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

APOTEX HOLDINGS INC. AND APOTEX INC.,

Claimants,

– and –

THE GOVERNMENT OF THE UNITED STATES OF AMERICA,

Respondent.

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

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

ARBITRAL TRIBUNAL:

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July 30, 2012

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CONFIDENTIAL

CONTENTS

GLOSSARY OF TERMS..... IV

INTRODUCTION.....2

STATEMENT OF THE FACTS6

I. THE PARTIES.....6

 A. *The Claimants and the Enterprise*.....6

 1. Claimant Apotex Holdings.....6

 2. Claimant Apotex-Canada7

 3. The Enterprise Apotex-US7

 B. *The Respondent* 8

II. THE BUSINESS OF GENERIC PHARMACEUTICAL PRODUCERS8

III. THE APOTEX GROUP10

 A. *Apotex Holdings* 10

 1. The Enterprise: Apotex-US.....11

 2. Apotex Holdings’ Other Investments in the USA.....13

 B. *Apotex-Canada*..... 13

IV. THE REGULATORY FRAMEWORK21

 A. *Inspections and Current Good Manufacturing Practices*.....21

 B. *FDA Form 483*24

 C. *Warning Letters*.....25

 D. *Refusal of Admission and Import Alerts*.....27

 1. Detention, Physical Examination and Refusal of Admission.....27

 2. Detention Without Physical Examination and Import Alerts.....28

 E. *Judicial Actions* 34

 1. Seizure34

 2. Injunctions35

 3. Criminal Actions38

V. FDA’S AND HEALTH CANADA’S INSPECTIONS OF SIGNET AND ETOBICOKE PRIOR TO 2008.....39

VI. FDA’S INSPECTIONS OF APOTEX’S FACILITIES IN 2008 AND 2009.....42

 A. *The Etobicoke Inspection* 42

 B. *FDA’s Enforcement Strategy*.....43

 C. *The Etobicoke Warning Letter*44

D.	<i>The Signet Inspection</i>	46
E.	<i>Communications with FDA Immediately After the Signet Inspection</i>	49
VII.	THE IMPORT ALERT	53
VIII.	HEALTH CANADA’S FINDINGS AND DECISIONS OF THIRD-COUNTRY AGENCIES AFTER THE IMPOSITION OF THE IMPORT ALERT	58
A.	<i>Health Canada’s Inspection in the Fall 2009</i>	58
B.	<i>Actions of Other Pharmaceutical Regulatory Agencies</i>	59
IX.	FDA’S DELAY IN LIFTING THE IMPORT ALERT AND APPROVING ANDAs.....	61
A.	<i>Apotex-Canada’s Remediation Plan and the September 2009 Meeting</i>	61
B.	<i>The Signet Warning Letter</i>	64
C.	<i>The March 2010 Meeting with FDA</i>	66
D.	<i>FDA’s Refusal to Resume Shipping of Certified Drugs</i>	69
E.	<i>FDA’s Refusal to Expedite Re-Inspection</i>	71
F.	<i>The Re-Inspection of Etobicoke and Signet from January 24 to February 11, 2011</i>	75
G.	<i>FDA’s Delay in Lifting the Import Alert</i>	76
1.	<i>Etobicoke</i>	76
2.	<i>Signet</i>	77
H.	<i>FDA’s Delay in Approving Pending ANDAs</i>	78
X.	THE EFFECT OF THE MEASURE ON APOTEX	80
XI.	FDA’S TREATMENT OF COMPARABLE INVESTORS AND INVESTMENTS	84
A.	<i>Baxter International and Baxter Healthcare</i>	85
B.	<i>Hospira</i>	88
C.	<i>Perrigo and L. Perrigo</i>	89
D.	<i>Sandoz and Novartis</i>	91
E.	<i>Teva Pharmaceutical Industries and Teva Parenteral Medicines</i>	94
	STATEMENT OF THE LAW	96
I.	THE TRIBUNAL HAS JURISDICTION TO DECIDE THESE CLAIMS	96
A.	<i>The Tribunal Has Jurisdiction over the Parties</i>	96
1.	<i>Apotex Holdings Is an Investor</i>	97
2.	<i>Apotex-Canada Is an Investor</i>	98
3.	<i>The Tribunal Has Jurisdiction over the United States</i>	98
B.	<i>The Tribunal Has Jurisdiction over the Subject-Matter of the Dispute</i>	99

1.	Apotex-US Is an Investment of Apotex Holdings.....	99
2.	Marketing Authorizations Are Investments of Apotex-Canada.....	99
3.	The Import Alert Is a Measure Relating to Investors and Investments.....	118
C.	<i>The Dispute Meets the Temporal Requirements of the NAFTA</i>	121
II.	THE US BREACHED ARTICLES 1102 AND 1103 BY ACCORDING APOTEX LESS FAVORABLE TREATMENT.....	123
A.	<i>The Legal Standard of Articles 1102 and 1103</i>	123
1.	“Like Circumstances”.....	126
2.	Less Favorable Treatment	129
B.	<i>The United States Accorded Apotex Less Favorable Treatment than Comparators in Like Circumstance</i>	131
1.	The Record Establishes Multiple Comparators in Like Circumstances....	131
2.	The Record Establishes That Apotex Received Less Favorable Treatment Than the Comparators	133
III.	THE IMPORT ALERT DENIED APOTEX FAIR AND EQUITABLE TREATMENT.....	134
A.	<i>The Import Alert Breached NAFTA Article 1105(1)</i>	134
1.	International Law Requires Due Process in Administrative Decision-Making Concerning Specific Persons	135
2.	Subsequent State Practice Confirms and Develops This International Obligation.....	139
3.	The United States Denied Apotex Due Process	144
B.	<i>The Import Alert Breached Article II of the US - Jamaica BIT</i>	146
IV.	APOTEX IS ENTITLED TO DAMAGES	149
A.	<i>Damages Resulting From Breach of the National Treatment and MFN Standards</i>	153
1.	Loss of New Business Opportunities / Lost Profits	155
2.	Out-of-Pocket Losses	162
B.	<i>Damages Resulting from Denial of Fair and Equitable Treatment</i>	165
C.	<i>Interest</i>	168
1.	Rate of Interest	168
2.	Eligible Period for Application of Interest	169
3.	Compound Interest	169
D.	<i>Costs and Attorneys’ Fees and Interest on Such Amounts</i>	170
	SUBMISSIONS	171

GLOSSARY OF TERMS

AIP	Application Integrity Policy (FDA)
ALI	American Law Institute
ANDA	Abbreviated New Drug Application (US)
APA	Administrative Procedure Act (US)
APAC	Asia Pacific
APHI	Apotex Pharmaceutical Holdings Inc.
API	Active Pharmaceutical Ingredient
ARPL	Apotex Research PTY Limited
CAP	Corrective Action Plan (Apotex)
CBER	Center for Biologics Evaluation and Research (FDA)
CBP	Customs and Border Protection (US)
CDER	Center for Drug Evaluation and Research (FDA)
CDER-OC	Center for Drug Evaluation and Research, Office of Compliance (FDA)
cGMP	Current Good Manufacturing Practices
CI	Continuous Improvement (Apotex)
CMC	Chemical Manufacturing Control
CROs	Contract Research Organizations
DIOP	Division of Import Operations and Policy (FDA)
DMPQ	Division of Manufacturing and Product Quality (FDA)
DOJ	Department of Justice (US)

DWPE	Detention Without Physical Examination (FDA)
EEA	European Economic Area
EI	Establishment Inspection (FDA)
EIR	Establishment Inspection Report (FDA)
EMA	European Medicine Agency
EMEA	Europe, Middle East and Africa
FDA	Food and Drug Administration (US)
GMP	Good Manufacturing Practices
GPOs	Group Purchasing Organizations
GQSR-CAP	Global Quality Systems Revitalization Corrective Action Plan (Apotex)
HHS	US Department of Health and Human Services
HPFBI	Health Product and Food Branch Inspectorate (Health Canada)
IGZ	Health Care Inspectorate (Netherlands)
IND	Investigational New Drugs (US)
IOM	Investigations Operations Manual (FDA)
IP	Intellectual Property
MRA	Mutual Recognition Agreement
NDA	New Drug Application (US)
OC	Office of Compliance (FDA)
OCC	Office of Chief Counsel (FDA)
OGD	Office of Generic Drugs (FDA)
OMPQ	Office of Manufacturing and Product Quality (FDA)

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

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

In accordance with Article 38 of the Arbitration (Additional Facility) Rules and the Tribunal's order of July 24, 2012, claimants Apotex Holdings Inc. ("Apotex Holdings") and Apotex Inc. ("Apotex-Canada") (collectively, "Apotex") respectfully submit this Memorial in support of their claims against respondent United States of America.

INTRODUCTION

1. In August 2009, the United States Food & Drug Administration (“FDA”) adopted a measure with crippling consequences for Apotex’s business in the US. The measure, called an import alert, cut off the supply of 80% of the products sold by the US business. Apotex’s US business was the sixth-largest seller of generic drugs in the US before the import alert was adopted. Two years later it was the 25th-largest.
2. The measure followed inspections of manufacturing practices at two Apotex facilities in Canada. The facilities produce finished drug products for the US market. FDA had repeatedly inspected both facilities before without incident. Six months after the 2008 inspection of the first facility, FDA issued a warning letter. The issuance of a warning letter signals a violation of regulatory significance that, if not promptly and adequately corrected, would lead to enforcement action. FDA had never before issued a warning letter to Apotex.
3. One month after the warning letter, FDA inspected the second facility. It adopted the import alert two weeks after the close of the inspection. It did so without issuing any warning letter, 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.
4. FDA’s actions shocked Apotex. While it believed that its processes were just as compliant with current good manufacturing practices as they had always been, Apotex could not afford to stay off the US market. It immediately hired outside consultants and embarked on an extensive and costly enhancement of its processes.
5. FDA’s actions also apparently shocked Health Canada, the primary regulator for the two facilities in question. Health Canada immediately committed substantial resources to a detailed inspection of the two facilities. The inspection began in September and ended in November 2009. Health Canada’s conclusion was that, while improvements could be made, both facilities complied with current good manufacturing practices. The regulators in every other jurisdiction in which Apotex sold products followed the findings of Health Canada and not those of FDA.

6. Apotex nonetheless continued the enhancement of its systems as it had promised FDA it would do. It also hired a consultant retrospectively to assess every batch of products released to the US market in the months preceding the import alert. That analysis confirmed that almost without exception there was no question as to the safety and efficacy of Apotex's products.
7. In August 2010, Apotex requested that FDA re-inspect its two facilities. FDA did not schedule the re-inspection until January 2011. Following the re-inspection, FDA concluded that the facilities complied with current good manufacturing practices.
8. Nonetheless, it was not until July 2011 that the import alert was lifted with respect to both facilities. It was not until November 2011 that FDA permitted Apotex to sell new drugs produced at both facilities.
9. The import alert damaged Apotex and its US investment in many respects. Among other things, the US business had to pay millions of dollars in penalties to customers when it was unable to deliver as promised. It lost many hundreds of millions of dollars in sales. It lost the opportunity to take a leading position in markets for new generic drugs. It has now reentered the US market with drugs produced at the two facilities and is regaining market position. But the import alert has irreversibly weakened its position with respect to future sales.
10. During the same time period, FDA accorded quite different treatment to comparable US- and foreign-owned companies and their investments in the US pharmaceutical market. To provide but one example, Baxter International Inc. had in the preceding decade received over twenty warning letters for violations of current good manufacturing practices at its facilities. In 2010, FDA issued two more warning letters to Baxter, this time citing significant violations at two facilities in Puerto Rico. Despite Baxter's history of chronic violations, FDA allowed Baxter an opportunity to respond to the warning letters and take corrective action. Less than six months later, FDA issued a letter closing out the warning letters. Baxter's US business continued to sell products from the two Puerto Rican facilities on the US market throughout this period without interruption or any disruption of its operations.
11. FDA's actions breached the investment chapter of the NAFTA in two principal respects.

12. *First*, the United States breached Articles 1102 and 1103 of the NAFTA by according Apotex and its investments less favorable treatment than it accorded in like circumstances to US and third-country investors and their investments in the US. FDA afforded Apotex no opportunity to respond to its investigative findings or to implement corrective actions before imposing a draconian measure that deprived Apotex's US business of 80% of the products it sold. By contrast, FDA afforded US – and foreign – pharmaceutical producers ample and repeated opportunities to respond and to implement corrective measures, despite finding violations of regulatory significance at their facilities. FDA took no enforcement measure with respect to these companies. Their products remained on the market, their sales continued, their businesses suffered no serious disruption. FDA accorded Apotex less favorable treatment than it accorded these competitors and their investments.
13. *Second*, the United States breached the minimum standard of treatment required by Article 1105 by adopting the import alert with no prior notice to Apotex, no possibility for Apotex to prepare a defense, no opportunity for Apotex to present its position and no decision by an impartial administrative authority. Customary international law has long required these basic elements of due process for an administrative decision in an individual case to be deemed minimally fair. The import alert imposed on Apotex fell far short of international standards. By contrast, had FDA applied to Apotex the procedure it follows for enforcement actions concerning US facilities, each of the requirements of customary international law would have been met – but the result for Apotex would have been diametrically different.
14. The United States' breach of Articles 1102, 1103 and 1105 caused Apotex and its investments damage in the hundreds of millions of US dollars.
15. This Memorial is supported by witness statements and expert reports from the following:

Witness/Expert	Title/Background
Sheldon T. Bradshaw, Expert	Partner, Hunton & Williams LLP; former Chief Counsel, United States Food & Drug Administration
Edmund Carey	Director, Corporate Compliance, Apotex Inc.

Bruce D. Clark	Senior Vice-President for Scientific and Medical Affairs, Apotex Inc.
Jeremy B. Desai	President and Chief Operating Officer, Apotex Inc.
Gordon Fahner	Vice President, Business Operations and Finance, Apotex Inc.
John J. Flinn	Vice President, Sales Operations, Apotex Corp.
Ron M. Johnson, Expert	President, Becker & Associates Consulting, Inc.; former Director of Pacific Region and Director of Compliance, Center for Devices and Radiological Health, United States Food & Drug Administration
Kiran Krishnan	Director, Regulatory Affairs, Apotex Corp.
Howard Rosen, Expert	Senior Managing Director, FTI Consulting; Accredited Senior Appraiser, Chartered Business Valuator, Chartered Accountant
Bernice Tao	Director, Global Regulatory Operations, Apotex Inc.
Jeff Watson	President, Apotex Corp.

16. This Memorial is further supported by documentary evidence and legal authorities. The factual exhibits are numbered in chronological order and begin with the prefix "C-". The legal authorities are organized based on the nature of the source and begin with the prefix "CLA-".
17. For the reasons set out below, Apotex respectfully requests that this Tribunal render an award in its favor and against the United States.

STATEMENT OF THE FACTS

I. THE PARTIES

A. The Claimants and the Enterprise

18. Claimants Apotex Holdings and Apotex-Canada are corporations organized under the laws of Canada.¹ They control investments in the United States.

1. Claimant Apotex Holdings

19. Apotex Holdings is a privately-held corporation organized under the Canada Business Corporations Act, a Canadian federal law. It is the largest investor in the pharmaceutical industry in Canada and an important investor in a range of pharmaceutical markets around the world.

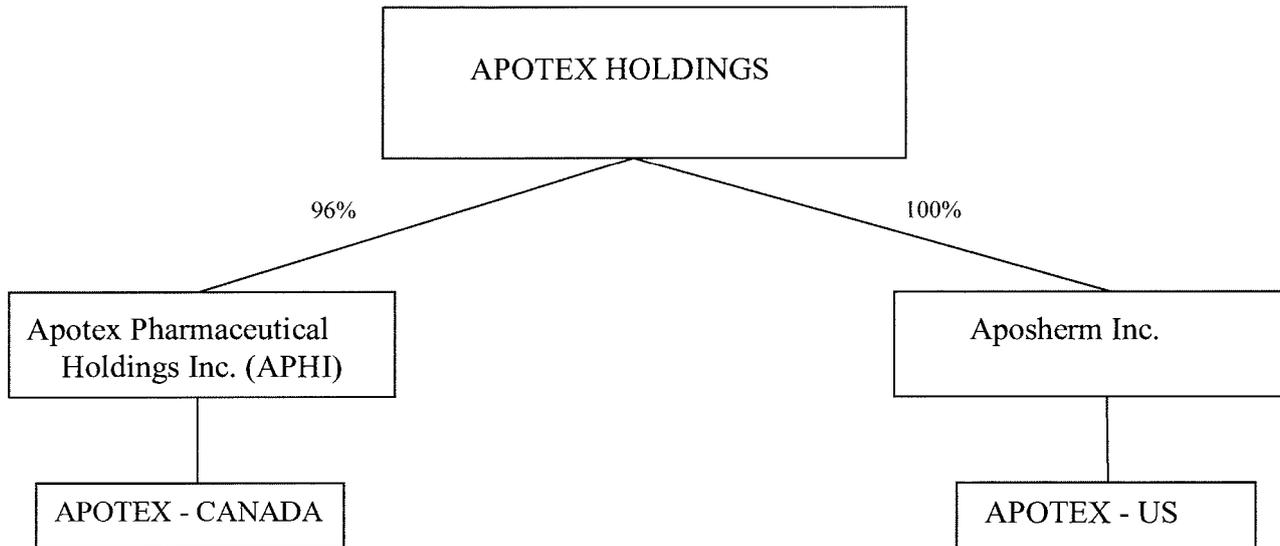
20. Apotex Holdings functions as a holding company for the Apotex group's investments in the United States, as well as for the group's operating companies in Canada. Among other things, Apotex Holdings wholly owns and controls the company Aposherm Inc., organized under the Canada Business Corporations Act, which in turn wholly owns and controls the Delaware Corporation Apotex Corp. ("Apotex-US").²

21. Apotex Holdings also owns 96% of the outstanding shares in Apotex Pharmaceutical Holdings Inc. (APHI), a company organized under the Canada Business Corporations Act. APHI in turn owns and controls Apotex-Canada.³ The diagram below indicates the relevant holding structure for Apotex Holdings.

¹ See **Exhibit C-291**, Certificate of Compliance of Apotex Holdings Inc., Certificate of Status of Apotex Inc., and Certificate of Good Standing of Apotex Corp. (July 7, 2012).

² **Exhibit C-312**, Share registry of Aposherm Inc. (Jul. 25, 2012); **Exhibit C-313**, Certification of Share Ownership of Apotex Corp. (Apotex-US) (Jul. 25, 2012).

³ **Exhibit C-314** and **Exhibit C-315**, Share registry of Apotex Inc. (Apotex-Canada) (Jul. 25, 2012) and Share registry of Apotex Pharmaceutical Holdings Inc. (APHI) (Jul. 25, 2012).



2. *Claimant Apotex-Canada*

22. Apotex-Canada is a company organized under the laws of the province of Ontario, Canada. It was created in 1974 and underwent several amalgamations (mergers) in 1991, 1992 and 2004. The latest merger was with TorPharm, Inc., a company also incorporated in Ontario, and the amalgamated company retained the name of “Apotex Inc.”⁴

23. Apotex-Canada is the principal operating company of the Apotex group. It concentrates on generic drugs and is the largest Canadian privately-owned pharmaceutical company. It produces more than 260 molecules in about 4,000 dosages and formats.⁵

3. *The Enterprise Apotex-US*

24. 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.⁶ As noted above, Apotex Holdings indirectly owns and controls this enterprise. Apotex-US distributes in

⁴ See Exhibit C-291, Certificates of Corporate Profile for Apotex-Canada in 1974, 1991, 1992 and 2004, at 2. The company called Novex, which was initially set up as a branch of Apotex-Canada, was also “merged” into Apotex-Canada in 2004. See Witness Statement of Jeremy Desai, para. 17.

⁵ See Witness Statement of Jeremy Desai, para. 18.

⁶ See Exhibit C-291, Certificate of Compliance of Apotex Holdings Inc., Certificate of Status of Apotex Inc., and Certificate of Good Standing of Apotex Corp. (July 7, 2012).

the US Apotex products sourced from Apotex-Canada.⁷ In 2009, Apotex-US relied almost exclusively on Apotex-Canada for supplies.⁸

B. The Respondent

25. The United States of America is a sovereign State and a Party to the NAFTA. It is a federal State, with a central government, as well as local executive branch in each of its 50 component states. The measure at issue in this arbitration was adopted by a federal agency, namely FDA.

II. THE BUSINESS OF GENERIC PHARMACEUTICAL PRODUCERS

26. Generic drugs allow greater access to health care for the public. They are copies of brand-name drugs with the same dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.⁹ The only material difference is their price. According to FDA, the cost of a generic drug is on average 80% to 85% lower than the brand-name product.¹⁰
27. The lower cost primarily results from the way generic drugs are developed and marketed. Generic drug companies are able to sell their products for lower prices because they are not required to repeat the costly clinical trials of innovative drugs. It is sufficient to establish that a generic drug is bio-equivalent to the brand-name drug.¹¹
28. In addition, generic manufacturers generally do not pay for costly advertising, marketing and promotion.¹² Most generic drugs are unbranded and sold under the name

⁷ Witness Statement of Jeremy Desai, para. 24; Witness Statement of John Flinn, para. 18. *See also Exhibit C-317*, Excerpt from Apotex-US website, “All Products” page.

⁸ Witness Statement of Jeremy Desai, para. 29; Witness Statement of John Flinn, para. 27.

⁹ **Exhibit C-295**, Excerpt from FDA’s website, “Understanding Generic Drugs” (last updated on March 19, 2012).

¹⁰ **Exhibit C-300**, Excerpt from FDA’s website, “Facts about Generic Drugs” (last updated on May 30, 2012). *See also* Witness Statement of Jeff Watson, para. 18.

¹¹ **Exhibit C-300**, Excerpt from FDA’s website, “Facts about Generic Drugs” (last updated on May 30, 2012). (“The generic drug manufacturer must prove its drug is the same as (bioequivalent) the brand name drug. For example, after the patient takes the generic drug, the amount of drug in the bloodstream is measured. If the levels of the drug in the bloodstream are the same as the levels found when the brand name product is used, the generic drug will work the same.”).

¹² *Id.*

of the molecule or active pharmaceutical ingredient. There is thus no need for generic manufacturers to foster brand-recognition.

29. No new prescription drug – whether innovative or generic – can be marketed and sold in the US until and unless FDA approves the drug and delivers a marketing authorization. Obtaining a marketing authorization is thus a prerequisite to going to market.¹³ The marketing authorizations delivered by FDA are country-specific in the sense that they authorize marketing only in the US.¹⁴
30. As explained in the Statement of Facts, Section III.B. *infra*, under certain conditions, a generic manufacturer may benefit from a statutory period of marketing exclusivity in the US. During a six-month time period, no competitor is entitled to launch its generic version of the brand-name drug. This gives a competitive advantage to the generic manufacturer that is first to go to market. Notably, the first entrant captures market share and gains a leadership position before other generic competitors enter the market.¹⁵
31. The return on investment for every generic drug manufacturer derives from sales made in the country.

¹³ Witness Statement of Bernice Tao, para. 20; Witness Statement of Kiran Krishnan, para. 16.

¹⁴ See **Legal Authority CLA-234**, Federal Food, Drug and Cosmetic Act, 21 USC § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.”). “Interstate commerce” is defined in the Act as “(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.” **Legal Authority CLA-224**, Federal Food, Drug and Cosmetic Act, 21 USC § 321(b). In turn, the term “State” is defined as “any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico” and the term “Territory” is defined as “any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.” **Legal Authority CLA-224**, Federal Food, Drug and Cosmetic Act, 21 USC § 321(a)(1) and (2). See also Witness Statement of Bernice Tao, para. 25; Witness Statement of Kiran Krishnan, para. 16.

¹⁵ Witness Statement of Bernice Tao, paras. 36-38.

32. The main players on the US generic drug market in recent years have included Actavis, Apotex, App, Baxter, Dr. Reddy's, Greenstone, Hospira, Mylan, Perrigo, Sandoz, Teva and Watson, among others.¹⁶

III. THE APOTEX GROUP

A. Apotex Holdings

33. Apotex was founded in 1974 in Toronto by Dr. Barry Sherman. At that time, the company had two employees. It now employs over 7,500 people in research, development, manufacturing and distribution facilities worldwide.
34. Over the years, Apotex has become a leader in the North American generic pharmaceutical market. The company currently distributes its products in 115 countries.¹⁷
35. Apotex is a vertically integrated group of companies. It develops and manufactures its own products, from active pharmaceutical ingredient (API) to finished drugs. It markets and distributes the finished drugs.¹⁸
36. The Apotex group also includes a biotechnology company, Cangene, which is publicly traded on the Toronto Stock Exchange, as well as Pharmachem Inc. in Brantford, Ontario, which operates the largest pharmaceutical fine chemicals research and development and manufacturing facility in Canada. The Apotex group operates additional sites in Winnipeg, Mexico, China and India.¹⁹

¹⁶ **Exhibit C-305**, IMS Medical, Top 25 Generic Manufacturers, Q2 2012; **Exhibit C-239**, IMS Medical, Top 25 Generic Manufacturers, Q1 2011; **Exhibit C-181**, IMS Medical, Top 25 Generic Manufacturers, Q2 2009. *See also* Witness Statement of Jeremy Desai, para. 23.

¹⁷ Witness Statement of Jeremy Desai, para. 20.

¹⁸ **Exhibit C-301**, Excerpt from Apotex-US website, "Security of Supply & Quality" page. Apotex manufactures some of its APIs and acquires others from different suppliers. *See* Witness Statement of Gordon Fahner, para. 27; Witness Statement of Bernice Tao, para. 12.

¹⁹ **Exhibit C-304**, Apotex Video and Video Transcript, *available at* <http://www.apotex.com/global/about/video.asp>.

37. As noted, Apotex Holdings is the holding company that indirectly owns and controls, among others, Apotex-Canada and Apotex-US.²⁰ As a holding company, Apotex Holdings does not itself produce or distribute any drugs.
38. Apotex Holdings has several investments in the US, including Apotex-US, as well as other companies that form part of Apotex's integrated group of companies.

1. The Enterprise: Apotex-US

39. Over the years Apotex Holdings, through its subsidiaries, has made substantial investments in the US market, including but not limited to its indirect investment in Apotex-US. Apotex Holdings, through its subsidiaries, invested capital, know-how and expertise into Apotex-US.
40. The Apotex group built Apotex-US into a highly successful business. In the second quarter of 2009, Apotex-US had the sixth-highest sales of any generic drug company in the United States.²¹
41. Apotex-US was created in order to market, sell and distribute Apotex products in the US.²² Apotex-US operates under a specific business model, designed to identify new business opportunities and open up the US market of generic drugs through litigation in the US.²³ To that end, Apotex spends USD [REDACTED] million every year in attorney's fees in the US. These fees are paid by Apotex-Canada.²⁴
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

²⁰ See *supra* Part I.A.1.

²¹ **Exhibit C-181**, IMS Medical, Top 25 Generic Manufacturers, Q2 2009. See also Witness Statement of Jeremy Desai, para. 23; Witness Statement of Gordon Fahner, para. 93.

²² Witness Statement of Jeremy Desai, para. 24; Witness Statement of Jeff Watson, para. 25; Witness Statement of Gordon Fahner, para. 33.

²³ Witness Statement of Kiran Krishnan, paras. 18-19; Witness Statement of Gordon Fahner, para. 45.

²⁴ Witness Statement of Gordon Fahner, para. 45; Witness Statement of Jeremy Desai, para. 27.

Apotex-Canada performs specific support functions for the benefit of Apotex-US and for a monthly fee.²⁵

43. Apotex-US's customer relationships and credibility on the market are important assets. Apotex-US has invested in customer relations management and recruited highly experienced sales staff.²⁶
44. In order to provide the best service to its customers, Apotex-US opened a new 156,000 square foot distribution center in Indianapolis in March of this year.²⁷ Apotex thus increased by more than 200% its distribution center in the US.²⁸ The facilities in Indianapolis are rented. All staff working at this facility is employed by Apotex-US.²⁹
45. Apotex-US employs a total number of 68 employees.³⁰
46. Before the Import Alert, Apotex-US depended principally on Apotex-Canada for supplies. During the time when the Import Alert was in effect, Apotex-US engaged more actively in contract manufacturing with third parties who manufactured drug products that Apotex-US sold. However, the percentage of third-party manufactured products sold by Apotex-US has decreased since the Import Alert was removed.³¹
47. From the date of its creation in 1994, Apotex-US has paid millions of US dollars in taxes in the United States and generated a significant return on investment for Apotex Holdings.³²

²⁵ **Exhibit C-14**, Services Agreement Between Apotex-Canada and Apotex-US, art. 4.1 (July 1, 2005) (“Apotex[-Canada] shall provide to [Apotex-US] administrative services, information systems and technology services, accounting and financial (including payroll) services, procurement services, human resource[s] services, logistic services including inventory management, quality assurance control services, facilities services, engineering services, and such additional services which may be requested by [Apotex-US] from time to time.”). See Witness Statement of Jeremy Desai, para. 26; Witness Statement of Gordon Fahner, para. 35.

²⁶ Witness Statement of Jeremy Desai, para. 25; Witness Statement of Gordon Fahner, para. 47.

²⁷ **Exhibit C-302**, Excerpt from Apotex-US website, “New Apotex Distribution Center is now open for business at our new location.” Apotex rents the warehouse facility in Indianapolis.

²⁸ *Id.*

²⁹ Witness Statement of John Flinn, para. 16.

³⁰ *Id.*, para. 15.

³¹ Witness Statement of Jeremy Desai, para. 29; Witness Statement of John Flinn, para. 28.

³² Witness Statement of Gordon Fahner, para. 29.

2. *Apotex Holdings' Other Investments in the USA*

48. The Apotex group includes US-based companies other than Apotex-US.
49. One such US-based company is Starplex Scientific Corp. (“Starplex”). Starplex is incorporated in the State of Delaware and is owned by Starplex Scientific Inc., a Canadian company, which in turn is owned by Apotex Holdings.³³ Starplex makes plastic bottles for the solid dose products produced at Signet and Etobicoke. Starplex leases its manufacturing facilities from another US company within the Apotex group, Aposherm Realty Inc. (“Aposherm Realty”). The manufacturing plant, located in Tennessee, is a large (68,000 square feet) facility. Starplex employs 40 people in the US.³⁴
50. Another US-based company within the Apotex group is ApoPharma USA Inc. (“ApoPharma”). ApoPharma is incorporated in Maryland and owned by APhi, which as noted, is controlled by Apotex Holdings. Unlike most companies within the Apotex group, Apopharma focuses on innovative drug products.³⁵

B. Apotex-Canada

51. Apotex-Canada is one of the principal operating companies of the Apotex group. In 2004, the company went through a process of internal corporate restructuring. Three units, namely Apotex Inc., Torpharm and Novex were merged and retained the name Apotex Inc. (i.e., Apotex-Canada).³⁶
52. Apotex-Canada develops and manufactures Apotex products that are distributed worldwide – and through Apotex-US in the United States.

³³ **Exhibit C-271**, Chart of Apotex Corporate Structure.

³⁴ Witness Statement of Gordon Fahner, paras. 38-40.

³⁵ Witness Statement of Gordon Fahner, para. 41.

³⁶ Witness Statement of Jeremy Desai, para. 17.

53. Apotex-Canada operates over 3.4 million square feet of manufacturing and R&D facilities in Canada. It employs close to 2,000 scientific staff including 110 PhDs. Manufacturing capacities are on the order of 20 billion dosages per annum.³⁷
54. Two of Apotex's main manufacturing sites for finished drug products are in Etobicoke, Ontario ("Etobicoke") and on a campus on Signet Drive near the border of Weston and Toronto, Ontario (the "Signet Campus" or "Signet").³⁸
55. Both Etobicoke and Signet produce solid oral dosage forms of medicinal products, such as tablets and capsules. Etobicoke is a single facility, while the Signet Campus houses several buildings.³⁹ There is a main production facility at 150 Signet Drive (which is also the headquarters), as well as a separate packaging facility, an antibiotic laboratory building, and smaller production facilities used for manufacturing special products, namely penicillin, cephalosporin and toxic compounds.
56. Apotex-Canada has additional facilities in Richmond Hill, Ontario. This site manufactures liquid sterile medications (oral solutions, eye drops and nasal sprays) and also performs microbiological testing.⁴⁰
57. As noted by FDA in a 2006 establishment inspection report for Etobicoke, the USA is a "primary, or major market" for Apotex generic drug products.⁴¹
58. Some 40% of Apotex group sales are in the Canadian market. The remaining 60% of its 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.⁴²

³⁷ **Exhibit C-304**, Apotex Video Transcript (video available at <http://www.apotex.com/global/about/-video.asp>).

³⁸ **Exhibit C-308**, Map of Etobicoke and Signet Campus. See also **Exhibit C-318**, Map of Etobicoke and Signet Campus.

³⁹ Witness Statement of Jeremy Desai, para. 19; Witness Statement of Edmund Carey, para. 14.

⁴⁰ Witness Statement of Jeremy Desai, para. 19; Witness Statement of Gordon Fahner, para. 64.

⁴¹ **Exhibit C-25**, Letter from FDA to Apotex-Canada enclosing Establishment Inspection Report (EIR) for Etobicoke, at 6 of EIR (July 6, 2007).

⁴² Witness Statement of Jeremy Desai, para. 20; Witness Statement of Bruce Clark, para. 14.

59. 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 oral-dose products accounted for about 80% of Apotex-US's sales.⁴³ Etobicoke accounted for the vast bulk of the products sold in the US in terms of value.⁴⁴
60. Apotex-Canada owns scores of authorizations to market and sell pharmaceutical products in the US.
61. Each person who desires to market and sell a new drug on the US market must first apply for, and obtain, a marketing authorization from FDA's Center for Drug Evaluation and Research (CDER).⁴⁵
62. Sellers of innovative drug products must submit a new drug application (NDA),⁴⁶ while generic drug marketers, for their part, may submit an abbreviated new drug application (ANDA).⁴⁷

A brand-name drug manufacturer seeking FDA approval must submit a New Drug Application ("NDA") which includes, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results establishing its safety and effectiveness, and labelling describing the use for which approval is requested. Once FDA approves a brand-name drug's NDA, a generic drug manufacturer seeking FDA approval may submit an Abbreviated New Drug Application ("ANDA"), meaning that it can "piggyback" on the safety and effectiveness findings of the NDA. This allows ANDA applicants "to proceed more quickly to the marketplace."⁴⁸

⁴³ See Exhibit C-319, Apotex Flowchart on Pre-Ban Product Portfolio Net Sales Forecast FY10.

⁴⁴ Witness Statement of Jeremy Desai, para. 21.

⁴⁵ **Legal Authority CLA-234**, Federal Food, Drug and Cosmetic Act, 21 USC § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."). See also *supra* fn. 14 on the territorial scope of US marketing authorizations; **Legal Authority CLA-278**, Applications for FDA Approval to Market a New Drug, 21 CFR 314.410 ("(a) Imports. (1) A new drug may be imported into the United States if: (i) It is the subject of an approved application under this part; or (ii) it complies with the regulations pertaining to investigational new drugs under part 312; and it complies with the general regulations pertaining to imports under subpart E of part 1.").

⁴⁶ **Legal Authority CLA-234**, Federal Food, Drug and Cosmetic Act, 21 USC § 355(b).

⁴⁷ *Id.*, § 355(j).

⁴⁸ **Legal Authority CLA-117**, *Apotex Inc. v. FDA*, 508 F. Supp. 2d 78, 81 (D.D.C. 2007) (citations omitted).

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.
64. The US, like many other countries, has acknowledged the public interest in “receiving generic competition to brand-name drugs as soon as is possible.”⁴⁹ In 1994, Congress enacted the Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act (the “Act”) in order to “expedite the process by which companies gain approval to sell generic versions of already-approved brand-name drugs”⁵⁰
65. ANDA applicants must submit information such as on the use prescribed for the new drug, the active ingredient(s), the route of administration, the dosage form and strength of the new drug, studies showing the new drug’s bioequivalence to the innovative drug, and the labeling proposed for the new drug.⁵¹
66. In addition, as part of the application package, the applicant must detail how the proposed generic drug relates to patents governing the innovative drug. More specifically, with respect to each patent listed in the Orange Book⁵² for the innovative drug, the applicant must make one of four certifications: (I) no patent has been filed; (II) the patent has expired; (III) the generic manufacturer is not seeking ANDA approval until after the patent expires; or (IV) the patent is invalid, not infringed by the generic

⁴⁹ **Legal Authority CLA-125**, *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997). *See also Legal Authority CLA-181*, *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 652 (D.D.C. 1992) (a “delay in the marketing of the [generic] drug could easily be against the public interest in reduced prices.”).

⁵⁰ **Legal Authority CLA-177**, *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004). The US Congress amended the Act in 1994 (21 USC § 355).

⁵¹ **Legal Authority CLA-234**, Federal Food, Drug, and Cosmetic Act, 21 USC § 355(j)(2)(A) (current version).

⁵² The Orange Book is an official list, required by law, of approved marketing authorizations. The Orange Book is prepared by the US Department of Health and Human Services (HHS). Congress granted power to HHS to “publish and make available to the public (I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness” *See Id.* § 355(j)(7)(A)(i) (current version). The Orange Book is also available online with monthly updates, *available at* <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

drug, or otherwise unenforceable against the generic manufacturer.⁵³ This last category is sometimes referred to as a “paragraph IV certification.”

67. Notice of a paragraph IV certification is provided to the holders of patents governing the innovative drug. The patent holders must thereafter decide whether or not to file suit for patent infringement against the ANDA applicant.⁵⁴
68. The first applicant to submit a complete application with a paragraph IV certification may be eligible for 180 days of market exclusivity.⁵⁵ In such a case, no other ANDA applicants referencing the same innovative drug and strength can be approved until the expiration of the 180-day exclusivity period.⁵⁶
69. Under the Act, as amended by the Hatch-Waxman amendments, the start of the 180-day exclusivity period is triggered by the first day of commercial marketing of the generic drug.⁵⁷
70. The statutory exclusivity period is important in practice since it provides a “first-entrant” advantage to the applicant who has obtained 180-day exclusivity and begins to market the approved generic drug: the applicant has six months to make sales and build market share before facing generic competition.⁵⁸
71. Once a complete application for a new generic drug has been submitted, FDA can grant tentative or final approval. Tentative approval is provided when there is something that

⁵³ *Id.* § 355(j)(2)(A)(vii) (current version).

⁵⁴ *Id.* § 355 (j)(5)(B)(iii) (current version). *See also Legal Authority CLA-289*, Excerpts from FDA’s website, “Small Business Assistance: 180-Day Generic Drug Exclusivity” (last updated on April 15, 2009) (“The submission of an ANDA for a drug product claimed in a patent is an infringing act if the generic product is intended to be marketed before expiration of the patent, and therefore, the ANDA applicant who submits an application containing a paragraph IV certification may be sued for patent infringement.”).

⁵⁵ **Legal Authority CLA-234**, Federal Food, Drug, and Cosmetic Act, 21 USC § 355(j)(5)(B)(iv) (current version).

⁵⁶ *Id.* § 355(j)(5)(B)(iv)(II)(aa) (current version).

⁵⁷ *Id.* § 355(j)(5)(B)(iv)(I) (current version). For a few drugs still governed by the previous version of the Hatch-Waxman amendments, the 180-day exclusivity also can be triggered by certain court decisions.

⁵⁸ **Legal Authority CLA-289**, Excerpts from FDA’s website, “Small Business Assistance: 180-Day Generic Drug Exclusivity” (last updated on April 15, 2009) (“Until an eligible ANDA applicant’s 180-day exclusivity period has expired, FDA cannot approve subsequently submitted ANDAs for the same drug, even if later ANDAs are otherwise ready for approval and the sponsors [applicants] are willing to immediately begin marketing. Therefore, an ANDA applicant who is eligible for exclusivity is often in the position to delay all generic competition for the innovator product.”).

prevents final approval, e.g., existing and unchallenged patents for the innovative drug that prevent final approval of the ANDA until those patents expire.⁵⁹

72. Furthermore, section 355(j)(4)(A) of the Act provides that FDA need not approve an ANDA if it has found that the “methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity.”⁶⁰ In cases of violations of current good manufacturing practices, approval of an ANDA is left to the discretion of the Agency.⁶¹
73. FDA may conduct pre-approval inspections (PAIs) and/or good manufacturing practice (GMP) inspections at the facilities of the generic drug manufacturer before making a recommendation as to whether or not to approve an ANDA submitted by the manufacturer or seller.⁶²
74. However, such inspections are not required by law⁶³ and in practice are not carried out for every application.⁶⁴
75. Once an ANDA has been approved, the applicant must regularly submit post-approval documentation to FDA.⁶⁵ For example, on each anniversary of the approved ANDA, the applicant must submit a maintenance report. In addition, post-approval pharmaco-

⁵⁹ **Legal Authority CLA-234**, Federal Food, Drug, and Cosmetic Act, 21 USC § 355(j)(5)(B)(iv)(II)(dd)(AA) (current version).

⁶⁰ *Id.* § 355(j)(4)(A). *See also* **Legal Authority CLA-277**, Applications for FDA Approval to Market a New Drug, 21 CFR § 314.127(a)(1).

⁶¹ **Legal Authority CLA-276**, Applications for FDA Approval to Market a New Drug, 21 CFR. § 314.125(b) (“FDA *may* refuse to approve an application for any of the following reasons: ... (13) The methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the drug substance or the drug product do not comply with the current good manufacturing practice regulations in parts 210 and 211.”) (emphasis added).

⁶² Witness Statement of Bernice Tao, para. 28 (noting that PAIs are specific to the US and represent a significant commitment in investing generic drugs in the US).

⁶³ **Legal Authority CLA-279**, New Drug and Abbreviated New Drug Applications; Preapproval Inspection Requirements, 58 Fed. Reg. 47340, 47342 (Sept. 8, 1993) (to be codified at 21 CFR. pt. 314).

⁶⁴ Witness Statement of Bernice Tao, para. 30 (compliant status of a facility deemed valid for two years).

⁶⁵ **Legal Authority CLA-234**, 21 USC § 355(k); **Legal Authority CLA-273**, Applications for FDA Approval to Market a New Drug, 21 CFR § 314.81; Witness Statement of Kiran Krishnan, paras. 32-41; Witness Statement of Bernice Tao, paras. 32-34.

vigilance studies must regularly be submitted in the form of quarterly reports during the first three years following approval, and annual reports thereafter.

76. Finally, an ANDA remains the property of the applicant or holder unless it decides to sell the ANDA.⁶⁶
77. It is against this statutory framework that Apotex prepared, filed, obtained and maintained scores of ANDAs and distributed drugs authorized under those ANDAs until the Import Alert was adopted. In doing so, Apotex specifically targeted the US and committed significant resources into this country.
78. *First*, as the largest pharmaceutical market in the world, the US market informs and directs many of Apotex's decisions on which products to develop. Apotex primarily targets the United States in its product development strategy.⁶⁷
79. Once a product has been developed, the application for marketing authorization in the US is designed to meet the requirements of FDA, and not those of another national regulatory agency. The territorial scope of a marketing authorization delivered by FDA is limited to the United States.⁶⁸ As such, although it can be owned by and transferred to a holder outside the United States, an ANDA can only be used in the United States. From inception, the application is therefore prepared and filed with a view to distributing the drug on the US market, and not anywhere else. In addition, FDA imposes specific requirements that no other national regulator imposes.⁶⁹
80. *Second*, as noted above, generic drug manufacturers must demonstrate that each of their products is bio-equivalent to the brand-name drug. To that end, Apotex resorts in part

⁶⁶ **Legal Authority CLA-272**, Applications for FDA Approval to Market a New Drug, 21 CFR § 314.72 (“(a) An applicant may transfer ownership of its application... .”); *id.* at § 314.72(a)(2)(iii) and § 314.72(b) (making clear that provision applies to approved ANDAs). *See also Id.* § 314.99(a) (“Other responsibilities of an applicant of an abbreviated application”) (“An applicant shall comply with the requirement of ... § 314.72 regarding a change in ownership of an abbreviated application.”); **Legal Authority CLA-312**, Internal Revenue Service, Office of Chief Counsel, Memorandum at 37 (Sept. 14, 2011) (“FDA-approved ANDAs, ... can be sold or used in [the] trade or business until such time, if ever, FDA withdraws its approval of the ANDAs.”).

⁶⁷ Witness Statement of Jeremy Desai, para. 33; Witness Statement of Bruce Clark, para. 14.

⁶⁸ *See supra* n. 14.

⁶⁹ Witness Statement of Kiran Krishan, para. 16; Witness Statement of Bernice Tao, para. 25.

to the services of specialized firms. About 20% of the contract research organizations used by Apotex for bio-equivalence studies were US-based as of 2009.⁷⁰

81. *Third*, while most of the product development and application preparation work is done by Apotex personnel in Canada, any Apotex ANDA reflects a substantial commitment of Apotex know-how to the US market. No Apotex ANDA could be approved or the target product put on the US market without a substantial commitment of human, intellectual, financial and logistic resources to preparation of the ANDA.⁷¹
82. *Fourth*, Apotex-US employs a full-time agent in Apotex-US's offices in Florida, Mr. Kiran Krishnan.⁷² Any Apotex application must be, and is, submitted in his name. The US agent handles all follow-up correspondence with FDA concerning applications.⁷³
83. *Fifth*, no ANDA can be maintained without significant reporting to FDA on an annual basis, as well as pharmacovigilance reports on a quarterly or annual basis. This is largely handled by a staff of seven salaried employees in Apotex-US's offices in Florida.⁷⁴
84. *Sixth*, ANDAs can be maintained only if the label of the product accurately reflects that of the original approved product and the file is supplemented with any relevant modifications to specifications, manufacturing process, name or shelf life. Again, these tasks largely handled by the regulatory staff of Apotex-US in Florida.⁷⁵

⁷⁰ See Witness Statement of Bernice Tao, para. 15; *see id.*, para. 18.

⁷¹ *See Id.*, paras. 12-32.

⁷² Witness Statement of Kiran Krishnan, para. 11.

⁷³ *Id.*, para. 11. *See also Legal Authority CLA-275*, Applications for FDA Approval to Market a New Drug, 21 CFR §314.102 (“(a) General principles. During the course of reviewing an application or an abbreviated application, FDA shall communicate with applicants about scientific, medical, and procedural issues that arise during the review process. Such communication may take the form of telephone conversations, letters, or meetings, whichever is most appropriate to discuss the particular issue at hand. Communications shall be appropriately documented in the application in accordance with 10.65 of this chapter. Further details on the procedures for communication between FDA and applicants are contained in a staff manual guide that is publicly available.”).

⁷⁴ Witness Statement of Kiran Krishnan, paras. 38-40; Witness Statement of Bernice Tao, para. 34.

⁷⁵ Witness Statement of Kiran Krishnan, paras. 34-37; *see, e.g., Exhibit C-267*, CBE for Change in Label for Paroxetine Hydrochloride Tablets USP, dated October 5, 2011.

85. *Finally*, the returns achieved by Apotex on its ANDAs arise in significant part from a substantial commitment of resources to patent litigation in the US.⁷⁶ This litigation creates opportunities for Apotex to enter the market as the first filer or otherwise places it in an advantageous market position.⁷⁷
86. As of August 2009, Apotex was the holder of more than 100 finally approved ANDAs.⁷⁸ At that time, the company also had [REDACTED] pending ANDAs for which an application had been submitted to FDA and was awaiting approval from the Agency.⁷⁹ In addition, Apotex was working on new drug products to be developed and brought to market and, as a result, had additional applications in the pipeline.

IV. THE REGULATORY FRAMEWORK

87. As a preliminary remark, it should be noted that the regulatory framework described below has remained materially the same from the time of the events giving rise to the Import Alert to the present. Apotex has included in the accompanying legal authorities relevant provisions of statutes, regulations and FDA's guidance documents in their current version, as well as in their 2009 version.

A. Inspections and Current Good Manufacturing Practices

88. As a Canadian drug manufacturer, Apotex-Canada is primarily regulated and controlled by Health Canada. Health Canada has an international reputation for being a sophisticated and demanding regulator. 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 been periodically inspected by FDA.

⁷⁶ Witness Statement of Jeremy Desai, para. 27; Witness Statement of Gordon Fahner, para. 45 (Apotex-Canada spends USD [REDACTED] million annually on patent and ANDA-related litigation in the US).

⁷⁷ Witness Statement of Kiran Krishnan, para. 19; Witness Statement of Gordon Fahner, para. 44.

⁷⁸ **Exhibit C-275**, Excerpts from 2012 Orange Book, ANDAs held by Apotex-Canada as of August 28, 2009; **Exhibit C-276**, Excerpts from 2012 Orange Book, ANDAs held by Apotex-US as of August 28, 2009 (scores of ANDAs were registered in the Orange Book under the holder's names "Apotex," "Apotex Inc.," "Torpharm" or "Novex" which all belonged to Apotex-Canada; in addition, Apotex Corp. was the holder of a few ANDAs). Witness Statement of Bernice Tao, para. 48.

⁷⁹ See **Exhibit C-48-a**, Apotex List of Pending ANDAs at time of Import Alert; Witness Statement of Bernice Tao, para. 49.

89. Health Canada’s and FDA’s inspections address a multitude of subjects associated with modern pharmaceutical production. These subjects include, inter alia, what are known as current good manufacturing practices (“cGMP”). These are a set of standards referenced in regulations.⁸⁰
90. The standards address the proper design, monitoring and control of manufacturing processes at facilities:

cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories.⁸¹

91. 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 and purity of the drug. Under Section 501 of the Act:

A drug or device shall be deemed to be adulterated—

(a) ... (2) ... (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;⁸²

⁸⁰ See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 43 *et seq.* (addressing cGMP regulation in depth). See also **Legal Authority CLA-250**, FDA Current Good Manufacturing Practice, 21 CFR § 210; **Legal Authority CLA-251**, FDA Current Good Manufacturing Practice, 21 CFR § 211.

⁸¹ **Legal Authority CLA-287**, Excerpts from FDA’s website, “Drugs – Facts About Current Good Manufacturing Practices (cGMPs)” (last updated June 25, 2009). See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 48-58 (providing overview of each main component of cGMP requirements).

⁸² **Legal Authority CLA-233**, Federal Food, Drug, and Cosmetic Act, 21 USC § 351(a)(2)(B).

92. While the statutory text suggests that “adulteration” could be deemed only if the cGMP violation called into question the drug’s safety or efficacy, this is not how FDA has applied the Act. As FDA explains its approach,

This kind of adulteration does mean that the drug was not manufactured under conditions that comply with cGMP. It does not mean that there is necessarily something wrong with the drug. ... A drug manufactured in violation of cGMP may still meet its labelled specifications, and risk that the drug is unsafe or ineffective could be minimal.⁸³

93. FDA principally assesses conformity with cGMP through on-site inspections of pharmaceutical manufacturing facilities.⁸⁴ Because FDA’s cGMP standards are by their nature general,⁸⁵ their application to specific processes, equipment and facilities leaves much to the discretion of inspectors.⁸⁶
94. FDA performs both domestic and foreign drug manufacturing inspections.⁸⁷ Foreign drug inspections are typically scheduled for five days. Inspections can be as short as three days for a control testing laboratory, and up to two weeks for a sterile product.⁸⁸ Sometimes inspections can be longer.

⁸³ **Legal Authority CLA-287**, Excerpts from FDA’s website, “Drugs – Facts About Current Good Manufacturing Practices (cGMPs)” (last updated June 25, 2009).

⁸⁴ *See* **Legal Authority CLA-237**, Federal Food, Drug, and Cosmetic Act, 21 USC § 374 (current version); **Legal Authority CLA-238**, Federal Food, Drug, and Cosmetic Act, 21 USC § 374 (version in effect at the time of the import alert and subsequent amendments). *See also* **Legal Authority CLA-287**, Excerpts from FDA’s website, “Drugs – Facts About Current Good Manufacturing Practices (cGMPs)” (last updated June 25, 2009) (“FDA inspects pharmaceutical manufacturing facilities worldwide using scientifically and cGMP-trained individuals whose job is to evaluate whether the company is following the cGMP regulations. FDA also relies on reports of potentially defective drug products from the public and the industry.”).

⁸⁵ *See* **Legal Authority CLA-250**, FDA Current Good Manufacturing Practice, 21 CFR § 210; **Legal Authority CLA-251**, FDA Current Good Manufacturing Practice, 21 CFR § 211. *See also* **Legal Authority CLA-287**, Excerpts from FDA’s website, “Drugs – Facts About Current Good Manufacturing Practices (cGMPs)” (last updated June 25, 2009) (“The cGMP requirements were established to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls by using scientifically sound design, processing methods, and testing procedures.”).

⁸⁶ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 45 (“Given that the cGMP requirements set forth broad standards, FDA investigators exercise a fair amount of discretion in determining whether a company’s manufacturing systems are in compliance with these requirements.”).

⁸⁷ *See* Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 60-67 (providing overview of FDA practice in inspecting domestic and foreign facilities for cGMP issues).

⁸⁸ **Exhibit C-27**, “FDA’s Foreign Drug Inspection Program”, Statement of FDA Commissioner Andrew C. von Eschenbach at 1 of 4 (Nov. 1, 2007).

B. FDA Form 483

95. At the conclusion of an inspection, FDA inspectors record their observations on a form known as form 483.⁸⁹ Such a form includes the following preprinted instruction:

This document lists observations made by FDA representative(s) during the inspection of your facility. They are inspectional observations; and do not represent a final agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement corrective action in response to an observation, you may discuss the objection or action with FDA representative(s) during the inspection or submit this information to FDA at the address [on the form].⁹⁰

96. This disclaimer makes it clear that a form 483 is not indicative of the firm's final compliance status.⁹¹ The inspected firm has the right to provide a written response to the observations stated on form 483.⁹² FDA will then "conduct a detailed review of the response before determining whether to issue a warning letter."⁹³

97. The United States District Court for the District of Utah (Central Division) described the form 483 process in these terms:

A Form FDA-483 is a list of concerns observed by an FDA inspector during the course of an inspection. The investigator's observations are subject to review and response by the [inspected] Company and are further

⁸⁹ **Legal Authority CLA-280**, Review of Post-Inspection Responses, 74 Fed. Reg. 40211-03, 2009 WL 2430727 (F.R.), at 1 (Aug. 11, 2009) ("FDA issues a form FDA 483, Inspectional Observations, upon completion of an inspection, to notify an inspected establishment's top management of objectionable conditions relating to products and/or processes, or other violations of the Federal Food, Drug, and Cosmetic Act and related acts, that were observed during the inspection.").

⁹⁰ *Id.*

⁹¹ See **Exhibit C-39**, FDA, Progress Report of the 483 Communications Working Group, "Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach" (last updated on April 30, 2009) (explaining that this disclaimer was designed to avoid any ambiguity that may result in inaccurate conclusions about the compliance status of the inspected firm).

⁹² **Legal Authority CLA-280**, Review of Post-Inspection Responses, 74 Fed. Reg. 40211-03, 2009 WL 2430727 (F.R.), at 2 (Aug. 11, 2009) ("Under the program [effective as of September 15, 2009], before issuing a warning letter, FDA will generally allow firms 15 business days to provide a response to FDA 483 observations.").

⁹³ *Id.* See also Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 69 ("FDA generally will consider management's response to each specific observation and give time frames ... for corrections and/or corrective action.") (internal quotation omitted).

reviewed by other FDA personnel before FDA makes a decision whether it believes the Company complies with applicable law and regulations.⁹⁴

C. Warning Letters

98. After having reviewed the firm's response to a form 483, FDA may – or may not – decide to issue a warning letter to the inspected company. Warning letters put companies on notice that serious deviations from the Act were observed during an inspection and must be corrected promptly:

Warning letters are issued only for significant violations that may lead to enforcement action if they are not promptly and adequately corrected. The decision to issue a warning letter is made by senior officials within FDA, often including the product center, after a thorough review of all of the relevant facts.⁹⁵

99. FDA's Regulatory Procedures Manual (RPM) is a reference manual for FDA personnel that provides information on internal procedures to be used in processing domestic and import regulatory and enforcement matters.⁹⁶ Chapter 4 of the RPM addresses "Advisory Actions," including warning letters.
100. The RPM describes warning letters as giving "firms an opportunity to take voluntary and prompt corrective action before [FDA] initiates an enforcement action."⁹⁷ Thus,

⁹⁴ **Legal Authority CLA-204**, *United States of America v. Utah Med. Prods., Inc.*, 404 F. Supp. 2d 1315 (D. Utah 2005) (case concerning Quality System Regulation for medical devices). *See also* Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 70-76 (providing overview of FDA practice in issuing Warning Letters).

⁹⁵ **Legal Authority CLA-280**, Review of Post-Inspection Responses, 74 Fed. Reg. 40211-03, 2009 WL 2430727 (F.R.), at 1-2 (Aug. 11, 2009).

⁹⁶ The March 2009 version of the RPM was subsequently updated, but these changes did not materially affect the content of the RPM. Changes made were either purely formal or procedural. For example, a unified approval process was set forth, applicable to both seizure and injunction cases. *See Legal Authority CLA 308*, FDA, Regulatory Procedures Manual, Chapter 6 (2011), subchapter 6-1 "Seizure", heading "6.1.5. Approval Process for Seizure and Injunction Cases", at 6-7 ("This process was established to increase collaboration and sharing of evidence at the early stages of case development, to reduce paperwork, to rule-out unsupportable cases, and to shorten approval times for all cases. This process is not meant to diminish the role or responsibility of any participant, nor does it diminish the expectation for quality. The district is not required to wait until a judicial action is likely to result before communicating concerns to any participants prior to the [Preliminary Assessment] call."). *See also Legal Authority CLA-288*, Excerpts from FDA's website, "RPM News 2009", "RPM News 2010", "RMP News 2011" and "RPM News 2012".

⁹⁷ **Legal Authority CLA-305**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2009), subchapter 4-1-1 "Warning Letters Procedures" at 4-1; **Legal Authority CLA-306**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2012), subchapter 4-1-1 "Warning Letters Procedures" at 4-2.

while representing a finding of “significant violations,” in this sense warning letters are only “informal and advisory” because they “do[] not commit FDA to taking enforcement action.”⁹⁸

101. The RPM lists the main factors that the Agency should consider in determining whether to issue a warning letter.⁹⁹ In particular, when a firm is in the process of correcting the violations or has made a written promise to take prompt corrective action, FDA should consider the following factors:

- a. The firm’s compliance history, e.g., a history of serious violations, or failure to prevent the recurrence of violations;
- b. The nature of the violation, e.g., a violation that the firm was aware of (was evident or discovered) but failed to correct;
- c. The risk associated with the product and the impact of the violations on such risk;
- d. The overall adequacy of the firm’s corrective action and whether the corrective action addresses the specific violations, related violations, related products or facilities, and contains provisions for monitoring and review to ensure effectiveness and prevent recurrence;
- e. Whether documentation of the corrective action was provided to enable the agency to undertake an informed evaluation;
- f. Whether the timeframe for the corrective action is appropriate and whether actual progress has been made in accordance with the timeframe; and

⁹⁸ **Legal Authority CLA-305**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2009), subchapter 4-1-1 “Warning Letters Procedures” at 4-2 to 4-3; **Legal Authority CLA-306**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2012), subchapter 4-1-1 “Warning Letters Procedures” at 4-3. Warning letters do not constitute final agency action subject to judicial review under the Administrative Procedure Act. See **Legal Authority CLA-157**, *Holistic Candles & Consumers Ass’n v. FDA*, 664 F.3d 940 (D.C. Cir. 2012) (“FDA’s warning letters ... neither marked the consummation of FDA’s decision making process nor determined the manufacturers’ legal rights or obligations.”).

⁹⁹ **Legal Authority CLA-305**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2009); **Legal Authority CLA-306**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2012), subchapter 4-1-3 “Issuing Warning Letters – Factors to Consider”, at 4-4.

- g. Whether the corrective action taken ensures sustained compliance with the law or regulations. ...¹⁰⁰

102. If FDA decides to issue a warning letter, the recipient company has an opportunity to comment in response to the warning letter. FDA will evaluate the response to the warning letter.¹⁰¹ If FDA considers the response to the warning letter to be inadequate, FDA can decide to take follow-up action as necessary to achieve correction.¹⁰² The form of enforcement action may vary depending on whether the products are in the US territory or offered for import.

D. Refusal of Admission and Import Alerts

103. The Act grants FDA the authority to refuse admission of goods offered for import if they appear adulterated. On that ground, FDA has developed a practice pursuant to which it may refuse admission without any physical examination of products at the border.¹⁰³

1. Detention, Physical Examination and Refusal of Admission

104. One form of enforcement action is to refuse admission to the United States of violative products offered for import. Section 801 of the Act authorizes the US Government to

¹⁰⁰ **Legal Authority CLA-305**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2009); **Legal Authority CLA-306**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2012), subchapter 4-1-3 “Issuing Warning Letters – Factors to Consider”, at 4-5. *See also* **Exhibit C-65**, “Undoing Bush: FDA begins ‘swift’ enforcement actions”, Dickinson’s FDA Review 6, 8 (Sept. 2009) (quoting remarks by Mr. Rivera-Martinez, chief of FDA’s CDER international compliance branch, made on August 24-26, 2009 explaining that in order to determine in practice whether or not a violation is significant and requires issuing a warning letter, FDA considers the form 483 observations and whether these findings have an impact on product quality or the manufacturing process).

¹⁰¹ **Legal Authority CLA-305**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2009); **Legal Authority CLA-306**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2012), subchapter 4-1-8 “Warning Letter Follow-Up”, at 4-13. *See also* Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 71-74 (describing FDA procedure for processing responses to Warning Letters).

¹⁰² *See* Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 75 (“When considering further action, FDA personnel should *ensure that prior notice* has been given to the firm, which can be accomplished ‘through issuance of a second Warning Letter’ or ‘a meeting with [the] firm’s management *prior to pursuing an administrative or regulatory action.*”) (emphasis added) (quoting **Legal Authority CLA-305**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2009)); **Legal Authority CLA-306**, FDA, Regulatory Procedures Manual, Ch. 4: Advisory Action (2012), subchapter 4-1-8 “Warning Letter Follow-Up”, at 4-13.

¹⁰³ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 87, 100.

detain, physically examine and refuse admission of a product into the United States if the product is adulterated. Section 801 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 admission¹⁰⁴

105. Section 801 was introduced into the Act in 1938.¹⁰⁵ The procedure set out in this section has not been significantly updated since the 1930s.¹⁰⁶

106. Section 801 was designed for situations where the goods offered for import were inspected at the US border and examined through the taking of samples. Under the provision, the owner of the goods was to be informed that he had an opportunity to give testimony to convince the US authorities to allow the goods into the US.¹⁰⁷

2. *Detention Without Physical Examination and Import Alerts*

107. Based on Section 801,¹⁰⁸ FDA practice has developed a measure known as Detention Without Physical Examination (DWPE), which is defined as follows in FDA's Investigations Operations Manual (IOM):

An action directed against specific products manufactured or shipped by specific foreign firms. "Import Alerts" list

¹⁰⁴ **Legal Authority CLA-239**, Federal Food, Drug, and Cosmetic Act, 21 USC § 381(a) (current version) (Jan. 4, 2011) (emphasis added); **Legal Authority CLA-240**, Federal Food, Drug, and Cosmetic Act, 21 USC § 381(a) (version in effect at the time of the import alert and subsequent amendments) (June 22, 2009 to Jan. 3, 2011).

¹⁰⁵ **Legal Authority CLA-242**, Public Law of June 25, 1938, c.675, 52 Stat.1040, 1058 (June 25, 1938).

¹⁰⁶ **Legal Authority CLA-239**, Federal Food, Drug, and Cosmetic Act, 21 USC § 381, legislative history.

¹⁰⁷ See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 88-99 (providing an overview of the procedures afforded to an owner whose goods were detained through the taking of samples).

¹⁰⁸ FDA maintains that the term "or otherwise" in Section 801(a) of the Act is a congressional grant of authority to refuse admission of drugs "based on information, other than the results of examination of samples, that causes an article to appear to violate the ... Act." See **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, subchapter 9-6 "Detention without Physical Examination (DWPE)", under the heading "Authority and Background", at 9-19 (2011).

products which may be detained without physical examination due to their violative history or potential.¹⁰⁹

108. An import alert is thus a notice by FDA to US customs officials¹¹⁰ that calls for detention without physical examination (DWPE) of a specific category of product that appears adulterated. In this context, detention is an administrative process, as opposed to physical hold of the products.¹¹¹
109. DWPE is based on an inspection or determination that does not take place at the border, but at a prior place and time. In the words of FDA's former Commissioner:

FDA issues Import Alerts for Detention Without Physical Exam (DWPE) when we have information that would cause future shipments of a product offered for entry to appear violative within the meaning of section 801 of the [Act]. This allows FDA field personnel to detain the product without physical examination, based on the appearance of a violation as documented in the Import Alert. Once FDA detains a product under 801(a) the burden shifts to the importer to demonstrate why, in fact, its product complies with U.S. law.¹¹²

¹⁰⁹ **Legal Authority CLA-302**, FDA, Investigations Operations Manual, Ch. 6: Imports (2009); **Legal Authority CLA-303**, FDA, Investigations Operations Manual, Ch. 6: Imports (2012), subchapter 6.7 "Glossary of Import Terms", under the heading "6.7.10 Detention Without Physical Examination (DWPE)". As noted on FDA's home page for the investigations Operations Manual (IOM), "The IOM is the primary guidance document on FDA inspection policy and procedures for field investigators and inspectors." See **Legal Authority CLA-300**, FDA, Investigations Operations Manual, Homepage.

¹¹⁰ United States Customs and Border Protection, (CBP). See **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, subchapter "9-6 Detention Without Physical Examination (DWPE)", under the heading "Party Notification of Detention Without Physical Examination Decision", at 9-25 (2011).

¹¹¹ See **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", slides 14-15 (May 22, 2012).

¹¹² **Exhibit C-27**, "FDA's Foreign Drug Inspection Program", Statement of FDA Commissioner Andrew C. von Eschenbach at 1 (Nov. 1, 2007). FDA's practice is that the foreign manufacturer can only demonstrate that its products comply with US law when FDA re-inspects its factories and approves them as cGMP-compliant. See **Legal Authority CLA-309**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter "9-6 Detention Without Physical Examination (DWPE)", under the heading "Removal Based Upon an Establishment Inspection" at 9-29 ("Firms or products placed on detention without physical examination based on a violative establishment inspection, or 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 [e.g., CDER]."). See also Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 101.

110. However, detention without physical examination (DWPE) must be supported by “substantial evidence of a documentary type, (i.e., a violation in a previous shipment of the entered product from the same firm ...).”¹¹³
111. FDA does not normally give notice to companies that they have been placed on import alert, other than posting the import alert on its website.¹¹⁴ This practice is contrary to FDA’s stated policy requiring that at least a copy of the import alert be transmitted to the foreign manufacturer.¹¹⁵
112. In practice, it is only when the foreign manufacturer offers a product for entry into the United States that the manufacturer will receive a notice from FDA stating that the product is being detained.¹¹⁶ This notice does not state, however, the specific reasons why the products have been placed on import alert in the first place.¹¹⁷

¹¹³ **Legal Authority CLA-309**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-7 Notice of Detention and Hearing” under the heading “Guidance” and sub-heading “Evidence Required for Detention”, at 9-31. *See also* Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 102.

¹¹⁴ **Legal Authority CLA-324**, Christine M. Humphrey, *The Food and Drug Administration’s Import Alerts Appear to Be “Misbranded”*, 58 Food and Drug L.J. 595, 599 (2003).

¹¹⁵ **Legal Authority CLA-309**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-6 Detention Without Physical Examination (DWPE)”, under the heading “Party Notification of Detention Without Physical Examination Decision”, at 9-25 (“In most instances, a copy of the Import Alert will suffice for notification ... If notification of the specific foreign manufacturer or shipper is deemed impractical or impossible ... notification should be sent to the importer, requesting transmittal of the notification to the foreign manufacturer and requesting a response to include what steps were taken to correct the conditions which brought about the detention without physical examination.”).

¹¹⁶ **Legal Authority CLA-309**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-6 Detention Without Physical Examination (DWPE)”, under the heading “Authority and Background”, at 9-19 (“To carry out the provisions of Section 801(a) [providing the importer with the right to introduce testimony on the admissibility of the articles], FDA detains an article that appears violative and provides notice to the importer of the nature of the violation and the right to present testimony regarding the admissibility of the article (21 CFR 1.94).”).

¹¹⁷ **Legal Authority CLA-324**, Christine M. Humphrey, *The Food and Drug Administration’s Import Alerts Appear to Be “Misbranded”*, 58 Food and Drug L.J., 599 (2003). For a concrete illustration, *see, e.g.*, Exhibit C-68, Email from Customs Broker (Juanita Zaziski) to Apotex, at 10:20 am (Sept. 1, 2009), attaching Notice of FDA Action No. EG6-1768658-9, “Hold Designated” (Aug. 31, 2009).

113. Again, this practice does not accord with federal regulations, which require the notice of detention to state the reasons why the articles may be subject to refusal of admission, and indicate a time for the introduction of testimony on the issue of admissibility.¹¹⁸

114. The detention hearing is only “informal” as noted in the RPM:

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].¹¹⁹

115. “This is not a full-blown, trial-type administrative hearing.”¹²⁰ The importer can introduce testimony orally or in writing to FDA’s district compliance officer in charge of the hearing.¹²¹ Testimony may be introduced by a telephone conversation, fax or

¹¹⁸ **Legal Authority CLA-245**, FDA Imports and Exports Rule, 21 CFR § 1.94 (“Hearing on Refusal of Admission. (a) 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. Upon timely request giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article, and may be introduced orally or in writing.”). Note that this provision has not been amended since 2009. Under FDA’s practice, the owner or consignee usually has 10 working days to provide FDA with testimony or evidence, but this time period may be extended under exceptional circumstances. *See Legal Authority CLA-309*, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-1 Import Procedures”, under the heading “Procedures When Violation Is Found,” under the sub-heading “Notice of Detention & Hearing,” at 9-8. *See also* Legal Authority CLA-309, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-7 Notice of Detention and Hearing”, under the heading “Guidance”, under the sub-heading “Preparation of Charges”, at 9-31 (statement of charges on the Notice of Detention “should be sufficiently informative and complete for the importer to understand clearly the alleged violation(s) so that the importer can prepare a reply for the hearing.”). *See also* Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 89.

¹¹⁹ **Legal Authority CLA-309**, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-1 Import Procedures”, under the heading “Procedures When Violation Is Found,” under the sub-heading “Notice of Detention & Hearing,” at 9-8.

¹²⁰ *See Legal Authority CLA-341*, Linda Horton, “US FDA Authority over Imports”, Regulatory Affairs Journal – Pharma 293, 294 (May 2009). *See also* Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 90.

¹²¹ **Legal Authority CLA-309**, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-8 Response (Hearing) to Notice of Detention and Hearing”, under the heading “Conduct of Hearing: Personal Appearance of Respondent”, at 9-35 (“The hearing officer (generally it is the district compliance officer, however, it may be any individual designated by the district to conduct such a hearing) ...”).

email and does not have to be introduced in person.¹²² The respondents at the hearing should “confine their comments to the submission of relevant evidence and not be permitted merely to attempt to question, probe, or pass judgment on FDA’s basis for detention.”¹²³ The district compliance officer for his part does not offer any evidence and there is no cross-examination, and often no recording or transcript made of the proceeding.¹²⁴ The district compliance officer listens to (or reviews) the importer’s presentation and then decides whether or not to release the goods for distribution in the US,¹²⁵ often immediately at the end of the hearing.¹²⁶

116. If, after the detention hearing, FDA concludes that the articles still appear to violate the Act, FDA may decide to refuse admission. In such a case, FDA issues a notice of refusal of admission,¹²⁷ which should state the charge(s) exactly as shown on the

¹²² **Legal Authority CLA-309**, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-8 Response (Hearing) to Notice of Detention and Hearing”, under the heading “Hearing and Postponements”, at 9-34.

¹²³ **Legal Authority CLA-309**, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-8 Response (Hearing) to Notice of Detention and Hearing”, under the heading “Conduct of Hearing: Personal Appearance of Respondent”, at 9-35.

¹²⁴ **Legal Authority CLA-309**, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-8 Response (Hearing) to Notice of Detention and Hearing”, under the heading “Conduct of Hearing: Personal Appearance of Respondent”, at 9-35 (“Formal memoranda covering import hearings are not required, although a written record should be made for the files.”).

¹²⁵ *See Legal Authority CLA-341*, Linda Horton, *US FDA Authority over Imports*, Regulatory Affairs Journal – Pharma 293 (May 2009).

¹²⁶ **Legal Authority CLA-309**, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-8 Response (Hearing) to Notice of Detention and Hearing”, under the heading “Conduct of Hearing: Personal Appearance of Respondent”, at 9-35 (“If the facts in the case are such that a decision can be reached regarding the validity of the detention charges at the termination of the hearing, the hearing officer should so advise the respondent of the decision with confirmation by the issuance of the appropriate “Notice,” (Refusal, Release, etc.).”).

¹²⁷ **Legal Authority CLA-309**, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-9 Notice of Refusal of Admission”, at 9-36 *et seq.*

original or amended notice of detention and hearing.¹²⁸ The articles under refusal of admission must usually be destroyed or exported.¹²⁹

117. The informal hearing procedure provided for by the 1938 law is not well adapted to the import alert measure that FDA developed many decades later. The district officer at the hearing ordinarily will have no knowledge of the circumstances that led to the adoption of an import alert. An import alert for drugs is adopted by hierarchically superior FDA officers at the relevant FDA Center, the Center for Drug Evaluation and Research (CDER).¹³⁰ The district director has no authority to overrule an import alert decision made by the Center.¹³¹
118. According to the US Government, FDA's import decisions are committed to agency discretion and thus are not subject to judicial review under the Administrative Procedure Act (APA).¹³² This is the position that the US government advocated for instance in a case where FDA had detained without physical examination, and refused admission into the United States, of electronic cigarettes.¹³³

¹²⁸ **Legal Authority CLA-309**, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter "9-1 Import Procedures", under the heading "Procedures When Violation Is Found", under the sub-heading "Procedure After Hearing – 'Refusal of Admission'", at 9-9.

¹²⁹ See **Legal Authority CLA-239**, Federal Food, Drug, and Cosmetic Act, 21 USC § 381(a) (Jan. 4, 2011) (current version) ("The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations."); **Legal Authority CLA-240**, Federal Food, Drug, and Cosmetic Act, 21 USC § 381(a) (June 22, 2009 to Jan 3, 2011) (version in effect at the time of the import alert and subsequent amendments). See also Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 98-99.

¹³⁰ **Legal Authority CLA-309**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, sec. 9-6, at 9-24 (2009) ("The final detention without physical examination decision rests with the Center.").

¹³¹ *Id.*, at 9-29 (2009) ("concurrence by the appropriate Center" required to remove detention without physical examination). See also Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 104

¹³² Codified at 5 USC § 701 et seq. See **Legal Authority CLA-220**, Administrative Procedure Act, 5 USC § 701 (Jan. 4, 2011).

¹³³ See **Legal Authority CLA-184**, *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 69 n.8 (D.D.C. 2010) *aff'd on other grounds sub nom.* **Legal Authority CLA-185**, *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010), *rehearing en banc denied* (2011).

E. Judicial Actions

119. While FDA has the authority to detain imports that appear adulterated, it lacks similar detention authority for domestically produced goods that appear adulterated.¹³⁴

120. The Act prohibits the introduction in interstate commerce of any adulterated drug.¹³⁵ If adulterated drugs are marketed in the US, FDA can initiate federal court proceedings in order to seize the adulterated products, or seek an injunction to stop their marketing.¹³⁶ FDA can also institute criminal proceedings against the persons who introduced adulterated articles in interstate commerce.

1. Seizure

121. The Act provides in relevant part:

Any article of ... drug ... that is adulterated ... when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce ... shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States¹³⁷

122. As such, adulterated drugs sold in the US may be seized by court order.¹³⁸ Under these circumstances, FDA requests that the district court order federal officials (US Marshals)

¹³⁴ See **Legal Authority CLA-341**, Linda Horton, *US FDA Authority over Imports*, Regulatory Affairs Journal – Pharma 293 (May 2009). FDA has the authority to administratively detain human and animal foods and medical devices while they are in commerce, but not pharmaceutical drugs.

¹³⁵ **Legal Authority CLA-226**, Federal Food, Drug, and Cosmetic Act, 21 USC § 331 (Jan. 4, 2011) (current version) (“The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.”); **Legal Authority CLA-227**, Federal Food, Drug, and Cosmetic Act, 21 USC § 331 (June 22, 2009 to Jan. 3, 2011) (version in effect at the time of the import alert and subsequent amendments).

¹³⁶ See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 77, 81.

¹³⁷ **Legal Authority CLA-231**, Federal Food, Drug, and Cosmetic Act, 21 USC § 334(a)(1) (June 22, 2009 (no subsequent amendment)) (current version).

¹³⁸ *Id.* § 334(b) (June 22, 2009 (no subsequent amendment)) (current version) (“The article ... proceeded against shall be liable to seizure by process pursuant to the libel”). The version of this provision in force at the time of the Import Alert has not been amended thereafter.

to take possession of adulterated drugs and destroy them. The action is an *in rem* proceeding, brought against the products themselves.¹³⁹

123. In FDA's parlance, a "mass seizure" is the seizure of all FDA-regulated products at a facility. Mass seizures may be conducted when all of the products are produced under the same conditions, e.g., non-conformance with cGMP.¹⁴⁰ As noted in the RPM, "[b]ecause of the effect that a mass seizure can have on a company, extra care should be taken to ensure that the evidence warrants the proposed action against all articles to be seized."¹⁴¹

124. The owner or the manufacturer of the seized products may immediately appear in court and has full rights as a party to present its claim to the products.¹⁴² The district court will render an order after a civil trial, i.e., adversarial proceedings where each party is given ample opportunity to present its case and supporting evidence.¹⁴³ In these proceedings, FDA bears the burden of proving that the products do violate the Act.

2. Injunctions

125. Another form of enforcement action is a civil action seeking injunctive relief, typically precluding continued marketing of products until FDA confirms compliance with

¹³⁹ See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 77-78.

¹⁴⁰ **Legal Authority CLA-307**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2009); **Legal Authority CLA-308**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2011), subchapter 6-1 "Seizure", under the heading "6-1-3. Types of Seizures", under sub-heading "1. Mass And Open-ended Seizures", at 6-5. See *id.* at 6-6 (as a general rule, the evidence of violative conditions supporting mass seizures, usually determined on the last day of Establishment Inspection (EI), should not be more than 30 days old when the case is transmitted to the US Attorney's Office for filing).

¹⁴¹ **Legal Authority CLA-307**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2009); **Legal Authority CLA-308**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2011), subchapter 6-1 "Seizure", under the heading "6-1-3. Types of Seizures", under sub-heading "3. Mass Seizure – Special Considerations", at 6-6.

¹⁴² See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 77.

¹⁴³ Occasionally, FDA may seek a temporary restraining order (TRO) from a federal judge and the hearing may be ex parte. Because the private party is not present, TROs are effective for relatively short time frames and are routinely followed up with a preliminary injunction hearing before a federal judge, where the private party participates and may submit affidavits and/or testimony. See **Legal Authority CLA-307**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2009); **Legal Authority CLA-308**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2011), subchapter "6.2. Injunctions", under the heading "6-2-3. Definitions", under the sub-headings "1. Temporary Restraining Order" and "2. Preliminary Injunction", at 6-26.

cGMP.¹⁴⁴ Injunctive relief is available whether the facility is located in the US or abroad as long as the manufacturer is subject to US jurisdiction.¹⁴⁵

126. In injunction cases, FDA requests the court to order the company to stop its violations, e.g., non-compliance with cGMP.
127. An injunction may be considered “for any significant out-of-compliance circumstance, but particularly when a health hazard has been identified.”¹⁴⁶ In practice, courts have been reluctant to grant injunctions in contested cases absent evidence of safety issues with the products.¹⁴⁷
128. Injunction actions generally can succeed only when FDA can show that “the defendants were notified of the violations (by letter, FDA 483, meeting, telephone call) and, despite having an opportunity to correct the violations, failed to do so.”¹⁴⁸ In this context, notice is deemed adequate if it insures that:

¹⁴⁴ **Legal Authority CLA-228**, Federal Food, Drug, and Cosmetic Act, 21 USC § 332 (Aug. 13, 1993) (no subsequent amendment) (“(a) Jurisdiction of courts – The district courts of the United States ... shall have jurisdiction, for cause shown ... to restrain violations of section 331 of this title [prohibition of the introduction into interstate commerce of adulterated drugs] ...”).

¹⁴⁵ See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 81.

¹⁴⁶ See **Legal Authority CLA-307**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2009); **Legal Authority CLA-308**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2011), subchapter “6.2. Injunctions”, under the heading “6-2-4. General Considerations”, sub-heading “1. When An Injunction May be Considered”, at 6-27. See also Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 82-83 (listing situations that FDA considers when seeking an injunction).

¹⁴⁷ See, e.g., **Legal Authority CLA-204**, *United States v. Utah Med. Prods., Inc.*, 404 F. Supp. 2d 1315, 1324 (D. Utah 2005) (in a case involving the Quality System Regulations (QSRs) for medical devices, which are similar in nature to cGMP for medical drugs, the court refused to grant a permanent injunction where the safety of the products had never been at issue, even though FDA had issued forms 483 to this company. The court reasoned that “[p]roduct safety [was] not an issue in this case. Processes and procedures [were].”). See also **Legal Authority CLA-309**, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2009); **Legal Authority CLA-310**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions (2011), subchapter “9-14 Priority Enforcement Strategy for Problem Importers”, under the heading “Seizure”, at 9-56 (“Seizure is an action against an article. Consequently, it will be necessary to show, through laboratory analysis or otherwise, that the article seized is actually violative. ... Seizure may be considered for an article which: 1. Represents a potential hazard to health”); *id.*, under the heading “Injunction”, at 9-58 (“Injunctions may require a pattern of actual violations with some recognizable danger of a recurrence.”).

¹⁴⁸ See **Legal Authority CLA-307**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2009); **Legal Authority CLA-308**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2011), subchapter “6.2. Injunctions”, under the heading “6-2-5. Adequate Notice Preceding Injunction Actions”, at 6-28.

- a. The individuals with authority to prevent or correct the violations have been given appropriate notice of the general conditions that are violative.
- b. There is sufficient information to conclude that proper action to correct the violations has not been taken or will not be taken promptly.
- c. Reasonable efforts on the part of the agency were made and documented to get the objectionable product and practice corrected without court involvement. Any attempts by the proposed defendants to correct the problem should also be reported.¹⁴⁹

129. Before bringing a seizure or injunction case, FDA must follow an internal approval process whereby FDA's Office of Chief Counsel (OCC) must provide final review and approve the action, before it is passed on to the United States Department of Justice (DOJ).¹⁵⁰ FDA must persuade DOJ to bring the case and DOJ must persuade the district court that it is entitled to the relief sought.

130. The owner of the goods, or any party with an interest in the article, may contest the court action (in a seizure or injunction case), in part or in its entirety.¹⁵¹ In such a case, the matter will be handled by the court in the same manner as any civil trial and will conclude by a decision of the court after appropriate consideration of the case.¹⁵²

131. Sometimes, FDA and a company alleged to have violated the Act will enter into an agreement to settle a case and avoid taking the case to trial. Such an agreement takes the form of a consent decree, in which the company agrees not to participate in certain

¹⁴⁹ See **Legal Authority CLA-307**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2009); **Legal Authority CLA-308**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2011), subchapter "6.2. Injunctions", under the heading "6-2-5. Adequate Notice Preceding Injunction Actions", under sub heading "1. Methods of Giving Notice", at 6-29.

¹⁵⁰ See **Legal Authority CLA-307**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2009); **Legal Authority CLA-308**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2011), subchapter "6.1. Seizure", under the headings "6-1-5. Approval Process for Seizure and Injunctions Cases" and "6-1-6. Responsibilities for Seizure Actions", at 6-7 to 6-16.

¹⁵¹ See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 78, 80.

¹⁵² See **Legal Authority CLA-307**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2009); **Legal Authority CLA-308**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2011), subchapter "6.1. Seizure", heading "6-1-9. Disposition of Seized Articles", sub-heading "6. Contest of Seizure", at 6-20. See also Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 80.

market activity (decree of temporary or permanent injunction, as the case may be) or consents to the seizure of its goods (decree of condemnation in a seizure action).¹⁵³

132. Consent decrees are negotiated, and often include specific, limited deadlines for the company to improve processes and for FDA to confirm the improvements, following which restrictions are lifted. Consent decrees often also provide for products shown to be safe and effective to continue to be sold while improvements are made.¹⁵⁴
133. If the parties do not consent to such a decree, “a trial is held, in which to prevail, the government must prove each element of its case by a preponderance of the evidence.”¹⁵⁵

3. *Criminal Actions*

134. Under US law, it is a crime to introduce adulterated drugs into interstate commerce.¹⁵⁶ However, the Act provides for a good faith defense for persons who delivered or received any article in interstate commerce in good faith.¹⁵⁷

¹⁵³ See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 78-79 (for seizures), 84-86 (for injunctions).

¹⁵⁴ See, e.g., **Legal Authority CLA-199**, *United States v. KV Pharm. Co.*, No. 4:09CV334(RWS), para. 6.A. (E.D. Mo. Mar. 6, 2009) (consent decree of permanent injunction) (“Defendants ... are permanently restrained and enjoined ... from ... manufacturing ... the drugs identified in Appendix A ...”); **Legal Authority CLA-196**, *United States v. Caraco Pharm. Labs., Ltd.*, No. 09-12498, para. 6 (E.D. Mich. Sept. 29, 2009) (consent decree of condemnation, forfeiture, and permanent injunction against company distributing products manufactured by third party).

¹⁵⁵ See **Legal Authority CLA-307**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2009); **Legal Authority CLA-308**, FDA, Regulatory Procedures Manual, Ch. 6: Judicial Actions (2011), subchapter “6.2. Injunctions”, under the heading “6-2-3. Definitions”, sub-heading “3. Permanent Injunction”, at 6-27.

¹⁵⁶ **Legal Authority CLA-229**, Federal Food, Drug, and Cosmetic Act, 21 USC § 333(a) (Jan 4, 2011) (current version) (“(1) Any person who violates the provision of section 331 of this title shall be imprisoned for not more than one year or fined for not more than \$1,000, or both.”); **Legal Authority CLA-230**, Federal Food, Drug, and Cosmetic Act, 21 USC § 333(a) (June 22, 2009 to Jan 3, 2011) (version in effect at the time of the import alert and subsequent amendments). See also Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 85 (criminal sanctions may also be enforced if the defendant does not comply with the terms of the consent decree).

¹⁵⁷ **Legal Authority CLA-229**, Federal Food, Drug, and Cosmetic Act, 21 USC § 333(c) (Jan 4, 2011) (current version) (“No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him;”); **Legal Authority CLA-230**, Federal Food, Drug, and Cosmetic Act, 21 USC § 333(c) (June 22, 2009 to Jan 3, 2011) (version in effect at the time of the import alert and subsequent amendments).

135. Before the institution of a criminal proceeding by FDA, the accused party must be given appropriate notice and an opportunity to present its views with regard to such contemplated proceeding.¹⁵⁸
136. Criminal proceedings, if instituted, are governed by the Federal Rules of Criminal Procedure and include the constitutional guarantees of due process, the right to legal counsel, the right to confront witnesses, the right to a jury trial, and the right not to testify against oneself. Proof must be established beyond a reasonable doubt, rather than by a preponderance of the evidence.
137. It is against this regulatory backdrop that FDA's actions with respect to Apotex and comparable companies took place.

V. FDA'S AND HEALTH CANADA'S INSPECTIONS OF SIGNET AND ETOBICOKE PRIOR TO 2008

138. FDA has inspected Apotex-Canada's facilities in Signet and Etobicoke on numerous occasions. Until 2008-2009, FDA never found any cGMP violation at these facilities – nor for that matter at any other Apotex group facility elsewhere – that it considered worthy even of a warning letter, much less enforcement action.
139. Meanwhile, Health Canada also inspected Etobicoke and Signet on a number of occasions and concluded each time that Apotex-Canada be “recommended for continuation of [its] current Establishment Licences.”¹⁵⁹

¹⁵⁸ **Legal Authority CLA-232**, Federal Food, Drug, and Cosmetic Act, 21 USC § 335 (Apr. 11, 1953 (no subsequent amendment)) (“Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.”). The version of this provision that was in force at the time of the Import Alert has not been amended thereafter.

¹⁵⁹ See, e.g., **Exhibit C-9**, Health Canada, Inspection Exit Notices for five facilities on the signet Campus at 2 (Aug. 11, 2003) (including 150 Signet Drive), (“Please note that your firm has been recommended for continuation of your current Establishment Licenses”); *id.*, Inspection Exit Notice for Inspection at 150 Signet Drive, dated August 7, 2003, at 3 (Rating C). Health Canada uses three inspection ratings: C = recommended for the continuation or issuance of the Establishment License; NC = not recommended for the continuation or issuance of the Establishment Licence; and NR = investigative or no recommendation at this stage. A rating of NC may lead to enforcement action, which could include suspension of the license for the establishment. See **Exhibit C-11**, Health Canada, Inspection Exit Notice for Inspection at Etobicoke, at 3 (May 28, 2004) (Rating C); **Exhibit C-12**, Health Canada, Inspection Exit Notice for Inspection at 150

140. FDA inspected Apotex-Canada's site at 400 Ormont Drive in Weston (near Toronto) from September 25 to 29, 2000. This facility is part of the Signet Campus and is used for research and development, housing of stability samples and manufacturing of Cephalosporin. A form 483 was issued at the close of this inspection, listing 11 observations.¹⁶⁰ Apotex-Canada submitted its response to this form 483 on November 13, 2000.¹⁶¹ FDA reviewed Apotex-Canada's response and decided to classify the inspected site "as acceptable."¹⁶² This inspection related to two ANDAs that were recommended for approval after the inspection.¹⁶³
141. FDA also conducted a pre-approval inspection at Etobicoke from April 29 to May 7, 2002. At the close of the inspection, FDA issued a form 483 to TorPharm, Inc., a predecessor to Apotex-Canada. The company responded to this form 483 on June 1, 2002¹⁶⁴ and, subsequently, FDA decided to classify the facility as "acceptable" on July 3, 2002.¹⁶⁵ As noted during this inspection, one of the company's goals at the time was to seek approval of 24 new US products annually.¹⁶⁶
142. The following year, FDA conducted an inspection at 150 Signet Drive from March 24 to 27, 2003. According to FDA, this was its initial inspection of this facility,¹⁶⁷ which was opened in 1999¹⁶⁸ and forms part of the Signet Campus. As part of this inspection, FDA also visited the facilities at 400 Ormont Road and 4100 Weston Road, both within

Signet Drive, at 3 (May 10, 2005) (Rating C); **Exhibit C-29**, Health Canada, Inspection Exit Notice for Inspection at Etobicoke, at 3 (Feb. 26, 2008) (Rating C).

¹⁶⁰ **Exhibit C-2**, Form 483 for 400 Ormont Drive (Signet Campus) (Sept. 29, 2000).

¹⁶¹ **Exhibit C-3**, Letter from Apotex-Canada to FDA (Nov. 13, 2000). As noted in the response, this inspection was in regard to two ANDA submissions for [REDACTED] (ANDA [REDACTED]) and [REDACTED] (ANDA [REDACTED]).

¹⁶² **Exhibit C-4**, Letter from FDA to Apotex-Canada enclosing Establishment Inspection Report (EIR) for Ormont Drive (Signet Campus) (Dec. 12, 2000).

¹⁶³ *Id.*, at 1 of EIR.

¹⁶⁴ **Exhibit C-5**, Letter from TorPharm, Inc. to FDA (June 1, 2002).

¹⁶⁵ **Exhibit C-6**, Letter from FDA to TorPharm, Inc., enclosing Establishment Inspection Report (EIR) (Jul. 3, 2002).

¹⁶⁶ *Id.*, at 3 of EIR.

¹⁶⁷ **Exhibit C-8**, Letter from FDA to Apotex-Canada enclosing Establishment Inspection Report (EIR), at 1 of EIR. (June 10, 2003)

¹⁶⁸ **Exhibit C-8**, Letter from FDA to Apotex-Canada enclosing Establishment Inspection Report (EIR), at 4 of EIR. (June 10, 2003)

walking distance from 150 Signet Drive.¹⁶⁹ No form 483 was issued at the close of this inspection.¹⁷⁰ As a result, FDA classified these facilities as “acceptable” on June 10, 2003.¹⁷¹ FDA also issued an approval recommendation for certain applications for new drugs.¹⁷²

143. FDA inspected Etobicoke during six days in May 2005 and decided to classify the facility “as acceptable.”¹⁷³ The Establishment Inspection Report (EIR) mentioned that “GMP coverage of the firm following a systems approach did not result in the issuance of an FDA-483. No significant issues were revealed, no refusals were encountered and no samples were collected.”¹⁷⁴ As a result, the applications for new generic drugs that were under consideration were recommended for approval.¹⁷⁵
144. FDA again inspected the Signet Campus from June 26 to July 13, 2006 and issued a form 483 at the close of this inspection.¹⁷⁶ Apotex-Canada submitted its response to the 483 on July 21, 2006.¹⁷⁷ After having reviewed the firm’s response, FDA classified the facility “as acceptable.”¹⁷⁸
145. Finally, FDA inspected Etobicoke from November 20 to 24, 2006 and issued a form 483 at the close of this inspection listing four observations.¹⁷⁹ Apotex-Canada submitted its response to the 483 on December 21, 2006.¹⁸⁰ While FDA noted that most

¹⁶⁹ *Id.*, at 3 of EIR (June 10, 2003). The location at 150 Signet Drive is used for the manufacture of oral solid dosage forms. The location at 400 Ormont Road is used for Research and Development, housing of stability samples and Cephalosporin Manufacturing. The location at 4100 Weston Road is used for packaging and distribution. *See id.*

¹⁷⁰ *Id.*, at 1 of EIR.

¹⁷¹ *Id.*

¹⁷² *Id.*, at 1 to 10 of EIR.

¹⁷³ **Exhibit C-15**, Letter from FDA to Apotex-Canada enclosing Establishment Inspection Report (EIR) (Aug. 18, 2005).

¹⁷⁴ *Id.*, at 2 of EIR (Aug. 18, 2005). FDA also noted that “[t]he firm’s responses to the observations listed on FDA-483 issued at the close of the previous inspection in April 2002 were found to be acceptable by the reviewing official.” *See id.*

¹⁷⁵ *Id.*

¹⁷⁶ **Exhibit C-17**, Form 483 for 150 Signet Drive (Jul. 13, 2006).

¹⁷⁷ **Exhibit C-18**, Letter from Apotex-Canada to FDA, dated July 21, 2006.

¹⁷⁸ **Exhibit C-20**, Letter from FDA to Apotex-Canada enclosing Establishment Inspection Report (EIR) for Signet Campus (Oct. 25, 2006).

¹⁷⁹ **Exhibit C-21**, Form 483 for Etobicoke (Nov. 24, 2006).

¹⁸⁰ **Exhibit C-22**, Letter from Apotex-Canada to FDA (Dec. 21, 2006).

of the firm's responses appeared acceptable, FDA requested additional clarifications in April 2007,¹⁸¹ which Apotex-Canada submitted on May 10, 2007.¹⁸² Thereafter, FDA notified Apotex-Canada on July 6, 2007 that "the concerns and questions [FDA had] raised in [its] April 2007 request appear[ed] to be satisfactorily addressed."¹⁸³

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

VI. FDA'S INSPECTIONS OF APOTEX'S FACILITIES IN 2008 AND 2009

A. The Etobicoke Inspection

147. From December 10 to 19, 2008, FDA inspected Apotex's facility in Etobicoke. The inspection included a weekend and lasted for a total of eight days. A summary of the inspection was prepared each day by an Apotex employee.¹⁸⁴ The inspection was conducted by one investigator, Ms. Emerson, and one chemist, Ms. Campbell.¹⁸⁵
148. At the close of the inspection, the inspectors issued a three-page form 483, listing 11 observations.¹⁸⁶ The first three observations concerned the firm's failure to transfer the methods for testing products between the different laboratories at Etobicoke, Signet and Richmond Hill (items 1 to 3). Three other observations addressed the failure to timely submit certain field alert reports, as well as certain quarterly or annual reports (items 4, 7 and 11). Two observations concerned the expiry date of some products (items 9 and 10). One observation related to the absence in the master batch records of a copy of all approved labels and labeling (item 8) and another observation was about the incomplete description of production and process controls in the approved production records (item 6). Finally, one observation was in relation to incomplete cleaning procedures (item 5).

¹⁸¹ **Exhibit C-23**, Letter from FDA to Apotex-Canada (Apr. 23, 2007).

¹⁸² **Exhibit C-24**, Letter from Apotex-Canada to FDA (May 10, 2007).

¹⁸³ **Exhibit C-25**, Letter from FDA to Apotex-Canada enclosing Establishment Inspection Report (EIR) for Etobicoke (Jul. 6, 2007).

¹⁸⁴ **Exhibit C-33**, Apotex Internal Emails, Summary Reports re: Etobicoke Inspection (Dec. 10, 11, 12, 15, 16, 17, 18 and 19, 2008).

¹⁸⁵ *Id.* (Dec. 10, 2008).

¹⁸⁶ **Exhibit C-34**, Form 483 for Etobicoke (Dec. 19, 2008).

149. Apotex-Canada responded to the inspectors' observations on January 30, 2009.¹⁸⁷ At the same time, Apotex immediately undertook to enhance its processes and equipment at Etobicoke.¹⁸⁸

B. FDA's Enforcement Strategy

150. In early June 2009, an FDA commissioner appointed by the incoming Obama administration took office.¹⁸⁹ In her first policy speech after taking office, Commissioner Hamburg announced a new emphasis on "effective enforcement" at FDA and a specific strategy developed to achieve this goal.¹⁹⁰ Part of the strategy the Commissioner outlined was to "send a strong message" by setting a precedent of major sanctions against at least one alleged offender:

FDA must be *strategic*. The agency must place greater emphasis on significant risks and violations, and use meaningful penalties to send a strong message to discourage future offenses.

FDA must be *quick*. The agency must be able to respond rapidly to egregious violations or violations that jeopardize public health.

And FDA must be *visible*. We must publicize our enforcement actions – and the rationale for those actions – widely and effectively.¹⁹¹

151. Amplifying on the point that "[t]he FDA must be quick," the Commissioner stated as follows:

Fifth, the FDA will be prepared to act swiftly and aggressively to protect the public. FDA will no longer issue multiple warning letters to noncompliant firms before taking enforcement action. If we find that we must move quickly to address significant health concerns or egregious violations,

¹⁸⁷ **Exhibit C-37**, Apotex-Canada's Responses to FDA 483 Observations (Etobicoke) (Jan. 30, 2009).

¹⁸⁸ See Witness Statement of Edmund Carey, para. 28. See also Witness Statement of Bruce Clark, para. 25.

¹⁸⁹ See **Exhibit C-51**, FDA, Remarks by Margaret A. Hamburg, Commissioner of Food and Drugs on "Effective Enforcement and Benefits to Public Health" at the Food and Drug Law Institute at 1 (Aug. 6, 2009).

¹⁹⁰ *Id.*

¹⁹¹ *Id.* (emphasis in original).

we will consider immediate action – even before we have issued a formal warning letter.¹⁹²

C. The Etobicoke Warning Letter

152. On June 25, 2009, after months of silence concerning Etobicoke, FDA issued a warning letter identifying three issues of remaining concern to the Agency (the “Etobicoke Warning Letter”).¹⁹³ Only two of these concerned cGMP. The remaining form 483 observations evidently had been resolved by Apotex-Canada’s response or otherwise not adopted by FDA.
153. The first alleged cGMP deviation stated in the 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.” The deviation was alleged to violate 21 CFR § 211.192.¹⁹⁴ In a nutshell, Apotex-Canada, as part of its quality control processes, regularly tests products at different stages in their fabrication. Some of the tested products were found not fully to meet specifications and, as a result, were rejected. However, according to FDA, Apotex-Canada did not adequately record the investigations for these rejected batches and did not identify the root cause of the problem.¹⁹⁵ This alleged deviation was not listed in the form 483 that had been issued at the close of the Etobicoke inspection.¹⁹⁶ The first allegation in the Etobicoke Warning Letter was thus made without the benefit of, and without Apotex having an opportunity to provide, Apotex’s response.

¹⁹² *Id.*, at 2 (Aug. 6, 2009).

¹⁹³ **Exhibit C-41**, Etobicoke Warning Letter, (WL: 320-09-06) (June 25, 2009).

¹⁹⁴ 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.” **Legal Authority CLA-269**, FDA Current Good Manufacturing Practice, 21 CFR § 211.192 (May 25, 2004). The version of this provision in force at the time of the Import Alert has not been amended thereafter.

¹⁹⁵ **Exhibit C-41**, Etobicoke Warning Letter, (WL: 320-09-06), at 1-2 (June 25, 2009). FDA concluded at page 3 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.”

¹⁹⁶ *See Exhibit C-34*, Form 483 for Etobicoke (Dec. 19, 2008).

154. The second alleged deviation stated in the Etobicoke Warning Letter was “[f]ailure to submit NDA/ANDA field alert reports (FARs) in the required time frame” The deviation was alleged to violate 21 CFR § 314.81(b)(1).¹⁹⁷ This provision falls outside parts 210 and 211 of chapter 21 of the Code of Federal Regulations addressing cGMP standards. This provision deals with ANDA post-approval reporting requirements. However, it can be addressed in cGMP inspections.¹⁹⁸
155. The third alleged cGMP deviation stated 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 deviation was alleged to violate 21 CFR § 211.186(b)(8).¹⁹⁹ FDA took issue with the fact that Apotex-Canada relied on electronic controls for labeling instead of including physical copies of the approved labels and labeling in the master record.²⁰⁰
156. The Etobicoke Warning Letter did not take into consideration the enhancement to processes at the facility put into place by Apotex in the first half of 2009. Apotex had detailed its immediate and planned remediation actions in the response to the Etobicoke

¹⁹⁷ This provision states in pertinent part: “(b) Reporting requirements. The applicant shall submit to the Food and Drug Administration at the specified times two copies of the following reports: (1)NDA--Field alert report. The applicant shall submit information of the following kinds about distributed drug products and articles to 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.” **Legal Authority CLA-273**, Applications for FDA Approval to Market a New Drug, 21 CFR § 314.81(b)(1) (Jan. 18, 2012) (current version with legislative history since March 2009).

¹⁹⁸ Witness Statement of Edmund Carey, para. 32.

¹⁹⁹ 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; ...” **Legal Authority CLA-268**, FDA Current Good Manufacturing Practice, 21 CFR § 211.186 (b)(8) (May 25, 2004). The version of this provision in force at the time of the Import Alert has not been amended thereafter.

²⁰⁰ **Exhibit C-41**, Etobicoke Warning Letter (WL: 320-09-06) at 6 (June 25, 2009). *See also* Witness Statement of Edmund Carey, para. 34 (noting that during the re-inspection of the facility in February 2011, FDA accepted the electronic system as cGMP-compliant).

form 483 submitted on January 30, 2009.²⁰¹ However, FDA never requested evidence of such remediation actions.²⁰²

157. On July 17, 2009, Apotex-Canada submitted a detailed, 24-page long, response to the Etobicoke Warning Letter.²⁰³ Notably, the firm explained that FDA's concern that two rejected batches of ██████████ had been shipped to the US was unfounded and caused by a misunderstanding of Apotex's batch numbering system.²⁰⁴

158. Apotex received no reply from FDA. On August 12, 2009, Apotex requested a meeting with FDA regarding the company's response to the Etobicoke Warning Letter.²⁰⁵

D. The Signet Inspection

159. From July 27 to August 14, 2009, a team of four FDA investigators inspected Apotex-Canada's Signet facility. The inspection lasted for 14 days in total.²⁰⁶ The inspection was initially scheduled as both a PAI (pre-approval inspection for pending ANDAs) and cGMP inspection.²⁰⁷ However, the PAI never took place.²⁰⁸

160. The initial team was composed of two district inspectors, as well as a young inspector from CDER, Ms. Zielny. The lead inspector who conducted the opening meeting was Mr. Payne, a senior district inspector. On the fifth day of the inspection, Apotex learned

²⁰¹ **Exhibit C-37**, Apotex-Canada's Responses to FDA 483 Observations (Etobicoke) (Jan. 30, 2009).

²⁰² Witness Statement of Jeremy Desai, para. 36. *See also* Witness Statement of Edmund Carey, para. 28.

²⁰³ **Exhibit C-44**, Letter from Apotex-Canada to FDA, (Jul. 17, 2009).

²⁰⁴ *Id.*, at 1, Item 1A. *See also* Witness Statement of Jeremy Desai, para. 39.

²⁰⁵ **Exhibit C-56**, Apotex Email to FDA, re: FDA Meeting Request (Aug. 12, 2009) (Apotex wanted to "ensure that [it had] fully understood and ... addressed all deviations"). *See also* **Exhibit C-57**, Email from FDA to Apotex at 2:53 p.m. and 5:25 p.m., re: Request for Meeting with FDA (Aug. 12, 2009).

²⁰⁶ *See* **Exhibit C-61**, Form 483 for 150 Signet Drive (Aug. 14, 2009) (dates of inspection in top right corner).

²⁰⁷ **Exhibit C-42**, Apotex Internal Email concerning FDA's inspection of the Signet Campus (June 29, 2009) ("FDA have confirmed that they will be performing an audit of the Apotex Signet campus from July 27th to August 14th. ... This will be a PAI and GMP compliance inspection."). *See also* **Exhibit C-46**, Apotex Internal Email, dated July 28, 2009 at 7:55 am, subject: "RE: FDA Inspection Day 1" ("The focus of the inspection this week will be on the GMP Compliance aspect. ... The PAI part of the inspection will probably start next week. The Lead Investigator Lloyd [Payne] has indicated that he wants to review all pending applications. ... He indicated that Docetaxel will be included in the inspection.").

²⁰⁸ Witness Statement of Bernice Tao, para. 42.

that a fourth investigator, Mr. Belz, would be joining FDA's team on the following day.²⁰⁹ He was also from CDER, as opposed to the district.

161. According to the company's summary of the inspection, this was a "very intense inspection."²¹⁰ Notably, FDA's inspectors requested a large number of documents.²¹¹ By way of example, "Day 6 of the inspection was a very busy day. Since the investigators had spent Monday reviewing various document copies [Apotex] had provided them last week, they arrived with a massive list of questions and additional document requests."²¹²
162. On Day 7, Apotex employees noted that the inspectors were "gathering up a fair number of observations or potential observations. I[t] [was] in [Apotex's] best interest to address as many of these (and any outstanding questions) before the end of the inspection."²¹³
163. On Day 10, once again, "the investigators had a large number of document requests based on their review of other documents over the weekend."²¹⁴ On that same day, the inspectors held a teleconference with their head office.²¹⁵
164. On the following day (Day 11), the inspectors from CDER seemed to be particularly concerned with data integrity with respect to a specific product, [REDACTED].²¹⁶ They "asked that the batch records for all submission batches and the batch records to support all submission amendments be pulled for their review."²¹⁷ Ms. Zielny stated

²⁰⁹ **Exhibit C-49**, Apotex Internal Email, dated August 3, 2009, subject: "FDA Inspection Day 5."

²¹⁰ **Exhibit C-47**, Apotex Internal Email, dated July 28, 2009 at 8:50 pm, subject: "FDA Inspection Day 2."

²¹¹ **Exhibit C-46**, Apotex Internal Email, dated July 27, 2009, subject: "FDA Inspection Day 1".

²¹² **Exhibit C-50**, Apotex Internal Email, dated August 5, 2009, subject: "FDA Inspection Day 6."

²¹³ **Exhibit C-52**, Apotex Internal Email, dated August 6, 2009, subject: "FDA Inspection Day 7."

²¹⁴ **Exhibit C-53**, Apotex Internal Email, dated August 11, 2009, subject: "FDA Inspection Day 10."

²¹⁵ *Id.*

²¹⁶ **Exhibit C-55**, Apotex Internal Email, dated August 12, 2009 at 8:10 am, subject: "FDA Inspection Day 11" ("There is concern that the information provided in the [REDACTED] CBE-30 regarding change in the addition of the excipient is misleading compared to information in other documents. Also, batches with these changes were released as of April 2008, but the CBE-30 was not filed until August 2008. (A presentation will be made to the investigators on April 12th to provide the entire story related to [REDACTED] and reduce/remove the concerns noted.)").

²¹⁷ *Id.*

that FDA may even trigger the Application Integrity Policy (AIP).²¹⁸ The AIP describes FDA's approach regarding the review of applications, such as ANDAs, that may be affected by intentional acts that raise significant questions regarding data reliability.²¹⁹

165. On Day 12, Apotex gave a presentation on the issues of [REDACTED] and data integrity. The inspectors concluded that “[t]he observation from [the day before] about this will stand [in the form 483], but the wording [would] be modified to remove the impression that [Apotex] were deliberately misleading OGD [the Office of Generic Drugs].”²²⁰
166. It also became clear in the course of the inspection that “the focus of the inspection ha[d] definitely changed and the PAI [pre-approval inspection] portion [would] not occur. This inspection [was] solely on cGMP compliance.”²²¹
167. At the end of the inspection, Apotex anticipated that there would be a number of observations on the form 483 and that it would have to prepare a detailed response by September 4, 2009.²²² The lead inspector, Mr. Payne, indicated that Apotex had to submit a “solid response ... within 15 days [of issuance of the form 483].”²²³ He also mentioned that FDA should indicate within a week of receipt of Apotex's response whether FDA deemed such response as adequate or not.²²⁴
168. On the very last day of the inspection, the inspectors requested that the Apotex employee in charge of Quality Control, Mr. Lovelock, give an affidavit before the form

²¹⁸ Witness Statement of Bruce Clark, para. 30.

²¹⁹ **Legal Authority CLA-290**, FDA, Application Integrity Policy Procedures, under Heading “1-1-1 Background”, <http://www.fda.gov/downloads/ICECI/EnforcementActions/ApplicationIntegrityPolicy/UCM072631.pdf> (Mar. 5, 1998).

²²⁰ **Exhibit C-59**, Apotex Internal Email, dated August 13, 2009, subject: “FDA Inspection Day 12.” *See also* Witness Statement of Bruce Clark, para. 31.

²²¹ **Exhibit C-55**, Apotex Internal Email, dated August 12, 2009, subject: “FDA Inspection Day 11.” *See also* **Exhibit C-58**, Apotex Internal Email, dated August 12, 2009, subject: “Possibility of PAI” (“We were told that there would be no PAI component to this inspection.”).

²²² **Exhibit C-60**, Apotex Internal Email, dated August 13, 2009, subject: “FDA Inspection Day 13.”

²²³ **Exhibit C-58**, Apotex Internal Email, dated August 12, 2009, subject: “Possibility of PAI.”

²²⁴ *Id.*

483 could be released.²²⁵ The inspectors threatened not to hold the close-out meeting until Mr. Lovelok signed his affidavit, which he did.²²⁶ This was unusual, as was the fact that the lead investigator had been sidelined by Ms. Zielny.²²⁷

169. At the close-out meeting, FDA inspectors issued a form 483 to then-President and COO of Apotex-Canada Mr. Jack Kay.²²⁸ Seventeen observations were listed on that form. The bulk of these observations concerned the failure to timely submit Field Alert Reports,²²⁹ or the failure to have complete written procedures or records and/or to follow such written procedures.²³⁰ The form 483 also stated that defective batches, although rejected, were not sufficiently investigated²³¹ or not sufficiently documented.²³²
170. FDA's inspectors also requested that Apotex call the Center for Drug Evaluation and Research, Office of Compliance (CDER-OC) on the following business day, which was quite unusual.²³³

E. Communications with FDA Immediately After the Signet Inspection

171. On August 17, 2009, as requested at the close-out meeting, Apotex called FDA. On that telephone conference, the firm committed to voluntary recall batches of drug products

²²⁵ Without first seeking legal advice on these issues, Mr. Lance Lovelock, then Vice President of Quality at Apotex-Canada, submitted two affidavits on FDA forms 463(a). *See* Witness Statement of Jeremy Desai, paras. 42-43. Mr. Lovelock testified that batches HD7983 and HD8259 of [REDACTED] received from Mexico were used in the production of a finished product ([REDACTED] 300mg 1000 count bottles) bearing batch number HV6312. In 2008, 834 bottles from batch HV6312 were shipped to Apotex-US and 24 bottles coming from this batch were actually distributed by Apotex-US to a US customer. Mr. Lovelock further testified that batch HP8402 of [REDACTED] received from India was used in the production of finished product [REDACTED] 1000mg 1000 count bottle as batch JC2151. In 2009, 831 bottles from that batch were sent to Apotex-US, which distributed six of these bottles to a US customer. *See* **Exhibit C-62**, Affidavit of Lance Lovelock to FDA re: two batches of [REDACTED], dated August 14, 2009; **Exhibit C-63**, Affidavit of Lance Lovelock to FDA re: one batch of [REDACTED], dated August 14, 2009.

²²⁶ Witness Statement of Jeremy Desai, paras. 42-43.

²²⁷ Witness Statement of Bruce Clark, para. 30 (noting that Ms. Zielny "did not seem to want to listen to [Apotex's] position").

²²⁸ **Exhibit C-61**, Signet Form 483, dated August 14, 2009.

²²⁹ **Exhibit C-61**, Signet Form 483, dated August 14, 2009, Observation 3.

²³⁰ *Id.*, Observations 2, 4, 6, 7, 8, 11, 12, 13, 14, 15.

²³¹ *Id.*, Observation 9.

²³² *Id.*, Observation 16.

²³³ Witness Statement of Jeremy Desai, para. 44; Witness Statement of Bernice Tao, para. 44.

manufactured at both Etobicoke and Signet and distributed in the US market.²³⁴ This recall was intended as a good will gesture on the part of Apotex. It became obvious to Apotex during the call that FDA was concerned because of black particles found in a certain product. The particles were the result of a charring process to produce an excipient of natural origin and raised no issue concerning the safety or quality of Apotex's products. In order to demonstrate to FDA that it took its concerns seriously, Apotex nonetheless agreed to recall batches of the product associated with the black particles. This recall was intended as a good will gesture on the part of Apotex.²³⁵

172. However, the recall did not produce the expected results.
173. Contrary to what was intended by Apotex, its proposal for voluntary recall raised concern within FDA. In an internal 3-page memorandum dated August 20, 2009, the director of CDER-OC noted that his office was "concerned about the firm's rationale and decision to only recall 675 batches and not address all products on the US market."²³⁶
174. The same memorandum further alleged that "[t]he inspection of [Apotex] Signet Campus uncovered several [cGMP] violations that [were] identical to those found during the previous inspection of the Etobicoke site."²³⁷ The memorandum stated that this raised concerns about a "lack of adequate process controls and ... the firm's quality and production systems."²³⁸ The memorandum did not note, however, that Apotex had already undertaken to address the issues raised during the Etobicoke inspection.
175. On that basis, CDER-OC requested the Division of Import Operations and Policy (DIOP) to place "all finished pharmaceutical products" manufactured at Etobicoke and

²³⁴ See **Exhibit C-64**, Memo from Director of CDER-OC (Rick Friedman) to DIOP, dated August 20, 2009, p. 2.

²³⁵ Witness Statement of Jeremy Desai, paras. 46-48.

²³⁶ *Id.*, pp. 1-2.

²³⁷ *Id.*, p. 2-3.

²³⁸ *Id.*

Signet on import alert and refuse them an admission on the ground of Section 801(a)(3) of the Act.²³⁹

176. There was no other justification for the measure stated elsewhere in this memorandum – or in any subsequent FDA documents.
177. The memorandum then announced that “[i]f and when the firm [could] demonstrate that it [was] in compliance with cGMPs, and a re-inspection confirm[ed] that appropriate corrections have been implemented,” the import alert would be lifted.²⁴⁰ In other words, a re-inspection of the Etobicoke and Signet sites was a prerequisite to removing these facilities from import alert.
178. As noted above, this August 20, 2009 memorandum was an internal FDA document and it was not communicated to Apotex at the time.²⁴¹
179. Consistent with the Commissioner’s earlier promise that FDA would “publicize [its] enforcement actions” and “use meaningful penalties to send a strong message to discourage future offenses,”²⁴² a high-ranking FDA official announced the example it would soon make of Apotex even before the action was taken. The official made the following statement on August 24, 2009 at the widely-attended industry conference “GMP by the Sea”:

I’m here to tell you that next week you will be reading about how FDA has placed a company on import alert only seven business days after the conclusion of a foreign inspection.²⁴³

180. The official did not suggest that the criteria identified by Commissioner Hamburg for “immediate action” – “significant health concerns or egregious violations” – justified

²³⁹ *Id.*, pp. 2-3.

²⁴⁰ *Id.*, p. 3.

²⁴¹ This internal memorandum was obtained through a FOIA request in early 2012.

²⁴² **Exhibit C-51**, Remarks by Margaret A. Hamburg, Commissioner of Food and Drugs on “Effective Enforcement and Benefits to Public Health” at the Food and Drug Law Institute on August 6, 2009.

²⁴³ **Exhibit C-65**, “Undoing Bush: FDA Begins ‘Swift’ Enforcement Action” (August 25, 2009) (quoting statement made by Edwin Rivera-Martinez, CDER international branch compliance chief, at the annual conference “GMP by the Sea” in Cambridge, Maryland).

the action that FDA planned to take.²⁴⁴ Nor, as noted above, was there any suggestion of such concerns or violations in the August 20, 2009 internal FDA memorandum.

181. On August 28, 2009, Apotex and FDA held a follow-up telephone conference, principally on the issue of Apotex's voluntary recall. FDA made no mention of the impending Import Alert then.²⁴⁵
182. On that same date, Apotex submitted a global description of its corrective action plan and reiterated in writing its prior oral commitment to voluntary recall batches that had already been distributed in the US.²⁴⁶ This voluntary recall was intended as a sign of good faith on the part of Apotex.²⁴⁷ Through this recall, and corrective actions, Apotex wanted to demonstrate its "commitment to cGMP compliance."²⁴⁸
183. Regarding the corrective actions, Apotex-Canada reiterated its commitment to "ensure[] that necessary actions [were] taken to address FDA's concerns," starting with the "retaining of an outside objective third party to evaluate [the firm's] quality systems."²⁴⁹ The firm also announced that the "[d]etails of the quality systems continuous improvement action plan or roadmap [would] be described in greater details in [Apotex's] initial FDA 483 Response to be submitted under separate cover on or before September 4, 2009."²⁵⁰
184. However, FDA did not wait for Apotex's answer to the form 483 before taking drastic enforcement action.

²⁴⁴ **Exhibit C-51**, Remarks by Margaret A. Hamburg, M.D., Commissioner of Food and Drugs on "Effective Enforcement and Benefits to Public Health" at the Food and Drug Law Institute on August 6, 2009.

²⁴⁵ Witness Statement of Jeremy Desai, para. 51, 55. *See also* **Exhibit C-92**, Apotex Slides, "Compliance Presentation to FDA", dated September 11, 2009, slide entitled "Chronology Signet", fifth bullet point.

²⁴⁶ **Exhibit C-66**, Letter from Apotex-Canada to FDA, dated August 28, 2009 pp. 1-2 (the recall concerned specific batches of Oxcarbazepine, and all strengths of Quinapril Tablets and Ranitidine Oral Solution).

²⁴⁷ Witness Statement of Jeremy Desai, para. 63.

²⁴⁸ **Exhibit C-66**, Letter from Apotex-Canada to FDA, dated August 28, 2009 p. 3.

²⁴⁹ *Id.*

²⁵⁰ *Id.*

VII. THE IMPORT ALERT

185. On August 28, 2009 the Director of DIOP implemented the request made by CDER-OC on August 20, 2009. By an August 28 email, DIOP included “[a]ll finished form drug products” from the Etobicoke and Signet facilities on “import alert 66-40.” This alert addresses “detention without physical examination of drugs from firms which have not met drug cGMPs” (the “Import Alert”).²⁵¹
186. At the time when Etobicoke and Signet were placed on Import Alert, FDA provided no indication, let alone notice, of this measure to any Apotex company.²⁵²
187. Two days after the absorption of the Import Alert, two shipments of products originating from Etobicoke and Signet arrived at the US border and were put on hold on August 30, 2009. In each case, FDA issued a notice of action, “Hold Designated,” dated August 31, 2009 that Apotex received through its customs broker on September 1, 2009.²⁵³
188. These notices of FDA action did not clearly state that the products were being detained, nor the reasons why the products might be detained. Rather, under the column “Current Status,” the statement “Pending FDA Review 08-30-2009” appeared.²⁵⁴ Nor did these notices make reference to a possible detention hearing.²⁵⁵

²⁵¹ **Exhibit C-67**, Email from Director of DIOP to Import Program Managers, dated August 28, 2009. FDA classifies import alerts by number. Number 66-40 corresponds to “Detention Without Physical Examination of Drugs From Firms Which Have Not met Drug CGMPs.” See **Exhibit C-316**, Excerpt from FDA’s website, “Import Alerts by Number” page.

²⁵² Witness Statement of Jeremy Desai, para. 55; Witness Statement of Bruce Clark, para. 34.

²⁵³ **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 (the dispatch site for this shipment was Barmac, which is part of the Signet campus).

²⁵⁴ **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.

²⁵⁵ **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. *But cf.* **Legal Authority CLA-245**, 21 C.F.R. §1.94(a) (requiring such notice).

189. On that same day of September 1, 2009, Apotex was informed that two further shipments from Etobicoke and Signet had also been put on hold,²⁵⁶ followed by a third one on the following day.²⁵⁷
190. Again, these new notices of “Hold Designated” did not state the reasons why the shipments were put on hold. Thus, in order to find out, Apotex emailed its customs broker on September 1.²⁵⁸ The customs broker immediately called FDA and was given the following explanation:
- Per my brief conversation with Erica @ FDA they have received a new notice (list) for finished products that are now flagged by FDA as an *import alert*. Due to this FDA will be conducting a closer evaluation of imports when they are flagged. This will be affecting many importers not just Apotex.²⁵⁹
191. While Apotex and its customs broker were attempting to find out why Apotex products were being held by FDA, two other shipments were put on hold later on that day of September 2, 2009.²⁶⁰
192. In total, seven shipments from Etobicoke and Signet were put on hold by FDA on August 30-31 and September 1, 2009.²⁶¹ At that time, Apotex did not know the reasons

²⁵⁶ See **Exhibit C-70**, Email from Apotex to Customs Broker, dated September 1, 2009 at 12:05 pm, referring to Notices of FDA Action re: Entry No. EG-6-1768378-4 and EG6-1767503-8. See also **Exhibit C-71**, Email from Customs Broker (Juanita Zaziski) 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 FDA Action re: Entry No. EG6-1768378-4, dated September 1, 2009.

²⁵⁷ **Exhibit C-80**, Notice of FDA Action re: Entry No. EG-6-1768454-3, Notice Number 1, dated September 2, 2009. See also **Exhibit C-73**, Email from Apotex to Custom Brokers, dated September 1, 2009 at 12:05 pm (“So far, 5 shipments have FDA notice of action.”).

²⁵⁸ **Exhibit C-73**, Email from Apotex to Custom Brokers, dated September 1, 2009 at 12:05 pm (“I really want to know what’s happening.”).

²⁵⁹ **Exhibit C-73**, Email from Customs Broker (Juanita Zaziski) to Apotex, dated September 1, 2009 at 12:24 pm. (emphasis in original).

²⁶⁰ **Exhibit C-78**, Notice of FDA Action re: Entry No. EG6-1768425-3, Notice Number 1, dated September 2, 2009; **Exhibit C-79**, Notice of FDA Action re: Entry No. EG6-1768429-5, Notice Number 1, dated September 2, 2009.

²⁶¹ Note that an eighth shipment originating from Richmond Hill was put on hold on September 29, 2009 before FDA released it on October 2009. See **Exhibit C-111**, Notice of FDA Action re: Entry Number: EG6-1770729-4, dated October 2, 2009.

why FDA decided to detain these shipments, nor was Apotex informed about a detention hearing and an opportunity to present testimony.²⁶²

193. On September 2, 2009, unaware of the Import Alert and following up on its written promise of August 28 to do a recall, Apotex issued a “Voluntary Drug Recall” with the list of all batches being recalled (659 in total).²⁶³ The recall notice clearly stated that “[n]o significant adverse health consequences [were] expected with these batches.”²⁶⁴ The notice also made clear that “[t]his voluntary recall [was] being made with the knowledge and consent of the [FDA].”²⁶⁵
194. On that same day of September 2, 2009, Apotex learned from Health Canada that FDA had imposed an Import Alert on Etobicoke and Signet effective August 28, 2009.²⁶⁶ Apotex contacted FDA and asked for a meeting or telephone conference to be

²⁶² On September 4, 2009, FDA issued new Notices of FDA Action with respect to some of the detained shipments and these notices mentioned “Detention Without Examination.” See **Exhibit C-84**, Notice of FDA Action re: Entry No. EG6-1768425-3, Notice Number 2, dated September 4, 2009 (mentioning Detention Without Examination); **Exhibit C-85**, Notice of FDA Action re: Entry No. EG6-1768429-5, Notice Number 2, dated September 4, 2009 (mentioning Detention Without Examination); **Exhibit C-86**, Notice of FDA Action re: Entry No. EG-6-1768454-3, Notice Number 2, dated September 4, 2009 (mentioning Detention Without Examination). See also **Exhibit C-96**, Notice of FDA Action re: Entry No. EG6-1768425-3, Notice Number 3, dated September 11, 2009 (mentioning Lines Released After Detention).

²⁶³ **Exhibit C-74**, Apotex-US, “Urgent: Voluntary Drug Recall”, dated September 2, 2009 and attached list of batches being recalled. See also **Exhibit C-83**, Letter from Apotex to FDA, dated September 4, 2009, enclosing the recall information package sent by email on August 31, 2009, p. 1 (“The remaining 659 batches will be identified on the recall letter and retrieved from the US market.”). Note that Apotex had ceased distribution of the affected batches on August 24, 2009. See *id.* at p. 5, item 7.(f).

²⁶⁴ **Exhibit C-74**, Apotex-US, “Urgent: Voluntary Drug Recall”, dated September 2, 2009, p. 1. In each case, the Hold Designation was for the entire shipment.

²⁶⁵ *Id.* See also **Exhibit C-122**, FDA, Enforcement Report for November 25, 2009, under “Recalls and Field Corrections: Drugs –Class II”; **Exhibit C-***, Apotex, Summary of US Recall Initiated in August 2009, dated July 18, 2012.

²⁶⁶ Witness Statement of Jeremy Desai, para. 56; Witness Statement of Bruce Clark, para. 33. See also **Exhibit C-76**, Email from Apotex-Canada to Apotex-US, dated September 2, 2009 (“We were just informed during a telecon with Health Canada (can you believe this!) that there is an Import Alert posted on FDA website dated August 28th for ‘All Finished Dosage Form’ from both Signet and Etobicoke. FDA have not provided us with any prior notification.”); **Exhibit C-75**, Apotex Internal Email Chain, dated September 2, 2009 (Bruce Clarke to Bernice Tao: “Can you check and see if FDA has issued an import alert on us?? TPD [Health Canada] says they have.”; Bruce Clark to Bernice Tao: “We just found it. Apparently it was issued in August and is posted on the website.”).

- scheduled.²⁶⁷ That telephone conference with FDA took place on September 3, 2009. It was only at this point in time that FDA notified Apotex of the Import Alert.²⁶⁸
195. Apotex sent its response to the form 483 for Signet on September 3, 2009, within the time limit imposed by FDA. The cover letter stated that Apotex had “retained an independent expert consultant to assist in executing corrective actions and ongoing monitoring for effectiveness.”²⁶⁹ The planned quality system improvements were designed to assure that all products manufactured by Apotex for US distribution met or exceeded the requirements of the GMP regulations and filed ANDAs.²⁷⁰
196. Apotex received no reply from FDA, which had already imposed the Import Alert without the benefit of Apotex’s response to the Signet form 483.²⁷¹
197. On September 28, 2009, FDA’s compliance officer for the district of Detroit, Michigan, faxed Apotex concerning its seven shipments that had been put on hold. FDA informed Apotex that these entries were “refused” and had to be destroyed or exported.²⁷² On the notices of FDA Action, “Hold Designated,” under the column “Current Status,” one could now read the following: “Refuse 09-28-2009.”²⁷³ These same notices of “Refusal of Admission” stated the charge of “Adulteration.”²⁷⁴
198. A series of Import Refusal Reports were also posted on FDA’s website for several Etobicoke products, indicating September 28, 2009 as the refusal date. The charge retained was that of appearance of adulteration.²⁷⁵

²⁶⁷ **Exhibit C-77**, Apotex Internal Email, dated September 2, 2009 (“We have put in a request to hold an urgent meeting with FDA Compliance to understand what this means [seven shipments held at the US border].”).

²⁶⁸ Witness Statement of Jeremy Desai, para. 59.

²⁶⁹ **Exhibit C-81**, Letter from Apotex-Canada to FDA, dated September 3, 2009, p. 1.

²⁷⁰ *Id.*

²⁷¹ **Exhibit C-110**, FDA’s website, Import Alert 66-40, dated October 2, 2009 (published on September 30, 2009 for Signet and Etobicoke).

²⁷² **Exhibit C-108**, Fax from FDA to Apotex, dated September 28, 2009. FDA indicated that all seven shipments in question originated from Etobicoke. This is a mistake. The shipments were sent both from Etobicoke and Signet.

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ **Exhibit C-109**, Import Refusal Reports for Etobicoke, dated September 28, 2009. After the imposition of the Import Alert, several Import Refusal Reports were entered into FDA’s system for Signet products. *See*

199. The Import Alert prevented Apotex-US from receiving for sale in the US any product manufactured at the Etobicoke and Signet facilities.²⁷⁶
200. In addition, while the Import Alert remained in place, FDA delayed review and approval of a large number of applications for new generic drugs produced at Etobicoke or Signet.²⁷⁷ For some of these applications, Apotex was the first filer of a paragraph IV certification, which would have opened the door to the 180-day exclusivity period upon final approval of the ANDA.²⁷⁸ The Import Alert therefore prohibited Apotex-US from timely bringing to market a large number of new oral-dose generic drugs – effectively eliminating Apotex-US’s ability to secure the advantage of statutory marketing exclusivity for new products.²⁷⁹
201. At no point, however, did FDA seize, or inform Apotex that it should recall, any product already in the US that had been manufactured at Etobicoke and/or Signet. Such a seizure or recall request would have been required if FDA had any serious concern as to the safety, quality or efficacy of these products.²⁸⁰
202. At no time during the eight months beginning December 2008 through August 28, 2009 (or at any time before), had FDA objected to the importation of any Etobicoke product or suggested that it was unsuitable for the US public.²⁸¹ Nothing had occurred in the eight months following the December 2008 inspection at Etobicoke except improvements and the implementation of additional measures to ensure the quality of products destined for the US market. However, FDA did not take these improvements into consideration when adopting the Import Alert.

e.g. **Exhibit C-125**, Import Refusal Report for Signet dated December 22, 2009. After the imposition of the Import Alert, several Refusal Reports were entered into FDA’s System for Signet products and for Etobicoke. However this shipment did not concern commercial products, but experimental medicines. See Witness Statement of Jeremy Desai, para. 58.

²⁷⁶ Witness Statement of Jeremy Desai, para. 89; Witness Statement of Gordon Fahner, para. 92.

²⁷⁷ Witness Statement of Bernice Tao, para. 51; Witness Statement of Kiran Krishan, para. 46.

²⁷⁸ See **Exhibit C-48a**, Apotex List of Pending ANDAs at time of Import Alert. Apotex was the first filer of a paragraph IV certification for several ANDAs that were pending at the time of the Import Alert.

²⁷⁹ Witness Statement of Gordon Fahner, para. 102 (noting that, “in some instances, Apotex lost the important opportunity to expand its product base and enter the market as early as possible.”).

²⁸⁰ Witness Statement of Jeremy Desai, para. 52.

²⁸¹ **Exhibit C-185**, Letter from Apotex’s Regulatory Counsel (Buc & Beardsley, LLP) to FDA, dated December 13, 2010, p. 4.

VIII. HEALTH CANADA'S FINDINGS AND DECISIONS OF THIRD-COUNTRY AGENCIES AFTER THE IMPOSITION OF THE IMPORT ALERT

A. Health Canada's Inspection in the Fall 2009

203. Following the adoption of the Import Alert, Health Canada conducted its own inspections of the Etobicoke and Signet facilities in September, October and early November 2009. The inspections together lasted for many weeks. Canadian and US cGMP standards at all relevant times were materially equivalent.²⁸²
204. While the inspection by Health Canada was underway, Apotex-Canada decided voluntarily to recall three products (in different dosages) from the Canadian market.²⁸³ Apotex wrote to Health Canada on September 8, 2009 to explain the rationale for this recall.²⁸⁴ The recall had no influence on the outcome of the inspection by Health Canada.²⁸⁵
205. At the end of the inspections, Health Canada concluded that, while manufacturing processes could be improved in ways that Apotex was addressing, both facilities were cGMP-compliant.²⁸⁶
206. On November 17, 2009, Apotex-Canada submitted its response to Health Canada's inspection observations for Signet.²⁸⁷ It did so for Etobicoke on December 8, 2009.²⁸⁸

²⁸² See **Legal Authority CLA-313**, Relevant Canadian Good Manufacturing Practices, in effect from April 23, 2009 to September 30, 2009 and from October 1, 2009 to February 22, 2010.

²⁸³ **Exhibit C-101**, Health Canada, Information Update, "Important Information on Apotex Health Products", dated September 17, 2009. See also **Exhibit C-105**, Reuters, "Update 1 – Apotex recalls certain lots of 3 drugs in Canada", dated September 18, 2009; **Exhibit C-104**, Excerpt from Apotex website, Press release, "Important Information on Apotex Health Products", dated September 17, 2009.

²⁸⁴ **Exhibit C-88**, Letter from Apotex to Health Canada, Ontario Operation Centre, dated September 8, 2009. See also **Exhibit C-90**, Letter from Apotex to Health Canada, dated September 9, 2009.

²⁸⁵ Witness Statement of Bruce Clark, para. 44.

²⁸⁶ **Exhibit C-112**, Health Canada, Inspection Exit Notice for Inspection at 150 Signet Drive, dated October 14, 2009, p. 3 (Rating C). As previously noted, Health Canada uses three inspection ratings: C = recommended for the continuation or issuance of the Establishment License; NC = not recommended for the continuation or issuance of the Establishment License; and NR = investigative or no recommendation at this stage. A rating of NC may lead to enforcement action, which could include suspension of the license for the establishment. On this Inspection Exit Notice, Health Canada recorded 26 observations, rated at risk categories 2 or 3 (risk category 1 being the most serious on Health Canada's scale). See also **Exhibit C-116**, Health Canada, Inspection Exit Notice for Inspection at Etobicoke, dated November 4, 2009, p. 3 (Rating C). On this Inspection Exit Notice, Health Canada recorded 26 observations, rated at risk categories 2 or 3.

207. On December 31, 2009, Health Canada issued its “Terms and Conditions Annex for 2010 Drug Establishment License 100375-A.”²⁸⁹ This document set out specific conditions imposed by Health Canada to Apotex Signet facility. In particular, Apotex was required to provide certain information to Health Canada in writing on a monthly basis.²⁹⁰
208. In the months that followed, Health Canada conducted regular follow-up inspections of the Apotex facilities. Health Canada consistently rated the facilities as “Compliant.”²⁹¹

B. Actions of Other Pharmaceutical Regulatory Agencies

209. 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. These agencies are signatories to the Mutual Recognition Agreements (MRA) on Medicinal Products, GMP Inspection and Batch Certification.²⁹²

²⁸⁷ **Exhibit C-119**, Letter from Apotex-Canada to Health Canada, dated November 17, 2009.

²⁸⁸ **Exhibit C-123**, Letter from Apotex-Canada to Health Canada, dated December 8, 2009.

²⁸⁹ **Exhibit C-126**, Health Canada, “Apotex Incorporated – Terms and Conditions Annex for 2010 Drug Establishment License 100375-A”, dated December 31, 2009 (valid until December 31, 2010). Establishment License 100375-A corresponds to 150 Signet Drive. *See, e.g.*, **Exhibit C-157**, Health Canada, Inspection Exit Notice for 150 Signet Drive, dated July 22, 2010 (“Licence Numbe(s) 100375-A”).

²⁹⁰ **Exhibit C-126**, Health Canada, “Apotex Incorporated – Terms and Conditions Annex for 2010 Drug Establishment License 100375-A”, dated December 31, 2009, p. 3, Item 3 (“Apotex shall provide the following information relating to the establishment in writing to Health Canada on a monthly basis beginning on February 1, 2010 ...”).

²⁹¹ Witness Statement of Edmund Carey, paras. 43,45. *See also* **Exhibit C-149**, Health Canada, Inspection Exit Notice for 4100 Weston Road (Signet Campus), dated June 1, 2010 (rating C); **Exhibit C-153**, Health Canada, Inspection Exit Notice for 200 Barmac Drive (Signet Campus), dated July 12, 2010 (rating C); **Exhibit C-154**, Health Canada, Inspection Exit Notice for Etobicoke, dated July 12, 2010 (rating C); **Exhibit C-157**, Health Canada, Inspection Exit Notice for 150 Signet Drive (Signet Campus), dated July 22, 2010 (rating C); **Exhibit C-161**, Health Canada, Inspection Exit Notice for 20 Kenhar (Signet Campus), dated August 6, 2010 (rating C); **Exhibit C-162**, Health Canada, Inspection Exit Notice for 3701 Weston Road (Signet Campus), dated August 6, 2010 (rating C); **Exhibit C-163**, Health Canada, Inspection Exit Notice for 400 Ormont Drive (Signet Campus), dated August 6, 2010 (rating C); **Exhibit C-151**, Health Canada, Inspection Exit Notice for 285 Garyray Drive (Signet Campus), dated October 29, 2010 (rating C); **Exhibit C-184**, Letter from Health Canada to Apotex-Canada, dated December 7, 2010 (“The corrective plan submitted by your firm has been reviewed and deemed acceptable at this time. The implementation of your corrective action plan will be verified during the next inspection.”).

²⁹² **Exhibit C-7**, European Agency for the Evaluation of Medicinal Products Inspections, *Mutual Recognition Agreements Between the EU and the respective Parties Australia, Canada, New Zealand and Switzerland*, dated May 5, 2003; **Exhibit C-10**, European Agency for the Evaluation of Medicinal Products Inspections, *Mutual Recognition Agreements, Sector Annex on Good Manufacturing Practices*, dated May 5, 2004 (MRA not operational with respect to the United States).

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 during the period of the Import Alert.²⁹³

210. While the results of the inspection conducted by Health Canada were pending, Medsafe, New Zealand's drug regulatory agency, announced on September 17, 2009 that Apotex would temporarily and voluntarily stop importing medicines produced by Apotex into New Zealand.²⁹⁴ This was a "precautionary measure" pending the results of the inspection conducted by Health Canada at Etobicoke and Signet in the fall of 2009.²⁹⁵ Medsafe also indicated that "[a]t this point, there [was] no reason for people to be concerned about taking any medicines manufactured by Apotex."²⁹⁶
211. About a month later, on October 20, 2009, Medsafe indicated that it had "no objection to Apotex NZ Ltd immediately lifting its voluntary import ban on products manufactured at the Signet Drive site."²⁹⁷ At this point in time, Health Canada had issued a compliance status report for this facility. However, the inspection at Etobicoke was still ongoing. Once Health Canada issued a compliance status report for Etobicoke as well, Medsafe also authorized Apotex to "immediately lift[] its voluntary import ban on products manufactured at the Etobicoke site."²⁹⁸
212. The sequence of events was almost the same with respect to the Australian regulatory authority. FDA's Import Alert created great concerns in Australia, such that Apotex, local subsidiary proposed a voluntary ban on imports from Etobicoke and Signet,

²⁹³ **Exhibit C-185**, Letter from Apotex's Regulatory Counsel (Buc & Beardsley, LLP) to FDA, dated December 13, 2010, pp. 8-9. *See also* Witness Statement of Bruce Clark, para. 46.

²⁹⁴ **Exhibit C-102**, Medsafe, Media Releases, "Import of Apotex Products under Close Monitoring", dated September 17, 2009 ("The Ministry of Health's drug regulatory arm Medsafe has negotiated an agreement with pharmaceutical manufacturer Apotex to temporarily restrict importation of medicines produced by Apotex at its two manufacturing sites in Toronto, Canada.").

²⁹⁵ *Id.* *See also* **Exhibit C-100**, Medsafe, Media Releases, "Medsafe closely monitoring Apotex", dated September 14, 2009 (quoting Medsafe group manager: "the Health Canada audit will provide us with further information about these manufacturing sites...").

²⁹⁶ **Exhibit C-102**, Medsafe, Media Releases, "Import of Apotex Products under Close Monitoring", dated September 17, 2009). *See also* **Exhibit C-100**, Medsafe, Media Releases, "Medsafe closely monitoring Apotex", dated September 14, 2009 (quoting Medsafe group manager: "Although FDA has raised questions about the manufacturing process at these two Canadian plants, there is no evidence that this had led to an increased risk to patient welfare for medicines made at these plants.").

²⁹⁷ **Exhibit C-113**, Letter from Medsafe to Apotex, dated October 20, 2009.

²⁹⁸ **Exhibit C-121**, Letter from Medsafe to Apotex, dated November 24, 2009.

pending the findings of Health Canada. As soon as Health Canada's inspection report was reviewed by the Australian Therapeutic Goods Administration (TGA), the latter accepted Health Canada's assessment and "agree[d] to lift the voluntary suspension of products from both sites as previously discussed."²⁹⁹

213. Similarly, the Netherlands Health Care Inspectorate (IGZ) requested, as a precautionary measure, that Apotex temporarily cease the import and distribution of all products imported into the European Economic Area (EEA), with the exception of one product. The European Medicines Agency (EMA) had indicated to Apotex that all communications in this respect should be handled through IGZ. IGZ had agreed to act as the supervising inspectorate to manage communications that would come from various EU member states' inspectorates. On Apotex's side, all communications with IGZ were handled by the group's Dutch subsidiary, Apotex Netherlands BV. As stated in a press release dated October 26, 2009, IGZ did not impose a recall of any Apotex products already on the European market since they did not pose any risk to public health. The import ban was purely a precautionary measure.³⁰⁰ This ban was lifted barely 10 days later, on November 5, 2009 after Health Canada had concluded that the Etobicoke and Signet sites were cGMP compliant.³⁰¹

IX. FDA'S DELAY IN LIFTING THE IMPORT ALERT AND APPROVING ANDAS

A. Apotex-Canada's Remediation Plan and the September 2009 Meeting

214. From the inception, Apotex-Canada rejected FDA's suggestion that its facilities were not compliant with cGMP. It nonetheless agreed to cooperate with FDA and to promptly address the issues the inspectors had raised.
215. On September 8, 2009, Apotex published on its website a news release about the Import Alert. Apotex then stated that it was "actively working with FDA to resolve the

²⁹⁹ **Exhibit C-118**, Letter from TGA to Apotex Australia, dated November 11, 2009.

³⁰⁰ **Exhibit C-114**, CBG-MEB, "Apotex stops import and distribution of medicinal products from Canada", dated October 26, 2009.

³⁰¹ **Exhibit C-117**, CBG-MEB, "Import and Distribution Medicinal Products from Apotex Canada resumed", dated November 6, 2009.

identified concerns as quickly as possible,” and that it was “optimistic that there [would] be a prompt resolution.”³⁰²

216. On September 11, 2009, Apotex representatives flew to Washington to meet with FDA.³⁰³ FDA opened the meeting with its presentation.³⁰⁴ Notably, FDA raised the Application Integrity Policy (AIP), which came as a surprise to Apotex since the inspectors had omitted any mention of AIP on the Signet form 483.³⁰⁵

217. Apotex then gave its presentation. First, Apotex explained the immediate actions that were taken at Etobicoke and Signet. The deviations that FDA had observed were systematically reviewed and the firm concluded that FDA’s form 483 observations were “isolated” occurrences.³⁰⁶ Second, Apotex outlined its corrective actions and an ambitious quality-control improvement plan aimed at enhancing Apotex processes to FDA’s satisfaction.³⁰⁷ Third, Apotex undertook to conduct a product quality assessment (PQA) in order to assess the quality of all products shipped to the US before the Import Alert and to verify that products met the appropriate standards and specifications.³⁰⁸

³⁰² **Exhibit C-89**, Apotex, Press Release, “FDA Pharmaceutical Import Alert”, September 8, 2009.

³⁰³ Apotex had requested a meeting with FDA on July 24, 2009 and FDA granted the meeting request on August 27, 2009, i.e., before the adoption of the Import Alert. *See* **Exhibit C-92**, Apotex Slides, “Compliance Presentation to FDA”, dated September 11, 2009, slides entitled “Chronology Etobicoke” and “Chronology Signet.” *See also* **Exhibit C-94**, Apotex, Minutes of Meeting with FDA on September 11, 2009. The Apotex slide on “Chronology Signet” presented at the September 11, 2009 meeting refers to a post-marketing audit conducted from August 24 to 28, 2009 at Etobicoke. However, this is a mistake. This inspection took place at the facility located at 465 Garyray Dr. in Toronto, which is a bioclinical facility on the Signet Campus. No form 483 was issued and the inspection was subsequently closed. *See* **Exhibit C-151**, Letter from FDA to Apotex-Canada, dated June 23, 2010, enclosing Establishment Inspection Report (EIR) for inspection at 465 Garyray Dr. from August 24 to 28, 2009.

³⁰⁴ **Exhibit C-93**, FDA Slides presented at the meeting held on September 11, 2009.

³⁰⁵ **Exhibit C-94**, Apotex Draft Minutes of Meeting on September 11, 2009, p. 2 (“Mr. Kay began Apotex’s substantive presentation by noting that this is the first time he has been aware of a data integrity question, and that is a matter of significant concern to him.”). *See also* Witness Statement of Bruce Clark, paras. 31, 37; Witness Statement of Jeremy Desai, para. 45.

³⁰⁶ **Exhibit C-92**, Apotex Slides, “Compliance Presentation to FDA”, dated September 11, 2009, slide entitled “Immediate Action Taken at Etobicoke and Signet.”

³⁰⁷ *Id.* Apotex retained in the third quarter of 2009 the services of independent consultants to support system review and re-development, deviation reduction and investigation clean up at Etobicoke. *See* **Exhibit C-197**, Letter from Apotex-Canada to FDA, dated March 1, 2011, p. 8.

³⁰⁸ **Exhibit C-92**, Apotex Slides, “Compliance Presentation to FDA”, dated September 11, 2009, slide entitled “Key Actions and Commitments”, fourth bullet point, and slides entitled “Product Quality Assessments (PQAs).” Apotex eventually retained the firm Lachman Consultant Services, Inc. to conduct this PQA.

218. Apotex's consultant, Mr. Yuen, stated that Apotex expected to be ready for re-inspection in the fourth quarter of 2009.³⁰⁹ Apotex requested that FDA, based on a satisfactory outcome of the product quality assessments and verification audits, initiate a prompt lifting of the Import Alert for Etobicoke and Signet (after re-inspection by FDA or third-party certification) and conduct a prompt pre-approval inspection (PAI) for Apotex's pending ANDAS.³¹⁰
219. FDA insisted on two key factors for the readiness for re-inspection: first, assurances of cGMP conformance and, second, complete resolution of deficiencies throughout all quality systems.³¹¹ Meanwhile, FDA gave assurances that both cGMP inspection and pre-approval inspections could be conducted at the same time during re-inspection of Etobicoke and Signet.³¹²
220. FDA also asked Apotex to provide a list of the products for which Apotex was market leader in the United States.³¹³
221. Mr. Rivera Martinez, on behalf of FDA, acknowledged that "there may have been some miscommunication regarding the Etobicoke inspection, due in part to the fact that the investigators may not have communicated deficiencies well."³¹⁴ He, therefore, promised that FDA would "assign high priority to keeping open communication" with Apotex.³¹⁵

³⁰⁹ **Exhibit C-94**, Apotex Draft Minutes of Meeting of September 11, 2009, p. 9.

³¹⁰ **Exhibit C-92**, Apotex Slides, "Compliance Presentation to FDA", dated September 11, 2009, slide entitled "Path Forward – Etobicoke", third bullet point and slide entitled "Path Forward – Signet", third bullet point.

³¹¹ **Exhibit C-93**, FDA slides, "CDER Office of Compliance, International Compliance Branch, Apotex Inc. Meeting", dated September 11, 2009, last slide entitled "Reinspections." *See also* **Exhibit C-94**, Apotex, Minutes of Meeting with FDA on September 11, 2009, p. 2 ("FDA would require reinspection and ... they will reinspect when they have assurance that GMP conformance has been instituted and that all deficiencies have been resolved.").

³¹² **Exhibit C-94**, Apotex, Minutes of Meeting with FDA on September 11, 2009, p. 7 ("He [Mr. Rivera Martinez] said that a reinspection could encompass both GMP inspection and PAIs.").

³¹³ **Exhibit C-97**, Apotex, "Products for Which Apotex Corp. Is Market Leader," "Products for Which Apotex Corp. Is in 2nd Place Marketshare Position" and "Products for Which Apotex Corp. Is in 3rd Place Marketshare Position," dated September 11, 2009.

³¹⁴ **Exhibit C-94**, Apotex Draft Minutes of Meeting of September 11, 2009, p. 6.

³¹⁵ *Id.*, p. 9.

222. At the end of that meeting, the Apotex team was confident that issues could be resolved relatively quickly and that the Import Alert would not last for long.³¹⁶
223. Less than a week after the meeting in Washington, D.C., Apotex and FDA held a telephone conference on September 17, 2009. FDA wanted to discuss two specific products manufactured by Apotex, namely Deferiprone and [REDACTED]. These were drugs supplied by Apotex into the US market for emergency or IND (Investigational New Drugs) treatment, where FDA endeavors to make promising new drugs available to desperately ill patients as early as possible in the drug development process. FDA wanted to avoid a shortage of these drugs for compassionate use and specified the conditions under which Apotex was allowed to continue shipping the drugs to the US.³¹⁷ On September 24, 2009 FDA allowed the shipping of a small quantity of Deferiprone into the United States to meet a specific patient's need (before completion of the PQA).³¹⁸
224. In the months that followed, Apotex and its independent consultants carried out their work with the PQA and remediation plan.³¹⁹

B. The Signet Warning Letter

225. 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 with top FDA officers.³²⁰

³¹⁶ Witness Statement of Jeremy Desai, para. 66; Witness Statement of Bruce Clark, para. 38.

³¹⁷ **Exhibit C-103**, Apotex Draft Minutes of Conference Call with FDA on September 17, 2009. FDA required that Apotex provide an independent third party quality assessment for each batch intended for the US market, and retest each batch three times using a different sample each time. During this telephone conference, Apotex also announced that it had retained the services of Lachman Consulting to carry out the PQA. *See id.*, p. 1 (“Dr. Desai [of Apotex] also shared [with FDA] that [Apotex] had, because of the size of the task, engaged the Lachman Consulting firm as the independent consultant performing the PQA.”).

³¹⁸ **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 amount of deferiprone into US Interstate Commerce.”). FDA granted approval of Apotex’s new drug application (NDA) for Deferiprone (commercialized under the name Ferriprox®) in October 2011. *See Exhibit C-269*, Email from Apotex to FDA, dated October 17, 2011, attaching approval letter.

³¹⁹ Witness Statement of Jeremy Desai, para. 68 (the Q6 program was launched in November-December 2009).

³²⁰ **Exhibit C-140**, Apotex-Canada, Draft Minutes of Meeting with FDA of March 31, 2010, p. 1 (under the heading “FDA Representatives”). Mr. Friedman, Director of the Division of Manufacturing and Product

226. At an industry GMP conference held on March 15-18, 2010, a top FDA official again publicly cited the Apotex Import Alert. He referred to it as an example of unprecedentedly swift sanctions imposed by FDA in furtherance of its policy to “use meaningful penalties to send a strong message to discourage future offenses.”³²¹ The official made clear the use FDA had in mind of Apotex as an example to deter other industry players:

“That import alert was implemented 10 days after the completion of an inspection. We’ve never done that before. Generally, we place companies on an import alert after a warning letter. This inspection was completed on Friday. On Monday FDA Office of Compliance International Alert Branch was on the phone with the executive officer and asked them what they intended to do with respect to the violations. They didn’t take us too seriously. ... Things are changing folks, and you need to react a lot faster because FDA is moving a lot faster.”³²²

227. In anticipation of the March 31 meeting, Apotex sent various background materials to FDA on March 17, 2010.³²³

228. This was the date when the various independent experts retained by Apotex submitted their respective reports. As such, Lachman Consultant Services, Inc. delivered its product quality assessment (PQA).³²⁴ Jeff Yuen & Associates, Inc. presented its independent review of Apotex quality structures and processes, taking into account all findings from numerous regulatory inspections conducted in 2008 and 2009.³²⁵ Finally,

Quality (DMPQ), Ms. Motta, Acting Branch Chief of International Compliance, Mr. Rosa, Team Leader International Compliance, among others, attended this meeting on FDA’s side.

³²¹ **Exhibit C-141**, “Enforcement on Steroids: FDA Delivers Twice the Drug GMP Warning Letters”, *The Gold Sheet*, pp. 1-2 (April 1, 2010) (quoting statement made by Edwin Rivera-Martinez, associate director of drug quality assurance for the division of manufacturing and product quality, at the 34th International GMP Conference in Athens, Georgia on March 15-18, 2010).

³²² *Id.* (quoting statement made by Mr. Rivera-Martinez) (ellipsis in original).

³²³ **Exhibit C-136**, Letter from Apotex to FDA, dated March 17, 2010.

³²⁴ **Exhibit C-120**, Lachman Consultants Services, Inc., Protocol for Product Quality Assessment, dated November 19, 2009 (with attachments); Product Quality Assessment Interim Summary Report for Wave 1 Products (with attachment), dated March 17, 2010 (Wave 2 of the PQA was completed shortly thereafter); Product Quality Assessment Summary Report, [REDACTED] 500 mg [REDACTED] Tablets (unsigned and undated).

³²⁵ **Exhibit C-137**, Jeff Yuen & Associates, Inc., Final Summary Report for: Apotex Corrective Action Plan Audit, dated March 17, 2010.

Paul Vogel Consulting Services LLC assisted Apotex in producing a corrective action plan (CAP) and a global quality systems enhancement program.³²⁶

229. On March 29, 2010, FDA issued a warning letter with respect to Signet (the “Signet Warning Letter”).³²⁷ 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. The timing of the warning letter contrasted with FDA’s stated policy:

FDA must be quick and respond quickly. No longer will you see warning letters issued six to eight months after an inspection.³²⁸

230. Apotex received no advance notice of that warning letter, although the firm had been in regular contact with FDA in the prior weeks and months.³²⁹
231. As noted above, at the close of the Signet inspection in August 2009, FDA inspectors had reported 17 observations on Signet Form 483. The Signet Warning Letter, however, listed four alleged cGMP deviations. One of these was based on events post-dating Apotex-Canada’s September 2009 response to the Signet Form 483. These findings were made without prior notice to Apotex and without affording Apotex any opportunity to respond.

C. The March 2010 Meeting with FDA

232. At the March 31, 2010 meeting, Apotex-Canada presented a preliminary response to the Signet Warning Letter and announced that it would submit a full response within 15 business days.³³⁰

³²⁶ **Exhibit C-132**, Apotex Global Quality Systems Revitalization Corrective Action Plan, Rev. 1, dated March 5, 2010 (signed on March 17, 2010); **Exhibit C-133**, Apotex, Quality Systems Revitalization Program & Project Management Manual, dated March 8, 2010 (signed on March 17, 2010).

³²⁷ **Exhibit C-138**, Signet Warning Letter (WL: 320-10-003), dated March 29, 2012.

³²⁸ **Exhibit C-141**, “Enforcement on Steroids: FDA Delivers Twice the Drug GMP Warning Letters”, *The Gold Sheet*, p. 1. (April 1, 2010) (quoting statement made by Edwin Rivera-Martinez, associate director of drug quality assurance for the division of manufacturing and product quality, at the 34th International GMP Conference in Athens, Georgia on March 15-18, 2010).

³²⁹ Witness Statement of Bruce Clark, para. 47; Witness Statement of Jeremy Desai, para. 72.

³³⁰ **Exhibit C-140**, Apotex-Canada, Draft Minutes of Meeting with FDA of March 31, 2010, pp. 2-3.

233. The bulk of the meeting concerned Apotex's Product Quality Assessment (PQA) and Corrective Action Plan (CAP).³³¹ For the first wave of the PQA, 27 products were assessed, and only three failed to meet the criteria.³³² For the wave 2 PQA, 30 products were assessed, and only one failed.³³³ In response, FDA stated that it needed clarification of why only 20% of the batch records were being reviewed as part of the PQA.³³⁴
234. With respect to the corrective action plan, Apotex explained that the objective of this ambitious program was a comprehensive cGMP enhancement of the quality systems across all development and manufacturing sites of Apotex.³³⁵ This program was structured around the "Six Quality Systems" model as originally set out by FDA in its *Guidance for Industry – Quality Systems Approach to Pharmaceutical CGMP Regulations, September 2006*.³³⁶
235. FDA replied that it wanted to see improvements to Quality System "at a company level" and also "wanted to see specifics on training" on employees involved with manufacturing and quality control.³³⁷
236. FDA undertook to Apotex that it would conduct an inspection of both the Etobicoke and Signet facilities once Apotex-Canada was ready for inspection. FDA asked that Apotex make a formal request for inspection when ready.³³⁸ FDA warned though that "the

³³¹ *Id.*, pp. 3-4 (under the header "Jeremy turned to the PQA's"). See also **Exhibit C-230**, Executive Summary – Apotex Global Quality Systems Revitalization Corrective Action Plan (Apotex GQSR-CAP), appended to Letter from Apotex-Canada to FDA, dated March 1, 2011, p. 1 (noting that "[t]his plan was provided to FDA-CDER in March, 2010.").

³³² **Exhibit C-140**, Apotex Draft Minutes of Meeting of March 31, 2010, p. 3.

³³³ *Id.*, pp. 3-4.

³³⁴ *Id.*, p. 6.

³³⁵ **Exhibit C-230**, Executive Summary – Apotex Global Quality Systems Revitalization Corrective Action Plan (Apotex GQSR-CAP), appended to Letter from Apotex-Canada to FDA, dated March 1, 2011, p. 1.

³³⁶ See *id.*

³³⁷ **Exhibit C-140**, Apotex Draft Minutes of Meeting of March 31, 2010, p. 4. FDA also noted that it had "devoted many resources to Apotex, and that it [was] still not clear that all sites underst[oo]d FDA's requirements ... FDA [was] not confident that all sites ha[d] clear understanding of FDA requirements, including GMPs." *Id.* at p. 6.

³³⁸ *Id.*, p. 6 ("FDA (CR) [i.e., Carmelo Rosa, Team Leader International Compliance] commented further that Apotex [was] moving in the right direction but he [was] not certain we [Apotex] [were] there. We (FDA) need to reinspect to verify. The current FDA policy is that after a WL is given and resolved, the company tells FDA they are ready for inspection. FDA will then schedule it.").

company must be sure they are ready for an inspection. [FDA] will not rush back if the first reinspection is not satisfactory. ... Before a re-inspection, Apotex must show a transformation.”³³⁹

237. FDA softened its stance on the issue of data integrity of certain Apotex ANDA supplements.³⁴⁰

238. At the close of the meeting, FDA noted that “there [was] some work to do and that FDA [would] expect some responses to questions raised [on that day] before resuming further review.”³⁴¹

239. As announced during the March 31 meeting, Apotex-Canada submitted its response to the Signet Warning Letter on April 17, 2010.³⁴²

240. Apotex emphasized the vast efforts it had undertaken in order to address FDA’s concerns:

Third-party led audits and gap analyses have been conducted, corrective action plans have been written, interim controls have been put into place, standard operating procedures (SOPs) have been revised and updated and the project has moved into the implementation phase.³⁴³

241. Apotex’s Corrective Action Plan (CAP) for the Global Quality Systems Assessment Program was appended to this letter of April 17, 2010.³⁴⁴ As part of the firm’s corrective actions, a new quality leadership team was put in place and new appointments were made to top positions.³⁴⁵

³³⁹ *Id.*

³⁴⁰ *Id.* p. 5 (“RF [Rick Friedman] commented that this was not a ‘big integrity issue’ but a ‘small integrity issue’.”); Witness Statement of Jeremy Desai, para. 76.

³⁴¹ **Exhibit C-140**, Apotex Draft Minutes of Meeting of March 31, 2010, p. 7.

³⁴² **Exhibit C-144**, Letter from Apotex to FDA, dated April 17, 2010.

³⁴³ *Id.*, p. 1.

³⁴⁴ *Id.* at 1, dated April 17, 2010; **Exhibit C-132**, Apotex Global Quality Systems Revitalization Corrective Action Plan, dated March 5, 2010 (Rev. 1) and signed on March 17, 2010.

³⁴⁵ **Exhibit C-144**, Letter from Apotex-Canada to FDA, at 2, dated April 17, 2010.

242. Some of Apotex's global quality systems enhancements were also implemented in its facilities in Bangalore, India and Richmond Hill, Canada.³⁴⁶ Both facilities were inspected to FDA's satisfaction in 2010.³⁴⁷ Likewise, Health Canada audited all Apotex operations (including Etobicoke and Signet) over a three-month period from June to August 2010 resulting in no "Critical" observations and a "Compliant" rating at all sites.³⁴⁸ In other words, Apotex's corrective actions met the requirements of both FDA and Health Canada.
243. A follow-up telephone conference on the issue of Apotex manufacturing supplements took place on May 7. Apotex provided its response to FDA's questions regarding the review of supplements on June 21, 2010.³⁴⁹ As requested by FDA, the scope of the draft protocol for the retrospective review of supplements was extended.³⁵⁰

D. FDA's Refusal to Resume Shipping of Certified Drugs

244. On May 13, 2010, Apotex wrote to FDA to request authorization to resume shipping from Apotex's warehouse in Indianapolis with respect to 22 drug product families that were affected by the Import Alert. Attached to this letter were the complete Product Quality Assessments (attachments A and B), as well as a list of specific products for

³⁴⁶ See **Exhibit C-166**, Apotex-Canada Letter to FDA, at 1, dated August 27, 2010.

³⁴⁷ FDA inspected Apotex's site in Bangalore from 13 to 17 April 2010. A form 483 was issued at the close of the inspection and Apotex submitted a response in the form of an audit compliance report on May 4, 2010. See **Exhibit C-147**, Letter from Apotex Research Private Limited (Bangalore, India) to FDA, dated May 4, 2010, enclosing Bangalore Form 483 of April 17, 2010. FDA reviewed this information and decided to classify the Bangalore site as "acceptable." See **Exhibit C-158**, Letter from FDA to Apotex Research Private Limited, dated August 2, 2010, enclosing Establishment Inspection Report (EIR) for Bangalore. Similarly, FDA inspected Apotex's site in Richmond Hill, Ontario, Canada from March to August 2010. A form 483 was issued at the close of the inspection. See **Exhibit C-165**, Richmond Hill Form 483, dated August 17, 2010. Apotex-Canada submitted its response thereafter. See **Exhibit C-167**, Apotex's Response to Form 483 for Richmond Hill, dated September 2010. Eventually, FDA classified the Richmond Hill facility as "acceptable." See **Exhibit C-176**, Letter from FDA to Apotex-Canada, dated November 10, 2010, enclosing Establishment Inspection Report (EIR) for Richmond Hill.

³⁴⁸ **Exhibit C-197**, Letter from Apotex to FDA, at 8, dated March 1, 2011. See also **Exhibits C-149, C-153, C-154, C-157, C-161, C-162, C-163 and C-174**, Health Canada, 2010 Inspection Exit Notices for Etobicoke and Signet Campus (150 Signet Drive, 4100 Weston Road, 3701 Weston Road, 400 Ormont Drive, 200 Barmac Drive, 20 Kenhar, 285 Garyray Drive).

³⁴⁹ **Exhibit C-150**, Email from Apotex to FDA, dated June 21, 2010. Witness Statement of Bernice Tao, para. 60.

³⁵⁰ **Exhibit C-150**, Email from Apotex to FDA, dated June 21, 2010. Witness Statement of Bernice Tao, para. 60.

which shipping should resume (attachment C).³⁵¹ FDA's official answer was that re-inspection was needed. However, a limited number of Apotex products could be shipped from the warehouse facility to retailers in the US.³⁵²

245. In June 2010, Apotex also sought FDA's approval to resume shipping of a limited number of shortage drug products from Etobicoke, under the supervision of a third party consultant who would certify the facility's compliance with cGMP, pending re-inspection by FDA.³⁵³ In its letter, Apotex stressed that it was aware that "the Agency ha[d] provided for the phased re-start of manufacturing and distribution in the context of GMP consent decrees involving domestic facilities and request[ed] that [FDA] consider according Apotex the same consideration."³⁵⁴

246. FDA rejected the request, except for [REDACTED], a drug used for compassionate use in the US that FDA had previously authorized under third-party supervision.³⁵⁵ Refusing Apotex to ship Apotex products under third-party supervision was thus contrary to FDA's prior decision regarding [REDACTED] and, more generally, it was contrary to FDA's practice with respect to domestic manufacturers under consent decree.³⁵⁶

247. Following completion of the PQA, in May 2010, Apotex recalled from its warehouse in Indianapolis some of the products that had been shipped there prior to the Import Alert. One of the main reasons for this recall was that the API for the products being recalled had expired.

³⁵¹ **Exhibit C-148**, Letter from Apotex to FDA, enclosing Lachman Consultant Services, Inc., Summary of PQA's Wave 1 and Wave 2; Lachman Consultant Services, Inc., PQA Protocol, dated November 19, 2009; Apotex, List of Products to be Shipped from Indianapolis Warehouse.

³⁵² Witness Statement of Jeremy Desai, para. 81. *See also* Witness Statement of Bernice Tao, para. 56.

³⁵³ **Exhibit C-152**, Letter from Apotex to FDA, dated June 25, 2010, with attachments A and B.

³⁵⁴ *Id.* at 1.

³⁵⁵ **Exhibit C-156**, Email from FDA to Apotex, dated July 21, 2010 ("Our office has determined that a market shortage does not exist for the indicated drugs since other manufacturers of these drugs are currently available to supply the US market. Nevertheless, the agency will continue to allow the importation of [REDACTED] tablets, currently under a treatment IND protocol and under the direct oversight of your third party consultant, as previously agreed.").

³⁵⁶ Witness Statement of Jeremy Desai, para. 80.

E. FDA's Refusal to Expedite Re-Inspection

248. As recalled above, Apotex retained Jeff Yuen & Associates, Inc. as expert GMP compliance consultants. This consultancy firm informed Apotex in June 2010 that it was prepared to certify that the Etobicoke facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs were in compliance with cGMP.³⁵⁷
249. Furthermore, as already mentioned, Health Canada re-inspected Etobicoke and classified the facility as "compliant" in July 2010.³⁵⁸
250. Consequently, on August 27, 2010, Apotex-Canada requested FDA to re-inspect its Etobicoke facility in early October.³⁵⁹
251. On September 29, 2010 Apotex-Canada requested re-inspection of its Signet facility, also noting that Health Canada had classified this facility as "Compliant" in July 2010.³⁶⁰
252. On October 6, 2010, Apotex also requested that FDA allow a limited pre-approval inspection necessary to enable Apotex to launch the first generic Docetaxel product in the United States.³⁶¹ At that time, Apotex had already requested re-inspection of its Signet facility but had received no answer from FDA. In these circumstances, Apotex attempted to expedite the inspection regarding Docetaxel. This product is an important and expensive chemotherapy drug marketed under the brand name Taxotere®. According to Sanofi-Aventis, sales in 2009 totaled over USD ■ billion in the United States. As a result of Apotex's successful efforts to challenge the Sanofi-Aventis

³⁵⁷ **Exhibit C-166**, Letter from Apotex to FDA, at 1, dated August 27, 2010.

³⁵⁸ **Exhibit C-154**, Health Canada, Inspection Exit Notice for Etobicoke, at 3, dated August 27, 2010 (C rating). *See also* Exhibit C-184, Letter from Health Canada to Apotex, dated December 7, 2010 ("The corrective plan submitted by your firm has been reviewed and deemed acceptable at this time. The implementation of your corrective action plan will be verified during the next inspection.").

³⁵⁹ **Exhibit C-166**, Letter from Apotex to FDA, dated August 27, 2010.

³⁶⁰ **Exhibit C-169**, Letter from Apotex to FDA, dated September 29, 2010.

³⁶¹ **Exhibit C-170**, Letter from Apotex to FDA, dated October 6, 2010.

patents, Apotex had earned the right to begin marketing Docetaxel beginning November 14, 2010.³⁶²

253. Apotex believed that the request for a pre-approval inspection for [REDACTED] made sense because the product is important to the public and to Apotex, and because it is an intravenous solution, the diluent for which is manufactured at Richmond Hill, an Apotex facility that was successfully inspected by FDA in August 2010 and was not subject to the Import Alert. Part of the manufacture of [REDACTED] requires a sterile facility and Apotex has such a site on the Signet Campus. Since the manufacture is conducted by Richmond Hill staff, utilizing Richmond Hill procedures, Apotex perceived it as a reasonable step for FDA to inspect the sterile building at Signet, which would clear the way for the approval and launch of [REDACTED].³⁶³ However, FDA rejected the proposal to inspect the sterile site in advance of the Signet inspection.³⁶⁴
254. On October 15, 2010, FDA informally confirmed that an inspection would take place from November 29 through December 17, 2010, focusing first on the Etobicoke facility, followed by Signet.³⁶⁵ The re-inspection was thus announced three months after Apotex-Canada had requested it for Etobicoke.
255. On October 21, 2010, FDA provided formal notification of the inspection date (November 29 to December 17, 2010).³⁶⁶ Apotex-Canada confirmed the inspection date on October 26, 2010, noting that it was also its “understanding that this inspection

³⁶² **Exhibit C-170**, Letter from Apotex to FDA, at 2, dated October 6, 2010. *See also* **Exhibit C-185**, Letter from Apotex’s Regulatory Counsel to FDA, at 5, dated December 13, 2010.

³⁶³ **Exhibit C-170**, Letter from Apotex to FDA, at 2, dated October 6, 2010. *See also* Witness Statement of Jeremy Desai, para. 82. A prior request for inspection of the sterile site on the Signet Campus necessary for manufacturing [REDACTED] had already been made in June 2010 when FDA was scheduling an inspection at Richmond Hill. *See* **Exhibit C-155**, Letter from Apotex to FDA, dated July 12, 2010 (“From a timing perspective, the need to have a PAI for [REDACTED] Injection at the SP facility [at Signet] is critical for the approval of the application since Apotex would be in a position to be able to provide this generic product to the US in December 2010 when the 30 month stay due to legal and patent issues is lifted.”). However, FDA denied to inspect the sterile site in advance of the re-inspection at Signet.

³⁶⁴ Witness Statement of Jeremy Desai, para. 82.

³⁶⁵ **Exhibit C-171**, Apotex Internal Email Chain, dated October 15, 2010. *See also* **Exhibit C-185**, Letter from Apotex’s Regulatory Counsel to FDA, at 6, dated December 13, 2010.

³⁶⁶ **Exhibit C-172**, FDA Official Notification of GMP Inspection, dated October 21, 2010.

[would] include a PAI,”³⁶⁷ i.e., a pre-approval inspection in relation to pending applications for new generic drugs.

256. Furthermore, because FDA refused to act on some of Apotex’s new generic drug applications (ANDAs) while the two facilities remained on Import Alert, the number of Apotex applications awaiting pre-approval inspection had grown to around 60 by fall of 2010.³⁶⁸ Concerned that FDA would not be able to accommodate pre-approval inspections for all of these products, Apotex attempted unsuccessfully to contact FDA to discuss the issue. On November 4, 2010, Apotex provided FDA with a list of a dozen priority products³⁶⁹ and called FDA to ensure that the pre-approval inspections would not delay clearance of the two facilities. FDA confirmed by email that a senior inspector had been assigned to the inspection and that Apotex-Canada would be informed of the assignments of additional inspectors.³⁷⁰ On November 22, another senior inspector called Apotex-Canada to confirm that she would arrive to conduct the inspection starting on November 29, 2010.³⁷¹

257. Curiously, on the same day of November 22, 2010, another FDA official cancelled the inspection of Etobicoke and Signet, and advised that it would not be rescheduled until late January or February 2011.³⁷² The reason advanced by FDA was that, by postponing the inspection start date, appropriate personnel would be available “but also sufficiently prepared” to conduct the re-inspection of Etobicoke and Signet.³⁷³

³⁶⁷ **Exhibit C-173**, Letter from Apotex to FDA, dated October 26, 2010.

³⁶⁸ **Exhibit C-175**, Email from Apotex to FDA, dated November 4, 2010 (“We [Apotex] acknowledge that we have a fairly substantial number of pending ANDAs (total number of ■)”); *id.* (attached worksheets entitled “PAI List for pending ANDAs – Site Etobicoke” (■ pending ANDAs) and “PAI list for pending ANDAs – Site Signet” (■ pending ANDAs)). *See also* Witness Statement of Bernice Tao, para. 52.

³⁶⁹ **Exhibit C-175**, Email from Apotex to FDA, dated November 4, 2010, attaching list of 12 priority ANDAs for PAI.

³⁷⁰ **Exhibit C-177**, Email from FDA to Apotex, dated November 10, 2010 at 7:29 AM (“Mike Goga will be the lead with another CSO and Chemist. The Chemist and additional CSO haven’t been identified as of yet. I should know by COB Friday.”).

³⁷¹ **Exhibit C-178**, Apotex Internal Email, dated November 22, 2010. *See also* **Exhibit C-179**, Email from FDA to Apotex, dated November 22, 2010 (“Good morning Mr. Simmons, It was a pleasure to speak to you”).

³⁷² **Exhibit C-180**, Apotex Internal Email, dated November 22, 2010 (“Melvin S called me [Stephen Simmons] at 2:35 today, and informed me FDA is DELAYING the Apotex audit until late Jan/Feb.”).

³⁷³ **Exhibit C-186**, Letter from FDA to Apotex’s Regulatory Counsel, at 4, dated December 23, 2010.

258. Apotex immediately contacted CDER-OC. During a telephone conference, FDA explained that, given the scope of the inspection, including the large number of products requiring pre-approval inspection, FDA had decided that it needed a bigger team, comprised of four inspectors, including a representative from CDER-OC. Apotex then reminded FDA that it had already reduced the number of pre-approval products and was prepared to reduce it further. In fact, as Apotex told FDA, it would agree to the postponement of other products requiring pre-approval inspections if FDA could handle Docetaxel and one other product (Pantoprazole DR Tabs) for which Apotex would have been in a position to launch upon patent expiration on January 19, 2011. As explained to FDA, Apotex's priority was to resume manufacturing for the United States. Apotex asked whether FDA would consider inspecting only one of the two facilities. FDA responded that it was not likely the Agency could do that and that, if it did, it meant that it could not guarantee that the inspection of the second facility could begin by January 24, 2011.³⁷⁴

259. Following refusal by FDA of any alternative that would allow the November 29, 2010 inspection to go forward, Apotex then requested that FDA consider accelerating the inspection so it could begin in early January. CDER-OC responded that it did not object to that date, but DFI would have to determine whether it could accommodate the request. In early December 2010, DFI informed Apotex that it could not assemble the team requested by CDER-OC by the beginning of January.³⁷⁵

260. On December 13, 2010, Apotex-Canada requested, once again, an expedited re-inspection,³⁷⁶ but to no avail.³⁷⁷ In consequence, the re-inspection was delayed until January 24, 2011, five months after Apotex-Canada had requested the re-inspection of Etobicoke.

³⁷⁴ **Exhibit C-185**, Letter from Apotex's Regulatory Counsel to FDA, at 6, dated December 13, 2010; Witness Statement of Bernice Tao, para. 68.

³⁷⁵ **Exhibit C-185**, Letter from Apotex's Regulatory Counsel to FDA, at 6, dated December 13, 2010.

³⁷⁶ *Id.*

³⁷⁷ **Exhibit C-186**, Letter from FDA to Apotex's Regulatory Counsel, at 8, dated December 23, 2010.

F. The Re-Inspection of Etobicoke and Signet from January 24 to February 11, 2011

261. A week before the start of re-inspection, Apotex submitted to FDA a report providing an extended, retrospective supplement review for solid dose products. This review was conducted according to a protocol that FDA had approved.³⁷⁸
262. The re-inspection at Signet extended from January 24, 2011 to February 11, 2011. The re-inspection at Etobicoke took place from February 3 to 10, 2011. The same team of four investigators conducted the inspection at both sites, under the supervision of Mr. Goga. Apotex communicated a list of 15 priority products for the PAI.³⁷⁹
263. At the conclusion of the inspection, FDA's lead inspector issued a one-page form 483 for Etobicoke³⁸⁰ and an eight-page form 483 for Signet.³⁸¹ As explained by Mr. Carey, Director for Corporate Compliance, "FDA indicated that it would like to understand our process to bring products back in the US market. We gathered from that that FDA wished to see the concrete steps we were prepared to undertake in connection with our re-launch process. Therefore, we prepared a US Re-Entry Protocol (URPA)."³⁸²
264. On February 24, 2011, Apotex-Canada produced the final version of its US Re-Entry Product Assessment Protocol (URPA).³⁸³ This document was designed to assess all commercial ANDA products in order to assure product robustness, quality and

³⁷⁸ **Exhibit C-188**, Apotex Letter to FDA, dated January 17, 2011. FDA requested that the report on supplement review be re-submitted during or after the re-inspection of Etobicoke and Signet. *See Exhibit C-192*, Email Chain between FDA and Apotex re: Apotex's Report on Supplement Review, dated January 31, 2011 ("I [Carmelo Rosa] recommend that any information, including corrective actions or retrospective reviews conducted as a result of past deficiencies be shared with the inspection team or submitted as a post inspectional or update package."). The report of supplement review pertaining to liquid dose products was submitted to FDA on March 28, 2011. *See Exhibit C-231*, Letter from Apotex to FDA, dated March 28, 2011.

³⁷⁹ **Exhibit C-187a**, Apotex Priority List of 15 Products for PAIs.

³⁸⁰ **Exhibit C-193**, Etobicoke Form 483, dated February 11, 2011.

³⁸¹ **Exhibit C-194**, Signet Form 483, dated February 11, 2011.

³⁸² Witness Statement of Edmund Carey, para. 63.

³⁸³ **Exhibit C-196**, Apotex Quality Division, Change Control Document and US Re-Entry Product Assessment Protocol, dated February 24, 2011.

regulatory compliance. Each product was to be reintroduced into the US market only after meeting the requirements of the protocol.³⁸⁴

265. On March 1, 2011, Apotex-Canada submitted its response to the forms 483 issued on February 11, 2011 for Etobicoke and Signet.³⁸⁵ The cover letter enclosing Apotex's response outlined the firm's ambitious overhaul of all its quality systems since 2009.³⁸⁶ Apotex emphasized its intention to begin manufacturing for the US market as soon as possible.³⁸⁷ The firm also requested approval to release new products from Etobicoke and Signet upon regulatory approval (and under third party certification for Signet).³⁸⁸

G. FDA's Delay in Lifting the Import Alert

1. Etobicoke

266. After having reviewed Apotex's response of March 1, 2011, as well as the establishment inspection report (EIR), FDA notified Apotex-Canada on May 6, 2011 that the Etobicoke facility was classified as "acceptable."³⁸⁹ CDER-OC undertook to "forward copy of this correspondence to the Division of Import Operations and request that the current import alert for this facility be removed."³⁹⁰
267. On May 9, 2011, CDER-OC, Division of Manufacturing and Product Quality, International Compliance Branch transmitted its recommendation to DIOP to remove Etobicoke from Import Alert 66-40.³⁹¹

³⁸⁴ Witness Statement of Jeremy Desai, para. 92; Witness Statement of Edmund Carey, para. 64. *See also Exhibit C-197*, Letter from Apotex to FDA enclosing responses to Forms 483 for Signet and Etobicoke Facilities, at 10, dated March 1, 2011.

³⁸⁵ *Exhibit C-197*, Letter from Apotex to FDA, dated March 1, 2011.

³⁸⁶ *Id.*; *Exhibit C-230*, Executive Summary – Apotex Global Quality Systems Revitalization Corrective Action Plan (Apotex GQSR – CAP), appended to Letter from Apotex to FDA, dated March 1, 2011.

³⁸⁷ *Exhibit C-197*, Letter from Apotex, at 10, to FDA, dated March 1, 2011.

³⁸⁸ *Id.* at pp. 10-11.

³⁸⁹ *Exhibit C-233*, FDA Letter to Apotex, enclosing Establishment Inspection Report (EIR) for Etobicoke, dated May 6, 2011.

³⁹⁰ *Id.*

³⁹¹ *Exhibit C-234*, Memorandum from CDER-OC to DIOP, dated May 9, 2011.

268. On June 7, 2011, CDER-OC, Office of Drug Security, Integrity and Recalls Import Operations Branch also transmitted its recommendation to DIOP to remove Etobicoke from Import Alert 66-40.³⁹²
269. Eventually, on June 15, 2011 the Director of DIOP sent an email to the Import Program Managers formally requesting them to remove Etobicoke from Import Alert 66-40.³⁹³

2. *Signet*

270. On May 20, 2011, FDA requested additional information and clarification regarding Apotex's Signet facility.³⁹⁴
271. On June 10, 2011, Apotex submitted additional information and clarification related to Signet, in response to FDA's request.³⁹⁵
272. FDA also considered the results of Health Canada's inspection of Signet and Etobicoke in May-June 2011 before deciding to lift the Import Alert with respect to Signet.³⁹⁶
273. On July 1, 2011, FDA classified the Signet facility as "acceptable" and announced that it would request DIOP to remove Signet from Import Alert.³⁹⁷ On that same date, FDA issued a close out letter in relation to the Signet Warning Letter.³⁹⁸ CDER-OC, Office

³⁹² **Exhibit C-241**, Memorandum from CDER-OC to DIOP, dated June 7, 2011.

³⁹³ **Exhibit C-245**, Email from Director of DIOP to Import Program Managers, dated June 15, 2011.

³⁹⁴ **Exhibit C-237**, Letter from FDA to Apotex, dated May 20, 2011.

³⁹⁵ **Exhibit C-242**, Letter from Apotex to FDA, dated June 10, 2011.

³⁹⁶ Health Canada's inspection took place from May 16 to June 10, 2011. *See Exhibit C-244*, Apotex Internal Email Chain, Daily Reports of Health Canada's Inspection at Signet and Etobicoke, dated June 11, 2011. FDA had asked Health Canada to cover specific topics during the inspection. *See Exhibit C-238*, Health Canada's Contact Report for Inspection at Signet and Etobicoke, dated May 24, 2011 (Day # 5), p. 1, under the heading "Inspector Comments" ("AL AL [Inspector Anthony Lostracco] indicated that FDA has provided further clarity and requested for them to look into the following items ... "); **Exhibit C-243**, Health Canada's Contact Report for Inspection at Signet and Etobicoke, dated June 10, 2011 (Day # 16), p. 1, under the heading "Status of regulatory CAPA review", third bullet point ("Note: AL [Inspector Anthony Lostracco] was quite *amused* that one of the q-notes FDA asked him to f/u [focus] on was dealing with the brown cardboard particulate noted on the cap ... ") (emphasis in original).

³⁹⁷ **Exhibit C-247**, Letter from FDA to Apotex-Canada, enclosing Establishment Inspection Report (EIR) for Signet, dated July 1, 2011.

³⁹⁸ **Exhibit C-248**, Signet Close Out Letter, dated July 1, 2011. It should be noted that close out letters are issued for warning letters adopted *after* September 1, 2009. There was no such close out letter mechanism in place for warning letters pre-dating the September 1, 2009 cut-off date.

of Manufacturing and Product Quality, Division of International Drug Quality also recommended to DIOP to remove Signet from Import Alert 66-40.³⁹⁹

274. On July 8, 2011, CDER-OC, Import Operations Branch informed DIOP that it concurred with the removal of Signet from Import Alert.⁴⁰⁰
275. On July 29, 2011, the Director of DIOP emailed the Import Program Managers to formally request that Signet be removed from Import Alert 66-40.⁴⁰¹
276. In short, the Import Alert was not removed until June 15, 2011 for Etobicoke and July 29, 2011 for Signet.

H. FDA's Delay in Approving Pending ANDAs

277. As noted above, when Apotex requested the re-inspection of Etobicoke and Signet, it made clear on October 26, 2010 that this inspection should also include a pre-approval inspection (PAI) for new generic drug applications.⁴⁰²
278. Following CDER's recommendation to lift the Import Alert for Etobicoke in early May 2011, Apotex again requested approval of the pending applications for new drugs produced at that facility.⁴⁰³
279. However, FDA informed Apotex that the limited pre-approval coverage during the January-February 2011 inspection of Etobicoke did not allow FDA to recommend approval of the pending applications for this site.⁴⁰⁴ A PAI was still needed for

³⁹⁹ **Exhibit C-249**, Memorandum from Director of CDER-OC (Office of Manufacturing and Product Quality, Division of International Drug Quality) to DIOP, dated July 1, 2011.

⁴⁰⁰ **Exhibit C-250**, Memorandum from CDER-OC (Import Operations Branch) to DIOP, dated July 8, 2011.

⁴⁰¹ **Exhibit C-252**, Email from Director of DIOP to Import Program Managers, dated July 29, 2011.

⁴⁰² **Exhibit C-173**, Letter from Apotex to FDA, dated October 26, 2010.

⁴⁰³ **Exhibit C-235**, Letter from Apotex to FDA, dated May 9, 2011 (requesting PAI for 7 pending ANDAs, including 2 applications where Apotex was the first filer of a paragraph IV certification).

⁴⁰⁴ **Exhibit C-246**, Email from FDA to Apotex's Regulatory Counsel, dated June 29, 2011. *See also* **Exhibit C-236**, Email from FDA to Apotex re: ANDA [REDACTED], dated May 11, 2011 ("The PAI has not been completed by the Office of Compliance."); **Exhibit C-240**, Email from FDA to Apotex re: ANDA [REDACTED], dated June 3, 2011 ("preapproval inspections will be needed for pending applications.").

Etobicoke.⁴⁰⁵ At the time, FDA assured Apotex that it would expedite this pre-approval inspection.⁴⁰⁶

280. On August 15, 2011, despite its earlier undertakings, FDA informed Apotex that the PAI likely would not take place until January 2012.⁴⁰⁷ Apotex requested reconsideration of that decision, to no avail. As a result, on August 23, 2011, Apotex's regulatory counsel wrote FDA, FDA later that same day transmitted a notice of inspection for September 18 to 30, 2011.⁴⁰⁸
281. On August 25, 2011, Apotex-Canada requested a meeting with FDA in order to advance the approval of ANDAs.⁴⁰⁹ In Apotex's view, since the Etobicoke facility was declared cGMP-compliant in May 2011, there was no basis for FDA to fail to approve pending ANDAs out of that facility under the Act.⁴¹⁰
282. FDA conducted a pre-approval inspection at Etobicoke from September 19 to 28, 2011.⁴¹¹ A couple of observations were issued at the close of the inspection.⁴¹² Apotex submitted its response to these observations on October 12, 2011.⁴¹³

⁴⁰⁵ **Exhibit C-246**, Email from FDA to Apotex's Regulatory Counsel, dated June 29, 2011 ("A Pre-Approval Inspection will still be needed for the Etobicoke facility.").

⁴⁰⁶ *Id.* ("Although the agency has limited resources to inspect generic drug manufacturers for the remaining of FY' 2011, an effort will be made to prioritized [sic] a PAI inspection for the Etobicoke facility.").

⁴⁰⁷ Witness Statement of Bernice Tao, para. 76; Witness Statement of Edmund Carey, para. 72. *See also* **Exhibit C-255**, Letter from Apotex's Regulatory Counsel to FDA, dated August 25, 2011, p. 3.

⁴⁰⁸ **Exhibit C-254**, Email from FDA to Apotex, dated August 23, 2011 transmitting notice of Etobicoke inspection scheduled on September 18-30, 2011. Note that Apotex had requested a PAI for 18 pending ANDAs.

⁴⁰⁹ **Exhibit C-255**, Letter from Apotex's Regulatory Counsel to FDA, dated August 25, 2011, p. 1.

⁴¹⁰ *Id.* at p. 5.

⁴¹¹ **Exhibit C-257**, Apotex slides, "Apotex Welcomes U.S. Food and Drug Administration", dated September 19, 2011; **Exhibit C-258**, Apotex Internal Emails, dated September 20, 2011, attaching Contact Report for Day 1 of PAI Inspection at Etobicoke; **Exhibit C-259**, Apotex Internal Email, dated September 21, 2011, attaching Contact Report for Day 2 of PAI Inspection at Etobicoke; **Exhibit C-260**, Apotex Internal Email, dated September 22, 2011, attaching Contact Report for Day 3 of PAI Inspection at Etobicoke; **Exhibit C-261**, Apotex Internal Email, dated September 23, 2011, attaching Contact Report for Day 4 of PAI Inspection at Etobicoke; **Exhibit C-262**, Apotex Internal Email, dated September 23, 2011, attaching Contact Report for Day 5 of PAI Inspection at Etobicoke; **Exhibit C-263**, Apotex Internal Email, dated September 27, 2011, attaching Contact Report for Day 6 of PAI Inspection at Etobicoke; **Exhibit C-264**, Apotex Internal Email, dated September 28, 2011, attaching Contact Report for Day 7 of PAI Inspection at Etobicoke; **Exhibit C-266**, Apotex Internal Email, dated September 29, 2011, attaching Contact Report for Day 8 of PAI Inspection at Etobicoke.

⁴¹² **Exhibit C-265**, Etobicoke Form 483, dated September 28, 2011.

283. On October 17, 2011, Apotex informed FDA of the specific products for which it was seeking FDA's approval.⁴¹⁴
284. It was only on October 31, 2011 that FDA recommended approval of Apotex's pending applications for new generic drugs.⁴¹⁵ Subsequently, the applications had still to be reviewed by FDA on the basis of the Establishment Inspection Report (EIR) for Etobicoke, before FDA would finally approve any pending ANDAs. Again, FDA committed to "give this review the highest priority."⁴¹⁶
285. It was only on November 25, 2011 that FDA finally approved the first pending ANDA at Etobicoke, followed by approval on December 7 and 30, 2011 and February 3, 2010. However, FDA has still not approved the ANDA for [REDACTED] for [REDACTED].⁴¹⁷

X. THE EFFECT OF THE MEASURE ON APOTEX

286. The Import Alert had a devastating effect on Apotex Holdings, Apotex-Canada and their investments in the United States, including Apotex-US. As a result of the Import Alert, Apotex sustained substantial losses. These losses can be categorized under several headings.
287. **Profits lost during the Import Alert.** The Import Alert prevented Apotex-US from being able to supply to its customers the great bulk of the products it was contractually obligated to deliver and had a crippling effect on its sales. As an independent analysis by JP Morgan observed in May 2011: "Apotex, which had been the fifth largest US generic manufacturer prior to its import ban, has lost an average of 85% of its pre-ban TRx volume."⁴¹⁸ As a direct result of the Import Alert, by the first quarter of 2011

⁴¹³ **Exhibit C-268**, Letter from Apotex to FDA, dated October 12, 2011.

⁴¹⁴ **Exhibit C-269**, Email from Apotex to FDA, dated October 17, 2011 (attaching approval letter for Ferroprox).

⁴¹⁵ **Exhibit C-270**, Email from FDA to Apotex's Regulatory Counsel, dated October 30, 2011 ("We will be entering an approval recommendation for the applications specifically covered during the inspection, by NLT Monday (if not done already).").

⁴¹⁶ *Id.*

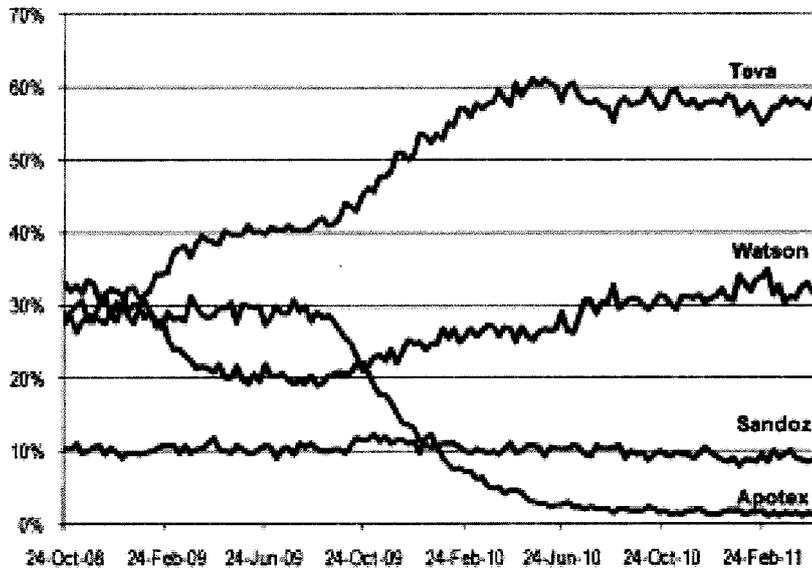
⁴¹⁷ Witness Statement of Bernice Tao, para. 79.

⁴¹⁸ **Exhibit C-236-a**, J.P. Morgan, "Generic Pharmaceuticals – Thoughts on Apotex's Return to Market", p. 1 (May 18, 2011).

Apotex-US had dropped from one of the top sellers of generic drugs to the 24th largest on the US market.⁴¹⁹

288. The following chart from the JP Morgan analysis⁴²⁰ illustrates well the impact of the Import Alert with respect to one generic drug, Cyclosporine:

Figure 7: Cyclosporine Market Share



Source: IMS Health, J.P. Morgan.

Before the Import Alert, Apotex-US held about 30% of the market, with Teva holding 40%, Watson 20% and Sandoz the remaining 10%. After the Import Alert, Apotex's market share plunged to near zero while Teva's and Watson's shares soared to 60% and 30% respectively.

289. The inevitable consequence of these lost sales was a loss of the profits that Apotex would otherwise have earned from those sales. As demonstrated in the accompanying expert report of Howard Rosen, Senior Managing Director of FTI Consulting, those lost profits amounted to hundreds of millions of dollars during the time of the Import Alert.

290. **Loss of goodwill and reputation.** Apart from the loss of sales and profits, Apotex-US lost an additional asset — its goodwill and reputation vis-à-vis its customers. In the

⁴¹⁹ Exhibit C-239, Top 25 Generic Manufacturers per IMS Medical Data, Q1 2011.

⁴²⁰ Exhibit C-236-a, J.P. Morgan, "Generic Pharmaceuticals – Thoughts on Apotex's Return to Market", p. 6 (May 18, 2011).

generic pharmaceutical business, the success of a pharmaceutical company is premised in significant part on its relationship with customers.⁴²¹ Disruption in product supply places the relationship in jeopardy. It causes the customer to take its business to another supplier and, consequently, causes the pharmaceutical company to lose the relationship and market share.⁴²² Once lost, that market share is not easily regained.⁴²³

291. **Lost profits incurred since the lifting of the import alert and future lost profits.** In addition to lost profits incurred during the Import Alert, Apotex has lost, and will continue to lose, further and future lost profits. As a result of being off the market for two years, Apotex-US has lost many customers and the reentry process has, so far, proved challenging. Its products could not be re-launched immediately after the lifting of the Import Alert.⁴²⁴ Having expended substantial financial and operational resources, Apotex has now re-launched some of its products. In the second quarter of 2012, Apotex-US's total share of the US generic drug market modestly climbed to 22nd place. This is an improvement but still far from where the company was before the Import Alert.⁴²⁵ These results are in line with JP Morgan's prediction in May 2011: "While we are not expecting Apotex to fully recapture its lost market share, we anticipate that the company will gradually regain a portion of prior volumes."⁴²⁶

Apotex-US also lost considerable momentum in developing its position on the US market. To put this in perspective, prior to the Import Alert, about [REDACTED] of Apotex-Canada's dosages (from Signet and Etobicoke) were sold in the US market per year.⁴²⁷ Based on market momentum and historical growth rates, Apotex anticipated that its annual US sales would grow to [REDACTED] to [REDACTED] in the medium-term.⁴²⁸ Instead, during

⁴²¹ Witness Statement of John Flinn, para. 32.

⁴²² Witness Statement of John Flinn, para. 41. *See also* Witness Statement of Gordon Fahner, para. 92.

⁴²³ Witness Statement of John Flinn, para. 43.

⁴²⁴ Witness Statement of Gordon Fahner, para. 93; Witness Statement of Jeremy Desai, para. 93.

⁴²⁵ Witness Statement of Jeremy Desai, para. 98; Witness Statement of John Flinn, para. 57; **Exhibit C-305**, Top 25 Generic Manufacturers per IMS Medical Data, Q2 2012.

⁴²⁶ **Exhibit C-236-a**, J.P. Morgan, "Generic Pharmaceuticals – Thoughts on Apotex's Return to Market", p. 1 (May 18, 2011).

⁴²⁷ Witness Statement of Jeremy Desai, para. 98; Witness Statement of Gord Fahner, para. 68; Witness Statement of John Flinn, para. 54.

⁴²⁸ Witness Statement of Jeremy Desai, para. 98.

the first 12 months following the Import Alert, Apotex-US sold in the US market less than [REDACTED] dosages from Etobicoke and Signet.⁴²⁹

292. **Loss of business opportunities with respect to new product launches.** Early entrants in the market for a new generic drug obtain an advantage that translates into increased market share, sales and profits. The Apotex group invests heavily in developing new product opportunities.⁴³⁰ As a result of the Import Alert, which caused FDA to suspend the approval of Apotex's ANDAs, Apotex-US could not launch in the US market a significant number of new products.⁴³¹ Apotex was thus prevented from capitalizing on its investments in ANDAs for these products and lost substantial profits associated with the expected new launches.⁴³²
293. **Significant out-of-pocket expenses.** As a result of the Import Alert, Apotex incurred substantial out-of-pocket expenses. Unable to supply its customers, Apotex-US had to pay contractual penalties to its customers for an "out-of-stock" position.⁴³³ Following recalls, Apotex-US became obligated to refund the price of the returned products and, also, incurred fees of its vendor that was administering the recall.
294. Apotex-Canada also had to destroy and write-off its inventory, such as finished products, semi-finished products and packaging materials. These products had to be

⁴²⁹ Witness Statement of John Flinn, para. 55.

⁴³⁰ Witness Statement of Gordon Fahner, para. 44.

⁴³¹ **Exhibit C-321**, List of Hindered Launches.

⁴³² Witness Statement of Gordon Fahner, para. 101.

⁴³³ *See, e.g., Exhibit C-43, [REDACTED] Group Purchasing Agreement – Pharmaceuticals, effective July 1, 2009, article 6.5 on Guarantee of Delivery (“... If Seller is unable to deliver any of the Products under this Agreement, the Participating Member may purchase therapeutically and generically equivalent replacement product(s) from another source(s) and Seller shall reimburse such member for the difference between such member’s actual F.O.B. destination costs for such product(s) and the price(s) such member would have paid for Seller’s Product(s) under this Agreement. If a therapeutically and generically equivalent product is not available in the U.S. market, Seller shall reimburse such member for the difference between such member’s actual F.O.B. destination acquisition cost for the brand equivalent product(s) and the price(s) such member would have paid for Seller’s Product(s) under this Agreement.”); Exhibit C-35, Letter from [REDACTED] to Apotex-US, dated January 15, 2009, [REDACTED] Generic Pharmaceuticals Business Standards effective September 1, 2007, section 13 on Warranty and Indemnification (similar provision).*

destroyed because Apotex-US was unable to distribute them due to the Import alert and their shelf life was relatively short.⁴³⁴

295. Furthermore, in its effort to lift the Import Alert, Apotex incurred substantial fees of legal and technical consultants.⁴³⁵ Because no process exists to effect an expeditious removal of an import alert, Apotex-Canada had no choice but to seek advice of reputable, yet expensive, consultants concerning possible ways to expedite a successful re-inspection by FDA.⁴³⁶

XI. FDA'S TREATMENT OF COMPARABLE INVESTORS AND INVESTMENTS

296. 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 and the ANDAs owned by Apotex-Canada, received more favorable treatment. The market included US investors in the pharmaceutical industry that owned ANDAs and sold drugs 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.

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

298. Sheldon T. Bradshaw and Ron M. Johnson have conducted a comprehensive review of FDA Warning Letters and enforcement actions for cGMP issues with finished drug products during the 2008 to 2011 period and presented their conclusions in an accompanying Expert Report.⁴³⁷ Mr. Bradshaw is currently a partner at a Washington law firm specializing in FDA regulation. He previously served as FDA Chief Counsel. In that capacity, he reviewed and cleared every significant Warning Letter issued by the

⁴³⁴ Witness Statement of Gordon Fahner, para. 104.

⁴³⁵ Witness Statement of Jeremy Desai, para. 95.

⁴³⁶ Witness Statement of Jeremy Desai, para. 95.

⁴³⁷ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 105-109.

FDA in his tenure, and advised on enforcement actions.⁴³⁸ Mr. Johnson is a consultant specializing in cGMP requirements for pharmaceutical and medical device companies. Earlier in his career, Mr. Johnson served as Director of the Pacific Region for FDA, where he oversaw the operations of FDA's three largest district offices, including its largest import office. He also served as Director of Compliance for the FDA Center for Medical Devices and Radiological Health, where he oversaw FDA enforcement action for medical devices.⁴³⁹ Together, they bring to bear vast experience on the context and practice of FDA regulation of manufacturing practices for finished drug products, Warning Letters and enforcement action.

299. As Messrs. Bradshaw and Johnson conclude, FDA inspected the facilities of these comparable investors and investments and found cGMP violations similar in significance 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.

300. As demonstrated below, each of the principal comparators addressed by Messrs. Bradshaw and Johnson qualifies as a US investor, a third-country investor, or an investment owned or controlled, directly or indirectly, by such an investor. As also demonstrated below, FDA accorded each of the comparators treatment that differed materially from that accorded to Apotex and its investments.

A. Baxter International and Baxter Healthcare

301. As observed by Messrs. Bradshaw and Johnson, Baxter International Inc. "is a global diversified healthcare company producing products for the medical device, pharmaceutical, and biotechnology markets."⁴⁴⁰ Baxter International Inc. is a company organized under the laws of the United States and its shares are publicly traded on the New York Stock Exchange.⁴⁴¹ Baxter International is a holding company and an

⁴³⁸ *Id.*, paras. 7-9.

⁴³⁹ *Id.*, paras. 15-18.

⁴⁴⁰ Bradshaw-Johnson Report, para. 106.

⁴⁴¹ **Exhibit C-292**, Baxter Int'l Inc., Annual Report (Form 10-K) 1 (Feb. 23, 2012).

investor in the businesses it owns; the company itself “does not price, sell, distribute, or market any drugs or therapies.”⁴⁴²

302. Its wholly owned subsidiary Baxter Healthcare Corporation is a company incorporated in the United States.⁴⁴³ Like Apotex-US, Baxter Healthcare Corporation sells finished drug products for human use, notably those related to blood-related therapies, medication delivery, and renal therapy.⁴⁴⁴ Baxter Healthcare Corporation and its divisions own in excess of 100 ANDAs.⁴⁴⁵
303. As observed by Messrs. Bradshaw and Johnson, “Baxter Healthcare has a chronic corporate-wide history of serious FDA violations during the period 1997 to 2011. Baxter has received at least 21 Warning Letters addressing significant violations at multiple business units and facilities.”⁴⁴⁶
304. In 2010, FDA inspected two Baxter Healthcare facilities in Puerto Rico: one in Jayuya (from July 14 to August 26, 2010) and another in Guayama (from September 21 through 30, 2010).⁴⁴⁷ The inspections identified significant cGMP violations.
305. On January 20, 2011, after review and approval by CDER, FDA issued a Warning Letter to Baxter Healthcare Corporation citing the cGMP violations found at both

⁴⁴² **Legal Authority CLA-116**, Answer and Affirmative Defenses of Baxter Int’l Inc. to Revised First Am. Consol. Compl., para. 51, *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 4806286 (D. Mass. Oct. 5, 2007).

⁴⁴³ **Exhibit C-292**, Baxter Int’l Inc., Annual Report (Form 10-K) Exhibit 21 (Feb. 23, 2012); **Legal Authority CLA-133**, Corporate Disclosure Statement, *Griswell v. Baxter Healthcare Corp.*, No. 5:10CV174(HL) (M.D. Ga. Apr. 28, 2010). *See also Legal Authority CLA-115*, Answer and Affirmative Defenses of Baxter Healthcare Corp. to Revised First Am. Consol. Compl. at para. 51, *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 4806286 (D. Mass. Oct. 5, 2007) (“Baxter Healthcare Corporation is the principal domestic operating subsidiary of Baxter International Inc....”).

⁴⁴⁴ **Legal Authority CLA-116**, Answer and Affirmative Defenses of Baxter Int’l Inc. to Revised First Am. Consol. Compl. at para. 51, *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 4806286 (D. Mass. Oct. 5, 2007). *See also Legal Authority CLA-115*, Answer and Affirmative Defenses of Baxter Healthcare Corp. to Revised First Am. Consol. Compl. at para. 51, *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 4806286 (D. Mass. Oct. 5, 2007).

⁴⁴⁵ **Exhibit C-281**, Ctr. for Drug Eval. and Res., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) B28-B32 (32nd ed. 2012); **Exhibit C-307**, FDA Electronic Drug Information Database Drugs@FDA, <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079750.htm#download> (follow “Drugs@FDA Download File” hyperlink, then search “Application” file) (ANDAs held by Baxter Healthcare indicated by the letter “A” for ANDA, as opposed to “N” for NDA).

⁴⁴⁶ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 113.

⁴⁴⁷ *Id.*, para. 114.

sites.⁴⁴⁸ The Warning Letter “pointed out the fact that some of the violations represented repeat findings from a previous 2008 inspection”⁴⁴⁹ As the Warning Letter noted, FDA had waited to review the company’s written responses to the inspectional findings before issuing the Warning Letter.⁴⁵⁰

306. Less than six months later, on July 14, 2011, FDA issued a close-out letter lifting the Warning Letter.⁴⁵¹

307. Messrs. Bradshaw and Johnson conclude as follows concerning this comparator:

In spite of a long corporate-wide history of serious non-compliance reflected by the 21 Warning Letters issued to Baxter Healthcare and in spite of the instant example of serious violations at two more Baxter-owned Puerto Rican facilities, FDA issued yet another Warning Letter to the CEO of Baxter. The Puerto Rican facilities were permitted to operate unabated while making corrections. FDA acknowledged in the Warning Letter that some violations at the Puerto Rican facilities persisted since 2008 indicating the continuing violative conduct of the facility as well as the corporate entity. Moreover, FDA apparently conducted timely inspections of both facilities leading to a Close Out Letter being promptly issued six months after issuance of the Warning Letter.

Unlike Apotex, FDA has permitted Baxter to operate multiple facilities with ongoing serious violations for many years without FDA sanctions or interference. In spite of Baxter’s history, FDA did not take enforcement action when its inspections of Baxter’s Puerto Rican facilities once again confirmed its chronic non-compliant history.⁴⁵²

⁴⁴⁸ **Exhibit C-189**, Baxter Healthcare Corp., FDA Warning Letter 11-SJN-WL-04 (Jan. 20, 2011).

⁴⁴⁹ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 115.

⁴⁵⁰ Exhibit C-189, Baxter Healthcare Corp., FDA Warning Letter 11-SJN-WL-04, p. 1 (Jan. 20, 2011). Baxter Healthcare Corporation owns or controls all of the ANDAs mentioned in the Warning Letter of January 20, 2011. See **Exhibit C-281**, Ctr. for Drug Eval. and Res., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) B31-B32 (32nd ed. 2012) (indicating Baxter Healthcare Corporation as ANDA holder for Sodium Chloride); **Exhibit C-311**, Ctr. for Drug Eval. and Res., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book), Electronic Orange Book (indicating Baxter Healthcare Corporation as ANDA holder for Clinisol).

⁴⁵¹ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 116.

⁴⁵² *Id.*, paras. 117-118 (paragraph numbers omitted).

B. Hospira

308. As noted in the Bradshaw-Johnson Report, “Hospira, Inc. is a pharmaceutical and medication delivery company that develops, manufactures, and markets healthcare products such as generic acute-care and oncology injectables, integrated infusion therapy, and medication management systems.”⁴⁵³ Hospira, Inc. is a company incorporated in the United States and its shares are publicly traded on the New York Stock Exchange.⁴⁵⁴
309. Like Apotex-US, Hospira, Inc., directly or through its US subsidiaries, sells finished drug products for human use, notably those related to generic acute-care and oncology injectables, integrated infusion therapy, and medication management products.⁴⁵⁵ Hospira, Inc. owns in excess of 300 ANDAs.⁴⁵⁶
310. In 2010, FDA inspected two Hospira facilities in North Carolina, United States: one in Rocky Mount (from January 12 through 19, 2010) and another in Clayton (from January 26 to February 23, 2010).⁴⁵⁷
311. On April 12, 2010, after approval by CDER, FDA issued a Warning Letter citing serious cGMP violations observed at the Clayton and Rocky Mount facilities.⁴⁵⁸ The

⁴⁵³ *Id.*, para. 123.

⁴⁵⁴ **Exhibit C-195**, Hospira, Inc., Annual Report (Form 10-K) 1 (Feb. 16, 2011).

⁴⁵⁵ *Id.* See also **Legal Authority CLA-206**, *Xie v. Hospira, Inc.*, No. 10C6777, 2011 WL 1575530, at *1 (N.D. Ill. Apr. 27, 2011) (“Hospira is an Illinois-based corporation that develops, manufactures, and sells medical delivery systems, pharmaceuticals, and other medical devices.”). See also **Exhibit C-290**, Hospira’s Dear Healthcare Professional Letter (Feb. 2012). (“Due to the current critical shortage of Methotrexate Injection, USP 1g/40mL (25 mg/mL) (Preservative-Free) in the United States (US) market, Hospira, Inc. ... has initiated temporary importation into the US market of a non-US-approved product, Methotrexate Injection...from Hospira Healthcare Corporation, Canada. Hospira Healthcare Corporation, Canada has appointed Hospira, Inc., as their distributor of this product in the US.”). See also **Exhibit C-195**, Hospira, Inc., Annual Report (Form 10-K) Exhibit 21.1 (Feb. 16, 2011) (list of Hospira, Inc.’s US subsidiaries).

⁴⁵⁶ **Exhibit C-285**, Ctr. for Drug Eval. and Res., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) B62-B67 (32nd ed. 2012); **Exhibit C-307**, FDA Electronic Drug Information Database <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079750.htm#download> (follow “Drugs@FDA Download File” hyperlink, then search “Application” file) (ANDAs held by Hospira, Inc.; some indicating only “Hospira” as registered owner).

⁴⁵⁷ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 126.

⁴⁵⁸ **Exhibit C-143**, Hospira, Inc., FDA Warning Letter 10-ATL-12 (Apr. 12, 2010). See also Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 126 (“FDA’s documented history of chronic serious cGMP violations at Hospira’s drug manufacturing facilities was again confirmed during FDA inspections” of these two facilities.). Hospira, Inc. owns or controls all ANDAs mentioned in the Warning Letter of

Warning Letter recalled “the long violative history of the Clayton facility which had resulted in numerous recalls of injectable drug products contaminated with metal particles”.⁴⁵⁹ In relation to the Rocky Mount facility, the Warning Letter noted “the facility’s long history of noncompliance”.⁴⁶⁰

312. As further noted by Messrs. Bradshaw and Johnson, “[t]he Warning Letter was addressed to the CEO of Hospira indicating FDA’s concern that the violations at two different facilities represented the need for a corporate solution.”⁴⁶¹ However, despite the serious violations and consistent violative conduct FDA has taken no enforcement action.⁴⁶²

313. Messrs. Bradshaw and Johnson conclude as follows:

Hospira has operated its Clayton and Rocky Mount facilities in serious violation of cGMPs and, as a result, has distributed contaminated and adulterated drug products into the U.S. marketplace even causing FDA to issue a public health advisory. Nevertheless, FDA has permitted Hospira to continue to operate its facilities without FDA intervention. Hospira has been permitted by FDA to operate these two facilities as well as others in violation for many years without interruption or interference. The manner in which FDA has addressed Hospira’s egregious violative conduct pales in comparison to the aggressive action it took against Apotex.⁴⁶³

C. Perrigo and L. Perrigo

314. The Bradshaw-Johnson Report describes Perrigo Company as “a global company engaged in the development, manufacture, and distribution of OTC and prescription generic pharmaceuticals, infant formulas, nutritional products, active pharmaceutical ingredients (API), and diagnostic products.”⁴⁶⁴ Perrigo Company is organized under the

April 12, 2010. See **Exhibit C-285**, Ctr. for Drug Eval. and Res., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) B62-B67 (32nd ed. 2012) (indicating Hospira, Inc. as ANDA’ holder for Propofol, Amikacin, Droperidol, Heparin Sodium and Fosphenytoin Sodium).

⁴⁵⁹ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 128.

⁴⁶⁰ *Id.* 129.

⁴⁶¹ *Id.* para. 133.

⁴⁶² *Id.*, para. 134.

⁴⁶³ *Id.*, para. 134.

⁴⁶⁴ *Id.*, para. 120.

laws of the United States and its shares are publicly traded on the NASDAQ exchange.⁴⁶⁵

315. Perrigo Company's wholly owned subsidiary L. Perrigo Company is organized under the laws of the United States.⁴⁶⁶ Like Apotex-US, L. Perrigo Company, and Perrigo Company's other US subsidiaries sell finished drug products for human use, notably over-the-counter and generic prescription pharmaceuticals, including those manufactured by Perrigo Company's subsidiaries in third countries.⁴⁶⁷ Perrigo Company, L. Perrigo Company and other US subsidiaries of the group own in excess of 100 ANDAs.⁴⁶⁸
316. FDA inspected L. Perrigo Company's facility located in Allegan, Michigan from November 17 to January 14, 2010.⁴⁶⁹ This inspection identified numerous cGMP violations.
317. On April 29, 2010, after review and approval by CDER, FDA issued a Warning Letter to L. Perrigo Company, identifying significant cGMP violations.⁴⁷⁰ As the Warning

⁴⁶⁵ **Exhibit C-164**, Perrigo Co., Annual Report (Form 10-K) 1 (Aug. 12, 2010).

⁴⁶⁶ *Id.*, **Exhibit 21**. See also **Legal Authority CLA-146**, Local Rule 103.3 Disclosure of Def. Perrigo Co.'s Affiliations and Financial Interests, *Dunston v. Perrigo Co.*, No. 1:06CV01732(JFM) (D. Md. July 17, 2006); **Legal Authority CLA-145**, Disclosure of Corporate Affiliations and Financial Interest, *Brown v. Perrigo Pharm. Co.*, No. 1:11CV727 (W.D. Mich. Sept. 13, 2011).

⁴⁶⁷ **Exhibit C-164**, Perrigo Co., Annual Report (Form 10-K) 1 (Aug. 12, 2010) ("Perrigo Company...is a leading global healthcare supplier that develops, manufactures and distributes over-the-counter (OTC) and generic prescription (Rx) pharmaceuticals.... Perrigo Company operates through several wholly owned subsidiaries. In the U.S., its operations are conducted primarily through L. Perrigo Company [and several other subsidiaries]."). See also **Legal Authority CLA-174**, *Pfizer Inc. v. Perrigo Co.*, 903 F. Supp. 14, 15-16 (S.D.N.Y. 1995); **Legal Authority CLA-141**, Defendants Perrigo Co. and Perrigo Israel Pharmaceuticals Ltd.'s Answer, Affirmative Defenses and Counterclaims, *Alcon Pharmaceuticals, Ltd. v. Perrigo Co.*, No. 4:11-cv-00732-Y-TRM, at p. 3 (N.D. Tex. Mar. 23, 2012) (showing that Perrigo Israel Pharmaceuticals Ltd. manufactures generic drugs for sale and use in the United States); **Exhibit C-309**, Mesalamine Kit, website DailyMed at <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=34262> (showing that the drug has been manufactured by Perrigo, Israel and distributed in the US by Perrigo New York Inc.).

⁴⁶⁸ **Exhibit C-282**, Ctr. for Drug Eval. and Res., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) B100-B101 (32nd ed. 2012); **Exhibit C-307**, FDA Electronic Drug Information Database Drugs@FDA, <http://www.fda.gov/Drugs/InformationOnDrugs/-ucm079750.htm#download> (follow "Drugs@FDA Download File" hyperlink, then search "Application" file) (indicating ANDAs held by L. Perrigo Company and other Perrigo Company's US subsidiaries, some being registered only in the name "Perrigo").

⁴⁶⁹ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 121.

⁴⁷⁰ **Exhibit C-146**, L. Perrigo Co., FDA Warning Letter 2010-DT-11 (Apr. 29, 2010). L. Perrigo Company owns or controls all of the ANDAs mentioned in the Warning Letter of April 29, 2010. **Exhibit C-282**, Ctr. for Drug Eval. and Res., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the

Letter noted, some of the cGMP violations included ones that had led directly to the release of contaminated drug products to the US market.⁴⁷¹ The Warning Letter also remarked “the chronic nature of the company’s violative conduct that had also previously resulted in the distribution of illegal products”.⁴⁷²

318. On May 9, 2011, FDA issued to L. Perrigo Company a close-out letter lifting the Warning Letter.⁴⁷³

319. Messrs. Bradshaw and Johnson conclude as follows concerning this comparator:

In spite of FDA’s awareness of a lengthy history of violative cGMP compliance documented in multiple FDA inspections since 1998 and the distribution of contaminated and misbranded products, FDA took no action to interrupt the operations of the company. FDA’s belated Warning Letter issued in 2010 did not prevent the company from continuing business as usual. Ultimately, FDA issued a Close Out letter on May 9, 2011. By contrast, 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”.⁴⁷⁴

D. Sandoz and Novartis

320. The Bradshaw-Johnson Report describes Novartis AG as the holding company for a group “engaged in the research, development, manufacture, and marketing of branded drugs, generic pharmaceutical products, preventive vaccines, diagnostic tools, and consumer health products.”⁴⁷⁵ Novartis AG is a company organized under the laws of

Orange Book) B101 (32nd ed. 2012) (indicating L. Perrigo Company as ANDA holder for Ibuprofen). *See also Exhibit C-128*, FDA Enforcement Report (Feb. 17, 2010) (showing that recalling firm for Milk of Magnesia is L. Perrigo Company); Exhibit C-128, FDA Enforcement Report Definitions, *available at* <http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm181313.htm> (indicating that recalling firm is “[t]he firm that initiates a recall or, in the case of an FDA requested recall or FDA Mandated recall, the firm that has primary responsibility for the manufacture and (or) marketing of the product to be recalled.”); Exhibit C-13, Press Release, Perrigo Co., Perrigo Co. Announces Approval for Orange Ibuprofen Tablets (June 24, 2005), *available at* <http://www.prnewswire.com/news-releases/perrigo-company-announces-approval-for-orange-ibuprofen-tablets-54912292.html> (indicating that it had received FDA approval for manufacturing and marketing of Orange Ibuprofen Tablets).

⁴⁷¹ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 123.

⁴⁷² *Id.*, para. 123.

⁴⁷³ *Id.*, para. 124.

⁴⁷⁴ *Id.*, para. 124.

⁴⁷⁵ *Id.*, para. 135.

Switzerland and its American Depository Shares are publicly traded on the New York Stock Exchange.⁴⁷⁶ Novartis AG is a holding company “that has no offices, facilities or bank accounts in the United States, and which does not manufacture, market or sell any of the pharmaceutical products”⁴⁷⁷

321. The Bradshaw-Johnson Report also observes that “Sandoz International GmbH (Sandoz) is the generic business division of Novartis” that is “engaged in the development, manufacture and marketing of generic medicines as well as pharmaceutical and biotechnological active ingredients.”⁴⁷⁸

322. Sandoz Inc. is part of the Sandoz division of the Novartis group of companies.⁴⁷⁹ Novartis AG is the indirect and ultimate parent company of Sandoz Inc., a company incorporated in the United States.⁴⁸⁰ Like Apotex-US, Sandoz Inc. and other Novartis group US subsidiaries sell drug products for human use, notably generic drugs.⁴⁸¹

⁴⁷⁶ See **Exhibit C-288**, Novartis AG, Annual Report (Form 20-F) 1 (Jan. 25, 2012). See also **Legal Authority CLA-150**, Fed. R. Civ. P. 7.1 Disclosure Statement, *Hospira, Inc. v. Sandoz Int’l GmbH*, No. 3:09CV04591(MLC)(TJB) (D.N.J. July 1, 2010).

⁴⁷⁷ See **Legal Authority CLA-139**, Def. Novartis AG’s Reply Mem. of Law in Further Supp. of Its Mot. to Dismiss at 5, *United States v. Novartis AG*, No. 1:04CV04265, 2010 WL 4088542 at * 4 (E.D.N.Y. 2010) (“NAG [Novartis AG] is a Swiss holding company that has no offices, facilities or bank accounts in the United States, and which does not manufacture, market or sell any of the pharmaceutical products in this case.”).

⁴⁷⁸ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 135.

⁴⁷⁹ **Exhibit C-288**, Novartis AG, Annual Report (Form 20-F) 10 (Jan. 25, 2012).

⁴⁸⁰ **Legal Authority CLA-142**, Def. Sandoz Inc.’s Corporate Disclosure Statement, *Washburn v. Johnson & Johnson*, No. 1:11CV12012(WGY) (D. Mass. Feb. 3, 2012). See also **Exhibit C-288**, Novartis AG, Annual Report (Form 20-F) 1, F-95 (Jan. 25, 2012). According to the recently filed Corporate Disclosure Statement, Sandoz Inc. is a direct subsidiary of Novartis Finance Corporation, a company organized under the laws of the United States.

⁴⁸¹ **Legal Authority CLA-180**, *Sandoz Inc. v. Pfizer, Inc.*, No. 09-cv-02457-CMA-MJW (2010 WL 502727) 4 (D. Colo. Feb. 8, 2010). See also **Legal Authority CLA-121**, *Aventis Pharma S.A. v. Sandoz Inc.*, No. 06-3671 (MLC) (2007 WL 1101228), at * 1 (D.N.J. Apr. 10, 2007). See also **Legal Authority CLA-139**, Def. Novartis AG’s Reply Mem. of Law in Further Supp. of Its Mot. to Dismiss at 5, *United States v. Novartis AG*, No. 1:04CV04265, 2010 WL 4088542, at * 5 (E.D.N.Y. 2010) (“NAG [Novartis AG] is merely ‘a holding company that manages its investments’, while its subsidiary NPC [Novartis Pharmaceuticals Corporation] is engaged in the manufacture and distribution of pharmaceuticals. ‘Since [NPC and NAG’s other] subsidiaries carry out their own businesses, and not the investment business of [NAG], the subsidiaries cannot be deemed the agents of [NAG].’”) (quoting *Gallelli v. Crown Imports, LLC*, 701 F. Supp. 2d 263, 274 (E.D.N.Y. 2010)); **Legal Authority CLA-140**, Def. Novartis Pharmaceuticals Corporation’s Corporate Disclosure Statement, *Maria C. Ibarra v. Novartis Pharmaceuticals Corporation*, No. 1:10-CV-4827-JFK (S.D. NY Jul. 19, 2010).

323. Sandoz Inc. and/or other companies in the Sandoz division own in excess of 600 ANDAs.⁴⁸²
324. In 2011, FDA inspected three different facilities of Novartis AG's Sandoz division as follows: (i) April 19 to May 6, 2011 – Sandoz Inc.'s facility in Broomfield, Colorado; (ii) June 6 to 22, 2011 – Sandoz Inc.'s facility in Wilson, North Carolina; and (iii) July 26 to August 4, 2011 – Sandoz Canada Inc.'s facility in Boucherville, Quebec, Canada. As noted by Messrs. Bradshaw and Johnson, “[a] coordinated approach such as this is commonly taken by FDA when it suspects that the corporate entity is not providing sufficient oversight and control of the state of compliance at its businesses/facilities, i.e. when FDA takes a corporate view of a perceived issue.”⁴⁸³
325. FDA issued a “corporate” Warning Letter on November 18, 2011, addressing serious cGMP violations at all three manufacturing facilities.⁴⁸⁴ In its Warning Letter “FDA pointed out the repeat nature of the violations cited and specifically noted that all of the findings cited from the Canadian facility were repeats.”⁴⁸⁵ The Warning Letter further instructed the company to contact FDA and arrange for a meeting.⁴⁸⁶
326. Messrs. Bradshaw and Johnson conclude as follows concerning this comparator:

The corporate nature of the problems and FDA's unusual request to meet with FDA indicate a high level of concern by FDA. Nonetheless, FDA did not issue a DWPE for the Canadian facility and has taken no enforcement action

⁴⁸² **Exhibit C-284**, Ctr. for Drug Eval. and Res., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) B113-B117 (32nd ed. 2012); **Exhibit C-307**, FDA Electronic Drug Information Database Drugs@FDA, <http://www.fda.gov/Drugs/InformationOnDrugs/-ucm079750.htm#download> (follow “Drugs@FDA Download File” hyperlink, then search “Application” file) (ANDAs held by Sandoz Inc., with many registered under the name “Sandoz”).

⁴⁸³ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 137.

⁴⁸⁴ **Exhibit C-273**, Novartis International AG, FDA Warning Letter 320-12-05 (Nov. 18, 2011). *See also* **Exhibit C-32**, issued to Sandoz Inc., FDA Warning Letter 08-ATL-13 (Aug. 12, 2008). Sandoz Inc. owns or controls the ANDA mentioned in the Warning Letter of November 18, 2011 and all but one ANDA mentioned in the Warning Letter of August 12, 2008. *See* **Exhibit C-284**, Ctr. for Drug Eval. and Res., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) B114-B117 (32nd ed. 2012) (indicating Sandoz Inc. as ANDA holder for Triamterene Hydrochlorothiazide, Metoprolol Succinate, Alprazolam, Orphenadrine Citrate, Clarithromycin, Doxycycline, Lisinopril, Azithromycin, Anagrelide Hydrochloride).

⁴⁸⁵ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 139.

⁴⁸⁶ **Exhibit C-273**, Novartis International AG, FDA Warning Letter 320-12-05, p. 4 (Nov. 18, 2011).

against it or either of the domestic facilities. The company is not on FDA's current DWPE list and it is unlikely that a DWPE implemented earlier could have been resolved by now... FDA's inaction in addressing the chronic and documented ongoing, corporate-wide non-compliance of Novartis Sandoz is in stark contrast to its treatment of Apotex.⁴⁸⁷

E. Teva Pharmaceutical Industries and Teva Parenteral Medicines

327. As observed in Bradshaw-Johnson Report, Teva Pharmaceutical Industries Limited "is the world's leading generic pharmaceutical company and the leading provider of generics to the U.S. market. Teva ... is engaged in the development, production, and marketing of generic pharmaceuticals, as well as proprietary branded pharmaceuticals and active pharmaceutical ingredients."⁴⁸⁸ Teva Pharmaceutical Industries Limited is a company organized under the laws of Israel and its American Depository Shares are publicly traded on the NASDAQ exchange.⁴⁸⁹
328. Teva Pharmaceuticals USA, Inc. is a company incorporated in the United States and is Teva Pharmaceutical Industries Ltd.'s "principal U.S. subsidiary".⁴⁹⁰ In its turn, Teva Parenteral Medicines, Inc. is a subsidiary of Teva Pharmaceuticals USA, Inc.⁴⁹¹ Teva Parenteral Medicines, Inc. is also a company incorporated in the United States.⁴⁹²
329. Like Apotex-US, Teva Parenteral Medicines, Inc. sells finished drug products for human use, notably those related to sterile injectable pharmaceuticals.⁴⁹³ Teva

⁴⁸⁷ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 140-141 (paragraph numbers omitted).

⁴⁸⁸ *Id.*, para. 142.

⁴⁸⁹ See **Exhibit C-129**, Teva Pharmaceutical Industries Limited Annual Report (Form 20-F) 1 (Feb 22, 2010).

⁴⁹⁰ **Exhibit C-129**, Teva Pharmaceutical Industries Limited Annual Report (Form 20-F) 18 (Feb 22, 2010) ("Our principal U.S. subsidiary, Teva Pharmaceuticals USA, Inc., is the leading generic drug company in the U.S. We market over 400 generic products in more than 1,300 dosage strengths and packaging sizes.").

⁴⁹¹ **Legal Authority CLA-188**, Statement of Teva Parenteral Meds., Inc. Pursuant to Federal Rule 7.1(a), *Abbott Labs. v. Teva Parenteral Meds., Inc.*, No. 09CV00884(GMS) (D. Del. Jan. 5, 2010). See also **Legal Authority CLA-187**, Statement of Defs. Teva Parenteral Meds., Inc. and Teva Pharm. USA, Inc. Pursuant to Federal Rule 7.1(a), *Cubist Pharm., Inc. v. Teva Parenteral Meds., Inc.*, No. 09-189-GMS (D. Del. Apr. 15, 2009).

⁴⁹² **Legal Authority CLA-188**, Statement of Teva Parenteral Meds., Inc. Pursuant to Federal Rule 7.1(a), *Abbott Labs. v. Teva Parenteral Meds., Inc.*, No. 09CV00884(GMS) (D. Del. Jan. 5, 2010) (stating Teva Parenteral Medicines, Inc. is a "Delaware corporation").

⁴⁹³ **Exhibit C-310**, *Our Products*, Teva North America website, <http://www.tevapharm-na.com/Our-Business/Teva-USA.aspx>.

Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc. and/or Teva Parenteral Medicines, Inc. own in excess of 600 ANDAs.⁴⁹⁴

330. FDA inspected Teva Parenteral Medicines, Inc.'s facility in Irvine, California from July 13 through 24, 2009.⁴⁹⁵ A subsequent Warning Letter, approved by CDER and issued by FDA on December 11, 2009, cited numerous cGMP violations.⁴⁹⁶ The Warning Letter pointed out that such "cGMP violations related to the serious issue of endotoxin contamination of injectable drugs".⁴⁹⁷
331. In 2010, FDA inspected Teva Pharmaceutical Industries Limited's Jerusalem, Israel facility (from September 12 through 16, 2010).⁴⁹⁸ After this FDA inspection, the company initiated several recalls, while "the major recall due to cGMP non-compliance was an 'FDA initiated' recall", which usually reflects "the unwillingness of a company to conduct a recall".⁴⁹⁹
332. On January 31, 2011, a Warning Letter was issued to the Israeli site, citing various significant cGMP violations.⁵⁰⁰ The Warning Letter acknowledged that FDA reviewed and evaluated the company's response to inspectional findings before issuing the Warning Letter.⁵⁰¹

⁴⁹⁴ **Exhibit C-283**, Ctr. for Drug Eval. and Res., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) B128-B133 (32nd ed. 2012); **Exhibit C-307**, FDA Electronic Drug Information Database Drugs@FDA, <http://www.fda.gov/Drugs/InformationOnDrugs/-ucm079750.htm#download> (follow "Drugs@FDA Download File" hyperlink, then search "Application" file) (ANDAs held by Teva Pharmaceuticals USA, Inc. and Teva Parenteral Medicines, Inc., as well as a large number registered in the names of "Teva Pharms" or "Teva").

⁴⁹⁵ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 143.

⁴⁹⁶ **Exhibit C-124**, Teva Parenteral Medicines, Inc., FDA Warning Letter 05-10 (Dec. 11, 2009). Teva Parenteral Medicines, Inc. owns and controls the ANDA mentioned in the Warning Letter of December 11, 2009. See **Exhibit C-283**, Ctr. for Drug Eval. and Res., FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book) B131 (32nd ed. 2012) (indicating Teva Parenteral Medicines, Inc. as ANDA holder for Propofol).

⁴⁹⁷ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 143.

⁴⁹⁸ *Id.*, para. 144.

⁴⁹⁹ *Id.*, para. 144.

⁵⁰⁰ **Exhibit C-191**, Teva Pharmaceutical Industries Limited, FDA Warning Letter 320-11-008 (Jan 31, 2011).

⁵⁰¹ *Id.*, p. 1.

333. As noted by Messrs. Bradshaw and Johnson, “[i]n spite of these serious concerns, FDA did not implement a DWPE [(Import Alert)].”⁵⁰² Seven months later, on September 9, 2011, FDA issued a close-out letter lifting the Warning Letter for the Israeli facility.⁵⁰³

334. Messrs. Bradshaw and Johnson conclude as follows concerning this comparator:

FDA did not take a “corporate” view of the company’s cGMP compliance. Even though FDA had issued a Warning Letter to Teva’s Irvine facility, it issued a second Warning Letter to Teva’s Israeli site 13 months later. GMP issues directly impacted product on the US market requiring numerous recalls (some of which were FDA initiated) of products produced by both facilities. Beyond the Warning Letters to both sites, FDA has not initiated any further administrative action against the Israeli site, i.e. DWPE, or enforcement action, i.e. seizure/injunction, against the Irvine, CA facility.⁵⁰⁴

STATEMENT OF THE LAW

I. THE TRIBUNAL HAS JURISDICTION TO DECIDE THESE CLAIMS

335. The Tribunal has jurisdiction over this dispute. Each of the requirements of jurisdiction – *rationae personae, materiae* and *temporis* – is amply satisfied on this record.

A. The Tribunal Has Jurisdiction over the Parties

336. Articles 1116(1) and 1117(1) of the NAFTA permit an investor of a Party to bring a claim itself, or on behalf of an enterprise of another Party that is a juridical person that

⁵⁰² Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 145.

⁵⁰³ *Id.*, para. 146.

⁵⁰⁴ *Id.*, para. 146. The examples provided in the text are illustrative rather than exhaustive. For example, on February 5, 2009 FDA issued a Warning Letter to Taro Pharmaceuticals U.S.A., Inc., a US company owned by Taro Pharmaceutical Industries Ltd., which in turn is an Israeli company publicly traded on the New York Stock Exchange. See **Exhibit C-306**, Taro Pharmaceutical Industries Ltd., Excerpts from Annual Report (Form 20-F) 1, F-10 (Jun. 28, 2012). The Warning Letter cited multiple serious cGMP deficiencies at a Taro facility in Canada that produces finished drug products. See **Exhibit C-37-a**, Warning Letter issued to Taro Pharmaceuticals U.S.A., Inc. (Feb. 5, 2009). FDA took no enforcement action with respect to the significant cGMP violations it found. In May 2009, after the issuance of the Warning Letter, FDA approved “one new product made at the Company’s Canadian facility”. See **Exhibit C-246-a**, Taro Pharmaceutical Industries Ltd., Excerpts from Annual Report (Form 20-F) F-11 (June, 29, 2011). In February 2011 FDA re-inspected Taro Pharmaceuticals U.S.A., Inc.’s site. On April 19, 2011 FDA found that the facility has an acceptable regulatory status and lifted the Warning Letter. See **Exhibit C-246-a**, Taro Pharmaceutical Industries Ltd., Excerpts from Annual Report (Form 20-F) F-11 (June, 29, 2011).

the investor owns or controls directly or indirectly, for loss or damage arising out of a breach of Section A of Chapter Eleven by the other Party.

337. Article 1139 defines an investor of a Party to include an enterprise of a NAFTA Party that seeks to make, is making or has made an investment. Article 201 defines enterprise as any “entity constituted or organized under applicable law, whether or not for profit, and whether privately-owned or governmentally-owned, including any corporation, trust, partnership, sole proprietorship, joint venture or other association,” and an enterprise of a party as “an enterprise constituted or organized under the law of a Party.”⁵⁰⁵

338. Each of the Claimants is an enterprise organized under the laws of Canada and therefore is an investor of Canada as defined by the treaty.

1. Apotex Holdings Is an Investor

339. Through intermediary holding companies, Apotex Holdings indirectly owns and controls Apotex-US. More specifically, Apotex Holdings wholly owns and controls Aposherm Inc., a company organized under the laws of Canada. Aposherm Inc. in turn wholly owns and controls Apotex-US.⁵⁰⁶

340. Apotex-US is organized under the laws of the State of Delaware in the United States.⁵⁰⁷ As a result, Apotex-US qualifies as an “enterprise” and an “investment” within Article 1139’s definitions of those terms. It also qualifies as an “investment of an investor of a Party” and an enterprise owned or controlled, directly or indirectly, by a Claimant within the meaning of Articles 1139 and 1117(1).

341. Furthermore, Apotex Holdings also indirectly owns and controls Apotex-Canada. More specifically, Apotex Holdings owns 96% of the shares in Apotex Pharmaceutical

⁵⁰⁵ **Legal Authority CLA-1**, North American Free Trade Agreement, U.S.-Can.-Mex., art. 201, December 17, 1992, 32 I.L.M. 289 (1993) (hereinafter “NAFTA”). NAFTA Article 1139 further states that “‘enterprise’ means an ‘enterprise’ as defined in Article 201 (Definitions of General Application), and a branch of an enterprise.” See Legal Authority CLA-1, NAFTA, art. 1139.

⁵⁰⁶ See **Exhibit C-271**, Chart of Apotex Corporate Structure. See also **Exhibit C-312**, Share registry of Aposherm Inc.; **Exhibit C-313**, Share registry of Apotex Corp. (Apotex-US).

⁵⁰⁷ See Exhibit C to the Request for Arbitration, reproduced at **Exhibit C-291**, Certificate of Status of Apotex Inc.; Certificate of Good Standing of Apotex Corp.

Holdings Inc. (APHI), which in turn owns 100% of Apotex-Canada.⁵⁰⁸ It follows that Apotex Holdings indirectly owns and controls Apotex-Canada and that company's investments in the US.

342. Apotex Holdings is an investor of a Party within the meaning of Articles 1116(1) and 1117(1) of the NAFTA.

2. *Apotex-Canada Is an Investor*

343. Apotex-Canada holds a number of investments in the US, including hundreds of marketing authorizations to market and sell pharmaceutical products in the US.

344. According to the Orange Book, as of August 28, 2009, Apotex was the holder of over 150 approved ANDAs (for both prescription drugs and over-the-counter or non-prescription drugs).⁵⁰⁹ In addition, Apotex-Canada had [REDACTED] applications pending with FDA and was working on pipeline applications to be submitted to FDA in the near future.⁵¹⁰ As such, when the Import Alert was adopted, Apotex-Canada had made an investment in the US (its approved and pending ANDAs) and was seeking to make an investment in the US (its pipeline ANDAs). These ANDAs constitute Apotex-Canada's investment in the US.

345. It follows that Apotex-Canada is an "investor of a Party" within the meaning of Article 1116(1).

346. Both Apotex Holdings and Apotex-Canada therefore fall within the Tribunal's jurisdiction *rationae personae* under Articles 1116(1) and 1117(1) of the NAFTA.

3. *The Tribunal Has Jurisdiction over the United States*

347. As a Party to the NAFTA, the United States is also subject to the jurisdiction of the Tribunal under Articles 1116 and 1117 of the NAFTA.

⁵⁰⁸ See **Exhibit C-271**, Chart of Apotex Corporate Structure. See also **Exhibit C-314**, Share registry of Apotex Inc. (Apotex-Canada); **Exhibit C-315**, Share registry of Apotex Pharmaceutical Holdings Inc. (APHI).

⁵⁰⁹ See **Exhibit C-275**, Excerpts from 2012 Orange Book, ANDA held by Apotex-Canada as of August 28, 2009; Witness Statement of Bernice Tao, para. 48.

⁵¹⁰ See Witness Statement of Bernice Tao, paras. 49-50.

348. The Tribunal therefore has jurisdiction over each of the parties to the arbitration.

B. The Tribunal Has Jurisdiction over the Subject-Matter of the Dispute

349. As noted above, Articles 1116 and 1117 of the NAFTA permit investor claims pertaining to loss or damage arising out of a breach of Section A of Chapter Eleven. That Section imposes obligations on the United States with respect to “investors of another Party” and “investments ... of another Party.” Under Article 1101, Chapter Eleven applies to measures adopted or maintained by a Party relating to investors of another Party and to their investments in the territory of the Party adopting or maintaining the measure. Apotex Holdings and Apotex-Canada hold investments in the United States and, as such, qualify as “investor[s] of a Party” within the meaning of Article 1139. The Import Alert is a measure that relates to these investors and their investments.

1. Apotex-US Is an Investment of Apotex Holdings

350. Article 1139(a) defines “investment” to include “an enterprise.”

351. As noted, Apotex Holdings indirectly owns and controls Apotex-US, which is an enterprise organized under the laws of the State of Delaware in the United States. Apotex Holdings therefore holds an investment within the meaning of Article 1139.

352. There can be no dispute that Apotex-US is an investment indirectly owned and controlled by Apotex Holdings. The Tribunal’s jurisdiction *rationae materiae* is clearly established, independent of the marketing authorizations of Apotex-Canada described in the next subsection.

2. Marketing Authorizations Are Investments of Apotex-Canada

353. Article 1139 further defines “investment” to include, *inter alia*, “real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes” (paragraph g), and “interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory” (paragraph h). Apotex-Canada has an investment in the US under each paragraph.

a) *Intangible Property Under NAFTA Article 1139(g)*

354. Apotex-Canada's marketing authorizations constitute intangible property acquired in the expectation or used for the purpose of economic benefit or other business purposes, within the meaning of NAFTA Article 1139(g). That provision provides in relevant part as follows:

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; ...⁵¹¹

355. The term "property, tangible or intangible" is not defined in the NAFTA and has not given rise to significant discussion to date in NAFTA jurisprudence.⁵¹² Whether one considers State practice and arbitral awards construing similar treaty language or the law of the NAFTA Parties, however, "property" has a broad connotation.

356. For example, Article 9(c) of the OECD Draft Convention on the Protection of Foreign Property (widely viewed as a precursor to the modern investment treaty) defines property as "all property, rights and interests, whether held directly or indirectly, including the interest which a member of a company is deemed to have in the property of the company."⁵¹³ The notes and comments to this provision observe that the definition "is in conformity with international judicial practice [and] shows that *it is meant to be used in its widest sense* which includes, but is not limited to, investments."⁵¹⁴

⁵¹¹ **Legal Authority CLA-1**, NAFTA, art. 1139(g).

⁵¹² *See, e.g., Legal Authority CLA-29, Grand River Enterprises Six Nations, Ltd., et al. v. United States of America*, UNCITRAL, Award, para. 79 (Jan. 12, 2011) (demonstrating no dispute between the parties that claimant Arthur Montour had an investment in the United States, in the form of a substantial tobacco distribution business, as well as a trademark which qualified as intangible property).

⁵¹³ **Legal Authority CLA-346**, OECD, *Draft Convention on the Protection of Foreign Property*, art. 9(c) (Oct. 16, 1967). This Draft Convention was endorsed by a Resolution of the Council of the OECD adopted on October 12, 1967, and thus, represents State practice. *See id.*, Resolution of the Council on the Draft Convention on the Protection of Foreign Property, adopted by the Council at its 150th meeting, on 12th October, 1967, document C(67)102 (Oct. 16, 1967).

⁵¹⁴ *Id.*

357. The Iran-US Claims Tribunal likewise adopted a broad interpretation of the term “property” in the Algiers Accords and has confirmed that it includes shareholder rights, contractual rights and other immaterial rights.⁵¹⁵ In construing the related term “possessions” in Article 1 of Protocol No. 1 to the European Convention on Human Rights, the Strasbourg Court has found it to cover a wide range of proprietary interests, such as “movable or immovable property, tangible or intangible interests, such as shares, patents, an arbitration award, the entitlement to a pension, a landlord’s entitlement to rent, the economic interests connected with the running of a business, the right to exercise a profession, a legitimate expectation that a certain state of affairs will apply, a legal claim, and the clientele of a cinema.”⁵¹⁶
358. Thus, property and related terms have been given expansive content in international practice. This position is entirely consistent with the approach to the subject taken in the law of each of the NAFTA Parties.
359. **US Law.** The Supreme Court of the United States has held that the term “property” reaches “every species of right or interest protected by law and having an exchangeable value.”⁵¹⁷ The term “property” thus includes a particular physical object but also extends to a “bundle of property rights” associated with that object.⁵¹⁸
360. The courts of the United States have developed a three-prong test to determine whether a property right exists: “first, there must be an interest capable of precise definition; second, it must be capable of exclusive possession or control; and third, the putative

⁵¹⁵ **Legal Authority CLA-81**, *Starrett Housing Corp. v. Islamic Republic of Iran*, 4 Iran-U.S. Cl. Trib. Rep. 122 (1983), X Yearbook of Commercial Arbitration 231, 233 (1985) (interest in a project, including land, buildings, equipment and the rights and obligations connected to them); **Legal Authority CLA-78**, *Amoco International Finance Corporation v. Iran*, 15 Iran-U.S. Cl. Trib. Rep. 189, paras. 107-09 (1987) (property interest in a joint venture); **Legal Authority CLA-80**, *Phillips Petroleum Iran v. Islamic Republic of Iran and National Iranian Oil Company*, 21 Iran-U.S. Cl. Trib. Rep. 106 (1989), paras. 105-06 (contractual rights).

⁵¹⁶ **Legal Authority CLA-345**, Monica Carss-Frisk, *The Right to Property: A Guide to Implementation of Article 1 of Protocol No. 1 of the European Convention on Human Rights*, 4 Human Rights Handbooks, para. 6 (Council of Europe 2001).

⁵¹⁷ **Legal Authority CLA-143**, *Dickman v. Comm’r*, 465 U.S. 330, 334 (1984). *See also Legal Authority CLA-207*, *Yuba River Power Co. v. Nevada Irr. Dist.*, 207 Cal. 521, 523 (Cal. 1929) (“[Property] extends to every species of right and interest capable of being enjoyed as such upon which it is practicable to place a money value.”).

⁵¹⁸ **Legal Authority CLA-163**, *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982) (internal quotations omitted).

owner must have established a legitimate claim to exclusivity.”⁵¹⁹ By way of illustration, a domain name was held to constitute intangible property because it satisfied this three-prong test for the existence of a property right.⁵²⁰ Similarly, other forms of intangible property, such as copyrights,⁵²¹ patents,⁵²² trade secrets,⁵²³ confidential business information,⁵²⁴ causes of action,⁵²⁵ corporate stock,⁵²⁶ contracts,⁵²⁷ and other “things of value”⁵²⁸ are entitled to the same broad legal protection as tangible property.

⁵¹⁹ **Legal Authority CLA-152**, *G.S. Rasmussen & Assoc. v. Kalitta Flying Serv., Inc.*, 958 F.2d 896, 902-03 (9th Cir. 1992) (footnotes omitted).

⁵²⁰ **Legal Authority CLA-162**, *Kremen v. Cohen*, 337 F.3d 1024, 1030 (9th Cir. 2003). *See also Legal Authority CLA-172*, *Office Depot Inc. v. Zuccarini*, 596 F.3d 696, 701-02 (9th Cir. 2010); **Legal Authority CLA-135**, *CRS Recovery, Inc. v. Laxton*, 600 F.3d 1138, 1144 (9th Cir. 2010).

⁵²¹ *See Legal Authority CLA-222*, Copyright Act, 17 USC § 201(d) (conferring copyrights with the status of personal property in regard to the transfer of ownership).

⁵²² *See Legal Authority CLA-241*, Patent Act, 35 USC § 261 (stating that patents have the attributes of personal property). *See also Legal Authority CLA-154*, *Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 (1945) (“That a patent is property, protected against appropriation both by individuals and by government, has long been settled.”) (footnote omitted).

⁵²³ *See, e.g.*, *Legal Authority CLA-179*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003-04 (1984) (holding that proprietary information submitted by an applicant for registration of a pesticide to the Environmental Protection Agency (“EPA”) was property protected against expropriation because, *inter alia*, it constituted a significant investment of the applicant in terms of its expenditure of time, effort and resources to develop that information).

⁵²⁴ **Legal Authority CLA-130**, *Carpenter v. United States*, 484 U.S. 19, 25 (1987) (“Here, the object of the scheme was to take [certain] confidential business information ... and its intangible nature does not make it any less ‘property’ [that is legally] protected”); **Legal Authority CLA-160**, *Int’l News Serv. v. Associated Press*, 248 U.S. 215, 236 (1918) (stating that news, while it is little susceptible for ownership or dominion in the general sense, is “stock in trade” for a news organization because it is “to be gathered at the cost of enterprise, organization, skill, labor, and money, and to be distributed and sold to those who will pay money for it, as for any other merchandise.”). *See also Legal Authority CLA-144*, *Dirks v. SEC*, 463 U.S. 646, 653 n.10 (1983) (discussing the duty that corporate insiders owe to the corporation’s shareholders not to trade on the company’s inside information).

⁵²⁵ **Legal Authority CLA-195**, *United States v. Adler*, 186 F.3d 574, 576-77 (4th Cir. 1999) (noting that property is “anything in which one has a ‘right that could be assigned, traded, bought, and otherwise disposed of.’” (quoting *United States v. Mancuso*, 42 F.3d 836, 845 (4th Cir.1994))); *Legal Authority CLA-197*, *United States v. Eisen*, No. CR-90-00018, 1990 WL 164681, at *3 (E.D.N.Y. Oct. 19, 1990), *aff’d*, 974 F.2d 246 (2nd Cir. 1992).

⁵²⁶ **Legal Authority CLA-193**, *Thyroff v. Nationwide Mut. Ins. Co.*, 460 F.3d 400, 405 (2d Cir. 2006) (recognizing that shares of stock are intangible property, although for practical purposes they are “merged” into the stock certificates that are instrumentalities of trade and commerce); **Legal Authority CLA-112**, *Agar v. Orda*, 190 N.E. 479, 251 (N.Y. 1934).

⁵²⁷ **Legal Authority CLA-198**, *United States v. Granberry*, 908 F.2d 278, 280 (8th Cir. 1990) (“An employment contract is property.”).

⁵²⁸ **Legal Authority CLA-201**, *United States v. Mullins*, 992 F.2d 1472, 1476-77 (9th Cir. 1993) (holding that frequent flyer miles were “things of value”); **Legal Authority CLA-200**, *United States v. Loney*, 959 F.2d 1332, 1336 (5th Cir.1992) (flight award coupons as property). *See also Legal Authority CLA-191*, *Swan Lake Hunting Club v. United States*, 381 F.2d 238, 240 (5th Cir. 1967) (upholding the condemnation of the

361. Furthermore, courts view government-issued permits and licenses as property of the licensees. In discussing the effects of government-issued licenses and permits, the United States Supreme Court noted that video poker licensees may have property interests in their licenses.⁵²⁹ In a similar fashion, the US Court of Appeals for the Sixth Circuit stated that a certificate of registration of a bingo license may be property in the hands of the licensee, once issued to it.⁵³⁰ Similarly, the US Court of Appeals for the Eighth Circuit has held in *dicta* that a governmental permit may be property of the person who receives it.⁵³¹ More recently, the US Court of Appeals for the Fifth Circuit reaffirmed that a business owner had a property interest in permits issued by the city’s planning and zoning board, especially since these permits allowed that person to operate her business “in the pursuit of a livelihood.”⁵³²
362. **Canadian Law.** Intangible property is a broad concept under Canadian law. For instance, the Supreme Court of Canada held that goodwill, although intangible in character, is part of the property of a business just as much as the premises, machinery

hunting rights and thus implicitly acknowledging that a privilege to hunt on private land is a type of property right); **Legal Authority CLA-119**, *Armstrong v. United States*, 364 U.S. 40, 44, 46 (1960) (a lien can constitute a property interest); **Legal Authority CLA-351A**, Wesley Newcomb Hohfeld, *Some Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 23 YLJ 16, 22 (1913) (“The term ‘property’, as commonly used denotes any external object *over which* the *right* of property is exercised. In this sense it is a very wide term, and includes every class of acquisitions which a man can own or have an interest in.”) (emphasis in original).

⁵²⁹ **Legal Authority CLA-131**, *Cleveland v. United States*, 531 U.S. 12, 25-26 (2000) (“Although we do not here question that video poker licensees may have property interests in their licenses, we nevertheless disagree with the Government’s [position that video licenses in the State’s hands are property under the mail fraud statute.]” (footnote omitted). *Id.* at 25 n.4 (“In some contexts, we have held that individuals have constitutionally protected property interests in state-issued licenses essential to pursuing an occupation or livelihood.”) (citation omitted).

⁵³⁰ **Legal Authority CLA-202**, *United States v. Murphy*, 836 F.2d 248, 253-54 (6th Cir. 1988) (“In our view, the certificate of registration or the bingo license may well be ‘property’ once issued, insofar as the charitable organization is concerned, but certainly an unissued certificate of registration is not property of the State of Tennessee and once issued, it is not the property of the State of Tennessee.”).

⁵³¹ **Legal Authority CLA-198**, *United States v. Granberry*, 908 F.2d 278, 280 (8th Cir. 1990) (“A governmental permit may in some sense be property in the hands of the person who receives it, but licensing authorities have no property interest in licenses or permits ...”).

⁵³² **Legal Authority CLA-127**, *Bowlby v. City of Aberdeen, Miss.*, 681 F.3d 215, 2012 WL 1662936, at *3 (5th Cir. 2012) (“Here, the Board issued permits to Bowlby, allowing her to operate a business ‘in the pursuit of a livelihood.’ As such, we find that she had a property interest in the permits.” (citation omitted); **Legal Authority CLA-205**, *Wells Fargo Armored Serv. Corp. v. Georgia Pub. Serv. Comm’n*, 547 F.2d 938, 941 (5th Cir. 1977) (“Privileges, licenses, certificates, and franchises now do qualify as property interests for purposes of procedural due process.”); **Legal Authority CLA-124**, *Bell v. Burson*, 402 U.S. 535, 539 (1971) (once issued, a permit or license “may become essential in the pursuit of a livelihood.”).

and equipment of that business.⁵³³ Similarly, the bundle of rights associated with a fishing license was found sufficient to qualify it as property for purposes of federal and provincial statutes.⁵³⁴ The courts of Ontario have also held that intellectual property, including domain names, constitute intangible property.⁵³⁵

363. **Mexican Law.** The Federal Civil Code of Mexico similarly provides a very broad definition of property. Under Mexican law “all things not excluded from trade” may be owned.⁵³⁶ Those excluded from trade are limited to those “that cannot be possessed by any individual exclusively, and by law, those that the law declares incapable of individual ownership.”⁵³⁷
364. Mexican law explicitly recognizes a wide variety of intangible property rights, such as “copyrights,”⁵³⁸ “shares held by each partner in partnerships or companies”⁵³⁹ or “natural fruits or fruits of industry.”⁵⁴⁰ It further holds to be movable property in general “all other [rights] not considered by the law to be immovable ... property.”⁵⁴¹

⁵³³ **Legal Authority CLA-209**, *Manitoba Fisheries Ltd. v. R.*, 1978 CanLII 22 (SCC), [1979] 1 S.C.R. 101, 108, 110, 118.

⁵³⁴ **Legal Authority CLA-212**, *Saulnier v. Royal Bank of Canada*, 2008 CanLII 58 (SCC), [2008] 3 S.C.C. 166, paras. 14, 16, 23, 28, 34 and 43 (the bundle of rights attached to the fishing license was sufficient to qualify it as property for the purposes of the *Bankruptcy and Insolvency Act* (R.S.C. 1985, c. B-3) and the *Nova Scotia Personal Property and Security Act* (S.N.S. 1995-96, c. 13)).

⁵³⁵ **Legal Authority CLA-213**, *Tucows.Com Co. v. Lojas Renner S.A.*, 2011 ONCA 548, paras. 65-66.

⁵³⁶ **Legal Authority CLA-315**, Código Civil Federal [Federal Civil Code], *as amended*, Diario Oficial de la Federación, 29 de Mayo 2000 (hereinafter “Federal Civil Code of Mexico”), art. 747 (2000) (“Capable of ownership are all things not excluded from trade.”). *See id.*, art. 748 (“Things may be excluded from trade by their nature or by provision of law.”).

⁵³⁷ *Id.*, art. 749 (translation by counsel) (“Excluded from trade by their nature are those that cannot be possessed by any individual exclusively, and by law, those that the law declares incapable of individual ownership.”).

⁵³⁸ *Id.*, art. 758 (translation by counsel) (“Copyrights are considered to be personal property.”).

⁵³⁹ *Id.*, art. 755 (translation by counsel) (“For the same reason, shares held by each partner in partnerships or companies are deemed to be personal property, even when real property belongs to these partnerships or companies.”).

⁵⁴⁰ *Id.*, art. 816 (translation by counsel) (“Natural fruits or fruits of industry are understood to have been collected when they are taken away or separated. Civil fruits (revenues) are produced day by day and belong to the owner in this proportion as soon as they are owed, even when he has not received them.”).

⁵⁴¹ *Id.*, art. 759 (translation by counsel) (“In general, all others not considered by the law to be immovable are movable property.”).

Similarly, the Constitution of Mexico protects the work of artists, inventors, or creators of an improvement in any branch of the industry.⁵⁴²

365. The courts of Mexico have thus afforded legal protection to various kinds of intangible property, such as trademarks,⁵⁴³ copyrights⁵⁴⁴ or brands.⁵⁴⁵ The Supreme Court also held that the right to sue for moral damages in a breach of contract case constituted an intangible property right.⁵⁴⁶
366. To sum up, the concept of intangible property is broadly defined in international law, as well as under the law of the three NAFTA Parties.
367. As demonstrated below, the record in the present case clearly establishes that Apotex-Canada's marketing authorizations or ANDAs are intangible property within the meaning of the NAFTA.

⁵⁴² **Legal Authority CLA-314**, Constitución Política de los Estados Unidos Mexicanos [Political Constitution of the United Mexican States], *as amended*, Diario Oficial de la Federación, 5 de Febrero de 1917 (hereinafter "Constitution of Mexico"), art. 28 (1917) (translation by counsel) ("Neither do the privileges that, for a certain time, are granted to authors or artists for the production of their works and those that, for the exclusive use of their inventions, are granted to inventors and creators of an improvement constitute monopolies."). Commentators have observed that the constitutional "privileges granted by the fundamental law are the *exclusive recognition* of the *pecuniary* attributes of the creators of intellectual works, granted temporarily by the State." See **Legal Authority CLA-348**, P.A. Villanueva, *Algunas Consideraciones Sobre el Derecho de Propiedad Intelectual en Mexico*, 6 Revista de Derecho Privado 25 (2003) (emphasis in original).

⁵⁴³ **Legal Authority CLA-216**, Segunda Sala de la Suprema Corte de Justicia [Second Division of the Supreme Court of Justice], *Semanario de la Suprema Corte de Justicia y su Gaceta*, Novena Época, tomo XIII, Febrero de 2001, Tesis 2a./J. 10/2001, at 250 (translation by counsel).

⁵⁴⁴ **Legal Authority CLA-217**, Sexto Tribunal Colegiado en Materia Penal del Primer Circuito [Sixth Appellate Criminal Court in the First Circuit], *Semanario de la Suprema Corte de Justicia y su Gaceta*, Novena Época, tomo XVI, Julio de 2002, Tesis Aislada I.6o.P.40 P, at 1283 (translation by counsel).

⁵⁴⁵ **Legal Authority CLA-214**, Cuarto Tribunal Colegiado en Materia Administrativa del Primer Circuito [Fourth Collegiate Court in the Administrative First Circuit], *Semanario de la Suprema Corte de Justicia y su Gaceta*, Novena Época, tomo XXXIII, Enero de 2011, Tesis I.4o.A. J/93, at 1 (translation by counsel) ("Brands are intangible assets and their components are: a) products or services with their peculiarities, advantages or characteristics that make them valuable or well known on the market, the title to which is claimed for the commercial use thereof with claims of exclusivity; b) a distinctive mark associated, as special and exclusive, with that product or service, which does not necessarily have to be original or new; c) wordmark, graphic mark or mixed mark, requiring depiction on a container, product or advertising expression, psychologically linked to an idea or concept of a product or service that evokes in the consumer the characteristics, the corporate provenance, level of quality or reputation, and d) union or correlation between the product or service and the mark that the consumers take note of and retain in their memories, which is what is [sic] proves to be creative, attributable to the entrepreneur, and is the subject of protection and a claim.").

⁵⁴⁶ **Legal Authority CLA-215**, Primera Sala de la Suprema Corte de Justicia [First Division of the Supreme Court of Justice], *Semanario de la Suprema Corte de Justicia y su Gaceta*, Novena Época, tomo XXXIII, Febrero de 2011, Tesis Aislada, 1a. XXVI/2011, at 1.

368. *First*, FDA's own regulations recognize that a pharmaceutical company may own an ANDA, and that it can be transferred for consideration subject to minor formalities:

An applicant may transfer *ownership* of its application. At the time of transfer the new and former *owners* are required to submit information to the Food and Drug Administration as follows:

(1) The former owner shall submit a letter or other document that states that all rights to the application have been transferred to the new owner.

(2) The new owner shall submit an application form signed by the new owner and a letter or other document containing the following ...⁵⁴⁷

369. The right of ownership, and its corollary, the right to transfer, form an integral element of property rights under US law. As elaborated by the US Court of Appeals for the 8th Circuit:

When we say that we own something, one of the things that we mean is that we can determine what to do with it. We can either keep it or transfer it to someone else. And we can choose those persons to whom we will transfer it.⁵⁴⁸

370. *Second*, ANDAs are regularly bought and sold for substantial amounts of money. ANDAs can be traded while the application is still pending or once the marketing authorization has been granted.⁵⁴⁹ By way of example, Apotex-US purchased ANDAs from Barr Laboratories, Inc. pursuant to an Asset Purchase Agreement of August 1, 2006.⁵⁵⁰ Similarly, in 2011, KV Pharmaceutical divested its generic subsidiary to

⁵⁴⁷ **Legal Authority CLA-272**, Applications for FDA Approval to Market a New Drug, 21 CFR § 314.72(a) (emphasis added). *See also id.* at § 314.72(a)(2)(iii) & 314.72(b) (making clear that provision also applies to *approved* ANDAs).

⁵⁴⁸ **Legal Authority CLA-198**, *United States v. Granberry*, 908 F.2d 278, 280 (8th Cir. 1990).

⁵⁴⁹ *See Legal Authority CLA-272*, Applications for FDA Approval to Market a New Drug, 21 CFR § 314.72. Witness Statement of Bernice Tao, para. 26.

⁵⁵⁰ **Exhibit C-19**, Asset Purchase Agreement between Barr Laboratories, Inc. and Apotex Corp. (excerpts), dated Aug. 1, 2006, §§ 1.1, 2.1, 2.2(a) (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) ...").

ZyduS Pharmaceuticals USA for approximately USD 60 million and this transaction included both existing and pipeline ANDAs.⁵⁵¹

371. *Third*, once a company has acquired the rights to an ANDA, courts recognize that the company has standing to intervene in a case where those rights might be affected. By way of example, in *Serono Labs., Inc. v. Shalala*, Lederle Parenterals, Inc. submitted an ANDA for a generic version of the drug Pergonal. While the application was still pending with FDA, Ferring Pharmaceuticals acquired the rights to the ANDA. FDA subsequently approved the ANDA. At this stage, the brand-name manufacturer of the drug Pergonal sued FDA for an order rescinding approval of the ANDA, arguing that it would suffer “an unrecoverable loss of sales to Ferring.”⁵⁵² Ferring was allowed to intervene as a party in interest, and the court throughout its opinion referred to “Ferring’s ANDA.”⁵⁵³ There was no suggestion that Lederle retained any rights, or that Ferring did not own the ANDA.
372. *Fourth*, US courts have also treated access to the US market under an approved ANDA as a protected interest. In *Caraco Pharm. Labs., Ltd. v. Forest Labs. Inc.*, the Federal Circuit Court of Appeals held that a defendant who delayed FDA approval of the plaintiff’s ANDA effectively prevented the plaintiff from exercising a legally protected right to enter the market. The court concluded that the denial of the “right to sell non-infringing generic drugs” was “precisely the type of injury” that declaratory judgments are meant to remedy.⁵⁵⁴ Thus, plaintiff’s “exclusion from the generic drug market” when it “ha[d] a right to enter” was a sufficient injury to allow the plaintiff to sue.⁵⁵⁵

⁵⁵¹ See **Exhibit C-253**, *World Generic Markets*, “ZyduS Acquires KV’s Generics Business” (August 5, 2011), available at 2011 WLNR 15529655 (“The acquired ANDA pipeline comprise[d] eight exiting files and five products under development ...”). See also **Legal Authority CLA-158**, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 902 (6th Cir. 2003) (brand-name manufacturer of the drug Cardizem and generic manufacturer Andrx Pharmaceuticals Inc. agreed that Andrx would not market generic version of Cardizem in exchange for USD 40 million a year).

⁵⁵² **Legal Authority CLA-183**, *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1316-17, 1326 (D.C. Cir. 1998).

⁵⁵³ *Id.* at 1326.

⁵⁵⁴ **Legal Authority CLA-129**, *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1292 (Fed. Cir. 2008).

⁵⁵⁵ *Id.* at 1292.

373. *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.⁵⁵⁶ A recent case involved a commercialization agreement between Andrx Pharmaceuticals and another company, “pursuant to which Andrx agreed to relinquish its exclusivity rights obtained by filing the ANDA covering products ... in exchange for a share in the net profits on the sales” of a different drug.⁵⁵⁷ Thus, Andrx realized the value of the exclusivity of its ANDA, while retaining the right to make the drug.

374. *Finally*, the approach taken by other US Government agencies confirms that ANDAs represent intangible property. In concluding that approved ANDAs are amortizable intangibles for purposes of the tax code, the Internal Revenue Service reasoned as follows:

ANDAs are within the definition of separate and distinct intangible assets. ANDAs can be transferred from the sponsor (original applicant) to another, separate and apart from a trade or business. ANDAs are subject to protection under Federal law. For example, when an ANDA holder has 180 days of exclusivity, federal law precludes any other generic for the referenced NDA from being approved during the period of exclusivity. An entire profitable industry, the generic pharmaceutical industry, has evolved around the value of the ANDAs. While it would take an expert, the expected stream of income from each ANDA could be projected and then valued at its net present value. Accordingly, each ANDA is a separate and distinct asset⁵⁵⁸

375. What the above discussion shows is that ANDAs, and the rights associated with them, are property. First, the applicant owns the ANDA and, most importantly, FDA’s own regulations permit the transfer of ownership of pending or approved ANDAs. Second, ANDAs are regularly bought and sold, just like any other property. Third, ANDA

⁵⁵⁶ See *supra* Statement of Facts, Part III.B, on the statutory 180-day exclusivity period applicable to the first-filer of a Paragraph IV certification.

⁵⁵⁷ **Legal Authority CLA-113**, *Aktiebolag v. Andrx Pharm., Inc.*, 695 F. Supp. 2d 21, 24 (S.D.N.Y. 2010).

⁵⁵⁸ **Legal Authority CLA-312A**, Internal Revenue Service, Office of Chief Counsel, Memorandum, at 4 n.3 (Sept. 27, 2011) (citations omitted). See *id.*, at 2, para. 1, under *Conclusions* (“As franchises, FDA-approved ANDAs are amortizable intangibles Alternatively, as government-granted rights within [Treasury Regulations], rights granted pursuant to ANDAs are licenses or other similar government-granted rights within the meaning of the [I.R.C.]”) (citations omitted).

owners have standing to intervene when their rights are affected and they can seek declaratory relief. Fourth, the right to market a drug under an approved ANDA is, itself, a protected property right, and so is the statutory exclusivity period. Finally, other US agency practice is fully consistent with ANDAs' status as intangible property. Apotex-Canada's marketing authorizations in the US (both approved and pending) constitute intangible property within the meaning of NAFTA Article 1139(g).

376. This property was "acquired in the expectation or used for the purpose of economic benefit or other business purposes," within the meaning of NAFTA Article 1139(g). Apotex-Canada prepared, filed and maintained its ANDAs in the United States for the purpose of selling its products on the US market and making a profit from these sales. There is thus a clear business purpose behind, and an economic benefit derived from, Apotex-Canada's marketing authorizations.⁵⁵⁹

b) Interests Arising from Commitment of Resources under NAFTA Article 1139(h)

377. Apotex-Canada's marketing authorizations and associated rights also constitute investments within the meaning of NAFTA Article 1139(h). That provision provides in pertinent part as follows in the English version of the NAFTA:

investment means:

(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;
⁵⁶⁰
...

⁵⁵⁹ Witness Statement of Bernice Tao, paras. 20, 25; Witness Statement of Kiran Krishnan, paras. 16-17; Witness Statement of Jeremy Desai, para. 27 (USD █████ million spent every year in the US on patent and ANDA-related litigation). *See also* Witness Statement of Gordon Fahner, paras. 43-46.

⁵⁶⁰ **Legal Authority CLA-1**, NAFTA, art. 1139(g).

378. It is notable that the Spanish version of the chapeau in paragraph (h) differs in some respects from the English version. It, along with a certified translation of the Spanish into English, are set out below:

(h) la participación que resulte del capital u otros recursos destinados para el desarrollo de una actividad económica en territorio de otra Parte, entre otros, conforme a: ...

(h) an interest resulting from capital or other resources devoted to the performance of an economic activity in the territory of another Party, in accordance with, inter alia: ...⁵⁶¹

379. The Spanish version uses the participle “*destinados*” or “devoted” to express the concept expressed in English through the noun “commitment.” Most important, the Spanish version contains only one reference to the territory of the Party, which appears twice in the English text. In both the Spanish and the English texts, it is clear that the capital or other resources must be devoted to economic activity in the relevant territory. The English text, however, is ambiguous as to whether the capital or other resources must be committed or devoted to the territory of the other Party, or whether the capital or other resources must be located in the territory of the other Party at the time of their commitment.

380. NAFTA Article 2206 provides that the English, French and Spanish texts of the treaty are equally authentic.⁵⁶² Under Article 33(4) of the Vienna Convention on the Law of Treaties, “when a comparison of the authentic texts discloses a difference of meaning which the application of articles 31 and 32 does not remove, the meaning which best

⁵⁶¹ **Legal Authority CLA-4**, Tratado de Libre Comercio en América del Norte (NAFTA), U.S.-Can.-Mex., art. 1139(h), Dec. 17, 1992, 32 I.L.M. 612, accompanied by certified English translation. *See also Legal Authority CLA-67*, *Kiliç İnşaat İthalat İhracat Sanayi Ve Ticaret Anonim Şirketi v. Turkmenistan*, ICSID Case No. ARB/10/1, Decision on Article VII.2 of the Turkey-Turkmenistan Bilateral Investment Treaty, para. 8.8 (May 7, 2012) (“The Tribunal thus considers it to be necessary and proper for a translation to convey accurately the complete sense of the Russian text when it is translated into English.”). *Id.*, para. 8.21 (“[T]he Tribunal notes that the revised translation provided by Respondent provides additional evidence before the Tribunal on the Russian sense (*i.e.*, the accurate translation into English of the Russian) of the Russian text version of Article VII.2.”).

⁵⁶² **Legal Authority CLA-1**, NAFTA, art. 2206. While the treaty makes reference to an authentic French version and a draft has been made available, the NAFTA Parties never agreed on an authenticated version of the treaty in French. The treaty has been authenticated only in English and Spanish.

reconciles the texts, having regard to the object and purpose of the treaty, shall be adopted.”⁵⁶³

381. Application of Articles 31 and 32 of the Vienna Convention demonstrates that Article 1139(h) requires that capital or resources be devoted or committed to economic activity in the territory of the host State, but not that they be in the host State before they are committed. This interpretation in any event is the one which best reconciles the texts, having regard to the object and purpose of the NAFTA.

382. 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.”⁵⁶⁴ The “context” includes the text of the treaty.⁵⁶⁵

383. As noted above, Article 1139(h) helpfully provides two examples of the type of interests it encompasses, namely:

(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; ...⁵⁶⁶

384. None of these examples of contracts presupposes capital or resources of the investor in the territory of the host State before the contract is signed. For instance, a construction

⁵⁶³ **Legal Authority CLA-17**, Vienna Convention on the Law of Treaties, art. 33(4), Apr. 24, 1970, S. Treaty Doc. No. 92-12, 1155 U.N.T.S. 331 (hereinafter “VCLT”). While the United States is not a party to the VCLT, it has repeatedly recognized that “the Convention is the ‘authoritative guide’ to treaty law and practice.” **Legal Authority CLA-38**, *Mobil Investments Inc. and Murphy Oil Corporation v. Canada*, ICSID Case No. ARB(AF)/07/4, Second Submission of the United States of America, para. 4 n.2 (Jan. 21, 2011) (quoting Letter from Secretary of State Rogers to President Nixon Transmitting the VCLT, Oct. 18, 1971, reprinted in 65 Dep’t of St. Bull. 684, 685 (1971)). See also **Legal Authority CLA-67**, *Kiliç İnşaat İthalat İhracat Sanayi Ve Ticaret Anonim Şirketi v. Turkmenistan*, ICSID Case No. ARB/10/1, Decision on Article VII.2 of the Turkey-Turkmenistan Bilateral Investment Treaty, para. 9.22 (May 7, 2012) (“To the extent that it might not be possible to resolve the possible difference in meaning of the English and Russian text through the application of Articles 31 and 32, the Tribunal can, in accordance with the principles reflected in Article 33(4) of the VCLT, adopt the meaning which would best reconcile the two texts.”).

⁵⁶⁴ **Legal Authority CLA-17**, VCLT, art. 31(1).

⁵⁶⁵ *Id.*, VCLT, 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).

⁵⁶⁶ **Legal Authority CLA-1**, NAFTA, art. 1139(h).

contract for infrastructure to be built in the United States may be and often is negotiated and signed outside of the US. The contractor may at the time of signing have no personnel, equipment or resources in the US. The contract may contemplate that the investor will only after the design phase bring its equipment and personnel into the US to construct the infrastructure.

385. The construction contract clearly reflects a *commitment* to place capital or other resources in the United States for purposes of economic activity in that country, in this example the construction of the infrastructure. And yet, nothing in the nature of a construction contract implies that the capital or resources will already be in the US before the commitment is made. The same goes for other types of contracts provided in the examples in Article 1139(h): management, joint venture and technology licensing agreements providing for remuneration depending on production, revenues or profits of an enterprise clearly fall within the examples in subparagraph (ii), but in many instances a foreign investor will not have made a contribution of capital or resources before signing the contract in question.

386. The object and purpose of the NAFTA only serves to reinforce this conclusion. As stated in Article 102(1) of the NAFTA:

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 ...⁵⁶⁷

387. Reading Article 1139(h) only to apply from interests resulting from commitment of capital or resources already invested in the host State would defeat this objective. Such a reading would not *increase* investment in the host State but merely change the form of investments already made in that State. By contrast, reading Article 1139(h) to, as the Spanish version provides, require only that the capital or resources be devoted or

⁵⁶⁷ Legal Authority CLA-1, NAFTA, art. 102(1).

committed to economic activity in the host State is fully consonant with the NAFTA's objective of substantially increasing investment.

388. Consideration of the preparatory work of Article 1139(h) confirms this interpretation.⁵⁶⁸

In the August 4, 1992 negotiating draft, the antecedent to Article 1139(h) read as follows:

interests arising from the commitment of capital or other resources in *or into* the territory of another Party to economic activity in such territory⁵⁶⁹

389. This was agreed text at that point; no brackets or notes accompanied this text. The use of the words "or into" as well as the word "in" demonstrates that the negotiators clearly understood that the capital or resources could be contributed either from outside or inside the host State.

390. The following day of negotiations, the text was revised to place brackets around the words "or into" and add a footnote:

interests arising from the commitment of capital or other resources in [*or into*]³⁰ the territory of another Party to economic activity in such territory

30 Checking to see if necessary.⁵⁷⁰

⁵⁶⁸ For an example of recourse to supplementary means such as preparatory work under Article 32 of the VCLT, *see, e.g., Legal Authority CLA-67, Kiliç İnşaat İthalat İhracat Sanayi Ve Ticaret Anonim Şirketi v. Turkmenistan*, ICSID Case No. ARB/10/1, Decision on Article VII.2 of the Turkey-Turkmenistan Bilateral Investment Treaty, para. 9.17-9.18 (May 7, 2012) ("In the event, the Tribunal concludes that attempting to interpret the relevant English text in accordance with Article 31 of the VCLT leaves its meaning ambiguous or obscure. In these circumstances, it is appropriate for the Tribunal to consider supplementary means of interpretation as permitted under Article 32 of the VCLT. ... One supplementary means of interpretation is to consider the circumstances of the conclusion of the BIT. The circumstances include the process relating to the negotiation, conclusion and signing of the BIT ... as well as events leading up to its ratification.").

⁵⁶⁹ **Legal Authority CLA-6**, NAFTA Trilateral Negotiating Draft Texts, Watergate Daily Update, at 25, August 4, 1992, available at http://www.ustr.gov/archive/assets/Trade_Agreements/Regional/NAFTA/NAFTA_Chapter_11_Trilateral_Negotiating_Draft_Texts/asset_upload_file269_5908.pdf (emphasis added).

⁵⁷⁰ **Legal Authority CLA-7**, NAFTA Trilateral Negotiating Draft Texts, Watergate Daily Update, at 25-26, August 11, 1992, available at http://www.ustr.gov/archive/assets/Trade_Agreements/Regional/NAFTA/NAFTA_Chapter_11_Trilateral_Negotiating_Draft_Texts/asset_upload_file865_5907.pdf (emphasis added).

391. The note “[c]hecking to see if necessary” signifies that the negotiators had in mind not a change in the substance of the definition, but rather questioned whether it was necessary to include the two closely related prepositions “in” and “into” in the same clause. Given that one of the ordinary meanings of the preposition “in” is, indeed, “into”, the question was perfectly logical.⁵⁷¹
392. The bracketed phrase “or into” was removed in the Lawyers’ Revision of August 27, 1992.⁵⁷² All decisions on substance were to be made by the policymakers on the negotiating teams; the lawyers’ revisions in principle were to address only style and consistency.⁵⁷³ The removal of this phrase in the Lawyers’ Revision is consistent with the footnote in the August 11, 1992 draft signaling no intent to change the content of the definition.
393. The negotiating history of Article 1139(h), therefore, demonstrates that the intention of the negotiators of the English text coincides with that expressed in the final Spanish text: the capital or resources could be either within or without the host State; what mattered was that they be committed or devoted to economic activity in the territory of the host State. The apparent difference in meaning between the English and the Spanish texts of Article 1139(h), thus, is removed by application of the techniques of

⁵⁷¹ See, e.g., **Legal Authority CLA-352**, American Heritage Dictionary, Definition of “in” (1973) (defining “in” as, among other things, “7. To or at the condition or situation of; into”); see also *id.* (under definition of “in” as adverb, “3. Into a given place or position”).

⁵⁷² **Legal Authority CLA-8**, NAFTA Trilateral Negotiating Draft Texts, Lawyers’ Revision, at 26, Aug. 27, 1992, available at http://www.ustr.gov/archive/assets/Trade_Agreements/Regional/NAFTA/NAFTA_Chapter_11_Trilateral_Negotiating_Draft_Texts/asset_upload_file680_5904.pdf (reflecting final text of “interests arising from the commitment of capital or other resources in the territory of another Party to economic activity in such territory”).

⁵⁷³ See **Legal Authority CLA-48**, *The Canadian Cattlemen for Fair Trade v. United States of America*, UNCITRAL, Memorial on the Preliminary Issue of Respondent, 18-19 (Dec. 1, 2006) (“In the ‘Lawyers’ Revision,’ counsel for all three NAFTA Parties performed a ‘legal scrub’ of the chapter. The purpose of a ‘legal scrub’ in any treaty negotiation is to conform language and terminology, as well as to eliminate redundancies and obvious conflicts within an agreement. It is not the purpose of a legal scrub to make substantive changes to an agreement’s terms, nor is it to radically expand an agreement’s scope.”). See also **Legal Authority CLA-46**, *Softwood Lumber Consolidated Cases (Canfor Corporation v. United States of America, Tembec et al. v. United States of America and Terminal Forest Products Ltd. v. United States of America)*, UNCITRAL, Order of the Consolidation Tribunal, para. 68 (Sept. 7, 2005) (“Thus, on 12 August 1992, the three States reached agreement in principle on the substance of the NAFTA, subject to a ‘scrubbing’ of the text by their lawyers, ensuring, *inter alia*, consistency of the texts of the many chapters negotiated by various teams.”) (Footnote omitted in part and quoting President Bush as stating that “[the text] had to be ‘scrubbed’ by lawyers into proper legal language” *Journal of Commerce*, 19 August 1992 p. 5A (“Citizens Group wants copy of NAFTA text”)).

interpretation of Articles 31 and 32 of the Vienna Convention on the Law of Treaties. And in any event, for the reasons noted above, the interpretation put forward is the one that best reconciles the texts with the object and purpose of the NAFTA, as required by Article 33(4) of the Vienna Convention.

394. Turning from the content of Article 1139(h) to its application in this case, the record clearly establishes that Apotex-Canada's approved ANDAs constitute "interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory" under any interpretation of the provision.
395. *First*, it is apparent that the marketing authorizations or ANDAs are an interest, as shown in the preceding subsection's discussion of ANDAs as property. As explained, the applicant owns the application materials submitted to FDA and, most importantly, FDA's own regulations permit transfer of ownership of pending or approved ANDAs. In practice, ANDAs are regularly bought and sold, just like any other property. ANDA owners have standing to intervene when their rights are affected and to seek declaratory relief. Finally, the right to market a drug under an approved ANDA is, itself, a protected property right, and so is the statutory exclusivity period afforded some ANDA holders. In sum, ANDAs are "property" within the meaning of Article 1139(g) – but even if they were not, there can be no doubt that they constitute "interests" within the meaning of Article 1139(h).
396. *Second*, it is beyond dispute that the ANDAs are devoted to economic activity in the territory of the United States. Indeed, ANDAs are specific to the United States. By filing an ANDA, Apotex seeks authorization to market its products *solely* in the United States. An approved ANDA cannot be used anywhere but in the US. This fact alone shows that whenever it submits an ANDA, Apotex-Canada makes an investment *in the United States*.⁵⁷⁴

⁵⁷⁴ **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) ("a salient characteristic" of an investment covered by the protections of Chapter Eleven is that "the investment is primarily regulated by the law of a State other than the State of the investor's nationality, and that this law is created and applied by that State which is not the State of the investor's nationality.").

397. *Third*, the record clearly demonstrates a commitment of capital or other resources in and into the United States for purposes of economic activity. Apotex-Canada has spent millions of dollars in developing new generic drugs and preparing the corresponding ANDAs. Each ANDA reflects proprietary information concerning the drug's formulation, development, testing, and the manufacturing processes needed for the commercialization of the drug in the US. These intellectual property rights, know-how and other resources, even if brought from Canada, are committed into the United States for purposes of economic activity in US territory.⁵⁷⁵
398. As part of the preparation of its ANDAs, Apotex-Canada also regularly engages in costly patent litigation before US courts. As explained above, Apotex-Canada may benefit from a 180-day statutory marketing exclusivity as first filer of a Paragraph IV certification. Such a filing very often leads to litigation as to whether the patent held by the brand-name manufacturer is invalid or not infringed upon.⁵⁷⁶ This kind of patent litigation can be quite expensive. To give an example, in the *Pentech* case, one generic manufacturer, after having already invested USD 7 million in obtaining an ANDA, had to enter into a partnership with another manufacturer because it was “in need of additional cash to fund its substantial ongoing litigation and development expenses.”⁵⁷⁷ In bringing patent litigations, Apotex-Canada incurs court costs, legal fees and other related expenses, all of which have to be borne in the United States.⁵⁷⁸ All of these expenses clearly constitute a commitment of capital and resources in the United States.
399. Aside from the development and preparation of its ANDAs, Apotex-Canada also commits various resources in the United States in relation to the filing and maintaining of its marketing authorizations. These resources are located in the United States.

⁵⁷⁵ Witness Statement of Gordon Fahner, paras. 30, 43; Witness Statement of Kiran Krishnan paras. 16-17. *See also* Witness Statement of Bernice Tao, para. 22.

⁵⁷⁶ *See supra* Statement of Facts, Part III.B.

⁵⁷⁷ **Legal Authority CLA-173**, *Pentech Pharm., Inc. v. Par Pharm., Inc.*, 597 F. Supp. 758, 765-66 (N.D. Ill. 2009). *See also* **Legal Authority CLA-159**, *In re Metropolol Succinate Direct Purchaser Antitrust Litig.*, Nos. 06-52 (GMS), 06-71 (GMS), 2010 WL 1485328, at *4 (D. Del. Apr. 13, 2010) (Plaintiff alleged that brand manufacturer “forc[ed] generic manufacturers to divert resources from FDA approval to patent infringement litigation ...”); **Legal Authority CLA-208**, *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, No. 91-3423, 1991 WL 267892, at *8 (D.N.J. Dec. 12, 1991) (The Court stated that it is “clear” that if the ANDA “was not of significant value to [plaintiff], it would not have chosen to engage in the protracted and costly litigation of this matter both here and at FDA.”).

⁵⁷⁸ Witness Statement of Gordon Fahner, para. 45 (USD ■ million per year).

Indeed, Apotex-Canada relies on a full-time employee based in Weston, Florida to act as its agent and liaison with FDA concerning the filing of ANDAs. Apotex-Canada's agent works with a team of six people in carrying out this work.⁵⁷⁹ In particular, this team addresses any questions that FDA may have once an ANDA has been filed. Apotex-Canada funds this team's work through a 2005 services agreement with Apotex-US.⁵⁸⁰ By arranging and maintaining such a workforce in the US, Apotex-Canada is committing resources in that territory.

400. *Finally*, once a marketing authorization is granted, the ANDA-holder is required by law to make a series of periodic, post-approval reports.⁵⁸¹ 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, and management of drug labels and patient information leaflets. In doing so, Apotex-Canada commits capital and other resources in the United States for the purpose of maintaining – and using – its ANDAs.⁵⁸²
401. On the whole, preparing, obtaining and maintaining an ANDA requires a significant commitment of capital and other resources in and into the United States.
402. ANDAs address economic activity in the United States. More specifically, ANDAs are necessary in order to realize sales on generic drugs in the US.⁵⁸³ As such, Apotex-Canada's ANDAs constitute interests arising out of the commitment of capital or other resources to economic activity in or into the United States.

⁵⁷⁹ Witness Statement of Kiran Krishnan, para. 13.

⁵⁸⁰ Witness Statement of Gordon Fahner, para. 37. *See also Exhibit C-14*, Services Agreement Between Apotex-Canada and Apotex-US, dated July 1, 2005.

⁵⁸¹ *See, e.g., Legal Authority CLA-123, Bartlett v. Mut. Pharm. Co., Inc.*, 2009 WL 3614987, at *2 (D.N.H. 2009) (“Federal regulations require companies that hold ... ‘ANDAs’ ... to file periodic reports with the [FDA] describing any adverse event information relating to those drugs, and also to file annual reports that summarize any ‘significant new information’ that might affect the drug’s ‘safety, effectiveness, or labelling.’”) (citations omitted).

⁵⁸² Witness Statement of Kiran Krishnan, paras. 32 *et seq.*; Witness Statement of Bernice Tao, paras. 33-35.

⁵⁸³ Witness Statement of Kiran Krishnan, para. 16; Witness Statements of Bernice Tao, paras. 20, 25. *See supra* fn. 15 (ANDAs required for and limited to generic drug sales in the US).

403. To sum up, Apotex-Canada's ANDAs constitute "investments" within the meaning of NAFTA Article 1139 (g) and (h).⁵⁸⁴

3. *The Import Alert Is a Measure Relating to Investors and Investments*

404. NAFTA Article 1101 provides in relevant part as follows:

1. This Chapter applies to measures adopted or maintained by a Party relating to:

a. investors of another Party;

b. investments of investors of another Party in the territory of the Party ...⁵⁸⁵

405. As set out in *Cargill v. Mexico*, the jurisdictional elements of Article 1101 "involve questions as to: whether there are 'measures'; whether they are 'relating to' the stipulated persons or things; whether they involve 'investors of another Party'; and whether they involve 'investments' of those investors 'in the territory of the Party' that would be subject to the claim."⁵⁸⁶

406. **The Import Alert is a measure adopted by the USA.** Article 201 defines a measure to include "any law, regulation, procedure, requirement or practice ..."⁵⁸⁷ The Import Alert is a decision of a US regulatory agency (FDA), which sets out a clear requirement to deny access of certain goods to the United States. Therefore, the Import Alert

⁵⁸⁴ Jurisdictional questions presented in two pending NAFTA arbitrations overlap in part with those addressed in this subsection. Those arbitrations, initiated under the UNCITRAL rules by Apotex-Canada against the United States in 2008 and 2009, present the question of whether ANDAs that at the time of the alleged breach had not yet been granted final FDA approval (because of the alleged breach) constitute property within the meaning of NAFTA Article 1139(g). Apotex-Canada also invoked NAFTA Article 1139(h) in those cases but the legal arguments and the factual record were not developed in a manner similar to that presented here. A tribunal consisting of Hon. Fern M. Smith, Mr. Clifford M. Davidson and Mr. Toby T. Landau QC (President) held a hearing on jurisdiction in both cases on February 15-16, 2012. The tribunal's award has not been rendered as of the date of this Memorial. For more information, see <http://www.state.gov/s/l/c27648.htm> and <http://www.state.gov/s/l/c31326.htm>.

⁵⁸⁵ **Legal Authority CLA-1**, NAFTA, art. 1101.

⁵⁸⁶ **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 163 (Sept. 18, 2009).

⁵⁸⁷ **Legal Authority CLA-1**, NAFTA, art. 201. See also **Legal Authority CLA-26**, *Ethyl Corporation v. The Government of Canada*, UNCITRAL, Award on Jurisdiction, para. 66 (June 24, 1998) (In commenting on NAFTA Article 201(1), the tribunal noted "[c]learly something other than a 'law,' even something in the nature of a 'practice,' which may not even amount to a legal stricture, may qualify [as a measure].").

constitutes a measure within the meaning of Article 201. The Import Alert was in effect from August 28, 2009 to July 29, 2011.

407. **The Claimants are Canadian investors with investments in the US.** NAFTA tribunals have read Article 1101(1)(a) to apply only to *investors* of another Party who have made, or are proposing to make, an investment in the host State.⁵⁸⁸ Article 1101(1)(b) applies to *investments* of investors of another Party in the territory of the Party. In *Cargill*, the claimant owned an enterprise in Mexico and, as such, held an investment in the territory of Mexico. The *Cargill* tribunal therefore concluded that “paragraphs (a) and (b) of Article 1101 [were] sufficiently satisfied.”⁵⁸⁹
408. In the present case, Apotex Holdings indirectly owns and controls Apotex-US, which is an enterprise incorporated under the laws of Delaware and an investment in the territory of the USA. This fact alone satisfies the jurisdictional requirement of Article 1101.
409. In addition, and as demonstrated above, Apotex-Canada is also an investor with investments in the territory of the United States. Apotex-Canada’s ANDAs qualify as investments under Article 1139(g) and (h). Furthermore, there can be no dispute that the ANDAs are investments made in the territory of the United States, since they involve a commitment of capital and other resources *into* the US and can only be used in that country.
410. **The Import Alert relates to the investors and their investments.** Still in the case of *Cargill v. Mexico*, the tribunal had no difficulty in concluding that an import permit requirement was a measure that affected the claimant’s investment in Mexico: the import permit requirement prevented claimant’s goods from crossing the border from

⁵⁸⁸ **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 165 (Sept. 18, 2009). See also **Legal Authority CLA-22**, *Bayview Irrigation District et al. v. United Mexican States*, ICSID Case No. ARB(AF)/05/1, Award, paras. 94-95 (June 19, 2007); **Legal Authority CLA-47**, *The Canadian Cattlemen for Fair Trade v. United States of America*, UNCITRAL, Award on Jurisdiction, para. 112 (Jan. 28, 2008) (“[I]nvestors do not exist in Chapter Eleven in isolation, but are explicitly linked to their investments. ... [I]t is clear from the text [of Articles 1101(1)(a) and 1102(1)] that the only ‘investments’ covered by Chapter Eleven are those that are made (or planned to be made) in the territory of another NAFTA Party by qualifying persons of one NAFTA Party – *i.e.*, foreign investments ...”) (internal quotation omitted).

⁵⁸⁹ **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 167 (Sept. 18, 2009).

the United States into Mexico and directly affected the business of the claimant's Mexican subsidiary (the investment).⁵⁹⁰ That same tribunal concluded that there was a "legally significant connection," as articulated in *Methanex*,⁵⁹¹ between the measure and the investor and its investment. The *Cargill* tribunal held as follows:

The import permit requirement not only had an immediate effect and direct effect on the business of Cargill de Mexico [the investment] 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.⁵⁹²

411. In the present case, the measure clearly relates to Apotex-US. Apotex-US was the consignee of the shipments of product interrupted by the Import Alert; FDA district office that intercepted Apotex-Canada's shipments expressly identified Apotex US as the party prevented from receiving them.⁵⁹³ Apotex-US was directly impacted by the Import Alert. It lost sales and market shares in the US because it could no longer supply the products it sold, and was contractually obliged to sell, in the US.

412. The measure also relates to Apotex-Canada and its marketing authorizations. The Import Alert specifically named Apotex-Canada as the affected party.⁵⁹⁴ The measure had the direct effect of rendering Apotex-Canada's marketing authorizations useless for

⁵⁹⁰ *Id.*, para. 173.

⁵⁹¹ **Legal Authority CLA-36**, *Methanex Corporation v. United States of America*, UNCITRAL, Preliminary Award on Jurisdiction, para. 147 (Aug. 7, 2002) ("[T]he phrase 'relating to' in Article 1101(1) NAFTA signifies something more than the mere effect of a measure on an investor or an investment ... it requires a legally significant connection between them ..."). *See also id.*, para. 137 ("If the threshold provided by Article 1101(1) was merely one of 'affecting', as Methanex contends, it would be satisfied wherever any economic impact was felt by an investor or an investment. ... A threshold which could be surmounted by an indeterminate class of investors making a claim alleging loss is no threshold at all It may be true, to adapt Pascal's statement, that the history of the world would have been much affected if Cleopatra's nose had been different, but by itself that cannot mean that we are all related to the royal nose."). On the facts of the case, the *Methanex* tribunal concluded that there was no legally significant connection between the US measures, Methanex and its investments. As such, the US measures did not "relate to" Methanex or its investments as required by Article 1101(1) and the tribunal lacked jurisdiction to determine Methanex's substantive claims under NAFTA Articles 1102, 1105 and 1110. *See Legal Authority CLA-34*, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award, Part IV, ch. E, para. 22 (Aug. 3, 2005).

⁵⁹² **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 175 (Sept. 18, 2009).

⁵⁹³ *See, e.g.*, **Exhibit C-68**, Email from Customs Broker to Apotex at 10:20 a.m., Sept. 1, 2009, attaching Notice of FDA Action No. EG6-1768658-9, dated Aug. 31, 2009.

⁵⁹⁴ **Exhibit C-110**, FDA's website, Import Alert 66-40, p.2, published on September 10, 2009 re: Apotex Inc., 150 Signet Drive and Apotex Inc., Etobicoke.

the purpose for which Apotex-Canada had acquired them: marketing the products covered by the ANDAs in the US. As a direct consequence of the measure, FDA refused to take further action on the Apotex-Canada ANDAs that were pending before it at the time of the Import Alert for products to be produced at Etobicoke or Signet, and refused to act on new ANDAs filed by the company⁵⁹⁵. The measure relates both to Apotex-Canada and to its investments.

413. Because Apotex Holdings is the ultimate owner of both Apotex-US and Apotex-Canada and their investments, the Import Alert also relates to it and its indirectly controlled investments as well.
414. It follows that the jurisdictional requirements of Article 1101 are met and, as a result, Apotex Holdings and Apotex-Canada have the right to submit their claims to arbitration in accordance with Articles 1116 and 1117.
415. For all the foregoing reasons, the Tribunal has jurisdiction *rationae materiae* over this dispute.

C. The Dispute Meets the Temporal Requirements of the NAFTA

416. Under Article 2203 of the NAFTA, the treaty has been in force for both Canada and the United States since January 1, 1994. The measure at issue – the Import Alert – was implemented well after the NAFTA entered into force, namely from August 2009 to July 2011.
417. In Chapter Eleven of the NAFTA, the United States of America agreed to submit to arbitration disputes pertaining to the substantive obligations undertaken therein. Claimants accepted this offer in their Request for Arbitration, which was received by the ICSID Secretary-General on March 6, 2012⁵⁹⁶. This acceptance formed an agreement to arbitrate on that date.⁵⁹⁷

⁵⁹⁵ Witness Statement of Kiran Krishnan, paras. 45-46. Witness Statement of Bernice Tao, paras. 49-52; Witness Statement of Gordon Fahner, paras. 89, 101.

⁵⁹⁶ **Exhibit C-293**, Letter from ICSID Secretariat, dated March 6, 2012.

⁵⁹⁷ See **Legal Authority CLA-1**, NAFTA, art. 1122(2) (“The consent given by paragraph 1 [i.e. consent to arbitration given by the State Parties] and the submission by a disputing investor of a claim to arbitration

418. Claimants' Request for Arbitration was timely received by the Secretary-General within the three-year period of limitations established in the NAFTA.⁵⁹⁸ Indeed, the Import Alert was adopted on August 28, 2009 and the Claimants learned about it in the days that followed. The Request for Arbitration was received by the ICSID Secretary-General on March 6, 2012,⁵⁹⁹ less than three years after the Claimants and Apotex-US first acquired knowledge of the treaty breaches and of the losses incurred.
419. Article 1120 of the NAFTA further requires that six months elapse between the events giving rise to a claim and the submission of a claim to arbitration. As just noted, the Import Alert was adopted on August 28, 2009 and the Claimants' Request for Arbitration was received by the ICSID Secretary-General on March 6, 2012, more than six months after the events giving rise to the dispute.
420. In addition, Article 1119 provides that the disputing investors shall deliver to the disputing Party written notice of their intention to submit a claim to arbitration at least 90 days before the claim is submitted. Here, the Claimants' notice of intent to submit a claim to arbitration, dated November 23, 2011, was delivered to the United States Government, Office of the Legal Adviser, Executive Director (L/EX) on November 25, 2011.⁶⁰⁰ The US Government acknowledged receipt of the notice of intent on November 28, 2011.⁶⁰¹ Again, the Claimants' Request for Arbitration was received by

shall satisfy the requirement of: (a) ... the Additional Facility Rules for written consent of the parties ..."). See also *id.*, art. 1137(1) ("A claim is submitted to arbitration under this Section when: ... (b) the notice of arbitration under Article 2 of Schedule C of the ICSID Additional Facility Rules has been received by the Secretary-General ...").

⁵⁹⁸ *Id.*, at art. 1116(2), 1117(2). Article 1116(2) states as follows: "An investor may not make a claim if more than three years have elapsed from the date on which the investor first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the investor has incurred loss or damage." Article 1117(2) similarly provides: "An investor may not make a claim on behalf of an enterprise described in paragraph 1 if more than three years have elapsed from the date on which the enterprise first acquired, or should have first acquired, knowledge of the alleged breach and knowledge that the enterprise has incurred loss or damage."

⁵⁹⁹ **Exhibit C-293**, Letter from the ICSID Secretariat to Claimants' counsel, dated March 6, 2012. The Secretary-General of ICSID approved access to the Additional Facility and registered the Request for Arbitration on March 16, 2012. See **Exhibit C-294**, Letter from Meg Kinnear, Secretary-General of ICSID, dated March 16, 2012.

⁶⁰⁰ See **Exhibit C-274**, Fedex Email confirming delivery of Notice of Intent to Submit a Claim to Arbitration, dated November 25, 2011.

⁶⁰¹ See **Exhibit C-286**, Letter from US Government to Salans, dated January 6, 2012.

the ICSID Secretary-General on March 6, 2012, more than 90 days after delivery of the notice of intent to submit a claim to arbitration.

421. The record thus establishes the Tribunal's jurisdiction *rationae temporis*.

II. THE US BREACHED ARTICLES 1102 AND 1103 BY ACCORDING APOTEX LESS FAVORABLE TREATMENT

422. By adopting and maintaining the Import Alert in the way that it did, the United States accorded Apotex and its investments treatment that was less favorable than the United States' treatment of comparable investors and investments in like circumstances. The United States therefore breached NAFTA Articles 1102 and 1103 on national treatment and most-favored-nation treatment.

423. In the discussion that follows, Apotex first reviews the legal standard of "no less favorable treatment" established by Articles 1102 and 1103. It then shows that the record here establishes the elements of a violation of these articles: Apotex and its investments were (i) in like circumstances to covered national and third-country investors and investments and (ii) the treatment the United States accorded Apotex was less favorable than that accorded to its covered comparators.

A. The Legal Standard of Articles 1102 and 1103

424. 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, 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.⁶⁰²

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

⁶⁰² **Legal Authority CLA-1**, NAFTA, art. 1102(1)-(2).

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.⁶⁰³

426. Articles 1102 and 1103 thus impose an identical obligation with respect to investors and investments of investors of another Party, the sole difference being the nationality of the comparator.⁶⁰⁴

427. Because of the definitional structure of the NAFTA investment chapter, a single measure directed to a single investment can breach both Article 1102 and Article 1103. Take the example of intangible property owned by a US company that is controlled by a Swiss company. The property is an “investment of an investor of a Party” within Article 1139 because it is directly owned by an “enterprise constituted or organized under the law of a Party.”⁶⁰⁵ At the same time, the property is an investment of an “investor of a non-Party” because it is controlled indirectly by “an investor other than an investor of a Party” within the meaning of Article 1139.⁶⁰⁶ If the measure grants the intangible property more favorable treatment than that accorded to a covered investment in like circumstances, the measure will at the same time violate each of Articles 1102 and 1103.

⁶⁰³ *Id.*, art. 1103(1)-(2). *See also id.*, art. 1104 (“Each Party shall accord to investors of another Party and to investments of investors of another Party the better of the treatment required by Articles 1102 and 1103.”).

⁶⁰⁴ **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 228 (Sept. 18, 2009) (framing the obligations of Articles 1102 and 1103 in unitary terms, except with respect to the nationality of the comparator).

⁶⁰⁵ **Legal Authority CLA-1**, NAFTA, art. 1139 (definitions of “enterprise of a Party”, “investment”, “investment of an investor of a Party”, and “investor of a Party”). *See also id.*, art. 1102(2) (identifying relevant comparator as “investments of [a Party’s] own investors”).

⁶⁰⁶ *Id.*, art. 1139 (definitions of “investment”, “investor of a Party” and “investor of a non-Party”). *See also id.*, art. 1103(2) (identifying relevant comparator as “investments of investors of any other Party or of a non-Party”).

428. Two basic elements are required to establish a violation of Article 1102 or 1103: like circumstances and less favorable treatment. As the tribunal in *Cargill v. Mexico* put it:

Accordingly, it must be demonstrated first that the Claimant, as an investor, is in “like circumstances” with the investor of another Party or of a non-Party, or that the Claimant’s investment is in “like circumstances” with the investment of an investor of another Party or of a non-Party. And second, it must be shown that the treatment received by Claimant was less favourable than the treatment received by the comparable investor or investment.⁶⁰⁷

429. As the above formulation suggests, an investor establishes a violation by demonstrating like circumstances and less favorable treatment in relation to a single eligible comparator; Articles 1102 and 1103 do not require a showing of class-based discrimination.⁶⁰⁸ Nor do these articles require any showing of discriminatory intent.⁶⁰⁹

⁶⁰⁷ **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 228 (Sept. 18, 2009). See also **Legal Authority CLA-343**, Meg N. Kinnear, Andrea K. Bjorklund, & John F.G. Hannaford, *Investment Disputes Under NAFTA: An Annotated Guide to NAFTA Chapter 11*, Kluwer Law International, 20-1102 (2006) (“Article 1102 requires that an investor, or an investment of an investor, be accorded (1) treatment that is (2) ‘no less favorable’ than that accorded to a domestic investor or investment (3) ‘in like circumstances’ with the covered investor or investment.”); **Legal Authority CLA-350**, Sergio Puig and Meg Kinnear, *NAFTA Chapter Eleven at Fifteen: Contributions to a Systemic Approach in Investment Arbitration*, 25 ICSID Review-Foreign Investment Law Journal 225, 241-42 (2010) ([A] majority of NAFTA tribunals treat “like circumstances” as “a first-level inquiry or as a threshold matter, i.e. only after determining that the two entities that allegedly received differential treatment were in fact in like circumstances did the Tribunal assess the treatment accorded to them.”).

⁶⁰⁸ **Legal Authority CLA-42**, *Pope & Talbot Inc v. The Government of Canada*, UNCITRAL, Award on the Merits of Phase 2, para. 36 (Apr. 10, 2001) (dismissing Canada’s argument that the use of “investments” and “investors” in Articles 1102 and 1103 required a showing concerning multiple comparators: “The Tribunal also rejects the contention that that plural form requires, as a matter of semantics, comparison of the treatment provided to the foreign investor with that accorded to more than one domestically owned investment.”). See, e.g., **Legal Authority CLA-31**, *Marvin Feldman v. Mexico*, ICSID Case No. ARB(AF)/99/1, Award, para. 187 (Dec. 16, 2002) (finding violation of Article 1102 based on showing of more favorable treatment of a single comparator).

⁶⁰⁹ *Id.*, para. 183 (Dec. 16, 2002) (rejecting Mexico’s argument that a showing of intent to discriminate was required, finding that “requiring a foreign investor to prove that discrimination is based on his nationality could be an insurmountable burden to the Claimant, as that information may only be available to the government.”). See also **Legal Authority CLA-30**, *International Thunderbird Gaming Corporation v. The United Mexican States*, UNCITRAL, Award, paras. 176-77 (Jan. 26, 2006) (“Thunderbird must show that its investment received treatment less favourable than Mexico has accorded, in like circumstances, to investments of Mexican nationals. It is not expected from Thunderbird that it shows *separately* that the less favourable treatment was motivated because of nationality.”) (emphasis in original); **Legal Authority CLA-29A**, *Grand River Enterprises Inc. v. United States*, UNCITRAL, Rejoinder of the United States, at 67 (May 13, 2009) (“[T]he requirement to show discrimination on the basis of nationality under Article 1102 does *not* require a showing of discriminatory intent. Rather, a Claimant must establish that a measure either on its face, or as applied, favors nationals over non-nationals.”) (emphasis in original).

430. We address each of the two elements of Articles 1102 and 1103 in turn.

1. “Like Circumstances”

431. In considering “like circumstances”, the NAFTA directs that the trade and investment-liberalizing objectives stated in Article 102(1) be taken into account.⁶¹⁰ That provision, in turn, specifically identifies as fundamental principles and rules “national treatment, most-favored-nation treatment and transparency” and states as objectives the elimination of barriers to trade, the promotion of conditions of fair competition, and a substantial increase in investment opportunities in the territories of the Parties.⁶¹¹ These objectives inform the approach to “like circumstances.”⁶¹²

432. As observed by one of the first arbitral tribunals to address the question, the “like circumstances” inquiry is inherently context-specific:

It goes without saying that the meaning of the term will vary according to the facts of a given case. By their very nature, “circumstances” are context dependent and have no unalterable meaning across the spectrum of fact situations.⁶¹³

As another tribunal put it, “all ‘circumstances’ in which the treatment was accorded are to be taken into account in order to identify the appropriate comparator.”⁶¹⁴

433. This being said, several common elements appear from the NAFTA jurisprudence on “like circumstances.” These include, notably, the usefulness of considering whether the comparators (a) are in the same economic sector and subsector as the claimant; (b) have

⁶¹⁰ **Legal Authority CLA-1**, NAFTA, art. 102(2) (“The Parties shall interpret and apply the provisions of this Agreement in the light of its objectives set out in paragraph 1 and in accordance with applicable rules of international law.”).

⁶¹¹ *Id.*, art. 102(1).

⁶¹² See **Legal Authority CLA-43**, *S.D. Myers, Inc. v. Government of Canada*, UNCITRAL, Partial Award, para. 250 (Nov. 13, 2000) (“The Tribunal considers that the interpretation of the phrase ‘like circumstances’ in Article 1102 must take into account the general principles that emerge from the legal context of the NAFTA, including both its concern with the environment and the need to avoid trade distortions that are not justified by environmental concerns.”); **Legal Authority CLA-42**, *Pope & Talbot Inc v. The Government of Canada*, UNCITRAL, Award on the Merits of Phase 2, para. 77 (Apr. 10, 2001) (“The Investor submits that the legal context of Article 1102 includes ‘the trade and investment-liberalizing objectives of the NAFTA’. The Tribunal agrees.”) (footnote omitted).

⁶¹³ *Id.*, para. 75 (Apr. 10, 2001) (footnotes omitted).

⁶¹⁴ **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).

invested in businesses that produce competing goods or services; and (c) are subject to the same regulatory regime that produced the offending measure.

434. *First*, it is generally accepted that “the treatment accorded a foreign owned investment protected by Article 1102(2) should be compared with that accorded domestic investment *in the same business sector or economic sector*.”⁶¹⁵ In this context, “the word ‘sector’ has a wide connotation that includes the concepts of ‘economic sector’ and ‘business sector’.”⁶¹⁶
435. By way of illustration, in *Feldman v. Mexico*, the claimant’s Mexican company was a reseller and exporter of cigarettes. The tribunal determined that “the ‘universe’ of firms in like circumstance [were] those foreign-owned and domestic-owned firms that [were] in the business of reselling/exporting cigarettes. Other Mexican firms that may also export cigarettes, such as Mexican cigarette producers, [were] not in like circumstances.”⁶¹⁷ In other words, the *Feldman* tribunal focused on “the trading companies, those in the business of purchasing Mexican cigarettes for export.”⁶¹⁸
436. The “like circumstances” element does not require that the investor identify a comparator in circumstances identical to its own.⁶¹⁹ However, as the tribunal in *Methanex* found, where the record establishes comparators whose circumstances closely

⁶¹⁵ **Legal Authority CLA-42**, *Pope & Talbot Inc v. The Government of Canada*, UNCITRAL, Award on the Merits of Phase 2, para. 78 (Apr. 10, 2001) (emphasis added).

⁶¹⁶ **Legal Authority CLA-43**, *S.D. Myers, Inc. v. The Government of Canada*, Partial Award, UNCITRAL, para. 250 (Nov. 13, 2000) (holding that the relevant sector in that case was that of PCB waste remediation services).

⁶¹⁷ **Legal Authority CLA-31**, *Marvin Feldman v. United Mexican States*, Case No. ARB(AF)/99/1, Award, para. 171 (Dec. 16, 2002).

⁶¹⁸ *Id.*, at para. 172 (Dec. 16, 2002).

⁶¹⁹ **Legal Authority CLA-34**, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award, Part IV, Ch. B, para. 15 (Aug. 3, 2005) (quoting US Rejoinder, para. 154: “[I]n like circumstances’ allows for a certain degree of flexibility in the national treatment analysis, such as where there is no identical domestically-owned counterpart to the foreign-owned investment. In such a case, a tribunal may look farther afield and expand the scope of domestically-owned comparators as long as they are similar enough to justify considering their circumstances to be ‘like’ that of the foreign investor or investment.”). *See also* **Legal Authority CLA-25**, *Corn Products International, Inc. v. The United Mexican States*, ICSID Case No. ARB(AF)/04/01, Decision on Responsibility, para. 129 (Jan. 15, 2008) (“Article 1102 requires that the investors (or investments) which are being compared are in *like not identical* circumstances.”) (emphasis in original).

correspond to those of the claimant, the “like circumstances” analysis logically narrows to the group of close comparators.⁶²⁰

437. *Second*, another factor repeatedly considered by tribunals in assessing like circumstances is whether the comparators have invested in businesses that compete in terms of goods or services.⁶²¹ This does not imply a conflation of “like circumstances” in Articles 1102 and 1103 with trade provisions such as “like goods” or “any like, directly competitive or substitutable goods.”⁶²² However, that the investor or the investment competes with the comparators is a pertinent factor in assessing “like

⁶²⁰ **Legal Authority CLA-34**, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award, Part IV, Ch. B, para. 17 (Aug. 3, 2005) (“[I]t 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. The difficulty which Methanex encounters in this regard is that there are comparators which are *identical* to it.”) (emphasis in original). *See also Legal Authority CLA-32*, *Merrill & Ring Forestry L. P. v. The Government of Canada*, UNCITRAL, Award, para. 90 (Mar. 31, 2010) (The tribunal concluded that there were identically situated investors comparable to the claimant, *i.e.*, log producers operating on lands under federal jurisdiction in British Columbia and subject to the same requirements under the federal regulatory framework of log exports.).

⁶²¹ *See, e.g., 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. 203 (Nov. 21, 2007) (“The evidence on the record does not show that there were identical Mexican-owned HFCS producers when the Tax was adopted. Only U.S. investors – including ALMEX [the investment] and CPI [a third party in this arbitration] – manufactured and distributed HFCS in Mexico. Therefore, the firms they can be compared with are the domestic sugar producers with which, at the time the Tax was in force, shared the market, competing directly in supplying sweeteners to soft drink bottlers and processed food firms in Mexico.”). *See also Legal Authority CLA-25*, *Corn Products International, Inc. v. United Mexican States*, ICSID Case No. ARB(AF)/04/01, Decision on Responsibility, para. 120 (Jan. 15, 2008) (same holding).

⁶²² *See Legal Authority CLA-34*, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award, Part IV, Chapter B, paras. 29-37 (Aug. 3, 2005). *See also Legal Authority CLA-32*, *Merrill & Ring Forestry L. P. v. The Government of Canada*, UNCITRAL, Award, para. 86 (Mar. 31, 2010) (The tribunal was “mindful of the need not to make expressions used in different contexts and treaties interchangeable in spite of their similarity, as is the case of ‘like products’ under GATT Article III:4 [and ‘like circumstances’ under NAFTA Article 1102].”); **Legal Authority CLA-25**, *Corn Products International, Inc. v. The United Mexican States*, ICSID Case No. ARB(AF)/04/01, Decision on Responsibility, para. 121 (Jan. 15, 2008) (The tribunal took note of the decisions of the WTO panel and appellate body holding that HFCS and sugar were “like products,” but noted that the test under Article 1102 is “separate and distinct.”).

circumstances”⁶²³ – even if such a showing, by itself, might not be sufficient to establish “like circumstances.”⁶²⁴

438. *Third*, the measure at issue and the legal regime pursuant to which it was adopted is a key element of the “like circumstances” analysis.⁶²⁵ As noted in a recent award, “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.”⁶²⁶ To put it slightly differently, the foreign and domestic entities that are being compared must be subject to a comparable legal regime or regulatory requirements.

2. *Less Favorable Treatment*

439. Articles 1102 and 1103 require the State Party to afford “no less favorable” “treatment” with respect to “the establishment, acquisition, expansion, management, conduct, operations, and sale or other disposition of the investments.” NAFTA tribunals have remarked the provisions’ “broad scope of application,”⁶²⁷ finding that “treatment”

⁶²³ *Id.*, at para. 126 (Jan. 15, 2008) (“We conclude that where the products at issue are interchangeable and indistinguishable from the point of view of the end-users (i.e. the purchaser of soft drinks), the products, and therefore the respective investments, are in like circumstances. Any other interpretation would negate the effect of the non-discrimination clauses, because it would always be possible to find differences between the way competing products are owned, managed, regulated, or priced.”).

⁶²⁴ **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 195 (Sept. 18, 2009) (“[S]omething more than the likeness of goods being produced has to be shown in order to establish that the investor and domestic producers are ‘in like circumstances,’ particularly where there are other factors that potentially differentiate the situation of the investor or its investment from that of domestic producers of the ‘like good’ in question.”).

⁶²⁵ *See Legal Authority CLA-42*, *Pope & Talbot Inc v. The Government of Canada*, UNCITRAL, Award on the Merits of Phase 2, para. 76 (Apr. 10, 2001) (“An important element of the surrounding facts will be the character of the measures under challenge.”); **Legal Authority CLA-25**, *Corn Products International, Inc. v. United Mexican States*, ICSID Case No. ARB(AF)/04/01, Decision on Responsibility, para. 118 (Jan. 15, 2008) (“The application of this three-fold test must, however, be sensitive to the particular circumstances of each case with the analysis focusing on the specific nature of the measure under challenge.”); **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 205 (Sept. 18, 2009) (quoting *Pope & Talbot, Inc v. The Government of Canada*, UNCITRAL, Award on the Merit Phase 2, para. 76 (Apr. 10, 2001)).

⁶²⁶ **Legal Authority CLA-29**, *Grand River Enterprises Six Nations, Ltd., et al. v. United States of America*, UNCITRAL, Award, para. 166 (Jan. 12, 2011).

⁶²⁷ **Legal Authority CLA-18**, *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Award, paras. 152-53 (Jan. 9, 2003) (referring to “the breadth of the definitional scope of the critical term ‘investment,’” to the definition of “investment” in Article 1139 and of “enterprise” in Article 201, and to the “range of the ‘treatment’ which must be accorded to the beneficiary ‘investor’ and ‘investment’: that is, ‘treatment’ ‘with respect to the establishment, acquisition, expansion, management, conduct, operation and sale or other disposition of investments.’”).

“includes almost any conceivable measure that can be with respect to the beginning, development, management and end of an investor’s business activity.”⁶²⁸

440. NAFTA tribunals have found that, in Articles 1102 and 1103, “treatment is no different than the aggregate of all the regulatory measures applied to that business.”⁶²⁹ Given the NAFTA’s widely encompassing definition of the term “measure,”⁶³⁰ tribunals have found the “treatment” requirement of Articles 1102 and 1103 satisfied by the way the Canadian customs processed postal and courier items to be delivered in Canada⁶³¹ and a Mexican excise tax that reduced the investors’ enterprise’s profits on the sale of a product and, consequently, “did impair to a certain extent the ability of [the enterprise] to conduct or expand operations to satisfy the domestic demand for [the product] in Mexico.”⁶³²

441. NAFTA tribunals have held that the term “‘no less favorable’ means equivalent to, not better or worse than, *the best treatment* accorded to the comparator.”⁶³³ In assessing the treatment of record, NAFTA tribunals have focused on the practical impact of the measure and made clear that a measure with a discriminatory impact as well as one

⁶²⁸ **Legal Authority CLA-32**, *Merrill & Ring Forestry L. P. v. The Government of Canada*, UNCITRAL, Award, para. 79 (Mar. 31, 2010).

⁶²⁹ *Id.*

⁶³⁰ **Legal Authority CLA-1**, NAFTA, art. 201 (“[M]easure includes any law, regulation, procedure, requirement or practice ...”).

⁶³¹ **Legal Authority CLA-51**, *United Parcel Service of America Inc v. The Government of Canada*, UNCITRAL, Award on the Merits, para. 85 (May 24, 2007).

⁶³² **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. 188 (Nov. 21, 2007). See also **Legal Authority CLA-25**, *Corn Products International, Inc. v. United Mexican States*, ICSID Case No. ARB(AF)/04/01, Decision on Responsibility, para. 119 (Jan. 15, 2008) (HFCS tax considered as “treatment”).

⁶³³ **Legal Authority CLA-42**, *Pope & Talbot Inc v. The Government of Canada*, UNCITRAL, Award on the Merits of Phase 2, para. 42 (Apr. 10, 2001) (emphasis added); *id.*, para. 41 ([N]ational governments, like states and provinces, “cannot comply with NAFTA by according foreign investments less than the most favourable treatment they accord their own investments.”); **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. 205 (Nov. 21, 2007) (“Accordingly, Claimants and their investment are entitled to the best level of treatment available to any other domestic investor or investment operating in like circumstances ...”).

discriminatory in its terms can accord less favorable treatment within Articles 1102 and 1103.⁶³⁴ In the words of the *Feldman* tribunal:

[I]t is not self-evident, as the Respondent argues, that any departure from national treatment must be *explicitly* shown to be a result of the investor's nationality. There is no such language in Article 1102. Rather, Article 1102 by its terms suggests that it is sufficient to show less favourable treatment for the foreign investor than for domestic investors in like circumstances.⁶³⁵

B. The United States Accorded Apotex Less Favorable Treatment than Comparators in Like Circumstance

442. The record establishes that Apotex and its investments received treatment less favorable than that afforded US and third-country investors and US-owned and third-country-owned investments in like circumstances. The United States breached its obligations of national treatment and most-favored-nation treatment under Articles 1102 and 1103.

443. As discussed below, the record establishes each of the two elements of a violation of Articles 1102 and 1103. We address each of the like circumstances and less favorable treatment elements below in turn.

1. The Record Establishes Multiple Comparators in Like Circumstances

444. The accompanying Bradshaw-Johnson Report identifies a number of US and third-country investors and investments in like circumstances with Apotex and its investments: Baxter, Hospira, Novartis/Sandoz, Perrigo, Teva. Mr. Bradshaw, it will be recalled, served as FDA Chief Counsel and in that capacity reviewed hundreds of warning letters and dozens of proposed enforcement actions. Mr. Johnson, it will be recalled, was an FDA district director and headed the compliance office of an FDA center dealing with medical devices. Messrs. Bradshaw and Johnson draw on great

⁶³⁴ **Legal Authority CLA-43**, *S.D. Myers, Inc. v. The Government of Canada*, UNCITRAL, Partial Award para. 254 (Nov. 13, 2000) (“The word ‘treatment’ suggests that *practical impact* is required to produce a breach of Article 1102, not merely a motive or intent that is in violation of Chapter 11.”) (emphasis added).

⁶³⁵ **Legal Authority CLA-31**, *Marvin Feldman v. United Mexican States*, Case No. ARB(AF)/99/1, Award, para. 181 (Dec. 16, 2002) (emphasis in original). *See id.*, para. 169 (“[I]f [the requirement of a federal law] is ignored or waived for domestic [investors], but not for foreign owned [similarly situated investors], that *de facto* difference in treatment is sufficient to establish a denial of national treatment under Article 1102.”).

combined experience in evaluating like circumstances in the context of FDA regulation of pharmaceutical products. They conclude, and the record reviewed in Part XI of the Statement of Facts establishes, that these comparators are in like circumstances with Apotex and its investments in every pertinent respect.

445. *First*, each of these comparators operates in precisely the same economic sector, and subsector as Apotex. Each is a pharmaceutical company. Each manufactures and markets finished drug products for human use in the United States. Each includes or focuses on generic drugs in its product line in the United States. Like Apotex, each is a major player on the US generic drug market; each relies on highly sophisticated, often globally integrated manufacturing to deploy its products on the US market.
446. *Second*, each of these comparators owns or controls investments in the United States that correspond to those of Apotex at issue here. Each owns or controls, directly or indirectly, a business in the United States that distributes and markets its products, just as Apotex-US does for Apotex. Each owns or controls, directly or indirectly, approved ANDAs or new drug applications that correspond to those owned by Apotex-Canada. Each of these comparators is a US company, a third-country company or is owned and controlled by a US or third-country company.
447. *Third*, each of the comparators competes with Apotex on the US pharmaceuticals market. Each has, at one or more points in 2008-2012, appeared on the industry-standard list of the top 25 sellers of generic pharmaceutical products in the United States prepared by IMS Health.⁶³⁶
448. *Fourth*, each of the comparators was in “like circumstances” in terms of the regulatory framework that gave rise to the measure in this case. During the 2008-2012 period, FDA sent each of the comparators one or more warning letters with respect to its

⁶³⁶ **Exhibit C-181** (in 2009, Teva was No. 1 in the rank, Sandoz No. 3, Hospira No. 7, Baxter No. 20; Apotex was No. 6 at the time); **Exhibit C-182** (in 2010, Teva and Sandoz continued to lead and occupied the 1st and the 3rd positions; Hospira moved up to the 6th place, Taro remained at the 21st place, and Perrigo entered the “25 top” list and took the 24th place; by then, Apotex fell to the 25th place); **Exhibit C-239** (in 2011, Teva, Sandoz and Hospira preserved their previous year’s positions; Taro and Perrigo moved up to the 19th and the 20th positions, respectively; Apotex moved slightly up, to the 24th place); **Exhibit C-305** (in 2012, Teva continues to lead, Sandoz holds the 4th place, Hospira moved down to 7th place, Taro moved up to 13th and Perrigo remains No. 20; Apotex is currently at the 22nd place.).

compliance with cGMP at a facility producing finished drug products for sale in the United States. As Messrs. Bradshaw and Johnson observe, FDA issues warning letters as a matter of policy only for violations of regulatory significance which, if not promptly and adequately corrected, may lead to enforcement action.⁶³⁷ From the perspective of a former FDA Chief Counsel, District Director and specialists in FDA regulation, the determination by FDA that cGMP issues at a facility are of regulatory significance is the best indicator that companies are in like circumstances in terms of the regulatory regime applicable to the measure at issue in this case.⁶³⁸ Nonetheless, Messrs. Bradshaw and Johnson also took into account the factors mentioned in FDA's 3-page internal memorandum concerning its decision to recommend an import alert in Apotex's case, notably the presence of perceived repeat or "corporate" violations of cGMP. In their expert opinion, each of the comparators was in like circumstances with Apotex from the perspective of the applicable regulatory regime.⁶³⁹

2. *The Record Establishes That Apotex Received Less Favorable Treatment Than the Comparators*

449. As demonstrated in Part XI of the Statement of Facts and in the Bradshaw-Johnson Report, FDA accorded each of the comparators treatment that was far more favorable than that accorded to Apotex and its investments.
450. Apotex was prevented from selling any product manufactured at Etobicoke or Signet for a period of two years. The Import Alert covered in excess of ■ different molecules, amounting to 80 percent of the sales of Apotex-US in the US. FDA refused to approve any pending Apotex ANDAs during the pendency of the Import Alert. Apotex had no opportunity to respond to the observations at Signet or to implement corrective action before the Import Alert was adopted.
451. By contrast, none of Baxter, Hospira, Novartis/Sandoz, Perrigo and Teva was prevented from selling its products on the US market. Instead, each was allowed to implement corrective action after receipt of a warning letter. Each had a full opportunity to

⁶³⁷ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 70.

⁶³⁸ *Id.*, para. 107

⁶³⁹ *Id.*, para. 141 ("FDA's inaction in addressing the chronic and documented ongoing, corporate-wide non-compliance of Novartis Sandoz is in stark contrast to its treatment of Apotex."); paras. 105-110.

respond to inspectional observations and to the warning letters. No enforcement action has been taken against any of them. Each has been able to continue to process new ANDAs.

452. In short, the record establishes that the United States accorded Apotex less favorable treatment than comparators in like circumstances. The record establishes a breach of NAFTA Articles 1102 and 1103.

III. THE IMPORT ALERT DENIED APOTEX FAIR AND EQUITABLE TREATMENT

453. By adopting the Import Alert, the US Government denied Apotex's investments the minimum standard of treatment required by NAFTA Article 1105 and the treatment required by the Jamaica-US investment treaty, applicable by virtue of NAFTA Article 1103 and Annex IV.

A. The Import Alert Breached NAFTA Article 1105(1)

454. 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.⁶⁴⁰

455. The standard of treatment imposed by this provision is an absolute standard. In contrast to Articles 1102 and 1103 mentioned above, Article 1105 does not define the standard of treatment by reference to the relative treatment accorded to a comparator. It requires instead that investments by NAFTA investors be treated according to a referenced body of international law.

456. According to the note of interpretation issued by the Free Trade Commission pursuant to NAFTA Article 2001:

1. Article 1105(1) prescribes the customary international law minimum standard of treatment of aliens as the minimum

⁶⁴⁰ **Legal Authority CLA-1**, NAFTA, art. 1105(1).

standard of treatment to be afforded to investments of investors of another Party.

2. The concepts of “fair and equitable treatment” and “full protection and security” do not require treatment in addition to or beyond that which is required by the customary international law minimum standard of treatment.⁶⁴¹

457. It follows that in order to prove a breach of NAFTA Article 1105, a claimant must demonstrate the breach of an existing rule of customary international law.⁶⁴²

458. As demonstrated below, it is well-established in international law that administrative authorities must afford certain procedural safeguards in deciding the rights and interests of individual parties. Recent State practice further reinforces this conclusion. International arbitral tribunals have found the relevant standard applied to the administrative process to have evolved over time.

1. International Law Requires Due Process in Administrative Decision-Making Concerning Specific Persons

459. As repeatedly observed by the NAFTA Parties and tribunals, the international minimum standard of treatment embraced by NAFTA Article 1105(1) is “an umbrella concept incorporating a set of rules that over the centuries have crystalized into customary international law in specific contexts.”⁶⁴³ This set of rules establishes different standards applicable to different contexts, such as denial of justice or expropriation, as well as other acts affecting aliens and their property.

⁶⁴¹ **Legal Authority CLA-5**, NAFTA Free Trade Commission, Notes of Interpretation of Certain Chapter 11 Provisions (July 31, 2001).

⁶⁴² **Legal Authority CLA-12**, U.S. Model Bilateral Investment Treaty, Annex A, Apr. 20, 2012 (“The Parties confirm their shared understanding that ‘customary international law’ generally and as specifically referenced in Article 5 [Minimum Standard of Treatment] and Annex B [Expropriation] results from a general and consistent practice of States that they follow from a sense of legal obligation. With regard to Article 5 [Minimum Standard of Treatment], the customary international law minimum standard of treatment of aliens refers to all customary international law principles that protect the economic rights and interests of aliens.”). *See also Legal Authority CLA-16*, Statute of the International Court of Justice, United Nations Charter, Article 38(1)(b) (including “international custom” among the sources of international law and defining it as “evidence of general practice accepted as law”).

⁶⁴³ **Legal Authority CLA-19**, *ADF Group Inc. v. United States of America*, ICSID Case No. ARB (AF)/00/1, Post-Hearing Submission of Respondent United States of America on Article 1105(1), at 2-3 (June 27, 2002); **Legal Authority CLA-35**, *Methanex Corporation v. United States of America*, UNCITRAL, Memorial on Jurisdiction and Admissibility of Respondent United States of America, 43 (Nov. 13, 2000). *See also Legal Authority CLA-23*, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 268 (Sept. 18, 2009).

460. As early as 1965, in an authoritative restatement of customary international law, the American Law Institute (ALI)⁶⁴⁴ concluded that the minimum standard of treatment of aliens encompasses the State's duty to afford certain procedural safeguards in the course of administrative proceedings. The Second Restatement states the following as black letter law:

[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 behalf⁶⁴⁵

⁶⁴⁴ The American Law Institute (ALI) is the leading independent organization in the United States producing scholarly work to clarify, modernize, and otherwise improve the law. ALI was founded in 1923 by a group of prominent American lawyers, teachers and judges and is comprised today of judges, practicing lawyers and legal scholars from across the globe. Among those who took part in the elaboration of the Restatement (Second) of the Foreign Relations Law of the United States were eminent jurists from the US (such as Eli Whitney Debevoise and Alwyn V. Freeman) and abroad (such as Lord McNair, Professor Charles Rousseau and Professor Ignaz Seidl-Hohenveldern). Some of those who contributed to the drafting of the Second Restatement served at the State Department (Louis B. Sohn was counselor to the Legal Adviser from 1970 to 1971 and Eugene V. Rostow was Under Secretary of State for Political Affairs from 1966 to 1969). Philip C. Jessup, who left ALI's Advisory Committee in 1961, was the US judge at the International Court of Justice until 1970. See **Legal Authority CLA-318**, American Law Institute, *Restatement of the Law (Second) - Foreign Relations Law of the United States* (American Law Institute Publishers 1965), Reportorial Staff and Advisory Committee Membership, et III-VI.

⁶⁴⁵ **Legal Authority CLA-317**, American Law Institute, Restatement (Second) of the Foreign Relations Law of the United States (1965), § 181. See also **Legal Authority CLA-320**, American Law Institute, Restatement (Third) of the Foreign Relations Law of the United States (1987), § 712, reporters note 13 (“[T]he previous Restatement dealt with economic injuries to aliens in [thirteen different sections]. The subject is treated here in fewer sections,... but without major change in substance.”). See also Article 17 (Denial of a Fair Hearing) of the revised Harvard Draft, which applies both to judicial and administrative proceedings, in **Legal Authority CLA-342**, Louis B. Sohn and R.R. Baxter, Responsibility of States for Injuries to the Economic Interests of Aliens, 55 AJIL 545, p. 550 (1961).

461. According to the American Law Institute, these requirements are part of the “international standard of justice” resulting from the “applicable principles of international law”, as well as a reflection of “[a]nalogous principles of justice generally recognized by states that have reasonably developed legal systems.”⁶⁴⁶ These requirements reflected established customary international law as it existed in 1965; they were not, and did not purport to be, a statement of aspirational or emerging rules.⁶⁴⁷

462. A multitude of scholars have echoed the views of the Restatement Second, repeatedly acknowledging in varying decades and words that:

[p]rocedural fairness is an elementary requirement of the rule of law and a vital element of fair and equitable treatment. It is the antithesis to the international delinquency of denial of justice. *This duty may be violated not only by the courts but also through executive action.*⁶⁴⁸

⁶⁴⁶ **Legal Authority CLA-317**, American Law Institute, *Restatement (Second) of the Foreign Relations Law of the United States* (1965), §§ 165, 178.

⁶⁴⁷ See **Legal Authority CLA-327**, Covey T. Oliver, *The American Law Institute’s Draft Restatement of the Foreign Relations Law of the United States*, 55 AJIL 428, 430 (1961) (alteration in original) (quoting American Law Institute, *Restatement (Second) of the Foreign Relations Law of the United States*, Tentative Draft No. 2 (May 8, 1958)) (“The rules described by the term ‘international law,’ as used in this Restatement, are rules for general application which are valid for any state whether or not it has subscribed to such rules in an international agreement ...”) (omission in original). See also **Legal Authority CLA-16**, Statute of the International Court of Justice, United Nations Charter, Article 38(1)(d) (describing “the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law”). The United States Government in submissions filed in NAFTA arbitrations as well as the US Supreme Court in its opinions has repeatedly recognized the authoritative value of the Second Restatement of the Foreign Relations Law of the United States by referring to its sections with approval. See, e.g., **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, 27 n.26, 36 n.40 (June 1, 2001) (referring to §§ 185, Comment 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, 127 n.98 (Mar. 30, 2001) (referring to § 182, Comment a); **Legal Authority CLA-37**, *Methanex Corporation v. United States of America*, UNCITRAL, Amended Statement of Defense of Respondent United States of America, 177 n.640 (Dec. 5, 2003) (referring to § 197(1)). See also **Legal Authority CLA-203**, *United States v. Stuart*, 489 U.S. 353, 376 (1989) (quoting § 154, Comment b(ii)); **Legal Authority CLA-178**, *Republic of Arg. v. Weltover, Inc.*, 504 U.S. 607, 617-18 (1992) (referring to § 18 on extraterritoriality of American laws); **Legal Authority CLA-169**, *Morrison v. Nat’l Austl. Bank Ltd.*, 130 U.S. 2869, 2893 (2010) (Stevens, J., concurring) (citing with accord § 38).

⁶⁴⁸ **Legal Authority CLA-325**, Christoph H. Schreuer, *Fair and Equitable Treatment in Arbitral Practice*, 6 Journal of World Investment and Trade 357, 381-382 (2005), (emphasis added). See also **Legal Authority CLA-340**, Kenneth Vandeveld, *A Unified Theory of Fair and Equitable Treatment*, 43 N.Y.U.J. Int’l L. & Pol. 43, 49-50 (2010) (“Due process in general requires that one to whom the coercive power of the state is to be applied receive notice of the intended application and an opportunity to contest that application before

463. Arbitral tribunals constituted under various investment agreements have on numerous occasions recognized that the executive's failure to accord due process breaches the fair and equitable treatment standard.⁶⁴⁹ As further confirmed by US treaty practice, "'fair and equitable treatment' includes the obligation not to deny justice in criminal, civil, or *administrative adjudicatory proceedings* in accordance with the principle of due process embodied in the principal legal systems of the world."⁶⁵⁰

an impartial tribunal. ... Customary international law long has required that foreign investors be accorded due process before ... administrative agencies."); **Legal Authority CLA-337**, Jan Paulsson, *Denial of Justice*, at 46 (Cambridge University Press, 2005), ("[O]nce one accepts as the fundamental postulate of the delict that states have an obligation to maintain a decent and available system of justice, it simply cannot be accepted that the state should be freed from its obligation by the simple expedient of preventing or perverting the judicial process by executive or legislative fiat.") (footnote omitted); **Legal Authority CLA-330**, Edwin Borchard, *The "Minimum Standard" of the Treatment of Aliens*, 38 Mich. L. Rev. 445, 460 (1940) ("It is probably less difficult to apply than to define these principles, and we have in their application the aid of innumerable precedents from international practice. In spite of the legislative effort strictly to narrow the conception of denial of justice and the privilege of diplomatic interposition, few foreign countries have been willing to abandon their nationals to the arbitrariness of corrupt courts or *administrative bodies*.") (emphasis added); **Legal Authority CLA-316**, Alwyn V. Freeman, *The International Responsibility of States for Denial of Justice*, at 150 (Longmans, Green & Co., 1938) ("No further evidence is needed to demonstrate that *administrative officials, performing services related to or in aid of the operation of judicial remedies, are capable of perpetrating denials of justice*.") (emphasis in the original); **Legal Authority CLA-323**, Charles De Visscher, *Le Déni de Justice en Droit International*, in 52 The Hague Academy of International Law, *Collected Courses* 365, 386 (1935 II) ("We can only approve [the point of view of several American scholars] when they insist upon the fact that the failures of judicial power are not the only possible basis for bringing diplomatic claims and that such claims may also well be motivated by deficiencies in legislation or the arbitrary conduct of agents of the executive.") (translation by counsel).

⁶⁴⁹ See, e.g., **Legal Authority CLA-75**, *Técnicas Medioambientales Tecmed, S.A. v. United Mexican States*, ICSID Case No. ARB (AF)/00/2, Award, paras. 166, 173 (May 29, 2003) (finding violation of the "fair and equitable treatment" obligation as a result of the non-renewal of a permit by a State agency); **Legal Authority CLA-72**, *PSEG Global, Inc., The North American Coal Corporation, and Konya Ingin Elektrik Uretim ve Ticaret Limited Sirketi v. Turkey*, ICSID Case No. ARB/02/5, Award, para. 252 (Jan. 19, 2007) ("Various examples of the breach of fair and equitable treatment obligation are to be found in the record of this case. Among such breaches, the most prominent are indeed those that have been discussed earlier in connection with the administration's negligence in the handling of the negotiations with the Claimants: an abuse of authority by [the Turkish Ministry of Energy and Natural Resources] ... and the numerous changes in the legislation and inconsistencies in the administration's practice, in particular with respect to the corporate status of the Project Company and the legal status of the concession."); **Legal Authority CLA-61**, *CME Czech Republic B.V. v. Czech Republic*, UNCITRAL, Partial Award, para. 575 (Sept. 13, 2001) ("The collapse of CME's investment was caused by the [Czech] Media Council's coercion against CME."); **Legal Authority CLA-65**, *Joseph Charles Lemire v. Ukraine*, ICSID Case No. ARB/06/18, Award (Mar. 28, 2011) (finding a breach of the FET clause of the US-Ukraine BIT by the Respondent due to the National Council's allocation of radio frequencies).

⁶⁵⁰ See **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 (emphasis added). See also **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

2. *Subsequent State Practice Confirms and Develops This International Obligation*

464. The minimum standard of treatment, like customary international law more generally, is not frozen in time, but evolves with the evolution of society and under the influence of the myriad of international agreements concluded by States during the last two decades.⁶⁵¹ It has therefore been emphasized that to “the modern eye, what is unfair or inequitable need not equate with the outrageous or the egregious.”⁶⁵² As noted by one scholar,

the minimum standard evolved long before the development of international human rights law, when Western notions of the rule of law were not embraced in many parts of the world. Moreover, paralleling the development of international law on human rights (and in some cases far outpacing it) has been the progressive development of procedural and substantive due process within the nation-state ...⁶⁵³

concerning the character of administrative proceedings that impact covered investments or investors of the other party).

⁶⁵¹ See **Legal Authority CLA-347**, OECD, *Fair and Equitable Treatment Standard in International Investment Law*, at 11-12 (OECD Working Papers on International Investment No. 2004/3) (“In considering the meaning and implications of the FTC interpretation, in the context of the NAFTA case *ADF Group Inc. v. United States of America* the *United States* expressed the view that the customary international law referred to in NAFTA Article 1105 (1) is not ‘frozen in time’ and that the minimum standard of treatment does evolve. The FTC interpretation in the view of the United States refers to customary international law ‘as it exists today’. ... *Canada* agreed with the US on the view that the minimum standard of treatment does evolve. ... *Mexico* also agrees that ‘the standard is relative and that conduct which may have not violated international law [in] the 1920s might very well be seen to offend internationally accepted principles today.’”) (last alteration in original) (footnote omitted). See also **Legal Authority CLA-24**, *Chemtura Corporation v. Government of Canada*, UNCITRAL, Award, para. 121 (August 2, 2010) (“At the outset, the Tribunal notes that it is not disputed that the scope of Article 1105 of NAFTA must be determined by reference to customary international law. Such determination cannot overlook the evolution of customary international law, nor the impact of BITs on this evolution.”); **Legal Authority CLA-39**, *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Award, para. 125 (Oct. 11, 2002) (“In holding that Article 1105(1) refers to customary international law, the FTC interpretations incorporate current international law, whose content is shaped by the conclusion of more than two thousand bilateral investment treaties and many treaties of friendship and commerce.”); **Legal Authority CLA-32**, *Merrill & Ring Forestry L. P. v. The Government of Canada*, UNCITRAL, Award, para. 210 (Mar. 31, 2010) (“A requirement that aliens be treated fairly and equitably in relation to business, trade and investment is the outcome of [a] changing reality and as such it has become sufficiently part of widespread and consistent practice so as to demonstrate that it is reflected today in customary international law as *opinio juris*.”) (footnote omitted).

⁶⁵² **Legal Authority CLA-39**, *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Award, para. 116 (Oct. 11, 2002).

⁶⁵³ **Legal Authority CLA-333**, J.C. Thomas, *Reflections on Article 1105 of NAFTA: History, State Practice and the Influence of Commentators*, 17 ICSID Review-Foreign Investment Law Journal 21, 35-36 (2002).

465. Today, principles of fair administrative proceedings are embodied in the legislation of every developed legal system.⁶⁵⁴ As explained by a comparative law scholar:

[A] number of national laws guarantee individuals, 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. These include the French laws of July 11, 1979 and April 12, 2000, the Italian law of August 7, 1990, the Swedish Administrative Procedure Act of 1986, and the Danish Public Administration Act of 1985. The German case is somewhat exceptional in that the proceduralization of individual decision making began immediately in the post-World War II period under the heavy influence of constitutional law and was eventually codified with the Federal Administrative Procedure Act of 1976. Spain is another interesting case: early on, notice and hearing procedures for licensing, procurement, and other types of decisions were set down in the Administrative Procedure Act of 1889. Many Latin American countries have adopted administrative procedure laws: Peru in 1972, Argentina in 1973, Costa Rica in 1978, and Columbia in 1984. The trend toward the proceduralization of individualized administrative determinations can also be observed in East Asia: Japan adopted an Administrative Procedure Act in 1993 and South Korea in 1995.⁶⁵⁵

See also Legal Authority CLA-351, Stephan W. Schill, *Fair and Equitable Treatment, the Rule of Law, and Comparative Public Law*, in *International Investment Law and Comparative Public Law* 159 (Stephan W. Schill ed., Oxford University Press 2010) (“A comparative analysis of municipal law reveals certain common ideas and standards that can be transferred to the international level and help to identify the paradigm features a state has to conform to in order to comply with the notions of ‘fairness and equitableness’ in international investment law.”); **Legal Authority CLA-76**, *Toto Costruzioni Generali S.p.A. v. Republic of Lebanon*, ICSID Case No. ARB/07/12, Award, para. 193 (June 7, 2012) (“Furthermore, fair and equitable treatment has to be interpreted with international and comparative standards of domestic public law as a benchmark.”).

⁶⁵⁴ Such principles are evidenced by State practice and may also be considered as “general principles of law recognized by civilized nations” within the meaning of art. 38(1)(c) of the Statute of the International Court of Justice. See **Legal Authority CLA-32**, *Merrill & Ring Forestry L. P. v. The Government of Canada*, UNCITRAL, Award, para. 184 (Mar. 31, 2010) (“In fact, the reference that Articles 1105(1) and 1131(1) make to ‘international law’ must be understood as a reference to the sources of this legal order as a whole, not just one of them.”).

⁶⁵⁵ **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, 897-898 (2011) (footnote omitted). See also **Legal Authority CLA-332**, Giacinto della Cananea, *Minimum Standards of Procedural Justice in Administrative Adjudication*, in *International Investment Law and Comparative Public Law*, at 69-70 (Stephan W. Schill ed., Oxford University Press 2010) (Procedural due process “include[s] the right to be heard and, as a consequence, that to present factual evidence; the duty, imposed on the administration, to take such evidence into account when taking a decision; and the duty to provide (adequate) grounds for such

466. Thus, the rule of law translates today into certain procedural requirements for the deployment of legal process that include the right to a hearing before a decision is made, the right to have the decision made in an unbiased and impartial fashion, the right to know the basis of the decision so that it can be contested, the right to reasons for the official's decision, and the right to a decision that is reasonably justified by all relevant legal and factual considerations. And in order to make these rights effective one must add the right to have the validity of the decision tested in a court of law.⁶⁵⁶ All these rights pertaining largely to the category of procedural rights are key elements in order to reach in the end a substantively sound decision.⁶⁵⁷

467. Principles of fair administration are also embodied in supra-national legal orders, such as the laws of the European Union (EU)⁶⁵⁸ and the jurisprudence of the World Trade

a decision.”); **Legal Authority CLA-218**, *Hari Khemu Gawali v. The Deputy Commissioner of Police of Bombay*, 1956 AIR 559, 1956 SCR 506 (May 8, 1956) (The Court considered that the restriction to the freedom of residence of an individual was justified, and observed that certain procedural safeguards were available, such as the right to be informed in writing of the general nature of the material allegations against him, the right to be heard and adduce evidence in his defense and the right to file an appeal to the State Government against the order.); **Legal Authority CLA-219**, *Ramana Dayaram Shetty v. The International Airport Authority of India*, 1979 AIR 1628, 1979 SCR (3) 1014, 1016 (May 4, 1979) (The Supreme Court of India held: “It is unthinkable that in a democracy governed by the rule of law the executive Government or any of its officers should possess arbitrary power over the interests of the individual. Every action of the executive Government must be informed with reason and should be free from arbitrariness. That is the very essence of the rule of law and its bare minimal requirement.” (reference omitted)).

⁶⁵⁶ See **Legal Authority CLA-328**, David Dyzenhaus, *The Rule of (Administrative) Law in International Law 3* (NYU Sch. of Law ILLJ, Working Paper No. 2005/1). See also **Legal Authority CLA-332**, Giacinto della Cananea, *Minimum Standards of Procedural Justice in Administrative Adjudication*, in *International Investment Law and Comparative Public Law*, at 63 (Stephan W. Schill ed., Oxford University Press 2010) (With respect to administrative action “even when written rules do not exist, domestic courts regularly do not hesitate to include procedural due process of law, in particular the right to be heard, among the general principles of law which they ensure observance.”).

⁶⁵⁷ See, e.g., **Legal Authority CLA-175**, *People’s Mojahedin Org. of Iran v. U.S. Dep’t of State*, 613 F.3d 220 (D.C. Cir. 2010) (demonstrating the US courts’ emphasis on the observance by the executive of due process rights in the context of the designation of foreign terrorist organizations; specifying that the Department of State was required, as a matter of due process, to notify the entity of the unclassified material the Department proposed to rely upon and to allow that entity to present evidence to rebut the administrative record before making a determination pursuant to § 1189 of the Anti-Terrorism and Effective Death Penalty Act).

⁶⁵⁸ See **Legal Authority CLA-13**, Charter of Fundamental Rights of the European Union, Article 41 (Right to good administration) (“1. Every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union. 2. This right includes: the right of every person to be heard, before any individual measure which would affect him or her adversely is taken; the right of every person to have access to his or her file, while respecting the legitimate interests of confidentiality and of professional and business secrecy; the obligation of the administration to give reasons for its decisions.”). See also **Legal Authority CLA-89**, *Technische Universität München v. Hauptzollamt München-Mitte*, Case C-269/90, Judgment, para. 28 (Nov. 21, 1991), ECR I-5469 (The European Court of Justice concluded that “the decision in question was adopted pursuant to an administrative procedure in

Organization (WTO).⁶⁵⁹ They have been set out in the case-law of international human rights courts, such as the European Court of Human Rights (ECHR)⁶⁶⁰ and the Inter-American Court of Human Rights (IACHR).⁶⁶¹ Moreover, the requirement of fundamentally fair administrative proceedings is reflected in NAFTA Chapter Eighteen. According to Article 1804 on Administrative Proceedings:

With a view to administering in a consistent, impartial and reasonable manner all measures of general application affecting matters covered by this Agreement, each Party shall ensure that in its administrative proceedings applying measures referred to in Article 1802 to particular persons, goods or services of another Party in specific cases that: (a) wherever possible, persons of another Party that are directly affected by a proceeding are provided reasonable notice, in accordance with domestic procedures, when a 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; (b) such persons are afforded a reasonable opportunity to present facts and arguments in support of their positions prior to any final administrative

which the obligation of the competent institution to examine carefully and impartially all the relevant aspects of the individual case before it, the right to be heard and the obligation to provide an adequate statement of reasons for the decision subsequently adopted were infringed.”); **Legal Authority CLA-90**, *Yassin Abdullah Kadi and Al Barakaat International Foundation v. Council of the European Union and Commission of the European Communities*, Cases C-402/05 P and C-415/05 P (Sept. 3, 2008), ECR I-6351, annulling Council Regulation (EC) No. 881/2002 of 27 May 2002 implementing the UN Security Council Resolution 1267 (1999) sanctions regime for violation of the rights of the defense, in particular the right to be heard and the right to effective judicial review.

⁶⁵⁹ **Legal Authority CLA-82**, *United States - Import Prohibition of Certain Shrimp and Shrimp Products*, Report of the WTO Appellate Body, Doc. WT/DS58/AB/R, paras. 180 (Oct. 12, 1998) (criticizing the unfairness of the US procedure for certifying the shrimp industries of particular States).

⁶⁶⁰ Although the European Convention on Human Rights does not contain any specific provision on administrative procedure, the European Court in Strasbourg has developed in its jurisprudence a set of principles that apply not only to the trial phase, but also to measures adopted by the executive prior to court proceedings. See **Legal Authority CLA-97**, *Imbrioscia v. Switzerland*, no. 13972/88, Ser. A, No. 275, para. 36 (Nov. 24, 1993) (“Other requirements of Article 6 (art. 6) - especially of paragraph 3 (art. 6-3) - may also be relevant before a case is sent for trial if and in so far as the fairness of the trial is likely to be seriously prejudiced by an initial failure to comply with them.”) (citation omitted). See also **Legal Authority CLA-94**, *Fischer v. Austria*, no.16922/90, ECHR Ser. A, No. 312, para. 28 (Apr. 26, 1995) (“It is necessary that, in the determination of ‘civil rights and obligations’, decisions taken by administrative authorities which do not themselves satisfy the requirements of that Article (art. 6-1) be subject to subsequent control by a ‘judicial body that has full jurisdiction’.”).

⁶⁶¹ See **Legal Authority CLA-105**, *Baena Ricardo et al v. Panama*, Inter-Am. Ct. H.R., Ser. C, No. 72, para. 127 (Feb. 2, 2001) (“The right to obtain all the guarantees through which it may be possible to arrive at fair decisions is a human right, and the administration is not exempt from its duty to comply with it. The minimum guarantees must be observed in the administrative process and in any other procedure whose decisions may affect the rights of persons.”).

action, when time, the nature of the proceeding and the public interest permit; and (c) its procedures are in accordance with domestic law.⁶⁶²

468. The NAFTA Parties recognized in 1994 that Chapter Eighteen and Article 1804 set out “basic procedures necessary to meet the requirements of due process and natural justice for all matters covered by the Agreement,”⁶⁶³ a view fully consistent with the approach of customary international law and State practice noted above.
469. Finally, under customary international law, procedural safeguards in judicial and administrative proceedings must be applied without discrimination to all those concerned, irrespective of their nationality. International law prohibits discrimination with respect to due process. It is well-established that a State may not discriminate against aliens in terms of access to judicial and administrative remedies in order to vindicate their rights.⁶⁶⁴

⁶⁶² **Legal Authority CLA-1**, NAFTA, art. 1804.

⁶⁶³ **Legal Authority CLA-3**, Department of External Affairs, Canadian Statement of Implementation, Canada Gazette Part I, 197 (Jan. 1, 1994). *See also Legal Authority CLA-2*, North American Free Trade Agreement Implementation Act, Statement of Administrative Action, H.R. Doc. No. 103-159, Vol. 1, 103d Cong. 1st Sess. (“SAA”) at 19 (1993) (“Chapter Eighteen sets out a number of requirements designed to foster openness, transparency and fairness in the adoption and application of the administrative measures covered by the Agreement. ... Article 1804 requires each government to accord *basic procedural guarantees* to firms and individuals from other NAFTA countries in specific types of administrative proceedings that affect matters covered by the Agreement. These guarantees include reasonable notice of proceedings and the opportunity to present arguments. In addition to these basic guarantees, Chapter Eighteen provides for review and appeal of final administrative action.”) (emphasis added).

⁶⁶⁴ *See Legal Authority CLA-106, Ambatielos (Greece v. UK)*, 12 R.I.A.A. 83, 111 (2006) (“The modern concept of ‘free access to the Courts’ represents a reaction against the practice of obstructing and hindering the appearance of foreigners in Court, a practice which existed in former times and in certain countries, and which constituted an unjust discrimination against foreigners. Hence, the essence of ‘free access’ is adherence to and effectiveness of the principle of non-discrimination against foreigners who are in need of seeking justice before the courts of the land for the protection and defence of their rights.”); **Legal Authority CLA-322**, C.F. Amerasinghe, *State Responsibility for Injuries to Aliens* 243 (Clarendon Press, Oxford, 1967) (“Especially in a suit between State and alien it is imperative that there should be no discrimination between nationals and aliens in the imposition of procedural requirements. The alien cannot be expected to undertake special burdens to obtain justice in the courts of the State against which he has a complaint.”); **Legal Authority CLA-317**, American Law Institute, *Restatement of the Law (Second) - Foreign Relations Law of the United States* (1965), § 166 (“(1) Conduct, attributable to a state and causing injury to an alien, that discriminates against aliens generally, against aliens of his nationality, or against him because he is an alien, departs from the international standard of justice specified in section 165. (2) Conduct discriminates against an alien within the meaning of subsection (1) if it involves treating the alien differently from nationals or from aliens of a different nationality without a reasonable basis for the difference.”); **Legal Authority CLA-37, Methanex v. United States**, UNCITRAL, Amended Statement of Defense of Respondent United States of America, para. 375 (Dec. 5, 2003) (“A second circumstance where non-discrimination is a recognized principle under international law’s minimum standard for the treatment

3. *The United States Denied Apotex Due Process*

470. Despite the devastating impact that the measure had, and that FDA knew it would have, on Apotex Holdings' and Apotex-Canada's investments in the United States, the Import Alert was adopted in breach of the fundamental due process required by the minimum standard of treatment of international law.
471. *First*, the United States provided no access to "an impartial ... administrative authority."⁶⁶⁵ It was the FDA Center for Drug Evaluation and Research (CDER) that recommended adoption of the Import Alert.⁶⁶⁶ Under FDA procedures, the Center had final authority to decide this issue.⁶⁶⁷ The same organ that proposed the measure decided to adopt it. No impartial administrative authority was provided to decide whether to adopt a measure with crippling consequences for Apotex's investments in the US.
472. *Second*, the United States failed to provide Apotex "[a]dequate information with respect to the nature of the proceedings so as to permit the alien to present his claim or defense"⁶⁶⁸ FDA, in fact, failed to inform Apotex even of the existence of the Center's proposal to adopt the Import Alert. The nature of the proceedings and the rationale for the proposal was set out only in an internal memorandum never communicated to

of aliens is denial of justice. The principle of denial of justice includes the notion that aliens should not be discriminated against in terms of access to judicial remedies or treatment by the courts."). *See also Legal Authority CLA-342*, Louis B. Sohn & R.R. Baxter, *Responsibility of States for Injuries to the Economic Interests of Aliens*, 55 AJIL 545, 550 (1961) (reproducing the revised draft Convention on Responsibility of States for Damage Done on Their Territory to the Person or Property of Foreigners, art. 6 (Denial of Access to a Tribunal or an Administrative Authority)); *Legal Authority CLA-15*, Council of Europe, European Convention on Establishment, Dec. 13, 1955, European Treaty Series No. 19, art. 7 ("Nationals of any Contracting Party shall enjoy in the territory of any other Party, under the same conditions as nationals of the latter Party, full legal and judicial protection of their persons and property and of their rights and interests. In particular they shall have, in the same manner as the nationals of the latter Party, the right of access to the competent judicial and administrative authorities and the right to obtain the assistance of any person of their choice who is qualified by the laws of the country.").

⁶⁶⁵ *Legal Authority CLA-317*, American Law Institute, *Restatement (Second) of the Foreign Relations Law of the United States* (1965), § 181(a).

⁶⁶⁶ *See Exhibit C-64*, Memorandum from Director of CDER-Compliance to DIOP, dated August 20, 2009.

⁶⁶⁷ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 102 ("The final DWPE [i.e., import alert] decision is made by the Center.") (citing *Legal Authority CLA-309*, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, sec. 9-6, p. 9-24 (2009)).

⁶⁶⁸ *Legal Authority CLA-317*, American Law Institute, *Restatement (Second) of the Foreign Relations Law of the United States* (1965), § 181(b).

Apotex, which was obtained by its counsel only years later through a FOIA request.⁶⁶⁹ Apotex had no notice and no information that would permit it to present a claim or defense.

473. *Third*, the United States afforded Apotex no “[r]easonable opportunity to contest evidence against [it]” and “to obtain and present witnesses and evidence in [its] own behalf.”⁶⁷⁰ Since FDA had provided no prior notice, Apotex had no possibility to be heard and adduce evidence in its defense. Apotex’s response dated September 3, 2009 to the Form 483 for Signet had not even been transmitted, let alone taken into account, when FDA decided to place the two facilities on Import Alert. Apotex had no opportunity to be heard or present its position before the Import Alert was adopted.

474. Moreover, as observed by Messrs. Bradshaw and Johnson, the post-detention hearing provided for under FDA regulations accorded Apotex no reasonable opportunity to be heard either.⁶⁷¹ The only hearing provided for is one before the “district director” of the district where articles have been detained.⁶⁷² Such a hearing might be useful where the district has detained an article based on physical examination of it or a sample and therefore has both knowledge of the reason for detention and authority to decide to admit the article. As Messrs. Bradshaw and Johnson conclude, however, such a hearing serves no useful purpose where – as was the case here – the district had nothing to do with the decision to detain the articles and hierarchically superior officials at the Center had sole authority to decide to issue the Import Alert and sole authority to lift it.⁶⁷³

475. *Fourth*, current international standards of due process also require that State authorities provide reasons for actions that materially impact the rights and interests of aliens. FDA never presented Apotex with reasons for its adoption of the Import Alert.

⁶⁶⁹ **Exhibit C-64**, memorandum from Director of CDER-Compliance to DIOP, dated August 20, 2009.

⁶⁷⁰ **Legal Authority CLA-317**, American Law Institute, *Restatement (Second) of the Foreign Relations Law of the United States* (1965), § 181(d) & (e).

⁶⁷¹ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 103.

⁶⁷² **Legal Authority CLA-245**, FDA Imports and Exports Rule, 21 CFR § 1.94(a).

⁶⁷³ See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 104. See also **Legal Authority CLA-309**, FDA, Regulatory Procedures Manual, Ch. 9: Import Operations and Actions, at p. 9-29 (2009) (import alert issued based on inspection finding cGMP violations may be lifted only with “concurrence by the appropriate Center”).

476. *Fifth*, Apotex had no meaningful recourse against the Import Alert before the courts of the United States. FDA regulations require it to oppose judicial review if a matter committed by law to its discretion is brought before a court.⁶⁷⁴ The United States' consistent position has been that import alerts constitute an exercise of discretion and, therefore, are not subject to judicial review.⁶⁷⁵
477. In sum, the Import Alert was adopted contrary to basic requirements of due process under customary international law. The violative nature of this measure is underscored by comparison to the procedure for FDA enforcement action where the facility allegedly non-compliant with cGMP is located in the United States. There, a seizure or injunction may be granted only by a court in an adversarial procedure only after due notice and hearing has been afforded to interested parties.⁶⁷⁶ The contrast to the procedure adopted with respect to Apotex is striking. As Messrs. Bradshaw and Johnson conclude, had Apotex been afforded the due process rights applicable in enforcement actions concerning domestic facilities, it would never have been prevented from selling its products in the United States.⁶⁷⁷

B. The Import Alert Breached Article II of the US - Jamaica BIT

478. As already noted, NAFTA Article 1103 provides that

⁶⁷⁴ See **Legal Authority CLA-220**, Administrative Procedure Act, 5 USC § 701(a)(1)-(2). See also **Legal Authority CLA-248**, FDA General Administrative Procedures, 21 CFR § 10.45(d)(2)(i).

⁶⁷⁵ See **Legal Authority CLA-136**, Defendants' Motion to Dismiss, *Allied Pac. Food (Dalian) Co. v. FDA*, No. 1:07CV01982, 2008 WL 667867, at *13, *14 (D.D.C. Jan. 2, 2008); **Legal Authority CLA-137**, Defendant's Memorandum in Support of Motion to Dismiss, *Newstar Fresh Foods, LLC v. United States*, No. 1:09CV01807, 2009 WL 5863952, at *12 (D.D.C. Nov. 23, 2009). See also **Legal Authority CLA-189**, *Sugarman v. Forbragd*, 267 F. Supp. 817, 824 (N.D. Cal. 1967) (accepting FDA argument: "Clearly, this is an instance where 'agency action is committed to agency discretion by law.'"), *aff'd*, **Legal Authority CLA-190**, *Sugarman v. Forbragd*, 405 F.2d 1189, 1190 (9th Cir. 1968) ("The question presented is whether (absent arbitrary or capricious action which is clearly lacking here) such an order excluding material from import ... is subject to judicial review. The District Court held that it was not. We agree") (footnote omitted). *But cf.* **Legal Authority CLA-184**, *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 69 n.8 (D.D.C. 2010) (stating in footnote that FDA discretion does not extend to "an article that obviously is beyond the scope of the FDCA," and that "the issue in this case is not whether a particular drug appears adulterated or misbranded, but whether a particular product is even a drug subject to the FDCA.") *aff'd on other grounds sub nom. Legal Authority CLA-185*, *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010), *rehearing en banc denied* (2011).

⁶⁷⁶ See Section IV.E [CHECK CROSS-REFERENCE].

⁶⁷⁷ See Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, paras. 154-164.

Each Party shall accord to investors of another Party [and 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 [and to their investments] with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.⁶⁷⁸

479. It is well-established that other substantive standards of protection are applicable by virtue of an MFN clause such as the one incorporated in NAFTA Article 1103.⁶⁷⁹ Indeed, the NAFTA explicitly acknowledges that this is so in its Annex IV:

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.⁶⁸⁰

480. Obviously, such an exception presumes that “bilateral ... international agreements” provide treatment covered by Article 1103. Had that not been the case, the limitation provided by the exception would serve no purpose. Under the NAFTA, Apotex may therefore avail itself of more favorable provisions included in other international investment agreements concluded by the United States if those agreements came into force and were signed after the entry into force of NAFTA on January 1, 1994.

481. This is the case of the bilateral investment treaty (BIT) entered into with Jamaica on February 4, 1994 and in force as of March 7, 1997.⁶⁸¹ This treaty contains several

⁶⁷⁸ **Legal Authority CLA-1**, NAFTA, art. 1103.

⁶⁷⁹ *See Legal Authority CLA-77*, *White Industries Australia Limited v. India*, UNCITRAL, Award, paras. 11.2.3-11.2.4 (Nov. 30, 2011) (White was “availing itself of the right to rely on more favourable substantive provisions in the third-party treaty. This does not ‘subvert’ the negotiated balance of the BIT. Instead, it achieves exactly the result which the parties intended by the incorporation in the BIT of an MFN clause.”); **Legal Authority CLA-59**, *Bayindir Insaat Turizm Ticaret Ve Sanayi A.S. v. Islamic Republic of Pakistan*, ICSID Case No. ARB/03/29, Award, para. 157 (“The ordinary meaning of the words used in Article II(2) together with the limitations provided in Article II(4) show that the parties to the Treaty did not intend to exclude the importation of a more favourable substantive standard of treatment accorded to investors of third countries.”). *See also Legal Authority CLA-349*, Rudolf Dolzer and Christoph Schreuer, *Principles of International Investment Law*, 190-191 (Oxford University Press, 2008) (“The weight of authority clearly supports the view that an MFN rule grants a claimant the right to benefit from substantive guarantees contained in third treaties.”).

⁶⁸⁰ **Legal Authority CLA-1**, NAFTA, Annex IV, Exceptions from Most-Favored-Nation Treatment (Chapter Eleven), Schedule of the United States.

⁶⁸¹ *See 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 (hereinafter “US-Jamaica BIT”).

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. Article II of the US-Jamaica BIT is of special relevance here.

482. *First*, the US Government failed to grant Apotex Holdings and Apotex-Canada effective means for asserting claims in relation to the Import Alert, in violation of Article II(6) of the BIT. Pursuant to this provision:

Each Party shall provide effective means of asserting claims and enforcing rights with respect to investments, investment agreements, and investment authorizations granted by a Party's foreign investment authority.⁶⁸²

483. Recent arbitral practice has recognized that such a provision setting out an “effective means” standard constitutes *lex specialis*, different from, and less demanding than, denial of justice under customary international law, to which it makes no explicit reference.⁶⁸³ Furthermore, that standard is “one of ‘effectiveness’ which applies to a variety of State conduct that has an effect on the ability of an investor to assert claims or enforce rights.”⁶⁸⁴ Apotex has demonstrated that the imposition of the Import Alert was the result of administrative proceedings during which it had no possibility to be heard and to defend itself. Therefore, Apotex was offered no effective means to assert its claims or enforce its rights in relation to its investments, in breach of the obligation set out in Article II(6) of the US-Jamaica BIT.

484. *Second*, paragraph 2(b) of the same Article provides that:

Neither Party shall in any way impair, by unreasonable or discriminatory measures the management, operation, maintenance, use, enjoyment, acquisition, expansion, or disposal of investments.⁶⁸⁵

⁶⁸² **Legal Authority CLA-10**, US-Jamaica BIT, art. II, para. 6.

⁶⁸³ **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. 242 (Mar. 30, 2010); **Legal Authority CLA-77**, *White Industries Australia Limited v. India*, UNCITRAL, Award, paras. 11.3.1-11.3.3 (Nov. 30, 2011) (adopting the same standard as Chevron).

⁶⁸⁴ **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).

⁶⁸⁵ **Legal Authority CLA-10**, US-Jamaica BIT, art. II, para. 2.

485. An unreasonable or discriminatory measure has been defined by arbitral case law as:

(i) a measure that inflicts damages on the investor without serving any apparent legitimate purpose;

(ii) a measure that is not based on legal standards but on discretion, prejudice or personal preference,

(iii) a measure taken for reasons that are different from those put forward by the decision maker, or

(iv) a measure taken in willful disregard of due process and proper procedure.⁶⁸⁶

486. FDA's measure against Apotex was, as already demonstrated, unreasonable. It was taken in violation of the most elementary due process rules. Apotex submits that, by its actions, the US Government breached the non-impairment obligation stemming from Article II(2)(b) of the US-Jamaica BIT.

487. From all of the above, it results that, by adopting the Import Alert against Apotex in disregard of due process, the United States breached its obligations under NAFTA Article 1105(1) and provisions of the US-Jamaica BIT applicable by virtue of NAFTA Article 1103 and Annex IV.

IV. APOTEX IS ENTITLED TO DAMAGES

488. As demonstrated above, the United States breached its NAFTA obligations by adopting and maintaining the Import Alert. Claimants are entitled under the NAFTA and international law to be made whole for the harm they suffered by reason of this breach.

489. Under NAFTA Article 1135, "a Tribunal [that] makes a final award against a Party ... may award, separately or in combination, only: (a) monetary damages and any applicable interest; or (b) restitution of property... ."⁶⁸⁷ In this case, because the harm inflicted by the Import Alert is pecuniary in nature, the appropriate remedy is monetary damages.

⁶⁸⁶ **Legal Authority CLA-76**, *Toto Costruzioni Generali S.p.A. v. Republic of Lebanon*, ICSID Case No. ARB/07/12, Award, para. 157 (June 7, 2012).

⁶⁸⁷ **Legal Authority CLA-1**, NAFTA, art. 1135.

490. The NAFTA does not prescribe how monetary damages are to be calculated. Therefore, the Tribunal should assess damages in accordance with rules of international law.⁶⁸⁸ The Permanent Court of International Justice formulated the relevant customary international law standard in the *Chorzów Factory* case:

The essential principle contained in the actual notion of an illegal act – a principle which seems to be established by international practice and in particular by the decisions of arbitral tribunals – is that reparation must, so far as possible, wipe out all the consequences of the illegal act and reestablish the situation which would, in all probability, have existed if that act had not been committed.⁶⁸⁹

491. Today, the *Chorzów Factory* standard enjoys universal recognition.⁶⁹⁰

492. This standard is also captured in Article 31 of the International Law Commission’s Articles on State Responsibility, which provides:

Reparation

1. The responsible State is under an obligation to make full reparation for the injury caused by the internationally wrongful act.

2. Injury includes any damage, whether material or moral, caused by the internationally wrongful act of a State.⁶⁹¹

⁶⁸⁸ See **Legal Authority CLA-1**, NAFTA, art. 1131(1) (“A Tribunal established under this Section shall decide the issues in dispute in accordance with this Agreement and applicable rules of international law”) (emphasis added).

⁶⁸⁹ **Legal Authority CLA-86**, *Factory at Chorzów*, Judgment of Sept. 13, 1928, P.C.I.J., Ser. A, No. 17, at 47.

⁶⁹⁰ See, e.g., **Legal Authority CLA-53**, *ADC Affiliate Ltd. v. Republic of Hungary*, ICSID Case No. ARB/03/16, Award, para. 493 (Oct. 2, 2006) (reviewing numerous decisions and concluding that “there can be no doubt about the present vitality of the *Chorzów Factory* principle, its full current vigor having been repeatedly attested by the International Court of Justice.”); **Legal Authority CLA-43**, *S.D. Myers, Inc. v. The Government of Canada*, UNCITRAL, Partial Award, para. 311 (Nov. 13, 2000); **Legal Authority CLA-63**, *Compañía de Aguas del Aconquija S.A. and Vivendi Universal S.A. v. Argentine Republic*, ICSID Case No. ARB/97/3, Award, para. 8.2.4-8.2.5 (Aug. 20, 2007); **Legal Authority CLA-74**, *Siemens v. Argentine Republic*, ICSID Case No. ARB/02/8, Award, para. 350-51 (Feb 6, 2007); **Legal Authority CLA-62**, *CMS Gas Transmission Company v. Argentine Republic*, ICSID Case No. ARB/01/8, Award, para. 400 (May 12, 2005); **Legal Authority CLA-78**, *Amoco International Finance Corporation v. Iran*, 15 Iran-U.S. Cl. Trib. Rep. 189 (1987), para. 191.

⁶⁹¹ **Legal Authority CLA-334**, James Crawford, *The International Law Commission’s Articles on State Responsibility* (Cambridge University Press 2002), Article 31.

493. In order to make Apotex whole, the Tribunal should enter an award for damages that will wipe out the economic consequences of the wrongful act, i.e., the Import Alert.
494. NAFTA tribunals have “required a causal link between the obligation breached and the compensation awarded.”⁶⁹² This is consistent with the wording of Articles 1116(1) and 1117(1), which provides for submission of a claim when the investor or investment “incurred loss or damage by reason of, or arising out of that breach.”⁶⁹³
495. NAFTA Articles 1116(1) and 1117(1) thus prescribe the causal link that is necessary between the breach and loss or damages. These provisions refer to two distinct concepts: “by reason of” and “arising out of.” If the record establishes either of these connections, then the causal requirement is satisfied. It is a well-established principle of treaty interpretation “that a legal text should be interpreted in such a way that a reason and a meaning can be attributed to every word in the text.”⁶⁹⁴ In other words, interpretation of the treaty text must avoid rendering any part superfluous and each part should be construed as meaningful.
496. 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.”⁶⁹⁵ The ordinary meaning of the term “by reason of” is “as a result of.” The ordinary meaning of the

⁶⁹² See **Legal Authority CLA-344**, Meg N. Kinnear, Andrea K. Bjorklund, John F.G. Hannaford, *Investment Disputes Under NAFTA – An Annotated Guide to Chapter 11*, Kluwer Law International, at 16-1135 (2006). See also **Legal Authority CLA-43**, *S.D. Myers, Inc. v. The Government of Canada*, UNCITRAL, Partial Award, para. 316 (Nov. 13 2000) (“[C]ompensation is payable only in respect of harm that is proved to have a sufficient causal link with the specific NAFTA provision that has been breached”); **Legal Authority CLA-31**, *Marvin Feldman v. United Mexican States*, Case No. ARB(AF)/99/1, Award, para. 194 (Dec. 16 2002) (amount of loss or damage must be “adequately connected” to the obligations breached); **Legal Authority CLA-41**, *Pope & Talbot, Inc. v. The Government of Canada*, UNCITRAL, Award in Respect of Damages, para. 80 (May 31, 2002).

⁶⁹³ **Legal Authority CLA-1**, NAFTA, art. 1116(1) and 1117(1).

⁶⁹⁴ **Legal Authority CLA-83**, *Anglo-Iranian Oil Co. (Jurisdiction)*, Judgment of July 22, 1952, I.C.J. Reports 1952, at 93, 105. See also **Legal Authority CLA-88**, *Territorial Dispute (Libya/Chad)*, Judgment of Feb. 3, 1994, I.C.J. Reports 1994, at 6, para. 51 (collecting authorities supporting “one of the fundamental principles of interpretation of treaties, consistently upheld by international jurisprudence, namely that of effectiveness” (citations omitted)); **Legal Authority CLA-87**, *Corfu Channel*, Judgment of Apr. 9, 1949, I.C.J. Reports 1949, at 4, 24 (“It would indeed be incompatible with the generally accepted rules of interpretation to admit that a provision of this sort occurring in a special agreement should be devoid of purport or effect.”).

⁶⁹⁵ **Legal Authority CLA-17**, VCLT, art. 31(1).

term “arising out of” is “originating from” or “growing out of” or “flowing from” or “done in connection with.” Notably, the *Methanex* tribunal “construe[d] Articles 1116 and 1117 as requiring a claim of loss or damage that *originates* in the measure adopted or maintained by the NAFTA Party.”⁶⁹⁶

497. The courts in the United States have also ascribed a broad meaning to the term “arising out of” in different contexts. For instance, the term “arising out of the contract” in an arbitration clause has a wide meaning.⁶⁹⁷ Similarly, the insurer’s obligation to cover all claims “arising out of” the insurance policy is very broad.⁶⁹⁸ Likewise, a waiver for claims “arising out of” an agreement was found to be “extremely broad.”⁶⁹⁹
498. It follows that Articles 1116(1) and 1117(1) contemplate any loss that “originates from” the Import Alert. The question thus becomes whether, but for the Import Alert, Apotex and its investments would have suffered damage.
499. NAFTA tribunals have denied claims for damages only when the investor and its claimed damages were too far removed from the measure breaching the treaty.⁷⁰⁰

⁶⁹⁶ **Legal Authority CLA-34**, *Methanex Corporation v. United States of America*, UNCITRAL, Final Award, pt. II, ch. F, para. 26 (Aug. 3, 2005) (emphasis added).

⁶⁹⁷ See, e.g., **Legal Authority CLA-192**, *Sweet Dreams Unltd., Inc. v. Dial-A-Mattress Int’l., Ltd.*, 1 F.3d 639, 641-42 (7th Cir. 1993) (The term “‘arising out of’ reaches all disputes having their origin or genesis in the contract, whether or not they implicate interpretation or performance of the contract per se.”); See also **Legal Authority CLA-353**, UNCTAD, “Dispute Settlement – International Commercial Arbitration – 5.2 The Arbitration Agreement”, UNCTAD/EDM/Misc.232/Add.39, at 41 (2005) (“[S]uch phrases as ‘arising out of the contract’ have a wide meaning and have been said to have wider meaning than ‘arising under a contract’, as the latter have been said not to cover rectification claims.”).

⁶⁹⁸ See, e.g., **Legal Authority CLA-149**, *Fed. Ins. Co. v. Tri-State Ins. Co.*, 157 F.3d 800, 803-04 (10th Cir. 1998) (“[T]he general consensus is that the phrase ‘arising out of’ should be given a broad reading such as ‘originating from’ or ‘growing out of’ or ‘flowing from’ or ‘done in connection with’... .”); **Legal Authority CLA-168**, *Merchants Ins. Co. of N.H. v. U.S. Fid. & Guar. Co.*, 143 F.3d 5, 8 (1st Cir. 1998) (concluding that the phrase “arising out of” was “synonymous with ‘originate’ or ‘come into being’ (quoting *New England Mut. Life Ins. Co. v Liberty Mut. Ins. Co.*, 667 N.E.2d 295, 298 (Mass App. Ct. 1996)); **Legal Authority CLA-114**, *Am. Econ. Ins. Co. v. DePaul Univ.*, 890 N.E.2d 582, 591 (Ill. App. Ct. 2008) (stating that the term “arising out of” satisfies “but for causation”).

⁶⁹⁹ **Legal Authority CLA-128**, *Brown v. Cushman & Wakefield, Inc.*, 235 F. Supp. 2d 291, 293-94 (S.D.N.Y. 2002). See also **Legal Authority CLA-153**, *Hammaker v. Brown & Brown, Inc.*, 214 F. Supp. 2d 575, 578 (E.D. Va. 2002); **Legal Authority CLA-118**, *Arakawa v. Japan Network Grp.*, 56 F. Supp. 2d 349, 353 (S.D.N.Y. 1999).

⁷⁰⁰ See, e.g., **Legal Authority CLA-33**, *Metalclad Corporation v. United Mexican States*, ICSID Case No. ARB/AF/97/1, Award, para. 115 (Aug. 30, 2000) (denying damages because the causal relationship was “too remote and uncertain” between respondent’s refusal of permit and the negative impact on the investor’s other operations leading to a drop in Metalclad’s share price); **Legal Authority CLA-44**, *S.D. Myers, Inc. v.*

500. There is no issue of remoteness of damages in the present arbitration since the injury occurred “by reason of,” i.e. as a result of the Import Alert. The Import Alert effectively shut down Apotex’s business in the US for two years, thus preventing it from selling any products manufactured at Etobicoke or Signet. The ensuing losses suffered by Apotex were therefore the result of the Import Alert.
501. Apotex’s injury also “ar[ose] out of” the Import Alert. Indeed, but for the Import Alert, Apotex would not have suffered any harm. Therefore, under either prong of the test (“by reason of” or “arising out of”), the injury to Apotex is not too far removed from the Import Alert, and therefore, Apotex is entitled to submit its claims under Articles 1116 and 1117 and recover under Article 1135.
502. It is a rudimentary principle of compensation that the investor is not entitled to double recovery. “Where more than one article of NAFTA has been breached, and damages are awarded, the damages for breach of any one NAFTA provision can take into account any damages already awarded under a breach of another NAFTA provision’ but should not result in double recovery.”⁷⁰¹

A. Damages Resulting From Breach of the National Treatment and MFN Standards

503. A remedy for violation of the national treatment standard should place the injured foreign investor and its investment in the same position they would have been in had they been treated the same way as the best-treated domestic investor or investment in “like circumstances.” This is the measure of damages because (1) the violation occurs when an investor of a Party or its investment are treated “less favorably” than any domestic investor or its investment⁷⁰² and (2) international law requires placing the aggrieved party in the position it would have been in “but for” the breach.⁷⁰³

The Government of Canada, UNCITRAL, Second Partial Award, paras. 161-62 (Oct. 21, 2002) (rejecting claim for loss of opportunity as too speculative and remote).

⁷⁰¹ See **Legal Authority CLA-344**, Meg N. Kinnear, Andrea K. Bjorklund, John F.G. Hannaford, *Investment Disputes Under NAFTA – An Annotated Guide to Chapter 11*, Kluwer Law International, at 17-1135 (2006) (footnote omitted) (quoting *S.D. Myers, Inc. v. The Government of Canada*, UNCITRAL, Partial Award, para. 316 (Nov. 13, 2000)).

⁷⁰² **Legal Authority CLA-42**, *Pope & Talbot Inc v. The Government of Canada*, UNCITRAL, Award on the Merits of Phase 2, paras. 36, 38, 42, 66 (Apr. 10, 2001) (rejecting respondent’s contention that claimant is

504. The compensation due Apotex for the breach of Article 1102 and the compensation due Apotex for the breach of Article 1103 is the same: Apotex must be placed in the same financial position it would have been in had it been treated no less favorably than the best treated of its comparators.⁷⁰⁴
505. Here, as discussed above in Part II.B.2, US investors in like circumstances to Apotex include Baxter, Hospira, and Perrigo, while third country investors in like circumstances include Novartis/Sandoz and Teva.
506. As also discussed above, Apotex received less favorable treatment than the above-referenced US and foreign comparators. Apotex's business was shut down for two years as a result of the Import Alert. Apotex was prevented from selling products in the US from its Etobicoke and Signet facilities and its ANDAs were not approved by FDA. Apotex had no opportunity to respond to the observations at Signet or implement any corrective actions before the Import Alert. By contrast, the comparators did not have their business interrupted while they addressed the observations contained in their respective warning letters. They continued to sell products and had their ANDAs approved by FDA. They were given the opportunity to respond to the warning letters issued to them without being subject to any enforcement action.
507. Had Apotex been accorded the same treatment as the best treated of its comparators, it would have continued to be able to sell its products on the US market while it took steps to address the concerns stated by FDA. It would not have had to incur a number of expenses that it incurred as a result of the Import Alert.

required to make a comparison with more than one domestic investor or investment). *See also Legal Authority CLA-31, Marvin Feldman v. United Mexican States*, Case No. ARB(AF)/99/1, Award, paras. 166, 181, 184-86 (Dec. 16, 2002) (recognizing the positions articulated by the *Pope & Talbot* and *S.D. Myers* tribunals); **Legal Authority CLA-25, *Corn Products International, Inc. v. United Mexican States***, ICSID Case No. ARB(AF)/04/01, Decision on Responsibility, para. 117 (Jan. 15, 2008) (making a reference to "the comparator," not class of comparators).

⁷⁰³ *See Legal Authority CLA-31, Marvin Feldman v. United Mexican States*, ICSID Case No. ARB(AF)/99/1, Award, para. 194, (Dec. 16, 2002) ("It follows that, in case of discrimination that constitutes a breach of Article 1102, what is owed by the responding Party is the amount of loss or damage that is adequately connected to the breach."); **Legal Authority CLA-86, *Factory at Chorzów***, Judgment of Sept. 13, 1928, P.C.I.J., Ser. A, No. 17, at 47.

⁷⁰⁴ *See Legal Authority CLA-1, NAFTA*, art. 1104 ("Each Party shall accord to investors of another Party and to investments of investors of another Party the better of the treatment required by Articles 1102 and 1103.").

508. A breach of an obligation (including an obligation under an international agreement, such as the NAFTA) typically implicates two types of damages: (i) compensation for expenses incurred as a result of the breach; and (ii) compensation for the profits that the injured party would have made but for the breach.⁷⁰⁵ This formulation takes its roots in Roman law and is well-recognized and accepted in international arbitration.⁷⁰⁶
509. Following this generally accepted formula, Apotex's losses suffered as a result of the Import Alert can be categorized as follows: (1) lost profits and lost new business opportunities; and (2) out-of-pocket losses. Each of the foregoing two categories is discussed individually below in the order of magnitude.

1. Loss of New Business Opportunities / Lost Profits

510. Lost profits constitute the largest item of damages sustained by Apotex as a result of the wrongful measure.
511. It is well-accepted that lost profits constitute a legally protected interest when an anticipated income stream attains sufficient certainty to be compensable.⁷⁰⁷ Lost profits have been recognized as a recoverable component of damages in NAFTA arbitrations.⁷⁰⁸

⁷⁰⁵ **Legal Authority CLA-326**, Christopher Dugan et al., *Investor-State Arbitration*, at 589 (Oxford University Press 2008). See also **Legal Authority CLA-107**, *Himpurna California Energy Ltd. v PT. (Persero) Perusahaan Listrik Negara*, 14(2) Mealey's Int'l Arb. Rep. 12/99 A-1, paras. 234-35 (1999).

⁷⁰⁶ **Legal Authority CLA-326**, Christopher Dugan et al., *Investor-State Arbitration*, at 589-90 (Oxford University Press 2008).

⁷⁰⁷ **Legal Authority CLA-335**, James Crawford, *The International Law Commission's Articles on State Responsibility* 228 (Cambridge University Press 2002), Article 36.

⁷⁰⁸ See **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, paras. 432-33, 444 (Sept. 18, 2009); See also **Legal Authority CLA-44**, *S.D. Myers, Inc. v. The Government of Canada*, UNCITRAL, Second Partial Award, paras. 100, 152 (Oct. 21, 2002) (stating that "[t]he authorities are clear that claims for loss of profits are recoverable," but declining to award lost profits on the facts). **Legal Authority CLA-31**, *Marvin Feldman v. United Mexican States*, Case No. ARB(AF)/99/1, Award, paras. 199-201 (Dec. 16, 2002) (recognizing the claim in principle, but declining to award lost profits on the facts); **Legal Authority CLA-41**, *Pope & Talbot, Inc. v. The Government of Canada*, UNCITRAL, Award in Respect of Damages, para. 84 (May 31, 2002) (acknowledging the existence of lost profit damages but finding the claimant did not suffer them).

512. Loss of new business opportunities are recoverable where such profits were “realistic” and “neither speculative nor too remote.”⁷⁰⁹
513. The standard of proof for lost business opportunities differs from the standard of proof for out-of-pocket losses. Specifically, it is not necessary to prove an exact or absolutely certain amount of lost business opportunities suffered in order to be entitled to recovery.⁷¹⁰ Additionally, “when such proof is impossible, particularly as a result of the behavior of the author of the damage, it is enough for the [tribunal] to be able to admit with sufficient probability the existence and extent of the damage.”⁷¹¹
514. Lost profits have been awarded in a number of investment arbitration cases, where the award was appropriate to make the claimant whole, including NAFTA cases.⁷¹²
515. Apotex’s injury in this category include the following heads of damages.
516. **Loss of profits associated with pre-existing products.** Prior to the Import Alert, Apotex operated a successful pharmaceutical business in the United States. It sold between [REDACTED] million dosages on a monthly basis and about [REDACTED] billion dosages per annum from its Etobicoke and Signet facilities alone.⁷¹³ Prior to the Import Alert, Apotex was the 6th largest generic pharmaceutical company in the US market.⁷¹⁴

⁷⁰⁹ **Legal Authority CLA-44**, *S.D. Myers, Inc. v. The Government of Canada*, UNCITRAL, Second Partial Award, paras. 156-60, 173 (Oct. 21, 2002).

⁷¹⁰ See **Legal Authority CLA-338**, Kantor, *Valuation for Arbitration*, at 16-17 (Kluwer Law International 2008) (“[L]ess certainty (perhaps none at all) is required in proof of the amount of damages. While the proof of the fact of damages must be certain, proof of the amount may be an estimate, uncertain or inexact.” (emphasis omitted) (footnote omitted) (quoting Robert L. Dunn, *Recovery of Damages for Lost Profits* § 1.6 at 17 (6th ed. 1998)).

⁷¹¹ **Legal Authority CLA-111**, *Sapphire International Petroleum Ltd. v. National Iranian Oil Company*, Award, 35 I.L.R. 136, 187-89 (1963); **Legal Authority CLA-107**, *Himpurna California Energy Ltd. v. PT. (Persero) Perusahaan Listrik Negara*, 14(2) Mealey’s Int’l Arb. Rep. 12/99 A-1, para. 237 (1999).

⁷¹² See **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States*, ICSID Case No. ARB(AF)/05/2, Award, para. 526 (Sept. 18, 2009); **Legal Authority CLA-54**, *Amco Asia Corp. et al. v. The Republic of Indonesia*, ICSID Case No. ARB/81/1, First Award, paras. 266-67, 269, 271, 1 ICSID Reports 413 (1993); **Legal Authority CLA-56**, *Amco Asia Corp. et al. v. The Republic of Indonesia* (Resubmitted case), Award, 17 Yearbook of Commercial Arbitration, 101-02 (1992).

⁷¹³ Witness Statement of Gordon Fahner, para. 68.

⁷¹⁴ Witness Statement of John Flinn, para. 57.

517. A large number of products sold in the US market were sourced from Etobicoke and Signet. 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.⁷¹⁵
518. Historically (as well as currently), Etobicoke supplied more solid dose products for sale in the US market than Signet. About █% of solid dose products sold in the US market were manufactured at Etobicoke.⁷¹⁶ In terms of revenues, Etobicoke played an even more important role because about █% of revenues derived from those sales were attributable to Etobicoke products.⁷¹⁷
519. As a result of the Import Alert, Apotex had no choice but to suspend distribution of products manufactured at Signet and Etobicoke for the duration of the measure, i.e., about two years, and, consequently, lose profits that it would have otherwise derived from such sales.⁷¹⁸
520. Moreover, even after the Import Alert was lifted, on June 15, 2011 for the Etobicoke facility and on July 29, 2011 for the Signet facility, Apotex could not resume the sale of its pre-existing molecules immediately.⁷¹⁹ It was not logistically possible to ramp up production for all products at once, and in response to FDA, Apotex put into place a robust process for testing processes for all products before they were put back on the US market. This has significantly slowed the launches for a number of products.⁷²⁰ In addition, Apotex has found it difficult to increase its share of the market for those products that have been reintroduced, because in the intervening years customers have developed supply relationships with competitors that are not easy to dislodge.⁷²¹
521. Since the date of imposition of the Import Alert, Apotex has suffered a very significant loss of profits. As explained more fully in the expert report of Howard Rosen, such lost

⁷¹⁵ Witness Statement of Gordon Fahner, para. 70.

⁷¹⁶ Witness Statement of John Flinn, para. 27.

⁷¹⁷ Witness Statement of Gordon Fahner, para. 69.

⁷¹⁸ Witness Statement of Gordon Fahner, para. 91;

⁷¹⁹ Witness Statement of Gordon Fahner, para. 93.

⁷²⁰ *Id.* at, paras. 94-99; Witness Statement of Jeremy Desai, para. 91, Witness Statement of Emund Carey, paras. 63-66. *See also* Exhibit C-196, US re – Entry Product Assessment Protocol – Revision 5, dated February 24, 2011.

⁷²¹ Witness Statement of John Flinn, paras 42-45.

profits amount to \$ [REDACTED].⁷²² That amount forms part of Apotex's damages caused by the Import Alert.

522. **Future lost profits.** In addition to profits lost to date, Apotex will continue losing profits in the future because of the continuing economic impact of the Import Alert.⁷²³ As a result of lost, diminished or delayed future sales, Apotex will continue to suffer lost profits.⁷²⁴

523. Mr. Rosen's calculation of future lost profits is based on two separate valuations. The first is a valuation of the present value of future profits for existing products that Apotex would have earned had it been granted an opportunity to implement corrective measures instead of being subjected to the Import Alert. This "but for" analysis is based on sales and sales forecasts from before the adoption of the Import Alert, among other data. The second is a valuation of the present value of the actual future profits Apotex is likely to earn in the challenging economic situation that has resulted from the Import Alert.⁷²⁵

524. Mr. Rosen calculates the future lost profits sustained by Apotex as the difference between those two amounts, i.e., Apotex's future profits under the "but for" analysis and Apotex's projected actual future profits.

525. Mr. Rosen explains that the former amount - the "but for" amount - is currently capable of being estimated with the requisite degree of reliability.⁷²⁶ This is because the principal data needed for this analysis exists at this point in time. On the other hand, there is at present limited empirical data on how easy or difficult it will be for Apotex to reenter the US market, because at this point a limited number of products have been relaunched and even for these products there are only a few months of historical data on their sales trajectory.⁷²⁷ In contrast, by May 2013 when the Reply and accompanying

⁷²² Expert Report of Howard Rosen, para. 4.10.

⁷²³ *Id.* at, para. 4.16.

⁷²⁴ *Id.*

⁷²⁵ *Id.* at, para. 4.17.

⁷²⁶ *Id.* at, para. 4.18.

⁷²⁷ *Id.* at, para. 4.19.

support including Mr. Rosen's reply expert report are due, there will be considerably more empirical data available.

526. After considerable reflection, Mr. Rosen concluded that, rather than put forward a calculation now based on insufficient data that would need to be revised next spring, in the interest of precision he would in this report only quantify the "but for" element of this calculation. He has not attempted to quantify projected actual future lost profits because there is limited data available to establish the likely trajectory of Apotex sales on reentry.⁷²⁸ Mr. Rosen sets forth in his report the principles for that calculation, but will await the more reliable data that will be available by May 2013 to complete this element of the valuation.
527. As noted above, in assessing future lost profits, Mr. Rosen has assigned present values to the expected future revenue stream. As explained recently by an international commercial arbitration tribunal, in this exercise the nominal amounts are decreased by applying a discount rate comprising two elements: "one reflecting the time value of money (i.e., the notion that a dollar to be received in the future is worth less than a dollar received today)" and the other a discount to reflect the risk.⁷²⁹
528. In calculating the application discount rate, Mr. Rosen took into account such factors as general and economic market conditions in the US, trends and conditions within the generic pharmaceutical industry in North America, including the expected regulatory environment and the financial condition and prospects of Apotex-US. Mr. Rosen came to a conclusion that, based on these factors, the applicable discount rate is ■% to ■% for the first five years and ■% to ■% for the remaining, or terminal, period.⁷³⁰
529. Based on that calculation, Mr. Rosen concluded that the present value of the total future lost profits that Apotex would have earned "but for" the Import Alert ranges between

⁷²⁸ *Id.*

⁷²⁹ **Legal Authority CLA-107**, Himpurna California Energy Ltd. v PT. (Persero) Perusahaan Listrik Negara, 14(2) Mealey's Int'l Arb. Rep. 12/99 A-1, para. 234 (1999). See also **Legal Authority CLA-23**, Cargill, Incorporated v. United Mexican States (ICSID Case No. ARB(AF)/05/2), Award, paras. 435, 444 (Sept. 18, 2009) (discussing appropriate discount rates in the context of NAFTA arbitration); **Legal Authority CLA-338**, Kantor, *Valuation for Arbitration*, at 16-17.

⁷³⁰ Expert Report of Howard Rosen, paras. 4.23-4.24.

\$ [REDACTED] and \$ [REDACTED]. As noted above, the projected actual future lost profits will need to be deducted from these amounts once quantified. The range just mentioned therefore represents the theoretical maximum amount of potential future lost profits that Apotex could claim, subject to deduction of the present value of the projected actual future lost profits.

530. **Loss of opportunity to launch new products.** As a rapidly growing company, prior to the Import Alert, Apotex strategically sought to expand its presence in the US market through new product launches. On average, Apotex launched [REDACTED] new products per year.⁷³¹ As described in the Statement of Facts, Part III.B, *supra*, new launches can be allowed only after FDA approval of abbreviated new drug applications (ANDAs).

531. Following the Import Alert, FDA stopped processing Apotex's ANDA applications, for Etobicoke and Signet, thus preventing Apotex from launching new products. As a result, by fall 2010, the number of Apotex's delayed ANDA applications increased to 60.⁷³²

532. These delays prevented Apotex from realizing significant profits associated with its investment in the ANDAs.⁷³³

533. Apotex's damage caused by delay of new launches is notable in two respects. First, Apotex was prevented from timely expanding its product base, which is one of its strategic goals.⁷³⁴ Second, Apotex was prevented from taking advantage of the favorable market environment available to an early entrant in the market.⁷³⁵ One example of a product impacted in this way is [REDACTED]. As discussed in greater detail in the Statement of the Facts, Part IX.E, [REDACTED] was one of the priority products for Apotex. Apotex won a patent litigation concerning that product.⁷³⁶ But for the Import

⁷³¹ Witness Statement of Gordon Fahner, para. 81.

⁷³² **Exhibit C-175**, Email from Apotex to FDA, dated November 4, 2010 ("We [Apotex] acknowledge that we have a fairly substantial number of pending ANDAs (total number of [REDACTED]) ...") and the attached spreadsheets entitled "PAI List for pending ANDAs – Site Etobicoke" ([REDACTED] pending ANDAs) and "PAI list for pending ANDAs – Site Signet" ([REDACTED] pending ANDAs). Witness Statement of Bernice Tao, para. 52.

⁷³³ Witness Statement of Gordon Fahner, para. 101.

⁷³⁴ *Id.*

⁷³⁵ *Id.*, para. 89.

⁷³⁶ Witness Statement of Jeremy Desai, para. 84.

due to lack of actual sales data concerning the hindered products and concerning the expected incremental profit that Apotex will likely experience subsequent to the Import Alert.⁷⁴³ Considerably more information will be available by May 2013 on both the markets and the pricing dynamic that has developed for these new generic drugs. Mr. Rosen has again set out the principles upon which his quantification will be based, but will await the more reliable data that will be available next Spring before conducting the quantification exercise.⁷⁴⁴

2. *Out-of-Pocket Losses*

539. It is also well established that out-of-pocket losses are recoverable in the event of a treaty breach.⁷⁴⁵

540. Apotex's injury in this category include the following heads of damages:

541. **Contractual penalties.** Apotex's customers in the US market include institutional clients (such as hospital buying groups, the US government, and distribution companies such as [REDACTED]) and retail clients (such as [REDACTED]). As a generic company, Apotex does not carry out extensive advertising campaigns. Instead, it builds its goodwill with the customers by striving for and providing excellent service at all times.⁷⁴⁶ From the customer's perspective, one of the key considerations in choosing a generic supplier is the reliability of supply.⁷⁴⁷ For that reason, customer contracts frequently contain a penalty provision obligating the supplier to pay penalties to the customer in the event of the supplier's failure to deliver.⁷⁴⁸ Such penalty provisions are present in Apotex's contracts as well.⁷⁴⁹

⁷⁴³ *Id.*, para. 4.36.

⁷⁴⁴ *Id.*

⁷⁴⁵ **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. 281 (Nov. 21, 2007). *See also Legal Authority CLA-41*, Pope & Talbot, Inc. v. The Government of Canada, UNCITRAL, Award in Respect of Damages, para. 85 (May 31, 2002); **Legal Authority CLA-110**, Shufeldt claim (U.S.A. v. Guatemala), 2 R.I.A.A. 1079, 1099 (2006); **Legal Authority CLA-335**, James Crawford, *The International Law Commission's Articles on State Responsibility* (Cambridge University Press 2002), Article 36.

⁷⁴⁶ Witness Statement of John Flinn, para. 32.

⁷⁴⁷ *Id.*, paras. 33, 39.

⁷⁴⁸ *Id.*, para. 41.

⁷⁴⁹ *Id.*, paras. 41-44.

542. Typically, such penalty provisions operate as follows. If a customer places an order that Apotex is unable to supply, the customer becomes entitled to purchase the requisite amount of products from another supplier and Apotex must pay the incremental price of such substitute supply.⁷⁵⁰ While such provision is commonplace in the industry, it subjects Apotex to harsh penalties for a failure to supply. Essentially, it permits the customer, for example [REDACTED] to purchase substitute products and charge any price difference to Apotex. Under such circumstances, not only is Apotex responsible for the price difference, but it also must essentially pay that price difference to its competitor.⁷⁵¹ Such competitor, being fully aware of Apotex's situation, has an incentive to inflate its prices, both because Apotex cannot decline to pay and because such high prices create an additional burden for Apotex and therefore increase the possibility of driving Apotex out of the US market.⁷⁵²
543. Due to the Import Alert, Apotex was unable to supply products ordered by its US customers. Apotex's failure to supply triggered the aforementioned penalty provisions. As a result, Apotex incurred and paid penalties in the amount of \$ [REDACTED].⁷⁵³ Such damages were caused by the Import Alert.
544. **Inventory Write-Offs.** A large number of finished products had been manufactured by Apotex prior to August 28, 2009. These products were manufactured specifically for sale on the United States market. As a result of the Import Alert, those products were either denied a right of entry into the United States or otherwise could not be distributed on the United States market due to the measure.⁷⁵⁴
545. One of the characteristics of pharmaceutical products as a commodity is their short shelf life. Given that safety and efficacy of pharmaceutical products are of paramount importance, product-specific specifications (such as its shelf life specifications) must be

⁷⁵⁰ *Id.*, para. 42; *see also* Exhibit C-43, [REDACTED] Group Purchasing Agreement – Pharmaceuticals, dated July 1, 2009, art. 6.5.

⁷⁵¹ Witness Statement of John Flinn, para. 43.

⁷⁵² *Id.*

⁷⁵³ Expert Report of Howard Rosen, para. 4.49.

⁷⁵⁴ Witness Statement of Gordon Fahner, para. 103.

strictly followed.⁷⁵⁵ As a result, Apotex had to destroy and write-off its finished products that it had been prevented from shipping into or selling in the United States.⁷⁵⁶ It also had to destroy and write-off corresponding packaging materials.⁷⁵⁷ In addition, Apotex also had to destroy and write-off semi-finished products.⁷⁵⁸

546. As calculated by Howard N. Rosen, the costs of Apotex's write-offs were as follows:⁷⁵⁹

Finished goods	\$ [REDACTED]
Semi-finished goods	\$ [REDACTED]
Packaging materials	\$ [REDACTED]

547. From those amounts, Mr. Rosen subtracted the amount of inventory normally written-off and arrived at the recoverable cost of \$ [REDACTED].⁷⁶⁰

548. **Recall Fees and Product Returns.** As described in the Statement of Facts, Part VI.E, during the August 17, 2009 call with FDA, Apotex voluntarily committed to recall 675 batches of its products. The company made that decision as it believed that doing so would eliminate what appeared to be FDA's source of concern.⁷⁶¹ Furthermore, following the completion of the Product Quality Assessment, in May 2010, Apotex recalled from its Indianapolis warehouse some of the products shipped there prior to the Import Alert. These recalls, although not mandated by FDA, were a direct response to FDA's actions. But for FDA's violations at issue here, the recalls would not have been necessary.

549. As a result of these recalls, Apotex incurred substantial: (1) product recall fees associated with implementation of the recalls; and (2) costs associated with the refund of the purchase price issued to the customers that wished to return their products. As

⁷⁵⁵ *Id.*, para. 104.

⁷⁵⁶ *Id.*

⁷⁵⁷ *Id.*

⁷⁵⁸ *Id.*, para. 105.

⁷⁵⁹ Expert Report of Howard Rosen, para. 4.39

⁷⁶⁰ *Id.*

⁷⁶¹ Witness Statement of Jeremy Desai, para. 48.

quantified by Mr. Howard N. Rosen, recall fees amounted to \$ [REDACTED] and product returns amounted to \$ [REDACTED].⁷⁶² Therefore, the total amount of recoverable costs incurred as a result of Apotex's voluntary recalls implemented as a result of FDA's actions is \$ [REDACTED].⁷⁶³

550. **Legal and Consultants' Fees.** As a result of the Import Alert, Apotex had to retain legal and technical consultants to receive professional advice concerning avenues available for Apotex to remove the Import Alert as promptly as possible.⁷⁶⁴ Apotex retained the law firms of Alston & Bird LLP, Buc & Beardsley LLP and, thereafter, Zuckerman Spaeder LLP to serve as their regulatory counsel.⁷⁶⁵ Apotex also had to retain technical consultants in its efforts to remove the Import Alert.⁷⁶⁶ Legal fees incurred and paid by Apotex in connection with those engagements amounted to \$ [REDACTED] and technical professionals' fees incurred and paid by Apotex amounted to \$ [REDACTED].⁷⁶⁷

B. Damages Resulting from Denial of Fair and Equitable Treatment

551. As demonstrated above in the Statement of the Law, Section III, the US Government breached NAFTA Article 1105.

552. Apotex is therefore entitled to recover for all "loss or damage by reason of, or arising out of, that breach".⁷⁶⁸ In order to establish what losses originate from this breach, it is necessary to consider the "but for" scenario: what the result would have been had Apotex been provided the fundamental due process required by international law.

553. There are at least two possible approaches to considering the but-for scenario in this context. First, imagining a hypothetical process for imposition of import alerts that does not at present exist and with which there can be no practical experience, but which does replicate the basic elements of due process required by international law. Second,

⁷⁶² Expert Report of Howard Rosen, para. 4.43.

⁷⁶³ *Id.*

⁷⁶⁴ Witness Statement of Jeremy Desai, para. 95.

⁷⁶⁵ *Id.*

⁷⁶⁶ *Id.*

⁷⁶⁷ Expert Report of Howard Rosen, para. 4.56, 4.65.

⁷⁶⁸ **Legal Authority CLA-1**, NAFTA, art. 1116(1).

referring to an existing procedure used by FDA to achieve the same result (interdiction of sale in the US of products from a given facility) and that indisputably complies with due process: the injunction procedure in US court.

554. Apotex respectfully submits that reference to the existing injunction procedure provides the most reliable comparison, because (a) it exists and therefore does not imply speculation; (b) there is extensive practical experience with its operation and therefore many data points for assessing what the result would have been had that procedure been applied; and (c) customary international law incorporated into Article 1105 prohibits discrimination as concerns due process, and the application of different due process standards to domestic and foreign facilities has a discriminatory impact on foreign investors.⁷⁶⁹

555. As explained more fully in the Expert Witness Report of Sheldon T. Bradshaw and Ron M. Johnson, if practice and procedures available for US-based facilities were extended to Apotex, Apotex would have been able to continue its operation and would not have been placed under an Import Alert or a similar enforcement action.⁷⁷⁰ Instead, FDA would have provided Apotex with opportunities to remediate any issues allegedly observed by FDA at Signet and Etobicoke.⁷⁷¹ As amply demonstrated by Apotex's actions, Apotex was willing to take all steps necessary to do so.⁷⁷² As demonstrated by the FDA's finding of full compliance with cGMP upon its re-inspection of the Etobicoke and Signet facilities in early 2011, had Apotex been given the chance, it would have succeeded in addressing any concerns FDA had raised. Apotex never would have been subject to an interdiction against selling products from Etobicoke and Signet on the US market had the procedures applicable to US facilities been applied to it.

⁷⁶⁹ See *supra* Statement of the Law, Part III.A.3 (international law prohibits discrimination against aliens as concerns due process); Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 109 (no instance of warning letter or import alert with respect to cGMP violations at a foreign finished drug manufacturing facility owned by a US company).

⁷⁷⁰ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 164.

⁷⁷¹ *Id.*, para. 163.

⁷⁷² See Witness Statement of Jeremy Desai, para. 96.

556. In addition, as further explained by Messrs. Bradshaw and Johnson, if practice and procedures available for US-based facilities were extended to Apotex, FDA would not have necessarily stopped approving ANDA applications pertaining to products manufactured at those two facilities.⁷⁷³

557. As a result of the losses, Apotex sustained by reason of the breach of Article 1105 are identical to those sustained as a result of the violations of Articles 1102 and 1103 of the NAFTA discussed above. Specifically, that damage comprises of:

Head of Damage	High	Low
Current lost profits for existing products	\$ [REDACTED]	\$ [REDACTED]
Future lost profit for existing products	Up to \$ [REDACTED]	Up to \$ [REDACTED]
Hindered launches	Up to \$ [REDACTED]	Up to \$ [REDACTED]
Inventory disposals	\$ [REDACTED]	\$ [REDACTED]
Failure to supply penalty	\$ [REDACTED]	\$ [REDACTED]
Product recalls	\$ [REDACTED]	\$ [REDACTED]
Consulting fees	\$ [REDACTED]	\$ [REDACTED]
Legal fees	\$ [REDACTED]	\$ [REDACTED]

⁷⁷³ Expert Report of Sheldon T. Bradshaw and Ron M. Johnson, para. 154.

558. If practice and procedures available for US-based facilities were extended to Apotex, none of the aforementioned damages listed immediately above would have been sustained by Apotex.

559. Accordingly, Apotex is entitled to recover, in full, each head of damages set forth above.

C. Interest

560. Article 1135(1) of the NAFTA provides that the Tribunal may award “monetary damages, along with any applicable interest.”⁷⁷⁴ It has been acknowledged by many international arbitration tribunals that interest is an integral part of compensation itself.⁷⁷⁵

561. Therefore, in order to fully compensate Apotex for damages caused by the NAFTA breaches, the United States must, in addition to paying compensation, also pay interest.

1. Rate of Interest

562. Apotex respectfully submits that, in order for it to be restored to a reasonable approximation of the position in which it would have been if the breach had not occurred, it should be awarded the rate of interest equal to Claimants’ cost of borrowing. Such rate of interest would be fair and reasonable, and thus comports with international law.⁷⁷⁶

563. The method of determining pre-award interest based on the commercial lending rate has been adopted by a number of international tribunals, including NAFTA.⁷⁷⁷ Apotex respectfully submits that the appropriate interest rate to apply is the group’s cost of

⁷⁷⁴ **Legal Authority CLA-1**, NAFTA, art. 1135 (1).

⁷⁷⁵ **Legal Authority CLA-33**, *Metalclad Corp. v. Mexico* (ICSID ARB(AF)/97/1), Award, para. 128 (Aug. 30, 2000); **Legal Authority CLA-57**, *Asian Agricultural Products v. Sri Lanka* (ICSID ARB/87/3), para. 114 (June 27, 1990).

⁷⁷⁶ **Legal Authority CLA-79**, *McCullough & Co. v. Ministry of Post, Telegraph and Telephone*, 11 Iran-U.S. Cl. Trib. Rep. 3, paras. 97-99, 100 (1986).

⁷⁷⁷ **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States* (ICSID Case No. ARB(AF)/05/2), Award, para. 544 (July 29, 2009); **Legal Authority CLA-64**, *Funnekotter v. Republic of Zimbabwe* (ICSID ARB/05/6), Award, paras. 143-44 (Apr. 22 2009); **Legal Authority CLA-69**, *MTD Equity Sdn. Bhd. v. Chile* (ICSID ARB/01/7), Award, para. 250 (May 25, 2004); **Legal Authority CLA-68**, *Maffezini v. Spain* (ICSID ARB/97/7), Award, para. 96 (Nov. 9, 2000).

borrowing. Absent the breaches, Apotex would have applied its profits to repay or lower the outstanding amount of its loans.

564. Borrowing for the Apotex group is undertaken by Apotex Pharmaceutical Holdings Inc. (APHI). APHI, a subsidiary of Apotex Holdings and the direct parent company for Apotex-Canada, borrowed at the interest rate of Bank of Canada's prime business rate plus ■% per annum from September 28, 2008 to August 4, 2011, and currently borrows at the rate of the Bank of Canada's prime business rate plus ■% per annum as from August 5, 2011.⁷⁷⁸ APHI's borrowing rate ranged between ■% in September 2009 to ■% in June 2012.

2. *Eligible Period for Application of Interest*

- Interest on all out-of-pocket expenses shall begin accruing on the date of the submission of the Request for Arbitration in this proceeding; and
- Interest on lost profits incurred prior to the time of the Final Award shall begin accruing on the date of the Final Award.

3. *Compound Interest*

565. As the primary function of pre-award interest is to provide full compensation to aggrieved investor, the rate of interest should be selected with the view of that purpose.

566. From an economic perspective, however, an award of simple interest does not accord with commercial realities.⁷⁷⁹ A number of international tribunals have acknowledged that compound interest fulfills the function of reparation more fully than simple interest. Specifically, the tribunals found that: (i) compound interest is capable of providing "integral compensation" to the claimant;⁷⁸⁰ (ii) compound interest reflects the reality of financial transactions and thus "best approximates the value lost by an investor";⁷⁸¹ and (iii) time value of money in free market economies is measured by compound

⁷⁷⁸ Expert Report of Howard Rosen, para. 4.71.

⁷⁷⁹ **Legal Authority CLA-336**, James Nicholson, *Calculating Pre-Judgment Interest*.

⁷⁸⁰ **Legal Authority CLA-75**, *Tecnicas Medioambientales Tecmed v. Mexico* (ARB (AF)/00/2), Award, para. 196 (May 29, 2003).

⁷⁸¹ **Legal Authority CLA-58**, *Azurix Corp v. Argentina* (ARB/01/12), Award, para. 440 (July 14, 2006).

interest.⁷⁸² Those tribunals have rightfully decided to award compound interest to the claimants.

567. Numerous NAFTA tribunals have awarded compound interest.⁷⁸³

568. Claimants respectfully request an award of interest compounded quarterly, as such compounding is appropriate here to compensate Claimants for the value of their losses suffered as a result of the NAFTA breaches.

D. Costs and Attorneys' Fees and Interest on Such Amounts

569. Article 1135 of the NAFTA provides that the Tribunal may award costs in accordance with the applicable arbitration rules. Article 58 of the ICSID Additional Facility Rules, which govern this proceeding, authorize the Tribunal to award the following cost items: (i) the fees and expenses of the members of the Tribunal; (ii) the expenses and charges of the Secretariat; and (iii) expenses incurred by the parties in connection with the proceeding. Accordingly, Claimants respectfully request an award of the above-referenced cost items. As the arbitration proceeding is still ongoing, Claimants are currently not in a position to provide a detailed statement of their costs and attorneys' fees. Should the Tribunal wish to see a detailed statement at a later state of this proceeding, Claimants will be prepared to provide the requisite information.

570. Claimants are also entitled to an award of interest on their costs award. As articulated by the tribunal in *S.D. Myers v. Canada*:

[T]here appears to be no good reason why the party that has been directed to pay an ascertained sum to the other in respect of costs should not pay interest on such sum for the

⁷⁸² **Legal Authority CLA-70**, *OKO Pankki Oyj et al. v. Republic of Estonia* (ARB/04/6). Award, para. 345 (Nov. 19, 2007).

⁷⁸³ **Legal Authority CLA-23**, *Cargill, Incorporated v. United Mexican States* (ICSID Case No. ARB(AF)/05/2), Award, para. 544 (July 29, 2009) (interest compounded annually); **Legal Authority CLA-44**, *S.D. Myers v. Canada* (UNCITRAL), Second Partial Award, paras. 306 (Oct. 21, 2002) (interest compounded annually); **Legal Authority CLA-41**, *Pope & Talbot, Inc. v. Canada* (UNCITRAL), Award in Respect of Damages, para. 90 (May 31, 2002) (interest compounded quarterly); **Legal Authority CLA-33**, *Metalclad Corp. v. Mexico* (ICSID ARB(AF)/97/1), Award, para. 128 (Aug. 30, 2000) (interest compounded annually).

period between the date on which the order was made and the date of payment.⁷⁸⁴

571. Accordingly, Claimants respectfully request an award of interest at the same rate as applicable to the award of compensation, compounded quarterly, from the date of the Tribunal's Final Award and until the date of Respondent's full payment of above-referenced costs and fees.

SUBMISSIONS

572. As a result of the actions and breaches of the Government of the United States of America described above, the Claimants respectfully intend to request an award in their favor:

- a. Declaring that the United States of America has breached its obligations under Articles 1102, 1103 and 1105 of the NAFTA;
- b. Ordering 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, including pre-award interest;
- c. Ordering the United States of America to pay the Claimants' interest and taxes on all sums awarded;
- d. Ordering 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.

⁷⁸⁴ **Legal Authority CLA-45**, *S.D. Myers, Inc. v. The Government of Canada*, UNCITRAL, Final Award, para. 50 (Dec. 30, 2002).

573. 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: July 30, 2012

Respectfully submitted,

SALANS LLP

A handwritten signature in black ink, appearing to read "Barton Legum", with a long horizontal line extending to the right.

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