiously ignore it. The Counter-Memorial does not dispute that Apotex's marketing authorizations are "interests." Nor does it contest that maintaining a staff devoted to filing ANDAs, submitting the reports necessary to keep them in force, contracting for the research needed for ANDA approval and litigation to add value to the ANDAs constitute "resources" committed to economic activity in US territory. Finally, it does not dispute that the marketing authorizations arose, were maintained and attracted value as a result of these activities.
82. Instead, Apotex's Reply will show, the Counter-Memorial attacks arguments that Apotex never made and which are not presented on this record. It is not Apotex's position, for example, that contract research or litigation qualifies as an "investment" in the United States. This issue is not presented. Article 1139(h) requires no such thing. It requires that "capital or other resources" be committed, not that that capital or

⁷¹ Memorial, paras. 377-402.

⁷² *Id.* at para. 395.

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resources independently qualify as investments. Apotex's Reply will show that the Counter-Memorial repeatedly builds and attacks a straw man.

83. *First*, Apotex's Reply will show that the US errs in suggesting that contract research, preparation and maintenance of ANDAs and ANDA-related litigation are "interests" within the meaning of Article 1139(h).⁷³ Apotex has argued no such thing. Apotex's position, as noted, is that the approved ANDAs are the "interests" within that Article. Apotex has shown that these activities constitute resources committed to US territory from which the marketing authorizations arose. Article 1139(h) requires no more than this.
84. *Second*, Apotex's Reply will show that the US misses the point in arguing that cross-border services contracts are not investments.⁷⁴ Again, that is not Apotex's position, and that is not what Article 1139(h) requires. The ordinary meaning of "resource" is "a source of supply or support: an available means – usually used in the plural."⁷⁵ It can hardly be disputed that services providing research necessary for approval of an ANDA is "a source of supply or support" for that ANDA. The US, again, attacks a straw man.
85. *Third*, the Reply will show that the US does not dispute that Apotex-US's filing and maintaining ANDAs constitutes a commitment of resources from which the ANDAs arose.⁷⁶ Instead, the US disputes only that Apotex-Canada contributes to these efforts. But nothing in Article 1139(h) requires that the same entity within a corporate group both own the interest and contribute the resources; all that it requires is that the interests arise from a commitment of such resources to economic activity in the territory of the

⁷³ US Counter-Memorial, para. 235.

⁷⁴ *Id.* at para. 236.

⁷⁵ **Legal Authority CLA-471**, Merriam-Webster Dictionary Online, definition 1a of "resource" (last visited on Dec. 26, 2012). *See also* **Legal Authority CLA-473**, Webster's II, New College Dictionary, definition 2 of "resource" (1999) ("An accessible supply that can be withdrawn from when necessary."); **Legal Authority CLA-472**, Oxford Dictionary Online, definition of "resource", first bullet ("a stock or supply of money, materials, staff, and other assets that can be drawn on by a person or organization in order to function effectively ...") (last visited on December 26, 2012).

⁷⁶ *See* US Counter-Memorial, paras. 237-39.

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Party. The US argument, even if it were correct (and the Reply will show that it is not), is beside the point.

86. Moreover, there appears to be no dispute that Apotex Holdings indirectly controls marketing authorizations that arise from the commitment of resources by Apotex-US (a company it also controls) to economic activity in the US. The US presents no objection to this base of jurisdiction.
87. *Fourth*, the Counter-Memorial's argument that litigation expenses are not investments also misses the point.⁷⁷ Again, the issue is whether the contribution of [REDACTED] dollars to patent litigation concerning specific products represents a commitment of resources that built the value of Apotex's marketing authorizations. The record shows that it was and did. The Reply will further demonstrate that the US arguments that Apotex made conflicting representations to US courts are without merit.
88. *Fifth*, the US also is wide of the mark in arguing that under Chapter Eleven the investment must be in the host State,⁷⁸ that the chapter deals with foreign investment of a cross-border nature,⁷⁹ and that the three NAFTA Parties have consistently agreed,⁸⁰ and NAFTA tribunals have consistently found,⁸¹ that the investment chapter applies only to investments in the host State. This, again, is not a matter in dispute, and is not the issue presented.
89. The issue here is not whether the authorizations granted by the FDA to Apotex-Canada exclusively to market products in the US are investments *in the US*. As already noted, there can be no dispute that these interests are in US territory, and the US offers no real argument to the contrary.

⁷⁷ *Id.* at paras. 241-44.

⁷⁸ *Id.* at paras. 250-51.

⁷⁹ *Id.* at paras. 252-53.

⁸⁰ *Id.* at paras. 255-59.

⁸¹ *Id.* at paras. 260-63.

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90. Instead, the issue here is whether under Article 1139(h) the capital or other resources contributed must already be situated in US territory *before* they are committed to activity in that territory and give rise to the interest, or whether *foreign* capital or resources can also qualify in giving rise to the interest. As the US and the authorities it cites recognize, the NAFTA “can only sensibly be considered as referring to[] opportunities for *foreign investment* in the territory of each Party made by investors of another Party” and as intended “to promote and increase *cross-border* investment opportunities[.]”⁸² The US arguments and authorities thus *support* Apotex’s position that foreign capital and resources can qualify for giving rise to an interest within the meaning of Article 1139(h).
91. Apotex demonstrated in its Memorial that the text and context of Article 1139(h) and the object and purpose of the NAFTA establish that foreign capital and resources are eligible to establish an investment under that provision. This showing fully accords with the approach reflected elsewhere in Article 1139. For example, the ordinary course in a cross-border loan under Article 1139(d) is for the bank to use its foreign resources to disburse funds to the debtor in the host State; the ordinary course in a cross-border equity acquisition under Article 1139(b) is for the foreign investor to use foreign funds or other consideration to acquire the shares in the host State. While it would of course be possible for the investor in either scenario to use resources in the host State to acquire the investment, that approach would not increase cross-border flows of capital and resources in the same way. The US, notably, offers no argument as to why a different approach should follow for investments under Article 1139(h).
92. In sum, Apotex will show in its Reply that the US arguments on Article 1139 do not meet the case put by Apotex and are without merit.

⁸² *Id.* at para. 253 (emphasis added by Counter-Memorial) (quoting *Bayview* and *Metalclad*).

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B. The Import Alert Related to Apotex's ANDAs

93. In its Reply, Apotex will show that the US errs in asserting that the Import Alert had no legally significant connection to Apotex's ANDAs. The US wrongly contends that the Import Alert did not prevent Apotex from using its approved ANDAs or prevent FDA from reviewing pending applications.⁸³ The US is wrong on both counts.
94. With respect to *approved* ANDAs, Apotex will show that the Import Alert rendered them useless since they could not be used for marketing the associated drug while the Import Alert was in effect.⁸⁴ If it is correct that Apotex's ANDAs technically remained approved during the Import Alert,⁸⁵ they could not be used for what they are, *i.e.*, authorization to market drug products, since the drug products in question could not be sold in the US due to the Import Alert. The US does not attempt to explain how a measure that prevents marketing of a product can be seen not to relate to the authorization to market the product.
95. Apotex will further show in its Reply that the US errs in arguing that Apotex in theory was free to transfer the technology necessary to manufacture those drugs to another Apotex facility or a third party.⁸⁶ This argument is relevant, if at all, to mitigation of damages. The US argument here, in reality, is not that the measure did not relate to the marketing authorizations, but that Apotex could have limited the measure's detrimental impact by transferring technology. Apotex in its Reply will show that this argument is without factual merit, as in practice obtaining the necessary authorizations from FDA would have been a long and cumbersome process.⁸⁷ The US argument, Apotex will show, is without legal or factual merit.

⁸³ *Id.* at para. 274.

⁸⁴ Memorial, para. 412.

⁸⁵ US Counter-Memorial, para. 284.

⁸⁶ *Id.* at para. 285.

⁸⁷ *See* Witness Statement of Jeremy Desai, para. 89.

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96. With respect to *pending* applications, Apotex will show that FDA slowed down its review and issued approval-on-hold letters, *i.e.*, refused to grant approval, while the Import Alert was in effect.⁸⁸ It was only after the Import Alert was lifted that FDA granted approvals for Signet and Etobicoke (for the latter, a pre-approval inspection was also necessary).⁸⁹ The Import Alert thus “related to” Apotex’s pending ANDAs.
97. Finally, in its Reply Apotex will show that the connection between measure and Apotex-Canada contemplated by Articles 1102, 1103 and 1105 of the NAFTA is established on this record. It will show that the Import Alert granted Apotex-Canada (and Apotex Holdings) treatment less favorable than that accorded national and third-country investors that, like Apotex, invested in marketing authorizations for generic drugs in the United States. It will show that the Import Alert failed to accord Apotex-Canada the most fundamental elements of due process required under the minimum standard of treatment. It will show that precisely the connection between measure, investor and investment required by the NAFTA is present, and that connection is legally significant.
98. In sum, in its Reply, Apotex will show that the Import Alert plainly “related to” Apotex-Canada and its pending and approved ANDAs.

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99. As noted at the outset, the preceding preliminary statement of Apotex’s response to the US jurisdictional objections is intended to provide the Tribunal with sufficient information concerning the issues presented on jurisdiction for it to address the US request for bifurcation. The preceding statement is the fruit of only two weeks of reflection on the US Counter-Memorial. Apotex reserves the right to amend, modify and supplement the arguments preliminarily stated above in the further submissions

⁸⁸ See Witness Statement of Kiran Krishnan, para. 45; *see also* Witness Statement of Bernice Tao, para. 51.

⁸⁹ See Witness Statement of Kiran Krishnan, paras. 46-47.

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contemplated by the First Procedural Order. The preceding statement nonetheless should provide the Tribunal with an understanding of the responsive case on jurisdiction sufficient to address the arguments and counter-arguments on bifurcation.

ARGUMENT

100. Whether to hold a separate phase of the arbitration devoted only to jurisdiction is a decision firmly committed to the discretion of the Tribunal under Article 45(4) of the ICSID Arbitration (Additional Facility) Rules. The United States correctly identifies “economy, efficiency, and fairness” as the primary considerations for such a decision under these rules and the NAFTA.⁹⁰
101. These factors call for a case-specific approach in which generalizations are of limited use. That said, it is well accepted that if the facts on which the challenge to jurisdiction is based are inseparable from the merits, the arbitral tribunal should proceed with a complete hearing and render an award that deals with jurisdiction and the merits together.⁹¹ As the drafters noted in a commentary accompanying the first edition of the ICSID rules, joinder is called for “where the facts on which the objection is based are

⁹⁰ US Counter-Memorial, para. 392. See **Legal Authority CLA-1**, NAFTA, art. 102(1)(e) (one of NAFTA objectives is to “create effective procedures for the implementation of this Agreement ... and for the resolution of disputes ...”).

⁹¹ See **Legal Authority CLA-467**, *Redfern and Hunter on International Arbitration*, 353, para. 5.116 (2009) (“[I]f the facts on which the challenge to jurisdiction are based are inseparable from the merits, the arbitral tribunal should continue with the hearing and make a final award that deals with both issues at the same time.”); **Legal Authority CLA-464**, Christoph H. Schreuer, *The ICSID Convention: A Commentary*, 538-39 (2nd ed., 2009) (“[N]eed for a joinder to the merits is apparent where the answer to the jurisdictional questions depends upon testimony and other evidence that can only be obtained through a full hearing of the case.”). See also, e.g., **Legal Authority CLA-452**, *Ioannis Kardassopoulos v. Georgia*, ICSID Case No. ARB/05/18, Decision on Jurisdiction, para. 260 (July 6, 2007) (“It is well settled that whenever a jurisdictional issue is closely related to the facts to be examined at the merits phase of the case, it can be joined to the merits. The Tribunal’s decision on jurisdiction here is closely related to the merits and will depend, to a large extent, on the same factual questions.”).

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closely connected with the merits and a decision on the objection might prejudice the decision on the latter.”⁹²

102. As demonstrated in the discussion below, the US objections should be joined to the merits. The US arguments based on a supposed rule favoring bifurcation of jurisdictional objections are without merit.

I. THE OBJECTIONS SHOULD BE JOINED TO THE MERITS

103. In the present case, the jurisdictional objections should be joined to the merits for two main reasons. First, the jurisdictional issues are so entwined with the merits, from both a legal and a factual standpoint, that they should be joined. Second, considerations of economy and efficiency as well as fairness overwhelmingly point to denial of bifurcation in this case.

A. The Jurisdictional Issues Are Entwined with the Merits

104. As the preceding preliminary statement of Apotex’s responsive case on jurisdiction demonstrates, the US errs in claiming that “[t]here is no overlap between issues of jurisdiction (*i.e.*, whether Apotex’s claims fall within the scope and coverage of NAFTA Chapter Eleven) and merits (*i.e.*, whether the challenged Import Alert violated the United States’ obligations of national treatment, most-favored-nation treatment, and minimum standard of treatment).”⁹³

105. Indeed, the US Counter-Memorial itself makes plain the lack of support for the US position. Its primary argument on the merits of the national-treatment and MFN treatment claims under Articles 1102 and 1103 is that the measure accords no “treatment” to Apotex. This argument is based on precisely the same arguments and evidence as the US puts forward for its “relating to” objection to jurisdiction. In its

⁹² **Legal Authority CLA-459**, Note E to Rule 41, ICSID Arbitration Rules (1968), *reprinted in* 1 ICSID Rep. 63, 102 (1993).

⁹³ US Counter-Memorial, para. 399.

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discussion on the merits of Apotex's claims under Articles 1102 and 1103, the US Counter-Memorial states as follows:

Apotex has failed to demonstrate the required elements of its Articles 1102 or 1103 claims. First, because the Import Alert did not "relate to" Apotex as an "investor" or to any "investments" in the United States, the United States accorded no "treatment" to "an investor of a Party" or "investments."⁹⁴

106. The argument that the Import Alert did not "relate to" the investors (Apotex Holding and Apotex-Canada) or their investments (Apotex-US and Apotex's ANDAs) is the first US defense under Articles 1102 and 1103, as well as the basis for its jurisdictional objection under Article 1101. This is no accident. The US "relating to" argument purports to address whether the Import Alert accorded Apotex-US treatment less favorable than that accorded to supposed "other U.S. distributors" of Apotex-Canada's products.⁹⁵ This argument is no more than a national-treatment or MFN contention recast in the words of Article 1101 rather than those of Articles 1102 or 1103. Whether treatment accorded a given investment is more favorable, less favorable or the same as that accorded to other investments, however, is fundamentally a merits question – as the US implicitly acknowledges by stating the same argument under the heading of its contentions on Articles 1102 and 1103 as it does under Article 1101.
107. As noted above in the preliminary statement of Apotex's responsive case on jurisdiction, Apotex will demonstrate in its Reply that the "relating to" argument is patently without support and has no chance of success. However, for present purposes it is sufficient to observe that all Parties agree that the US arguments and evidence on "relating to" go both to jurisdiction and the merits. If the jurisdictional objection is

⁹⁴ *Id.* at para. 327.

⁹⁵ *See id.* at para. 299 (purporting to address whether "the Import Alert has some 'legally significant connection' to Apotex[-US] that distinguishes it from the dozens of other U.S. distributors of Apotex[-Canada]'s products.").

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dismissed (which, Apotex submits, is inevitable), then the same issues would have to be adjudicated twice in case of bifurcation.

108. Furthermore, as noted in the preliminary statement above and as the *Methanex* final award makes clear, an assessment of the merits of the substantive claims is highly pertinent to the Tribunal's task in assessing whether the "legally significant connection" required by Article 1101 is present.⁹⁶ If the connection between measure and investment or investor required by the NAFTA to establish a Chapter Eleven violation is established, it is difficult to conclude that a connection of legal significance is absent. As *Methanex* makes clear, the US "relating to" objection cannot be considered independently from the Tribunal's consideration of the merits of Apotex's claims under Articles 1102, 1103 and 1105 of the NAFTA.
109. The record before this Tribunal, in short, establishes a classic case of overlap between merits issues and those presented by the objections to jurisdiction. The objections should be joined to the merits.

B. Bifurcation in This Case Would Decrease Efficiency

110. Economy, efficiency and fairness favor a single hearing in November 2013 on all issues.
111. *First*, no efficiency in terms of time can be gained here. Under the schedule agreed by the parties and reflected in the First Procedural Order, the hearing will take place in November no matter whether it addresses all issues or addresses only jurisdiction.⁹⁷ The date on which this case is resolved cannot be advanced by bifurcation.

⁹⁶ See *supra*, paras. 5, 45-46 (discussing **Legal Authority CLA-34**, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award of the Tribunal on Jurisdiction and the Merits (Aug. 3, 2005)).

⁹⁷ Compare First Procedural Order, para. 14.2.7(xiii) (Nov. 29, 2012) (hearing on all issues to be held on November 18-26, 2013 if bifurcation is denied ("scenario 1")) with *id.* at para. 14.2.8(ix) (hearing on jurisdiction to be held on November 18-26, 2013 if bifurcation is granted ("scenario 2")).

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112. *Second*, the economies and efficiencies that the US posits in its request for bifurcation depend on a bet that both of its jurisdictional objections will succeed.⁹⁸ If one or more of the two objections fails, a hearing on the merits will need to be held with no difference in scope from the presently contemplated merits hearing.
113. There can be no dispute, however, that *if the US bid to oust the Tribunal's jurisdiction is rejected*, bifurcation will greatly increase the length and cost of the proceedings. In that instance, bifurcation would lead to two hearings, one on jurisdiction and one on the merits, with a duplication of the arguments and supporting evidence. Having two hearings instead of one would be highly inefficient, both in terms of time and expense. In terms of time, it is not uncommon that several years may pass between the decision on jurisdiction and the hearings on the merits.⁹⁹ Bifurcation if one or more of the US objections fails would only create unnecessary procedural delays.
114. In terms of expense, bifurcation would greatly increase the cost of the proceedings. The same complex and fact-intensive issues would have to be pleaded and adjudicated twice. The same documentary evidence would be submitted and reviewed twice. The same fact witnesses would have to be heard twice. And these witnesses would have to prepare twice for cross-examination. Two hearings instead of one could double the cost of the proceedings. In contrast, a hearing on all issues is only marginally more expensive than a hearing limited to jurisdiction.
115. *Third*, Apotex submits that the fairest approach would be for the Tribunal to decline the US invitation to assess the likelihood of success of the jurisdictional objections based on the incomplete record that exists at this point. Apotex submits that the Tribunal should instead assess those objections based on a full record in November along with the other issues presented in the case.

⁹⁸ US Counter-Memorial, para. 392 (arguing that US jurisdictional objections, "if sustained," would eliminate Apotex's entire case and eliminate the need for proceedings on the merits and quantum, which would save time and money).

⁹⁹ *See infra*, paras. 125-130.

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116. Nonetheless, should the Tribunal decide to engage in a preliminary assessment of the US objections at this stage, it will find those objections to be hopeless. The Import Alert plainly relates to each of Apotex-Canada, Apotex-US and Apotex Holdings. The sole extant official evidence of the adoption of the Import Alert makes this clear by addressing notices of action to both Apotex-Canada and Apotex-US. The only evidence submitted by the US to support its “relating to” argument is off-point and in any event only confirms that shipments of Apotex products by third parties were admitted by the FDA during the Import Alert, even as the FDA denied admission to commercial shipments of Apotex products to Apotex-US. Apotex-US was the *only* company denied the ability to import products made at Etobicoke and Signet for commercial sale in the United States. The US “relating to” argument is patently without merit, contrary to the terms of the measure at issue, contrary to the terms of the law supposedly authorizing that measure and irreconcilable with the record.

117. Bifurcation under these circumstances cannot foster procedural efficiency.

118. For all of the foregoing reasons, the US jurisdictional objections should be joined to the merits.

II. ARBITRATION PRACTICE DOES NOT SUPPORT BIFURCATION IN THIS CASE

119. As noted above, the issue of whether or not to order bifurcation of the proceedings depends on the particularities of the case at hand. The US arguments based on a supposed general presumption in favor of bifurcation, therefore, are beside the point.¹⁰⁰ However, as demonstrated below, those arguments are without merit in any event.

¹⁰⁰ US Counter-Memorial, paras. 393-98.

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A. The Applicable Rules Establish No Presumption in Favor of Bifurcation

120. The US errs in arguing that there is a presumption in favor of bifurcation when the respondent is a State.¹⁰¹ The US relies for this proposition exclusively on decisions of the International Court of Justice. However, the ICJ rules of procedure under which these cases were decided reflect a policy judgment that jurisdictional objections should presumptively be heard as a preliminary question by requiring proceedings on the merits to be suspended upon filing of an objection to competence.¹⁰²
121. This, however, is precisely the same system that the Administrative Council of ICSID *rejected* by amendments adopted in 2006 in order to provide tribunals more “flexibility.”¹⁰³ Prior to the 2006 amendments, Article 45(4) of the ICSID Arbitration (AF) Rules provided that “[u]pon the formal raising of an objection relating to the dispute, the proceeding on the merits *shall* be suspended.”¹⁰⁴ However, the current version of the rules provides that “[u]pon the formal raising of an objection relating to the dispute, the Tribunal *may* decide to suspend the proceeding on the merits.”¹⁰⁵ In other words, the suspension of the merits of the case, on the raising of a preliminary objection, is no longer automatic but rather discretionary.¹⁰⁶

¹⁰¹ *Id.* at para. 397 & nn.942-944.

¹⁰² See **Legal Authority CLA-457**, ICJ, Rules of Court, art. 79(5) (1978) (“Upon receipt by the Registry of a preliminary objection, the proceedings on the merits shall be suspended[.]”); **Legal Authority CLA-458**, ICJ, Amended Rules of Court, 11 I.L.M. 899, art. 67(3) (1972) (“Upon receipt by the Registrar of a preliminary objection filed by a party, the proceedings on the merits shall be suspended[.]”); **Legal Authority CLA-468**, Shabtai Rosenne, *The 1972 Revision of the Rules of ICJ*, 8 Isr. L. Rev. 197, 237 (1973) (quoting art. 62(3) of the ICJ Rules of Court (1946) (same)); **Legal Authority CLA-462**, PCIJ, Statute and Rules of Court, 1940 PCIJ (ser. D) No.1, art. 62(3) (1936) (same).

¹⁰³ **Legal Authority CLA-470**, Working Paper of the ICSID Secretariat, *Suggested Changes to the ICSID Rules and Regulations*, 8 (May 12, 2005) (“At the same time, this may be an opportunity to introduce some flexibility and make the suspension of the proceeding on the merits of the case, on the raising of a preliminary objection to jurisdiction, discretionary for the tribunal.”).

¹⁰⁴ **Legal Authority CLA-460**, ICSID Arbitration (Additional Facility) Rules, art. 45(4) (2003).

¹⁰⁵ **Legal Authority CLA-461**, ICSID Arbitration (Additional Facility) Rules, art. 45(4) (2006) (emphasis added).

¹⁰⁶ See, e.g., **Legal Authority CLA-463**, Antonio R. Parra, *The Development of the Regulations and Rules of the International Centre for Settlement of Investment Disputes*, 22 ICSID Rev. 55, 65 (2007) (“A related

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122. The 2006 ICSID rules govern these proceedings.¹⁰⁷ Contrary to the US position,¹⁰⁸ no presumption in favor of bifurcation applies in these proceedings. This issue is entirely left to the discretion of the Tribunal.
123. The ICSID rules in this respect accord with recognized international best practices today. The UNCITRAL Arbitration Rules were amended in 2010 similarly to eliminate any presumption in favor of separation of jurisdiction from the merits.¹⁰⁹ The 2012 ICC Rules on Arbitration also recognize no such presumption, but merely identify bifurcation as a case management technique that may be used by a tribunal “when doing so may genuinely be expected to result in a more efficient resolution of the case.”¹¹⁰ There is, in short, no support for the US contention that “the ICSID Additional Facility Rules are consistent with ... [a]ll principal arbitration rules involving States ... most [of which] have a presumption in favor of bifurcation.”¹¹¹
124. Nor is there merit to the US suggestion that its arguments deserve special weight because of the necessity for the parties, notably States, to consent to arbitration.¹¹² All

change of Rule 41 [in 2006] was to make discretionary rather than automatic the suspension of the proceeding on the merits upon the formal raising of an objection to jurisdiction.”).

¹⁰⁷ First Procedural Order, para. 1.1 (Nov. 29, 2012) (“These proceedings are conducted in accordance with the ICSID Arbitration (Additional Facility) Rules in force as of April 2006 (Arbitration (AF) Rules), except to the extent that they are modified by Section B of NAFTA Chapter 11.”).

¹⁰⁸ US Counter-Memorial, para. 395, n.939 (quoting, in particular, Rule 41(3) of the ICSID Arbitration Rules).

¹⁰⁹ **Legal Authority CLA-407**, UNCITRAL Arbitration Rules, art. 23(3) (as revised in 2010) (“[t]he arbitral tribunal may rule on a plea referred to in paragraph 2 *either* as a preliminary question or in an award on the merits.”) (emphasis added). This provision is consistent with Article 16(3) of the UNCITRAL Model Law. *See Legal Authority CLA-408*, UNCITRAL Model Law on International Commercial Arbitration, art. 16(3) (as revised in 2006) (same).

¹¹⁰ **Legal Authority CLA-456**, ICC, Rules of Arbitration of the International Chamber of Commerce, Appendix IV(a) (2012). *See also Legal Authority CLA-465*, ICC Commission on Arbitration Task Force on the Revision of the ICC Rules of Arbitration, *Annex 3 to the Working Paper Concerning the Revision of the ICC Rules of Arbitration*, para. 13 (Jan. 24-25, 2011) (“It was noted that the ICSID and UNCITRAL arbitration rules no longer include a presumption in favour of bifurcation and that, accordingly, no such presumption needs to be included in the ICC Rules and that it was sufficient to draw the arbitral tribunal’s attention to the possibility of bifurcating proceedings in cases where a serious issue of jurisdiction is raised. This was preferable to drawing the arbitral tribunal’s attention to the possibility of bifurcating proceedings in cases involving states or state entities since it is neutral.”).

¹¹¹ US Counter-Memorial, para. 395.

¹¹² *Id.* at paras. 397-98.

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Parties here have clearly expressed their consent to arbitrate this claim, the US in NAFTA Article 1122(1) and Apotex in Annex D to its Request for Arbitration of February 29, 2012.¹¹³ In reality, this argument by the US is just a variation of the argument for a restrictive interpretation of clauses granting jurisdiction that NAFTA tribunals have repeatedly rejected.¹¹⁴

B. The Empirical Evidence Does Not Support Bifurcation Here

125. The US erroneously argues that bifurcation is “standard procedure” in ICSID arbitration and argues that empirical data presented by one observer supports bifurcation.¹¹⁵

¹¹³ **Legal Authority CLA-1**, NAFTA, art. 1122(1) (“Each Party consents to the submission of a claim to arbitration in accordance with the procedures set out in this Agreement.”). Contrary to the US suggestion at paragraph 397 of its Counter-Memorial, consent to arbitration does not have to be proven “beyond reasonable doubt.” The sole support for the US opinion is a separate opinion from the 1950s of a single ICJ judge, Judge Lauterpacht (**Legal Authority RLA-55**, *Certain Norwegian Loans (France v. Norway)*, 1957 I.C.J. 9 (July 6) (separate opinion of Lauterpacht, J.)). This separate opinion has not been followed by the Court in its jurisprudence. See **Legal Authority CLA-454**, *Case of Certain Norwegian Loans (France v. Norway)*, Judgement of July 6, 1957, I.C.J., p. 9 (July 6, 1957) (no mention of a requirement to prove consent beyond reasonable doubt); **Legal Authority CLA-453**, *Border and Transborder Armed Actions (Nicaragua v. Honduras)*, Jurisdiction and Admissibility, Judgment, I.C.J. Reports 1988, 76, para. 16 (“The Court will therefore in this case have to consider whether the force of the arguments militating in favour of jurisdiction is preponderant” (quoting *Chorzów Factory* case, Jurisdiction, P.C.I.J. Series A, No. 9, p. 32 (quotations omitted))).

¹¹⁴ See, e.g., **Legal Authority CLA-36**, *Methanex Corporation v. United States of America*, UNCITRAL, Preliminary Award on Jurisdiction, Chapter I, para. 105 (Aug. 7, 2002) (“We accept that the NAFTA Parties intended that the provisions of Chapter 11, particularly Article 1101(1) NAFTA, should be interpreted in good faith in accordance with their ordinary meaning (in accordance with Article 31(1) of the Vienna Convention), without any one-sided doctrinal advantage built into their text to disadvantage procedurally an investor seeking arbitral relief.”); **Legal Authority CLA-450**, *The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Decision on Hearing of Respondent’s Objection to Competence and Jurisdiction, para. 51 (Jan. 5, 2001) (“[W]e do not accept the Respondent’s submission that NAFTA is to be understood in accordance with the principle that treaties are to be interpreted in deference to the sovereignty of States.... Whatever the status of this suggested principle may have been in earlier times, the Vienna Convention on the Law of Treaties is the primary guide to the interpretation of the provisions of NAFTA....”); **Legal Authority CLA-39**, *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Award, para. 43 (Oct. 11, 2002) (“[T]here is no principle either of extensive or restrictive interpretation of jurisdictional provisions in treaties. In the end the question is what the relevant provisions mean, interpreted in accordance with the applicable rules of interpretation of treaties.”). See also **Legal Authority CLA-451**, *Suez, Sociedad General de Aguas de Barcelona, S.A., and Vivendi Universal, S.A. v. The Argentine Republic*, ICSID Case No. ARB/03/19 & *AWG Group Ltd. v. The Argentine Republic*, UNCITRAL, Decision on Jurisdiction, para. 66 (Aug. 3, 2006) (“dispute resolution provisions are subject to interpretation like any other provisions of a treaty, neither more restrictive nor more liberal.”).

¹¹⁵ US Counter-Memorial, para. 394.

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However, all the record demonstrates is that while requesting bifurcation appears to be “standard procedure” for the US in NAFTA cases, bifurcation when granted has rarely resulted in efficiencies.

126. To date, ten NAFTA investment arbitrations against the US have been finally resolved. The US sought bifurcation of jurisdiction in each of these arbitrations except one – the *ADF Group* case, in which it agreed to hear jurisdiction and the merits together.¹¹⁶ Of the remaining nine, the tribunals in two cases rejected the US requests for bifurcation (*Mondev* and *Glamis Gold*).¹¹⁷
127. This leaves seven cases in which jurisdiction was heard as a preliminary question, whether because the disputing parties agreed to such bifurcation or the relevant tribunal ordered it. The US objection in *six of these seven cases* failed to dispose of the entire case, requiring the parties and the tribunal to go on to a second main hearing, devoted to the merits. The average time from notice of arbitration to award or other resolution in these six cases was *five years*; if one includes only cases resolved by an award the average time is six years.¹¹⁸ In only one case – the *BSE* or “mad cow” disease

¹¹⁶ See **Legal Authority CLA-442**, *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Minutes of the First Session of the Tribunal, para. 14 (Feb. 3, 2001) (“The President noted the parties['] agreement that, notwithstanding paragraphs 2 and 4 of Article 46 of the Additional Facility Arbitration Rules, there shall be a single written proceeding that addresses both the question of liability and any defenses that might be characterized as objection to the competence of the Tribunal. After completion of the written procedure, the parties agree that there shall be a hearing to address both legal and factual issues pertaining to competence and liability. The parties agree to bifurcate the issue of liability from that of damages.”).

¹¹⁷ **Legal Authority CLA-39**, *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Award, para. 26 (Oct. 11, 2002) (“Regarding the bifurcation of the proceedings, the Tribunal considered that the Respondent’s objections to competence could conveniently be, and should be, joined to the merits of the case.”); **Legal Authority CLA-444**, *Glamis Gold, Ltd. v. United States of America*, UNCITRAL, Procedural Order No. 2 (Revised), para. 16 (May 31, 2005) (finding that bifurcating jurisdiction and merits “would not ultimately avoid expense for the Parties, contribute to Tribunal efficiency, or be practical.”).

¹¹⁸ See website of the US Department of State, NAFTA Investor-State Arbitration, available at <http://www.state.gov/s/l/c3741.htm> (last visited on December 26, 2012). See also **Legal Authority CLA-49**, *The Loewen Group, Ind. and Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Award (June 26, 2003) (the notice of arbitration was filed in November 1998, six years prior to the award); **Legal Authority CLA-34**, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award of the Tribunal on Jurisdiction and Merits (Aug. 3, 2005) (the notice of

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arbitration – was the case resolved after a single hearing.¹¹⁹ Despite the fact that that case (unlike this one) presented no significant issues of fact, it still took three years from notice of arbitration to final award.¹²⁰

128. The record of NAFTA arbitrations involving the US, thus, shows that the result of bifurcation was, with only one exception, delay and a failure of bifurcation to contribute significantly to the efficiency of the proceedings. To the extent that decisions in cases before other tribunals are relevant to the present application (and Apotex submits they are not), they do not support the US position.
129. The US also misplaces its repeated reliance on findings from one survey of bifurcation in ICSID practice. Ms. Lucy Greenwood does indeed conclude that 45 ICSID tribunals have bifurcated their proceedings between jurisdiction and merits or merits and damages. However, her survey also observed that 129 ICSID tribunals did not bifurcate – placing in context the US suggestion that bifurcation is “standard procedure.”¹²¹ Far from supporting the US position, the survey concluded that on average cases that were

arbitration was filed in August 1999, six years prior to the award); **Legal Authority CLA-29**, *Grand River Enterprises Six Nations, Ltd., et al. v. United States of America*, UNCITRAL, Award (Jan. 12, 2011) (the notice of arbitration was filed in March 2004, seven years prior to the Award); **Legal Authority CLA-443**, *Canfor Corp. v. United States of America*, UNCITRAL, Notice of Arbitration and Statement of Claim (Sept. 7, 2002) (the notice of arbitration was filed in September 2002, five years before final resolution of this case); **Legal Authority CLA-448**, *Tembec Inc. v. United States of America*, UNCITRAL, Notice of Arbitration and Statement of Claim (Dec. 3, 2003) (the notice of arbitration was filed in December 2003, four years before final resolution); **Legal Authority CLA-449**, *Terminal Forest Prods. Ltd. v. United States of America*, Notice of Arbitration (Mar. 31, 2004) (the notice of arbitration was filed in March 2004, three years before final resolution). *Canfor*, *Tembec* and *Terminal Forest* were consolidated and ultimately terminated by a settlement between the US and Canada of all softwood lumber disputes. See website of the US Department of State, NAFTA Investor-State Arbitration, *Softwood Lumber Consolidated Proceeding*, available at <http://www.state.gov/s/l/c14432.htm> (last visited on December 26, 2012).

¹¹⁹ **Legal Authority CLA-47**, *Canadian Cattlemen for Fair Trade v. United States of America*, UNCITRAL, Award on Jurisdiction, para. 27 (Jan. 28, 2008) (“On October 9-10, 2007, the hearing on the Preliminary Issue was held in Washington, D.C.”).

¹²⁰ See website of the US Department of State, NAFTA Investor-State Arbitration, available at <http://www.state.gov/s/l/c14683.htm> (last visited on December 26, 2012) (all notices of arbitration in this case were filed in 2005).

¹²¹ See **Legal Authority RLA-35**, Lucy Greenwood, *Does Bifurcation Really Promote Efficiency?*, 28 Int’l Arb. 105, 106 (2011).

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bifurcated took longer to conclude than the cases that were not bifurcated.¹²² Moreover, according to statistics published by ICSID, in cases decided by arbitral tribunals only 22% of awards have terminated a case for lack of jurisdiction.¹²³ These data suggest that most jurisdictional objections are without merit.

130. As noted by an observer who conducted empirical studies, “holding consolidated proceedings to deal with all the issues of the case in a single process ... might appear to be the more popular approach of tribunals” in investment treaty arbitration.¹²⁴

III. DAMAGES SHOULD BE ADDRESSED WITH JURISDICTION AND THE MERITS

131. As noted above, one of the key factors that the Tribunal should consider in deciding bifurcation is procedural efficiency. With that goal in mind, Apotex respectfully submits that the issues on quantum should be addressed together with those on jurisdiction and liability. In this way, the Tribunal will be in a position to decide the entire case after the November 2013 hearing.

132. To that end, Apotex proposes the following procedural schedule:

- A week after the Tribunal’s decision on bifurcation in February 2013, Apotex shall file 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;
- By April 12, 2013, the US shall file its written submission on damages, including any damages expert’s report (9 weeks from the supplemental report by Mr. Rosen);

¹²² *Id.* (the reported ICSID cases that were bifurcated took an average of 3.62 years to conclude versus 3.04 years for the cases that were not bifurcated; for ICSID Additional Facility cases, the average length is 3.39 years (bifurcated cases) versus 2.96 years (non-bifurcated cases)). The author concludes as follows: “The assumption that bifurcation is always beneficial in terms of saving costs and time in international arbitration may not always be warranted and, as ever, each case should be looked at on its own merits.” *Id.* at 110.

¹²³ See **Legal Authority CLA-466**, ICSID, *The ICSID Caseload - Statistics*, 13, Chart 9 (2012).

¹²⁴ **Legal Authority CLA-469**, Susan D. Franck, *Empirically Evaluating Claims About Investment Treaty Arbitration*, 86 N.C.L. Rev. 1, 25 (2007) (footnotes omitted).

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- On May 24, 2013,¹²⁵ Apotex shall file a Reply on the merits (including damages) and Counter-Memorial on jurisdiction (6 weeks from the US submission on damages);
- On September 20, 2013,¹²⁶ the US shall file a Rejoinder on the merits (including damages) and Reply on jurisdiction (17 weeks from Reply).

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133. 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 above, or as the Tribunal deems appropriate in order to have all issues in this case presented at the November 2013 hearing.

Date: December 28, 2012

Respectfully submitted,

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¹²⁵ As initially agreed by the Parties and ordered by the Tribunal. *See* First Procedural Order, para. 14.2.7 (viii) (Nov. 29, 2012).

¹²⁶ As initially agreed by the Parties and ordered by the Tribunal. *See id.* at para. 14.2.7 (ix).

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