

# Public Version

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

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APOTEX HOLDINGS INC. AND APOTEX INC.,

*Claimants,*

– and –

THE GOVERNMENT OF THE UNITED STATES OF AMERICA,

*Respondent.*

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

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**REPLY OF CLAIMANTS  
APOTEX HOLDINGS INC. AND APOTEX INC.**

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May 24, 2013

CONFIDENTIAL

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## **GLOSSARY OF TERMS**

<b>AIP</b>	Application Integrity Policy (FDA)
<b>ALI</b>	American Law Institute
<b>ANDA</b>	Abbreviated New Drug Application (US)
<b>APA</b>	Administrative Procedure Act (US)
<b>APAC</b>	Asia Pacific
<b>APHI</b>	Apotex Pharmaceutical Holdings Inc.
<b>API</b>	Active Pharmaceutical Ingredient
<b>ARPL</b>	Apotex Research PTY Limited
<b>CAP</b>	Corrective Action Plan (Apotex)
<b>CBER</b>	Center for Biologics Evaluation and Research (FDA)
<b>CBP</b>	Customs and Border Protection (US)
<b>CDER</b>	Center for Drug Evaluation and Research (FDA)
<b>CDER-OC</b>	Center for Drug Evaluation and Research, Office of Compliance (FDA)
<b>cGMP</b>	Current Good Manufacturing Practices
<b>CI</b>	Continuous Improvement (Apotex)
<b>CMC</b>	Chemical Manufacturing Control
<b>CROs</b>	Contract Research Organizations
<b>DIOP</b>	Division of Import Operations and Policy (FDA)
<b>DMPQ</b>	Division of Manufacturing and Product Quality (FDA)
<b>DOJ</b>	Department of Justice (US)
<b>DWPE</b>	Detention Without Physical Examination (FDA)

<b>EEA</b>	European Economic Area
<b>EI</b>	Establishment Inspection (FDA)
<b>EIR</b>	Establishment Inspection Report (FDA)
<b>EMA</b>	European Medicine Agency
<b>EMEA</b>	Europe, Middle East and Africa
<b>FDA</b>	Food and Drug Administration (US)
<b>GMP</b>	Good Manufacturing Practices
<b>GPOs</b>	Group Purchasing Organizations
<b>GQSR-CAP</b>	Global Quality Systems Revitalization Corrective Action Plan (Apotex)
<b>HHS</b>	US Department of Health and Human Services
<b>HPFBI</b>	Health Product and Food Branch Inspectorate (Health Canada)
<b>IGZ</b>	Health Care Inspectorate (Netherlands)
<b>IND</b>	Investigational New Drugs (US)
<b>IOM</b>	Investigations Operations Manual (FDA)
<b>IP</b>	Intellectual Property
<b>MRA</b>	Mutual Recognition Agreement
<b>NDA</b>	New Drug Application (US)
<b>OC</b>	Office of Compliance (FDA)
<b>OCC</b>	Office of Chief Counsel (FDA)
<b>OGD</b>	Office of Generic Drugs (FDA)
<b>OMPQ</b>	Office of Manufacturing and Product Quality (FDA)
<b>OOS</b>	Out-of-specification

<b>ORO</b>	Office of Regional Operations (FDA)
<b>OTC</b>	Over-the-counter drugs
<b>PAI</b>	Pre-Approval Inspection (FDA)
<b>PhRMA</b>	Pharmaceutical Research and Manufacturers of America
<b>PQA</b>	Product Quality Assessment (Apotex)
<b>PST</b>	Product Selection Team (Apotex)
<b>QA</b>	Quality Assurance
<b>QSR</b>	Quality System Regulation (US)
<b>R&amp;D</b>	Research and Development
<b>RLD</b>	Reference Listed Drug
<b>RPM</b>	Regulatory Procedures Manual (FDA)
<b>Rx</b>	Prescription Drugs (US)
<b>SKUs</b>	Stock-Keeping Units
<b>SOPs</b>	Standard Operating Procedures
<b>SP</b>	Special Products
<b>TGA</b>	Therapeutic Goods Administration (Australia)
<b>TRO</b>	Temporary Restraining Order (US)
<b>URPA</b>	US Re-Entry Product Assessment Protocol (Apotex)

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**REPLY OF CLAIMANTS  
APOTEX HOLDINGS INC. AND APOTEX INC.**

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In accordance with Article 38 of the Arbitration (Additional Facility) Rules, the Tribunal's First Procedural Order of November 12, 2012 and the Procedural Order of January 25, 2013, claimants Apotex Holdings Inc. ("Apotex Holdings") and Apotex Inc. ("Apotex-Canada") (collectively, "Apotex") respectfully submit this Reply on the merits and counter-memorial on jurisdiction in support of their claims against respondent United States of America.

## **INTRODUCTION**

1. The US Counter-Memorial largely confirms the case established by Apotex in its Memorial. The US does not dispute that FDA repeatedly inspected Apotex's facilities without incident for many years. The parties concur that, six months after the 2008 Etobicoke inspection, FDA issued Apotex a warning letter. A warning letter, the parties agree, signals a violation of regulatory significance that, if not promptly and adequately corrected, would lead to enforcement action. Apotex had never before received a warning letter.
2. The parties also agree that, one month after the warning letter, FDA inspected the Signet facility. Two weeks after that inspection, FDA adopted the Import Alert. The US does not dispute that FDA did so without issuing a warning letter concerning the facility, without notice, without providing Apotex an opportunity to present its position, without any suggestion that Apotex's products were unsafe or ineffective and without providing Apotex any opportunity to correct the issues raised by FDA before the measure was adopted.
3. The US acknowledges that during the past several years FDA issued warning letters to US and foreign investors. It does not contest that those investors owned pharmaceutical businesses and marketing authorizations in the US, comparable to those of Apotex. It is not in dispute that FDA found cGMP violations as to these investors and investments comparable to those FDA found for Apotex's Etobicoke and Signet facilities. FDA, however, adopted no enforcement measure with respect to any of the US or foreign investors or investments identified in the Memorial. By contrast, the FDA Import Alert crippled Apotex's US business.
4. The Counter-Memorial thus leaves the core of Apotex's case on liability unrefuted. The US has no response to the factual record establishing Apotex's claims of less favorable treatment under Articles 1102 and 1103 and failure to accord the procedural safeguards required by the international minimum standard under Article 1105 of the NAFTA.

5. The US adopts in its Counter-Memorial three strategies to attempt to compensate for this lacunae in its case. First, the US places great emphasis on FDA's findings of current good manufacturing practice (cGMP) violations.
6. The claims before the Tribunal, however, do not place this topic in issue. They do not require a determination of whether FDA was right or wrong in its cGMP findings as to Apotex. FDA found cGMP violations of regulatory significance with respect to each of the comparator investors and investments identified in the Memorial. It is not disputed that, as concerns the cGMP findings, Apotex and the comparators are in like circumstances.
7. The issue presented for the national treatment and most-favored-nation treatment claims is whether Apotex received less favorable treatment when its US investment was cut off from its principal source of supply for two years, while its comparators' supply from their affiliated plants continued without impediment. The substance of FDA's cGMP findings is not at issue.
8. Nor does the claim under the minimum standard of treatment implicate the substance of FDA's cGMP findings. This claim, like that under the "effective means" clause of the US-Jamaica treaty, addresses the lack of procedural safeguards afforded Apotex by FDA in adopting the Import Alert. The substance of the cGMP findings is not an element of the claim or any defense asserted by the US.
9. The US emphasizes the cGMP findings not because they are relevant to any issue the Tribunal must decide. Instead, the US attempts to paint Apotex as a bad actor unworthy of the Tribunal's sympathy. The US, however, repeatedly exaggerates the record in its efforts to create this impression.
10. As one example, the US dramatically asserts that "FDA found that Apotex had distributed products in the U.S. market contaminated with hair, glue, plastic, nylon, metal, rust, acetate fibers, fluorocarbons, and PVC-based material."<sup>1</sup> What the record shows, however, is that it was *Apotex*, not FDA, that found these foreign materials in

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<sup>1</sup> US Counter-Memorial, para. 5. *See also id.*, para. 87 (relying on **Exhibit R-42**, 2009 Signet Establishment Inspection Report (EIR)).

one container of a multiple-container batch of active pharmaceutical ingredient supplied by a third party. Apotex destroyed the contaminated container and all products made from it. It tested materials made from other containers. It concluded that the contamination was limited to the single container. It released the uncontaminated materials to market. The FDA inspector faulted Apotex for not being able to document in its record-keeping system which container was contaminated and destroyed, and which was not.<sup>2</sup> FDA took the position that, as a precaution, all tablets made from other containers in a batch including one contaminated container should be destroyed, even if the tablets in question were tested and found to be uncontaminated.<sup>3</sup> However, the record contains no evidence of any shipment of contaminated drugs by Apotex to the US, and FDA made no finding to this effect.

11. Second, the US attempts to discredit Apotex through a search for “inconsistencies” in statements made in US courts, and even accuses Apotex of participating in a “scheme” 20 years ago because an FDA official copied Apotex on a letter addressed to a company that sold Canadian Apotex products on the US market. The record, however, does not support the US tactic. It reveals no such inconsistency. Far from supporting the US attempt to discredit Apotex, the record shows Apotex to be one of the top generic pharmaceutical companies in the world, with a professional, diverse staff and an unrelenting approach to competition that greatly benefits consumers in the United States and every other country in which it does business.
12. Third, the US places great reliance on its jurisdictional objections. In a pleading spanning over 200 pages, the Counter-Memorial devotes only 13 pages to the US defense on national and most-favored-nation treatment and 22 pages to the minimum standard of treatment. The rest is taken up by its in-depth review of cGMP issues and jurisdictional objections. The allocation is telling.
13. In this Reply, Apotex demonstrates that the objections and defense presented in the US Counter-Memorial do not withstand scrutiny.

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<sup>2</sup> See **Exhibit R-42**, 2009 Signet EIR at 42.

<sup>3</sup> See *id.*; **Exhibit C-61**, 2009 Signet Form 483 at 1 (Item 1(a)).

14. Facts. The Reply begins with a counter-statement of the facts. As noted above, the US contentions concerning the substance of the alleged cGMP violations are not pertinent to the issues presented before this Tribunal. Because the US has devoted so much of its submission to this topic, however, Apotex nonetheless begins by demonstrating that the record does not support the US's suggestion that Apotex products posed a health risk to consumers.
15. Apotex then examines the perspective on the factual chronology in this case provided by documentation produced by the US. While Apotex has not had an opportunity to review the full US production, the documents produced and reviewed to date shed a new light on the suspicions that led FDA aggressively to investigate Apotex – and to adopt the Import Alert without providing Apotex an opportunity to explain or correct. The record shows that FDA's suspicions proved to be unfounded. Key misunderstandings of Apotex data underlying those suspicions were clarified when the company had an opportunity to address FDA's concerns. The tragedy, from Apotex's perspective, is that this opportunity was accorded only after the Import Alert was adopted.
16. Jurisdiction. In its Counter-Memorial on jurisdiction, Apotex shows the error in the US's assertion that a ban cutting Apotex-US off from its supply of Apotex-Canada products does not “relate to” either Apotex-US or Apotex-Canada. It establishes, applying the familiar tools of the Vienna Convention on the Law of Treaties, the content of the “relating to” provision in this context. It shows that the connection between measure and investor or investment prescribed by Articles 1102, 1103 and 1105 is necessarily “legally significant” for purposes of that provision. Because that connection is present on this record, the “relating to” requirement is satisfied.
17. Apotex shows conversely that the NAFTA does not support the apparent US argument that a measure must “directly apply” to, or “constitute a legal impediment to the business of,” an investment. In any event, FDA import alerts do apply to both importers and consignees, like Apotex-US here. The law authorizing the measure makes this clear, and the evidence proffered with the Counter-Memorial proves the opposite of what the US asserts: it shows that the Import Alert uniquely applied to Apotex-US.

18. In addition, the US “relating to” argument as to Apotex-Canada is baseless. The US contends that a measure preventing products from being marketed bears no relation to the authorizations to market the product. Merely to state the argument is to reveal its lack of merit.
19. The Counter-Memorial equally errs in contending that authorizations to market drugs (referred to as ANDAs) are not “intangible property” and therefore “investments” within the NAFTA. Notably, the US does not attempt to address the Memorial’s showing that ANDAs are intangible property. The Counter-Memorial does not dispute that FDA regulations explicitly recognize that ANDAs are “owned” by the applicant. It does not contest that the ANDA owner can sell the ANDA like any other property or that sales of ANDAs are commonplace in the US market and often ascribe to them a high value. The US does not dispute that a company that has acquired rights to an ANDA has standing to intervene if these rights are affected. It does not deny that access to the US market under an approved ANDA is a protected interest in the eyes of US courts, as is the marketing exclusivity afforded to certain ANDA holders. Nor does the Counter-Memorial deny that US tax law treats ANDAs as franchises or intangibles for purposes of the US tax code.
20. Instead, the US argues, based entirely on national case law construing the term “private property” in the Takings Clause of the US Constitution, that “property” in the NAFTA does not encompass interests that are subject to revocation by the State. Apotex demonstrates that this argument is irreconcilable with the text of the NAFTA, which explicitly includes revocable intangible property as “investments.” Apotex further shows that the US argument lacks support in both US and NAFTA jurisprudence.
21. Finally, the US Counter-Memorial does not come to grips with the Memorial’s showing that Apotex-Canada’s ANDAs constitute interests arising from the commitment of capital or other resources and therefore an “investment” under Article 1139(h). The US asserts that the “investment” must be in US territory and cross-border services contracts are not “investments.” These arguments miss the mark. Apotex disputes neither point. Neither is presented here. Instead, the issue is whether resources and capital committed to the territory of the US must be in that territory before they are committed. The record demonstrates that Apotex committed resources both within and without the US

to establish and maintain its ANDAs. The ANDAs themselves are clearly interests in US territory. The US jurisdictional objection, in short, is without merit.

22. Liability. The US defense to Apotex's claims under Articles 1102, 1103 and 1105 is without support.
23. Legal error infects the US argument that comparators with sites in the US are not "in like circumstances" with Apotex. The US relies for this point exclusively on the observation that import alerts apply to sites outside the US.
24. The US argument confuses the element of "in like circumstances" with that of "less favorable treatment" in Articles 1102 and 1103. Circumstances relevant here include, notably, standards regulating the conduct of investors and investments in the pharmaceutical industry, such as cGMP standards. There is no dispute that these circumstances are "like" as concerns Apotex and its comparators. Nor could there be, since the same cGMP standards apply regardless of the facility's location.
25. The Import Alert, however, represents the *treatment* accorded to Apotex. The NAFTA does not require that treatment accorded national or third-country investors or investments be identical to that accorded Apotex. It does, however, require that it be *no less favorable* than that accorded the comparators in like circumstances. The undisputed record here shows that FDA accorded treatment to comparators with sites in the US that was more favorable than that accorded to Apotex in like circumstances.
26. By contrast, the US agrees that comparators with sites outside the US are "in like circumstances" with Apotex. But it erroneously disputes that Apotex received less favorable treatment.
27. The record does not support the US. It shows, for example, that FDA issued Teva a warning letter noting serious cGMP violations at its Jerusalem facility. The parties agree that FDA accorded Teva Jerusalem an opportunity to respond both to inspectional observations and the warning letter as well as to implement corrective actions. FDA re-inspected the facility and closed out the warning letter within six months of the date on which it was issued. FDA did all of this without adopting any enforcement action or interrupting Teva's access to the US market. By contrast, FDA banned Apotex from the

US market for almost two years, accorded it no opportunity to respond or to implement corrective action before taking that enforcement action, and took over a year fully to lift the enforcement actions after Apotex requested re-inspection.

28. The only argument advanced by the US on its treatment of Teva Jerusalem appears in a single paragraph. In that paragraph, the US makes a terse, unsupported reference to FDA's "risk-based approach" and asserts, with equally absent support, that FDA reached "a different conclusion for Teva's products" than it did for Apotex. This is all the US offers on the difference in treatment between Apotex and Teva. It is not much.
29. The record, in short, establishes that the US accorded Apotex less favorable treatment than Teva Jerusalem, which indisputably was in like circumstances with Apotex. The record establishes breaches of Articles 1102 and 1103.
30. The record also does not support the US defense on Article 1105. In 1965, the American Law Institute considered it blackletter law that procedural safeguards were required in administrative proceedings. Its understanding of "proceedings" included decisions with a material effect on the rights of a person, such as granting or revoking a license. The US has repeatedly relied on the Institute's *Restatement* as an authoritative statement of customary international law. Yet in this arbitration the US now places it in a "grab bag of soft law." The US position – and more broadly its view in these proceedings that international law requires nothing of a State in deciding the essential rights and interest of individuals if the State declines to provide a trial – cannot be reconciled with the rule of law that the US and other States have long espoused.
31. Nor is there merit to the US suggestion that Apotex had available to it means to seek review of the Import Alert. The record shows that none of the four "avenues" proposed by the US were either available, adequate or effective. None meets the minimum standard of treatment reflected in Article 1105.
32. In sum, the record shows that the US jurisdiction objections are without foundation. It establishes that in adopting the Import Alert, the US denied Apotex national-treatment, most-favored-nation treatment and the minimum standard of treatment. For the reasons set out in more detail in the pages that follow, the Tribunal should render a decision dismissing the US jurisdictional objections, finding the US to have engaged its

responsibility under Articles 1102, 1103 and 1105 of the NAFTA and ordering the parties to proceed to written and oral proceedings on damages.

### **EVIDENCE: BURDEN OF PROOF**

33. As recently observed by the *Rompetrol* tribunal, “the 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.”<sup>4</sup>

34. The burden of proof rests upon the party alleging the fact at issue.<sup>5</sup> As such, it is for the claimant to prove its claim and then for the respondent to prove its defense. In the words of *Rompetrol*:

[I]f [the respondent] fails where necessary to throw sufficient doubt on the claimant’s factual premises, it runs the risk in turn of losing the arbitration; but only ‘the risk,’ because the particular factual premise may not in the event turn out to be decisive in the legal analysis. Conversely, if the respondent chooses to put forward fresh allegations of its own in order to counter or undermine the claimant’s case, then by doing so the respondent takes upon itself the burden of proving what it has alleged.<sup>6</sup>

35. In a similar fashion, the NAFTA tribunal in *Feldman v. Mexico* explained that once the claimant has sufficiently established its case, the respondent then has the burden of rebutting it:

[V]arious international tribunals, including the International Court of Justice, have generally and consistently accepted and applied the rule that the party who asserts a fact, whether

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<sup>4</sup> **Legal Authority CLA-508**, *Rompetrol Group N.V. v. Romania*, ICSID Case No. ARB/06/3, Award, para. 178 (May 6, 2013).

<sup>5</sup> *See, e.g.*, **Legal Authority CLA-514**, *Pulp Mills on the River Uruguay* (Arg. v. Uru.), 2010 I.C.J. para. 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. This principle which has been consistently upheld by the Court applies to the assertions of fact both by the Applicant and the Respondent.”) (citations omitted).

<sup>6</sup> **Legal Authority CLA-508**, *Rompetrol Group N.V. v. Romania*, ICSID Case No. ARB/06/3, Award, para. 179 (May 6, 2013). *See also id.*, para. 178 (“[I]f a factual allegation is put forward by one side and conceded by the other, it no longer requires to be ‘proved’.”).

the claimant or respondent, is responsible for providing proof thereof. Also, it is a generally accepted canon of evidence in civil law, common law and, in fact, most jurisdictions, that the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a claim or defence. *If that party adduces evidence sufficient to raise a presumption that what is claimed is true, the burden then shifts to the other party, who will fail unless it adduces sufficient evidence to rebut the presumption.*<sup>7</sup>

36. In the Memorial, Apotex proved each element of its case on jurisdiction and the merits. The US Counter-Memorial fails to rebut Apotex's case, as will be shown in this Reply.
37. Under the rules applicable to these proceedings, the Counter-Memorial represents the definitive statement of the responsive case Apotex must meet. The US Rejoinder is limited to a response to this Reply; it may not present a response to evidence presented with the Memorial.<sup>8</sup>
38. For the reasons set out below, the US Counter-Memorial fails to rebut the evidence and argument presented in Apotex's Memorial. The US defense does not withstand scrutiny.

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<sup>7</sup> **Legal Authority CLA-31**, *Marvin Feldman v. United Mexican States*, ICSID Case No. ARB(AF)/99/1, Award, para. 177 (Dec. 16, 2002) (quoting Appellate Body Report, *United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/AB/R at 14 (May 23, 1997) (emphasis added by the *Feldman* tribunal; internal quotation omitted). See also **Legal Authority CLA-30**, *International Thunderbird Gaming Corporation v. United Mexican States*, UNCITRAL, Award, para. 95 (Jan. 26, 2006) (“The Tribunal shall apply the well-established principle that the party alleging a violation of international law giving rise to international responsibility has the burden of proving its assertion. If said Party adduces evidence that *prima facie* supports its allegation, the burden of proof may be shifted to the other Party, if the circumstances so justify.”) (footnotes omitted).

<sup>8</sup> See First Procedural Order, para. 16.4 (“In their second written submissions, the Parties shall include only additional written witness testimony, expert opinion testimony, documents or other evidence that responds to or rebuts matters raised by the opposing Party’s prior written submission.”); ICSID (Additional Facility) Arbitration Rules, art. 38(3) (“A counter-memorial, reply or rejoinder shall contain an admission or denial of the facts stated in the last previous pleading; any additional facts, if necessary; observations concerning the statement of law in the last previous pleading; a statement of law in answer thereto; and the submissions.”). See also **Legal Authority CLA-509**, *Von Pezold v. Republic of Zimbabwe*, ICSID Case No. ARB/10/25, Procedural Order No. 3, para. 48 (Jan. 11, 2013) (David A. R. Williams, Q.C., An Chen & L. Yves Fortier, Q.C. (President), arbitrators) (finding that defenses raised in rejoinder improperly responded to points asserted in memorial and therefore could be admitted only with special leave of tribunal).

## COUNTER-STATEMENT OF FACTS<sup>9</sup>

39. The US Counter-Memorial asserts that “[t]he material facts of this case are largely undisputed.”<sup>10</sup> The parties are agreed as to the chronology of events, the parameters of the applicable regulatory framework and the comparability of the alleged cGMP violations of Apotex and its comparators. The parties also agree that “adulteration” is a defined term that includes products fully meeting specifications and that are safe and effective.<sup>11</sup>
40. The US Counter-Memorial erroneously suggests that Apotex’s products were defective, unsafe and ineffective.<sup>12</sup> As noted in the Introduction to this Reply, the US Counter-Memorial places great emphasis on FDA’s cGMP findings. As also noted, the US errs in implying that the correctness of cGMP findings is at issue in this arbitration. It is not. Apotex’s claims do not put into issue whether or not FDA erred in its observations and conclusions regarding cGMP. Instead, they place into issue: (i) whether, in adopting the Import Alert, FDA accorded Apotex treatment less favorable than that accorded to comparable investors and investments as to which FDA made comparable observations; and (ii) whether the Import Alert was accompanied by procedural safeguards meeting the minimum standard of treatment under international law.
41. Neither of these claims depends even in part on an examination of the correctness of FDA’s cGMP findings. However, because the US has little to offer by way of a defense on the main factual issues in the case, the US Counter-Memorial devotes considerable attention to the cGMP findings – in an apparent effort to paint Apotex as a “bad actor” and distract the Tribunal from the issues actually presented by Apotex’s claims. The US exaggerates and distorts the record in so doing. While these issues are legally irrelevant, Apotex nonetheless sets the record straight in the discussion that follows.

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<sup>9</sup> Apotex’s Reply submission takes into account all documents produced by the US by April 19, 2013 and some of the US documents produced thereafter. Apotex has not yet had an opportunity to review carefully or in many cases at all the documents produced after April 19. Pursuant to the Procedural Order dated May 14, 2013 (para. 13(h)), Apotex reserves the right to file a supplemental submission taking into account documents produced by the US after April 19, 2013.

<sup>10</sup> US Counter-Memorial, para. 4.

<sup>11</sup> *Id.* para. 37 (“Under the statute, a drug does not actually need to be defective to be ‘adulterated.’”). *See also id.*, paras. 17, 38.

<sup>12</sup> *Id.*, para. 5; Witness Statement of Carmelo Rosa, para. 59.

42. Except to the extent expressly admitted in this Reply or in the Memorial, Apotex denies the facts stated in the Counter-Memorial.<sup>13</sup>

## I. APOTEX PRODUCTS POSED NO RISK TO CONSUMERS

### A. The Record Does Not Support the US's Suggestion of Contamination

43. The US erroneously asserts that FDA found Apotex to have released to market products contaminated with “hair, glue, plastic, nylon, metal, rust, acetate fibers, fluorocarbons, and PVC-based material.”<sup>14</sup> However, the record does not support the US's suggestion.<sup>15</sup> The US's suggestion of contamination is based on reports on the production of two specific products, Cetirizine and Metformin.<sup>16</sup>

44. With respect to Cetirizine, Apotex discovered the contamination in August 2008 on a filter screen during processing of a mix batch, *i.e.*, an in-process batch. Its investigation determined that the contamination originated from a container of active pharmaceutical ingredient (API) supplied by a third party.<sup>17</sup> Apotex tested batches made from other containers and found them not to be contaminated.<sup>18</sup> Apotex determined that the contamination was limited to a single container of API. That container was rejected, as well as all batches of product derived from it (mix and finished batches).<sup>19</sup> Since the contamination was “container specific,” it did not impact the quality of products made from other containers of the same API, which were therefore safely released to market.<sup>20</sup> The record does not support the US's suggestion that Apotex released

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<sup>13</sup> See ICSID (Additional Facility) Arbitration Rules, art. 38(3) (“A counter-memorial, reply or rejoinder shall contain an admission or denial of the facts stated in the last previous pleading; any additional facts, if necessary; observations concerning the statement of law in the last previous pleading; a statement of law in answer thereto; and the submissions.”).

<sup>14</sup> US Counter-Memorial, para. 5; *See also id.*, paras. 87-88.

<sup>15</sup> Second Witness Statement of Jeremy Desai, para. 7; Second Witness Statement of Edmund Carey, paras. 9-10. *See also Exhibit R-42*, 2009 Signet EIR at 38-39, 41-44.

<sup>16</sup> *See* US Counter-Memorial, paras. 87-88.

<sup>17</sup> **Exhibit R-42**, 2009 Signet EIR at 38 (“The foreign material was identified as originating from the active pharmaceutical ingredient ...”).

<sup>18</sup> *Id.* at 43.

<sup>19</sup> *Id.* (“Mix batch [REDACTED] was to be rejected as of 8/29/08 due to this incident ... . Batches derived from this mix batch were rejected as well as the remainder of the API batch HY2470[.]”).

<sup>20</sup> *Id.* at 42 (“Q-Note [Quality-Note] ... states ‘it was determined that foreign material observed during dispensing process of the third mix batch Cetirizine ... , batch [REDACTED] was container specific and it does not impact rest of batches which consumed active material HY2470. Therefore, batches which consumed [API] batch HY2470, other than [REDACTED] [the contaminated mix batch] can be further released[.]”). These two

Cetirizine product contaminated with hair, glue, plastic, nylon, metal, rust, acetate fibers, fluorocarbons or similar impurities.

45. With respect to Metformin, during the processing of a mix batch in March 2008, black specks were observed in the active API supplied by a third party.<sup>21</sup> The mix batch was sent to the laboratory for analysis and blocked from further use.<sup>22</sup> The black specks were identified as metallic material that may not be detected by normal metal detection.<sup>23</sup> Consequently, Apotex decided that the product derived from this mix batch could “only be released for further use if it [was] metal inspected using a more sensitive set-up, which would allow for the removal of metal contamination.”<sup>24</sup> The product was tested and cleared before being released to the US.<sup>25</sup> There is thus no evidence that Apotex distributed in the US market drugs contaminated with metal.

**B. FDA’s Own Actions Are Inconsistent with Apotex Products Posing Any Public Safety Risk**

46. If FDA had serious concerns over the safety of Apotex products, it should have and would have taken further preventative steps to limit any negative effect of the purportedly unsafe products. FDA had a number of tools in its arsenal.<sup>26</sup> However, the record shows that FDA used none of those tools – besides the unlawful measure at issue here.

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batches that were released to the US market were later included in Apotex’s voluntary recall in September 2009, as a precautionary measure. **Exhibit C-81**, Apotex’s Response to Signet 483, dated September 3, 2009 at 1.

<sup>21</sup> **Exhibit R-42**, 2009 Signet EIR. *Id.* at 43 (“During the processing of Metformin Mix batch HT2731, black specs [sic] were observed in the active raw material (API lot [REDACTED]).”).

<sup>22</sup> *Id.* at 43. The EIR also quotes Apotex’s Q-Notes: ““No issues or deviations were reported when different container of the same API batch [REDACTED] was used in the manufacture of another blend batch [REDACTED]. [.]”” *Id.*

<sup>23</sup> *Id.* at 38-39.

<sup>24</sup> *Id.* at 43. The batch at issue did not leave the Signet Campus until the completion of the investigation into the metal contamination. *Id.*

<sup>25</sup> *Id.* at 44 (batch in question metal checked on February 12, 2009 before being repackaged on February 24, 2009 and released to the US on February 27, 2009). Additionally, these released batches were part of the voluntary recall that took place in September 2009. **Exhibit C-81**, Apotex’s Response to Signet 483, dated September 3, 2009 at 2.

<sup>26</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 11-18, 22. *See also* Witness Statement of Carmelo Rosa, para. 6.

- a. FDA did not request Apotex to recall any product already shipped to the Indianapolis warehouse facility or distributed in the US market.<sup>27</sup>
- b. After Apotex, at its own initiative and as a preventive measure, recalled 675 batches from the US market in September of 2009, FDA classified it as a Class II recall, demonstrating its belief that “the probability of serious adverse health consequences [was] *remote*.”<sup>28</sup> Thus, while in September 2009 FDA represented to the US consumers that Apotex’s products did not pose any significant safety issue, the US now suggests that they did.
- c. FDA did not seize any of Apotex’s products in the US market,<sup>29</sup> although FDA considered “possible market action(s) based on public health risk” (and apparently concluded that there was none).<sup>30</sup>
- d. FDA did not issue any Public Health Advisory or Healthcare Provider Advisory regarding safety concerns associated with Apotex’s drugs.<sup>31</sup>
- e. To the best of Apotex’s knowledge, FDA did not require third-party testing of any of Apotex’s products on the US market.<sup>32</sup>
- f. According to the documents produced by the US, FDA performed a number of tests on Apotex products, but never communicated any negative results of such testing to Apotex – presumably because there was none.<sup>33</sup>

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<sup>27</sup> Witness Statement of Jeremy Desai, para. 52; Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 13. The record shows that CDER initially contemplated taking regulatory action against Apotex’s Indianapolis warehouse, but it decided not to do so, consistent with FDA’s lack of concern with Apotex’s products. **Exhibit C-400**, FDA Internal Email, dated October 22, 2009.

<sup>28</sup> **Exhibit C-364**, Excerpts from FDA’s website, *Background and Definitions*, dated June 24, 2009 (emphasis added); Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 14.

<sup>29</sup> Witness Statement of Jeremy Desai, para. 52; Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 22(d).

<sup>30</sup> **Exhibit C-373**, FDA Internal Email Chain, dated August 18, 2009 (Email from Joseph Famulare to Murray Lumpkin). This absence of any market action on the part of FDA is not in line with its position that the voluntary recall proposed by Apotex on August 28, 2009 did “not meet with FDA’s expectations given the significance of the documented GMP violations.” See **Exhibit R-45**, FDA, Minutes of Teleconference with Apotex on September 3, 2009. On September 11, 2009, Apotex, as a good will gesture, voluntarily agreed to cease distribution of any product from the warehouse in Indianapolis until the completion of the Product Quality Assessment (PQA). See Witness Statement of Jeremy Desai, para. 63.

<sup>31</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 22(e). See also **Exhibit C-361**, FDA Internal Email Chain, dated June 9, 2009 at US7266 (Email from Elizabeth Giaquinto to Deborah Autor, Director of CDER’s Office of Compliance, recommended limiting outreach to the press) (“I know you indicated earlier that you didn’t want much press on this.”).

<sup>32</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 22(c). Second Witness Statement of Edmund Carey, para. 10.

<sup>33</sup> Second Witness Statement of Edmund Carey, para. 10. **Exhibit C-349**, FDA Internal Email Chain, dated April 3, 2009 at US6444 (Email from Sally Eberhard to Helen Saccone) (showing samples taken on March 31, 2009 and April 2, 2009); **Exhibit C-346**, FDA Internal Email Chain, dated April 1, 2009 at US7097 (Email from Huascar Batista to Aleka Srinivasan) (discussing taking samples while Apotex products were

- g. It took FDA over six months from the Etobicoke Inspection to issue a Warning Letter to Apotex.<sup>34</sup>
  - h. It took FDA eight months to put Etobicoke on Import Alert after the inspection of that facility, and the inspection was initially “deemed VAI (voluntary action indicated) by the District.”<sup>35</sup> In the interim, FDA did not prevent Apotex from shipping product made at Etobicoke to the United States.
47. This lack of action on FDA’s part (other than the Import Alert) cannot be reconciled with the US’s suggestion that Apotex’s products were unsafe. The record does not support the US’s suggestion.

## **II. FDA’S SUSPICIONS LEADING TO THE IMPORT ALERT PROVED UNJUSTIFIED**

48. Documentation made available by the United States after the Memorial was submitted, both with its Counter-Memorial and in document disclosure, offers a new perspective on the nine-month period preceding FDA’s adoption of the Import Alert in August 2009. The record shows that a series of suspicions led FDA aggressively to pursue enforcement action against Apotex. FDA neither shared those suspicions with Apotex nor considered Apotex’s response before adopting the Import Alert. The suspicions proved to be unjustified. Apotex briefly reviews the record in this regard below.

### **A. Carbidopa-Levodopa and the Etobicoke Inspection**

49. The Counter-Memorial states that FDA scheduled the Etobicoke inspection in response to six consumer complaints and a “congressional inquiry” concerning an Apotex product called Carbidopa-Levodopa.<sup>36</sup> At the close of the Etobicoke inspection in December 2008, FDA issued to Apotex a Form 483 that included observations concerning this product, the raw material supplier and the data Apotex used concerning

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“in imports status”); **Exhibit C-348**, FDA Internal Email Chain, dated April 3, 2009 at US7186 (directing Investigations Branch to take samples of Apotex’s products).

<sup>34</sup> **Exhibit C-41**, Etobicoke Warning Letter, dated June 25, 2009.

<sup>35</sup> **Exhibit C-373**, FDA Internal Email Chain, dated August 18, 2009 (Email from Joseph Famulare to Murray Lumpkin). A VAI inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance. Inspections classified with VAI violations are typically technical violations of the Act.

<sup>36</sup> US Counter-Memorial, para. 72; Witness Statement of Debra Emerson, paras. 5, 8. In fact, the “congressional inquiry” was merely a letter from a constituent forwarded by a member of the House of Representatives. *See Exhibit C-339*, FDA Internal File on Carbidopa-Levodopa, dated February 9, 2009 at US300.

the stability of the compound over time.<sup>37</sup> Following the inspection, FDA inspectors internally recommended a recall and an import alert concerning the product.<sup>38</sup>

50. On January 30, 2009, Apotex submitted its response to the Etobicoke Form 483 and addressed FDA's concerns about the stability data.<sup>39</sup> Apotex noted that FDA had expressly approved the raw material supplier based on three-month accelerated stability data, in accordance with FDA's Guidance for Submitting Documents for the Stability of Human Drugs and Biologics of February 1987.<sup>40</sup> It further observed that FDA had recently confirmed in January 2009 that the approach to stability data provided for in that Guidance remained acceptable.<sup>41</sup>
51. In February 2009, FDA inspectors continued their internal analysis of Apotex's production of Carbidopa-Levodopa and its efficacy. The inspectors ultimately concluded that there was no issue in that regard.<sup>42</sup>

#### **B. Consumer Complaints in 2009**

52. In early 2009, FDA received two consumer complaints concerning Apotex's products. The first concerned the drug [REDACTED], and reported that a round [REDACTED] [REDACTED] had been found in a bottle of triangular [REDACTED].<sup>43</sup> The second concerned [REDACTED] and reported an overly thick tablet.<sup>44</sup>

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<sup>37</sup> US Counter-Memorial, paras. 76-77. See **Exhibit C-34**, Etobicoke Form 483, dated December 19, 2008 at 2 (Observation 9).

<sup>38</sup> US Counter-Memorial, para. 80; Witness Statement of Debra Emerson, para. 27.

<sup>39</sup> **Exhibit C-37**, Apotex's Response to Etobicoke Form 483, dated January 30, 2009 at 6-7.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.* See also Second Witness Statement of Bernice Tao, para. 45.

<sup>42</sup> **Exhibit C-339**, FDA Internal File on Carbidopa-Levodopa, dated February 9, 2009 at US296-97 (FDA carefully reviewed documents pertaining to 10 Apotex internal investigations, 3 out-of-specifications (OOS) deviations, 26 other deviations due to process issues, dissolution matters and foreign material issues – and found “no issues” with any of them. FDA also reviewed Apotex's investigations of all six complaints pertaining to Carbidopa-Levodopa and noted that all were “well documented.” Investigators reviewed annual product quality reviews and concluded that “no trends or issues [were] found.”). See also **Exhibit C-41**, Etobicoke Warning Letter, dated June 25, 2009 (no mention of Carbidopa-Levodopa). The record does not support the US's statement in its Counter-Memorial that “[t]here was no assurance ... that drugs shipped to the United States were potent and effective for the two years advertised by Apotex.” US Counter-Memorial, para. 76.

<sup>43</sup> **Exhibit R-31**, Medwatch Report for [REDACTED], dated January 8, 2009.

<sup>44</sup> **Exhibit R-32**, Medwatch Report for [REDACTED], dated January 13, 2009.

53. FDA treated the complaints internally as “top priority[.]”<sup>45</sup> FDA searched for reports of prior adverse events. It found none.<sup>46</sup> It collected samples of the products for its internal analysis.<sup>47</sup> FDA’s practice is to contact the producer if its analysis reveals any concern about the product.<sup>48</sup> FDA did not contact Apotex or inform it of any concerns regarding these complaints.<sup>49</sup>
54. Meanwhile, unaware of FDA’s attention to the issue, Apotex diligently investigated the two complaints.<sup>50</sup> Apotex’s investigation concluded that these two incidents were isolated ones that posed no health hazard.<sup>51</sup>

### C. “Withdrawn” ANDAs and Rejected Batches

55. In the second quarter of 2009, while CDER was reviewing the observations made during the Etobicoke Inspection, FDA’s concerns were heightened by two suspicions not mentioned in the Form 483, and which Apotex had no occasion to address. Both suspicions were unfounded.
56. First, FDA mistakenly assumed that Apotex had “withdrawn” multiple ANDA applications.<sup>52</sup> FDA took this concern seriously because it addressed the integrity of

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<sup>45</sup> **Exhibit C-336**, FDA Internal Email Chain, dated January 16, 2009 at US2547 (Email from Edwin Rivera-Martinez to Carmelo Rosa) (“Top priority! Please assign to someone in ICB [Inspection and Compliance Branch] for review and follow-up. We should contact the pharmacist that submitted the MedWatch report first thing next Wednesday morning to see if they have intact unopened bottles of the product available that could be picked up by Kansas City District for FDA analysis. We should also consider a for-cause inspection request at the manufacturer in Canada.”).

<sup>46</sup> **Exhibit R-34**, FDA Internal Email, dated January 22, 2009 at 1 (“[A Consumer Safety Officer] searched the DQRS database and [] did not find any similar reports regarding this issue.”).

<sup>47</sup> **Exhibit C-336**, FDA Internal Email Chain, dated January 16, 2009 at US2547; **Exhibit C-342**, FDA Internal Email Chain, dated March 9, 2009 (indicating the sample had been obtained by FDA’s field office).

<sup>48</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 22(c).

<sup>49</sup> Second Witness Statement of Edmund Carey, para. 11.

<sup>50</sup> *Id.*, para. 26. **Exhibit C-350**, Apotex, ██████████ Investigation, dated April 13, 2009; **Exhibit C-340**, Apotex ██████████ Investigation, dated February 9, 2009.

<sup>51</sup> Second Witness Statement of Edmund Carey, para. 26.

<sup>52</sup> See, e.g., **Exhibit R-33**, FDA Internal Email Chain, dated January 21, 2009; **Exhibit C-338**, FDA Internal Email Chain, dated March 2, 2009 at US268 (Email from Heriberto Negron-Rivera to Carmelo Rosa, dated February 18, 2009) (“As we can appreciate they are not ready for most of them and they are stating they will withdraw almost all of them. From 52 applications they only ‘feel’ they are ready for 12.”); **Exhibit C-344**, FDA Internal Email, dated March 19, 2009 at US283 (noting the firm “not being ready for pre-approval inspection for about 50 ANDAs they have lined up[.]”); **Exhibit C-356**, FDA Internal Email Chain, dated May 22, 2009 at US5363 (referring to “cancelled” applications).

Apotex's applications.<sup>53</sup> However, FDA did not communicate this concern to Apotex. It was based on a misinterpretation of information. As Ms. Bernice Tao explains in her second witness statement, Apotex did not withdraw any ANDA application, but simply withdrew certain alternative testing and manufacturing *sites* from certain of its ANDA applications.<sup>54</sup> Apotex withdrew these sites to expedite pre-approval inspections: it believed that the inspections would be scheduled sooner if the applications listed only one manufacturing or testing site, as opposed to several.<sup>55</sup> FDA's concern was a result of a misunderstanding of Apotex's "withdrawal" requests.<sup>56</sup>

57. Second, FDA also misunderstood the data provided at the end of the Etobicoke Inspection concerning the number of "rejected batches," which appeared high and suggested to FDA that Apotex's manufacturing practices were out of control.<sup>57</sup> The Etobicoke inspectors did not note this concern in the Etobicoke Form 483.<sup>58</sup> Apotex was therefore unaware of it and had no opportunity to address it in its response to the Form 483. FDA later stated this concern in the Etobicoke Warning Letter.<sup>59</sup> As noted in the Memorial, Apotex addressed this concern in its response to the Warning Letter, showing that FDA's concern was in significant part based on a misunderstanding of

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<sup>53</sup> **Exhibit C-334**, FDA Internal Email Chain, dated January 15, 2009 at US5401 (Email from Susan Laska to Carmelo Rosa, Concepcion Cruz and Shawnte Adams) ("Firms are supposed to be ready at the time of filing looks like the applications have some integrity issues regarding sites identified.").

<sup>54</sup> Second Witness Statement of Bernice Tao, para. 21. *See also* **Exhibit C-352**, Email Chain between Apotex and FDA, dated April 28, 2009 at US6226 (Email from Carol Austin (Apotex) to Heriberto Negron-Rivera (FDA), dated April 27, 2009) ("Please note that a number of the rows, though indicating ready for inspection, are not applicable to Apotex (Signet campus)." (withdrawing Signet as an alternative site and leaving Etobicoke)); **Exhibit R-33**, Email Chain Between FDA and Apotex, dated January 21, 2009 (Email from Apotex (Carol Austin) to FDA (Heriberto Negron-Rivera), dated January 15, 2009) ("The submission included the 4100 Weston facility as an *alternative* packaging site. We will *withdraw this site* since manufacturing and packaging is done at our India facility." (emphasis added)).

<sup>55</sup> Second Witness Statement of Jeremy Desai, paras. 40-45. *See also* **Exhibit C-354**, FDA Internal Email, dated May 20, 2009 at US4042 (Email from Carol Austin to Heriberto Negron-Rivera, dated May 19, 2009 ("We are definitely looking forward to getting this inspection booked.")).

<sup>56</sup> Second Witness Statement of Bernice Tao, paras. 19-20.

<sup>57</sup> **Exhibit C-358**, FDA Internal Memorandum, dated June 4, 2009 at US3014. *See also* Witness Statement of Carmelo Rosa, para. 36.

<sup>58</sup> **Exhibit C-34**, Etobicoke Form 483, dated December 19, 2008 (omitting any reference to high batch rejection rate, failure to investigate batch failures, or hydrochlorothiazide).

<sup>59</sup> **Exhibit C-41**, Etobicoke Warning Letter, dated June 25, 2009 at 2 (Item I.A).

Apotex's batch rejection system.<sup>60</sup> Unfortunately for Apotex, FDA adopted the Import Alert before it completed its review of Apotex's response to the Etobicoke Warning Letter, as discussed below.

#### **D. FDA's Decision to Adopt the Import Alert**

58. By April 1, 2009, FDA already prepared and circulated internally the second draft of the Etobicoke Warning Letter.<sup>61</sup> In April and May, FDA was already contemplating an import alert.<sup>62</sup>
59. On Sunday, June 7, 2009, Ms. Deborah Autor, Director of CDER's Office of Compliance, sent a note regarding the impending Etobicoke warning letter to CDER's Director, Janet Woodcock.<sup>63</sup> Ms. Autor's note was accompanied by four documents: a draft of the warning letter, a list of "key issues," the Etobicoke Form 483 and the inspectors' Establishment Inspection Report (EIR).<sup>64</sup> Because the draft warning letter was in principal part not based on the inspectors' observations, Ms. Autor advised that the Form 483 and inspection report "were not of much use."<sup>65</sup>
60. On the following day, Monday, June 8, 2009, Ms. Woodcock responded in these terms:

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<sup>60</sup> Memorial, para. 157 (citing **Exhibit C-44**, Apotex's Response to Etobicoke Warning Letter, dated July 17, 2009); Witness Statement of Jeremy Desai, para. 39. *See also* **Exhibit C-410**, letter from Apotex to FDA, dated November 24, 2009.

<sup>61</sup> **Exhibit C-345**, FDA Internal Email, dated April 1, 2009.

<sup>62</sup> **Exhibit C-351**, FDA Internal Email Chain, dated April 15, 2009 at US7232; **Exhibit C-355**, FDA Internal Email, dated May 22, 2009 (transmitting sample import alert and recommending that it could be used "as a model for drafting the Apotex [Import Alert]").

<sup>63</sup> **Exhibit C-359**, FDA Internal Email Chain, dated June 8, 2009 at US7270-71 (Email from Deborah Autor to Janet Woodcock, dated June 7, 2009).

<sup>64</sup> These documents were not attached to the email produced as document US7270 (**Exhibit C-359** herein).

<sup>65</sup> **Exhibit C-359**, FDA Internal Email Chain, dated June 8, 2009 at US7270. Ordinarily, any enforcement action would be recommended by the inspectors and CDER would provide a second-level review to ensure that the recommended action was warranted. It appears that in Apotex's case the inspectors' findings concerning Etobicoke were simply ignored. *See* **Exhibit R-18**, US Government Accountability Office, GAO-08-970, *Drug Safety: Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program*, at 14 (2008) (ORA writes the EIR and makes a recommendation; CDER reviews the EIR and any response the firm has provided; then "CDER determines whether the establishment complied with GMPs"). *Accord* US Counter-Memorial, paras. 41-42 ("Any recommendation for enforcement action proceeds through *multiple levels* within FDA." (emphasis added)). *See generally*, **Exhibit R-16**, FDA, *Establishment Inspection Report* (June 2007) ("Compliance Branch will evaluate the IB referral and take appropriate action as required.").

Thanks, this is helpful. Obviously this firm should not be shipping drug [sic] to the US! What are we going to do about it besides WL?<sup>66</sup>

61. Upon receipt of this email, Ms. Autor immediately asked her team if they could “do an import alert sooner rather than later[.]”<sup>67</sup> The response was that a drug shortage determination had to be completed.<sup>68</sup> It had already been initiated on June 1, 2009.<sup>69</sup>
62. Apotex immediately became a subject of discussion at the highest levels of FDA. The company was discussed at a meeting between the FDA Commissioner and her executive staff on Tuesday, June 9, 2009.<sup>70</sup> On June 24, 2009, FDA informed the Secretary of the US Department of Health and Human Services of the impending Etobicoke warning letter.<sup>71</sup>
63. Elevation to political levels of the issuance of a warning letter is highly unusual.<sup>72</sup> Political officers are informed of CDER action typically only when, due to the significance of the underlying issues, FDA expects high level of publicity to be associated with its proposed action.<sup>73</sup>

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<sup>66</sup> **Exhibit C-359**, FDA Internal Email Chain, dated June 8, 2009 at US7270 (Email from Janet Woodcock to Deborah Autor, dated June 8, 2009 at 17:08).

<sup>67</sup> *Id.* (Email from Deborah Autor to Joseph Famulare, Rick Friedman, Edwin Rivera Martinez and Hidee Molina, dated June 8, 2009 at 17:16).

<sup>68</sup> *Id.* (Email from Joseph Famulare to Deborah Autor and others, dated June 8, 2009 at 21:55).

<sup>69</sup> **Exhibit C-357**, FDA Internal Email, dated June 1, 2009 (CDER-OC requesting information about possible shortage of certain Apotex products because it was “considering regulatory action[.]”).

<sup>70</sup> **Exhibit C-360**, FDA Internal Email Chain, dated June 9, 2009 at US6161-62. *See also* **Exhibit C-362**, FDA Internal Email Chain, dated June 16, 2009 at US7154 (Email from Carmelo Rosa to Irma Rivera, dated June 10, 2009) (“There is a big issue and interest in this case, and we (CDER) need to brief Canada Health on the upcoming WL and concerns we have with this firm. This has been taken to the level of Deb Autor and Janet Woodcock. The new commissioner is also being briefed.”); **Exhibit C-363**, FDA Email Chain, dated June 16, 2009 at US6387 (Email from Giuseppe Randazzo to Claire Picard, dated June 16, 2009) (providing model for Apotex Information Advisory used to brief higher ranking officials).

<sup>71</sup> **Exhibit C-365**, FDA, Information Advisory to the Secretary of US Dep’t of Health & Human Services, dated June 24, 2009 at US7470 (noting “CDER is evaluating whether a product shortage will result by placing this firm on Import Alert”).

<sup>72</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 10.

<sup>73</sup> *Id.*

## E. The Etobicoke Warning Letter

64. As noted in the Memorial, while the Etobicoke Form 483 listed 11 inspectional observations, only *three* appeared in the Etobicoke Warning Letter issued in June 25, 2009:
- a. Failure to thoroughly investigate failure of a batch (21 CFR § 211.192),<sup>74</sup> an alleged violation that was not stated in the Etobicoke Form 483.<sup>75</sup> This was the manifestation of FDA's concerns as to the number of rejected batches.
  - b. Failure to timely submit field alert reports (21 CFR § 314.81(b)(1)).<sup>76</sup>
  - c. Failure to include a specimen or copy of the approved label in the batch master record (21 CFR § 211.186(b)(8)).<sup>77</sup>

Apotex addressed each of these issues – and, significantly, the underlying concern as to batch rejections – in its July 17, 2009 response to the Warning Letter.<sup>78</sup>

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<sup>74</sup> **Exhibit C-41**, Etobicoke Warning Letter, dated June 25, 2009. **Legal Authority CLA-269**, 21 CFR § 211.192 reads as follows:

“All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup.”

<sup>75</sup> See Memorial, para. 153. The US does not dispute this point.

<sup>76</sup> **Exhibit C-41**, Etobicoke Warning Letter, dated June 25, 2009. **Legal Authority CLA-273**, 21 CFR § 314.81(b)(1) reads as follows:

“NDA--Field alert report. The applicant shall submit information of the following kinds about distributed drug products and articles to the FDA district office that is responsible for the facility involved within 3 working days of receipt by the applicant. The information may be provided by telephone or other rapid communication means, with prompt written followup. The report and its mailing cover should be plainly marked: ‘NDA--Field Alert Report.’ (i) Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article. (ii) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specification established for it in the application.”

<sup>77</sup> **Exhibit C-41**, Etobicoke Warning Letter, dated June 25, 2009. **Legal Authority CLA-268**, 21 CFR § 211.186(b)(8) reads as follows:

“Master production and control records shall include ... [a] description of the drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labelling[.]”

<sup>78</sup> See Memorial, para. 157.

### *1. Apotex's Batch Rejection System*

65. Apotex showed in its response to the Etobicoke Warning Letter that the suggestion that Apotex had a “high” batch failure rate was based in significant part on a misunderstanding on FDA’s part.<sup>79</sup> The US figure of 554 batch rejections<sup>80</sup> included hundreds of production decisions that had nothing to do with product failing to meet specifications.<sup>81</sup> As explained to FDA, the overall rejection rate for in-process batch was [REDACTED], while the overall rejection rule for finished batches was [REDACTED].<sup>82</sup>
66. As to the Warning Letter’s specific suggestion that Apotex failed to investigate an assay failure pertaining to its product Hydrochlorothiazide, Apotex explained that, in or about October 2008, Apotex had conducted a business review of the value of this product and decided – for commercial reasons – that the firm “would not pursue the launch of this product.”<sup>83</sup> In its response to the Etobicoke Warning Letter, Apotex also provided documents showing that all batches of the product that failed assay had been destroyed and none released on the market.<sup>84</sup>

### *2. Field Alert Reports and Labels*

67. The alleged violations of failure to timely submit field alert reports (FARs) and failure to include product label samples in the master records addressed record-keeping practices rather than manufacturing issues.<sup>85</sup>
68. Apotex had filed certain FARs behind schedule.<sup>86</sup> However, it did file them.<sup>87</sup> Moreover, unlike many other firms reviewed by FDA, Apotex diligently filed required

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<sup>79</sup> **Exhibit C-44**, Apotex’s Response to the Etobicoke Warning Letter, dated July 17, 2009 at 1, 5-6 (indicating only [REDACTED] of the 554 batches were true batch failures).

<sup>80</sup> US Counter-Memorial, paras. 79-80, 180; Witness Statement of Carmelo Rosa, paras. 35, 36, 43; Witness Statement of Debra Emerson, paras. 22, 23, 29, 30.

<sup>81</sup> **Exhibit C-44**, Apotex’s Response to the Etobicoke Warning Letter, dated July 17, 2009 at 5-6.

<sup>82</sup> **Exhibit C-410**, Letter from Apotex to FDA, dated November 24, 2009 at US4284-85 (“The [REDACTED] [unexpired] rejected batches can be classified into two major groups, process related and non-process related. ... During this time period a total of [REDACTED] intermediate batches were manufactured resulting in [REDACTED] finish product batches.) (rejection rate of [REDACTED] for in-process batches and [REDACTED] for finish product batches.”). *See also* Second Witness Statement of Edmund Carey, para. 19.

<sup>83</sup> **Exhibit C-44**, Apotex’s Response to the Etobicoke Warning Letter, dated July 17, 2009 at 14.

<sup>84</sup> *Id.* at 14-15.

<sup>85</sup> Second Witness Statement of Edmund Carey, para. 21.

<sup>86</sup> **Exhibit C-41**, Etobicoke Warning Letter, dated June 25, 2009 at 4-5.

follow-up and close-out reports for all of its FARs.<sup>88</sup> Indeed, the record leaves unanswered why timely filing of FARs was cited in the Etobicoke Warning Letter at all, given that FDA considered Apotex's answer on this issue (in its response to the Etobicoke Form 483) to be "adequate."<sup>89</sup>

69. Apotex's practice was to maintain labeling information regarding each batch in electronic form.<sup>90</sup> FDA ultimately accepted as satisfactory Apotex's practice of keeping electronic copies of labels.<sup>91</sup>

#### **F. The Signet Inspection**

70. FDA had begun preparing for the Signet Inspection as the Etobicoke Warning Letter was being drafted. However, Janet Woodcock's instruction to bar Apotex from the US market in early June 2009 changed FDA's approach to the inspection. A June 10, 2009 internal FDA email concerning "Apotex Canada" stated as follows:

This case has reached very high levels, including the preparation of an advisory paper and other communications in progress for Health Canada (being coordinated by OIP). OCC deadline to clear the WL is 6/19/09 (I just received their draft for review and comments today). *Rick [Friedman] and Joe [Famulare] are interested in revising the original strategy for many reasons, which should not affect the time of the inspection, only the approach.*<sup>92</sup>

71. The approach adopted included adding a CDER compliance officer to a team of experienced field inspectors and an experienced chemist. CDER official Kristy Zielny

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<sup>87</sup> Second Witness Statement of Edmund Carey, para. 24; **Exhibit C-44**, Apotex's Response to the Etobicoke Warning Letter, dated July 17, 2009 ("Upon communication to senior management, specifically the Vice President, Quality, problems were promptly ... reported.") (listing timeline of FARs once the problem was properly escalated to senior management).

<sup>88</sup> Second Witness Statement of Edmund Carey, para. 24.

<sup>89</sup> **Exhibit C-337**, FDA, OAI Case Review (2008 Etobicoke Inspection), dated January 30, 2009 at US6357.

<sup>90</sup> **Exhibit C-37**, Apotex's Response to Etobicoke Form 483, dated January 30, 2009 at 5-6 ("We believe that our processes as currently designed, documented and followed allow us to meet the intent of the regulations and that no action needs to be taken at this time.").

<sup>91</sup> Second Witness Statement of Edmund Carey, para. 25.

<sup>92</sup> **Exhibit C-362**, FDA Internal Email, dated June 16, 2009 at US7154 (emphasis added) (Apotex understands FDA's abbreviations used in Mr. Rosa's emails as follows: "Rick" – Rick Friedman, Director of CDER Office of Manufacturing and Product Quality; "Joe" – Joseph Famulare, Deputy Director of CDER Office of Compliance; "WL" – Etobicoke then-proposed Warning Letter; "OIP" – FDA's Office of International Programs; "OCC" – FDA's Office of Chief Counsel).

volunteered for the Signet Inspection,<sup>93</sup> with the support of her hierarchy noting that she was “brief[ed] on the issues and objective of this inspection.”<sup>94</sup> As detailed in the Memorial, Ms. Zielny was the investigator who sidelined the lead investigator, Lloyd Payne, and took an aggressive approach in the Signet Inspection, allowing Apotex only limited opportunities to provide explanations concerning her findings.<sup>95</sup>

72. On July 10, 2009, FDA notified Apotex of the Signet Inspection.<sup>96</sup> Unusually, as part of its preparation for the inspection, FDA analyzed the potential impact of an import alert on Apotex’s Signet products.<sup>97</sup>

73. The Signet Inspection began on July 27, 2009. As the Memorial noted, and as the Counter-Memorial highlights, during the inspection Ms. Zielny developed a suspicion that Apotex had submitted incomplete and inaccurate information on its application-related filings, potentially triggering FDA’s Application Integrity Policy.<sup>98</sup> Application integrity issues are serious. Apotex fully responded to the concerns expressed by the inspectors.<sup>99</sup> As noted in the Memorial, the inspectors concluded that no observation concerning application integrity was warranted, and none appears in the Signet Form 483.<sup>100</sup>

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<sup>93</sup> **Exhibit C-366**, FDA Internal Email Chain, dated June 29, 2009.

<sup>94</sup> *Id.* See also **Exhibit C-367**, FDA Internal Email Chain, dated July 8, 2009 at US1406-07 (Email from Carmelo Rosa to Rebecca Hackett) (confirming Ms. Zielny’s appointment).

<sup>95</sup> Memorial, para. 168 (citing Witness Statement of Bruce Clark, para. 30 (noting that Ms. Zielny “did not seem to want to listen to [Apotex’s] position[ ]”)); Memorial, para. 164.

<sup>96</sup> **Exhibit C-368**, Letter from FDA to Apotex, dated July 10, 2009.

<sup>97</sup> **Exhibit C-369**, FDA Internal Email Chain, dated July 17, 2009 at US223 (analyzing Apotex’s market share to determine “if the product was not available how would this impact supply”).

<sup>98</sup> See Memorial, paras. 164-65; US Counter-Memorial, paras. 90, 107 n.245. The US Counter-Memorial distorts the record in suggesting that “Apotex management ... acknowledged that the information provided to FDA [in its supplements] ‘was inaccurate and incomplete.’” *Id.* para. 90 (quoting **Exhibit R-42**, 2009 Signet EIR at 59). The 2009 Signet EIR makes it clear that Apotex “did not agree with the term ‘inaccurate’ in the statement made regarding information provided in the [supplement at issue].” See **Exhibit R-42**, 2009 Signet EIR at 59. See also Second Witness Statement of Bernice Tao, paras. 9-10 (Ms. Tao recalled the FDA inspectors coming to the conclusion that the information was inaccurate, but did not recall Apotex coming to that conclusion); Witness Statement of Bruce Clark, para. 30.

<sup>99</sup> Memorial, para. 165 (“On Day 12, Apotex gave a presentation on the issues of Oxcarbazepine and data integrity.”); **Exhibit C-59**, Internal FDA Email, dated August 13, 2009 (“For Kristy and Brian, a presentation was made regarding the Oxcarbazepine and our interactions with OGD for this product.”).

<sup>100</sup> Memorial, para. 165. See **Exhibit C-61**, Signet Form 483, dated August 14, 2009.

74. In order to clear any doubt concerning the integrity of its supplements to drug applications, Apotex conducted a comprehensive retrospective supplement review under a protocol approved by FDA.<sup>101</sup> To Apotex's best knowledge, FDA was ultimately satisfied with Apotex's information and cleared the issue.<sup>102</sup>

### **G. The Import Alert**

75. The close-out meeting for the Signet Inspection took place on Friday, August 14, 2009.<sup>103</sup> That same day, FDA investigators advised Apotex that the firm had until the close of business on the following business day, Monday, August 17, 2009 to revert to FDA with a proposal as to the firm's next steps.<sup>104</sup>

76. FDA began preparing the draft Import Alert recommendation even before the call with Apotex. At 11:31 am on Monday, August 17, 2009, Ms. Zielny transmitted the Signet Form 483 to her superiors in FDA CDER and requested that they "disseminate to whoever will be writing recommendations regarding the Import Alert, AIP [Application Integrity Policy], etc., so that they [did] not have to re-write sections that they may need to reference from the 483."<sup>105</sup>

77. At 2 pm that day Apotex called FDA as requested.<sup>106</sup> During that call, Apotex restated its commitment to take all reasonably necessary remediation steps. It advised FDA that

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<sup>101</sup> Witness Statement of Bernice Tao, paras. 60-61. *See also* **Exhibit C-136**, Letter from Apotex to FDA, dated March 17, 2010 at 2 (enclosing review of Manufacturing Process ANDA Supplements); **Exhibit C-188**, Letter from Apotex to FDA, dated January 17, 2011 (enclosing summary report of extended retrospective supplement review, dated January 17, 2011); **Exhibit C-231**, Letter from Apotex to FDA, dated March 28, 2011 (enclosing extended retrospective supplement review for liquid dose products).

<sup>102</sup> Witness Statement of Bernice Tao, para. 62. *See also* **Exhibit C-233**, Letter from FDA to Apotex, dated May 6, 2011 (indicating FDA had reviewed Apotex's response to Etobicoke Form 483 and supporting documentation and "classifying [Apotex's Etobicoke] facility as acceptable[ ]"); **Exhibit C-249**, FDA Memorandum from CDER-OC to DIOP, dated July 1, 2011 (stating comprehensive written responses were reviewed and that corrective actions adequately addressed deficiencies found at Signet); **Exhibit C-247**, Letter from FDA to Apotex, dated July 1, 2011 (classifying Signet "as acceptable").

<sup>103</sup> **Exhibit R-42**, 2009 Signet EIR at 38.

<sup>104</sup> **Exhibit C-379**, FDA Internal Email Chain, dated August, 21, 2009 at US4075.

<sup>105</sup> **Exhibit C-371**, FDA Internal Email Chain, dated August, 17, 2009.

<sup>106</sup> **Exhibit R-43**, FDA, Minutes of Teleconference with Apotex on August 17, 2009 at 2:00 PM.

it had already engaged an outside consulting group, Jeff Yuen, to guide the firm in that process.<sup>107</sup>

78. At approximately 5 pm, FDA internally circulated a draft of the memorandum recommending the Import Alert.<sup>108</sup>
79. An August 18, 2009 internal FDA communication acknowledges that FDA was recommending the Import Alert even though it had not completed review of Apotex's response to the Etobicoke Warning Letter.<sup>109</sup>
80. On August 19, 2009, FDA determined that Apotex's proposed recall would not create a shortage.<sup>110</sup>
81. The final version of the Import Alert recommendation was prepared on August 20, 2009,<sup>111</sup> and endorsed by CDER on August 24, 2009.<sup>112</sup> CDER sent its recommendation to DIOP on August 25, 2009.<sup>113</sup> The Director of DIOP followed up within 15 minutes with a member of his team, noting:

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<sup>107</sup> *Id.*

<sup>108</sup> **Exhibit C-374**, FDA Internal Email Chain, dated August 18, 2009 (Email from Hidee Molina to Carmelo Rosa); **Exhibit C-372**, CDER's Draft Memorandum, dated August 17, 2009 (recommending putting Apotex on import alert).

<sup>109</sup> **Exhibit C-373**, FDA Internal Email Chain, dated August 18, 2009. Notably, the field in the report requiring listing of any "known/suspect injuries" was blank.

<sup>110</sup> **Exhibit C-376**, FDA Internal Email Chain, dated August 19, 2009 at US6152 (Email from Israel Santiago to Edwin Rivera Martinez and others, dated August 19, 2009) ("Bottom line, there is little to no concern with recalling the products on the list."). On August 19, 2009, John Verbeten, the Director of DIOP, emailed Rick Friedman (CDER-OC), noting: "We reached out to the Import-Export team for Apotex info on Tuesday . . . . One of them will process the IA addition and shouldn't have to wait on anything from me to begin." See **Exhibit C-380**, FDA Internal Email Chain, dated August 25, 2009 at US6203.

<sup>111</sup> **Exhibit C-378**, FDA Internal Email, dated August 20, 2009 (Email from Edwin Rivera Martinez to Hidee Molina copying Carmelo Rosa, dated August 20, 2009 at 16:19 ("Attached is the draft IA memo with my corrections. . . . Let's try to get this done and to Rick today.")); **Exhibit C-64**, Memorandum from Director of CDER-OC DMPQ (Rick Friedman) to Director DIOP (Dominic Veneziano), dated August 20, 2009.

<sup>112</sup> **Exhibit C-380**, FDA Internal Email Chain, dated August 25, 2009 at US6202 (Email from Rick Friedman to John Verbeten, dated August 24, 2009 at 11:32 PM) (the date of the Import Alert recommendation remained August 20, 2009).

<sup>113</sup> **Exhibit C-381**, FDA Internal Email Chain, dated August 25, 2009 at US6191 (Email from Hidee Molina to John Verbeten and others, dated August 25, 2009).

We already have Center concurrence; *this should be a quick win for you*. Please create a CMS case and process so that we can quickly add the firms to IA 66-40.<sup>114</sup>

82. The Import Alert came into effect on Friday, August 28, 2009, at around 12 pm,<sup>115</sup> about 20 minutes after CDER requested an update of DIOP on the status of the Import Alert.<sup>116</sup>
83. Late that day, Edwin Rivera Martinez emphasized the swiftness of FDA's action to his superiors within CDER:

The Apotex manufacturing sites at Etobicoke and Signet Drive ... have been added to Import Alert #66-40 for all finished form drug products. *This action was taken just 10 business days after the close-out of the inspection of the Signet Drive facility*. The inspection was concluded on August 14.<sup>117</sup>

### III. NO OTHER REGULATOR ADOPTED A MEASURE EQUIVALENT TO FDA'S IMPORT ALERT

#### A. Health Canada's "Supervision" over Apotex Was Not Equivalent to FDA's Import Alert

84. The US alleges that FDA's findings about Apotex "spurred Health Canada to action," referring to an on-site supervision Health Canada established over Apotex.<sup>118</sup> However, Apotex rejects any suggestion that this "supervision" was comparable to FDA's two-year long Import Alert. Unlike Health Canada and other national regulators, FDA never gave Apotex a chance voluntarily to address its concerns. Moreover, Health Canada's approach accords with the approach taken by FDA with respect to Apotex's

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<sup>114</sup> *Id.* (Email from John Verbeten to Patrick Bowen, dated August 25, 2009) (emphasis added). See also **Exhibit C-382**, FDA Internal Email Chain, dated August 26, 2009 at US6215 (Email from Patrick Bowen to John Verbeten, dated August 26, 2009) ("This action is being processed ...").

<sup>115</sup> **Exhibit C-67**, Email from Director of DIOP to Import Program Managers, dated August 28, 2009 at 12:01 pm.

<sup>116</sup> **Exhibit C-383**, FDA Internal Email, dated August 28, 2009 at 11:34 am ("Just wondering if we have any information on the status of this Import Alert. The firm continues to ship adulterated product into the US. Please let us know as soon as the IA is in effect.").

<sup>117</sup> **Exhibit C-384**, FDA Internal Email, dated August 28, 2009 at US7254 (Email from Edwin Martinez Rivera to Rick Friedman, Joseph Famulare, and Deborah Autor) (emphasis added). See also **Exhibit C-407**, FDA Internal Email Chain, dated November 13, 2009 (Email from David Jaworski to Hidee Molina) (CDER prepared a one-slide summary on the Apotex case that "may be used for a presentation by Janet Woodcock. The focus of the slide should be timeline (Swift aggressive action) Key issues that led to the Import Alert.").

<sup>118</sup> US Counter-Memorial, paras. 143-53.

comparators: Health Canada worked with Apotex to address its concerns, rather than blocking market access.

85. It also bears noting in this context that the US dwells on discussing the alleged “problems” purportedly found by Health Canada during its September to November 2009 inspections.<sup>119</sup> However, as noted in the Memorial, following two lengthy and thorough inspections of the Etobicoke and Signet facilities, Health Canada approved both facilities as cGMP compliant.<sup>120</sup> The US’s discussion misses the mark. FDA was certainly aware of Health Canada’s finding of cGMP compliance, but the US omits to mention it.<sup>121</sup>

### **B. The IGZ, Medsafe and TGA Measures Were Not Equivalent to FDA’s Import Alert**

86. The US further errs in suggestions that public health authorities in the EU, New Zealand and Australia “banned” Apotex products due to their shared concerns over “seriousness of the problems at Etobicoke and Signet.”<sup>122</sup>

87. *First*, the alleged “bans” adopted by IGZ, Medsafe and TGA were purely precautionary actions based on FDA’s Import Alert. These regulators did not perform an independent assessment of Apotex’s facilities; they simply reacted to FDA’s Import Alert.<sup>123</sup> Acknowledging the harshness of the measure, IGZ, Medsafe and TGA negotiated *temporary* bans with Apotex, pending Health Canada’s confirmation that there were no cGMP concerns at Etobicoke and Signet.

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<sup>119</sup> *Id.*, paras. 111-34.

<sup>120</sup> **Exhibit C-112**, Health Canada, Inspection Exit Notice for Signet, dated October 14, 2009 at 3 (Rating C); **Exhibit C-116**, Health Canada, Inspection Exit Notice for Etobicoke, dated November 4, 2009 at 3 (Rating C).

<sup>121</sup> *See, e.g.*, **Exhibit C-398**, Email from Health Canada to FDA, dated October 16, 2009 at US1112 (attaching Inspection Exit Notice for Signet); **Exhibit C-408**, Email from Apotex to FDA, dated November 16, 2009 (transmitting Health Canada Inspection Exit Notices for Etobicoke, Signet and Richmond Hill).

<sup>122</sup> US Counter-Memorial at 66, heading L.

<sup>123</sup> *See, e.g.*, **Exhibit C-396**, FDA Internal Email Chain, dated September 16, 2009 (Email from Edwin Rivera-Martinez to Israel Santiago and Rick Friedman) (“In my 32 years with the agency, this is the first time I’ve seen a foreign regulatory body take prompt and effective action *based on FDA’s inspection and IA action.*”(emphasis added)).

88. *Second*, all such concerns were indeed soon addressed by Health Canada's thorough inspection of Apotex's facilities in September to November 2009, following which Health Canada found Apotex's facilities to be cGMP compliant.<sup>124</sup>
89. *Third*, in light of Health Canada's findings of cGMP compliance, each of the import bans referred to by the US was short-lived. IGZ's ban in the Netherlands lasted for about *two weeks* (from October 26, 2009 until November 6, 2009).<sup>125</sup> Medsafe's ban in New Zealand lasted for about *two months* (from September 17, 2009 until October 20, 2009 for Signet and November 24, 2009 for Etobicoke).<sup>126</sup> TGA's ban in Australia also lasted for about *two months* (from September 11, 2009 until November 11, 2009).<sup>127</sup> None of these bans resembled the draconian measure imposed on Apotex by FDA for two years.

## COUNTER-MEMORIAL ON JURISDICTION

90. The US Counter-Memorial reflects substantial common ground between the disputing parties as concerns jurisdiction. The US does not dispute that each of Apotex Holdings and Apotex-Canada is an investor of Canada and thus meets the NAFTA's requirement of jurisdiction *rationae personae*. There is no dispute that, through intermediary holding companies, Apotex Holdings indirectly owns and controls Apotex-US.<sup>128</sup> Nor is there any disagreement that Apotex-US is an "enterprise" and, as such, qualifies as an "investment" and "an investment of an investor of a Party" within the meaning of Article 1139,<sup>129</sup> as well as "an enterprise of another Party" under Article 1117(1).<sup>130</sup>

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<sup>124</sup> **Exhibit C-112**, Health Canada, Inspection Exit Notice for Signet, dated October 14, 2009 at 3 (Rating C); **Exhibit C-116**, Health Canada, Inspection Exit Notice for Etobicoke, dated November 4, 2009 at 3 (Rating C).

<sup>125</sup> **Exhibit C-114**, CBG-MEB, *Apotex Stops Import and Distribution of Medicinal Products from Canada*, dated October 26, 2009; **Exhibit C-117**, CBG-MEB, *Import and Distribution Medicinal Products from Apotex Canada Resumed*, dated November 6, 2009.

<sup>126</sup> **Exhibit C-102**, Medsafe, Media Releases, *Import of Apotex Products Under Close Monitoring*, dated September 17, 2009; **Exhibit C-113**, Letter from Medsafe to Apotex, dated October 20, 2009; **Exhibit C-121**, Letter from Medsafe to Apotex, dated November 24, 2009.

<sup>127</sup> **Exhibit C-95**, Email Chain between Apotex-Australia and Apotex-Canada, dated September 11, 2009; **Exhibit C-118**, Email from TGA to Apotex-Australia, dated November 11, 2009.

<sup>128</sup> Memorial, paras. 20, 339.

<sup>129</sup> *Id.*, para. 340; **Legal Authority CLA-1**, North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289 (1993) (hereinafter "**Legal Authority CLA-1, NAFTA**"). *See id.*, art. 1139

91. The US also does not dispute that the Import Alert is a “measure” within the meaning of the NAFTA.<sup>131</sup> There is no disagreement that the temporal requirements of the NAFTA are satisfied in this case.
92. The US objections are limited to jurisdiction *rationae materiae* with respect to the investments of each claimant. The US erroneously claims that neither Apotex-Canada nor Apotex Holdings “sustained losses as an ‘investor of a Party’”<sup>132</sup> because neither had an investment in the United States, or an investment to which the Import Alert related.<sup>133</sup> *First*, contrary to the US’s assertion, Apotex-Canada holds investments in the United States because its marketing authorizations (or ANDAs) fall within the definition of investment in Article 1139(g) and (h).<sup>134</sup> The US’s alternative argument that the Import Alert did not “relate to” Apotex-Canada’s ANDAs as per Article 1101(1) equally lacks merit.<sup>135</sup> *Second*, the US errs in suggesting that the Import Alert did not “relate to” Apotex-US – and, thus, Apotex-Holdings – within the meaning of Article 1101(1).<sup>136</sup>
93. The US’s sole objection with respect to claimant Apotex Holdings is that the Import Alert did not “relate to” Apotex-US under Article 1101(1).<sup>137</sup> If this objection fails, the Tribunal has jurisdiction over the dispute irrespective of the US arguments as to Apotex-Canada’s ANDAs. For this reason, Apotex addresses the “relating to” argument first, followed by the issue of ANDAs as covered investments.

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(“**[I]nvestment** means: (a) an enterprise; ... **investment of an investor of a Party** means an investment owned or controlled directly or indirectly by an investor of such Party[.]”.

<sup>130</sup> **Legal Authority CLA-1**, NAFTA, art. 1117 (“An investor of a Party, on behalf of an enterprise of another Party that is a juridical person that the investor owns or controls directly or indirectly, may submit to arbitration under this Section [B] a claim that the other Party has breached an obligation under: (a) Section A ...”).

<sup>131</sup> **Legal Authority CLA-1**, NAFTA, art. 201. *See also* Memorial, para. 406; US Counter-Memorial, paras. 213, 219.

<sup>132</sup> US Counter-Memorial, para. 216.

<sup>133</sup> *Id.*, para. 219.

<sup>134</sup> *Id.*, para. 221 (“Apotex [] nonetheless claims to hold two kind of ‘investments’ in the United States for purposes of NAFTA Chapter Eleven: (1) ‘intangible property’, through its abbreviated new drug applications, and; (2) ‘interests arising from the commitment of capital’ made ‘in and into’ the United States. Apotex has failed to substantiate either claim.”).

<sup>135</sup> *Id.*, para. 274 (“The Import Alert had no legally significant connection to Apotex’s ANDAs.”).

<sup>136</sup> *Id.*, para. 289 (“The Import Alert does not ‘relate to’ Apotex Holdings in its capacity as an investor or to its claimed U.S. investment, [Apotex-US], within the meaning of Article 1101(1).”).

<sup>137</sup> *Id.*

## I. THE IMPORT ALERT RELATES TO APOTEX-US

94. As noted, the US does not dispute that Apotex-US is an “investment” of Apotex Holdings in the United States. The US asserts, and Apotex concurs, 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” within the meaning of Article 1101(1).<sup>138</sup> 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.<sup>139</sup> This, however, is about as far as the parties’ agreement on this point goes.
95. The US’s position is that in this case “there is no legally significant connection between the challenged measure and the investor or its investment[.]”<sup>140</sup> But the US avoids any affirmative statement of what “legally significant connection” Article 1101(1) requires, instead asserting a series of factual arguments unified by no stated guiding principle.<sup>141</sup> Apotex begins in **Section A** below by determining the content of Article 1101(1) pursuant to the rules of interpretation set out in Article 31(1) of the Vienna Convention on the Law of Treaties (the “Vienna Convention”). It then shows in **Section B** that the US arguments cannot be reconciled with the text and context of Article 1101(1) or the object and purpose of the NAFTA. In any event, the record shows that, contrary to the US arguments, the Import Alert clearly “applied to” Apotex-US and constituted an impediment to its business, as discussed in **Section C**. The US arguments to the

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<sup>138</sup> US Counter-Memorial, para. 288.

<sup>139</sup> **Legal Authority CLA-36**, *Methanex Corporation v. United States of America*, UNCITRAL, Preliminary Award on Jurisdiction, para. 147 (Aug. 7, 2002) (“We decide that the phrase ‘relating to’ in Article 1101(1) NAFTA signifies something more than the mere effect of a measure on an investor or an investment and that it requires a legally significant connection between them[.]”).

<sup>140</sup> US Counter-Memorial, para. 289.

<sup>141</sup> *Id.*, paras. 288-320. As noted in the briefing on bifurcation, a heading in the Counter-Memorial suggested that the US test for “legally significant connection” was that the measure apply to the investment, directly or indirectly, or constitute a legal impediment to its business. *See* Claimants’ Opposition to Bifurcation, para. 21 (referring to US Counter-Memorial at 141). However, in its reply on bifurcation, the US did not confirm that that was the test it posited, instead pretending that it was Apotex that had introduced the notions of a measure applying to or constituting a legal impediment to the business of an investment. *See* US Reply on Bifurcation, paras. 8-23. The US position therefore is unexplained.

contrary are based on a series of mistaken assumptions and contradicted by the US's own evidence, as shown in **Section D**.

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

96. What constitutes a “legally significant connection” for purposes of Article 1101(1) in a given case must be informed by the substantive NAFTA provisions at issue. If the connection between measure and investment that is required to establish a breach of a substantive provision is present, it is difficult to conclude that that connection is not of legal significance. Apotex has established the requisite legally significant connection because the record shows that the Import Alert breached Articles 1102, 1103 and 1105 as concerns the investors and investments in question here.<sup>142</sup>
97. Article 31(1) of the Vienna Convention provides that “[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”<sup>143</sup> The context of Article 1101(1) includes the substantive obligations set out in other provisions of Chapter Eleven.<sup>144</sup> Each of these obligations provides a requisite connection between the measure giving rise to a treaty breach and the investor/investment.
98. Article 1102 on national treatment provides that each NAFTA Party “shall accord to *investors* of another Party [or to their *investments*] treatment no less favorable than that it accords, in like circumstances, to its own investors [or investments]... .”<sup>145</sup> If a NAFTA Party adopts a measure that accords the given investor/investment treatment less favorable than that accorded national investors/investments, it will be in breach of Article 1102. Breach of an international law obligation is in and of itself “legally significant” since it gives rise to State responsibility. The breach stems from the measure granting less favorable treatment to the aggrieved investor/investment under

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<sup>142</sup> See Memorial, Statement of the Law, Sections II and III. See also *infra*, Merits Section.

<sup>143</sup> **Legal Authority CLA-17**, Vienna Convention on the Law of Treaties, art. 31(1), Apr. 24, 1970, S. Treaty Doc. No. 92-12, 1155 U.N.T.S. 331 (1969).

<sup>144</sup> *Id.*, art. 31(2) (“The context for the purpose of the interpretation of a treaty shall comprise, *in addition to the text*, including its preamble and annexes ... .” (emphasis added)).

<sup>145</sup> **Legal Authority CLA-1**, NAFTA, art. 1102(1) (with respect to investors), art. 1102(2) (with respect to investments) (emphasis added).

conditions specified in the Article. The specified connection between measure and investor/investment is therefore “legally significant.”

99. Similarly, Article 1103 on MFN treatment sets out an obligation to “accord to *investors* of another Party [or to their *investments*] treatment no less favorable than that it accords, in like circumstances, to investors of any other Party or of a non-Party [or to their investments] ... .”<sup>146</sup> If a NAFTA Party adopts a measure that accords the given investor/investment treatment less favorable than that accorded third-party investors/investments, it will be in breach of Article 1103. The treaty breach establishes that the connection between the challenged measure and the investor/investment in question is legally significant.
100. Article 1105 states for its part that each NAFTA Party “shall accord to *investments* of investors of another Party treatment in accordance with international law ... .”<sup>147</sup> If a NAFTA Party adopts a measure that does not accord to the investment the minimum standard of treatment provided by international law, that Party will have breached Article 1105. Again, the connection between measure and investment showing the treaty breach necessarily is of legal significance.
101. The context of Article 1101(1) thus informs the content of the “legally significant connection” between measure and investor/investment that this provision requires. If a measure breaches a substantive provision of Chapter Eleven, the connection between the measure and the investor/investment necessarily is “legally significant.”
102. The object and purpose of the NAFTA reinforces this interpretation of Article 1101(1). Article 102(1) lists as one of the objectives of the NAFTA, “as elaborated more specifically through its principles and *rules*, including national treatment, most-favored-nation treatment and transparency ... *increas[ing] substantially investment opportunities* in the territories of the Parties[.]”<sup>148</sup> Article 1101(1), the gateway provision to Chapter Eleven, must therefore be interpreted so as to increase substantially investment opportunities in the NAFTA Parties. If, as the US contends, the legally

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<sup>146</sup> *Id.*, art. 1103(1) (with respect to investors), art. 1103(2) (with respect to investments) (emphasis added).

<sup>147</sup> *Id.*, art. 1105(1) (emphasis added).

<sup>148</sup> *Id.*, art. 102(1) (emphasis added).

significant connection between measure and investor/investment sets too narrow a gateway, it will not increase the investment opportunities in the NAFTA Parties. A gateway thinner than the principles and rules elaborated by the NAFTA to fulfill its objectives, “including national treatment, most-favored-nation treatment and transparency,” is a gateway too narrow.

103. In its final award, the *Methanex* tribunal recognized that the legally significant connection under Article 1101(1) must be informed by the substantive provisions of Chapter Eleven. The tribunal repeatedly recognized the relevance of its assessment of the claims under the substantive provisions to the “relating to” question under Article 1101(1). The award stated as follows in its analysis of the national treatment claim:

An affirmative finding of the requisite “relation” under NAFTA Article 1101, as decided in the Partial Award for the purposes of this case, does not necessarily establish that there has been a corresponding violation of NAFTA Article 1102 by the USA. But an affirmative finding under NAFTA Article 1102, which does not require the demonstration of the malign intent alleged by Methanex, could conceivably provide evidence relevant to a determination as to whether the “relation” required by NAFTA Article 1101 exists in this case.<sup>149</sup>

104. The tribunal systematically considered whether the evidence of breach of each substantive provision established the connection contemplated by that provision. The tribunal found that Methanex had not proven a national treatment violation. It followed that “Methanex’s case under Article 1101 [was] not assisted by its arguments under Article 1102.”<sup>150</sup> The tribunal also concluded that the US did not breach the minimum standard of treatment under international law and, as a result, “Methanex’s case under

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<sup>149</sup> **Legal Authority CLA-34**, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award, Pt. IV, Ch. B, para. 1 (Aug. 3, 2005). See also *id.*, Pt. IV, Ch. C, para. 1 (“[A]n affirmative finding of a malign intent under NAFTA Article 1101 might satisfy the requirements of a showing of the requisite ‘relation’ under NAFTA Article 1105. But a failure to find a malign intent under Article 1101 might yet be repaired by an affirmative finding that an investor had not been accorded treatment in accordance with international law.” (emphasis added)); *id.*, Pt. IV, Ch. D, para. 1 (“[T]he Tribunal has considered it appropriate to examine Methanex’s claim arising under Article 1110 in order to determine if Methanex could thereby satisfy the threshold requirements of the required ‘relation’ under Article 1101 NAFTA.”).

<sup>150</sup> *Id.*, Pt. IV, Ch. B, para. 38.

Article 1101 [was] not assisted by its arguments under Article 1105.”<sup>151</sup> The tribunal held that there was no expropriation and that “Methanex’s case under Article 1101 [was] not assisted by its arguments under Article 1110.”<sup>152</sup> There was thus no breach of any substantive provisions of Chapter Eleven that could have established the “legally significant connection” required by Article 1101.

105. Consistent with the tribunal’s approach in *Methanex*, Apotex in its Memorial systematically reviewed the evidence of record establishing breaches of Articles 1102 and 1103.<sup>153</sup> The record here shows that FDA repeatedly accorded more favorable treatment to US-owned and foreign-owned investors and investments in like circumstances with Apotex. Precisely the connection between measure and investor/investment contemplated by Articles 1102 and 1103 is established here. That connection indisputably is legally significant.
106. Similarly, the Memorial showed that the Import Alert was adopted and enforced against Apotex without even the barest trappings of due process required by customary international law.<sup>154</sup> Procedural requirements for administrative decisions on the material rights and interests of aliens have long been part of the minimum standard of treatment. The United States’ actions did not satisfy such requirements. Precisely the connection between measure and investment contemplated by Article 1105(1) is present on this record and that connection is one of legal significance.<sup>155</sup>
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 Article 1101(1) then has. The provision, Apotex submits, performs the essential functions of (1) limiting Chapter Eleven’s scope to foreign investment, as the only provision in the chapter specifying that investments must be “in the territory of the Party” adopting the measure; (2) making clear that, while “investors of another Party” need not be in the territory of the Party, their investment must be there for them to be

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<sup>151</sup> *Id.*, Pt. IV, Ch. C, p. 12, para. 27.

<sup>152</sup> *Id.*, at Pt. IV, Ch. D, p. 8, para. 18.

<sup>153</sup> *See* Memorial, Statement of the Law, Section II. *See also infra*, Merits, Section I.

<sup>154</sup> *See* Memorial, Statement of the Law, Section III. *See also infra*, Merits Section II.

<sup>155</sup> *See* US Counter-Memorial, para. 381.

covered by the chapter;<sup>156</sup> (3) specifying that Articles 1106 and 1114 apply to all investments in the territory of the Party, whether or not owned by investors who are nationals of NAFTA States; and (4) in extreme cases, such as in *Methanex*, where the measure addressed a product the claimant did not manufacture, serving as a basis for summary dismissal of the claim.<sup>157</sup>

108. This case does not at all resemble the facts of *Methanex*. The Import Alert plainly “related to” Apotex.

**B. The NAFTA Does Not Support the US’s Apparent View That the Measure Must “Apply to” the Investment**

109. The US Counter-Memorial suggests in a heading that the US test for a legally significant connection is whether the measure “applied to” the investment, “directly or indirectly,” or imposed a “legal impediment” to its business operations.<sup>158</sup> While the Counter-Memorial’s arguments on “relating to” are broadly consistent with such a test, in its reply on bifurcation the US pointedly declined to confirm that the heading reflected the content it ascribed to “legally significant connection.”<sup>159</sup> The record at this point, therefore, is unclear whether the unexplained heading in the Counter-Memorial does, or does not, reflect the US approach. Apotex demonstrates in this section that, if such is the US approach, it cannot be reconciled with the NAFTA.

110. It is well established that Article 1102’s requirement of national treatment addresses the situation where a State measure does nothing more than grant more favorable treatment to investments owned by nationals.<sup>160</sup> In such a situation, there is no measure that

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<sup>156</sup> See **Legal Authority CLA-22**, *Bayview Irrigation District et al. v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award, para. 105 (June 19, 2007) (finding based on Article 1101(1)(b) that “in order to be an ‘investor’ under Article 1139 one must make an investment in the territory of another NAFTA State, not in one’s own.”).

<sup>157</sup> **Legal Authority CLA-36**, *Methanex Corporation v. United States of America*, UNCITRAL, Preliminary Award on Jurisdiction, para. 150 (Aug. 7, 2002) (finding that Methanex’s claim, as originally pleaded, was subject to dismissal as a preliminary matter for failure to establish “a legally significant connection between the US measures, Methanex and its investments”).

<sup>158</sup> US Counter-Memorial, at 141, heading 1 (“The Import Alert Neither Applied to Apotex Corp., Directly or Indirectly, Nor Imposed any Legal Impediment to Its Business Operations”).

<sup>159</sup> See *supra* n.141.

<sup>160</sup> See, e.g., **Legal Authority CLA-31**, *Marvin Feldman v. United Mexican States*, ICSID Case No. ARB(AF)/99/1, Award, para. 187 (Dec. 16, 2002) (holding that “Mexico has violated the Claimant’s rights to non-discrimination under Article 1102 of NAFTA[]” because “the Claimant has been effectively denied

“applies” to the foreign-owned investments or which “constitutes a legal impediment” to those investments conducting business. The measure does not address the foreigners’ investments. The measure “applies” only to the investments owned by nationals and makes their business easier. Under the US’s approach, however, Article 1101(1) would exclude Article 1102 from addressing this scenario. The US’s approach cannot be reconciled with the clear text of the treaty.

111. Similarly, it is accepted that breaches of the obligation of full protection and security result only from the *failure* of the State to take a protective measure.<sup>161</sup> Again, in this scenario there is no measure that “applies” to the affected investment. There is no measure at all. Nor is there any “legal impediment” to carrying out the business of the investment. A mob may cause property damage that constitutes a practical impediment to business, but there is no *legal* impediment. Again, the US’s test would write out of the NAFTA the obligation of full protection and security set out in Article 1105(1).
112. It is also well established that an indirect expropriation can result from measures that do not purport to apply to the specific investment at issue or impose any legal impediment as to that investment. For example, in *Biloune v. Ghana*, there was no measure that “applied” to or imposed a legal impediment as concerned the hotel concession contract that was the investment.<sup>162</sup> Instead, the State adopted other measures, such as issuing stop-work orders, denying a building permit, demolition of works, and arresting and deporting the president of the investor.<sup>163</sup> Although these measures did not apply to the contract, which remained in force, they amounted to a constructive expropriation of

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IEPS rebates for the April 1996 through November 1997 period, while domestic export trading companies have been given rebates not only for much of that period but through at least May 2000, suggesting that Article 4(III) of the law has been *de facto* waived for some if not all domestic firms. While the Claimant has also been effectively precluded from exporting cigarettes from 1998 to 2000, there is evidence that the Poblano Group companies have apparently been allowed to do so, notwithstanding Article 11 of the IEPS law. Finally, the Claimant has not been permitted to register as an exporting trading company, while the Poblano Group firms have been granted this registration.”).

<sup>161</sup> See, e.g., **Legal Authority CLA-50**, *The Loewen Group, Inc. and Raymond L. Loewen v. United States*, ICSID Case No. ARB(AF)/98/3, Counter-Memorial of the United States of America, at 179 (Mar. 30, 2001) (noting that tribunals have found a breach of the full protection and security obligation under customary international law when “a State *failed* to provide reasonable police protection against acts of a criminal nature that physically invaded the person or property of an alien[.]” (emphasis added)).

<sup>162</sup> **Legal Authority CLA-455**, *Antoine Biloune (Syria) and Marine Drive Complex Ltd. (Ghana) v. Ghana Investments Centre and the Government of Ghana*, UNCITRAL, 19 Y.B. Comm. Arb. 11 (1994).

<sup>163</sup> *Id.* at 13-14 (summarizing the facts).

those contract rights.<sup>164</sup> Again, the US's interpretation cannot be reconciled with the coverage of indirect expropriation in Article 1110(1).

113. Finally, the purpose of the NAFTA "is to eliminate barriers to trade and increase investment opportunities within the NAFTA Parties."<sup>165</sup> In the context of Chapter Eleven, and contrary to the US suggestion, trade measures and investment measures are not necessarily mutually exclusive, as is evident from the text of Chapter Eleven and the case law.

114. Chapter Eleven explicitly addresses measures directed to imports and exports in connection with an investment. For instance, Article 1106 states in relevant part:

No party may impose or enforce any of the following requirements, or enforce any commitment or undertaking, in connection with the establishment, acquisition, expansion, management, conduct or operation of an investment of an investor of a Party or of a non-Party in its territory:

(a) to *export* a given level or percentage of goods or services;  
...

(d) to relate in any way the volume or value of *imports* to the volume or value of *exports* or to the amount of foreign exchange inflows associated with such investment;

(e) to restrict sales of goods or services in its territory that such investment produces or provides by relating such sales in any way to the volume or value of its *exports* or foreign exchange earnings[.]<sup>166</sup>

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<sup>164</sup> *Id.* at 20-21, para. 26 ("What is clear is that the conjunction of the stop work order, the demolition, the summons, the arrest, the detention, the requirement of filing assets declaration forms, and the deportation of Mr. Biloune without possibility of re-entry had the effect of causing the irreparable cessation of work on the project. Given the central role of Mr. Biloune in promoting, financing and managing MDCL, his expulsion from the country effectively prevented MDCL from further pursuing the project. In the view of the Tribunal, such prevention of MDCL from pursuing its approved project would constitute constructive expropriation of MDCL's contractual rights in the project and, accordingly, the expropriation of the value of Mr. Biloune's interest in MDCL, unless the respondents can establish by persuasive evidence sufficient for these events [sic]."); *id.*, at 21, para. 30 ("The Tribunal therefore holds that the Government of Ghana, by its actions and omissions culminating with Mr. Biloune's deportation, constructively expropriated MDCL's assets, and Mr. Biloune's interest therein ...").

<sup>165</sup> **Legal Authority CLA-446**, *Mobil Investments Inc. and Murphy Oil Corporation v. Canada*, ICSID Case No. ARB(AF)/07/4, Decision on Liability and on Principles of Quantum, para. 225 (May 22, 2012) (citing **Legal Authority CLA-1**, NAFTA, art. 102).

<sup>166</sup> **Legal Authority CLA-1**, NAFTA, art. 1106(1) (emphasis added).

115. The case law rendered under Chapter Eleven similarly demonstrates that import/export measures can relate to investors and their investments. In *Cargill*, the tribunal held that the import permit requirement imposed by Mexico related to Cargill’s local subsidiary, i.e., the investment.<sup>167</sup> In *Pope & Talbot*, the tribunal found that “[t]here is no provision to the express effect that investment and trade in goods are to be treated as wholly divorced from each other.”<sup>168</sup> As such, “the fact that a measure may primarily be concerned with trade in goods does not necessarily mean that it does not also relate to investment or investors.”<sup>169</sup> The *S.D. Myers* tribunal reiterated that “[t]here is no reason why a measure which concerns goods (Chapter 3) cannot be a measure relating to an investor or an investment (Chapter 11).”<sup>170</sup> In that case, the export ban on PCB wastes imposed by Canada was deemed to be “in relation” to the US investor and its investment in Canada.<sup>171</sup>
116. By way of summary, the US’s approach to Article 1101(1) resembles the argument long ago rejected in *Pope & Talbot* “that a measure can only relate to an investment if it is primarily directed at that investment[.]”<sup>172</sup> The US in *Methanex* expressly declined any

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<sup>167</sup> **Legal Authority CLA-23**, *Cargill Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 175 (Sept. 18, 2009).

<sup>168</sup> **Legal Authority CLA-447**, *Pope & Talbot, Inc. v. The Government of Canada*, UNCITRAL, Award in Relation to Preliminary Motion by Government of Canada, para. 26 (Jan. 26, 2000). See also **Legal Authority CLA-32**, *Merrill & Ring Forestry L.P. v. The Government of Canada*, UNCITRAL, Award, para. 87 (March 31, 2010) (emphasizing that it was “necessary to understand [Chapter Eleven] in a broader sense that will allow for the comparison of other relevant elements, not excluding trade where appropriate.”).

<sup>169</sup> **Legal Authority CLA-447**, *Pope & Talbot, Inc. v. The Government of Canada*, UNCITRAL, Award in Relation to Preliminary Motion by Government of Canada, para. 33 (Jan. 26, 2000). Similarly, in *Ethyl v. Canada*, the tribunal refused to dismiss the claim at the jurisdictional phase simply because the measure, excluding MMT (a fuel additive used for unleaded gasoline) from importation into Canada, could be viewed as affecting trade in goods. See **Legal Authority CLA-26**, *Ethyl Corporation v. The Government of Canada*, UNCITRAL, Award on Jurisdiction, paras. 62-64 (June 24, 1998).

<sup>170</sup> **Legal Authority CLA-43**, *S.D. Myers, Inc. v. The Government of Canada*, UNCITRAL, Partial Award, para. 294 (Nov. 13, 2000).

<sup>171</sup> *Id.*, para. 234 (Nov. 13, 2000) (“In this case, the requirement that the import ban be ‘in relation’ to SDMI and its investment in Canada is easily satisfied. It was the prospect that SDMI would carry through with its plans to expand its Canadian operations that was the specific inspiration for the export ban. It was raised to address specifically the operations of SDMI and its investment.”).

<sup>172</sup> **Legal Authority CLA-447**, *Pope & Talbot Inc. v. The Government of Canada*, UNCITRAL, Award in Relation to Preliminary Motion by Government of Canada, para. 34 (Jan. 26, 2000).

reliance on this argument.<sup>173</sup> The US's attempt here to resurrect this long-discredited argument is baseless.

117. In contrast, interpreting Article 1101(1), and the contours of the legally significant connection, in accordance with the text, context, object and purpose of the NAFTA accords with the Vienna Convention. From a policy perspective, it also ensures that the gateway to Chapter Eleven arbitration is not too narrow (i.e., does not exclude from arbitration claims expressly authorized by this Chapter) and not too broad (i.e., does not allow claims otherwise not authorized by this Chapter).

### **C. The Import Alert Directly Applied to Apotex-US**

118. The US wrongly argues that “Apotex does not and cannot claim that the Import Alert was *applied* to Apotex Holdings or ... [Apotex-US].”<sup>174</sup> The US's arguments in this respect are without support in fact or in law. The Import Alert did apply directly to Apotex-US and certainly was a legal impediment to its business operations. Under even the US's unexplained positive test, the measure plainly related to Apotex-US and Apotex Holdings.

119. The US argues that because the Import Alert specifically targeted two of Apotex-Canada's facilities, it was not applied to Apotex-US or Apotex Holdings.<sup>175</sup> It is wrong. The Import Alert interrupted the transactions on which Apotex-US depended for 80 percent of its sales.<sup>176</sup> The transactions that the Import Alert interrupted had two parties. Apotex-Canada was on one side as the seller and importer of record into the

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<sup>173</sup> See **Legal Authority CLA-445**, *Methanex Corp. v. United States of America*, UNCITRAL, Reply Memorial of Respondent United States of America on Jurisdiction, Admissibility and the Proposed Amendments at 44 (Apr. 12, 2001) (noting that *Pope & Talbot* “rejected the test proffered by Canada ‘that a measure can only relate to an investment if it is primarily directed at that investment,’ a test that the United States is not advancing here.” (internal citation omitted)).

<sup>174</sup> US Counter-Memorial, para. 292 (emphasis original).

<sup>175</sup> *Id.*, paras. 290-92.

<sup>176</sup> Witness Statement of Gordon Fahner, para. 70 (“Roughly speaking, about 80%-85% of all Apotex solid dose products historically sold on the US market were produced at those two facilities [Etobicoke and Signet].”).

United States. Apotex-US was the purchaser and consignee of record on the other side.<sup>177</sup>

120. The Import Alert made it legally impossible for the transactions between Apotex-Canada and Apotex-US to be carried out. To use the alternative expression posited by the US, the Import Alert was a “legal impediment” to the conduct of these transactions.<sup>178</sup> The Import Alert applied equally to both parties to the transactions: to Apotex-Canada as the owner and to Apotex-US as the consignee of the products whose shipment was interrupted by the Import Alert. This is clear in law and fact.

*1. Relevant Provisions of US Law Apply to Both the Owner and the Consignee*

121. The statute relied upon by the US to authorize import alerts confirms that import measures such as these apply to both the importer and the consignee.<sup>179</sup> Section 801 of the Act states in relevant part:

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of ... drugs ... which are being imported or offered for import into the United States, giving notice thereof to the *owner or consignee*, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. ... If it appears from the examination of such samples or otherwise that ... (3) such article is adulterated ..., then such article shall be refused admission ... .<sup>180</sup>

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

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<sup>177</sup> See, e.g., **Exhibit R-44**, Notices of FDA Action re: Entry No EG6-1768425-3, Notice 1, dated September 2, 2009 (“Importer of Record: Apotex[-Canada], Etobicoke, Ontario, Canada ...” and “Consignee: Apotex[-US], Weston, FL ...”); **Exhibit C-71**, Email from Customs Broker (Juanita Zaziksi) to Apotex, dated September 1, 2009, at 12:36 pm, attaching Notice of FDA Action re: Entry No. EG6-1767503-8, Notice 1, dated September 1, 2009 (same) and Commercial Invoice, dated August 31, 2009 (indicating Apotex-Canada has “Shipper” and Apotex-US as “Buyer”).

<sup>178</sup> US Counter-Memorial, at 141, heading 1 (“The Import Alert Neither Applied to Apotex Corp., Directly or Indirectly, Nor Imposed any Legal Impediment to Its Business Operations”); *id.*, para. 295.

<sup>179</sup> *Id.*, para. 49 & nn.74-75 (citing **Legal Authority CLA-240**, 21 USC § 381(a) (2009-2011) (commonly referred to as “Section 801” of the Federal Food, Drug and Cosmetic Act (the “Act”))). See also *id.*, para. 332 (“Import Alert 66-40 operates in conjunction with Section 801(a) of the [Act], which authorizes FDA district offices to detain at the U.S. border, without physical examination, drugs that appear to be adulterated because they were not manufactured in conformity with current good manufacturing practice.”).

<sup>180</sup> **Legal Authority CLA-239**, Federal Food, Drug, and Cosmetic Act, 21 USC § 381(a) (emphasis added).

If it appears that the article may be subject to refusal of admission, the district director shall give the *owner or consignee* a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the *owner or consignee* shall have an opportunity to introduce testimony.<sup>181</sup>

123. FDA's Regulatory Procedures Manual (RPM) also states that:

The *owner or consignee* is entitled to an informal hearing before FDA, in order to provide testimony in support of admissibility of the article[s].<sup>182</sup>

124. The relevant domestic law and regulations, as well as FDA's guidance documents, concord in recognizing that the import measures "apply to" and "relate to" the consignee. If products offered for import may be refused admission because the manufacturer is on import alert, consignees like Apotex-US must be given notice that the products are being detained, and an opportunity to provide testimony concerning their admissibility.

125. Section 801 of the Act requires that consignees be given notice and an opportunity to be heard precisely because the statute relates to that person, i.e., is susceptible of affecting the consignee's rights. In the words of the US Supreme Court, "[f]or more than a century the central meaning of procedural due process has been clear: 'Parties whose rights are to be affected are entitled to be heard; and in order that they may enjoy that right they must first be notified.'"<sup>183</sup> As such, "when the government seeks to deprive an individual of property, it must provide a hearing before an impartial decision maker where the individual may be heard 'at a meaningful time and in a meaningful manner.'"<sup>184</sup>

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<sup>181</sup> **Legal Authority CLA-245**, FDA Imports and Exports Rule, 21 CFR § 1.94 (emphasis added).

<sup>182</sup> **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, subchapter "9-1 Import Procedures", under the heading "Procedures When Violation Is Found," under the sub-heading "Notice of Detention & Hearing," at 9-8 (2011) (emphasis added).

<sup>183</sup> **Legal Authority CLA-532**, *Fuentes v. Shevin*, 407 U.S. 67, 80 (1972) (quoting *Baldwin v. Hale*, 68 U.S. 223 (1863)).

<sup>184</sup> **Legal Authority CLA-552**, *Simms v. District of Columbia*, 872 F. Supp. 2d 90, 96 (D.D.C. 2012) (quoting *Mathews v. Elridge*, 424 U.S. 319, 333 (1976)).

126. In the case at bar, Section 801 specifically provides that the consignee must be given notice and an opportunity to be heard as to the products' admissibility. It thus recognizes that these import measures "apply" to the consignee and relate to its rights.

2. *The FDA Notices of Action Were Addressed to Apotex-US Directly*

127. The only contemporaneous official evidence of the adoption of the Import Alert<sup>185</sup> consists of the FDA notices of action concerning specific transactions that the US interrupted in the days immediately following adoption of the Import Alert.<sup>186</sup> The notices specifically identified Apotex-US as the "consignee" in the interrupted transactions and, according to the US, were specifically addressed to Apotex-US, as the excerpt from the following US exhibit illustrates:

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<sup>185</sup> The US argued that "[t]he contemporaneous official evidence of the adoption of the Import Alert is the Import Alert itself." See US Reply on Bifurcation, para. 13 (Jan. 10, 2013) (internal quotation marks omitted). However, Apotex never received a copy of the Import Alert. See Witness Statement of Jeremy Desai, para. 55. The Import Alert concerning Apotex was not published on FDA's website before September 30, 2009. See **Exhibit C-110**, FDA's website, Import Alert 66-40, dated October 2, 2009, at 2 (stating for each entry concerning Apotex: "Date Published: 09/30/2009"). By contrast, the Notices of FDA Action were issued at the time when Apotex's specific shipments were detained and refused admission.

<sup>186</sup> See **Exhibit R-44**, Notices of FDA Action re: Entry No EG6-1768425-3, Notice 1, dated September 2, 2009; **Exhibit C-68**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009, at 10:20 am, attaching Notice of FDA Action re: Entry No. EG6-1768658-9, dated August 31, 2009; **Exhibit C-69**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009, at 10:21 am, attaching Notice of FDA Action re: Entry No. EG6-1768659-7, dated August 31, 2009; **Exhibit C-71**, Email from Customs Broker (Juanita Zaziksi) to Apotex, dated September 1, 2009, at 12:36 pm, attaching Notice of FDA Action re: Entry No. EG6-1767503-8, dated September 1, 2009; **Exhibit C-72**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009, at 12:52 pm, attaching Notice of Action re: Entry No. EG6-1768378-4, dated September 1, 2009; **Exhibit C-78**, Notice of FDA Action re: Entry No. EG6-1768425-3, Notice 1, dated September 2, 2009; **Exhibit C-79**, Notice of FDA Action re: Entry No. EG6-1768429-5, Notice 1, dated September 2, 2009; **Exhibit C-80**, Notice of FDA Action re: Entry No. EG6-1768454-3, Notice 1, dated September 2, 2009.

<b>United States Food and Drug Administration</b>	
Detroit District Office	
<b>Notice of FDA Action</b>	
Entry Number: EG6-1768425-3	Notice Number: 1 September 2, 2009
<b>Consignee:</b>	
Apotex Corp.	
2400 N Commerce Pkwy Ste 400	
Weston, FL 33326-3253	
>	<
Port of Entry: 3801, Detroit, MI	
Carrier: LIONS GATE TRANSPORT INC;	
Date Received: September 1, 2009	
Arrival Date: September 1, 2009	
Filer of Record: Affiliated Customs Brokers, Detroit, MI 48216-2063	
Importer of Record: Apotex, Inc., Etobicoke, Ontario, Canada M9W 6Y3	
<b>HOLD DESIGNATED</b>	
<u>Summary of Current Status of Individual Lines</u>	

**Figure 1, Exhibit R-44**<sup>187</sup>

128. The only contemporaneous, official manifestation of the Import Alert thus not only recognized that the measure applied to Apotex-US, it *was specifically addressed to Apotex-US*.
129. The US acknowledges that the notices of FDA action “informed” Apotex-US “as the consignee” of specific shipments offered for import into the United States that: “(1) the product appeared to be adulterated and thus was being detained; and (2) Apotex[-US] could introduce testimony regarding the admission of that shipment into the United States.”<sup>188</sup> The US does not attempt to explain why FDA would notify Apotex-US if the measure did not relate to it.
130. Furthermore, as the FDA notices of action observe, Lions Gate Transport Inc. was the “carrier” of Apotex’s products.<sup>189</sup> According to Apotex’s commercial invoices,

<sup>187</sup> **Exhibit R-44**, Notices of FDA Action re: Entry No EG6-1768425-3, Notice 1 at 5, dated September 2, 2009 (highlighting added).

<sup>188</sup> US Reply on Bifurcation, para. 14.

<sup>189</sup> See, e.g., **Exhibit R-44**, Notices of FDA Action re; Entry No EG6-1768425-3, dated September 2, 2009. See also **Exhibit C-68**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009,

Apotex-Canada was the “shipper,” Apotex-US was the “buyer,” and the products were to be shipped to Apotex-US’s warehouse in Indianapolis (as indicated under the box “ship to”).<sup>190</sup>

131. Pursuant to Article 67(1) of the United Nations Convention on Contracts for the International Sale of Goods (CISG), to which both Canada and the US are parties, the risk of loss or damage to the goods passes to the buyer when the goods are handed over to the carrier for transmission to the buyer.<sup>191</sup>
132. Here, the risk of loss passed to Apotex-US when Apotex-Canada handed over its products to Lions Gate Transport Inc. at the facilities in Etobicoke and Signet.<sup>192</sup> The US errs in arguing that the Import Alert did not “relate to” Apotex-US, given that Apotex-US bore the risk of loss or damage to the products at the time of their detention pursuant to the Import Alert.
133. The legal and factual record thus clearly establishes that the Import Alert “relates to” Apotex-US.

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

<sup>190</sup> See, e.g., **Exhibit C-71**, Email from Customs Broker (Juanita Zaziksi) to Apotex, dated September 1, 2009, at 12:36 pm, attaching Commercial Invoice, dated August 31, 2009.

<sup>191</sup> **Legal Authority CLA-441**, United Nations Convention on Contracts for the International Sale of Goods, art. 67(1), Apr. 11, 1980, 1489 U.N.T.S. 3 (1980) (hereinafter the “CISG”) (“If the contract of sale involves carriage of the goods and the seller is not bound to hand them over at a particular place, the risk passes to the buyer when the goods are handed over to the first carrier for transmission to the buyer in accordance with the contract of sale. If the seller is bound to hand the goods over to a carrier at a particular place, the risk does not pass to the buyer until the goods are handed over to the carrier at that place. The fact that the seller is authorized to retain documents controlling the disposition of the goods does not affect the passage of the risk.”). Contrary to the US assertion at paragraph 10 of its Reply on Bifurcation, Apotex never argued that *title* to the products passed to Apotex-US when Apotex-Canada handed over its products to a carrier at the Etobicoke and Signet facilities. The CISG does not address when title passes from seller to buyer. See *id.*, art. 4(b).

<sup>192</sup> Second Witness Statement of Gordon Fahner, para. 62.

### 3. *The US Fails to Distinguish Cargill*

134. Contrary to the US's suggestion, *Cargill v. Mexico* is directly on point and confirms that the Import Alert relates to Apotex-US.<sup>193</sup> As noted by the US, "Cargill de Mexico [the investment] was established to import [high fructose corn syrup] HFCS from Cargill Inc.'s U.S. facilities and distribute it within Mexico"<sup>194</sup> – just as Apotex-US was established to import and distribute Apotex-Canada's pharmaceutical drugs in the United States.

135. In *Cargill*, the tribunal addressed an import permit requirement that prevented sales of goods between the US parent company and its subsidiary/investment in Mexico. The tribunal found that the measure "directly affected the business" of the investment in Mexico, which consisted, among others, in reselling the goods "sourced from the United States."<sup>195</sup> The tribunal held that a legally significant connection was established:

Regardless of whether or not the test espoused in *Methanex* is too restrictive, it is satisfied in this case. The import permit requirement not only had an immediate and direct effect on the business of Cargill de Mexico but also constituted a legal impediment to carrying on the business of Cargill de Mexico in sourcing HFCS [high fructose corn syrup] in the United States and re-selling it in Mexico.<sup>196</sup>

136. Just as in *Cargill*, the measure here made it impossible for Apotex-US legally to receive the drugs produced by Apotex-Canada at Etobicoke and Signet. Just as the import permit requirement prevented Cargill de Mexico from "carrying on the business of ... sourcing HFCS in the United States and re-selling it in Mexico[.]"<sup>197</sup> the Import Alert prevented Apotex-US from carrying on the business of sourcing product from Apotex-Canada in Canada and re-selling it in the United States.

137. The US misleadingly mixes into its discussion of *Cargill's* analysis on "relating to" a quotation of a different part of the decision, where the tribunal in addressing the claim

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<sup>193</sup> US Counter-Memorial, para. 293.

<sup>194</sup> *Id.* (footnote omitted).

<sup>195</sup> **Legal Authority CLA-23**, *Cargill Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 173 (Sept. 18, 2009).

<sup>196</sup> *Id.*, para. 175.

<sup>197</sup> *Id.*

under Article 1105 considered whether the import permit requirement targeted a specific class of companies in Mexico.<sup>198</sup> That discussion, however, formed no part of the *Cargill* tribunal’s reasoning on “relating to” under Article 1101. The US’s attempt to rewrite the *Cargill* award is without merit.<sup>199</sup>

138. Under the US theory, a measure could only relate to an investor if that measure amounted to a substantial deprivation of the investment and its business.<sup>200</sup> If the Tribunal were to follow the US’s argument, no claim could ever pass through the gateway of Chapter Eleven except expropriation claims. *Cargill* does not support such a restrictive interpretation of Article 1101(1).
139. Finally, the US argues that the Import Alert was no “legal impediment” to Apotex-US’s operations since Apotex-US distributed third party product while the Import Alert remained in effect.<sup>201</sup> Yet, the Import Alert interrupted the transactions on which Apotex-US depended for 80% of its sales. It follows that even if Apotex-US sold products manufactured by third parties, these sales did not make up for the lost 80% of Apotex-US’s sales.<sup>202</sup>
140. Apotex-US’s contract manufacturing activities were not its principal line of business. As noted by the US, the exclusive agreement with Hisamitsu concerned only one line of products, its transdermal patch for chronic pain.<sup>203</sup> The exclusive supply and

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<sup>198</sup> See US Counter-Memorial, para. 294, n.702 and accompanying text (quoting *Cargill*, para. 300).

<sup>199</sup> The US also errs in describing the measure in *Cargill* as a measure targeted at Mexican importers, rather than foreign exporters. See *id.*, para. 294 & n.699 (quoting *Cargill Legal Authority CLA-23, Cargill Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 173 (Sept. 18, 2009)). The passage from the award that the US relies upon addresses Mexico’s argument that the import permit requirement was a trade measure, as opposed to an investment measure. See **Legal Authority CLA-23, Cargill Incorporated v. United Mexican States**, ICSID Case No. ARB(AF)/05/2, Award, para. 172 (Sept. 18, 2009). The *Cargill* tribunal refused to adopt a rigid distinction between trade and investment for purposes of Chapter Eleven of the NAFTA and observed that, while the measure on its face barred exports to Mexico, it nonetheless related to the investment. See *id.*, para. 173 (“Although the import permit requirement is a measure that notionally prevented Claimant’s goods from crossing the border from the United States into Mexico, it directly affected the business of Cargill de Mexico ... By preventing the importation of sourced goods, the measure affected Claimant’s investment in Mexico.”).

<sup>200</sup> US Counter-Memorial, paras. 295, 298.

<sup>201</sup> *Id.*, paras. 295-97.

<sup>202</sup> Second Witness Statement of Gordon Fahner, paras. 83-84.

<sup>203</sup> US Counter-Memorial, para. 296 & n.704 (citing **Exhibit R-48**, Apotex-US Press Statement, “*Apotex to Distribute Important Transdermal System for Management of Chronic Pain in the U.S. Market*”, dated October 20, 2009).

distribution agreement with GSK was part of a larger settlement agreement concluded in May 2010.<sup>204</sup> This settlement agreement spared Apotex-US from serious working capital deficiencies resulting from the Import Alert. The terms provided for a cash payment of USD 300 million to Apotex-US and a guaranteed USD 180 million to be earned through sales of GSK products.<sup>205</sup> Neither, however, was part of Apotex-US's long-term business plan.<sup>206</sup>

141. Therefore, the US wrongly concludes that “[l]ike any distributor that lost access to one of its suppliers, Apotex[-US] readily began procuring products from other suppliers.”<sup>207</sup> During the Import Alert, Apotex-US never managed to make up for 80% of its sales through alternative suppliers. To the contrary, the Import Alert so severely impacted Apotex-US that it dropped from the 6<sup>th</sup> position on the US generic drug market in 2009 to the 25<sup>th</sup> in 2011.<sup>208</sup>

142. In brief, the Import Alert directly applied to Apotex-US and constituted a legal impediment to the conduct of its business. Under even the test suggested by the United States, the measure clearly “related to” Apotex-US and therefore to its indirect owner, Apotex Holdings.

**D. The US Arguments Based on Distributorship Arrangements and Apotex-US's Relationship with Apotex-Canada Lack Support**

143. The US erroneously claims that the Import Alert “affected *all* U.S. distributors of Apotex[-Canada's] drugs, including Apotex[-US]” which, according to the US, proves that the Import Alert was *not* “applied to” Apotex-US.<sup>209</sup> The US position is based on a series of mistaken suppositions as to distributorship arrangements and unsupported

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<sup>204</sup> *Id.*, para. 297 & n.706 (citing **Legal Authority RLA-90**, *Mylan Inc. v. Smithkline Beecham Corp.*, No. 10-cv-4809 (JAP), 2012 WL 603804, at \*2 (D.N.J. Feb. 23, 2012)).

<sup>205</sup> **Legal Authority RLA-90**, *Mylan Inc. v. Smithkline Beecham Corp.*, No. 10-cv-4809 (JAP), 2012 WL 603804, at \*2 (D.N.J. Feb. 23, 2012).

<sup>206</sup> Second Witness Statement of Gordon Fahner, para. 84.

<sup>207</sup> US Counter-Memorial, para. 298.

<sup>208</sup> Compare **Exhibit C-181**, IMS Medical, Top 25 Generic Manufacturers (Q2 2009) with **Exhibit C-182**, IMS Medical, Top 25 Generic Manufacturers (Q4 2010).

<sup>209</sup> US Counter-Memorial, para. 292 (emphasis original). See also *id.*, para. 298 (The US's overall conclusion is that the Import Alert imposed no “legal impediment” to Apotex-US's business because “[t]he impact that the Import Alert had on Apotex[-US] was no different, legally, from that felt by any of the many other U.S. companies that imported drugs from Apotex[-Canada]'s Etobicoke and Signet facilities.”).

contentions concerning the relationship between Apotex-Canada and Apotex-US,<sup>210</sup> as discussed in greater detail in this section.

144. But, more fundamentally, the US position that the Import Alert did not relate to Apotex-US because it allegedly affected other US distributors is untenable as a matter of law. Even if it were correct (which is not) that the Import Alert applied to more than one consignee, it certainly would not follow that the Import Alert applied to *none of them*.
145. The jurisprudence is replete with instances of the same measure applying to multiple parties – the Mexican high-fructose corn syrup and Argentine emergency measure arbitrations being only two of many such examples.<sup>211</sup> The fact that a measure applies to more than one party does not mean that no party has an investment claim (including a NAFTA claim). There is no requirement in the NAFTA or anywhere else that a measure must “uniquely affect[.]” an investment, as the US suggests.<sup>212</sup>
146. In any event, far from supporting the US position that *other* distributors were impacted by the Import Alert, the record in fact shows that Apotex-US was *uniquely* affected by the measure. Apotex-US was the only US-based company that Apotex-Canada supplied with Etobicoke and Signet products for *commercial* sale. In addition, the evidence submitted by the US shows that 99% of shipments of Apotex products to consignees other than Apotex-US were allowed to reach their destination while the Import Alert was in effect. Apotex-US, by contrast, received none.

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<sup>210</sup> *Id.*, paras. 15, 299, 301.

<sup>211</sup> See **Legal Authority CLA-474**, *Corn Products International, Inc. v. United Mexican States* (ICSID Case No. ARB(AF)/04/1) and *Archer Daniels Midland Company and Tate & Lyle Ingredients Americas, Inc. v. United Mexican States* (ICSID Case No. ARB(AF)/04/5), Order of the Consolidation Tribunal, para. 1 (May 20, 2005) (three different companies submitted similar NAFTA claims against Mexico “based on the same tax measure”); **Legal Authority CLA-475**, Marie Christine Hoelck Thjoernelund, State of Necessity as an Exemption from State Responsibility for Investments, 13 Max Planck UNYB 423, 440-41 (2009) (“Among others, [Argentina] enacted the Public Emergency and Exchange Regime Reform Act . . . . That situation led investors to initiate arbitration procedures under the ICSID requesting reparation.”).

<sup>212</sup> US Reply on Bifurcation, para. 15.

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

147. The US errs in suggesting that there were “dozens of other U.S. distributors of Apotex[-Canada’s] products.”<sup>213</sup> Apotex-US was the *only* US company that imported drugs manufactured at Etobicoke and Signet for commercial sale in the United States.<sup>214</sup> Apotex-Canada sells Apotex products to Apotex-US. Apotex-US then sells those products to various customers in the United States.<sup>215</sup> This is why IMS data showed Apotex-US, not Apotex-Canada, to be the sixth largest generic seller on the US market in 2009.<sup>216</sup>
148. FDA was on notice that Apotex-US was the distributor of record of products made at Etobicoke and Signet.<sup>217</sup> The label on every Apotex product commercially sold in the US, and every medication guide, identified Apotex-US as the distributor of record.<sup>218</sup>
149. By way of illustration, the FDA-approved label for Apotex Pravastatin Sodium Tablets is reproduced below:<sup>219</sup>

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<sup>213</sup> US Counter-Memorial, para. 299.

<sup>214</sup> See Second Witness Statement of Gordon Fahner, paras. 17-47.

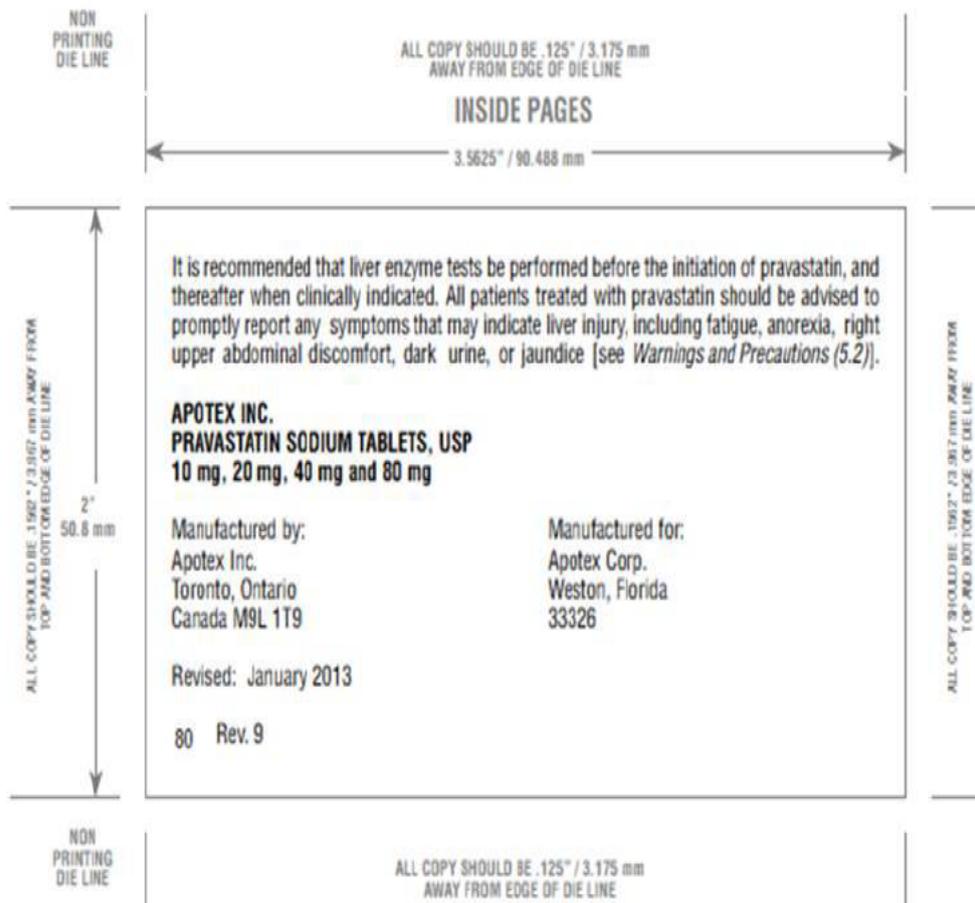
<sup>215</sup> See **Legal Authority RLA-92**, *Pfizer Inc. et al. v. Apotex Inc. and Apotex Corp.*, No. 1:08-cv-00948 (LDD) (D. Del.), Declaration of Bernice Tao, para. 12 (Feb. 10, 2009) (“In fact, Apotex[-Canada] does not directly sell any products of any kind in the United States.”).

<sup>216</sup> **Exhibit C-181**, IMS Medical, Top 25 Generic Manufacturer (Q2 2009).

<sup>217</sup> See **Legal Authority CLA-566**, 21 CFR 201.1 (2012) (“(a) A drug or drug product ... in finished package form is misbranded under section 502(a) and (b)(1) of the act if its label does not bear conspicuously the name and place of business of the manufacturer, packer, or distributor. ... (h)(5) If the distributor is named on the label, the name shall be qualified by one of the following phrases: ‘Manufactured for \_\_\_\_\_’, ‘Distributed by \_\_\_\_\_’, ‘Manufactured by \_\_\_\_\_ for \_\_\_\_\_’, ‘Manufactured for \_\_\_\_\_ by \_\_\_\_\_’, ‘Distributor: \_\_\_\_\_’, ‘Marketed by \_\_\_\_\_’.”); **Exhibit C-440**, FDA, Drug Approvals and Databases, Glossary (last updated on Feb. 2, 2012) (“**Label** – The FDA approved label is the official description of a drug product which includes indication (what the drug is used for); who should take it; adverse events (side effects); instructions for uses in pregnancy, children, and other populations; and safety information for the patient. Labels are often found inside drug product packaging.”). See also Second Witness Statement of Kiran Krishnan, paras. 12, 14.

<sup>218</sup> Second Witness Statement of Kiran Krishnan, para. 12. See also **Exhibit C-267**, CBE for Change in Label for Paroxetine, dated October 5, 2011 at 88.

<sup>219</sup> **Exhibit C-464**, Prescribing Information for Pravastatin Tablets, dated April 2, 2013.



150. Furthermore, the US misconstrues its own evidence. That evidence, far from supporting the US, demonstrates the opposite of what the US attempts to prove. That evidence falls into two categories: recall documents, and spreadsheets taken from FDA import databases. Apotex addresses each in turn.

a) *Apotex Recall Documents Do Not Support the US*

151. The first category of evidence relied upon by the US is a listing of customers from which Apotex product was recalled in September 2009.<sup>220</sup> This, however, is a listing of customers of *Apotex-US* that bought recalled product from it.<sup>221</sup>

<sup>220</sup> See **Exhibit C-83**, Letter from Apotex to FDA enclosing recall information package, dated September 4, 2009; **Exhibit R-5**, Apotex, Distribution List for Recall Products (“5-Consignees.xls” in Recall Report Questionnaire), dated September 4, 2009.

<sup>221</sup> Compare **Exhibit R-5**, Apotex, Distribution List for Recall Products (“5-Consignees.xls” in Recall Report Questionnaire), dated September 4, 2009, e.g., line 100 (██████), line 146 (██████), line 150

152. Contrary to the Counter-Memorial's supposition,<sup>222</sup> the listing does not purport to describe companies that purchased and imported product from Apotex-Canada. These documents in no way support the US's position.<sup>223</sup>

*b) The Three FDA Spreadsheets Do Not Support the US*

153. The second category of evidence put forward by the US consists of three spreadsheets,<sup>224</sup> prepared by FDA from its import action database.<sup>225</sup> The spreadsheets purport to list all shipments that identified Apotex-Canada in Etobicoke or Signet as the "manufacturer" and identified a "consignee" other than Apotex-US. Three main points can be made based on review of these documents.

*(i) Unrelated Third Party Shippers Do Not Support the US*

154. Most of the entries on exhibits R-115, R-118 and R-119 show an unrelated third party as the shipper. During the Import Alert, there were a total of 322 shipments of Apotex products to the United States.<sup>226</sup> Only 11 of these shipments were shipped by Apotex. The rest, i.e., 311 shipments were shipped by an unrelated third party.

155. For example, exhibit R-119 shows that on November 3, 2009 Parexel Ukraine LLC of 9 Moskovskiy Prospect in Kyiv, Ukraine shipped "Glipizide placebo tablets" to Apotex's competitor Merck & Co., Inc. in Whitehouse Station, New Jersey, and identified Apotex

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( [REDACTED] ), line 237 ( [REDACTED] ) with Witness Statement of Jeff Watson, para. 26 ("Generally speaking, [Apotex-US's] customers include institutional clients (such as hospital buying groups, the U.S. government and distribution companies such as [REDACTED]) and retail clients (such as [REDACTED])").

<sup>222</sup> US Counter-Memorial, para. 301 (quoting Memorial, para. 411).

<sup>223</sup> Compare **Exhibit R-5**, Distribution List of Recall Products with Witness Statement of Jeff Watson, para. 26. See also Second Witness Statement of Gordon Fahner, para. 13.

<sup>224</sup> **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated); **Exhibit R-118**, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated); **Exhibit R-119**, FDA, Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated).

<sup>225</sup> US Reply on Bifurcation, para. 18.

<sup>226</sup> Apotex initially stated that the US spreadsheets listed 328 shipments to consignees other than Apotex-US during the Import Alert. See Claimants' Opposition to Bifurcation, para. 58. Upon further study, Apotex realized that the FDA spreadsheets listed the same shipment several times (same shipment number and same submission date) under separate charges (adulteration and unapproved new drug). See, e.g., **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011), at 1, lines 3 and 4 and lines 5 and 6 (undated).

Etobicoke as the manufacturer of the tablets.<sup>227</sup> It is likely, since Parexel is a company that specializes in clinical trials and the product shipped was a placebo with no active substance, that this shipment had to do with a clinical trial being conducted for Merck.<sup>228</sup>

156. Apotex had nothing to do with this shipment and nothing suggests that it was for commercial sale. Notably, although the shipment occurred during the Import Alert, the final admissibility activity description column states “MPro Issued” two days later on November 5, 2009 – indicating that the US authorities decided the shipment “may proceed” into the US.<sup>229</sup>
157. The unrelated shippers such as Parexel apparently bought Apotex-manufactured products on the market in whatever country they were located and ultimately shipped them to the United States for purposes unknown to Apotex (but most likely clinical trials).
158. For each entry on exhibits R-115, R-118 and R-119 where a third party was the shipper, most if not all of these shipments were by companies, like Parexel, involved in clinical trials or testing of pharmaceutical products. Most of the entries concerned the drug Warfarin which was used as “comparator” or “placebo.”<sup>230</sup> Other entries concerned the drug “Metformin” which was used as a “lab research drug.”<sup>231</sup>

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<sup>227</sup> **Exhibit R-119**, FDA, Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009), at 1, line 7 (undated).

<sup>228</sup> **Exhibit C-468**, Excerpt from Parexel website, *available at* <http://www.parexel.com/about/experience-and-expertise/> (last visited on April 18, 2013) (“PAREXEL is a contract research organization that has performed services in connection with clinical research trials for 30 years in all major therapeutic areas ...”). *See id.* at <http://www.parexel.com/about/global-presence/europe/ukraine/> (last visited on April 18, 2013) (Parexel’s office in Ukraine is located at “9, Moskovskiy prosp., Building 2, Office 204, 04073, Kiev...”).

<sup>229</sup> *See* **Exhibit R-119**, FDA, Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009), at 1, line 7 (undated); **Exhibit C-479**, FDA, Final Admissibility Activity Descriptions and Explanations at US158 (undated) (“MPro Issued” means “FDA Release issued at the time of Entry Review, without conducting any type of physical field examination or sample collection.”). *See also* **Exhibit C-451**, DIOP, “Predictive Risk-based Evaluation for Dynamic Compliance Targeting (PREDICT)”, slides 5-6 on Electronic Transactions Import Entry Lines (updated July 2012).

<sup>230</sup> *See, e.g.,* **Exhibit R-118**, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009), at 1 (undated) (“Accountability IND 75238 Warfarin, Comparator or Placebo”); *id.* at 2, second line from the bottom (“Warfarin Comparator Sponsor Bayer”). As noted, the drug Glipizide was

159. Furthermore, Apotex's Canadian counsel, [REDACTED] shipped [REDACTED] powder to the Massachusetts Institute of Technology (MIT) for testing in connection with patent litigation relating to that product.<sup>232</sup> This shipment was not for commercial sale in the US.<sup>233</sup>

160. The shipments to consignees other than Apotex-US were thus made by unrelated third parties and did not reflect commercial sales in the United States.

*(ii) Non-Commercial Shipments from Apotex Do Not Support the US*

161. A much smaller number of entries on exhibits R-115, R-118 and R-119 concerns Apotex-Canada as the shipper.<sup>234</sup> As stated above, the spreadsheets show that, during the Import Alert, a total of 322 shipments of Apotex products manufactured at Signet and Etobicoke were shipped to the United States. Out of these 322, Apotex-Canada was the shipper of 11 shipments. However, these 11 shipments were not for commercial sale of products, but rather for uses other than commercial sales, such as clinical trials, testing, or other purposes.<sup>235</sup>

162. For example, 9 of the 11 entries with Apotex-Canada as the shipper concerned Deferiprone, the drug sold under the brand Ferriprox®. This drug was not yet authorized for sale in the US during the Import Alert.<sup>236</sup> However, FDA allowed

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also used as a placebo. *See Exhibit R-119*, FDA, Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009), at 1, line 7 (undated) (“Glipizide Placebo Tablets”).

<sup>231</sup> *See, e.g., Exhibit R-115*, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011), at 1, last line (undated) (“Metformin Tablets/850mg, Labre [sic] Search Drug”); *id.* at 2, last line (“Metformin/850mg, Lab Research Drug”).

<sup>232</sup> *See Exhibit R-118*, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009), at 10, line 10 (undated). *See id.* at 11, line 7 (shipment from [REDACTED] for “Exhibits – Other Drug Related Items N.E.C”).

<sup>233</sup> Second Witness Statement of Gordon Fahner, para. 25.

<sup>234</sup> *Exhibit R-115*, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated); *Exhibit R-118*, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated); *Exhibit R-119*, FDA, Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated).

<sup>235</sup> *See* Second Witness Statement of Gordon Fahner, paras. 39-46.

<sup>236</sup> *See* Second Witness Statement of Gordon Fahner, para. 26.

Apotex to ship deferiprone to the United States during the Import Alert for compassionate use in cancer treatment.<sup>237</sup>

163. Apotex-Canada also shipped [REDACTED] to [REDACTED], a company involved in providing microanalysis services.<sup>238</sup> This shipment was a sample on which testing was to be performed. Apotex does not hold an ANDA for [REDACTED] and does not sell this product in the United States. This shipment was not made for commercial sale.<sup>239</sup>
164. In addition, it appears that Apotex-Canada shipped [REDACTED] to its US counsel, [REDACTED], in connection with a patent infringement lawsuit to which Apotex was a party.<sup>240</sup> This shipment, again, was not for commercial sale but for use as evidence in the US lawsuit.<sup>241</sup>
165. Contrary to the US supposition of other distributors of Apotex-Canada products equally impacted by the Import Alert,<sup>242</sup> the record shows a total of 11 shipments by Apotex-Canada to the United States in the relevant period, for alleviation of pain in cancer treatment, testing of products or evidence in patent litigation. The record does not support the US.

*(iii) 99% of the Shipments to Consignees Other than Apotex-US Were Allowed into the United States*

166. In fact, exhibits R-115, R-118 and R-119 affirmatively refute the US hypothesis that other consignees received the same treatment as Apotex-US. The final admissibility activity description column in these documents shows that, of the 322 shipments to

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<sup>237</sup> See **Exhibit R-119**, FDA, Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009) at 1 (undated). See also Memorial, paras. 223, 246; Second Witness Statement of Gordon Fahner, para. 26.

<sup>238</sup> See **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) at 1, line 9 (undated); **Exhibit C-469**, Excerpts from website [REDACTED]).

<sup>239</sup> Second Witness Statement of Gordon Fahner, para. 46.

<sup>240</sup> See **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) at 1, 8<sup>th</sup> entry (undated).

<sup>241</sup> Second Witness Statement of Gordon Fahner, para. 45.

<sup>242</sup> US Counter-Memorial, para. 292.

other consignees during the Import Alert, *every single shipment* was allowed into the United States<sup>243</sup> – with only three, unexplained exceptions:

- 1) Myoderm Medical Supply in Norristown, Pennsylvania;<sup>244</sup>
- 2) Walgreens Pharmacy in Phoenix, Arizona;<sup>245</sup>
- 3) Good Samaritan Hospital and Medical Centre in Portland, Oregon.<sup>246</sup>

167. The shipment to Myoderm Medical Supply was shipped by Rx Source in Canada.<sup>247</sup> That company's website indicates that Rx Source offers services in connection with investigational/clinical trials.<sup>248</sup> This specific shipment was for Naproxen, an anti-inflammatory drug used as "comparator to AZD-3585."<sup>249</sup> The notice of FDA action for this shipment shows that Myoderm wished to import a rather small quantity of Naproxen (221 bottles).<sup>250</sup> It is more than likely that this product was to be used in

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<sup>243</sup> See **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated); **Exhibit R-118**, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated); **Exhibit R-119**, FDA, Apotex Inc. – Etobicoke Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated). All shipments listed during the Import Alert period (except three shipments listed on page 1 of Exhibit R-115 and pages 2 and 23 of Exhibit R-118) received either a "May Proceed" (MPro), "Released", "Released with Comment", or "IB Release" (Rel/IB) determination. Rel/IB means "FDA Release issued after physical examination of the product for which no apparent violations were revealed." See **Exhibit C-479**, FDA, *Final Admissibility Activity Descriptions and Explanations* at US158 (undated).

<sup>244</sup> **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated) at 1, line 2 (Entry No. 334-2761279-2/1/1, Submission Date: September 3, 2009). See also **Exhibit R-118**, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated), at 23, line 6 (same shipment).

<sup>245</sup> **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated) at 1, lines 3 and 4 (Entry No. 112-5302968-4/1/1, Submission Date: December 17, 2009). See also **Exhibit R-118**, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated), at 2, line 4 (same shipment).

<sup>246</sup> **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated) at 1, lines 5 and 6 (Entry No. 112-8628167-4/1/1, Submission Date: August 24, 2010).

<sup>247</sup> *Id.* at 1, line 2 (Entry No. 334-2761279-2/1/1, Submission Date: September 3, 2009). See also **Exhibit R-118**, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated), at 23, line 6 (same shipment).

<sup>248</sup> **Exhibit C-471**, Excerpts from website of Rx Source, available at <http://rxsource.ca/rxsource-services> (last visited on April 19, 2013).

<sup>249</sup> **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated) at 1, line 2 (Entry No. 334-2761279-2/1/1, Submission Date: September 3, 2009). See also **Exhibit R-118**, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated), at 23, line 6 (same shipment).

<sup>250</sup> See **Exhibit C-387**, Notices of FDA Action to Myoderm Medical Supply, dated September 4 - October 5, 2009.

clinical trials or bio-equivalence studies. In other words, this shipment was not for commercial sale in the United States.<sup>251</sup>

168. The shipment to Walgreens in Phoenix was made by a pharmacy in Quebec called Brunet.<sup>252</sup> It was for one pack of an anti-inflammatory drug (Allopurinol 200 mg).<sup>253</sup> It is quite possible that Walgreens asked Brunet to send a refill on a prescription for a Canadian patient who had extended his or her stay in Arizona. This seems probable given that the shipment was for only one pack of product.<sup>254</sup>
169. This same shipment of Allopurinol 200 mg was refused admission on two different grounds, namely “drug GMPs” and “unapproved” new drug.<sup>255</sup> Allopurinol is authorized in the US in various strengths, but Apotex does not own an ANDA for the 200 mg dosage.<sup>256</sup> In other words, Apotex’s Allopurinol 200 mg was not authorized for sale, and never sold, in the United States. This shipment was not for commercial sale in the US.
170. Finally, the shipment to Good Samaritan Hospital and Medical Centre in Portland, Oregon was shipped by Bay Area Health Trust in Hamilton, Ontario, which is a company that offers clinical trial logistic services and is part of a group of hospitals in Toronto.<sup>257</sup> The shipment was for the drug Metformin,<sup>258</sup> sometimes used as a “lab research drug.”<sup>259</sup> The shipment contained only “one box” of Metformin, which may

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<sup>251</sup> See Second Witness Statement of Gordon Fahner, para. 52.

<sup>252</sup> See **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated) at 1, lines 3 and 4 (Entry No. 112-5302968-4/1/1, Submission Date: December 17, 2009). See also **Exhibit R-118**, FDA, Apotex Inc. – Signet Shipments – Non-Apotex Entities as Consignees (2006-2009) (undated), at 2, line 4 (same shipment); **Exhibit C-475**, Excerpt from Brunet website, available at <http://www.brunet.ca/en/news/corporate-information.html> (last visited on May 20, 2013).

<sup>253</sup> See **Exhibit C-411**, Notices of FDA Action to Walgreens Pharmacy, dated December 21-22, 2009.

<sup>254</sup> See Second Witness Statement of Gordon Fahner, para. 53.

<sup>255</sup> **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated) at 1, lines 3 and 4 (Entry No. 112-5302968-4/1/1, Submission Date: December 17, 2009).

<sup>256</sup> See **Exhibit C-456**, Excerpts from Orange Book, Allopurinol (2013); Second Witness Statement of Gordon Fahner, para. 58.

<sup>257</sup> See **Exhibit C-470**, Excerpts from website of Bay Area Research Logistics, available at <http://www.barl.ca/> (last visited on April 18, 2013).

<sup>258</sup> **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) (undated) at 1, lines 5 and 6 (Entry No. 112-8628167-4/1/1, Submission Date: August 24, 2010).

<sup>259</sup> See, e.g., **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011), at 2, last line (undated) (“... Metformin/850mg, Lab Research Drug”).

have been used in clinical trials or for the care of a specific Canadian patient spending time in Portland.<sup>260</sup>

171. This shipment was initially detained both on grounds of “drug GMPs” and “unapproved” new drug.<sup>261</sup> The shipment of Metformin may have been for a dosage and strength that was not approved in the United States.<sup>262</sup> This confirms, as well as the small size of the shipment, that this shipment was not for commercial sale in the United States.<sup>263</sup>
172. As observed in the Second Witness Statement of Gordon Fahner, the maximum amount of dosages implicated by the blocked shipment of these three packages was about 22,000 – based on the assumption that every unit contained the maximum dosages made by Apotex-Canada for that product.<sup>264</sup> By contrast, before the Import Alert, Apotex-US sold [REDACTED] *dosages per year* on the US market. It received over [REDACTED] packages from Apotex-Canada in the 2006 to 2009 period.<sup>265</sup> The vast difference in the number of the transactions blocked for Apotex-US and that for these three other consignees underscores the lack of merit of the US suggestion that the Import Alert did not relate to Apotex-US.
173. Thus, during the Import Alert, Apotex-US was permitted to receive no shipment of product made by Apotex-Canada in Etobicoke or Signet. In contrast, the US evidence shows that other consignees were permitted to receive hundreds of shipments of such products – 99% of these shipments were allowed into the US. Far from supporting the US, the evidence it has submitted confirms that the Import Alert related to Apotex-US in a unique way.

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<sup>260</sup> **Exhibit C-419**, Notices of FDA Action to Good Samaritan Hospital & Medical Center, Notice 1, dated August 25, 2010.

<sup>261</sup> **Exhibit R-115**, FDA, Apotex Inc. – Detained Shipments – Non-Apotex Entities as Consignees (2009-2011) at 1, lines 5 and 6 (undated).

<sup>262</sup> Apotex holds ANDAs for Metformin. *See Exhibit C-457*, Excerpts from Orange Book, Metformin (2013).

<sup>263</sup> *See* Second Witness Statement of Gordon Fahner, para. 54.

<sup>264</sup> *Id.*, paras. 57-60.

<sup>265</sup> *Id.*, para. 61.

174. While the US may be correct that “[u]nder NAFTA Chapter Eleven, a measure affecting a foreign supplier cannot be said to affect, legally, every domestic company which that supplier supplies,”<sup>266</sup> this statement is inapposite to the facts of this case: Apotex-US was the only US-based company that Apotex-Canada supplied with drugs for commercial sale from its Etobicoke and Signet facilities.<sup>267</sup> Whether the Import Alert “relates to” Apotex-US’s customers, and the customers of those customers, is an interesting question. But it is not a question that is posed in this case. The US’s contention that other distributors were affected by the Import Alert is without merit.

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

175. The US errs in its lengthy arguments concerning supposedly conflicting statements about the relationship between Apotex-Canada and Apotex-US.<sup>268</sup> Before turning to a point by point answer, Apotex offers four general observations.

176. *First*, Apotex did not suggest in its Memorial that the relationship between Apotex-Canada and Apotex-US was pertinent to the “relating to” issue.<sup>269</sup> Instead, it posited that that relationship was relevant to establishing a “commitment of capital or other resources” within the meaning of NAFTA Article 1139(h).<sup>270</sup> It is not clear why the US has decided to reclassify this issue as concerning “relating to” rather than a “commitment of capital or other resources.” What is clear, however, is that the US argument is beside the point.

177. *Second*, the US argument reflects a fundamental misunderstanding of how multinational companies operate in the world today. Apotex-Canada and Apotex-US are separate and distinct companies whose officers and directors scrupulously respect the corporate form. And yet they coordinate and collaborate closely to ensure that customers in the US have access to the medicinal products they need in a timely, efficient and seamless manner.

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<sup>266</sup> US Counter-Memorial, para. 298.

<sup>267</sup> See Second Witness Statement of Gordon Fahner, paras. 17-47.

<sup>268</sup> See US Counter-Memorial, paras. 299-320.

<sup>269</sup> See Memorial, paras. 410-15.

<sup>270</sup> See *id.*, paras. 339-400.

Contrary to the US suggestion, there is nothing incompatible in these two statements – and in fact, this is how sophisticated companies operate throughout the world today.

178. *Third*, NAFTA tribunals have rejected, for good reason, previous efforts to avoid the obligations of the investment chapter through arguments addressed to the form rather than substance of a corporate group’s organization. In *S.D. Myers*, the tribunal rejected a jurisdictional objection concerning an alleged lack of control by the US investor (SDMI) of the Canadian investment (Myers Canada) – the shares of the latter being held by four members of the Myers family rather than by SDMI:

Taking into account the objectives of the NAFTA, the obligation of the Parties to interpret and apply its provisions in light of those objectives, the Tribunal does not accept that an otherwise meritorious claim should fail solely by reason of the corporate structure adopted by a claimant in order to organise the way in which it conducts its business affairs.<sup>271</sup>

179. The *S.D. Myers* tribunal concluded that SDMI was an investor and Myers Canada an investment.<sup>272</sup>

180. *Fourth*, the statements made by Apotex in US courts on which the US attempts to rely are taken out of context and distorted. The US is wrong when it argues that “Apotex routinely says one thing in order to create jurisdiction before this Tribunal while saying precisely the opposite when seeking to avoid jurisdiction in U.S. courts.”<sup>273</sup> Each of the statements quoted in the Counter-Memorial are taken from the same litigation in which AstraZeneca Pharmaceuticals LP and related companies sued Apotex and other generic drug manufacturers for patent infringement stemming from their respective ANDA applications for an anti-cholesterol drug (Rosuvastatin Calcium tablets).<sup>274</sup> AstraZeneca’s case against Apotex-US proceeded before the federal courts of

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<sup>271</sup> **Legal Authority CLA-43**, *S.D. Myers, Inc. v. The Government of Canada*, UNCITRAL, Partial Award, para. 229 (Nov. 13, 2000).

<sup>272</sup> *Id.*, para. 231.

<sup>273</sup> US Counter-Memorial, para. 300.

<sup>274</sup> See **Legal Authority RLA-80**, *In re: Rosuvastatin Calcium Patent Litigation*, 719 F. Supp. 2d 388 (D. Del. 2010).

Delaware,<sup>275</sup> while the case against Apotex-Canada was transferred to the Southern District of Florida at the request of Apotex-Canada.<sup>276</sup> As such, Apotex-Canada was not trying to avoid jurisdiction in US courts but rather sought to establish jurisdiction in the proper forum. It is against this backdrop that the various statements made by Apotex in the AstraZeneca litigation must be interpreted.

a) *Apotex-US and Apotex-Canada Operate Within a Vertically Integrated Group*

181. Apotex showed, notably through witness statements, that Apotex-US and Apotex-Canada operate within the same vertically integrated *group* of companies.<sup>277</sup> In its Counter-Memorial, the US mischaracterizes Apotex's showing by arguing that Apotex-Canada and Apotex-US are not "vertically integrated *companies*."<sup>278</sup> The US then alleges that Apotex has argued "precisely the opposite" in US courts.<sup>279</sup> The US attempts – to no avail – to rely on statements made by Apotex's employees in the AstraZeneca litigation where, as noted by the US, Apotex insisted that Apotex-Canada and Apotex-US "are each maintained as completely separate corporate entities" with no parent-subsidary relationship.<sup>280</sup> This is in line with Apotex's position in this

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<sup>275</sup> See *id.*; **Legal Authority CLA-536**, *In re : Rosuvastatin Calcium Patent Litigation*, 703 F.3d 511 (Fed. Cir. 2012).

<sup>276</sup> See **Legal Authority RLA-73**, *AstraZeneca Pharmaceutical LP et al. v. Apotex Inc. and Apotex Corp.*, No. 1:07-cv-00809 JFF-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 1-2 (Jan. 31, 2008) ("Apotex[-Canada] requests that this matter be transferred to the Middle District of Florida ... and agrees to submit to personal jurisdiction there."); **Legal Authority CLA-537**, *In re Rosuvastatin Calcium Patent Litig.*, MDL No. 08-1949-JFF, 2010 WL 661599, at \*2 (D. Del. Feb. 19, 2010) (mem.) ("Reviewing the Report and Recommendation of Magistrate Judge Stark *de novo*, the Court concludes that Magistrate Judge Stark did not err in concluding that the Court lacks personal jurisdiction over Apotex. ... In addition, the Court further concludes that Magistrate Judge Stark appropriately concluded that this action should be transferred to the Southern District of Florida.").

<sup>277</sup> See Memorial, para. 35 ("Apotex is a vertically integrated group of companies."). *Id.* at para. 42 ("Apotex-US is integrated within the Apotex group. It shares centralized functions, such as finance, intellectual property, human resources and information technology, with Apotex-Canada. The companies are parties to an inter-company agreement whereby Apotex-Canada performs specific support functions for the benefit of Apotex-US and for a monthly fee.") (footnote omitted). See also Witness Statement of Jeremy Desai, para. 26; Witness Statement of Gordon Fahner, paras. 26, 35.

<sup>278</sup> US Counter-Memorial, at 148, heading b ("Apotex Corp. and Apotex Inc. are not 'vertically integrated' *companies*") (emphasis added).

<sup>279</sup> *Id.*, para. 303.

<sup>280</sup> *Id.*, para. 303 & nn.717, 719. In its complaint, AstraZeneca had alleged that Apotex-US was a wholly owned subsidiary of Apotex-Canada. See **Legal Authority CLA-549**, Report and Recommendation Regarding Motions for Summary Judgment and to Dismiss, and Order on Evidentiary Motions, *In re Rosuvastatin Calcium Patent Litig.*, MDL No. 08-1949, 2009 WL 4800702, at \*1 (D. Del. Dec. 11, 2009).

arbitration, where Apotex made it clear from the inception that Apotex-Canada does not own Apotex-US.<sup>281</sup>

182. In the AstraZeneca litigation, the plaintiffs argued, among other things, that Apotex-US's actions could be imputed to Apotex-Canada under an agency theory. This argument was rejected because Apotex-US and Apotex-Canada were separate corporations that strictly adhered to the corporate form.<sup>282</sup> Apotex-Canada nonetheless acknowledged that Apotex-US was “a related corporate entity that happen[ed] to distribute products manufactured by [Apotex-Canada].”<sup>283</sup> The US courts concluded that “Apotex U.S. acts as the marketing and distribution arm of Apotex Canada in the United States[.]”<sup>284</sup> There is thus nothing contradictory between Apotex's position in the present arbitration and in the AstraZeneca litigation.

b) *Apotex-US Received No Loans or Capital from Apotex-Canada But It Received Other Resources*

183. The US disputes that Apotex-Canada “commits various resources in the United States in relation to the filing and maintaining of its [ANDAs].”<sup>285</sup> The US asserts, correctly, that the 2005 services agreement between Apotex-Canada and Apotex-US requires that Apotex-US make a cash payment to Apotex-Canada for certain administrative support, and not the other way around.<sup>286</sup> However, the services agreement reflects a large contribution from Apotex-Canada to Apotex-US, including administrative services,

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AstraZeneca maintained this allegation even after Apotex had stated otherwise in various submissions. See **Legal Authority RLA-76**, *AstraZeneca Pharmaceuticals LP et al. v. Apotex Inc. and Apotex Corp.*, No. 1:07-cv-00809 JJF-LPS (D. Del.), Answer, Defenses and Counterclaims of Defendants Apotex Inc. and Apotex Corp., at 3 (Jan. 28, 2009).

<sup>281</sup> Request for Arbitration, paras. 7-8 (Feb. 29, 2012) (noting that both Apotex-Canada and Apotex-US are indirectly owned and controlled by Apotex Holdings).

<sup>282</sup> See **Legal Authority CLA-537**, *In re Rosuvastatin Calcium Patent Litig.*, MDL No. 08-1949-JJF, 2010 WL 661599, at \*2 (D. Del. Feb. 19, 2010) (mem.) (“As Magistrate Judge Stark pointed out, Apotex[-Canada] and Apotex[-US] are distinct corporations whose relationship is insufficient to support an agency theory.”).

<sup>283</sup> **Legal Authority RLA-75**, *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 in Support of its Motion to Dismiss, at 10 (May 5, 2008).

<sup>284</sup> See **Legal Authority CLA-536**, *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 527 (Fed. Cir. 2012).

<sup>285</sup> US Counter-Memorial, para. 304 (quoting Memorial, para. 399).

<sup>286</sup> See *id.*, para. 305 (citing to **Exhibit C-14**, Services Agreement Between Apotex-Canada and Apotex-US, dated July 1, 2005, paras. 3, 4.1).

accounting and financial (including payroll) services, information systems and technology services, as well as any other services that may be, from time to time, requested by Apotex-US.<sup>287</sup> The cash payment only compensates Apotex-Canada for a small portion of the services that Apotex-Canada provides to Apotex-US. In other words, Apotex-Canada commits various resources to Apotex-US through the services agreement.<sup>288</sup>

184. Consistent with its position before US courts, Apotex never claimed in this arbitration that Apotex-US directly received “loans or other capital” from Apotex-Canada in relation to the maintaining of its ANDAs.<sup>289</sup> Yet, Apotex-Canada does commit other resources to the United States for that purpose. Notably, through the services agreement, Apotex-Canada supports the work of a team of seven Florida-based employees dedicated to ANDA-related work.<sup>290</sup> Apotex-Canada also incurs legal fees in connection with ANDA-related litigation.<sup>291</sup>
185. Moreover, the US argument is based on a false premise – that there can be no “commitment of capital or other resources” if the investor receives some consideration as a counterpart to that commitment. An equity investor contributing capital to an enterprise, whether in cash, know-how or other form, often receives shares in return for that contribution. An investor contributing cash to an enterprise often will receive promise of repayment through a shareholder or intercompany loan agreement. That the investor receives a valuable counterpart for its contribution, however, in no way diminishes the contribution made.
186. Here, Apotex-Canada provided valuable services to Apotex-US on a range of different topics. Those services permitted Apotex-US to put in place a team devoted to

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<sup>287</sup> See Witness Statement of Gordon Fahner, para. 37.

<sup>288</sup> See *id.*, paras. 76-79.

<sup>289</sup> US Counter-Memorial, para. 307 & n.733 (quoting **Legal Authority RLA-77**, *Astrazeneca Pharmaceutical 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)).

<sup>290</sup> See Memorial, para. 83; Witness Statement of Kiran Krishnan, para. 13.

<sup>291</sup> See Memorial, para. 41; Witness Statement of Gordon Fahner, para. 45.

maintaining Apotex-Canada's ANDAs and make payments to Apotex-Canada under the services agreement. The US argument is without merit.

c) *Apotex-US Was Set Up Specifically as the Distributor of Apotex Drugs in the United States*

187. In its case-in-chief, Apotex explained that Apotex-US was “set up specifically to market, distribute and sell the Apotex products on the US market,”<sup>292</sup> although it also distributes a small portion of third-party products in the United States.<sup>293</sup> The US wrongly argues that Apotex’s position in the arbitration is “belied by representations Apotex had made to U.S. courts.”<sup>294</sup> The US attempt to draw support from the AstraZeneca litigation is without merit.
188. As noted by the US, Apotex stated before US courts that “Apotex[-US] markets pharmaceutical products made by manufacturers other than Apotex[-Canada]. In 2007, approximately *fifteen percent* of Apotex[-US’s] sales resulted from products not manufactured by Apotex[-Canada].”<sup>295</sup> In other words, 85% of Apotex-US’s sales pre-Import Alert were generated by Apotex products. This is fully consistent with Apotex’s position in the arbitration.<sup>296</sup>
189. Apotex’s position in neither this arbitration nor the *AstraZeneca* case is that Apotex-US distributes the *entire* catalogue of products manufactured by Apotex-Canada.<sup>297</sup>

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<sup>292</sup> Witness Statement of Jeremy Desai, para. 24. *See also* Witness Statement of Gordon Fahner, para. 33 (“Apotex-US markets and distributes in the United States Apotex products manufactured by Apotex Inc.”).

<sup>293</sup> Memorial, para. 46.

<sup>294</sup> US Counter-Memorial, para. 309.

<sup>295</sup> *Id.*, para. 309 & n.743 (quoting **Legal Authority RLA-84**, *In re: Rosuvastatin Calcium Patent Litigation*, No. 1:08-md-01949 JF (D. Del.), Apotex Corp.’s Proposed Post-Trial Findings of Fact and Conclusions of Law – Noninfringement, at 1 (Apr. 16, 2010) (citation omitted; emphasis added)).

<sup>296</sup> Memorial, para. 517 (“Combined, about 80% to 85% of all Apotex solid dose products sold on the US market pre-Import Alert were produced at those two facilities [Etobicoke and Signet.]”); Second Witness Statement of Gordon Fahner, para. 67. *See also* Witness Statement of John Flinn, para. 18 (“... Apotex-US markets, sells and distributes Apotex products, as well as third-party products, in the US.”); *id.*, para. 51 (“To address the impact of the Import Alert on Apotex-US, we increased the ratio of third-party products in our portfolio. ... However, selling third-party products is not a strategic goal of the company. Therefore, our current goal is to reverse the ratio in favor of selling more Apotex products.”).

<sup>297</sup> *Compare* Witness Statement of Gordon Fahner, para. 69 (“A large portion of products manufactured at Signet and Etobicoke are produced for the US market.”) with US Counter-Memorial, para. 309 (Apotex-US distributes “*some* of those” products made by Apotex-Canada) (quoting **Legal Authority RLA-84**, Apotex Corp.’s Proposed Post-Trial Findings of Fact and Conclusions of Law – Noninfringement, at 1, *In re:*

Apotex's position both here and in US courts was and is that "Apotex[-US] selects which Apotex[-Canada] products Apotex[-US] will market."<sup>298</sup> The record does not support the "inconsistency" posited by the US.

*d) Apotex-US and Apotex-Canada Are Mutually Dependent*

190. Apotex showed that prior to the Import Alert, Apotex-US depended on Apotex-Canada's supplies, while Apotex-Canada depended on Apotex-US's marketing and distribution expertise in the United States.<sup>299</sup> The US disputes the accuracy of Apotex's description and attempts to draw support from the AstraZeneca litigation where Apotex stressed that Apotex-US "is a separate and distinct corporation" from Apotex-Canada.<sup>300</sup> As noted above, Apotex-Canada and Apotex-US are distinct corporate entities. From a business point of view, they operate hand-in-hand as part of a vertically integrated group of companies.<sup>301</sup>
191. The interdependence between the two companies does not mean, however, that Apotex-US's functions are subsumed in Apotex-Canada. Apotex-US generates its own revenues, "finances its operations independent of Apotex[-Canada],"<sup>302</sup> for instance by employing and paying its own sales team. Similarly, Apotex-US "manages its own financial plans,"<sup>303</sup> "authorizes its own expenditures,"<sup>304</sup> "creates its own forecasts,"<sup>305</sup> "commits to its own contracts,"<sup>306</sup> "determines which customers will receive

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*Rosuvastatin Calcium Patent Litigation*, No. 1:08-md-01949 JJF (D. Del. Apr. 16, 2010) (emphasis in US Counter-Memorial)).

<sup>298</sup> US Counter-Memorial, para. 309 & n.742 (quoting **Legal Authority RLA-84**, *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 1 (Apr. 16, 2010)); Second Witness Statement of Gordon Fahner, para. 80.

<sup>299</sup> Witness Statement of John Flinn, para. 29.

<sup>300</sup> US Counter-Memorial, para. 311 & n.748 (quoting **Legal Authority RLA-77**, *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 4 (Nov. 2, 2009)).

<sup>301</sup> Second Witness Statement of Gordon Fahner, paras. 15-16.

<sup>302</sup> US Counter-Memorial, para. 311 & n.749 (internal quotation omitted).

<sup>303</sup> *Id.*, para. 311 & n.750 (internal quotation omitted).

<sup>304</sup> *Id.*, para. 311 & n.751 (internal quotation omitted).

<sup>305</sup> *Id.*, para. 311 & n.752 (internal quotation omitted).

<sup>306</sup> *Id.*, para. 311 & n.753 (internal quotation omitted).

shipments,”<sup>307</sup> “sells products from companies other than Apotex[-Canada],”<sup>308</sup> and “does not market every generic pharmaceutical product manufactured by Apotex[-Canada]”<sup>309</sup> – only “some of those[.]”<sup>310</sup> There is no contradiction between Apotex’s statements before US courts and before this Tribunal.<sup>311</sup>

e) *Apotex-Canada Decides Which Products Will Be Developed for the US Market*

192. The US wrongly suggests a contradiction in Apotex’s statements concerning its Product Selection Team (PST).<sup>312</sup> There is none. In this arbitration, Apotex has explained that Apotex-US provides feedback to that team which then decides which new products should be developed and added to Apotex’s product portfolio.<sup>313</sup> This is consistent with Apotex’s statements before US courts that “Apotex[-Canada] consults with Apotex[-US] to understand the market demand in the United States for Apotex[-Canada’s] various generic pharmaceutical products. For this reasons, Apotex[-US] provides sales forecasts to Apotex[-Canada] so that Apotex[-Canada] can ensure it has adequate stocks of generic pharmaceuticals.”<sup>314</sup> However, Apotex-US is in charge of marketing and sale on the US market.<sup>315</sup> Consequently, “Apotex[-Canada] has *no involvement* in the ... process by which Apotex[-US] obtains business” with its customers in the United States.<sup>316</sup>

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<sup>307</sup> *Id.*, para. 311 & n.754 (internal quotation omitted).

<sup>308</sup> *Id.*, para. 311 & n.755 (internal quotation omitted).

<sup>309</sup> *Id.*, para. 311 & n.756 (internal quotation omitted).

<sup>310</sup> **Legal Authority RLA-84**, *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 1 (Apr. 16, 2010).

<sup>311</sup> Second Witness Statement of Gordon Fahner, paras. 68-87.

<sup>312</sup> US Counter-Memorial, para. 312.

<sup>313</sup> Witness Statement of Gordon Fahner, paras. 84-87.

<sup>314</sup> **Legal Authority RLA-77**, *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 6-7 (Nov. 2, 2009).

<sup>315</sup> Second Witness Statement of Gordon Fahner, para. 13.

<sup>316</sup> US Counter-Memorial, para. 313 & n.763 (quoting **Legal Authority RLA-75**, *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 in Support of its Motion to Dismiss (May 5, 2008), Ex. B, Declaration of Tammy L. McIntire, para. 6 (May 2, 2008) (emphasis added by Counter-Memorial)).

193. In short, Apotex-Canada is in charge of product development and manufacturing, while Apotex-US is in charge of marketing, distribution and sale in the United States. Apotex did not state differently in US courts.<sup>317</sup>

*f) Apotex-US Plays a Significant Role in the ANDA Process*

194. In its Memorial, Apotex also detailed the role that Apotex-US plays in the preparation, filing and maintenance of Apotex's ANDAs, while noting that "most of the product development and application preparation work is done by Apotex personnel in Canada."<sup>318</sup> Apotex emphasized the role of its regulatory agent with FDA, Mr. Krishnan, and his team, all of whom are employees of Apotex-US.<sup>319</sup> The US argues that Apotex's position in the arbitration is contrary to prior statements in US courts where Apotex allegedly "downplayed any role for Apotex[-US] in the ANDA process."<sup>320</sup> However, when read in context, the statements made by Apotex in the AstraZeneca litigation are consistent with its current position.

195. As noted, AstraZeneca sued Apotex for patent infringement in the courts of Delaware. Apotex-Canada was not a party to the Delaware litigation and Apotex-US pleaded that it had not "submitted" the ANDA application at stake, such that it could not be liable for infringement.<sup>321</sup> In order to make out its case, Apotex-US had to convince the court that it was not the ANDA "applicant" as per FDA regulations, but that Apotex-Canada was. Apotex-US acknowledged that it was the authorized US agent for the ANDA and that it

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<sup>317</sup> See **Legal Authority RLA-77**, *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 8 (Nov. 2, 2009) ("... Apotex[-Canada] develops and manufactures generic pharmaceutical products and Apotex[-US] 'lines up business for [generic pharmaceutical products]' in the United States.").

<sup>318</sup> Memorial, para. 81.

<sup>319</sup> See *id.*, para. 82; See also Witness Statement of Kiran Krishnan, paras. 11, 13.

<sup>320</sup> US Counter-Memorial, para. 316 & nn.774-86.

<sup>321</sup> **Legal Authority RLA-80**, *In re Rosuvastatin Calcium Patent Litigation*, 719 F. Supp. 2d 388, 395 (D. Del. 2010) ("In response, Apotex[-US] contends that it did not 'submit' the ANDA within the meaning of Section 271(e)(2)(A). According to Apotex[-US], the FDA regulations make it clear that only the 'applicant' submits an ANDA. Apotex[-US] contends that it has not sought approval to commercially manufacture, use, or sell the claimed invention and that every certification made in the ANDA was made by Apotex[-Canada], not Apotex[-US].") (citations omitted).

had signed the application. However, Apotex-US argued that the act of signing was not sufficient to make Apotex-US the “submitter” of the application.<sup>322</sup>

196. Apotex-US faced another hurdle since US courts have held that parties “actively involved” in preparing an ANDA are deemed to have “submitted” the ANDA, regardless of whether they are the named applicant.<sup>323</sup> In this context, Apotex-US argued unsuccessfully that its involvement was not in the preparation of the specific ANDA at stake was insufficiently “active” to make it a proper defendant. The statements quoted by the US at paragraph 316 of the Counter-Memorial must be read in light of Apotex-US’s defense in the *AstraZeneca* case.

197. The Delaware district court rejected Apotex-US’s arguments and found, based on Apotex’s evidence, that it was actively involved in the preparation of the ANDA at issue:

Apotex[-US] is identified in the ANDA and its amendments as the authorized U.S. agent for Apotex[-Canada], and these documents were signed by Mr. Kiran Krishnan, Manager of Regulatory Affairs for Apotex[-US], using the address and phone number of Apotex[-US]. ... Although Apotex[-US] is not a wholly owned subsidiary of Apotex[-Canada], the two companies are closely related. ... Apotex[-Canada] and Apotex[-US] hold themselves out publically and internally as part of the same Apotex Group of companies.

In addition, *the Court is persuaded that Apotex[-US] actively participated in activities related to the ANDA submission.* The FDA directed inquiries to Apotex[-US] regarding the ANDA application, ..., and Mr. Krishnan stayed at the headquarters of Apotex[-Canada] to assist in the preparation of the ANDA and answer questions while the Director of Regulatory Affairs for Apotex[-Canada], Ms. Bernice Atao [sic], was out of the office. ... Mr. Krishnan reviewed the draft ANDA prior to submission to the FDA and consulted with and answered substantive questions posed by the regulatory staff of Apotex[-Canada], in connection with the submission.<sup>324</sup>

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<sup>322</sup> *Id.* at 395.

<sup>323</sup> *Id.* at 396 (citation omitted).

<sup>324</sup> *Id.* at 397 (D. Del. 2010) (citations omitted) (emphasis added), *aff’d* **Legal Authority CLA-536**, *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 529 (Fed. Cir. 2012) (“The [district] court found that the

198. Therefore, the US court found, based on a similar record, that Apotex-US played a substantial role in the ANDA at issue in the *AstraZeneca* case. It is curious that the US urges this Tribunal to reach a conclusion different from that of its own judicial organ.
199. At paragraph 316 of the Counter-Memorial, the US also quotes excerpts from the declaration of Bernice Tao in an action for patent infringement brought by Pfizer against Apotex concerning the brand-name drug Lipitor.<sup>325</sup> Pfizer sued both Apotex-Canada and Apotex-US in Delaware.<sup>326</sup> Apotex challenged the jurisdiction of the courts of Delaware over Apotex-Canada since “[n]one of the relevant work regarding Apotex[-Canada’s] ANDA product, the preparation of the ANDA, or the filing of the ANDA occurred or was otherwise performed *in Delaware*.”<sup>327</sup> Apotex therefore moved to have the case transferred to Illinois.<sup>328</sup>
200. Ms. Tao also stated before the courts of Delaware that “Apotex[-Canada] conducted all of the research, development and manufacturing of the generic ... products that are the subject of [this specific] ANDA,” and “[a]ll of this work was performed in Canada.”<sup>329</sup> These statements accord with Apotex’s position in the arbitration that most of the preparation work for Apotex’s ANDAs is carried out in Canada, except for certain bio-

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interests of Apotex Canada in this action are represented by its agent and subsidiary, Apotex U.S., and that Apotex U.S. participated in preparation of the ANDA and represented that it would sell the product in the United States. That relationship is not denied. We conclude that the district court did not err in holding that Apotex U.S. is properly named as a defendant in this action.”)

<sup>325</sup> See **Legal Authority RLA-92**, *Pfizer Inc. et al. v. Apotex Inc. and Apotex Corp.*, No. 1:08-cv-00948 (LDD) (D. Del.), Declaration of Bernice Tao (Feb. 10, 2009).

<sup>326</sup> See **Legal Authority CLA-527**, Complaint, *Pfizer Inc. v. Apotex Inc.*, No. 1:08-cv-00948-LDD, para. 26 (D. Del. Dec. 17, 2008) (Pfizer argued that “[p]ersonal jurisdiction over Apotex[-Canada] is proper because it purposefully avails itself of the privilege of selling its generic products in the State of Delaware and can therefore reasonably expect to be subject to jurisdiction in courts in Delaware.”).

<sup>327</sup> **Legal Authority RLA-92**, *Pfizer Inc. et al. v. Apotex Inc. and Apotex Corp.*, No. 1:08-cv-00948 (LDD) (D. Del.), Declaration of Bernice Tao, para. 25 (Feb. 10, 2009) (emphasis added).

<sup>328</sup> Anticipating that Apotex would challenge the jurisdiction of Delaware courts, Pfizer also filed an identical suit against Apotex in the courts of Illinois where the case was stayed pending resolution of the jurisdictional objection in Delaware. See **Legal Authority CLA-546**, *Pfizer Inc. v. Apotex Inc.*, 640 F. Supp. 2d 1006 (2009). At Apotex’s request, the Delaware case was transferred to Illinois. See **Legal Authority CLA-535**, *In re Pfizer Inc.*, 364 Fed. Appx. 620 (Fed. Cir. 2010) (denying Pfizer’s writ of mandamus to vacate transfer order). Eventually, Pfizer and Apotex settled their dispute over Lipitor. See **Legal Authority CLA-538**, Joint Motion to Dismiss, *Pfizer Inc. v. Apotex Inc.*, Nos. 1:08-07231, 1:09-cv-6053, 2012 WL 20107327 (N.D. Ill. Feb. 29, 2012).

<sup>329</sup> **Legal Authority RLA-92**, *Pfizer Inc. et al. v. Apotex Inc. and Apotex Corp.*, No. 1:08-cv-00948 (LDD) (D. Del.), Declaration of Bernice Tao, para. 17 (Feb. 10, 2009).

equivalence studies that were performed by US-based CROs in 2009.<sup>330</sup> The applications are submitted by Apotex's US agent, Mr. Krishnan, who acts as liaison with FDA.<sup>331</sup> Mr. Krishnan and his team are also responsible for post-approval reporting requirements with FDA.<sup>332</sup>

201. Contrary to what the US alleges, Apotex's current position that Apotex-US plays a key role in preparing, submitting, and maintaining ANDAs is not "belied by" prior statements in US courts. Significantly, US courts have held that Apotex-US "actively participate[s] in activities related to the ANDA submission."<sup>333</sup>

*g) US Litigation Is a Key Part of Apotex's Regular Activity in the US*

202. Apotex explained to this Tribunal that "[o]pening up the generic market in the US is Apotex's principal commercial strategy."<sup>334</sup> To fulfill this strategy, "Apotex does not hesitate to invest in litigation in the US courts"<sup>335</sup> up to [REDACTED] annually.<sup>336</sup> The US wrongly argues that Apotex made contradictory representations in the AstraZeneca litigation.<sup>337</sup>

203. The statements quoted by the US at paragraph 318 of the Counter-Memorial are taken out of context. The main point that Apotex-Canada was trying to make before the Delaware District Court was that its prior participation in nine unrelated court actions in *that state* was not enough to attract personal jurisdiction. Notably, Apotex's involvement in the other court cases did not amount to "regularly do[ing] business" in Delaware – the test for general personal jurisdiction.<sup>338</sup> Far from denying that it is

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<sup>330</sup> Memorial, para. 81; Witness Statement of Bernice Tao, para. 15; Second Witness Statement of Bernice Tao, para. 33

<sup>331</sup> Witness Statement of Kiran Krishnan, paras. 11, 23, 26; Second Witness Statement of Kiran Krishnan, para. 17; Witness Statement of Bernice Tao, paras. 11, 23; Second Witness Statement of Bernice Tao, para. 35.

<sup>332</sup> Witness Statement of Kiran Krishnan, para. 32; Second Witness Statement of Kiran Krishnan, paras. 16-18.

<sup>333</sup> **Legal Authority RLA-80**, *In re Rosuvastatin Calcium Patent Litigation*, 719 F. Supp. 2d 388, 397 (D. Del. 2010).

<sup>334</sup> Witness Statement of Kiran Krishnan, para. 18.

<sup>335</sup> *Id.*, para. 19.

<sup>336</sup> Witness Statement of Gordon Fahner, para. 45.

<sup>337</sup> *See, e.g.*, US Counter-Memorial, para. 318.

<sup>338</sup> **Legal Authority RLA-75**, *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 in Support of its Motion to Dismiss, at 2 (May 5, 2008).

frequently involved in ANDA-related litigation in the United States generally, Apotex expressly acknowledged this fact but argued it to be insufficient to establish general personal jurisdiction over Apotex-Canada in Delaware.<sup>339</sup>

204. More generally, the US errs in contending that “Apotex’s own evidence and statements in U.S. courts thus undermine Apotex’s claim in this arbitration that Apotex[-US] has some special relationship with Apotex[-Canada] ... .”<sup>340</sup> Apotex-US does have a special relationship with Apotex-Canada – it is part of the same integrated group of companies and the distributor and consignee of record for Apotex products in the United States. Apotex-US’s relationship with Apotex-Canada respects the separate corporate personality of each of the two companies, but it is nonetheless a special one in the sense just described.
205. To summarize the discussion on “relating to” under Article 1101(1), the NAFTA does not support the US argument that a measure, to be covered by Chapter Eleven, must “apply to” an investment or “impose a legal impediment” to the investment’s business. Applying the rules of interpretation in Article 31(1) of the Vienna Convention, a measure that meets the criteria set out in the substantive provisions of Chapter Eleven necessarily has a legally significant connection to the investor and investment at stake. Precisely that type of connection is present in the case at bar since Apotex has established that the Import Alert breached NAFTA Articles 1102, 1103 and 1105. In any event, the evidence submitted by the US shows that the Import Alert was directly “applied to” Apotex-US – the test apparently proffered by the US. Apotex-US is the sole *commercial* consignee in the United States for products manufactured by Apotex-Canada. The Import Alert interrupted all transactions between Apotex-Canada and Apotex-US – while 99% of shipments to other non-commercial consignees were admitted in the United States. The Import Alert related to Apotex-US within the meaning of Article 1101(1).

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<sup>339</sup> *Id.* at 5.

<sup>340</sup> US Counter-Memorial, para. 319.

## II. APOTEX-CANADA'S ANDAS ARE COVERED INVESTMENTS

206. The US wrongly asserts that Apotex-Canada is not an “investor” that made or sought to make “investments” in the United States, but merely “a Canadian company that exports its products in the United States from outside the United States.”<sup>341</sup> The US ignores already-mentioned NAFTA jurisprudence according to which trade and investment matters are not mutually exclusive.<sup>342</sup> More importantly, the US fails to rebut Apotex’s demonstration that its marketing authorizations (ANDAs) are covered by Article 1139(g) and (h). Indeed, the US does not even attempt to respond to the bulk of the arguments and evidence put forward by Apotex. Instead, it addresses arguments that Apotex did not make. Such techniques of rhetoric do not withstand scrutiny. Marketing authorizations such as Apotex’s ANDAs do constitute “investments” within the meaning of Article 1139, as discussed in **Section A** below.
207. The US also erroneously argues *in the alternative* that the Import Alert did not “relate to” Apotex’s ANDAs because the measure concerned *products* made at the Etobicoke and Signet facilities and, allegedly, had no “legally significant connection” to the *authorizations to market those products*.<sup>343</sup> The US argument is without merit, as explained in **Section B** below.

### A. Apotex-Canada’s ANDAs Are “Investments” Under Chapter Eleven

208. As explained in the Memorial, Apotex-Canada’s ANDAs fall within the definition of investment in Article 1139(g) (intangible property) and Article 1139(h) (interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory).<sup>344</sup> The US’s contentions to the contrary must fail for the reasons set out in what follows.

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<sup>341</sup> *Id.*, paras. 220-21. *See also id.*, para. 216 (“Apotex must show, therefore, that Apotex[-Canada] or Apotex Holdings sustained losses as an ‘investor of a Party,’ and not merely as a foreign trader.”).

<sup>342</sup> *See supra* para. 113.

<sup>343</sup> US Counter-Memorial, para. 274.

<sup>344</sup> *Id.*, para. 221.

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

209. In the Memorial, Apotex demonstrated that its ANDAs constitute intangible property within the meaning of Article 1139(g) for six main reasons. *First*, FDA's own regulations recognize that a pharmaceutical company may own an ANDA, and that it may be transferred for consideration.<sup>345</sup> *Second*, ANDAs are regularly bought and sold for substantial amounts of money.<sup>346</sup> *Third*, once a company has acquired the rights to an ANDA, US courts recognize that the company has standing to intervene in a case where those rights might be affected.<sup>347</sup> *Fourth*, US courts have also treated access to the US market under an approved ANDA as a protected interest.<sup>348</sup> *Fifth*, US case law further demonstrates that the marketing exclusivity afforded to certain ANDA holders is a valuable protected interest, which can also be traded.<sup>349</sup> *Sixth*, the approach taken by other US Government agencies confirms that ANDAs are considered as intangible assets.<sup>350</sup>

210. The US is silent on all of these points.<sup>351</sup> The US Counter-Memorial does not dispute that FDA regulations explicitly recognize that ANDAs are "owned" by the applicant. It does not contest that the ANDA owner can sell the ANDA like any other property and that, as the record reflects, sales of ANDAs are commonplace in the US market and often ascribe a high value to these rights. The US Counter-Memorial does not dispute that a company that has acquired rights to an ANDA has standing to intervene if these rights are affected. It does not dispute that access to the US market under an approved

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<sup>345</sup> Memorial, para. 368 (quoting **Legal Authority CLA-272**, Applications for FDA Approval to Market a New Drug, 21 CFR § 314.72(a)). *See also id.*, para. 369.

<sup>346</sup> *Id.*, para. 370 (citing to **Exhibit C-19**, Asset Purchase Agreement between Barr Laboratories, Inc. and Apotex Corp. (excerpts), §§ 1.1, 2.1, 2.2(a), dated August 1, 2006, (the "Purchased Assets" under the agreement included "Product Registrations," defined as "the approvals, registrations, applications, licenses, and permits (including, but not limited to, each Product ANDA) ...")).

<sup>347</sup> *Id.*, para. 371 (quoting **Legal Authority CLA-183**, *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313 (D.C. Cir. 1998)).

<sup>348</sup> *Id.*, para. 372 (quoting **Legal Authority CLA-129**, *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008)).

<sup>349</sup> *Id.*, para. 373 (quoting **Legal Authority CLA 113**, *Aktiebolag v. Andrx Pharm., Inc.*, 695 F. Supp. 2d 21 (S.D.N.Y. 2010)).

<sup>350</sup> *Id.*, para. 374 (quoting **Legal Authority CLA-312A**, Internal Revenue Service, Office of Chief Counsel, Memorandum (Sept. 27, 2011)).

<sup>351</sup> *See* US Counter-Memorial, paras. 222-32 (addressing jurisdiction under Article 1139(g)).

ANDA is a protected interest in the eyes of US courts, and that so is the marketing exclusivity afforded to certain ANDA holders. Nor does the Counter-Memorial dispute that US tax law treats ANDAs as franchises or intangibles for purposes of the US tax code.<sup>352</sup>

211. Rather, the US argues that Apotex's ANDAs "are not property in the United States within the meaning of [Chapter Eleven],"<sup>353</sup> noting that "[t]he NAFTA, in contrast with other treaties, does not list intellectual property rights or 'licenses, authorizations, permits, and similar rights' as among investments covered under Article 1139."<sup>354</sup> In fact, the NAFTA covers these assets through Article 1139(g)'s definition of "investment" as including "intangible property."

212. As a preliminary remark, it should be noted that the US mischaracterizes Apotex's claim with respect to ANDAs. The US wrongly describes Apotex's ANDAs as mere "applications" that cannot be construed as licenses or permits.<sup>355</sup> However, Apotex has been clear that if the acronym "ANDAs" stands for abbreviated new drug *applications*, the investments at stake here are Apotex's finally-approved ANDAs, i.e., its marketing *authorizations* in the United States.<sup>356</sup>

a) *The NAFTA Does Not Support the US Argument That Revocable Intangible Rights Fail to Qualify as Investments*

213. The thrust of the US argument under Article 1139(g) is that Apotex's ANDAs can be revoked and, thus, constitute mere "contingent interests" that cannot be recognized as

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<sup>352</sup> See *id.*, para. 229. At note 577 of its Counter-Memorial, the US criticizes Apotex's reliance on an Internal Revenue Service memorandum as support for the proposition that "ANDAs constitute 'intangible property' under the NAFTA." Apotex's point was that ANDAs are considered as intangible assets under the US tax code. See Memorial, para. 374; **Exhibit CLA-312A**, Internal Revenue Service, Office of Chief Counsel, Memorandum, at 8 (Sept. 27, 2011) (concluding that "[a]n ANDA granted by the FDA is a franchise for purposes of the [Treasury] regulations. For the same reasons, an ANDA is also [an] intangible [under the tax code].").

<sup>353</sup> US Counter-Memorial, para. 222.

<sup>354</sup> *Id.*, para. 223 (quotation and footnote omitted).

<sup>355</sup> See *id.*, para. 226.

<sup>356</sup> See Memorial, para. 60 ("Apotex-Canada owns scores of authorizations to market and sell pharmaceutical products in the US."); *id.*, para. 63 ("In the industry, the term 'ANDA' is sometimes used to refer both to the application for new generic drug, as well as the authorization to market and sell this drug. In this Memorial, Apotex will use the term to refer to approved applications, unless expressly stated otherwise.").

“property” under Chapter Eleven.<sup>357</sup> However, the US argument that revocable intangible rights are not “intangible property” cannot be reconciled with the text and context of the Article or object and purpose of the NAFTA.

214. Article 1139(g) covers “intangible property.” Its reference to intangible property is unqualified. The text of that provision does not exclude “revocable” intangible property rights.<sup>358</sup>

215. The context of Article 1139(g) in the investment chapter is also instructive. Article 1110, which sets out the prohibition to expropriate without compensation, refutes the US contention that revocable rights cannot qualify as “intangible property” and therefore “investments.” Paragraph 7 of that Article provides as follows:

This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the *revocation, limitation or creation of intellectual property rights*, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property).<sup>359</sup>

216. This provision recognizes that intellectual property rights are revocable. It acknowledges that States have a role in determining whether to grant (or create) or limit such rights. The provision establishes an exception to the obligation to compensate for expropriation. The exception is limited to those revocations authorized by Chapter Seventeen of the NAFTA.<sup>360</sup> The provision makes clear, *a contrario*, that a revocation

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<sup>357</sup> US Counter-Memorial, para. 224 (arguing that ANDAs are not intangible property because “FDA has significant discretion to withhold or refuse approval of the applications – and even when finally approved, the ANDAs are revocable by the government.”).

<sup>358</sup> **Legal Authority CLA-1**, NAFTA, art. 1139(g) (“**Investment** means ... (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[.]”).

<sup>359</sup> *Id.*, art. 1110(7) (emphasis added). Chapter Seventeen defines intellectual property rights “[f]or purposes of this Agreement” to mean “copyright and related rights, trademark rights, patent rights, rights in layout designs of semiconductor integrated circuits, trade secret rights, plant breeders’ rights, rights in geographical indications and industrial design rights.” *Id.*, art. 1721(2).

<sup>360</sup> *See, e.g., id.*, art. 1709(8) (“A Party may revoke a patent only when: (a) grounds exist that would have justified a refusal to grant the patent; or (b) the grant of a compulsory license has not remedied the lack of exploitation of the patent.”); *id.*, art. 1708(4)(e) (Parties must provide a “reasonable opportunity for interested persons to petition to cancel the registration of a trademark”); *id.*, art. 1708(8) (trademark “registration may be cancelled for the reason of non-use only after an uninterrupted period of at least two

of intellectual property rights *inconsistent* with Chapter Seventeen is subject to Article 1110's prohibition of expropriation without compensation.

217. Article 1110(7) would have no reason to exist, however, if the US argument were correct. If *revocable* intangible property rights were not "investments" within the meaning of Article 1139, the investment chapter and Article 1110 would have no application to them. Article 1110(7) reflects the NAFTA Parties' clear understanding that revocable intangible rights *are investments* that give rise to obligations under the NAFTA investment chapter. The US argument that rights such as these cannot be investments would render Article 1110(7) ineffective and thus breach a primary principle of treaty interpretation.<sup>361</sup>
218. Similarly, Article 1108(1)(a)(i) 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.<sup>362</sup> The US Schedule to Annex I, for instance, excludes from Article 1102 *licenses* granted under the US Atomic Energy Act to persons approved to "transfer, manufacture, produce, use or import any facilities that produce or use nuclear materials."<sup>363</sup> The licenses are revocable under US law.<sup>364</sup>
219. If 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. Under the US's reading of Article 1139(g), such licenses would

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years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner.").

<sup>361</sup> See, e.g., **Legal Authority CLA-88**, *Territorial Dispute (Libya/Chad)*, Judgment of Feb. 3, 1994, I.C.J. Reports 1994, at 23, para. 51 (collecting authorities supporting "one of the fundamental principles of interpretation of treaties, consistently upheld by international jurisprudence, namely that of effectiveness" (citations omitted)); **Legal Authority CLA-87**, *Corfu Channel*, Judgment of Apr. 9, 1949, I.C.J. Reports 1949, at 24 ("It would indeed be incompatible with the generally accepted rules of interpretation to admit that a provision of this sort occurring in a special agreement should be devoid of purport or effect.").

<sup>362</sup> **Legal Authority CLA-1**, NAFTA, art. 1108 ("1. Articles 1102, 1103, 1106 and 1107 do not apply to: (a) any existing non-conforming measure that is maintained by (i) a Party at the federal level, as set out in its Schedule to Annex I or III[.]").

<sup>363</sup> *Id.*, Annex I, Schedule of the United States at 752.

<sup>364</sup> **Legal Authority CLA-560**, 42 USC § 2133, on commercial licenses ("(f) ... Violation of the condition prescribed by the subsection may, in the Commission's discretion, constitute grounds for license revocation. ...").

not have been covered by Chapter Eleven in the first place. Yet, the US *expressly* stated that Article 1102 does not apply to licenses issued pursuant to the Atomic Energy Act.

220. Likewise, the US excluded from the coverage of NAFTA Article 1102 customs broker licenses issued under 19 USC § 1641(b).<sup>365</sup> This type of license is also revocable under US law.<sup>366</sup> Again, if revocable interests do not fall within the definition of investment in Article 1139(g), there would have been no occasion to make an exception in Annex I to the NAFTA for US customs broker licenses. The US's interpretation of Article 1139(g) cannot be reconciled with the context of the provision.

221. Nor does the US interpretation accord with the object and purpose of the NAFTA. Among other things, the treaty's objectives include "provid[ing] adequate and effective protection and enforcement of intellectual property rights in each Party's territory" and "increas[ing] substantially investment opportunities in the territories of the Parties."<sup>367</sup> As the US observes, "[t]he NAFTA, in contrast with other treaties, does not list intellectual property rights or licenses, authorizations, permits, and similar rights as among investments covered under Article 1139."<sup>368</sup> The NAFTA investment chapter covers these assets only through Article 1139(g)'s definition of "investment" as including "intangible property." Because, as noted above, intellectual property rights are necessarily revocable, the US reading of Article 1139(g) would mean no investment protection for intellectual property or these other essential intangible interests. This approach does not accord with the stated objectives of the NAFTA.

222. Therefore, the US's interpretation of Article 1139(g) – excluding revocable intangible property rights from the definition of investment – fails to accord with the text, context, object and purpose of the NAFTA. It is untenable.

*b) The Takings Clause Cases the US Cites Do Not Support It*

223. The US argument that revocable interests are not property relies exclusively on national court decisions addressing whether, for purposes of the Takings Clause of the US

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<sup>365</sup> **Legal Authority CLA-1**, NAFTA, Annex I, Schedule of the United States at 765.

<sup>366</sup> **Legal Authority CLA-559**, 19 USC § 1641(b)(5) (lapse of license).

<sup>367</sup> **Legal Authority CLA-1**, NAFTA, art. 102(1)(c), (d).

<sup>368</sup> US Counter-Memorial, para. 223 (internal quotation omitted).

Constitution, *other types of authorizations* can be considered “property” for purposes of that 18<sup>th</sup> Century provision.<sup>369</sup> Contrary to the US assertion, US law is of limited assistance in interpreting the meaning of “intangible property” under NAFTA Article 1139(g).<sup>370</sup> What matters is the meaning of this term under the treaty, not under the US Constitution. At any rate, the US’s reliance on US law is misplaced.

224. *First*, the US fails to explain why Due Process Clause jurisprudence should be disregarded, while Takings Clause jurisprudence should not. The word “property” appears twice in the Fifth Amendment to the United States Constitution, once in connection with due process and once in connection with governmental takings.<sup>371</sup> US jurisprudence has given a more restrictive reading of property for purposes of the Takings Clause than for the Due Process Clause.<sup>372</sup> While the US acknowledges that this is so, it does not attempt to explain why Takings Clause jurisprudence would be more relevant than Due Process Clause jurisprudence.<sup>373</sup>
225. *Second*, the US’s reliance on Takings Clause jurisprudence is particularly puzzling since no taking is in question in this case. The US acknowledges that “deprivation of

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<sup>369</sup> *Id.*, para. 226 & n.562 (discussing “attachments” to licenses and a helicopter “airworthiness certificate”).

<sup>370</sup> *Id.*, para. 226 (“As the host State of Apotex’s putative ‘investments,’ it is appropriate to look at the law of the United States in this regard.”).

<sup>371</sup> The Fifth Amendment to the US Constitution provides in relevant part: “No person shall be ... deprived of ... *property*, without due process of law ... ; nor shall *private property* be taken for public use, without just compensation.” See **Legal Authority CLA-557**, US Const. amend. V (emphasis added).

<sup>372</sup> See, e.g., **Legal Authority RLA-72**, *Arctic King Fisheries, Inc. v. United States*, 59 Fed. Cl. 2360, 372, n.27 (Ct. Fed. Cl. 2004) (noting dissimilar concepts of “property” for purposes of the Takings Clause and “property interest” under the Due Process Clause); **Legal Authority RLA-67**, *American Pelagic Fishing Company v. United States*, 379 F.3d 1363, 1373 (Fed. Cir. 2004) *rehearing en banc denied* (“In addition, the government distinguishes a constitutionally protected right to a permit under a due process analysis from a compensable property rights under a Takings Clause analysis[.]”); **Legal Authority CLA-530**, *Eastern Enters. v. Apfel*, 524 U.S. 498, 557 (1998) (In dissent, Justice Breyer noted: “Nor does application of the Due Process Clause automatically trigger the Takings Clause, just because the word ‘property’ appears in both. That word appears in the midst of different phrases with somewhat different objectives, thereby permitting differences in the way in which the term is interpreted.”); **Legal Authority CLA-541**, *Kizas v. Webster*, 707 F.2d 524, 534 (D.C. Cir. 1983) (“analogizing ‘property interests’ protected by the due process clause to ‘property’ protected by the takings clause, is fundamentally misconceived.”); **Legal Authority CLA-525**, *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 571-72 (1972) (holding that, under the Due Process Clause of the 14<sup>th</sup> Amendment, “property interests protected by procedural due process extend well beyond actual ownership of real estate, chattels, or money[.]” (citations omitted)).

<sup>373</sup> US Counter-Memorial, para. 226 & n.561 (noting that “[a]lthough due process may protect against arbitrary government deprivation of certain licenses previously granted, courts determine the scope of ‘property’ for purposes of compensation using a different analysis.”) (citing to **Legal Authority RLA-72**, *Arctic King Fisheries, Inc. v. United States*, 59 Fed. Cl. 2360, 372, n.27 (Ct. Fed. Cl. 2004)).

Apotex's ANDAs is not at issue here.”<sup>374</sup> In contrast, the cases mentioned by the US involved the *revocation* by the government of the interest claimed to be protected. As such, in *Mike's Contracting, LLC v. United States*, a helicopter airworthiness certificate was suspended by the Federal Aviation Administration on regulatory grounds.<sup>375</sup> Since there is no issue of Apotex's ANDAs being revoked here, the cases discussed in the US Counter-Memorial are not on point.

226. *Third*, contrary to the US argument, governmental ability to revoke a right under limited circumstances in no way removes the “exclusivity” required for a right to constitute property.<sup>376</sup> From a conceptual point of view, *any* property interest can be revoked by an organ of the State under certain circumstances. This does not mean, however, that the revoked property right was not exclusive. For instance, under US law, the owner of real property enjoys exclusive ownership. And yet, his title can be revoked by adverse possession.<sup>377</sup>

227. *Fourth*, according to the US, the fact that ANDAs are treated as intangible assets for US tax purposes is irrelevant to the NAFTA definition of property.<sup>378</sup> The US relies on *Members of Peanut Quota Holders Association*, which addressed the meaning of

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<sup>374</sup> *Id.*, para. 226, n.561.

<sup>375</sup> **Legal Authority RLA-87**, *Mike's Contracting, LLC v. United States*, 92 Fed. Cl. 302, 305, 309-10 (Ct. Fed. Cl. 2010) (holding that the plaintiff had no vested interest in its airworthiness certificate or in commercial aviation and no compensable property interest under the Takings Clause). The US also relies on *Dames & Moore v. Regan*. See US Counter-Memorial, para. 226 & n.562. In that case, responding to the taking of American hostages in Teheran, the President issued an order blocking “all property and interests in property of the Government of Iran ... subject to the jurisdiction of the United States” and the Treasury Department adopted regulations providing that judicial process on Iranian interests was void unless licensed. See **Legal Authority RLA-79**, *Dames & Moore v. Regan*, 453 U.S. 654, 662-63 (1981). The petitioner thereafter obtained a prejudgment attachment of assets of certain Iranian banks, which the President later nullified. The Court addressed the Takings Clause claim only in a footnote. It found that under the circumstances “the attachments obtained by petitioner were specifically made subordinate to further actions which the President might take ...” and dismissed the claim. *Id.* at 674 n.6. *Dames & Moore* has no application to the facts of this case.

<sup>376</sup> US Counter-Memorial, para. 227 (noting that property must be capable of exclusive possession or control) (quotation and footnote omitted). More largely, the notion of property includes “the right to possess, use, and dispose ... .” See **Legal Authority CLA-547**, *Phillips v. Washington Legal Found.*, 524 U.S. 156, 170 (1998) (citation omitted).

<sup>377</sup> See, e.g., **Legal Authority CLA-562**, N.Y. Real Prop. Acts. Law §§ 501-551 (2008); **Legal Authority CLA-578**, 3 Am. Jur. 2d *Adverse Possession* § 1 (2013) (“Because an interest in real property generally cannot be abandoned, a fee owner can be divested of title only through adverse possession.”).

<sup>378</sup> US Counter-Memorial, para. 229.

property under the Takings Clause.<sup>379</sup> The US Court of Federal Claims held in that case that peanuts quotas, although treated as property under tax law, did not constitute property protected by the Fifth Amendment because the quota holders “could not have held a reasonable investment-backed expectation that the quotas would continue . . . .”<sup>380</sup> Whatever the relevance of this case may be to the definition of “intangible property” in NAFTA Article 1139(g), it has no application to the present arbitration. Apotex complied with post-approval requirements for maintaining its ANDAs and had no reason to believe that any of its ANDAs might be revoked – and they were not.<sup>381</sup> To put it differently, Apotex had a “reasonable investment-backed expectation” that its ANDAs “would continue” –thus meeting the test for “property” spelled out in *Peanut Quota Holders Association*. This case does not support the US position in this arbitration.

228. *Fifth*, the US attempts to infer that ANDAs are not property from the fact that Apotex did not seek compensation under the Takings Clause when FDA temporarily demoted the status of one of its ANDAs in 2007.<sup>382</sup> The record does not support the inference the US wishes to draw. There was no reason for Apotex to sue the US government for a taking because the change in status of Apotex’s ANDA was only temporary.<sup>383</sup> In that case, FDA decided to demote Apotex’s ANDA from “finally-approved” to “tentatively approved” status pending the expiry of a six-month statutory pediatric exclusivity that the brand-name drug manufacturer asserted, along with patent infringement.<sup>384</sup> Apotex sought to prevent FDA from changing the status of its ANDA but did not succeed.<sup>385</sup>

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<sup>379</sup> *Id.*, para. 229 & n. 578.

<sup>380</sup> **Legal Authority RLA-86**, *Members of Peanut Quota Holders Association, Inc. v. United States*, 60 Fed. Cl. 524, 531 (2004) (citation omitted). *See id.* at 529 (“Even though the quotas are business assets that create an expectation of enhanced commercial activity, they do not come within the safe harbour of property protected by the Fifth Amendment. The termination of plaintiffs’ quotas by the Government has had no compensable effects on plaintiffs’ protected property, *i.e.*, on their farms, crops, or equipment.”).

<sup>381</sup> Second Witness Statement of Kiran Krishnan, para. 21.

<sup>382</sup> US Counter-Memorial, para. 230.

<sup>383</sup> Second Witness Statement of Kiran Krishnan, para. 26.

<sup>384</sup> **Legal Authority RLA-71**, *Apotex Inc. v. FDA*, 508 F. Supp. 2d 78, 82 (D.D.C. 2007) (“... the FDA revoked final approval of the plaintiff’s ANDA until at least October 20, 2007. The plaintiff opposed this action, but on June 28, 2007, the FDA issued a two-page letter decision revoking Apotex’s final approval for generic omeprazole and converting it to tentative approval until the expiration of the exclusivity period imposed by the New York court.”) (citations omitted).

<sup>385</sup> *Id.* at 89 (denying Apotex’s motion for injunctive relief and motion for stay pending appeal).

As soon as the statutory exclusivity period lapsed, Apotex's ANDA regained its "finally-approved" status on October 22, 2007.<sup>386</sup> In practice, Apotex was prevented from using its ANDA for four months (between the date when the court's decision was rendered and the end of the exclusivity period).<sup>387</sup> The US does not attempt to explain why, under these circumstances, a suit against it was so propitious that an inference could be drawn from Apotex's failure to bring it.

229. In sum, the US's reliance on Takings Clause jurisprudence is unavailing. Most important, the issue presented here is not what "property" means in the Takings Clause of the US Constitution, but what it means in NAFTA Chapter Eleven.

*c) The NAFTA Jurisprudence Does Not Support the US*

230. The NAFTA decisions cited in the Counter-Memorial also do not advance the US's case here. While NAFTA tribunals have declined to recognize as property "mere contingent" interests,<sup>388</sup> Apotex's ANDAs in no way can be viewed as "mere contingent" interests. Apotex recalls that it withdrew its damages claim as concerns loss of the opportunity to launch new products during the Import Alert.<sup>389</sup> As a result, *tentatively-approved* ANDAs are no longer in dispute in this arbitration. Only Apotex's *finally-approved* ANDAs are. Finally-approved ANDAs are vested rights, i.e., marketing authorizations that have been granted and do allow the generic manufacturer to go to market in the United States.<sup>390</sup> Even though finally-approved ANDAs can be revoked on specific statutory grounds, that does not make them *contingent* interests.

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<sup>386</sup> **Exhibit C-326**, Letter from FDA to Apotex, dated October 22, 2007; **Exhibit C-476**, Excerpts from Orange Book, Omeprazole (2013).

<sup>387</sup> Second Witness Statement of Kiran Krishnan, para. 26.

<sup>388</sup> US Counter-Memorial, para. 224 & n.555. Apotex notes that the US reliance on *Bayview* is misplaced. The issue in that case was not whether water rights in Mexico were contingent interests, but rather whether they could constitute an investment in the territory of the United States. See **Legal Authority CLA-22**, *Bayview Irrigation District et al. v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award, paras. 110-11, 122 (June 19, 2007). See also **Legal Authority CLA-504**, *Bayview Irrigation District v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Submission of the United States of America, para. 3 (Nov. 27, 2006) ("As described below, all of the protections afforded by the NAFTA's investment chapter extend only to investments that are made by an investor of a NAFTA Party in the territory of another NAFTA Party, or to investors of a NAFTA Party that seek to make, are making, or have made an investment in the territory of another NAFTA Party.").

<sup>389</sup> **Exhibit C-461**, Letter from Apotex to Tribunal, dated February 7, 2013.

<sup>390</sup> Second Witness Statement of Kiran Krishnan, para. 27.

And as noted above, Apotex's ANDAs have not been revoked in the case at bar – as the US acknowledges.<sup>391</sup>

231. In *Grand River*, the tribunal held that a US trademark constituted an investment for the purposes of Chapter Eleven.<sup>392</sup> Trademarks are revocable under US law.<sup>393</sup> The *Grand River* award thus recognized that a *revocable* intangible property right such as a trademark constituted an investment within the meaning of Article 1139(g).
232. Finally, there is no merit to the US terse suggestion that Apotex's ANDAs are not property “*in the United States*.”<sup>394</sup> The sole reasoning provided by the US for this suggestion is that “Apotex acknowledges that its ANDAs are prepared and held by Apotex[-Canada] *in Canada*.”<sup>395</sup> The US does not explain how an authorization granted by a US agency that permits economic activity *only* in the United States – and nowhere else in the world – could possibly be considered to be an investment in Canada. Under the US's reasoning, a long-term loan by a Canadian bank to a US debtor would fall outside the scope of Chapter Eleven if the bank prepared the loan documentation in-house (as is customary). This is plainly wrong.<sup>396</sup> The US argument, again, cannot be squared with the plain text of the treaty or the record.
233. Furthermore, as acknowledged by prior Chapter Eleven tribunals, 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.”<sup>397</sup> Here, the investors

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<sup>391</sup> US Counter-Memorial, para. 226 n.561; Second Witness Statement of Kiran Krishnan, para. 21.

<sup>392</sup> **Legal Authority CLA-29**, *Grand River Enterprises Six Nations, Ltd., et al. v. United States of America*, UNCITRAL, Award, para. 79 (Jan. 12, 2011) (Both parties “agree that Claimant Arthur Montour has an investment in the United States. The record demonstrates that he owns a substantial tobacco distribution business in the United States as well as the Seneca® trademark, as that he has made substantial marketing efforts and expenditures to promote the brand in the United States.”).

<sup>393</sup> **Legal Authority CLA-558**, 15 USC § 1064 (providing for cancellation of trademark under certain circumstances).

<sup>394</sup> US Counter-Memorial, para. 231 (emphasis original).

<sup>395</sup> *Id.* (emphasis original).

<sup>396</sup> *See Legal Authority CLA-1*, NAFTA, art. 1139 (“investment means ... (d) a loan to an enterprise (i) where the enterprise is an affiliate of the investor, or (ii) where the original maturity of the loan is at least three years, ...”).

<sup>397</sup> **Legal Authority CLA-22**, *Bayview Irrigation District et al. v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award, para. 98 (June 19, 2007).

are Canadian but their ANDAs are regulated by US law. This is the usual foreign investment scenario.

234. In sum, the fact that a right or authorization may be revoked by the State does not mean that the right or authorization cannot constitute a property interest protected under the NAFTA. Notably, in the present case, the US does not claim that there were grounds for revoking Apotex-Canada's ANDAs. Apotex-Canada's ANDAs are not mere "contingent" interests. To the contrary, Apotex-Canada's ANDAs constitute vested intangible property rights in the United States protected under Article 1139(g).

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

235. In its Memorial, Apotex demonstrated that its ANDAs also constitute investments under Article 1139(h).<sup>398</sup> The provision includes within the definition of "investment" "interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory[.]"<sup>399</sup> Investments falling under this provision need not meet the criteria for "property" under Article 1139(g), but may instead take the form of "interests."<sup>400</sup> Under this provision, the "interest" is the "investment." But to qualify, that interest must "*aris[e]* from the commitment of capital or other resources" to economic activity in the territory of the Party. Apotex showed in its Memorial that its marketing authorizations (ANDAs) qualify as interests arising from the commitment of resources both within and without the United States to economic activity in the United States, for four main reasons.

236. *First*, Apotex's ANDAs represent "interests" for all of the reasons stated in the preceding section and in the Memorial.<sup>401</sup> The record, Apotex submits, establishes that ANDAs are intangible property. Even if that were not the case (and Apotex fully submits that it is), however, there can be no doubt that they qualify as "interests."

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<sup>398</sup> Memorial, paras. 377-402.

<sup>399</sup> **Legal Authority CLA-1**, NAFTA, art. 1139(h).

<sup>400</sup> Memorial, para. 395.

<sup>401</sup> *Id.*

237. *Second*, Apotex's ANDAs are committed to economic activity in the territory of the United States. By filing an ANDA, Apotex seeks authorization to market its products in the United States and not anywhere else in the world. It is undisputed that an approved ANDA cannot be used outside the United States.<sup>402</sup> As such, whenever Apotex submits an ANDA, it commits to economic activity in the United States.
238. *Third*, 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. Each ANDA reflects proprietary information concerning the drug's formulation, development, testing and the manufacturing processes for the commercialization of the drug in the US. All of that information, even if developed in Canada, is committed into the United States upon the filing of the ANDA.<sup>403</sup> In addition, Apotex-Canada regularly engages in costly patent litigation before US courts to give value to its ANDAs. The litigation and its attendant expense represent a commitment of capital and resources into the United States.<sup>404</sup> Apotex-Canada also commits various resources in the United States in relation to the filing and maintaining of its ANDAs. Apotex relies on a full-time employee based in Florida (Kiran Krishnan) to act as its agent and liaison with FDA concerning its ANDAs. This agent works with a team of six people dedicated to filing and maintaining Apotex's ANDAs. Apotex-Canada supports this team's work through a 2005 services agreement with Apotex-US.<sup>405</sup> The expenses incurred in supporting that workforce in the US are resources committed by Apotex-Canada to the US.<sup>406</sup> Similarly, Apotex-Canada uses resources in Apotex-US's Florida office to comply with the post-approval reporting obligations for its ANDAs, such as preparation and submission of annual reports, drug safety reports, management of drug labels and patient information leaflets. The record reflects a substantial commitment of capital and

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<sup>402</sup> See, e.g., US Counter-Memorial, para. 226 ("Generic manufacturers submit abbreviated new drug applications in order to market and sell generic products *in the United States*.") (footnote omitted) (emphasis added). See also Witness Statement of Bernice Tao, para. 25 ("ANDAs are only valid in the United States..."); Witness Statement of Kiran Krishnan, para. 16 ("Approved ANDAs are only valid in the US.").

<sup>403</sup> Memorial, para. 397.

<sup>404</sup> *Id.*, para. 398.

<sup>405</sup> **Exhibit C-14**, Services Agreement Between Apotex-Canada and Apotex-US, dated July 1, 2005. See also Witness Statement of Gordon Fahner, para. 37.

<sup>406</sup> Memorial, para. 399-400.

other resources in the United States for the purpose of maintaining and using its ANDAs on the US market.<sup>407</sup>

239. The US Counter-Memorial does not so much respond to the Memorial's showing as studiously ignore it.<sup>408</sup> The Counter-Memorial does not dispute that Apotex's marketing authorizations are "interests." Nor does it contest that maintaining a staff devoted to filing ANDAs, submitting the reports necessary to keep them in force, contracting for the research needed for ANDA approval and litigation to add value to the ANDAs constitute "resources" committed to economic activity in US territory. Finally, it does not dispute that the marketing authorizations arose, were maintained and attracted value as a result of these activities.

240. Instead, the Counter-Memorial attacks arguments that Apotex never made and which are not presented on this record. The US addresses only three of Apotex's various commitments of resources in relation to its ANDAs, namely "(1) procuring 'contract research' for ANDAs from 'specialized firms' in the United States; (2) 'commit[ting] various resources in the United States in relation to the filing and maintaining of its [ANDAs]'; and (3) funding 'costly patent litigation before US courts.'"<sup>409</sup> The US concludes that "[n]one of these activities constitutes an investment within the meaning of Article 1139(h)."<sup>410</sup> But it has never been Apotex's case that these activities constitute an investment. Apotex addresses these straw-man arguments below.

a) *Apotex-Canada Contributes Various Resources to the United States in Order to Obtain Marketing Authorizations – But These Resources Are Not the "Investment"*

241. The US errs in suggesting that contract research, preparation and maintenance of ANDAs and ANDA-related litigation are "interests" within the meaning of Article 1139(h).<sup>411</sup> Apotex has argued no such thing. It is not Apotex's position that contract research, or any other information that go into an ANDA application, or patent litigation

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<sup>407</sup> *Id.*, para. 400.

<sup>408</sup> *See* US Counter-Memorial, paras. 233-44 (addressing jurisdiction under Article 1139(h)).

<sup>409</sup> *Id.*, para. 233 (footnotes omitted).

<sup>410</sup> *Id.*

<sup>411</sup> *Id.*

qualify as an “investment” in the United States. Article 1139(h) requires no such thing. It requires that “capital or other resources” be committed, not that that capital or resources independently qualify as investments.

242. Apotex’s position, as noted, is that the approved ANDAs are the “interests” within Article 1139(h).<sup>412</sup> Apotex has shown that the ANDA-related activities (contract research, preparation and maintenance of ANDAs, ANDA-related litigation) constitute resources committed to the US territory from which the marketing authorizations arose.<sup>413</sup> Article 1139(h) requires no more than this.

*b) It Is Not Apotex’s Case That Cross-Border Services Contracts Constitute an “Investment”*

243. The US misses the point in arguing that cross-border services contracts are not investments.<sup>414</sup> Again, that is not Apotex’s position, and that is not what Article 1139(h) requires.<sup>415</sup> The ordinary meaning of “resource” is “a source of supply or support: an available means – usually used in the plural.”<sup>416</sup> It can hardly be disputed that services providing research necessary for approval of an ANDA is “a source of supply or support” for that ANDA. The US, again, attacks a straw man.

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<sup>412</sup> Memorial, para. 394.

<sup>413</sup> *Id.*, paras. 397-401.

<sup>414</sup> US Counter-Memorial, para. 236 (“Article 1139(h), however, does not recognize as ‘investments’ mere contracts for services in the United States.”) (footnote omitted). In the Memorial, Apotex explained that generic drug manufacturer must demonstrate that each of their products is bioequivalent to the reference drug. To that end, Apotex resorts in part to the services of specialized firms or CROs (contract research organizations). In 2009, about 20% of the CROs used by Apotex for bio-equivalence studies were US-based. See Memorial, para. 80. Nowhere in the Memorial did Apotex state that contracts with CROs constituted an “investment” as per the definition of Article 1139.

<sup>415</sup> Memorial, paras. 399-400.

<sup>416</sup> **Legal Authority CLA-471**, *Resource Definition 1a*, Merriam-Webster.com (last visited on Dec. 26, 2012). See also **Legal Authority CLA-473**, *Resource Definition 2*, Webster’s II, New College Dictionary (1999) (“An accessible supply that can be withdrawn from when necessary.”); **Legal Authority CLA-472**, *Resource Definition*, first bullet, OxfordDictionaries.com (“a stock or supply of money, materials, staff, and other assets that can be drawn on by a person or organization in order to function effectively ...”) (last visited on December 26, 2012).

c) *The US Does Not Dispute that Filing and Maintaining ANDAs Is a Commitment of Resources*

244. The US does not dispute that Apotex-US's filing and maintaining ANDAs constitutes a commitment of resources from which the ANDAs arose.<sup>417</sup> Instead, the US disputes only that Apotex-Canada contributes to these efforts.<sup>418</sup> But nothing in Article 1139(h) requires that the same entity within a corporate group both own the interest and contribute the resources. All that it requires is that the interests arise from a commitment of such resources to economic activity in the territory of the Party.<sup>419</sup> The US argument, even if it were correct, is thus beside the point.
245. In any event, the US argument is factually incorrect. The US asserts that the 2005 services agreement between Apotex-Canada and Apotex-US requires that Apotex-US pay Apotex-Canada for certain administrative support, and not the other way around.<sup>420</sup> However, as discussed above, the services agreement reflects a large contribution of resources from Apotex-Canada to Apotex-US, including administrative services, accounting and financial (including payroll) services, information systems and technology services, as well as any other services that may be, from time to time, requested by Apotex-US.<sup>421</sup> For the reasons discussed earlier,<sup>422</sup> Apotex-Canada clearly has contributed resources to Apotex-US that gave rise to the ANDAs.
246. Moreover, there appears to be no dispute that Apotex Holdings indirectly controls ANDAs that arise from the commitment of resources by Apotex-US (a company it also controls) to economic activity in the US.<sup>423</sup> Apotex Holdings has indisputably

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<sup>417</sup> See US Counter-Memorial, paras. 237-39.

<sup>418</sup> *Id.*

<sup>419</sup> **Legal Authority CLA-1**, NAFTA, art. 1139(h) (“**Investment** mean ... (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[.]”).

<sup>420</sup> US Counter-Memorial, para. 238 (citing **Exhibit C-14**, Services Agreement Between Apotex-Canada and Apotex-US, dated July 1, 2005, paras. 3, 4.1).

<sup>421</sup> See Witness Statement of Gordon Fahner, para. 37.

<sup>422</sup> See *supra* Jurisdiction, Section II.A.2.a.

<sup>423</sup> See Memorial, para. 341 (“Apotex Holdings indirectly owns and controls Apotex-Canada and that company's investments in the US.”); Claimants' Opposition to Bifurcation, para. 86 (Dec. 28, 2012). See also Second Witness Statement of Gordon Fahner, para. 79.

contributed resources it controls to give rise to interests that it equally controls, meeting the requirements of Article 1139(h). The US has presented no objection to this basis for jurisdiction.<sup>424</sup>

*d) ANDA-Related Litigation Constitutes “Resources”*

247. The Counter-Memorial’s argument that litigation expenses are not investments also misses the point.<sup>425</sup> Again, the issue is whether the contribution of [REDACTED] to ANDA-related litigation concerning specific products represents a commitment of resources that built the value of Apotex’s marketing authorizations. The record shows that it was and did.

248. As demonstrated earlier,<sup>426</sup> arguments about conflicting representations by Apotex before US courts are without merit.<sup>427</sup> Irrespective of whether Apotex’s participation in US litigation can be described as “a regular business activity” or “a by-product of its attempts to gain entry into the U.S. market,”<sup>428</sup> the fact remains that Apotex-Canada spends around [REDACTED] per year in ANDA-related litigation in the United States.<sup>429</sup> This is a significant contribution of resources towards developing ANDAs for the US market.

*e) The NAFTA Protects Interests Arising From the Commitment of Foreign Capital in the Host State*

249. The US also is wide of the mark in arguing that under Chapter Eleven the investment must be in the host State,<sup>430</sup> that the chapter deals with foreign investment of a cross-

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<sup>424</sup> US Reply on Bifurcation, paras. 27-31 (Jan. 10, 2010) (addressing Apotex’s ANDAs but ignoring the point on Apotex Holdings’ indirect ownership of same).

<sup>425</sup> US Counter-Memorial, paras. 241-44 & n.614 (“In addition, the legal fees Apotex may have incurred in the course of its U.S. litigation do not constitute ‘investments’ because they are commercial contracts for services, which are squarely excluded from NAFTA’s definition of investment in Article 1139(i).”).

<sup>426</sup> *See supra* paras. 175-204.

<sup>427</sup> US Counter-Memorial, paras. 243-44.

<sup>428</sup> *Id.*, para. 243 (footnotes omitted).

<sup>429</sup> *See, e.g.*, Witness Statement of Gordon Fahner, para. 45 (“Apotex-Canada expends about [REDACTED] annually in legal fees in the US, the lion share of which is attributed to various ANDA-related litigations (such as lawsuits involving challenge to a patent and/or defense of an ANDA submission).”).

<sup>430</sup> *See* US Counter-Memorial, paras. 250-51. Mexico advances a similarly inapposite argument on territoriality in its submission under Article 1128. *See* Submission of the United Mexican States, para. 5 (Feb. 8, 2013).

border nature,<sup>431</sup> and that the three NAFTA Parties have consistently agreed,<sup>432</sup> and NAFTA tribunals have consistently found,<sup>433</sup> that the investment chapter applies only to investments in the host State. These, again, are not matters in dispute, and are not the issue presented.

250. The issue here is not whether the authorizations granted by the FDA to Apotex-Canada exclusively to market products in the US are investments *in the United States*.<sup>434</sup> As already noted, there can be no dispute that these interests are in US territory, and the US offers no real argument to the contrary.<sup>435</sup>

251. Rather, the issue is whether under Article 1139(h) the capital or other resources contributed must already be situated in US territory *before* they are committed to activity in that territory and give rise to the interest, or whether *foreign* capital or resources can also qualify in giving rise to the interest. As the US and the authorities it cites recognize, the NAFTA “can only sensibly be considered as referring to [] opportunities for *foreign investment* in the territory of each Party made by investors of another Party” and as intended “to promote and increase *cross-border* investment opportunities[.]”<sup>436</sup> The US arguments and authorities thus support Apotex’s position

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<sup>431</sup> US Counter-Memorial, paras. 252-53.

<sup>432</sup> *Id.*, paras. 255-59.

<sup>433</sup> *Id.*, paras. 260-63.

<sup>434</sup> *See id.*, para. 259 & n.636 (quoting *Canadian Cattlemen for Fair Trade*) (Chapter Eleven is “applicable only to investors of one NAFTA Party who seeks to make, are making, or have made, an investment *in another NAFTA Party*.”) (emphasis added by Counter-Memorial); *id.*, para. 261 & n.640 (quoting *Grand River*) (same holding).

<sup>435</sup> The US discussion of *Grand River* at paragraph 261 of the Counter-Memorial is misleading. The US asserts that “[t]he tribunal determined that the claimants’ activities, similar to those of Apotex, ‘centered on the manufacture of cigarettes at Grand River’s manufacturing plant in Canada for export to the United States,’” which was not sufficient to attract the tribunal’s jurisdiction (citations omitted). However, in that case, the tribunal also held that Arthur Montour’s tobacco distribution business in the United States, and the Sonoca® trademark, constituted a valid investment for purposes of Chapter Eleven. *See Legal Authority CLA-29, Grand River Enterprises Six Nations, Ltd. et al. v. United States of America*, UNCITRAL, Award, para. 79 (Jan. 12, 2011).

<sup>436</sup> US Counter-Memorial, para. 253 (quoting **Legal Authority CLA-22**, *Bayview Irrigation District et al. v. The United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award, para. 100 (June 19, 2007); **Legal Authority CLA-33**, *Metalclad Corporation v. The United Mexican States*, ICSID Case No. ARB(AF)/97/1, Award, para. 75 (Aug. 30, 2000) (emphasis added by US). *See also Legal Authority CLA-47*, *Canadian Cattlemen for Fair Trade v. United States of America*, UNCITRAL, Award on Jurisdiction, para. 111 (Jan. 28, 2008) (the only investors covered by Chapter Eleven are actual or prospective *foreign* investors in another NAFTA party)).

that *foreign* capital and resources must qualify for giving rise to an interest within the meaning of Article 1139(h).

252. Apotex demonstrated in its Memorial that the text and context of Article 1139(h) and the object and purpose of the NAFTA establish that foreign capital and resources are eligible to establish an investment under that provision.<sup>437</sup> This showing fully accords with the approach reflected elsewhere in Article 1139. For example, the ordinary course in a cross-border loan under Article 1139(d) is for the bank to use its foreign resources to disburse funds to the debtor in the host State; the ordinary course in a cross-border equity acquisition under Article 1139(b) is for the foreign investor to use foreign funds or other consideration to acquire the shares in the host State. While it would of course be possible for the investor in either scenario to use resources in the host State to acquire the investment, that approach would not increase cross-border flows of capital and resources in the same way. The US, notably, offers no argument as to why a different approach should follow for investments under Article 1139(h).
253. In sum, the US Counter-Memorial on Article 1139(h) repeatedly builds and attacks a straw man. More generally, the US arguments on Article 1139(g) and (h) do not meet the case put forward by Apotex and are without merit.

#### **B. The Import Alert Related to Apotex’s Finally-Approved ANDAs**

254. Assuming alternatively that Apotex-Canada’s ANDAs are investments within the meaning of Article 1139, the US argues that the measure at stake – the Import Alert – did not “relate to” Apotex’s ANDAs.<sup>438</sup> The US argument that a measure preventing marketing of products does not relate to authorizations to market the products does not withstand scrutiny.
255. As noted in the second witness statement of Kiran Krishnan, ANDAs are authorizations to market specified drugs produced only at the manufacturing facility identified in the

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<sup>437</sup> Memorial, paras. 377-87. It is noteworthy that Mexico’s Article 1128 submission does not dispute the reading of the Spanish text of Article 1139(h) stated in paragraphs 378 and 379 of the Memorial. *See* Submission of the United Mexican States, para. 7 (Feb. 8, 2013).

<sup>438</sup> *See* US Counter-Memorial, paras. 274-86.

ANDA.<sup>439</sup> The Import Alert undid the ANDAs held by Apotex for products made at Etobicoke and Signet. While on paper Apotex-Canada continued to be authorized to market the products through Apotex-US, the Import Alert made such marketing legally impossible.

256. The US thus errs in asserting that “[t]he Import Alert had no legally significant connection to Apotex’s ANDAs.”<sup>440</sup> Contrary to the US assertion, the Import Alert rendered the ANDAs useless since they could not be used for marketing the associated drug while the Import Alert was in effect.<sup>441</sup> If it is correct that Apotex’s ANDAs technically remained approved during the Import Alert,<sup>442</sup> 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.<sup>443</sup> The US does not attempt to explain how a measure that prevents marketing of a product can be seen not to relate to the authorization to market the product.
257. According to FDA’s own calculations, at the time of re-inspection in January 2011, Apotex had a total of 436 approved ANDAs for its Etobicoke and Signet sites.<sup>444</sup> The Import Alert destroyed the economic value of the ANDAs, because the products authorized to be marketed by the ANDAs could not be marketed at all while the Import Alert remained in effect.
258. The US also errs in arguing that Apotex was free to transfer the technology necessary to manufacture those drugs to another Apotex facility or to a third party.<sup>445</sup> This argument is relevant, if at all, to mitigation of damages. The US argument here, in reality, is not that the measure did not relate to the marketing authorizations, but that Apotex could have limited the measure’s detrimental impact by transferring technology. The US

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<sup>439</sup> Second Witness Statement of Kiran Krishnan, para. 30.

<sup>440</sup> US Counter-Memorial, para. 274.

<sup>441</sup> Memorial, para. 412.

<sup>442</sup> US Counter-Memorial, para. 284.

<sup>443</sup> Second Witness Statement of Kiran Krishnan, para. 28.

<sup>444</sup> **Exhibit C-428**, FDA Internal Email Chain, dated January 4, 2011.

<sup>445</sup> US Counter-Memorial, para. 285.

argument is without factual merit, as in practice obtaining the necessary authorizations from FDA would have been impracticable.<sup>446</sup>

259. In sum, the Import Alert plainly “related to” Apotex-Canada’s finally-approved ANDAs.

260. For all of the foregoing reasons, the Tribunal has jurisdiction to hear the claims brought by both Apotex Holdings and Apotex-Canada against the United States.

## REPLY ON THE MERITS

### I. THE US FAILS TO REBUT APOTEX’S NATIONAL TREATMENT AND MOST-FAVORED-NATION TREATMENT CLAIMS

261. The Memorial demonstrated at length that the Import Alert afforded Apotex Holdings and Apotex-Canada, and their investments in the United States, treatment less favorable than that afforded US and third-country owned investors and investments in like circumstances.<sup>447</sup> The US has failed to rebut Apotex’s case on Articles 1102 and 1103 for three main reasons.

262. *First*, as discussed in **Section A** below, the US errs in asserting that Apotex received no treatment.<sup>448</sup> Here, the US attempts to recast its jurisdictional objection based on Article 1101 into a defense on the merits. However, the record clearly shows that the Import Alert “related to” Apotex-US and to Apotex-Canada’s ANDAs. As such, Apotex Holdings and Apotex-Canada did indeed receive treatment with respect to their respective investments in the United States.

263. *Second*, **Section B** shows that, contrary to what the US alleges, Apotex was in like circumstances with the US-based comparators.<sup>449</sup> Under the guise of “like circumstances,” the US in fact addresses the issue of differential treatment: the US wrongly argues that, solely because domestic facilities cannot be placed on import alert

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<sup>446</sup> See Witness Statement of Jeremy Desai, paras. 89-90; Second Witness Statement of Jeremy Desai, para. 42; Second Witness Statement of Kiran Krishnan, para. 35.

<sup>447</sup> Memorial, paras. 422-52.

<sup>448</sup> US Counter-Memorial, para. 327.

<sup>449</sup> *Id.*, para. 327.

(due to their location), they cannot be in like circumstances to Apotex. But the Import Alert effected the treatment Apotex received, not the circumstances it was in. The US argument fails as a matter of law.

264. *Third*, as for comparators with facilities outside the United States, the US does not dispute that they are in like circumstances to Apotex. Here, the US defense is that these comparators received no better treatment than that afforded Apotex.<sup>450</sup> The record does not support the US assertion, as demonstrated in **Section C**.

**A. Apotex Received Treatment**

265. The US errs in suggesting that the Import Alert failed to accord Apotex any “treatment” with respect to the “establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.”<sup>451</sup> The US argument is premised entirely on its misplaced objection that the Import Alert did not “relate to” Apotex-US or to Apotex-Canada’s ANDAs.

266. As demonstrated at length in the counter-memorial on jurisdiction above, the record amply shows that there was a legally significant connection between the Import Alert and Apotex-US, Apotex Holdings and Apotex-Canada.<sup>452</sup> Therefore, Apotex’s case meets the first prong of the test under Articles 1102 and 1103, i.e., by adopting the Import Alert, the US accorded Apotex treatment.

**B. Comparators with Drug Manufacturing Facilities in the United States Are in “Like Circumstances” with Apotex**

267. As to the second part of the test under Articles 1102 and 1103, the US misses the point when it argues that facilities located in the United States, because they cannot be placed on import alert, are not in like circumstances with Apotex.<sup>453</sup> Aside from this purely

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<sup>450</sup> *Id.*, para. 334.

<sup>451</sup> *Id.*, para. 329 (quoting **Legal Authority RLA-149**, Kenneth J. Vandeveld, *U.S. International Investment Agreements* 248 (2009)).

<sup>452</sup> Memorial, paras. 404-15. *See supra*, paras. 94-205, 254-259.

<sup>453</sup> US Counter-Memorial, para. 332.

legal defense, the US does not dispute that the selected comparators were otherwise in like circumstances.<sup>454</sup>

268. Apotex submitted with its Memorial the expert report of Messrs. Bradshaw and Johnson, which detailed the various cGMP deficiencies that FDA found at each of the selected comparators' manufacturing facilities.<sup>455</sup> Messrs. Bradshaw and Johnson concluded that each of the comparators discussed was in like circumstances with Apotex. The US ignores this expert report in its entirety. It also fails to address the case on like circumstances Apotex put forward in its Memorial.
269. *First*, the US does not dispute that the comparators are in the same economic sector as Apotex or the importance of this factor in evaluating appropriate comparators.<sup>456</sup>
270. *Second*, the US does not dispute that each of the comparators is an investor that owns or controls investments in the United States that correspond to those of Apotex – each comparator “owns or controls, directly or indirectly, a business in the United States that distributes and markets its products,” and each comparator “owns or controls, directly or indirectly, approved ANDAs[.]”<sup>457</sup>
271. *Third*, the US does not dispute that each comparator “competes with Apotex on the US pharmaceuticals market” and was a leading seller of generic drugs during 2008 to 2012.<sup>458</sup>
272. *Fourth*, the US does not dispute that receiving a warning letter from FDA for violations of “cGMP at a facility producing finished drug products for sale in the United States[.]” places a company in “like circumstances” to Apotex.<sup>459</sup>

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<sup>454</sup> In a footnote to the Counter-Memorial, the US erroneously claims, without any substantiation, that Apotex failed to establish that it was accorded less favourable treatment than “U.S.-owned domestic facilities... .” The US only cursorily refers to Baxter, which is addressed in detail below. *See id.* at n.840 and *infra* Merits, Section I.B.

<sup>455</sup> Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 112-34. The US does not dispute the qualifications or expertise of Messrs. Bradshaw and Johnson.

<sup>456</sup> Memorial, para. 445. US Counter-Memorial, para. 330.

<sup>457</sup> Memorial, para. 446. *See* US Counter-Memorial, para. 333.

<sup>458</sup> Memorial, para. 447. *See* US Counter-Memorial, para. 330.

<sup>459</sup> Memorial, para. 448. *See* US Counter-Memorial at 169 n.821.

273. *Fifth*, the US does not dispute that “the presence of perceived repeat or ‘corporate’ violations of cGMP[]” is an important factor in identifying appropriate comparators.<sup>460</sup>
274. *Sixth*, the US does not dispute that FDA found similar – or worse – cGMP violations at the facilities of each of the comparators during its inspections.<sup>461</sup>
275. The absence of disagreement between the parties on the “treatment” element is also noteworthy. To the above list, on “like circumstances” can be added the following on treatment.
276. *Seventh*, the US does not dispute that each comparator was afforded the opportunity to respond to and implement corrective action after receiving a warning letter.<sup>462</sup>
277. *Eighth*, the US does not dispute that none of the comparators “was prevented [by FDA] from selling its products on the US market.”<sup>463</sup>
278. *Ninth*, the US does not dispute that FDA has taken no enforcement action against any of the comparators identified by Apotex.<sup>464</sup>
279. The US’s sole objection with respect to “like circumstances” goes to the legal regime that applies to Apotex and comparable investors with facilities in the United States. The US erroneously excluded as comparators all US – or third-country – owned investments supplied by *US-based* drug manufacturing facilities because these facilities cannot be placed on import alert.<sup>465</sup>

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<sup>460</sup> Memorial, para. 448. *See* US Counter-Memorial, paras. 335-38.

<sup>461</sup> *See* Memorial, para. 299; Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 154 (noting that certain domestic comparators had “a history of far worse compliance with cGMPs than Apotex”). *See also* Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 24, 30-31 (a comparison of the conduct discussed in each of the warning letters issued to comparators reveals that Apotex and the comparable business were, at a minimum, engaged in similar conduct. In some respects, the comparable businesses’ conduct was worse than Apotex’s.).

<sup>462</sup> *See* Memorial, para. 451. *See also* US Counter-Memorial, paras. 170-71 & nn. 823, 827.

<sup>463</sup> Memorial, para. 451.

<sup>464</sup> Memorial, paras. 299, 451. The US only addresses Ranbaxy (US Counter-Memorial, paras. 338-40) but this company is not an apt comparator. *See infra* paras. 377-387.

<sup>465</sup> US Counter-Memorial, para. 333.

280. The Tribunal will recall that Messrs. Bradshaw and Johnson in their initial report noted a curious fact: no US investor or investment supplied by facilities outside the United States received a warning letter or was placed on import alert during the relevant period.<sup>466</sup>

281. The US does not suggest otherwise. It identifies no US-owned pharmaceutical company with facilities located outside the United States that were inspected by FDA and issued a warning letter for cGMP violations similar to those found at Etobicoke and Signet. In other words, the US does not suggest that there exist US-owned comparators identical to Apotex. In these circumstances, it is appropriate to consider “less ‘like’” comparators.<sup>467</sup>

282. Messrs. Bradshaw and Johnson identified several investors with drug manufacturing facilities in the United States and which are in like circumstances to Apotex.<sup>468</sup> These include:

- Baxter Healthcare Corporation in Puerto Rico (“Baxter”);
- L. Perrigo Company in Michigan (“L. Perrigo”);
- Hospira, Inc. in North Carolina (“Hospira”);
- Sandoz Inc. in Colorado and North Carolina (“Sandoz Inc.”);
- Teva Parenteral Medicines, Inc. in California (“Teva Parenteral”).

283. The US argument that these comparators are not in like circumstances fails for two main reasons. First, the US cannot reduce the pertinent legal regime to just one form of enforcement measure, namely the import alert. The relevant legal regime is that which regulates the conduct of the actors and the conditions in which they establish, acquire,

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<sup>466</sup> Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 111 (“At the outset, we note that, despite an extensive survey, we were unable to uncover any instance of an FDA warning letter or enforcement action concerning cGMP violations at any manufacturing facility outside of US territory of a US-owned company manufacturing finished dosage forms for human consumption.”).

<sup>467</sup> **Legal Authority CLA-34**, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award, Part IV, Chapter B, para. 17 (Aug. 3, 2005) (“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’, as it would be perverse to refuse to find and to apply less ‘like’ comparators when no identical comparators existed.”).

<sup>468</sup> Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 112-34.

expand, manage, conduct, operate, sell and dispose of their investments. The pertinent regime here is that of the cGMP regulations. Because US and foreign facilities must conform their operations to the *same* cGMP regulations, they are subject to the *same* legal regime. Hence, investments dependent upon such facilities are in like circumstances.

284. Second, in its attempt to reduce the legal regime to the Import Alert, the US focuses on the challenged measure and, hence, the treatment received by Apotex. In doing so, the US confuses the element of “like circumstances” with that of “less favorable treatment.” However, these are two separate prongs of the test for establishing a violation of Articles 1102 and 1103, as acknowledged by the US.<sup>469</sup> This test does not require that, for there to be like circumstances, the treatment afforded to Apotex shall be exactly the same as that afforded to the comparators.

*1. The Pertinent Legal Regime Is That of cGMP Regulations*

285. As the tribunal held in *ADM v. Mexico*, “all ‘circumstances’ in which the treatment was accorded are to be taken into account in order to identify the appropriate comparator.”<sup>470</sup> The parties are agreed that the “like circumstances” test includes considering whether the investor/investment and the comparators are subject to like legal requirements.<sup>471</sup>

286. The US, however, attempts to narrow the relevant legal regime to the “sole challenged measure,” i.e., the Import Alert, excluding from the analysis all other features of the legal environment, the economic sector and conditions of competition therein.<sup>472</sup> For

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<sup>469</sup> US Counter-Memorial, para. 324 (“Establishing a national-treatment violation is a fact-specific inquiry calling for a three-step analysis ... (1) ... *treatment* ... ; (2) ... *like circumstances* ... ; and (3) ... *treatment less favorable* ....”) (emphasis in Counter-Memorial); *id.*, para. 325 (“Establishing a violation of Article 1103 is the same as establishing a violation of Article 1102, except that the applicable comparator in step two is a *foreign* investor or its investments.”) (emphasis in original).

<sup>470</sup> **Legal Authority CLA-20**, *Archer Daniels Midland Company and Tate & Lyle Ingredients Americas, Inc. v. The United Mexican States*, ICSID Case No. ARB(AF)/04/05, Award, para. 197 (Nov. 21, 2007) (emphasis added).

<sup>471</sup> *See* Memorial, para. 438; US Counter-Memorial, para. 331 (both quoting **Legal Authority CLA-29**, *Grand River Enterprises Six Nations, Ltd., et al. v. United States of America*, UNCITRAL, Award, para. 166 (Jan. 12, 2011) (“NAFTA tribunals have given significant weight to the legal regimes applicable to particular entities in assessing whether they are in ‘like circumstances’ under Articles 1102 and 1103.”)).

<sup>472</sup> US Counter-Memorial, para. 332.

the US, there is only one pertinent circumstance, and that is the disputed measure. The US approach is plainly wrong.

287. In the case at bar, the most pertinent legal regime consists of current good manufacturing practices (cGMPs) for finished pharmaceuticals, set forth in Parts 210 and 211 of the Code of Federal Regulations.<sup>473</sup> These regulations address the conduct of actors in the economic sector and the conditions in which they operate. They provide the regulatory backdrop against which the challenged measure was adopted. The US acknowledges that these requirements apply to manufacturing facilities *in the United States and abroad* that produce drugs for the US market.<sup>474</sup>
288. The parties are also agreed that failure to comply with cGMP regulations may subject the drug manufacturer to regulatory action, such as import alert, injunction or seizure.<sup>475</sup>
289. Such regulatory action constitutes the treatment received, and not like circumstances, as explained below.

## 2. *The Import Alert Is the Measure That Accorded Treatment*

290. As just mentioned, the US's starting point on like circumstances is that US-based facilities cannot be subject to an import alert.<sup>476</sup> By focusing solely on the measure that accords treatment, i.e., the import alert, the US in fact addresses the treatment received rather than "like circumstances." The US's approach, which consists of analyzing the treatment as the only element relevant to like circumstances, finds no support in the relevant text and context, or the object and purpose of the NAFTA.
291. Under Articles 1102 and 1103, the treatment received by the investor/investment must be compared to the treatment received in like circumstances by domestic or foreign investor/investment. Articles 1102 and 1103 provide in relevant part:

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<sup>473</sup> Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 46.

<sup>474</sup> US Counter-Memorial, para. 38 ("These [cGMP] requirements are identical for domestic and foreign pharmaceutical manufacturing facilities producing drugs for the U.S. market.").

<sup>475</sup> Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 47, 77, 81, 100; US Counter-Memorial, paras. 49, 53.

<sup>476</sup> US Counter-Memorial, paras. 332-33.

Each Party shall accord to investors of another Party *treatment* no less favourable than that *it accords, in like circumstances*, to its own investors with respect to the establishment, acquisition, expansion, management, conduct operation, and sale or other disposition of investments.<sup>477</sup>

Each Party shall accord to investors of another Party *treatment* no less favourable than that *it accords, in like circumstances*, to 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.<sup>478</sup>

292. NAFTA Article 1102 on national treatment and Article 1103 on most-favored-nation treatment thus provide that the host State shall accord to the investors and investments at stake “treatment” no less favorable than that “it accords” in like circumstances to national investors and investments or those of another Party or of a non-Party.

293. The according of “treatment” by the State Party is the active verb and the central element in these provisions. The ordinary meaning of treatment is conduct, behavior or action towards a person.<sup>479</sup> The phrase “in like circumstances” in Articles 1102 and 1103 directly qualifies the verb “accord.”

294. The term “circumstances” denotes conditions or facts that *accompany* an action. As stated by the *ADM* tribunal:

The ordinary meaning of the word “circumstances” under Article 1102 requires an examination of the surrounding situation in its entirety [citing *Methanex*]. ... The dictionary meaning of the word “circumstance” refers to a condition,

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<sup>477</sup> **Legal Authority CLA-1**, NAFTA, art. 1102(1) (emphasis added). *See also id.* art. 1102(2) (structurally identical for investments).

<sup>478</sup> *Id.*, art. 1103(1) (emphasis added). *See also id.*, art. 1103(2) (same for investments).

<sup>479</sup> *See Legal Authority CLA-579*, Andrew Newcombe & Lluís Paradell, *Law and Practice of Investment Treaties: Standards of Treatment* 181 (Kluwer Law International 2009) (Although the term treatment is used in both national and MFN treatment and fair and equitable treatment provisions, “IIAs do not define the term treatment. Treatment is a broad term that the Oxford English Dictionary defines as ‘Conduct, behaviour; action or behaviour towards a person.’ In *Siemens*, the tribunal stated that ‘treatment’ ordinarily means ‘behaviour in respect of an entity or a person.’”); *id.* at 229 (“Treatment has a wide meaning and includes the effect of any type of state conduct.”).

fact, or event accompanying, conditioning, or determining another, or the logical surroundings of an action.<sup>480</sup>

295. The “action” in Articles 1102 and 1103 clearly is the according of treatment. The circumstances are not the action but the facts that accompany or determine the action. Under these provisions, treatment is different from circumstances. Circumstances are the set of facts that surround the according of treatment. “Treatment” and “circumstances”, as used in these provisions, cannot be the same thing. The text of Articles 1102 and 1103 therefore does not support the US argument that the Import Alert reflects the *circumstances* surrounding the treatment of Apotex and the comparators. Quite the contrary, the Import Alert constitutes the action of the State, i.e., the according of *treatment* to Apotex and the comparators in like circumstances.
296. This point is important because Articles 1102 and 1103 assign different values to each of the treatment and like circumstances elements. Treatment must be different. Circumstances must be like.
297. The US argument that the treatment – the Import Alert - is the only relevant circumstance would render Articles 1102 and 1103 ineffective and is inconsistent with the object and purpose of the NAFTA.<sup>481</sup>
298. By merging these two concepts (treatment and like circumstances), the US presents a circular argument that defeats the policy objectives of the NAFTA. The US argument is that a foreign investor who receives *treatment* different from that afforded domestic investors cannot be *in like circumstances* with the domestic investors. Under the US’s

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<sup>480</sup> **Legal Authority CLA-20**, *Archer Daniels Midland Company and Tate & Lyle Ingredients Americas, Inc. v. The United Mexican States*, ICSID Case No. ARB(AF)/04/05, Award, para. 197 (Nov. 21, 2007) (citing **Legal Authority CLA-34**, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award, Part IV, Ch. B, para. 37 (Aug. 3, 2005)). See also **Legal Authority CLA-592**, *Circumstance Definition*, Merriam-Webster.com, <http://www.merriam-webster.com/dictionary/circumstance> (last visited May 5, 2013) (“**1 a**: a condition, fact, or event accompanying, conditioning, or determining another: an essential or concomitant ...”); Oxford dictionaries.com, <http://oxforddictionaries.com/definition/english/circumstance> (last visited May 5, 2013) (1 (usually **circumstances**) a fact or condition connected with or relevant to an event or action ...”); The American Heritage Dictionary of the English Language 244 (William Morris, ed., 3d ed. 1973) (“**1**. One of the conditions or facts attending an event and having some bearing upon it; a determining or modifying factor.”).

<sup>481</sup> **Legal Authority CLA-1**, NAFTA, Art. 102(1)(c) (“The objectives of this Agreement, as elaborated more specifically through its principles and rules, including national treatment, most-favored-nation treatment and transparency, are to: ... (c) increase substantially investment opportunities in the territories of the Parties[.]”).

reasoning, no claim under Article 1102 (or Article 1103) could ever succeed: if a claimant prevails on the issue of differential treatment, it automatically fails on that of like circumstances. The US's reasoning cannot be accepted, for it would render Articles 1102 and 1103 ineffective.<sup>482</sup>

299. The *High Fructose Corn Syrup* cases provide a concrete illustration of the fallacy of the US approach. There, the measure was a 20% excise tax imposed on corn syrup as a sweetener for beverages, but not on sugar. Under the US's reasoning, because the tax was not and according to its terms could not be imposed on sugar producers, they would not be in like circumstances with foreign corn syrup producers. Under the US approach, the foreign corn syrup producers would have no Article 1102 claim. However, three separate NAFTA tribunals held that corn syrup producers and sugar producers were in like circumstances, and the tax measure in question constituted treatment of foreign corn syrup producers less favorable than the treatment accorded domestic sugar producers.<sup>483</sup> If ever there were a clear national treatment breach, this was it. Yet the US approach would have reached a different result. It cannot be reconciled with the treaty.

300. The Import Alert, Apotex submits, must be considered under the heading of treatment rather than like circumstances. Here, Apotex and the US agree that "Article 1102 is not intended to prohibit *all* differential treatment among investors and investments[.]"<sup>484</sup> Articles 1102 and 1103 only prohibit "less favorable" treatment.

301. The US Statement of Administrative Action on the investment chapter simply paraphrases Articles 1102 and 1103.<sup>485</sup> However, with respect to their structurally identical counterparts in the chapter on cross-border trade in services, the instrument states the following:

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<sup>482</sup> See *supra* n.361.

<sup>483</sup> **Legal Authority CLA-20**, *Archer Daniels Midland Company and Tate & Lyle Ingredients Americas, Inc. v. The United Mexican States*, ICSID Case No. ARB(AF)/04/05, Award (Nov. 21, 2007); **Legal Authority CLA-25**, *Corn Products International, Inc. v. United Mexican States*, ICSID Case No. ARB(AF)/04/01, Decision on Responsibility (Jan. 15, 2008); **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award (Sept. 18, 2009).

<sup>484</sup> US Counter-Memorial, para. 323 (footnote omitted; emphasis added).

<sup>485</sup> **Legal Authority CLA-2**, North American Free Trade Agreement Implementation Act, Statement of Administrative Action, H.R. Doc. No. 103-159, Vol. I, 103d Cong. 1st sess. at 140-41 (1993).

The “no less favourable” standard applied in Articles 1202 and 1203 does not require that service providers from other NAFTA countries receive the same or even “equal” treatment as that provided to local companies or other foreign firms. Foreign service providers *can be treated differently if circumstances warrant*. For example, a state may impose special requirements on Canadian and Mexican service providers if necessary to protect consumers to the same degree as they are protected in respect of local firms. NAFTA’s non-discrimination provisions prohibit the imposition of laws and regulations designed to skew the terms of competition in favor of local firms; they *do not bar legitimate regulatory distinctions* between such firms and foreign service providers.<sup>486</sup>

302. The Parties at the time of the adoption of the NAFTA considered that the national treatment and most-favored-nation treatment obligations contained in the NAFTA allow some legitimate differences in treatment between nationals and foreigners. However, the treatment cannot be – qualitatively – less favorable to foreigners. In the present case, Canadian investors and investments must be treated “as well as” US-owned or third-country-owned investors and investments in like circumstances.<sup>487</sup> But the treatment does not have to be strictly identical.<sup>488</sup>

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<sup>486</sup> *Id.* at 152 (emphasis added). Articles 1202 and 1203 contain the same requirement of “no less favorable” treatment as Article 1102 and 1103. See **Legal Authority CLA-1**, NAFTA, art. 1202(1) (“Each Party shall accord to service providers of another Party treatment no less favorable than that it accords, in like circumstances, to its own service providers.”); *id.*, art. 1203 (“Each Party shall accord to service providers of another Party treatment no less favorable than that it accords, in like circumstances, to service providers of any other Party or of a non-Party.”).

<sup>487</sup> Cf. **Legal Authority CLA-576**, *Bilateral Investment Treaties with: Argentina, Treaty Doc. 130-2; Armenia, Treaty Doc. 103-11; Bulgaria, Treaty Doc. 103-3; Ecuador, Treaty Doc. 103-15; Kazakhstan, Treaty Doc. 103-12; Kyrgyzstan, Treaty Doc. 103-13; Moldova, Treaty Doc. 103-14; and Romania, Treaty Doc. 102-36*, Hearing Before the Committee on Foreign Relations, United States Senate, 103rd Cong. at 6 (Sept. 10, 1993) (Prepared Statement of Daniel K. Tarullo, Assistant Secretary of State for Economic and Business Affairs, Dep’t of State) (commenting on specific US BITs that contain the same language of “no less favorable treatment” in their national-treatment and MFN-treatment provisions, Mr. Tarullo stated the following: “Our treaties specify that U.S. investors will be treated *as well as* domestic investors (national treatment). If a country chooses to treat foreign investors more favorably than domestic investors, these treaties also ensure that U.S. investors will be treated *as well as* any other foreign investor (most favored nation treatment).”) (emphasis added).

<sup>488</sup> See, e.g., **Legal Authority CLA-591**, Todd Weiler, *Saving Oscar Chinn: Non-Discrimination in International Investment Law*, in 19 *Arbitrating Foreign Investment Disputes* 159, 163 (Norbert Horn & Stefan Michael Kröll eds., Kluwer Law International 2004) (“It does not matter whether the measure accords identical treatment to investors/investments and the relevant comparators. The test is whether *any* relevant comparator is receiving *more favourable* treatment than the claiming investor or its investment.”); **Legal Authority CLA-588**, Pia Acconci, *The Essential Features of the MFN Standard*, in *The Oxford Handbook of International Investment Law* 365 (Peter Muchlinski, Federico Ortino & Christoph Schreuer

303. The regulatory actions that FDA can adopt against non-cGMP-compliant drug manufacturers can take different forms. As explained by Messrs. Bradshaw and Johnson:

FDA’s primary enforcement tools for facilities located within the United States are Warning Letters, seizures, and injunctions. FDA’s primary enforcement tools for facilities located outside the United States are Warning Letters, detentions without physical examination, and import alerts.<sup>489</sup>

304. Messrs. Bradshaw and Johnson also noted that “FDA could also use seizures and injunctions for products produced at foreign facilities, but as a matter of practice it does so infrequently, likely because it is easier for FDA to issue an import alert than obtain an injunction or seizure.”<sup>490</sup> The US does not challenge this point.<sup>491</sup>

305. It follows that an import alert is just one enforcement measure within FDA’s arsenal to ensure cGMP compliance. Import alerts can be applied only to *foreign* manufacturers that offer drugs for import into the United States. However, if a *domestic* drug manufacturer fails to comply with cGMP requirements, FDA can adopt alternative enforcement measures, such as an injunction or seizure. Injunctions and seizures have the same effect as an import alert: they prevent pharmaceutical drugs from being sold in the United States.

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eds., Oxford University Press 2008) (“Commonly, uniformity and equality are deemed appropriate terms to define what consequences are supposed to derive from reference to the non-discrimination principle. Undoubtedly, this does not mean that such a principle obliges a host state to grant an ‘equal or identical treatment’ to all investors operating on its territory. A host state can grant different treatment to investors from different foreign states, if they are in a different objective situation.”); **Legal Authority CLA-579**, Andrew Newcombe & Lluís Paradell, *Law and Practice of Investment Treaties: Standards of Treatment* 183 (Kluwer Law International 2009) (“... most IIAs do not provide that investors must be given identical treatment; rather the requirement is to ensure that the treatment is no less favourable. Treatment is more or less favourable where the effect on the investment or investor is to impose advantages or burdens.”).

<sup>489</sup> Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 41.

<sup>490</sup> Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 41 n.5. *See also* Memorial, para. 125 (“Injunctive relief is available whether the facility is located in the US or abroad as long as the manufacturer is subject to US jurisdiction.”) (footnote omitted).

<sup>491</sup> *See* US Counter-Memorial, para. 53 (“For facilities abroad, FDA may pursue some of those actions (such as agreement to an injunction, or criminal prosecution through extradition), but significant legal and procedural hurdles prevent meaningful reliance on these typically domestic enforcement tools.”) (footnote omitted). The US notes that, with respect to seizure actions, the adulterated drugs must be in the United States. *See id.* at para. 53 nn.87, 90. It also notes that two Indian facilities of Ranbaxy Laboratories, Ltd. were subject to import alert 66-40, while the US filed a complaint seeking an injunction against the company – enjoining it to refrain from manufacturing drugs for the US market at these facilities. *See id.*, paras. 338-39.

306. To use the terms of the US Statement of Administrative Action, Articles 1102 and 1103 did not prohibit FDA from adopting a measure as to Apotex (the import alert) that was different from measures that it could adopt as to firms with facilities in the US (injunction or seizure only). The provisions imposed no obligation to accord Apotex the same or equal treatment as its comparators. While the provisions permitted FDA to accord Apotex different treatment, they nonetheless prohibited it from according *less favorable treatment*. The record here, however, establishes that FDA did precisely that.
307. The legal regime at issue in this case did not require FDA to place Apotex on import alert. Rather, FDA had discretion to ban Apotex's products from the US market by imposing an import alert, or to achieve the same result by seeking an injunction or seizure. By placing Etobicoke and Signet on import alert, the US afforded Apotex less favorable treatment compared to the US facilities of Baxter, L. Perrigo, Hospira, Sandoz Inc. and Teva Parenteral. Because of the Import Alert, Apotex was prevented from selling any products manufactured at Etobicoke and Signet during a period of two years. By contrast, FDA did not prevent Baxter, L. Perrigo, Hospira, Sandoz Inc. or Teva Parenteral from selling their products in the United States – even though these products were manufactured at US facilities that failed to comply with cGMP regulations. This point the US does not contest.<sup>492</sup>
308. In sum, the US is wrong to conclude that “[g]oods and facilities inside the United States ... are not subject to the same legal regime as goods and facilities outside the United States.”<sup>493</sup> To the contrary, domestic and foreign facilities must comply with the same current good manufacturing practices. Failure to do so may lead to enforcement actions that may take different forms but all have the same practical effect: to ban drugs from the US market. Drugs produced at the US facilities of Baxter, L. Perrigo, Hospira,

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<sup>492</sup> See *id.*, paras. 330-32. The US's reliance on *Pope and Talbot* is misplaced. See *id.*, para. 168 n.819. The *Pope & Talbot* tribunal held that differences in treatment will presumptively violate Article 1102(2) unless the differences “have a reasonable nexus to rational government policies that (1) do not distinguish, on their face or *de facto*, between foreign-owned and domestic companies, and (2) do not otherwise unduly undermine the investment liberalizing objectives of NAFTA.” The US insists that the import alert measures aim at protecting the public health and do not distinguish on their face between companies or facilities on the basis of nationality. However, the Import Alert discriminated against Apotex's Canadian facilities, while FDA did nothing to protect the public from Baxter's, L. Perrigo's, Hospira's, Sandoz Inc.'s and Teva Parenteral's US-based facilities that failed to comply with cGMP regulations and received warning letters.

<sup>493</sup> US Counter-Memorial, para. 332.

Sandoz Inc. and Teva Parenteral were not banned from the market, while Apotex products from Etobicoke and Signet were. As a result, Apotex received less favorable treatment than these comparators and the US breached Articles 1102 and 1103 of the NAFTA. The US cannot avoid liability by mixing up the different prongs of the test for establishing a national-treatment violation (or a most-favored-nation treatment violation). The fact that Apotex received differential, less favorable, treatment does not alter the conclusion that Apotex was in like circumstances with investors with facilities in the United States.

**C. The Record Shows that Apotex Was Treated Less Favorably Than the Comparators**

309. The Counter-Memorial limits the discussion on “less favorable treatment” to those comparators with facilities outside the United States, namely Sandoz Canada and Teva.<sup>494</sup> However, the US’s arguments as to either category of comparator do not withstand scrutiny. With respect to comparators with facilities in the United States, the US offers no defense other than the US location of the facilities. The US does not address at all the treatment – or lack thereof – received by Baxter, Hospira, L. Perrigo and Sandoz Inc. Each category of comparators – foreign and domestic – is addressed in turn below. Lastly, the US errs in suggesting that Ranbaxy Laboratories, Ltd. (“Ranbaxy”) may be an apt comparator.

*1. The US Treated Apotex Less Favorably Than the Comparators With Facilities Outside the United States*

310. With respect to the comparators with drug manufacturing facilities located outside the United States, Apotex selected two third-country-owned companies with such facilities. These are:

- Novartis AG and Sandoz Inc., as concerns supplies from Sandoz Canada Inc. in Boucherville, Quebec, Canada (“Sandoz Canada”);

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<sup>494</sup> The US also treats Ranbaxy as a potential comparator for Apotex’s most-favored-nation treatment claim under Article 1103, which Apotex categorically rejects. *See* US Counter-Memorial, para. 334 & *infra* paras. 377-387.

- Teva Pharmaceutical Industries Limited, as concerns supplies from its facility in Jerusalem, Israel (“Teva”).<sup>495</sup>

311. At the outset, the US considers that Sandoz and Teva are in like circumstances with Apotex since these facilities are “eligible for Import Alert 66-40.”<sup>496</sup>

312. The US’s sole defense with respect to Sandoz and Teva is that they did not receive more favorable treatment than that afforded Apotex.<sup>497</sup> However, the record rebuts the US defense.

a) *The Record Shows that Apotex Received Less Favorable Treatment Than Sandoz / Novartis*

313. FDA took a coordinated approach towards Sandoz/Novartis. It inspected Sandoz Canada’s facility in Boucherville, Quebec around the same time as Sandoz Inc.’s facilities in Wilson, North Carolina and Broomfield, Colorado.<sup>498</sup> Due to the serious, repeat cGMP violations that it found at these three sites, FDA issued a corporate warning letter to Novartis in November 2011, covering all three sites.<sup>499</sup>

314. The US does not dispute that FDA was concerned with serious, repeat violations at Boucherville.<sup>500</sup> Notably, FDA was concerned with crystal formation in an injectable medication, as well as microbiological contamination of drug products purported to be sterile, all repeat violations from the July 2009 inspection.<sup>501</sup> As noted by FDA, crystals

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<sup>495</sup> Memorial, paras. 320-34. Taro Pharmaceuticals was another apt comparator for Apotex’s claim under Article 1103. *See id.*, para. 334 & n.504. Messrs. Bradshaw and Johnson also identified Jelfa Pharmaceutical Company SA as another comparator for Apotex’s most-favored-nation treatment claim. *See* Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 148-53. The US does not respond to any of the facts regarding Taro and Jelfa. *See* US Counter-Memorial, para. 334 & n.821.

<sup>496</sup> US Counter-Memorial, para. 334.

<sup>497</sup> *Id.*

<sup>498</sup> *See infra* para. 366.

<sup>499</sup> **Exhibit C-273**, Novartis Warning Letter, dated November 18, 2011.

<sup>500</sup> Memorial, para. 325; Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 139 (“... all of the findings cited from the Canadian facility were repeats.”); **Exhibit C-273**, Novartis Warning Letter, dated November 18, 2011 at 2 (noting for each of the three inspectional observations concerning Boucherville: “This is a repeat observation from the July 2009 inspection at the Boucherville, Quebec facility.”); US Counter-Memorial, para. 335.

<sup>501</sup> *See* **Exhibit C-273**, Novartis Warning Letter, dated November 18, 2011 at 1-2. FDA concluded that Sandoz Canada had failed to thoroughly investigate this problem and identify the root cause of the crystallization. In addition, Sandoz Canada failed to conduct specific identity test (including routine tests for endotoxin) and establish the reliability of the supplier’s analysis through appropriate validation of the supplier’s test results. Finally, the company failed to submit Field Alert Reports on time. *See id.* at 2-3.

in injectable solutions could lead to patient injury requiring medical intervention, or a disruption in the concentration of the drug, making it less effective.<sup>502</sup> Microbiological contamination “compromised the sterility of the products and could result in contaminated products that would severely injure patients if administered.”<sup>503</sup>

315. The US acknowledges that FDA sent a warning letter to Novartis “concerning serious cGMP violations at Sandoz Canada’s Boucherville, Quebec, facility, but did not put the facility on import alert.”<sup>504</sup> In contrast, FDA placed Apotex’s Etobicoke and Signet facilities on Import Alert for cGMP violations that implicated no adverse serious health consequence or health hazard.<sup>505</sup> The difference in treatment between Apotex and Sandoz / Novartis is thus obvious.
316. Faced with these irrefutable facts, the US states that Sandoz Canada *voluntarily* committed to “*shut down* production at its Boucherville manufacturing facility” which, according to the US, “obviated any need to place it on Import Alert 66-40.”<sup>506</sup>
317. At the outset, it is telling that the US provides no direct evidence in support of its allegations with respect to Sandoz Canada’s voluntary “shutdown.” The only evidence submitted by the US consists of two articles from *CBC News* and the *Globe & Mail*, which are generalist newspapers.<sup>507</sup> The US has not adduced any supporting evidence from FDA or Health Canada with respect to the Boucherville facility and its alleged shutdown. The US position lacks support in law or fact.
318. *First*, Article 1103 provides that “[e]ach Party shall accord to investors of another Party [and their investments] treatment no less favorable than that *it accords*, in like circumstances, to investors of any other Party or of a non-Party [or their

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<sup>502</sup> **Exhibit C-452**, Letter from Jeanne Ireland, FDA, Assistant Commissioner for Legislation to the Hon. Elijah E. Cummings, Committee on Oversight and Government Reform, House of Representatives, dated July 23, 2012 at 5.

<sup>503</sup> *Id.* at 5.

<sup>504</sup> US Counter-Memorial, para. 335.

<sup>505</sup> See Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 44.

<sup>506</sup> US Counter-Memorial, para. 335 (emphasis in original).

<sup>507</sup> **Exhibit R-92**, Drug Shortage Feared as Quebec Plant Retools, *CBC News* (Feb. 20, 2012); **Exhibit R-91**, Sean Silcoff, *Sandoz Canada’s Production Slows to a Crawl After Harsh Criticism from U.S. Regulators*, *GLOBE & MAIL* (Feb. 19, 2012).

investments].”<sup>508</sup> The repeated subject (“Party”; “it”) makes plain that the comparison required is between the treatment accorded *by the Party* to the investor or investment and the treatment accorded by that same Party to a comparator. In other words, this provision covers the treatment accorded *by the State* to investors/investments and comparators. Private acts, such as an investor’s or a comparator’s voluntary actions, are not eligible as a matter of the ordinary language of the text.

319. Indeed, this reading fully accords with the context of Articles 1102 and 1103 in a treaty establishing the responsibilities of States under public international law. Each of the provisions of the investment chapter of the NAFTA deals with the responsibility of a Party for its own acts and acts attributable to it as a State under international law. None ascribes liability to a Party for acts of private persons. It would make no sense, given this context, to read Articles 1102 and 1103 as permitting comparison between treatment accorded by or attributable to a State and treatment voluntarily adopted by private persons.
320. Transposed to the facts of our case, FDA (i.e., the State) adopted the Import Alert against Apotex, but took no enforcement action against Sandoz Canada. There can be no “like” treatment here. An import alert constitutes enforcement action by the Agency for failure to comply with cGMP requirements. With respect to Sandoz Canada, FDA refrained from taking any enforcement action against the company despite serious cGMP violations at its Boucherville facility. FDA did not require Sandoz to stop production at Boucherville.<sup>509</sup> Nor did FDA ban Boucherville drugs from the US market. FDA had imposed no measure requiring that Sandoz Canada live up to its supposed commitment to “essentially *shut down* production.”<sup>510</sup> It follows that the

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<sup>508</sup> **Legal Authority CLA-1**, NAFTA, art. 1103(1) (emphasis added).

<sup>509</sup> *See Exhibit C-452*, Letter from Jeanne Ireland, FDA, Assistant Commissioner for Legislation to the Hon. Elijah E. Cummings, dated July 23, 2012 at 3 (“FDA did not require the firms to shut down and even worked with each of them to try to avoid a shutdown, offering assistance to help assess and address manufacturing and quality concerns.”); *id.* at 5 (“Sandoz voluntarily suspended some production of these products to correct the quality concern.”).

<sup>510</sup> US Counter-Memorial, para. 335 (emphasis in original).

firm's voluntary action could not have "obviated any need to place it on Import Alert 66-40[.]" contrary to the US assertion.<sup>511</sup>

321. *Second*, the US position in this arbitration is difficult to reconcile with FDA's historical approach to voluntary action by a firm. Messrs. Bradshaw and Johnson state the following:

[W]e are not aware 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 for a prolonged period, much less temporarily suspending some operations for several weeks. Indeed, in our experience, firms that have voluntarily shut down their operations have still been subject to FDA enforcement actions requiring them to cease manufacturing. In fact, recently both Ben Venue and Hill Dermaceuticals were subjected to consent decalls after voluntarily ceasing operations for a prolonged period.<sup>512</sup>

322. *Third*, the US states that Sandoz Canada committed to a "shutdown" of its production at the Boucherville facility.<sup>513</sup> This is not what the record shows. The Boucherville facility was not shut down. Production there was only *temporarily slowed down*. As noted in Sandoz Canada's media release of February 29, 2012:

- Ongoing efforts to strengthen high-quality manufacturing standards have resulted in a *temporary slow-down* of production at the Boucherville, Quebec, manufacturing site
- *Production at the site continues* and is prioritized around essential products to help ensure continued supply of critical drugs to patients[.]<sup>514</sup>

323. The only complete "shutdown" was caused by force majeure and only lasted a couple of days, after a fire broke out in the Boucherville facility on March 4, 2012.<sup>515</sup> Production

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<sup>511</sup> US Counter-Memorial, para. 335.

<sup>512</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 42. For example, the US-based facility of Ranbaxy in Gloversville shut down operations prior to the Ranbaxy consent decree, and yet this facility was still included in the consent decree. See **Legal Authority CLA-422**, Ranbaxy Consent Decree (2012) at 4, 17-18, 23.

<sup>513</sup> US Counter-Memorial, para. 335.

<sup>514</sup> **Exhibit C-441**, Sandoz Canada, Media Release, dated February 29, 2012 at 1 (emphasis added). See also *id.* ("As production continues, the company is focusing its efforts on essential medicines and prioritizing resources to ensure normal supply is restored as quickly as possible.").

resumed a few days later, yet only partially, before full resumption on March 23, 2012.<sup>516</sup> The fire was a sudden unforeseen event disconnected from the firm's actions. The US is silent on this event that could explain, at least in part, the slowdown at Boucherville, in particular during the month of March 2012.

324. By May 16, 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.<sup>517</sup> In other words, the slowdown lasted for a few months only, whereas Apotex stayed on Import Alert for two years.
325. *Fourth*, even if a firm's voluntary action could be equated with FDA's enforcement action (which is wrong), Sandoz / Novartis still received more favorable treatment than Apotex. Sandoz Canada did not "slow down" its Boucherville facility for several months after the inspection and the warning letter,<sup>518</sup> whereas the Import Alert on Apotex was immediate (less than two weeks after the close of the Signet inspection and months *before* the issuance of the Signet Warning Letter). To put it differently, FDA

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<sup>515</sup> See **Exhibit C-442**, Sandoz-Canada, Media Release, dated March 6, 2012 ("A fire broke out on Sunday, March 4, shortly after 12:30 pm, in the ceiling above the boiler room of one section of the Sandoz Canada production plant in Boucherville. ... Production has been temporarily suspended and will partially resume during the week of March 12, once cleaning activities have been completed. We ... are working to restore previous levels of production.").

<sup>516</sup> See **Exhibit C-444**, Sandoz Canada, Media Release, dated March 12, 2012 ("Sandoz Canada has resumed production over the weekend in the portion of the plant that was not directly affected by the incident which took place on March 4<sup>th</sup>. The site has implemented additional controls to assure the segregation of the affected areas. Production at the site is prioritized around essential products to help ensure continued supply of critical drugs to patients."); **Exhibit C-446**, Sandoz Canada, News Flash, "Production fully resumed at Boucherville plant," dated March 27, 2012 ("Sandoz Canada is pleased to announce that production has fully resumed as of March 23<sup>rd</sup> [2012], following the fire that broke out earlier this month. All necessary actions have now been completed, and all capacity is again fully focused on the production and supply of critical medicines."); **Exhibit C-450**, House of Commons of Canada, Report of the Standing Committee on Health, Drug Supply in Canada : A Multi-Stakeholder Responsibility, 41st Parliament, 1st Sess. (June 2012).

<sup>517</sup> **Exhibit C-447**, Sandoz Canada, Media Release, dated May 16, 2012 ("While Sandoz continues to work on site remediation efforts and strengthen manufacturing compliance at the Boucherville site, production output has been optimized, allowing Sandoz to meet the vast majority of Canadian market needs for its entire injectable portfolio. At present, Sandoz Canada is supplying more than 80% market needs for its entire injectable portfolio, and more than 90% for the products currently in production. ... Further improvements in output are expected which should increase allocation levels for all products in production to at least 100% of forecasted market needs by November 2012.").

<sup>518</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 41 ("FDA issued the Warning Letter to Novartis ... on November 18, 2011. Three full months later, on February 19, 2012, Sandoz announced in a press release that it would 'temporarily suspend or discontinue the production of certain products at [the] Boucherville site.'") (footnote omitted).

allowed Sandoz / Novartis to propose corrective actions, while it denied this option to Apotex.<sup>519</sup> At the close of the Signet inspection on Friday, August 14, 2009, the inspectors asked Apotex to call CDER on the following Monday, August 17, 2009.<sup>520</sup> However, before Apotex even had a chance to speak with CDER, the Import Alert recommendation was already under way.<sup>521</sup>

326. *Fifth*, Sandoz Canada could resume production and distribution in the US at any time without FDA's involvement. FDA has not re-inspected Sandoz Canada's Boucherville facility since the issuance of the Novartis Warning Letter.<sup>522</sup> By contrast, Apotex could not resume selling its products from Etobicoke and Signet in the United States until FDA re-inspected and approved both facilities as cGMP-compliant.
327. Sandoz's US sales of products manufactured at Boucherville seem to have remained stable despite the "slow down." Apotex had hoped to be able to put forward precise information on the US sales of specific products manufactured by Sandoz Canada at Boucherville.<sup>523</sup> However, the US refused to produce the requested documents.<sup>524</sup> As a result, the best available information concerns Sandoz Inc.'s general position on the US generic market, which remained the same before and after the Boucherville alleged

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<sup>519</sup> See **Exhibit C-288**, Novartis AG, Excerpts from Annual Report (Form 20-F) at 10 (Jan. 25, 2012) ("Sandoz is collaborating with the FDA to promptly correct all concerns raised in the Warning Letter ... However, if we fail to fully resolve the issues raised in the Warning Letter then we could be subject to legal action without further notice including, without limitation, seizure and injunction."); **Exhibit C-458**, Novartis AG, Excerpts from Annual Report (Form 20-F) at 79 (Jan. 23, 2013) ("In the fourth quarter of 2012, Sandoz announced that the FDA upgraded the compliance status of its Broomfield, Colorado site. Nonetheless, if we fail to fully resolve the issues raised in the Warning Letter then we could be subject to legal action without further notice including, without limitation, seizure and injunction.").

<sup>520</sup> Witness Statement of Jeremy Desai, para. 44; Witness Statement of Bernice Tao, para. 44.

<sup>521</sup> Compare **Exhibit C-371**, FDA Internal Email, dated August 17, 2009 at 11:31 AM (transmitting the Signet Form 483 to be "disseminate[d] to whoever will be writing the recommendations regarding the Import Alert, AIP, etc.") with **Exhibit R-43**, FDA, Minutes of Teleconference with Apotex, dated August 17, 2009 at 2:00 pm. See **Exhibit C-372**, Draft Memorandum from Richard Friedman to Director of DIOP, dated August 17, 2009 (entitled "Request to add firm to import alert 66-40"). See also **Exhibit C-373**, FDA Internal Email, dated August 18, 2009 (CDER was proceeding with the Import Alert while Apotex's response to the Etobicoke Warning Letter received on August 4, 2009 was still "under review" by CDER).

<sup>522</sup> See **Exhibit C-332**, FDA List of Foreign Inspections (2009-March 2013) at US1323 (undated) (Sandoz Canada's Boucherville facility was inspected in 2009 and 2011).

<sup>523</sup> See Claimants' Requests for Production of Documents, Request No. 31(a) at 36-37 (Feb. 8, 2013).

<sup>524</sup> See Respondent's Responses and Objections to Claimants' Requests for Production of Documents, Request No. 31(a) at 48 (Mar. 1, 2013).

slowdown.<sup>525</sup> In contrast, Apotex-US suffered millions in lost sales due to the Import Alert and dropped from the 6<sup>th</sup> to the 25<sup>th</sup> position on the US generic drug market between 2009 and 2011.<sup>526</sup>

328. The effect of the voluntary slowdown at Boucherville was thus immaterial for Sandoz, such that it was not even mentioned in Novartis's 2012 or 2013 annual reports, contrary to the voluntary shutdown of another Novartis's US plant (which was not mentioned in the Novartis corporate warning letter).<sup>527</sup>
329. *Finally*, in order to avoid a shortage in May 2012 FDA allowed Sandoz to import into the United States Phentolamine Mesylate, a drug manufactured at Boucherville but not authorized for sale in the United States.<sup>528</sup> According to Sandoz Canada, this drug was "manufactured in compliance with good manufacturing practices in Quebec, Canada at an FDA inspected facility, Sandoz Canada Inc."<sup>529</sup> Apparently, Sandoz Canada supplied the US market with this drug for almost a year.<sup>530</sup> Clearly, the alleged slowdown did not prevent the US distribution of drugs from Boucherville. By contrast,

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<sup>525</sup> **Exhibit C-327**, IMS Medical, data on comparators' ranking on the US generic drug market (2008-2012) (undated) (Sandoz remained in second position in 2011 and 2012).

<sup>526</sup> **Exhibit C-181**, Top 25 Generic Manufacturers per IMS Medical Data, Q2 2009; **Exhibit C-182**, Top 25 Generic Manufacturers per IMS Medical Data, Q4 2010.

<sup>527</sup> *Compare Exhibit C-288*, Novartis AG, Excerpts from Annual Report (Form 20-F) at 10 *with id.* at 11 (Jan. 25, 2012) (mentioning that Sandoz was collaborating with FDA to correct concerns at the three sites mentioned in the Novartis warning letter but not mentioning the shutdown of Novartis's Lincoln, Nebraska, facility). *Also compare Exhibit C-458*, Novartis AG, Excerpts from Annual Report (Form 20-F) at 12 (Jan. 23, 2013) ("In the fourth quarter of 2012, Sandoz announced that the FDA upgraded the compliance status of its Broomfield, Colorado site. The division is on track to meet its remediation commitments for the other two sites as well [Wilson, North Carolina and Boucherville, Quebec]") *with id.* ("In addition, in December 2011, we suspended operations and shipments from the OTC Division facility located at Lincoln, Nebraska ... as of the date of this Form 20-F, it is not possible to determine when the plant will resume signification operations.").

<sup>528</sup> **Exhibit C-472**, FDA, Health Care Provider Letter re: Phentolamine Mesylate Injection Sandoz Standard 5 mg/ml, dated May 8, 2012 at 1 (noting that Sandoz drug, which had been approved by Health Canada but not FDA, was temporarily allowed in the US to avoid a shortage). *See also Exhibit C-477*, Health Canada, Drug Database, Phentolamine Mesylate Injection Sandoz Standard, *available at* <http://webprod5.hc-sc.gc.ca/dpd-bdpp/dispatch-repartition.do?lang=eng> (last visited on May 21, 2013).

<sup>529</sup> **Exhibit C-448**, Sandoz, Letter to Health Care Professionals re: Phentolamine Mesylate Injection, dated May 18, 2012 at 2. Sandoz Canada has only one manufacturing facility in Canada, in Boucherville. *See Exhibit C-474*, Excerpts from Novartis Website, Worldwide offices (last visited on May 17, 2013).

<sup>530</sup> *See Exhibit C-463*, American Society of Health-System Pharmacists, "Phentolamine Mesylate for Injection", dated March 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.").

all products from Apotex's facilities in Etobicoke and Signet were placed on Import Alert.<sup>531</sup>

330. To conclude, the US has not proved – for it cannot – that Sandoz Canada/Novartis received similar treatment to that received by Apotex. Quite the contrary, the record clearly shows that Sandoz Canada received more favorable treatment. It follows that the US did not accord Apotex and its investments national treatment and most-favored-nation treatment, in breach of Articles 1102 and 1103 of the NAFTA.

*b) The Record Shows that Apotex Received Less Favorable Treatment Than Teva*

331. The Tribunal will recall that Teva is the world's leading generic pharmaceutical company and the leading provider of generic drugs to the US market.<sup>532</sup> It manufactures drugs in several locations, including at its facility in Jerusalem, and “own[s] in excess of 600 ANDAs.”<sup>533</sup>

332. The undisputed facts of record establish a violation of the most-favored-nation treatment under NAFTA Article 1103. The US does not dispute that Teva Jerusalem was in like circumstances with Apotex. Nor does the US contest that FDA imposed no import alert on Teva or even suggest that Teva voluntarily shut down or slowed down its production at all.<sup>534</sup> For the Tribunal's convenience, the main elements of Apotex's claim *vis-à-vis* Teva are summarized below.

333. The US acknowledges that Teva's Jerusalem facility was in like circumstances with Apotex because products manufactured there are “subject to Section 801(a) of the FD&C Act and are eligible for Import Alert 66-40.”<sup>535</sup>

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<sup>531</sup> The US allowed Apotex to ship to the United States a small number of shipments of deferiprone, a drug for compassionate use. See **Exhibit C-107**, Email from FDA to Apotex, dated September 24, 2009 (“CDER Office of Compliance will exercise regulatory discretion and therefore not object to Apotex's decision to release a predetermined minimal amount of deferiprone into the US Interstate Commerce.”).

<sup>532</sup> Memorial, para. 327 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 142).

<sup>533</sup> *Id.*, para. 329.

<sup>534</sup> US Counter-Memorial, para. 337.

<sup>535</sup> *Id.*, para. 334.

334. The US does not contest that FDA inspected Teva's Jerusalem facility in 2010 and found serious cGMP violations that forced the company to initiate several recalls – including a major “FDA initiated” recall.<sup>536</sup>
335. Similarly, the US does not dispute that Teva received a warning letter for its Jerusalem facility on January 31, 2011.<sup>537</sup>
336. The US does not deny that “[i]n spite of these serious concerns [at Teva's Jerusalem facility], FDA did not implement a DWPE [detention without physical examination]”.<sup>538</sup> This is in stark contradiction with the treatment received by Apotex, whose products from Etobicoke and Signet were detained without physical examination and refused admission into the United States as a result of the Import Alert.
337. As noted in Messrs. Bradshaw and Johnson's expert report, “FDA did not take a ‘corporate’ view of [Teva's] cGMP compliance”, even though FDA had issued a prior warning letter to Teva Parenteral's facility in Irvine, California 13 months earlier.<sup>539</sup> Although Teva (like Apotex) received two warning letters concerning separate facilities, FDA took no enforcement action against Teva (no import alert, injunction or seizure).<sup>540</sup> These facts are undisputed.<sup>541</sup>
338. Finally, it is not contested that Teva was granted more favorable treatment in the timeliness of its Jerusalem facility's re-inspection and issuance of a close-out letter on September 9, 2011 – seven months after the warning letter.<sup>542</sup> In the case of Apotex,

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<sup>536</sup> Memorial, para. 331 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 144); US Counter-Memorial, para. 337. FDA defines a recall as “a firm's removal or correction of a marketed product that the [FDA] considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure, ... .” See **Legal Authority CLA-563**, 21 CFR § 7.3(g). Most recalls are voluntarily initiated by the responsible company, but there are situations when a company does not voluntarily initiate a recall prompting FDA to make an official request to recall. See Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 45.

<sup>537</sup> Memorial, para. 332 (citing **Exhibit C-191**, Teva Warning Letter, dated January 31, 2011); US Counter-Memorial, para. 337.

<sup>538</sup> Memorial, para. 333 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 145); US Counter-Memorial, para. 337.

<sup>539</sup> Memorial, para. 334 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 146).

<sup>540</sup> *Id.*

<sup>541</sup> US Counter-Memorial, para. 337.

<sup>542</sup> Memorial, para. 333; US Counter-Memorial, para. 337.

FDA delayed re-inspection at Etobicoke and Signet and the company remained on Import Alert for two years.<sup>543</sup>

339. In sum, Apotex demonstrated in its Memorial that Teva was afforded more favorable treatment than Apotex in like circumstances. The US has offered no defense on any of these points.
340. The only defense raised by the US with respect to Teva Jerusalem concerns FDA's so-called "risk-based approach."<sup>544</sup> In essence, the US argues that FDA reviewed Apotex's situation and Teva's situation and came to different conclusions, i.e., an import alert v. no enforcement action. However, the US has not adduced any supporting evidence to justify the difference in treatment.
341. The discussion on Teva Jerusalem in the US Counter-Memorial is limited to one paragraph, which states as follows:

A second warning letter was sent to Teva Pharmaceuticals Inc. concerning a Jerusalem-based facility, one of Teva's 56 manufacturing facilities worldwide. When determining whether to take enforcement action, FDA applies a risk-based approach, assessing the seriousness of the violations; the risk of those violations to consumers; the company's responses to the violations; and whether the products may be medically necessary and in short supply. FDA's analysis produced a different conclusion for Teva's products from its Jerusalem facility than for Apotex's products from its Etobicoke and Signet facilities. This result demonstrates merely that FDA's expert assessments are fact-specific, not that FDA treated Teva more favorably than Apotex.<sup>545</sup>

342. The US defense as to Teva is deficient both on the law and on the facts. It is deficient on the law because Articles 1102 and 1103 require consistency in a Party's actions concerning covered investors and investments, even when an evaluation of the factual context forms part of the Party's considerations. Fact-specificity is the essence of "like circumstances" – the full factual context is to be taken into account in assessing whether

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<sup>543</sup> See *supra* para. 369

<sup>544</sup> US Counter-Memorial, para. 337.

<sup>545</sup> *Id.* (footnotes omitted).

the treatment accorded is less favorable.<sup>546</sup> The obligation imposed by Articles 1102 and 1103 is for the Party to ensure that it does not accord less favorable treatment to covered investors and investments in making determinations that depend on the circumstances. That the determination is fact-specific in no way establishes that the treatment is not less favorable. The US defense fails as a matter of law.

343. Nor does the record support the US defence on the facts. Although the US insists on the “fact-specific” nature of FDA’s assessments, it offers no evidence on FDA’s assessment of the facts.<sup>547</sup>

344. The only support referenced by the US on the alleged “risk-based approach” consists of FDA’s close-out letter to Teva and one paragraph in Dr. Rosa’s witness statement.<sup>548</sup> None explains how FDA’s “risk-based approach” was applied to Teva.

345. The September 9, 2011 close-out letter does not mention FDA’s “risk-based approach,” let alone how it may have been applied to Teva.<sup>549</sup> This short document merely states that FDA “completed an evaluation of [Teva’s] corrective actions in response to [the] Warning Letter” and concluded that Teva “ha[d] addressed the violation(s) contained in this Warning Letter.”<sup>550</sup>

346. The one paragraph in Dr. Rosa’s statement that the US cites similarly sheds no light on the case of Teva Jerusalem. At paragraph 20 of his statement, Dr. Rosa, who is in charge of CDER’s International Compliance Branch for drug manufacturing and

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<sup>546</sup> Memorial, para. 432 (“the ‘like circumstances’ inquiry is inherently context-specific”) (citing **Legal Authority CLA-20**, *Archer Daniels Midland Company and Tate & Lyle Ingredients Americas, Inc. v. The United Mexican States*, ICSID Case No. ARB/(AF)/04/04, Award, para. 197 (Nov. 21, 2007) (“all ‘circumstances’ in which the treatment was accorded are to be taken into account ...”); **Legal Authority CLA-42**, *Pope & Talbot Inc. v. The Government of Canada*, UNCITRAL, Award on the Merits of Phase 2, para. 75 (Apr. 10, 2001) (“By their very nature, ‘circumstances’ are context dependent and have no unalterable meaning across the spectrum of fact situations.”)).

<sup>547</sup> US Counter-Memorial, para. 337 (noting that FDA assesses “the seriousness of the violations; the risk of those violations to consumers; the company’s responses to the violations; and whether the products may be medically necessary and in short supply.” (citing Witness Statement of Carmelo Rosa, para. 20)).

<sup>548</sup> US Counter-Memorial, para. 337 & nn.828-829 (citing Witness Statement of Carmelo Rosa, para. 20 and **Exhibit C-256**, FDA Close-Out Letter to Teva, dated September 9, 2011).

<sup>549</sup> **Exhibit C-256**, FDA Close-Out Letter to Teva, dated September 9, 2011.

<sup>550</sup> *Id.*

quality, explains that CDER is responsible “for initiating enforcement action [against a drug manufacturer], when appropriate.”<sup>551</sup> He further states as follows:

We [CDER] carefully review and discuss all available information before initiating regulatory action. It is my responsibility to review relevant information – including the nature and significance of the violations, the firm’s regulatory history, the risk to public health, and, if the risk to public health does not require immediate action, the firm’s promised and ongoing corrective actions, past commitments made by the firm, and attempts or other efforts made by the FDA to allow the firm to voluntarily correct the problems – before deciding whether to take regulatory action.<sup>552</sup>

347. Dr. Rosa’s statement is general and does not explain how, in practice, FDA assessed the situation presented by Teva Jerusalem. The rest of Dr. Rosa’s statement does not address Teva either.
348. During the document production phase, Apotex requested documents showing how FDA applied its “risk-based approach” to Teva Jerusalem.<sup>553</sup> However, the US refused to produce such documents.<sup>554</sup>
349. The US has presented no evidentiary case for Apotex to meet as concerns Teva Jerusalem. The record establishes Apotex’s most-favored-nation treatment claim with respect to Teva.
350. To conclude, the record clearly shows that Apotex received less favorable treatment than both Sandoz / Novartis and Teva. Apotex has thus made out its case under NAFTA Article 1103.

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<sup>551</sup> Witness Statement of Carmelo Rosa, para. 20.

<sup>552</sup> *Id.*

<sup>553</sup> Claimants’ Requests for Production of Documents, Request No. 33(b) at 41-42 (Feb. 8, 2013) (“all Documents regarding FDA’s consideration of whether to take an enforcement action against the company [Teva], including any risk-based approaches used, including all Documents containing recommendations (either for or against) issuing the company a Warning Letter, placing the company on Import Alert 66-40, seeking an injunction, or seizing the company’s products.”).

<sup>554</sup> Respondent’s Responses and Objections to Claimants’ Requests for Production of Documents, Request No. 33(b) (March 1, 2013) (objecting to producing anything except final agency decisions). The Tribunal upheld the US objection.

2. *The US Treated Apotex Less Favorably Than the Comparators With Facilities Inside the United States*

351. As discussed above, with respect to the US-based comparators, the US presents a legal defense based only on the fact that the US facilities of Baxter, L. Perrigo, Hospira, Sandoz Inc. and Teva Parenteral are not eligible for import alert. However, for the reasons set out above, the US's legal defense must fail.

352. The US does not address *at all* the third prong of the test, i.e., less favorable treatment concerning the US facilities of Baxter, L. Perrigo, Hospira and Sandoz Inc.<sup>555</sup> Since the US does not contest Apotex's points in this respect, the US presents no case for Apotex to rebut. In the discussion that follows, Apotex recalls, for the convenience of the Tribunal, the case that it has presented in its Memorial and which stands undisputed.

a) *The US Does Not Dispute That Apotex Received Less Favorable Treatment Than Baxter*

353. As stated in the Memorial, Baxter Healthcare Corporation, a wholly owned subsidiary of Baxter International Inc., "sells finished drug products for human use" and "own[s] in excess of 100 ANDAs."<sup>556</sup> The US does not dispute that, aside from the location of its facilities, Baxter serves as an apt comparator.<sup>557</sup>

354. The US does not dispute that "Baxter Healthcare has a chronic corporate-wide history of serious FDA violations", evidenced by 21 warning letters issued by FDA from 1997 to 2011.<sup>558</sup> The US does not dispute that the 2010 inspection of Baxter's facilities in Puerto Rico "identified significant cGMP violations."<sup>559</sup> Nor does the US dispute that this 2010 inspection revealed repeat cGMP violations discovered during a previous

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<sup>555</sup> With respect to Teva Parenteral, the US argues in essence that the firm's voluntary actions alleviated the need for an import alert. *See* US Counter-Memorial, para. 336. However, for the reasons set out below, the US claim does not withstand scrutiny.

<sup>556</sup> Memorial, para. 302.

<sup>557</sup> *See* US Counter-Memorial, para. 333.

<sup>558</sup> Memorial, para. 303 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 113); US Counter-Memorial, para. 333. The US attempts to minimize the significance of these 21 warning letters by arguing that cGMP violations for *finished pharmaceutical* products had not been cited between 2001 and 2011. *See* US Counter-Memorial, para. 343 n.840. Sixteen of the 21 warning letters issued to Baxter since 1997 were for cGMP violations. These violations were in the areas of finished drug products (4), biologics (2), and devices (10).

<sup>559</sup> Memorial, para. 304

inspection in 2008, and that FDA not only allowed Baxter to respond to the recent inspectional findings before it issued the warning letter, but it had allowed Baxter two years to respond to and correct findings from the previous inspection – which Baxter failed to do.<sup>560</sup> The 2011 warning letter issued to Baxter identified, among others, product leaks, bursts, and premature activation.<sup>561</sup> Finally, the US does not dispute that FDA afforded Baxter more favorable treatment with respect to timely issuing the close-out letter within six months of issuing the 2011 warning letter.<sup>562</sup>

355. The US does not dispute any of Messrs. Bradshaw and Johnson’s findings with respect to FDA’s more favorable treatment of Baxter, which was permitted “to operate multiple facilities with ongoing serious violations for many years without FDA sanctions or interference.”<sup>563</sup>

356. In short, FDA did not take any enforcement action (such as an injunction or seizure) against any of Baxter’s non-compliant facilities or drugs. FDA accorded more favorable treatment to Baxter than to Apotex. The US does not contest this point.

*b) The US Does Not Dispute That Apotex Received Less Favorable Treatment Than Hospira*

357. Hospira is a US-owned pharmaceutical company. “Like Apotex-US, Hospira, Inc., directly or through its US subsidiaries, sells finished drug products for human use” and “owns in excess of 300 ANDAs.”<sup>564</sup> Other than the location of its manufacturing facilities, the US does not object to any other characteristic of Hospira that make it a suitable comparator.<sup>565</sup> In fact, the US does not dispute the evidence offered by Apotex regarding Hospira.

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<sup>560</sup> *Id.*, para. 305 (citing **Exhibit C-189**, Baxter Warning Letter, dated January 20, 2011); US Counter-Memorial, para. 333.

<sup>561</sup> **Exhibit C-189**, Baxter Warning Letter, dated January 20, 2011 at 2 (noting that “[t]hese are critical defects that can impact sterility and stability of [Baxter] product[s].”).

<sup>562</sup> *See* Memorial, para. 306; US Counter-Memorial, para. 333.

<sup>563</sup> Memorial, para. 307 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 117-18); US Counter-Memorial, para. 333.

<sup>564</sup> Memorial, para. 309.

<sup>565</sup> *See* US Counter-Memorial, para. 333.

358. The US does not dispute that the April 12, 2010 warning letter documents a long violative history of non-compliance of both the Rocky Mount and Clayton facilities in North Carolina, citing numerous repeat violations from previous inspections.<sup>566</sup> In particular, stainless steel particles were found in several injectables (including the anaesthetic drug propofol) and drug cartridges were overfilled (including morphine).<sup>567</sup> Nor does the US dispute that FDA has not taken any enforcement action against Hospira and, instead, has allowed this company to continue manufacturing and distributing drug products under conditions that violate cGMPs and cause Hospira drugs to be adulterated and even contaminated.<sup>568</sup>

359. The US does not object to any of the experts' conclusions, including that (1) FDA has allowed Hospira to operate its Rocky Mount and Clayton facilities in "serious violation of cGMPs" for many years; (2) FDA has allowed Hospira to release contaminated and adulterated drug products into the US leading to major recent recalls; (3) FDA has had to issue a public health advisory warning of contaminated and adulterated products; (4) FDA has not issued any enforcement action against Hospira; (5) "[t]he manner in which FDA has addressed Hospira's egregious violative conduct pales in comparison to the aggressive action it took against Apotex."<sup>569</sup>

360. It is undisputed that Hospira was accorded more favorable treatment than Apotex.

*c) The US Does Not Dispute That Apotex Received Less Favorable Treatment Than L. Perrigo*

361. Similarly, the US fails to address any of the evidence offered supporting L. Perrigo as a comparator. L. Perrigo Company is a wholly owned subsidiary of Perrigo Company. Like Apotex-US, L. Perrigo sells in the United States finished drug products for human

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<sup>566</sup> Memorial, para. 311 (citing **Exhibit C-143**, Hospira Warning Letter, dated April 12, 2010); US Counter-Memorial, para. 333.

<sup>567</sup> See **Exhibit C-452**, Letter from Jeanne Ireland, FDA Assistant Commissioner for Legislation to The Hon. Elijah E. Cummings, dated July 23, 2012 at 4 (drug cartridges, including morphine, were overfilled "by as much as twice the indicated amount, a defect that could lead to incorrect dosing, respiratory distress, and in severe cases, death.").

<sup>568</sup> See Memorial, para. 312; US Counter-Memorial, para. 333.

<sup>569</sup> Memorial, para. 313 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 134); US Counter-Memorial, para. 333.

use manufactured by Perrigo Company's subsidiaries.<sup>570</sup> Again, the US's only objection to this comparator regards the location of its manufacturing facilities.<sup>571</sup>

362. The US does not dispute that FDA cited L. Perrigo for its failure to observe cGMPs and that this failure "led directly to the release of contaminated drug products to the US market."<sup>572</sup> For example, L. Perrigo released in the United States Ibuprofen Tablets contaminated with metal shavings<sup>573</sup> and failed to prevent "mix ups" of drugs.<sup>574</sup> It is also undisputed that "FDA took no action to interrupt the operations of the company."<sup>575</sup> The US does not contest any of the experts' conclusions regarding Perrigo and L. Perrigo, including that FDA allowed the company to manufacture and distribute drugs on the US market that violated cGMPs and were adulterated and contaminated.<sup>576</sup> In addition, it is undisputed that L. Perrigo received a close-out letter about a year after the warning letter was issued.<sup>577</sup>

363. Finally, the US does not dispute that Apotex suffered a complete ban from the US market, "even though it did not have a history of non-compliance and had not produced hazardous drugs[]," like Perrigo did.<sup>578</sup> Despite the fact that L. Perrigo was distributing contaminated and misbranded drugs in the US, FDA took no action to interrupt the operations of L. Perrigo and did not prevent that company from continuing business as usual.<sup>579</sup>

364. As such, the US afforded less favorable treatment to Apotex than to Perrigo and L. Perrigo. The US does not contest this conclusion or the reasons thereof.

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<sup>570</sup> See Memorial, para. 315.

<sup>571</sup> See US Counter-Memorial, para. 333.

<sup>572</sup> Memorial, para. 317; US Counter-Memorial, para. 333.

<sup>573</sup> **Exhibit C-146**, L. Perrigo Warning Letter, dated April 29, 2010 at 1-2.

<sup>574</sup> *Id.* at 2-3.

<sup>575</sup> Memorial, para. 319 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 124); US Counter-Memorial, para. 333.

<sup>576</sup> Memorial, para. 319 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 124); US Counter-Memorial, para. 333.

<sup>577</sup> Memorial, para. 318.

<sup>578</sup> *Id.*, para. 319 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 124); US Counter-Memorial, para. 333.

<sup>579</sup> See Memorial, para. 319 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 124); US Counter-Memorial, para. 333.

d) *The US Does Not Dispute That Apotex Received Less Favorable Treatment Than Sandoz Inc.*

365. Sandoz Inc. is part of the generic division of Novartis AG, a Swiss company. Sandoz Inc. distributes in the United States drug products for human use manufactured by other arms of the Novartis Group, which own in total an excess of 600 ANDAs.<sup>580</sup> The US does not dispute that Sandoz Inc.'s US facilities would make an apt comparator but for their location.<sup>581</sup>
366. The US does not dispute that FDA inspected Sandoz Inc.'s facilities in Wilson, North Carolina and Broomfield, Colorado and found severe and repeat cGMP violations that led to the issuance of a "corporate" warning letter.<sup>582</sup> As mentioned above, the FDA took a coordinated approach and inspected these two US facilities together with the Canadian facility of Sandoz Canada (located in Boucherville, Quebec). The three facilities were the object of the same warning letter issued to the Chief Executive Officer of Novartis.<sup>583</sup>
367. The US does not dispute FDA's concern that Novartis was "not providing sufficient oversight and control of the state of compliance at its [] facilities... ." <sup>584</sup> The warning letter requested Novartis to contact FDA to arrange a meeting, which was unusual and indicated a "high level of concern by FDA." <sup>585</sup> Again, this point is uncontested.<sup>586</sup>
368. It is also uncontested that FDA did not take any enforcement action against any Sandoz Inc. facilities to address "the chronic and documented ongoing, corporate-wide non-compliance of Novartis Sandoz ... ." <sup>587</sup> Pharmaceutical drugs manufactured at these

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<sup>580</sup> See Memorial, paras. 322-23.

<sup>581</sup> US Counter-Memorial, para. 333.

<sup>582</sup> See Memorial, paras. 324-25 (citing **Exhibit C-273**, Novartis Warning Letter, dated November 18, 2011); US Counter-Memorial, para. 333.

<sup>583</sup> See Memorial, para. 325; **Exhibit C-273**, Novartis Warning Letter, dated November 18, 2011.

<sup>584</sup> Memorial, para. 324 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 139); US Counter-Memorial, para. 333.

<sup>585</sup> Memorial, para. 326 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 140).

<sup>586</sup> US Counter-Memorial, para. 333.

<sup>587</sup> Memorial, para. 326 (quoting Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 141); US Counter-Memorial, para. 333.

facilities have not been banned from the US market, contrary to Apotex's drugs from Etobicoke and Signet.

369. Furthermore, FDA re-inspected Sandoz Inc.'s facility in Broomfield, Colorado in August 2012 and found it cGMP-compliant.<sup>588</sup> In other words, it took FDA nine months from the issuance of the Warning Letter to re-inspect this facility and classify it as cGMP compliant. In the case of Apotex, FDA delayed the re-inspection of Etobicoke and Signet (from November 2010 to January-February 2011) and it then took several months to lift the Import Alert (the Import Alert was removed on June 15, 2011 for Etobicoke and July 29, 2011 for Signet).<sup>589</sup> Once again, the difference in treatment between Apotex and Sandoz Inc. is obvious.

e) *The Record Shows that Teva Parenteral Received Less Favorable Treatment than Apotex*

370. The US does not dispute that FDA's inspection of the Irvine site revealed serious cGMP violations that led to the issuance of a warning letter on December 11, 2009.<sup>590</sup> For instance, "[t]he inspection confirmed the presence of endotoxins in finished product, which are parts of bacteria cells that if injected into the body cause a severe fever and even death."<sup>591</sup> Teva Parenteral had to recall multiple lots of propofol manufactured at this facility after a total of 41 reported patients suffered from post-operative chills and flu-like symptoms due to elevated levels of endotoxins in this product.<sup>592</sup> By contrast, Apotex products never contaminated any patient.<sup>593</sup>

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<sup>588</sup> See **Exhibit C-458**, Novartis AG, Form F-20 for Fiscal Year 2012 dated January 23, 2013 at 79 ("In the fourth quarter of 2012, Sandoz announced that the FDA upgraded the compliance status of its Broomfield, Colorado site."); **Exhibit C-454**, FiercePharma Manufacturing, "FDA confirms Novartis plant, renewing CEO's confidence", November 13, 2012 ("The FDA confirmed on November 7, 2012 that our Sandoz manufacturing site in Broomfield, Colorado ... has achieved positive compliance status following a re-inspection in August. ... Wilson and Boucherville are currently pending FDA re-inspection ...").

<sup>589</sup> See Memorial, paras. 248-60, 266-76.

<sup>590</sup> US Counter-Memorial, para. 336 (citing **Exhibit C-124**, Teva Parenteral Warning Letter, dated December 11, 2009).

<sup>591</sup> **Exhibit C-452**, Letter from Jeanne Ireland, FDA, Assistant Commissioner for Legislation to The Hon. Elijah E. Cummings, dated July 23, 2012 at 4. Teva Parenteral also failed to control aseptic conditions. See *id.*

<sup>592</sup> *Id.* at 6.

<sup>593</sup> See Second Witness Statement of Jeremy Desai, para. 22.

371. Despite the severity of Teva Parenteral’s cGMP problems, FDA took no enforcement action against this company. The US wrongly claims that “there was no need for FDA to undertake any enforcement action (such as a seizure or an injunction), given that the company voluntarily shut down production for more than a year to address the cCMP [sic] violations.”<sup>594</sup>
372. *First*, as discussed above, Articles 1102 and 1103 address the treatment afforded by a NAFTA Party.<sup>595</sup> A firm’s voluntary action cannot compare with State action. Here, FDA did not require Teva Parenteral to stop production at Irvine,<sup>596</sup> whereas it imposed the Import Alert on Apotex. As a consequence, Teva Parenteral was free to resume production and distribution when it wished, while Apotex had to secure re-inspection and clearance by FDA.
373. *Second*, FDA allowed Teva Parenteral to resolve its cGMP problems before deciding whether or not to take any enforcement action (such as an injunction or seizure). As noted by Messrs. Bradshaw and Johnson, “[t]he company submitted at least 6 responses to the inspectional findings.”<sup>597</sup> Apotex, in contrast, was put on Import Alert immediately after the Signet inspection and before it could submit any substantive response to FDA’s inspectional observations.
374. *Third*, Apotex remained on Import Alert for two years, which is twice as long as the voluntary shutdown at Irvine.<sup>598</sup> In short, the treatment afforded each company differs significantly and was less favorable to Apotex.

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<sup>594</sup> US Counter-Memorial, para. 336.

<sup>595</sup> *See supra* para. 318 (discussing NAFTA Article 1103). The relevant language in NAFTA Article 1102 is identical (“Each Party shall accord to investors of another Party [and their investments] treatment no less favorable than that *it accords*, in like circumstances, to its own investors [and their investments] ... .” (emphasis added)).

<sup>596</sup> *See Exhibit C-452*, Letter from Jeanne Ireland, FDA, Assistant Commissioner for Legislation to The Hon. Elijah E. Cummings, dated July 23, 2012 at 3 (“FDA did not require the firms to shut down and even worked with each of them to try to avoid a shutdown, offering assistance to help assess and address manufacturing and quality concerns.”).

<sup>597</sup> Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 143.

<sup>598</sup> US Counter-Memorial, para. 336 (“... the company voluntarily shut down production for more than a year ... .”).

375. In sum, with respect to Baxter, Hospira, L. Perrigo, Sandoz Inc. and Teva Parenteral, the US's defense – which must be rejected – is that they are not apt comparators because their US facilities cannot be placed on import alert. However, the US does not contest any other point made with respect to these comparators. The US does not dispute that FDA found very serious cGMP violations at Baxter's, Hospira's, L. Perrigo's, Sandoz Inc.'s and Teva Parenteral's US facilities such that FDA issued warning letters to these companies. Although drugs manufactured at these facilities were adulterated (and sometimes even contaminated), they were never banned from the US market. In contrast, Apotex's drugs from Etobicoke and Signet were banned from the US market for two years. The US does not dispute that Apotex received less favorable treatment than that afforded to the US comparators.
376. For the foregoing reasons, Apotex has established all of the elements for a breach of national treatment under NAFTA Article 1102 and most-favored-nation treatment under NAFTA Article 1103.

3. *Apotex Does Not Compare to a Felon Like Ranbaxy*

377. The expert report of Messrs. Johnson and Bradshaw cited in a *single footnote* the consent decree of permanent injunction against Ranbaxy. Apotex never presented Ranbaxy as a potential comparator for its most-favored-nation treatment claim. Rather, Apotex's point was that a company can be subject to both an import alert and a consent decree of seizure or injunction.<sup>599</sup> However, the US argues that Ranbaxy may be “an apt comparator” for Apotex's most-favored-nation treatment claim.<sup>600</sup> It is the US's burden to prove its assertion.<sup>601</sup> The US fails to meet that burden.
378. The US wrongly states that “Ranbaxy may be an apt comparator, given that FDA sent Ranbaxy warning letters identifying cGMP problems at two of Ranbaxy's foreign facilities that were similar to those found at Apotex's Etobicoke and Signet facilities,”

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<sup>599</sup> Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 81 n.107 (citing **Legal Authority CLA-202A**, Ranbaxy Consent Decree of Permanent Injunction, Case 1:12-cv-00250 (JFM) (D. Md. Jan. 25, 2012). Ranbaxy was Indian-owned until a Japanese company, Daiichi Sankyo Co., bought a controlling stake in 2012.

<sup>600</sup> US Counter-Memorial, para. 338.

<sup>601</sup> *See supra*, Evidence: Burden of Proof.

and FDA adopted an import alert against Ranbaxy.<sup>602</sup> However, this is only part of the story about Ranbaxy.

379. The violations committed by Ranbaxy went far beyond mere “cGMP problems.”<sup>603</sup> In fact, Ranbaxy recently agreed to settle alleged civil violations of the False Claims Act with the U.S., all 50 states and the District of Columbia.<sup>604</sup> The claims were that Ranbaxy had knowingly and deliberately manufactured and sold drugs that did not have the strength, purity or quality they purported to have, and various government agencies had purchased the defective drugs based on false information. In addition, Ranbaxy USA pleaded guilty to felony charges of knowingly making material false statements to FDA and committing felony violations of the Food, Drug and Cosmetic Act.<sup>605</sup> In pleading guilty to the felony charges under the Act, Ranbaxy USA waived any defense that it had acted in good faith.<sup>606</sup> Apotex acted in good faith and never made any false statement to FDA. FDA never accused Apotex of bad faith, false claims or criminal acts. Ranbaxy clearly is in circumstances unlike those of Apotex.
380. The US authorities had discovered in the course of a complex investigation that Ranbaxy had submitted false information to FDA.<sup>607</sup> Notably, the US suspected that Ranbaxy had violated the Act by introducing adulterated or misbranded drug products

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<sup>602</sup> *Id.*, 338. See also *id.*, para. 334 n.821 (“Ranbaxy, however, appears to have been in circumstances most like Apotex’s, because both companies received multiple warning letters identifying cGMP violations at more than one foreign facility”).

<sup>603</sup> *Id.*, para. 338.

<sup>604</sup> **Exhibit C-473**, US Dep’t of Justice News Release, Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay \$500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA (May 13, 2013).

<sup>605</sup> *Id.*

<sup>606</sup> Memorial, para. 134 & n.157 (describing defense provided by Act for those who deliver or receive adulterated drugs in good faith).

<sup>607</sup> Ranbaxy’s Pahonta Sahib facility in India was issued a warning letter on June 15, 2006. FDA re-inspected the API (active pharmaceutical ingredient) site of the Pahonta Sahib facility in late January 2007. In early February 2007, FDA executed search warrants at Ranbaxy’s facilities in New Jersey. In December 2007, the government served Ranbaxy with an administrative subpoena for the production of documents, which it sought to enforce in July 2008, after FDA inspected Ranbaxy’s Dewas and Paonta Sahib (Batamandi) facilities in early 2008. See **Legal Authority CLA-543**, Motion to Enforce Subpoenas and Points and Authorities, *United States v. Ranbaxy, Inc.*, No. 08-cv-1764 at 14-15 (D. Md. July 3, 2008).

into interstate commerce “with the intent to defraud or mislead[.]”<sup>608</sup> The US also alleged conspiracy, false statements and health care fraud on the part of Ranbaxy.<sup>609</sup>

381. On September 16, 2008, FDA issued two Warning Letters against Ranbaxy’s Paonta Sahib (Batamandi) and Dewas facilities in which FDA announced that these facilities had been placed on import alert.<sup>610</sup>
382. On February 25, 2009, FDA placed Ranbaxy Paonta Sahib facility on Application Integrity Policy (AIP).<sup>611</sup> This policy focuses on how FDA should approach the review of applications that may be affected by wrongful acts that raise significant questions regarding data reliability.<sup>612</sup> FDA observed “a pattern and practice of submitting untrue statements of material fact and other wrongful conduct, which raise significant questions regarding the reliability of the data and information contained in applications (pending and approved)” filed by Ranbaxy.<sup>613</sup> As a result, the Agency stopped “its normal substantive scientific review” of pending and new applications originating from Paonta Sahib.<sup>614</sup> The fact that Ranbaxy was placed on FDA’s Application Integrity

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<sup>608</sup> *Id.* at 2.

<sup>609</sup> *Id.* See also *id.* at 3 (“a pattern of systemic fraudulent conduct, including submissions by Ranbaxy to the FDA that contain false and fabricated information about stability and bioequivalence, failure to timely report the distribution of drugs that were out-of-specifications (‘OOS’), and attempts to conceal violations of current Good Manufacturing Practices (‘cGMP’) regulations from the FDA.”). Eventually, the government withdrew its motion to enforce subpoenas in the fall of 2008 after Ranbaxy agreed to produce the requested documents. See **Legal Authority CLA-544**, Notice of Withdrawal of Motion, *United States of America v. Ranbaxy, Inc., et al.*, Civil No. PJM-08-1764 (D. Md. October 6, 2008).

<sup>610</sup> **Exhibit C-329**, Ranbaxy Dewas Warning Letter, WL 320-08-03, dated September 16, 2008 at 12 (“... shipments of articles manufactured by your firm are subject to refusal of admission pursuant to Section 801(a)(3) of the [Act].”); **Exhibit C-330**, Ranbaxy (Batamandi) Paonta Sahib Warning Letter, WL 320-08-02, dated September 16, 2008 at 6 (same). Note that the Batamandi site was under the same production and quality management as the Paonta Sahib site that received a prior Warning Letter in 2006. FDA thus treated the Batamandi facility as part of the existing Paonta Sahib facility. See *id.* at 1.

<sup>611</sup> **Exhibit C-341**, Letter from FDA to Ranbaxy, dated February 25, 2009. See also **Exhibit C-437**, Excerpts from FDA website, Application Integrity Policy List (last updated on October 12, 2011).

<sup>612</sup> See **Exhibit C-323**, Excerpt from FDA’s website, Application Integrity Policy at 2 (March 5, 1998), available at <http://www.fda.gov/downloads/ICECI/EnforcementActions/ApplicationIntegrityPolicy/UCM072631.pdf> (last visited on May 21, 2013).

<sup>613</sup> **Exhibit C-341**, Letter from FDA to Ranbaxy, dated February 25, 2009, para. 7.

<sup>614</sup> *Id.*

Policy places it in circumstances unlike Apotex, as was reported in the specialized press.<sup>615</sup>

383. On January 25, 2012, the US Department of Justice (DOJ) filed a consent decree against Ranbaxy at the request of FDA.<sup>616</sup> That consent decree addresses “outstanding current good manufacturing practice (CGMP) and data integrity issues at Ranbaxy’s Paonta Sahib, Batamandi and Dewas, India facilities as well as CGMP issues at Ranbaxy Inc.’s wholly owned subsidiary Ohm Laboratories facility located in Gloversville, N.Y.”<sup>617</sup> The government determined, among other things, that Ranbaxy had submitted false data in drug applications to FDA, “including the backdating of tests and the submitting of test data for which no test samples existed.”<sup>618</sup> And as already mentioned, Ranbaxy recently agreed to a settlement with the US Department of Justice and pleaded guilty to various charges.
384. Apotex never committed any criminal offense. Apotex did not submit false data to FDA and was never placed on Application Integrity Policy. Apotex did not introduce adulterated products into interstate commerce “with the intent to defraud or mislead[.]” Apotex was not accused of conspiracy, false statements, and health care fraud. Apotex was not the object of an investigation by the DOJ and did not plead guilty to criminal charges. And above all, Apotex products never caused any health hazard.
385. On this record, it is clear that Ranbaxy was not in like circumstances with Apotex.<sup>619</sup>
386. Even assuming for the sake of the argumentation that Apotex and Ranbaxy could be deemed in like circumstances (which is not the case), Ranbaxy still received better treatment than Apotex. *First*, Ranbaxy was not placed on import alert until more than

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<sup>615</sup> **Exhibit C-432**, Internal FDA Email Chain, dated May 16, 2011 at US7114 (copying text of The Pink Sheet, *FDA Import Alert Lifted, Apotex Says; Will Lipitor ANDA Approvals Be Far Behind* (May 16, 2011) (“Clearly, the Indian generic drug maker’s problems are more serious than those of Apotex, as evidenced by its placement on FDA’s Application Integrity Policy list in February 2009.”)).

<sup>616</sup> **Exhibit R-88**, US Dep’t of Justice News Release, U.S. Files Consent Decree for Permanent Injunction Against Pharmaceutical Ranbaxy Laboratories (Jan. 25, 2012).

<sup>617</sup> **Exhibit R-87**, FDA News Release, Department of Justice Files Consent Decree of Permanent Injunction Against Ranbaxy at 1 (Jan. 25, 2012).

<sup>618</sup> **Exhibit R-88**, US Department of Justice News Release, U.S. Files Consent Decree for Permanent Injunction Against Pharmaceutical Ranbaxy Laboratories at 1 (Jan. 25, 2012).

<sup>619</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 53.

two years after receiving the 2006 warning letter for Paonta Sahib. In the case of Apotex, the Import Alert became effective two months after the first warning letter issued to the firm.<sup>620</sup> *Second*, Ranbaxy was afforded opportunities to correct the problems before FDA decided to take enforcement action. FDA acknowledged that it “had a lot of work with [Ranbaxy] to try to correct the deficiencies” and in 2008 FDA gave Ranbaxy “an opportunity to come back and tell [FDA] how they were going to correct those deficiencies and they did ... but again we [FDA] weren’t satisfied.”<sup>621</sup> Apotex was never given a chance to correct its cGMP problems before it was placed on Import Alert. *Third*, the Ranbaxy consent decree had to be reviewed and approved by an independent federal judge following written and oral briefing from all impacted parties, supported by appropriate documentation,<sup>622</sup> whereas Apotex was placed on Import Alert without the barest strappings of due process.

387. Contrary to the US assertion, Ranbaxy is not an “apt comparator” because it was not in like circumstances with Apotex – and even if it were, Ranbaxy still received better treatment than Apotex.
388. Finally, the US’s reliance on *Thunderbird* is misplaced for two main reasons.<sup>623</sup> *First*, the tribunal in that case concluded that the Mexican authorities enforced anti-gambling laws against all known domestic and foreign investors indiscriminately, such that there was no difference in treatment.<sup>624</sup> In contrast, in the case at bar, FDA took enforcement action against Apotex but not against comparable US-owned or third-country-owned investors. Far from supporting the US, *Thunderbird* thus supports the opposite conclusion. *Second*, the US erroneously insists on *obiter dicta* in *Thunderbird*, in which the tribunal noted the illicit character of gambling activities in Mexico.<sup>625</sup> However,

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<sup>620</sup> *Id.*

<sup>621</sup> **Exhibit C-331**, FDA, Transcript of Media Briefing on Ranbaxy, dated September 17, 2008 at US450.

<sup>622</sup> *See* Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 155-59 (addressing consent decree in general).

<sup>623</sup> US Counter-Memorial, para. 343.

<sup>624</sup> **Legal Authority CLA-30**, *International Thunderbird Gaming Corporation v. United Mexican States*, UNCITRAL, Award, para. 182 (Jan. 26, 2006). The tribunal found that the Mexican-owned facilities that remained opened were exceptions – they could not be closed because of ongoing legal proceedings or they were clandestine facilities unknown to the authorities. *Id.* at paras. 179-80.

<sup>625</sup> US Counter Memorial, para. 343 (quoting **Legal Authority CLA-30**, *International Thunderbird Gaming Corporation v. United Mexican States*, UNCITRAL, Award, para. 183 (Jan. 26, 2006) (“In the Tribunal’s

there is no suggestion in the present arbitration that Apotex or any of the comparators it selected committed criminal acts.<sup>626</sup>

## II. THE IMPORT ALERT DENIED APOTEX THE DUE PROCESS REQUIRED BY INTERNATIONAL LAW

389. Contrary to the US's assertion, Apotex has amply demonstrated that the US denied Apotex's investments the minimum standard of treatment compelled by NAFTA Article 1105. The US failed to accord Apotex the due process required by customary international law and US treaty practice when imposing the Import Alert. The US argument misses the mark in four fundamental respects, as shown in the pages that follow.

390. First, the US errs in suggesting a distinction in customary international law between due process rights in administrative adjudication and in administrative decision-making. State practice, however, does not support the artificial distinction posited by the US. To the contrary, State practice and *opinio juris* require administrative authorities to provide procedural safeguards in proceedings of any kind that decide the rights and interests of individual persons. Those safeguards were recognized as blackletter law in the 1965 *Restatement of the Law (Second) – Foreign Relations Law of the United States*:

[A] trial or other proceeding to determine the rights or liabilities of an alien must be fair. In determining whether the proceeding is fair, it is relevant to consider, among other factors whether the alien has had the benefit of

(a) An impartial ... administrative authority,

(b) Adequate information with respect to the nature of the proceedings so as to permit the alien to present his claim or defense,

...

(d) Reasonable opportunity to contest evidence against him,

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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.”)).

<sup>626</sup> As just discussed, Ranbaxy pleaded guilty to criminal charges, whereas Apotex was never accused of any criminal offense. Ranbaxy is not a proper comparator.

(e) Reasonable opportunity to obtain and present witnesses and evidence in his own behalf ...<sup>627</sup>

391. Contrary to the US's assertion, such a rule is not new.<sup>628</sup> Apotex demonstrated its existence in a variety of well-established sources of customary international law, including US treaty practice, foreign state practice, and domestic and international arbitral case law, as well as authoritative restatements of law and legal scholarship that reflect that status.
392. Second, the US's suggestion that FDA accorded basic due process in adopting the Import Alert does not withstand scrutiny. The record shows that FDA CDER did not act as an impartial administrative authority in adopting the Import Alert that it itself proposed, and that FDA DIOP did not act as a reviewing authority. Nor does it provide any support for the argument advanced in the Counter-Memorial – but nowhere reflected in any contemporaneous document – that adoption of the Import Alert without any notice or opportunity to present a defense was compelled by a risk that Apotex would “flood the US market”. The record shows that the Import Alert was adopted with no notice, no opportunity to contest the assertions and no statement of reasons for the decision.
393. Third, there is equally little merit to the US argument that, after the Import Alert was imposed, Apotex could have availed itself of several supposed “avenues” in order to seek redress. However, under established international law, these remedies were inadequate, being neither available nor effective in providing Apotex with due process rights or the relief Apotex sought.
394. Fourth, the US's failure to provide procedural safeguards also breached the US-Jamaica bilateral investment treaty (“BIT”). The US erroneously implies that Apotex invokes NAFTA's MFN clause to expand the scope of Article 1105. Rather, Apotex has demonstrated that substantive provisions of the US-Jamaica BIT properly apply by virtue of NAFTA Article 1103. Apotex has also demonstrated that the BIT contains a

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<sup>627</sup> **Legal Authority RLA-138**, American Law Institute, *Restatement of the Law (Second) – Foreign Relations Law of the United States* § 181 (1965).

<sup>628</sup> US Counter-Memorial, para. 345.

set of various standards of treatment, including, among others, the investor's right to effective means for asserting claims. This provision, like other international law authorities, makes no distinction between administrative "adjudication" and "decision-making".

**A. Customary International Law Requires Due Process in Administrative Decision-Making**

395. The US errs in suggesting that due process rights in administrative decision-making are not required under customary international law.<sup>629</sup>

396. *First*, while the parties agree that "[c]ustomary international law is derived from the general and consistent practice of States followed from a sense of legal obligation[.]" the US does not address the State practice and *opinio juris* Apotex has assembled in support of this customary international law obligation.<sup>630</sup> Apotex has demonstrated that a variety of international law sources reflect a consensus that due process is required in administrative decision-making.

397. *Second*, these authoritative sources of customary international law do not distinguish, as the US incorrectly does, between the procedural safeguards required in administrative adjudication and those required in administrative decision-making proceedings more generally. The US has provided no support for such an artificial distinction. The fact that the decision to impose the Import Alert involves discretion does not obviate the requirement of due process safeguards.

*1. Customary International Law Requires Due Process in Decisions on Persons' Rights and Interests*

398. The US errs in suggesting that sufficiently broad State practice and *opinio juris* have failed to establish minimum standards of State conduct with respect to due process requirements. As Apotex has demonstrated, there is considerable international authority in support of this settled position.

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<sup>629</sup> See US Counter-Memorial, para. 346.

<sup>630</sup> *Id.*, para. 345.

399. NAFTA Article 1105 incorporates “certain fundamental protections to foreign investors” that are “rooted in the customary international law of protection of aliens.”<sup>631</sup> Of course, “any general requirement to accord ‘fair and equitable treatment’ and ‘full protection and security’ must be disciplined by being based upon State practice and judicial or arbitral caselaw or other sources of customary or general international law.”<sup>632</sup>

400. The record establishes general State practice and *opinio juris* on the due process that must be provided in administrative proceedings. The material sources of custom include varied manifestations of State positions, including:

diplomatic correspondence, policy statements, press releases, the opinions of government legal advisers, official manuals on legal questions (e.g. manuals of military law), executive decisions and practices, orders to military forces (e.g. rules of engagement), comments by governments on ILC drafts and accompanying commentary, legislation, international and national judicial decisions, recitals in treaties and other international instruments (especially when in ‘all states’ form), an extensive pattern of treaties in the same terms, the practice of international organs, and resolutions relating to legal questions in UN organs, notably the General Assembly.<sup>633</sup>

401. Thus, “trustworthy evidence of what [international] law really is” can be found in a wide range of evidence proffered by Apotex, including “the works of jurists and commentators, who by years of labor, research and experience, have made themselves peculiarly well acquainted with the subjects of which they treat.”<sup>634</sup> This includes

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<sup>631</sup> **Legal Authority CLA-584**, Meg N. Kinnear, Andrea K. Bjorklund, & John F.G. Hannaford, *Investment Disputes Under NAFTA – An Annotated Guide to Chapter 11* at 1105-6 to 1105-7 (Kluwer Law International 2006).

<sup>632</sup> **Legal Authority CLA-18**, *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Award, para. 184 (Jan. 9, 2003).

<sup>633</sup> **Legal Authority CLA-583**, James Crawford, *Brownlie’s Principles of Public International Law* 24 (Oxford University Press 8th ed. 2012) (footnote omitted). See also **Legal Authority CLA-585**, Michael Akehurst, *Custom as a Source of International Law*, 47 Brit. Y.B. Int’l L. 1, 11 (1975) (Because “the practice of international organizations can also create rules of customary law[,]” European Union decisions may be seen as both reflective of the practice of the Member States and represent the practice of a supranational organization. On administrative procedure, they reflect a synthesis of the legal systems and constitutional traditions of the Member States.).

<sup>634</sup> **Legal Authority CLA-554**, *The Paquete Habana*, 175 U.S. 677, 700 (1900); **Legal Authority CLA-515**, *S.S. Lotus* (Fr. v. Turk.), 1927 P.C.I.J. (ser. A) No. 10 at 31 (Sept. 7) (“The Court ... observes that in the

comparisons of the laws of different countries, national laws, regulations and judgments.<sup>635</sup>

402. Contrary to the US's assertion that "Apotex offers no relevant State practice[.]"<sup>636</sup> Apotex has offered numerous well-established sources of customary international law in support of its position, including State practice,<sup>637</sup> national and international case law,<sup>638</sup>

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fulfillment of its task of itself ascertaining what the international law is, it has not confined itself to a consideration of the arguments put forward, but has included in its researches all precedents, *teachings* and facts to which it had access and which might possibly have revealed the existence of one of the principles of international law contemplated in the special agreement." (emphasis added)).

<sup>635</sup> See **Legal Authority CLA-585**, Michael Akehurst, *Custom as a Source of International Law*, 47 Brit. Y.B. Int'l L. 1, 9 (1975) ("There have been many cases where national courts have inferred the existence of rules of customary international law from a comparison of the laws of different countries, on questions ranging from diplomatic immunity to ships' lights, and the rights of enemy fishing vessel ... . Moreover, the International Law Commission and other bodies engaged in codification always treat national laws, regulations and judgments 'as primary evidence of State practice'.") (footnotes omitted).

<sup>636</sup> US Counter-Memorial, para. 367.

<sup>637</sup> See Memorial, para. 465 (citing **Legal Authority CLA-331**, Francesca Bignami, *From Expert Administration to Accountability Network: A New Paradigm for Comparative Administrative Law*, 59 Am. J. Comp. L. 859, 897-98 (2011), and noting that the laws of France, Italy, Sweden, Denmark, Germany, Spain, Peru, Argentina, Costa Rica, Colombia, Japan and South Korea all contain principles of fair administrative proceedings. That there is widespread State practice requiring procedural fairness in administrative actions is further evidenced by laws on the right of access to public documents, which encourage public oversight, transparency, and impartiality in administrative actions. See *id.* at 903-04.) See also Memorial, para. 467 (noting that "[p]rinciples of fair administration are embodied in supra-national legal orders, such as the laws of the European Union (EU) and the jurisprudence of the World Trade Organization (WTO)" and "have been set out in the case-law of international human rights courts, such as the European Court of Human Rights (ECHR) and the Inter-American Court of Human Rights (IACHR)[.]" (footnotes omitted); **Legal Authority CLA-589**, Srvulo Correia, *Administrative Due or Fair Process: Different Paths in the Evolutionary Formation of a Global Principle and of a Global Right*, in *Values in Global Administrative Law*, para. 13 (G. Anthony, J.B. Auby, J. Morison & T. Zwart eds., Hart Publishing 2011) (Constitutions of Spain, Greece and Portugal provide individuals with a right to a hearing in administrative proceedings which may lead to a decision affecting their interests.); **Legal Authority CLA-556**, *Office of the Ombudsman v. Reyes*, G.R. No. 170512 at 13 (S.C., Oct. 5, 2011) (Phil.), available at <http://sc.judiciary.gov.ph/jurisprudence/2011-october2011/170512.htm> ("[D]ue process in administrative proceedings requires compliance with the following cardinal principles: (1) the respondents' right to a hearing, which includes the right to present one's case and submit supporting evidence, must be observed; (2) the tribunal must consider the evidence presented; (3) the decision must have some basis to support itself; (4) there must be substantial evidence; (5) *the decision must be rendered on the evidence presented at the hearing, or at least contained in the record and disclosed to the parties affected*; (6) in arriving at a decision, the tribunal must have acted on its own consideration of the law and the facts of the controversy and must not have simply accepted the views of a subordinate; and (7) the decision must be rendered in such manner that respondents would know the reasons for it and the various issues involved.") (emphasis in original).

<sup>638</sup> See Memorial, paras. 465 & n.655, 463 n.649, 467 nn. 658-61 (collecting examples under national law, international arbitral decisions under various investment agreements that recognize that the executive's failure to accord due process breaches the fair and equitable standard, and decisions of supra-national legal orders and international human rights courts).

and authoritative restatements of law and legal scholarship that reflect that status.<sup>639</sup> It cannot be disputed that such manifestations are able to establish *opinio juris*, especially when they emanate from authorities representing the State in international relations.<sup>640</sup>

403. Nor should the Tribunal credit the US's meritless suggestion to disregard the *Restatement* as a "soft law source[]." <sup>641</sup> The *Restatement* is a widely regarded and authoritative restatement of law that codifies custom and reflects the status of international law.<sup>642</sup> Due to its authoritativeness, the United States Supreme Court has cited to the *Restatement (Second) and (Third) of the Foreign Relations Law* numerous times.<sup>643</sup> More importantly, the US's assertion is belied by the many times the US Government has itself cited to the *Restatement* with approval in this and other arbitrations.<sup>644</sup>

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<sup>639</sup> *Id.*, paras. 460 & n.645, 462 n.648.

<sup>640</sup> See **Legal Authority CLA-582**, Custom, 1 Whiteman Digest § 6 (1963) (quoting J.L. Brierly, *The Law of Nations*, 60-63 (5th ed. 1955) ("Such evidence [of State custom] will obviously be very voluminous and also very diverse. There are multifarious occasions on which persons who act or speak in the name of a state do acts or make declarations which either express or imply some view on a matter of international law . . . . Particularly important as sources of evidence are diplomatic correspondence; official instructions to diplomatists, consults, naval and military commanders; acts of state legislation and decisions of state courts, . . . and opinions of law officers, especially when these are published, as they are in the United States.")).

<sup>641</sup> US Counter-Memorial, para. 346.

<sup>642</sup> For a discussion of how the history of the drafting of the *Restatement (Second) of the Foreign Relations Law* reveals that the drafters sought to clarify and compile the law, as an international tribunal would apply it, see generally, **Legal Authority CLA-581**, Charles H. Brower II, *Hollow Spaces (The Omission of Drafting Standards in the Draft Restatement of the U.S. Law of International Commercial Arbitration)* at 8-9 (undated) (unpublished manuscript; to be published in 61 Buff. L. Rev. (forthcoming Aug. 2013)) (noting that the final draft of the *Restatement* that was adopted in 1965 incorporated the standard proposed in Council Draft No. 1 in 1956, which sought to reflect "the rules that an *international tribunal* would apply if charged with deciding a controversy in accordance with international law[]" (emphasis original) (quoting *Restatement of the Law (Second) – Foreign Relations Law of the United States* (Council Draft No. 1, 1957) at 4)). Such a standard provided a "fixed yardstick" against which provisions of the *Restatement* were tested. *Id.* at 10.

<sup>643</sup> See, e.g., **Legal Authority CLA-553**, *Hartford Fire Ins. Co. v. California*, 509 U.S. 764, 818 (1993) (Scalia, J., dissenting) ("I shall rely on the Restatement (Third) for the relevant principles of international law."); **Legal Authority CLA-381**, *Sanchez-Llamas v. Oregon*, 548 U.S. 331 (2006); **Legal Authority CLA-553**, *Sosa v. Alvarez-Machain*, 542 U.S. 692, 761, 762 (2004); **Legal Authority CLA-531**, *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 164-65 (2004); **Legal Authority CLA-550**, *Saudi Arabia v. Nelson*, 507 U.S. 349, 360 (1993); **Legal Authority RLA-079**, *Dames & Moore v. Regan*, 453 U.S. 654, 680 (1981); **Legal Authority CLA-524**, *Banco Nacional de Cuba v. Sabbatino*, 376 U.S. 398, 429 n.30, 431 n.35 (1964).

<sup>644</sup> See US Counter-Memorial, para. 353 n.853 (citing **Legal Authority RLA-138**, American Law Institute, *Restatement of the Law (Second) – Foreign Relations Law of the United States* §§ 185-92 (1965)). See also, e.g., Memorial, para. 461 n.647 (noting the US's reliance on *Restatements* in international arbitration and

404. While State practice must be “general and consistent,” absolute consistency is not required. As the International Court of Justice has recognized:

It is not to be expected that in the practice of States the application of the rules in question should have been perfect, in the sense that States should have refrained, with complete consistency, from the use of force or from intervention in each other’s internal affairs. *The Court does not consider that, for a rule to be established as customary, the corresponding practice must be in absolutely rigorous conformity with the rule.* In order to deduce the existence of customary rules, the Court deems it sufficient that the conduct of States should, in general, be consistent with such rules, and that instances of State conduct inconsistent with a given rule should generally have been treated as breaches of that rule, not as indications of the recognition of a new rule. If a State acts in a way prima facie incompatible with a recognized rule, but defends its conduct by appealing to exceptions or justifications contained within the rule itself, then whether or not the State’s conduct is in fact justifiable on that basis, the significance of that attitude is to confirm rather than to weaken the rule.<sup>645</sup>

405. Nor is State practice required to be unanimous. The International Court of Justice has stated that: “With respect to the other elements usually regarded as necessary before a conventional rule can be considered to have become a general rule of international law, it might be that, even without the passage of any considerable period of time, a very widespread and representative participation in the convention might suffice of itself, provided it included that of States whose interests were specially affected.”<sup>646</sup>

406. As Apotex noted in its Memorial, the practice of affording due process in administrative decision-making is widespread and consistent. Nearly every developed legal system

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domestic litigation); **Legal Authority CLA-40**, *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Counter-Memorial on Competence and Liability of Respondent United States of America, at 27 n.26, 36 n.40 (June 1, 2001) (citing §§ 185 cmt. c, 193(3)); **Legal Authority CLA-50**, *The Loewen Group, Inc. and Raymond L. Loewen v. United States*, ICSID Case No. ARB(AF)/98/3, Counter-Memorial of the United States of America, at 127 n.98 (Mar. 30, 2001) (citing § 182 cmt. a); **Legal Authority CLA-37**, *Methanex Corporation v. United States of America*, UNCITRAL, Amended Statement of Defense of Respondent United States of America, at 177 n.640 (Dec. 5, 2003) (citing § 197(1)).

<sup>645</sup> **Legal Authority RLA-120**, *Military and Paramilitary Activities in and against Nicaragua* (Nicar. v. U.S.), 1986 I.C.J. 14, 98 (June 27) (emphasis added).

<sup>646</sup> **Legal Authority CLA-512**, *North Sea Continental Shelf Cases* (Ger. v. Den.; Ger. v. Neth.), 1969 I.C.J. 3, 42 (Feb. 20).

incorporates principles of fair administrative proceedings.<sup>647</sup> These include “in the context of individualized administrative determinations, the right to receive notice of the proposed decision, to respond in writing, and to receive a statement of reasons with the final decision.”<sup>648</sup>

407. Moreover, Apotex has shown that the US demonstrates its commitment to due process and the rule of law in its treaty practice.<sup>649</sup> For example, the US-Rwanda BIT, which entered into force on January 1, 2012, expressly incorporates the due process provisions Apotex argues should have been accorded to it by FDA: “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.”<sup>650</sup> Likewise, the NAFTA reflects the requirement of fundamentally fair administrative proceedings in Article 1804, which the NAFTA Parties expressly recognized to reflect “basic procedures necessary to meet the requirements of due process and natural justice for all matters covered by the Agreement.”<sup>651</sup>

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<sup>647</sup> See Memorial, para. 465 (citing **Legal Authority CLA-331**, Francesca Bignami, *From Expert Administration to Accountability Network: A New Paradigm for Comparative Administrative Law*, 59 Am. J. Comp. L. 859, 897-98 (2011)).

<sup>648</sup> **Legal Authority CLA-331**, Francesca Bignami, *From Expert Administration to Accountability Network: A New Paradigm for Comparative Administrative Law*, 59 Am. J. Comp. L. 859, 897 (2011).

<sup>649</sup> See Memorial, para. 463 n.650 (citing **Legal Authority CLA-11**, Treaty Between the Government of the United States of America and the Government of the Republic of Rwanda Concerning the Encouragement of Reciprocal Protection of Investment, U.S.-Rwanda, art. 5(2)(a), Feb. 19, 2008, S. Treaty Doc. No. 110-23; **Legal Authority CLA-9**, The Dominican Republic-Central America-United States Free Trade Agreement, ch. 10, art. 10.5(2)(a), Aug. 5, 2004, 43 I.L.M. 514).

<sup>650</sup> **Legal Authority CLA-11**, 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. 11(4), (5), Feb. 19, 2008, S. Treaty Doc. No. 110-23. See also **Legal Authority CLA-577**, S. Exec. R. 111-8 at 12 (2010) (“Article 11 ... addresses transparency measures to be taken by the two parties.”).

<sup>651</sup> **Legal Authority CLA-3**, Department of External Affairs, Canadian Statement of Implementation, Canada Gazette Part I, 197 (Jan. 1, 1994). See also Memorial, paras. 467-68 (citing **Legal Authority CLA-1**,

408. Rather than “extrapolate[]” from administrative adjudicatory proceedings to administrative decision-making as a whole, Apotex has demonstrated that US treaty practice addresses the due process requirements necessary when applying administrative decision-making – whether adjudicatory or not – to an alien’s investment.<sup>652</sup>
409. However, the US simply ignores the evidence Apotex proffered regarding how due process rights in administrative proceedings have been incorporated into US treaty practice.<sup>653</sup> In light of the volume of evidence Apotex has provided, it should be beyond dispute that Apotex has demonstrated that customary international law requires due process safeguards in administrative decision-making.

2. *The Minimum Standard of Treatment Extends to Administrative Decisions Such as the Imposition of an Import Alert*

410. The US errs in suggesting that the procedural safeguards listed in Section 181 of the *Restatement (Second) of the Foreign Relations Law of the United States* only apply to a trial, and distinguishing the elements of due process required for “administrative decision-making concerning specific persons.”<sup>654</sup> For the US, the formula used by the

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NAFTA art. 1804; **Legal Authority CLA-2**, North American Free Trade Agreement Implementation Act, Statement of Administrative Action, H.R. Doc. No. 103-159, Vol. I, 103d Cong., 1<sup>st</sup> Sess. at 19 (1993)).

<sup>652</sup> US Counter-Memorial, para. 371. *See, e.g.*, Memorial, para. 463.

<sup>653</sup> *Compare* Memorial, para. 463 n.650 (citing **Legal Authority CLA-9**, The Dominican Republic-Central America-United States Free Trade Agreement, ch. 10, art. 10.5(2)(a), Aug. 5, 2004, 43 I.L.M. 514; **Legal Authority CLA-11**, 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. 5(2)(a), Feb. 19, 2008, S. Treaty Doc. No. 110-23; *id.*, art. 11(4) (providing detailed provisions concerning the character of administrative proceedings that impact covered investments or investors of the other party)) *with* US Counter-Memorial, para. 371 (focusing exclusively on CAFTA-DR).

<sup>654</sup> US Counter-Memorial, para. 369 (emphasis original). Notably, however, US courts have long recognized that procedural safeguards must be observed before a party is deprived of property, absent the most extraordinary circumstances. This is because “[t]he purpose of an adversary hearing is to ensure the requisite neutrality that must inform all governmental decisionmaking.” **Legal Authority CLA-555**, *United States v. James Daniel Good Real Prop.*, 510 U.S. 43, 55-56 (1993). *See also* **Legal Authority CLA-532**, *Fuentes v. Shevin*, 407 U.S. 67, 80-81 (1972) (“The constitutional right to be heard is a basic aspect of the duty of government to follow a fair process of decisionmaking when it acts to deprive a person of his possessions.”). Such a requirement applies to *all* governmental decisionmaking, not just formal adjudication. *See id.* at 82 (US courts recognize that “due process tolerates variances in the form of a hearing ‘appropriate to the nature of the case,’” but “traditionally insist[] that, whatever its form, opportunity for that hearing must be provided before the deprivation at issue takes effect.”) (quoting **Legal Authority CLA-170**, *Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 313 (1950)).

*Second Restatement* refers solely to adjudicatory proceedings, connoting a “formal process for dispute resolution.”<sup>655</sup>

411. *First*, the US fails to support this assertion. This distinction is nowhere to be found in the text of, or commentary to, Section 181 of the *Second Restatement*. Section 181 of the *Restatement* states that “a trial or *other proceeding* to determine the rights or liabilities of an alien must be fair.”<sup>656</sup> It underscores the generality of its application by referring, in each provision addressing the decision-maker in the proceedings, to the “tribunal or *administrative authority*.”<sup>657</sup> It thus makes clear that its rule applies not only to a “trial” before a “tribunal” but also to “other proceedings” before an “administrative authority.”
412. In any event, the concept of “adjudication” does not necessarily have in international law the meaning ascribed to it in US law or even common law more generally. It is well-established that international law, when adopting terms used in national law, gives them an autonomous content.<sup>658</sup> Such content is adapted to the object and purpose of the international rule in question and may be wider or more narrow than that adopted by a particular legal system.<sup>659</sup>
413. The *Restatement* does not define “proceeding” but, as the US admits,<sup>660</sup> the commentary enumerates the following examples: “the issuance or revocation of a license to engage in a particular occupation,” “granting or denying of a variance under a zoning ordinance, the granting and termination of parole to a convicted criminal, the exercise of

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<sup>655</sup> US Counter-Memorial, para. 371. *See also id.*, para. 370.

<sup>656</sup> **Legal Authority RLA-138**, American Law Institute, *Restatement of the Law (Second) – Foreign Relations Law of the United States* § 181 (1965).

<sup>657</sup> *Id.* § 181(a) (emphasis added) (requiring “impartial tribunal or *administrative authority*”); *id.* § 181(h) (requiring “[r]easonable dispatch by the tribunal or administrative authority in reaching a determination”).

<sup>658</sup> *See, e.g.*, **Legal Authority CLA-518**, *König v. Germany* [Plenary], no. 6232/73, ECHR Ser. 1, No. 27, para. 88 (June 28, 1978) (on the autonomous meaning of the phrase “civil rights and obligations” employed in Article 6-1 of the European Convention on Human Rights regarding the right to a fair trial) (“Again, the Court has already acknowledged, implicitly, that the concept of “civil rights and obligations” is autonomous[.]”).

<sup>659</sup> *See Legal Authority CLA-587*, Nuala Mole & Catharina Harby, *The Right to a Fair Trial: A Guide to the Implementation of Article 6 of the European Convention on Human Rights* (Council of Europe 2d. ed 2006) (noting the wide definition of the term “trial” as part of the right to a fair trial in human rights law) (“The guarantees provided for in Article 6 apply not only to the court proceedings, but also to the stages which both *precede* and *follow* them.” (emphasis in original)).

<sup>660</sup> US Counter-Memorial, para. 370 & n.891.

executive clemency, the waiver of assessment of a penalty for overdue taxes, the granting of a permit to travel in a restricted area, and the granting of a public utility franchise.”<sup>661</sup> These examples demonstrate that a “proceeding,” as used in the *Restatement*, involves a determination of the liberty, economic or property “rights or liabilities of an alien” but is not limited to adjudication, as the US suggests.<sup>662</sup>

414. By attempting to distinguish between administrative adjudication and administrative determination or decision-making, the US asserts without any support in State practice that a two-tiered system exists with respect to the minimum standard of due process that must be accorded to an alien’s investment.<sup>663</sup> However, this distinction between “proceedings” and the “decisions” made during those proceedings is an artificial one that is refuted by the authorities cited by the US.<sup>664</sup>
415. The Import Alert plainly involves a determination of Apotex’s rights, as it is a decision rendered by FDA that affected Apotex’s right to conduct business. Like a “revocation of a license,” the Import Alert effectively prevented Apotex-US from carrying on its business by barring the importation of any Apotex products manufactured at Etobicoke or Signet.<sup>665</sup> Furthermore, Apotex-Canada’s ANDAs became useless because Apotex was prevented from selling drug products on the US market. As a result, Apotex lost hundreds of millions of dollars in sales and lost market share in the US.<sup>666</sup>
416. *Second*, the US’s current insistence that the Import Alert does not constitute a “proceeding” in this arbitration contradicts positions it has taken in U.S. courts. While suggesting in its Counter-Memorial that it is improper to “routinely say[] one thing ...

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<sup>661</sup> **Legal Authority RLA-138**, American Law Institute, *Restatement of the Law (Second) – Foreign Relations Law of the United States* § 181 cmt. b (1965).

<sup>662</sup> *Id.* § 181 (1965).

<sup>663</sup> US Counter-Memorial, paras. 369, 375.

<sup>664</sup> *See, e.g., id.*, para. 356 (citing **Legal Authority CLA-30**, *International Thunderbird Gaming Corporation v. United Mexican States*, UNCITRAL, Award, para. 127 (Jan. 26, 2006)); *id.*, para. 361 (citing **Legal Authority RLA-109**, *Genin v. Republic of Estonia*, ICSID Case No. ARB/99/2, Award, paras. 363-65 (June 25, 2001)). *See infra* nn.671-673, 682-696 and accompanying text (addressing authorities cited by US).

<sup>665</sup> Memorial, paras. 516-521. *See also* Second Witness Statement of Kiran Krishnan, paras. 33.

<sup>666</sup> Memorial, paras. 1, 557.

before this Tribunal while saying precisely the opposite ... in U.S. courts[.]”<sup>667</sup> the US has done just that, by insisting in US courts that the decision to detain products pursuant to an import alert should be characterized as a “proceeding”.<sup>668</sup> It is only now that the US adopts a contradictory position by attempting to distinguish the type of “administrative decision-making” undertaken by FDA in issuing and removing an Import Alert from “a trial or other proceeding.”<sup>669</sup> However, the US fails to provide any support for its assertion that a procedure resulting in an administrative decision affecting the rights of a party – such as an Import Alert – is not a “proceeding” under the *Restatement* and customary international law.

417. *Third*, the US’s argument suggests that governments need provide no procedural fairness in making decisions addressing the essential interests of an individual, unless they decide to provide for adjudication. If the government does not deign to provide a trial, the US suggests, it may act however it wishes. However, international law does not support government impunity for acts that address liberty or property rights of persons.
418. Indeed, in other contexts, the US has always considered “the rule of law [as] essential”<sup>670</sup> and has consistently condemned other States for failing to provide procedural due process when taking executive and administrative action.<sup>671</sup>

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<sup>667</sup> US Counter-Memorial, para. 300.

<sup>668</sup> See **Legal Authority CLA-138**, Defendants’ Memorandum in Opposition to Plaintiff’s Motion for Preliminary Injunction, *Smoking Everywhere, Inc. v. FDA*, No. 09-cv-771 (RJL), at 1, 2, 26-27, 37 (D.D.C. May 11, 2009) (describing how FDA made a “determination” that shipments of e-cigarettes may be refused admission during an import “proceeding”).

<sup>669</sup> US Counter-Memorial, para. 369.

<sup>670</sup> **Legal Authority CLA-595**, Attorney General Eric H. Holder, Jr., Remarks at the United Nations General Assembly – High-level Meeting on the Rule of Law (Sept. 24, 2012). See generally **Legal Authority CLA-606**, US Dept. of State, *Digest of United States Practice in International Law*, Ch. 3: International Criminal Law § C at 151 (2002) (“The United States has been a world leader in promoting the rule of law.”).

<sup>671</sup> See e.g., **Legal Authority CLA-603**, US Dep’t of State, *2008 Country Reports on Human Rights Practices: Tajikistan* at 3 (Feb. 25, 2009) (criticizing Tajikistan local authorities for failing to provide due process in administrative procedures to modify town plans, and noting that “[m]unicipal governments that developed these plans did not share them with the public, and evictees were afforded only a cursory degree of due process[.]”); **Legal Authority CLA-607**, US Dep’t of State, *Digest of United States Practice in International Law*, Ch. 6: Human Rights § I at 388 (2004) (“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 the exercise of their personal freedoms.”); **Legal Authority CLA-604**, US Dep’t of State, *2009 Investment Climate Statement – Zimbabwe* (Feb. 2009),

419. Contrary to the US's assertion, international law does not authorize State impunity in disposing of personal rights. For example, the United Nations General Assembly recently reaffirmed its commitment to the international rule of law, including the necessity of providing due process, at the High-Level Meeting on the Rule of Law on September 24, 2012. There, Member States adopted the *Declaration of the High-level Meeting of the General Assembly on the Rule of Law at the National and International Levels*, which "recognize[s] that the rule of law applies to all States equally, ... and that respect for and promotion of the rule of law and justice should guide *all* of their activities and accord predictability and legitimacy to their actions."<sup>672</sup> The Declaration further "reaffirm[s] the principle of good governance and commit[s] to an effective, just, non-discriminatory and equitable delivery of public services pertaining to the rule of law, including criminal, civil and *administrative justice*, commercial dispute settlement and legal aid."<sup>673</sup>
420. Statements delivered by Member States and observers revealed international consensus regarding the importance of rule-of-law fundamentals, like due process, and their application to administrative proceedings.<sup>674</sup> The US position in the Counter-Memorial

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*available at* <http://www.state.gov/e/eb/rls/othr/ics/2009/117667.htm> (last visited Feb. 1, 2013) ("[T]he erosion of the rule of law and sanctity of contracts has had a chilling effect on business and on foreign direct investment."); **Legal Authority CLA-605**, US Dep't of State, *2012 Investment Climate Statement - Argentina* (June 2012), *available at* <http://www.state.gov/e/eb/rls/othr/ics/2012/191099.htm> (last visited Feb. 6, 2013) (expressing "longstanding and renewed concerns regarding the stability of contractual rights and the regulatory environment diminish the attractiveness of prospective investments in some sectors[]"); **Legal Authority CLA-601**, Press Statement from Victoria Nuland, Department Spokesperson, US Dep't of State, *Impeachment Proceedings Brought Against Sri Lanka Chief Justice*, Nov. 2, 2012, *available at* <http://www.state.gov/r/pa/prs/ps/2012/11/200062.htm> (last visited Jan. 23, 2013) (condemning impeachment and urging Sri Lanka to "address outstanding issues of the rule of law, democratic governance, accountability and reconciliation[]"); **Legal Authority CLA-602**, Press Statement from Victoria Nuland, Department Spokesperson, US Dep't of State, *Statement on the Forced Resignation of Interim Prime Minister Diarra*, Dec. 11, 2012, *available at* <http://www.state.gov/r/pa/prs/ps/2012/12/201809.htm> (last visited Jan. 29, 2013) ("condemn[ing] the arbitrary arrest and forced resignation of Mali's Interim Prime Minister, Cheikh Modibo Diarra, by members of the military junta" and "underlin[ing] the importance of the respect for rule of law"); **Legal Authority CLA-600**, Press Statement from Hillary Rodham Clinton, Secretary of State, US Dep't of State, *Situation in Honduras*, June 28, 2009, *available at* <http://www.state.gov/secretary/rm/2009a/06/125452.htm> (last visited Jan. 20, 2013) ("call[ing] on all parties in Honduras to respect the constitutional order and the rule of law").

<sup>672</sup> **Legal Authority CLA-499**, Declaration of the High-level Meeting of the General Assembly on the Rule of Law at the National and International Levels, G.A. Res. 67/1, U.N. Doc. UN A/RES/67/1, para. 2 (Nov. 30, 2012) (emphasis added).

<sup>673</sup> *Id.* para. 12 (emphasis added).

<sup>674</sup> See **Legal Authority CLA-597**, Hrvoje Sikirić, Chair of the United Nations Commission on International Trade Law (UNCITRAL), Statement at the United Nations General Assembly – High-level Meeting on the

– that unless a State decides to grant a trial it may act with impunity in making material decisions concerning a person’s essential interests – cannot be reconciled with the rule of law that it and UN Member States have enthusiastically endorsed.

421. Apotex accepts that due process requirements may be more stringent when liberty interests are implicated, such as in a criminal proceeding, than may be required in the administrative context.<sup>675</sup> For example, reasonable opportunity to communicate with a government representative with respect to the proceedings must be afforded to an alien when he faces criminal charges and is placed in custody.<sup>676</sup>

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Rule of Law at 1-2 (Sept. 24, 2012) (“[R]ule of law is also about the capacity of the States to mobilize resources to invest in such rule-of-law fundamentals as due process and judicial and legal infrastructure . . . . It is about the recognition and enforcement of property rights and contracts; and, of course, also about guaranteeing the legal security required to promote entrepreneurship, investment and job creation.”); **Legal Authority CLA-599**, Navanethem Pillay, High Commissioner for Human Rights, Statement at the United Nations General Assembly – High-level Meeting on the Rule of Law at 4 (Sept. 24, 2012) (“Accountability, however, must extend beyond the criminal law realm to include responsive civil and administrative policies and procedures to address grievances and, when required, effective vetting processes.”); **Legal Authority CLA-598**, José Manuel Durão Barroso, President, European Commission, Statement at the United Nations General Assembly – High-level Meeting on the Rule of Law at 1 (Sept. 24, 2012) (The rule of law is one of “the pillars on which our European Union is built.”); **Legal Authority CLA-596**, H.E. Dr. Guido Westerwelle, President of the Security Council, Statement at the United Nations General Assembly – High-level Meeting on the Rule of Law at 2 (Sept. 24, 2012) (“Both [the rule of law at the national and international level] are inherently linked, for every nation that proclaims the rule of law at home must respect it abroad, and every nation that insists on it abroad must enforce it at home.”).

<sup>675</sup> **Legal Authority RLA-138**, American Law Institute, *Restatement of the Law (Second) – Foreign Relations Law of the United States* § 181 cmt. b (1965).

<sup>676</sup> *See Legal Authority CLA-498*, Vienna Convention on Consular Relations, art. 36, Apr. 24, 1963, 21 U.S.T. 77, 596 U.N.T.S. 261 (codifying customary international law regarding communication and contact with nationals of the sending State) (“1. With a view to facilitating the exercise of consular functions relating to nationals of the sending State: (a) consular officers shall be free to communicate with nationals of the sending State and to have access to them. Nationals of the sending State shall have the same freedom with respect to communication with and access to consular officers of the sending State; (b) if he so requests, the competent authorities of the receiving State shall, without delay, inform the consular post of the sending State if, within its consular district, a national of that State is arrested or committed to prison or to custody pending trial or is detained in any other manner. Any communication addressed to the consular post by the person arrested, in prison, custody or detention shall be forwarded by the said authorities without delay. The said authorities shall inform the person concerned without delay of his rights under this subparagraph; (c) consular officers shall have the right to visit a national of the sending State who is in prison, custody or detention, to converse and correspond with him and to arrange for his legal representation. They shall also have the right to visit any national of the sending State who is in prison, custody or detention in their district in pursuance of a judgment. Nevertheless, consular officers shall refrain from taking action on behalf of a national who is in prison, custody or detention if he expressly opposes such action. 2. The rights referred to in paragraph 1 of this article shall be exercised in conformity with the laws and regulations of the receiving State, subject to the proviso, however, that the said laws and regulations must enable full effect to be given to the purposes for which the rights accorded under this article are intended.”).

422. While “[i]n an administrative proceeding ... the specific safeguards may not *all* be necessary[,]” customary international law also “indicate[s] that [the absence of] *any one of the factors* might have been determinative[.]” of whether an alien was denied procedural fairness.<sup>677</sup> Thus, there is no question that at least some due process safeguards must be present.<sup>678</sup>
423. In any event, the procedural safeguards identified by Apotex are applicable today in most if not all countries with developed legal systems, contrary to the US’s assertion that “Apotex does not address how other States prevent importation of adulterated drugs, and whether those States provide the six ‘safeguards’ claimed by Apotex.”<sup>679</sup> Apotex notes that the products at issue here were not “adulterated” but “appeared to be adulterated” based on a finding of non-compliance with cGMPs by the manufacturing facilities. Furthermore, the practice of other States demonstrates that the safeguards claimed by Apotex are considered essential when a regulatory agency decides to suspend the importation of pharmaceutical products for non-compliance with rules and regulations in force on the territory of the relevant State.<sup>680</sup>
424. *Fourth*, the US erroneously attempts to distinguish the Import Alert from a “proceeding” by characterizing the Import Alert as involving “significant discretion”.<sup>681</sup> The US argues that arbitral tribunals should not second-guess the merits of discretionary regulatory decisions given “the high degree of deference that international law accords States in regulatory decision-making.”<sup>682</sup>

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<sup>677</sup> **Legal Authority RLA-138**, American Law Institute, *Restatement of the Law (Second) – Foreign Relations Law of the United States* § 181 cmt. b (1965) (emphasis added).

<sup>678</sup> See **Legal Authority RLA-138**, American Law Institute, *Restatement of the Law (Second) – Foreign Relations Law of the United States* § 181 cmt. b (1965).

<sup>679</sup> US Counter-Memorial, para. 22.

<sup>680</sup> Memorial, Section III.A.2.

<sup>681</sup> US Counter-Memorial, para. 346.

<sup>682</sup> *Id.*, para. 356. The US also asserts in passing that “Chapter Eleven does not permit a claimant to challenge a legal regime existing at the time of its investment, only the application of that regime.” *Id.*, para. 355 (citing *obiter dicta* in **Legal Authority CLA-27**, *Gami Investments, Inc. v. The Government of the United Mexican States*, UNCITRAL, Award, para. 94 (Nov. 15, 2004)). The US does not attempt to justify this surprising assertion. This is likely because the text of Chapter Eleven in Article 1108 makes plain that the chapter fully applies to existing measures except to the extent specifically excepted under the terms of that Article. Notably, Article 1108 provides no exceptions at all for claims under Article 1105, and no applicable exception applies as concerns the Article 1102 and 1103 claims presented here.

425. Apotex’s Article 1105 claim, however, in no way asks the Tribunal to second-guess the substance of FDA’s decision. Rather, the claim is that the process by which FDA’s decision was reached must be robust and meet international law standards. The mere exercise of discretion does not obviate the need for due process.
426. Contrary to the US’s assertion, arbitral decisions repeatedly recognize that due process is required in administrative proceedings.<sup>683</sup> Arbitral precedent establishes that “the minimum standard of treatment of fair and equitable treatment is infringed by conduct attributable to the State and harmful to the claimant if the conduct ... involves a lack of due process leading to an outcome which offends judicial propriety – as might be the case with ... a complete lack of transparency and candour in an administrative process.”<sup>684</sup>
427. Moreover, the examples of a “proceeding” enumerated in the *Restatement* demonstrate that a determination entitled to due process can rest upon considerable discretion, as in the case of “the exercise of executive clemency[.]”<sup>685</sup> The very reference to discretion

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<sup>683</sup> **Legal Authority CLA-52**, *Waste Management, Inc. v. United Mexican States*, ICSID Case No. ARB(AF)/00/3, Award, para. 98 (Apr. 30, 2004) (emphasis added) (“Taken together, the S.D. Myers, Mondev, ADF and Loewen cases suggest that the minimum standard of treatment of fair and equitable treatment is infringed by conduct attributable to the State and harmful to the claimant if the conduct is arbitrary, grossly unfair, unjust or idiosyncratic, is discriminatory and exposes the claimant to sectional or racial prejudice, or 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. In applying this standard it is relevant that the treatment is in breach of representations made by the host State which were reasonably relied on by the claimant.”). *See also Legal Authority CLA-30*, *International Thunderbird Gaming Corporation v. United Mexican States*, UNCITRAL, Award, paras. 197-201 (Jan. 26, 2006) (determining that due process requirements under NAFTA Art. 1105 were met in administrative hearing that resulted in official closure order because Thunderbird “was given a full opportunity to be heard and to present evidence at the Administrative Hearing, and that it made use of this opportunity[]”; the 31-page Administrative Order was “adequately detailed and reasoned” and “review[ed] the evidence presented by [claimant]”; and the administrative proceedings “were subject to judicial review before the Mexican courts[]”); **Legal Authority CLA-507**, *Middle East Cement Shipping & Handling Co. v. Arab Republic of Egypt*, ICSID Case No. ARB/99/6, Award, para. 143 (April 12, 2002) (holding that a failure to provide notification of the seizure and auctioning of property (even when there was no domestic law requirement to do so) breached fair and equitable treatment); **Legal Authority CLA-589**, Sérvulo Correia, *Administrative Due or Fair Process: Different Paths in the Evolutionary Formation of a Global Principle and of a Global Right*, in *Values in Global Administrative Law*, para. 13 (G. Anthony, J.B. Auby, J. Morison & T. Zwart eds., Hart Publishing 2011) (The constitutions of Spain, Greece and Portugal provide individuals with a right to a hearing in administrative proceedings which may lead to a decision affecting their interests.).

<sup>684</sup> **Legal Authority CLA-52**, *Waste Management, Inc. v. United Mexican States*, ICSID Case No. ARB(AF)/00/3, Award, para. 98 (Apr. 30, 2004).

<sup>685</sup> **Legal Authority RLA-138**, American Law Institute, *Restatement of the Law (Second) – Foreign Relations Law of the United States* § 181 cmt. b (1965).

in the commentary to Section 181 indicates that discretionary action does not exclude due process rights. The extent to which all of the procedural safeguards enumerated in the *Restatement* are required depends upon “(1) the seriousness of the consequences to the alien, and (2) the extent to which the exercise of administrative discretion is reasonably involved in the determination of the case[.]” but in all cases – including those which involve administrative discretion – the safeguards must be “reasonable”.<sup>686</sup>

428. While 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. In order to preserve the “strong presumption of regularity” in administrative decisions, systematic application of procedural safeguards must be adhered to.<sup>687</sup>

429. However, the US improperly conflates a tribunal’s ability to review the merits of a decision (which is presumptively valid) with its ability to review the procedure by which that decision was reached. The “remedy ... for errors in modern government,” including errors of law or fact, is through “internal political and legal processes[.]” the effectiveness of which depends on the procedural safeguards found therein.<sup>688</sup>

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<sup>686</sup> *Id.* § 181 cmt. b (1965) (requiring “reasonable opportunity to contest evidence,” “reasonable opportunity to obtain and present witnesses and evidence,” “reasonable opportunity to communicate with a representative ...,” “reasonable opportunity to consult counsel ...” and “reasonable dispatch by the ... administrative authority in reaching a determination.”) (emphasis added).

<sup>687</sup> US Counter-Memorial, para. 359 (citing **Legal Authority RLA-108**, *Flegenheimer Claim*, Italian-United States Conciliation Commission, Decision No. 182, 14 R.I.A.A. 327 (Sept. 20, 1958)). While the US cites *Flegenheimer Claim* in support of its assertion that there is a presumption of regularity to administrative decisions, that case addressed the substantive question of whether Flegenheimer was a US national for purposes of compensation under the terms of a peace treaty between the US and Italy. See **Legal Authority RLA-108**, *Flegenheimer Claim*, Italian-United States Conciliation Commission, Decision No. 182, 14 R.I.A.A. 327 (Sept. 20, 1958). Further, as is acknowledged in the decision, but omitted by the US, while official authorities’ decisions may be presumptively true, such presumption may be rebutted by contrary evidence. See *id.* para. 32. See also **Legal Authority CLA-545**, *Pacific Molasses Co. v. F.T.C.*, 356 F.2d 386, 389-90 (5th Cir. 1966) (“When an administrative agency promulgates rules to govern its proceedings, these rules must be scrupulously observed. This is so even when the defined procedures are ‘ \* \* \* generous beyond the requirements that bind such agency \* \* \*’ For once an agency exercises its discretion and creates the procedural rules under which it desires to have its actions judged, it denies itself the right to violate these rules.”) (internal citations omitted).

<sup>688</sup> See US Counter-Memorial, para. 356 (quoting **Legal Authority CLA-43**, *S.D. Myers Inc. v. The Government of Canada*, UNCITRAL, Partial Award, para. 261 (Nov. 13, 2000)).

430. International case law confirms this conclusion, emphasizing that even when domestic administrative authorities enjoy wide discretion, due process rights must be observed.<sup>689</sup>
431. In support of its assertion that the Tribunal should accord a high degree of deference to FDA's actions, the US relies inappositely on arbitral awards issued in *International Thunderbird Gaming Corporation v. United Mexican States*, *Genin v. Republic of Estonia*, and *Gami Investments, Inc. v. The Government of the United Mexican States*. The US's reliance on these cases is misplaced: the deference accorded in those cases was with respect to substantive decisions, not procedural ones.<sup>690</sup> Here, the issue is whether FDA complied with international law by providing procedural safeguards to Apotex in deciding to issue the Import Alert, not whether the substance of FDA's decision breached Article 1105.
432. For example, in *Thunderbird*, Thunderbird had secured a legal opinion that its gaming machines did not violate Mexico's prohibition against gambling. The legal opinion relied on Thunderbird's representations that its machines required video game skills and did not involve any betting activities or rely upon luck – representations that the tribunal later found to be incomplete.<sup>691</sup> An administrative hearing was later held, where Thunderbird was represented by legal counsel and had the opportunity to provide documentary evidence and witness testimony.<sup>692</sup> At the conclusion of the hearing, Mexico determined Thunderbird's games violated Mexican law because they included betting and ordered that Thunderbird's facilities be closed.<sup>693</sup>

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<sup>689</sup> See **Legal Authority CLA-517**, *Johansen v. Norway*, no. 17383/90, ECHR 1996-III, paras. 64, 66 (Aug. 7, 1996) (The European Court of Human Rights held that, despite the wide margin of appreciation enjoyed by domestic authorities, due process rights applied to administrative proceedings regarding the placement of children in public care).

<sup>690</sup> See, e.g., **Legal Authority CLA-30**, *International Thunderbird Gaming Corporation v. United Mexican States*, UNCITRAL, Award, paras. 125-26 (Jan. 26, 2006) (“It is not the Tribunal’s function to act as a court of appeal or review in relation to the Mexican judicial system regarding the subject matter of the present claims . . . . Rather, the Tribunal shall examine whether the conduct of Mexico and the measures employed by SEGOB in relation to the EDM entities were consistent with Mexico’s obligations under Chapter Eleven of the NAFTA.”).

<sup>691</sup> See *id.*

<sup>692</sup> *Id.*, para. 70.

<sup>693</sup> See *id.*, para. 73.

433. In rejecting Thunderbird’s challenge to that decision and concluding that Thunderbird was not denied due process, the tribunal “note[d] that Thunderbird was given a full opportunity to be heard and to present evidence at the Administrative Hearing, and that it made use of this opportunity.”<sup>694</sup> The proceedings were also subject to judicial review.<sup>695</sup> Moreover, by failing to “supply adequate information and make a proper disclosure” of the true nature of its games, Thunderbird had assumed the risk that its facilities would be deemed illegal.<sup>696</sup>
434. In stark contrast, Apotex was not “given a full opportunity to be heard and to present evidence.” It was afforded no process. Unlike Thunderbird, Apotex did not mislead FDA or omit necessary information about its facilities and therefore cannot be said to have assumed the risk of FDA enforcement action.
435. In *Genin v. Estonia*, the tribunal expressed deep discomfort with the Bank of Estonia’s failure to provide advance notice or an opportunity to be heard to the claimant’s company before revoking its banking license, stating that the process followed “invites criticism” and stating its “hope[] ... that Bank of Estonia will exercise its regulatory and supervisory functions with greater caution regarding procedure in the future.”<sup>697</sup> However, the evidence before the tribunal had confirmed that the revocation was entirely justified: at the arbitration hearing it was revealed, for the first time, “that all of the companies in question, including Eurocapital, were owned, at all relevant times, by Mr. Genin himself, either directly or indirectly” in flagrant violation of Estonian law requiring disclosure and approval of bank holdings exceeding 10 percent.<sup>698</sup> Due process, had it been accorded, would not have changed the result. Also figuring in the tribunal’s approach was Estonia’s status in the mid-1990s as “a renascent independent

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<sup>694</sup> *Id.*, para. 198.

<sup>695</sup> *See id.*, para. 201.

<sup>696</sup> *Id.*, para. 159. *See also id.*, para. 164 (“Thunderbird knew when it chose to invest in gaming activities in Mexico that gambling was an illegal activity under Mexican law ... [and] must be deemed to have been aware of the potential risk of closure of its own gaming facilities ...”).

<sup>697</sup> **Legal Authority RLA-109**, *Genin v. Republic of Estonia*, ICSID Case No. ARB/99/2, Award, paras. 365, 372 (June 25, 2001).

<sup>698</sup> *Id.*, para. 352.

state, coming rapidly to grips with the reality of modern financial, commercial and banking practices.”<sup>699</sup>

436. *Genin* is of limited application here. Whereas *Genin* obfuscated even the most basic facts of his businesses, including its address, who its shareholders were, and its ownership,<sup>700</sup> Apotex has cooperated with FDA and complied with the US regulatory scheme by opening its facilities to inspections, “maintaining open dialogue” with FDA,<sup>701</sup> complying with pre- and post-approval ANDA reporting obligations,<sup>702</sup> and taking proactive steps to cooperate with FDA and alleviate its concerns, such as initiating a voluntary recall.<sup>703</sup> Whereas *Genin* knowingly chose to invest in a place where emerging “state institutions [were] responsible for overseeing and regulating areas of activity perhaps previously unknown” and “the circumstances of political and economic transition prevailing in Estonia at the time justified heightened scrutiny of the banking sector,”<sup>704</sup> Apotex’s operations in the United States take place in the context of a highly-developed legal and regulatory framework that provides thorough oversight. Most important, while due process in *Genin* would have not impacted the result had it been accorded, the undisputed record in this case demonstrates that if Apotex had been afforded the due process protections available to investors with plants in the United States, FDA would never have barred its products from access to the US market.<sup>705</sup>
437. Finally, the US’s reliance on *Gami Investments, Inc. v. The Government of the United Mexican States* is also misplaced.<sup>706</sup> *Gami* did not address the requirement of procedural due process at all, but rather claims that the Mexican government had failed to implement certain provisions of its own law. It is inapposite.

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<sup>699</sup> *Id.*, para. 348.

<sup>700</sup> *Id.*, para. 352.

<sup>701</sup> US Counter-Memorial, para. 154.

<sup>702</sup> See Witness Statement of Kiran Krishnan, paras. 23-41; Second Witness Statement of Kiran Krishnan, para. 19.

<sup>703</sup> See **Exhibit C-64**, Memorandum from Director of CDER-Compliance to DIOP, dated August 20, 2009 at 2; Witness Statement of Jeremy Desai, paras. 46-48.

<sup>704</sup> **Legal Authority RLA-109**, *Genin v. Republic of Estonia*, ICSID Case No. ARB/99/2, Award, paras. 348, 370 (June 25, 2001).

<sup>705</sup> See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 164.

<sup>706</sup> US Counter-Memorial, para. 360 (citing **Legal Authority CLA-27**, *Gami Investments, Inc. v. The Government of the United Mexican States*, UNCITRAL, Award, para. 97 (Nov. 15, 2004)).

**B. The US Breached Customary International Law by Denying Apotex Due Process**

438. Contrary to the US suggestion, Apotex has amply demonstrated that FDA breached customary international law by failing to provide the procedural due process required by the minimum standard of treatment recognized by customary international law.<sup>707</sup> As the Expert Report of Sheldon T. Bradshaw and Ron M. Johnson explained, and which the US does not dispute or address, this breach caused Apotex significant harm which Apotex would not have suffered had it been afforded the due process available for facilities in the US.<sup>708</sup>

439. As noted above, the *Second Restatement* states that customary international law requires:

[A] trial or other proceeding to determine the rights or liabilities of an alien must be fair. In determining whether the proceeding is fair, it is relevant to consider, among other factors whether the alien has had the benefit of

(a) An impartial ... administrative authority,

(b) Adequate information with respect to the nature of the proceedings so as to permit the alien to present his claim or defense,

...

(d) Reasonable opportunity to contest evidence against him,

(e) Reasonable opportunity to obtain and present witnesses and evidence in his own behalf ...<sup>709</sup>

The US failed to provide even one of these safeguards.

440. *First*, contrary to the US suggestion, CDER did not act as “an impartial ... administrative authority” when recommending the decision to adopt the Import Alert,

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<sup>707</sup> See Memorial, paras. 470-477.

<sup>708</sup> See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 154-164.

<sup>709</sup> **Legal Authority RLA-138**, American Law Institute, *Restatement of the Law (Second) – Foreign Relations Law of the United States* § 181 (1965).

and neither did DIOP when accepting CDER's recommendation.<sup>710</sup> The US suggests that the decision to adopt the Import Alert was impartial because CDER and DIOP are separate and distinct entities.<sup>711</sup> However, DIOP generally adopts without question recommendations from CDER to adopt an Import Alert and does not exercise autonomous review and judgment – and the record confirms that such was the approach here.<sup>712</sup> Internal agency clearance by DIOP, particularly when it relies exclusively upon CDER's recommendations, does not reflect impartiality.

441. Moreover, any suggestion that the decision to adopt the Import Alert was impartial and complied with due process lacks credibility on this record. The factual record reveals that the inspection of the Signet facility ended on Friday, August 14, 2009. While "FDA's general policy is to review a firm's response to the FDA Form 483,"<sup>713</sup> in this case, CDER hurriedly convened a meeting to discuss the inspection findings and agreed to recommend the Import Alert without evaluating Apotex's response to the Form 483.<sup>714</sup> Indeed, FDA had not even completed its review of Apotex's July 17, 2009 response to the Etobicoke Warning Letter at the time.<sup>715</sup> That draft recommendation was completed, reviewed and cleared on Wednesday, August 19, 2009.<sup>716</sup> The next day, both CDER's Branch Chief and Division of Import/Export rushed to review and clear the recommendation.<sup>717</sup> The DMPQ Division Director then cleared the recommendation and sent it to DIOP for review.<sup>718</sup> After only a few business days,

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<sup>710</sup> See US Counter-Memorial, para. 377; See also **Legal Authority RLA-138**, American Law Institute, *Restatement of the Law (Second) – Foreign Relations Law of the United States* § 181 (1965).

<sup>711</sup> See US Counter-Memorial, para. 377.

<sup>712</sup> See Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 9 ("In most instances, DIOP does not perform an independent analysis, but defers to the District's or Center's recommendation. DIOP's vote is essentially administrative. "). See also **Exhibit C-382**, FDA Internal Email Chain, dated August 25-26, 2009 at US6215 (without asking for DIOP to review and reach its own conclusion as to the propriety of adding Apotex to the Import Alert, CDER requested DIOP to open a case and "process so that we can quickly add the firms to IA 66-40."); **Exhibit C-380**, FDA Internal Email Chain, dated August 19-25, 2009 at US6202 (reflecting the rushed review process).

<sup>713</sup> Witness Statement of Carmelo Rosa, para. 60.

<sup>714</sup> See *id.*, para. 59.

<sup>715</sup> **Exhibit C-373**, FDA Internal Email, dated August 18, 2009.

<sup>716</sup> See Witness Statement of Carmelo Rosa, para. 61.

<sup>717</sup> See *id.*

<sup>718</sup> Documents produced by the US suggest that DMPQ endorsed the Import Alert recommendation on August 24, 2009 and that it was sent to DIOP some time after. See **Exhibit C-380**, FDA Internal Email Chain,

DIOP approved CDER's recommendation and approved the Import Alert on Thursday, August 28. The record does not support the US suggestion of an impartial review.

442. *Second*, Apotex was deprived of notice or any opportunity to defend itself from being placed on Import Alert. The US's assertion in the Counter-Memorial that advance notice of an Import Alert would have allowed Apotex to "flood the U.S. market with adulterated drugs" finds no support in documents reflecting FDA's reasoning for the Import Alert.<sup>719</sup> No evidence of record supports this assertion.
443. Nor is the supposed "flood the market" assertion plausible. As a nearly 40-year old company and the sixth-largest seller of generic drugs in the US before the Import Alert was adopted,<sup>720</sup> Apotex had every incentive to comply with FDA directions. The US's suggestion that Apotex was inclined to jeopardize its reputation, risk losing sales to large-scale purchasers such as Wal-Mart and the US government itself, and invite regulatory enforcement actions by flooding the market lacks credibility.
444. Moreover, FDA's argument that Apotex would flood the market with pharmaceuticals is undercut by Apotex's actions to initiate a voluntary recall in a display of caution and cooperation with FDA.<sup>721</sup> This voluntary action, which Apotex undertook *before* FDA even suggested it, is inconsistent with the US's argument that Apotex may have been tempted to "flood the U.S. market."
445. The US's argument that it was necessary to withhold advance notice from Apotex to prevent flooding the market is also inconsistent with its position that the warning letter issued after the Etobicoke inspection and the verbal warning at the end of the Signet inspection provided "ample notice that [Apotex's] facilities were subject to an Import Alert."<sup>722</sup> Despite receiving what the US deems "ample notice," Apotex nonetheless did not flood the market with purportedly adulterated drugs. This illustrates the lack of

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dated August 24-25, 2009 at US6202 (indicating on August 25, 2009, Hidee Molina was "ready to send this to DIOP, but ... I'm not sure who do I send it over at DIOP.").

<sup>719</sup> US Counter-Memorial, para. 378.

<sup>720</sup> Memorial, paras. 22, 40 (citing **Exhibit C-181**, IMS Medical, Top 25 Generic Manufacturers, Q2 2009; Witness Statement of Jeremy Desai, para. 23; Witness Statement of Gordon Fahner, para. 93).

<sup>721</sup> *See Exhibit C-64*, Memorandum from Director of CDER-Compliance to DIOP, dated August 20, 2009 at 2; Witness Statement of Jeremy Desai, paras. 46-48.

<sup>722</sup> US Counter-Memorial, para. 379.

support for the US's concerns that providing notice of the Import Alert would "undermin[e] the very protections to public health afforded by U.S. law".<sup>723</sup>

446. Additionally, FDA would also have been able to prevent any such "flooding" because it monitors all shipments into the US by reviewing import forms custom brokers submit in advance of all shipments. These forms are input into FDA's computer system and would have alerted FDA to any dramatic increase in proposed imports.<sup>724</sup> Thus, FDA would have been able to determine if Apotex proposed to increase its shipments to the US by reviewing the data in its computer system.
447. Moreover, there is no evidence in the US's Counter-Memorial or supporting witness statements that any Apotex products shipped to the US were contaminated, defective or posed a health hazard.<sup>725</sup> FDA is empowered with a range of options to maintain public health and safety in cases where a health hazard exists, including the ability to institute recalls, initiate seizure actions, and issue public statements.<sup>726</sup> With such tools in FDA's arsenal, the US's assertion that advance notice to Apotex would have resulted in any real risk to public health is unfounded.
448. *Third*, FDA never presented Apotex with reasons for its adoption of the Import Alert. The Import Alert itself contains no explanation of why a particular importer is subject to the alert.<sup>727</sup> The notices provided to importers that products have been detained without

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<sup>723</sup> *Id.*, para. 378.

<sup>724</sup> See **Exhibit C-451**, Presentation by DIOP, "Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)", dated July 2012 at 14 (PREDICT system automatically validates information contained in affirmations of compliance customs brokers submit to FDA to expedite the entry review process); *id.* at 3 (Operational and Administrative System for Import Support ("OASIS") provides "[e]lectronic screening of entry lines"). See also **Exhibit C-298**, Presentation by John E. Verbeten, FDA, Division of Import Operations and Policy (DIOP) Director, Operations and Policy Branch, "FDA's Import Operations: How FDA Regulates Imported Products", dated May 22, 2012 at 12 ("FDA has trained individuals who review entry declarations and evaluate the admissibility of a product.").

<sup>725</sup> See Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 19 (noting that FDA's failure to take actions, such as issuing warning letters or requiring third-party testing of products, is inconsistent with the US's argument that Apotex's products posed health risks to US consumers).

<sup>726</sup> See *id.*, para. 14 (noting that FDA classifies recalls based on risk by performing a health hazard evaluation and assigning risk classes in which use of, or exposure to, a violative product is not likely to cause adverse health consequences, may cause temporary health consequences, or will cause serious health consequences).

<sup>727</sup> See **Legal Authority CLA-324**, Christine M. Humphrey, *The Food and Drug Administration's Import Alerts Appear to Be "Misbranded"*, 58 Food & Drug L.J. 595, 599 (2003) (arguing that Import Alerts do not provide fair notice, and stating that "FDA does not have a formal procedure for notifying parties potentially affected by the issuance of an Alert .... there are no procedures specifically requiring or even stating that an

physical examination also fail to provide any indication as to why FDA has decided to adopt such an alert.<sup>728</sup>

449. While the US argues those reasons were contained in “the Form 483s, Establishment Inspection Reports, the warning letter sent to Apotex, and in FDA’s many meetings and telephone calls with the firm,” this argument conflates inspectional cGMP observations with the decision to issue an Import Alert.<sup>729</sup> As Apotex noted in its Memorial, the Form 483 “do[es] not represent a final agency determination regarding your compliance.”<sup>730</sup>
450. Next, the Import Alert was issued nearly 7 months *before* Apotex received certain of these documents, such as the Signet Warning Letter dated March 29, 2010.<sup>731</sup> That Warning Letter provides neither notice of, nor justification for, the Import Alert.
451. In addition, while many inspections result in Forms 483 or warning letters being issued, not every Form 483 or warning letter leads to an Import Alert being imposed. In fact, as the Expert Report of Sheldon T. Bradshaw and Ron M. Johnson explains, FDA declined to place other pharmaceutical manufacturers such as Sandoz/Novartis and Teva on Import Alert, despite similar or dramatically worse cGMP violations. In light of FDA’s comparatively lenient treatment of other manufacturers that received Forms 483 or Warning Letters, FDA’s process for determining when cGMP violations rise to the level necessary to warrant imposition of an Import Alert lacks transparency or consistency. The mere fact that a company received a Form 483 or warning letter is insufficient to explain why one manufacturer is placed on Import Alert while another is not.<sup>732</sup>

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importer or foreign manufacturer *will* be sent a copy of the Alert.”). *See also id.* at 608 (“FDA has no rules or guidance for these affected importers as to how to avoid application of DWPE to their product. Fair notice of DWPE — including agency-created rules like Alerts — is essential in order to give affected importers a reasonable opportunity to meet the obligations that an Alert imposes.”).

<sup>728</sup> **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-31 (2011) (“The statement of charges on the Notice of Detention and Hearing issued for a detained product is the only information the importer has regarding the apparent violation(s) with which the importation is charged.”).

<sup>729</sup> US Counter-Memorial, para. 380.

<sup>730</sup> Memorial, para. 95 (quoting the preprinted instruction included on Forms 483).

<sup>731</sup> *Id.*, paras. 229-231.

<sup>732</sup> *See* Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 140-141, 146.

452. *Fourth*, the record shows that, not only did the US fail to provide any procedural safeguard before the Import Alert was adopted, the US also failed to provide any meaningful route for Apotex to obtain due process after the adoption of the measure. The sole response offered by the US on the lack of post-Import Alert procedural safeguards is to point to supposed “avenues” purportedly “available” to Apotex. As demonstrated in the discussion that follows, the US response does not withstand scrutiny.

453. In sum, the US complied with none of the procedural due process requirements required by customary international law. It breached the minimum standard of treatment.

**C. Inadequate Local Remedies Do Not Rebut Apotex’s Showing that the US Breached Article 1105**

454. In its Memorial, Apotex demonstrated that the treatment accorded it by FDA in adopting and maintaining the Import Alert did not comport with customary international law, and therefore violated Article 1105’s minimum standard of treatment. In its response, the US erroneously argues that Apotex did not avail itself of several “avenues”, which would purportedly “address its complaints in this arbitration.”<sup>733</sup> The US suggests that these “avenues” were adequate and available for Apotex to exhaust, and hence that FDA’s adoption of the Import Alert met international standards for fair process. The US argument fails on the facts and the law.

455. *First*, this argument is directly contradicted by statements made by FDA at the time of the Import Alert that the only way for Apotex to seek relief from the Import Alert was through successful re-inspection of its facilities.

456. *Second*, the US’s argument is meritless because Apotex’s grievances could not be adequately addressed by the relief offered by these alleged alternative remedies.

457. Customary international law provides standards for assessing whether remedies are, from an international perspective, unavailable or ineffective.<sup>734</sup> These standards are

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<sup>733</sup> US Counter-Memorial, para. 381.

<sup>734</sup> **Legal Authority CLA-502**, U.N., Int’l Law Comm’n, *Draft Articles on Responsibility of States for Internationally Wrongful Acts*, art. 44, Supp. No. 10, U.N. Doc A/56/10, ch.IV.E.1 (Nov. 2001).

most often applied in the context of the local remedies rule. They are, however, equally apposite to the assessment of whether a State has met its obligation to provide access to justice, as found in the *Loewen* case. There, the US argued that claimants were not denied justice because remedies existed that were available to them and were adequate and effective,<sup>735</sup> as determined under local remedies standards.<sup>736</sup> The *Loewen* tribunal agreed that in order to meet the minimum standard of treatment, local remedies must be available or effective, and upheld the US's argument on the merits.<sup>737</sup> Therefore, only remedies that are available, adequate, and effective accord with the minimum standard of treatment.<sup>738</sup>

458. However, in this case, because the remedies proposed by the US could not have provided available or effective relief as to the Import Alert, these "avenues" fail to accord Apotex the minimum standard of treatment and their existence is inapposite.

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<sup>735</sup> **Legal Authority CLA-50**, *The Loewen Group, Inc. and Raymond L. Loewen v. United States*, ICSID Case No. ARB(AF)/98/3, Counter-Memorial of the United States of America, 5 (Mar. 30, 2001) ("Because the jury verdict was unquestionably subject to appeal in a higher court, and because Loewen had effective means of pursuing that appeal (and, indeed, was advised and fully prepared to pursue them), Claimants cannot make out a claim for 'denial of justice' on the facts of this case."). See also **Legal Authority CLA-505**, *The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Rejoinder of the United States of America, 106 (Aug. 27, 2001) ("The United States has shown that the substantive obligations of customary international law, as incorporated in NAFTA Article 1105, cannot be breached by decisions of domestic courts from which effective appeals were available.").

<sup>736</sup> **Legal Authority CLA-50**, *The Loewen Group, Inc. and Raymond L. Loewen v. United States*, ICSID Case No. ARB(AF)/98/3, Counter-Memorial of the United States of America, 7 (Mar. 30, 2001) ("Because Loewen's means of appeal 'cannot be dismissed as 'obviously futile or manifestly ineffective,' Professor Greenwood concludes that Claimants cannot make out a claim for a denial of justice."). See also **Legal Authority CLA-505**, *The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Rejoinder of the United States of America, 109 (Aug. 27, 2001) ("This, of course, is precisely the United States' point: because Loewen's means of appeal were not manifestly ineffective or obviously futile, the Mississippi judgments cannot be said to have constituted a denial of justice.").

<sup>737</sup> **Legal Authority CLA-49**, *The Loewen Group, Inc. and Raymond L. Loewen v. The United States of America*, ICSID Case No. ARB(AF)/98/3, Award, paras. 142, 157-59, 165-171 (June 26, 2003). See also *id.*, para. 2 ("[T]he conclusion rests on the Claimants' failure to show that Loewen had no reasonably available and adequate remedy under United States municipal law in respect of the matters of which it complains, being matters alleged to be violations of NAFTA."); *id.* para. 217 ("Accordingly, our conclusion is that Loewen failed to pursue its domestic remedies, ... and that, in consequence, Loewen has not shown a violation of customary international law and a violation of NAFTA for which Respondent is responsible.").

<sup>738</sup> See **Legal Authority CLA-505**, *The Loewen Group, Inc. and Raymond L. Loewen v. United States of America*, ICSID Case No. ARB(AF)/98/3, Rejoinder of the United States of America, 3 (Aug. 27, 2001) ("Because Loewen had effective means of appeal open to it, those court judgments cannot be internationally wrongful under established customary international law principles of state responsibility.").

I. *The US Has Not Met Its Burden of Demonstrating That Effective Local Remedies Existed*

459. It is well-established that the party alleging the existence of remedies that have not been exhausted must prove their availability.<sup>739</sup> As the International Court of Justice recalled in a recent judgment, “[i]t is for the respondent to convince the Court that there were effective remedies in its domestic legal system that were not exhausted.”<sup>740</sup> The respondent must show that the proposed remedy is capable of relieving the claimant’s injury.<sup>741</sup> For a remedy to be available, the relief provided by that remedy must be able to have a “significant effect” on “the resolution of the wrong.”<sup>742</sup> The availability and effectiveness of a remedy must be judged in regard to the circumstances at the time the remedy supposedly should have been pursued.<sup>743</sup>
460. In its Counter-Memorial, the US offered no evidence that the posited remedies were either available or capable of redressing the type of claims that Apotex would have made. Instead, the US provided a mere list of four ineffective and irrelevant “avenues” – (1) administratively challenging FDA’s cGMP findings by filing a citizen petition under 21 CFR §§ 10.25, 10.30; (2) requesting that CDER reconsider its decision under

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<sup>739</sup> **Legal Authority CLA-511**, *Elettronica Sicula S.p.A. (ELSI)* (U.S. v. Italy), 1989 I.C.J. 15, para. 62 (July 20); **Legal Authority CLA-510**, *Ahmadou Sadio Diallo* (Guinea v. Dem. Rep. Congo), 2007 I.C.J., para. 44 (May 24); **Legal Authority CLA-106**, *Ambatielos* (Greece v. UK), 12 R.I.A.A. 83, 119 (2006) (Mar. 6, 1956); **Legal Authority CLA-60**, *Chevron Corporation (USA) and Texaco Petroleum Company (USA) v. The Republic of Ecuador*, UNCITRAL, PCA Case No. 34877, Partial Award, para. 329 (Mar. 30, 2010). See also **Legal Authority CLA-503**, U.N., Int’l Law Comm’n, *Third Report on Diplomatic Protection*, para. 102, U.N. Doc. A/CN.4/523 (Mar. 7, 2002) (prepared by John Dugard) (under the principle of “onus probandi incumbit ei qui dicit” it is “generally accepted that the burden of proof is on the party which makes an assertion”).

<sup>740</sup> **Legal Authority CLA-510**, *Ahmadou Sadio Diallo* (Guinea v. Dem. Rep. Congo), 2007 I.C.J., para. 44 (May 24). See also **Legal Authority CLA-511**, *Elettronica Sicula S.p.A. (ELSI)* (U.S. v. Italy), 1989 I.C.J. 15, para. 62 (July 20) (respondent’s burden “to show, as a matter of fact, the existence of a remedy which was open to [claimants] and which they failed to employ.”); **Legal Authority CLA-60**, *Chevron Corporation (USA) and Texaco Petroleum Company (USA) v. The Republic of Ecuador*, UNCITRAL, PCA Case No. 34877, Partial Award, para. 329 (Mar. 30, 2010) (respondent must prove the proposed remedy is available “before a claimant will be required to prove their ineffectiveness or futility.”) (emphasis added).

<sup>741</sup> See **Legal Authority CLA-60**, *Chevron Corporation (USA) and Texaco Petroleum Company (USA) v. The Republic of Ecuador*, UNCITRAL, PCA Case No. 34877, Partial Award, para. 329 (Mar. 30, 2010) (“Proving the availability of remedies extends to proving a direct and objective relationship between the proposed device and the resolution of the wrong . . .”).

<sup>742</sup> *Id.*, para. 329.

<sup>743</sup> See **Legal Authority CLA-503**, U.N., Int’l Law Comm’n, *Third Report on Diplomatic Protection*, para. 37, U.N. Doc. A/CN.4/523 (Mar. 7, 2002) (prepared by John Dugard); **Legal Authority CLA-49**, *The Loewen Group, Inc. and Raymond L. Loewen v. The United States of America*, ICSID Case No. ARB(AF)/98/3, Award, para. 169 (June 26, 2003).

21 CFR § 10.75; (3) appearing at detention hearings to present evidence after drugs were detained without physical examination; or (4) bringing suit under the Administrative Procedure Act.<sup>744</sup> The US argued that Apotex could have used the “avenues” “to contest FDA’s decisions, or otherwise seek relief to address its complaints in this arbitration.”<sup>745</sup> However, the US offered no evidence that any of the proposed “avenues” of relief could have provided Apotex the opportunity to contest evidence against it, obtain and present witnesses and evidence, or afforded Apotex adequate relief that would have had a “significant effect”.

461. The US failed to discharge its burden of proving the existence of such remedies, that these remedies were available to Apotex, or that these remedies were capable of affording Apotex effective relief. Each of the US’s proposed “avenues” was unavailable to Apotex and ineffective, as demonstrated below. In addition, as noted below, the US’s present position that these “remedies” were available and effective is flatly inconsistent with what it told Apotex was the case at the time – representations on which Apotex was entitled to rely.

2. *FDA Continuously Maintained That Re-Inspection and Approval by CDER Was the Only “Avenue” Available*

462. Although the US now asserts that Apotex had four “avenues” available to it, at the time the Import Alert was imposed, FDA repeatedly made clear that the only way Apotex could seek relief from the Import Alert was through re-inspection. As early as September 3, 2009, FDA stated that in order to lift the Import Alert, “the issues identified in the reports issued would need to be corrected and that the corrections would need to be verified by a re-inspection by FDA.”<sup>746</sup> FDA reiterated this position during a meeting on September 11, 2009: “Mr. Rivera Martinez also said that the Commissioner had made it *very clear that a reinspection would be necessary* to close out actions of this kind.”<sup>747</sup>

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<sup>744</sup> US Counter-Memorial, para. 381.

<sup>745</sup> *Id.*, para. 381.

<sup>746</sup> **Exhibit C-386**, Apotex Minutes of Meeting with FDA, dated September 3, 2009 at 2.

<sup>747</sup> **Exhibit C-94**, Apotex Draft Minutes of Meeting with FDA, dated September 11, 2009 at 7 (emphasis added).

463. FDA’s representations to Apotex fully accorded with its Regulatory Procedures Manual. The manual confirms that Import Alerts issued for cGMP violations can be remedied only by re-inspection of the facility. It directly contradicts the US’s current position that other remedies were available to Apotex.
464. Chapter 9 of FDA’s Regulatory Procedures Manual (“RPM”), “Detention Without Physical Examination (DWPE)” provides that:

FDA decisions to remove a product, manufacturer, packer, shipper, grower, country, or importer from detention without physical examination should be based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and the agency has confidence that future entries will be in compliance with the Act.

...

If a product has been placed on detention without physical examination *because it appears violative under Section 801(a)(1) or (2), analysis of samples from* representative shipments will generally not be sufficient to overcome the appearance of the violation and warrant *removal from detention* without physical examination. An establishment inspection, or other appropriate action, may be required (i.e., documentation that a product is no longer forbidden or restricted for sale from the government of the country in which it was produced or from which it was exported).<sup>748</sup>

465. Apotex was placed on Import Alert because its products appeared violative under Section 801(a)(2). Thus, Apotex would not have been able to resolve the Import Alert by analyzing samples of its products.
466. Nor did the text of Import Alert 66-40 or the RPM mention any of the four “avenues” the US now proposes as a remedy for imposition of an Import Alert.<sup>749</sup> Under FDA’s own statements and regulations, the only remedy capable of removing Apotex from Import Alert was re-inspection and reconsideration by CDER after receiving sufficient evidence establishing compliance.

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<sup>748</sup> **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, Detention without Physical Examination (DWPE), at 9-25 – 9-26 (2011) (emphasis added).

<sup>749</sup> *See, e.g., Exhibit C-110*, FDA’s website, Import Alert 66-40, dated October 2, 2009.

467. Apotex appropriately relied upon FDA's statements that the Import Alert could be lifted only upon successful re-inspection.<sup>750</sup> As the ICJ has held, a claimant is "justified in relying on the consequences of the legal characterization thus given by the [executive] authorities, including for purposes of the local remedies rule."<sup>751</sup> The US argument cannot be admitted.

3. *The "Avenues" Proposed by the United States Are Not Effective Remedies under International Law*

468. Even if FDA had not represented that Apotex could seek relief from the Import Alert only through successful re-inspection, the four alternatives the US now suggests could not have provided Apotex with the minimum standard of treatment in any event.

469. As shown below, the first "avenue", reconsideration administrative challenges, is ineffective because it is discretionary and unconstrained by due process strictures.

470. The second "avenue", citizen petitions, fails for the same reasons.

471. The third "avenue", appearance at detention hearings, also fails. Detention hearings do not permit a challenge to the Import Alert as a whole and hearing officers are not empowered to lift an Import Alert of their own accord.

472. The fourth "avenue", institution of a lawsuit under the US Administrative Procedure Act ("APA"), is not only irrelevant to international arbitral proceedings, but also is ineffective. US courts do not have jurisdiction to review discretionary and non-final acts like an Import Alert under the APA.

a) *The Reconsideration Procedure Was Not Available or Effective*

473. The first administrative challenge the US proposes, asking FDA to reconsider its decision on cGMP compliance under 21 CFR § 10.75, is unavailing. Section 10.75

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<sup>750</sup> See Second Witness Statement of Jeremy Desai, paras. 39; See also **Exhibit C-395**, Letter from Apotex to customers, dated September 14, 2009 (based on meetings with FDA, Apotex believed that "[u]ntil such time that the facilities are re-inspected, the Import Alert will not be lifted.").

<sup>751</sup> **Legal Authority CLA-510**, *Ahmadou Sadio Diallo* (Guinea v. Dem. Rep. Congo), 2007 I.C.J., para. 46 (May 24).

provides that any decision made by an employee of FDA is reviewable by that employee's supervisor.<sup>752</sup>

474. As will be shown below, the reconsideration process under 21 CFR § 10.75 is not an adequate remedy for the following reasons, any one of which renders it insufficient under international law: (1) reconsideration appeals to the grace of the executive; (2) it does not provide the ability to vindicate a right; (3) it is within the absolute discretion of the agency; (4) there are no legal standards governing decision; (5) it is addressed to the same office that rendered the first decision; (6) it is not impartial; and (7) by regulation, there is no ability to offer new evidence, present witnesses, or contest evidence.

475. *First*, the International Court of Justice has specifically rejected the view that executive reconsideration of a decision, such as under 21 CFR § 10.75, could constitute a remedy under international law.<sup>753</sup> In *Diallo*, the ICJ noted that under Congolese law “reconsideration of a decision can in all cases be requested from the authority having taken it and, if necessary, from that authority’s superior.”<sup>754</sup> The Court held that this was not an effective remedy that required exhaustion because “administrative remedies can only be taken into consideration for purposes of the local remedies rule if they are aimed at vindicating a right and not obtaining a favour.”<sup>755</sup> It added “the possibility ... of submitting a request for reconsideration of the expulsion decision to the administrative authority having taken it ... in hope that he would retract his decision as a matter of grace cannot be deemed a local remedy to be exhausted.”<sup>756</sup>

476. *Diallo* echoes a principle supported by the jurisprudence of the ICJ, the ECHR,<sup>757</sup> the UN Human Rights Committee,<sup>758</sup> the ILC,<sup>759</sup> and various scholars<sup>760</sup> that remedies aimed at obtaining a favor and not vindicating a right are not adequate remedies.

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<sup>752</sup> **Legal Authority RLA-161**, 21 CFR § 10.75(a).

<sup>753</sup> **Legal Authority CLA-510**, *Ahmadou Sadio Diallo* (Guinea v. Dem. Rep. Congo), 2007 I.C.J., para. 47 (May 24).

<sup>754</sup> *Id.*, para. 36.

<sup>755</sup> *Id.*, para. 47.

<sup>756</sup> *Id.*, para. 36.

<sup>757</sup> *See e.g. Legal Authority CLA-516*, *De Becker v. Belgium*, no. 214/56, Commission Decision, 1958-1959 Yearbook of the European Convention on Human Rights at 16 (English translation provided by counsel) (holding that the “rehabilitation action” did not seem to present the characteristics of the type of ordinary

477. Section 10.75 grants precisely the same genre of review that the International Court of Justice analyzed and rejected in *Diallo* as insufficient to meet the standards of international law. Rather than vindicating a right, a reconsideration application is merely a request for a favor to “retract [that] decision as a matter of grace.”<sup>761</sup>
478. *Second*, as is well-settled under international law, a remedy that is within the discretion of the decision-maker is not a remedy under customary international law.<sup>762</sup> The

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remedy which had to be exhausted under generally accepted principles of international law, as its aim was obtaining a favor rather than vindication of a legal right).

<sup>758</sup> See e.g. **Legal Authority CLA-520**, *Ellis v. Jamaica*, Communication No. 276/1988, H.R. Comm., U.N. Doc. CCPR/C/45/D/276/1988, para. 9.1 (Aug. 26, 1992) (“[A] petition for mercy addressed to the Governor General cannot be considered a domestic remedy [to be exhausted] within the meaning of ... the Optional Protocol.”); **Legal Authority CLA-521**, *Kankanamge v. Sri Lanka*, Communication No. 909/2000, H.R. Comm., U.N. Doc. CCPR/C/81/D/909/2000, para. 6.3 (July 27, 2004) (“The State party had not demonstrated that ... making representations to the Attorney-General or complaining to the Ombudsman or to the National Human Rights Commission would constitute an effective remedy.”); **Legal Authority CLA-522**, *Warsame v. Canada*, Communication No. 1959/2010, H.R. Comm., U.N. Doc. CCPR/C/102/D/1959/2010, para. 7.4 (July 21, 2011) (finding the remedy was not exhaustible because “the remedy is discretionary to obtain the privilege of expediting a permanent residency application and not to vindicate a right.”). See also **Legal Authority CLA-590**, Silvia D’Ascoli & Kathrin Maria Scherr, *The Rule of Prior Exhaustion of Local Remedies in the International Law Doctrine and its Application in the Specific Context of Human Rights Protection* at 14 (Eur. Univ. Inst. Dep’t of Law, Working Paper No. 2007/2); **Legal Authority CLA-586**, Nsongurua J. Udombana, *So Far, So Fair, the Local Remedies Rule in the Jurisprudence of the African Commission on Human and People’s Rights*, 97 Am. J. of Int’l Law 1, 8 (2003).

<sup>759</sup> **Legal Authority CLA-501**, U.N., Int’l Law Comm’n, *Draft Articles on Diplomatic Protection*, art. 14 cmt. 5, U.N. Doc. A/61/10 (2006) (“Local remedies do not include remedies whose ‘purpose is to obtain a favour and not to vindicate a right’ nor do they include remedies of grace ... ” (quoting **Legal Authority CLA-516**, *De Becker v. Belgium*, no. 214/56, Commission Decision, 1958-1959 Yearbook of the European Convention on Human Rights (English translation provided by counsel) (citing **Legal Authority CLA-523**, *Claims of Finnish shipowners against Great Britain in respect of the use of certain Finnish vessels during the war (Finland v. Great Britain)*, 3 R.I.A.A. 1479 (2006))).

<sup>760</sup> See, e.g., **Legal Authority CLA-580**, C.F. Amerasinghe, *The Local Remedies Rule in an Appropriate Perspective* at 747 (1976), available at [http://www.zaoerv.de/36\\_1976/36\\_1976\\_1\\_3\\_a\\_727\\_759.pdf](http://www.zaoerv.de/36_1976/36_1976_1_3_a_727_759.pdf) (“[W]here a remedy consists of dispensing a favour and not of making a determination of rights, resort need not be had to it.”); **Legal Authority CLA-583**, James Crawford, *Brownlie’s Principles of Public International Law* at 713 (Oxford University Press 2012) (“The remedies to be exhausted comprise all forms of recourse as of right, including administrative remedies of a legal character, but not extra-legal remedies such as *ex gratia* payments.” (citations omitted)).

<sup>761</sup> **Legal Authority CLA-510**, *Ahmadou Sadio Diallo* (Guinea v. Dem. Rep. Congo), 2007 I.C.J., para. 47 (May 24).

<sup>762</sup> **Legal Authority CLA-580**, C.F. Amerasinghe, *The Local Remedies Rule in an Appropriate Perspective* at 747 (1976), available at [http://www.zaoerv.de/36\\_1976/36\\_1976\\_1\\_3\\_a\\_727\\_759.pdf](http://www.zaoerv.de/36_1976/36_1976_1_3_a_727_759.pdf) (“On this basis, for instance, where an international wrong is made subject to redress by reference to a political body exercising an uncontrolled or absolute discretion, it would appear that no resort need be had to such body in order to exhaust remedies.”). See also **Legal Authority CLA-510**, *Ahmadou Sadio Diallo* (Guinea v. Dem. Rep. Congo), 2007 I.C.J., para. 47 (May 24); **Legal Authority CLA-516**, *De Becker v. Belgium*, no. 214/56, Commission Decision, 1958-1959 Yearbook of the European Convention on Human Rights (English translation provided by counsel); **Legal Authority CLA-501**, U.N., Int’l Law Comm’n, *Draft Articles on*

relevant criterion is whether the dispensing body is “exercising an uncontrolled or absolute discretion.”<sup>763</sup> In evaluating the type of discretion at issue, the question turns on whether there are principles to guide the exercise of discretion.<sup>764</sup>

479. The reconsideration application does not constitute an effective remedy because the decision to reconsider is within the absolute discretion of the agency officials, and there are no standards to guide the decision-makers.<sup>765</sup>
480. *Third*, an application for reconsideration could not have provided Apotex the necessary due process or adequate relief.<sup>766</sup> It does not provide an impartial administrative authority, as the reconsideration process goes through CDER, the same office that originally recommended the Import Alert.<sup>767</sup>
481. *Fourth*, Apotex would be unable to contest the evidence against it or mount an adequate defense, because the decision to reconsider is made on the same record as the original decision. If any new evidence or information is presented, the process is restarted at the lower level of the agency.<sup>768</sup> However, Apotex never knew the basis for the original decision, because it never received notice of the Import Alert or the information upon which the Import Alert was based.<sup>769</sup> Additionally, Apotex would have been unable to

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*Diplomatic Protection*, art. 14 cmt 5, U.N. Doc. A/61/10 (2006); **Legal Authority CLA-520**, *Ellis v. Jamaica*, Communication No. 276/1988, H.R. Comm., U.N. Doc. CCPR/C/45/D/276/1988, para. 9.1 (Aug. 26, 1992); **Legal Authority CLA-521**, *Kankanamge v. Sri Lanka*, Communication No. 909/2000, H.R. Comm., U.N. Doc. CCPR/C/81/D/909/2000, para. 6.3 (July 27, 2004); **Legal Authority CLA-522**, *Warsame v. Canada*, Communication No. 1959/2010, H.R. Comm., U.N. Doc. CCPR/C/102/D/1959/2010, para. 7.4 (July 21, 2011).

<sup>763</sup> **Legal Authority CLA-580**, C.F. Amerasinghe, *The Local Remedies Rule in an Appropriate Perspective* at 747 (1976), available at [http://www.zaoerv.de/36\\_1976/36\\_1976\\_1\\_3\\_a\\_727\\_759.pdf](http://www.zaoerv.de/36_1976/36_1976_1_3_a_727_759.pdf).

<sup>764</sup> *Id.*

<sup>765</sup> *Id.* (arguing that when there are no standards to judge the decision this is “non-judicial discretion”, and the remedy is not effective).

<sup>766</sup> See Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 62.

<sup>767</sup> **Legal Authority RLA-161**, 21 CFR § 10.75(b)(1) (“The review will ordinarily follow the established agency channels of supervision or review for that matter.”); *id.* § 10.75(c) (“An interested person outside the agency may request internal agency review of a decision through the established agency channels of supervision or review.”).

<sup>768</sup> *Id.* § 10.75(d) (“Internal agency review of a decision must be based on the information in the administrative file. If an interested person presents new information not in the file, the matter will be returned to the appropriate lower level in the agency for reevaluation based on the new information.”).

<sup>769</sup> **Exhibit C-386**, Apotex Draft Minutes of Meeting with FDA, dated September 3, 2009 at 1 (“FDA indicated that there was no requirement for FDA to notify as the information was publically available on their website.”).

determine whether and what evidence might be new or old and therefore could be submitted to adequately contest the original decision.

482. *Finally*, there is no specified time limit in which the agency must respond to a reconsideration decision. Agency guidance documents suggest only that “the Official should make all reasonable efforts to resolve the dispute as expeditiously as possible, taking into consideration available resources.”<sup>770</sup>

483. Not only is the reconsideration application ineffective as a remedy under customary international law, but Apotex essentially partook in the process offered by § 10.75 through its continuous discussion with the relevant FDA officials. Apotex spent over two years attempting to secure relief from FDA. It held numerous calls and meetings with FDA and submitted copious documentation, including reports and other evidence of its compliance provided by independent third party consultants.<sup>771</sup> Therefore, the remedy provided by § 10.75 cannot be viewed as providing a different remedy to Apotex than the informal communications with the same officials that proved fruitless.<sup>772</sup>

*b) A Citizen Petition Was Not Available or Effective*

484. A citizen petition allows a person to request the Commissioner to take or refrain from taking any form of administrative action.<sup>773</sup> Under this process, the petitioner is required to submit a full statement of the factual and legal grounds on which the

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<sup>770</sup> **Legal Authority CLA-574**, FDA, *Guidance for Industry, Formal Dispute Resolution: Appeals Above the Division Level*, at 6 (2000), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079743.pdf>.

<sup>771</sup> See Memorial, paras. 216-224, 227-228.

<sup>772</sup> **Legal Authority CLA-60**, *Chevron Corporation (USA) and Texaco Petroleum Company (USA) v. The Republic of Ecuador*, UNCITRAL, PCA Case No. 34877, Partial Award, para. 331 (March 30, 2010). See also **Legal Authority CLA-511**, *Elettronica Sicula S.p.A. (ELSI) (U.S. v. Italy)*, 1989 I.C.J. 15, para. 59 (July 20) (“[F]or an international claim to be admissible, it is sufficient if the essence of the claim has been brought before the competent tribunals and pursued as far as permitted by local law and procedures, and without success.”). Accord **Legal Authority CLA-501**, U.N. GAOR, Int’l Law Comm’n, *Draft Articles on Diplomatic Protection*, art. 14 cmt. 6, U.N. Doc. A/61/10 (2006); **Legal Authority CLA-500**, U.N., Int’l Law Comm’n, *Diplomatic Protection, Comments and Observations Received from Governments* at 38, UN Doc. A/CN.4/561 (Jan. 27, 2006) (“The United States agrees that the International Court of Justice’s decision in ELSI correctly captures the customary international law exhaustion requirement.”).

<sup>773</sup> **Legal Authority RLA-159**, 21 CFR § 10.25(a).

petitioner relies supporting the requested action to be taken.<sup>774</sup> Under the regulation, petitions are put on public display and are available for public examination and copying.<sup>775</sup> Moreover, any interested person may submit written comments that support or oppose the petition.<sup>776</sup>

485. The FDA describes the citizen petition process as follows:

Ultimately, FDA management decides whether to grant a petition. But first, agency staffers evaluate it, a process that may take several weeks to more than a year, depending on the issue's complexity. After FDA grants or denies the petition, the agency will notify the petitioner directly. If not satisfied, the petitioner can take the matter to court.<sup>777</sup>

486. The citizen petition process is not a remedy within the meaning given under customary international law for the same reasons as the reconsideration procedure.

487. *First*, as previously stated, when the decision-maker has absolute and unfettered discretion, the remedy is ineffective under international law. The review of citizen petitions is within the absolute discretion of the agency.<sup>778</sup> There are no standards or principles that guide this decision. It is therefore ineffective.

488. *Second*, according to the Draft Articles of Diplomatic Protection, only administrative remedies that result in a binding decision need to be exhausted.<sup>779</sup> However, the relief granted by the citizen petition does not necessarily result in a binding decision, as the Commissioner may grant or deny the petition or grant such other relief or take other action as the petition warrants.<sup>780</sup> Although the regulation states that a response should be provided within 180 days, the response may be a tentative response that merely discloses reasons why the agency needs more time to provide a decision. The

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<sup>774</sup> *Id.* § 10.30(b).

<sup>775</sup> **Legal Authority CLA-565**, 21 CFR § 10.20(j).

<sup>776</sup> **Legal Authority RLA-159**, 21 CFR § 10.30(d).

<sup>777</sup> **Legal Authority CLA-571**, FDA, *Comment on Proposed Regulations and Submit Petitions* (Feb. 3, 2012), available at <http://www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm> (last visited May 17, 2013).

<sup>778</sup> **Legal Authority RLA-159**, 21 CFR § 10.30(e)(1).

<sup>779</sup> **Legal Authority CLA-501**, U.N., Int'l Law Comm'n, *Draft Articles on Diplomatic Protection*, art. 14 cmt 5, U.N. Doc. A/61/10 (2006).

<sup>780</sup> **Legal Authority RLA-159**, 21 CFR § 10.30(e)(3).

regulation allows the agency to delay responding to citizen petitions for an indeterminate period rather than issue a final decision.<sup>781</sup>

489. *Third*, if the remedy could afford no relief at the time the remedy was to have been utilized, then the remedy is ineffective under international law.<sup>782</sup> FDA's unchanging position was that re-inspection was required to grant Apotex the relief that it sought. Because the citizen petition process would not have allowed Apotex to contest the imposition of the Import Alert before it was adopted or lift the Import Alert after it was adopted, the remedy is ineffective under international law.

490. The citizen review process also lacks the procedural safeguards required for effective local remedies under international law. As FDA itself states:

The right to petition, however, is not absolute; it does not include the right to speak to government officials, nor does it include the *right to an oral hearing*. Neither does the right to petition the government *create an affirmative duty on the government to act or to investigate*.

In fact, court opinions indicate that agencies have broad discretion in establishing and applying rules for public participation in agency matters. Moreover, the Supreme Court has indicated that courts cannot require more than *minimum procedural boundaries* even if a proposed regulation would establish complex or technical factual issues or important public issues; in those instances, *an agency is to decide whether additional procedures are needed*.<sup>783</sup>

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<sup>781</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 61.

<sup>782</sup> **Legal Authority CLA-523**, *Claims of Finnish shipowners against Great Britain in respect of the use of certain Finnish vessels during the war* (Finland v. Great Britain), 3 R.I.A.A. 1479, 1495 (2006); **Legal Authority CLA-106**, *Ambatielos* (Greece v. UK), 12 R.I.A.A. 83, 119 (2006) (March 6, 1956) ("Remedies which could not rectify the situation cannot be relied upon by the defendant State as precluding an international action."); **Legal Authority CLA-60**, *Chevron Corporation (USA) and Texaco Petroleum Company (USA) v. The Republic of Ecuador*, UNCITRAL, PCA Case No. 34877, Partial Award, para. 329 (March 30, 2010); **Legal Authority CLA-519**, *X, Y, & Z. v. United Kingdom*, nos. 8022/77, 8025/77 & 8027/77, ECHR Ser. A, No. 35, at 74 (Dec. 8, 1979) ("[R]emedies which do not in reality offer any chance of redress need not be exhausted ...." (emphasis added)).

<sup>783</sup> **Legal Authority CLA-567**, *Citizen Petitions; Actions that Can Be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action*, 64 Fed. Reg. 66822, 66822 (Nov. 30, 1999) (emphasis added).

491. Unless the Commissioner decides otherwise, the Commissioner makes a decision based on written submissions.<sup>784</sup> Thus, while Apotex would be permitted to submit its petition, it would not be allowed access to any information relevant to the position held by FDA and would be denied the opportunity to address that information. Therefore, Apotex was still precluded from preparing an adequate defense and contesting the evidence against it.

492. FDA itself has acknowledged that

[i]n many instances, it is readily apparent that citizen petitions may not be the best or most efficient mechanism for addressing the underlying subject or issue. ... In contrast, a telephone call, letter, or a request for a meeting, while lacking the formal processing associated with citizen petitions, is usually an easier, faster, and more efficient way to discuss the same issue with the agency.<sup>785</sup>

493. Apotex's continuous contact with FDA through meetings, telephone conferences, and letters performed essentially the same function and was aimed at producing the same result. When a claimant has "generally tried various different remedies ... to no avail" as Apotex did, failure to attempt a specific remedy would not "preclude a finding of breach."<sup>786</sup>

494. Finally, as the Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson makes clear, the citizen review process would not have provided Apotex with adequate or timely relief.<sup>787</sup>

*c) A Detention Hearing Would Not Have Accorded Apotex the Minimum Standard of Treatment*

495. The third "avenue" suggested by the US – the "right to present evidence in detention hearings" regarding drug shipments that were detained without physical examination –

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<sup>784</sup> **Legal Authority RLA-159**, 21 CFR §10.30(h), (j). Section 10.30(i)(4) refers to the procedures listed under § 10.30(h), which includes a hearing, as "optional procedures".

<sup>785</sup> **Legal Authority CLA-567**, Citizen Petitions, Actions that can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action, 64 Fed. Reg. 66822, 66822 (Nov. 30, 1999).

<sup>786</sup> *See Legal Authority CLA-60, Chevron Corporation (USA) and Texaco Petroleum Company (USA) v. The Republic of Ecuador*, UNCITRAL, PCA Case No. 34877, Partial Award, para. 331 (March 30, 2010).

<sup>787</sup> Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 61.

also plainly fails to meet Article 1105's minimum standard of treatment.<sup>788</sup> Detention hearings could not have provided Apotex any effective relief, because FDA practice does not grant the hearing officer the discretion to lift the Import Alert absent re-inspection.<sup>789</sup> Nor does the detention hearing provide necessary due process.

496. Apotex demonstrated in its Memorial that this remedy was inadequate.<sup>790</sup> Apotex showed that this "hearing" "serves no useful purpose"<sup>791</sup> because "[t]he district director has no authority to overrule an import alert decision made by the Center."<sup>792</sup> The US does not respond to this observation in its Counter-Memorial. There is no response.

497. Under FDA regulations, FDA must provide written notice of its decision to refuse admission of articles, the nature of the purported violation, "and the right to present testimony regarding the admissibility of the article."<sup>793</sup> To do so, FDA uses a specific form of notice called "Notice of FDA Action"<sup>794</sup> and need only designate a shipment's current status as "Detained" in order to fulfill the requirements set forth in FDA's policy manual in providing notice to the owner or consignee.<sup>795</sup>

498. The policy manual acknowledges that "[t]he statement of charges on the Notice of Detention and Hearing issued for a detained product is *the only information* the importer has regarding the apparent violation(s) with which the importation is charged."<sup>796</sup>

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<sup>788</sup> US Counter-Memorial, para. 381.

<sup>789</sup> See Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 63-66.

<sup>790</sup> Memorial, paras. 117, 474. See also Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 103-04.

<sup>791</sup> Memorial, para. 474.

<sup>792</sup> *Id.*, para. 117.

<sup>793</sup> **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-19 (2011); **Legal Authority CLA-245**, FDA Imports and Exports Rule, 21 CFR § 1.94.

<sup>794</sup> **Legal Authority CLA-309**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-33 (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-33 (2011).

<sup>795</sup> **Legal Authority CLA-309**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-33 (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-33 (2011).

<sup>796</sup> **Legal Authority CLA-309**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-31 (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-31 (2011) (emphasis added).

Indicating a shipment as “Detained” hardly provides information sufficient to inform an owner such as Apotex of the charges and to prepare an adequate defense.<sup>797</sup>

499. Moreover, detention hearings are limited to shipments that have already been detained. They do not provide an opportunity for firms to challenge the imposition of an Import Alert.<sup>798</sup> Detention hearings could not provide the necessary relief.
500. FDA acknowledged this limited scope when it described Apotex’s “right to present evidence in detention hearings” during a meeting: “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 dating [sic] showing that the issue(s) resulting in the Import Alert had been addressed.”<sup>799</sup>
501. Apotex would not have been able to present any such data, because the reasons for adopting the Import Alert were not disclosed to Apotex. Moreover, FDA regulations provide that the respondent may only introduce evidence on the admissibility of the article and cannot “question, probe, or pass judgment on FDA’s basis for detention.”<sup>800</sup>
502. Also due to the limited scope of allowable evidence, Apotex could not obtain and present favorable witnesses and evidence in order to contest adoption of the Import Alert. Thus, the US’s contention that “Apotex could have exercised its right to present evidence in detention hearings after its drug shipments had been detained without physical examination” is unsupported.<sup>801</sup>
503. Moreover, the detention hearing was an inadequate remedy because individual hearing officers (generally the district compliance officer) lack authority to lift DWPE orders

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<sup>797</sup> See, e.g., **Exhibit R-44**, Notice of FDA Action Entry No. EG6-1768425-3, Notice No. 2, dated September 4, 2009.

<sup>798</sup> **Legal Authority CLA-245**, FDA Imports and Exports Rule, 21 CFR § 1.94(a) (Respondent’s “testimony shall be confined to matters relevant to the admissibility of the article, and may be introduced orally or in writing.”). See **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-34 (2011). See also Second Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 63-66.

<sup>799</sup> **Exhibit C-386**, Apotex Draft Minutes of Meeting with FDA, dated September 3, 2009 at 1.

<sup>800</sup> **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-35 (2011).

<sup>801</sup> US Counter-Memorial, para. 381.

for products detained for alleged non-compliance with cGMP without Center concurrence.<sup>802</sup>

504. Put simply, this alleged “remedy” would not have been sufficient to remove Apotex from Import Alert, and as such could not provide Apotex with effective or adequate relief. Under international law, a remedy that cannot afford effective relief is inadequate.<sup>803</sup>

*d) The APA Provides No Judicial Review of Import Alerts*

505. The fourth and final “avenue” the US suggests, to file suit in US courts, is irrelevant and inapplicable.

506. Again, Apotex addressed this point in its Memorial, and the US failed to respond.<sup>804</sup> Apotex demonstrated that under US law import alerts are “committed to agency discretion and thus are not subject to judicial review under the Administrative Procedure Act (APA).”<sup>805</sup> It further observed that such has been the consistent position of the US before the courts in cases where FDA’s DWPE (import alert) has been challenged.<sup>806</sup> The US does not dispute that this is so.

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<sup>802</sup> **Legal Authority CLA-309** FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-29 (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at 9-29 (2011) (“[P]roducts placed on detention without physical examination ... because the products appear to have been manufactured in violation of GMPs, may generally be removed from detention without physical examination following a reinspection ... that confirms that corrective actions have been instituted and *after concurrence by the appropriate Center*. In some instances, a firm may present information or documentation sufficient to demonstrate that appropriate corrections are in place to overcome the appearance of a violation and, with *the appropriate Center concurrence*, may be removed from detention without physical examination.” (emphasis added)).

<sup>803</sup> *E.g.*, **Legal Authority CLA-523**, *Claims of Finnish shipowners against Great Britain in respect of the use of certain Finnish vessels during the war* (Finland v. Great Britain), 3 R.I.A.A. 1479, 1495 (2006) (“[T]he rule that local remedies must be exhausted before diplomatic interposition is proper is in its application subject to the important condition that the local remedy is effective in securing redress’ ... .”); **Legal Authority CLA-106**, *Ambatielos* (Greece v. UK), 12 R.I.A.A. 83, 119 (2006) (March 6, 1956) (“Remedies which could not rectify the situation cannot be relied upon by the defendant State as precluding an international action.”); **Legal Authority CLA-501**, U.N., Int’l Law Comm’n, *Draft Articles on Diplomatic Protection*, art. 14 cmt. 4, U.N. Doc. A/61/10 (2006) (“[T]he crucial question is not the ordinary or extraordinary character of a legal remedy but whether it gives the possibility of an effective and sufficient means of redress[.]” (citation and internal quotations omitted)).

<sup>804</sup> Memorial, paras. 118, 476.

<sup>805</sup> *Id.*, para. 118.

<sup>806</sup> *Id.*

507. Under international law, it is widely accepted that a remedy is futile when the court has no jurisdiction over the dispute.<sup>807</sup> Filing suit under the APA would have been futile because the APA applies only to final agency actions,<sup>808</sup> and according to FDA, Import Alerts are not final agency action.<sup>809</sup>
508. Furthermore, the APA specifically excludes from review actions that are committed to agency discretion by law.<sup>810</sup> As the US Supreme Court has noted, judicial review is precluded where “the statute in question is drawn so that a court would have no meaningful standard against which to judge the agency’s exercise of discretion.”<sup>811</sup> The Act’s domestic enforcement provisions have been deemed to “commit complete discretion to the Secretary to decide how and when they should be exercised.”<sup>812</sup>
509. Citing Supreme Court precedent, the FDA has recently advocated the same position with respect to the foreign enforcement provision of the Act, Section 801 (codified as 21 USC § 381), because that section “does not provide ‘law to apply.’”<sup>813</sup> FDA notes

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<sup>807</sup> **Legal Authority CLA-503**, U.N., Int’l Law Comm’n, *Third Report on Diplomatic Protection*, para. 38 n.54, U.N. Doc. A/CN.4/523 (Mar. 7, 2002) (prepared by John Dugard), **Legal Authority CLA-513**, *Panevezys-Saldutiskis Railway* (Est. v. Lith.), 1938 P.C.I.J. (ser. A/B) No. 76, at 18 (Feb. 28) (“There can be no need to resort to the municipal courts if those courts have no jurisdiction to afford relief . . . .”); **Legal Authority CLA-501**, U.N., Int’l Law Comm’n, *Draft Articles on Diplomatic Protection*, art. 15 cmt 3, U.N. Doc. A/61/10 (2006) (“[L]ocal remedies need not be exhausted where the local court has no jurisdiction over the dispute in question . . . .”).

<sup>808</sup> **Legal Authority CLA-561**, Administrative Procedure Act, 5 USC § 704 (“Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review.”).

<sup>809</sup> **Legal Authority CLA-138**, Defendants’ Memorandum in Opposition to Plaintiff’s Motion for Preliminary Injunction, *Smoking Everywhere, Inc. v. FDA*, No. 09-cv-0771 (RJL) at 35 n.7 (D.D.C. May 11, 2009) (“Also, for the same reasons that IA 66-41 is not a substantive rule, it is not final agency action subject to challenge.”). FDA argues that Import Alerts do not constitute final agency action because they are only a “preliminary stage” in the import proceeding, the detention of products, and not the final decision, the refusal of products, which is made by the detention officer. *Id.* at 26-27. *See also Legal Authority CLA-529*, Defendants’ Supplemental Brief in Opposition to Plaintiff’s and Intervenor’s Motions for a Preliminary Injunction, *Smoking Everywhere, Inc. v. FDA*, No. 09-cv-0771 (RJL) (D.D.C. July 10, 2009).

<sup>810</sup> **Legal Authority CLA-220**, Administrative Procedure Act, 5 USC § 701(a)(2).

<sup>811</sup> **Legal Authority CLA-534**, *Heckler v. Chaney*, 470 U.S. 821, 821 (1985).

<sup>812</sup> *Id.* at 835. The Court has previously ruled that the FDA’s decision not to institute an enforcement action is immune from judicial review because it is within the agency’s absolute discretion. *Id.* at 832-33.

<sup>813</sup> **Legal Authority CLA-542**, Memorandum in Support of Defendants’ Motion to Dismiss and in Opposition to Plaintiffs’ Motion for Injunctive Relief, *K-V Pharm. Co. v. FDA*, No. 1:12-cv-01105-ABJ, 2012 WL 5884076, at § D, \*12-13 (D.D.C. July 20, 2012). *But see Legal Authority CLA-526*, *Beaty v. FDA*, 853 F. Supp. 2d 30, 40-41 (D.D.C. 2012) (finding that FDCA § 381(a) provided sufficient standards with which to judge the agency’s action, therefore allowing judicial review of the decision not to detain the shipments).

that the “long line of court decisions confirms that the use of the terms ‘appear[]’ and ‘otherwise’ in section 381(a) establishes Congress’ intent to provide FDA with broad discretion in determining whether an article appears to violate the [Act].”<sup>814</sup> Under the Court’s jurisprudence, if section 381(a) does not provide sufficient standards for courts to assess agency action, it is non-reviewable under the APA as committed to agency discretion.

510. Under international law, when legislation denies that the remedy is available, the party alleging non-exhaustion bears the burden of proving that the remedy was in fact available.<sup>815</sup> The US has failed to demonstrate that the APA does not preclude judicial review of an Import Alert, an action that on its face is a non-reviewable, non-final, discretionary agency action.<sup>816</sup> Because a US court would lack jurisdiction to review such an act, the US has failed to meet its burden of showing “as a matter of fact, the existence of a remedy which was open to [claimants] and which they failed to employ.”<sup>817</sup>

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*Cf. Legal Authority CLA-539, K-V Pharm. v. FDA*, No. 12-1105(ABJ), 2012 WL 3860543, at \*19 (D.D.C. Sept. 6, 2012) (distinguishing *Beaty* on the grounds that *Beaty* applied to a specific shipment that FDA had determined violated the Act but decided not to detain). Moreover, FDA disagrees with the *Beaty* court’s conclusion.

<sup>814</sup> **Legal Authority CLA-542**, Memorandum in Support of Defendants’ Motion to Dismiss and in Opposition to Plaintiffs’ Motion for Injunctive Relief, *K-V Pharm. Co. v. FDA*, No. 1:12-cv-01105-ABJ, 2012 WL 5884076 (D.D.C. July 20, 2012). *See, e.g., Legal Authority CLA-540, K & K Merch. Group v. Shalala*, No. 95-10082, 1996 WL 183023, at \*8 (S.D.N.Y. Apr. 17, 1996) (noting “the wide discretionary power FDA enjoys to determine the factors regarding its decision to grant or refuse admission of imported goods.”); **Legal Authority CLA-551, Seabrook Int’l Foods, Inc. v. Harris**, 501 F. Supp. 1086, 1090-91 (D.D.C. 1980) (The “use of the term ‘appears’ in the statute is a striking and clear indication of Congress’ intent to forego formal procedural requirements.”), *aff’d sub nom., Cont’l Seafoods, Inc. v. Schweiker*, 674 F.2d 38 (D.C. Cir. 1982). *See also Legal Authority CLA-548*, Reply to Plaintiffs’ Opposition to Defendants’ Motion to Dismiss, *K-V Pharm. Co. v. FDA*, No. 1:12-cv-01105-ABJ, 2012 WL 5883953, at \*8 (D.D.C. Aug. 3, 2012) (“In any event, section 381(a) is, at most, ambiguous, and thus FDA’s long-standing interpretation of “shall be refused admission” as permitting the agency to exercise enforcement discretion is a permissible construction of the statute that is entitled to deference under the second prong of *Chevron*.”); **Legal Authority CLA-190, Sugarman v. Forbragd**, 405 F.2d 1189, 1190-91 (9th Cir. 1968), *cert. denied*, 395 U.S. 960 (1969) (finding that 21 USC § 381(a) is committed to the FDA’s discretion and is not reviewable).

<sup>815</sup> **Legal Authority CLA-454, Case of Certain Norwegian Loans (Fr. v. Nor.)**, 1957 I.C.J. 9, 39 (Separate Opinion of Sir Lauterpacht) (July 6).

<sup>816</sup> *Id.*

<sup>817</sup> **Legal Authority CLA-511, Elettronica Sicula S.p.A. (ELSI) (U.S. v. Italy)**, 1989 I.C.J. 15, para. 62 (July 20).

511. Apotex thus could not have brought suit for FDA’s “unreasonable delay in lifting the Import Alert” because the decision to re-inspect – the only way the Import Alert could have been removed – is committed to agency discretion and is non-reviewable under the APA.<sup>818</sup>
512. In the same way, there is no judicial review of either the administrative reconsideration procedure under 21 CFR section 10.75 or the citizen petition. There is no effective judicial review for the reconsideration decision because it is also a discretionary decision and not a final agency act.<sup>819</sup>
513. Although the citizen petition is final agency action subject to review under the APA, the FDA can prevent judicial review because it “has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination.”<sup>820</sup> Additionally, the regulations require the Commissioner to object to judicial review if “[t]he matter is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action under sections 302, 303, and

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<sup>818</sup> The US’s suggestion that the APA provided an available remedy with respect to the Import Alert simply because Apotex filed suit against FDA under the APA with respect to a different matter is misleading and irrelevant. See US Counter-Memorial, para. 381 n.918. Apotex’s suit sought to remedy FDA’s unacceptable delay in performing a *non-discretionary* act, which unlike the Import Alert, is reviewable under the APA. In that suit, Apotex requested declaratory and injunctive relief based on FDA’s “clear, nondiscretionary duty” to approve ANDAs that have been delayed “for no reason other than FDA’s inability to process necessary paperwork.” See **Legal Authority RLA-68**, Complaint for Declaratory, Injunctive and Other Relief, *Apotex Inc. & Apotex Corp. v. U.S. Department of Health and Human Services*, No. 1:12-cv-01647, paras. 48, 51 (D.D.C. Oct. 3, 2012). Following inspection of Apotex’s Bangalore facility, FDA deemed it compliant with cGMPs and approved several of Apotex’s pending ANDAs. Approval of two other ANDAs remained pending, solely because a compliance recommendation from the Office of Compliance was needed. *Id.* para. 37. Although the Office of Compliance had previously assured Apotex that the necessary compliance recommendations had been timely made, it later informed Apotex that the delay was due to a missing EIR for the Bangalore inspection. *Id.* paras. 38-39. However, that EIR was necessary to approve the previously approved ANDAs. *Id.* Because FDA had already made the necessary determinations in conducting the inspection, deeming the facility compliant, and approving other ANDAs reliant upon that same inspection, the delay in approving the remaining two ANDAs is not “committed to agency discretion by law.” See **Legal Authority CLA-220**, Administrative Procedure Act, 5 USC § 701(a)(2).

<sup>819</sup> **Legal Authority CLA-220**, Administrative Procedure Act, 5 USC §§ 701(a)(2), 704.

<sup>820</sup> **Legal Authority RLA-159**, 21 CFR § 10.25(b).

304 of the act.”<sup>821</sup> Therefore, FDA could object to a court’s review of Apotex’s petition against the FDA’s decision to take enforcement action or it could ask the court to remand for the agency to further consider the issue, causing more delay.

514. In sum, customary international law does indeed require that a State apply minimum procedural safeguards in deciding the essential interests of a person. The record shows that FDA did not afford Apotex any of those safeguards in adopting the Import Alert. And the US suggestion that Apotex could have obtained due process by pursuing four supposed “avenues” does not withstand examination. The record, in short, establishes that the US breached Article 1105.

#### **D. Apotex’s Claim for Breach of the US-Jamaica BIT Is Meritorious**

515. Apotex notes that the US Counter-Memorial reflects important common ground between the parties on Apotex’s claim under Article 1103 and the US-Jamaica BIT. The United States does not dispute that substantive provisions, such as those set out in Article II of the US-Jamaica BIT, may be attracted by virtue of the MFN clause in NAFTA Article 1103.<sup>822</sup> Furthermore, it does not dispute that treatment provided to foreign investors by BITs concluded by the US after the entry into force of the NAFTA, including the US-Jamaica BIT, constitutes “treatment” for the purposes of Article 1103.<sup>823</sup> The parties’ disagreement is limited to two points.

516. *First*, the US asserts, without offering any authority or even argument, that the provisions of Article II of the U.S.-Jamaica BIT do not “provide Apotex with more favorable treatment than NAFTA Article 1105 with respect to Apotex’s due process claims.”<sup>824</sup> This argument is misplaced and based on an incorrect reading of Apotex’s

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<sup>821</sup> **Legal Authority CLA-248**, 21 CFR § 10.45(d)(2)(i). The regulation gives as an example enforcement actions for domestic firms, therefore it seems that the agency would equally view enforcement actions for foreign firms as within the agency’s discretion as well.

<sup>822</sup> *See* Memorial, para. 479. In addition to the authority already cited in footnote 679 of the Memorial, this has most recently been confirmed by the tribunal in the arbitration between Franck Charles Arif and the Republic of Moldova, which found that the MFN provision in Article 4 of the France-Moldova BIT could import an “umbrella” clause (which is substantive in nature) from either the Moldova-UK or the Moldova-US BIT. *See Legal Authority CLA-506, Arif v. Republic of Moldova*, ICSID Case No. ARB/11/23, Award, para. 396 (Apr. 8, 2013).

<sup>823</sup> *See* Memorial, para. 480.

<sup>824</sup> US Counter-Memorial, para. 384.

Memorial. Contrary to the US's assertions, Apotex has indeed "alleged" and "demonstrated" that the US-Jamaica BIT affords more favorable treatment than Article 1105.<sup>825</sup>

517. *Second*, the US erroneously suggests that Apotex attempts to interpret Article 1105 through the provisions of the US-Jamaica BIT so as to "expand the scope of fair and equitable treatment" under the NAFTA.<sup>826</sup> This is not, however, an argument that Apotex has made. The United States attacks a straw man and mischaracterizes Apotex's position.

*1. Article II of the US-Jamaica BIT Provides for More Favorable Treatment than NAFTA Article 1105*

518. As already stated in its Memorial, Apotex relies upon the more favorable provisions of Article II of the US-Jamaica BIT, which was signed and became effective after the entry into force of the NAFTA on January 1, 1994.<sup>827</sup> This Article sets forth several obligations of treatment, including the investor's right to effective means for asserting claims and enforcing rights (Article II, paragraph 6).

519. A reading of Article II, paragraph 6, of the US-Jamaica BIT in light of the rules of interpretation set out in the Vienna Convention on the Law of Treaties supports Apotex's position and contradicts US's assertion that this provision does not afford "more favorable treatment than NAFTA Article 1105."<sup>828</sup>

520. Article 31(1) of the Vienna Convention requires a treaty to be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."<sup>829</sup> According to Article II(6) of the US-Jamaica BIT:

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<sup>825</sup> See Memorial, para. 481 ("[The US-Jamaica BIT] contains several provisions which confer rights upon investors of the other Contracting Party, in like circumstances, rights that are not granted upon the Claimants by virtue of NAFTA Chapter Eleven.").

<sup>826</sup> US Counter-Memorial, para. 385.

<sup>827</sup> Memorial, paras. 480-481.

<sup>828</sup> US Counter-Memorial, para. 384.

<sup>829</sup> See **Legal Authority CLA-17**, Vienna Convention on the Law of Treaties, Apr. 24, 1970, S. Treaty Doc. No. 92-12, 1155 U.N.T.S. 331.

Each Party shall provide effective means of asserting claims  
and enforcing rights with respect to investments . . . .<sup>830</sup>

521. The primary meaning of “effective” is that of “[h]aving the intended or expected effect; serving the purpose.”<sup>831</sup> As to the term “means,” it is ordinarily defined as a “method, course of action, or instrument by which some act can be accomplished or some end achieved.”<sup>832</sup> “Effective means” are therefore those representing a “method, course of action, or instrument” which has “the intended or expected effect.”
522. “[E]ffective means of asserting claims and enforcing rights” are those that serve the purpose of permitting vindication of claims and rights with respect to investments.<sup>833</sup>
523. Article II(6) contains no limitation of the terms employed. The obligation to provide “effective means” applies with respect to investment in unqualified terms. There is no restriction as to the nature of the proceedings concerned. Notably, there is no limitation to “adjudication.” Accordingly, the argument advanced by the US under Article 1105 is unsupported by the text of Article II(6) of the US-Jamaica BIT.
524. Further confirmation that Article II(6) affords more favorable treatment to investors than NAFTA Article 1105 comes from its context. Article II paragraph 2(a) sets out an obligation to accord to investments at all times “fair and equitable treatment,” which cannot be “less than that required by international law.” In the *ADF Group* case, the US argued that identically worded provisions in other US BITs had “much the same effect as Article 1105(1) of NAFTA as construed by the FTC Interpretation of 31 July 2001” – and the tribunal agreed.<sup>834</sup> It follows that if the “effective means” obligation in

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<sup>830</sup> **Legal Authority CLA-10**, Treaty Between the United States of America and Jamaica Concerning the Reciprocal Encouragement and Protection of Investment, U.S.-Jam., Feb. 4, 1994, T.I.A.S. No. 00103.

<sup>831</sup> **Legal Authority CLA-593**, *Effective Definition*, The American Heritage Dictionary of the English Language 416 (William Morris, ed., 3d ed. 1973).

<sup>832</sup> **Legal Authority CLA-594**, *Mean Definition (plural)*, The American Heritage Dictionary of the English Language 810 (William Morris, ed., 3d ed. 1973).

<sup>833</sup> See **Legal Authority CLA-60**, *Chevron Corporation (USA) and Texaco Petroleum Company (USA) v. The Republic of Ecuador*, UNCITRAL, PCA Case No. 34877, Partial Award, para. 248 (Mar. 30, 2010) (reminding that the “effective means” obligation “is stated as a positive obligation of the host State to provide” such means, “as opposed to a negative obligation not to interfere in the functioning of those means.”).

<sup>834</sup> **Legal Authority CLA-18**, *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Award, para. 195 (Jan. 9, 2003).

paragraph 6 provided for the same investment guarantees as NAFTA Article 1105, then this provision would be just a repetition of the fair and equitable treatment obligation in paragraph 2 and, therefore, useless. The principle of effectiveness recognized by the law of treaties cannot be reconciled with such a conclusion.<sup>835</sup> The context confirms that paragraph 6 of Article II establishes a different, higher standard of treatment than the customary international law minimum standard of treatment in paragraph 2 and NAFTA Article 1105.<sup>836</sup>

525. Finally, the object and purpose of the US-Jamaica BIT is to “stimulate the flow of private capital,” as a result of “agreement upon the treatment to be accorded ... such investment.”<sup>837</sup> This objective can be met only if the words of the treaty are read to mean what they say.

526. Recent arbitral case law supports Apotex’s position that different standards of treatment are set out in Article II(6) of the US-Jamaica BIT and in NAFTA Article 1105. The tribunal in *Chevron v. Ecuador* has held that the “effective means” standard “constitutes a *lex specialis* and not a mere restatement of the law on denial of justice” in customary international law.<sup>838</sup> In view of these considerations, the tribunal accepted that “a distinct and potentially less-demanding test is applicable under this provision as compared to denial of justice under customary international law.”<sup>839</sup> More recently, the tribunal in *White Industries v. India* considered “this description of the ‘effective means’ standard to be equally appropriate for application” in cases where similar provisions were applicable.<sup>840</sup>

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<sup>835</sup> See *supra* n.361.

<sup>836</sup> See Memorial, para. 483.

<sup>837</sup> **Legal Authority CLA-10**, Treaty Between the United States of America and Jamaica Concerning the Reciprocal Encouragement and Protection of Investment, U.S.-Jam., Feb. 4, 1994, T.I.A.S. No. 00103, preamble.

<sup>838</sup> **Legal Authority CLA-60**, *Chevron Corporation (USA) v. The Republic of Ecuador*, UNCITRAL, PCA Case No. 34877, Partial Award, para. 242 (Mar. 30, 2010).

<sup>839</sup> *Id.*, para. 244.

<sup>840</sup> See **Legal Authority CLA-77**, *White Industries Australia Limited v. India*, UNCITRAL, Award, para. 11.3.3 (Nov. 30, 2011).

527. As already demonstrated, none of the “avenues” supposedly offered to Apotex as a means to assert its claims in relation to the Import Alert was effective.<sup>841</sup> The four “avenues” of relief proposed (the citizen petition under 21 CFR §§ 10.25 and 10.30; the reconsideration procedure under 21 CFR § 10.75; the detention hearing under 21 CFR § 1.94; and judicial review under the APA for delay in re-inspection) were not able to afford Apotex any meaningful redress since they could not lead to the lifting of the Import Alert. The US provided Apotex no other means. Consequently, the US has breached Article II(6) of the US-Jamaica BIT.

2. *Apotex’s Position Has Never Been That NAFTA Article 1105 Should Be Interpreted in Light of the US-Jamaica BIT*

528. The United States puzzlingly attacks at some length a position that Apotex has never asserted: namely, that Apotex could use “the most-favored-nation treatment provision in Article 1103 to expand the scope of fair and equitable treatment.”<sup>842</sup>

529. By invoking Article 1103, Apotex has never sought to expand the scope of Article 1105. Apotex has never claimed, as the US contends, that the MFN clause could “alter the substantive content” of the minimum standard of treatment,<sup>843</sup> nor that it could be used to interpret general international law so as to include different obligations from those established by customary rules.

530. Apotex’s position is and has always been that NAFTA Article 1103, like any other MFN provision, allows for the application of more favorable substantive standards of investment protection. This position is undisputed between the parties. It is equally undisputed that Apotex’s claim concerning the breach of the US-Jamaica BIT falls squarely within the ambit of Article 1103.

531. Contrary to the US’s submission, Apotex does not assert that a breach of Article 1103 establishes that there has been a breach of Article 1105(1). Apotex’s position is that failure to accord the treatment provided by Article II(6) of the US-Jamaica BIT breaches Article 1103, not Article 1105. The FTC’s Note of Interpretation on NAFTA

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<sup>841</sup> See *supra* Part II(c).

<sup>842</sup> US Counter-Memorial, para. 385.

<sup>843</sup> *Id.*, para. 389.

Article 1105 is limited to that particular provision and is unrelated to Article 1103. The NAFTA Parties' interpretation of Article 1105 does not limit the scope of Article 1103. The US argument attacks a straw man. In sum, the US was required by Article 1103 of the NAFTA and Article II(6) of the US-Jamaica BIT to provide Apotex with effective means of asserting its claims and enforcing its rights with respect to its investments. The US adopted the Import Alert without providing Apotex any such means. The record establishes that the US breached Article 1103 of the NAFTA.

## **SUBMISSIONS**

532. As a result of the actions and breaches of the Government of the United States of America described above, the Claimants respectfully request a decision in their favor:

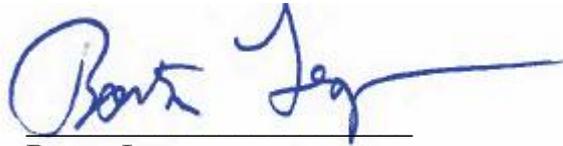
- a. Dismissing the US jurisdictional objections;
- b. Declaring that the United States of America has breached its obligations under Articles 1102, 1103 and 1105 of the NAFTA;
- c. Ordering that the Claimants' claims to damages and interest be addressed in the subsequent phase of this arbitration, and decided in the final award;
- d. Reserving decision on Claimants' request for an award of costs, including professional fees and disbursements, until the next phase of this arbitration;
- e. Ordering such other and further relief as the Tribunal deems appropriate in the circumstances.

533. Apotex Holdings and Apotex-Canada reserve the right to amend and modify their prayers for relief and to refine their position in the course of the arbitration.

Date: May 24, 2013

*Respectfully submitted,*

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