INTERNATIONAL CENTRE FOR
SETTLEMENT OF INVESTMENT DISPUTES

APOTEX HOLDINGS INC. *and* APOTEX INC.,

Claimants,

– and –

THE GOVERNMENT OF THE UNITED STATES OF AMERICA,

Respondent.

ICSID CASE NO. ARB(AF)/12/__

REQUEST FOR ARBITRATION

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February 29, 2012

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Pursuant to Article 4 of the Additional Facility Rules, Article 2 of the Arbitration (Additional Facility) Rules and Articles 1116(1), 1117(1) and 1120(1)(b) of the North American Free Trade Agreement ("NAFTA"), Apotex Holdings Inc. and Apotex Inc. (together, the "Claimants"), on their own behalf and on behalf of Apotex Holdings Inc.'s enterprise, Apotex Corp. (collectively, "Apotex"), hereby respectfully request approval of access to the Additional Facility and institution of arbitration proceedings concerning the claims stated herein.

I. INTRODUCTION

1. Apotex Holdings Inc. ("Apotex Holdings") is a Canadian investor in the generic pharmaceutical industry. It has over the past two decades made substantial investments in Apotex Corp. ("Apotex-US"), a US company that it indirectly owns and controls. Apotex-US's business is the sale in the United States of drugs produced by other Apotex companies, notably Apotex Inc. ("Apotex-Canada"), a Canadian

generic drug manufacturer that Apotex Holdings also indirectly owns and controls. Due to the substantial investment of capital, know-how and expertise by Apotex Holdings, Apotex-US at the beginning of 2009 was one of the top generic drug companies in the United States in terms of sales volume.

2. On August 28, 2009, the US Food and Drug Administration ("FDA" or the "Agency") adopted a measure with respect to two Canadian facilities operated by Apotex-Canada. Together these two facilities produced about 80 percent of the products sold by Apotex-US. The measure, called an import alert, prevented Apotex-US from receiving any drugs produced at these two facilities. FDA did not fully lift the import alert until the end of July 2011.

3. Because of the import alert, Apotex-US's business was decimated. It lost hundreds of millions of dollars of sales and was prevented from bringing any new drug to the US market. Apotex Holdings, Apotex-Canada and Apotex-US suffered substantial damage as a result of the measure – damage that continues today.

4. During the relevant time period, FDA accorded more favorable treatment to US investors and US-owned investments in like circumstances to Apotex Holdings, Apotex-Canada and Apotex-US. No such investor or investment was subjected to a measure as severe as the import alert imposed on the Apotex companies. Investors of other countries and investments owned by such investors in like circumstances also received more favorable treatment than that accorded to the Apotex companies.

5. The import alert violated NAFTA Article 1102 (National Treatment), Article 1103 (Most-Favored-Nation Treatment) and Article 1105 (Minimum Standard of Treatment). Damage to the Claimants and Apotex-US through August 2011 resulting from the violations exceeds USD 520 million. Total damages greatly exceed this amount.

II. THE PARTIES

A. THE CLAIMANTS

6. Claimant Apotex Holdings is a privately-held corporation organized under the Canada Business Corporations Act, a Canadian federal law. It functions as a holding company for the Apotex group's investments. Its principal place of business is:

150 Signet Drive
Toronto, Ontario M9L 1T9
Canada

7. Claimant Apotex-Canada is a company incorporated under the laws of the province of Ontario, Canada. It is indirectly owned and controlled by Apotex Holdings. Apotex-Canada holds a number of investments in the US, including but not limited to scores of authorizations to market and sell pharmaceutical products in the US, bundles of intellectual property rights associated with those products and other investments. The principal place of business of Apotex-Canada is:

150 Signet Drive
Toronto, Ontario M9L 1T9
Canada

8. Apotex-US is a corporation organized under the laws of Delaware, United States of America, and authorized to transact business in the state of Florida. It is an "investment" and an "enterprise" within the meaning of Article 1139 of the NAFTA. Its principal place of business is:

2400 North Commerce Parkway, Suite 400
Weston, Florida 33326
United States of America

Claimant Apotex Holdings indirectly owns and controls this enterprise.

B. THE RESPONDENT

9. The United States of America is a sovereign State and a Party to the NAFTA.

10. Under Article 1137(2) of the NAFTA, delivery of notices and documents to the Government of the United States of America shall be made to the following address:

Executive Director (L/EX)
Office of the Legal Adviser
U.S. Department of State
Washington, D.C. 20520
United States of America

III. FACTUAL BACKGROUND

A. THE APOTEX GROUP OF COMPANIES

11. Apotex Holdings is the largest investor in the pharmaceutical industry in Canada and an important investor in a range of pharmaceutical markets around the world.

12. Some 40% of Apotex group sales are in the Canadian market. The remaining 60% of group sales are in markets outside of Canada. In the first half of 2009, the United States market accounted for the majority of the 60% of Apotex group sales outside of Canada.

13. Apotex-Canada is the largest Canadian-owned pharmaceutical company. It is an innovative global research and technology leader in generic pharmaceuticals. It produces more than 300 kinds of generic drugs in about 4,000 dosages and formats.

14. Apotex-Canada operates several production sites in Canada. Two of Apotex-Canada's facilities are located at Signet Drive in Toronto, Ontario ("Signet") and in Etobicoke, Ontario ("Etobicoke"). Signet and Etobicoke produce solid-dose medicinal products, such as tablets.

15. Over the past years, Apotex Holdings made substantial investments in the US market, including but not limited to its indirect investment in Apotex-US. It built Apotex-US into a highly successful business. As of the end of June 2009, Apotex-US had the sixth-highest sales of any generic drug company in the United States.

16. The Signet and Etobicoke facilities produced the solid-dose products sold by Apotex-US on the US market prior to August 2009. As of that date, these solid-dose products accounted for about 80% of Apotex-US's sales.

B. THE REGULATORY ENVIRONMENT

17. As a Canadian drug manufacturer, Apotex-Canada is primarily regulated and controlled by Health Canada. Apotex-Canada's facilities have been regularly inspected by Health Canada since the mid-1970s. Because Apotex-Canada also supplies the US drug market, its production sites have also periodically been inspected by FDA.

18. Health Canada's and FDA's inspections address a multitude of subjects associated with modern pharmaceutical production. These subjects include what is known as current good manufacturing practices ("cGMP"). These are a set of standards developed through consultations between industry and regulatory agencies and codified in regulations. The standards address, among other topics, the proper design, monitoring and control of manufacturing processes at facilities.

19. Under US law, a drug is considered "adulterated" if the methods or facilities used to produce it do not conform to cGMP so as to ensure the safety, identity, strength, quality and purity of the drug required by the Federal Food, Drug and Cosmetic Act (the "Act").[1]

20. FDA assesses conformity with cGMP in part through on-site inspections of pharmaceutical manufacturing facilities. Because the FDA's cGMP standards are by their nature general, their application to specific processes, equipment and facilities leaves much to the discretion of manufacturers.

21. At the conclusion of an inspection, FDA inspectors record their observations on a form known as form 483. A form 483 lists "'inspectional observations; [these] do not represent a final agency determination regarding [a manufacturer's] compliance.'"[2] A manufacturer may provide comments on the inspectors' observations. The observations and responses are reviewed by FDA.

22. If FDA believes that the company has not adequately responded to all the observations, and there are significant cGMP violations at the facility, it may issue a warning letter. Companies have an opportunity to comment in response to a warning letter. FDA typically takes the response into account in determining whether additional enforcement action against the facility is warranted.

23. Additional enforcement action could include seizure of products on the market or a civil action seeking injunctive relief. Such an injunction typically precludes continued marketing of affected products until FDA confirms compliance with cGMP.

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1 *See* 21 USC § 351(a)(2)(B). The US codification of cGMP for drugs can be found at Parts 210 and 211 of Title 21 of the Code of Federal Regulations (21 CFR § 210-211).

2 FDA, Notice on Review of Post-Inspection Responses, 74 Fed. Reg. 40211-03, 2009 WL 2430727, p. 1 (August 11, 2009) (quoting form 483 instructions).

24. Section 801 of the Act authorizes the US Government to detain, physically examine and refuse admission of a product into the United States if the product is adulterated. The Act permits such a measure after samples of specific products have been taken and the owner has been provided notice and an opportunity to appear and give testimony.[3]

25. Purportedly based on this provision, FDA has created a measure known as an import alert. This is a notice by FDA to US customs officials that calls for detention without physical examination of a specified category of products. In practice, the result often is not detention of any product or sample but a refusal of admission of all products meeting the stated category, without examination of any sample of a product.

C. FDA'S INSPECTIONS OF APOTEX'S FACILITIES IN 2008 TO 2009

26. FDA has inspected Apotex-Canada's facilities in Signet and Etobicoke on numerous occasions. Until 2009, FDA never found any cGMP violation at these facilities – nor for that matter at any other Apotex group facility elsewhere. Thus, in April 2002, May 2005 and November 2006, FDA inspected Etobicoke; it inspected Signet in September 2000, March 2003 and June 2006. While during the 2000, 2002 and 2006 inspections FDA inspectors made some observations concerning cGMP at these facilities, after receiving Apotex-Canada's clarifications, FDA found cGMP compliance at the facilities to be sufficient.

27. There was no material change in the applicable legal regime or FDA practices between these inspections and the inspections described below.

1. The Etobicoke Inspection

28. From December 10 to 19, 2008, FDA inspected Apotex-Canada's facility in Etobicoke.

29. At the close of the inspection, the inspectors issued three pages of observations on form 483, listing 11 alleged deviations from cGMP. The inspectors did not suggest that their observations raised any concern as to the continued manufacture or distribution in the United States of drugs manufactured at Etobicoke.

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[3] 21 USC § 381(a) (codifying Section 801(a) of the Act).

30. Apotex-Canada provided an eight-page response to the inspectors' observations on January 30, 2009. As promised in its response, Apotex-Canada enhanced its quality and manufacturing processes and equipment at Etobicoke in the first half of 2009. Apotex-Canada received no further communication from the FDA concerning Etobicoke for several months.

31. On June 25, 2009, FDA issued a warning letter identifying three issues of concern to the Agency (the "Etobicoke Warning Letter"). Only two of these concerned cGMP. Of these, one was not identified as an issue by the inspectors on their form 483 observations, and the other was stated as a request for further information rather than a finding of a violation. The remaining form 483 observations were either resolved by Apotex-Canada's response or otherwise not adopted by FDA.

32. The first alleged cGMP observation in the Etobicoke Warning Letter was a "[f]ailure to thoroughly investigate the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed," in violation of 21 CFR § 211.192.[4] No such deficiency had previously been mentioned in the form 483. Apotex-Canada, as part of its quality control processes, regularly tests products at different stages in their fabrication. Apotex-Canada's own testing revealed that some of the tested products did not fully meet specifications and, as a result, were rejected by the company after an internal investigation. However, according to FDA, Apotex-Canada (A) had not provided FDA with records of its investigations of batch failures during a two-year period (though these records were available for review at the facility and FDA never previously requested them); (B) had not completed an investigation of a failure of a batch that was never intended for commercial distribution; and (C) with regard to one record of an investigation, did not identify the root cause of the problem detected during Apotex-Canada's routine testing.[5]

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[4] This provision states in pertinent part: "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."

[5] Etobicoke Warning Letter, (WL: 320-09-06), dated June 25, 2009, pp. 1-3, item 1, available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm170912.htm (last visited on February

33. The second alleged cGMP issue identified in the Etobicoke Warning Letter was "[f]ailure to include a specimen or copy of each approved label and all other labeling in the master production and control record." The cGMP standard identified as pertinent was 21 CFR § 211.186(b)(8).[6] FDA questioned Apotex-Canada's practice of relying on electronic controls for labeling instead of including physical copies of the approved labels and labeling in the master record. FDA requested additional explanations concerning the operation of Apotex-Canada's systems.[7]

34. The Etobicoke Warning Letter did not take into consideration the enhancements to processes at the facility that were put into place by Apotex-Canada in the first half of 2009. On July 17, 2009, Apotex-Canada provided a 24-page response to the Etobicoke Warning Letter. It received no reply from FDA. Again, FDA did not question the continued manufacture for or distribution in the United States of drug products manufactured at Etobicoke.

2. The Signet Inspection

35. From July 27 to August 14, 2009, a large team of FDA inspectors inspected Apotex-Canada's Signet facility. At the close of the inspection, the inspectors issued a 17-item list of observations on form 483. The inspectors asked Apotex-Canada to schedule a conference call with FDA to discuss the observations. Under recently-announced FDA procedures, Apotex's response to the form 483 observations was due on or before September 4, 2009.[8]

36. On August 17, 2009, Apotex officers held a conference call with FDA. While noting that it was still studying the form 483 observations (which it had received the

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9, 2012). FDA concluded at page 2 of this letter: "These examples illustrate problems in the quality control unit's ability to conduct thorough investigations, as required by 21 CFR 211.192, to determine the cause of OOS [out-of-specifications] results."

6 This provision states in pertinent part as follows: "Master production and control records shall include: ... (8) 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 labeling; ..."

7 Etobicoke Warning Letter, (WL: 320-09-06), dated June 25, 2009, p. 3, item 3, available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm170912.htm (last visited on February 9, 2012).

8 *See* FDA, Notice on Review of Post-Inspection Responses, 74 Fed. Reg. 40211-03, 2009 WL 2430727, p. 2 (August 11, 2009) ("If we receive a response to FDA 483 observations within 15 business days after the FDA 483 was issued, we plan to conduct a detailed review of the response before determining whether to issue a warning letter.").

preceding business day), Apotex committed voluntarily to recall 675 batches of product from the US market as a precautionary measure.

37. By a three-page internal memorandum dated August 20, 2009, the FDA's director of compliance for drug products requested that the FDA director of import operations amend Import Alert 66-40 to include all products manufactured at Apotex's Etobicoke and Signet facilities. The request was made without the benefit of Apotex's response to the Signet form 483, which was due on September 4. The FDA provided no notice to Apotex of its proposed action or its reasoning.[9]

D. THE IMPORT ALERT

38. On August 28, 2009, FDA amended Import Alert 66-40 to include all products produced by the Etobicoke and Signet facilities (the "Import Alert"). FDA provided no notice of this measure to any Apotex company. The measure prevented Apotex-US from receiving for sale in the US any product manufactured at the Etobicoke and Signet facilities. In addition, FDA suspended consideration of any Abbreviated New Drug Applications ("ANDAs") for drugs produced or to be produced at these two facilities. It therefore prohibited Apotex-US from bringing to market any new solid-dose generic drugs – effectively eliminating Apotex-US's ability to secure the advantage of statutory marketing exclusivity for new products.

39. At no point, however, did FDA seize, or indicate to Apotex that it should recall, any product already being marketed in the US that had been manufactured at Etobicoke or Signet under the same cGMP systems that led to the Import Alert. FDA had enforcement mechanisms by which it could have removed those products from the US market, but it elected not to do so.

40. Apotex-Canada submitted its response to the form 483 for Signet on September 3, 2009. It received no reply from FDA, which had already imposed the Import Alert without the benefit of Apotex's response.

41. In September, October and part of November 2009, Health Canada conducted its own inspections of the Etobicoke and Signet facilities. The inspections together lasted for seven weeks. At the end, Health Canada concluded that, while manufacturing

[9] Apotex obtained a copy of the internal FDA memorandum only in February 2012 following a Freedom of Information Act request.

processes could be improved in ways that Apotex-Canada was addressing, both facilities were cGMP-compliant.

42. Other governmental agencies worldwide, including the European Medicines Agency, the Australian Therapeutic Goods Administration and New Zealand's Medicines and Medical Devices Safety Authority, followed Health Canada's determination and disregarded that of FDA. As a result, the Apotex products manufactured at Etobicoke and Signet continued to be distributed in every one of its markets around the world except the US market.

E. FDA'S DELAY IN LIFTING THE IMPORT ALERT AND IN GRANTING NEW DRUG APPROVALS

43. Apotex-Canada rejected FDA's suggestion that its facilities were not compliant with cGMP. It nonetheless rapidly agreed, again, to cooperate with FDA and promptly address the issues the inspectors had raised.

44. On September 11, 2009, Apotex representatives flew to Washington to meet with FDA. They outlined a quality-control improvement plan aimed at enhancing Apotex processes to FDA's satisfaction. This plan was implemented in all Apotex facilities worldwide.

45. In February 2010, Apotex asked FDA for a face-to-face meeting concerning the Etobicoke and Signet facilities. This meeting was scheduled for March 31, 2010.

46. On March 29, 2010, FDA issued a warning letter with respect to Signet (the "Signet Warning Letter").[10] This letter came seven months after the Import Alert and almost eight months after the Signet inspection, but two days before the face-to-face meeting. As noted above, at the close of the inspection, FDA inspectors had reported 17 observations on form 483. The Signet Warning Letter, however, listed four alleged cGMP deviations. One of these was based on events post-dating Apotex's September 2009 response to the Signet form 483.[11] These findings were made without prior notice to Apotex-Canada and without affording Apotex any opportunity to respond.

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[10] Signet Warning Letter (WL: 320-10-003), dated March 29, 2010, available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm207508.htm (last visited on February 9, 2012).

[11] *Id.* at p. 2, item 4.

47. At the March 31, 2010 meeting, FDA committed to Apotex-Canada that it would conduct an expedited inspection of both the Etobicoke and Signet facilities. FDA asked that Apotex-Canada make a formal request for inspection when it was ready.

48. On August 27, 2010, Apotex-Canada made a formal request that FDA re-inspect its Etobicoke facility. It requested that the inspection include pre-approval inspections for a number of new drug applications. On September 29, 2010, Apotex-Canada made a formal request for re-inspection of its Signet facility.

49. On October 15, 2010, FDA's Division of Foreign Inspection (DFI) confirmed that an inspection would take place from November 29 through December 17, 2010, focusing first on the Etobicoke facility, followed by Signet.

50. On October 21, 2010, FDA provided formal notification of the inspection date (November 29, 2010). Apotex-Canada confirmed the inspection date on October 26, 2010.

51. Because FDA refused to act on any new generic drug applications while the two facilities remained on Import Alert, the number of Apotex-Canada's applications awaiting pre-approval inspection had grown to around 56. Concerned that FDA would not be able to accommodate pre-approval inspections for all these products, Apotex-Canada attempted unsuccessfully to contact FDA to discuss the issue. On November 4, 2010, Apotex-Canada provided FDA with a list of 15 priority products and called FDA to ensure that the pre-approval inspections would not delay clearance of the two facilities. Apotex-Canada was told that a senior inspector had been assigned and that Apotex-Canada would be informed of the assignments of additional inspectors. On November 22, 2010, another senior inspector called Apotex-Canada to confirm that she would arrive to conduct the inspection starting on November 29.

52. Curiously, on that same day of November 22, 2010, another FDA official cancelled the inspection of the two facilities and advised that it would not be rescheduled until January 24, 2011.

53. The inspection of both Etobicoke and Signet was thus delayed until January 24, 2011, five months after Apotex-Canada's first request for inspection had been made. During this five month period, FDA had no reason to believe that any of Apotex's

products were not manufactured in compliance with cGMP or was otherwise adulterated. Indeed, at the conclusion of the inspection on February 11, 2011, FDA found no violation of cGMP standards justifying continuation of the Import Alert or any enforcement action.

54. Despite this conclusion in February 2011, FDA delayed lifting the Import Alert for the Etobicoke facility until June 15, 2011. It was only on July 29, 2011 that it finally lifted the Import Alert with respect to Signet. During this five-month period, FDA maintained the Import Alert, even though FDA itself had confirmed the cGMP-compliant status of the facilities.

55. FDA also continued to refuse to consider Apotex-Canada's new product applications during this five-month period. Apotex-Canada expected that FDA would begin issuing new product approvals upon its determination that the Etobicoke and Signet facilities were cGMP-compliant. Apotex based this expectation on its communications with FDA leading up to the re-inspection in January-February 2011, FDA's practice to conduct pre-approval inspections in connection with any ongoing cGMP inspection, and FDA's collection of records regarding new products waiting for approvals. Following FDA's determination that the Etobicoke facility was substantially compliant, Apotex-Canada requested approval of the pending applications for new drugs produced at that facility in May 2011.

56. FDA refused to do so. Instead, FDA insisted on conducting still another inspection of the Etobicoke facility. FDA assured Apotex-Canada that it would expedite this pre-approval inspection. But FDA did not conduct the inspection until late September 2011. It recommended approval of the pending applications only on October 31, 2011.

57. Due to the Import Alert and FDA's course of action, Apotex-US was prevented from selling billions of dosages of products on the US market from August 28, 2009 to July 29, 2011. Apotex Holdings was prevented from realizing any returns on such sales. During this period, Apotex also missed the window of opportunity to launch the first generic versions of several patented products on the American market. Thus, Apotex lost sales, market share and momentum as a result of the Import Alert and Apotex Holdings lost the ability to realize substantial returns on its investments. In addition, Apotex-US was forced to pay significant penalties to its customers in the US due to

its inability to deliver products because of the Import Alert. Apotex-US and Apotex-Canada were forced to write off inventory that could not be sold as a result of the Import Alert. Finally, Apotex-Canada incurred significant legal fees and advisers' fees as a result of the Import Alert and in order to enhance its facilities to FDA's satisfaction. All of these negatively impacted Apotex Holdings' and Apotex-Canada's realization of returns on their investments.

F. FDA'S TREATMENT OF COMPARABLE INVESTORS AND INVESTMENTS

58. During the relevant time, comparable US and foreign counterparts to Apotex Holdings and Apotex-Canada, and comparable US-owned and foreign-owned counterparts to Apotex-US, received more favorable treatment. The market included US investors in the pharmaceutical industry that sold drugs on the US market through a US company and sourced at least some product from factories located outside of the US. Other US investors in that industry sold drugs on the US market through a US company and sourced their product from factories located in the US.

59. The market also included third-country investors in the pharmaceutical industry that owned a US company that sold drugs on the US market and sourced at least some product from factories located outside the US.

60. During the relevant time period, FDA inspected the facilities of these comparable investors and investments and found cGMP violations similar to those that it purported to find at Etobicoke and Signet. However, FDA took no enforcement action even remotely as severe as the Import Alert with respect to these investors and investments.

61. By way of example, in September 2010, FDA inspected a facility of Teva Pharmaceutical Industries, Ltd. ("Teva") in Jerusalem, Israel. Teva is a generic drug producer organized under the laws of Israel. It is publicly traded. Most of its shareholders of record reside or are domiciled in the US. At the end of the second half of 2009, when Apotex-US was the sixth-largest seller of generic drugs, Teva was the number one seller of generic drugs on the US market. Teva manufactures its products at different facilities across the globe, including the Jerusalem facility, and exports them to the US for distribution by its wholly-owned US subsidiary, Teva Pharmaceuticals USA, Inc.

62. Like Apotex-Canada's Etobicoke and Signet plants, Teva's plant in Jerusalem manufactures solid dosage drugs. This facility was inspected by FDA in September 2008 and again, in September 2010. Each time, FDA inspectors issued a form 483 and Teva submitted its answer. After having reviewed Teva's response to the second form 483, FDA decided to issue a warning letter dated January 31, 2011 (the "Teva Jerusalem Warning Letter").

63. As was the case for Etobicoke, the Teva Jerusalem Warning Letter alleged two cGMP violations. Again, like Etobicoke, the first alleged violation was a failure to "thoroughly investigate the failure of a batch or any of its components to meet its specifications whether or not the batch has already been distributed" on the basis of 21 CFR § 211.192.[12] In particular, black particles were found in the sample powder during laboratory analysis. FDA noted that "the black particles were not identified and source was not determined." In addition, Teva had made no attempt to determine if additional lots were affected.[13]

64. The second alleged cGMP violation stated in the Teva Jerusalem Warning Letter was a failure to establish "separate or defined areas or such other control systems as necessary to prevent contamination or mix-ups during drug manufacturing" (21 CFR § 211.42(c)). There were a number of shared manufacturing areas at Teva's plant where equipment used for multiple products manufactured potentially hazardous compounds, generating large amounts of powder in the process. According to FDA, Teva's Jerusalem facility lacked both the requisite separation and an adequate contamination prevention strategy.[14]

65. Like the Etobicoke Warning Letter, the Teva Jerusalem Warning Letter concluded with a general warning:

> FDA may withhold approval of any new applications or supplements listing your firm as a drug product manufacturer. In addition, failure to correct these violations may result in FDA refusing admission of articles manufactured at Teva Pharmaceutical Industries,

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[12] Teva Jerusalem Warning Letter (WL: 320-11-008), dated January 31, 2011, pp. 1-2, item 1, available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm253437.htm (last visited on February 9, 2012).

[13] *Id.* at p. 2, item 1(b).

[14] *Id.* at p. 2, item 2.

> Ltd. located at … Jerusalem, Israel into the United States.[15]

66. The cGMP violations alleged in the Teva Jerusalem Warning Letter were not isolated ones. Other Teva factories had been inspected by FDA prior to issuance of that warning letter. These inspections observed significant cGMP violations and resulted in the issuance of a warning letter.[16]

67. However, FDA did not issue an import alert for the Teva Jerusalem facility. Nor did it take enforcement action regarding any other Teva facility. FDA formally closed its file concerning the Teva Jerusalem Warning Letter only seven months after the warning letter was issued.[17] During the relevant period, Teva Pharmaceuticals USA, Inc. was never prevented from receiving Teva products and selling them on the US market. Similarly, during the relevant period, Teva was never prevented from applying for new marketing authorizations in the US.

68. By contrast, as a direct result of the Import Alert, Apotex-US fell from the sixth-largest seller of generic drugs in the US at the end of the first half of 2009 to the 25th-largest at the end of the first half of 2011. Teva, on the other hand, retained its leading position in the US market.

IV. PROVISIONS BREACHED AND OTHER RELEVANT PROVISIONS

A. ARTICLE 1102 ON NATIONAL TREATMENT

69. NAFTA Article 1102 provides in relevant part as follows:

> 1. Each Party shall accord to investors of another Party treatment no less favorable than that it accords, in like circumstances, to its own investors with respect to the establishment, acquisition, expansion, management,

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15 *Id.* at p. 3. *Compare with* Etobicoke Warning Letter, (WL: 320-09-06), dated June 25, 2009, p. 4, available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm170912.htm (last visited on February 9, 2012) ("this office may recommend withholding approval of any new applications or supplements listing your firm as a drug product manufacturer. In addition, failure to correct these violations may result in FDA denying entry of articles manufactured at Apotex, Inc. Etobicoke, Canada into the U.S.").

16 *See* Teva Parenterals Medicines, Inc., Irvine, California, USA, Warning Letter W/L 05-10, dated December 11, 2009, available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm209222.htm (last visited on February 9, 2012). FDA stated no less than 13 alleged cGMP violations.

17 Teva (Jerusalem facility) Close Out Letter, dated September 9, 2011 available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm271596.htm (last visited on February 9, 2012).

> conduct, operation, and sale or other disposition of investments.
>
> 2. Each Party shall accord to investments of investors of another Party treatment no less favorable than that it accords, in like circumstances, to investments of its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.[18]

70. By placing the Etobicoke and Signet facilities on Import Alert, the United States accorded Apotex Holdings treatment less favorable than that afforded to US investors in like circumstances regarding the expansion, management, conduct and operation of investments in the form of enterprises selling pharmaceutical products in the US.

71. By placing the Etobicoke and Signet facilities on Import Alert, the United States accorded Apotex Holdings and Apotex-Canada treatment less favorable than that afforded to US investors in like circumstances regarding the establishment, acquisition, expansion, management, conduct, operation and sale of investments in the form of authorizations to sell pharmaceutical products and other investments in the US.

72. By placing the Etobicoke and Signet facilities on Import Alert, the United States accorded Apotex-US treatment less favorable than that afforded to US-owned enterprises in like circumstances with respect to its expansion, management, conduct and operation.

73. The Import Alert put Apotex Holdings and Apotex-Canada at a clear disadvantage compared to US investors in like circumstances, which were not prevented from applying for authorization of new generic drugs or from benefiting from sales of their pharmaceutical products on the US market, including by their US subsidiary.

74. The Import Alert placed Apotex-US at a clear disadvantage compared to US-owned enterprises in like circumstances, which were not prevented from selling and distributing in the US the great majority of the pharmaceutical products in their portfolio.

75. The Import Alert breached the United States' obligations under Article 1102.

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[18] NAFTA, US-Can.-Mex., US Gov. Printing Office, entered into force Jan. 1, 1994, Art. 1102(1)-(2).

B. ARTICLE 1103 ON MOST-FAVORED-NATION TREATMENT

76. NAFTA Article 1103 provides in relevant part as follows:

> 1. Each Party shall accord to investors of another Party treatment no less favorable 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.
>
> 2. Each Party shall accord to investments of investors of another Party treatment no less favorable than that it accords, in like circumstances, to investments of investors of any other Party or of a non-Party with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.[19]

1. Third-Country Investor or Investment in Like Circumstances

77. By placing the Etobicoke and Signet facilities on Import Alert, the United States accorded Apotex Holdings treatment less favorable than that afforded to third-country investors in like circumstances regarding the expansion, management, conduct and operation of investments in the form of enterprises distributing pharmaceutical products for sales in the US. Such third-country investors included, without limitation, Teva.

78. By placing the Etobicoke and Signet facilities on Import Alert, the United States accorded Apotex Holdings and Apotex-Canada treatment less favorable than that afforded to third-country investors in like circumstances regarding the establishment, acquisition, expansion, management, conduct, operation and sale of investments in the form of authorizations to sell pharmaceutical products and other investments in the US. Such third-country investors included, without limitation, Teva.

79. By placing the Etobicoke and Signet facilities on Import Alert, the United States accorded Apotex-US treatment less favorable than that afforded to third-country-owned enterprises in like circumstances with respect to its expansion, management, conduct and operation. Such third-country-owned enterprises included, without limitation, Teva Pharmaceuticals USA, Inc.

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[19] *Id.*, Art. 1103(1)-(2).

80. The Import Alert breached the United States' obligations under Article 1103.

2. The US-Jamaica BIT

81. The US Schedule to Annex IV to NAFTA reads in relevant part as follows:

> The United States takes an exception to Article 1103 for treatment accorded under all bilateral or multilateral international agreements in force or signed prior to the date of entry into force of this Agreement [i.e., January 1, 1994].[20]

82. As the Annex necessarily recognizes, Article 1103's obligation of most-favored nation treatment fully applies with respect to any bilateral or multilateral agreement that entered into force for the United States or was signed after the date of entry into force of the NAFTA on January 1, 1994.

83. The US-Jamaica BIT was signed on February 4, 1994 and entered into force on March 7, 1997. Article II of this treaty provides in relevant part:

> 2. ... (b) Neither Party shall in any way impair, by unreasonable or discriminatory measures the management, operation, maintenance, use, enjoyment, acquisition, expansion, or disposal of investments.
>
> (c) Each Party shall observe any obligation it may have entered into with regard to investments.
>
> ...
>
> 6. Each Party shall provide effective means of asserting claims and enforcing rights with respect to investments ...[21]

84. The United States measure (the Import Alert) impaired Apotex Holdings' and Apotex-Canada's investments and this measure was unreasonable even apart from its being discriminatory. FDA failed to observe its obligations with respect to Apotex Holdings' and Apotex-Canada's investments. And the United States failed to provide effective means for asserting claims and enforcing rights with respect to those investments. Consequently, the US violated Article II of the US-Jamaica BIT and, by the same token, Article 1103 of the NAFTA.

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[20] *Id.*, Annex IV, Exceptions to Most-Favored-Nation Treatment, Schedule of the United States.

[21] US-Jamaica BIT, signed on February 4, 1994 and entered into force on March 7, 1997 available at http://www.unctad.org/sections/dite/iia/docs/bits/us_jamaica.pdf (last visited on February 20, 2012), Art. II(2)(b)-(c), and II(6).

C. ARTICLE 1105(1) ON MINIMUM STANDARD OF TREATMENT

85. NAFTA Article 1105 provides in relevant part as follows:

> 1. Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security.[22]

86. Despite the devastating impact that the measure had, and that FDA knew it would have, on Apotex Holdings' and Apotex-Canada's investments, the Import Alert was adopted without the barest trappings of due process. FDA provided no notice of the measure, no opportunity for Apotex to be heard, no consideration by an independent and impartial adjudicator, and no right of appeal. FDA did not even issue a "warning letter" for Signet until many months after adopting the Import Alert, and even that *post-hoc* rationalization did not purport to justify the Import Alert in terms of FDA's limited statutory authority to impose such a measure. The arbitrary nature of the measure is confirmed by comparison to the procedures for enforcement action in the US, which may only be granted by a court in an adversary procedure after due notice and hearing both parties.

87. Despite FDA's assurances that it would expedite its re-inspection of the Etobicoke and Signet facilities, it inexcusably delayed that re-inspection and lifting of the Import Alert following its findings that the facilities fully met cGMP. As a result of this arbitrary conduct, Apotex-US was prevented for an unduly long period of time from selling its pharmaceutical products on the US market and launching the first generic versions of major patented drugs.

88. The United States breached the minimum standard of treatment of Article 1105(1).

V. RELIEF REQUESTED

89. As a result of the actions and breaches of the Government of the United States of America described above, the Claimants, on behalf of Apotex-US and on their own behalf, respectfully intend to request an award in their favor:

a. Finding that the United States of America has breached its obligations under the NAFTA;

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[22] NAFTA, US-Can.-Mex., US Gov. Printing Office, entered into force January 1, 1994, Art. 1105(1).

b. Directing the United States of America to pay damages in an amount to be proven at the hearing but which the Claimants presently estimate to be in the hundreds of millions of US dollars;

c. Directing the United States of America to pay interest on all sums awarded;

d. Directing the United States of America to pay the Claimants' costs associated with these proceedings, including professional fees and disbursements;

e. Ordering such other and further relief as the Tribunal deems appropriate in the circumstances.

90. Apotex Holdings and Apotex-Canada reserve the right to amend and modify this request for arbitration and to refine their position in the course of the proceedings.

VI. THE AGREEMENT TO ARBITRATE

91. The text of the agreement to refer this dispute to arbitration under the Additional Facility Rules is set forth in the NAFTA. In Chapter Eleven of that treaty, the United States of America made a unilateral offer to submit to arbitration claims for breaches of a substantive obligation of the chapter. The Claimants have accepted the United States' offer, thus forming the agreement to arbitrate between the parties to the dispute.

92. Article 1120(1)(b) of the NAFTA states that, "provided that six months have elapsed since the events giving rise to a claim, a disputing investor may submit the claim to arbitration under ... the Additional Facility Rules of ICSID, provided that either the disputing Party or the Party of the investor, but not both, is a party to the ICSID Convention." Article 1122(1) provides that "[e]ach [NAFTA] Party consents to the submission of a claim to arbitration in accordance with the procedures set out in this Agreement." Further, NAFTA Article 1122(2)(a) states that "[t]he consent given by paragraph 1 and the submission by a disputing investor of a claim to arbitration shall satisfy the requirement of ... the Additional Facility Rules for written consent of the parties." Article 1121 requires as conditions precedent to submission of a claim to arbitration that certain consents and waivers be provided by the Claimants and their enterprise.

93. Each of the requirements to establish an agreement to arbitrate is met here. *First*, the NAFTA entered into force on January 1, 1994 and remains in force between Canada and the United States. (An excerpt from the U.S. State Department publication *Treaties in Force* (2011) showing that the NAFTA is in effect, as well as a copy of Chapter Eleven of the NAFTA, is attached as **Annex A**.)

94. *Second*, more than six months have elapsed since the Import Alert was adopted in August 2009. The temporal condition stated in Article 1120(1) is therefore met. In addition, more than 90 days have elapsed since the Claimants submitted to the US Government their notice of intent to submit a claim to arbitration. (Documentation of the date of receipt of the notice of intent by the US Government is attached as **Annex B**.)

95. *Third*, each of the Claimants is an enterprise organized under the laws of Canada, and therefore an investor of Canada under the definition set out in Article 1139 of the NAFTA. (Certificates of good standing issued by the Federal Canadian Government and by the Province of Ontario, as well as an equivalent US document for Apotex-US, are attached as **Annex C**.) Although Canada signed the ICSID Convention in December 2006, it has not yet deposited an instrument of ratification, acceptance or approval of the Convention. As such, Canada is not a Contracting State to the ICSID Convention, whereas the United States is. The requirement of jurisdiction *rationae personae* of Article 1120(1)(b) of the NAFTA is therefore met.

96. *Lastly*, each of the Claimants and Apotex-US has provided the requisite consent to arbitration under the Additional Facility and waiver in the form contemplated by Article 1121 of the NAFTA. (The consents and waivers are attached hereto as **Annex D**.) The conditions precedent to arbitration imposed by that Article have been met.

97. The annexes to this request for arbitration therefore establish and delimit the agreement to arbitrate among the parties.

VII. APPROVAL FOR ACCESS TO THE ADDITIONAL FACILITY

98. The Secretary-General has not yet formally approved the parties' agreement to arbitrate under the Additional Facility Rules. The Claimants hereby request such approval. Each of the requirements of Articles 2(a) and 4(2) of the Additional Facility Rules is met here.

99. As demonstrated in paragraph 95 above, this dispute is one "not within the jurisdiction of the Centre because ... the State whose national is a party to the dispute is not a Contracting State," as contemplated by Article 2(a) of the Additional Facility Rules. In addition, as demonstrated above in part III (Factual Background) and part IV (Provisions Breached) of this request for arbitration, the dispute is a legal one "arising out of an investment" in the form of an enterprise controlled by Claimant Apotex Holdings, and in the form of authorizations to market and sell pharmaceutical products in the US and bundles of intellectual property rights associated with those products, held by Claimant Apotex-Canada.

100. Finally, as required by Article 4(2) of the Additional Facility Rules, the Claimants have expressly consented to the jurisdiction of the Centre under Article 25 of the Convention (in lieu of Additional Facility) in the event that the jurisdictional requirements *rationae personae* of that Article shall have been met at the time when proceedings are instituted. (The instruments reflecting this consent are included in **Annex D** hereto.)

VIII. INTERNAL AUTHORIZATION TO MAKE THIS REQUEST FOR ARBITRATION

101. Each of the Claimants has taken all necessary internal steps to authorize this request for arbitration. The board of directors of each of the Claimants has considered the matter and issued resolutions authorizing consent to arbitration and execution of the instruments necessary to make this request. (Resolutions of the boards are included in **Annex D** hereto.) Under Article 102(1) of the Canada Business Corporations Act, the business and affairs of a corporation are managed by or under the direction of the board of directors, subject to delegation to officers or other persons. Similarly, under Article 115(1) of the Ontario Business Corporations Act, the business and affairs of a corporation are managed by or under the direction of the board of directors, subject to delegation to officers or other persons. In addition, each of the Claimants has, as reflected in **Annex D**, appointed the undersigned as attorneys in this matter and specifically authorized the undersigned to file this request for arbitration. This request has been fully authorized in accordance with the law and applicable corporate instruments.

IX. AGREED PROVISIONS REGARDING THE NUMBER OF ARBITRATORS AND THE METHOD OF THEIR APPOINTMENT

102. The disputing parties have agreed to the NAFTA's provisions on the number and method of appointment of the arbitrators. Article 1123 of the NAFTA specifies that "the Tribunal shall comprise three arbitrators, one arbitrator appointed by each of the disputing parties and the third, who shall be the presiding arbitrator, appointed by agreement of the disputing parties." Article 1125 reflects an agreement by the disputing parties that the limitations on the nationality of arbitrators stated in Article 7 of the Arbitration (Additional Facility) Rules shall not apply in these proceedings.

103. Pursuant to NAFTA Article 1123 and Article 11(1) of the Arbitration (Additional Facility) Rules, Claimants Apotex Holdings and Apotex-Canada hereby notify the Secretary-General of their appointment of the following as first arbitrator, effective upon registration of the request for arbitration:

J. William Rowley, QC

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20 Essex Street
London, England, WC2R 3AL
Tel. +44 (20) 7842 6702
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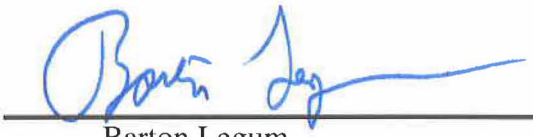
Date: February 29, 2012

Respectfully submitted,



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