Public Version

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

APOTEX HOLDINGS INC. *and* APOTEX INC.,

Claimants/Investors,

-and-

THE UNITED STATES OF AMERICA,

Respondent/Party.

Case No. ARB(AF)/12/1

REJOINDER ON MERITS AND REPLY ON OBJECTIONS TO JURISDICTION OF RESPONDENT UNITED STATES OF AMERICA

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TABLE OF CONTENTS

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REJOINDER ON MERITS AND REPLY ON OBJECTIONS TO JURISDICTION OF RESPONDENT UNITED STATES OF AMERICA

In accordance with the Tribunal's First Procedural Order and its Order of May 14, 2013, Respondent United States of America respectfully submits this Rejoinder on Merits and Reply on Objections to Jurisdiction to the claims of Apotex Inc. and Apotex Holdings Inc., on its own behalf and on behalf of its U.S. enterprise, Apotex Corp. (collectively, "Apotex").

The United States also respectfully submits a supplemental witness statement of Dr. Carmelo Rosa and an expert report of William W. Vodra, which respond to new arguments and allegations contained in Apotex's May 24, 2013 Reply; the witness statements and expert report accompanying the Reply; and the July 22, 2013 Supplement to the Reply.

PRELIMINARY STATEMENT

1. The U.S. Counter-Memorial established that the Tribunal lacks jurisdiction to hear Apotex's claims, which in any event fail on the merits. The Tribunal should reject Apotex's improper attempt to manufacture an "investment" dispute and foist onto the U.S. taxpayer the costs of bringing Apotex's *Canadian* manufacturing facilities up to the minimum regulatory standards required for *exporting* its drugs to the United States for sale by others.

2. Three notable developments have occurred since the United States filed its Counter-Memorial, all of which confirm the U.S. arguments. *First*, on June 14, 2013, the tribunal in two claims captioned *Apotex Inc. v. United States* issued an award on jurisdiction and admissibility, holding that Apotex Inc. "does not qualify as an '*investor*', who has made an '*investment*' in the U.S., for the purposes of NAFTA Articles 1116 and 1139."[1]

3. 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 Inc., 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."[2]

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).

[1] *Apotex Inc. v. United States*, NAFTA/UNCITRAL, Award on Jurisdiction and Admissibility ¶ 358(a) (June 14, 2013) (emphasis in original) ("*Apotex I-II* Award") [RLA-263].

[2] *Id.* (emphasis in original).

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."[3]

5. The tribunal not only rejected Apotex Inc.'s claim to be an "investor" with "investments" in the United States for purposes of NAFTA Chapter Eleven, but also concluded that the United States "ought never have been embroiled in this process."[4] The tribunal unanimously dismissed Apotex's claims for lack of jurisdiction and ordered Apotex to pay all of the United States' legal and arbitration costs.

6. The tribunal's decision is *res judicata*. It thus bars Apotex from requiring the United States to relitigate, for purposes of NAFTA Chapter Eleven, Apotex Inc.'s claim to be an "investor" with "investments" in the United States based on ANDAs.

7. *Second*, in a February 7, 2013 letter, Apotex informed this Tribunal that it was withdrawing all claims arising from Apotex Inc.'s unapproved ANDAs. That is, just two weeks after the Tribunal decided the United States' request for bifurcated proceedings on jurisdiction and the merits, Apotex abandoned one of the claimed grounds for jurisdiction in this case. Apotex slashed its damages claim by nearly 75 percent, from upward of $[redacted] billion to $[redacted] billion.

8. *Third*, Apotex confirmed in its May 24 Reply that it does not challenge FDA's determination that the Etobicoke and Signet facilities failed to comply with current good manufacturing practice (cGMP), as legally required to export drugs to the United States. Apotex

[3] *Id.* ¶ 235.

[4] *Id.* ¶ 342.

previously argued the opposite, stating that it "rejected FDA's suggestion that its facilities were not compliant with cGMP."[5] Before withdrawing its assertion, Apotex had disputed FDA's "alleged" cGMP violations, the "allegations" in FDA's warning letters, and the "unfounded" conclusions caused by FDA's "misunderstanding."[6] On that basis, Apotex sought to recover in this arbitration the money it spent bringing its Canadian manufacturing facilities into cGMP compliance.

9. Apotex now dismisses its undisputed cGMP violations as "legally irrelevant" to this case.[7] Apotex argues that the United States has drawn attention to Apotex's violations of U.S. law merely "to paint Apotex as a bad actor unworthy of the Tribunal's sympathy."[8] The president of Apotex Inc., Dr. Desai, observes that Apotex drugs were only "deemed" to be adulterated under U.S. law because the company's manufacturing practice did not "strictly conform" to cGMP.[9] FDA, he notes, only "found one instance of Apotex products being contaminated."[10] "Apotex products," he assures the Tribunal, "never posed imminent risks to public health."[11] Apotex denies that its products released to the U.S. market were "unsafe or ineffective."[12]

[5] Claimants' Request for Arbitration ¶¶ 33, 43 (Feb. 29, 2012) ("Request for Arbitration").

[6] Request for Arbitration ¶¶ 32-33; Memorial of Claimants Apotex Holdings Inc. and Apotex Inc. ¶¶ 153, 154, 157 (July 30, 2012) ("Memorial").

[7] Reply of Claimants Apotex Holdings Inc. and Apotex Inc. ¶ 41 (May 24, 2013) ("Reply").

[8] *Id.* ¶ 9.

[9] Second Witness Statement of Jeremy B. Desai ¶ 9 (May 23, 2103) (emphasis added) ("Second Desai Statement").

[10] *Id.* ¶ 9.

[11] *Id.* ¶ 10.

[12] Reply ¶ 2.

10. The contemporaneous record belies Apotex's *post hoc* assertions. FDA documented numerous concerns with the safety and efficacy of Apotex products during several inspections over many years. Apotex had been found, for example, to have manufactured drugs for the U.S. market using contaminated ingredients; misbranded drug products and packaging; failed to follow established procedures for cleaning its manufacturing equipment; repackaged failed products; failed to investigate manufacturing problems; and failed to establish adequate processes to prevent adulteration and cross-contamination.[13] These findings, *which are now undisputed*, reinforced FDA's concerns about the safety and efficacy of Apotex's products.

11. FDA's findings were "consistent" with those of Apotex's own third-party consultant, who "confirmed that system level improvements were needed for all six [cGMP] systems."[14] Another consultant hired to assess the products Apotex released to the U.S. market in the months preceding the Import Alert confirmed an [redacted] percent failure rate during product testing.[15]

12. Complaints from pharmacists and consumers highlighted these safety and efficacy concerns.[16] Problems ranged from a lack of intended pharmaceutical effect, to double-sized narcotic tablets, to the mixing of different drugs and different dosages in the same package.

13. FDA obtained further corroboration from a confidential Apotex informant, who contacted FDA to blow the whistle on Apotex's poor manufacturing practice.[17] Apotex's production line,

[13] *See* Counter-Memorial on Merits and Objections to Jurisdiction of Respondent United States of America ¶¶ 72-80, 86-93 (and sources cited) ("Counter-Memorial").

[14] Jeff Yuen & Associates, Inc., Final Summary Report for Apotex Corrective Action Plan Audit, at 2 (Mar. 17, 2010) [C-137].

[15] Apotex, Draft Minutes of Meeting with FDA, at 3 (Mar. 31, 2010) (citing failures in [redacted] of [redacted] products assessed in Wave 1) [C-140].

[16] *See infra* ¶¶ 45-47, 50.

the informant reported, ran too quickly and continuously to maintain quality control. The informant also stated that production workers moved from room to room without taking steps to prevent cross-contamination; workers were given no time to clean their shoes or change their clothes after using the restroom or cafeteria, let alone to properly clean the equipment and facilities; technicians were told not to document or investigate product failures, and even to *misreport* product failures; and if employees voiced their concerns to management, they were fired. Apotex's self-proclaimed "unrelenting approach to competition,"[18] the informant confirmed, prioritized profits over safety, putting consumers in danger of receiving contaminated drugs.

14. Health Canada similarly corroborated FDA's concerns about the safety and efficacy of Apotex drugs.[19] Apotex was found, for instance, to have misreported test results; released failed products for sale; failed to conduct timely investigations of potentially unsafe products; and delayed product recalls after learning of health risks to consumers. Most significantly, Apotex was found to have commingled toxic and nontoxic material without taking adequate measures to prevent cross-contamination – a violation that alone would have justified stripping Apotex of its establishment license under Canadian law. Dr. Desai's admission following Health Canada's inspection perfectly captures the source of Apotex's self-inflicted problems: "*[O]ur quality systems lack quality*."[20]

[17] *See* email from confidential Apotex informant to M. Goga re "Follow-up questions" (Feb. 8, 2011) [R-254]; *see also* emails from confidential Apotex informant to M. Goga (Jan. 30, 2011) [R-251]; (Feb. 7, 2011) [R-253].

[18] Reply ¶ 11.

[19] *See* Counter-Memorial ¶¶ 111-34 (discussing Health Canada's findings).

[20] Email from J. Desai to B. Sherman (Nov. 26, 2009) (emphasis added) [R-175].

15. Although Apotex now downplays its failure to "strictly conform" to cGMP, poor manufacturing practice can be deadly.[21] Given the real risks of adulterated drugs, FDA takes no comfort in Apotex's assurance that its drugs were safe and effective "almost without exception"[22] and posed no "imminent" risk to consumers.[23]

16. Apotex's Reply attempts to shift the focus from its undisputed failure to comply with cGMP to a *post hoc* inquiry into the safety and efficacy of its drugs. But Apotex itself has acknowledged that safety and efficacy are components of the broader notion of "adulteration." Apotex thus recognizes that, "[u]nder U.S. law, a drug is considered 'adulterated' if the methods or facilities used to produce it do not conform to cGMP so as to ensure the safety, identity, strength, quality and purity of the drug[.]"[24] Apotex further recognizes that U.S. law "grants FDA the authority to refuse admission of goods offered for import if they *appear* adulterated."[25] Because Apotex does not dispute FDA's cGMP determinations for Etobicoke and Signet, Apotex necessarily recognizes that, under U.S. law, drugs from those facilities were "deemed to be adulterated" and thus could be refused admission to the United States.[26] Apotex's acknowledgements have important implications for Apotex's claims on jurisdiction and the merits.

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[21] *See, e.g.*, Centers for Disease Control and Prevention, *Multistate Fungal Meningitis Outbreak – Case Count* (Sept. 10, 2013) (reporting that 63 deaths and 749 illnesses have been linked to contaminated steroids manufactured in Massachusetts) [R-239].

[22] Memorial ¶ 6 (emphasis added).

[23] Second Desai Statement ¶ 10.

[24] Request for Arbitration ¶ 19.

[25] Memorial ¶ 103 (emphasis added).

[26] There is no basis for Apotex's attempt to shift the preventative standard embodied in cGMP and accepted industry practice across the globe for a discredited standard that would require patients to be put in harm's way before FDA or other regulators could act.

17. Jurisdiction. The Tribunal lacks jurisdiction to hear any claims by Apotex Inc. or Apotex Holdings. Apotex Inc. claims to be an "investor" in the United States, but admits that it has no presence of any kind in the United States, conducts no business operations in the United States, and pays no taxes in the United States.[27] The sole "investments" claimed by Apotex Inc. are its abbreviated new drug applications. ANDAs, however, are not "investments" in the United States for purposes of NAFTA Chapter Eleven. As the *Apotex I-II* tribunal recently confirmed, they are Apotex's *revocable applications* to engage in cross-border trade.[28]

18. Even if Apotex had carried its burden of proving that its ANDAs are "investments" in the United States, the Tribunal still would lack jurisdiction over Apotex Inc.'s claims. Article 1101(1) confirms that Chapter Eleven applies only to measures adopted or maintained by a NAFTA Party that "relate to" a qualifying investor with a covered investment in its territory. The parties agree that Article 1101(1) requires a "legally significant connection" between the challenged measure and the investor or its investment.[29] There is no legally significant connection between the sole challenged measure in this case (the Import Alert) and the sole investment claimed by Apotex Inc. (its approved ANDAs). Indeed, Apotex has acknowledged that its ANDAs remained approved throughout the period of the Import Alert and thus could have been sold or transferred to another Apotex (or third-party) cGMP-compliant facility.[30]

19. Nor did the Import Alert "relate to" Apotex Holdings or its U.S. investment, Apotex Corp. Apotex Corp. and Apotex Inc. are elements of a large international conglomerate, but

[27] *See infra* ¶¶ 95-131.

[28] *Apotex I-II* Award ¶ 207 (emphasis in original) [RLA-263].

[29] *See infra* ¶¶ 91, 178.

[30] Witness Statement of Jeremy B. Desai ¶ 89 (July 30, 2012) ("First Desai Statement").

there is no relationship of direct ownership or control between the two entities. Apotex claims that the Import Alert constituted a "legal impediment" to Apotex Corp's business operations because it interrupted transactions between Apotex Inc. and Apotex Corp.[31] But that is not true. Apotex has acknowledged in U.S. and Canadian court proceedings that Apotex Corp. purchases drugs from Apotex Inc. *in Canada*. The Import Alert thus had no effect on those sales.

20. Although Apotex Corp. could not *import* drugs from Etobicoke and Signet into the United States during the period of the Import Alert, the legal impediment was not the Import Alert itself. An Import Alert is not legally binding and does not obligate U.S. officials to refuse to admit drugs from listed facilities into the United States. To the contrary, an Import Alert is advisory information sent to FDA district offices "concerning unusual or new problems affecting imports which gives *background and compliance guidance information* for each product and problem."[32] Outside of this arbitration, in fact, Apotex has acknowledged that the Import Alert was merely a "*temporary import advisory*."[33]

21. The underlying measures that actually prevented the importation and sale of products from Etobicoke and Signet in the United States are:

(1) FDA's determination that drugs from those facilities were "deemed to be adulterated" because of serious, systemic cGMP violations and thus could be refused admission to the United States; and

(2) FDA's detention of drugs from those facilities for the "appearance" of adulteration and, following an administrative process, the refusal to admit those drugs into the United States.

[31] Reply ¶¶ 118, 119.

[32] FDA, *Regulatory Procedures Manual*, Chapter 11 (Glossary) (defining "Import Alerts") (emphasis added) [R-37].

[33] *Apotex Inc. v. Cephalon, Inc.*, No. 06-cv-02768 MSG (E.D. Pa.), Response of Apotex to Cephalon's Request for Conference, at 1-2 (Apr. 21, 2010) (emphasis added) [RLA-70].

Apotex does not challenge either measure in this arbitration. Instead, Apotex challenges only FDA's "temporary import advisory," which did not cause Apotex's alleged injuries. The Import Alert necessarily lacked a "legally significant connection" to Apotex's alleged investments. The Import Alert, therefore, did not "relate to" any claimed investor or investment for purposes of Article 1101(1). Accordingly, the Tribunal lacks jurisdiction over any claims by Apotex Holdings, on behalf of its U.S. enterprise, Apotex Corp.

22. Merits. Apotex's failure to challenge the relevant measures underscores the inherent defects in its claims under Articles 1102 (national treatment), 1103 (most-favored-nation treatment), and 1105 (minimum standard of treatment).

23. Apotex's national treatment claim is legally defective and internally contradictory. Apotex previously argued that different legal enforcement regimes govern facilities outside and inside the United States. Apotex now asserts that a single regime controls, and that the United States accorded Apotex Inc.'s manufacturing facilities *in Canada* less favorable treatment than it accorded other companies' facilities *in the United States*. Despite all authority and its previous arguments to the contrary, Apotex asserts that all such facilities are in "like circumstances" for purposes of Article 1102.

24. Apotex's new argument is erroneous. For facilities outside the United States (whether U.S.- or foreign-owned), the U.S. government may *administratively* detain without physical examination, and refuse to admit into the United States, drugs that "appear" to be adulterated. By contrast, for facilities inside the United States (whether U.S.- or foreign-owned), the government must *establish* adulteration through *judicial* action (*e.g.*, seizure, injunction) in order to bar drugs from the marketplace. To use Apotex's own terms: "While FDA has the authority to

detain imports that appear adulterated, it lacks similar detention authority for domestically produced goods that appear adulterated."[34]

25. This distinction in U.S. law is not based on the *nationality* of the trader, but on the *location* of its goods. Apotex does not challenge the legitimacy of this distinction, which reflects FDA's limited authority and resources to operate outside of U.S. borders.[35] Because Apotex does not allege that the United States accorded better treatment to any U.S. investor or investment with (or supplied by) manufacturing facilities *outside* the United States, Apotex's national treatment claim fails as a matter of law. As a factual matter, moreover, Apotex failed to establish that the United States accorded more favorable treatment to any U.S. investor or investment, in like circumstances, regardless of the location of its manufacturing facilities.

26. Apotex's most-favored-nation treatment claim is equally defective and contradictory. Apotex, a Canadian company, has brought a claim for *nationality-based* discrimination, but alleges FDA "discrimination" in favor of Sandoz Canada, another *Canadian* company. This is nonsensical.

27. Apotex, moreover, now makes clear that it does not challenge FDA's cGMP determinations for Etobicoke and Signet. Instead, Apotex contends that the United States violated Article 1103 by declining to put *other* companies on Import Alert, despite having issued those companies warning letters for cGMP violations. Apotex thus suggests that once FDA issues warning letters for serious cGMP violations, FDA will violate the obligations of the

[34] Memorial ¶ 119.

[35] The consequences of the use of these authorities are also different. Drugs that have been refused admission for cGMP violations usually may be freely sold outside the United States, while seized drugs manufactured domestically in this category ordinarily cannot be resold or reconditioned. *See* 21 U.S.C. § 334(d) (2009) [CLA-231].

United States under Chapter Eleven unless the agency takes the same enforcement action against all such firms, regardless of circumstances weighing for or against such action.

28. Apotex's legal experts, by contrast, underscore the many "factors that FDA considers when determining whether to bring an enforcement action."[36] When comparing Apotex to Teva, for instance, Apotex's legal experts invite the Tribunal to consider:

- "how Apotex's cGMP violations were more serious than Teva's";
- "how the risk to consumers as a result of Apotex's cGMP violations was greater than the risk to consumers as a result of Teva's";
- "how Teva's response to the violations was superior to that of Apotex's"; and
- "whether any of the products implicated were medically necessary or in short supply."[37]

Thus, while Apotex seeks to strip FDA of any enforcement judgment in determining appropriate action, its legal experts acknowledge that FDA properly weighs many factors when deciding what enforcement action to take against a company – confirming that no formula dictates a particular enforcement action.

29. Both Apotex and its experts, however, invite the Tribunal to substitute its judgment for that of FDA and to evaluate the relative seriousness of each company's cGMP violations, the potential risk to consumers, the appropriateness of each company's response, and the medical necessity or shortage of drugs manufactured at each facility. That is neither possible nor appropriate. The NAFTA Parties did not establish Chapter Eleven as a mechanism to second-

[36] Second Expert Report of Sheldon T. Bradshaw, J.D. and Ron M. Johnson ¶ 48 (May 24, 2103) ("Second Bradshaw Report").

[37] *Id.* ¶¶ 47-48.

guess specialized agencies' fact-finding in exercising their enforcement discretion in matters of public health and safety.

30. In any event, even if this Tribunal were to step into FDA's shoes and assess FDA's regulatory enforcement actions, the evidence shows that Apotex was not accorded less favorable treatment than the treatment accorded to any investor or investment in like circumstances.

31. Apotex's Article 1105 argument also is faulty and contradictory, in four respects. *First*, Apotex has failed to state a proper claim. Article 1105(1) requires the NAFTA Parties to accord the customary international law minimum standard of treatment to "investments" of investors. Apotex's 1105(1) claim, however, does not challenge any treatment with respect to any alleged *investment* in this arbitration. Rather, Apotex's 1105(1) claim challenges the treatment allegedly accorded to Apotex as an *investor*. That claim is not permitted under NAFTA Chapter Eleven.

32. *Second*, although Apotex claims that it was entitled to "due process" before FDA could refuse to admit its drugs into the United States, Apotex has failed to establish that the customary international law minimum standard of treatment requires any process *before* a State may permissibly prevent importation of drugs that are lawfully deemed to be adulterated. Apotex, in fact, has failed to identify a single State that provides the due process that Apotex claims. And although Apotex's own pleadings discuss relevant practice from Australia, Canada, the Netherlands, and New Zealand, Apotex does not argue that any of these States provide such "due process" before blocking the importation of adulterated drugs.

33. *Third*, Apotex complains about a lack of "due process," but never invoked any process afforded to it by U.S. law. Apotex never protested or challenged FDA's cGMP determinations; never protested or challenged the addition of Etobicoke and Signet to the Import Alert; never

availed itself of an administrative hearing to challenge the detention of its drugs; and never commenced judicial proceedings to challenge FDA's actions.[38] For a company that touts litigation as part of its "business model,"[39] it is telling that Apotex failed to assert *any* of the administrative or judicial remedies available to it, opting instead to acknowledge its violations and take steps to bring its manufacturing facilities into compliance with U.S. law.

34. *Fourth*, Apotex's Article 1105 argument is inherently contradictory. Apotex has conceded that its "claim under the minimum standard of treatment [does not] implicate the substance of FDA's cGMP findings."[40] Apotex thus recognizes that drugs from Etobicoke and Signet were deemed to be adulterated and, on that basis, could be denied admission to the United States. Apotex cannot claim that the injury it alleges – the inability to market drugs from those facilities in the United States – would have been different if it had received the process it now claims was lacking.

35. Finally, Apotex impermissibly invokes NAFTA's most-favored-nation treatment clause to claim protection of the U.S.-Jamaica BIT. Apotex alleges that it lacked "effective means of asserting claims and enforcing rights." Under U.S. law, however, Apotex had no right to import adulterated products into the United States. Apotex, moreover, does not challenge that its drugs were deemed to be adulterated under U.S. law because of cGMP violations at Signet and Etobicoke. Apotex thus had no "claim" to assert or "right" to enforce under U.S. law through the means available, regardless of whether those means were "effective."

[38] *See infra* ¶¶ 321-31, 341-65.

[39] Memorial ¶ 41.

[40] Reply ¶ 8.

36. Apotex's arguments on jurisdiction and merits are baseless. We respectfully request that the Tribunal dismiss all claims and award all costs to the United States.

I. FACTS

A. The Key Facts Remain Uncontested

37. The U.S. Counter-Memorial observed that "[t]he material facts of this case are largely undisputed."[41] Although Apotex's Reply and Supplement highlight certain factual disagreements between the parties, neither pleading puts at issue the material facts of this case. There remains no dispute between the parties that:

1. FDA inspections of Apotex's Etobicoke and Signet facilities revealed significant violations of U.S. law, including numerous deviations from current good manufacturing practice;[42]

2. Apotex acknowledged and accepted responsibility for its cGMP violations and pledged comprehensive corrective action to return to sustainable compliance with U.S. law;[43]

3. Apotex recalled various drug batches in the United States, but declined to cease producing drugs for the U.S. market from those same facilities, despite ongoing, systemic problems with its manufacturing practice;[44]

4. FDA subsequently added drugs from Etobicoke and Signet to the Import Alert, apprising FDA field offices of the cGMP violations at those facilities;[45]

[41] Counter-Memorial ¶ 4.

[42] *See, e.g.*, Letter from R. Friedman to L. Lovelock, at 1 (June 25, 2009) (highlighting cGMP violations at Etobicoke) [C-41]; Letter from R. Friedman to J. Kay (Mar. 29, 2010) (highlighting cGMP violations at Signet) [C-138].

[43] Apotex Responses to 2009 Signet Form 483, at 7 (Sept. 3, 2009) (attached to letter) (acknowledging the "systemic nature" of the cGMP violations; assuring FDA that Apotex was in the "process of evaluating, with the aid of independent expert consultants, our entire quality System, the management structure, roles and responsibilities and manufacturing operations systems supporting our products"; and pledging "global actions to improve effectiveness of our Quality System at all Apotex sites.") [C-81].

[44] FDA, Minutes of Teleconference with Apotex (Aug. 17, 2009) (emphasis added) [R-43].

[45] Email from "ORA HQ DIOP Import Alerts" to Regina Barrell et al. (Aug. 28, 2009) [C-67].

5. After FDA field offices detained Apotex drug shipments for the appearance of adulteration, Apotex did not respond to the detention notice or appear at a detention hearing;[46]

6. Apotex's primary regulator, Health Canada, similarly identified major cGMP violations at Etobicoke and Signet, but opted to supervise Apotex's compliance efforts on site in lieu of shutting Apotex down;[47] and

7. Other national health authorities promptly banned importation of drugs from Etobicoke and Signet pending Health Canada's compliance determination, and at least one health authority (New Zealand's Medsafe) informed Apotex that if it had been a New Zealand company, Medsafe "*would have shut them down*."[48]

These undisputed facts confirm the United States' lawful and appropriate exercise of its discretionary authority in issuing a "temporary import advisory" for Etobicoke and Signet to protect public health.

B. Apotex's New Allegations Do Not Support Its Claims

38. Apotex's Reply and Supplement make various new allegations. But because the material facts remain uncontested, the new allegations do not support and are largely irrelevant to Apotex's claims. For completeness, this section rebuts Apotex's new allegations concerning (1) the effect of the Import Alert; (2) the problems with Apotex drugs that prompted FDA to order "for cause" inspections of Etobicoke and Signet; (3) Health Canada's efforts to respond to

[46] Reply ¶ 495 (acknowledging that Apotex did not attend a detention hearing).

[47] Health Canada, Inspection Exit Notice for Signet (Oct. 14, 2009) [C-112]; Health Canada, Inspection Exit Notice for Etobicoke (Nov. 4, 2009) [C-116]; Health Canada, Terms and Conditions Annex for 2010 Drug Establishment License 100375-A (Dec. 31, 2009) [C-126].

[48] Email from B. Clark to L. Lovelock et al. (Sept. 12, 2009) (emphasis added) (reporting that Medsafe "very clearly stated to us that if they are not provided a satisfactory position from Apotex, they will be taking decisive action which we can understand to be an import ban with [the] possibility of full recall of all products," and that "it was stated that if the [Form] 483 findings had been made for a NZ company by Medsafe, they would have shut them down") [C-99]; *see also* email from R. Millichamp to C. Baxter et al. (Sept. 11, 2009) (reporting that Australia's Therapeutic Goods Administration had imposed on Apotex-Australia "[n]on negotiable" demands to "[s]uspend all shipments of products manufactured by the Signet and Etobicoke sites for Australia with immediate effect . . . until Health Canada has completed its review of the Signet site" and to commence "a voluntary recall of [redacted] batches," which were tainted with a "green colour") [C-95]; IGZ News Release, "Apotex Stops Import and Distribution of Medicinal Products from Canada" (Oct. 26, 2009) (addressing ban of Apotex drugs into the European Economic Area) [C-114]; letter from L. Lovelock to R. Kirchner (Sept. 8, 2009) [C-88].

Apotex's cGMP violations amidst a severe drug shortage in Canada; (4) FDA's alleged "misunderstandings" prior to issuance of the Import Alert; and (5) the amount of time between FDA's determination that Apotex's facilities failed to comply with U.S. law and FDA's decision to take enforcement action.

1. Apotex Mischaracterizes the Import Alert

39. Apotex mistakenly characterizes the Import Alert as a measure that "directly applied" to Apotex Inc. and Apotex Corp. and that decided their "rights and interests."[49] By its terms, however, the Import Alert is an internal FDA memorandum sent to FDA district offices "concerning unusual or new problems affecting imports which gives *background and compliance guidance information* for each product and problem."[50] The purpose of an Import Alert is "[t]o identify and disseminate import information (problems, violative trends, etc.) for providing an effective import coverage program."[51]

40. The very first sentence of the Import Alert to which the Etobicoke and Signet facilities were added clearly states, in bold text:

> **This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or product(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public.**[52]

[49] Reply ¶¶ 142, 390.

[50] FDA, *Regulatory Procedures Manual*, Chapter 11 (Glossary) (defining "Import Alerts") (emphasis added) [R-37]; *see also* Expert Report of William W. Vodra ¶¶ 86-91 (Sept. 20, 2013) ("Vodra Report").

[51] FDA, *Regulatory Procedures Manual* § 9-13 [CLA-309]. The recommendation "may identify one firm, multiple locations of a firm, or specific products from one or more firms as appropriate." *Id.* § 9-6, at 9-24.

[52] FDA Import Alert #66-40, *Detention Without Physical Examination of Drugs from Firms Which Have Not Met Drug GMPs* (Oct. 2, 2009) [C-110] ("The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the methods and controls used in its manufacture and control of pharmaceutical products do not appear to

41. The Import Alert further states that "[d]istricts *may* detain the specified pharmaceutical products from the firms listed in the attachment to this alert."[53] As Mr. Vodra has put it, the Import Alert "*advises* FDA employees to detain them in accordance with regular FDA procedures," but does not *require* them to do so, as "an FDA official still must determine whether a specific shipment appears to violate the law."[54] An Import Alert, therefore, "is neither a necessary nor a sufficient prerequisite for an import detention."[55] Apotex itself, outside of this arbitration, has acknowledged that the Import Alert is "a temporary import *advisory*."[56]

42. The Import Alert also clearly identifies the *foreign* facilities to which it applies. Here, the Import Alert challenged by Apotex expressly identifies Apotex Inc.'s Etobicoke and Signet facilities.[57] The Import Alert nowhere mentions any other company (or facility) in the Apotex group, including Apotex Corp. Outside of this arbitration, Apotex has acknowledged that "[t]he import alert and related [warning] letters apply to only *two Apotex facilities*,"[58] neither of which are Apotex Corp. facilities.

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conform to current good manufacturing practices within the meaning of Section 501(a)(2)(b)"); *see also* Vodra Report ¶ 88.

[53] FDA Import Alert #66-40, *Detention Without Physical Examination of Drugs from Firms Which Have Not Met Drug GMPs* (Oct. 2, 2009) [C-110]; *see also* Vodra Report ¶ 89.

[54] Vodra Report ¶¶ 88-89.

[55] *Id.* ¶ 89.

[56] *Apotex Inc. v. Cephalon, Inc.*, No. 06-cv-02768 MSG (E.D. Pa.), Response of Apotex to Cephalon's Request for Conference, at 1 (Apr. 21, 2010) (emphasis added) [RLA-70].

[57] FDA Import Alert #66-40, *Detention Without Physical Examination of Drugs from Firms Which Have Not Met Drug GMPs* (Oct. 2, 2009) (identifying "Apotex Inc., 150 Signet Drive, North York, Ontario," and "Apotex Inc., 50 Steinway Blvd., Etobicoke, Ontario") [C-110].

[58] *Apotex Inc. v. Cephalon, Inc.*, No. 06-cv-02768 MSG (E.D. Pa.), Response of Apotex to Cephalon's Request for Conference, at 2 (Apr. 21, 2010) (emphasis added) [RLA-70]; *see also* Apotex Press Statement, "FDA Pharmaceutical Import Alert," at 1 (Sept. 8, 2009) ("The Import Alert recently posted by FDA applies to products manufactured at 2 of Apotex's many facilities.") [R-160].

43. The Import Alert thus *advised* FDA district offices that they could detain goods being offered for import from Etobicoke and Signet.[59] It did not decide the "rights and interests"[60] of any party, including Apotex Inc. and Apotex Corp.

2. FDA's "For Cause" Inspections of Etobicoke and Signet Corroborated Concerns Raised by Consumers and Pharmacists Regarding Apotex Drugs

44. Apotex erroneously asserts that "FDA's suspicions leading to the Import Alert proved unjustified."[61] To the contrary, FDA confirmed its "suspicions" through rigorous onsite inspections of Apotex's Etobicoke and Signet facilities. *The results of those inspections are undisputed in this arbitration*.

45. In the two years prior to FDA's 2008 inspection of Etobicoke, FDA received an alarming number of negative reports about Apotex drugs. FDA received some [redacted] Adverse Event Reports[62] and [redacted] consumer complaints.[63] Dr. Desai contends that [redacted] consumer complaints "does not seem unreasonable," as "a customer may complain because he had difficulty to remove the seal of a bottle or because he did not like the color of his tablets."[64] But the complaints about

[59] Indeed, Apotex itself saw the Import Alert as a *trade* measure (rather than an *investment* measure) in 2010, when Apotex's lawyers invoked NAFTA Article 301 in a letter to FDA. Letter from C. Shepard and K. Beardsley, Buc & Beardsley LLP, to R. Tyler, FDA Chief Counsel, and D. Autor, Director, CDER-Office of Compliance, at 10-11 (Dec. 13, 2010) (accusing FDA of violating NAFTA's objectives of the "elimination of trade barriers, facilitation of cross-border movement of goods and services and promotion of conditions of fair competition" (citing NAFTA, art. 301, GATT Art. III, and decisions of WTO panels and the WTO Appellate Body)) [C-185].

[60] Reply ¶ 390.

[61] *Id.* ¶¶ 48-83; Supplement to Reply of Claimants Apotex Holdings Inc. and Apotex Inc. ¶¶ 11-51 (July 22, 2013) ("Supplement to Reply").

[62] FDA's Adverse Event Reporting System is a database that contains information on adverse event and medication error reports submitted to FDA. *See* FDA, Adverse Event Report System (FAERS) [R-212].

[63] Email from H. Molina to S. Eberhard (Mar. 20, 2009) [C-486]; *see also* email from H. Molina to C. Rosa (Mar. 19, 2009) (reporting "a large number of consumer complaints regarding lack of therapeutic effect in the past 12 months") [C-344].

[64] Second Desai Statement ¶ 13.

Apotex drugs raised very serious issues,[65] including a lack of intended therapeutic effect of Apotex drugs.[66] The dangers identified by FDA included "potentially life-threatening prolonged seizure causing neuronal injury"; "transplant rejection"; and "neuroleptic malignant syndrome, which is life-threatening and characterized by fever, muscular rigidity, altered mental status and autonomic dysfunction."[67]

46. While the "color of [Apotex's] tablets" may appear trivial, it is a serious concern to consumers and to drug regulators.[68] Apotex, in fact, recently issued in Canada an "urgent drug recall" of 50,000 packages of birth control pills that "contained blisters with extra placebo tablets (white) in place of active tablets (pink)."[69] The packages were distributed with two, rather than three, rows of active tablets, reportedly leading to scores of unplanned pregnancies.[70] For some women, pregnancy can be dangerous, even life-threatening.[71] Health Canada thus understandably issued a Class I recall of the defective product, signaling "a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health

[65] Supplemental Statement of Dr. Carmelo Rosa ¶ 18 (Sept. 27, 2013) ("Supplemental Rosa Statement").

[66] *See, e.g.*, email from C. Gould to H. Molina re "Apotex: Highest risks for lack of therapeutic effect" (Apr. 9, 2009) [R-145].

[67] *See, e.g.*, *id.*; *see also* Vodra Report ¶ 38 (discussing the life-threatening danger of the lack of therapeutic effect of an Apotex drug used to control seizures in patients with epilepsy).

[68] Apotex has acknowledged that color also is an important way that consumers distinguish between medications. Following a packaging mix-up between two drugs, Apotex assured FDA, in a March 2009 Field Alert Report, that consumers would not take the wrong medication because the drugs were "different in colour, size, shape and markings." Field Alert Report re mix-up between [redacted] (Feb. 20, 2009) [R-142].

[69] Apotex Inc., "Urgent Drug Recall" (Apr. 12, 2013) [R-223].

[70] *Id.*; Canadian Medical Association, *Birth Control 'Debacle' Prompts Calls for Swifter Public Notices* (May 2, 2013) [R-225]; Justin Fauteux, *Class Action Launched Against Maker of Recalled Birth Control Pills*, GLOBE AND MAIL (May 16, 2013) [R-226].

[71] Erin Anderssen, *Women Not Alerted Immediately of Alysena 28 Birth Control Pill Recall*, GLOBE AND MAIL (Apr. 9, 2013) (reporting that "Health Canada raised the level of the recall out of concern for women who had been advised not to get pregnant for medical reasons or who might be using drugs that could be harmful to a developing fetus") [R-221].

consequences or death."[72] Apotex reportedly delayed notifying consumers of the initial recall for five days after identifying the problem, prompting Canada's health minister to order an investigation into the delay.[73] Although Apotex publicly characterized the problem as a mere "packaging error," the CEO of the Society of Obstetricians and Gynaecologists of Canada called it a "totally unprecedented event" and a "debacle."[74]

47. The number of reported consumer complaints, moreover, invariably understates the actual number of adulterated products distributed on the U.S. market, as complaints are received only from customers who are aware of a defect and have the knowledge and inclination to report it to FDA.[75]

48. Apotex's late reporting provided a second ground for FDA's decision to order a for-cause inspection of Etobicoke. Federal regulations require pharmaceutical companies to submit Field Alert Reports, or FARs, within three days of discovering problems.[76] Late filings deprive FDA of the timely information it requires to take effective action to protect public health. Apotex routinely filed its FARs months late.[77] Apotex was cited for this failure after a 2006 inspection of its Etobicoke facility,[78] but nonetheless persisted in filing its FARs late. Apotex, for instance, delayed six months in 2008 before informing FDA of a double-thick tablet of [redacted], which is

[72] Health Canada, Product Recall Procedures [R-137].

[73] Carly Weeks, *Minister Orders Inquiry into Delay in Notifying Public of Alysena Recall*, GLOBE AND MAIL (Apr. 11, 2013) ("Federal Health Minister Leona Aglukkaq has ordered an investigation to determine why Canadian women were not immediately informed of a recall of potentially faulty birth-control pills.") [R-222].

[74] Canadian Medical Association, *Birth Control 'Debacle' Prompts Calls for Swifter Public Notices* (May 2, 2013) (quoting Dr. Jennifer Blake) [R-225].

[75] Vodra Report ¶¶ 21-23.

[76] 21 C.F.R. § 314.81(b)(I)(i)-(ii) [CLA-273].

[77] *See* Counter-Memorial ¶¶ 74-75, 89.

[78] FDA Establishment Inspection Report, Apotex Inc., Etobicoke, at 2 (Nov. 20-24, 2006) [C-25]; *see also* Witness Statement of Debra M. Emerson ¶ 16 (Dec. 13, 2012).

used to treat cardiovascular disease.[79] Although Apotex had received [redacted] similar complaints in the preceding two years and shipped [redacted] bottles with potentially oversized tablets to the United States, it reported the double-thick tablet as "a unique, non-recurring issue."[80]

49. These are the kinds of serious concerns that prompted FDA to order a "for cause" inspection of Etobicoke. As the U.S. Counter-Memorial discussed, the inspection revealed systemic problems with Apotex's manufacturing and quality control procedures.[81] At the inspection's closeout meeting, FDA presented Apotex management with 11 written observations and raised five additional concerns verbally.[82] The most serious violations included failed stability testing, improper investigation of batch failures, and late reporting of FARs.[83] The investigators designated their report "Official Action Indicated,"[84] or OAI, indicating that "objectionable conditions were found and FDA regulatory action is necessary to compel correction."[85]

50. While FDA was considering possible enforcement action against Etobicoke, the agency continued to receive alarming reports concerning drugs from Apotex's Signet facility. The most serious complaints concerned the commingling in a single package of different drug products[86]

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[79] Field Alert Report for [redacted] 20mg (Nov. 18, 2008) [R-28].

[80] *Id*.

[81] Counter-Memorial ¶¶ 72-80.

[82] FDA Establishment Inspection Report, Apotex Inc., Etobicoke,, at 1-2, 35 (Dec. 10-19, 2008) ("2008 Etobicoke EIR") [R-26].

[83] *See* Counter-Memorial ¶¶ 72-80.

[84] 2008 Etobicoke EIR [R-26]; Field Accomplishments Compliance Tracking System (FACTS) Cover Sheet, Apotex Inc., Etobicoke (Dec. 10-19, 2008) [R-25].

[85] FDA, *Inspections – Background* [CLA-575].

[86] *See* Field Alert Report re mix-up between [redacted] (Feb. 20, 2009) (reporting that a pharmacist had found a tablet of the hypertension drug [redacted] in a bottle of [redacted] tablets, which is used to treat diabetes,

and different drug dosages,[87] as well as double-thick tablets,[88] which can lead to a deadly overdose.[89] In light of these serious problems, the Division of Compliance Risk Management and Surveillance in the Center for Drug Evaluation and Research (CDER) promptly recommended a "for cause" inspection of Signet.[90]

51. Pending that inspection, FDA declined to place drugs from Etobicoke on Import Alert, opting instead to issue a "warning letter."[91] That letter expressed FDA's serious concerns about "the capability and reliability of [Apotex's] processes to consistently manufacture drug products" in conformity with U.S. law.[92] FDA concluded that "the methods and controls used in their manufacture do not appear to conform to current good manufacturing practice."[93] FDA thus apprised Apotex that drugs from Etobicoke were deemed to be adulterated under U.S. law and thus "could be subject to refusal of admission."[94] FDA requested that Apotex respond to the

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and noting that [redacted] and [redacted] tablets of these strengths were packaged in the same facility on adjacent packaging lines during the same time period and this is being investigated as a potential root cause.") [R-142].

[87] DQRS/Medwatch Report for [redacted], Form FDA 3500 (Jan. 9, 2009) (reporting that a pharmacist had found a 10 mg tablet in a bottle of 20 mg tablets of Apotex [redacted] which is used is used to treat rheumatoid arthritis) [R-31].

[88] *See* DQRS/Medwatch Report for [redacted], Form FDA 3500 (Jan. 14, 2009) (noting that a pharmacy had found a double-thick tablet of [redacted] which is used to treat arthritis, fibromyalgia, and other diseases) [R-32].

[89] Email from M. Thomas to J. Martinez and E. Rivera Martinez re oversized [redacted] tablet (Jan. 22, 2009) [R-34].

[90] Email from E. Rivera Martinez to C. Rosa re Potential Mix-up of [redacted] 20mg Tablets Made by Apotex in Canada (Jan. 16, 2009) [C-336].

[91] Warning letters invite the warned entity to respond by a specified date and contain contact information for questions or concerns. *See, e.g.*, 2009 Etobicoke Warning Letter, at 6 (June 25, 2009) [C-41]. Warning letters are intended to give a firm or facility an opportunity, where possible, to take prompt corrective action. FDA, *Regulatory Procedures Manual* § 4-1-1 (Mar. 2009) [CLA-305]. Warning letters thus seek to achieve voluntary compliance and are a primary means of notifying a firm or facility that it may be subject to enforcement action. *Id.* Warning letters, however, are not the exclusive means of giving prior notice of an enforcement action. *Id.* § 10-2-4.

[92] 2009 Etobicoke Warning Letter, at 2 [C-41].

[93] *Id.* at 6.

[94] *Id.*.

agency's concerns within 30 days and invited Apotex to contact one of the FDA officials identified in the letter.[95]

52. The following month, an Apotex employee emailed FDA confidentially to express concern that Apotex was not taking FDA's warning seriously.[96] The informant reported that Apotex had not alerted its employees to the warning letter until after it had been reported in the press.[97] Only then did employees receive an email detailing the situation.[98]

53. While FDA was reviewing Apotex's response to the Etobicoke warning letter, it simultaneously was inspecting Apotex's Signet facility. As discussed in the U.S. Counter-Memorial, that inspection also revealed many significant cGMP violations.[99] The most serious included contamination of active pharmaceutical ingredients used to manufacture drugs for the U.S. market;[100] failure to investigate the root cause of failed batches;[101] failure to submit FARs on time;[102] repackaging of failed products;[103] and failure to maintain written procedures for preventing cross-contamination and adulteration.[104] These deviations affected multiple products and confirmed *systemic* quality-control problems with Apotex's manufacturing practice. At the

[95] 2009 Etobicoke Warning Letter, at 6 [C-41].

[96] Email from G. Randazzo to C. Rosa and B. Belz re "Apotex informant info" (July 27, 2009) [R-245].

[97] *Id.*

[98] *Id.*

[99] Counter-Memorial ¶¶ 86-93.

[100] FDA Establishment Inspection Report, Apotex Inc., Signet, at 38, 41-42 (July 27-Aug. 14, 2009) ("2009 Signet EIR") [R-42]; Witness Statement of Lloyd Payne ¶ 17 (Dec. 12, 2012) ("Payne Statement").

[101] Form FDA 483, Inspectional Observations, Apotex Inc., Signet, at 9-10 (Aug. 14, 2009) ("2009 Signet Form 483") [C-61]; 2009 Signet EIR, at 76-80 [R-42].

[102] 2009 Signet Form 483, at 4-5 (Observation 3) [C-61]; 2009 Signet EIR, at 59-63 [R-42]; Payne Statement ¶ 21.

[103] 2009 Signet Form 483, at 1-2 [C-61]; 2009 Signet EIR, at 39, 43-44 [R-42].

[104] 2009 Signet Form 483, at 10 [C-61]; 2009 Signet EIR, at 80-82 [R-42].

end of the inspection for Signet, FDA investigators recorded 17 written observations and raised 10 additional verbal concerns with Apotex management.[105]

54. After reviewing all relevant information, CDER determined that Signet had "significant, systemic CGMP violations" and "posed significant potential public health risks," such that drugs from the facility were deemed to be adulterated within the meaning of U.S. law.[106] CDER further determined that the problems at Signet were similar to those found at Etobicoke,[107] thus demonstrating "a lack of adequate process controls" and raising "serious concerns regarding the firm's quality and production systems" at both sites.[108]

55. Given the number and systemic nature of the cGMP violations, as well as their potential impact on public health, CDER recommended that "all finished pharmaceutical products" from Etobicoke and Signet be placed on Import Alert 66-40 ("Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug GMPs") until the "firm can demonstrate that it is in compliance with CGMPs, and a re-inspection confirms that appropriate corrections have been implemented."[109] FDA's Division of Import Operations and Policy (DIOP) concurred with CDER's recommendation and placed Etobicoke and Signet on the Import

[105] 2009 Signet EIR, at 93-96 [R-42]; Payne Statement ¶ 15; Counter-Memorial ¶ 86.

[106] Witness Statement of Dr. Carmelo Rosa ¶ 59 (Dec. 14, 2012) ("First Rosa Statement").

[107] Memorandum from Director, Division of Manufacturing and Product Quality, CDER – Office of Compliance, to Director, DIOP, at 2 (Aug. 20, 2009) [C-64]; First Rosa Statement ¶ 48.

[108] Memorandum from Director, Division of Manufacturing and Product Quality, CDER – Office of Compliance, to Director, DIOP, at 2 (Aug. 20, 2009) [C-64]; First Rosa Statement ¶¶ 61, 66.

[109] Memorandum from Director, Division of Manufacturing and Product Quality, CDER – Office of Compliance, to Director, DIOP, at 3 (Aug. 20, 2009) [C-64].

Alert on August 28, 2009.[110] The Import Alert did not apply to other Apotex facilities in Canada or elsewhere.

56. Following the addition of Etobicoke and Signet to the Import Alert, [redacted] shipments of Apotex drugs were detained without physical examination at the border for the appearance of adulteration, based on cGMP violations at those facilities.[111] In each case, FDA followed its standard operating procedures. While the products were being held pending agency review, FDA sent Apotex "Notices of FDA Action," apprising the firm that the listed products were being held, and providing contact information for an agency investigator.[112]

57. Once the products had been screened and detained without physical examination, FDA sent a second set of Notices of FDA Action.[113] These notices explained that the listed products were being detained and "were subject to refusal," because "it appear[ed] that the methods used in or the facilities or controls used for the manufacture, processing, packaging, or holding do not conform to or [were] not operated or administered in conformity with current good

[110] Email from "ORA HQ DIOP Import Alerts" to Regina Barrell et al. (Aug. 28, 2009) [C-67]; *see also* First Rosa Statement ¶ 62.

[111] Memorial ¶ 192 ("In total, [redacted] shipments from Etobicoke and Signet were put on hold by FDA on August 30-31 and September 1, 2009.").

[112] *See*, *e.g.*, Notice of FDA Action re: Entry No EG6-1768425-3, Notice No. 1 (Sept. 2, 2009) (sent to Filer, Affiliated Customs Brokers) [C-78]; Notices of FDA Action re: Entry No EG6-1768425-3, Notice No. 1 (Sept. 2, 2009) (sent to Importer of Record Apotex Inc. and to Consignee Apotex Corp.) [R-44].

[113] *See*, *e.g.*, Notice of FDA Action re: Entry No EG6-1768425-3, Notice No. 2 (Sept. 4, 2009) (sent to Filer, Affiliated Customs Brokers) [C-84]; Notices of FDA Action re: Entry No EG6-1768425-3, Notice No. 2 (Sept. 4, 2009) (sent to Importer of Record Apotex Inc. and to Consignee Apotex Corp.) [R-44]. Not all Apotex products, however, were detained without physical examination. *See* Memorial ¶ 192 n.261 (noting that a shipment from Apotex Inc.'s Richmond Hill facility was initially held pending review and then released); Notice of FDA Action re: Entry No EG6-1770729-4, Notice No. 2 (Oct. 2, 2009) (noting that the listed product was released for import) [C-111].

manufacturing practices."[114] These notices also reminded Apotex of its right to a hearing to submit oral and written testimony in advance of any decision to refuse admission of the products to the United States, and they provided contact information for an agency compliance officer.[115] Apotex declined to submit testimony for any of the [redacted] shipments.

58. After the time to submit testimony had lapsed, the FDA district office refused to admit the [redacted] shipments. FDA then sent Apotex a third set of Notices of FDA Action explaining its decision.[116] Apotex did not respond to any of these notices.[117]

3. Apotex's Primary Regulator, Health Canada, Corroborated FDA's Findings, Identifying Recurrent, Major cGMP Violations at Etobicoke and Signet

59. Health Canada shared FDA's concerns, and its inspections of Etobicoke and Signet corroborated those concerns. After reviewing FDA's reports and Apotex's responses, Health Canada requested that Apotex provide "evidence as to why products being made at these two sites should not be recalled from the Canadian market."[118] Health Canada had understood that Apotex would recall from the Canadian market the same 42 products that Apotex had recalled

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[114] *See, e.g.*, Notice of FDA Action re: Entry No EG6-1768425-3, Notice No. 2 (Sept. 4, 2009) (sent to Filer, Affiliated Customs Brokers) [C-84]; Notices of FDA Action re: Entry No EG6-1768425-3, Notice No. 2 (Sept. 4, 2009) (sent to Importer of Record Apotex Inc. and to Consignee Apotex Corp.) [R-44].

[115] *Id.* ("You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above [September 25, 2009]."). A detention hearing can take many forms, including an in-person meeting, telephone conference, or letter exchange. FDA, *Regulatory Procedures Manual* § 9-8, at 9-34 (Mar. 2009) [CLA-309]. The owner or consignee may introduce written or oral testimony to establish the admissibility of any detained goods. 21 C.F.R. § 1.94 (2012) [CLA-245]; 21 U.S.C. § 381(a) (2009-2011) [CLA-240]; FDA, *Regulatory Procedures Manual* § 9-8, at 9-33 (Mar. 2009) [CLA-309]. A final decision as to the admissibility of detained goods is made only after an opportunity to present testimony has been afforded. If the district office ultimately determines that a violation exists, or appears to exist, then the product will be refused admission. 21 U.S.C. § 381(a) (2009-2011) [CLA-240]

[116] *See, e.g.*, Notices of FDA Action (Sept. 28, 2009) [C-108].

[117] *See infra* ¶¶ 342-45.

[118] Email from J. Desai to J. Watson et al. (Sept. 2, 2009) [C-76].

from the U.S. market.[119] But Apotex agreed to recall only three products in Canada.[120] Apotex argued that some of the products recalled from the United States "are either not sold in Canada or are produced and tested differently," and that the impact on other products was "*limited to US batches*."[121]

60. Health Canada rejected Apotex's explanation and decided "to undertake a thorough review of [Apotex's] Good Manufacturing Practices."[122] Health Canada launched rigorous inspections of Etobicoke and Signet, which were "exceptional not only in terms of length, but also in terms of [the] size of the team."[123] Having confirmed many of the problems identified by FDA, Health Canada increased the number of inspectors and length of the inspection.[124] In the end, given the magnitude of the violations, *14 investigators* participated in the inspections, as opposed to the normal two or three investigators.[125] The inspections also occurred over *two months*, as opposed to the normal ten days.[126] At the end of the inspection, Health Canada recorded [redacted] separate observations, including [redacted] Risk 2 observations ("major observations") and [redacted] repeat Risk 2 observations.[127]

[119] Email from S. Mullin to B. Clark (Sept. 4, 2009) [C-87].

[120] *Id.*; letter from L. Lovelock to R. Kirchner, Health Canada (Sept. 8, 2009) [C-88].

[121] Letter from L. Lovelock to S. Mullin, Director, HPFB Inspectorate, Compliance & Enforcement Coordination Division (Sept. 9, 2009) (emphasis added) [C-90].

[122] Health Canada Press Statement, "Important Information on Apotex Health Products" (Sept. 17, 2009) [C-101].

[123] Witness Statement of Edmund Carey ¶ 43 (July 29, 2012) ("First Carey Statement").

[124] Voicemail from S. Mullen to E. Rivera-Martinez (Sept. 30, 2009) [R-166].

[125] First Carey Statement ¶ 43.

[126] *Id.* ¶ 43.

[127] Health Canada, Inspection Exit Notice for Signet (Oct. 14, 2009) [C-112].

61. Health Canada's inspection of Etobicoke raised equally serious problems. Health Canada recorded [redacted] separate observations, including [redacted] Risk 2 observations and [redacted] repeat Risk 2 observations.[128] Health Canada faulted Apotex's recurring failures of quality control. The agency noted, for instance, that when [redacted] batches of a drug manufactured for the U.S. market failed testing, they were "rescreened" and released for sale in Canada.[129]

62. Apotex did not dispute Health Canada's observations.[130] To the contrary, Apotex informed Health Canada that "Apotex acknowledges the observations in this exit notice and is committed to addressing them and the *system deficiencies* highlighted by them."[131] Following Health Canada's inspection, in fact, Dr. Desai informed Apotex CEO Bernard Sherman that "*our quality systems lack quality*."[132] The inspections had identified so many serious problems that, under Canadian law, Health Canada could have stripped Apotex of its operating license and shut its facilities down.[133]

63. At that time, however, Canada was suffering from a national drug shortage, which reportedly made it difficult for Canadians to obtain antibiotics, antidepressants, and many other essential and common drugs.[134] Apotex is the largest generic drug company in Canada, with a

[128] Health Canada, Inspection Exit Notice for Etobicoke (Nov. 4, 2009) [C-116].

[129] *Id.* at 12.

[130] Letter from C. Austin to A. Lostracco, at 1 (Dec. 8, 2009) (emphasis added) [C-123].

[131] *Id.*

[132] Email from J. Desai to B. Sherman (Nov. 26, 2009) (emphasis added) [R-175].

[133] Letter from C. Austin to A. Lostracco, at 1 (Dec. 8, 2009) [C-123]; *see also* Health Canada, Health Products and Food Batch Inspectorate, Risk Classification of Good Manufacturing Practices (GMP) Observations, GUI-0023, at 3 [R-97].

[134] *Drug Shortages Must be Addressed – Pharmacists* (Nov. 2, 2010), CBC News (reporting national drug shortage that began in 2009) [R-64].

24 percent share of the Canadian market.[135] Apotex reports that nearly one in five prescriptions in Canada is filled with an Apotex drug.[136] Between 2006 and 2010, Apotex alone reportedly was responsible for 19 percent of all drug shortages in Canada, far more than any other generic drug manufacturer.[137]

64. Health Canada thus opted not to shut Apotex down, but to commit "substantial resources" to inspecting Apotex's facilities[138] and to "monitor and ensure effective implementation of [Apotex's] corrective actions."[139] To that end, Health Canada decided to find Etobicoke and Signet "compliant," but imposed a series of extraordinary "terms and conditions" for the issuance of Apotex's 2010 establishment license.[140] Under Canadian law, Health Canada imposes such "terms and conditions" where there is a concern that the drugs will be "unsafe for use," or "to prevent injury to the health of consumers."[141] Health Canada required that Apotex, among other things, provide weekly progress reports and monthly investigation and quality updates, and to submit to monthly visits by Health Canada inspectors. On this basis only, and under Health Canada's close, continuous, onsite supervision, Apotex's drug establishment license was extended for a year, until December 31, 2010.[142]

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[135] First Desai Statement ¶ 22.

[136] Apotex Inc., "Important Information on Apotex Health Products" (Sept. 17, 2009) [C-104].

[137] Geraldine Ottino et al., *Drug Shortages in Health Care Institutions: Perspectives in Early 2012*, 65(2) CAN. J. HOSP. PHARM. 151–52 (Mar.-Apr. 2012) [R-205].

[138] Memorial ¶ 5.

[139] Letter from S. Jessamine to C. Robertson (Oct. 20, 2009) [C-113].

[140] Terms and Conditions Annex for 2010 Drug Establishment License 100375-A (Dec. 31, 2009) [C-126].

[141] Food and Drug Regulation C.01A.008(4) [RLA-173], cited in Terms and Conditions Annex for 2010 Drug Establishment License 100375-A (Dec. 31, 2009) [C-126].

[142] Establishment License 100375-A, at 3 (Dec. 31, 2009) ("These terms and conditions are valid until December 31, 2010.") [C-126]. Apotex's vice president for Quality, Mr. Carey, testified that, "in 2011, Health Canada *only* required that we file quarterly reports." Second Witness Statement of Edmund Carey ¶ 32 (May 24, 2013) (emphasis added) ("Second Carey Statement"). Stressing the seriousness of Apotex's problems, he noted that

65. Other drug agencies around the world were just as alarmed about the state of Apotex's cGMP violations.[143] Inspectors from the Netherlands, the United Kingdom, New Zealand, and Singapore all participated in follow-up visits to Etobicoke and Signet immediately following Health Canada's fall 2009 inspection.[144] At the closeout meeting of the visit, Health Canada agreed to hold *monthly* telephone conferences with other national drug agencies, to advise them of the state of Apotex's compliance.[145] Health Canada, moreover, conducted an additional *31-day* inspection of Apotex's facilities during June and July 2010.[146]

66. Health Canada's dim view of Apotex's cGMP conditions in 2009 is confirmed by a May 2011 internal Apotex report, which records a Health Canada inspector's observation that Apotex was in "a much better state of control" of cGMP in 2011 than it had been in 2009.[147] The inspector added: "Compared to Apotex of the past, this is a dramatic improvement."[148] Apotex noted the inspector's observation that "[i]t is a '*new Apotex*' compared to when he was here in Fall of 2009,"[149] placing "Apotex in a *lower risk level* compared to inspections from 2009 and 2010."[150] A representative from the Netherlands' drug agency who attended the inspection

"Apotex diligently complied with all the terms and conditions imposed by Health Canada," and thus "Health Canada did not cancel our manufacturing license." *Id.*

[143] *See* Counter-Memorial ¶¶ 135-142 (discussing temporary import bans imposed by drug authorities in Australia, New Zealand, and the Netherlands (for the European Economic Area)).

[144] Email from J. Desai to B. Sherman (Nov. 26, 2009) [R-175].

[145] *Id.*

[146] Email from T. Dang to S. Simmons et al. (July 30, 2010) (noting "Day #31 overall" of Health Canada's inspection) [R-189].

[147] Contact Report, May 17, 2011 [R-195].

[148] *Id.*

[149] *Id.* (emphasis in original).

[150] Contact Report, May 31, 2011 (emphasis in original) [R-198].

similarly remarked that "there is a quality culture shift within Apotex . . . perhaps a combination of new people and renewed focus on Quality."[151]

67. The observations of the Dutch and Canadian health regulators in 2011 confirm how bad Apotex's manufacturing practice was in the fall of 2009, when FDA added Etobicoke and Signet to the Import Alert, and how much better Apotex's manufacturing practice was by the summer of 2011, when FDA removed Etobicoke and Signet from the Import Alert.

4. FDA's Alleged "Misunderstandings" Are Irrelevant to Apotex's Claims

68. Apotex invites the Tribunal to re-examine FDA's conclusions about the severity of Apotex's cGMP violations, pointing to a handful of supposed FDA "misunderstandings" about the state of Apotex's manufacturing practice.[152] But because Apotex now dismisses its cGMP violations as "legally irrelevant" to this case,[153] it is not clear why Apotex has raised these alleged misunderstandings. In any event, these few alleged misunderstandings – which almost exclusively concern the 2008 Etobicoke inspection[154] – pale in comparison to Apotex's significant violations of U.S. law, which were confirmed during extensive onsite inspections of Apotex's manufacturing facilities. It is these *undisputed* violations of U.S. law that resulted in the Import Alert for Apotex drugs, and not any of the misunderstandings alleged by Apotex.[155]

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[151] Contact Report, May 18, 2011 [R-196].

[152] Reply ¶¶ 15, 51, 56-57, 65.

[153] *Id.* ¶ 41.

[154] Only five of the 35 numbered paragraphs in the facts section of Apotex's Reply concern the Signet inspection, which immediately preceded Apotex's addition to the Import Alert. Reply ¶¶ 70-74. Only three of the 41 numbered paragraphs in Apotex's Supplement concern Signet. Supplement to Reply ¶¶ 40-42. Apotex's unbalanced analysis ignores the pivotal Signet inspection and Apotex's immediate response, in which Apotex refused to consider cessation of exports to the United States while it addressed its cGMP violations. *See infra* ¶¶ 78-81.

[155] *See* Counter-Memorial ¶¶ 72-80, 86-93.

69. Apotex contends, for example, that FDA acted out of a mistaken belief that the stability data of Apotex's carbidopa-levodopa product did not meet regulatory requirements.[156] Apotex addressed this issue in its January 30, 2009 response to the investigators' Form 483 inspectional observations for Etobicoke.[157] Apotex cites nothing after this date identifying the stability testing of carbidopa-levodopa as a justification for the Import Alert *seven months later*. Further, nothing in FDA's Import Alert recommendation identified concerns about carbidopa-levodopa.[158]

70. Similarly, Apotex claims that FDA's concerns were heightened by a mistaken assumption that Apotex had withdrawn multiple marketing applications because of concerns over "application integrity."[159] To that end, Apotex cites an internal FDA email dated January 15, 2009, more than *eight months* prior to the issuance of the Import Alert.[160] But Apotex cites nothing after January 15 to suggest that FDA's action was predicated on that particular concern about application integrity.[161] Further, nothing in the Import Alert recommendation identified concerns with application integrity.

71. Apotex also claims that FDA confused the firm with Teva and Novopharm.[162] Apotex cites two emails from March and April 2009, more than four months before the Import Alert was

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[156] Reply ¶¶ 49-51.

[157] Apotex Response to Etobicoke Form 483 (Jan. 30, 2009) [C-37].

[158] *See, e.g.,* Memorandum from Director, Division of Manufacturing and Product Quality, to Director, Division of Import Operations and Policy (Aug. 20, 2009) [C-64]; email from J. Famulare to M. Lumpkin (Aug. 18, 2009) [C-373].

[159] Reply ¶¶ 55-56.

[160] Email from S. Laska to C. Rosa (Jan. 15, 2009) [C-334].

[161] While an application integrity concern was raised during the Signet inspection, it does not appear in the Form 483 or Establishment Inspection Report for that inspection.

[162] Supplement to Reply § II(F).

issued.[163] Apotex cites nothing else to suggest that FDA was confused when it issued the Import Alert on August 28, 2009. Further, nothing in the Import Alert recommendation concerned cGMP violations in any facilities other than Apotex's.

72. Apotex also complains that FDA "misunderstood" Apotex data concerning the number of rejected drug batches, "which appeared high and suggested that Apotex's manufacturing practices were out of control."[164] Although Apotex raised the issue in its July 2009 response to the Etobicoke warning letter, it failed to provide a more complete explanation of its batching system until November 2009, three months *after* issuance of the Import Alert.[165] In any event, Apotex itself concedes that [redacted] of the 554 batches were *true batch failures*,"[166] thus confirming that the number of batch failures *was* high and that Apotex's manufacturing practices *were* out of control.

73. Finally, Apotex claims that a list addressing [redacted] plus Adverse Event Reports involving Apotex was never "verified," citing emails in which FDA officials inquired about the author of that list.[167] But these officials subsequently confirmed in July 2009 – two months prior to the issuance of the import alert – that CDER compliance officer Hidee Molina and FDA's Division of Compliance Risk Management and Surveillance had compiled the list.[168] There is no evidence to suggest further confusion on this issue or any concern about the accuracy of the

[163] Email from H. Negron-Rivera to C. Rosa (Mar. 4, 2009) [C-485]; email from H. Negron-Rivera to H. Molina (Mar. 23, 2009) [C-487]; email from S. Eberhard to H. Saccone (Apr. 3, 2009) [C-349].

[164] Reply ¶ 57; *see also* Supplement to Reply ¶¶ 18-20.

[165] Reply ¶ 66.

[166] *Id.* ¶ 65 n.79.

[167] Supplement to Reply ¶¶ 21-33.

[168] *See* email from H. Molina to C. Rosa (June 9, 2009) (citing information requested) [C-498].

Adverse Event Reports list. Apotex thus has presented no evidence calling into question FDA's analysis with respect to the Adverse Event Reports.

5. FDA Afforded Apotex Multiple Opportunities to Address its cGMP Violations and Considered Adoption of the Import Alert Over Eight Months

74. Apotex's Quality director, Mr. Carey, complains that FDA "imposed a blanket import ban on all products manufactured at Signet and Etobicoke, without allowing for any meaningful dialogue prior to or after its imposition."[169] Mr. Carey, however, was not hired by Apotex until September 2010, more than a year after issuance of the Import Alert.[170] The basis for his statement is thus unclear. In any event, his assertion flatly contradicts the firsthand testimony of his colleagues. Dr. Desai, for instance, testified that Apotex had "been in a frequent dialogue with FDA since August 2009,"[171] citing Apotex's regular correspondence, telephone calls, and meetings with FDA before[172] and after[173] issuance of the Import Alert. The contemporaneous evidence further confirms that FDA not only engaged in "meaningful dialogue" with Apotex, but devoted countless hours to addressing Apotex's ongoing compliance problems.[174]

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[169] Second Carey Statement ¶ 35.

[170] First Carey Statement ¶ 7 (noting that he joined Apotex Inc. in September 2010).

[171] First Desai Statement ¶ 72.

[172] *Id.* ¶ 34 (noting his presence at the opening and closing meetings of the December 2008 Etobicoke inspection); *id.* ¶ 39 (noting a July 17, 2009 call with FDA to discuss Etobicoke warning letter and explain Apotex's batch failures); *id.* ¶ 41 (noting his presence at the opening and closing meetings of the July 27-August 14 Signet inspection); *id.* (noting a telephone call with CDER's Director the Division of Manufacturing and Product Quality); *id.* (noting a "follow-up call with FDA" to discuss Apotex recall and "the enhancements that we were going to take at our facilities in order to improve our Quality Systems").

[173] *Id.* ¶ 59 (noting a September 3, 2009 telephone call with FDA to discuss the Import Alert); *id.* ¶ 61 (noting a September 2009 meeting among FDA, Apotex, and Apotex's consultant to discuss Apotex's proposed improvements to its Quality Systems); *id.* ¶ 68 (noting "teleconference calls with FDA in November 2009 and January 2010 to discuss issues of potential cross contamination"); *id.* ¶ 69 (noting a "face-to-face meeting with FDA" on March 31, 2010); *id.* ¶ 81 (noting a June 2010 teleconference with FDA to discuss Apotex's request to ship products to the United States).

[174] *See, e.g.*, Memorial ¶¶ 167-171, 181-183, 194-195, 215-223, 227-246 (and exhibits cited therein); Counter-Memorial ¶¶ 81, 84-85, 94-98, 105-110, 154-171 (and exhibits cited therein); *see also* email from C. Austin (Apotex Inc.) to H. Negron-Rivera (FDA) re Signet inspection (Apr. 2-3, 2009) [R-144]; email from C. Austin to C. Rosa,

75. Apotex also contends that FDA's adoption of the Import Alert was the result of a "rush to judgment."[175] But given Apotex's admission that "[t]he substance of FDA's cGMP findings is not at issue" in this arbitration,[176] the relevance of the timing of FDA's decision-making process remains unclear. In any event, the factual record belies Apotex's assertion: FDA carefully considered whether to add Apotex to the Import Alert *over eight months*.

76. FDA first considered the possibility of including Apotex drugs on the Import Alert when determining the appropriate response to the cGMP violations found during the December 2008

FDA, re Etobicoke inspection and Apotex response (May 11, 2009) [R-146]; email exchange between L. Lovelock, Apotex Inc., and G. Randazzo, FDA, re Etobicoke Warning Letter, noting call that occurred on July 2, 2009 (July 2-6, 2009) [R-149]; email from L. Lovelock to C. Rosa including slides for teleconference to discuss Etobicoke Warning Letter (July 9, 2009) [R-151]; Teleconference appointment with agenda for July 9, 2009 teleconference to discuss Etobicoke Warning Letter (July 9, 2009) [R-150]; email from L. Lovelock to G. Randazzo re Etobicoke Warning Letter (Aug. 4, 2009) [R-152]; email exchange between L. Lovelock and E. Rivera-Martinez re August 17 call (Aug. 17, 2009) [R-153]; email from L. Lovelock to I. Pettit, FDA, listing batches for voluntary recall (Aug. 19, 2009) [R-155]; email from L. Lovelock to E. Rivera-Martinez attaching Investigation Report for [redacted] (Aug. 21, 2009) [R-156]; email exchange between G. Randazzo to L. Lovelock re [redacted] and teleconference (Aug. 25-28, 2009) [R-157]; email from C. Austin to G. Randazzo re phone conversation with Apotex's consultant and attaching response to Signet Form 483 (Sept. 4, 2009) [R-159]; email exchange between L. Lovelock and G. Randazzo re agenda for Sept. 11, 2009 meeting (Sept. 9, 2009) [R-161]; email from L. Lovelock to G. Randazzo attaching minutes from Sept. 17, 2009 teleconference (Sept. 18, 2009) [R-162]; email from L. Lovelock to G. Randazzo re PQA protocol requested at Sept. 11, 2009 meeting (Sept. 24, 2009) [R-163]; email from L. Lovelock to G. Randazzo and C. Rosa re Compassionate Use of Deferiprone (Sept. 28, 2009) [R-164]; email exchange between L. Lovelock and I. Pettit re powder residue in air inlets (Oct. 2-9, 2009) [R-167]; email from G. Randazzo to L. Lovelock re teleconference (Oct. 15, 2009) [R-169]; email from L. Lovelock to FDA re compassionate use exception (Oct. 16, 2009) [R-170]; email from J. Desai to G. Randazzo re Import Alert on FDA web site (Nov. 3, 2009) [R-171]; email from G. Randazzo to J. Desai re teleconference (Nov. 3, 2009) [R-172]; email from J. Desai to G. Randazzo with final list of batches recalled from U.S. market (Nov. 16, 2009) [R-173]; email from J. Desai to E. Rivera-Martinez attaching analysis of Etobicoke batch rejection (Nov. 24, 2009) [R-174]; email exchange between G. Randazzo and J. Desai re compassionate use of Deferiprone (Dec. 2, 2009) [R-176]; email exchange between G. Randazzo and J. Desai re compassionate use of Deferiprone (Dec. 17-18, 2009) [R-177]; email from J. Desai to FDA attaching information for compassionate use exception (Jan, 19, 2010) [R-179]; email from J. Desai to G. Randazzo thanking FDA for a follow-up meeting (Feb. 18, 2010) [R-180]; email exchange between G. Randazzo and J. Desai setting future meetings dates (Feb, 24, 2010) [R-181]; email exchange between P. Balcer and J. Desai re March 31, 2010 meeting materials [R-183]; email exchange between S. Quiros and C. Austin re Field Alert Report (July 20-22, 2010) [R-188].

[175] Supplement to Reply ¶¶ 11, 44; *see also* Reply ¶ 441 (arguing that FDA's decision was "hurried" and "rushed"). Despite its contention that FDA rushed to judgment, Apotex elsewhere criticizes FDA for not acting sooner, emphasizing that"[i]t took FDA eight months to put Etobicoke on Import Alert after the inspection of that facility." Reply ¶ 46(h); *see also* Second Bradshaw Report ¶ 22(a) (same).

[176] Reply ¶ 7.

inspection of Apotex's Etobicoke facility.[177] On May 22, 2009, CDER circulated a sample Import Alert memorandum for use in drafting a possible Apotex recommendation.[178] By June 24, 2009, CDER had drafted an information advisory to the FDA Commissioner, but cautioned that CDER was still "evaluating whether product shortage will result by placing this firm on Import Alert."[179]

77. FDA decided against the Import Alert at that time, instead choosing to issue a warning letter for Etobicoke and to inspect Signet, which operated under the same quality-control management. This afforded Apotex another opportunity to demonstrate its understanding of and commitment to cGMP. CDER decided to meet with Apotex in July, before deciding whether to adopt an Import Alert.[180]

78. Neither that meeting nor the August 2009 Signet inspection demonstrated Apotex's understanding of cGMP or commitment to quality control. To the contrary, FDA investigators at the Signet facility found systemic problems with *all six cGMP systems*: materials; equipment and facilities; production; packaging and labeling; laboratory controls; and quality assurance.[181] After reviewing a draft of the inspectional observations, CDER began preparing an Import Alert

[177] *See, e.g.*, email from R. Friedman to S. Eberhard re FDA on Hold (Apr. 15, 2009) [C-351].

[178] Email from E. Rivera Martinez to H. Molina re Revision to Import Alert Recommendation (May 22, 2009) [C-355].

[179] Draft Information Advisory (June 24, 2009) [C-365].

[180] CDER Office of Compliance, Update on Emerging Drug Product Quality Concerns, at 18 (Entry for July 2, 2009) [C-501]. The meeting was held on July 9, 2009.

[181] 2009 Signet EIR [R-42]. Apotex's third-party consultant later "*confirmed that system level improvements were needed for all six [cGMP] systems*." Jeff Yuen & Associates, Inc. (JYA), Final Summary Report for Apotex Corrective Action Plan Audit, at 2 (Mar. 17, 2010) (emphasis added) [C-137].

recommendation.[182] At the same time, the FDA investigators at Signet were holding *daily* meetings with Apotex to discuss their cGMP findings.

79. Immediately after the inspection, FDA held a lengthy telephone conference with Apotex to discuss FDA's findings and the firm's proposed remediation measures. Apotex's own minutes of the call show that:

- FDA informed Apotex that it had found systemic deficiencies in all six cGMP systems;
- Apotex's then-vice president for Quality acknowledged that these deficiencies were *"significant"*;
- Apotex advised FDA that it had focused on the first two (of 17) inspectional observations, and that it had decided to recall approximately 640 batches of 42 different Apotex drug products (out of a total of 120) on the U.S. market; and
- Although "Apotex acknowledge[d] significant deficiencies," Apotex stated that it "*does intend* to continue distributing" products in the U.S. market.[183]

80. Apotex thus admitted that its cGMP violations at Etobicoke and Signet were "significant," but vowed to continue producing drugs from those facilities for the U.S. market. This attitude troubled FDA staff. An internal FDA memorandum records:

> Our office is concerned about the level of the comprehensive evaluation conducted to determine the batches selected for voluntary recall . . . . Moreover, the firm expressed commitment to stop distribution to the U.S. market for only a specific number of products that they determined need further evaluation.[184]

[182] Email from C. Rosa to H. Molina (Aug. 13, 2009) (forwarding an email with the draft Form 483 from the FDA investigators at Signet, with request to "[p]lease start updating the Import Alert Recommendation.") [C-512].

[183] FDA, Minutes of Teleconference with Apotex (Aug. 17, 2009) (emphasis added) [R-43].

[184] FDA Internal Memorandum (Aug. 17, 2009) [C-372].

81. Once Apotex confirmed its intention to continue manufacturing drugs for the U.S. market, CDER determined that it had to take immediate action.[185] The August 17 call thus proved decisive to FDA's decision to put Apotex on the Import Alert.[186]

82. Prior to doing so, however, FDA needed to consider possible drug shortages. FDA personnel had begun that inquiry by June 1, 2009.[187] On June 8, CDER's Director of Compliance determined that any Import Alert decision required a "full evaluation of the [drug] shortage issues."[188] On July 17, FDA's unit responsible for managing drug shortages identified Apotex drug products of potential concern.[189] But by August 19, that unit had advised CDER's Office of Compliance that "Apotex is not a sole [source] of any product of concern" and that, from a drug-shortage perspective, it had "little to no concern" with respect to Apotex's products.[190]

83. The following day, CDER recommended that Apotex products be placed on Import Alert 66-40, for cGMP violations.[191] Apotex responded to the Signet Form 483 on August 28,

[185] *See* Supplemental Rosa Statement ¶ 24.

[186] *See id*. ¶¶ 23-24; Vodra Report ¶¶ 72-75.

[187] Email from M. Smedley to V. Jensen re Apotex List of Products Request (June 1, 2009) [C-357].

[188] Email from D. Autor to R. Friedman re Apotex (June 8, 2009) [C-499].

[189] *See, e.g.*, email from V. Jensen to M. Smedley and C. Gould (June 18, 2009) (identifying products with shortage concerns, and outlining steps to prevent unacceptable drug shortages) [C-502].

[190] Email from I. Santiago to E. Rivera Martinez re "Apotex information requested for Aug 19, 2009" (Aug. 19, 2009) [C-376].

[191] Memorandum from Director, Division of Manufacturing and Product Quality, CDER-Office of Compliance, to Director, DIOP, at 2 (Aug. 20, 2009) [C-64].

reiterating the points it had made during the August 17 teleconference.[192] That same day, Apotex drugs were added to the Import Alert.[193]

84. Apotex thus had ample opportunity, throughout July and August 2009, to address FDA's concerns about potentially adulterated drugs entering the U.S. market. Apotex failed to demonstrate to FDA that the firm was taking appropriate steps to address the serious, systemic cGMP violations found at both Etobicoke and Signet. After many months of analysis, FDA exercised its legal authority to add Etobicoke and Signet to the Import Alert.

85. Apotex acknowledged that, following issuance of the Import Alert, it was in "continuous contact with FDA through meetings, telephone conferences, and letters[.]"[194] These included a telephone conference on September 3, 2009; an in-person meeting at FDA headquarters on September 11; another telephone conference on September 17 regarding a "compassionate use" exception for certain drugs; emails throughout fall 2009 regarding the "compassionate use" issue; a telephone conference on January 27, 2010; a comprehensive regulatory meeting on March 31; and many other emails and phone calls through 2010.[195]

86. During none of these numerous meetings, telephone conferences, or email exchanges did Apotex protest having been placed on the Import Alert.[196] To the contrary, Apotex admitted its

[192] Letter from J. Desai to E. Rivera-Martinez (Aug. 28, 2009) [C-66]; *see also* Apotex Responses to 2009 Signet Form 483, at 7 (Sept. 3, 2009) (attached to letter) [C-81].

[193] Email from "ORA HQ DIOP Import Alerts" to R. Barrell et al. (Aug. 28, 2009) ("All finished form drug products" from Apotex Inc.'s Etobicoke and Signet facilities "have met the criteria for addition to detention without physical examination") [C-67]; *see also* First Rosa Statement ¶ 62.

[194] Reply ¶ 493 (citing "numerous calls and meetings with FDA").

[195] *See* Counter-Memorial ¶¶ 105-110; 154-171.

[196] *See infra* ¶¶ 321-27.

cGMP violations, touted its hiring of several cGMP consultants, and committed to invite FDA to reinspect the Etobicoke and Signet facilities only after the cGMP problems had been fixed.[197]

87. In sum, Apotex admitted "significant" cGMP violations in 2009; Apotex does not contest those cGMP findings in this arbitration; and Apotex has not denied that, under U.S. law, the cGMP findings resulted in Apotex's products being deemed "adulterated" and subject to detention at the U.S. border. None of the alleged "misunderstandings" cited by Apotex have any bearing on Apotex's claims, given its failure to contest the serious, systemic violations of U.S. law that prompted the Import Alert. Apotex has given the Tribunal no reason to second-guess the judgment of trained FDA specialists, who carried out their duties conscientiously to protect the health of the U.S. consumer. Apotex's assertions that the Import Alert – a "temporary advisory" alerting FDA district offices to Apotex Inc.'s cGMP violations at Etobicoke and Signet – was a "rush to judgment" that deprived Apotex of an opportunity to respond to the accusations against it, are not only irrelevant, but are flatly contradicted by the evidentiary record.

II. THE TRIBUNAL LACKS JURISDICTION OVER ANY OF APOTEX'S CLAIMS

88. The Tribunal lacks jurisdiction over any claims by Apotex Inc. or Apotex Holdings, on behalf of its U.S. enterprise, Apotex Corp.

89. The parties agree on four key jurisdictional issues. First, as set forth in Article 1122, for purposes of Apotex's claims, the United States "consents to the submission of a claim to arbitration in accordance with the procedures set out" in NAFTA Chapter Eleven.[198]

[197] It was not until December 13, 2010 that Apotex, through its attorneys, complained to FDA officials concerning the addition of Etobicoke and Signet to the Import Alert. *See* letter from C. Shepard and K. Beardsley, Buc & Beardsley LLP, to R. Tyler, Chief Counsel, Office of Chief Counsel, FDA, and D. Autor, Director, CDER-Office of Compliance (Dec. 13, 2010) (complaining that the Import Alert violated NAFTA's *trade* provisions, not its investment provisions) [C-185].

90. Second, the parties agree that Apotex may bring a claim only if Apotex Inc. or Apotex Holdings qualifies as an "investor of a Party" that has incurred (on its own behalf or on behalf of a qualifying enterprise) loss or damage arising out of a breach of Chapter Eleven's substantive provisions by the United States.[199]

91. Third, the parties agree that NAFTA Chapter Eleven applies only to measures adopted or maintained by a NAFTA Party that "relate to" qualifying investors with covered investments. As such, under Article 1101(1), there must be a "legally significant connection" between the challenged measure and the investor or its investment.[200]

92. Fourth, the parties agree that Apotex, as claimant, bears the burden of proving that it has standing and that the Tribunal has jurisdiction to hear the claims submitted.[201] The claimant's burden of proof, the *Rompetrol* tribunal recently confirmed, is "absolute," never shifting to the

[198] Memorial ¶ 417 n.597 (citing NAFTA art. 1122); *see, e.g.*, *Methanex Corp. v. United States of America*, NAFTA/UNCITRAL, First Partial Award ¶ 120 (Aug. 7, 2002) ("*Methanex* First Partial Award") [CLA-36] ("In order to establish the necessary consent to arbitration, it is sufficient to show (i) that Chapter 11 applies in the first place, i.e. that the requirements of Article 1101 are met, and (ii) that a claim has been brought by a claimant investor in accordance with Articles 1116 or 1117 (and that all pre-conditions and formalities required under Articles 1118-1121 are satisfied). Where these requirements are met by a claimant, Article 1122 is satisfied; and the NAFTA Party's consent to arbitration is established."); *Apotex I-II* Award ¶ 10 ("Subject to its jurisdictional / admissibility objections, the Respondent has consented to arbitration by virtue of Article 1122 of NAFTA") [RLA-263].

[199] Memorial ¶ 336 (citing NAFTA arts. 1116(1) and 1117(1)); Reply ¶¶ 90-92.

[200] Reply ¶ 94 ("The parties further agree 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.").

[201] Reply ¶ 34 ("The burden of proof rests upon the party alleging the fact at issue.") (citing, *e.g.*, *Pulp Mills on the River Uruguay* (Argentina v. Uruguay), 2010 I.C.J. ¶ 162 (Apr. 20) ("[T]he Court considers that, in accordance with the well-established principle of *onus probandi incumbit actori*, it is the duty of the party which asserts certain facts to establish the existence of such facts.") [CLA-514]); *Vito G. Gallo v. Canada*, NAFTA/UNCITRAL, Award ¶ 277 (Sept. 15, 2011) ("Both parties submit, and the Tribunal concurs, that the maxim "who asserts must prove", or *actori incumbit probatio*, applies also in the jurisdictional phase of this investment arbitration: a claimant bears the burden of proving that he has standing and the tribunal has jurisdiction to hear the claims submitted. If jurisdiction rests on the existence of certain facts, these must be proven at the jurisdictional stage[.]") (citation omitted) [RLA-137]; *Apotex I-II*, Transcript of Hearing on Jurisdiction and Admissibility, at 208 (Feb. 15, 2012) (acknowledging that "generally the Claimant must prove jurisdiction") [R-204].

respondent.[202] "A claimant before an international tribunal," therefore, "must establish the facts on which it bases its case or else it will lose the arbitration."[203] The respondent, by contrast, "does not in that sense bear any 'burden of proof' of its own[.]"[204]

93. Apotex has failed to carry its burden of proving that it has standing and that the Tribunal has jurisdiction to hear the claims submitted. Apotex has failed to show that Apotex Inc. is a qualified "investor" with covered "investments" in the territory of the United States. To the contrary, the record establishes that Apotex Inc. is a Canadian manufacturing company with no presence of any kind in the United States. The sole "investments" claimed by Apotex Inc. are its abbreviated new drug applications. As the *Apotex I-II* tribunal recently confirmed, Apotex's ANDAs are not "investments" for purposes of NAFTA Chapter Eleven.[205] They are merely revocable applications to export products to the United States for sale by others.[206] Consequently, Apotex Inc. is not an "investor" protected by NAFTA Chapter Eleven. The *Apotex I-II* tribunal's dismissal of Apotex Inc.'s claims, for lack of jurisdiction, precludes relitigation of that issue against the United States.

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[202] *Rompetrol Group N.V. v. Romania*, ICSID Case No. ARB/06/3, Award ¶ 178 (May 6, 2013) ("[T]he burden of proof defines which party has to prove what, in order for its case to prevail; the standard of proof defines how much evidence is needed to establish either an individual issue or the party's case as a whole. As soon as the distinction is stated in that way, it becomes evident that the burden of proof is absolute, whereas the standard of proof is relative. By this the Tribunal means (again, in simple terms) that if, according to basic principle, it is for the one party, or for the other, to establish a particular factual assertion, that will remain the position throughout the forensic process, starting from when the assertion is first put forward and all the way through to the end. Operating within an international system characterised by principle rather than procedural formality, the Tribunal is not enamoured of arguments setting out to show that a burden of proof can under certain circumstances shift from the party that originally bore it to the other party, and then perhaps in appropriate circumstances shift back again to the original party.") [CLA-508].

[203] *Id.* ¶ 179.

[204] *Id.*

[205] *Apotex I-II* Award ¶ 207-08 [RLA-263].

[206] *Id.*

94. In addition, the sole challenged measure in this case[207] – the Import Alert – had no "legally significant connection" to Apotex Inc.'s ANDAs or to Apotex Corp. That measure, therefore, did not "relate to" any alleged investor or investment in this arbitration. As such, the Tribunal lacks jurisdiction to adjudicate Apotex's claims.

A. Apotex Inc. Is Not a Qualifying Investor with Covered Investments in the United States

95. Although Apotex Inc. claims to be an "investor" with "investments" in the territory of the United States, there is no dispute that:

- Apotex Inc. is a pharmaceutical company based and incorporated in Canada;[208]
- "All of Apotex Inc.'s facilities or offices, manufacturing or otherwise, are located solely in Canada";[209]
- Apotex Inc. "does not reside or have a place of business in the United States";[210]
- Apotex Inc. does not have any "business operations in the United States";[211]
- Apotex Inc. does not claim to share in the income or profits of any U.S. company;[212]
- Apotex Inc. does not claim to have an equity or debt interest in any U.S. company;[213]

[207] *See* Reply ¶ 254 (confirming that the Import Alert is the sole challenged measure in this case).

[208] Memorial ¶¶ 22-23.

[209] *Cephalon, Inc. and Cephalon France v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS, Motion to Dismiss Complaint by Apotex Inc. and Apotex Corp. or in the Alternative to Transfer, at 8 (Oct. 18, 2010) [RLA-236].

[210] *Apotex I-II*, Claimant Apotex Inc.'s Counter-Memorial on Respondent's Objections to Jurisdiction ¶ 50 & n.56 (Aug. 1, 2011) [RLA-102].

[211] *Novartis v. Apotex*, No. 12-cv-05574 (D. N.J.), Answers, Defenses, and Counterclaims of Apotex Inc. and Apotex Corp., at 2 (Doc. 12) (Feb. 11, 2013) [RLA-250].

[212] *Id.* (describing Apotex Inc.'s alleged investments).

[213] *Id.*; Second Witness Statement of Gordon Fahner ¶ 71 (May 24, 2013) ("Apotex [Inc.] has no direct or indirect equity stake in Apotex [Corp.] ("Second Fahner Statement"); *id.* ¶ 78 (Apotex Corp. "has never borrowed any funds from Apotex [Inc.]; *Apotex I-II* Award ¶ 167 ("Similarly, Apotex has not claimed to have an equity or a debt interest in any U.S. company. It has not claimed to have purchased property or to have built facilities or to have hired a workforce in the U.S. And it has not claimed to have developed, tested, or manufactured its drugs in the United States.") [RLA-263].

- Apotex Inc. does not pay tax in the United States, including on the transfer or sale of its alleged U.S. investments, its ANDAs;[214]

- Apotex Inc. does not itself develop, test or manufacture any products in the United States;[215]

- Apotex Inc. "does not directly sell any products of any kind in the U.S.";[216]

- Apotex Inc. "has put nothing into the stream of commerce in the United States";[217] and

- Apotex Inc. prepares its ANDAs in Canada.[218]

96. Apotex thus advances the extraordinary claim that a *Canadian exporter with no presence of any kind in the United States* qualifies as an "investor" with "investments" in the United States for purposes of NAFTA's investment chapter. Apotex Inc.'s entire jurisdictional claim rests on its argument that its abbreviated new drug applications constitute "investments" in the United

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[214] Apotex Responses to U.S. Redfern, Document Request No. 13 (asserting that "no documents responsive" exist to show that Apotex Inc. paid U.S. tax on ANDA sales).

[215] *See Apotex I-II* Award ¶ 175 ("Apotex could, of course, have invested in U.S.-based manufacturing, development, or testing facilities, but opted instead to create and manufacture its generic pharmaceuticals in Canadian factories.") [RLA-263]; *see also Pfizer Inc. v. Apotex Inc. and Apotex Corp.*, No. 1:08-cv-00948 (LDD) (D. Del.), Declaration of Bernice Tao (Feb. 10, 2009) ¶ 17 ("Apotex Inc. conducted all of the research, development and manufacturing of the generic . . . products that are the subject of its ANDA. All of this work was performed in Canada[.]") [RLA-92].

[216] *Shire LLC v. Apotex Inc., Apotex Corp. and Apotex Pharmaceutical Holdings Inc.*, No. 2:08-cv-265 (E.D. Tex.), Declaration of Bernice Tao ¶ 12 (Aug. 6, 2008) [RLA-183]; *see also Cephalon Inc. et al. v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS (D. Del.), Reply Brief in Support of Motion to Dismiss Complaint by Apotex Inc. and Apotex Corp. or in the Alternative to Transfer, at 7 (Nov. 15, 2010) ("Because Apotex Inc. does not directly sell any products in the U.S. it must rely on the products [being] sold by others, such as Apotex Corp.[.]") [RLA-179]; *Abbott Laboratories, Inc. and Abbott GMBH & Co. KG v. Apotex Inc. and Apotex Corp.*, No. 1:09-cv-00990-JJF (D. Del.), Defendant Apotex Inc.'s Brief in Support of its Motion to Dismiss for Lack of Personal Jurisdiction Pursuant to Fed. R. Civ. P. 12(b)(2), at 10 (Jan. 13, 2010) (Apotex "does not sell any products directly in the United States") [RLA-175].

[217] *Abbott Laboratories Inc. and Abbott GMBH & Co. KG v. Apotex Inc. and Apotex Corp.*, No. 1:09-cv-00990-JJF (D. Del.), Defendant Apotex Inc.'s Brief in Support of its Motion to Dismiss for Lack of Personal Jurisdiction Pursuant to Fed. R. Civ. P. 12(b)(2), at 10-11 (Jan. 13, 2010) [RLA-175].

[218] Counter-Memorial ¶ 220, n.546-47 (citing *Pfizer Inc. v. Apotex Inc. and Apotex Corp.*, No. 1:08-cv-00948 (LDD) (D. Del.), Declaration of Bernice Tao ¶ 25 (Feb. 10, 2009) ("None of the relevant work regarding Apotex Inc.'s ANDA product, the preparation of the ANDA, or the filing of the ANDA occurred or was otherwise performed in Delaware. All such work occurred in Canada.")).

States for purposes of NAFTA Chapter Eleven. In particular, Apotex claims that those applications constitute:

(1) "intangible property," for purposes of Article 1139(g); and

(2) "interests arising from the commitment of capital" in the United States, for purposes of Article 1139(h).[219]

97. As the *Apotex I-II* tribunal recently confirmed, Apotex Inc.'s applications are neither "intangible property" nor "interests arising from the commitment of capital" in the United States.[220] Apotex's applications, therefore, are not "investments" for purposes of NAFTA Chapter Eleven. Accordingly, Apotex Inc. is not an "investor" in the United States, and the Tribunal necessarily lacks jurisdiction over any of its claims.[221]

1. The Tribunal Should Give Effect to the *Apotex I-II* Tribunal's Decision Rejecting Apotex Inc.'s Claim to Be an "Investor" with "Investments" Under NAFTA Chapter Eleven

98. The *Apotex I-II* tribunal decided the identical jurisdictional issue presented by Apotex Inc. in this arbitration – namely, whether Apotex's ANDAs constitute "investments" for purposes of Article 1139 such that Apotex Inc. qualifies as an "investor" for purposes of Article 1116.[222] The *Apotex I-II* tribunal determined that ANDAs, whether tentatively or finally

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[219] Reply ¶ 92.

[220] *Apotex I-II* Award ¶¶ 207, 235 [RLA-263].

[221] Apotex erroneously contends that the United States "does not dispute that . . . Apotex [Inc.] is an investor of Canada and thus meets the NAFTA's requirement of jurisdiction *ratione personae*." Reply ¶ 90. The United States' Counter-Memorial, however, expressly argued that "Apotex has failed to establish that Apotex Inc. is an 'investor' that made or sought to make 'investments' in the United States, as it claims." Counter-Memorial ¶ 220.

[222] Memorial ¶¶ 343-44 ("Apotex [Inc.] holds a number of investments in the US, including hundreds of marketing authorizations to market and sell pharmaceutical products in the US . . . . These ANDAs constitute Apotex [Inc.'s] investment in the US."); Reply ¶ 208 ("As explained in the Memorial, Apotex [Inc.'s] ANDAs fall within the definition of investment in Article 1139(g) (intangible property) and Article 1139(h) (interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory).").

In *Apotex I-II,* Apotex Inc. claimed that:

approved, are not covered "investments" under Article 1139, and thus Apotex Inc. is not a qualifying "investor" for purposes of Article 1116. On that basis, the tribunal dismissed all claims by Apotex Inc. for lack of jurisdiction.

99. Consistent with the principle of *res judicata*, this Tribunal should give effect to the decision of the *Apotex I-II* tribunal and dismiss Apotex Inc.'s claim for lack of jurisdiction. *Res judicata*, which includes the principle of issue estoppel, precludes relitigation of an issue of fact or law decided between two parties.

100. *Res judicata* – which applies to these proceedings pursuant to NAFTA's governing law provision[223] – is a well-established general principle of international law.[224] As early as 1905, the French-Venezuelan Mixed Claims Commission recognized:

> Apotex's ANDA is "property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes" and thus an "investment" under Article 1139(g). Apotex also has made other significant investments in the United States that involve "the commitment of capital or other resources in the [United States] to economic activity in such territory," including "contracts involving the presence of [Apotex's] property in the [United States]" that qualify as "investments" under Article 1139(h). Apotex is thus a proper Claimant in this NAFTA arbitration.

Apotex I-II, Claimant Apotex Inc.'s Counter-Memorial on Respondent's Objections to Jurisdiction ¶ 35 (citations omitted) [RLA-102].

[223] NAFTA art. 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."); *see also* Memorial ¶ 490 n.688 (acknowledging NAFTA's governing law provision). NAFTA Article 1136(1) states that "[a]n award made by a Tribunal shall have no binding force except between the disputing parties and in respect of the particular case." This provision, which mirrors the language of Article 59 of the ICJ Statute (and the Statute of the PCIJ), does not preclude the *res judicata* effect of the *Apotex I-II* award here. Rather, the language simply "makes clear that the rule of *stare decisis* does not apply to awards rendered under Chapter 11." MEG N. KINNEAR, ANDREA K. BJORKLUND, ET AL., 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) [RLA-288]. The ICJ, for its part, has recognized the binding force and *res judicata* effect of its decisions in subsequent cases. *See, e.g.*, *Haya de la Torre* (Colombia v. Peru), 1951 I.C.J. 71, 77 (June 13) (rejecting Cuba's intervention to the extent it dealt with questions the Court determined in the *Asylum Case*, which it had "decided with the authority of *res judicata*") [RLA-271].

[224] *Waste Management*, Decision on Mexico's Preliminary Objection concerning the Previous Proceedings ¶ 39 (June 26, 2002) (citing BIN CHENG, GENERAL PRINCIPLES OF LAW AS APPLIED BY INTERNATIONAL COURTS AND TRIBUNALS 366-72 (1987 rep.) and authorities there cited) [RLA-279]. *Res judicata* is so well established as a general principle of law that "it was even one of the examples cited by Lord Phillimore of the Advisory Committee of Jurists to describe the possible content of the provision in article 38(3) of the PCIJ Statute referring to the PCIJ's power to resort to 'general principles of law' as a source of international law." CHESTER BROWN, A COMMON LAW

> The general principle announced in numerous cases is that a *right, question or fact distinctly put in issue and directly determined* by a court of competent jurisdiction as a ground of recovery, cannot be disputed.[225]

101. Over the ensuing century, international courts and tribunals repeatedly have applied this general principle in order to promote the twin goals of efficiency and finality. These include the Permanent Court of International Justice (*e.g.*, in *Chorzów Factory*), the International Court of Justice (*e.g.*, in *Land and Maritime Boundary Between Cameroon and Nigeria*), interstate arbitral tribunals (*e.g.*, in *UK-French Continental Shelf*), and investor-State arbitral tribunals (*e.g.*, in *Amco Asia v. Indonesia*).[226]

102. The International Law Association (ILA) more recently confirmed the crucial role *res judicata* plays in promoting efficiency and finality in international commercial arbitration.[227] The ILA's "Recommendations on *Res Judicata* and Arbitration" recognize that an arbitral award is conclusive and preclusive where it (1) has become final and binding; (2) has disposed of a claim for relief sought or reargued in further arbitral proceedings; (3) is based upon the same

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OF INTERNATIONAL ADJUDICATION 155 (2007) (quoting PCIJ/Advisory Committee of Jurists, Procès-Verbaux of the Proceedings of the Committee of Jurists 335 (1920)) [RLA-280].

[225] *Company General of the Orinoco Case*, Award (July 31, 1905), 10 UNRIAA 184, 276 (emphasis altered) (citing *Southern Pacific Railroad Co. v. United States*, 168 SCR 1) [RLA-267].

[226] *See* Vaughan Lowe, *Res Judicata and the Rule of Law in International Arbitration*, 8 RADIC 38, 39-40 (1996) (citing cases) [RLA-295]; *see also Land and Maritime Boundary Between Cameroon and Nigeria*, 1999 I.C.J. 28, 39 ¶ 16 (Mar. 25) (recognizing that its earlier 1998 Judgment, given on a number of preliminary objections to jurisdiction and admissibility, constituted *res judicata*) [RLA-273]; *Application of the Convention on the Prevention and Punishment of the Crime of Genocide (Bosnia and Herzegovina v. Serbia and Montenegro)*, 2007 I.C.J. 40, 101 ¶ 140 (Feb. 26) (finding that its earlier 1996 Judgment on preliminary jurisdictional issues "precludes the reopening of the decision") [RLA-264].

[227] *See* International Law Association, Resolution No. 1/2006, Annex 2, Recommendations on *Res Judicata* and Arbitration (June 4, 2006) ("ILA Recommendations on *Res Judicata* and Arbitration") [RLA-282]. The ILA Committee on International Law on Foreign Investment has recognized the value of *res judicata* in avoiding inconsistent decisions in investor-State arbitrations, noting the "acceptance of *res judicata* as a general principle operative in the international order." The ILA Committee on International Law on Foreign Investment further endorsed the ILA Recommendations on *Res Judicata* as "[a] product of eminent jurists and practitioners including arbitrators, [which], although non-legally binding, may constitute a first step towards recognition and more regular and less formalistic application of these principles in international arbitration." International Law Association, Rio de Janeiro Conference (2008), Final Report, at 21 [RLA-283].

cause of action in subsequent proceedings or forms the basis for subsequent proceedings; and (4) has been rendered between the same parties.[228] The ILA further recommended that arbitral awards have conclusive and preclusive effects in subsequent arbitral proceedings as to:

> 4.1 determinations and relief contained in its dispositive part as well as in all reasoning necessary thereto; and
>
> 4.2 *issues of fact or law* which have actually been *arbitrated* and *determined* by it, provided any such determination was essential or fundamental to the dispositive part of the arbitral award.[229]

103. Recommendation 4.1 endorses the more extensive notion "followed in public international law, under which *res judicata* not only is to be read from the dispositive part of an award but also from its underlying reasoning."[230] Recommendation 4.2 "endorses common law concepts of issue estoppel, which for reasons of procedural efficiency and finality, seem to be acceptable on a worldwide basis, notwithstanding the fact that they are yet unknown in civil law jurisdictions."[231] The ILA Final Report confirmed that issue estoppel applies not only to the same claim, but also to "different claims in further arbitral proceedings."[232]

104. Issue estoppel also is widely recognized in domestic law. In the United States[233] and Canada,[234] for instance, a party is precluded from relitigating the same issue between the same

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[228] *See* International Law Association, Resolution No. 1/2006, Annex 2, Recommendations on *Res Judicata* and Arbitration, Recommendation No. 3 (June 4, 2006) [RLA-282].

[229] *Id.*, Recommendation No. 4.

[230] International Law Association, Toronto Conference (2006), Final Report on *Res Judicata* and Arbitration ¶ 52 (citations omitted) ("ILA Final Report on *Res Judicata* and Arbitration") [RLA-284].

[231] *Id.* ¶ 56 (citation omitted). Issue estoppel generally serves to preclude the reopening of issues already determined by an earlier court or tribunal. *See* Lowe, *Res Judicata and the Rule of Law in International Arbitration*, 8 RADIC at 41-42 [RLA-295].

[232] ILA Final Report on *Res Judicata* and Arbitration ¶ 57 [RLA-284].

[233] *San Remo Hotel, L.P. v. City and County of San Francisco*, 545 U.S. 323, 336 n.16 (2005) ("Under *res judicata*, a final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or

parties in a different suit involving a different cause of action if a court has finally decided that issue.

105. Here, Apotex Inc.'s claims fall squarely within the ILA's Recommendations on *Res Judicata* and Arbitration. *First*, the parties are the same. In both cases, Apotex Inc. is a claimant, and the United States is the respondent.

106. *Second*, the issue in both arbitrations is the same, notwithstanding the different claims raised on the merits. In both cases, Apotex Inc. contends that it qualifies as an "investor" whose ANDAs constitute "investments" in the United States for purposes of NAFTA Articles 1116 and 1139.

107. *Third*, the issue of whether Apotex Inc. is a qualifying "investor" with covered "investments" was fully arbitrated and determined in the *Apotex I-II* claims. The tribunal in that case rendered a lengthy, reasoned decision after two rounds of briefing and an oral hearing.

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could have been raised in that action. Under collateral estoppel, once a court has decided an issue of fact or law necessary to its judgment, that decision may preclude relitigation of the issue in a suit on a different cause of action involving a party to the first case.") (citations omitted)) [RLA-252].

[234] *See Danyluk v. Ainsworth Technologies Inc.*, 2001 SCC 44, [2001], 2 S.C.R. 460 ¶¶ 24, 25, 33 (setting out three preconditions to the operation of issue estoppel: "(1) that the same question has been decided; (2) that the judicial decision which is said to create the estoppel was final; and, (3) that the parties to the judicial decision or their privies were the same persons as the parties to the proceedings in which the estoppel is raised or their privies," and *quoting McIntosh v. Parent*, [1924] 4 D.L.R. 420, 422, for the following definition of issue estoppel: "When a question is litigated, the judgment of the Court is a final determination as between the parties and their privies. Any right, question, or fact distinctly put in issue and directly determined by a Court of competent jurisdiction as a ground of recovery, or as an answer to a claim set up, cannot be re-tried in a subsequent suit between the same parties or their privies, though for a different cause of action. The right, question, or fact, once determined, must, as between them, be taken to be conclusively established so long as the judgment remains.") [RLA-238].

108. *Fourth*, the *Apotex I-II* tribunal decided the issue in a final and binding award.[235] The tribunal's unanimous decision addressed the issue in its operative part as well as in the associated reasoning[236] and was essential to its *dispositif*.[237]

109. Although Apotex has presented additional argument in this case to try to bolster its jurisdictional claim, issue estoppel precludes relitigation of the *entire issue*, not simply arguments raised in connection with that issue in the prior case.[238] Were it otherwise, any party could evade the preclusive effect of issue estoppel simply by devising new legal arguments for repeated cases that raise the same issues.

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[235] Apotex Inc. declined to seek to set aside the award within the time permitted by the law of the place of arbitration (New York).

[236] *See Apotex I-II* Award ¶ 358(a) (stating in the "Operative Order" that "Apotex does not qualify as an '*investor'*, who has made an '*investment*' in the U.S., for the purposes of NAFTA Articles 1116 and 1139, and accordingly both the Sertraline and Pravastatin Claims are hereby dismissed in their entirety, on the basis that the Tribunal lacks jurisdiction in relation thereto.") [RLA-263]; *see also id.* ¶¶ 177-247.

[237] *See id.* ¶¶ 243-247, 336, 358(a).

[238] *See* ILA Resolution No. 1/2006, Annex 2, Recommendations on *Res Judicata* and Arbitration, Recommendation No. 5 (June 4, 2006) ("An arbitral award has preclusive effects in the further arbitral proceedings as to a claim, cause of action or issue of fact or law, which could have been raised, but was not, in the proceedings resulting in that award, provided that the raising of any such new claim, cause of action or new issue of fact or law amounts to procedural unfairness or abuse.") [RLA-282]. The ILA further recognized that "policy objectives of efficiency and finality can also be taken into account to protect respondents from being exposed to further arbitration if a claimant fails to raise claims, causes of action or issues of fact or law in prior proceedings." *Id.* ¶ 61 (citation omitted). Given that none of Apotex Inc.'s new arguments in this proceeding concerning its ANDAs rely on facts or law that were unavailable to Apotex in the earlier proceeding, it would be unfair to expose the United States to relitigation of this issue. *See also Laaman v. United States*, 973 F.2d 107, 112 (2d Cir. 1992) ("Collateral estoppel does not turn upon a determination that a prior ruling was correctly rendered, *or that all possibly relevant arguments were made and authorities cited in the initial proceeding*, but rather upon a recognition that an issue tendered for resolution in a later litigation has been finally determined in a prior adjudication after a full and fair opportunity for litigation in which the issue was actually litigated and necessary to the prior decision.") (emphasis altered; citations omitted) [RLA-242]; *Yamaha Corp. of America v. United States*, 961 F.2d 245, 254 (D.C.Cir. 1992), *cert. denied*, 506 U.S. 1078, 113 S.Ct. 1044, 122 L.Ed.2d 353 (1993) ("[O]nce an issue is raised and determined, it is the *entire issue that is precluded, not just the particular arguments* raised in support of it in the first case.") (emphasis altered) [RLA-258]; *see also* RESTATEMENT (SECOND) OF JUDGMENTS § 27 *cmt. c*. ("[I]f the party against whom preclusion is sought did in fact litigate an issue . . . and suffered an adverse determination . . . new arguments may not be presented to obtain a different determination of that issue.") [RLA-292]; MOORE'S FEDERAL PRACTICE § 132.02[02][c] (Matthew Bender 3d ed. 2013) ("If a new legal theory or factual assertion raised in the second action is relevant to the issues that were litigated and adjudicated previously, the prior determination of the issue is conclusive on the issue despite the fact that new evidence or argument relevant to the issue was not in fact expressly pleaded, introduced into evidence, or otherwise urged.") [RLA-290].

110. In sum, in accordance with the well-established principle of *res judicata*, which includes issue estoppel, Apotex should be barred "from contradicting an issue of fact or law that has already been distinctly and finally decided in earlier proceedings between the same parties."[239]

2. The *Apotex I-II* Tribunal Recently Confirmed that Apotex Inc.'s Drug Applications Are Not "Property" Within the Meaning of Article 1139(g)

111. Even if Apotex were permitted to relitigate the very issue that the *Apotex I-II* tribunal recently considered and rejected, Apotex has failed to establish that Apotex Inc. is a qualifying "investor" under Article 1116, as the sole investment Apotex Inc. claims in this arbitration – its ANDAs – do not qualify as "investments" for purposes of NAFTA Article 1139.

112. Apotex ANDAs do not constitute "property" in the United States for purposes of Article 1139(g). Article 1139 defines "investment" as including:

> (g) real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes.

113. As the *Apotex I-II* tribunal concluded, an ANDA is not "property" in the United States for purposes of Article 1139(g). To the contrary, for companies such as Apotex Inc., 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."[240]

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[239] *See* V.V. Veeder, *Issue Estoppel, Reasons for Awards and Transnational Arbitration*, COMPLEX ARBITRATIONS – ICC INT'L CT. ARB. BULL. 73, 73-74 (Spec. Supp. 2003) (citation omitted) ("Just as it would be absurd for parties to re-litigate the same dispute time and again, like Sisyphus or the hero in 'Ground-Hog Day', would it not be equally absurd for parties to re-litigate issues in a different arbitration where those same issues have already been decided in the reasons for an earlier award between the same parties?") [RLA-294].

[240] *Apotex I-II* Award ¶ 207 (emphasis in original) [RLA-263].

i. The Apotex I-II Tribunal Explicitly Rejected the Arguments Apotex Advances Here

114. At least four of Apotex's current arguments concerning Article 1139(g) were considered and rejected by the *Apotex I-II* tribunal.

115. *First*, Apotex argues that "FDA's own regulations recognize that a pharmaceutical company may own an ANDA, and that it may be transferred for consideration."[241] In its previous claims, Apotex similarly argued that "an ANDA applicant owns its ANDA,"[242] and that "FDA regulations explicitly state that . . . only the 'applicant may transfer ownership of its application.'"[243] But "ownership," the *Apotex I-II* tribunal concluded, is not enough to establish an ANDA as "property" for purposes of Article 1139(g). Rather, "[e]ven if, as a technical matter, the application may be 'owned', unlike Apotex's approach, the Tribunal does not consider that NAFTA Article 1139(g) can be approached by divorcing the concept of '*property*' from its context, and applying it in the abstract."[244] Similarly, the fact that "only the applicant may transfer ownership of its application," the *Apotex I-II* tribunal concluded, "cannot transform the application into "property" for purposes of NAFTA Chapter Eleven."[245]

116. *Second,* Apotex argues that "ANDAs are regularly bought and sold."[246] In its previous claims, Apotex similarly argued that "[a]n ANDA can be bought and sold like all other

[241] Reply ¶ 209 (citing Memorial ¶ 368).

[242] *Apotex I-II*, Claimant Apotex Inc.'s Rejoinder Memorial on Respondent's Reply on Objections to Jurisdiction ¶ 15 (Dec. 16, 2011) [RLA-266].

[243] *Id.* (quoting 21 C.F.R. § 314.72(a) [CLA-272]).

[244] *Apotex I-II* Award ¶ 207 [RLA-263].

[245] *Id.* ¶¶ 199, 206 (quoting Apotex's submission) (internal quotations omitted).

[246] Reply ¶¶ 209-10 (citing Memorial ¶ 368).

property."[247] The ability to buy and sell an ANDA, the *Apotex I-II* tribunal concluded, also is not enough to fall within Article 1139(g). That is, "even if an ANDA may be bought and sold as Apotex argues, this would still not change its essential character, which is an application to (in this case) export generic drugs into the United States."[248]

117. *Third,* Apotex argues that "the right to market a drug under an approved ANDA is, itself, a protected property right, and so is the statutory exclusivity period afforded some ANDA holders."[249] In its previous claims, Apotex similarly argued that an ANDA applicant "has the *exclusive* right to possess, use and enjoy the ANDA."[250] 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."[251] 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."[252]

[247] *Apotex I-II*, Claimant Apotex Inc.'s Counter-Memorial on Respondent's Reply on Objections to Jurisdiction ¶ 37 (Aug. 1, 2011) [RLA-102].

[248] *Apotex I-II* Award ¶ 221 [RLA-263]. "Claims to money," which are excluded from the definition of investment under Article 1139(i), may also be bought and sold, so this argument is unavailing in any event.

[249] Memorial ¶ 395; Reply ¶ 236; *see also* Memorial ¶ 373; Reply ¶ 209.

[250] *Apotex I-II*, Claimant Apotex Inc.'s Counter-Memorial on Respondent's Reply on Objections to Jurisdiction ¶ 37 (Aug. 1, 2011) (emphasis in original) [RLA-102].

[251] *See* Reply ¶¶ 209-10 (citing Memorial ¶ 373).

[252] *Apotex I-II* Award ¶ 222 [RLA-263]. The tribunal also found that "even assuming that the ANDAs were Apotex's exclusive 'property,' they remained no more than applications for permission to . . . export, and as such neither fell within NAFTA Article 1139(g), nor constituted 'investments' as contemplated more generally by NAFTA Chapter Eleven." *Id.* ¶ 224.

118. In any event, the tribunal confirmed that the ANDA applicant does *not* enjoy "exclusivity" over its ANDAs, because FDA "has an ongoing health and safety responsibility to perform."[253] Accordingly, the *Apotex I-II* tribunal stated:

> FDA may revoke tentative approval, or even final approval, of ANDAs for a variety of reasons related to the new products' safety and effectiveness, including (*inter alia*) a finding that there is an imminent hazard to public health; that clinical or other tests or scientific data indicate any lack of safety; or a lack of substantial evidence from adequate and well controlled investigations that the drug will have the effect it is reported or represented to have.[254]

119. Apotex makes much of the fact that it withdrew its damages claims with respect to "tentatively approved" ANDAs, and thus its jurisdictional claims rest only on its "finally approved" ANDAs.[255] Apotex previously conceded, however, that "distinctions between tentatively approved ANDAs and finally approved ANDAs are distinctions without a difference."[256] The *Apotex I-II* tribunal confirmed Apotex's concession.[257] The tribunal noted that federal regulations in the United States "expressly afford the FDA a broad discretion" in revoking tentative or *even final approval* of ANDAs, and that even when "finally approved, Apotex was not protected from changes to, or revocation of, its ANDAs."[258] Apotex's ANDAs

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[253] *Id.* n.81 (citing *Ranbaxy Labs Ltd. V. FDA*, 307 F. Supp. 2d 15, 19, 21 (D.D.C. 2004)). *See id.* ¶ 223 ("Apotex's asserted '*exclusivity*' is open to question in any event . . . . [E]ven when finally approved, Apotex was not protected from changes to, or revocation of, its ANDAs.") (emphasis in original). FDA may also revoke the final approval status of an ANDA in circumstances not listed under 21 U.S.C. § 355(e) (2012) [RLA-299]. *See Mylan Labs v. Thompson*, 389 F.3d 1272, 1282-83 (finding that section 355(e) "does not prohibit the FDA from withdrawing approval under other circumstances – or, more precisely does not prohibit the FDA from changing a final into a tentative approval under circumstances different from those named in section 355(e)") [RLA-248]. Nor does "marketing exclusivity" associated with ANDAs confer absolute exclusivity, as marketing exclusivity may be granted to more than one ANDA applicant at a time. *See* Counter-Memorial ¶¶ 227-28 (citing authorities).

[254] *Apotex I-II* Award ¶ 210 [RLA-263].

[255] Reply ¶ 212.

[256] *Apotex I-II*, Claimant Apotex Inc.'s Rejoinder Memorial on Respondent's Reply on Objections to Jurisdiction ¶ 13 (Dec. 16, 2011) [RLA-266].

[257] *See Apotex I-II* Award ¶¶ 210, 223 [RLA-263].

[258] *Id.*

in the United States were thus "at all times entirely subject to the exercise of [FDA's] regulatory power," and therefore lacked the exclusivity necessary to be considered property.[259]

120. Apotex argues that because its ANDAs were not revoked, it had a "reasonable investment backed expectation" that its ANDAs "would continue," meeting the test for "property" under U.S. law.[260] Apotex elsewhere argues that while its "ANDAs technically remained approved during the Import Alert, they could not be used for what they are, i.e., authorization to market drug products, since the drug products in question could not be sold in the US due to the Import Alert."[261] Apotex's assumption that it could sell its drugs in the United States free from regulatory oversight is not a "reasonable investment backed expectation," nor does it meet the test for "property."

121. *Fourth*, Apotex argues that its ANDAs constitute property because they "are regulated by US law."[262] Apotex cites *Bayview* for the proposition that a "salient characteristic [of an investment] will be that the investment is primarily regulated by the law of a state other than the state of the investor's nationality."[263] In its previous claims, Apotex similarly cited *Bayview* for the proposition that, because Apotex made "an investment that falls under the laws and the jurisdiction of the authorities of another NAFTA Party, it [should] be treated as a foreign

[259] *See, e.g., B-West Imports, Inc. v. United States*, 75 F.3d 633, 638 (Fed. Cir. 1996) (*citing Mitchell Arms Inc. v. United States*, 7 F.3d 212, 216 [RLA-247]) [RLA-235]; *see also id.* at 638-39 ("The Due Process Clause does not require the government to stand as a surety against the adverse consequences sometimes suffered by persons who knowingly undertake . . . commercial risk.").

[260] Reply ¶ 227.

[261] *Id.* ¶ 256.

[262] *Id.* ¶¶ 232-33.

[263] *Id.* ¶ 233 (citing *Bayview Irrigation District et al. v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award ¶ 98 (June 19, 2007) [CLA-22]).

investor."[264] The *Apotex I-II* tribunal rejected this argument, concluding that "the mere regulation of Apotex's foreign products (however extensive) cannot transform the costs incurred in developing those products into investments in the United States."[265] Further, the tribunal concluded that ANDAs constitute no more than "an exercise in securing regulatory clearance," stating:

> [E]ven if Apotex had incurred these regulatory costs in the United States, the expenditures incurred in the preparation and filing of an ANDA submission, being no more than an exercise in securing regulatory clearance, do not fall within the scope of NAFTA Article 1139. Nor do they change the inherent nature of the activity for which clearance is sought.[266]

122. The *Grand River* tribunal recognized that "where a company must meet 'regulatory requirements' to sell its products in the United States, the costs of such compliance themselves are not '*investments*.'"[267] Rather, those costs are "incident to 'commercial contracts for the sale of goods or services,' which fall outside of Article 1139's definition of investment."[268] Were it otherwise, the *Apotex I-II* tribunal confirmed, "then any Canadian or Mexican exporter requiring U.S. regulatory clearance to have its goods sold by third parties in the United States could potentially bring an investment claim under NAFTA Chapter Eleven, whenever such clearance, in the exporter's view, was wrongly denied or delayed."[269] The tribunal concluded that

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[264] *Apotex I-II*, Claimant Apotex Inc.'s Rejoinder Memorial on Respondent's Reply on Objections to Jurisdiction ¶ 31 (Dec. 16, 2011) (citing *Bayview* Award ¶ 102 [CLA-22]) [RLA-266].

[265] *Apotex I-II* Award ¶ 192 (also noting that "both the *Grand River* and *Bayview* tribunals made clear that the law of the host State is only one "*salient*" factor in determining whether expenditures qualify as an '*investment*' under NAFTA Article 1139. It is not, in itself, a sufficient factor") (emphasis in original) [RLA-263]. To the extent that Apotex also makes this argument in favor of its position that its ANDAs constitute "interests" under Article 1139(h), Apotex's argument fails for the same reasons.

[266] *Id.* ¶ 193.

[267] *Id.* ¶ 194 (emphasis in original) (quoting *Grand River Enterprises Six Nations Ltd. v. United States*, NAFTA/UNCITRAL, Award ¶ 87 (Jan. 12, 2011) ("*Grand River Enterprises* Award") [CLA-29]).

[268] *Id.* (quoting *Grand River Enterprises* Award ¶ 87 (quoting NAFTA Article 1139(i) [CLA-1]) [CLA-29]).

[269] *Id.* ¶ 195.

"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."[270]

123. The *Apotex I-II* tribunal acknowledged that ANDAs "may be characterised for certain purposes as '*property*.'"[271] But the tribunal did "not consider that the nature of an ANDA is such as to fall within the contemplated scope of NAFTA Article 1139(g), as that provision must be understood as a whole, by reference to the objects and purposes of NAFTA Chapter Eleven."[272] An ANDA "ultimately remains simply an application for revocable permission to (in this case) export a product for sale (by others) in the United States,"[273] making Apotex Inc. "a mere exporter of goods into the United States."[274] The tribunal thus rejected the argument advanced here that an ANDA constitutes "intangible property" for purposes of Article 1139(g).

ii. Apotex's New Arguments Are Baseless

124. Apotex advances four new arguments in this case to bolster its claim that its drug applications constitute "intangible property" under Article 1139(g). None of these arguments withstands scrutiny.

125. *First*, Apotex mistakenly seeks support in Article 1110, Chapter Eleven's expropriation provision. Article 1110(7) states:

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[270] *Id.*

[271] *Id.* ¶ 207 (emphasis in original).

[272] *Id.*

[273] *Id.* (emphasis in original).

[274] *Id.* ¶ 206.

> This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property).

Apotex argues that Article 1110(7) "establishes an exception to the obligation to compensate for expropriation," which is "limited to those revocations authorized by Chapter Seventeen of the NAFTA."[275] Apotex contends that this Article "makes clear, *a contrario,* that a revocation of intellectual property rights inconsistent with Chapter Seventeen is subject to Article 1110's prohibition against expropriation without compensation."[276] According to Apotex, "Article 1110(7) reflects the NAFTA Parties' clear understanding that revocable intangible rights are investments that give rise to obligations under the NAFTA investment chapter."[277]

126. Apotex's *a contrario* reasoning is flawed. Article 1110(7) makes clear that a NAFTA Party may revoke or limit certain intellectual property rights without violating its obligations relating to expropriation under the treaty, provided that such actions are consistent with Chapter Seventeen.[278] Apotex mistakenly reads into Article 1110(7) an assumption that, because some revocable intangible rights (such as patents and trademarks) may be considered "investments"

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[275] *Id.* ¶ 216.

[276] *Id.* Apotex also notes that trademarks are revocable under U.S. law and points to *Grand River* as authority for its contention that its revocable ANDAs constitute "investments" under Article 1139(g). *See* Reply ¶ 231. Apotex is wrong. The *Grand River* tribunal found that one of the claimants, Arthur Montour, had an "investment" by virtue of his ownership of Native Wholesale Supply (NWS), a "substantial tobacco distribution business in the United States," together with NWS's ownership of the "Seneca® trademark," where he also made substantial marketing expenditures to promote the brand in the United States. *Grand River Enterprises* Award ¶ 79 [CLA-29]. Here, by contrast, Apotex Inc.'s ANDAs merely facilitate the cross-border sales of Apotex Inc. drugs from Canada to others in the United States. There is no "business" in the United States which Apotex Inc. owns or conducts. *See supra* ¶ 95, n.210.

[277] Reply ¶ 216.

[278] Specifically, with respect to patents, Chapter Seventeen provides that patents may be revoked only where grounds exist that would have justified a refusal to grant the patent or where the grant of a compulsory license has not remedied the lack of a patent's exploitation. NAFTA art. 1709(8). If a Party were to revoke a patent inconsistent with Chapter Seventeen, the limitation in Article 1110(7) would not apply. In contrast, there are no provisions in Chapter Seventeen limiting the rights of the Parties to withdraw or revoke and ANDA.

for purposes of the NAFTA, *all* revocable intangible rights (such as Apotex's applications to export its drugs to the United States) necessarily are investments. This conclusion is a *non sequitur*, as Article 1110(7) does not purport to define which intangible property rights are investments.

127. *Second*, Apotex mistakenly seeks support in Article 1108(1)(a)(i), noting that the provision "permits limited exceptions to certain protections of Chapter Eleven (such as national treatment and MFN treatment) for certain measures listed in Annexes to the NAFTA."[279] Apotex further notes that the U.S. schedule to Annex 1 excludes from Article 1102 revocable licenses granted under the U.S. Atomic Energy Act. Apotex thus concludes that "[i]f the US were correct in its interpretation that revocable intangible rights, such as licenses, are not covered by Chapter Eleven, there would have been no need for the US to exclude from Article 1102's coverage the commercial licenses granted under the US Atomic Energy Act."[280]

128. Again, Apotex's reasoning is flawed. NAFTA Article 1102 requires national treatment with respect to the *establishment*, acquisition, expansion, management, *conduct*, operation, and sale or other disposition *of investments*.[281] A license may be required for the establishment or conduct of an investment. A reservation means that the United States may discriminate on the basis of nationality when granting these licenses. A reservation allowing the United States to deny such licenses, however, does not necessarily mean that the licenses themselves are investments. Apotex's first example concerns a mandatory, revocable commercial license for

[279] Reply ¶ 218.

[280] *Id.* ¶ 219.

[281] Emphasis added.

nuclear reactors and production facilities in the United States.[282] Its second example concerns a revocable customs broker's license.[283] Both licenses are necessary for the *establishment* and *conduct* of investments, and both reserved measures are discriminatory, as non-U.S. nationals cannot obtain them.[284] It thus was logical for the United States to exclude these regimes from a non-discrimination provision, such as Article 1102. That exclusion, however, does not mean that *all* revocable licenses themselves constitute "investments" under Article 1139(g).

129. Indeed, the *Apotex I-II* tribunal described ANDAs not as "investments," but as applications to conduct certain *trade* activity:

> Whilst an ANDA itself may not be, in strict technical terms, an export or import licence, it operated – in this case – in precisely the same way. As already noted, all Apotex's operations were outside of the U.S. Apotex wanted to export its goods to the U.S., to be marketed and sold there by other entities. In order to do this, Apotex was required to obtain permission, which was to be secured by the submission of an ANDA. The ANDA was thus a requirement in order to conduct an export business.[285]

130. *Third*, Apotex asserts that its "standing" in U.S. courts over its ANDAs shows that it has "property" rights in those ANDAs for purposes of NAFTA Article 1139.[286] But that is untrue. The U.S. cases cited by Apotex merely recognize that an ANDA holder may have an economic or legal interest in the outcome of litigation in the context of the relevant statutory framework

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[282] *See* 42 U.S.C. § 2133 [CLA-560].

[283] *See* 19 U.S.C. § 1641(b)(1) ("No person may conduct customs business (other than solely on behalf of that person) unless that person holds a valid customs broker's license issued by the Secretary under paragraph (2) or (3).") [CLA-559].

[284] 42 U.S.C. § 2133(d) ("No license may be issued to an alien or any [ ] corporation or other entity if the Commission knows or has reason to believe it is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.") [CLA-560]; 19 U.S.C. § 1641(b)(2)-(3) ("The Secretary may grant an individual a customs broker's license only if that individual is a citizen of the United States. [T]he Secretary may grant a customs broker's license to any corporation, association, or partnership that is organized or existing under the laws of any of the several States of the United States[.]") [CLA-559].

[285] *Apotex I-II* Award ¶ 217 [RLA-263].

[286] *See* Reply ¶¶ 209-10 (citing Apotex Memorial ¶¶ 371-73).

(the so-called Hatch-Waxman Amendments) sufficient to give the ANDA holder legal standing in court.[287] The cases do not discuss ANDAs in terms of a "legally cognizable *property* interest."[288] Standing is conferred upon parties with a variety of interests guaranteed by the U.S. Constitution, by common law, or by statute.[289] That ANDA holders may have an economic interest in patent litigation, for example, is a matter regulated by statute (Hatch-Waxman), but does not prove that U.S. courts recognize an ANDA as "property."[290]

131. *Fourth*, Apotex contends that the Tribunal should recognize ANDAs as "property" because the U.S. tax authority treats ANDAs as "intangible property" for certain purposes under U.S. law.[291] But Apotex has failed to show the relevance of its argument under U.S. tax law to

[287] *See, e.g., Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc*., 527 F.3d 1278, 1288 (Fed. Cir. 2008) ("[U]nder the Hatch-Waxman framework Caraco has an *economic interest* in determining whether the '941 patent is invalid or not infringed by the drug described in its ANDA[.]") (emphasis added) [CLA-129].

[288] It is well established that "no legally cognizable property interest exists in uses of property dependent upon revocable permits" under U.S. law. *McGuire v. United States*, 2012 WL 569359 *10 (Fed. Cl.) ("In this case, McGuire essentially argues that he had a compensable right to use a bridge that could only be 'constructed and maintained under [a] revocable permit[ ]' . . . . This argument is foreclosed by Federal Circuit case law, since decisions of the Federal Circuit have made clear that *no legally cognizable property interest exists in uses of property dependent upon revocable permits.*") (emphasis added) (citing *Mitchell Arms, Inc. v. United States*, 7 F.3d 212, 217 (Fed.Cir.1993) [RLA-247] and *Am. Pelagic Fishing Co. v. United States*, 379 F.3d 1363, 1380-81 (Fed.Cir.2004) [RLA-229]) [RLA-244]; *see also* Counter-Memorial ¶¶ 227-28 (citing cases).

[289] *See, e.g.*, BLACK'S LAW DICTIONARY (2009) ("Standing, n. A party's right to make a legal claim or seek judicial enforcement of a duty or right. To have standing in federal court, a plaintiff must show (1) that the challenged conduct has caused the plaintiff actual injury, and (2) that the interest sought to be protected is within the zone of interests meant to be regulated by the statutory or constitutional guarantee in question.") [RLA-300].

[290] Moreover, other provisions in Article 1139, such as those covering commercial sales contracts and short-term loans to non-affiliates, show that even though a claimant may have standing in U.S. court to protect certain interests, such interests nonetheless are excluded as "investments." *See* NAFTA art. 1139(d) (defining "investment" to include "a loan to an enterprise (i) where the enterprise is an affiliate of the investor, or (ii) where the original maturity of the loan is at least three years"); art. 1139(i) (defining "investment" as not including "claims to money that arise solely from (i) commercial contracts for the sale of goods or services by a national or enterprise in the territory of a Party to an enterprise in the territory of another Party").

[291] Memorial ¶ 374; Reply ¶¶ 209-10; *see also Apotex I-II* Award ¶ 207, n.78 ("The Tribunal accepts Apotex's submission that U.S. law is informative in defining '*property*', because it is the law of the host State.") (citing Rosalyn Higgins, *The Taking of Property by the State: Recent Developments in International Law*, 176 RECUEIL DES COURS 263, 270 (1982) (for a definition of "property . . . [w]e necessarily draw on municipal law sources and on general principles of law") [RLA-263]; *Glamis Gold Ltd. v. United States*, NAFTA/UNCITRAL, Award ¶ 37 (8 June 2009) (examining U.S. law to determine whether an "unpatented mining claim" constituted "property") [CLA-28]; MONIQUE SASSON, SUBSTANTIVE LAW IN INVESTMENT TREATY ARBITRATION: THE UNSETTLED RELATIONSHIP

the analysis under Article 1139(g), particularly when it admits that it *pays no tax in the United States on its ANDA sales*. The United States requested that Apotex produce U.S. tax returns showing taxes paid on the sale or transfer of its ANDAs, highlighting Apotex's 2006 sale or transfer of ANDA No. [redacted] to [redacted] in 2006. Apotex stated that the request was inappropriate, because it "assumed that the transfer of the ANDAs at issue constituted taxable events in the U.S. for Apotex [Inc.]."[292] Apotex also admitted that "no documents responsive to this request exist."[293] Apotex has thus conceded that it *pays no U.S. taxes whatsoever* on the sale or transfer of its ANDAs. Apotex must therefore believe either that the sale of an ANDA is not a taxable event or that the ANDA is an asset that exists outside the United States, such that its transfer or sale does not constitute a taxable event in the United States. Apotex has failed to explain why this Tribunal should find a U.S. investment in an *application* prepared *in Canada* that involves "*no business operations* in the United States" and for which *no taxes* are paid on its sale.[294]

132. In short, none of Apotex's arguments support its contention that its ANDAs are "intangible property" constituting an "investment" in the territory of the United States. An ANDA application may be owned, transferred, or bought and sold, but that cannot change its essential character. For companies such as Apotex Inc., whose manufacturing facilities are

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BETWEEN INTERNATIONAL LAW AND MUNICIPAL LAW, xxv, xxvii (2010) ("[I]nternational law does not define property rights, and a definition that disregards the content of municipal law would be an ad hoc (usually post hoc) definition adopted by the tribunal.") [RLA-289].

[292] Apotex Responses to U.S. Redfern, Document Request No.13.

[293] *Id.*

[294] Apotex argues elsewhere in its Reply, in its attempt to discount the significance of U.S. takings law finding that interests similar to ANDAs do not constitute "property," that "US law is of limited assistance in interpreting the meaning of 'intangible property' under Article 1139(g)." Reply ¶ 223. This argument is far more apt with respect to Apotex's opportunistic selection of U.S. tax law to support the status of ANDAs as "intangible property" under Article 1139(g).

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."[295]

3. The *Apotex I-II* Tribunal Confirmed that Apotex's Applications Are Not "Interests Arising from the Commitment of Capital or Other Resources" Within the Meaning of Article 1139(h)

133. Apotex erroneously claims that its ANDAs constitute "interests arising from the commitment of capital or other resources" in the United States for purposes of NAFTA Article 1139(h).[296] ANDAs, however, are nothing like the kinds of interests the NAFTA Parties agreed to recognize as interests under the NAFTA.[297]

134. NAFTA Article 1139 defines "investment" as including:

> h) interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory, such as under
>
> (i) contracts involving the presence of an investor's property in the territory of the Party, including turnkey or construction contracts, or concessions, or
>
> (ii) contracts where remuneration depends substantially on the production, revenues or profits of an enterprise[.]

The *Apotex I-II* tribunal recently illustrated the application of Article 1139(h) by reference to the *Mondev* award:

> By way of example, in *Mondev v. United States*, the Canadian claimant alleged that through its wholly owned U.S. limited partnership, it obtained interests arising from the contractual rights to develop large parcels of property in downtown Boston. The tribunal thus concluded that, through the rights acquired in these construction contracts:

[295] *Apotex I-II* Award ¶ 207 [RLA-263].

[296] Memorial ¶¶ 353-403; Reply ¶¶ 235-53.

[297] *Apotex I-II* Award ¶ 219 (identifying an ANDA, for a foreign company such as Apotex Inc., as "an application for permission to export goods into the United States") [RLA-263].

> "Mondev's claims involved interests arising from the commitment of capital or other resources in the territory of the United States"
>
> which fell squarely within the definition of "*investment*" under NAFTA Article 1139(h).[298]

135. Apotex, by contrast, does not claim any interests arising from contracts involving the presence of property in the United States, such as a turnkey contract or concession. Nor does Apotex claim any interests arising from contracts where remuneration depends substantially on the production, revenues or profits of an enterprise.

136. Instead, Apotex claims that its ANDA applications themselves "qualify as interests arising from the commitment of resources both *within and without* the United States to economic activity in the United States[.]"[299] In particular, Apotex argues that (1) ANDAs constitute "intangible property" under Article 1139(g) and hence separately constitute "interests" under Article 1139(h);[300] (2) ANDAs "are devoted to economic activity in the territory of the United States";[301] (3) the "interests arising from the commitment of capital or other resources *in the territory"* of the host State can arise "before they are committed" to the host State;[302] and (4) "when Apotex develops, files and maintains an ANDA, it commits capital, intellectual property rights, know-how and other resources *in and into* the United States."[303] These arguments are baseless, and the *Apotex I-II* tribunal rejected them accordingly.

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[298] *Id.* ¶ 234 (quoting *Mondev International, Ltd. v. United States of America*, NAFTA/ICSID Case No. ARB(AF)/99/2, Award (Oct. 11, 2002) [CLA-39]).

[299] Memorial ¶ 393; Reply ¶ 235 (emphasis added).

[300] Memorial ¶ 395; Reply ¶ 236.

[301] Memorial ¶ 396; Reply ¶ 237.

[302] Reply ¶ 251 (emphasis in original).

[303] Memorial ¶ 401; Reply ¶ 238.

i. The Apotex I-II Tribunal Confirmed that Apotex's ANDAs Are Not Property Interests for Purposes of Article 1139(h)

137. Apotex erroneously claims that its ANDAs constitute "interests" under Article 1139(h) because they are "intangible property."[304] For purposes of Article 1139(h), Apotex highlights four points: (1) an ANDA "applicant owns the application materials submitted to FDA";[305] (2) an ANDA may "be bought and sold, just like any other property";[306] (3) "the right to market a drug under an approved ANDA is, itself, a protected property right, and so is the statutory exclusivity period afforded some ANDA holders";[307] and (4) "most importantly, FDA's own regulations permit transfer of ownership of pending or approved ANDAs."[308]

138. As discussed above, the *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";[309]

(2) "[E]ven if an ANDA may be bought and sold as Apotex argues, this would still not change its essential character, which is an application to (in this case) export generic drugs into the United States";[310]

(3) "Even if Apotex has exclusive rights over the ANDA, this cannot change the inherent nature of the ANDA itself. In other words, an application to export generic drugs into the United States is not transformed into an 'investment' for the purposes

[304] Reply ¶ 236; Memorial ¶ 395.

[305] Memorial ¶ 395.

[306] *Id.*

[307] *Id.*; Reply ¶ 236.

[308] Memorial ¶ 395. Apotex further argued that "ANDA owners have standing when their rights are affected and to seek declaratory relief." *Id.* As noted above, parties have standing to seek declaratory relief to enforce many rights (e.g., certain licenses or permits) that are not property rights. Thus, the ability to enforce a right in court cannot transform the right into a "property" right.

[309] *Apotex I-II* Award ¶ 224 (emphasis in original) [RLA-263].

[310] *Id.* ¶ 221.

of NAFTA Chapter Eleven, because the holder of the application has exclusive rights thereto";[311] and

(4) The fact that "only the applicant may transfer ownership of its application" cannot transform the application into "property" for purposes of NAFTA Chapter Eleven.[312]

139. The tribunal thus rejected the argument advanced here that an ANDA constitutes "intangible property" for purposes of Article 1139(g) and, hence, separately constitutes a qualifying "interest" for purposes of Article 1139(h). Apotex has offered no compelling reason for this Tribunal to conclude differently.

ii. The Apotex I-II Tribunal Confirmed that ANDAs Are Not "Interests" Under Article 1139(h) Merely Because They Are Committed to Economic Activity in the United States

140. Apotex also contends that its ANDAs constitute "interests" under Article 1139(h) because these applications "are committed to economic activity in the territory of the United States."[313] Apotex argues that "[b]y filing an ANDA, Apotex seeks authorization to market products *solely in the United States*."[314]

141. Again, this is the same argument Apotex unsuccessfully advanced in the *Apotex I-II* claims. There, Apotex argued that its "ANDAs seek approval to market the subject products *solely in the United States*,"[315] adding:

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[311] *Id.* ¶ 222.

[312] *Apotex I-II* Award ¶¶ 199, 206 (quoting Apotex's submission) (internal quotations omitted) [RLA-263].

[313] Reply ¶ 237.

[314] Memorial ¶ 396 (emphasis added).

[315] *Apotex I-II*, Claimant Apotex Inc.'s Rejoinder Memorial on Respondent's Reply on Objections to Jurisdiction ¶ 30 (Dec. 16, 2011) (emphasis in original) [RLA-266]; *see also Apotex I-II* Award ¶ 183 (citing Apotex's argument that "the only reason Apotex undertook the enormous expense and effort to comply with these U.S.-specific requirements was to obtain approval for, and to market and sell, its . . . ANDA products *in the United States*") (emphasis in original) [RLA-263].

> Apotex cannot export and commercialize anything in the United States without an approved ANDA, and without undertaking the investment and development that goes into that ANDA. An ANDA is therefore a uniquely United States investment.[316]

142. The *Apotex I-II* tribunal was "unpersuaded that the costs and effort expended in preparing ANDAs either constitutes or evidences an '*investment*' in the United States, for the purpose of NAFTA Chapter Eleven."[317] The tribunal concluded that "whilst ANDAs are of course filed within the territory of the United States, the actual activity in question (the preparation of each submission) is evidently conducted by Apotex outside of the United States."[318] The tribunal cited evidence that, at Apotex's Signet facility, "operations focus on product development activities . . . *as well as the creation and submission of generic drug approvals*."[319] Apotex, in fact, has admitted in U.S. court that its "ANDA[s] and all supporting materials therefor were prepared by Apotex Inc. employees in Canada."[320]

143. The *Apotex I-II* tribunal further observed that "an ANDA must be submitted by any manufacturer of generic drugs that seeks to have its products sold in the United States . . . regardless of whether the manufacturer is investing in, or merely exporting to, the United

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[316] *Apotex I-II*, Claimant Apotex Inc.'s Counter-Memorial on Respondent's Reply on Objections to Jurisdiction ¶ 38 (Aug. 1, 2011) [RLA-102]; *see also Apotex I-II* Award ¶ 148 (citing Apotex's contention that "[t]he sole purpose of Apotex's development and submission of its ANDAs was to obtain FDA permission to commercialise its ANDA products in the United States") [RLA-263].

[317] *Apotex I-II* Award ¶ 186 (emphasis in original) [RLA-263].

[318] *Id.* ¶ 187 (emphasis in original).

[319] *Id.* (emphasis in original) (quoting GlobalData–Business Description, Apotex, Inc. (Jan. 3, 2001)).

[320] *Astrazeneca Pharmaceuticals LP, et al. v. Apotex Inc. and Apotex Corp.*, No. 1:07-cv-00809 JJF-LPS (D. Del.), Apotex Inc.'s Brief in Support of Its Rule 12(b)(2) Motion to Dismiss for Lack of Personal Jurisdiction or in the Alternative to Transfer to the Middle District of Florida, at 2 (Jan. 31, 2008) (emphasis added) [RLA-73]; *see also Pfizer Inc. et al. v. Apotex Inc. and Apotex Corp.*, No. 1:08-cv-00948 (LDD) (D. Del.), Declaration of Bernice Tao ¶ 18 (Feb. 10, 2009) (emphasis added) ("Apotex Inc. *prepared, filed and submitted* the ANDA that is the subject of this dispute. All of this work was done in Canada.") [RLA-92]; *id.* ¶ 25 ("None of the relevant work regarding Apotex Inc.'s ANDA product, the preparation of the ANDA, or the filing of the ANDA occurred or was otherwise performed in Delaware. All such work occurred in Canada.").

States."[321] Accordingly, committing resources toward "the preparation of the filing, in and of itself, does not establish that a generic drug manufacturer is investing in, rather than exporting products to, the United States."[322]

144. This Tribunal likewise should reject Apotex's argument that its ANDAs – "mere application[s] for regulatory clearance to export goods into the United States" that are prepared in Canada – constitute investments in the territory of the United States for purposes of Article 1139(h).

iii. The Three NAFTA Parties and NAFTA Tribunals Have Unanimously Rejected the Claim that Committing Capital Outside the Territory of the Respondent State Establishes an Investment Inside the Respondent State Under Article 1139(h)

145. Apotex's Reply acknowledges Chapter Eleven's important territorial limitations relevant to its ANDAs, which were prepared entirely in Canada. Apotex accepts, for jurisdictional purposes, "that under Chapter Eleven the investment must be in the host State, that the chapter deals with foreign investment of a cross-border nature, and that the three NAFTA Parties have consistently agreed, and NAFTA tribunals have consistently found, that the investment chapter applies only to investments in the host State."[323] Apotex nonetheless argues that, for purposes of NAFTA Article 1139(h), the "interests" that arise from the commitment of capital or other resources "in the territory" of the United States need not "already be situated in US territory *before* they are committed to activity in that territory and give rise to the interest."[324] Apotex claims that the NAFTA's *travaux préparatoires*, object and purpose, and Spanish-language text

[321] *Apotex I-II* Award ¶ 188 [RLA-263].

[322] *Id.*

[323] Reply ¶ 249.

[324] *Id.* ¶ 251 (emphasis in original).

support its position. The United States refuted these arguments at paragraphs 245-263 of its Counter-Memorial.

146. Mexico similarly rejected Apotex's arguments. In a February 8, 2013 non-disputing Party submission, Mexico stated that it "fully concurs with the US submissions stated in the counter memorial (¶¶ 245-263) with respect to the interpretation of Article 1139(h)."[325] Mexico urged the Tribunal to "take into account Article 1101(1) as part of the context to correctly interpret Article 1139(h)."[326] Mexico observed that "Article 1101(1) has been correctly described as the 'gateway leading to the dispute resolution provisions of Chapter 11,'" as it "establishes and places limits on its 'scope and coverage.'"[327] Mexico further observed that "Article 1101(1) provides clear guidance, as interpreted by previous submissions of the NAFTA Parties and previous tribunals, to conclude that only 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."[328] Mexico thus concluded:

> Therefore, each and every kind of investment listed in Article 1139 must comply with this "territorial" requirement, and applying this component as part of the context to interpret Article 1139(h), it is clear that it requires a commitment of capital or other resources of an investor of a Party *in the territory* of another Party.[329]

147. Mexico thus recognizes that, for purposes of Article 1139(h), the investor must commit capital or other resources "in the territory" of the respondent State. Mexico expressly rejects

[325] Submission of the United Mexican States, *Apotex Holdings Inc. and Apotex Inc. v. United States* ¶ 3 (Feb. 8, 2013).

[326] *Id.*

[327] *Id.* ¶ 4.

[328] *Id.* ¶ 5.

[329] *Id.* ¶ 6 (emphasis in original).

Apotex's argument that those resources need not "already be situated in US territory *before* they are committed to activity in that territory and give rise to the interest."[330] Apotex's Reply ignores Mexico's non-disputing Party submission.[331]

148. Canada shares Mexico's and the United States' understanding. In *S.D. Myers*, for instance, Canada objected to the claim that, for purposes of Article 1139(h), the claimant had "committed capital by way of operating loan financing and invested capital by way of common shares in its Canadian affiliate."[332] Canada argued that the claimant had failed to prove that the "alleged commitment of capital . . . was more than some sort of accounting entry as opposed to a *real investment in Canada*."[333] Canada further observed that "there is no evidence that the funds were actually *disbursed in Canada*."[334] Thus, like the United States and Mexico, Canada recognizes that Article 1139(h) requires a commitment of capital or other resources "in the territory" of a respondent State. All three NAFTA Parties, therefore, have expressed the same interpretation of Article 1139(h). Such common, concordant, and consistent interpretations of the NAFTA provide the best evidence of its meaning.[335]

149. NAFTA Chapter Eleven tribunals, moreover, have rejected arguments that investments made outside the territory of the respondent State but "devoted to" that State may support claims under Article 1139(h). In *Grand River*, for instance, the claimants unsuccessfully argued that it

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[330] Reply ¶ 251.

[331] *Id.* ¶ 249 n.430 (dismissing Mexico's submission, in a footnote, as "inapposite").

[332] *S.D. Myers, Inc. v. Canada*, NAFTA/UNCITRAL, Counter-Memorial of the Government of Canada ¶ 238 (Oct. 5, 1999) [RLA-131].

[333] *Id.* (emphasis added) (internal quotation marks omitted).

[334] *Id.* (emphasis added).

[335] *See* Memorial ¶ 259 n.636-37 (citing authority, including Article 31(3)(b) of the Vienna Convention on the Law of Treaties).

had an investment in the United States because it had spent millions of dollars to purchase "state of the art equipment" *in Canada* for the sole purpose of marketing its generic products in the United States.[336] The *Grand River* tribunal correctly observed:

> Prior NAFTA tribunals have held, following extensive briefing and argument, that they do not have jurisdiction over claims that are based upon injury to investments located in one NAFTA Party on account of actions taken by authorities in another. Chapter Eleven would be applicable only to investors of one NAFTA Party who seek to make, are making, or have made an investment in another NAFTA Party: absent those conditions, both the substantive protections of Section A and the remedies provided in Section B of Chapter Eleven are unavailable to an investor.[337]

150. The *Canadian Cattlemen* tribunal similarly concluded that "something more permanent – such as a commitment of capital or other resources *in the territory of a Party* to economic activity in such territory – is necessary for a contractual claim for money based on cross-border trade to rise to the level of an investment."[338] NAFTA tribunals thus have squarely rejected Apotex's claim that Chapter Eleven protects as "investments" capital or other resources "*before* they are committed" to the host State.[339]

iv. The Apotex I-II Tribunal Confirmed that Merely Committing Resources in the United States Is Insufficient to Establish an Investment Under Article 1139(h)

151. Apotex claims that it commits resources "in and into" the United States for purposes of Article 1139(h), in three respects: (1) by funding lawsuits in the United States; (2) through the 2005 services agreement with Apotex Corp.; and (3) by including in its ANDAs know-how,

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[336] *Grand River Enterprises* Award ¶ 86 (noting that claimants withdrew this claim during closing argument at the hearing) [CLA-29].

[337] *Id.* ¶ 87.

[338] *See Canadian Cattlemen for Fair Trade v. United States*, NAFTA/UNCITRAL, Award on Jurisdiction ¶ 144 (Jan. 28, 2008) (emphasis added) ("*Canadian Cattlemen* Award on Jurisdiction") [CLA-47].

[339] Reply ¶ 251.

intellectual property, and proprietary information. The *Apotex I-II* tribunal considered and rejected these arguments, which in any event contradict representations Apotex has made in U.S. court proceedings.

a. Apotex's Litigation Expenses Do Not Give Rise to Investment Interests in the United States

152. Apotex contends that Apotex Inc. "regularly engages in costly patent litigation before US courts to give value to its ANDAs."[340] Apotex advances the bold claim that these expenses "represent a commitment of capital and resources into the United States" for purposes of establishing an investment under Article 1139(h).[341]

153. This is precisely the argument that Apotex unsuccessfully advanced in the *Apotex I-II* claims. There, Apotex argued that it incurs "substantial litigation costs" in "patent litigation" in U.S. courts, which represent a "commitment of money and other resources" in the United States for purposes of Article 1139(h).[342] The United States observed that if a Canadian or Mexican exporter could transform itself into an "investor" with an "investment" in the United States simply by filing a lawsuit to further its cross-border trade, then presumably every such exporter could bring its trade-related disputes to investment arbitration under the NAFTA.[343] NAFTA Chapter Eleven, however, expressly defines the "investors" and "investments" entitled to protection so as to prohibit such bootstrapping.

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[340] Reply ¶ 238.

[341] *Id.*

[342] *Apotex I-II*, Transcript of Hearing on Jurisdiction and Admissibility, at 241 , (Feb. 15, 2012) [R-204]; *Apotex I-II*, Claimant Apotex Inc.'s Counter-Memorial on Respondent's Objection to Jurisdiction ¶¶ 62-63 (Aug. 1, 2011) [RLA-102].

[343] *Apotex I-II*, Reply on Objections to Jurisdiction of Respondent United States of America ¶ 3 (Oct. 17, 2011) [RLA-276].

154. The *Apotex I-II* tribunal agreed with the United States. It thus rejected the argument that Apotex's litigation expenditures, even when made in the United States, support an investment claim under Article 1139(h). The tribunal stressed that "this article must be read with Article 1139(i) and (j), which clarify that investment does *not* mean":

> (i) claims to money that arise solely from
>
> (i) commercial contracts for the sale of goods or services by a national or enterprise in the territory of a Party to an enterprise in the territory of another Party, or
>
> (ii) the extension of credit in connection with a commercial transaction, such as trade financing, other than a loan covered by subparagraph (d); or
>
> (j) any other claims to money,
>
> that do not involve the kinds of interests set out in subparagraphs (a) through (h)[.]

155. The tribunal observed that:

> NAFTA Article 1139(h)'s focus on interests arising from the commitment of capital in the host State to economic activity in such territory – excludes simple cross-border trade interests. Something more permanent is necessary.[344]

Accordingly:

> 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. Each is, again, no more than an incident of the regulatory requirements of the U.S. market, and a step Apotex took in order to facilitate its export business. NAFTA Article 1139(i) once again applies.[345]

156. This Tribunal likewise should recognize that any expenditures Apotex Inc. may have made in the United States were "no more than an incident of the regulatory requirements of the

[344] *Apotex I-II* Award ¶ 233 [RLA-263].

[345] *Id.* ¶ 240 (emphasis in original).

U.S. market, and a step Apotex took in order to facilitate its export business," rather than an actual investment in the United States.[346]

b. Apotex Inc.'s Services Agreement with Apotex Corp. Does Not Give Rise to Investment Interests

157. Apotex initially claimed that Apotex Inc. "funds" Apotex Corp. through a 2005 services agreement.[347] The U.S. Counter-Memorial debunked this claim, pointing out that the 2005 services agreement, by its terms, does not require Apotex Inc. to "fund" any aspect of Apotex Corp.'s work.[348] To the contrary, the contract calls for Apotex Corp. to pay Apotex Inc. for certain administrative support.[349]

158. Apotex's Reply acknowledges that "[t]he US asserts, correctly, that the 2005 services agreement between Apotex [Inc.] and Apotex [Corp.] requires that Apotex [Corp.] make a cash payment to Apotex [Inc.] for certain administrative support, and not the other way around."[350] Apotex nonetheless contends that "the services agreement reflects a large contribution from Apotex [Inc.] to Apotex [Corp.], including administrative services, accounting and financial (including payroll) services, information systems and technology services, as well as any other

[346] *Id.* The same analysis disposed of Apotex's claim that purchasing ingredients in the United States for drug production in Canada supported an investment claim under Article 1139(h). *Id.* ¶ 235 (rejecting such expenses as "no more than the ordinary conduct of a business for the export and sale of goods"). The tribunal's holding applies equally to Apotex's current argument that it procured "contract research" services from U.S. companies. Memorial ¶ 80. Such expenses "simply supported and facilitated [Apotex's] Canadian-based manufacturing and export operations." *Apotex I-II* Award ¶ 235 [RLA-263].

[347] Memorial ¶ 399 ("Apotex [Inc.] funds this team's work through a 2005 services agreement with Apotex [Corp.].").

[348] Counter-Memorial ¶ 238 (citing 2005 services agreement [C-14]).

[349] *Id.*

[350] Reply ¶ 183 (citing U.S. Counter-Memorial); *see also* Services Agreement Between Apotex Inc. and Apotex Corp. ¶¶ 3, 4.1 (July 1, 2005) [C-14].

services that may be, from time to time, requested by Apotex [Corp.]."[351] Apotex asserts that the payment Apotex Corp. makes to Apotex Inc. "only compensates Apotex [Inc.] for a small portion of the services that Apotex [Inc.] provides to Apotex [Corp.]."[352] Apotex thus claims that Apotex Inc. "commits various resources to Apotex [Corp.] through the services agreement" for purposes of Article 1139(h).[353]

159. These assertions flatly contradict (1) the terms of the 2005 services agreement; and (2) representations Apotex has made in U.S. court proceedings. *First*, the plain language of the services agreement forecloses Apotex's argument. Paragraph 4.1 of the agreement sets out the scope of services provided to Apotex Corp. by Apotex Inc.:

> Apotex [Inc.] shall provide to [Apotex] Corp *administrative services*, information systems and technology services, *accounting and financial (including payroll) services*, procurement services, human resource services, logistic services including inventory management, quality assurance control services, facilities services, engineering services, and such additional services which may be requested by [Apotex] Corp from time to time.[354]

160. Paragraph 3 establishes Apotex Corp.'s agreement to pay Apotex Inc. for *all* such services:

> In consideration of Apotex [Inc.] providing the services herein for and on behalf of [Apotex] Corp, Corp shall pay to Apotex [Inc.] during the Term hereof the sum of [redacted] on a monthly basis *for all services rendered by Apotex [Inc.] to [Apotex] Corp pursuant to paragraph 4*[.][355]

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[351] Reply ¶ 183.

[352] *Id.*

[353] *Id.*

[354] Services Agreement Between Apotex Inc. and Apotex Corp. ¶ 4.1 (July 1, 2005) (emphasis added) [C-14].

[355] *Id.* ¶ 3 (emphasis added).

161. Paragraph 11.1 makes clear that the terms of the 2005 agreement "constitute[] the *entire Agreement* between the parties with no representations, warranties, covenants, Agreements or understanding relative thereto except as otherwise set forth herein."[356]

162. Nothing in the 2005 services agreement, therefore, supports Apotex's argument that Apotex Corp. "only compensates Apotex [Inc.] for a small portion of the services that Apotex [Inc.] provides to Apotex [Corp.]."[357]

163. *Second*, Apotex's current argument contradicts statements Apotex has made in U.S. court proceedings. When seeking to avoid jurisdiction in the United States,[358] Apotex stated that Apotex Corp. "pays for administrative services" through an "arms-length" agreement with Apotex Inc.[359] Apotex Corp.'s president testified under oath that "Apotex Corp. has not received any loans *or other capital* from Apotex Inc."[360]

164. Even in this arbitration, in fact, Mr. Fahner has testified that:

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[356] *Id.* ¶ 11.1.

[357] Reply ¶ 183.

[358] Apotex contends that, in the *AstraZeneca* case, Apotex Inc. "was not trying to avoid jurisdiction in US courts but rather sought to establish jurisdiction in the proper forum." Reply ¶ 180. That is demonstrably false. Apotex Corp.'s pleading states: "Defendant Apotex Corp. respectfully requests that the Complaint against it be dismissed for failure to state a claim for which relief can be granted; for lack of subject matter jurisdiction; and/or for failure to join an indispensable party." *Astrazeneca Pharmaceuticals LP, et al. v. Apotex Inc. and Apotex Corp.*, No. 1:07-cv-00809 JJF-LPS (D. Del.), Apotex Corp.'s Brief in Support of its Motion to Dismiss, at 11 (Jan. 31, 2008) [RLA-73a]. Likewise, Apotex Inc.'s pleading states: "Defendant Apotex Inc. respectfully requests that the Complaint against it be dismissed for lack of personal jurisdiction or, *in the alternative*, that this case be transferred to the Middle District of Florida." *Id.*, Apotex Inc.'s Brief in Support of Its Rule 12(b)(2) Motion to Dismiss for Lack of Personal Jurisdiction or in the Alternative to Transfer to the Middle District of Florida, at 9 (Jan. 31, 2008) (emphasis added) [RLA-73].

[359] *Astrazeneca Pharmaceuticals LP, et al. v. Apotex Inc. and Apotex Corp.*, No. 1:07-cv-00809 JJF-LPS (D. Del.), Apotex Inc.'s Reply Brief to Plaintiffs' Opposition to Apotex Inc.'s Renewed 12(b)(2) Motion to Dismiss for Lack of Personal Jurisdiction or in the Alternative to Transfer to the Middle District of Florida, at 6 (Nov. 2, 2009) [RLA-77].

[360] *Id.* ("Plaintiffs have not shown that Apotex Corp. receives *any financing* from or through Apotex Inc.") (emphasis added) (citing sworn testimony) [RLA-77].

- "Apotex [Inc.] has no direct or indirect equity stake in Apotex [Corp.];[361]
- Apotex Corp. "has never borrowed any funds from Apotex [Inc.]"; [362] and
- "Apotex [Inc.] has never provided any financing to Apotex [Corp.]."[363]

165. Apotex thus concedes that Apotex Inc. has no equity or debt interest in Apotex Corp. and has never provided any financing to Apotex Corp. Yet Apotex simultaneously argues that Apotex Corp. receives services from Apotex Inc. that it does not pay for. This is not consistent with statements Apotex has made in U.S. court. In the *Astrazeneca* case, for instance, Apotex argued that:

> Apotex Corp. and Apotex Inc. are each maintained as completely separate corporate entities. They each maintain their own books and records, financial statements and tax returns . . . . Likewise, Apotex Corp. and Apotex Inc. have studiously observed all corporate formalities.[364]

Apotex cannot permissibly argue that Apotex Corp. "only compensates Apotex [Inc.] for a small portion of the services that Apotex [Inc.] provides to Apotex [Corp.][365] while simultaneously arguing that the companies are maintained as "completely separate corporate entities" and "studiously observe[] all corporate formalities."[366] Apotex, moreover, has failed to present relevant evidence bearing on the issue, which it presumably would have if its assertion were true. Apotex thus has not carried its burden of proving that the payment Apotex Corp. makes to

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[361] Second Fahner Statement ¶ 71.

[362] *Id.* ¶ 78.

[363] *Id.*

[364] *Astrazeneca Pharmaceuticals LP, et al. v. Apotex Inc. and Apotex Corp.*, No. 07-809-JJF-LPS (D. Del.), Apotex Inc.'s Reply Brief in Support of its Motion to Dismiss, at 15-16 (May 12, 2008) (internal quotation marks omitted) [RLA-75].

[365] Reply ¶ 183.

[366] *Astrazeneca Pharmaceuticals LP, et al. v. Apotex Inc. and Apotex Corp.*, No. 07-809-JJF-LPS (D. Del.), Apotex Inc.'s Reply Brief in Support of its Motion to Dismiss, at 11-12 (May 12, 2008) (internal quotation marks omitted) [RLA-75].

Apotex Inc. under the services agreement "only compensates Apotex [Inc.] for a small portion of the services that Apotex [Inc.] provides to Apotex [Corp.]."[367]

c. Any "Know-How" or "Proprietary Information" that May Be Contained in Apotex's ANDAs Cannot Transform Those Applications into Investments

166. Apotex contends that when Apotex Inc. "develops, files and maintains an ANDA, it commits capital, intellectual property rights, know-how and other resources in and into the United States."[368] An ANDA, Apotex asserts, "reflects proprietary information containing the drug's formulation, development, testing and the manufacturing processes for the commercialization of the drug in the US."[369] As such, "[a]ll of that information, even if developed in Canada, is committed into the United States upon the filing of the ANDA."[370]

167. Once again, Apotex unsuccessfully advanced this argument in the *Apotex I-II* claims. There, Apotex argued that each ANDA contains "extremely confidential and proprietary information pertaining to the formulation, development, manufacture, processing, testing, packaging, labeling, and storage of the proposed generic drug product."[371] For companies such as Apotex, "all of their know-how, their secrets, their technology are bound up in these applications."[372]

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[367] Reply ¶ 183.

[368] *Id.* ¶ 238.

[369] *Id.*

[370] *Id.*

[371] *Apotex I-II*, Claimant Apotex Inc.'s Counter-Memorial on Respondent's Objection to Jurisdiction ¶ 40 (Aug. 1, 2011) [RLA-102].

[372] *Apotex I-II*, Transcript of Hearing on Jurisdiction and Admissibility, at 238 (Feb. 15, 2012) [R-204]; *id*. at 192 (noting that ANDAs contain the applicants' intellectual property).

168. The *Apotex I-II* tribunal rejected these arguments as insufficient, concluding that such data and information cannot "transform the inherent nature of the ANDA itself, from an application for permission to export goods into the United States, into some form of investment" under NAFTA Article 1139(h).[373]

169. Apotex's arguments, individually and collectively, failed to establish that ANDAs constitute investments for purposes of Article 1139(h). "Having carefully considered the entire record in this case, the tribunal [was] clear that none of Apotex's characterisations of its alleged '*investments*' meet the requirements of NAFTA Article 1139, whether considered separately or together."[374]

170. To the contrary, Apotex's activities are "those of an exporter, not an investor[.]"[375] The *Apotex I-II* tribunal concluded that Apotex Inc.'s position

> is analogous to that in *Grand River Enterprises, Inc. v. United States*, where the tribunal found that:
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> > "claimants' activities centered on the manufacture of cigarettes at Grand River's manufacturing plant in Canada for export to the United States."
>
> and, as a result, determined that
>
> > "such activities and investments by investors in the territory of one NAFTA party do not satisfy the jurisdictional requirements for a claim against another NAFTA party."[376]

171. The *Apotex I-II* tribunal observed that "Apotex, like any company that intends to export generic drug products to the United States for sale in the U.S. market, sought regulatory approval

[373] *Apotex I-II* Award ¶ 219 [RLA-263].

[374] *Id.* ¶ 158.

[375] *Id.* ¶ 244 (quoting *Grand River Enterprises* Award ¶ 5 [CLA-29]).

[376] *Id.* (quoting *Grand River Enterprises* Award ¶ 5 [CLA-29]).

from the FDA through the submission of ANDAs."[377] But it rightly concluded that "this process cannot change the nature of the underlying activity, or constitute an "*investment*" in and of itself, within the meaning and scope of NAFTA Article 1139."[378] The tribunal thus declared that it lacked jurisdiction over any of Apotex's claims, dismissed them in their entirety, and awarded the United States all legal and arbitration costs.[379] We respectfully submit that this Tribunal should do the same.

B. The Import Alert Did Not Relate to Any "Investor" or "Investment" in this Arbitration

172. Apotex's claims fall outside the "scope and coverage" provision of NAFTA Chapter Eleven. NAFTA Article 1101(1) states:

> This Chapter applies to measures adopted or maintained by a Party relating to:
>
> (a) investors of another Party; [and]
>
> (b) investments of investors of another Party in the territory of the Party[.][380]

No claim for breach of a Chapter Eleven obligation may be arbitrated unless these fundamental jurisdictional prerequisites are established.

173. Apotex's Reply acknowledges three important jurisdictional limitations contained in this provision. *First*, Apotex accepts that Article 1101(1) is the "gateway" to NAFTA Chapter Eleven.[381] This gateway limits the claims that may be arbitrated under Chapter Eleven.

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[377] *Id.* ¶ 245.

[378] *Id.* (emphasis in original).

[379] *Id.* ¶ 358.

[380] Despite the clear statement in Article 1101(1) that the "Chapter applies to measures adopted or maintained by a Party," Apotex suggests hypothetical circumstances (involving a full protection and security claim) in which the Chapter would apply in the absence of "measures adopted or maintained by a Party." *See* Reply ¶ 111. This arbitration does not present that issue.

174. Article 1101(1)(b) expressly states that NAFTA Chapter Eleven applies only to those measures relating to "investments of investors of another Party *in the territory of the Party*" that has adopted or maintained those measures.[382] NAFTA Chapter Eleven, therefore, provides for arbitration of claims only when those investments are located in the territory of the Party that has accorded the treatment.

175. Accordingly, arbitration of claims for failure to accord *investments* the minimum standard of treatment in breach of Article 1105(1) is provided for only with respect to the treatment of investments in the territory of the State that has adopted the challenged measure.[383] And arbitration of claims for failure to accord *investments* national or most-favored-nation treatment in breach of Articles 1102(2) and 1103(2) is provided for only with respect to measures relating to the treatment of *investments* in the territory of the State according the treatment.[384]

176. Just as Article 1101(1)(b) expressly limits arbitration of disputes to measures relating to covered investments, Article 1101(a) limits arbitration of disputes to measures relating to qualified investors. That is, Article 1101(1)(a) limits the scope of Chapter Eleven to disputes

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[381] Reply ¶ 102; *see also Methanex* First Partial Award ¶ 106(i) ("*Article 1101(1)* . . . is the gateway leading to the dispute resolution provisions of Chapter 11.") (emphasis in original) [CLA-36].

[382] NAFTA art. 1101(1)(b) (emphasis added). This accords with a principal object and purpose of the NAFTA. Article 102(1)(c) states, as an objective of the NAFTA, to "increase substantially investment opportunities *in the territories* of the Parties," which evidences the Parties' specific intent "to promote and increase *cross-border* investment opportunities." *Metalclad Corp. v. United Mexican States*, NAFTA/ICSID Case No. ARB(AF)/97/1, Award ¶ 75 (Aug. 30, 2000) (emphasis added) [CLA-33].

[383] NAFTA art. 1105(1) ("Each Party shall accord to investments of investors of another Party treatment in accordance with international law[.]") [CLA-1].

[384] NAFTA art. 1102(2) ("Each Party shall accord to investments of investors of another Party treatment no less favorable than that it accords, in like circumstances, to investments of its own investors with respect to the establishment . . . or other disposition of investments."); *Id.* art. 1103(2) ("Each Party shall accord to investments of investors of another Party treatment no less favorable than that it accords, in like circumstances, to investments of investors of any other Party or of a non-Party with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.") [CLA-1].

relating to investors only with respect to investments *in the territory* of the State that adopted or maintained the challenged measure.

177. *Second*, Apotex accepts that "[h]aving an investment in the territory of another Party is not sufficient to establish jurisdiction under NAFTA Chapter Eleven; the challenged measure must also 'relate to' the investor or its U.S. investment."[385]

178. *Third*, 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."[386] According to Apotex, however, "[i]f a measure breaches a substantive provision of Chapter Eleven, the connection between the measure and the investor/investment necessarily is 'legally significant.'"[387] Apotex thus believes that a claimant may pass through NAFTA's jurisdictional "gateway" by proving its merits claim.[388] This is entirely circular, and even Apotex acknowledges that its argument "begs the question of what gateway function [] Article 1101(1) then has."[389] The answer, the *Methanex* tribunal confirmed, is that the "powers of the Tribunal can *only* come into legal existence if the requirements of Article 1101(1) are met."[390]

179. Apotex misinterprets, and hence misstates, the *Methanex* tribunal's decision. According to Apotex, "the *Methanex* tribunal recognized that the legally significant connection under

[385] Reply ¶ 94 (internal quotation marks omitted).

[386] *Id.* (quoting *Methanex* First Partial Award ¶ 147 [CLA-36]).

[387] *Id.* ¶ 101.

[388] *Id.* ¶ 101, 107.

[389] *Id.* ¶ 107 ("The conclusion that the connection required by Article 1101(1) is that prescribed in the relevant substantive NAFTA obligation begs the question of what gateway function of [*sic*] Article 1101(1) then has.").

[390] *Methanex* First Partial Award ¶ 106 (emphasis added) [CLA-36].

Article 1101(1) *must* be informed by the substantive provisions of Chapter Eleven."[391] In fact, the *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."[392] 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. Instead, a merits finding "might repair the deficiency with respect to the necessary showing of the 'relation' under Article 1101."[393] As discussed below, the defects in Apotex's jurisdictional claims are confirmed, not repaired, by a review of its merits claims.

180. The sole challenged 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). Apotex, therefore, cannot pass through NAFTA's gateway, and all of its claims must be dismissed for lack of jurisdiction.

1. The Import Alert Did Not Relate to Apotex Inc. as an Alleged Investor or to Its Alleged Investments

181. Even if Apotex had carried its burden of proving that its ANDAs are "investments" in the United States, the Tribunal still would lack jurisdiction over Apotex Inc.'s claims, as the Import Alert did not "relate to" Apotex Inc. as an "investor" and to its ANDA "investments." Apotex argued in its Memorial that the Import Alert "related to" to Apotex Inc. and its ANDAs because

[391] Reply ¶ 103 (emphasis added).

[392] *Methanex Corp. v. United States*, NAFTA/UNCITRAL, Final Award on Jurisdiction and Merits, Part IV, Ch. B ¶ 1 (Aug. 3, 2005) (emphasis added) ("*Methanex* Final Award") [CLA-34].

[393] *Id.* Part IV, Ch. B ¶ 2.

it (1) prevented FDA from reviewing Apotex's pending and pipeline ANDAs; and (2) prevented Apotex from using its existing ANDAs. Apotex has since abandoned the first argument and made concessions undermining the second.

i. Apotex Abandoned All Claims Based on Pending and Pipeline ANDAs, Obviating the Issue of Whether the Import Alert Related to Them

182. Apotex initially claimed as "investments" various "applications pending with FDA," as well as "pipeline applications" that it planned to submit to FDA.[394] The U.S. Counter-Memorial established that the Import Alert did not "relate to" these alleged investments, citing U.S. law and contemporaneous documents showing that FDA declined to approve Apotex's ANDAs *not* because of the Import Alert, but because of the firm's cGMP violations.[395]

183. The Counter-Memorial cited U.S. law authorizing FDA to refuse to approve an abbreviated application for a new drug for a number of stated reasons, including:

> The methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug product are inadequate to ensure and preserve its identity, strength, quality, and purity.[396]

Thus, if a facility does not comply with cGMP, FDA withholds approval of an ANDA. The provision nowhere mentions import alerts, and has nothing to do with them.

184. In a February 7, 2013 letter, Apotex informed the Tribunal that it was abandoning its claims arising from its pending and pipeline ANDAs as investments.[397] Apotex stated that,

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[394] Memorial ¶ 344.

[395] Counter-Memorial ¶¶ 275-83.

[396] *Id.* ¶ 278 (quoting 2009 Etobicoke Warning Letter, at 6 [C-41] and 21 C.F.R. § 314.127(a)(1) (2012) [CLA-277]).

[397] Letter from B. Legum to Tribunal (Feb. 7, 2013) (stating that "the question of whether pending or tentatively-approved ANDAs constitute investments is no longer presented here").

"[f]or the avoidance of doubt, claims for damages now are based only on Apotex [Corp.] and *finally approved ANDAs* as investments."[398] Accordingly, while it is clear that the Import Alert did not "relate to" Apotex Inc.'s pending and pipeline ANDAs, the Tribunal is no longer called upon to decide the issue.

ii. The Import Alert Did Not Relate to Apotex Inc.'s Approved ANDAs

185. The Import Alert does not have any legal effect on an approved ANDA, and in fact does not reference ANDAs at all. Apotex nonetheless claims that the Import Alert related to its approved ANDAs, because it "destroyed [their] economic value" and "because the products authorized to be marketed by the ANDAs could not be marketed at all while the Import Alert remained in effect."[399] These claims are false.

186. The Import Alert did not destroy the economic value of Apotex's ANDAs or prevent their use. Indeed, there is no evidence that the ANDAs themselves lost any value during the period of the Import Alert. Apotex admits, in fact, that its ANDAs remained approved during the period of the Import Alert, and thus could have been licensed or sold to another company or transferred to another Apotex or third-party facility.[400] The evidence shows that Apotex considered licensing its ANDAs to other companies in the weeks immediately following the Import Alert.[401] In April and May 2010, Apotex similarly considered transferring its ANDAs for

[398] Letter from B. Legum to Tribunal, at 2 (Feb. 7, 2013) (emphasis added).

[399] Reply ¶ 257.

[400] First Desai Statement ¶ 89.

[401] *See, e.g.*, chart of approved Apotex ANDAs and potential licensees [R-236]; meeting minutes re Site Transfer of US Products (Sept. 10, 2009) [C-392]; email from K. Krishnan to B. Tao (Sept. 7, 2009) (discussing potential licensing arrangements for Apotex ANDAs) [C-388]; email from K. Krishnan to B. Clark (Sept. 8, 2009) (same) [C-390]; email from K. Krishnan to P. Elchidana (Sept. 9, 2009) (same) [C-391]; email from P. Gordon to P. Sanghvi (Oct. 2, 2009) (same) [R-168].

Signet to Etobicoke, assuming the latter facility would be found cGMP-compliant first.[402] Apotex thus is well aware that it could have transferred its ANDAs to one of its cGMP-compliant facilities or to another manufacturer. Dr. Desai has testified that Apotex concluded in November 2009 that it would have been "impractical" to transfer Apotex's ANDAs to another Apotex or third-party facility.[403] Six months later, however, Apotex represented in U.S. court proceedings that the Import Alert posed no "barrier to FDA approval" of its modafinil ANDA, because its ANDAs were freely transferable.[404] Apotex explained:

> Apotex has plants throughout the world. The import alert and related [warning] letters apply to only two Apotex facilities. While Apotex's ANDA for modafinil identifies one of two Ontario facilities as the manufacturing site, Apotex can file appropriate technology transfer documents with the FDA that would allow manufacture at another FDA approved Apotex manufacturing site. See, 21 CFR 314.70(a). Apotex continues to manufacture product at such sites and to import such product into the United States because those facilities are not subject to the import alert.[405]

Thus, Apotex's contemporaneous court submissions confirm that the "import alert and related [warning] letters apply to only two Apotex *facilities*," and Apotex could have utilized its ANDAs at other Apotex or third-party facilities. Had it done so, Apotex Inc. could have continued exporting its ANDA products to the United States, and Apotex Corp. and other companies could have continued marketing them in the United States.[406] Apotex's decision not to transfer its ANDAs to other facilities for practical reasons does not create a legally significant connection

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[402] Email from K. Krishnan to P. Sanghvi (May 25, 2010) [R-182].

[403] Second Desai Statement ¶¶ 40-42.

[404] *Apotex Inc. v. Cephalon, Inc.*, No. 06-cv-02768 MSG (E.D. Pa.), Order ¶ 17 (Mar. 15, 2011) [RLA-69].

[405] *Apotex Inc. v. Cephalon, Inc.*, No. 06-cv-02768 MSG (E.D. Pa.), Response of Apotex to Cephalon's Request for Conference, at 2 (Apr. 21, 2010) [RLA-70]. Apotex also acknowledged that its ANDA for modafinil would not have been finally approved until 2012, for reasons wholly apart from the Import Alert. *Id.* at 3.

[406] Alternatively, Apotex could have sold the ANDAs at fair market value, as the Import Alert applied only to Apotex's Etobicoke and Signet facilities, and not to the ANDAs themselves.

between the ANDAs and the Import Alert. Far from having "destroyed the economic value of [its] ANDAs" or prevented their use, the Import Alert had no *legal effect* on Apotex's ANDAs at all.

2. The Import Alert Did Not Relate to Apotex Corp.

187. Apotex erroneously contends that the Import Alert "related to" Apotex Corp. because it "interrupted" sales from Apotex Inc. to Apotex Corp. and thereby "made it legally impossible for the transactions between Apotex [Inc.] and Apotex [Corp.] to be carried out."[407] Apotex is mistaken, in three respects. *First*, Apotex has admitted that Apotex Corp. purchases drugs from Apotex Inc. exclusively in Canada,[408] and thus neither the Import Alert nor any other U.S. government measure "interrupted" sales between Apotex Inc. and Apotex Corp. or made it "legally impossible" for Apotex Corp. to purchase drugs from Apotex Inc. *Second*, to the extent that Apotex alleges injury from Apotex Corp.'s inability to *import* into the United States drugs from Apotex Inc.'s Etobicoke and Signet facilities, the Import Alert was not the actual cause of the alleged injury. The reason Apotex Corp. (or any other company) could not import those drugs is because (1) they were deemed to be adulterated for cGMP violations and, as such, (2) were detained and refused admission for the appearance of adulteration – and Apotex challenges neither measure in this arbitration. *Third*, even if the Import Alert had itself prevented importation of drugs from Apotex Inc.'s Etobicoke and Signet facilities, the Import Alert still did not "relate to" Apotex Corp. for purposes of Article 1101(1). The link between the challenged measure (FDA's import guidance concerning drugs from two of Apotex Inc.'s Canadian

[407] Reply ¶¶ 119-20.

[408] *Apotex Inc. et al. v. Sanofi Aventis et al.*, 2010 Fed. Ct. 182, ¶ 26 (Feb. 18, 2010) [RLA-230].

manufacturing facilities) and Apotex Corp. (Apotex's Inc.'s "tangential" corporate relative)[409] is simply too remote to establish a legally significant connection for purposes of Article 1101(1).

i. Apotex Corp.'s Purchase of Drugs From Apotex Inc. Occurs in Canada

188. A critical element of Apotex's "relating to" claim is that the Import Alert "interrupted" sales from Apotex Inc. to Apotex Corp.[410] From the inception of this case, however, Apotex has studiously avoided stating whether Apotex Corp. purchases drugs from Apotex Inc. in the United States or in Canada. Apotex is the claimant in these proceedings and thus carries the burden to establish that the challenged measure relates to Apotex and its alleged investments. Apotex, however, has withheld crucial facts in its exclusive control concerning the location of Apotex's drug sales, impermissibly inviting the Tribunal to intuit a central element of Apotex's claims:

- Apotex's Notice of Intent vaguely stated that the Import Alert "prevented Apotex Corp. from *receiving* any drugs produced at [Etobicoke and Signet]";[411]
- Apotex's Request for Arbitration similarly alleged that the Import Alert "prevented Apotex [Corp.] from receiving *for sale in the US* any product manufactured at the Etobicoke and Signet facilities";[412]
- Apotex's Memorial added that Apotex Inc. "develops and manufactures Apotex products that are distributed worldwide – *and through Apotex [Corp.] in the United States*";[413] and

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

[410] Reply ¶¶ 119-20 ("The Import Alert interrupted the transactions on which Apotex [Corp.] depended for 80 percent of its sales. The transactions that the Import Alert interrupted had two parties. Apotex [Inc.] was on one side as the seller and importer of record into the United States. Apotex [Corp.] was the purchaser and consignee of record on the other side.").

[411] Notice of Intent ¶ 2 (emphasis added).

[412] Request for Arbitration ¶ 38 (emphasis added).

[413] Memorial ¶ 52 (emphasis added); *see also id.* ¶ 1 (alleging that the Import Alert "cut off the supply of 80% of the products sold by the US business"). Apotex Corp.'s vice-president of commercial operations, Mr. Flinn, has

- Apotex's Opposition to Bifurcation stated that Apotex Inc. is the "shipper" and Apotex Corp. the "buyer" of products from Etobicoke and Signet,[414] adding that "risk of loss passed to Apotex [Corp.] when Apotex [Inc.] handed over its products to [a carrier] at the facilities in Etobicoke and Signet."[415]

189. The United States interpreted these statements to suggest that "transactions between Apotex Corp. and Apotex Inc. occurred *in Canada*, with title and risk of loss passing to Apotex Corp. when Apotex Inc. 'handed over its products' to a carrier 'at the facilities in Etobicoke and Signet.'"[416] Apotex's representations in U.S. court provided further support for the United States' interpretation. When seeking to avoid jurisdiction in U.S. courts, Apotex has argued:

- "Apotex Inc. does not directly sell any products of any kind in the United States";[417]
- "Because Apotex Inc. does not directly sell any products in the U.S. it must rely on the products [being] sold by others, such as Apotex Corp.";[418] and
- "Apotex Inc. has put nothing into the stream of commerce in the United States."[419]

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testified that Apotex Corp. "markets and sells products manufactured by Apotex [Inc.]," by Apotex-India, and "some third-party products." Witness Statement of John Flinn ¶¶ 25-27 (July 20, 2012). Apotex Corp.'s president, Mr. Watson, provided no additional information in his witness statement.

[414] Claimants' Opposition to Bifurcation ¶ 31 (Dec. 28, 2012).

[415] *Id.*

[416] Reply of Respondent United States of America on Bifurcation ¶ 10 (Jan. 10, 2013) (emphasis in original).

[417] *Id.* (quoting *Shire LLC v. Apotex Inc., Apotex Corp. and Apotex Pharmaceutical Holdings Inc.*, No. 2:08-cv-265 (E.D. Tex.), Declaration of Bernice Tao ¶ 12 (Aug. 6, 2008) [RLA-183]; *Cephalon, Inc. et al. v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS (D. Del.), Declaration of Bernice Tao ¶ 11 (Oct. 12, 2010) (stating same) [RLA-178]); *see also Novartis v. Apotex*, No. 12-cv-05574 (D. N.J.), Answers Defenses and Counterclaims, at 2 (Feb. 11, 2013) ("Apotex Inc. sells various drug products *for delivery into* the United States.") (emphasis added) [RLA-250].

[418] Reply of Respondent United States of America on Bifurcation ¶ 19 (Jan. 10, 2013) (internal quotation marks and ellipsis omitted) (quoting *Cephalon, Inc. et al. v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS (D. Del.), Reply Brief in Support of Motion to Dismiss Complaint by Apotex Inc. and Apotex Corp. or in the Alternative to Transfer, at 7 (Nov. 15, 2010) [RLA-179]).

[419] Reply of Respondent United States of America on Bifurcation ¶ 7 (Jan. 10, 2013) (emphasis added) (quoting *Abbott Laboratories Inc. and Abbott GMBH & Co. KG v. Apotex Inc. and Apotex Corp.*, No. 1:09-cv-00990-JJF (D. Del.), Defendant Apotex Inc.'s Brief in Support of its Motion to Dismiss for Lack of Personal Jurisdiction Pursuant to Fed. R. Civ. P. 12(b)(2), at 10-11 (Jan. 13, 2010) (denying that "Apotex Inc. sells various products unrelated to this case in the United States," and affirming that "Apotex Inc. has put nothing into the stream of commerce") [RLA-175]).

190. In its Reply, Apotex rejected the United States' interpretation, stating: "Contrary to the U.S. contention, Apotex has never suggested that title passed to Apotex [Corp.] on delivery of the goods to the carrier."[420] Apotex thus suggests that title does *not* pass in Ontario, although Apotex conspicuously declined to say so expressly.[421]

191. Despite Apotex's persistent obfuscation, Apotex has admitted in Canadian court proceedings, in *Apotex v. Sanofi*, that at least some sales from Apotex Inc. to Apotex Corp. occur exclusively in Ontario. There, Apotex had sought a declaration from the Federal Court in Ottawa that Apotex's intended sales of the drug clopidogrel to Apotex Corp. would not violate Sanofi's Canadian patent for that drug.[422] Apotex Corp. sells clopidogrel in the United States.[423] Apotex's complaint "appeared to deny any sale [of clopidogrel] by Apotex in Canada."[424] After Sanofi counterclaimed against Apotex for patent infringement, however, Apotex reversed course. To take advantage of a shorter limitations period provided by Ontario law,[425] Apotex argued that the "cause of action arose entirely in the province of Ontario."[426] Apotex stated:

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[420] Claimants' Rejoinder on Bifurcation ¶ 42 n.53 (Jan. 16, 2013); *see also* Reply ¶ 131 n.191 ("Apotex never argued that *title* to the products passed to Apotex [Corp.] when Apotex [Inc.] handed over its products to a carrier at the Etobicoke and Signet facilities.") (emphasis in original).

[421] *See, e.g.*, Second Desai Statement ¶ 37 (May 23, 2013) ("Apotex [Inc.], as seller, could no longer export the Apotex products from Etobicoke and Signet to the United States, while Apotex [Corp.], as purchaser, could no longer import these products into the United States."); Second Fahner Statement ¶ 62 ("Apotex [Inc.] sells its products to Apotex [Corp.] for marketing, sale and distribution in the US . . . . The products are shipped from Canada to the US by a transportation carrier that picks up Apotex products from Apotex [Inc.'s] facilities in Canada.").

[422] *Apotex Inc. et al. v. Sanofi Aventis et al.*, 2010 Fed. Ct. 182 ¶ 1 (Feb. 18, 2010) [RLA-230].

[423] *See* Apotex, "Clopidogrel Tablets USP" ("On this website we provide information to the public on results of certain clinical trials sponsored by Apotex Inc., for products marketed in the United States.") [R-234].

[424] *Apotex Inc. et al. v. Sanofi Aventis et al.*, 2010 Fed. Ct. 182 ¶ 30 (Feb. 18, 2010) [RLA-230].

[425] Apotex invoked the two-year limitations period provided by the Ontario Limitations Act, arguing that the Patent Act (which has a six-year limitations period) did not apply. *Id.*

[426] *Id.* (emphasis added) (internal quotation marks omitted).

> 59. Any manufacture, *sale* or use of clopidogrel or any clopidogrel-containing product by Apotex Inc. or Apotex Pharmachem took place *in and only in Ontario*. Any manufacture, sale or use of clopidogrel or any clopidogrel-containing product by Apotex Inc. or Apotex Pharmachem outside of Ontario, *which is denied*, does not constitute infringement of [Sanofi-Aventis'] patent.
>
> 60. Specifically with respect to the U.S., the Apotex Defendants state that, at all times prior to June 9, 2007, the Plaintiffs knew that the U.S. Apo-clopidogrel Product:
>
> . . .
>
> (b) *Was manufactured, sold and used (if at all) by Apotex Inc. solely in Ontario, Canada*.[427]

192. The Federal Court rebuked Apotex for its about-face.[428] But the court nonetheless acknowledged Apotex's "clear statement to the effect that any sales of [the product] by Apotex occurred in Ontario and in Ontario only."[429] The court found it "inescapable on the pleadings" that "any sales by Apotex Inc. of product eventually sold in the U.S. were made in Ontario, either directly to Apotex Corp. or to an intermediary, and that any export was therefore made by Apotex Corp. or this intermediary."[430] Apotex's amended pleading, the court concluded, "negates and denies any export by Apotex [Inc.][.]"[431]

193. Given Apotex's admission that "any sales by Apotex Inc. of product eventually sold in the U.S. were made in Ontario," Apotex should not be heard to argue the contrary in this

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[427] *Id.*

[428] *Id.* ¶ 4-5 ("Not a single one of Apotex's proposed new allegations could not have been made at the time Apotex filed its original pleadings" and "the proposed amendments reflect a now clearly developed and articulated theory of the case, or this new pleading represents the very illustration of the fishing expeditions, cobbled strategy and inability to articulate a coherent theory of the case which the Court [previously] censured.") (emphasis in original).

[429] *Id.* ¶ 26.

[430] *Id.* ¶ 27 (emphasis in original).

[431] *Id.* ¶ 26.

arbitration.[432] Apotex's argument before the Canadian Federal Court, coupled with its conspicuous refusal in this arbitration to identify where its drug sales occur, strongly suggests that Apotex Corp. purchases products from Apotex Inc. *in Canada*. This conclusion is consistent with Apotex's categorical statements in U.S. court proceedings that "Apotex Inc. does not directly sell any products of any kind in the United States"[433] and "has put nothing into the stream of commerce in the United States."[434] Apotex has failed to explain how the Import Alert could conceivably have prevented drug sales that occurred "*in and only in Ontario.*" The Import Alert clearly had no impact on such sales.[435]

ii. Apotex Inc.'s cGMP Violations, Not the Import Alert, Constituted the Legal Impediment to the Importation of Drugs from Etobicoke and Signet

194. To the extent that Apotex alleges injury from Apotex Corp.'s inability to *import* into the United States drugs from Apotex Inc.'s Etobicoke and Signet facilities, the Import Alert was not the actual cause of the alleged injury. Apotex's claims in this arbitration conflate three discrete measures:

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[432] *Id.* ¶ 22.

[433] Reply of Respondent United States of America on Bifurcation ¶ 10 (Jan. 10, 2013) (emphasis omitted) (quoting *Shire LLC v. Apotex Inc., Apotex Corp. and Apotex Pharmaceutical Holdings Inc.*, No. 2:08-cv-265 (E.D. Tex.), Declaration of Bernice Tao ¶ 12 (Aug. 6, 2008) [RLA-183]; *Cephalon, Inc. et al. v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS (D. Del.), Declaration of Bernice Tao ¶ 11 (Oct. 12, 2010) (stating same) [RLA-178]); *see also Novartis v. Apotex*, No. 12-cv-05574 (D. N.J.), Answers Defenses and Counterclaims, at 2 (Feb. 11, 2013) ("Apotex Inc. sells various drug products *for delivery into* the United States.") (emphasis added) [RLA-250].

[434] Reply of Respondent United States of America on Bifurcation ¶ 7 (Jan. 10, 2013) (emphasis omitted) (quoting *Abbott Laboratories Inc. and Abbott GMBH & Co. KG v. Apotex Inc. and Apotex Corp.*, No. 1:09-cv-00990-JJF (D. Del.), Defendant Apotex Inc.'s Brief in Support of its Motion to Dismiss for Lack of Personal Jurisdiction Pursuant to Fed. R. Civ. P. 12(b)(2), at 10-11 (Jan. 13, 2010) (denying that "Apotex Inc. sells various products unrelated to this case in the United States," and affirming that "Apotex Inc. has put nothing into the stream of commerce") [RLA-175]).

[435] *See Grand River Enterprises*, Award ¶ 95 (noting that Grand River's cigarettes "have been sold at all times on the F.O.B. basis, with title and risk of loss transferring to these third parties at Grand River's facilities in Ohsweken, Canada," and dismissing Grand River's Chapter Eleven claims for lack of an "investment" in the United States) (citing affidavit from U.S. court proceedings) [CLA-29].

- Measure One: FDA's determinations that drugs from two of Apotex Inc.'s Canadian manufacturing facilities were not cGMP-compliant and thus were "deemed to be adulterated" under U.S. law and could be refused admission in the United States;[436]

- Measure Two: FDA's addition of drugs from those facilities to Import Alert 66-40;[437] and

- Measure Three: FDA field personnel's decision to detain without physical examination and, following an administrative process, refuse to admit into the United States [redacted] shipments of drugs from those facilities.[438]

195. Apotex challenges only the Import Alert in this arbitration. That measure, however, is not the underlying cause of Apotex's alleged injuries. As discussed, the Import Alert is an internal FDA memorandum sent to FDA district offices "concerning unusual or new problems affecting imports which gives *background and compliance guidance information* for each product and problem."[439] By its very terms, the Import Alert "does not create or confer any rights for or on any person, and does not operate to bind FDA or the public."[440]

196. The stated "Import Alert Name" for Etobicoke and Signet is "Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug GMPs."[441] The stated "Reason for [the] Alert" is that the "firm is not operating in conformity with current good manufacturing

[436] *See infra* ¶¶ 37-38, 49.

[437] Counter-Memorial ¶¶ 45-47.

[438] *Id.* ¶¶ 50-51.

[439] FDA, *Regulatory Procedures Manual*, Chapter 11 (Glossary) (defining "Import Alerts") (emphasis added) [R-37]; *see also* Vodra Report ¶¶ 86-91.

[440] FDA Import Alert #66-40, *Detention Without Physical Examination of Drugs from Firms Which Have Not Met Drug GMPs* (Oct. 2, 2009) [C-110] ("The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the methods and controls used in its manufacture and control of pharmaceutical products do not appear to conform to current good manufacturing practices within the meaning of Section 501(a)(2)(b)"); *see also* Vodra Report ¶ 88; *supra* ¶ 40.

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

practices (CGMPs)."[442] Thus, the actual reason that drugs from Etobicoke and Signet could not be *marketed* in the United States was because of FDA's finding that Apotex's facilities were not operating in conformity with cGMP, and thus drugs from those facilities were deemed to be adulterated (Measure One).

197. The reason that drugs from Etobicoke and Signet were *refused admission* to the United States is because FDA field personnel determined that drugs from those facilities appeared to be adulterated for non-cGMP compliance (Measure Three).[443]

198. *Apotex does not challenge either measure in this arbitration*. Instead, Apotex challenges only the Import Alert (Measure Two), an internal FDA memorandum that by its terms "**does not operate to bind FDA or the public."**[444]

199. The Import Alert, therefore, was not the measure that prevented Apotex Corp. from marketing drugs from Etobicoke and Signet in the United States, and Apotex's evidence does not establish otherwise. To the contrary, all evidence shows that the measures that actually prevented Apotex Corp. (or any other company) from marketing those drugs were (1) FDA's determinations that drugs from two of Apotex Inc.'s Canadian manufacturing facilities were not cGMP-compliant; and (2) FDA field personnel's decision to detain without physical examination and refuse to admit into the United States [redacted] shipments of drugs from those facilities. The

[442] *Id.*

[443] *See infra* ¶ 280 (discussing detention without physical examination of shipments of drugs from Teva Pharmaceutical Inc.'s Jerusalem facility even though they were not listed on the Import Alert).

[444] FDA Import Alert #66-40, *Detention Without Physical Examination of Drugs from Firms Which Have Not Met Drug GMPs* (Oct. 2, 2009) [C-110]; *see also* Vodra Report ¶ 89.

Import Alert, therefore, was not a legal impediment to the importation of drugs from Etobicoke and Signet.[445]

iii. The Import Alert Was Not "Specifically Addressed" or "Applied" to Apotex Corp.

200. Even if the Import Alert had itself prevented importation of drugs from Apotex Inc.'s Etobicoke and Signet facilities, the Import Alert still would not have "related to" Apotex Corp. for purposes of Article 1101(1). The impact that the Import Alert had on Apotex Corp. was no different, legally, from that felt by any of the many other U.S. companies that sought to receive drugs from Apotex Inc.'s Etobicoke and Signet facilities for sale in the United States, and thus the link between the challenged measure and Apotex Corp. is simply too remote to establish a legally significant connection for purposes of Article 1101(1). As the International Law Commission recognized:

> *[C]ausality in fact is a necessary but not a sufficient condition for reparation.* There is a further element, associated with *the exclusion of injury that is too "remote" or "consequential" to be the subject of reparation*. In some cases, the criterion of "directness" may be used, in others "foreseeability" or "proximity". But other factors may also be relevant: for example, whether State organs deliberately caused the harm in question, or whether the harm caused was within the ambit of the rule which was breached, having regard to the purpose of that rule. In other words, the requirement of a causal link is not necessarily the same in relation to every breach of an international obligation. In international as in national law, the question of remoteness of damage "is not a part of the law which can be satisfactorily solved by search for a single verbal formula". The notion of a sufficient causal link which is not too remote is embodied in the general requirement in article 31 [of the Draft Articles of State Responsibility] that the

[445] *Compare with Cargill Inc. v. United Mexican States*, NAFTA/ICSID Case No. ARB(AF)/05/2, Award ¶ 175 (Sept. 18, 2009) (finding that the "import permit requirement not only had an immediate and direct effect on the business of Cargill de Mexico but also constituted a *legal impediment* to carrying on the business of Cargill de Mexico in sourcing HFCS in the United States and re-selling it in Mexico" (emphasis added) ("*Cargill* Award") [CLA-23].

> injury should be in consequence of the wrongful act, but without the addition of any particular qualifying phrase.[446]

Here, there is too great a distance between the Import Alert and Apotex Corp. to support a claim for damages under international law.

201. Apotex seeks to bridge the legal gulf by claiming that the Import Alert was "*specifically addressed*"[447] and "uniquely applied" to Apotex Corp., because of its "special relationship" to Apotex Inc.[448] These claims are baseless. The Import Alert was not addressed or applied to Apotex Corp. in any way.[449] The Import Alert was addressed to FDA field offices and applied, by its terms, to drugs manufactured at Apotex Inc.'s Etobicoke and Signet facilities.[450]

202. In support of its argument that the Import Alert "applied to" Apotex Corp., Apotex does not cite the Import Alert itself. Instead, Apotex cites a September 2, 2009 "Notice of FDA Action," a copy of which was sent to Apotex Corp. as the stated "owner or consignee" of the detained products.[451] This notice, Apotex claims, was the "contemporaneous" evidence of the Import Alert.[452] According to Apotex, "[t]he Import Alert concerning Apotex was not published

[446] International Law Commission, Draft Articles on Responsibility of States for Internationally Wrongful Acts, With Commentaries, art. 31 ¶ 10 (emphasis added and citations omitted) (2001) [RLA-285].

[447] Reply ¶ 128 (emphasis in original).

[448] *Id.* ¶¶ 17, 204.

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

[450] *Id.*

[451] Notice of FDA Action, Entry No. EG6-1768425-3, Notice No. 1, at 2 (Sept. 2, 2009) [R-44].

[452] Reply ¶ 127 ("The only contemporaneous official evidence of the adoption of the Import Alert consists of the FDA notices of action concerning specific transactions that the US interrupted in the days immediately following adoption of the Import Alert.") (internal citation omitted).

on FDA's website before September 30, 2009," and thus was not contemporaneous evidence of the Import Alert [453]

203. This statement is contradicted by Apotex's own witness testimony and evidence. Dr. Desai testified that he discovered the Import Alert on FDA's website on *September 2, 2009*:

> I remember that while on the phone with Health Canada [on September 2], I walked to my desk *to look up . . . the Import Alert on FDA's website*. I saw the Import Alert, *effective as from August 28, 2009*, for all products from Etobicoke and Signet.[454]

That same day, Dr. Desai sent an email stating that "there is an Import Alert *posted on the FDA website dated August 28th* for 'All Finished Dosage Forms' from both Signet and Etobicoke."[455] Earlier on September 2, two other Apotex employees (and affiants in this arbitration), Bernice Tao and Bruce Clark, exchanged emails indicating that they too had found the Import Alert on FDA's website.[456] The assertion, then, that "[t]he Import Alert concerning Apotex was not published on FDA's website before September 30, 2009" is demonstrably false.

204. The FDA notices of detention, therefore, are *not* the contemporaneous evidence of the Import Alert.[457] They are evidence that drug shipments from Etobicoke and Signet were being

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[453] *Id.* n.185.

[454] First Desai Statement ¶ 56 (emphasis added). *But see* Second Desai Statement ¶ 30 (stating that "Apotex never received a copy of the Import Alert, which to my knowledge was only posted on FDA's website on September 30, 2009").

[455] Email from J. Desai to J. Watson (Sept. 2, 2009) (emphasis added) [C-76].

[456] Email from B. Tao to B. Clark (Sept. 2, 2009) ("We just found [the Import Alert]. Apparently it was issued in August and is posted on the website.") [C-75]; *see also* Apotex Press Statement, "FDA Pharmaceutical Import Alert," at 1 (Sept. 8, 2009) ("The Import Alert *recently posted by FDA* applies to products manufactured at 2 of Apotex's many facilities.") (emphasis added) [R-160].

[457] Reply ¶ 127.

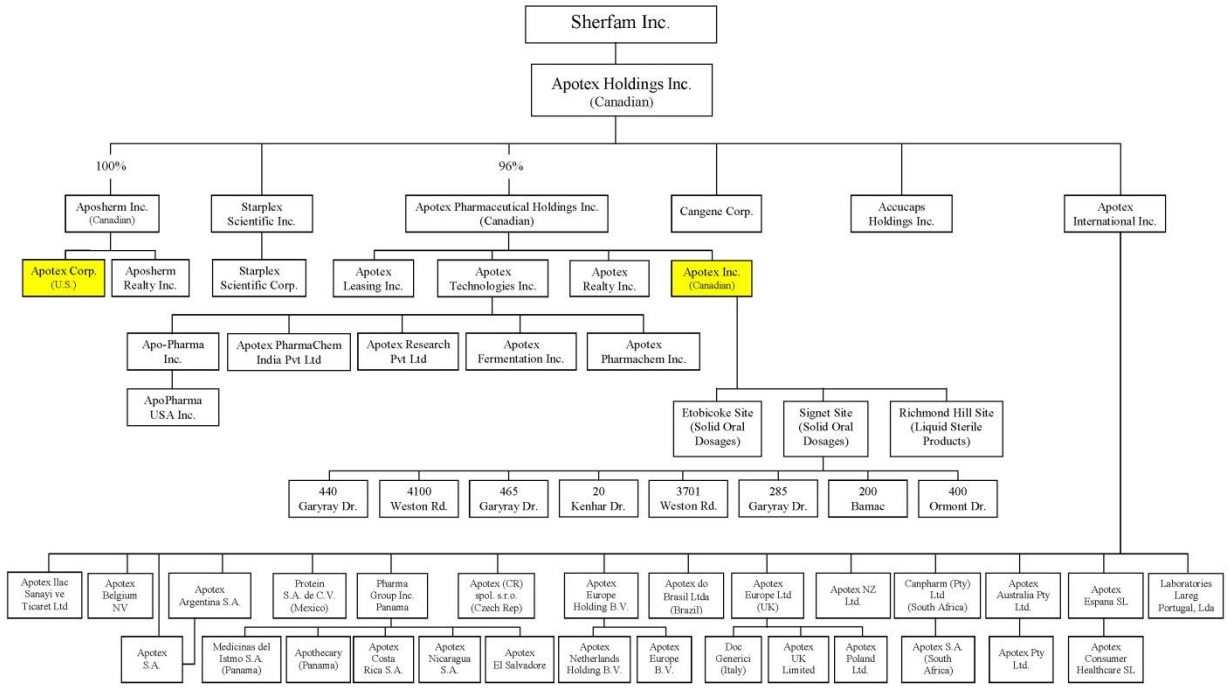
detained for the appearance of adulteration because of cGMP violations at those facilities.[458] Contrary to Apotex's argument, the "contemporaneous, official manifestation of the Import Alert" is not the detention notices, but the Import Alert itself, which nowhere mentions Apotex Corp.

205. Nor is there any validity to the claim that Apotex Corp. has a "special relationship" with Apotex Inc. such that an Import Alert issued for Apotex Inc. drugs applies, by extension, to Apotex Corp.[459] The Import Alert concerns products manufactured by Apotex Inc. Apotex Inc. does not own or control, directly or indirectly, the U.S. enterprise Apotex Corp.[460] Rather, Apotex Corp. is owned by Aposherm Inc., a Canadian company, which in turn is owned by Apotex Holdings, another Canadian company:

[458] *See, e.g.*, Notices of FDA Action (Sept. 28, 2009) (listing the appearance of adulteration as the basis for the refusals of admission) [C-108]; *see also infra* ¶ 280 (discussing detention without physical examination of shipments of drugs from Teva Pharmaceutical Inc.'s Jerusalem facility even though they were not listed on the Import Alert).

[459] Reply ¶ 204. 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." *Id.* ¶ 116 (citing *Pope & Talbot v. Government of Canada*, NAFTA/ UNCITRAL, Award in Relation to Preliminary Motion by Government of Canada ¶ 34 (Jan. 26, 2000) [CLA-447]). The United States has not advanced that argument, and nothing cited shows that it has.

[460] In *Cargill*, by contrast, the claimant's Mexican investment, Cargill de Mexico, was a wholly owned subsidiary of the U.S. investor, Cargill, Inc., and thus Apotex's reliance on that case is misplaced. *Cargill Award* ¶ 1 [CLA-23].



As this chart clearly illustrates,[461] Apotex Inc. and Apotex Corp. are elements of a large international conglomerate, but there is no relationship of direct ownership or control between the two entities.[462] As Apotex has repeatedly made clear when seeking to avoid jurisdiction in U.S. court, Apotex Inc. and Apotex Corp. are "entirely separate and independent . . . *tangential corporate relatives*."[463] Apotex has denied that "Apotex Corp. and Apotex Inc. are two arms of the same business group, operate in concert with each other, and enter into agreements with each

[461] Memorial ¶¶ 20-21.

[462] Apotex does not dispute the accuracy of this chart.

[463] *Shire LLC v. Apotex Inc., Apotex Corp. and Apotex Pharmaceutical Holdings Inc.*, No. 2:08-cv-265 (E.D. Tex.), Defendants Apotex Corp.'s and Apotex Pharmaceutical Holdings Inc.'s Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(1) and/or 12(b)(6), at 2, 13 n.7 (Aug. 6, 2008) ("Apotex Corp. and [Apotex Inc. parent Apotex Pharmaceutical Holdings Inc.] are purportedly *tangential* corporate relatives of Apotex Inc." and "Apotex Corp. is not a subsidiary of APHI, but rather is wholly owned by an *entirely separate and independent foreign entity*.") (emphasis added) [RLA-182]. In *Shire*, Apotex asked the court to "dismiss Apotex Corp. and [its parent] APHI as parties to this suit as a matter of law for *lack of subject matter jurisdiction and/or for failure to state a claim upon which relief can be granted*." *Id.* at 15 (emphasis added).

other that are nearer than arm[']s length."[464] Apotex has denied that "Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc."[465] Apotex has gone so far as to deny the existence of "*any facts* showing a corporate relationship between Apotex Corp. and Apotex Inc."[466] Apotex, moreover, has stressed that:

- "Apotex [Inc.] has no direct or indirect equity stake in Apotex [Corp.]"[467] and Apotex Corp. "has never borrowed any funds from Apotex [Inc.]";[468]
- Apotex Corp. "generates its own revenues"; "finances its operations independent of Apotex [Inc.]," including "by employing and paying its own sales team"; "manages its own financial plans, authorizes its own expenditures, [and] creates its own forecasts"; "commits to its own contracts"; "determines which customers will receive shipments"; "sells products from companies other than Apotex [Inc.]"; and "does not market every generic pharmaceutical product manufactured by Apotex Inc.";[469]
- "Apotex Corp. decides which of Apotex Inc.'s products it will market" and "generates its own revenue, with which it purchases the products it sells";[470] and
- Apotex Corp. "did not have *any substantive involvement*" in preparing Apotex's ANDAs,"[471] that it "merely serves as a conduit between Apotex Inc. and the FDA,"[472] and that it has, "at best, only *tertiary participation*" in the ANDA process.[473]

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[464] *Cephalon, Inc. and Cephalon France v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS, Motion to Dismiss Complaint by Apotex Inc. and Apotex Corp. or in the Alternative to Transfer ¶ 18 (Aug. 19, 2010) [RLA-236].

[465] When suing the United States in 2012, Apotex represented: "Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc." *See Apotex Inc. & Apotex Corp. v. U.S. Department of Health and Human Services*, No. 1:12-cv-01647 (D.D.C.), Complaint for Declaratory, Injunctive and Other Relief ¶ 6 (Oct. 3, 2012) [RLA-68]. But when seeking to avoid jurisdiction in U.S. court just seven months later, Apotex argued the opposite. Based on the sworn testimony of Apotex officials (including Ms. Tao), Apotex "denied" the allegation that "[o]n information and belief, Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc." *Pharmacia & Upjohn Co. et al. v. Apotex Inc. and Apotex Corp.*, No. 1:13-cv-02034 (N.D. Ill), Answer, Defenses and Counterclaims of Defendants Apotex Inc. and Apotex Corp. ¶ 9 (May 10, 2013) [RLA-251].

[466] *Id.* at 14-15 (emphasis added).

[467] Second Fahner Statement ¶ 71.

[468] *Id.* ¶ 78.

[469] Reply ¶ 191 (internal quotation marks omitted).

[470] *Cephalon, Inc. and Cephalon France v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS, Motion to Dismiss Complaint by Apotex Inc. and Apotex Corp. or in the Alternative to Transfer ¶ 6 (Oct. 18, 2010) [RLA-236]; *see also Cephalon, Inc. and Cephalon France v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS, Reply Brief in Support of Motion to Dismiss Complaint by Apotex Inc. and Apotex Corp. or in the Alternative to Transfer, at 3 (Nov. 15, 2010) [RLA-179].

206. Apotex argues the contrary in this arbitration, brushing off its inconsistent statements with the assertion that its business dealings reflect "how sophisticated companies operate throughout the world today."[474] But Apotex has failed to explain why even sophisticated companies should be permitted to argue, opportunistically, one set of "facts" when seeking to avoid jurisdiction in U.S. court and precisely the opposite when seeking to establish jurisdiction before an international tribunal in a case against the United States.

207. Apotex further contends that Apotex Corp. was "uniquely affected" by the Import Alert, because "Apotex [Corp.] was the *only* US company that imported drugs manufactured at Etobicoke and Signet for commercial sale in the United States."[475] But as the testimony of Apotex Inc.'s own witness makes clear, that statement is not true. Apotex Inc.'s vice-president of business operations and finance, Mr. Fahner, confirmed that Apotex Inc. sends products to *other US consignees* for commercial sale in the United States. Mr. Fahner has identified so-

[471] *In re: Rosuvastatin Calcium Patent Litigation*, No. 1:08-md-01949-JJF (D. Del.), Apotex Corp.'s Post-Trial Rebuttal Brief—Noninfringement, at 14 (Apr. 16, 2010) (emphasis added) [RLA-83].

[472] *In re: Rosuvastatin Calcium Patent Litigation*, No. 1:08-md-01949-JJF (D. Del.), Apotex Corp.'s Proposed Post-Trial Findings of Fact and Conclusions of Law—Noninfringement, at 6 (Apr. 16, 2010) [RLA-84]. Contrary to Apotex's suggestion, the *AstraZeneca/ Rosuvastatin Calcium Patent Litigation* is not the only case in which Apotex downplayed any role by Apotex Corp. in the ANDA process. In the *Pfizer* case, for instance, Apotex argued that Apotex Inc. "*prepared, filed and submitted* the ANDA that is the subject of this dispute," stressing that "[a]ll of this work was done in Canada" by Apotex Inc. *Pfizer Inc. et al. v. Apotex Inc. and Apotex Corp.*, No. 1:08-cv-00948 (LDD) (D. Del.), Declaration of Bernice Tao ¶ 18 (Feb. 10, 2009) (emphasis added) [RLA-92]; *id.* ¶ 25 ("None of the relevant work regarding Apotex Inc.'s ANDA product, the preparation of the ANDA, or the filing of the ANDA occurred or was otherwise performed in Delaware. All such work occurred in Canada."). In the *Cephalon* case, Apotex similarly argued that "Apotex Inc. prepared the ANDA in Canada." Apotex emphasized that "[a]ll of the research and development activities related to the ANDA were conducted in Canada, and the ANDA was submitted to the FDA in Maryland directly from Canada." *Cephalon, Inc. and Cephalon France v. Apotex Corp. and Apotex Inc.*, No. 1:10-cv-00695-GMS, Brief in Support of Motion to Dismiss Complaint by Apotex Inc. and Apotex Corp. or in the Alternative to Transfer ¶ 4 (Oct. 18, 2010) [RLA-236]. Apotex, in fact, stressed to the court that there was "no evidence that Apotex Corp. was involved in the preparation of the ANDA at issue in this suit or involved in any of the research or development activities related to the ANDA." *Id.* ¶ 7.

[473] *Astrazeneca Pharmaceuticals LP, et al. v. Apotex Inc. and Apotex Corp.*, No. 1:07-cv-00809-JJF (D. Del.), Apotex Corp.'s Brief in Support of its Motion to Dismiss, at 5 (Jan. 31, 2008) (emphasis added) [RLA-73a].

[474] Reply ¶ 177.

[475] *Id.* ¶ 147 (emphasis in original).

called "drop shipments" from Apotex Inc. directly to three U.S. distributors: [redacted], which Mr. Fahner identifies as "a pharmaceutical distributor" in the United States;[476] [redacted], one of the largest U.S. pharmaceutical distributors;[477] and [redacted], an Arizona-based distributor.[478] Each of these distributors imported drugs from Etobicoke or Signet for commercial sale in the United States. Apotex thus is not correct in stating that "Apotex [Corp.] was the *only* US company that imported drugs manufactured at Etobicoke and Signet for commercial sale in the United States."[479]

208. Apotex's own evidence shows that the impact the Import Alert had on Apotex Corp. was no different, legally, from that felt by any of the many other U.S. companies that sought to receive drugs from Apotex Inc.'s Etobicoke and Signet facilities for sale in the United States. As the *Methanex* tribunal concluded, no legally significant connection can be found in such circumstances.[480] Apotex has failed to establish that the sole challenged measure in this case – the Import Alert – relates to Apotex Inc. (or its ANDAs) or to Apotex Holdings (or its U.S. affiliate, Apotex Corp). Accordingly, the Tribunal should dismiss all of Apotex's claims for lack of jurisdiction.

III. APOTEX'S CLAIMS ALSO FAIL ON THE MERITS

209. Even if the Tribunal concludes that it has jurisdiction, Apotex has failed to prove its claims on the merits. Apotex has had an opportunity to submit three pleadings on the merits, to which it appended two lengthy expert reports and 13 witness statements containing nearly 200

[476] Second Fahner Statement ¶ 33.

[477] [redacted], "Who We Are" [R-238].

[478] Second Fahner Statement ¶¶ 33-35.

[479] Reply ¶ 147 (emphasis in original).

[480] *Methanex* First Partial Award ¶ 137 [CLA-36].

pages of testimony. Apotex also has had the opportunity to review thousands of pages of FDA documents, including internal agency emails, reports, charts, minutes, and memoranda. After all of this, Apotex is no closer to establishing a breach of NAFTA Chapter Eleven. To the contrary, Apotex has presented no evidence showing that the United States violated any obligation to accord Apotex and its alleged investments national treatment, most-favored-nation treatment, or the customary international law minimum standard of treatment.

A. Apotex Failed to Establish a National Treatment Claim (Article 1102) or a Most-Favored-Nation Treatment Claim (Article 1103)

210. Apotex wrongly asserts that the United States "failed to rebut" its claims under Articles 1102 and 1103.[481] It is for Apotex to prove its claims, and it has not done so.

211. Apotex has failed to establish any of the three elements of its national treatment and most-favored-nation treatment claims.[482] *First*, Apotex has failed to show that the challenged measure accorded Apotex any "treatment" in the United States. *Second*, Apotex has failed to show that Apotex and its alleged investments were in "like circumstances" with its alleged comparators. *Third*, Apotex has failed to show that FDA accorded Apotex and its alleged investments "less favorable" treatment than that accorded to any comparator in like circumstances. As the *UPS* tribunal confirmed, "[f]ailure by the investor to establish one of those three elements will be fatal to its case. This is a legal burden that rests squarely with the

[481] Reply ¶ 261.

[482] Article 1102 requires that each NAFTA Party accord to investors of another Party, and to their investments, "treatment no less favorable than that it accords, in like circumstances, to its own investors [or investments] with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments." NAFTA art. 1102(1)-(2) [CLA-1]. Article 1103 requires the same, except that the applicable comparison is to "investors [or investments] of any other Party or of a non-Party[.]" *Id.* art. 1103(1)-(2).

Claimant. That burden never shifts to the Party[.]"[483] Apotex's 1102 and 1103 claims thus comprehensively fail and they should be dismissed accordingly.

1. Apotex Failed to Demonstrate that the Import Alert Accorded "Treatment" to Apotex and Its Alleged Investments in the United States

212. Articles 1102 and 1103 require that each NAFTA Party accord to investors of another Party, and to their investments, "treatment" no less favorable than that accorded, in like circumstances, to other investors or investments "with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments."[484] Apotex erroneously claims that the sole challenged measure in this case, the Import Alert, accorded such treatment in two respects. First, Apotex alleges that the Import Alert "destroyed the economic value of [its] ANDAs."[485] By Apotex's own admission, however, this statement is not true. Apotex has acknowledged that its ANDAs remained approved during the period of the Import Alert, and could have been licensed or sold to another company or transferred to another Apotex or third-party facility.[486]

213. Second, Apotex alleges that the Import Alert accorded Apotex "treatment" "because the products authorized to be marketed by the ANDAs could not be marketed at all while the Import Alert remained in effect."[487] As discussed above, however, it was not the Import Alert that prevented Apotex from marketing drugs from Etobicoke and Signet in the United States.[488]

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[483] *UPS* Award ¶ 84 [CLA-51].

[484] NAFTA arts. 1102(1)-(2), 1103(1)-(2) [CLA-1].

[485] Reply ¶ 257.

[486] First Desai Statement ¶ 89.

[487] Reply ¶ 257.

[488] *See supra* ¶¶ 39-43.

Rather, the reason that Apotex Corp. (or any other company) could not market drugs from those facilities in the United States is that those drugs appeared to be adulterated for cGMP violations and, on that basis, were detained and ultimately refused admission.[489] Given that the Import Alert – FDA's internal, nonbinding guidance to its field offices – had no direct legal effect on Apotex's drugs, the measure cannot be said to have accorded any treatment with respect to Apotex Inc.'s ANDAs for those drugs.

214. The sole challenged measure in this case thus accorded Apotex's alleged investments – Apotex Inc.'s ANDAs and Apotex Corp. – no "treatment" for purposes of Articles 1102 and 1103. Accordingly, Apotex has not established the first element of its national treatment and most-favored-nation treatment claims, and its claims fail for that reason alone.[490]

2. Apotex Failed to Demonstrate that It Was in "Like Circumstances" With Its Alleged Comparators

215. For the second element, Articles 1102 and 1103 require that Apotex demonstrate that it is in "like circumstances" with its alleged comparators. As addressed below, Apotex's "like circumstances" analysis fails in two principal respects. First, Apotex has failed to establish that

[489] Vodra Report ¶ 89.

[490] As described in Part II(B) above, Apotex's contentions on the relationship between NAFTA Articles 1101 and 1102-1103 are circular. Apotex's criticism of the U.S. arguments in this regard is similarly confused. Apotex previously convinced the Tribunal that the proceedings could better proceed without bifurcation, because the United States' "relating to" objection concerned merits issues, arguing that this objection "is the first US defense under Articles 1102 and 1103[,]" "is no more than a national-treatment or MFN contention recast in the words of Article 1101 rather than those of Articles 1102 or 1103[,]" and is "fundamentally a merits question[.]" Claimants' Opposition to Bifurcation ¶ 106 (Dec. 28, 2012); *see also id.* ¶ 5 (stating that the "'relating to' argument . . . is merely a MFN argument on the element of 'less favorable treatment' packaged as a jurisdictional objection"); Claimants' Rejoinder on Bifurcation ¶ 18 (Jan. 16, 2013) (arguing that "the 'relating to' objection here is just a 'like circumstances' argument repackaged as a jurisdiction argument."). Now, Apotex asserts that the first U.S. defense under Articles 1102 and 1103 is actually "premised *entirely* on its misplaced [jurisdictional] objection that the Import Alert did not 'relate to' Apotex [Corp.] or to Apotex [Inc.'s] ANDAs." Reply ¶ 265 (emphasis added).

its *Canadian* manufacturing facilities were in "like circumstances" with *U.S.-based* manufacturing facilities, whether U.S.- or foreign-owned.

216. Second, Apotex recognizes (but then ignores) that the *circumstances* accompanying FDA's exercise of enforcement discretion may produce different results. Mr. Vodra has identified the inherent difficulties in comparing cGMP enforcement against different companies, because of the unique circumstances surrounding each enforcement decision.[491] Mr. Vodra explains that FDA's decision to take enforcement action – or to refrain from taking enforcement action – in any particular case "involves a complicated balancing of a number of factors . . . requir[ing] multiple judgments, which are made daily by experienced FDA professionals."[492] Given the variety of factors the FDA must weigh in making an enforcement decision, "[i]t would be an extraordinarily difficult – probably impossible – task to reduce the decision-making process to a mathematical formula or computer program."[493] Each enforcement decision depends on the circumstances of that particular case and, ultimately, the judgment of trained FDA professionals.[494]

217. To the extent that any comparison is possible in the enforcement context, Apotex focuses on the wrong comparators. Dozens of pharmaceutical companies have been placed on Import Alert 66-40 over the past five years. Many more have been subject to other forms of enforcement action. FDA has determined not to take enforcement action with respect to other companies. Apotex chooses to focus solely on the last category, arguing that the only

[491] Vodra Report ¶¶ 59-67.

[492] *Id.* ¶ 66 (citing *Heckler v. Chaney*, 470 U.S. 821, 831 (1985) [RLA-240]).

[493] *Id.* ¶ 67.

[494] *Id.*

comparators in like circumstances with Apotex were those that avoided enforcement action. These few comparators on which Apotex relies are not, in fact, in like circumstances with Apotex. Apotex, moreover, ignores or incorrectly attempts to distinguish the many other companies against which FDA did take enforcement action, many of which are better comparators for Apotex.[495] For the reasons discussed below, Apotex's "like circumstances" arguments are unavailing.

i. Apotex Failed to Establish that it Was in "Like Circumstances" With U.S.-Based Manufacturing Facilities, Whether U.S.- or Foreign-Owned

218. Apotex erroneously alleges that its *Canadian* manufacturing facilities are in "like circumstances" with U.S.- and foreign-owned manufacturing facilities *in the United States*. 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 unless they are exported and re-imported.[496]

219. This territorial distinction in U.S. law between drugs produced at facilities outside and inside the United States is a critical part of FDA's ability to protect U.S. consumers from violative products with limited resources. As Apotex acknowledges, FDA is not the primary regulator of drugs produced outside the United States.[497] FDA does not have the ability to

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[495] *See Methanex* Final Award, Part IV, Ch. B ¶ 19 (noting that the *Pope & Talbot* tribunal "selected the entities that were in the most 'like circumstances' and not comparators that were in less 'like circumstances' and recognizing that "[i]t would be a forced application of Article 1102 if a tribunal were to ignore the identical comparator and to try to lever in an, at best, approximate (and arguably inappropriate) comparator") [CLA-34].

[496] *See* Counter-Memorial ¶¶ 330-33. Section 801(a) of the FD&C Act is codified at 21 U.S.C. § 381(a) [CLA-240].

[497] *See* Memorial ¶ 5 (describing Health Canada as "the primary regulator for the two facilities in question," Etobicoke and Signet); Memorandum of Meeting Minutes (Sept. 11, 2009) (memorializing Apotex Inc. President Jack Kay's statement that Apotex "accept[s] 100% that it is the responsibility of Apotex to be compliant. It is not the FDA role to inspect Apotex into compliance[;] it is our responsibility") [C-394].

examine every import under its jurisdiction or closely monitor foreign pharmaceutical facilities seeking to export drugs into the United States.[498]

220. Nothing in NAFTA Chapter Eleven, moreover, prohibits such a territorial distinction, which is not based on the *nationality* of the trader, but on the *location* of its goods.[499] As described below, the result of this distinction is that different considerations – including a different standard for establishing adulteration – apply to drugs produced at domestic and foreign facilities, and comparisons between those facilities are inapt.[500]

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[498] Counter-Memorial ¶ 52; *accord* Vodra Report ¶ 46.

[499] All three NAFTA Parties, for example, have confirmed that a measure applying to only a particular location *within a Party's territory* (i.e. in its domestic territory) is not prohibited by Chapter Eleven, unless it discriminates on the basis of nationality of ownership of an investment. *See, e.g.*, Government of Canada Submission Respecting Post-Hearing Article 1128 Submissions Filed by the United Mexican States and the United States of America, *Pope & Talbot, Inc. v. Canada*, NAFTA/UNCITRAL ¶¶ 24, 27-28 (June 1, 2000) ("[A]s the NAFTA parties indicate, Article 1102 does not prevent the NAFTA Parties from implementing location-based measures to achieve regulatory objectives. Where location-based measures exist, NAFTA Article 1102 is not breached simply because an investment *within* the location is not accorded the same treatment accorded investors or investments *outside* the location.") [RLA-270]; Supplemental Submission of the United Mexican States, *Pope & Talbot, Inc. v. Canada*, NAFTA/UNCITRAL at 3, 6 (May 25, 2000) ("Mexico concurs in the view that Article 1102 does not prevent the NAFTA Parties from implementing location-based measures to achieve regulatory objectives.") [RLA-278]; Submission of the United States of America, *Pope & Talbot, Inc. v. Canada*, NAFTA/UNCITRAL ¶ 5 (Apr. 7, 2000) ("The national treatment obligation does not, as a general matter, prohibit a Party from adopting or maintaining measures that apply to or affect only a part of its national territory. Any suggestion to the contrary misconstrues the obligation to provide 'national treatment' – whose object and purpose are to prevent nationality-based discrimination – as an obligation to provide 'nationally uniform treatment.'") [RLA-277]; *see also* Counter-Memorial ¶ 323 n.799 (discussing the requirement of nationality-based discrimination); Government of Canada Rejoinder, *Bilcon et al. v. Government of Canada*, NAFTA/UNCITRAL ¶ 169 (Mar. 21, 2013) ("[I]n order to make out a claim under Articles 1102 and 1103, the Claimants must show that they suffered discriminatory treatment on the basis of their nationality.") [RLA-269]. Similarly, NAFTA Chapter Eleven does not prohibit a measure, such as Section 801(a) of the FD&C Act, that applies to all drugs produced by drug manufacturing facilities – whether U.S.- or foreign-owned – located *outside that Party's territory* (i.e. in foreign territory) and offered for import into the United States. Submission of the United States of America, *Pope & Talbot, Inc. v. Canada*, NAFTA/UNCITRAL ¶ 6 (Apr. 7, 2000) ("Nothing in Article 1102 constitutes a general prohibition against the adoption or maintenance of measures that apply differently to investments located or operating in different places, or of measures that apply differently to products depending on where they are grown or harvested. Such measures do not inherently discriminate on the basis of nationality.") [RLA-277]; *see also Canadian Cattlemen* Award on Jurisdiction ¶ 169 ("The fact that the NAFTA indisputably seeks to promote economic integration among industries in the three States Parties does not mean that the border has been eliminated for purposes of investor protection, no matter how similar or integrated the industries on each side of the border may be.") [CLA-47].

[500] Vodra Report ¶¶ 54, 58.

221. Apotex's Reply has offered new arguments in this regard. But these arguments compound the legal error in Apotex's claim, in three respects:

(1) Apotex now argues, erroneously, that FDA's Import Alert and related detention authority are *irrelevant* to the "like circumstances" analysis;[501]

(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";[502] and

(3) Apotex improperly foists onto the United States the burden of identifying appropriate comparators.[503]

These arguments are not only baseless, they also directly contradict Apotex's previous arguments.

a. The Import Alert Is a "Key Element" of the Like Circumstances Analysis

222. In its Memorial, Apotex acknowledged that "the measure at issue [the Import Alert] and the legal regime pursuant to which it was adopted is a *key element* of the 'like circumstances' analysis."[504] The U.S. Counter-Memorial similarly recognized the importance of the Import Alert (and the related legal regime) to Apotex's "like circumstances" analysis.[505] It pointed out, however, that products from facilities in the United States are never subject to import alerts or detentions without physical examination, and therefore U.S. facilities are not in "like circumstances" with foreign facilities such as Apotex's. Thus, this "key element" of Apotex's

[501] Reply ¶¶ 290, 300.

[502] *Id.* ¶ 283.

[503] *Id.* ¶ 281.

[504] Memorial ¶ 438 (emphasis added).

[505] Contrary to Apotex's assertion, the United States accepts that the Import Alert is a "key" consideration in the like circumstances analysis – and not the "only" relevant consideration. Reply ¶ 290. For this reason, Apotex's argument based on the *High Fructose Corn Syrup* cases is misplaced. *Id.* ¶ 299. That argument, moreover, ignores the fact that there are "more like" comparators supplied by facilities outside the United States that received a warning letter or were placed on import alert.

like circumstances analysis undermined Apotex's claim to be "like" U.S.-based manufacturing facilities.

223. Realizing its error, Apotex now argues in its Reply that the Import Alert is *irrelevant* to the like circumstances analysis and "must be considered under the heading of treatment rather than like circumstances."[506]

224. Apotex's new argument is incorrect. The Import Alert constitutes guidance from FDA headquarters to help FDA field offices exercise administrative authority to detain without physical examination, and refuse to admit, drugs that appear to be adulterated.[507] As discussed below, the Import Alert thus operates within a different legal regime than the regime governing products from domestic facilities. Accordingly, as Apotex correctly acknowledged, "the [Import Alert] and the legal regime pursuant to which it was adopted is a *key element* of the 'like circumstances' analysis."

b. Different Legal Regimes Govern Drugs Manufactured Inside and Outside the United States

225. Apotex has similarly reversed course on the legal regimes governing drugs made inside and outside the United States. Apotex's Memorial correctly stated that FDA is authorized to "refuse admission of regulated articles [into the United States] based on information, other than the results of examination of samples, such as information from facility inspections, that causes

[506] Reply ¶¶ 290, 300.

[507] Counter-Memorial ¶ 46; Vodra Report ¶¶ 86-91.

an article to *appear* to violate the [FD&C] Act."[508] Messrs. Bradshaw and Johnson highlighted the point in their first expert report:

> During the inspection of a foreign drug manufacturer, it is not necessary to obtain the same level of documentation expected from a domestic inspection to establish evidence of GMP violations or data integrity problems. The agency has the authority under the FD&C Act *to administratively restrict the importation of a product without demonstrating the adulteration of the product*. The burden of proof is placed on the importing party.[509]

226. Apotex and its experts thus acknowledged the different regimes governing facilities inside and outside the United States. This acknowledgement, the U.S. Counter-Memorial observed, demonstrated that Apotex's foreign manufacturing facilities were not in like circumstances with any U.S.-based facilities.[510]

227. Realizing its error, Apotex now argues that facilities outside and inside the United States are "subject to the *same* legal regime"[511] because FDA has "ultimate authority to halt US sales of drug products manufactured in violation of cGMPs."[512]

228. Apotex's new argument is incorrect.[513] As Apotex and its legal experts previously acknowledged, for facilities *outside* the United States (whether U.S.- or foreign-owned), FDA

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[508] *See* Memorial ¶ 107 n.108 (quoting FDA's *Regulatory Procedures Manual* [CLA-310]) (internal quotation marks omitted and emphasis altered).

[509] Expert Report of Sheldon T. Bradshaw, J.D. and Ron M. Johnson ¶ 63 (July 30, 2012) quoting FDA, *Guide to Inspections of Foreign Pharmaceutical Manufacturers* [CLA-297]) (emphasis added) ("First Bradshaw Report").

[510] *See* Counter-Memorial § III.A.2.

[511] Reply ¶ 283 (emphasis in original).

[512] Second Bradshaw Report ¶ 29.

[513] Similarly, Messrs. Bradshaw and Johnson's view that "US based manufacturing facilities are in like circumstances with Apotex because they are subject to the same cGMP regulations and the provisions and regulations under the FD&C Act" is also belied by their recognition that Section 801(a) of the FD&C Act does not apply to drugs supplied to U.S.-based distributors by U.S.-based manufacturing facilities. *Id.* ¶ 33; *see id.* ¶ 16 (noting that Section 801(a) is only "for imported drugs").

may *administratively* detain without physical examination, and refuse to admit into the United States, drugs that "appear" to be adulterated.[514] For facilities *inside* the United States (whether U.S. or foreign-owned), FDA was required[515] to *establish* adulteration through *judicial* action (*e.g.*, seizure, injunction) in order to bar drugs from the marketplace.[516] To quote Apotex's own Memorial: "While FDA has the authority to detain imports that appear adulterated, it lacks similar detention authority for domestically produced goods that appear adulterated."[517] Further, the consequences of such actions are different, in that a drug refused entry into the United States usually may be resold, while drugs manufactured in the United States generally may not be sold after seizure.[518]

229. Although Apotex's legal experts try to support Apotex's shift in position, they reiterate the point in their second expert report. Messrs. Bradshaw and Johnson acknowledge:

> FDA has authority to "refuse admission" to drug products manufactured outside of the United States and offered for import if "it appears from the examination of such samples or otherwise" that the drug is adulterated or misbranded.[519] By

[514] *See* FD&C Act § 801(a) [CLA-242]; *see also* Vodra Report ¶¶ 53-54.

[515] Under the FDA Safety and Innovation Act of 2012, FDA's authority to detain administratively devices and tobacco products that an FDA investigator has reason to believe are adulterated or misbranded was extended to drugs, subject to FDA's issuance of regulations no later than July 9, 2014. *See* Pub. L. No. 112-144 § 709 [CLA-244]. This new authority will allow FDA to detain drugs temporarily while determining whether to initiate judicial action. *See* Administrative Detention of Drugs Intended for Human or Animal Use, 78 FED. REG. 42382 (July 15, 2013) (stating that "FDA's administrative detention authority . . . is intended to protect the public by preventing distribution and subsequent use of drugs encountered during inspections that may be adulterated or misbranded, until FDA has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate.") [RLA-211a].

[516] Apotex recognizes elsewhere in its Reply that FDA does not have the ultimate authority to approve a consent decree or issue an injunction. *See* Reply ¶ 386 (noting that FDA and Ranbaxy's request for a consent decree for permanent injunction "had to be *reviewed and approved by an independent federal judge* following written and oral briefing") (emphasis added); *see also* Vodra Report ¶¶ 50, 56, 62.

[517] Memorial ¶ 119; *accord* Vodra Report ¶¶ 52-57; *see also* Reply ¶ 305 ("Import alerts can be applied only to *foreign* manufacturers that offer drugs for import into the United States") (emphasis in original).

[518] *See* 21 U.S.C. § 334(d) [CLA-231].

[519] Second Bradshaw Report ¶ 29 (citing FD&C Act, 21 U.S.C. § 381(a) [CLA-239]); First Bradshaw Report ¶¶ 88-104).

> definition, a drug is deemed adulterated if it is not manufactured in compliance with cGMPs.[520]

Apotex's experts then illustrate the critical distinction between FDA's own *administrative* authority to refuse to admit into the United States drugs that "appear" to be adulterated, and its obligation to *establish* adulteration through *judicial* action in order to bar drugs in the United States from the marketplace:

> FDA has similar authority to prevent adulterated drug products manufactured in the United States in violation of cGMPs from being sold in the United States. Specifically, FDA may *file a seizure action in federal district court* against a drug manufactured in violation of cGMP requirements.[521] . . . Alternatively, FDA has authority to *seek an injunction in federal district court* to stop a drug manufactured in violation of cGMP requirements from being sold.[522]

Apotex's experts thus highlight the critical dissimilarity between drugs manufactured inside and outside the United States, contradicting the claim that FDA alone has "ultimate authority to halt US sales of drug products manufactured in violation of cGMPs."[523] Messrs. Bradshaw and Johnson therefore confirm the *unlike* circumstances between the legal enforcement regimes governing U.S.-based manufacturers and foreign-based manufacturers, such as Apotex.[524] They

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[520] *Id.* (citing FD&C Act, 21 U.S.C. § 351 [CLA-233]; FDA Current Good Manufacturing Practice, 21 C.F.R. § 210.1(b) [CLA-252]).

[521] *Id.* (citing 21 U.S.C. § 334 [CLA-231]; First Bradshaw Report ¶¶ 77-80).

[522] *Id.* (citing 21 U.S.C. § 332 [CLA-228]; First Bradshaw Report ¶¶ 81-86).

[523] *Id*.

[524] Apotex acknowledged in its Memorial that one of the "common elements" of the "like circumstances" analysis is whether the alleged comparators "have invested in businesses that produce competing goods or services." Memorial ¶ 433. Here, Apotex has invested in businesses that *produce* (i.e., manufacture) competing goods *entirely outside the United States*. Unlike Apotex, all the U.S. and foreign comparators alleged by both Apotex and its legal experts – Baxter, Hospira, L. Perrigo, Novartis/Sandoz, and Teva – have invested in pharmaceutical manufacturing in the United States. And although Apotex cursorily asserts in its Reply (¶ 310 n.495) that Taro Pharmaceuticals was "another apt comparator" for Apotex's Article 1103 claim, Apotex's legal experts never mention Taro in either of their reports. Similarly, although Apotex's experts assert in their second report (¶ 26) that Jelfa Pharmaceutical is an apt comparator, Apotex's Memorial never mentions Jelfa, and its Reply merely observes that Jelfa was "identified" by Messrs. Bradshaw and Johnson. Reply ¶ 310 n.495. Although the United States highlighted the disagreements in its Counter-Memorial (¶ 334 n.821), Apotex declined to address them, let alone argue that Apotex was treated less favorably than Taro or Jelfa. *See* Memorial ¶ 451 (alleging less favorable treatment with respect to

nonetheless seek to downplay these differences, relying solely on the fact that U.S. and foreign facilities must adhere to the same level of manufacturing quality.

230. There are other relevant differences between domestic facilities and foreign facilities. Domestic facilities, for instance, are subject to unannounced FDA inspections,[525] whereas foreign facilities (such as Apotex's) usually receive advance notice.[526] Domestic facilities, moreover, must pay U.S. taxes, whereas foreign facilities (such as Apotex's) may not.[527] Apotex asks to be treated as if its manufacturing facilities were in the United States, but without assuming the same legal responsibilities.[528] As the *Apotex I-II* tribunal observed, "Apotex could, of course, have invested in U.S.-based manufacturing, development, or testing facilities, but opted instead to create and manufacture its generic pharmaceuticals in Canadian factories."[529]

"Baxter, Hospira, Novartis/Sandoz, Perrigo and Teva"); Reply ¶ 310 (acknowledging that "[w]ith respect to the comparators with drug manufacturing facilities outside the United States, Apotex selected *two* third-country-owned companies with such facilities" and listing Novartis/Sandoz and Teva Pharmaceutical) (emphasis added).

[525] Vodra Report ¶ 46. U.S.-based facilities may be inspected at any reasonable time. *See* Counter-Memorial ¶ 40 (citing 21 U.S.C. § 374 (2007-2011) [CLA-238]).

[526] Vodra Report ¶ 46. Given legal and logistical challenges, foreign facilities may receive several weeks, or even months, of advance notice. *See* Counter-Memorial ¶ 40 (citing FDA/ORA Field Management Directive No. 13A, at 1-2 (Mar. 2009) [R-39]). Apotex received advance notice of, and thus had the opportunity to prepare for, FDA's inspections of the Etobicoke and Signet facilities.

[527] Instead, Apotex Inc. avails itself of Ontario's comparatively low corporate tax rate. *See* Ontario, Canada: Competitive Business Costs (Aug. 7, 2013) (stating that Ontario's 26.5% combined corporate income tax rate is "lower than the average of G8 and G20 countries and lower than the average federal-state CIT rate in the United States [of 39.3%]") [R-229].

[528] *See UPS v. Canada*, NAFTA/UNCITRAL, Award ¶¶ 180-81 (June 11, 2007) ("*UPS* Award") (stating that "[e]xtending 'no less favourable' treatment to UPS Canada, in like circumstances, would require that the Heritage Department offer it the same arrangement as is offered to Canada Post; which would entail, among other things, the assumption by UPS Canada of the same responsibilities as those assumed by Canada Post under such an arrangement. However, that is manifestly not what UPS seeks"; concluding that "UPS Canada is not 'in like circumstances' to Canada Post . . . and, indeed, for essentially the same reasons, is not accorded less favorable treatment than Canada Post or treated differently because of nationality") [CLA-51].

[529] *Apotex I-II* Award ¶ 175 [RLA-263]. Notably, Apotex opted to close Apotex Corp.'s "facility manufacturing injectable products in Chicago" in 2004. *See* First Desai Statement ¶ 16 ("Apotex [Corp.] at one point operated a facility manufacturing injectable products in Chicago. This facility closed in 2004.").

This Tribunal similarly should reject Apotex's attempt to masquerade as a U.S.-based manufacturer.

c. Apotex Failed to Identify Appropriate U.S. Comparators

231. Although Apotex has the burden to establish appropriate U.S. comparators for its Article 1102 claim, it asserts that its experts could not find any "US investor or investment supplied by facilities outside the United States [that] received a warning letter or w[ere] placed on import alert[.]"[530] Apotex thus seeks to foist onto the United States the burden of identifying such comparators,[531] and it invites the Tribunal "to consider less 'like' comparators."[532]

232. Apotex's request is improper. Although it is not the United States' burden to identify comparators for Apotex, there is no reason for the Tribunal to consider "less like" (i.e., unlike) comparators. Apotex's own submissions highlight a U.S.-owned company, Pfizer, that meets Apotex's "like circumstances" criteria.[533] Like Apotex:

- Pfizer is a global pharmaceutical company that exports its drugs internationally;[534]
- Pfizer has U.S. subsidiaries that distribute and market Pfizer and third-party products in the United States;[535]
- Pfizer has ANDAs and authorized generics under NDAs;[536]
- Pfizer "competes with Apotex on the US pharmaceutical market";[537] and

[530] Reply ¶ 280 (citing First Bradshaw Report ¶ 111).

[531] *Id.* ¶ 281.

[532] *Id.* ¶¶ 280-81.

[533] *See, e.g.*, Memorial ¶¶ 315 n.467, 322 n.481; Reply ¶¶ 147 n.215, 199-200 (identifying Pfizer).

[534] *See generally* Pfizer Inc., Annual Report (Form 10-K) (Feb. 28, 2013) [R-218].

[535] Reply ¶ 270; Pfizer Inc., Annual Report (Form 10-K) at 18 (Feb. 28, 2013) ("In the U.S., Pfizer's Greenstone subsidiary and Pfizer Injectables sell generic versions of Pfizer's, as well as certain competitors', solid oral dose and sterile injectable pharmaceutical products, respectively[.]") [R-218].

[536] Reply ¶ 270; Greenstone, About Us [R-237].

- Pfizer's U.S. distribution subsidiaries are (to borrow Apotex's test) "supplied by facilities outside the United States [that] received a warning letter or w[ere] placed on import alert[.]"[538]

233. Pfizer is but one example of a U.S.-owned company that meets Apotex's test of a U.S. entity supplied by foreign facilities that received warning letters or were placed on Import Alert 66-40.[539] These companies and facilities are more appropriate comparators than the ones alleged by Apotex, which are supplied by *U.S.-based manufacturing facilities* and thus are not in like legal circumstances.[540]

234. Because Apotex is not in like circumstances with the comparators it alleges (companies supplied by *U.S.-based* manufacturing facilities), Apotex's Articles 1102 and 1103 claims concerning U.S.- and foreign-owned *domestic* manufacturing facilities should be rejected.

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[537] Reply ¶ 271; *see also* Memorial ¶ 447 (citing top 25 sellers of generic pharmaceutical products in the United States, including Pfizer's Greenestone [C-181]; [C-182]; [C-239]; and [C-305]).

[538] Reply ¶ 280. In particular, Pfizer's U.S. subsidiaries are supplied by Wyeth Lederle, S.p.A., a Pfizer subsidiary that received a warning letter for cGMP violations at its Catania, Italy manufacturing facility (*see* FDA Warning Letter to Wyeth Lederle S.p.A. (Mar. 27, 2013) [R-220]; Pfizer Catania, Chi Siamo, Stabilimento di Catania (including translation by counsel of Pfizer Catania, "About Us, Catania Facility") [R-243]); Aurobindo Pharma, a Pfizer licensing and supply partner that received a warning letter for cGMP violations at its Hyderabad, India manufacturing facility and was placed on Import Alert 66-40 from 2011-13 (*see* Pfizer Expands Portfolio of Generic Medicines in the U.S. and Europe Through Licensing Agreements with Aurobindo (Mar. 2, 2009) [R-143]; FDA Warning Letter to Aurobindo Pharma Limited (May 20, 2011) [R-197]; FDA Import Alert #66-40 (as of Nov. 9, 2011) [R-202]); and Claris Lifesciences, a Pfizer licensing and supply partner that was placed on Import Alert 66-40 from 2010-12 even *before* it was inspected and received a warning letter for cGMP violations regarding a manufacturing facility in Ahmedabad, India (*see* Pfizer Expands Its Generics Portfolio Through Innovative Licensing Deals, Increasing Access to Medicines for Billions Worldwide (May 19, 2009) [R-147]; FDA Warning Letter to Claris Lifesciences Limited (Nov. 1, 2010) [R-190]; FDA Import Alert #66-40 (as of Nov. 9, 2011) [R-202]).

[539] Contrary to Apotex's suggestion, U.S.-owned *foreign* manufacturing facilities also have been added to Import Alert 66-40. For example, a Vadodara, India manufacturing facility of Asence Pharma Private Limited, a subsidiary of the U.S. company Asence Inc. USA was placed on Import Alert in 2011. *See* FDA Import Alert #66-40 (as of Nov. 9, 2011) (listing Asence Pharma Private Limited) [R-202]; *see also* About Asence (noting that Asence Pharma Private Limited is a subsidiary of Asence Inc. USA, a U.S. company) [R-241].

[540] *See Methanex* Final Award, Part IV, Ch. B ¶ 17 ("Given the object of Article 1102 and the flexibility which the provision provides in its adoption of 'like circumstances', it would be as perverse to ignore identical comparators if they were available and to use comparators that were less 'like'[.]") [CLA-34].

ii. Apotex Ignores the Factors that FDA Considers When Taking Enforcement Action and Seeks to Strip FDA of Enforcement Discretion

235. To support its shift in position, Apotex has made two key concessions regarding the "like circumstances" analysis. First, Apotex acknowledges that the "term 'circumstances' denotes conditions or facts that *accompany* an action."[541] Second, Apotex acknowledges that its alleged comparators "can be treated differently if circumstances warrant."[542] Despite these concessions, however, Apotex ignores the conditions or facts accompanying FDA's exercise of enforcement discretion, and ignores the circumstances that may compel non-enforcement in matters of public health. Apotex thus does not meet its burden of demonstrating "like circumstances" – taking into account all of the relevant circumstances – with its alleged comparators.

236. Significantly, Apotex does not dispute FDA's authority to have put Apotex's Etobicoke and Signet facilities on Import Alert or to have detained Apotex drugs. Apotex accepts that, long before it made its alleged investments in the United States, U.S. law authorized FDA to refuse to admit into the United States drugs that appeared to be adulterated for cGMP violations.

237. Nor does Apotex challenge FDA's cGMP determinations for Etobicoke and Signet. Apotex now stresses, in fact, that "[t]he substance of FDA's cGMP findings is not at issue" in this arbitration.[543] Thus, under U.S. law, FDA could prevent the importation of Apotex's drugs under the "appearance of adulteration" standard.

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[541] Reply ¶ 294 (quoting *ADM* Award ¶ 197 ("The ordinary meaning of the word "circumstances" under Article 1102 requires an examination of the surrounding situation in its entirety.") (emphasis in original) [CLA-20]).

[542] *Id.* ¶ 301 (quoting NAFTA Implementation Act, Statement of Administrative Action, H.R. Doc. No. 103-159, Vol. 1, 103d Cong., 1st Sess. at 140-41 [CLA-2]).

[543] *Id.* ¶ 7.

238. Instead, Apotex contends that the United States violated Articles 1102 and 1103 by declining to put *other companies* with cGMP violations on Import Alert.[544] Apotex considers two main factors in its "like circumstances" analysis: whether the comparator is a generic manufacturer, and whether the comparator received a warning letter.[545] Apotex argues, in effect, that once FDA issues a warning letter to another company, it must take the same enforcement action that it took against Apotex, regardless of differing circumstances weighing for or against such action.

239. Apotex's proposal is flawed in at least five respects. *First*, it is inimical to public health. If accepted, Apotex's proposal would require FDA either to refuse or to admit all drugs from facilities whose cGMP violations justify a warning letter,[546] thereby stripping FDA of the enforcement discretion that is at the heart of its public health mandate.

240. *Second*, it finds no support in law. The exercise of enforcement discretion with respect to companies other than a claimant does not amount to a violation of Chapter Eleven's non-

[544] *Id.*

[545] *Id.* ¶¶ 271-272.

[546] Vodra Report ¶ 60.

discrimination provisions,[547] which are intended to prevent discrimination on the basis of nationality.[548]

241. *Third*, Apotex impermissibly invites the Tribunal to step into FDA's shoes and make factual findings that an international tribunal is not qualified to make. The U.S. Counter-Memorial identified the complex risk-based approach FDA uses when making enforcement decisions. Although Apotex professes ignorance of FDA's "alleged 'risk-based approach,'" Apotex's own legal experts highlight the "factors that FDA considers when determining whether to bring an enforcement action."[549] When comparing Apotex to Teva, for instance, Messrs. Bradshaw and Johnson invite the Tribunal to consider:

- "how Apotex's cGMP violations were more serious than Teva's";
- "how the risk to consumers as a result of Apotex's cGMP violations was greater than the risk to consumers as a result of Teva's";
- "how Teva's response to the violations was superior to that of Apotex's"; and
- "whether any of the products implicated were medically necessary or in short supply."[550]

[547] *See International Thunderbird Gaming Corp. v. United Mexican States*, NAFTA/UNCITRAL, Award ¶ 183 (Jan. 26, 2006) ("Even if Thunderbird had established without doubt that Mexico's line of conduct with respect to gambling operations was not uniform and consistent, one cannot overlook the fact that gambling is illegal in Mexico. In the Tribunal's view, it would be inappropriate for a NAFTA tribunal to allow a party to rely on Article 1102 of the NAFTA to vindicate equality of non-enforcement within the sphere of an activity that a Contracting Party deems illicit.") ("*Thunderbird* Award") [CLA-30]. Apotex seeks to distinguish *Thunderbird* in two ways, but fails. *See* Reply ¶ 388. First, in asserting that the Mexican authorities enforced the gambling law indiscriminately, whereas FDA failed to take enforcement action against its alleged comparators, Apotex once again ignores the circumstances accompanying FDA's exercise of enforcement discretion. *Id.* Second, in emphasizing that gambling is unlawful in Mexico, Apotex ignores that it is unlawful to introduce into U.S. commerce drugs that are adulterated or misbranded. *See* Counter-Memorial ¶ 37 (quoting 21 U.S.C. § 331(a) (2012) [CLA-226]).

[548] *See supra* ¶ 220 n.499.

[549] Second Bradshaw Report ¶ 48.

[550] *Id.* ¶¶ 47-48.

242. These are among the circumstances that a specialized regulatory agency such as FDA may consider before taking enforcement action against regulated entities, and it is not appropriate for an international tribunal to step into the agency's shoes and second-guess its expert factual determinations.[551] This tribunal is not equipped with the scientific and technical expertise, and has no mandate, to assess the relative seriousness of each company's cGMP violations, the potential risk to consumers, the appropriateness of each company's response, and the medical necessity or potential shortage of drugs from each facility.[552] International tribunals must refrain from acting as "science courts and from frustrating democratically adopted preferences of risk in matters of fundamental importance such as public health."[553]

243. *Fourth*, Apotex fails to consider critical elements of FDA's risk-based approach. Apotex ignores, for instance, FDA's occasional decision to refrain from enforcement action in appropriate circumstances, including to avoid cutting off supplies of medically necessary drugs. Apotex itself relies on a July 2012 letter in which members of U.S. Congress urged FDA to ensure continued production of medically necessary drugs[554] – particularly sterile, injectable

[551] *See* Counter-Memorial ¶¶ 356-359.

[552] As the *Thunderbird* tribunal recognized, the proper scope of a Chapter Eleven tribunal's mandate is more limited. *See Thunderbird* Award ¶ 127 ("The role of Chapter Eleven in this case is therefore to measure the conduct of Mexico towards Thunderbird against the international law standards set up by Chapter Eleven of the NAFTA. Mexico has in this context a wide regulatory 'space' for regulation; in the regulation of the gambling industry, governments have a particularly wide scope of regulation reflecting national views on public morals. Mexico can permit or prohibit any forms of gambling as far as the NAFTA is concerned. It can change its regulatory policy and it has wide discretion with respect to how it carries out such policies by regulation and administrative conduct.") [CLA-30].

[553] Marcos Orellana, *Science, Risk and Uncertainty: Public Health Measures and Investment Disciplines*, in NEW ASPECTS OF INTERNATIONAL INVESTMENT LAW 671 (Phillippe Kahn & Thomas Wälde eds., 2007) [RLA-287].

[554] *See* letter from J. Ireland to Hon. E. Cummings at 1-2 (July 23, 2012) [C-452]; Reply ¶¶ 314 n.502, ¶ 320 n.509 (citing FDA letter regarding Sandoz Canada); *id.* ¶ 358 n.567 (regarding Hospira); *id.* ¶ 370 n.591 and *id.* ¶ 372 n.596 (regarding Teva Parenteral). Significantly, the FDA letter discusses the following facilities, three of which Apotex's legal experts propose as comparators: (1) Teva Parenteral's Irvine, California injectable facility; (2) Ben Venue Laboratories' Bedford, Ohio injectable facility; (3) Hospira's injectable facilities; and (4) Sandoz Canada's

drugs – despite ongoing cGMP problems at the facilities making those drugs.[555] In order to ensure that consumers have a steady supply of potentially life-saving drugs, FDA considers possible drug shortages when taking enforcement action against drug manufacturers.

244. Although both parties recognize that Ben Venue is not an apt comparator,[556] the example underscores the importance of FDA's enforcement discretion in the drug-shortage context. Apotex argues that, because FDA took enforcement action against Ben Venue's Bedford, Ohio facility in January 2013[557] – more than a year after Canada and the EU banned the firm's products – FDA is "applying its discretion in an arbitrary manner" and "turn[ing] a blind eye towards a situation that has already been acknowledged as warranting an enforcement action by other first-tier regulators."[558] It is Apotex, however, that turns a blind eye to the circumstances that FDA considered when it applied its risk-based approach to Ben Venue. Apotex ignores that:

injectable facility (as well as Sandoz Inc.'s Lincoln, Nebraska over-the-counter and animal health medicine facility which is discussed in note 624 below). Letter from J. Ireland to Hon. E. Cummings at 4-5 (July 23, 2012) [C-452].

[555] *See* letter from J. Ireland to Hon. E. Cummings at 1-2 (July 23, 2012) [C-452]; Jonathan D. Rockoff, *Drug Makers' Rising Interest in Injectables Could Ease Shortages*, WALL ST. J. (Mar. 26, 2013) ("[T]he number of sterile injectables experiencing shortages jumped to 183 in 2011, from 23 five years earlier.") [R-219]. Injectable drugs remain predominate on the drug shortages lists maintained on FDA's website. *See* Compilation of Current Drug Shortages [R-232]. Apotex's legal experts fail to acknowledge that injectable drugs require additional sterile manufacturing considerations and present unique challenges over pills and tablets. *See*, *e.g.*, Liz Szabo, *Drug shortages set to reach record levels*, USA TODAY (Aug. 15, 2011) ("Most hard-to-find medications are liquid, injectable drugs that need to be kept sterile according to the FDA. These drugs are more complicated to manufacture, store and ship than pills or tablets, FDA spokeswoman Shelly Burgess says.") [R-200]; *see also* FDA Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice (Sept. 2005) [R-139].

[556] For the United States, Ben Venue, a subsidiary of Boehringer Ingelheim, a German company, is not an appropriate comparator because Ben Venue's manufacturing facility is in the United States (Bedford, Ohio), and thus is subject to a different legal regime than Apotex's foreign manufacturing facilities. For Apotex, it is because Ben Venue "is a contract manufacturer and owns only a few ANDAs." Second Bradshaw Report ¶ 57.

[557] *See United States v. Ben Venue Laboratories et al.*, No. 1:13-cv-00154-LW (N.D. Ohio), Consent Decree of Personal Injunction (Jan. 22, 2013) [RLA-256].

[558] Second Bradshaw Report ¶ 58.

- Ben Venue *voluntarily shut down its facility in November 2011*, even though FDA had been monitoring its production of drugs in critically short supply, such as an injectable chemotherapy drug;[559]

- Ben Venue's voluntary shutdown led to a "dire" shortage, in February 2012, of an injectable drug used to treat childhood leukemia and rheumatoid arthritis;[560] and

- Health Canada's own August 2011 import advisory on Ben Venue made an exception for drugs "deemed medically necessary" to Canadian consumers.[561]

FDA thus took appropriate enforcement action against Ben Venue. FDA carefully balanced potential risks for U.S. consumers against other public health considerations, in light of all relevant circumstances. Health Canada acted similarly as regards Apotex in 2009, weighing the need to enforce Canadian cGMP regulations with the need to avoid a national drug shortage.

245. *Fifth*, Apotex ignores the importance of a firm's voluntary action (including production shutdowns) in response to cGMP violations. Apotex's legal experts state that they are unaware of "FDA ever taking the position that a manufacturer of an FDA-regulated product may avoid being placed on an import alert by voluntarily ceasing all operations[.]"[562] It is not FDA's

[559] *See* FDA News Release: Ben Venue Laboratories – Voluntary Shutdown (Nov. 30, 2011) [C-439].

[560] Gardiner Harris, *Supply of a Cancer Drug May Run Out Within Weeks*, NEW YORK TIMES (Feb. 10, 2012) [R-203].

[561] *See* Counter-Memorial ¶ 52 n.86; Health Canada, Notice to Hospitals, *Health Canada Important Safety Information on Certain Drug Products Imported into Canada from Ben Venue Laboratories* (Aug. 17, 2011) ("A recent assessment by Health Canada has identified deficiencies in the area of Good Manufacturing Practices (GMP) at the [Ben Venue Laboratories (BVL) Bedford, Ohio] manufacturing site. In light of these deficiencies, Health Canada is allowing only the importation of drugs deemed medically necessary[.]") [R-79].

[562] Second Bradshaw Report ¶ 42. Instead, Messrs. Bradshaw and Johnson cite two consent decrees agreed to by U.S.-based companies whose drugs from U.S.-based manufacturing facilities are not subject to Section 801(a) of the FD&C Act and thus are not eligible for addition to an import alert. *Id.* (citing Ben Venue (Bedford, Ohio facility) and Hill Dermaceuticals (Sanford, Florida facility)). They fail to mention, however, that the consent decrees not only prohibit those companies from introducing adulterated drugs into interstate commerce but also establish a series of steps which must occur before they can fully resume operations. *See* FDA News Release: FDA Enters Consent Decree of Permanent Injunction Against Florida Drug Companies (Sept. 28, 2011) (noting that the consent decree "include[s] provisions to prevent Hill [Dermaceuticals] from introducing adulterated drugs into interstate commerce . . . to ensure the authenticity of data submitted to [FDA,]" and to "verify the adequacy of Hill's corrective actions" [C-436]; FDA News Release, *Federal Judge Approves Consent Decree with Ben Venue Laboratories* (Jan. 31,

policy, however, to waste scarce resources preventing the importation of drugs *after* a firm has voluntarily ceased production.[563]

246. Apotex itself, moreover, has acknowledged the importance of voluntary action in the enforcement context. Dr. Desai testified, for instance, that Apotex had "concluded that a voluntary recall of products with which FDA had a concern over [*sic*] *would alleviate a need for any enforcement action*."[564] Apotex, however, refused to suspend shipments from Etobicoke and Signet, and Apotex's recall was too limited.[565] Teva Pharmaceutical's response to cGMP violations at its Jerusalem facility, by contrast, was swift and comprehensive.[566]

2013) (noting that (1) under the consent decree, "Ben Venue has agreed to adhere to a strict timetable to bring the facility under compliance with regulatory requirements, or face substantial fines and other consequences," and "FDA may order Ben Venue to stop manufacturing, recall products, and take other corrective action as necessary to ensure that patients receive safe and effective drugs" and (2) "FDA is working with Ben Venue during the company's remediation to prioritize and ensure the availability of the company's medically necessary drugs") [R-214]. In citing to this portion of the Second Expert Report, Apotex notes in its Reply that the Gloversville, New York facility of Ohm Laboratories, a Ranbaxy subsidiary in the United States, "shut down operations prior to the Ranbaxy consent decree . . . yet this facility was still included in the consent decree." Reply ¶ 321 n.512. Apotex fails to mention, in this instance as well, that the consent decree not only prohibits Ranbaxy and its subsidiary from introducing adulterated drugs into interstate commerce but also establishes a series of steps which must occur before they fully can resume operations. *See* FDA News Release, *Department of Justice Files Consent Decree of Permanent Injunction Against Ranbaxy* (Jan. 25, 2012) [R-87].

[563] Vodra Report ¶¶ 64, 76.

[564] First Desai Statement ¶ 49 (emphasis added); *id.* ¶ 48 ("In order to prove our commitment to placing only the highest quality products in the U.S. market, Mr. Lovelock and I decided to voluntary recall the batches associated with these black particles."); *see also* Expert Report of Howard N. Rosen ¶ 4.44 (July 30, 2012) (stating that, in describing Apotex's claim seeking the costs of its voluntary recalls, "[o]ne recall began in August 2009 as a precautionary measure which Apotex believed would alleviate any need for an enforcement action by the FDA") ("Rosen Report"); Memorial ¶¶ 172-73 (Apotex "committed to voluntary recall batches of drug products manufactured at both Etobicoke and Signet and distributed in the US market," but the recall "did not produce the expected results").

[565] *See* Vodra Report ¶ 75; *see also* Memorial ¶ 173 (noting FDA's concerns about Apotex's "rationale and decision to only recall 675 batches and not address all products on the US market"); First Desai Statement ¶ 48 ("[W]e told FDA on the call that we would do a recall. Mr. Friedman asked whether this would be enough and whether Apotex felt that it should cease distribution in the US. I explained that we believed the recall was more than sufficient and that we did not need to stop distribution in the US."). Similarly, Apotex errs in reading FDA's decision not to "request Apotex to recall any product already shipped to [Apotex Corp.'s] Indianapolis warehouse" as signaling "FDA's lack of concern with Apotex's products." Reply ¶ 46 (citing FDA Internal Email (Oct. 22, 2009) [C-400]). The very email that Apotex cites for this point makes clear that the need for regulatory action was obviated by Apotex's indication that it had "suspended distribution from its US warehouse of Etobicoke and Signet products." *See* FDA Internal Email (Oct. 22, 2009) [C-400]; *see also* Rosen Report ¶ 4.40 (stating that, in describing Apotex's claims seeking the costs of inventory write-offs, "some products that had been placed in the Indianapolis warehouse

247. Health Canada similarly considers voluntary actions. In response to Health Canada's October 2009 observation that Apotex was commingling toxic and nontoxic material at Signet, Apotex immediately committed to cease manufacturing any cytotoxic products at Signet.[567] As a result, Health Canada was able to record this observation in the second-highest, rather than the highest, risk category, which would have resulted in a "non-compliant" rating, potentially costing Apotex its establishment license.[568]

248. In sum, FDA's risk-based approach affords the agency discretion to apply the appropriate regulatory tools in light of all relevant circumstances.[569] The "circumstances" accompanying FDA's exercise of enforcement discretion, for example, would not be "like" where a facility had voluntarily shut down, slowed production or committed not to export, and another had not; or where a facility was producing medically necessary drugs, and another was not. It is, moreover, precisely this discretion that led FDA to place Apotex's Etobicoke and Signet facilities on Import Alert for cGMP violations in August 2009, while declining to place Apotex's Richmond Hill facility on Import Alert for cGMP violations in 2010.[570] Despite its concessions on the "like circumstances" analysis, Apotex largely ignores the circumstances accompanying FDA's exercise of enforcement discretion, such as consideration of drug shortages, and thus has not

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could not be distributed based on Apotex's decision to voluntarily stop distribution as a proactive way to address the FDA's concerns").

[566] *See* Supplemental Rosa Statement ¶ 31.

[567] *See* Counter-Memorial ¶ 118 (citing Health Canada, Inspection Exit Notice for Signet (Oct. 14, 2009) [C-112]; letter from C. Austin, Associate Director, Compliance, Apotex, to A. Lostracco, Health Products and Food Branch Inspectorate, Health Canada, at 1 (Nov. 17, 2009) ("Apotex further commits that no cytotoxic products will be manufactured at the 150 Signet Road Facility.") [C-119]).

[568] *See* Counter-Memorial ¶ 118 (citing Health Canada, Inspection Exit Notice for Signet (Oct. 14, 2009) [C-112]).

[569] Vodra Report ¶¶ 62-67.

[570] *See infra* n.647.

even attempted to meet its burden to establish that it was in like circumstances with its alleged comparators.[571]

3. Apotex Failed to Show that Its Alleged Investments Were Accorded Less Favorable Treatment

249. Apotex has failed to demonstrate that the United States accorded Apotex or its investments "less favorable" treatment than the United States accorded any U.S.- or foreign-owned comparator in like circumstances. As such, Apotex has failed to establish the third element of its national treatment and most-favored-nation treatment claims, and its claims fail for that additional reason.

i. FDA Did Not Accord Less Favorable Treatment to Apotex than to Comparators in Like Circumstances

250. Although Apotex has failed to allege any comparators that were in "like circumstances" for purposes of its national treatment and most-favored-nation treatment claims, there are arguably two companies in more like circumstances: Pfizer (for Article 1102), and Ranbaxy (for Article 1103). The evidence shows that FDA did not accord Apotex less favorable treatment than it accorded either comparator.

a. FDA Did Not Accord Less Favorable Treatment to Apotex than to Pfizer (Article 1102)

251. FDA did not accord less favorable treatment to Apotex than the agency accorded to Pfizer, a U.S.-owned company arguably in most like circumstances with Apotex for purposes of

[571] *See S.D. Myers v. Government of Canada*, NAFTA/UNCITRAL, First Partial Award ¶ 250 (Nov. 13, 2000) ("The assessment of 'like circumstances' must also take into account circumstances that would justify governmental regulations that treat them differently in order to protect the public interest.") [CLA-43]. The United States considers each of the comparators' particular circumstances accompanying FDA's exercise of enforcement discretion together with Apotex's allegation of "less favorable" treatment below, so that "the full factual context" can "be taken into account[.]" *See* Reply ¶ 342.

its Article 1102 claims (to the extent such a comparison is possible). Just as foreign facilities supplying Apotex Corp. were placed on Import Alert 66-40, foreign facilities supplying Pfizer's U.S. distribution enterprises were placed on that Import Alert.[572] Drugs supplied to Pfizer, for instance, from Aurobindo Pharma's Hyderabad manufacturing facility were placed on Import Alert. FDA's inspection of the Hyderabad facility ended on December 22, 2010, and drugs from that facility were added to the Import Alert less than two months later, on February 7, 2011.[573] FDA did not issue a warning letter for cGMP violations at that facility until May 20, 2011.[574] By comparison, the Import Alert with respect to Apotex's Etobicoke and Signet facilities "became effective two months *after* the first warning letter issued to the firm."[575]

252. As a second example, drugs supplied to Pfizer from Claris Lifesciences' Ahmedabad manufacturing facility similarly were placed on Import Alert. On June 1, 2010, FDA issued a Public Health Alert providing notice of Claris's recall – prior to "any reports of injuries" – of certain intravenous bag products manufactured at the Ahmedabad facility.[576] On June 3, FDA placed that facility on Import Alert 66-40.[577] On June 5-16, FDA inspected the Ahmedabad

[572] Just as there is "no legally sufficient connection" between Apotex Corp. and the placement of Apotex Inc.'s Etobicoke and Signet facilities on Import Alert 66-40, no such connection exists between Pfizer's U.S. distribution enterprises and the placement of (1) Aurobindo Pharma's Hyderabad, India facility or (2) Claris Lifesciences' Ahmedabad, India facility. Nevertheless, the comparison makes clear that Apotex was not "treated" less favorably.

[573] *See* FDA Warning Letter to Aurobindo Pharma Limited (May 20, 2011) [R-197]; FDA Import Alert #66-40 (as of Nov. 9, 2011) [R-202]. The Hyderabad facility's non-sterile products (e.g., oral dose tablets) were removed from Import Alert 66-40 on March 27, 2013, and sterile products from that facility (e.g., injectables) remain on import alert to this day. *See* FDA Import Alert #66-40 (as of Sept. 26, 2013) [R-242].

[574] *See* FDA Warning Letter to Aurobindo Pharma Limited (May 20, 2011) [R-197].

[575] Reply ¶ 386 (emphasis added).

[576] FDA Public Health Alert: Healthcare Professionals Warned Not to Use Certain Intravenous Metronidazole, Ondansetron, and Ciprofloxacin Due to Potential Contamination (June 1, 2010) [C-417].

[577] FDA Import Alert 66-40 (as of Nov. 9, 2011) [R-202]. Drugs from the Ahmedabad facility remained on Import Alert until FDA closed out its investigation in August 2012. FDA Close Out Letter to Claris Lifesciences Limited (Aug. 14, 2012) [R-209]; *see* Import Alert 66-40 (as of Aug. 27, 2012) (no longer listing drugs from Claris Lifesciences) [R-210].

facility.[578] FDA did not issue a warning letter for cGMP violations at that facility until November 1, 2010.[579] Drugs from the Ahmedabad facility thus were added to the Import Alert *before* FDA's inspection and *prior to* the issuance of a warning letter or any response by the company.[580] By comparison, Apotex received a warning letter, was afforded an opportunity to respond, and both of Apotex's facilities were inspected *before* those facilities were added to the Import Alert.[581]

253. Because FDA did not accord Apotex and its alleged investments less favorable treatment than it accorded any comparator in most "like circumstances" (such as Pfizer), Apotex's Article 1102 claim fails as a matter of law.

b. FDA Did Not Accord Less Favorable Treatment to Apotex than to Ranbaxy (Article 1103)

254. The comparator arguably in most like circumstances with Apotex for purposes of its Article 1103 claim is Ranbaxy.[582] Ranbaxy was an Indian-owned company until 2008, when a Japanese company purchased a controlling stake.[583] Applying Apotex's "like circumstances" test, Ranbaxy's U.S. distribution subsidiary was "supplied by facilities outside the United States [that] received a warning letter or w[ere] placed on import alert[.]"[584]

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[578] *See* FDA Warning Letter to Claris Lifesciences Limited (Nov. 1, 2010) [R-190].

[579] *Id.*

[580] Other recent examples of companies whose drugs from foreign manufacturing facilities were added to Import Alert 66-40 on the same day as or before the issuance of a warning letter are listed at R-244.

[581] *See* 2009 Etobicoke Warning Letter (noting the dates of the inspection from "December 10-18, 2008") [C-41]; 2010 Signet Warning Letter (Mar. 29, 2010) (noting the dates of the inspection from "July 27-August 14, 2009") [C-138].

[582] Counter-Memorial ¶ 334 n.821.

[583] Kanoko Matsuyama, *Daiichi Sankyo Plunges After FDA Restricts Ranbaxy Exports*, BUSINESSWEEK (Sept. 17, 2013) [R-240].

[584] Reply ¶ 280.

255. Apotex denies being in "like circumstances" with Ranbaxy, but its arguments are specious. Apotex's legal experts observe that Ranbaxy "was not placed on the Import Alert until more than two years had elapsed since it first received a Warning Letter about cGMP violations" at one of its facilities, whereas Apotex "was placed on the Import Alert only two months after first receiving a Warning Letter" for Etobicoke.[585] This is legally irrelevant. As the Counter-Memorial observed,[586] warning letters are intended to give a firm or facility an opportunity, where possible, to take prompt corrective action.[587] They are not prerequisites to enforcement action.[588] Issuance of a warning letter may be deemed inappropriate (such as when there are exigent circumstances) or unnecessary (such as when a firm's conduct is repeated, continuing, intentional, flagrant, or criminal).[589] FDA's *Regulatory Procedures Manual*, which is published online,[590] states that FDA "is under no legal obligation to warn individuals or firms that they or their products are in violation of the law before taking enforcement action."[591] The manual notes that "responsible officials in positions of authority in regulated firms" have a "legal duty to

[585] Second Bradshaw Report ¶ 51 (mentioning the 2006 warning letter regarding Ranbaxy's Paonta Sahib facility).

[586] Counter-Memorial ¶¶ 43-44.

[587] FDA, *Regulatory Procedures Manual* § 4-1-1 (Mar. 2009) [CLA-305].

[588] *Id.* § 4-1-1 ("There are instances when issuing a Warning Letter is not appropriate, and, as previously stated, a Warning Letter is not a prerequisite to taking enforcement action.") [CLA-305].

[589] *Id.* (stating that a warning letter is not appropriate if a firm or facility's conduct (1) "reflects a history of repeated or continual conduct of a similar or substantially similar nature during which time the individual and/or firm has been notified of a similar or substantially similar violation"; (2) "is intentional or flagrant"; (3) "presents a reasonable possibility of injury or death"; (4) constitutes an "intentional and willful" criminal act; or (5) "[w]hen adequate notice has been given by other means" and the "violations have not been corrected, or are continuing").

[590] The *Regulatory Procedures Manual*:

> is a reference manual for FDA personnel. It provides FDA personnel with information on internal procedures to be used in processing domestic and import regulatory and enforcement matters. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Id., Introduction [R-38].

[591] *Id.* § 4-1-1 [CLA-305]. There are exceptions not relevant here. *See id.* (discussing FDA's notification requirements when acting under the authority of the subchapter concerning electronic product radiation control).

implement whatever measures are necessary to ensure that their products, practices, processes, or other activities comply with the law."[592] Accordingly, "responsible individuals should not assume that they would receive a warning letter, or other prior notice, before FDA initiates enforcement action."[593] Thus, the time between FDA's issuance of a warning letter to Ranbaxy and adoption of the Import Alert is immaterial as a matter of law.

256. As a factual matter, moreover, Apotex's comparison is inapt. Apotex failed to mention that FDA had considered possible enforcement action against Etobicoke following the *2006* inspection, more than three years prior to issuance of the Import Alert.[594] FDA declined to take action,[595] even though FDA field personnel classified the facility as "Official Action Indicated" – indicating that "significant objectionable conditions or practices were found and regulatory action is warranted[.]"[596]

257. Apotex also argues that Ranbaxy was not in like circumstances because Apotex "never committed any criminal offense" and "was never placed on [FDA's] Application Integrity Policy."[597] Yet Apotex acknowledges that FDA issued two warning letters to Ranbaxy and placed its Paonta Sahib and Dewas facilities on Import Alert 66-40 on September 16, 2008.[598]

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[592] *Id.*

[593] *Id.*

[594] FACTS Cover Sheet, Apotex Inc., Etobicoke, at 1 (Nov. 20-24, 2006) [R-141]. The inspection uncovered that Apotex had (1) failed to file FARs on time; (2) manufactured and distributed drug products in the United States using active pharmaceutical ingredients (API) that were out-of-specification; and (3) lacked adequate processing validation for those same tablets. *Id.*; *see also* Form FDA 483, Inspectional Observations, Apotex Inc., Etobicoke (Nov. 24, 2006) [C-21].

[595] Letter from FDA to Apotex Inc. (Apr. 23, 2007) [C-23].

[596] FDA, *Inspections – Background* [CLA-575]; *see also* Memorial ¶ 145 (discussing Apotex's multiple responses to FDA regarding the 2006 Etobicoke inspection).

[597] Reply ¶ 384.

[598] *Id.* ¶ 381.

At that time, Apotex further acknowledges, Ranbaxy had not pled guilty to any criminal offense (it did not do so until May 2013)[599] and was not on the Application Integrity Policy (it was not listed until February 2009).[600] Thus, when Ranbaxy was placed on Import Alert in 2008, it was not, as Apotex suggests, an incomparable "felon."[601]

258. Apotex also contends that FDA accorded Apotex less favorable treatment, because Ranbaxy was "afforded opportunities to correct the problems before FDA decided to take enforcement action."[602] Apotex, however, also was afforded the opportunity to remedy the problems identified in the 2008 Etobicoke inspection for almost nine months prior to being added to the Import Alert. FDA did not add Apotex to the Import Alert until after an *additional* inspection of a different facility in August 2009.

259. Apotex wrongly asserts that it was accorded less favorable treatment because "the Ranbaxy consent decree had to be reviewed and approved by an independent federal judge," whereas FDA itself placed Apotex on Import Alert.[603] In fact, FDA had placed Ranbaxy's two

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[599] *See id.* ¶ 379 (citing U.S. Dept. of Justice News Release: Generic Drugs Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations (May 13, 2013) [C-473]).

[600] *See id.* ¶ 382 (citing letter from CDER to Ranbaxy Laboratories Limited (Feb. 25, 2009) (notifying Ranbaxy that its Paonta Sahib site had been added to the Application Integrity Policy List [C-341]; Application Integrity Policy List (last updated Oct. 12, 2011 [C-437]).

[601] *Id.* ¶ 377. Apotex states that the United States "accuses Apotex of participating in a 'scheme' 20 years ago because an FDA official copied Apotex on a [warning] letter addressed to a company that sold Canadian Apotex products on the U.S. market." Reply ¶ 11. *But see Syntex (U.S.A.), Inc. et al. v. Interpharm, Inc., Apotex Inc., Allen Barry Shectman, Bernard C. Sherman, et al.*, 1993 WL 643372 at *4-8 (N.D.Ga. 1993) (granting Syntex's request for a preliminary injunction, finding that Syntex was "substantially likely" to prevail on its federal claims that defendants had sold Apotex drugs to U.S. consumers through the mail, made deceptive representations to U.S. consumers, and improperly used promotional labeling, advertisements, and solicitations") [RLA-94]; David Spurgeon, *Mail-order sales of drugs without prescriptions under investigation by US, Canadian agencies*, CAN. MED. ASSOC. J. (Dec. 1, 1993) [R-136]; *Apotex, Inc. and Bernard C. Sherman v. Eon Labs Manufacturing, Inc.*, 2007 WL 656256 at *9, *12 (E.D.N.Y. 2007) [RLA-231]; *Merck & Co. Inc. v. Apotex Inc.*, 5 C.P.R. (4th) 1, ¶¶ 19, 60 (Fed. Ct. Mar. 7, 2000) [RLA-246].

[602] Reply ¶ 386.

[603] *Id*.

foreign facilities on import alert in September 2008, *more than three years* prior to the January 2012 consent decree.[604] It is nonsensical to argue that Apotex received less favorable treatment because Ranbaxy voluntarily accepted a consent decree – with sweeping provisions and obligations – by the time that Apotex's Etobicoke and Signet facilities *were already off the import alert*.[605] Apotex cannot show that it was treated less favorably than Ranbaxy.[606]

260. The facts demonstrate that FDA treated Apotex and its alleged investments no less favorably than FDA treated Ranbaxy, the foreign manufacturer in "most like circumstances" with Apotex. Apotex's Article 1103 claim thus also fails on this basis.

ii. FDA Did Not Accord Less Favorable Treatment to Apotex than to Apotex's Alleged Comparators Regarding Domestic Manufacturing Facilities (Articles 1102 and 1103)

261. For the reasons discussed, the U.S.-based "comparators" alleged by Apotex are not appropriate, given the different legal regime governing drug manufacturing facilities inside and outside the United States.[607] Nor is it appropriate for this Tribunal to step into FDA's shoes and to make the kinds of comparisons that Apotex invites it to make.[608] In any event, the United

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[604] *Id.*¶ 383.

[605] Indeed, well before the elapse of three years, FDA had already exercised its discretion to classify Apotex's Etobicoke and Signet facilities as acceptable and remove them from the import alert, even though the FDA investigators who conducted the January 24 to February 11, 2011 Signet and Etobicoke inspections recommended that those facilities both remain classified as OAI and on the import alert. *See* Witness Statement of Michael Goga ¶ 29 (Dec. 12, 2012) ("For both Apotex sites, we recommended 'OAI' and that the two sites remain on import alert, based on the observations the team made during the January-February 2011 inspections.") ("Goga Statement").

[606] As described in the U.S. Counter-Memorial, through the consent decree, FDA established a host of measures that Ranbaxy must satisfy before FDA will review applications involving the data from the facilities named or before FDA could deem the cGMP status of the facilities to be acceptable for the U.S. market. *See* Counter-Memorial ¶ 339. Under that decree, moreover, Ranbaxy requested withdrawal of approval of 27 ANDAs. *See Ranbaxy Laboratories Limited; Withdrawal of Approval of 27 Abbreviated New Drug Applications*, FED. REGISTER (Aug. 22, 2012) [R-96].

[607] *See supra* ¶¶ 225-30.

[608] *See supra* ¶¶ 241-42.

States categorically rejects Apotex's new allegation that "the Import Alert discriminated against Apotex's Canadian facilities, while FDA "*did nothing*" to protect the public health from Baxter's, L. Perrigo's, Hospira's, Sandoz Inc.'s and Teva Parenteral's US-based facilities."[609] Apotex's allegation is false, for at least four reasons.

262. *First,* despite an extended and costly fishing expedition through FDA's documents, Apotex has submitted *no* evidence that FDA discriminated against Apotex on the basis of its Canadian nationality. Apotex's claims of nationality-based discrimination should be dismissed for this reason alone.[610]

263. *Second,* as discussed above, the distinction in U.S. law between

(1) manufacturing facilities *outside* the United States (whether U.S.- or foreign-owned), from which FDA may *administratively* refuse to admit drugs that *appear* to be adulterated; and

(2) manufacturing facilities *inside* the United States (whether U.S.- or foreign-owned), where FDA must *establish* adulteration through *judicial* action

[609] Reply ¶ 307 n.492.

[610] *See GAMI Investments, Inc. v. United Mexican States*, NAFTA/UNCITRAL, Final Award ¶ 114 (Nov. 15, 2004) (stating that, in rejecting an Article 1102 claim where nationality was irrelevant to Mexico's nationalization of certain sugar mills, but not others: "The Arbitral Tribunal has not been persuaded that GAM's circumstances were demonstrably so 'like' those of non-expropriated mill owners that it was wrong to treat GAM differently. Mexico determined that nearly half of the mills in the country should be expropriated in the public interest. The reason was not that they were prosperous and the Government was greedy. To the contrary: Mexico perceived that mills operating in conditions of effective insolvency needed public participation in the interest of the national economy in a broad sense. The Government may have been misguided. That is a matter of policy and politics. The Government may have been clumsy in its analysis of the relevant criteria for the cutoff line between candidates and non-candidates for expropriation. Its understanding of corporate finance may have been deficient. But ineffectiveness is not discrimination. The arbitrators are satisfied that a reason exists for the measure which was not itself discriminatory. That measure was plausibly connected with a legitimate goal of policy (ensuring that the sugar industry was in the hands of solvent enterprises) and was applied neither in a discriminatory manner nor as a disguised barrier to equal opportunity.") ("*GAMI* Award") [CLA-27].

does not discriminate on the basis of nationality of ownership and is not prohibited by NAFTA Chapter Eleven.[611] Apotex's simultaneous assertion of Articles 1102 and 1103 violations regarding both *U.S.- and foreign-owned domestic* manufacturing facilities respectively makes clear that the distinction does not discriminate on the basis of nationality of ownership.

264. *Third*, Apotex cannot show that FDA's Import Alert guidance and Section 801(a) of the FD&C Act are based on illegitimate regulatory distinctions.[612] Apotex, moreover, does not challenge the underlying legality of the Import Alert policy, which predates its investment and is consistent with the practice of other drug-importing countries.[613]

265. *Fourth*, there is no truth to Apotex's new allegation that FDA "did nothing" with respect to Apotex's alleged U.S.-based comparators (which are both U.S.- and foreign-owned).[614] Apotex's suggestion implies that, absent *actual* enforcement action, FDA takes no steps to protect the public health.[615] But that is not true; FDA has many options between "doing nothing" and seeking a court order to seize drugs or stop production at a domestic facility. In exercising

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[611] *See supra* ¶¶ 225-30.

[612] *See supra* ¶ 219 (noting that, as Apotex acknowledges, FDA is not the primary regulator outside its territory and does not have the resources to examine every drug that is offered for import into the United States).

[613] *See* Counter-Memorial ¶ 52 (discussing EU and Canadian practice regarding Ben Venue's Bedford, Ohio facility). Apotex's legal experts, moreover, similarly acknowledge that "other regulators (in Canada and the EU) imposed a ban on Ben Venue's products." Second Bradshaw Report ¶ 57.

[614] Apotex wrongly claims that "[t]he US does not address *at all* the third prong of the test, i.e., less favorable treatment concerning the US facilities[.]" Reply ¶ 352. Earlier in the Reply, however, Apotex addresses the United States' discussion of the third prong of the test. Reply ¶ 267 n.454.

[615] By Apotex's logic, then, Health Canada too "did nothing" with respect to Apotex's Etobicoke and Signet facilities. Although Health Canada declined to exercise its authority to shut Apotex down, it nonetheless put Apotex under close, continuous, onsite supervision for more than a year. *See* Counter-Memorial ¶¶ 117-18 (discussing Apotex's commingling of toxic and nontoxic materials, for which it could have lost its establishment license); *id.* ¶¶ 143-150 (discussing Health Canada's close, continuous, onsite supervision of Etobicoke and Signet for more than a year); *see also* Second Carey Statement ¶ 32 (noting that Health Canada's extraordinary supervision of Apotex extended an additional year, through 2011).

its enforcement discretion, FDA monitored and evaluated the circumstances with respect to Apotex's alleged comparators:

- **Baxter (Jayuya and Guayama, Puerto Rico):** Baxter recalled product and committed to sufficient corrective actions,[616] which were timely and fully implemented, thereby allowing FDA to issue a closeout letter within a year of the initial inspections[617] (in contrast to Apotex, who required more than a year even to request reinspections, which were found *not* to have responded to all of FDA's initial cGMP concerns);[618]

- **L. Perrigo (Allegan, Michigan):** Perrigo pledged timely corrective action, but FDA nevertheless withheld approval of Perrigo's requests for export certificates[619] (an option not available for *foreign* facilities, such as Apotex's Etobicoke and Signet facilities);

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[616] The 2011 warning letter to Baxter identified cGMP violations, a misbranding violation regarding a product label, and the failure to submit FARs within the required time period at the Jayuya facility, whereas it identified only the failure to submit timely FARs at the Guayama facility. FDA Warning Letter to Baxter Healthcare Corp. (Jan. 20, 2011) [C-189]. Apotex, moreover, does not dispute that, before the 2011 warning letter, the most recent FDA warning letter issued to a Baxter facility concerning cGMP violations for finished pharmaceutical drugs is from 2001. *See* Counter-Memorial ¶ 343 n.840. Instead, Apotex asserts that the United States "attempts to minimize the significance" of warning letters issued to Baxter since 1997 in other areas, such as ten warning letters for cGMP violations regarding medical devices. Reply ¶ 354 n.558. Contrary to Apotex's allegation that FDA "did nothing" with respect to Baxter, Apotex fails to mention, for example, that FDA issued in 2010 its final order under a 2006 consent decree requiring Baxter "to recall all Colleague infusion pumps currently in use in the United States and to provide refunds or replacement pumps to customers at no cost." FDA's Final Order to Baxter to Recall, Refund, or Replace the Colleague Infusion Pumps (July 13, 2010) [R-187]; *see also* Baxter Announces Final Details Regarding Previously Communicated COLLEAGUE Infusion Pump Recall in the U.S. (July 13, 2010) (noting that "Baxter recorded a charge of $588 million in connection with the COLLEAGUE infusion pump recall and additional actions") [R-186].

[617] *See* FDA Warning Letter to Baxter Healthcare Corp. (Jan. 20, 2011) (noting that the Jayuya inspection was from July 14 to August 26, 2010 and the Guayama inspection was from September 30, 2010) [C-189]; FDA Close Out Letter to Baxter Healthcare Corp. (July 14, 2011) [R-199].

[618] *See* Memorial ¶ 147 (noting that the Etobicoke inspection lasted from December 10 to 19, 2008); *id.* ¶ 159 (noting that the Signet inspection lasted from July 27 to August 14, 2009); Counter-Memorial ¶ 172 (noting that Apotex first requested, in an August 27 letter, that FDA reinspect the Etobicoke facility in October 2010 and that Apotex further requested, in a September 29, 2010 letter, that FDA reinspect the Signet facility, without specifying any preferred timetable); *see also* Goga Statement ¶¶ 28-29 (noting that the reinspections resulted in ■ written observations and an OAI recommendation, including that the two sites remain on import alert).

[619] FDA Warning Letter to L. Perrigo Co. (Apr. 29, 2010) (noting, in a warning letter issued by the Detroit District Office, recalls of affected lots of Ibuprofen tablets, as well as mislabeled Milk of Magnesia products, and Perrigo's commitment "to conduct deviation investigations, ensure appropriate corrective actions, initiate improvements to reduce or eliminate potential 'hiding places' for drug product including equipment modifications, and provide updates on all such improvements to the Detroit District") [C-146]. U.S.-based manufacturing facilities "are often asked by foreign customers or foreign governments to supply a 'certificate' for products regulated by [FDA]" that contains "information about a product's regulatory or marketing status." FDA Guidance for Industry: FDA Export Certificates (Apr. 2005) [R-138]. Foreign customers or governments "seek[] official assurance that products exported to their countries can be marketed in the United States or meet specific U.S. regulations, for example

- **Hospira (Rocky Mount and Clayton, North Carolina):** Hospira committed $375 million to its remediation efforts, slowed production lines, and even temporarily shut down both facilities,[620] despite its production of medically necessary and short-supply injectable drugs[621] (compared to Apotex's more modest remediation efforts and its refusal to stop, or even slow, production of drugs that were not in short-supply);[622]

[cGMP] regulations. Review of an FDA Export Certificate may be a required part of the process to register or import a product into another country." *Id.*; letter from CDER's Office of Compliance to Perrigo International (in response to Jan. 15, 2010 application) [R-178]; *see also Perrigo Announces Conclusion of the FDA Re-Inspection*, FIERCEPHARMA (Apr. 14, 2011) (recording Perrigo's announcement that it would "once again be eligible for review and approval" of "any pending export license and ANDA applications from [the Allegan] facility") [R-193].

[620] *See* Eric Palmer, *Hospira slowly ramps up production*, FIERCEPHARMA MANUFACTURING (Nov. 8, 2012) ("Hospira is slowly ramping up production at the manufacturing plants it has been upgrading to get critical drugs back on the market, CEO Michael Ball told analysts Wednesday. It, however, will not hesitate to cut that off if there is any sign that higher production is putting its extensive remediation efforts in jeopardy. Hospira . . . has undertaken improvements throughout its manufacturing system after the FDA last year found extensive problems, steps that have led to shortages of a number of commonly prescribed generic sterile injectable drugs. Ball said the work is taking longer and costing more than he has twice projected and will now top out at more than $375 million.") [R-213]; Anjali Athavaley, *Hospira profit slumps 73% on charges*, WALL ST. MARKET WATCH (May 1, 2012) ("At a key facility in Rocky Mount, N.C., 'we remain on track with the remediation efforts at the plant,' said Chief Executive F. Michael Ball. In February, Ball said the plant has resumed production levels of 60% to 70% following a temporary shutdown in December and early January.") [R-206]; Eric Palmer, *Hospira says temporary production glitch affecting propofol supplies*, FIERCEPHARMA MANUFACTURING (May 3, 2012) (noting that a "problem in manufacturing led Hospira . . . to shut down production in its Clayton, NC, plant in March, and while lines are back up, the result is a disruption of supplies of the sedative propofol") [R-207]; Jonathan D. Rockoff, *Drug Makers' Rising Interest in Injectables Could Ease Shortages*, WALL ST. J. (Mar. 26, 2013) ("[M]anufacturing problems, supply constraints and government scrutiny of aging plants in recent years forced remaining firms, such as market leaders Hospira Inc., Boehringer Ingelheim GmBH's Ben Venue Laboratories business and Novartis AG's Sandoz unit, to shut down facilities or scale back production. The result was that the number of sterile injectables experiencing shortages jumped to 183 in 2011, from 23 five years earlier.") [R-219].

[621] In an FDA letter responding to Congressional criticism on drug shortages, FDA noted that "Hospira conducted a voluntary recall of particulate contaminated products in 2009 and 2010, leading to *shortages of affected products*." Letter from J. Ireland, FDA Assistance Commissioner for Legislation, to Hon. E. Cummings, Member, U.S. House of Representatives at 4 (July 23, 2012) (emphasis added) [C-452]; *see also* FDA Warning Letter to Hospira, Inc. (Apr. 12, 2010) (noting that Hospira had conducted "three recent major recalls") [C-143]. That letter emphasized, moreover, that "quality-related problems and delays have continued to account for the majority of shortages, *especially those involving sterile injectable drugs*." *Id.* at 5 (emphasis added).

[622] *See supra* ¶¶ 82, 274 (noting FDA's finding that Apotex's Etobicoke and Signet facilities did not produce medically necessary drugs with the exception of deferiprone); Apotex, PowerPoint Presentation to FDA, Apotex Inc. – Compliance Update Presentation to FDA (Mar. 31, 2010), slide titled "Opening Remarks" (noting that Apotex spent only $[redacted] million on cGMP remediation as of March 31, 2010) [R-53]. FDA, moreover, has taken additional actions regarding other Hospira facilities. FDA, for instance, adopted an import alert with respect to a range of medical devices from a Costa Rican facility owned by a Hospira subsidiary. *See Hospira withdraws outlook on FDA import ban, shares fall*, CHICAGO TRIB. (Feb. 14, 2013) [R-216]; *see also* FDA Import Alert #89-04, *Detention Without Physical Examination of Devices From Firms That Have Not Met Device GMP's* (listing infusion pumps from Hospira Costa Rica Ltd.) [R-231]. FDA, as another example, issued a warning letter regarding a Hospira injectable manufacturing facility in India. FDA Warning Letter to Hospira Healthcare India Pvt. Ltd. (May 28, 2013) [R-227]. Before that warning letter was issued, a recall of injectable products was initiated both by the manufacturer, Hospira, and the distributor, Apotex Corp. Apotex: Public Advisories (May 10, 2013) ("Apotex Corp. announced today that it is conducting, on behalf of manufacturer Hospira, Inc., a voluntary nationwide recall

- **Sandoz Inc. (Broomfield, Colorado and Wilson, North Carolina):** Sandoz committed over $170 million to remediation efforts at its facilities,[623] including slowing its production and changing its leadership[624] (again, in contrast to Apotex's more modest remediation efforts);[625] and

- **Teva Parenteral (Irvine, California):** Teva Parenteral shut down the Irvine facility in order to effectuate the firm's remediation plan,[626] despite producing medically necessary and short-supply injectable drugs[627] (in contrast to Apotex's decision not to shut down its facilities, which in any event did not produce medically necessary or short-supply drugs).[628]

266. The allegation, therefore, that FDA "did nothing" with respect to these U.S.-based facilities is false. Thus, even if Apotex had established "treatment" that was "less favorable,"

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of 21 lots of Piperacillin and Tazobactam for Injection . . . to the hospital / healthcare provider /user level. The impacted lots . . . may show precipitation / crystallization in IV bag or IV line after reconstitution.") [R-235]; Cheryl A. Thompson, *Pharmacy News: Apotex Recalls Hospira's 40.5-g Piperacillin-Tazobactam for Injection*, American Society of Health-System Pharmacists (Apr. 29, 2013) (noting Apotex Corp.'s recall of pharmacy bulk packages manufactured by Hospira at a generic injectables pharmaceutical facility in India acquired from India-based Orchid Healthcare in 2010) [R-224].

[623] FDA Warning Letter to Novartis International AG at 3 (Nov. 18, 2011) (noting recall of Triamterene Hydrochlorothiazide) [C-273]. As of February 2012, Sandoz said it "had committed a total of over $170-million (U.S.) to improve quality" at the Broomfield, Colorado and Wilson, North Carolina facilities, as well as its Boucherville, Quebec facility. Sean Silcoff, *Sandoz Canada's Production Slows to a Crawl After Harsh Criticism from U.S. Regulators*, GLOBE & MAIL (Feb. 19, 2012) [R-91]. Sandoz Canada's Boucherville, Quebec facility is addressed below. *See infra* ¶¶ 269-75.

[624] *See* Novartis, Financial Report Q2 2012 (July 19, 2012) (noting that "Sandoz has upgraded senior leadership in quality and manufacturing operations, both globally and at the site level, and is further strengthening organizational capabilities, facilities and systems. While Sandoz slowed down production to implement remediation activities at its three North American sites, delivery performance across all sites has improved. Further improvements in service levels and output are expected as remediation progresses.") [R-208]. Sandoz also recalled affected products and voluntarily suspended production at an over-the-counter and veterinary medicine facility in Lincoln, Nebraska and, as a result, had to outsource production of certain drugs. *See id.*

[625] *See supra* n.622 (noting that Apotex spent only $[redacted] million on cGMP remediation as of March 31, 2010).

[626] Teva Pharmaceutical Industries, Annual Report (Form 20-F), at 61 (Feb. 12, 2013) ("In December 2009, the FDA issued a warning letter relating to our Irvine, California injectable products manufacturing facility. We voluntarily ceased production at the facility during the second quarter of 2010 and executed a remediation plan required by the FDA. In April 2011, we resumed limited manufacturing activity. We have been working closely with the FDA and are gradually releasing more products for distribution. On October 23, 2012, we received a letter from the FDA acknowledging that our corrective actions addressed the violations noted in the December 2009 warning letter. During 2012, we incurred uncapitalized production costs, consulting expenses and write-offs of inventory of approximately $88 million relating to this facility.") [R-215].

[627] *See* FDA Warning Letter to Teva Parenteral Medicines, Inc. (Dec. 11, 2009) (noting recall of affected lot of injectable product) [C-124]; Dan Stanton, *Propofol Off FDA List but Manufacturing Issues Cause 75% of Shortages*, IN-PHARMA TECHNOLOGIST (June 4, 2013) [R-228].

[628] *See supra* ¶¶ 82, 274 (noting FDA's finding that Apotex's Etobicoke and Signet facilities did not produce medically necessary drugs with the exception of deferiprone).

those claims fail in any event because Apotex cannot show that such "treatment" was unwarranted by the circumstances or based on illegitimate regulatory distinctions.[629]

iii. FDA Did Not Accord Less Favorable Treatment to Apotex than to Apotex's Alleged Comparators Regarding Foreign Manufacturing Facilities (Article 1103)

267. Finally, Apotex has not shown that FDA accorded less favorable treatment to the *foreign* facilities that Apotex (erroneously) claims are in like circumstances with Apotex: (1) Sandoz Canada, "as concerns supplies" from its Boucherville, Quebec facility; and (2) Teva Pharmaceutical "as concerns supplies" from its Jerusalem, Israel facility.[630]

268. Apotex has acknowledged that comparators "can be treated differently if circumstances warrant,"[631] and that NAFTA's non-discrimination obligations "allow some legitimate differences in treatment" and "do not bar legitimate regulatory distinctions."[632] Thus, even if Apotex had established "treatment" that was "less favorable," Apotex still has not shown that the "treatment" was unwarranted by the circumstances or based on illegitimate regulatory distinctions. That is, taking the "full factual context" into account, Apotex was not accorded "less favorable treatment," in like circumstances, than these companies and facilities.

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[629] Indeed, "*any* difference in treatment" is "justified" because "it bears a reasonable relationship to rational policies," such as the prevention of drug shortages, that are "not motivated by preference of domestic over foreign owned investments" in the United States. *Pope & Talbot, Inc. v. Canada*, NAFTA/UNCITAL, Award on the Merits of Phase 2 ¶ 79 (Apr. 10, 2001) (emphasis in original) [CLA-42].

[630] Reply ¶ 310. The U.S. Counter-Memorial identified Sandoz Canada and Teva Pharmaceutical as "potential comparators," as they have "facilities outside the United States that manufacture drugs for export to the U.S. market, and thus those goods are subject to Section 801(a) of the FD&C Act and are eligible for Import Alert 66-40." Counter-Memorial ¶ 334.

[631] Reply ¶ 301 (quoting North American Free Trade Agreement, Implementation Act, Statement of Administrative Action, H.R. Doc. No. 103-159, Vol. 1, 103d Cong., 1st Sess. at 140-41 [CLA-2]).

[632] *Id.* (quoting North American Free Trade Agreement, Implementation Act, Statement of Administrative Action, H.R. Doc. No. 103-159, Vol. 1, 103d Cong., 1st Sess. at 140-41 [CLA-2]).

a. FDA Did Not Accord Less Favorable Treatment to Apotex than to Sandoz Canada

269. Apotex's arguments fail to establish that Apotex received less favorable treatment, in like circumstances, than Sandoz Canada.[633] *First*, Apotex wrongly asserts that Apotex was accorded less favorable treatment, in like circumstances, because "FDA did not require Sandoz to stop production at Boucherville."[634] But the challenged measure, an FDA Import Alert, does not direct a foreign manufacturing facility to stop production. Indeed, Apotex did not stop production at its Etobicoke and Signet facilities when drugs from those facilities were on the Import Alert.

270. *Second*, Apotex wrongly asserts that Sandoz Canada's voluntary action cannot have obviated the need for further enforcement action.[635] FDA's decision, however, falls squarely within its regulatory discretion, and reflects its legitimate need to assess the potential risk to consumers and the appropriateness of each company's response.[636] Apotex's assertion, moreover, is inconsistent with its own voluntary actions, which it admits "did not produce the *expected* results."[637]

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[633] FDA sent a warning letter in November 2011 to Novartis/Sandoz concerning serious cGMP violations at the Boucherville, Quebec facility of Sandoz Canada Inc., a Canadian subsidiary, and at the Broomfield, Colorado and Wilson, North Carolina facilities of Sandoz Inc., a U.S. subsidiary. FDA Warning Letter to Novartis International AG (Nov. 18, 2011) [C-273]. As of February 2012, Sandoz reported having "committed a total of over $170-million (U.S.) to improve quality" at these plants. Sean Silcoff, *Sandoz Canada's Production Slows to a Crawl after Harsh Criticism from U.S. Regulators*, GLOBE & MAIL (Feb. 19, 2012) [R-91]. Sandoz Inc.'s *U.S.-based* facilities are addressed in Part III(A)(3)(ii) *supra*.

[634] Reply ¶ 320.

[635] *Id.* ¶¶ 318-21. In raising Sandoz Canada's voluntary action to "temporarily suspend or discontinue the production of certain products," the United States sought not for the company's voluntary action to be equated with FDA's enforcement determinations. Counter-Memorial ¶ 335 (quoting Sandoz Canada's public response to a CBC inquiry, Drug Shortage Feared as Quebec Plant Retools, CBC News (Feb. 20, 2012) [R-92]). Instead, the United States highlighted the circumstances in which FDA made its enforcement determinations regarding Sandoz Canada.

[636] *See* Vodra Report ¶¶ 62-67.

[637] *See supra* ¶¶ 246 and n. 564.

271. In this regard, Apotex's legal experts assert that "Apotex was not given the opportunity to voluntarily shut down manufacturing operations and thereby avoid FDA enforcement action."[638] But that is not the case. Apotex was given several such opportunities to address the cGMP findings at its Etobicoke and Signet facilities, most notably during the August 17, 2009 teleconference immediately after the close of the Signet inspection. Apotex, however, did not want to "address all products on the US market" and did not offer to shut down or slow down voluntarily manufacturing operations, preferring to recall only some drugs from the United States as a "goodwill gesture."[639]

272. *Third*, Apotex criticizes the United States' observation that the Boucherville facility, in response to FDA's warning letter, "essentially shut down production," as the facility continued to produce some drugs.[640] But the United States explained in the Counter-Memorial that the production shutdown was "save for medically necessary drugs" as well as "'critical medicines' to be distributed in Canada."[641] Further, the Counter-Memorial quoted Sandoz Canada's response to the November 2011 warning letter, which stated the firm's intention to:

> temporarily suspend or discontinue the production of certain products at [the] Boucherville site, most of which have alternatives in the marketplace, to prioritize production of most medically necessary products, and focus on the supply of critical medicines to the Canadian market.[642]

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[638] Second Bradshaw Report ¶ 44.

[639] *See* Memorial ¶¶ 171-73.

[640] Counter-Memorial ¶ 335.

[641] *Id.* (quoting Sandoz Canada's public response to a CBC inquiry, *see* Drug Shortage Feared as Quebec Plant Retools, CBC News (Feb. 20, 2012) [R-92]).

[642] *Id.* (quoting Sandoz Canada's public response to a CBC inquiry, *see* Drug Shortage Feared as Quebec Plant Retools, CBC News (Feb. 20, 2012) [R-92]). Notably, Apotex makes clear just how "critical" Sandoz Canada's medicines are to Canada. Apotex observes that by May 2012, Sandoz Canada "was already supplying 80% of the Canada market needs for its entire injectable portfolio and more than 90% for the products then in production." Reply ¶ 324.

273. FDA exercised its discretion to ensure that Sandoz Canada continued to export medically necessary drugs to the United States.[643] By contrast, FDA analyzed the drugs from Apotex Inc.'s Etobicoke and Signet facilities and determined that placement of drugs from facilities on Import Alert would not create significant shortages.[644]

274. To show that Sandoz Canada's remediation efforts "did not prevent the US distribution of drugs from Boucherville," Apotex acknowledges that the circumstances surrounding Sandoz Canada involved medical necessity, stating that:

> *in order to prevent a shortage* in May 2012, FDA allowed Sandoz [Canada] to import into the United States Phentolamine Mesylate, a drug manufactured at Boucherville but not authorized for sale in the United States.[645]

Apotex also acknowledges that such distribution was temporary and was abandoned once an alternative supplier became available.[646] Apotex further admits that it too shipped a medically

[643] *See* Supplemental Rosa Statement ¶ 31. FDA has not closed out its investigation of Sandoz Canada's Boucherville facility, which remains under review. *Id.*

[644] *See* email from C. Rosa to R. Friedman (June 19, 2009) (noting that any decision regarding addition of the Etobicoke and Signet facilities to the Import Alert "needs to be carefully evaluated[,]" but that "other companies can ramp up") [C-502]; email from C. Rosa to T. Lopez (Aug. 19, 2009) (stating that there are "[n]o medically necessary product issue[s,]" and forwarding an email from I. Santiago stating that "Apotex is not the sole [source] of any product of concern") [R-154]. Apotex cites a September 8, 2009 FDA email to suggest that "[i]t was only after the Import Alert was adopted that FDA performed a comprehensive drug shortage analysis covering products manufactured at Etobicoke." Supplement to Reply ¶ 46 (citing FDA internal email chain (Sept. 8, 2009) [C-520]). Apotex, however, disregards emails in the U.S. productions that demonstrate that FDA's drug shortage analysis, performed prior to adoption of the Import Alert, included drugs from the Etobicoke facility. *See, e.g.*, email from C. Rosa to R. Friedman (June 19, 2009) (covering, in forwarded email chain, drugs from Etobicoke, such as acyclovir, carbidopa/levodopa, gabapentin, and topiramate) [C-502]; email from C. Rosa to T. Lopez (Aug. 19, 2009) [R-154].

[645] Reply ¶ 329 (emphasis added).

[646] *Id.* ¶ 329 (citing American Society of Health-System Pharmacists, Phentolamine Mesylate for Injection (Mar. 22, 2013) ("In cooperation with FDA, Sandoz Canada was providing phentolamine mesylate to the US market but this is no longer needed since Bedford has supply.") [C-463].

necessary drug, deferiprone, to the United States for compassionate use, despite the Import Alert.[647]

275. Apotex has failed to establish that FDA discriminated against its Canadian facilities in favor of Sandoz Canada's Canadian facility. Taking into account the full factual context, Apotex and its alleged investments were not accorded less favorable treatment, in like circumstances, than Sandoz Canada.

b. FDA Did Not Accord Less Favorable Treatment to Apotex than to Teva Pharmaceutical

276. Apotex's own arguments make clear that Apotex was not accorded less favorable treatment, in like circumstances, than Teva Pharmaceutical Industries Ltd. Apotex reaffirms its criticism of FDA for not taking "a 'corporate' view" of Teva's cGMP compliance.[648] Apotex wrongly alleges less favorable treatment because FDA did not adopt such a view once FDA determined that there were cGMP violations at Teva Pharmaceutical's Jerusalem facility, "even

[647] Reply ¶ 329 n.531. Apotex, however, fails to acknowledge that, like Sandoz Canada, Apotex had significant cGMP problems manufacturing sterile, injectable and other non-sterile liquid products at its Richmond Hill, Ontario facility. *See* FDA Warning Letter to Novartis International AG (Nov. 18, 2011) (listing, with respect to Sandoz Canada's Boucherville facility, only cGMP violations regarding production of sterile products) [C-273]. By June 2010, FDA had received numerous FARs from the Richmond Hill facility, reporting sterile nasal and ophthalmic products contaminated with [redacted] and, in some instances, metal fragments. Email from C. Rosa to D. Autor et al. (June 14, 2010) [R-185]. [redacted] contamination, for example, "may cause mild, transient local irritation and has a remote probability of resulting in permanent impairment of a body structure or function." *Id.* FDA considered adding the Richmond Hill facility to the Import Alert. *See* email from D. Autor to C. Rosa (June 15, 2010) [R-185]. At that time, in the exercise of enforcement discretion, FDA opted not to do so. *See* First Desai Statement ¶ 83 ("Richmond Hill was not placed on Import Alert even though our facility at Richmond Hill, is geographically close to Etobicoke and Signet and has always been operated under the same Quality Systems as those applicable to Etobicoke and Signet. Further, even though the FDA did not impose an Import Alert on Richmond Hill, it did require that its Quality Control systems and process be enhanced along with those at our other facilities."). Apotex also speculates that "US sales of products manufactured at Boucherville seem to have remained stable despite the 'slow down,'" citing "Sandoz Inc.'s general position on the U.S. generic market[.]" *See* Reply ¶ 327. But, as Apotex effectively admits, Sandoz Canada – with its one manufacturing facility in Boucherville, Quebec – focuses on the supply of products to the Canadian market. *See id.* ¶ 324. That facility, moreover, is but one of Novartis/Sandoz's 45 manufacturing facilities located in 19 countries. *See* Novartis Ag, Excerpts from Annual Reports (Form 20-F), at 79 (Jan. 23, 2013) [C-458].

[648] Reply ¶ 337.

though FDA had issued a prior warning letter to Teva Parenteral's facility in Irvine, California *13 months earlier*."[649]

277. But Apotex fails to explain why FDA should have adopted such a view. In fact, a comparison to Apotex reveals a number of distinctions:

- Teva Pharmaceutical's Jerusalem, Israel facility and Teva Parenteral's Irvine, California facility are not located in the same province or country, unlike Apotex Inc.'s Etobicoke and Signet facilities;[650]

- The Jerusalem facility (oral solid dose) and the Irvine facility (liquid injectable) do not produce the same form of products, unlike Apotex Inc.'s Etobicoke and Signet facilities (both oral solid dose);[651] and

- By the time the Jerusalem facility was warned (or even inspected), the Irvine facility had already been voluntarily shut down, unlike Apotex's facilities.[652]

278. Apotex also criticizes the United States for not explaining its "alleged 'risk-based approach'" and for not producing "documents showing how FDA applied its 'risk-based approach' to Teva Jerusalem."[653] Although Apotex's legal experts acknowledge FDA's risk-based approach, they assert that, upon their "review of the *circumstances* here . . . none of the

[649] *Id.* ¶ 337 (emphasis added). Other than addressing Apotex's argument regarding FDA's alleged failure to adopt a "corporate" view, Apotex's claim regarding Teva Parenteral's Irvine facility is addressed above. *See supra* ¶ 265.

[650] First Desai Statement ¶ 19 (stating that Apotex's Etobicoke, Signet, and Richmond Hill facilities "are located near Toronto in Ontario, Canada").

[651] First Desai Statement ¶ 19 (noting that the Etobicoke and Signet facilities both "produce[] solid dose products").

[652] Teva Parenteral's Irvine facility voluntarily shut down on April 16, 2010. Letter from J. Ireland to Hon. E. Cummings, at 4 (July 23, 2012) [C-452]. FDA inspected Teva Pharmaceutical's Jerusalem facility from September 12-16, 2010 and issued a warning letter regarding cGMP violations at that facility on January 31, 2011. FDA Warning Letter to Teva Pharmaceutical Industries, Ltd. (Jan. 31, 2011) [C-191]. As Apotex recognizes, there was a 13 month time period between issuance of the warning letters to Teva, *see* Reply ¶ 337, which was longer than the time period between issuance of the warning letters to Apotex.

[653] Reply ¶¶ 344, 348.

factors that FDA considers when determining whether to bring an enforcement action suggests that Apotex is riskier than Teva[.]"[654]

279. Both Apotex and its legal experts ignore the "evidence on FDA's assessment of the facts" contained in the U.S. document productions.[655] Apotex received numerous documents produced by the United States showing how FDA applied its risk-based approach to Teva's Jerusalem facility.[656] In conducting a drug-shortage analysis of products from that facility in connection with Teva's recall of products, for example, FDA recognized:

> [The] Firm has made the decision to recall 30 lots involving 21 different drug products made at the Jerusalem facility. There is real concern about patient impact – these are chronic medications that patients won't have when they go to get their medications from the pharmacy (including common blood pressure drugs, cholesterol lowering drugs, diabetes drugs, arthritis drugs, antidepressants and other widely used medications). We see the need for a teleconference with Teva as soon as possible to let them know the medical need for these and to work with them to *keep manufacturing medically necessary drugs at the supply levels needed to meet patient needs while fixing their problems (as long as benefit outweighs any potential risks).*
>
> We don't see any products on the list that would not be impacting patients and we are worried about the impact of any supply disruption at the Jerusalem facility. 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).[657]

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[654] Second Bradshaw Report ¶¶ 47-48 (emphasis added).

[655] Reply ¶ 343.

[656] Although the Tribunal upheld the United States' objections to Apotex's requests for certain third-party documents, the United States produced, with appropriate redaction, Apotex-related documents, which in some instances included information regarding third parties.

[657] Email from V. Jensen to H. Saccone et al. (Feb. 24, 2011) (emphasis added) [R-131]. In addition to Apotex, this email identifies the following companies that were affected by cGMP violations: Caraco, a U.S.-based manufacturer (Michigan); Ranbaxy, *see* Part III(A)(3)(ii)(b) *supra*; Actavis Inc., a U.S.-based manufacturer (New Jersey); and KV Pharmaceutical, another U.S.-based manufacturer (Missouri). *Id.* Caraco's drug products at its Detroit and Wixom facilities were seized in June 2009 after a May 2009 inspected found unresolved cGMP violations, including the production of "oversized tablets." Question and Answers: Seizure of Drug Products Manufactured by Caraco Pharmaceutical Laboratories Ltd. (June 25, 2009) [R-148]. Caraco entered into a consent

Given the voluntary shutdown of Teva Parenteral's Irvine facility, FDA officials feared that Teva Pharmaceutical would voluntarily shut down its Jerusalem facility as well, creating shortages of medically necessary drugs.[658] By contrast, FDA's analysis of drugs from Apotex Inc.'s Etobicoke and Signet facilities determined that placement of those facilities on Import Alert would not create any significant shortages.[659] Apotex fails to mention any of these documents in its Reply or Supplement.

280. *Third*, both Apotex and its legal experts assert that Apotex was accorded less favorable treatment because "FDA did not implement a DWPE [detention without physical examination]" with respect to drug products from the Jerusalem facility.[660] FDA, however, *did* detain shipments from Teva's Jerusalem facility, even though drugs from that facility *were not on the Import Alert*. The Philadelphia District Office, in March 2011, detained shipments on the basis of the warning letter.[661] CDER recommended the "exercise [of] enforcement discretion to allow these products to be imported,"[662] because "of the shortage situation."[663]

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decree under which it agreed to cease production until "it receive[d] written notification from independent experts and the FDA that it is in compliance with the decree and regulations and can resume operations[.]" *Caraco enters into consent decree with FDA*, REUTERS (Sep. 29, 2009) [R-165]. Caraco did not receive such written notification from the FDA until August 2012. Eric Palmer, *Sun Says FDA Clears Plants where Marshals Seized Products in 2009: Michigan plants cleared to make 2 products under strict supervision*, FIERCEPHARMA MANUFACTURING (Aug. 28, 2012) [R-211].

[658] Email from S. Lynn to R. Friedman (Feb. 24, 2011) ("We'll be talking [to] Teva at tomorrow afternoon's Drug Shortage Working Group meeting . . . and [will] tell them not to shut down. *We definitely don't need a shortage of this magnitude*.") (emphasis added) [R-131].

[659] *See* n.628 *supra*.

[660] Reply ¶ 336; Second Bradshaw Report ¶ 45.

[661] Email from R. Stokes to S. Notzon (Mar. 16, 2011) [R-192].

[662] Email from H. Batista to F. Bormel (Mar. 21, 2011) [R-192].

[663] Email from C. Rosa to H. Batista et al. (Mar. 21, 2011) [R-192].

281. Apotex has failed to establish that FDA discriminated against its Canadian facilities in favor of Teva Pharmaceutical's Israeli facility. Taking into account the full factual context, Apotex and its alleged investments were not accorded less favorable treatment, in like circumstances, than Teva Pharmaceutical.

282. In short, Apotex has failed to demonstrate any of the three elements required to prove a breach of national treatment or most-favored-nation treatment: (1) that *treatment* was accorded, (2) in *like circumstances*, and (3) that it was *less favorable* on the basis of nationality of ownership. Apotex's claims under Article 1102 and 1103 thus comprehensively fail, and should be dismissed accordingly.

B. Apotex Has Failed to Establish a Breach of Article 1105 (Minimum Standard of Treatment)

283. Apotex erroneously claims that the process by which the United States exercised its enforcement discretion against two of Apotex's Canadian manufacturing facilities violated Article 1105(1), which prescribes the customary international law minimum standard of treatment of "*investments* of investors of another Party."[664] Apotex's argument is defective in four principal respects.

284. *First*, Apotex failed to state a proper claim for a breach of Article 1105(1). Apotex challenges treatment accorded to Apotex as an "investor," and not to any alleged "investment," as required by Article 1105(1).

[664] NAFTA, art. 1105(1) (emphasis added) [CLA-1]; *see also* NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter 11 Provisions ¶ 2 (July 31, 2001) [CLA-5].

285. *Second*, Apotex failed to establish a rule of customary international law requiring States to provide the "due process" claimed by Apotex (including an oral hearing) *before* a State may block the importation of adulterated drugs. Indeed, Apotex has failed to identify a single State anywhere in the world that recognizes Apotex's proposed rule of customary international law.

286. *Third*, in any event, U.S. law makes available all four processes that Apotex alleges are required under customary international law: (1) an impartial administrative authority; (2) adequate information with respect to the nature of the proceedings so as to permit the alien to present his claim or defense; (3) a reasonable opportunity to contest evidence against him; and (4) a reasonable opportunity to obtain and present witnesses and evidence in his own behalf. Apotex, however, never invoked this process. Apotex never protested or challenged FDA's cGMP determinations; never protested or challenged the addition of Etobicoke and Signet to the Import Alert; never availed itself of an administrative hearing to challenge the detention of its drugs; and never commenced judicial proceedings to challenge FDA's actions.

287. *Fourth*, Apotex does not challenge FDA's cGMP findings for Etobicoke and Signet, and thus cannot claim that the injury it alleges – FDA's refusal to admit drugs from those facilities into the United States – would have been different if Apotex had received the process it now claims was lacking. Apotex's Article 1105 claim is legally unsupported and logically incoherent. It should be dismissed accordingly.

1. Apotex Failed to Allege a Breach of the Minimum Standard of Treatment with Respect to Its *Investments*, as Required by Article 1105(1)

288. Apotex has not properly stated a claim for a breach of Article 1105(1). That provision requires each Party to "accord to investments of investors of another Party treatment in

accordance with international law."[665] By its terms, therefore, Article 1105(1) applies to "*investments* of investors," and not to investors themselves. Apotex alleges two investments in the arbitration: (1) Apotex Inc.'s finally approved ANDAs, and (2) Apotex Holdings' U.S. enterprise, Apotex Corp.[666] To establish a breach of Article 1105(1), therefore, Apotex must demonstrate that the United States failed to accord the customary international law minimum standard of treatment to its claimed investments.

289. Apotex's Article 1105(1) claim, however, does not allege any treatment with respect to either "investment." Instead, Apotex alleges that "[t]he US failed to accord *Apotex* the due process required by customary international law[.]"[667] "Apotex" is defined as Apotex Holdings Inc. and Apotex Inc.[668] Apotex, therefore, alleges that the United States breached Article 1105(1) by failing to provide the minimum standard of treatment to *Apotex* as an *investor*, and not to any of Apotex's alleged investments.[669] Its Article 1105(1) claim thus fails as a matter of law on this basis alone.

[665] NAFTA art. 1105(1). *Cf.* NAFTA art. 1105(2), which applies to both investors and investments of investors under circumstances not at issue here.

[666] Letter from B. Legum to Tribunal at 2 (Feb. 7, 2013) ("For the avoidance of doubt, Apotex's claims for damages now are based only on Apotex [Corp.] and finally approved ANDAs as investments.").

[667] Reply ¶ 389 (emphasis added); *see also id.* ¶ 106 (arguing that the Import Alert violated Article 1105(1) because it "was adopted and enforced against *Apotex*") (emphasis added); *id.* ¶ 8 (stating that Apotex's 1105 claim "addresses the lack of procedural safeguards afforded *Apotex* by FDA in adopting the Import Alert") (emphasis added).

[668] Reply, at 1 (identifying "claimants Apotex Holdings Inc. ('Apotex Holdings') and Apotex Inc. ('Apotex-Canada') (collectively, 'Apotex')").

[669] *See supra* n.667; *see also* Reply ¶ 452 (alleging that "the US also failed to provide any meaningful route *for Apotex* to obtain due process after the adoption of the measure") (emphasis added).

2. Apotex Has Failed to Establish that the Customary International Law Minimum Standard of Treatment Imposes a Blanket "Due Process" Obligation on States *Before* Blocking Importation of Adulterated Drugs

290. Further undermining its claim, Apotex has failed to identify a rule of customary international law that could be applied to its alleged investments. Although Apotex claims that it was entitled to "due process" before the United States could lawfully prevent importation of its drugs, Apotex failed to establish that customary international law requires any process *before* a State may permissibly block importation of adulterated drugs.[670] And although Apotex purports to state a rule based on State practice and *opinio juris*, it has failed to identity a single State anywhere in the world that provides such process prior to blocking the importation of drugs that appear to be adulterated under domestic law.

291. The parties agree that Article 1105 prescribes the customary international law minimum standard of treatment of aliens.[671] The minimum standard of treatment is an umbrella concept incorporating a set of rules that has evolved over time and forms part of the customary international law of State responsibility for injuries to aliens.[672] These rules seek to ensure that the treatment of aliens does not fall below a minimum floor or "civilized standard."[673]

292. The parties further agree that a rule crystallizes into customary international law through a general and consistent practice of States that is adhered to from a sense of legal obligation.[674]

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[670] Apotex has the burden of establishing the existence and content of any applicable rule of customary international law. *See* Counter Memorial ¶ 354 (citing authority).

[671] Memorial ¶¶ 454-57; Counter-Memorial ¶ 348; Reply ¶ 399.

[672] Counter-Memorial ¶ 349 and n.846 (citing IAN BROWNLIE, PRINCIPLES OF PUBLIC INTERNATIONAL LAW 506 (6th ed. 2003) ("[T]here is no single standard but different standards relating to different situations.") [RLA-145]); *Cargill* Award ¶ 268 [CLA-23]).

[673] Counter-Memorial ¶ 349 and n.847 (citing Edwin Borchard, *The "Minimum Standard" of the Treatment of Aliens*, 38 MICH. L. REV. 445, 454 (1940) [CLA-330]).

[674] *See* Memorial ¶ 457, n.642; Counter-Memorial ¶ 345; Reply ¶ 396.

Establishing such a rule of customary international law thus requires proof of (1) general and consistent State practice, and (2) *opinio juris*.[675]

293. Apotex asserts that the United States violated such a rule of customary international law, although the content of its putative rule has evolved throughout these proceedings. Apotex's Memorial stated that international law requires six "procedural safeguards in deciding the rights and interests of individual parties" in "administrative decision-making": (1) a hearing (2) with advance notice (3) before an impartial decision maker (4) at which the individual may present evidence and contest the decision and (5) obtain a reasoned decision relying on all relevant legal and factual considerations and (6) affording judicial review of the validity of any decision.[676] The failure to afford these six "procedural safeguards," Apotex argued, constitutes a breach of the minimum standard of treatment under customary international law.[677]

294. The U.S. Counter-Memorial debunked this claim, noting that Apotex had selectively quoted a law school working paper as authority for its proposed rule. The author of the working paper did not purport to address the minimum standard of treatment that States must accord under customary international law. To the contrary, the author discussed, in the text omitted by Apotex, the *maximum* procedural rights that *may* apply in *common law* jurisdictions.[678]

295. In its Reply, Apotex has scaled back its proposed six-prong rule of customary international law, and now advances a four-prong rule. Apotex argues that State practice and

[675] Counter-Memorial ¶ 345; Reply ¶ 396.

[676] Memorial ¶¶ 458-59, 466 (and accompanying caption) (capitalization altered).

[677] *Id.* ¶¶ 470-77.

[678] Counter-Memorial ¶¶ 372-74 (quoting David Dyzenhaus, *The Rule of (Administrative) Law in International Law* 3 (NYU Sch. of Law IILJ, Working Paper No. 2005/1) (emphasis added) [CLA-328]).

opinio juris require administrative authorities to provide, *in advance of any decision*, four "procedural safeguards in proceedings of any kind that decide the rights and interests of individual persons":

> (1) An impartial administrative authority;
>
> (2) Adequate information with respect to the nature of the proceedings so as to permit the alien to present his claim or defense;
>
> (3) Reasonable opportunity to contest evidence against him; and
>
> (4) Reasonable opportunity to obtain and present witnesses and evidence in his own behalf.[679]

296. According to Apotex, these four "procedural safeguards" apply across the board in all administrative decision making related to individual persons, and not just in adjudicative proceedings. Apotex further argues that, "[w]hile regulatory agencies may have some discretion as to the substance of decisions in the interest of the community, *no such deference exists with respect to the process by which those decisions are reached*, which must always respect procedural safeguards."[680] Thus, in Apotex's view, before an administrative agency can make any decision impacting individuals' "rights and interests," it must offer an oral hearing to all affected parties, even where the parties have the right to challenge the decision after its adoption.

297. As a preliminary matter, Apotex's argument assumes that it had a "right" to import its drugs into the United States. This assumption is incorrect. It has long been established under

[679] Reply ¶¶ 390, 439.

[680] *Id.* ¶ 428 (emphasis added).

U.S. law that there is no right to import products into the United States,[681] and Apotex has pointed to no authority establishing such a right.[682]

298. But even if Apotex had such a right, it has failed to demonstrate that its radical new rule of customary international law – which would grind modern government to a halt – finds support in State practice and *opinio juris*. The arbitral decisions Apotex relies on, moreover, do not support any such rule. And the sundry sources cited by Apotex concerning domestic violence against women, children placed in public care, persons evicted from their property, and other such matters are wholly irrelevant to these proceedings.

i. State Practice and Opinio Juris Do Not Support Apotex's Proposed Blanket "Due Process" Rule

299. Apotex has failed to identify State practice showing that the process typically accorded in judicial or quasi-judicial proceedings must be applied to all administrative decision making. In the United States, for instance, the U.S. Supreme Court has recognized the "truism that 'due process,' unlike some legal rules, is not a technical conception with a fixed content unrelated to time, place and circumstances."[683] Rather, the standard is "flexible" and only "calls for such

[681] *See, e.g., Buttfield v. Stranahan*, 192 U.S. 470, 491-92 (1904) (holding that plaintiff was in error in asserting that it "had a vested right to engage as a trader in foreign commerce and as such to import teas into the United States which, as a matter of fact, were pure, wholesome, and free from adulteration, fraud, and deception, and which were fit for consumption; [and] that the establishment and enforcement of standards of quality of teas, which operated to deprive the alleged vested right, constituted a deprivation of property without due process of law[.]") [RLA-234]; *see also Board of Trustees v. United States*, 289 U.S. 48, 57 (1933) ("No one can be said to have a vested right to carry on foreign commerce with the United States.") [RLA-233]; *Arjay Assocs., Inc. v. Bush*, 891 F.2d 894, 896 (Fed. Cir. 1989) ("It is beyond cavil that no one has a constitutional right to conduct foreign commerce in products excluded by Congress.") [RLA-232]; *Gilda Indus. v. United States*, 446 F.3d 1271, 1284 (Fed. Cir. 2006) ("It has long been settled that executive actions involving foreign trade, such as the imposition of tariffs, do not constitute the taking of property without due process of law") [RLA-239].

[682] Although the United States provides detention hearings with respect to pharmaceutical products detained at the U.S. border, it is not required to do so under the Fifth Amendment's due process clause of the U.S. Constitution.

[683] *Mathews v. Eldridge*, 424 U.S. 319, 334 (1976) (citation and internal quotation marks omitted) [RLA-243].

procedural protections as the particular situation demands."[684] The process, therefore, does not require separate judicial or administrative review prior to taking enforcement action, regardless of time, place and circumstances. This is particularly true where, as here, the law expressly affords the individual an opportunity to contest the administrative decision in a later proceeding.[685]

300. Canada appears to have adopted a similar rule, distinguishing quasi-judicial decision making from administrative or executive decision making more broadly.[686] Civil law jurisdictions have "focused on the substantive correctness of administrative decisions," rather than "procedural principles of fair play" in administrative decision making.[687]

301. Strikingly, Apotex has failed to identify a single State anywhere in the world that recognizes Apotex's proposed rule of customary international law. Indeed, all evidence is to the contrary. Apotex does not argue that Canada followed this rule before blocking importation of

[684] *Id.*

[685] *See, e.g.*, *Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 599 (1950) (in reviewing the seizure of misbranded vitamins on an administrative finding of probable cause, without hearing, the court held that "it is not a requirement of due process that there be judicial inquiry before discretion can be exercised. It is sufficient where only property rights are concerned, that there is at some stage an opportunity for a hearing and a judicial determination.") [RLA-215]; *see also* Vodra Report ¶ 91 ("It is well-established in American law that when there is a subsequent proceeding on the merits, a potentially affected party may not interrupt the commencement of that process with judicial review of preliminary administrative decisions.").

[686] *Nicholson v. Haldimand-Norfolk Reg. Police Commrs.*, 1 S.C.R. 311, 324 (1979) (Laskin, C.J.) (citations omitted) ("[I]n the sphere of the so-called quasi-judicial the rules of natural justice run," but "in the administrative or executive field there is a general duty of fairness[.]") [RLA-249].

[687] Francesca Bignami, *Comparative Administrative Law, in* THE CAMBRIDGE COMPANION TO COMPARATIVE LAW § 3.2.1 (Mauro Bussani & Ugo Mattei eds., 2012) (noting that "[c]ommon law countries have institutionalized the judicial model within the administrative process to a greater extent than other legal systems," and that "[t]his institutionalization of dispute resolution stands in contrast with continental bureaucracies, where there is generally a right of appeal up the chain-of- command to administrative superiors, but where the main opportunity for an independent hearing is in judicial review before a full-fledged court.") [RLA-281].

drugs from Ben Venue's Bedford, Ohio facility.[688] Apotex does not argue that New Zealand followed this rule when Apotex drugs were "placed on import ban by the New Zealand Authorities."[689] Apotex does not argue that the Netherlands followed this rule when it blocked importation of Apotex drugs into the European Economic Area.[690] Apotex does not argue that Australia followed this rule when it required Apotex "to suspend all shipments of products manufactured by the Signet and Etobicoke sites for Australia with immediate effect."[691] It is untenable for Apotex to argue for a rule of customary international law when the only State practice it has identified appears to contradict that very rule.

ii. The Arbitral Decisions Cited by Apotex Do Not Support Its Proposed Four-Prong "Due Process" Rule

302. Apotex further claims that "arbitral decisions repeatedly recognize that due process is required in administrative proceedings."[692] Arbitral decisions themselves do not constitute State practice or *opinio juris.* In any event, the awards Apotex cites are unavailing, as are its attempts to distinguish the awards cited by the United States.

303. The holding in the *Thunderbird* award, which Apotex cites for the proposition that "due process" is required in administrative proceedings,[693] directly supports the U.S. position in this

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[688] *See* Reply ¶ 321; Second Bradshaw Report ¶ 58 (discussing FDA consent decree with Ben Venue, issued "after Canadian and EU regulators imposed their respective bans on [Ben Venue's] products"); *see also* Counter-Memorial ¶ 52 n.86 (discussing Canadian import ban of all but medically necessary drugs as well as the EU's import ban from Ben Venue's Bedford, Ohio facility).

[689] *See* Witness Statement of Bruce D. Clark ¶ 45 (July 27, 2012) ("Clark Statement"); Reply ¶¶ 87, 89 (discussing Medsafe's two-month ban on importation of Apotex products into New Zealand).

[690] *See* Clark Statement ¶ 45; *see* Reply ¶¶ 87, 89 (discussing the Netherlands Health Care Inspectorate's "temporary ban" on importation of Apotex products into the European Economic Area).

[691] Email from R. Millichamp to C. Baxter et al. (Sept. 11, 2009) [C-95]; *see also* Reply ¶¶ 87, 89 (discussing TGA's two-month ban on importation of Apotex products into Australia); Clark Statement ¶ 45.

[692] Reply ¶ 426.

[693] Reply n.683.

case. The claimant in that case had challenged the Mexican government's closure of its gaming facilities, after determining that its operations constituted illegal gambling. In rejecting the claim, the *Thunderbird* tribunal stated:

> The role of Chapter Eleven in this case is therefore to measure the conduct of Mexico towards Thunderbird against the international law standards set up by Chapter Eleven of the NAFTA. Mexico has in this context a wide regulatory 'space' for regulation; in the regulation of the gambling industry, governments have a particularly wide scope of regulation reflecting national views on public morals. Mexico can permit or prohibit any forms of gambling as far as the NAFTA is concerned. It can change its regulatory policy and it has wide discretion with respect to how it carries out such policies by regulation and administrative conduct.[694]

The regulation of drug safety, like the regulation of gambling, requires a wide scope of regulation, given the implications for public health and safety.

304. Apotex seeks to distinguish *Thunderbird* on the ground that the award did not address "procedural" conduct.[695] The award, however, precisely concerned Mexican administrative procedures and its alleged "failure to provide *due process* (constituting an *administrative* denial of justice)."[696] The tribunal's reasoning thus is directly on point, as Apotex similarly alleges a lack of administrative due process. The arbitral tribunal determined that the claimant failed to provide sufficient evidence to sustain the due process allegation, as Mexico's conduct was not "manifestly arbitrary or unfair."[697] Here, there is no suggestion that FDA's actions were

[694] *Thunderbird* Award ¶ 127 [CLA-30].

[695] Reply ¶ 431.

[696] *Thunderbird* Award ¶ 197 (emphasis added) [CLA-30].

[697] *Id.* ¶ 197; *see also id.* ¶ 194 (identifying the standard as a "gross denial of justice or manifest arbitrariness falling below acceptable international standards").

manifestly arbitrary or unfair.[698] In any event, the *Thunderbird* award addressed due process in the context of an "administrative proceeding" similar to the detention hearing the United States offered to Apotex in this case; it does not stand for the proposition that due process is required before a government makes any decision affecting an individuals' rights and interests. Indeed, by the facts of the case, Mexico initially closed the claimant's gaming operations without any administrative hearing.[699]

305. Apotex similarly seeks to distinguish *Genin* on grounds that the award allegedly involved deference accorded to substantive decisions, not procedural ones.[700] This argument does not withstand scrutiny. As the United States noted in its Counter-Memorial,[701] the *Genin* tribunal concluded that there was no minimum standard of treatment violation even though Estonia revoked a commercial bank license with no notice, no invitation to attend the revocation meeting, and no ability to challenge the revocation. These are the precise *procedural safeguards*

[698] *See supra* ¶¶ 11-14. Apotex also cites the *Waste Management* tribunal's statement that a State may violate international law if conduct attributable to the State "involves a lack of due process leading to an outcome which offends judicial propriety – as might be the case with a manifest failure of natural justice in judicial proceedings or a complete lack of transparency and candour in an administrative process." Reply ¶ 426 n.683 (citing *Waste Management, Inc. v. United Mexican States*, ICSID Case No. ARB(AF)/00/3, Award ¶ 98 (Apr. 30, 2004) [CLA-52]). This statement is not tied to State practice and *opinio juris*, and thus cannot be said to state a rule of customary international law. In any event, Apotex cannot allege in this case a "lack of due process leading to an outcome which offends judicial propriety," precisely because Apotex failed to avail itself of any judicial process. As addressed below, moreover, the record demonstrates complete transparency and candor in the administrative process accorded to Apotex. Additionally, Apotex cites to *Middle East Cement* for the proposition that the seizure and auctioning of a ship without notice to the ship's owner was a violation of fair and equitable treatment. *Id.* (citing *Middle East Cement Shipping and Handling Co. v. Arab Republic of Egypt*, ICSID Case No. ARB/99/6, Award ¶ 143 (Apr. 12, 2002) [CLA-589]). Here, however, FDA did not seize or sell Apotex's drugs. Rather, the drugs were refused admission to the United States. Apotex still owned the drugs and was free to sell them in any country that would accept them.

[699] *Thunderbird* Award ¶¶ 65, 70 (Mexico originally closed down one of the claimant's facilities on February 25, 2001. An administrative hearing was held on July 10, 2001 [CLA-30].

[700] Reply ¶ 431.

[701] Counter-Memorial ¶¶ 361-65.

that Apotex alleges the United States failed to provide in this case, making *Genin* directly on point.

306. Apotex further seeks to distinguish *Genin* by arguing that the result in that case would have been the same even if the Estonian authorities had provided due process.[702] But that is precisely the case here. Apotex does not dispute FDA's determinations that Etobicoke and Signet failed to comply with cGMP.[703] And Apotex does not dispute that drugs made at facilities that do not comply with cGMP are "deemed to be adulterated" and, on that basis, may be denied entry into the United States.[704] Accordingly, because Apotex does not challenge the *substance* of FDA's findings or the legal *consequences* of those findings, it cannot contend that any additional *process* would have allowed it to export its admittedly adulterated drugs for resale in the United States. Here, as in *Genin*: "Due process, had it been accorded, would not have changed the result."[705]

307. Apotex also makes a passing attempt to distinguish *GAMI* on grounds that the case concerned the State's alleged failure to implement provisions of its own law, rather than "procedural" due process.[706] *GAMI*, however, discusses the broad scope of permissible administrative conduct under the customary international law minimum standard of treatment.[707] It thus also is on point.

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[702] Reply ¶¶ 435-36.

[703] *Id.* ¶¶ 5-8.

[704] *Id.*

[705] *Id.* ¶ 435.

[706] *Id.* ¶¶ 431, 437.

[707] *GAMI* Award ¶ 97 (drawing four conclusions for assessing regulatory action under Article 1105: "(1) The failure to fulfil the objectives of administrative regulations without more does not necessarily rise to a breach of international law. (2) A failure to satisfy requirements of national law does not necessarily violate international law.

308. More broadly, Apotex complains that the regulatory regime that existed *at the time* Apotex made its purported investment provides inadequate remedies to challenge FDA decisions, and as such constitutes a violation of Article 1105. *GAMI* also directly addressed this type of complaint in its discussion of Article 1105, stating: "To repeat: NAFTA arbitrators have no mandate to evaluate laws and regulations that predate the decision of a foreign investor to invest."[708] Moreover, although Apotex argues that *GAMI* is not relevant because it involves substantive decisions, not procedural ones, the *GAMI* award does not distinguish between procedural or substantive decisions in its discussion of the four principles relevant to determining whether regulatory action constituted a violation of Article 1105.[709] Apotex's attempted distinction thus is not one recognized by the *GAMI* tribunal. In any event, the procedures provided by the United States appear greater than those provided in any of the cases cited by Apotex.

iii. The Remaining Sources Cited by Apotex Do Not Purport to Establish a Rule of Customary International Law, and Thus Are Irrelevant

309. Having failed to find support in State practice and *opinio juris* or in the arbitral awards it cites, Apotex has cast a wide net for possible authority. Apotex's catch, however, is rather meager, and none of the sources it cites support the proposition that a country must provide the procedural safeguards (including an oral hearing) *before* a State may bar the importation of adulterated drugs.

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(3) Proof of a good faith effort by the Government to achieve the objectives of its laws and regulations may counter-balance instances of disregard of legal or regulatory requirements. (4) The record as a whole – not isolated events – determines whether there has been a breach of international law. It is in this light that GAMI's allegations with respect to Article 1105 fall to be examined.") [CLA-27]. In any event, Apotex also has alleged that FDA declined to follow its practice related to providing notice of the Import Alert to the foreign manufacturer. Memorial ¶ 111.

[708] *GAMI* Award ¶ 93 [CLA-27].

[709] *Id.* ¶ 97.

310. Apotex cites, for instance, the United Nations Declaration of the High-level Meeting of the General Assembly on the Rule of Law at the National and International Levels, which observes that "respect for and promotion of the rule of law and justice should guide all [States' and international organizations'] activities and accord predictability and legitimacy to their actions."[710] Apotex further cites a statement of the U.S. Attorney General supporting the declaration. The Attorney General reiterated the United States' commitment "to take steps to improve access to justice for those who cannot afford representation," and to remain "focused on launching a new domestic violence prevention initiative, strengthening safety net programs that help increase the availability of legal aid, and enhancing our focus on protecting the essential rights of women and girls."[711] Apotex has failed to explain how the United States' support in these areas has anything to do with a customary international law rule regarding States' ability to block importation of adulterated drugs or how those political statements relate to the standards under customary international law to protect covered investments.

311. Apotex further cites a decision of the European Court of Human Rights for the proposition that, "even when domestic administrative authorities enjoy wide discretion, due process rights must be observed."[712] This case, however, concerned the liberty interests of children being placed in public care.[713] Apotex itself "accepts that due process requirements

[710] Reply ¶ 419 n.672 (citing U.N. General Assembly Resolution A/RES/67/1 (Nov. 30, 2012) [CLA-499]) (emphasis omitted).

[711] *Id.* ¶ 418 n.670 (citing Attorney General Eric H. Holder, Jr., Remarks at the United Nations General Assembly – High-level Meeting on the Rule of Law, at 1-2 (Sept. 24, 2012) [CLA-595]).

[712] *Id.* ¶ 430 (citing *Johansen v. Norway*, no. 17383/90, ECHR 1996-III (Aug. 7, 1996) [CLA-517]).

[713] *Id.* n.689.

may be more stringent when liberty interests are implicated . . . than may be required in the administrative context."[714] The case, therefore, is not on point.

312. Apotex further cites various State Department reports as evidence of the United States' strong commitment to the rule of law internationally. Apotex notes, for instance, that the State Department criticized local authorities in Tajikistan for having given evictees a "cursory degree of due process."[715] One can readily agree that persons being evicted from their property should be given appropriate due process. Indeed, one can readily agree with the various other U.S. government statements quoted by Apotex concerning the rule of law, the sanctity of contracts, democratic governance, and arbitrary arrests and detention.[716] But none of these statements reveals anything about the minimum standard of treatment required of States, much less in connection with the importation of adulterated drugs.

313. Apotex also cites NAFTA Article 1804 and the provision of a U.S. bilateral investment treaty to demonstrate the United States' "commitment to due process and the rule of law in its treaty practice."[717] Apotex has not established that these two provisions reflect State practice or *opinio juris*, and thus they do not advance its cause.

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[714] *Id.* ¶ 421.

[715] *Id.* ¶ 418 n.671.

[716] Apotex cites the following U.S. government statements: "A strong rule of law tradition is necessary to build stable, political and economic environments that benefit all countries and protect citizens from unjust or capricious actions by government that interfere with their personal freedoms"; "The erosion of the rule of law and sanctity of contracts has had a chilling effect on business and on foreign direct investments"; "[L]ongstanding and renewed concerns regarding the stability of contractual rights and the regulatory environment diminish the attractiveness of prospective investments in some sectors"; "Sri Lanka [should] address outstanding issues of the rule of law, democratic governance, accountability, and reconciliation"; "[T]he arbitrary arrest and forced resignation of Mali's Interim Prime Minister . . . by members of the military junta . . . underline[s] the importance of the rule of law"; "[A]ll parties in Honduras [should] respect the constitutional order and the rule of law." *Id.*

[717] Reply ¶ 407; *see also* Memorial ¶ 463.

314. Further, the provisions Apotex cites are not part of the minimum standard of treatment obligation in these agreements, and are not subject to the investor-State dispute resolution mechanism in either agreement. Rather, they are subject to State-to-State arbitration.[718]

315. Neither of these provisions, moreover, set forth a "one-size-fits-all" rule reflecting an international standard. To the contrary, both refer to domestic procedures. Apotex cites, for example, provisions of the U.S.-Rwanda BIT as "*expressly incorporat[ing]* the due process provisions Apotex argues should have been accorded to it by FDA":[719]

> 'reasonable notice . . . when [an administrative] proceeding is initiated, including a description of the nature of the proceeding, a statement of the legal authority under which the proceeding is initiated, and a general description of any issues in controversy[,]' 'a reasonable opportunity to present facts and arguments in support of their positions prior to any final administrative action,' and impartial 'administrative tribunals or procedures for the purpose of the prompt review, and where warranted, correction of final administrative actions regarding matters covered by this Treaty.'[720]

316. But Apotex has omitted key language, making the obligations appear obligatory under the treaty. In fact, Article 11(4) clearly refers to domestic procedures that States *should* apply:

> 4. **Administrative Proceedings**
>
> With a view to administering in a consistent, impartial, and reasonable manner all measures referred to in Article 10(1)(a), each Party shall ensure that in its administrative proceedings applying such measures to particular covered investments or investors of the other Party in specific cases:
>
> (a) **wherever possible**, covered investments or investors of the other Party that are directly affected by a proceeding are provided reasonable notice, **in accordance with domestic procedures,** when a proceeding is initiated, including

[718] *See* NAFTA, Chapter 20, Section B, Dispute Settlement [RLA-259]; Treaty between the Government of the United States of America and the Government of the Republic of Rwanda Concerning the Encouragement and Reciprocal Protection of Investment, U.S.-Rwanda, art. 37 (Feb. 19, 2008), S. Treaty Doc. No. 110-23 ("U.S.-Rwanda BIT") [CLA-11].

[719] Reply ¶ 407 (emphasis added).

[720] *Id.* (quoting Article 11(4)-(5) of the U.S.-Rwanda BIT (brackets supplied by Apotex) [CLA-11]).

> a description of the nature of the proceeding, a statement of the legal authority under which the proceeding is initiated, and a general description of any issues in controversy;
>
> (b) such persons are afforded a reasonable opportunity to present facts and arguments in support of their positions prior to any final administrative action, **when time, the nature of the proceeding, and the public interest permit; and**
>
> (c) **its procedures are in accordance with domestic law**.[721]

Thus, in "administrative *proceedings*," "*wherever possible*," and "*in accordance with domestic procedures,"* the treaty parties have pledged certain procedural rights "*when time, the nature of the proceeding, and the public interest permit."*[722] The terms that Apotex omitted from its quotation are critical context for the reader.[723] They are, moreover, critical in this case, where time, the nature of the proceeding, and the public interest called for speedy action to block the importation of drugs deemed to be adulterated after Apotex refused to cease voluntarily exporting to the United States, followed by a later opportunity to challenge the products'

[721] U.S.-Rwanda BIT, art. 11(4) (brackets in original text) (emphases added) [CLA-11].

[722] *Id.* (emphases added).

[723] Even if Apotex had quoted the provision accurately, reference to three international investment agreements is not sufficient to show a rule of customary international law absent a showing of the requisite State practice and *opinio juris*. *See* Counter-Memorial ¶¶ 352-54 (citing authority on the establishment of a rule of customary international law). Apotex's failure to address *opinio juris* is particularly glaring with respect to the U.S.-Rwanda bilateral investment treaty, given that this agreement contains a customary international law annex, which specifically refers to the provisions in the respective agreements and which the Parties consider to reflect customary international law, whereas the "administrative proceedings" provision is not among them. U.S.-Rwanda BIT, Annex A [CLA-11]; The Dominican Republic – Central America – United States Free Trade Agreement, Annex 10-B, Aug. 5, 2004, 43 I.L.M. 514 ("CAFTA-DR") [CLA-9]. With respect to the third agreement, the NAFTA, Apotex's citation to Article 1804 contains caveats similar to those contained in the U.S.-Rwanda BIT. Reply ¶ 407 n.651. For this reason, and for reasons discussed above and in the U.S. Counter-Memorial, which Apotex does not dispute, nor even address, Apotex's reliance on this provision is irrelevant. Among other things, had the Parties wanted to make Article 1804 subject to investor-State arbitration, they would have included it within the scope of those arbitration procedures. They did not. It would be astonishing, then, if the very provisions the Parties had excluded from investor-State arbitration became subject to such arbitration via Article 1105. The third international investment agreement Apotex cites is the CAFTA-DR. Reply ¶ 409, n.653. For reasons explained at paragraph 371 of the U.S. Counter Memorial, this provision is not relevant to the dispute at issue here. Apotex claims to have established U.S. "treaty practice" by referring to three international agreements. *Id.* The United States, however, is party to many investment and trade agreements, and citing to three of them (even had they been accurately characterized) does not establish "treaty practice."

detention. Apotex's omission of these key terms is misleading and unacceptable in international adjudication.

317. Finally, in the absence of relevant arbitral awards to draw on, Apotex cites the *Restatement (Second) of the Foreign Relations Law of the United States*.[724] Section 181 of the *Restatement* lists eight "factors" that are "relevant to consider, among other factors" in determining whether a "trial or other proceeding" is fair.[725] Apotex has cherry-picked four of them, and from them pronounces a rule of customary international law.[726]

318. Apotex's reliance on the *Restatement* is misplaced in three respects. *First*, the eight factors listed in Section 181 (including the four identified by Apotex) expressly apply to "trials or other proceedings."[727] They do not purport to apply to all administrative decision making. If a State had to provide the full panoply of due process rights to every administrative decision affecting an individual's rights or interests, administrators simply could not perform their

[724] Reply ¶ 410.

[725] RESTATEMENT (SECOND) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 181 (1965) ("RESTATEMENT (SECOND)") [RLA-138].

[726] Reply ¶¶ 390, 439.

[727] RESTATEMENT (SECOND) § 181 [RLA-138]. Apotex asserts that the United States has said one thing about the definition of "proceeding" to this Tribunal, but has taken a "contradictory position" in a submission to a U.S. court. Reply ¶ 416. Those statements, however, show no inconsistency. The "import proceeding" discussed in the submission to the U.S. court refers to the detention of the goods *upon import*, not to the prior decision made to add certain electronic cigarettes to the Import Alert. *Smoking Everywhere, Inc. v. FDA*, No. 09-cv-771, Defendants' Memorandum in Opposition to Plaintiff's Motion for Preliminary Injunction, at 1 ("In the proceeding *following* [the plaintiff's] attempt to import two shipments of E-Cigarettes, FDA found that [the plaintiff's] product met the definition of both a drug and device under the Federal Food, Drug, and Cosmetic Act[.]") (emphasis added) [CLA-138]. The decision to amend an Import Alert does not constitute a proceeding, although that does not mean this decision might not later be used in an import proceeding if there is an actual shipment of an item falling within the scope of the Import Alert. Indeed, U.S. law provides for a proceeding in instances of detention without physical examination in the form of a detention hearing. *See* 21 U.S.C. § 381(a) (2011) (noting that the owner or consignee of food, drugs, devices, tobacco products, and cosmetics that have been denied entry has the right to appear before the Secretary of Health and Human services and to introduce testimony) [CLA-239]; 21 C.F.R. § 1.94 (2012) ("Hearing on refusal of admission") [CLA-245]; Counter-Memorial ¶ 381 (discussing same). Had Apotex chosen to avail itself of this proceeding, it could have presented testimony to dispute the determinations that gave rise to its inclusion on the Import Alert, but as discussed below in Part III(B)(3)(iv), Apotex declined this opportunity.

essential work. Apotex has not identified a single State that considers itself bound by international law to provide, for example, the right to "present witnesses and evidence" when making all administrative decisions affecting individuals.[728]

319. *Second*, even if Section 181 applied to all administrative decision making, it does not purport to require that a State provide all procedural rights *before* taking action. A State might decide, for instance, to revoke an export license before an item is exported, and provide any procedural safeguards *after* the decision had been made to revoke the license. Here, as discussed below, Apotex had several avenues to challenge the detention of its products and the Import Alert itself after its issuance, but failed to avail itself of any of them.

320. *Third*, as stated in the Counter-Memorial, the *Restatement* is not a source of customary international law.[729] It is a private organization's attempt to restate U.S. law, and it does not represent the views of the U.S. government.[730] The U.S. government accepts some provisions of the *Restatement* as accurately stating the law, while disagreeing that other provisions do so.[731]

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[728] Reply ¶¶ 390, 439.

[729] Counter-Memorial ¶ 369.

[730] RESTATEMENT (SECOND), Preface, XI ("This work has no official standing as a statement of the position of the United States.") [RLA-291]; RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES, Foreword, IX (1987) ("As was said of the prior Restatement, it is 'in no sense an official document of the United States.' In a number of particulars the formulations in this Restatement are at a variance with positions that have been taken by the United States Government.") [RLA-293].

[731] *See, e.g.*, *Permanent Mission of India to the United Nations v. City of New York, New York*, Brief for the United States as Amicus Curiae Supporting Petitioners, 2007 WL 736599, at *11, n.8 ("The Third Restatement [on Foreign Relations Law] asserts that, in addition to 'controversies relating to rights of ownership, possession, occupation, or use,' the immovable property exception extends 'as well' to 'controversies concerning payment of rent, taxes, and other fees concerning' foreign state property. That statement, for which the Third Restatement offers no authority, appears to be aspirational rather than a statement of existing law.") (citation omitted) [RLA-255]; *Kingdom of Spain v. Estate of Claude Cassirer*, Brief for the United States as Amicus Curiae, 2011 WL 2135028, at *13 ("Even assuming that the drafters of the Restatement intended to address, *sub silentio*, jurisdiction over a nonexpropriating state, petitioners cite no authority for the proposition that the text of the Restatement (and its commentary) should control over the quite different and broad text of the FSIA itself.") [RLA-241]. Apotex pointed to the reliance on the *Restatement* in a dissenting opinion of a U.S. Supreme Court Justice. Reply ¶ 403, n.643 (citing *Hartford Fire Ins. Co. v. California*, 509 U.S. 764, 818 (1993) (Scalia J., dissenting) [CLA-533]). But Apotex failed to mention

The *Restatement* principle (and related commentary) cited by Apotex do not purport to express the customary international law rule claimed by Apotex.[732]

3. The United States Accorded Apotex Extensive Due Process

321. Although not based on a rule of customary international law, U.S. law provides numerous mechanisms for Apotex to have protested or challenged FDA's actions. Apotex, however, failed to avail itself of them. Apotex never protested or challenged FDA's cGMP determinations through available mechanisms; never protested or challenged the addition of drugs from Etobicoke and Signet to the Import Alert through internal FDA challenge mechanisms; never availed itself of an administrative hearing to challenge the detention of its drugs despite the clear notification of the right to a hearing in the detention notice itself; and never commenced judicial proceedings to challenge FDA's actions. Apotex now argues that the United States bears the burden of proving that U.S. law could have provided Apotex the relief it sought, *if Apotex actually had sought that relief*. This argument is not only specious, but directly contradicts Apotex's previous argument. In the *Apotex I-II* claims, when discussing the judicial finality doctrine, Apotex acknowledged that the claimant itself must demonstrate the "obvious futility" of any domestic remedies.[733] Here, Apotex has failed to demonstrate the "obvious futility" of any, let alone all, of the many remedies available to it under U.S. law.

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the justice's observation that the *Restatement* "standard appears fairly supported in the decisions of the [U.S. Supreme] Court construing international choice-of-law principles . . . and in the decisions of other federal courts." *Id.*

[732] *See, e.g.*, *United States v. Stuart*, 489 U.S. 353, 375 (1989) (Scalia J., concurring) (noting that a particular provision of the *Restatement* "must be regarded as a proposal for change rather than a restatement of existing doctrine, since the commentary refers not to a single case, of this or any other United States court, that has employed the practice") (citations omitted) [RLA-257].

[733] *Apotex I-II*, Claimant Apotex Inc.'s Rejoinder Memorial on Respondent's Reply on Objections to Jurisdiction ¶ 46 (Dec. 16, 2011) (arguing for the obvious futility standard) [RLA-266]; *Apotex I-II*, Claimant Apotex Inc.'s Counter-Memorial on Respondent's Objections to Jurisdiction ¶ 89 (Aug. 1, 2011) (arguing that it was obviously futile to exhaust local remedies) [RLA-102]; *see also Apotex I-II*, Transcript of Hearing on Jurisdiction and

322. After FDA inspected Apotex's Etobicoke facility, Apotex provided a written letter responding to the Form 483 listing Apotex's cGMP violations.[734] After the warning letter for Etobicoke was issued on June 25, 2009,[735] FDA held a teleconference with Apotex regarding issues that were noted in the July 8 warning letter, and Apotex again responded in writing on July 17.[736] Following the Signet inspection, Apotex and FDA held another teleconference on August 17.

323. In these communications and others, Apotex did not protest or challenge the majority of FDA's cGMP findings. Nor did Apotex ever challenge the cGMP findings through the citizen petition and other mechanisms available for such a challenge, despite their widespread use and availability.[737] Instead, Apotex acknowledged the serious problems with its manufacturing practice and retained several outside consultants to help fix them.[738]

324. 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. Instead, it recalled problem drugs from the U.S. market and pledged additional corrective actions.

Admissibility, at 267 (Feb. 15, 2012) (Apotex's counsel: "I don't think there is a lot of dispute about what the finality requirement is [obvious futility]. The major dispute seems to be, *did Apotex meet it*[.]") (emphasis added) [R-204].

[734] *See* Apotex Responses to 2008 Etobicoke Form 483 (Jan. 30, 2009) [C-37].

[735] *See* 2009 Etobicoke Warning Letter (June 25, 2009) [C-41].

[736] *See* letter from L. Lovelock to R. Friedman (July 17, 2009) [C-44]; *id.* at 1 (noting the conference call between FDA and Apotex regarding Apotex's system for Batch Control on July 8, 2009).

[737] Vodra Report ¶ 103 (noting that he often encouraged clients to use the citizen petition mechanism).

[738] *See, e.g.,* FDA, Minutes of Teleconference with Apotex (Aug. 17, 2009) [R-43].

325. After U.S. officials detained without physical examination drug shipments from Etobicoke and Signet, Apotex declined FDA's express invitation to provide oral or written testimony for a detention hearing.[739] Notice of this detention hearing was included in the notice of detention itself.[740] Apotex, in fact, never even responded to FDA's detention notice.

326. Finally, Apotex did not sue FDA in U.S. courts for any claim related to the Import Alert. For a company that claims to spend $[redacted] million a year on U.S. litigation,[741] and even touts litigation as part of its "business model,"[742] Apotex's failure to assert any right in any U.S. forum is telling.

327. None of Apotex's contemporaneous actions indicate any disagreement with the substance of FDA's decision or the process employed by FDA in implementing those actions. Apotex's *post hoc* arguments must be viewed in light of this uncontroverted fact.

328. Apotex now seeks to excuse its failure to challenge any aspect of FDA's enforcement action against Etobicoke and Signet. Apotex argues that none of the remedies available under U.S. law would have been adequate to provide Apotex the relief it sought, *if Apotex actually had sought that relief*. Apotex even argues that the United States is required to prove the effectiveness of remedies Apotex might have sought. Thus, in Apotex's view, when a party has

[739] *See* Apotex Inc./FDA Meeting Minutes (Sept. 3, 2009) ("Apotex opened the meeting by asking for clarification on what the import alert meant in terms of product entering the United States. FDA clarified that this meant that all shipments would be held at the border. Appeal could be made to the district in which the shipments were being held to have them released on a case by case basis but that this would require showing that the issue(s) resulting in the Import Alert had been addressed.") [C-386].

[740] *See* 21 C.F.R. § 1.94 (2012) [CLA-245]; *see also* Counter-Memorial ¶¶ 102-04, n.235-37 (citing examples, including the notice: "You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.").

[741] Memorial ¶ 41.

[742] *Id.* ¶ 41.

a dispute with a State, it can file a claim alleging the lack of due process after having ignored all the legal process provided for by the laws of that State, and then claim that the burden is on the State to prove that the legal process the claimant ignored would have been effective in resolving the dispute. That is not the state of international law. Apotex has misstated both the standard for when local remedies need not be exhausted and the party on which the burden of proof falls.

329. As Apotex previously acknowledged, the applicable international law standard is whether domestic remedies would have been "obviously futile."[743] That is, as the *Apotex I-II* tribunal recently confirmed, the standard

> requires an actual unavailability of recourse, or recourse that is proven to be '*manifestly ineffective*' – which, in turn, requires more than one side simply proffering its best estimate or prediction as to its likely prospects of success, if available recourse had been pursued.[744]

The tribunal thus concluded that it is for the claimant to prove "unavailability" or "manifest ineffectiveness," and not for the respondent to prove "availability" or "effectiveness."[745]

330. The tribunal continued:

> It is not enough, therefore, to allege the "*absence of a reasonable prospect of success or the improbability of success, which are both less strict tests*." In the (frequently quoted) words of Professor Borchard, a claimant is not:
>
> > "relieved from exhausting his local remedies by alleging . . . a pretended impossibility or uselessness of action before the local courts."[746]

[743] *Apotex I-II* Award ¶¶ 257, 279 (noting party agreement on the "obvious futility" standard, and that the standard's "threshold is a high one") [RLA-263]; *see also Apotex I-II*, Claimant Apotex Inc.'s Rejoinder Memorial on Respondent's Reply on Objections to Jurisdiction ¶ 46 (Dec. 16, 2011) (arguing for the obvious futility standard) [RLA-266]; *Apotex I-II*, Claimant Apotex Inc.'s Counter-Memorial on Respondent's Objections to Jurisdiction ¶ 89 (Aug. 1, 2011) (arguing that it was obviously futile to exhaust local remedies) [RLA-102].

[744] *Apotex I-II* Award ¶ 284 (June 14, 2003) (emphases in original) (citations omitted) [RLA-263].

[745] *Id.* ¶ 293 ("[T]he Tribunal does not consider that *Apotex has met* the 'obvious futility' exception here.") (emphasis added).

331. Thus, not only is the burden on the claimant, but that burden is not easily met. As Judge Lauterpacht stated in *Norwegian Loans*, "however contingent and theoretical these remedies may be, an attempt ought to have been made to exhaust them."[747]

332. United States law makes available all four processes that Apotex alleges are required under customary international law: (1) an impartial administrative authority; (2) adequate information with respect to the nature of the proceedings so as to permit the alien to present his claim or defense; (3) reasonable opportunity to contest evidence against him; and (4) reasonable opportunity to obtain and present witnesses and evidence in his own behalf.[748]

i. The United States Provided Apotex with an Impartial Administrative Authority

333. The U.S. Counter-Memorial and accompanying statement of Dr. Carmelo Rosa outlined the process by which FDA makes enforcement decisions for drugs from facilities that appear to be adulterated for cGMP violations.[749] Multiple offices participate in the process.[750] The onsite investigators serve as expert fact-finders and record their observations on a standard form (FDA 483 Inspectional Observations).[751] CDER reviews investigator findings and, applying a risk-based approach, decides whether to recommend addition to the Import Alert or other action.[752]

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[746] *Id.* ¶ 285 (emphasis in original) (citing E. BORCHARD, THE DIPLOMATIC PROTECTION OF CITIZENS ABROAD 824 (1916)).

[747] *Norwegian Loans (France v. Norway)*, 1957 I.C.J. 9, 39, Separate Opinion of Judge Lauterpacht [RLA-274].

[748] Reply ¶ 439.

[749] Counter-Memorial ¶¶ 99-101; First Rosa Statement ¶¶ 10-23.

[750] First Rosa Statement ¶¶ 10-23, 39-40, 62 (noting the roles of the various FDA offices, including CDER, OGC, OMPTO, ORA and DIOP).

[751] *Id.* ¶¶ 16-17.

[752] *Id.* ¶¶ 20-23.

DIOP reviews CDER's recommendations for approval.[753] The Office of Chief Counsel advises on applicable legal considerations.[754] FDA district offices determine whether the drugs meet the statutory standard for detention and refusal of admission.[755] The various checks and balances help ensure that FDA acts as an impartial administrative authority. Apotex has not alleged that any of these individuals or offices had any relationship with Apotex or its competitors, or had any interests other than public health that would have impacted the decision maker's impartiality.

334. Apotex erroneously asserts that DIOP is not impartial because it "*generally* adopts without question recommendations from CDER[.]"[756] This does not render DIOP biased. Courts, after all, *generally* defer to agency decisions in some contexts, but that hardly makes those courts partial.[757] In any event, as Dr. Rosa testified, FDA has many checks and balances built into its procedures.[758] Apotex itself, in fact, benefited from those checks and balances. Mr. Goga, an FDA investigator, testified that he recommended *against* removing Etobicoke and Signet from the Import Alert following the 2011 reinspections of those facilities, but DIOP

[753] *Id.* ¶¶ 23, 62.

[754] *See, e.g., id.* ¶ 40.

[755] Counter-Memorial ¶¶ 99-101; First Rosa Statement ¶¶ 59-62; *see also* First Bradshaw Report ¶ 102.

[756] Reply ¶ 440 (emphasis added).

[757] *See, e.g., Chevron, USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984) ("[T]he principle of deference to administrative interpretations 'has been consistently followed by this Court whenever decision as to the meaning or reach of a statute has involved reconciling conflicting policies, and a full understanding of the force of the statutory policy in the given situation has depended upon more than ordinary knowledge respecting the matters subjected to agency regulations.'") (citation omitted) [RLA-237]; *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) ("We consider that the rulings, interpretations and opinions of the Administrator under this Act, while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.") [RLA-253].

[758] First Rosa Statement ¶¶ 11-23, 59-62 (describing both the inspections of the facilities, as well as the review at FDA headquarters).

accepted CDER's recommendation to lift the Import Alert for both facilities.[759] Apotex cannot credibly claim that FDA was in any way biased against Apotex in its decision making.

ii. The United States Provided Apotex Ample Information on the Nature of the Enforcement Action

335. Apotex states in its Reply, *for the first time*, that FDA "never presented Apotex with reasons for its adoption of the Import Alert."[760] This statement is baffling. 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."[761] Further, the Notices of Detention FDA issued regarding Apotex's products confirmed that the products were being detained because of cGMP deficiencies.[762]

336. Further, FDA repeatedly explained, in other documents and at other times, the reasons that Etobicoke and Signet had failed to meet cGMP and thus had been added to the Import Alert. First, FDA investigators met daily with Apotex during the course of the inspections of Etobicoke and Signet, and presented their cGMP findings at those daily meetings.[763] The investigators presented their most significant cGMP observations (in writing and verbally) at closeout meetings following the Etobicoke and Signet inspections. Second, FDA furnished Apotex with

[759] Goga Statement ¶¶ 29-30. Apotex appears to confuse "impartial" with "independent." "Impartial" is defined as "unbiased; disinterested." BLACK'S LAW DICTIONARY 9th ed. (2009) [RLA-301]. Apotex has not alleged that FDA personnel were biased or interested parties.

[760] Reply ¶ 448.

[761] *See* Memorial at 53, n.251 (noting that Import Alert "Number 66-40 corresponds to 'Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug CGMPs'").

[762] *E.g.,* Notice of FDA Action re Entry EG6-1768425-3, Notice No. 2 at 2 (Sept. 4, 2009) ("It appears that the methods used in, or the facilities or controls used for, manufacture, processing, packing, or holding do not conform to or *are not operated or administered in conformity with current good manufacturing practices*.") (emphasis added) [R-44].

[763] *See* Memorial, at 42, n.184 (citing Apotex Inc. internal emails for December 10, 11, 12, 15, 16, 17, 18 and 19, 2008 regarding the 2008 Etobicoke inspection); *id.* at 46, n.207, 209-217, 220-222 (citing internal Apotex Inc. emails for Days 1, 2, 5-7, and 10-13 of the 2009 Signet inspection).

the narrative Establishment Inspection Reports (EIRs), which further elaborated on cGMP problems in significant detail. Third, FDA sent Apotex warning letters for both Etobicoke and Signet, highlighting the most significant cGMP violations. FDA's warning letter regarding Etobicoke predated the Import Alert and apprised Apotex that, because of cGMP violations at Etobicoke, drugs from that facility "could be subject to refusal of admission."[764] Fourth, FDA held numerous teleconferences with Apotex, including on July 9 and August 17, 2009, during which FDA presented its most serious concerns. Finally, FDA regularly discussed these issues with Apotex and its third-party consultants by telephone, by email, and in numerous meetings following Apotex's addition to the Import Alert. For more than a year, FDA was in close communication with Apotex and its consultants,[765] explaining in detail why Apotex had been added to the Import Alert, and what it needed to demonstrate to be removed from the Import Alert.[766]

337. By applying to manufacture drugs for the U.S. market, moreover, Apotex agreed to abide by U.S. law, including U.S. regulations governing cGMP. These statutes and regulations long predate Apotex's alleged "investment" in the United States.

[764] 2009 Etobicoke Warning Letter at 6 [C-41].

[765] Apotex characterized the communication as "continuous." Reply ¶¶ 483, 493; *see also supra* n.174.

[766] Apotex argues that the Form 483s, EIRs, the Warning Letter, and the FDA's many meetings and telephone calls with Apotex did not constitute notice to Apotex of the reasons for the Import Alert because this "conflates inspectional cGMP observations with the decision to issue the Import Alert," and because the Form 483 does "not represent a final agency determination regarding [a company's] compliance.'" Reply ¶ 449. But it is Apotex that is conflating the inspectional observations on the Form 483s with the reasons for the Import Alert that the FDA communicated to Apotex in the many meetings and phone calls they had with each other after Apotex was placed on Import Alert. Although observations listed on a Form 483 do not constitute final agency action, FDA repeatedly informed Apotex of the reasons for the Import Alert and what Apotex needed to do to be removed from it. Supplemental Rosa Statement ¶ 26.

338. The United States, moreover, has made available online, and free of charge, a vast store of relevant information – in statutes, regulations, procedural manuals, forms, frequently-asked questions, warning letters, and import alerts – for manufacturers such as Apotex. The United States cannot be faulted for Apotex's failure to have availed itself of this easily accessible, pertinent information regarding the requirements of U.S. law and the consequences of delinquency.[767]

339. Consistent with its practice regarding Import Alerts,[768] FDA did not inform Apotex of its deliberations about whether to add Apotex's facilities to the Import Alert prior to making that decision.[769] This preserved the agency's decision-making process and also prevented Apotex from having flooded the market with its adulterated drugs. This was no idle concern. As the U.S. Counter-Memorial observed, Apotex is capable of importing a large amount of products into the United States very quickly.[770]

340. Although Apotex asserts that it would not have flooded the market with adulterated drugs, FDA's policy naturally is not specific to Apotex, but applies to all companies. If customary international law really did require advance notice and a hearing before a State could flag drug products it believes are subject to exclusion from domestic commerce because they appear to be adulterated, then States would be powerless to take meaningful measures to protect

[767] Apotex also retained experienced counsel, including Buc & Beardsley, who advised Apotex regarding its violations of U.S. law, and who were well placed to advise Apotex of the reasons it had been placed on the Import Alert. *See, e.g.,* letter from C. Shepard, Buc & Beardsley LLP, to J. Yuen, Jeff Yuen & Associates, Inc. re Agreement for Consulting Services Relative to Apotex, Inc. (Sept. 22, 2009) [R-125].

[768] First Rosa Statement ¶ 23; Supplemental Rosa Statement ¶ 25.

[769] Supplemental Rosa Statement ¶ 25.

[770] Counter-Memorial ¶ 378 (noting that in 2006 Apotex exported to the United States a six months' supply of a drug in the brief 23-day period between Apotex's launch of a product, a competitor's request for preliminary injunction that followed shortly thereafter, and the issuance of that injunction). Apotex failed to address this issue in its Reply.

public health pending the outcome of an administrative hearing.[771] That proposition is inimical to public health and utterly unsupported in State practice. In any event, the fact that Apotex was not apprised in advance of its addition to the Import Alert does not mean that Apotex was unaware of its violations of U.S. law or the consequences of those violations.

iii. The United States Provided Apotex with a Reasonable Opportunity to Contest Evidence and a Reasonable Opportunity to Present Witnesses and Evidence

341. The U.S. Counter-Memorial discussed the avenues available to Apotex to contest evidence against it and to present witnesses and evidence on its behalf. Apotex continues to argue that it had no "meaningful route" to challenge FDA's enforcement action.[772] In fact, Apotex had a variety of meaningful routes, but chose not to utilize any of them.

iv. The Remedies Provided by U.S. Law Were Adequate by any Standard

342. *District Hearing*: The primary route that Apotex had to challenge the FDA decision in this case was through a hearing in the district that detained Apotex's goods.[773] The section of the FD&C Act that authorizes FDA to prevent the importation of adulterated drugs also provides a right to a hearing, so the affected owner or consignee can present testimony – orally or in writing[774] – to challenge FDA import decisions.[775] The regulations also allow the owner or consignee to submit an application to perform actions that would bring the adulterated articles

[771] Contrary to Apotex's suggestion, FDA did not have the capacity then to monitor "all shipments into the US by reviewing import forms customs brokers submit in advance of all shipments." Reply ¶ 446; *see* Supplemental Rosa Statement ¶ 25.

[772] Reply ¶ 452.

[773] Vodra Report ¶¶ 92-97.

[774] 21 C.F.R. § 1.94(a) [CLA-245].

[775] 21 U.S.C. § 381(a) [CLA-239].

into compliance, and submit a proposal for reconditioning.[776] Thus, the very law authorizing FDA to protect public health also provides more than adequate process to allow an owner or consignee to challenge the FDA in the event the trader believes any mistakes have been made.

343. Although Apotex's own evidence shows that it was informed of its right to such a hearing,[777] it never invoked its right to present testimony or other evidence. Apotex alleges that this was because the hearing "could not have provided any effective relief because FDA practice does not grant the hearing officer the discretion to lift the Import Alert absent re-inspection."[778] This misstates FDA practice, which allows appeals to the Center responsible for the detained article.[779] If Apotex disagreed with the results of the hearing, it had the right to appeal the decision to the decision maker's supervisor.[780] Indeed, Apotex could have utilized its right of appeal all the way up to the FDA Commissioner.[781] Although Apotex argues (without evidence) that CDER was not impartial, Apotex failed to invoke these procedures, which ultimately would have put the decision before an individual higher in the FDA hierarchy than CDER.[782] Further,

[776] 21 C.F.R. § 1.94(b) [CLA-245].

[777] *See, e.g.,* Notice of FDA Action re Entry Number EG6-1768425-3, Notice Number 2, at 2 (Sept. 4, 2009) ("You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. The testimony must be provided to FDA on or before the dates shown above.") [C-84].

[778] Reply ¶ 495.

[779] FDA, *Regulatory Procedures Manual* § 9-8, at 9-35 ("If the question arises, the respondent should be made aware of their rights of appeal to a higher level of review in the agency, including to the specific Center responsible for the detained article, to the Associate Commissioner for Regulatory Affairs, to the Commissioner of FDA, to the Secretary of Health and Human Services, and to file legal actions with the court.") [CLA-309].

[780] 21 C.F.R. § 10.75 [RLA-161].

[781] *Id.*

[782] First Bradshaw Report ¶ 91 ("If an issue arises at an import hearing as to the hearing officer's prejudice or pre-judgment, the respondent should be informed of its right to 'appeal to a higher level of review in the agency, including to the specific Center responsible for the detained article, to the Associate Commissioner for Regulatory Affairs, to the Commissioner of FDA, to the Secretary of Health and Human Services, and to file legal actions with the court.'") (quoting FDA, *Regulatory Procedures Manual* § 9-8, at 9-35 (2011) [CLA-310]).

once administrative review is exhausted, a claimant can potentially seek review in the U.S. court system, based on the record established in the agency proceeding.[783]

344. Moreover, Apotex could have invoked its right to a district hearing and subsequent appeal at any time. In other words, if Apotex agreed that it was out of cGMP compliance at the time of the FDA inspection, but believed that due to subsequent changes it later came into compliance, it could have attempted to ship product to the United States, and invoked its right to a hearing when the products were detained to establish their admissibility.[784] During such a hearing, Apotex could have contested the reasons for the detention, which would likely have been based on the Import Alert, by presenting evidence that it had come into compliance.[785] But Apotex never did so.

345. Far from being "obviously futile," the district hearing would have provided Apotex with an effective and meaningful opportunity to make its case. Apotex simply chose not to engage this process, presumably because Apotex *accepted* FDA's conclusions about the cGMP violations. Apotex expressly agreed with FDA that its cGMP violations were "significant."[786] Apotex had informed FDA that it was taking steps to return to compliance with U.S. law. Apotex hired several cGMP consultants, who also agreed with FDA's cGMP conclusions.[787] The "obvious futility" standard cannot be met if the alleged futility is due to the fact that the

[783] *See* 5 U.S.C. §§ 701-06 (2012) [RLA-298].

[784] Vodra Report ¶¶ 94, 100.

[785] *See generally* FDA, *Regulatory Procedures Manual* § 9-8 (2009) [CLA-309].

[786] FDA, Minutes of Teleconference with Apotex (Aug. 17, 2009) [R-43].

[787] First Rosa Statement ¶ 69; Jeff Yuen & Associates, Inc., Final Summary Report for Apotex Corrective Action Plan Audit, at 2 (Mar. 17, 2010) [C-137] ("confirm[ing] that system level improvements were needed for all six [cGMP] systems").

Claimant contemporaneously agreed with the State on the merits. Even today, Apotex does not contend that the FDA's determinations were wrong.[788]

346. *Administrative Appeals Process*: Apotex had other routes available to effectively challenge FDA's conclusions. For example, it could have *appealed* any FDA decision to the supervisor of the person responsible for making that decision, without even having to go through the district hearing process.[789] FDA regulations allow an interested person outside the FDA to raise for review any decision by an FDA employee with the supervisor of that employee.[790] Apotex mischaracterizes this process as one of *reconsideration* instead of *appeal*, and argues that "reconsideration" is not required to exhaust local remedies.[791] "Reconsideration" involves a second consideration of a matter by the same decision maker,[792] whereas "appeal" involves having the decision reviewed by a higher authority.[793] Apotex's authority discussing

[788] Reply ¶¶ 5-8.

[789] Vodra Report ¶ 104.

[790] 21 C.F.R. § 10.75(a)(3) [RLA-161].

[791] Reply ¶¶ 473-83. *But see Generation Ukraine Inc. v. Ukraine*, ICSID Case No. ARB/00/9, Award ¶ 20.30 (Sept. 15, 2003) ("[I]t is not enough for an investor to seize upon an act of maladministration, no matter how low the level of the relevant governmental authority; to abandon his investment without any effort at overturning the administrative fault; and thus to claim an international delict on the theory that there had been an uncompensated virtual expropriation. In such instances, an international tribunal may deem that the failure to seek redress from national authorities disqualifies the international claim, not because there is a requirement of *exhaustion* of local remedies but because the very reality of conduct tantamount to expropriation is doubtful in the absence of a *reasonable* – not necessarily exhaustive – effort by the investor to obtain correction.") (emphasis in original) [RLA-268].

[792] *See, e.g., McKnight v. General Motors Corp.* 973 F.2d 1366, 1369 (7th Cir. 1992) ("As Black's dictionary defines it (and as we used the term in *McKnight II*), 'reconsideration implies reexamination, and possibly a different decision *by the entity that initially decided it.*'") (emphasis added) [RLA-245].

[793] For example, at the International Criminal Court, appeals are made to the Appeals Chamber, not resubmitted to the Trial Chamber. Rome Statute of the International Criminal Court, arts. 81-84 [RLA-260], and ICC Rules of Procedure and Evidence, Rules 149-61 [RLA-302]. Additionally, at the WTO, appeals are heard by the Appellate Body, not resubmitted to the original panel that first ruled on the dispute. *See* Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 17 [RLA-303], and more generally, *Dispute Settlement, Appellate Body*. [R-233].

"reconsideration" is irrelevant to the discussion of Apotex's right to appeal under FDA regulations.[794]

347. Apotex further argues that the right to appeal is "insufficient under international law," because it is within the absolute discretion of the agency, appeals to the grace of the executive, and lacks legal standards governing the decision.[795] This is wrong. Although FDA takes the position that its decisions about whether to take enforcement action are not reviewable, Apotex could have challenged FDA's cGMP determinations. FDA's cGMP standards are set forth in its regulations, and provide objective standards for decision makers.[796] Apotex could have based its appeal on regulations setting forth standards applying to all drug manufacturers, not on the grace of the executive. Additionally, FDA publishes guidance for industry explaining its dispute-resolution process for FDA's cGMP conclusions.[797]

348. Apotex also argues this right to appeal is insufficient because it "goes through"[798] the same office that rendered the initial decision, and that that office was "not impartial."[799] If by "goes through," Apotex means that the office which made the initial decision provides its input

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[794] Apotex cites, for example, the *Ahmadou Sadio Diallo* case to support its argument that it need not have exercised its right to appeal under 21. C.F.R. § 10.75 to exhaust local remedies. Reply ¶ 459, n.740 (citing *Ahmadou Sadio Diallo* (Guinea v. Democratic Republic of the Congo), 2007 I.C.J. (May 24) [CLA-510]). That case, however, involved an argument that a second request for consideration should have been made to *the same person* (the Prime Minister), and not to a higher authority. *Diallo* ¶¶ 15, 47 [CLA-510]. Thus, the case is irrelevant here, as the right at issue is one of appeal, not reconsideration.

[795] Reply ¶ 474.

[796] For drugs, the cGMP regulations are found in 21 C.F.R. Pts. 210-12, 225 and 226 [RLA-296]. Other regulations also apply to drugs, such as post-marketing reporting requirements in 21 C.F.R. § 314.81 (b)(1) (requiring NDA holders to file Field Alert Reports within three days) [CLA-273]; 21 C.F.R. § 314.98 (extending certain post-marketing requirements to ANDA holders) [CLA-274].

[797] *See* "Guidance for Industry, Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP" (Jan. 2006) [RLA-140].

[798] Reply ¶ 480.

[799] *Id.* ¶¶ 474, 480.

to the higher authority deciding the appeal, Apotex is correct. There is nothing improper about this. In fact, within and outside the drug context, it is common practice for decision makers considering an appeal (be they courts, administrative authorities, or any other authority) to consider the rationale for the decision that is being appealed. This is not contrary to customary international law. Nor does it mean that the new decision maker would have lacked impartiality. In fact, one would expect the new decision maker to have expertise with respect to the decision. But expertise should not be confused with partiality or bias.

349. Apotex also argues the appeal mechanism is insufficient because "there is no ability to offer new evidence, present witnesses, or contest evidence."[800] This is wrong. Although the regulations state that the supervisor's review must be based on the information in the administrative file,[801] this simply reflects standard appeal practice, where an appeal must be based on the record below. Unlike the appeal rules one might find in use by a court, however, the regulations specifically contemplate that new information may be presented, but simply require that if such is the case, the decision be returned to the original decision maker so it can consider the new information.[802] This allows the office with the technical expertise to consider the new information and decide whether a different decision is warranted. After a subsequent decision is made by the relevant office, the right to appeal still exists. There is nothing contrary to customary international law about this.

[800] *Id.* ¶ 474.

[801] 21 C.F.R. § 10.75(d) [RLA-161].

[802] *Id.*

350. Apotex next argues that it could not have appealed the decision because it "never received notice of the Import Alert or the information upon which the Import Alert was based."[803] This is nonsense. As discussed above, Apotex received both.[804]

351. Apotex also asserts that there is no time limit in which the decision maker must decide the appeal, complaining that "Agency guidance documents suggest only that 'the Official should make all reasonable efforts to resolve the dispute as expeditiously as possible, taking into account available resources.'"[805] It is hard to understand how guidance urging "reasonable efforts" to act expeditiously renders the process "ineffective."

352. Finally, Apotex argues that it "essentially partook in the process offered by 21 C.F.R. § 10.75 through its continuous discussions with the relevant FDA officials,"[806] while simultaneously arguing that these officials never told Apotex of the reasons for the Import Alert.[807] But Apotex has failed to point to any application or other evidence showing that it appealed any FDA decision. Although Apotex engaged in continuous discussions with the *same* FDA officials involved in the initial decision, Apotex never engaged the appeals process as set forth by section 10.75 to appeal to these officials' supervisors. Moreover, in the discussions it did have with FDA officials, Apotex never once challenged FDA's cGMP findings or the imposition of the Import Alert.

[803] Reply ¶ 481.

[804] *See supra* ¶¶ 74-86, 335-40.

[805] Reply ¶ 482.

[806] *Id.* ¶ 483.

[807] *Id.* ¶ 448.

353. *Citizen Petition*: Another route Apotex could have taken to dispute FDA's decision was to file a citizen petition.[808] United States law permits a citizen petition with FDA, asking it, among other things, to "order, or take or refrain from taking any other form of administrative action."[809] A citizen petition would have allowed Apotex to take any objections to FDA decisions directly to the FDA Commissioner.[810] Again, Apotex chose not to do so.

354. Apotex argues that this process was insufficient, complaining that a "petitioner is required to submit a full statement of the factual and legal grounds on which the petitioner relies" and that the petition would be "available for public examination and copying."[811] For the appeals process discussed above, by contrast, Apotex complained (incorrectly) that it would *not* be allowed to submit new information. It appears that no legal process can be designed that satisfies Apotex's view of the due process required under customary international law.

355. As for the requirement that the petition be publicly available, FDA does allow certain confidential information to be withheld from public display.[812] It is hard to understand, however, how the transparency of other, nonconfidential information could be contrary to customary international law. Apotex claimed in its Memorial that customary international law required that Apotex be able to challenge the FDA's decision in a U.S. court,[813] which also would have entailed making nonconfidential documents available for public examination and copying.

[808] 21 C.F.R. §§ 10.25(a), 10.30 [RLA-159].

[809] 21 C.F.R. § 10.25(a) [RLA-159].

[810] *Id.*

[811] Reply ¶ 484.

[812] 21 C.F.R. § 10.20(j) [CLA-565].

[813] Memorial ¶ 466.

Apotex apparently did not want to expose the details of its cGMP violations to the public, just as it sought to hide that information in Canada and Australia.[814]

356. Apotex further argues that, "when the decision-maker has absolute and unfettered discretion, the remedy is ineffective under international law" and that "[t]here are no standards or principles that guide this decision."[815] As the United States explained above,[816] this is wrong. The legal standards are provided in the cGMP regulations.[817] The agency's exercise of discretion, contrary to Apotex's allegations, is not unbounded by the rule of law.

357. Apotex argues that it need not have exhausted this citizen petition remedy because "the relief granted by the citizen petition *does not necessarily* result in a binding decision," as the Commissioner is authorized to "grant or deny the petition, or grant such other relief or take other action as the petition warrants."[818] Simply because the decision *might* have resulted in a non-binding decision does not mean that it *would* have resulted in such a decision. Indeed, if the Commissioner had found Apotex's facilities cGMP-compliant, that decision *would have* bound those in FDA below. Having ignored this route to challenge the decisions at issue here, Apotex should not now be able to speculate that a non-binding decision *might* have been issued. The "obvious futility" standard is much higher than that.

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[814] *See* email from R. Millichamp to C. Baxter (Sept. 11, 2009) ("This will not go to any website or publication that is accessible to consumers, customers, competitors media etc. in Australia. Keep it that way also in Canada please.") [C-95].

[815] Reply ¶ 487.

[816] *See supra* ¶ 347.

[817] Apotex also incorporates by reference all its arguments regarding the appeals route under 21 C.F.R. § 10.75 into its argument regarding the citizen petition. Reply ¶ 486. The United States thus incorporates all of its arguments regarding the appeals route (*see supra* ¶¶ 346-52) into its argument regarding the citizen petition as well.

[818] Reply ¶ 488 (emphasis added).

358. Apotex next argues that "FDA's unchanging position was that re-inspection was required to grant Apotex relief that it sought[,]" and that a citizen petition would not have allowed Apotex to challenge the Import Alert after it was adopted.[819] A citizen petition, however, puts the issue before the FDA Commissioner, who could have changed FDA's position had Apotex made a compelling case.[820] Moreover, FDA's position that reinspection was required was based on the correctness of its cGMP determinations. If Apotex could have shown these determinations were incorrect, FDA could have changed its position. Furthermore, contrary to Apotex's assertion, it could have used the citizen petition process to challenge the Import Alert after Apotex had been placed on it. This process allows a petitioner to request the Commissioner "to issue, amend, or revoke a regulation or order, or to take or refrain from taking *any other form of administrative action*."[821] Indeed, Apotex does not allege that anyone from FDA ever stated that Apotex was forbidden from exercising its regulatory rights.[822]

359. Next, Apotex argues that it "would not be allowed access to any information relevant to the position held by FDA" and thus could not adequately address this supposedly missing information. But as discussed above, FDA personnel were being exceptionally transparent, not only providing written documents explaining which cGMP violations were at issue, but also being (in Apotex's words) in "continuous contact" with Apotex through "meetings, telephone conferences, and letters."[823] Apotex knew exactly what it needed to address.[824]

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[819] *Id.* ¶ 489.

[820] Vodra Report ¶ 103.

[821] 21 C.F.R. § 10.25(a) (emphasis added) [RLA-159].

[822] In fact, the minutes of the September 3, 2009 meeting between FDA and Apotex show that the possibility of a district hearing was discussed. Apotex, Apotex Inc./FDA Teleconference Minutes ¶ 2 (Sept. 3, 2009) [C-386].

[823] Reply ¶ 493.

360. Apotex argues that this "continuous contact . . . performed essentially the same function" as a citizen petition, and that therefore there was no point in filing a citizen petition.[825] Apotex, however, was not in continuous contact with the Commissioner or her delegees, who actually respond to citizen petitions, and who could have overruled CDER's Import Alert decision.[826]

361. In sum, Apotex should not be heard to speculate now how all three of these administrative processes *might* not have produced the results it desired.

362. But even if U.S. law had not accorded Apotex any administrative remedy, Apotex could have attempted to bring a claim in U.S. court under the Administrative Procedure Act (APA). In fact, Apotex could have brought at least two distinct types of APA actions in a U.S. court.

363. First, it could have brought an "unreasonable delay" action,[827] alleging that FDA unreasonably delayed (1) *removing* Apotex from the Import Alert, (2) re-inspecting the Etobicoke or Signet facilities, or (3) the approval of Apotex's ANDAs.[828]

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[824] Apotex also could have obtained additional documents through the Freedom of Information Act. *See* 5 U.S.C. § 552 (2012) [RLA-297].

[825] Reply ¶ 493.

[826] *See* FDA Staff Manual Guide 1410.30(1)(L) (June 4, 2010) delegating authority for certain CDER petition responses to high-level CDER officials) [RLA-184]; *see also* delegations listed at http://www fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm136380.htm (last visited Sept. 27, 2009).

[827] In fact, Apotex filed a suit against FDA in 2012 for the agency's alleged delay in making a compliance determination for certain facilities and the resulting delay in approval of two of its ANDAs. *See Apotex Inc. & Apotex Corp. v. U.S. Department of Health and Human Services*, No. 1:12-cv-01647 (D.D.C.), Complaint for Declaratory, Injunctive and Other Relief (Oct. 3, 2012) (relying on the Administrative Procedure Act, and citing 5 U.S.C. §§ 551-53, 701-06) [RLA-68]. Apotex requested the court to order FDA to make the necessary compliance determination. *Id*. ¶ 1.

[828] 5 U.S.C. § 706(1) (2012) [RLA-298]. Apotex erroneously states that unreasonable delay actions are only available for agency delays involving a non-discretionary act. Reply, at 173 n.818. A court could evaluate a claim for unreasonable delay of a discretionary act under the factors set forth in *Telecommunications Research and Action Center v. Federal Communications Commission*, 750 F.2d 70 (D.C. Cir. 1984) [RLA-254].

364. Second, it could have attempted to challenge the Import Alert itself. Although the U.S. Executive branch takes the position that placement on the Import Alert could not be challenged under the APA because such decisions are committed to FDA discretion, at least two courts have allowed claims challenging certain other aspects of FDA's implementation of 21 U.S.C. § 381(a).[829] Thus, Apotex's argument that it could not have brought an action challenging its placement on the Import Alert under section 701(2) is wrong, and a company that claims litigation as part of its "business model" should have no trouble understanding this.[830]

365. Apotex, in fact, itself threatened to sue FDA on more than one occasion for issues related to its Etobicoke and Signet facilities. First, on May 4, 2011, prior to Apotex's removal from the Import Alert, Apotex's lawyer sent an email to the FDA stating that her client had "authorized us to work on bringing a lawsuit. I know from our exchange last year that CDER believes it cannot be sued for this. I do not agree."[831] Additionally, later that year Apotex threatened to sue FDA for not addressing Apotex's ANDA applications as quickly as Apotex wanted following Apotex's removal from the Import Alert.[832] Apotex's sudden reticence about its ability to bring

[829] *Smoking Everywhere, Inc. v. FDA* 680 F. Supp. 2d 62, 69. n.8 (D.D.C. 2010) *aff'd on other grounds sub nom.*, *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010) [CLA-184]; *Cook v. FDA*, No. 12-5176 (D.C. Cir. 2013) [RLA-214].

[830] Memorial ¶ 41. Apotex's position before this Tribunal, moreover, contradicts the position it took with FDA prior to initiating its NAFTA claim. *See* letter from C. Shepard and K. Beardsley, Buc & Beardsley LLP, to R. Tyler, FDA Chief Counsel, and D. Autor, Director, CDER Office of Compliance, at 7 (Dec. 13, 2010) (arguing that the statute does not authorize indefinite detention, and threatening litigation) [C-185].

[831] Email from C. Shepard to R. Tyler (May 3, 2011) [R-194].

[832] Email from Apotex counsel C. Shepard to E. Blumberg (Sept. 7, 2011) ("I am writing because my client has asked me to prepare a suit, but agreed to let me inform you first.") [R-201]; email from C. Shepard to E. Blumberg and A. Brandel (Sept. 16, 2011) ("Apotex intended to file suit to challenge that practice [of allegedly "hold[ing] up the approvals of ANDAs and site transfers"] but held up filing the suit because of the representations that the inspectors had not been able to complete the PAI part during the February inspection and CDER would expeditiously move to complete it.") [R-201].

suit against the FDA is starkly at odds with the positions it has previously taken. The courthouse door was not closed to Apotex; Apotex simply refused to walk through it.

4. Because Apotex Does Not Challenge the Substance of FDA's cGMP Determinations, Apotex Drugs Would Have Been Detained Even if Apotex Had Received the "Due Process" It Claims

366. Apotex's 1105 argument contains an inherent contradiction. On the one hand, Apotex argues that it does not dispute FDA's determination that Apotex's Etobicoke and Signet facilities failed to comply with cGMP.[833] Nor does Apotex dispute that, under U.S. law, drugs manufactured at non-cGMP-compliant facilities are deemed to be adulterated and, on that basis, may be detained without physical examination and denied admission to the United States.

367. On the other hand, Apotex argues that FDA denied Apotex "due process" in deciding whether to add Etobicoke and Signet to Import Alert 66-40 for failure to comply with cGMP. In the absence of any challenge to the merits of the cGMP determinations, Apotex's facilities still would have been non-cGMP-compliant; its drugs still would have been deemed to be adulterated; and its products still would have been subject to detention without physical examination and refusal of admission to the United States. Thus, *no additional due process* could have prevented the injury that Apotex alleges, as no amount of process can alter a decision that is uncontested. Apotex's Article 1105 argument is inherently flawed, and should be dismissed accordingly.

5. Apotex Cannot Rely on Provisions of the U.S.-Jamaica BIT

368. Apotex improperly invokes NAFTA's most-favored-nation treatment provision to claim the benefit of the "effective means of asserting claims and enforcing rights" clause of the U.S.-

[833] Reply ¶¶ 5-8.

Jamaica BIT. Apotex's argument is defective in at least two respects:[834] (1) Apotex has not shown how, by the facts of this case, it would have been entitled to receive better treatment under the U.S.-Jamaica BIT than under the NAFTA; and (2) Apotex does not dispute that its facilities were non-cGMP-compliant, and therefore Apotex had no "claim" it could assert or "right" it could enforce before U.S. authorities.

369. As a threshold matter, Apotex has not met the basic requirement of Article 1103 to identify a comparator "in like circumstances." Unlike many investment treaties, the NAFTA MFN clause expressly requires a claimant to demonstrate that investors of another Party or a non-Party "in like circumstances" were afforded more favorable treatment. Simply ignoring the "in like circumstances" requirement, as Apotex has done, would serve impermissibly to excise key words from the treaty.

370. In any event, Apotex failed to demonstrate that it would have been entitled to receive better treatment under the "effective means" provision of the U.S.-Jamaica BIT than under NAFTA Article 1105. It is not contested that, to claim the benefit of a third-treaty provision by virtue of a basic treaty's MFN clause, a claimant must show that the treatment afforded to investors in like circumstances under the third treaty is more favorable than under the basic treaty. On the facts of this case, the treatment provided under both treaties would have been identical, because neither the U.S-Jamaica BIT nor the NAFTA require the United States to provide investors with specific "due process" before preventing importation of drugs that appear to be adulterated.

[834] Apotex's claims with respect to the U.S.-Jamaica BIT have narrowed. In its Memorial, Apotex claimed the benefit of both the "effective means" provision (Art. II(6)) and the "unreasonable or discriminatory measures" provision (Art. II(2)(b)) of the U.S.-Jamaica BIT. *See* Memorial ¶¶ 478-87. In its Reply, Apotex limits its arguments solely to the "effective means" clause. *See* Reply ¶¶ 515-531.

371. In its Reply, Apotex relies on two awards – *Chevron v. Ecuador* and *White Industries v. India* – to argue that, in theory, the "effective means" provision in some U.S. treaties provides a different standard than the customary international law denial of justice standard reflected in Article 1105.[835] Both of those cases, however, addressed supposed failures in the respondent State's judicial system that prevented the claimants from effectively asserting their claims in court. This case does not involve any attempts by Apotex to pursue claims in U.S. court. Neither *Chevron* nor *White Industries* – nor any authority cited by Apotex – suggests that the "effective means" provision requires a State to provide due process *before* a government may administratively prevent importation of adulterated drugs.[836]

372. Lacking any support for its argument, Apotex attempts to bolster its case through a flawed textual analysis. Apotex first divorces the phrase "effective means" from the full clause,[837] and then provides dictionary definitions for the two words "effective" and "means."[838]

[835] *See* Reply ¶ 526. Apotex has not demonstrated that the "effective means" provision provides a different standard than NAFTA Article 1105. Notably, Apotex does not address the holding in *Duke Energy Electroquil Partners and Electroquil, S.A. v. Republic of Ecuador*, ICSID Case No. ARB/04/19, Award ¶ 391 (Aug. 18, 2008) (holding that the "effective means" clause "seeks to implement and form part of the more general guarantee against denial of justice.") [RLA-267A]; *see also* KENNETH VANDEVELDE, U.S. INTERNATIONAL INVESTMENT AGREEMENTS 415 (2009) ("U.S. drafters believed that the customary international law principle prohibiting denial of justice provides adequate protection and that a separate treaty obligation was unnecessary.") [RLA-149].

[836] In its Memorial, Apotex based its "effective means" argument on its misguided complaint that "the imposition of the Import Alert was the result of administrative proceedings during which it had no possibility to be heard and to defend itself." Memorial ¶ 483. If the "effective means" clause truly stood for the extraordinary proposition that investors are entitled to hearings before governments make any administrative decisions affecting them, one would expect to see such a view discussed in the negotiating history or in the transmittal memorandum from the President to Congress forwarding the treaty. *See Canadian Cattlemen* Award on Jurisdiction ¶ 168 (noting that if the NAFTA Parties had intended to expand the scope of their treaty obligations in the manner proposed by the claimants, the Parties would have "highlighted, and thoroughly analyzed," the proposed change in their "official documents") [CLA-47]. Apotex has cited no official documents – or any other authority – for its expansive interpretation of "effective means."

[837] *See* Reply ¶ 521.

[838] *Id.* ¶ 523.

Apotex concludes based on this limited analysis that the full clause includes "no limitation to 'adjudication.'"[839]

373. Although the words "effective means" are not by themselves limited to adjudication, the full provision makes clear that a State must provide "effective means for asserting claims or enforcing rights" – that is, an effective adjudicatory forum – with respect to covered investments. The plain meaning of the phrase "effective means of asserting claims and enforcing rights" is confirmed by the evolution of this provision. The clause was derived from similar provisions in U.S. Friendship, Commerce, and Navigation treaties requiring "access to courts of justice and administrative tribunals."[840] The original investment-treaty version of this clause, appearing in the 1982 U.S. Model BIT, included the additional specification that investors would receive MFN and national treatment for "the right of access to its courts of justice, administrative tribunals and agencies, *and all other bodies exercising adjudicatory authority . . .* for the purpose of asserting claims, and enforcing rights, with respect to their investments."[841] This provision

[839] *Id.* ¶ 523.

[840] *See* KENNETH VANDEVELDE, U.S. INTERNATIONAL INVESTMENT AGREEMENTS 411-12 (2009) [RLA-286]. Professor Vandevelde explains that the "effective means" provision served as a backstop in those U.S. BITs that required investors to choose exclusively between pursuing their claims through domestic remedies and opting for international arbitration, *i.e.*, the so-called "fork-in-the-road" provision. *See id.* at 580 ("An investor that chooses to invoke local remedies and forego its right to investor-state arbitration under the BIT would be entitled to the protection of the judicial-access provision," which require "the parties [to the BIT] to provide investors with 'effective means' of asserting claims and enforcing rights with respect to investment agreements, investment authorizations, and properties[.]"). The "fork-in-the-road" provision later was viewed as discouraging investors from resorting to domestic remedies, and was replaced in U.S. practice with the "no-U turn" provision. The "no-U turn" provision did not lock investors into either domestic litigation or arbitration, but rather allowed investors to pursue remedies in local court for three years unless and until they pursue arbitration. *See, e.g.*, NAFTA 1121. Under such a provision, unlike the fork-in-the-road provision, an investor dissatisfied with proceedings local courts could then turn to international arbitration, as long as it initiated arbitration within the three-year limitations period. When the United States abandoned the "fork-in-the-road" provision in favor of the "no U-turn" approach, the United States also dropped the "effective means" from its investment protection approach. *Compare, e.g.*, U.S. 1994 Model BIT arts. 2(5) and 9 [RLA-262] *with* NAFTA Article 1121 [CLA-1].

[841] *See* U.S. 1982 Model BIT Art. 2(8) [RLA-261].

was ultimately revised and condensed in future U.S. BITs because it was deemed "superfluous" in light of the more general "effective means" clause.[842]

374. Thus, in reading the terms of the provision itself, discretion is left to the State as to the precise form of such adjudicatory means, as long as they are effective. Here, the United States provided such means to Apotex through a variety of adjudicatory claims mechanisms, including the detention hearing,[843] the citizen petition to FDA,[844] and the U.S. judiciary.[845] Whether "effective means" is interpreted as equivalent to or different from the "denial of justice" standard, the "effective means" clause did not obligate the United States to provide Apotex with a hearing *prior* to its non-adjudicatory administrative decision to add Apotex to the Import Alert, particularly in the context of health and safety.

375. In summary, Apotex has not demonstrated that the "effective means" clause in the U.S.-Jamaica BIT, however it is interpreted, would provide it with any better treatment than NAFTA Article 1105 by the facts of this case. Neither treaty clause required the United States to provide investors with due process in internal, non-adjudicatory administrative decision making.

376. Tacitly conceding this point, Apotex argues for the first time in its Reply that the adjudicatory means the United States actually provided to Apotex – the detention hearing, citizen petition, and the APA – were ineffective.[846] But here again, the U.S.-Jamaica BIT's "effective means" clause affords investors with no better treatment than NAFTA Article 1105, because

[842] *See* VANDEVELDE, U.S. INTERNATIONAL INVESTMENT AGREEMENTS 414 (2009) [RLA-286]. (discussing the change between the U.S. 1984 and 1983 Model BITs).

[843] *See supra* ¶¶ 342-45; Vodra Report ¶¶ 92-95.

[844] *See supra* ¶¶ 353-60; Vodra Report ¶ 103.

[845] *See supra* ¶¶ 362-65; Vodra Report ¶ 96-97.

[846] Reply ¶ 527.

meritorious "effective means" claims – like successful denial of justice claims – require claimants to have at least attempted to utilize the means provided by the State.[847] Because Apotex failed to challenge FDA's actions through the available domestic remedies, there is no difference between a denial of justice and an effective means claim by the facts of this case – both claims fail.[848]

377. Even if Apotex had demonstrated that the United States failed to provide an effective forum for asserting claims or enforcing rights, Apotex's "effective means" claim nonetheless would fail, because Apotex had no claims that it could have asserted or rights it could have enforced with respect to its covered investments. Apotex claims only that it was denied "a[n effective] means to assert its claim in relation to the Import Alert."[849] The Import Alert applied only to Apotex Inc., not to the claimed investments (the approved ANDAs and Apotex Corp.), and thus Apotex had no claim or right to assert "with respect to [covered] investments," as required by the U.S.-Jamaica BIT.[850] Even assuming that the Import Alert related to Apotex Corp., it has long been established under U.S. law that there is no "right" to import products into the United States, and Apotex therefore had no "claim" to assert.[851] Further, Apotex admitted in 2009 (and does not dispute in this arbitration) that its facilities were not cGMP-compliant.

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[847] *See Chevron Corp. and Texaco Petroleum Co. v. Republic of Ecuador*, Partial Award ¶ 268 (Mar. 30, 2010) (holding that while claimants need not exhaust local remedies, claimants must have "utilized the means available to them") [CLA-60]; *White Industries Australia Ltd. v. Republic of India*, UNCITRAL, Final Award ¶ 11.3.2(g) (Nov. 30, 2011) (reiterating the *Chevron* tribunal's holding) [CLA-77].

[848] Indeed, Apotex itself does not seem to view its effective means claim as different from its denial of justice claim: instead of separately addressing the effectiveness of the means the United States provided in the relevant part of its Reply, Apotex simply refers the Tribunal to its earlier denial of justice arguments. *See* Reply ¶ 527 (noting that its "effectiveness" argument was "already demonstrated," citing Part II(c) of its Reply, in which Apotex asserted its denial of justice argument). As discussed above, the administrative and judicial means provided to Apotex in this case were effective and appropriate. *See supra* ¶¶ 342-65.

[849] *See, e.g.,* Reply ¶ 527.

[850] U.S.-Jamaica BIT, art. II(6) [CLA-103].

[851] *See supra* ¶ 297.

Under longstanding U.S. law, this lack of cGMP compliance resulted in Apotex's products being deemed adulterated, Apotex's facilities being placed on the Import Alert, and its products being subject to detention and refusal of admission at the border.[852] Because Apotex has conceded that its facilities were not cGMP-compliant, it had no "claim" under U.S. law that its products should not be detained or removed, nor any "right" under U.S. law[853] to export its adulterated goods into the United States.[854]

CONCLUSION

378. For the foregoing reasons, and those set out in the U.S. Counter-Memorial, the United States respectfully requests that the Tribunal dismiss Apotex's claims in their entirety and with prejudice, and order that Apotex bear the costs of these proceedings, including the United States' costs for legal representation and assistance.

[852] Vodra Report ¶¶ 52-57.

[853] To the extent that Apotex's "claims" were that it was treated differently than its competitors – *i.e.* its MFN and national treatment claims – the United States provided "effective means" by agreeing to arbitration before this very Tribunal.

[854] Finally, although Apotex appeared to have sought to expand the scope of Article 1105 beyond customary international law in its Memorial, when it included its "effective means" claim under the argument heading "The Import Alert Denied Apotex Fair and Equitable Treatment" (Memorial at 134), Apotex asserts in its Reply that it never had meant to make such an argument. Given Apotex's abandonment of this argument, the United States will not comment on it further, other than to note that Apotex had no basis to make such an argument in the first place, as the NAFTA Parties have agreed that "the NAFTA cannot operate so as to create a conflict between Article 1103 and the [FTC Note of] interpretation." *See Pope & Talbot, Inc. v. Canada*, NAFTA/UNCITRAL, Letter from M. Kinnear, General Counsel, Trade Law Division, Canada, to Tribunal, at 3 (Oct. 1, 2001) [RLA-128]; *Pope & Talbot*, Letter from H. Perezcano Díaz, Consultor Jurídico de Negociaciones, Mexico, to Tribunal, at 1 (Oct. 1, 2001) [RLA-127]; *Pope & Talbot*, Sixth Submission (Corrected) of the United States of America ¶ 2 (Oct. 2, 2001) [RLA-129].

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