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

REJOINDER ON JURISDICTION OF CLAIMANTS APOTEX HOLDINGS INC. AND APOTEX INC.

ARBITRAL TRIBUNAL:

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CONFIDENTIAL

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In accordance with paragraph 13(j) of the Procedural Order of May 14, 2013, claimants Apotex Holdings Inc. ("Apotex Holdings") and Apotex Inc. ("Apotex-Canada") (collectively, "Apotex") respectfully submit this rejoinder on jurisdiction in support of their claims against respondent United States of America.

INTRODUCTION

1. The US Rejoinder, in addressing jurisdiction as well as the merits, repeatedly declines to join issue with the case that Apotex presents. It leaves arguments fully developed in the Reply without answer. It mischaracterizes many arguments that the Reply did advance. It repeatedly favors techniques of rhetoric over substance, reimagining the record, the authorities and Apotex's contentions rather than addressing the arguments Apotex put forward.

"Relating to"

2. On "relating to," the US Rejoinder frustratingly continues the US's previous silence on the content of the "legally significant connection" that it relies upon for its jurisdictional objection. The US rejects Apotex's view that the connection between measure and investment established by the substantive provisions of NAFTA's investment chapter is necessarily "legally significant." It does so without contesting or even addressing the analysis supporting the Reply's opposite conclusion based on a detailed review of the relevant text, context and object and purpose as concerns "relating to." The US rejects the "legal impediment," "directly applied to" and "addressed to" approaches that the Reply inferred from the US Counter-Memorial. The US offers no standard of its own and no principled basis for its jurisdictional objection, only a disparate array of factual arguments.

3. The Rejoinder places new emphasis on a philosophical deconstruction of the Import Alert into a trinity of separate measures. The real measure that prevented Apotex-US from receiving the supplies it counted on for 80% of its sales, the US asserts, was FDA's finding of cGMP noncompliance, not the Import Alert. The US, however, makes no attempt to reconcile this argument with the record in this case. For Signet, the US identifies only the March 2010 Warning Letter as reflecting this finding. The Rejoinder does not attempt to explain how US border officials in August 2009 could have refused admission of Signet products based on a finding that was unwritten and uncommunicated at the time.

4. The record in no way supports the new operative "measure" identified by the US. The record shows that the comparators continued to distribute on the US market without impediment products that FDA found, in comparable warning letters, to be non-cGMP

compliant. The FDA findings did not prevent the comparators' products from being sold on the US market. By contrast, the record shows that border officials began refusing admission of Signet and Etobicoke products immediately after the Import Alert was issued, and not at some earlier period when the unwritten findings supposedly were adopted.

5. The US Rejoinder also includes an equally philosophical argument that the sales of products by Apotex-Canada to Apotex-US took place in Canada. The US Rejoinder, again, makes no attempt to ground this assertion in the record. The commercial invoices in the record evidence a sale by Apotex-Canada in Ontario to Apotex-US of drugs to be delivered in Indiana. The record also includes FDA notices of action reflecting FDA's contemporaneous understanding that Apotex-Canada was the importer and Apotex-US was the consignee of the products sold. As previously noted, applicable law shows that the risk of loss passed to Apotex-US in Canada. It does not address passage of title.

6. Moreover, the Rejoinder does not attempt to explain why, even if title had passed in Canada, a different conclusion on "relating to" would be required. Apotex-US's ownership of the products that the Import Alert prevented it from receiving could only *reinforce* the conclusion that the Import Alert related to Apotex-US.

7. Most important, the Rejoinder does not dispute Apotex's factual showing on "relating to." It does not contest that, before the Import Alert, Apotex-US sold [redacted] dosages of Etobicoke and Signet products on the US market per year. The Import Alert cut off Apotex-US's supply of products for commercial sale from Etobicoke and Signet. The US does not dispute that 99 percent of all shipments of Etobicoke and Signet products to other consignees were admitted into the US. It does not contest that the remaining 1 percent consisted of three shipments to other consignees amounting to no more than 22,000 dosages, and were not for commercial sales. Nor does the US contest that every FDA-approved label for Signet and Etobicoke products sold in the US identifies Apotex-US as the distributor of record; that FDA specifically provided notice to Apotex-US of FDA's refusal to admit products subject to the Import Alert; or that the law authorizing the Import Alert required such notice.

8. The record shows that the measure here "related to" Apotex-US within the meaning of the NAFTA. The US "relating to" objection is baseless.

Marketing Authorizations as "Investments"

9. The US Rejoinder similarly resorts to rhetoric in its discussion of Apotex's case that Apotex-Canada's authorizations to market drugs made at Etobicoke and Signet constitute investments within the meaning of NAFTA Article 1139(g) and (h).

10. Apotex's Reply observed that the US Counter-Memorial had offered no response to the Memorial's detailed showing that the marketing authorizations constituted interests resulting from the commitment of resources by Apotex to the territory of the United States and therefore investments within the meaning of Article 1139(h). The US Rejoinder again refrains from joining issue with Apotex's case. Instead, the Rejoinder attempts to distract from its absence of response by suggesting that the tribunal in the *Apotex I&II* case had decided the question in a manner constituting "*res judicata*" for this case.

11. The US position is without merit. Article 1136(1) of the NAFTA – a provision curiously unmentioned in the text of the US Rejoinder's discussion of *res judicata* – specifically addresses the extent to which previous NAFTA awards are binding. It provides as follows:

> An award made by a Tribunal shall have no binding force except between the disputing parties *and in respect of the particular case.*[1]

12. The treaty text is clear: the *Apotex I&II* award is binding between Apotex-Canada and the US, but only in respect of that case. It is not binding as concerns this one.

13. Moreover, the US errs in suggesting that *res judicata* in international law includes the common law concept of issue estoppel. It does not, as even the authorities cited by the US state. Instead, international tribunals require a triple identity of parties, object and cause of action for *res judicata* to apply.

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[1] **Legal Authority CLA-1**, North American Free Trade Agreement, U.S.-Can.-Mex., art. 1136(1), Dec. 17, 1992, 32 I.L.M. 289 (1993) (hereinafter "NAFTA") (emphasis added).

14. Finally, even if the US were correct that issue estoppel had a role to play here – which it clearly does not – the US position would still lack merit. The common law concept of issue estoppel applies only to issues *actually litigated and decided* in the previous case. The *Apotex I&II* tribunal was presented with the issue of whether two *applications* to market new drugs were investments even though the application had not finally been approved. It was not called upon to decide, and did not decide, whether approved marketing authorizations were investments.

15. As this Tribunal observed in its decision on the BNM amicus petition:

> Even though Apotex[-Canada], for the UNCITRAL proceedings, and Apotex Holdings [] and Apotex[-Canada] for this arbitration, rely on Article 1139 of the NAFTA, the context and the claims are materially different ... .[2]

16. Apotex respectfully submits that the Tribunal's finding is correct. *Apotex I&II* did not decide the issues before this Tribunal. The US arguments on the application of Articles 1139(g) and (h) to this case are without support.

17. The subject of this rejoinder is jurisdiction. Apotex does not address here the US Rejoinder's contentions on the merits, except to the extent pertinent to jurisdiction. It notes, however, that those contentions on the merits are infected by the same erroneous approach that pervades the US Rejoinder's arguments on jurisdiction. The US Rejoinder heavily relies on a supposed "concession" of cGMP violations at Signet and Etobicoke that Apotex has never made. It mentions in the same phrase the tragic contamination of sterile injectable products at a Massachusetts compounding facility, resulting in dozens of deaths, and the Apotex systems that resulted in a recall of products in 2009 that FDA classified as having a remote risk of patient injury.[3] These and other misstatements and distortions will be addressed at the hearing on the merits in November. That they are not addressed here should in no way be understood as acquiescence in them on the part of Apotex.

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[2] Procedural Order on the Participation of the Applicant, BNM, as a Non-Disputing Party, para. 25 (Mar. 4, 2013). *See also id.* (noting that in the two cases "the issues are quite different").

[3] US Rejoinder, para. 16 & n.21.

I. THE IMPORT ALERT CLEARLY RELATED TO APOTEX

18. None of the three US arguments on "relating to" as to Apotex-US withstands scrutiny. *First*, while the US now identifies as a key question the location of the "sales" between Apotex-Canada and Apotex-US, it never explains the pertinence of the answer to this rather abstract question. It is undisputed that the Import Alert cut off Apotex-US from the source of 80% of supplies it depended upon to remain in business. The measure clearly related to Apotex-US, whether it was the owner of the products subject to the Import Alert, the consignee or the purchaser.

19. *Second*, the US attempt to deconstruct the Import Alert into a trilogy of measures is contrary to the record, inconsistent with the arguments advanced by the US in this arbitration and based on a mischaracterization of the case Apotex has put in this arbitration. It is without merit.

20. *Third*, the record provides no support for the US Rejoinder's characterization as "remote" the link between Apotex-US and the Import Alert that decimated its business.

21. *Finally*, contrary to the US Rejoinder's suggestion, the record here clearly establishes the connection between measure and investment contemplated by Articles 1102, 1103 and 1105, and that connection is legally significant.

A. The Import Alert Related to Apotex-US No Matter the Location of "Sales"

22. The US Rejoinder's arguments concerning the "location of Apotex's drug sales" are without merit.

23. *First*, the US erroneously suggests that "Apotex … has withheld crucial facts in its exclusive control concerning the location of Apotex's drug sales …" and that said location is "a central element of Apotex's claims."[4] Neither is so.

24. Apotex has produced as exhibits in this arbitration the only documentation of sales between Apotex-Canada and Apotex-US. This documentation takes the form of commercial invoices. These show that Apotex-Canada was the shipper, Apotex-US the

[4] US Rejoinder, para. 188.

buyer, the drugs were shipped from Apotex-Canada and shipped to Apotex-US's facility in Indianapolis, Indiana.[5] Apotex has also produced the FDA notices of action reflecting the US's contemporaneous understanding of the transactions. These show Apotex-Canada in Ontario as the importer of record and Apotex-US in Florida as the consignee of the shipments.[6] These are the pertinent facts concerning these transactions. The US does not identify what other "crucial facts" it believes are lacking.

25. Moreover, Apotex is at a loss to understand how the location of "sales" is "a central element of Apotex's claims."[7] Articles 1102, 1103 and 1105 of the NAFTA, read with Article 1101(1), require a showing as to the location of Apotex's *investments*. Apotex has made that showing. The location of the "sales," if anything, is pertinent to a US defense, not to Apotex's claims. The US had an opportunity to request documents from Apotex in this arbitration. It did not request any documents on this topic.[8] It errs in attempting to blame Apotex for the US's failure to support its own assertions.

26. *Second*, the "location of sales" is not a fact, but a legal conclusion. It is also a legal conclusion that, in cross-border transactions, is subject to considerable debate and depends in significant part on the context in which the question is asked.[9] The location

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5 *See, e.g.*, **Exhibit C-68**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated Sept. 1, 2009 at 10:20 am, attaching Notice of FDA Action re: Entry No. EG6-1768658-9, dated Aug. 31, 2009; **Exhibit C-69**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated Sept. 1, 2009 at 10:21 am, attaching Notice of FDA Action re: Entry No. EG6-1768659-7, dated Aug. 31, 2009; **Exhibit C-71**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated Sept. 1, 2009 at 12:36 pm, attaching Notice of FDA Action re: Entry No. EG6-1767503-8, dated Sept. 1, 2009; **Exhibit C-72**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated Sept. 1, 2009 at 12:52 pm, attaching Notice of FDA Action re: Entry No. EG6-1768378-4, dated Sept. 1, 2009.

6 *See, e.g.*, **Exhibit C-78**, Notice of FDA Action re: Entry No. EG6-1768425-3, dated Sept. 2, 2009; **Exhibit C-80**, Notice of FDA Action re: Entry No. EG6-1768454-3, dated Sept. 2, 2009; **Exhibit C-68**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated Sept. 1, 2009 at 10:20 am, attaching Notice of FDA Action re: Entry No. EG6-1768658-9, dated Aug. 31, 2009; **Exhibit C-69**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated Sept. 1, 2009 at 10:21 am, attaching Notice of FDA Action re: Entry No. EG6-1768659-7, dated Aug. 31, 2009; **Exhibit C-71**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated Sept. 1, 2009 at 12:36 pm, attaching Notice of FDA Action re: Entry No. EG6-1767503-8, dated Sept. 1, 2009; **Exhibit C-72**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated Sept. 1, 2009 at 12:52 pm, attaching Notice of FDA Action re: Entry No. EG6-1768378-4, dated Sept. 1, 2009.

7 US Rejoinder, para. 188.

8 *See* Respondent's Document Requests (Feb. 8, 2013) (listing 14 requests, none regarding the location of sales between Apotex-Canada and Apotex-US).

9 *See, e.g.*, **Legal Authority CLA-628**, Geoffrey C. Cheshire, *Private International Law*, 51 L.Q.R. 76, 84 (1935) (noting that the determination of *lex situs* with respect to the transfer of movables is complex and cannot be resolved by a single principle); **Legal Authority CLA-626**, Fletcher R. Andrews, *Situs of Intangibles in Suits Against Nonresident Claimants*, 49 Yale L.J. 241, 272-73 (1939) (exploring different

of a sale for purposes of determining the validity of the contract may be different from the location for purposes of determining whether the buyer or the seller bears the risk of loss of the goods or who owns goods in transit.[10]

27. The US places considerable reliance on arguments made in proceedings in Canadian court that addressed the location of sales for purposes of the limitations period applicable to a claim of infringement of a Canadian patent.[11] That context bears little resemblance to that present here, where the issue posed by the US jurisdictional objection is whether the Import Alert relates to Apotex-US for purposes of NAFTA Article 1101(1).

28. *Third,* the US Rejoinder does not articulate why or how any of this is relevant to the relationship between Apotex-US and the Import Alert. The US suggests, but does not state specifically, that the question of interest to it is the location where title passes.[12] If the US were correct as to where title passes, Apotex-US would be the owner of the products that were the subject of the Import Alert. The US does not explain why the Import Alert would any less relate to an owner prevented from receiving its products than it relates to a purchaser similarly prevented from receiving products to which it had not yet acquired title. The salient point here is undisputed: the Import Alert cut Apotex-US off from the supply it depended on for 80% of its revenues.

29. *Finally*, the US does not dispute any of the points made at length in Apotex's Reply. For instance, the US has avoided any affirmative statement as to what the "legally

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legal tests for the determination of situs of intangibles such as bonds, funds, insurance policies, debts, and stocks).

[10] *See, e.g.*, **Legal Authority CLA-629**, Ralph H. Folsom, 1 *International Business Transactions* § 1:20 (3d ed. 2012) ("In most situations, title and risk are treated separately. … [I]f the goods are already in transit when sold, the risk passes when the contract is 'concluded.' This rule reflects a use of 'title' concepts in risk allocation … ." (footnote omitted)); **Legal Authority CLA-627**, Fritz Hellendall, *The Characterization of Proprietary Rights to Tangible Movables in the Conflict of Laws*, 15 Tul. L. Rev. 374, 374 (1941) ("Where the title to tangible movables is in issue and the factual situation contains a foreign element, a problem may arise as to the law to be applied in determining the ownership. It is important to distinguish this problem from that which centers about what law governs the contract to create, transfer, or extinguish the title." (emphasis omitted)).

[11] *See* US Rejoinder, paras. 191-93.

[12] *See id.*, para. 190. As Apotex has already noted, the location where title passes is not specified in the sales documentation and is not addressed in the applicable UN Convention on the International Sale of Goods. Reply, para. 131 n.191. Apotex does not take a position here on where title passes because, as explained in the text, it is irrelevant to the issue before this Tribunal.

significant connection" required by Article 1101 actually entails.[13] The US rejects, without any explanation, Apotex's interpretation based on the Vienna Convention that the legally significant connection is informed by the substantive provisions of the NAFTA.[14] The US also does not address the point that trade measures and investment measures are not mutually exclusive,[15] and it fails to address *Cargill*.[16] It offers no response to the fact that Apotex was the sole commercial importer from Apotex-Canada in the United States and, as such, was uniquely impacted by the Import Alert.[17] Lastly, the US does not respond to Apotex's detailed arguments concerning the relationship between Apotex-Canada and Apotex-US.[18]

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[13] In its Counter-Memorial, the US suggested in a heading that the Import Alert did not "relate to" Apotex Holdings or Apotex-US because the Import Alert did not "apply to" Apotex-US and did not constitute a "legal impediment to its business operations." *See* US Counter-Memorial, at 141, heading 1. Thereafter, the US declined to confirm that this heading reflected the content the US ascribes to "legally significant connection." *See* Reply, para. 109 (footnote omitted). Apotex demonstrated that the NAFTA does not support the US's view that the measure must "apply to" the investment. *See id.*, paras. 109-17. This point is unaddressed in the US Rejoinder. Similarly, the US does not dispute that even the unexplained test proffered in its Counter-Memorial (that the Import Alert "apply to" Apotex-US) is amply met on this record. *See id.*, paras. 118-33. In a footnote in its Rejoinder, the US now claims that "Apotex misattributes to the United States the argument that 'a measure can only relate to an investment if it is primarily directed at that investment.'" US Rejoinder, para. 205 n.459. Yet, the US still fails to explain how the phrase "legally significant connection" should be interpreted. *See id.*, para. 94 ("In addition, the sole challenged measure in this case – the Import Alert – had no 'legally significant connection' to Apotex[-Canada]'s ANDAs or to Apotex[-US]. That measure, therefore, did not 'relate to' any alleged investor or investment in this arbitration." (footnote omitted)); *id.*, para. 178 ("Apotex accepts that the 'relating to' language in Article 1101(1) requires a 'legally significant connection' between measure and investment/investor, as held by the *Methanex* tribunal." (internal quotation marks omitted)); *id.*, para. 180 ("The sole challenge measure in this case – the Import Alert – had no legally significant connection to any alleged investor or investment in this arbitration. As such, the Import Alert did not 'relate to' any alleged investor or investment within the meaning of Article 1101(1).").

[14] Reply, paras. 96-108; US Rejoinder, para. 179 ("[T]he *Methanex* tribunal concluded that a breach of a substantive provision of the NAFTA *could conceivably provide evidence* relevant to a determination as to whether the relation required by NAFTA Article 1101 exists in this case. A tribunal's determination that there has been a breach of a provision of the NAFTA, however, cannot by itself establish the relationship between an impugned measure and any particular investor or investment." (footnote and internal quotation marks omitted)). If a measure breaches a substantive provision of Chapter Eleven, Apotex fails to see how that measure would not have a legally significant connection to the investor/investment harmed.

[15] Reply, para. 114 (citing **Legal Authority CLA-1**, NAFTA, art. 1106 (provision addressing measures directed at imports and exports); *id.*, para. 115 (discussing *Cargill*, *Pope & Talbot*, and *S.D. Myers, i.e.,* cases "demonstrat[ing] that import/export measures can relate to investors and their investments").

[16] Reply, paras. 134-42. *See* US Rejoinder, paras. 199 n.445, 205 n.460.

[17] Reply, paras. 147-74. *See also* US Rejoinder, para. 207 (discussing three "drop shipments" from Apotex-Canada to Apotex-US customers, but ignoring the fact that those were shipped on behalf of Apotex-US and paid to Apotex-US by the customers and omitting any reference to previously produced recall documents and spreadsheets). *See* Second Witness Statement of Gordon Fahner, paras. 33-35. *See infra*, para. 48.

[18] *See* Reply, paras. 175-204. *See also* US Rejoinder, paras. 205-06 (rehashing the same arguments made in the Counter-Memorial and disproved by Apotex in its Reply).

B. The Import Alert Is a Measure and Not Three

30. The US Rejoinder develops at some length a new objection that appeared nowhere in the Counter-Memorial: that there were in fact a trinity of measures here, and the Import Alert was the only one in the trinity that had no impact on Apotex-US.[19] This new objection must be dismissed for several reasons.

31. *First*, the ICSID rules do not permit new objections to jurisdiction to be raised so late in the proceedings. Article 45(2) of the ICSID Arbitration (AF) Rules provides in pertinent part as follows:

> Any objection that the dispute is not within the competence of the Tribunal shall be filed with the Secretary-General as soon as possible after the constitution of the Tribunal and *in any event no later than the expiration of the time limit fixed for the filing of the counter-memorial* … —unless the facts on which the objection is based are unknown to the party at that time.[20]

32. The US Counter-Memorial, as noted, contains no objection or even argument that FDA's finding of cGMP violations and not the Import Alert was the measure that related to Apotex-US.[21] The ICSID rules do not permit such an objection to be advanced at this point. The US objection should be dismissed on this ground alone.

33. *Second*, the US objection artificially disaggregates a decision from the reasons that support it and the means to enforce it. Under the US approach, a court order would not be a measure because the operative part would not exist without supporting reasoning and cannot be enforced without subsequent acts by judicial or other authorities. In practice, however, a court order is understood to encompass the reasoning supporting it and the means to enforce it. This has been Apotex's approach to the Import Alert throughout this case.[22] It is also FDA's approach, as shown by the title of the Import

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19 US Rejoinder, paras. 194-99.

20 ICSID Arbitration (Additional Facility) Rules, art. 45(2) (emphasis added).

21 The first time the US mentioned such an objection was in a single paragraph in its Reply on Bifurcation, which post-dated the Counter-Memorial. *See* US Reply on Bifurcation, para. 11.

22 *See, e.g.*, Reply, para. 127 (referring to FDA notices of action documenting detention and refusal of admission of Signet and Etobicoke products as "contemporaneous official evidence of the adoption of the Import Alert … ."); Memorial, paras. 173-75 (describing FDA's reasoning purportedly justifying Import Alert). *See also* **Legal Authority CLA-341**, Linda Horton, *US FDA Authority over Imports*, Reg. Affairs J.

Alert that was posted on FDA's website: "Import Alert 66-40 – Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug CGMPs."[23]

34. *Third*, the NAFTA's definition of "measure" "includes any law, regulation, procedure, requirement *or practice*[.]"[24] As the *Ethyl* tribunal noted, "even something in the nature of a 'practice,' which may not even amount to a legal stricture, may qualify" as a measure.[25] As noted in the Memorial, while not expressly authorized by any law or regulation, import alerts are a practice developed by FDA and a measure within the meaning of the NAFTA.[26]

35. *Fourth*, the record does not support the US suggestion that, in practice, import alerts are unimportant "guidance" and the real measure was FDA's final determination that Signet and Etobicoke did not meet cGMP requirements.

36. As an initial matter, at some point between the issuance of a Form 483 for the Signet inspection on August 14, 2009 (which explicitly did "*not* represent a final agency determination regarding [Apotex's] compliance") and the adoption of the Import Alert on August 28, 2009, FDA must have made a determination that Signet did not meet cGMP requirements.[27] Under the US's theory, the March 2010 Warning Letter was the only document that reflected this determination,[28] but the US does not attempt to explain how US border officials in August 2009 could have refused admission of Signet products based on a finding that was nonexistent, unwritten and uncommunicated at the time. The only evidence of such a determination is CDER's August 20, 2009

Pharma 293, 294 (May 2009) ("To *implement* a detention without physical examination, FDA headquarters issues to its investigators and to Customs and *import alert* … ." (emphasis added)); *id.* ("FDA actions on imports are *implemented* through FDA documents known as *Import Alerts*." (emphasis added)).

23 **Exhibit C-110**, Excerpt from FDA website, *Import Alert 66-40*, dated Oct. 2, 2009.

24 **Legal Authority CLA-1**, NAFTA, art. 201 (emphasis added).

25 **Legal Authority CLA-26**, *Ethyl Corp. v. Government of Canada*, NAFTA/UNCITRAL, Award on Jurisdiction, para. 66 (June 24, 1998).

26 *See* Memorial, para. 103 ("FDA has developed a practice pursuant to which it may refuse admission without any physical examination of products at the border."); *id.*, para. 406 ("The Import Alert is a decision of a US regulatory agency (FDA), which sets out a clear requirement to deny access of certain goods to the United States. Therefore, the Import Alert constitutes a measure within the meaning of Article 201.").

27 **Exhibit C-61**, 2009 Signet Form 483, at 1 ("This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do *not* represent a final agency determination regarding your compliance." (emphasis added)).

28 US Rejoinder, paras. 194-99.

memorandum to DIOP.[29] There is no evidence that the August 20, 2009 memorandum was communicated to FDA or Customs and Border Protection personnel at the US-Canadian border. No shipments from Signet to Apotex-US were detained in the days following this determination. Precisely because the determination reflected in the August 20 memorandum was not by itself operative, on August 28, 2009 Carmelo Rosa wrote to DIOP to follow up on CDER's request for an Import Alert to be issued to bar further Apotex shipments.[30]

37. It was only two days *after* the Import Alert was issued on August 28, 2009 and disseminated to officials at the border that Apotex's shipments from Signet and Etobicoke were turned back by US authorities.[31] In other words, it was only after the two facilities were added to the Import Alert that products were detained and refused admission, not after the cGMP inspections.

38. Similarly, for Etobicoke, FDA issued a warning letter in June 2009, which indisputably does represent an agency finding of cGMP violations.[32] No product from Etobicoke, however, was detained and refused admission until the Import Alert was issued on August 28, 2009.

39. Moreover, as noted at length in Apotex's pleadings, Apotex's comparators each also received warning letters representing FDA findings of cGMP violations. The record contains no evidence of any product of Sandoz (Canada) or Teva (Jerusalem) that was refused admission. Neither Sandoz nor Teva was put on import alert. The FDA findings did not result in a refusal of admission of their products.

40. The contemporaneous correspondence both within and without FDA confirms that it was the Import Alert that blocked shipments to Apotex-US from Signet and Etobicoke,

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[29] **Exhibit C-64**, Memorandum from Director of CDER-OC DMPQ (Rick Friedman) to Director DIOP (Domenic Veneziano), dated Aug. 20, 2009.

[30] *See* **Exhibit C-383**, FDA Internal Email, dated Aug. 28, 2009 at 11:34 am (Email from Carmelo Rosa to John Verbeten and Domenic Veneziano) ("Just wondering if we have any information on the status of this Import Alert. The firm continues to ship adulterated product into the US. Please let us know as soon as the IA is in effect.").

[31] *See* Memorial, paras. 187-92; **Exhibit C-67**, Email from Director of DIOP to Import Program Managers, dated Aug. 28, 2009 at 12:01 pm (disseminating the decision to add Signet and Etobicoke to Import Alert No. 66-40).

[32] Memorial, paras. 98, 152.

and not some other measure. FDA officials repeatedly made reference to the Import Alert as the pertinent enforcement action in their internal discussions, not to a determination of cGMP violations.[33] FDA officials in their interactions with Apotex took a similar stance.[34] The record confirms that the US argument for a trinity of measures is an after-the-fact, intellectual exercise rather than one grounded in fact.

41. *Finally*, it is impossible to reconcile the US position that the pertinent measure is the cGMP determination rather than the Import Alert with its position on other points in this arbitration. The US argues, for purposes of "relating to" and MFN/NT "treatment," that the Import Alert was mere guidance that afforded Apotex no treatment and only the findings of cGMP violations were relevant. For purposes of "like circumstances," however, the US argues that the cGMP findings did not make the circumstances like and the only pertinent measure was the Import Alert.[35] Similarly, with respect to

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[33] *See, e.g.*, **Exhibit C-67**, Email from Director of DIOP to Import Program Managers, dated Aug. 28, 2009 (stating that Apotex "met the criteria for addition to detention without physical examination" and therefore should be added to "Import Alert #66-40"); **Exhibit C-351**, FDA Internal Email Chain, dated Apr. 15, 2009, at US7232 (Email from Rick Friedman to Sally Eberhard et al.) ("CDER/DMPQ procedure requires that any progression to a decision for any Import Alert action must be signed off by DMPQ … ."); **Exhibit C-355**, FDA Internal Email, dated May 22, 2009 (transmitting sample import alert to be used "as a model for drafting the Apotex IA"); **Exhibit C-359**, FDA Internal Email Chain, dated June 8, 2009, at US7270 (Email from Deborah Autor to Joseph Famulare et al.) (asking her team to "do an import alert sooner rather than later"); **Exhibit C-374**, FDA Internal Email Chain, dated Aug. 18, 2009 (Email from Hidee Molina to Carmelo Rosa) ("Attached is the Apotex IA draft for your review."); **Exhibit C-378**, FDA Internal Email Chain, dated Aug. 20, 2009 (Email from Edwin Rivera Martinez to Hidee Molina) ("Attached is the draft IA memo with my corrections."); **Exhibit C-380**, FDA Internal Email Chain, dated Aug. 25, 2009, at US6202 (Email from Rick Friedman to Carmelo Rosa et al., dated Aug. 24, 2009) ("The approved IA is in Carmelo [Rosa]'s inbox … ."); **Exhibit C-381**, FDA Internal Email Chain, dated Aug. 25, 2009, at US6191 (Email from Hidee Molina to John Verbeten et al.) ("Please find attached the import alert recommendation memo for Apotex[-Canada]."); **Exhibit C-383**, FDA Internal Email, dated Aug. 28, 2009 ("Just wondering if we have any information on the status of this Import Alert.").

[34] *See, e.g.*, **Exhibit C-427**, FDA Internal Email Chain, dated Dec. 9, 2010, at US138 (Email from Carmelo Rosa to Melvin Szymanski, dated Nov. 30, 2010) (noting that FDA informed Apotex that it "could not grant [Apotex's] request to start the GMP inspection Monday in order to lift the import alert"); **Exhibit C-246**, Email Chain between Apotex and FDA, dated June 29, 2011, at 1 (Email from Carmelo Rosa to Carmen Shepard) (noting that CDER would request the removal of the Import Alert from the Signet site); **Exhibit C-430**, Email Chain between Apotex's Regulatory Counsel and FDA, dated Apr. 5, 2011 (Email from Carmen Shepard to Carmelo Rosa et al.) (discussing review of EIRs in order to remove the Import Alert).

[35] US Rejoinder, para. 222 ("The U.S. Counter-Memorial similarly recognized the importance of the Import Alert … to Apotex's 'like circumstances' analysis."); *id.*, para. 221(2) ("Apotex mistakenly asserts that U.S. and foreign manufacturing facilities are subject to the same 'legal regime' merely because they 'must conform their operations to the same cGMP regulations'[.]"); *id.*, para. 218 ("The U.S. Counter-Memorial debunked this claim, pointing out that drugs produced at domestic facilities cannot be subject to Section 801(a) of the FD&C Act, *import alerts*, or detentions without physical examination … ." (emphasis added)); *id.*, para. 335 ("Drugs from Etobicoke and Signet were added to 'Import Alert 66-40,' which is itself entitled 'Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug GMPs.'"); US

Article 1105, the US argues: "After FDA added drugs from those facilities to the Import Alert, Apotex did not protest or challenge FDA's decision through the FDA administrative challenge mechanisms or through judicial action."[36] The US fails to explain how an internal guidance document that allegedly does not affect any "rights and interests" is able to be challenged through judicial action.[37] The US's position that Apotex both had available remedies "to challenge FDA's enforcement action"[38] and that these remedies could have provided Apotex effective relief is irreconcilable with its position that "[t]he Import Alert … was not the measure that prevented Apotex[-US] from marketing drugs from Etobicoke and Signet in the United States[.]"[39]

C. The Import Alert Specifically and Uniquely Applied to Apotex-US

42. The final portion of the US argument on "relating to" does not attempt to respond to the showing made in Apotex's Reply. In its Reply, Apotex showed that the US law on which the Import Alert was based applied both to the owner of the products and the consignee to whom they were to be delivered.[40] It demonstrated that Apotex-US was the consignee and the notices of FDA action implementing the Import Alert were specifically addressed to Apotex-US as a concerned party.[41] The Reply further showed that 99% of all shipments of Etobicoke and Signet products to consignees other than Apotex-US were admitted into the US.[42] By contrast, Apotex-US – which previously

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Counter-Memorial, para. 332 (treating the import alert, detentions without physical examination, and section 801(a) together).

36 US Rejoinder, para. 324; *id*., para. 326 (claiming that "Apotex did not sue FDA in U.S. courts for any claim related to the Import Alert[,]" nor any claim related to the cGMP violations or detention decisions); *id.*, para. 364 (noting that Apotex "could have attempted to challenge the Import Alert itself" even though the US explicitly maintains that "placement on the Import Alert could not be challenged under the APA because such decisions are committed to FDA discretion[.]"). The US also argues that Apotex could have brought a court action "alleging that FDA unreasonably delayed … removing Apotex from the Import Alert[.]" *Id.*, para. 363 (emphasis omitted). The US fails to explain how removal from Import Alert would have allowed Apotex to resume importation into the US if the Import Alert was not the measure impeding Apotex from importation in the first place.

37 *See id.*, para. 39.

38 *Id.*, para. 341.

39 *Id.*, para. 199.

40 Reply, paras. 121-26 (discussing Section 801 of the Act, the Code of Federal Regulations, and FDA's Regulatory Procedures Manual).

41 *Id.*, paras. 127-29.

42 *Id.*, paras. 146, 166-73 (explaining that of the 322 shipments listed in the US's spreadsheets, every one was allowed into the US except for three non-commercial shipments).

had sold [redacted] *billion dosages* of Etobicoke and Signet products on the US market – was permitted to receive none.[43] The Reply demonstrated that the award in *Cargill v. Mexico* was on point and fully supported the view that the Import Alert "related to" Apotex-US.[44] In response to the US's extended arguments concerning the relationship between Apotex-Canada and Apotex-US, the Reply noted that Apotex had never suggested that that relationship was pertinent to the "relating to" question and the US never explained what the pertinence might be.[45] The Reply nonetheless rebutted each of the US assertions.[46]

43. The US Rejoinder does not so much address the showing made by Apotex as attempt to distract from the absence of a response. The arguments put forward do not withstand scrutiny.

44. *First*, on Apotex-US's status as consignee, the US Rejoinder does not dispute any of the points made in the Reply. It agrees with Apotex that DWPE import alerts are founded on Section 801(a) of the Act.[47] It does not contest the Reply's showing that Section 801(a) confirms that import measures such as these apply to both the owner of the goods and the consignee by requiring that notice and an opportunity to provide testimony be provided to both.[48] Nor does it dispute that the notices of action

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43 *Id.*, para. 172.

44 *Id.*, paras. 134-38.

45 *Id.*, para. 176. *Compare* US Counter-Memorial, para. 299 ("Apotex offers several explanations as to how the Import Alert has some 'legally significant connection' to Apotex[-US]. … Apotex[-Canada] does not claim to own or control Apotex[-US], and mere business linkages between affiliated manufacturers and distributors are insufficient to establish a legally significant connection.") *with* Memorial, paras. 410-13 (discussing the import alert's relation to Apotex-Canada, Apotex-US, and Apotex Holdings, but not Apotex-Canada's business relationship with Apotex-US).

46 Reply, paras. 181-205 (rebutting each of the US's eight false assertions).

47 US Rejoinder, para. 40 n.52 (quoting text from **Exhibit C-110**, Excerpt from FDA website, *Import Alert 66-40*, dated Oct. 2, 2009 stating "[t]he article is subject to refusal of admission pursuant to Section 801(a)(3)"). *See also id.*, para. 228 ("FDA may *administratively* detain without physical examination, and refuse to admit into the United States, drugs that 'appear' to be adulterated." (citing **Legal Authority CLA-242**, Federal Food Drug, and Cosmetic Act, § 801(a))); *id.*, para. 267 n.630 (agreeing that Sandoz and Teva are potential comparators because their products "are subject to Section 801(a) of the FD&C Act and are eligible for Import Alert 66-40" (internal quotation marks omitted)). *Accord* Expert Report of William W. Vodra, para. 53.

48 Reply, para. 121 (noting that Section 801(a) required "'notice [of import measures] to the *owner or consignee*, who may appear before the Secretary … .'" (emphasis in Reply) (quoting **Legal Authority CLA-239**, Federal Food, Drug and Cosmetic Act, 21 USC § 381(a))).

implementing the Import Alert were specifically addressed to Apotex-US.[49]

45. Instead, the US debates at some length whether the Import Alert was contemporaneously posted to FDA's website, arguing that it was published before September 30, 2009 even though the Import Alert itself recites that it was published on that date.[50] It also argues that on its face "[t]he Import Alert was addressed to FDA field offices" and did not mention Apotex-US.[51] The US, in short, makes no attempt to address Apotex's detailed showing on the significance of Apotex-US's status as consignee.[52]

46. *Second*, the US rehashes its arguments concerning supposed inconsistencies in Apotex's position before this Tribunal and before the courts concerning the relationship between Apotex-Canada and Apotex-US. Apotex devoted a dozen pages in its Reply to showing that there were no such inconsistencies.[53] It will not repeat that showing here.

47. More importantly, Apotex in its Reply observed that the relationship between Apotex-Canada and Apotex-US was irrelevant to the question of "relating to," and that Apotex had never suggested that it was relevant.[54] The US Rejoinder repeats its baseless arguments without ever attempting to explain how they might be pertinent to any issue before the Tribunal.[55] The arguments are beside the point as well as without merit.

48. *Third*, the US distorts the record in suggesting that Apotex-Canada sold products to three distributors in the US, and that therefore Apotex-US was not the only US company that imported Signet and Etobicoke products for commercial sale in the US.[56] These distributors were customers of Apotex-US, not Apotex-Canada. The three

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49 Expert Report of William W. Vodra, para. 98.

50 US Rejoinder, paras. 202-04. *But see* **Exhibit C-110**, Excerpt from FDA website, *Import Alert 66-40*, dated Oct. 2, 2009 (stating that it was published on September 30, 2009 for Signet and Etobicoke). The US does not explain why FDA's Import Alert states that it was published on September 30, 2009 if it was published before, and does not produce contemporaneous evidence of an earlier published import alert.

51 US Rejoinder, para. 201.

52 *See* Reply, paras. 121-33.

53 *See id.* at 59-71.

54 *Id.*, para. 176.

55 US Rejoinder, paras. 205-06.

56 *Id.*, para. 207.

shipments in question were made by Apotex-Canada on behalf of Apotex-US.[57] Apotex-US paid Apotex-Canada for the products and sold the products to the distributors.[58]

49. It is therefore no surprise that the US provides no record support for its statement that "the impact the Import Alert had on Apotex[-US] was no different, legally, from that felt by any of the many other U.S. companies that sought to receive drugs from Apotex[-Canada]'s Etobicoke and Signet facilities for sale in the United States."[59] There is no support. This is not what the record shows.

50. *Finally*, the US does not attempt to address Apotex's showing as to the pertinence of the *Cargill* award, which grappled with the NAFTA's "relating to" requirement in an analogous context. Instead, the US Rejoinder places heavy reliance on a commentary to Article 31 of the Draft Articles on State Responsibility.[60] Article 31 addresses a State's obligation to make full reparation for the injury, including material and moral damage, caused by an internationally wrongful act.[61] The commentary relied upon by the US states the time-worn proposition, dating from the *Alabama* cases, that indirect or remote damages may not be awarded.[62] While Apotex does not necessarily disagree with the proposition stated in the commentary, it is pertinent if at all only to the damages phase

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57 **Exhibit C-547**, Documents re: Drop Shipment to [redacted] dated Oct. 26, 2007 (FedEx delivery slip showing that shipment was shipped by Apotex-Canada to [redacted] Apotex commercial invoices stating: "Sold By: Apotex[-US]," "Distributed By: Apotex[-US]," "Sold To [redacted]." and "Ship To [redacted]."); **Exhibit C-548**, Documents re: Drop Shipment to [redacted], dated Oct. 26, 2007 (US Customs Form showing Apotex-US as "ultimate consignee." FedEx delivery slip showing that shipment was shipped by Apotex-Canada to [redacted]. Apotex commercial invoices stating: "Sold By: Apotex[-US]," "Distributed By: Apotex[-US]," "Sold To [redacted]" and "Ship To [redacted]"); **Exhibit C-549**, Documents re: Drop Shipment to [redacted]., dated Oct. 27, 2007 (FedEx delivery slip showing that shipment was shipped by Apotex-Canada to [redacted]. Apotex commercial invoice stating: "Sold By: Apotex[-US]," "Distributed By: Apotex[-US]", "Sold To [redacted]" and "Ship To [redacted]").

58 *See* Second Witness Statement of Gordon Fahner, paras. 33-35.

59 US Rejoinder, para. 208.

60 *Id.*, para. 200.

61 **Legal Authority CLA-502**, U.N., Int'l Law Comm'n, *Draft Articles on Responsibility of States for Internationally Wrongful Acts, with Commentaries*, art. 31, Supp. No. 10, U.N. Doc A/56/10 (Nov. 2001) ("1. The responsible State is under an obligation to make full reparation for the injury caused by the internationally wrongful act. 2. Injury includes any damage, whether material or moral, caused by the internationally wrongful act of a State.").

62 US Rejoinder, para. 200 (quoting **Legal Authority RLA-285**, U.N., Int'l Law Comm'n, *Draft Articles on Responsibility of States for Internationally Wrongful Acts, with Commentaries*, art. 31, para. 10 (2001)).

of this arbitration. It sheds no light on the content of "relating to" in NAFTA Article 1101(1), which must be determined in accordance with the principles of treaty interpretation stated in the Vienna Convention.[63]

51. The US shies away from the analysis required by the Vienna Convention because application of the principles of Article 31 of that Convention, as demonstrated in Apotex's Reply, compels the conclusion that the existence of the connection between measure and investment required by the substantive provisions of the NAFTA investment chapter necessarily is "legally significant" for purposes of Article 1101(1).[64] The sole response offered by the US to Apotex's showing is to characterize it as "circular," without addressing the points made by the Reply in anticipation of this very contention by the US.[65] The US argument is without merit.

D. The Record Establishes the Connection between Measure and Investment Contemplated by the Substantive Provisions at Issue

52. Nor is the US correct in suggesting that "the defects in Apotex's jurisdictional claims are confirmed, not repaired, by a review of its merits claims."[66] To the contrary, the record establishes the connection between measure and investor or investment required by Articles 1102, 1103 and 1105(1) of the NAFTA. This connection is "legally significant" for purposes of the "relating to" analysis of Article 1101(1).

53. In its Memorial, Apotex demonstrated that the US accorded less favorable treatment to Apotex and its investments than it did to comparable US- and third-country-owned investors and investments. In its Counter-Memorial, the US elected to present little to no evidence to support its arguments to the contrary, instead relying principally on (flawed) legal arguments.

54. The US Rejoinder attempts to correct the deficiency in its response to the Memorial by presenting for the first time evidence on a new proposed comparator, Pfizer, and

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63 **Legal Authority CLA-1**, NAFTA, art. 102(2) (The Parties shall interpret and apply the provisions of this Agreement in the light of its objectives set out in paragraph 1 and in accordance with applicable rules of international law.).

64 Reply, paras. 97-102.

65 US Rejoinder, para. 178. *See* Reply, para. 107.

66 US Rejoinder, para. 179.

evidence concerning Teva Jerusalem and the US-based comparators.[67] This tactic is without merit and should be dismissed for the two reasons discussed below: the late introduction of this evidence breaches the procedural rules applicable to this arbitration and materially prejudices Apotex, and in any event the new US contentions fail to rebut Apotex's showing that the requisite "legally significant connections" between measure and investment is met on this record.

1. The New US Evidence Is Inadmissible

55. The new materials presented by the US with its Rejoinder are inadmissible under the rules applicable to these proceedings. The procedural order agreed by the Parties provides that:

> In their second written submissions, the Parties shall include *only* additional written witness testimony, expert opinion testimony, documents or other evidence that responds to or rebuts matters raised by the opposing Party's *prior* written submission.[68]

56. The US suggestion that its new defenses respond to Apotex's Reply does not withstand scrutiny. The US Rejoinder attempts to excuse its introduction of Pfizer as a comparator by suggesting that "Apotex's own submissions highlight a U.S.-owned company, Pfizer, that meets Apotex's 'like circumstances' criteria."[69] It cites the Memorial and Reply in support.[70]

57. However, paragraph 315 of the Memorial (to which the US now refers)[71] does not address Pfizer. Rather, it addresses L. Perrigo Company, which like Apotex-US "sell[s] finished drug products … including those manufactured by Perrigo Company's

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67 *Id.*, paras. 232-33, 232 n.538, 265-66, 279.

68 First Procedural Order, para. 16(4) (emphasis added). *See also* ICSID Arbitration (Additional Facility) Rules, art. 38(3) ("A counter-memorial, reply or rejoinder shall contain an admission or denial of the facts stated in the last previous pleading; any additional facts, if necessary; observations concerning the statement of law in the last previous pleading; a statement of law in answer thereto; and the submissions."). *See also* **Legal Authority CLA-509**, *Von Pezold v. Republic of Zimbabwe*, ICSID Case No. ARB/10/25, Procedural Order No. 3, para. 48 (Jan. 11, 2013) (David A. R. Williams, Q.C., An Chen & L. Yves Fortier, Q.C. (President), arbitrators) (finding that defenses raised in rejoinder improperly responded to points asserted in memorial and therefore could be admitted only with special leave of tribunal).

69 US Rejoinder, para. 232 (footnote and citations omitted).

70 *Id.*, para. 232 n.533 (citations omitted) (arguing that Apotex "identif[ied] Pfizer").

71 *Id.*

subsidiaries in third countries."[72] Apotex did not "identify[]" Pfizer in the course of its discussion on Perrigo.[73] Rather, one of the legal authorities cited by Apotex was *Pfizer Inc. v. Perrigo Company*, where the court found that "several wholly-owned subsidiaries" of Perrigo Company "manufacture[d] and distribute[d] over-the-counter pharmaceuticals …" such that Perrigo Company was deemed to transact business in New York and to have subjected itself to the jurisdiction of New York courts.[74] This legal authority did not discuss Pfizer, other than the fact that Pfizer was suing Perrigo Company for patent infringement and unfair trade practices before the US District Court for the Southern District of New York.[75]

58. Similarly, the US cites to paragraph 147 of the Reply, which states that "Apotex-US … sells those products [supplied by Apotex-Canada] to various customers in the United States."[76] The accompanying supporting authority was introduced into the record by the US, not Apotex, and it does not address Pfizer at all.[77] The US contention that Apotex's Reply "highlight[ed]" Pfizer in the context of the discussion on "like circumstances" is baseless.[78]

59. With respect to Teva Jerusalem, Apotex's Reply introduced no new evidence and limited itself to a discussion of the evidence submitted with the US Counter-

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[72] Memorial, para. 315 (footnote and citations omitted).

[73] US Rejoinder, para. 232 n.533 (citations omitted).

[74] Memorial, para. 315 n.467 (citing **Legal Authority CLA-174**, *Pfizer Inc. v. Perrigo Co*., 903 F. Supp. 14, 15-16 (S.D.N.Y. 1995)).

[75] *See* **Legal Authority CLA-174**, *Pfizer Inc. v. Perrigo Co*., 903 F. Supp. 14, 15-16 (S.D.N.Y. 1995). Similarly, the US refers to paragraph 322 of the Memorial addressing Sandoz Inc., which like Apotex-US sells pharmaceutical products, including generic drugs. One of the legal authorities cited in support is **Legal Authority CLA-180**, *Sandoz Inc. v. Pfizer, Inc*., No. 09-cv-02457-CMA-MJW, 2010 WL 502727 (D. Colo. Feb. 8, 2010). This was again a patent infringement case where Sandoz was contesting the jurisdiction of the District of Delaware, although Sandoz had admitted, among others, that it was licensed to distribute pharmaceuticals in Delaware and was "in the business of making and selling generic pharmaceutical products for sale throughout the United States, including Delaware." *Id.* at *3.

[76] Reply, para. 147.

[77] *See* **Legal Authority RLA-92**, Declaration of Bernice Tao, *Pfizer Inc. v. Apotex Inc.*, No. 1:08-cv-00948 (LDD) (D. Del. Feb. 10, 2009) (not discussing Pfizer at all). Similarly, the US refers to paragraphs 199-200 of the Reply, discussing this same legal authority. *See* US Rejoinder, para. 232 n.533. As explained in the Reply, Pfizer sued Apotex-Canada and Apotex-US in Delaware for patent infringement concerning the brand-name drug Lipitor. Apotex challenged the jurisdiction of the courts of Delaware over Apotex-Canada and Ms. Tao submitted a declaration focusing exclusively on Apotex, not Pfizer. *See* Reply, paras. 199-200 (footnotes and citations omitted); **Legal Authority RLA-92**, Declaration of Bernice Tao, *Pfizer Inc. v. Apotex Inc.*, No. 1:08-cv-00948 (LDD) (D. Del. Feb. 10, 2009).

[78] US Rejoinder, para. 232 n.533 (citations omitted).

Memorial.[79] The US does not even attempt to justify its introduction of new evidence concerning a supposed potential shortage of medically necessary drugs excusing its different treatment of Teva's Jerusalem facility.[80] This evidence in no way responds to matters raised in Apotex's Reply. The US offers no justification for failing to present this evidence with the US Counter-Memorial.

60. Nor does the US attempt to justify its failure to present its new evidence on US-based comparators with its Counter-Memorial. In that pleading, the US relied purely on legal arguments as concerned US-based comparators (arguing that facilities located in the United States, because they cannot be placed on import alert, are not in like circumstances with Apotex). It did not, however, otherwise dispute that the selected comparators were in like circumstances[81] or received more favorable treatment than Apotex.[82] Apotex's Reply introduced no new evidence pertaining to US-based comparators. In its Rejoinder, the US now concedes that FDA did not "seek[] a court order to seize drugs or stop production at a domestic facility" of the selected comparators.[83] However, the US offers new evidence in support of its equally new contention that "FDA monitored and evaluated the circumstances with respect to Apotex's alleged comparators."[84] The new evidence submitted by the US, to the extent it is pertinent at all, responds to matters raised in Apotex's Memorial and, as such, should have been submitted with the US Counter-Memorial.

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79 Reply, paras. 28, 340-41, 344-47 (footnotes and citations omitted).

80 US Rejoinder, para. 279. Apotex specifically requested documents concerning application of the risk-based approach to Teva Jerusalem. *See* Claimants' Requests for Production of Documents, request 33(b) (Feb. 8, 2013). Drug shortage analysis is one out of four parts of the risk-based approach. *See* US Counter-Memorial, para. 337. The US objected on relevancy and deliberative process privilege grounds and the Tribunal upheld the US's objection (based on relevancy among other reasons). *See* Procedural Order on the Parties' Respective Requests for Document Production, at 16, para. 33, 33(b) (Mar. 29, 2013) ("[T]he Tribunal rejects this sub-request because the requested documentation is insufficiently shown to be relevant and material … ." (citation omitted)). Contrary to the US's current suggestion, Apotex therefore did not "receive[] numerous documents produced by the United States showing how FDA applied its risk-based approach to Teva's Jerusalem facility." *See* US Rejoinder, para. 279. In addition, the US should not be allowed to use its objections to document requests as a shield and as a sword. The US cannot invoke the deliberative process privilege and claim irrelevance to refuse to produce documents, and later partially submit purportedly "privileged" and "irrelevant" information when it suits the US's purposes.

81 Reply, para. 267.

82 *Id.*, paras. 353-75.

83 US Rejoinder, para. 265.

84 *Id.*

61. The US's tactic materially prejudices Apotex. Because the US introduced this material less than two months before the hearing, it deprived Apotex of any opportunity to test the US's contentions by seeking production of relevant documents, the disclosure phase having been completed months ago.[85] The US's tardy introduction of this material has left Apotex only three weeks to consider and prepare a response, rather than the months it would have had if the material had been introduced with the Counter-Memorial. Apotex therefore respectfully submits that the Tribunal should order that this evidence is inadmissible in accordance with Article 41(1) of the Arbitration (AF) Rules and Paragraph 16.4 of the First Procedural Order.

2. The New US Materials Do Not Rebut the "Legally Significant Connection" Established by the Record

62. Contrary to the US's contention, the new materials it offers on Teva, Pfizer and the US-based comparators in any event do not impact the analysis of whether a legally significant connection between measure and investment is present here.

a) Teva (Jerusalem)

63. The US Rejoinder offers new materials to support two propositions: medical necessity established by a drug shortage analysis justified its different treatment of Teva, and some Teva products may have been temporarily detained before being released. Neither withstands scrutiny.

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[85] *See* Claimants' Requests for Production of Documents (Feb. 8, 2013) (no document requests concerning Pfizer; no document requests concerning Teva Jerusalem's drug shortages; no document requests concerning Baxter, Hospira, L. Perrigo, or Sandoz Inc.'s two US facilities).

64. Article 25 of the Draft Articles on State Responsibility provides in pertinent part as follows:

> 1. Necessity may not be invoked by a State as a ground for precluding the wrongfulness of an act not in conformity with an international obligation of that State unless the act:
>
> (a) is the *only way* for the State to safeguard an essential interest against a grave and imminent peril; …
>
> …
>
> 2. In any case, necessity may not be invoked by a State as a ground for precluding wrongfulness if:
>
> …
>
> (b) the State *has contributed to the situation of necessity*.[86]

65. *First*, and as a preliminary matter, there is no dispute that Apotex and Teva were in like circumstances as concerns the FDA findings of cGMP violations at Teva's Jerusalem facility.[87] The violations were sufficiently severe at Teva Jerusalem that FDA initiated a recall of products produced by the facility.[88] While the US Rejoinder repeats its earlier references to a supposed "risk-based analysis" by FDA, the only justification for FDA's decision to grant Teva more favorable treatment supported by the new materials

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[86] **Legal Authority CLA-502**, U.N., Int'l Law Comm'n, *Draft Articles on Responsibility of States for Internationally Wrongful Acts, with Commentaries*, art. 25, Supp. No. 10, U.N. Doc A/56/10 (Nov. 2001) (emphasis added). *See also* **Legal Authority CLA-622**, *Gabčíkovo-Nagymaros Project* (Hun./Slovk.), 1997 I.C.J. 7, para. 57 (Sept. 25) ("[I]n the present case, even if it had been established that there was, in 1989, a state of necessity linked to the performance of the 1977 Treaty, Hungary would not have been permitted to rely upon that state of necessity in order to justify its failure to comply with its treaty obligations, as it had helped, by act or omission to bring it about."); **Legal Authority CLA-621**, *LG&E Energy Corp. v. Argentine Republic,* ICSID Case No. ARB/02/1, Decision on Liability, para. 256 (Oct. 3, 2006) ("It seems logical that if the State has contributed to cause the emergency, it should be prevented from invoking the state of necessity. If there is fault by the State, the exception disappears, since in such case the causal relationship between the State's act and the damage caused is produced.").

[87] Reply, paras. 334-35; US Rejoinder, paras. 276-81 (no challenge over the seriousness of the cGMP violations at Teva's Jerusalem facility).

[88] *See* Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 144; Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 14-15 (describing the circumstances warranting an FDA initiated recall). *See also* **Exhibit C-566**, FDA, Enforcement Report for Nov. 24, 2010 (showing a Class II recall initiated by letter of Sept. 22, 2010 for Teva Jerusalem's Tamoxifen Citrate Tablets due to overthick tablets (Recall # D-082-2011)); **Exhibit C-574**, FDA Internal Email Chain, dated Aug. 24, 2011, at US11068 (Email from Carmelo Rosa to Ilisa Bernstein et al., dated Aug. 23, 2011) ("[G]lass [was] found in the API produced at [Teva's] Jerusalem site.").

is medical necessity resulting from an alleged drug shortage analysis.[89]

66. *Second*, nothing in the new materials presented with the US Rejoinder justifies *permitting every one* of the scores of drugs produced at Teva Jerusalem to remain on the market while *banning* every one of the scores of drugs produced at Etobicoke and Signet save a single drug. The US has presented only two emails with its Rejoinder. It has not introduced the drug shortage analysis supposedly establishing the medical necessity upon which it relies. That analysis, if it existed, would presumably show the specific products that were medically necessary. It would also show the many products that were *not* medically necessary. The US failure to produce the analysis underscores the absence of any evidence suggesting that all of the scores of products fabricated at Teva Jerusalem were medically necessary.

67. FDA imposed the Import Alert on Apotex but excepted one product that it deemed medically necessary.[90] There can be no doubt that FDA had authority to adopt an import alert as to Teva Jerusalem that excluded any product that was medically necessary.[91] The record does not, and cannot, justify the more favorable treatment accorded to Teva.

68. The US Rejoinder, notably, suggests that there is relevant evidence supporting its position that it has not introduced into the record. It asserts that "Apotex received numerous documents produced by the United States showing how FDA applied its risk-based approach to Teva's Jerusalem facility."[92] In fact, in the totality of its document

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89 **Exhibit R-192**, FDA Internal Email Chain, dated Mar. 21, 2011, at US7100 (Email from Carmelo Rosa to Huascar Batista et al.) (noting that FDA was prepared to use enforcement discretion to allow import of Teva's violative drugs "on the basis of the shortage situation").

90 US Rejoinder, para. 274 ("Apotex further admits that it too shipped a medically necessary drug, deferiprone, to the United States for compassionate use, despite the Import Alert.") (footnote omitted). *See also* **Exhibit C-107**, Email from FDA to Apotex, dated Sept. 24, 2009 ("CDER/Office of Compliance will exercise regulatory discretion and therefore not object to Apotex's decision to release a predetermined minimal amount of deferiprone into US Interstate Commerce.").

91 *See, e.g.*, **Exhibit C-329**, Ranbaxy Dewas Warning Letter, WL 320-08-03, dated Sept. 16, 2008, at US432 ("While all shipments of articles manufactured at the Dewas site are subject to refusal of admission, under the circumstances FDA generally would not refuse shipments of Ganciclovir API. Because you are the sole source supplier of Ganciclovir API, FDA considers it important to maintain a sufficient supply of this drug product."). *See also* **Exhibit C-343**, Excerpt from FDA website, *List of Drugs Manufactured at the Dewas and Paonta Sahib Facilities of Ranbaxy Laboratories, Ltd.* (Dec. 3, 2009) (Ganciclovir exempted from import alert).

92 US Rejoinder, para. 279 (footnote and citation omitted).

production, the United States produced less than 62 documents containing the term "Teva." The vast majority of these documents, although they mention Teva, are simply not responsive.[93] Other documents are email chains in which the same email appears several times.[94] To dispel any illusion concerning produced documents that supposedly support the US case, Apotex with this submission includes all of the responsive documents concerning Teva Jerusalem.[95] Contrary to the US suggestion, the documents confirm that the US accorded far more favorable treatment to Teva than Apotex – for example, by accommodatingly "inspecting [Teva Jerusalem] into compliance" while advising Apotex that "FDA does not intend to serve as their QA/QC Unit, nor inspect them into compliance."[96]

69. In short, nothing in the new materials submitted by the US or produced in discovery suggests that allowing every one of the products made at Teva Jerusalem to remain on the market, regardless of their medical necessity, was "the only way for the State to safeguard an essential interest against a grave and imminent peril" within the meaning of Article 25(1)(a) of the Draft Articles on State Responsibility.[97] The more favorable

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93 *See, e.g.*, **Exhibit C-560**, FDA Internal Email Chains, dated July 6, 2009, at US12683; July 13, 2009, at US12986; July 21, 2009, at US10396; Aug. 3, 2009, at US10964; Aug. 4, 2009, at US12705, US12708; Aug. 4, 2009, at US12970; Mar. 9, 2011, at US11656 (Teva case assigned to specific team members but no analysis provided). *See also* **Exhibit C-561**, FDA Internal Email Chains, dated Aug. 5, 2009 ("Teva- any news on the HHE? Updates on telecon with DO?"); *id.*, dated Aug. 27, 2009 at US11754 ("Catherine – Any updates on Teva clonazepam or Ben Venue?").

94 *See, e.g.*, **Exhibit C-552**, FDA Internal Email, dated Mar. 4, 2009 (same email produced at US6927 and US7049) (attachments missing); **Exhibit C-554**, FDA Internal Email Chain, dated Mar. 5, 2009 (same chain produced at US12385 and US12142); **Exhibit C-556**, FDA Internal Email Chain, dated Mar. 23, 2009 (same chain produced at US7276 and US11772) (the only mention of Teva is in the last email in the chain) ("Please place special[]attention to Observation 2 keeping in mind that this firm [Novopharm] is also Teva, Ivax, Apotex related[.]"). *See also* **Exhibit C-555**, FDA Internal Email Chains, dated Mar. 20, 2009, Apr. 2, 2009, Apr. 3, 2009, undated (same email from Hidee Molina, dated Mar. 20, 2009 appearing at US7184-85, US7463-64, US6442-43, US6447-48, US6646); **Exhibit C-558**, FDA Internal Email Chains, dated June 19, 2009 (same market share analysis appearing at US11703-04, US12400-01, US12484-85).

95 The US document productions contained Teva Jerusalem's Form 483 and EIR for the 2010 inspection (the 51-page EIR was produced twice). These two documents have not been submitted into evidence since they do not add anything new to what was already stated about Teva Jerusalem's cGMP problems.

96 *Compare* **Exhibit C-574**, FDA Internal Email Chain, dated Aug. 24, 2011, at US11068 (Email from Carmelo Rosa to Ilisa Bernstein et al., dated Aug. 23, 2011) ("FDA has been *inspecting them into compliance* … ." (emphasis added)) *with* **Exhibit C-523**, FDA Internal Email Chain, dated Sept. 17, 2009, at US9807 (Email from Carmelo Rosa to Elizabeth Johnson, dated Sept. 16, 2009) ("During the recent meeting with Apotex we informed them that FDA does not intend to serve as their QA/QC Unit, *nor inspect them into compliance*." (emphasis added)).

97 **Legal Authority CLA-502**, U.N., Int'l Law Comm'n, *Draft Articles on Responsibility of States for Internationally Wrongful Acts, with Commentaries*, art. 25(1)(a), Supp. No. 10, U.N. Doc A/56/10 (Nov. 2001).

treatment accorded to Teva is unjustifiable on this ground alone.

70. *Third*, the record establishes that the US "has contributed to the situation of necessity" that it invokes to justify the more favorable treatment accorded to Teva and that therefore "necessity may not be invoked."[98]

71. The US Rejoinder itself recognizes that the Import Alert was in part responsible for the drug supply situation that existed in the first half of 2011:

> Teva has a very large market share for these products and acquired additional market share when CGMP issues occurred in recent years at other manufacturers making these drugs (Caraco, Ranbaxy, *Apotex*, Actavis, and KV).[99]

72. In fact, the record shows that the removal of drugs manufactured at Etobicoke and Signet from the US market was the principal contributor to Teva's "very large market share." Of these firms, in 2009 only Teva, Apotex, Actavis and Ranbaxy were among the top 25 generic producers. Teva was number 1, Apotex number 6, Actavis number 13 and Ranbaxy number 22 on the list.[100] At the time, FDA noted that Apotex had "significant market share for multiple products" and anticipated that Teva and others would be "able to ramp up" following the Import Alert.[101] FDA was right: by the end of the first quarter of 2011, Apotex had dropped to number 24, Actavis had risen to number 7, Ranbaxy ascended to number 15 and Teva remained number 1 but with almost double the amount of sales in dollars.[102] Of those mentioned by FDA as contributing to Teva's "very large market share," Apotex was the only one of the top 25 generic sellers on the US market that dropped in position during the Import Alert.

73. The Import Alert imposed by the US on Apotex thus substantially contributed to the

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98 *Id.*, art. 25(2).

99 US Rejoinder, para. 279 (emphasis added) (quoting **Exhibit R-131**, FDA Internal Email Chain, dated Feb. 25, 2011, at US11077 (Email from Valerie Jensen to Helen Saccone et al., dated Feb. 24, 2011)).

100 *See* **Exhibit C-181**, IMS Medical, Top 25 Generic Manufacturers (sales from June 30, 2008 to July 1, 2009).

101 **Exhibit C-502**, FDA Internal Email Chain, dated June 19, 2009, at US12400 (Email from Valerie Jensen to Michael Smedley et al., dated June 18, 2009).

102 *See* **Exhibit C-239**, IMS Medical, Top 25 Generic Manufacturers (2011).

situation of necessity invoked by the US.[103] Under established international law recognized in the Draft Articles on State Responsibility, the US Rejoinder's tardy invocation of necessity is without merit.

74. *Fourth*, the US Rejoinder errs in suggesting that "FDA officials feared that Teva Pharmaceutical would voluntarily shut down its Jerusalem facility … ."[104] To the contrary, the record demonstrates FDA's unequivocal understanding that "[t]he firm is not shutting down. … [W]e have no information that they intend to shut down the site."[105]

75. In sum, the record does not support the US Rejoinder's attempt to justify on grounds of medical necessity its decision to allow Teva to keep all of the products produced in its Jerusalem facility on the market while banning all but one of those produced in Apotex's Etobicoke and Signet facilities. The new materials submitted by the US concerning Teva Jerusalem in no way call into question the legally significant connection between measure and investment established in the Memorial and confirmed in the Reply.

b) Pfizer

76. The US Rejoinder offers new materials to support, again, two propositions with respect to Pfizer: first, that Pfizer is in like circumstances with Apotex for purposes of Article 1102; and second, that Pfizer was accorded treatment no more favorable than that accorded to Apotex. Neither proposition, again, withstands scrutiny.

77. *First*, the US Rejoinder errs in suggesting that Pfizer Injectables is an "investment" of Pfizer eligible to serve as a point of comparison under Article 1102. That article

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[103] US Rejoinder, para. 279**.**

[104] *Id*. (citing **Exhibit R-131**, FDA Internal Email Chain, dated Feb. 25, 2011, at US11076 (Email from Steven Lynn to Rick Friedman, dated Feb. 24, 2011) ("We'll be talking Teva [sic] at tomorrow afternoon's Drug Shortage Working Group meeting. … Beforehand I'll speak with Catherine to find out if there are already plans in the works to get them on the horn and tell them not to shut down.")); **Exhibit C-569**, FDA Internal Email Chain, dated Feb. 23, 2011, at US10878 (Email from Carmelo Rosa to Valerie Jensen et al.) ("There appears to be some confusion. The firm is initiated [sic] a recall of 23 lots of different products (but not all products in the market), and *continues to manufacture and release drug products*." (emphasis added)).

[105] **Exhibit R-131**, FDA Internal Email Chain, dated Feb. 25, 2011, at US11076 (Email from Carmelo Rosa to Rick Friedman).

requires a comparison of treatment "with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition *of investments*."[106] Pfizer Injectables is not an investment of Pfizer. It *is* Pfizer. It is a division of Pfizer.[107] It is not a subsidiary.[108]

78. Under the NAFTA, an investor is one who "seeks to make, is making or has made an investment."[109] The investor and the investment cannot be one and the same. Pfizer Injectables is not an investment of Pfizer and Pfizer is not an investor as concerns Pfizer Injectables. Treatment concerning Pfizer Injectables is not eligible for comparison under the ordinary meaning of the text of Article 1102.

79. *Second*, contrary to the US Rejoinder's suggestion, Aurobindo and Claris are not to Pfizer what Apotex-Canada is to Apotex-US. Aurobindo and Claris are *competitors* of Pfizer, as illustrated by patent litigation between them.[110] There is no shared commitment between them to long-term supply or development of a customer base in the US, as demonstrated by Pfizer's termination of its limited relationship with Claris just a few years after it began (and after the Claris import alert was lifted).[111] Pfizer has

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106 **Legal Authority CLA-1**, NAFTA, art. 1102 (emphasis added).

107 **Exhibit C-585**, Excerpts from Pharmacy Practice News website, *Corporate Profiles 2010: Pfizer Injectables*, *available at* http://www.pharmacypracticenews.com/ppncp/0810/content/ppn0810profiles_009a.html?page name=Pfizer_Injectables_Corporate_Profile (last visited on Oct. 08, 2013) ("Launched in 2009, Pfizer Injectables, a division of Pfizer Inc … ."); **Exhibit C-578**, Pfizer Injectables Press Release, *Pfizer Injectables Adds Methotrexate Injection, USP to Its Portfolio of Off-Patent Oncology Products* (Sept. 19, 2012), *available at* http://www.pfizerinjectables.com/sites/default/files/news_press_release/USI494416-01%20Methotrexate%20Press%20Release.pdf ("Pfizer Injectables, part of Pfizer Inc.'s … Established Products Business Unit … .").

108 **Exhibit R-218**, Pfizer Inc., Annual Report (Form 10-K), at Exhibit 21 to Pfizer 2012 Financial Report (Feb. 28, 2013) (Pfizer Injectables not listed on the list of "Subsidiaries of the Company").

109 **Legal Authority CLA-1**, NAFTA, art. 1139.

110 *See, e.g.*, **Legal Authority CLA-624**, Complaint, *Pfizer Inc. v. Aurobindo Pharma Ltd.*, No. 1:11-cv-00569-UNA (D. Del. June 27, 2011); **Exhibit C-575**, Excerpt from Patent Docs website, *Pfizer Settles Lipitor Patent Suits with Aurobindo, Kremers* (Nov. 23, 2011), *available at* http://www.patentdocs.org/2011/11/biotechpharma-docket html (stating that Pfizer sued Aurobindo for patent infringement due to Aurobindo filing an ANDA application for Pfizer's Lipitor). *See also* **Exhibit C-417**, Excerpt from FDA website, *Public Health Alert: Healthcare Professionals Warned Not to Use Certain Intravenous Metronidazole, Ondansetron, and Ciprofloxacin Due To Potential Contamination*, dated June 1, 2010 (stating that Claris products were sold in the United States under the Claris and Pfizer labels, among others).

111 *See* **Exhibit C-576**, Excerpt from The Economic Times website, *Pfizer Ends Supply Deal with Claris Lifesciences* (Aug. 24, 2012), *available at* http://articles.economictimes.indiatimes.com/2012-08-24/news/33366786_1_claris-lifesciences-claris-shares-pfizer; **Exhibit C-577**, Excerpt from Business Standard website, *Claris to Go Alone in US Post Termination of Deal with Pfizer* (Aug. 27, 2012), *available at* http://www.business-standard.com/article/companies/claris-to-go-alone-in-us-post-termination-of-deal-

no incentive to give value to the ANDAs of Aurobindo or Claris.

80. By contrast, Apotex-Canada and Apotex-US are part of a vertically-integrated corporate group. Apotex-Canada invests millions every year in identifying new business opportunities and opening up the US generic drug market through patent litigation.[112] It also invests millions in developing new generic drugs, as well as preparing, filing and maintaining ANDAs with the FDA. Apotex's investments in Apotex-US have built it into a highly successful business.[113] Apotex-US collaborates in Apotex-Canada's decisions as to which products to develop for the US market, when to launch the products, how to sell them and at what price. Their close collaboration ensures long-term supply and seamless delivery to Apotex-US's customers.

81. The short-term, limited licensing arrangements between competitors[114] that the US relies upon are in no sense like the relationship between Apotex-Canada and Apotex-US, which prior to the Import Alert depended on Apotex-Canada for 80% of its supply.[115]

82. It is for this reason that, from the outset of this arbitration, Apotex has maintained that an appropriate comparator would be one that "owns or controls, directly or indirectly, a business in the United States that distributes and markets *its* products, *just like Apotex-US does for Apotex*."[116] The US does not attempt to justify its effort to broaden the net to include a business model focusing on distributing products of competitors. It is without merit.

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with-pfizer-112082700019_1 html (Claris will no longer supply the US through any of its partners including Pfizer, West-Ward Pharmaceuticals Inc. and Sagent but, rather, "Claris will sell on its own through its [US] subsidiary Claris Lifesciences Inc.").

112 Memorial, para. 41.

113 *Id.*, para. 40 ("In the second quarter of 2009, Apotex-US had the sixth-highest sales of any generic drug company in the United States."). *See also* **Exhibit C-181**, IMS Medical, Top 25 Generic Manufacturers (sales from June 30, 2008 to July 1, 2009) (in comparison, Pfizer's Greenstone then ranked 11th).

114 In the US's own words, Aurobindo and Claris are "Pfizer licensing and supply partner[s][.]" US Rejoinder, para. 232 n.538. *See* **Exhibit C-553**, Excerpt from The Economic Times website, *Pfizer, Aurobindo Ink Marketing Deal* (Mar. 4, 2009), *available at* http://articles.economictimes.indiatimes.com/ 2009-03-04/news/28398344_1_aurobindo-pharma-ink-marketing-deal-zoloft ("Aurobindo will manufacture the products and [Pfizer] will be responsible for the marketing[.]").

115 Memorial, para. 1 (80% of Apotex-US supply came from Etobicoke and Signet (not including supply from Apotex's Richmond Hill and Bangalore facilities)). *See also id.*, para. 46 ("Before the Import Alert, Apotex-US depended principally on Apotex-Canada for supplies.").

116 *Id.*, para. 446 (emphasis added); Reply, para. 270 (same quote).

83. *Third*, assuming that Claris and Aurobindo could be to Pfizer what Apotex-Canada is to Apotex-US (which is clearly not the case), the Claris and Aurobindo facilities at issue are not in like circumstances with those at Etobicoke and Signet.

84. Claris's cGMP violations presented a clear health hazard in a manner that those identified by FDA at Etobicoke and Signet clearly did not.[117] Supposedly sterile intravenous bags produced at the Claris facility were contaminated with fungus, as reported in several complaints from Claris customers, including Pfizer.[118] FDA observed that "at least eight batches of two products" were found contaminated with fungus.[119] As a result, FDA issued a public health alert for three drugs manufactured by Claris and distributed in the United States.[120] In contrast, in the case of Apotex, FDA never issued a public heath alert.[121]

85. With respect to Aurobindo's Indian facilities, FDA inspected Unit III, which produces oral solid dose products, as well as Unit VI, a facility that manufactures cephalosporin

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[117] Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 19-23.

[118] **Exhibit R-190**, Claris Warning Letter, WL 320-11-003, dated Nov. 1, 2010, at 2, item 3 ("[Y]our customer (Pfizer) reported that Metronidazole Injection USP IV bags … were contaminated with fungi … and Gram positive bacteria … ."). *See also* **Exhibit C-565**, Excerpt from Pharmalot website, *Claris Receives Import Alert over Contaminants* (Nov. 10, 2010), *available at* http://www.pharmalive.com/claris-receives-import-alert-over-contaminants.

[119] **Exhibit R-190**, Claris Warning Letter, WL 320-11-003, dated Nov. 1, 2010, at 3, item 6(b).

[120] **Exhibit C-417**, Excerpt from FDA website, *Public Health Alert: Healthcare Professionals Warned Not to Use Certain Intravenous Metronidazole, Ondansetron, and Ciprofloxacin Due To Potential Contamination*, dated June 1, 2010. FDA had already inspected Claris's Indian facility in November 2009 and issued a Form 483. Following customer complaints about fungus observed in Claris's products, FDA issued a public health alert on June 1, 2010. Claris was put on import alert on June 3, 2010. *See* **Exhibit R-202**, Excerpt from FDA website, Import Alert #66-40 (last updated on Oct. 18, 2011). On June 5, 2010, FDA re-inspected Claris's Indian facility and issued a warning letter on November 1, 2010. *See* **Exhibit R-190**, Claris Warning Letter, WL 320-11-003, dated Nov. 1, 2010.

[121] *See* Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 19 (noting that "FDA's actions, and more specifically, its inaction, at the time of the inspections belie" the US's overstated potential public health risks caused by Apotex's drugs). *See also id.*, para. 11 (listing the tools FDA has to address health risks, including "issuance of a Public Health Advisory or a Healthcare Provider Advisory"); *id.*, para. 22 (listing all of the actions FDA did and did not take indicating it did not believe there was a public health risk). *Accord* Expert Report of William W. Vodra, para. 11 ("The argument ignores legislative history showing that Congress explicitly eliminated any need to show product defects, and thus consequential harm, before enforcing cGMP requirements; … The argument incorrectly assumes that the absence of evidence of injuries constitutes evidence that there were no such injuries … ."); *id.*, para. 20 (noting that "[n]oncompliance with cGMP requirements **always** implicates the safety and effectiveness of drugs, regardless of whether a consumer has already been injured[,]" even though FDA did not take equivalent enforcement action against comparators' drugs who were not in cGMP compliance (emphasis in original)).

active pharmaceutical ingredient (API) and cephalosporin finished drug products.[122] Unit III was not placed on import alert; only Unit VI – the one producing cephalosporin API and sterile products – was.[123]

86. Manufacturing processes for APIs and finished drug products are materially different, and there are no cGMP standards for the manufacture of API.[124] For this reason, Apotex excluded from potential comparators those whose facilities at issue produced API. Aurobindo's Unit VI is not comparable with Etobicoke and Signet, which exclusively produce finished drug products. It is not like those facilities.

87. *Fourth*, the treatment accorded Pfizer was in any event more favorable than that accorded Apotex. As reported by Pfizer, the Aurobindo import alert only impacted five solid dose products manufactured by Aurobindo for Pfizer's Greenstone.[125] By contrast, the Import Alert imposed on Apotex covered all products manufactured at Etobicoke and Signet by Apotex-Canada for Apotex-US, accounting for 80% of Apotex-US's supply.

88. Because of the Import Alert, Apotex dropped from the 6th to the 25th position on the US generic drug market.[126] Greenstone's market ranking was unaffected by the import alert imposed on Aurobindo.[127]

89. According to a press release included in the new US materials, Claris manufactured 15

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122 *See* **Exhibit R-197**, Aurobindo Warning Letter, WL 320-11-013, dated May 20, 2011.

123 **Exhibit R-202**, Excerpt from FDA website, *Import Alert #66-40*, at 16 (last updated on Oct. 18, 2011) (listing "Aurobindo Pharma Limited Unit VI, Cephalosporin" (date published: Feb. 7, 2011, Feb. 28, 2011, March 1, 2011)).

124 When inspecting API facilities, FDA uses a guidance document for cGMPs for APIs. *See* **Legal Authority CLA-625**, FDA, *Guidance for Industry*, *Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* (Aug. 2001). As a result, warning letters concerning the manufacture of API typically do not contain any references to Parts 210 and 211 of Title 21 of the Code of Federal Regulations codifying the cGMP requirements applicable to finished pharmaceuticals. *See, e.g.*, **Exhibit C-567**, Synbiotics Warning Letter, WL 320-11-06, dated Dec. 16, 2010.

125 **Exhibit C-570**, Excerpt from Automated Trader website, *Pfizer Sees US Ban on Aurobindo's Facility Hitting Some Supplies* (Feb. 28, 2011), *available at* http://www.automatedtrader.net/real-time-dow-jones/49181/update-pfizer-sees-us-ban-on-aurobindo039s-facility-hitting-some-supplies ("Five … products – cefadroxil, cefidinir, cefprozil, cefprozil for oral Suspension and cefuroxime axetil – for supply to Pfizer's generics unit Greenstone LLC have … been affected by the ban[.]").

126 Reply, para. 141.

127 **Exhibit C-550**, Apotex, Top 25 Generic Rankings Based on IMS Data (2008-2012).

drugs for distribution by Pfizer around the world.[128] However, it seems that Pfizer was only marketing three of these drugs for sale in the United States (Ciprofloxacin, Metronidazole and Ondansetron).[129] The Claris import alert, therefore, affected only three injectable products distributed in the United States by Pfizer Injectables. Similarly, the import alert imposed on Aurobindo's Unit VI affected only four injectable products distributed in the United States by Pfizer Injectables.[130] Again, this cannot compare in scope or scale to the devastating impact the Import Alert had on Apotex-US's business.[131]

c) US-Based Comparators

90. The US Rejoinder offers new evidence on Baxter, L. Perrigo, Hospira, Sandoz Inc. and Teva Parenteral.[132] However, the US evidence fails to rebut the showing that the Import Alert related to Apotex-US. None of the US's new evidence justifies the markedly less favorable treatment accorded to Apotex.

91. The US argues that FDA did not need to take enforcement action against the US-based comparators because they either: recalled products;[133] took expensive corrective

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[128] **Exhibit R-147**, Pfizer Press Release, *Pfizer Expands its Generics Portfolio Through Innovative Licensing Deals, Increasing Access to Medicines for Billions Worldwide* (May 19, 2009) ("Pfizer has acquired rights to 15 injectable products" made by Claris).

[129] After checking the FDA drug labels for all ANDAs held by Claris listed in the Orange Book, it turns out that Pfizer had labels for only three products manufactured by Claris, therefore only these three products were distributed in the United States by Pfizer. *See* **Exhibit C-562**, Excerpt from FDA Label for Pfizer Ciprofloxacin (Sept. 2009) (listing Claris as manufacturer); **Exhibit C-563**, Excerpt from FDA Label for Pfizer Metronidazole (Jan. 2010) (listing Claris as manufacturer); **Exhibit C-564**, Excerpt from FDA Label for Pfizer Ondansetron (Apr. 2010) (listing Claris as manufacturer). *See also* **Exhibit C-417**, Excerpt from FDA website, *Public Health Alert: Healthcare Professionals Warned Not to Use Certain Intravenous Metronidazole, Ondansetron, and Ciprofloxacin Due To Potential Contamination*, dated June 1, 2010 (alert for these three Claris products distributed by Pfizer in the United States). Claris is the holder of the ANDAs for these three products. *See* **Exhibit C-579**, Excerpts from Orange Book, at 3-96, 3-288, 3-319 (33rd ed. 2013).

[130] **Exhibit C-571**, Excerpt from Bloomberg website, *Pfizer to Work With Supplier After U.S. Restricts Imports* (Mar. 4, 2011), *available at* http://mobile.bloomberg.com/news/2011-03-04/pfizer-to-work-with-aurobindo-after-u-s-restricts-drug-imports.html ("In the Aurobindo case, the alert affects four of Pfizer's injectable antibiotics and five products sold to Pfizer's Greenstone LLC generic-drug subsidiary, [Pfizer Inc.] said.").

[131] The US mentions in a footnote that Pfizer's Italian subsidiary, Wyeth Lederle, S.p.A. ("Wyeth Italy"), received a warning letter for its facility in Catania on Mar. 27, 2013. *See* US Rejoinder, para. 232 & n.538. *See also* **Exhibit R-220**, Wyeth Italy Warning Letter, WL 320-13-10, dated Mar. 27, 2013. The US took no enforcement action against Wyeth Italy and presents no argument as to its receiving treatment no more favorable than that accorded to Apotex.

[132] US Rejoinder at 135-37.

[133] *Id.* at 135 (Baxter).

actions;[134] changed leadership;[135] slowed down production lines or temporarily shut down facilities despite producing medically necessary drugs.[136]

92. None of these contentions withstands scrutiny. Like Baxter, Apotex recalled products in September 2009.[137] Like the US-based comparators, Apotex took expensive corrective actions.[138] Like Sandoz Inc., Apotex changed its leadership for quality.[139] However, the US – unlike all these others – afforded Apotex no opportunity to slow down or shut down production because it was immediately put on Import Alert. The Signet Inspection closed on Friday, August 14, 2009. On the following Monday, Apotex was required to call FDA. Apotex had not a single working day to consider its response and obtain the considered advice of experts as to what FDA's expectations might be or to prepare a detailed plan of corrective actions to present. FDA did not inform Apotex of its expectations during the call on Monday, August 17, 2009.[140] In other words, unlike the comparators, the US accorded Apotex no opportunity to prepare and present corrective actions before it was placed on Import Alert.[141]

93. In sum, the new materials introduced by the US as to Teva Jerusalem, Pfizer and the comparators' domestic facilities in no way refute the showing in Apotex's submissions that the connection between measure and investment contemplated by Articles 1102 and 1103 is present here. That connection is, as Apotex has previously demonstrated, legally significant for purposes of Article 1101(1). The US objection on "relating to" grounds should be dismissed.

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134 *Id.* (Baxter, Perrigo); *id*. at 136 (Hospira); *id*. at 137 (Sandoz Inc., Teva Parenteral).

135 *Id.* at 137 (Sandoz Inc.).

136 *Id.* at 136 (Hospira); *id*. at 137 (Sandoz Inc., Teva Parenteral). Note that the US did not produce any evidence about which drugs were medically necessary and allegedly affected by the firms' voluntary production slowdown or temporary shutdown.

137 Memorial, para. 193; Reply, para. 46(b).

138 Memorial, para. 217 & n.307. *See, e.g.*, **Exhibit R-207**, Excerpt from FiercePharma Manufacturing, *Hospira Says Temporary Production Glitch Affecting Propofol Supplies* (May 3, 2012).

139 Memorial, para. 241.

140 *See* **Exhibit R-43**, FDA, Minutes of Teleconference with Apotex, dated Aug. 17, 2008. *See also* First Witness Statement of Jeremy Desai, para. 48.

141 Memorial, paras. 12, 450-451.

II. APOTEX-CANADA'S MARKETING AUTHORIZATIONS ARE COVERED INVESTMENTS

94. The US Rejoinder misplaces its reliance on the *Apotex I&II* award, which did not decide the issues before this Tribunal. It fails to respond to the bulk of Apotex's arguments in this case under Articles 1139(g) and 1139(h) of the NAFTA. The arguments that it does make are without merit, as demonstrated below.

A. *Apotex I&II* Did Not Decide the Issues Before this Tribunal

95. The US Rejoinder founds its arguments concerning Articles 1139(g) and 1139(h) on the proposition that the *Apotex I&II* award decided the issues presented here and is *res judicata*. That proposition is without support.

96. *First*, as a preliminary matter, Apotex agrees with the US that this Tribunal must decide the binding effect of a prior NAFTA award pursuant to NAFTA Article 1131(1): "A Tribunal established under this Section shall decide the issues in dispute *in accordance with this Agreement* and applicable rules of international law."[142] The binding effect of a NAFTA award thus must be determined under the NAFTA and international law.

97. The NAFTA specifically addresses the binding effect of investment-chapter awards in Article 1136(1). It provides as follows:

> An award made by a Tribunal shall have no binding force except between the disputing parties *and in respect of the particular case*.[143]

98. The treaty text is clear: the *Apotex I&II* award is binding between Apotex-Canada and the US, but only in respect of that case. It is not binding as concerns this one.

99. The US, in a footnote, acknowledges the pertinence of Article 1136(1), notes (correctly) that identical language appears in the ICJ Statute and observes (also correctly) that the

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[142] **Legal Authority CLA-1**, NAFTA, art. 1131(1) (emphasis added). *See* US Rejoinder, para. 100 ("*Res judicata* – which applies to these proceedings pursuant to NAFTA's governing law provision – is a well-established general principle of international law." (citing **Legal Authority CLA-1**, NAFTA, art. 1131(1))).

[143] **Legal Authority CLA-1**, NAFTA, art. 1136(1) (emphasis added). *See also* US Rejoinder, para. 100 n.223 ("[T]he language simply 'makes clear that the rule of *stare decisis* does not apply to awards rendered under Chapter 11.'" (quoting **Legal Authority RLA-288**, Meg N. Kinnear, Andrea K. Bjorklund, & John F.G. Hannaford, *Investment Disputes under NAFTA: An Annotated Guide to NAFTA Chapter 11, Article 1136 – Finality and Enforcement of an Award*, at 1136-3 (Mar. 2008 Supplement))).

ICJ "has recognized the binding force and *res judicata* effect of its decisions in subsequent cases."[144] The US fails, however, to note that the binding force recognized by the ICJ is precisely that contemplated by the ICJ Statute and NAFTA Article 1136(1). As Professor Vaughan Lowe observes in an article relied upon by the US Rejoinder, "there are three conditions for the application of the principle of *res judicata*. They are: identity of parties; identity of cause; and identity of object (or subject matter) in the subsequent proceedings."[145] The triple-identity test for *res judicata*, as it is known, is the accepted standard in international law for determining the binding effect of a prior decision.[146] Because here the object and the cause as well as one of the parties are different, the triple-identity test is not satisfied. The US argument fails as a matter of established international law.

100. Indeed, the US Rejoinder acknowledges that its argument hinges on the proposition that in international law "*res judicata* … includes the principle of issue estoppel[.]"[147] Issue estoppel or issue preclusion is a common-law concept not followed in international law.[148] As stated by Professor Lowe, "[t]here does not appear to be any explicit decision of a prominent international tribunal on the question of issue estoppel."[149]

101. The US misplaces its reliance on the two authorities it cites specifically for the

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144 US Rejoinder, para. 100 n.223.

145 **Legal Authority RLA-295**, Vaughan Lowe, *Res Judicata and the Rule of Law in International Arbitration*, 8 Afr. J. Int'l & Comp. L. 38, 40 (1996).

146 *See* **Legal Authority CLA-623**, *Trail Smelter Case* (U.S. v. Can.), 3 R.I.A.A. 1938, 1952 (Mar. 11, 1941) ("There is no doubt that in the present case, there is *res judicata***.** The three traditional elements for identification: parties, object and cause are the same." (citations omitted)); **Legal Authority CLA-620**, *CME Czech Republic B.V. v. Czech Republic*, UNCITRAL, Final Award, para. 435 (Mar. 14, 2003) ("The principle of res judicata requires, for the 'same' dispute, identical parties, the same subject matter and the same cause of action. This is accepted by international tribunals."). *See also* **Legal Authority CLA-630**, Shabtai Rosenne, *Res Judicata: Some Recent Decisions of the International Court of Justice*, 28 British Y.B. Int'l L. 365, 366 (1951) ("[T]he essential conditions for the existence of a *res judicata* [are] the existence of a final judgment together with identity of parties, identity of cause, and identity of object in the subsequent proceedings.").

147 US Rejoinder, para. 99.

148 *See, e.g.*, **Legal Authority RLA-295**, Vaughan Lowe, *Res Judicata and the Rule of Law in International Arbitration*, 8 Afr. J. Int'l & Comp. L. 38, 42 (1996) ("[The English] requirements for issue estoppel have the same effect as the classical international law requirements for *res judicata*, minus the requirement of identity of cause.").

149 *Id.* Professor Lowe suggests that the tribunal in the resubmitted case in *AMCO v. Indonesia* applied principles of issue estoppel. *Id.* In that instance, however, it was the very same case and the triple-identity test was met; the novelty of the decision was that the prior award had been annulled, not that identity of object or cause was lacking.

proposition that issue estoppel is recognized in international law. The umpire in the *Company General of the Orinoco* case was not asked to apply international law, but to "decide all claims upon a basis of *absolute equity* without regard to objections of a technical nature, or of the provisions of local legislation."[150] In justifying his equitable decision, the umpire made a passing reference to a US Supreme Court decision applying the common-law notion of issue estoppel.[151] It speaks volumes that the US must resort to a reference of this nature to justify its position on issue estoppel.

102. The US Rejoinder's reliance on recommendations in an International Law Association ("ILA") report is similarly to no avail, for two reasons.[152] First, the ILA recommendations set forth proposals for principles of *res judicata* in international *commercial* arbitration. They expressly declined to address investment treaty arbitrations "because they pertain more to public international law than to international commercial arbitration or at least to the hybrid legal order of BIT arbitrations."[153] The recommendations do not address the rules of public international law applicable here. Second, even with respect to the principles of international commercial arbitration they do address, the recommendations merely reflect the views of a certain number of scholars on how applicable law might progressively be developed and are *de lege ferenda*.[154] They do not address the law as it exists, but rather as how it should be imagined.

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150 **Legal Authority CLA-619**, *Mixed Claims Commission Protocol*, Fr.-Venez., art. I, Feb. 27, 1903, 10 R.I.A.A. 3, 3 (emphasis added) ("The Commissioners, or in case of their disagreement, the umpire, shall decide all claims upon a basis of absolute equity without regard to objections of a technical nature, or of the provisions of local legislation.").

151 **Legal Authority RLA-267**, *Company General of Orinoco Case*, (Fr. v. Venez.), 10 R.I.A.A. 184, 276 (Fr.-Venez. Mixed Claims Comm'n July 31, 1905) (citing *S. Pac. R. Co. v. United States*, 168 U.S. 1 (1897) (note that the citation provided by the umpire to Supreme Court Reports is in error; the reference should be to the official US Supreme Court reporter).

152 US Rejoinder, paras. 102-03 (citing **Legal Authority RLA-282**, Int'l Law Ass'n, Res. No. 1/2006, Annex 2, *Recommendations on* Res Judicata *and Arbitration*, recommendations 4.1, 4.2 (June 4, 2006)).

153 **Legal Authority RLA-284**, Int'l Law Ass'n, *Final Report on* Res Judicata *and Arbitration*, para. 36 & n.108 (2006) ("The Recommendations do not address [issues related to investment arbitration] because they pertain more to public international law than to international commercial arbitration or at least to the hybrid legal order of BIT arbitrations" and because "the ILA Committee on Law of Foreign Investment is studying res judicata of BIT awards." Accordingly, they have only "some indirect relevance for BIT arbitrations.").

154 *See id.*, para. 6 (noting that "transnational rules can be developed" regarding *res judicata* in international commercial arbitration). *See also id.*, para. 24 (The ILA Committee acknowledges the existence of differences between the various legal systems in this area and states that the purpose of the recommendations is "whether and to what extent" to propose uniform rules which "should be developed to the benefit of international commercial arbitration.").

103. Thus, no authority supports the US proposition that issue estoppel forms part of public international law today. Neither the NAFTA provision expressly addressing the effect of previous NAFTA awards nor international law more generally supports the conclusion that *Apotex I&II* precludes this Tribunal from addressing the issues before it.[155]

104. However, even if the US Rejoinder were correct and issue estoppel was relevant (which it is not), a different conclusion would not be called for. For issue estoppel to apply, the issue of fact or law in question must have been "*actually litigated and determined* by a valid and final judgment, *and the determination … essential to the judgment* … ."[156]

105. The issue before the *Apotex I&II* tribunal was whether mere applications for an authorization to market drugs could constitute an "investment" under the NAFTA, even though the applications had not yet been finally approved.[157] The tribunal was not called upon to decide, and it did not decide, whether finally approved marketing authorizations were investments. Whatever the merit of its decision on the status of

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[155] The US also cites two ICJ cases as supposedly applying the principle of issue estoppel. *See* US Rejoinder, para. 101 & n.226 (citing **Legal Authority RLA-273**, *Land and Maritime Boundary Between Cameroon and Nigeria* (Nig. v. Cam.), Request for Interpretation of Judgment, 1999 I.C.J. 31 (Mar. 25); **Legal Authority RLA-264**, *Application of Convention on Prevention and Punishment of Crime of Genocide* (Bosn. & Herz. v. Serb. & Mont.), 2007 I.C.J. 43 (Feb. 26)). However, each of these cases addressed the *res judicata* effect of a prior judgment in the same case between the same parties concerning the same issues; none presents a context in which issue estoppel was or could have been applied. *See* **Legal Authority RLA-273**, *Land and Maritime Boundary Between Cameroon and Nigeria* (Nig. v. Cam.), Request for Interpretation of Judgment, 1999 I.C.J. 31 (Mar. 25) (addressing request for interpretation of a judgment in the same case and between the same parties); **Legal Authority RLA-264**, *Application of Convention on Prevention and Punishment of Crime of Genocide* (Bosn. & Herz. v. Serb. & Mont.), 2007 I.C.J. 43, para. 84 (Feb. 26) ("Both Parties recognize that each of these Judgments has the force of *res judicata* in the specific case for the parties thereto; but they also recognize that these Judgments, not having been rendered in the present case, and involving as parties States not parties to the present case, do not constitute *res judicata* for the purposes of the present proceedings."); *id.*, para. 115 ("That principle [*res judicata*] signifies that the decisions of the Court are not only binding on the parties, but are final, in the sense that they cannot be reopened by the parties as regards the issues that have been determined … .").

[156] **Legal Authority RLA-292**, American Law Institute, *Restatement of the Law (Second) – Judgments* § 27 (1982) ("When an issue of fact or law is *actually litigated and determined* by a valid and final judgment, *and the determination is essential to the judgment*, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim." (emphasis added)).

[157] **Legal Authority RLA-263**, *Apotex Inc. v. United* States, NAFTA/UNCITRAL, Award on Jurisdiction and Admissibility, para. 15 (June 14, 2013) ("The Sertraline Claim arises out of three decisions of the US Federal Courts in relation to Apotex's *application* seeking FDA approval for a generic version of a drug manufactured by Pfizer Inc., called 'Zoloft®'[.]" (emphasis added)); *id.*, para. 16 ("The Pravastatin Claim arises out of a decision of the FDA, and three decisions of the US Federal Courts, in relation to Apotex's new drug *application* seeking FDA approval for a generic version of a drug manufactured by Bristol Myers Squibb, called 'Pravachol®'[.]" (emphasis added)).

applications,[158] the status of marketing authorizations was not "actually litigated and determined" and certainly no determination on that topic in *Apotex I&II* could be "essential to the judgment."

106. In sum, *Apotex I&II* addressed whether applications for approval of two products could be considered property under Article 1139(g) in the context of decisions by courts and the FDA concerning those applications. It did not address whether marketing authorizations concerning scores of other products can be considered investments under Article 1139(g) and 1139(h) in the context of an Import Alert that prevented marketing of the products that were authorized. *Apotex I&II* is binding "in respect of the particular case" presented to that tribunal. It does not prevent this Tribunal from addressing the issues before it.

B. Apotex-Canada's Marketing Authorizations Are Property

107. Rather than respond to the points made in Apotex's Reply on marketing authorizations as property, the US Rejoinder erroneously relies on the *Apotex I&II* award as having decided the issue and studiously avoids joining issue even with those points it does consider.

108. *First*, the fact that it was dealing with applications to market drugs rather than approved marketing authorizations was central to the tribunal's reasoning in *Apotex I&II*. The US attempts to blur this distinction by addressing its argument to "ANDAs," but even the portions of the award that it quotes make clear that *Apotex I&II* addressed only the interest before it: applications, not marketing authorizations.[159]

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[158] *Id.*, para. 195 ("The Tribunal is persuaded by the Respondent's submission that allowing a mere *application* for regulatory clearance to export goods into the United States to give rise to an '*investment*' claim under Chapter Eleven would be inconsistent with the core objectives of NAFTA's investment chapter." (first emphasis added)). *But cf.* **Legal Authority CLA-91**, *Anheuser-Busch Inc. v. Portugal* [GC], No. 73049/01, ECHR 2007-I, para. 78 (Jan. 11, 2007) ("These elements taken as a whole suggest that the applicant company's legal position as an applicant for the registration of a trade mark came within Article 1 of Protocol No. 1, as it gave rise to *interests of a proprietary* nature. … The applicant company therefore *owned a set of proprietary rights* – linked to its *application* for the registration of a trade mark – that were recognized under Portuguese law, even though they could be revoked under certain conditions." (emphasis added)).

[159] US Rejoinder, para. 3 (quoting **Legal Authority RLA-263**, *Apotex Inc. v. United States*, NAFTA/UNCITRAL, Award on Jurisdiction and Admissibility, para. 358(a) (June 14, 2013) (note that the US mistakenly cites to para. 358(a) but the quoted passage is actually located in para. 207 of the decision))

109. As Apotex demonstrated in its Reply, there is a fundamental difference between the contingent interest created by an application for approval and the unconditional interest reflected in an approved marketing authorization.[160] The US does not attempt to address this difference. Instead, it again resorts to rhetoric rather than substance, arguing in error that a passing suggestion in *Apotex I&II* of a "distinction without a difference" amounts to a "concession" by Apotex and that the *Apotex I&II* tribunal "confirmed Apotex's concession."[161] The US does not attempt to come to grips with

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("The *Apotex I-II* tribunal determined, in particular, that an abbreviated new drug application (ANDA), *whether tentatively or finally approved*, is not 'property' in the United States for purposes of Article 1139(g). To the contrary, for companies such as Apotex[-Canada], whose manufacturing facilities are outside the United States, an ANDA is 'simply an application for revocable permission to (in this case) export a product for sale (by others) in the United States.'" (emphasis in original)); *id.*, para. 4 ("The tribunal further determined that ANDAs are not 'interests arising from the commitment of capital or other resources' in the United States for purposes of Article 1139(h). Apotex's *applications*, it determined, 'amount to no more than the ordinary conduct of a business for the export and sale of goods,' and thus are excluded as 'investments.'" (emphasis added)); *id.*, para. 97 ("As the *Apotex I-II* tribunal recently confirmed, Apotex Inc.'s *applications* are neither 'intangible property' nor 'interests arising from commitment of capital' in the United States. Apotex's *applications*, therefore, are not 'investments' for purposes of NAFTA Chapter Eleven." (emphasis added by US Rejoinder)); *id.*, para. 117 ("But '[e]ven if Apotex has exclusive rights over the ANDA,' the *Apotex I-II* tribunal concluded, 'this cannot change the inherent nature of the ANDA itself.' That is, 'an *application* to export generic drugs into the United States is not transformed into an 'investment' for the purposes of NAFTA Chapter Eleven, because the holder of the *application* has exclusive rights thereto.'" (emphasis added by US Rejoinder)); *id.*, para. 138 ("[T]he *Apotex I-II* tribunal specifically rejected each of these arguments: (1) '[E]ven assuming that the ANDAs were Apotex's exclusive '*property*,' they remained no more than applications for permission to (in this case) export and as such neither fell within NAFTA Article 1139(g), nor constituted '*investments*', as contemplated more generally by NAFTA Chapter Eleven." (emphasis in original)).

[160] Reply, para. 230 ("Finally-approved ANDAs are vested rights, i.e., marketing authorizations that have been granted and do allow the generic manufacturer to go to market in the United States. Even though finally-approved ANDAs can be revoked on specific statutory grounds, that does not make them *contingent* interests." (emphasis in original) (footnote omitted)).

[161] US Rejoinder, para. 119. The US claimed that the *Apotex I&II* tribunal confirmed that there is no difference between tentatively- and finally-approved ANDAs. This is not true. In fact, the tribunal made clear that it only addressed tentatively-approved applications for new generic drugs and, in doing so, distinguished those from finally-approved ANDAs. *See* **Legal Authority RLA-263**, *Apotex Inc. v. United States*, NAFTA/UNCITRAL, Award on Jurisdiction and Admissibility, para. 15 (June 14, 2013) ("The Sertraline Claim arises out of three decisions of the US Federal Courts in relation to Apotex's *application* seeking FDA approval for a generic version of a drug manufactured by Pfizer Inc., called 'Zoloft®'[.]") (emphasis added); *id*., para. 16 ("The Pravastatin Claim arises out of a decision of the FDA, and three decisions of the US Federal Courts, in relation to Apotex's *new drug application* seeking FDA approval for a generic version of a drug manufactured by Bristol Myers Squibb, called 'Pravachol®'[.]") (emphasis added); *id*., para. 209 ("[O]n the date of the alleged NAFTA breaches, the sertraline and pravastatin ANDAs were only *tentatively* approved by the FDA." (emphasis in original)); *id*., para. 210 ("The FDA grants 'tentative approval' to an ANDA when all scientific and procedural conditions for approval have been met. But the FDA does not finally approve an ANDA until various other barriers to approval no longer apply, and an application with a tentative approval will not become finally approved until the FDA issues a final approval letter.") (footnotes omitted); *id*., para. 220 ("[I]t remains entirely unclear whether a tentatively-approved ANDA (*i.e.* as distinct from (i) a finally-approved ANDA, and (ii) a finally-approved ANDA plus associated products) has value."); *id*., para. 223 ("[N]o products could be sold until the ANDAs had been finally

the issue posed in this case and the arguments before this Tribunal.

110. *Second*, the US Rejoinder repeatedly attacks straw-man arguments. It suggests that Apotex "assum[ed] that it could sell its drugs in the United States free from regulatory oversight" – an absurd suggestion never put forward by Apotex – and attacks its straw man by arguing that this "is not a 'reasonable investment backed expectation[.]'"[162] It suggests that "Apotex argues that its ANDAs constitute property because they 'are regulated by US law'" and then addresses an argument based on the *Bayview* award advanced in *Apotex I&II* (but not here).[163] In fact, it was the US's baseless and now-abandoned argument that Apotex-Canada's marketing authorizations were not investments *in the United States* that prompted Apotex to observe that their regulation by US law was pertinent to the territory in which they were located, a point reinforced by *Bayview*.[164] Apotex has not suggested here that the fact of regulation by US law established that marketing authorizations are property. Yet again the US attacks a straw man.

111. *Third*, the US Rejoinder – because it has no answer – repeatedly avoids joining issue with what it characterizes as the "new arguments" made in the Reply. Apotex pointed out that the NAFTA's text belied the US position that no revocable intangible interest could qualify as "property" within Article 1139(g), referring to the fact that Article 1110(7) explicitly encompassed at least some revocable intangible interests.[165] The US addresses this point not by responding to it but by mischaracterizing it: the US pretends that Apotex's argument was "*all* revocable intangible rights … are investments."[166] It does not attempt to address the logical fallacy in its own contention that revocable intangible rights can never be investments, a contention incompatible with the treaty.

112. Apotex's Reply also noted that licenses and marketing authorizations clearly were capable of possessing the attributes of an investment, as recognized in the US Model

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approved. All that Apotex held at the relevant time were *tentatively-approved applications* for revocable permission[.]"(emphasis added)).

162 US Rejoinder, para. 120.

163 *Id.*, para. 121.

164 Reply, para. 233.

165 *Id.*, paras. 215-17.

166 US Rejoinder, para. 126 (emphasis in original).

BIT (which expressly covers them as investments) and confirmed by multiple references in the NAFTA to licenses and permits.[167] Again, the US Rejoinder chooses evasion over substance, responding only that "[a] license may be required for the establishment or conduct of an investment."[168] That may well be in some circumstances, but it is no response to the point that licenses or permits may themselves be investments as well.

113. *Fourth*, the US rehashes arguments on standing and tax treatment that Apotex has already demonstrated to be without merit.[169] The US Rejoinder embellishes its prior arguments by suggesting an inconsistency due to the fact that Apotex-Canada did not pay tax on the sale of certain marketing authorizations.[170] The US, however, does not explain why, in the particular circumstances of that sale, the sale gave rise to an event taxable in the United States. Its argument is without foundation.

114. *Finally*, the US Rejoinder offers no response to the bulk of the points made in Apotex's Reply. The US concedes that "[a]n ANDA application may be owned, transferred, or bought and sold[.]"[171] The US fails to explain why Due Process Clause jurisprudence on the meaning of "property" should be disregarded, while Takings Clause jurisprudence should not, especially as there is no taking in the present case.[172] The US also does not dispute that, from a conceptual point of view, any property interest can be revoked by the State under certain circumstances.[173] Lastly, the US does not contest that the *Grand River* tribunal held that a US trademark constituted an investment for purposes of Chapter Eleven, although trademarks are revocable under US law.[174]

C. Apotex-Canada Holds Interests Arising from the Commitment of Capital and Other Resources to Economic Activity in the US

115. The US Rejoinder again places principal reliance on the *Apotex I&II* award in its

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[167] Reply, paras. 218, 220.
[168] US Rejoinder, para. 128.
[169] *Id.*, paras. 130-31. *But see* Reply, paras. 209, 216.
[170] US Rejoinder, para. 131.
[171] *Id.*, para. 132; Reply, para. 210.
[172] Reply, paras. 224-25, 228.
[173] *Id.*, para. 226.
[174] *Id.*, para. 231.

arguments on Article 1139(h), repeating for this provision its contention that *Apotex I&II* decided the issues before this Tribunal. This approach is surprising, given that that award made clear that the arguments under Article 1139(h) before it were undeveloped: "In the course of its oral submissions, Apotex then made clear that its submissions under NAFTA Article 1139(h) were to be treated as part of its submissions under NAFTA Article 1139(g), and not as independent grounds."[175]

116. The US reliance on *Apotex I&II* is misplaced. That tribunal did not consider any of the arguments advanced here in support of jurisdiction under Article 1139(h), even in the different context before it of applications rather than approved marketing authorizations. The issues before this Tribunal were not "actually litigated and determined" in *Apotex I&II*, nor was the "determination essential to the judgment" in that case.[176]

117. The remainder of the US Rejoinder's discussion of Article 1139(h) largely consists of silence. *First*, in its Memorial, Apotex presented a detailed review of the text, context, object and purpose, Spanish-language version and *travaux préparatoires* of Article 1139(h), and demonstrated that under Articles 31 through 33 of the Vienna Convention, the commitment of capital or other resources contemplated by the provision implicated foreign capital or resources as well as capital or resources already within the host State.[177] The US Counter-Memorial presented no response to this argument, instead addressing at length an argument that Apotex never made – that the "investment" did not need to be in the host State.[178] Apotex's Reply explicitly took note of this state of affairs, and observed that the bulk of the arguments under Article 1139(h) found no answer in the Counter-Memorial.[179]

118. The principal response of the US Rejoinder is to assert that "[t]he United States refuted these arguments at paragraphs 245-263 of its Counter-Memorial."[180] As noted in the

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[175] **Legal Authority RLA-263**, *Apotex Inc. v. United* States, NAFTA/UNCITRAL, Award on Jurisdiction and Admissibility, para. 229 (June 14, 2013).

[176] *See supra* para. 104 & n.156.

[177] Memorial, paras. 377-93.

[178] US Counter-Memorial, paras. 245-63. For example, the US stated that "[i]f an investment is not 'in the territory of the Party,' it is not an investment for purposes of NAFTA Chapter Eleven." *Id.*, para. 250.

[179] Reply, paras. 239-40, 249-52.

[180] US Rejoinder, para. 145.

Reply, the arguments the US Counter-Memorial addressed were not those made by Apotex. The US has no response to those arguments.

119. *Second*, the US Rejoinder does not contest that, if the marketing authorizations at issue do not constitute property rights under Article 1139(g) (which Apotex contends that they do), they nonetheless constitute "interests" within the meaning of Article 1139(h). Instead, it recognizes that ANDA owners have standing to sue in court and that "[s]tanding is conferred upon parties with a variety of *interests* guaranteed by the U.S. Constitution, by common law, or by statute."[181] The closest the US Rejoinder comes to presenting an argument on this point is its assertion that *Apotex I&II* rejected that an application constitutes property, "and, hence, separately constitutes a qualifying 'interest' for purposes of Article 1139(h)."[182] The US thus suggests for the first time in its Rejoinder, without support or explanation, that "property" in Article 1139 means the same thing as "interests." A cursory review of Article 1139(h) and the examples listed therein make clear that the point of the provision was precisely to protect interests that might not necessarily be viewed as constituting property.[183]

120. *Third*, as already noted, the US Rejoinder does not repeat the Counter-Memorial's unsupported argument that marketing authorizations are not interests "in the territory of" the US.[184]

121. *Fourth*, the US Rejoinder errs in its attempt to cobble together a binding interpretation of Article 1139(h). Mexico's Article 1128 submission merely addressed the proposition that an investment must be in the territory of the host State to be covered by Article 1101(1).[185] As noted in the Reply, Apotex agrees with this proposition – but it in no

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[181] *Id.*, para. 130 (emphasis added).

[182] *Id.*, para. 139.

[183] **Legal Authority CLA-1**, NAFTA, art. 1139 ("investment means: … (h) interests … such as under (i) contracts involving the presence of an investor's property in the territory of the Party, … or (ii) contracts where remuneration depends substantially on the production, revenues or profits of an enterprise").

[184] US Counter-Memorial, paras. 250-51. *See* Reply, paras. 249-52 (rebutting this argument); US Rejoinder, paras. 145-50 (no longer addressing this argument).

[185] Submission of the United Mexican States, *Apotex Holdings Inc. and Apotex Inc. v. United States*, para. 5 (Feb. 8, 2013) ("[O]nly investments (as defined in Article 1139) of an investor of a Party located *in the territory* of another Party fall within the scope and coverage of Chapter Eleven." (emphasis in original)); *id.*, para. 6 ("[I]t is clear that [Article 1139(h)] requires a commitment of capital or other resources of an investor of a Party *in the territory* of another Party." (emphasis in original)). Apotex demonstrated that

way addresses whether the capital or other resources contemplated by Article 1139(h) need already to be in the host State before they are committed to and give rise to the interests in question.[186] Mexico's submission sheds no light on this question, other than tacitly confirming that the Spanish language version of Article 1139(h) varies from the English.[187] And the US Rejoinder further errs in its suggestion that Canada's submissions in *S.D. Myers* shed light on the question before this Tribunal.[188]

122. *Finally*, Apotex demonstrated a multitude of resources committed to establishing, giving value to and maintaining its marketing authorizations in the US. Notably: Apotex has spent millions of dollars in developing new generic drugs and preparing the corresponding ANDA applications, which include intellectual property rights and know-how;[189] as part of the development of its ANDAs, Apotex-Canada also regularly engages in costly patent litigation before US courts;[190] Apotex-Canada relies on a team of seven full-time employees based in the United States, in accordance with the 2005 services agreement with Apotex-US, to act as its agent and liaison with FDA concerning the filing of applications;[191] in order to maintain its approved ANDAs, Apotex-Canada relies on that same team to make a series of periodic reports required by law (such as annual reports, drugs safety reports, updates to drug labels and patient

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various resources were committed to the United States. *See* Memorial, paras. 397-400; Reply, paras. 21, 238.

186 Reply, paras. 249-51, 249 n.430.

187 Submission of the United Mexican States, *Apotex Holdings Inc. and Apotex Inc. v. United States*, para. 7 (Feb. 8, 2013) ("[T]he text of the English and French versions are on their face consistent with the Article 1101(1) [sic] and thus any perceived discrepancy with the Spanish text is best reconciled by upholding the territoriality requirement.").

188 US Rejoinder, para. 148 (quoting **Legal Authority RLA-131**, *S.D. Myers, Inc. v. Canada*, NAFTA/UNCITRAL, Counter-Memorial of Canada, para. 238 (Oct. 5, 1999)). In *S.D. Myers*, the investor (SDMI) argued that it had committed capital in Canada by way of operating loan financing and by way of common shares in the Canadian company (Myers Canada). Canada argued that Myers Canada was held by four individuals, as opposed to SDMI, and therefore there was no evidence of "'invested capitals by way of common shares' of SDMI." **Legal Authority RLA-131**, *S.D. Myers, Inc. v. Canada*, NAFTA/UNCITRAL, Counter-Memorial of Canada, para. 239 (Oct. 5, 1999). Canada further argued that "[t]he alleged 'commitment of capital by way of operating loan financing' may or may not be the same money that is said to constitute SDMI as Myers Canada's creditor. If so, SDMI has failed to prove that this was more than some sort of accounting entry as opposed to a real investment in Canada. If it is something different, again there is no evidence as to how much it was, when it was made and how it was made. In any event, there is no evidence that the funds were actually disbursed in Canada." *Id.*, para. 240. Canada therefore did not discuss the location of the capital or resources at the time these are committed.

189 Memorial, para. 397.

190 *Id.*, para. 398.

191 *Id.*, para. 399.

information leaflets).[192] The few points the US Rejoinder does make in response to this showing are without merit.

123. *First*, the US relies only on the *Apotex I&II* decision in support of its contention that Apotex's patent litigation expenses do not give rise to investment interests in the United States.[193] However, the tribunal in *Apotex I&II* did not conclude that Apotex's legal expenses could not constitute a commitment of "resources" in the United States. Rather, that tribunal found that "'Apotex's submission to U.S. jurisdiction; its engagement of U.S. attorneys; and its expenditure on legal fees again neither amount to '*investments*', nor change the nature of Apotex's activity.'"[194] To be clear, Apotex's position in the present arbitration is not that its litigation expenses constitute an "investment" in the United States. Rather, Apotex's position is that such expenditures constitute a commitment of "resources" giving rise to an investment interest in the United States.[195]

124. *Second*, the US arguments on the 2005 services agreement miss the mark. Apotex explained that, although the services agreement requires Apotex-US to make a cash payment to Apotex-Canada for certain administrative support, this agreement reflects a larger contribution from Apotex-Canada to Apotex-US.[196] The US attempts to rebut this fact by focusing on the text of specific provisions of the services agreement taken in isolation, rather than the record on how that agreement was implemented in practice.[197] However, in doing so, the US ignores the spirit of the agreement and the way operations are carried out in a vertically-integrated group of companies. Moreover the US offers no response to Apotex's observation that the mere fact that consideration is paid for a contribution of capital or resources in no way negates the existence of that contribution, as shown by the examples of share issuance for capital contributions or a shareholder

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[192] *Id.*, para. 400. *See also* Reply, para. 238 (summarizing the various commitments of capital and resources made by Apotex-Canada in and into the United States for developing, filing and maintaining its ANDAs).

[193] US Rejoinder, paras. 153-56.

[194] *Id.*, para. 155 (quoting **Legal Authority RLA-263**, *Apotex Inc. v. United States*, NAFTA/UNCITRAL, Award on Jurisdiction and Admissibility, para. 240 (June 14, 2013) (emphasis in original)).

[195] Reply, paras. 247-48.

[196] *Id.*, para. 183.

[197] US Rejoinder, paras. 159-61 (quoting **Exhibit C-14**, Services Agreement Between Apotex-Canada and Apotex-US, dated July 1, 2005, paras. 3, 4.1, 11.1).

loan for cash contributions noted in Apotex's Reply.[198] Nor is there merit to the US Rejoinder's attempts to create an inconsistency between Apotex's statements in this arbitration and those made before US courts.[199] There is no such inconsistency.[200]

125. *Third*, the US relies on the *Apotex I&II* decision in support of its argument that the know-how or proprietary information contained in the ANDAs "cannot transform those applications into investments[.]"[201] Apotex's position is that such know-how and proprietary information constitute "resources" – not the investment itself.[202] In addition, *Apotex I&II* was concerned with "two 'application[s]'" for ANDAs.[203] In contrast, the investments at stake in the present arbitration are Apotex-Canada's scores of approved marketing authorizations (and not just two applications). The US reliance on *Apotex I&II* is thus misplaced.

126. *Finally*, the US quotes – once more – the *Apotex I&II* decision where the tribunal concluded that Apotex-Canada's position was analogous to *Grand River*.[204] In that

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198 Reply, para. 185.

199 *Id.*, paras. 163-65.

200 As noted by the US, Apotex testified in US courts that Apotex-US had not received any loans or other capital from Apotex-Canada. *See* US Rejoinder, para. 163. This is consistent with Mr. Fahner's witness statement that Apotex-Canada had no direct or indirect equity stake in Apotex-US, that Apotex-US has never borrowed any funds from Apotex-Canada and that Apotex-Canada has never provided any financing to Apotex-US. *See id.*, para. 164; Second Witness Statement of Gordon Fahner, paras. 71, 75, 78. The fact remains that Apotex-Canada has contributed a lot of different resources, other than capital, to Apotex-US. Similarly, Apotex-US received resources from Apotex-Canada, but both companies are maintained as "completely separate corporate entities." *See* US Rejoinder, para. 165 (quoting **Legal Authority RLA-75**, Apotex Inc.'s Reply Brief in Support of its Motion to Dismiss, *Astrazeneca Pharmaceutical LP v. Apotex Inc.*, No. 07-809-JJF-LPS, at 15-16 (D. Del. May 12, 2008)).

201 US Rejoinder at 79, heading c.

202 Memorial, para. 397. ("[T]he record clearly demonstrates a commitment of capital or other resources in and into the United States for purposes of economic activity. … Each ANDA reflects proprietary information concerning the drug's formulation, development, testing, and the manufacturing processes needed for the commercialization of the drug in the US. These intellectual property rights, know-how and other resources, even if brought from Canada, are committed into the United States for purposes of economic activity in US territory." (footnote omitted)).

203 US Rejoinder, para. 168 (quoting **Legal Authority RLA-263**, *Apotex Inc. v. United States*, NAFTA/UNCITRAL, Award on Jurisdiction and Admissibility, para. 219 (June 14, 2013)). The US also quotes the claimant's counter-memorial and the transcript of the hearing on jurisdiction and admissibility in *Apotex I&II*. *See id.*, para. 167 & n.372. However, as mentioned above, and as made clear in the *Apotex I&II* decision, the claimant's arguments under Articles 1139(h) were not fully developed. *See supra* para. 115.

204 *Id.*, para. 170 (quoting **Legal Authority RLA-263**, *Apotex Inc. v. United States*, NAFTA/UNCITRAL, Award on Jurisdiction and Admissibility, para. 244 (June 14, 2013) (quoting **Legal Authority CLA-29**, *Grand River Enterprises Six Nations, Ltd. v. United States*, NAFTA/UNCITRAL, Award, para. 5 (Jan. 12, 2011))).

case, the tribunal concluded with respect to Grand River and its stockholders, Jerry Montour and Kenneth Hill, that they had no investment in the United States, in particular because Grand River's cigarette manufacturing plant was in Canada.[205] However, the tribunal held that claimant Arthur Montour did have an investment in the United States, namely its tobacco distribution business (distributing cigarettes made at Grand River's Canadian plant) and the trademark Seneca®.[206] In the instant arbitration, it is not disputed that Apotex-US is an investment in the United States that distributes drugs made at Apotex-Canada's Canadian facilities under marketing authorizations (or ANDAs) held by Apotex-Canada. In this respect, Apotex's activities are similar to those of Arthur Montour. The US contention is without merit.

CONCLUSION

127. For the foregoing reasons and those set out in its previous submissions, claimants Apotex Holdings and Apotex-Canada respectfully submit that the US objections to jurisdiction should be dismissed, the new materials presented by the US in violation of paragraph 16.4 of the First Procedural Order excluded from the record and a decision entered in accordance with the submissions set out at paragraph 532 of the Apotex Reply.

Date: October 18, 2013

Respectfully submitted,

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[205] **Legal Authority CLA-29**, *Grand River Enterprises Six Nations, Ltd. v. United States*, NAFTA/UNCITRAL, Award, paras. 87-89 (Jan. 12, 2011).

[206] *Id.*

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