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NAFTA UPDATE AND AMERICAN TRADE NEWS HIGHLIGHTS FROM JANUARY 2012 THROUGH MARCH 2012

Miranda Barton

I. CANADIAN PHARMACEUTICAL COMPANY SEEKS DAMAGES UNDER NAFTA FROM UNITED STATES FOR IMPORT RESTRICTIONS ON GENERIC PRESCRIPTION DRUGS

CANADIAN pharmaceutical manufacturer Apotex Holdings, the largest generic drug maker in Canada, requested institution of arbitration proceedings concerning an import alert issued by the U.S. Food and Drug Administration (FDA) in 2009.¹ The pharmaceutical company was restricted from exporting its generic prescription drugs to the United States pending an FDA evaluation of the manufacturer's safety and quality controls.² Although the ban was lifted in July 2011, Apotex has since filed a complaint under NAFTA, claiming that the United States is liable for \$520 million in damages that it suffered in lost export volume as a result of the import restrictions.³

A. THE INITIAL CONCERNS REGARDING APOTEX AND THE FDA IMPORT RESTRICTIONS

The FDA first issued a warning letter to Apotex in June 2009 and then issued a second letter in April 2010.⁴ Observers called the practice of issuing two letters within one year “unusual.”⁵ The warning letters cited problems including “charred particles in a diabetes drug; contamination of an antihistamine, and drug cross-contamination that resulted from inadequate cleaning of manufacturing equipment,” and failure to notify the FDA about such problems.⁶ The first letter, from June 2009, included

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1. Dana Flavelle, *Apotex Drug Maker Sues U.S. for \$520 Million Under NAFTA*, TORONTO STAR, Mar. 14, 2012, available at <http://www.thestar.com/business/article/1146372—apotex-drug-maker-sues-u-s-for-520-million-under-nafta>.
 2. Letter from Teddi Lopez for Richard L. Freidman, Dir., U.S. Food and Drug Admin., to Jack M. Kay, President and COO, Apotex, Inc. (Mar. 29, 2010), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm207508.htm>.
 3. Flavelle, *supra* note 1.
 4. Natasha Singer, *F.D.A. Again Warns a Generic Maker About Conditions at Its Plants*, N.Y. TIMES (Apr. 15, 2010), <http://www.nytimes.com/2010/04/16/business/16generic.html>.
 5. *Id.*
 6. *Id.*

what the FDA referred to as “significant violations of the Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals.”⁷ These violations occurred at the Etobicoke, Ontario manufacturing location and included failure to report the nonconformities with CGMP regulations as well as the safety and quality control violations themselves.⁸

A subsequent inspection of the company’s Toronto, Ontario location in July and August 2009 revealed several violations identical to those cited at the Etobicoke location; the manufacturer had also failed to report these violations to the FDA.⁹ In light of the repeated violations at the two plants along with Apotex’s failure to report them as required under FDA regulations, the agency placed both Apotex locations under an import alert as of August 28, 2009.¹⁰ The import alert imposed by the FDA restricted all “finished drug products offered for entry into the United States” that were manufactured at either the Etobicoke or Toronto Apotex locations.¹¹ Such products were “detained without physical examination” prior to their entry into the United States.¹²

The specific CGMP violations that the FDA cited in its 2010 letter included failure to have “adequate written procedures for production and process controls” to ensure that the products “have the identity, strength, quality, and purity they purport or are represented to possess.”¹³ The FDA also cited the company’s failure to “thoroughly investigate unexplained discrepancies or the failure of a batch or any of its components to meet any of its specifications,” such as the discovery of contaminants in batches of finished pharmaceuticals without a subsequent follow-up investigation to determine the source of the contaminants.¹⁴ The FDA’s third violation cited Apotex’s failure to have “adequate equipment cleaning and maintenance procedure[s].”¹⁵ The agency referenced instances of finding “foreign materials,” “charred material,” and “powder residues” in the finished pharmaceutical products, and also of defective finished products or materials being returned back into inventory upon discovery of contaminants or foreign material.¹⁶

B. APOTEX’S CORRECTIVE ACTIONS

After issuance of the FDA warning letter, Apotex acknowledged “certain shortcomings in its operations” and voluntarily recalled certain prod-

7. Letter from Teddi Lopez to Jack M. Kay, *supra* note 2.

8. *Id.*

9. *Id.* Such reports (NDA Field Alert Reports) are required by 21 CFR § 314.81(b)(1) and § 505(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(k)).

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

ucts.¹⁷ This included about 659 batches of prescription generics recalled from July 2007 until August 2009.¹⁸ Apotex says that it corrected the issues cited by the FDA in its warning letters and noted that other countries did not ban its products from import.¹⁹ It also points out that Health Canada gave the two plants, cited by the FDA, “a passing grade” in 2009, after the alleged violations had been remedied.²⁰ The FDA asserted that at the time of the warning letter, the company had “serious and repeat violations from the 2008 and 2009 inspections” and had demonstrated an “inadequate” response to prior warnings.²¹

As a result of the corrective actions taken by the company in July 2011, the FDA issued a close-out letter regarding the violations.²² Although an FDA close-out letter is not a protection from future regulatory action regarding violations, the letter did acknowledge that the company had “addressed the violations” from the March 29, 2010 warning letter.²³ Apotex complains that the letter was unnecessarily delayed by various FDA actions including subsequent inspections, administrative delays, and repeated inspections during the import alert period despite Apotex having corrected the issues cited by the FDA.²⁴

C. APOTEX’S LEGAL RESPONSE

Apotex claims that the import restrictions did irreparable damage to its distribution business in the United States, causing it to fall from the sixth largest exporter of generic pharmaceuticals at the time the restrictions were issued, to the twenty-fifth largest exporter by the time they were lifted.²⁵ Apotex’s Request for Arbitration characterizes the import alert as something that, in practice, “is not detention of any product or sample but a refusal of admission of all products meeting the stated category, without examination . . .”²⁶ The company claims that the FDA’s import alert “decimated” its U.S. export business.²⁷ It has filed a suit in the World Bank Group’s International Centre for Settlement of Investment Disputes seeking \$520 million in damages under NAFTA.²⁸

17. Flavelle, *supra* note 1.

18. Singer, *supra* note 4.

19. Flavelle, *supra* note 1.

20. *Id.*

21. Singer, *supra* note 4.

22. Letter from Maan Abduldayem, Compliance Officer, U.S. Food and Drug Admin., to Jeremy B. Desai, Chief Operating Officer, Apotex, Inc. (July 1, 2011), www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm267086.htm.

23. *Id.*

24. See Apotex Holdings Inc. and Apotex Inc. v. United States, ICSID Case No. ARB(AF)/12/1, Request for Arbitration, ¶¶ 54-56 (Feb. 29, 2012), available at <http://www.state.gov/documents/organization/185626.pdf> [hereinafter Apotex Request for Arbitration].

25. Flavelle, *supra* note 1.

26. Apotex Request for Arbitration, *supra* note 24, ¶ 25.

27. Apotex Sues Government, Says 2009 Import Ban ‘Decimated’ Its U.S. Business, FDANEWS (Mar. 19, 2012), <http://www.fdanews.com/newsletter/article?issueId=15605&articleId=144887>.

28. *Id.*

In the suit, Apotex claims that it quickly recalled the affected drugs, but despite its prompt attention, the United States failed to withdraw the import alert until nearly two years later.²⁹ The company says that the ban was not only “devastating” to the company’s distribution, but also that it was discriminatory because other pharmaceutical companies with similar violations were not punished as strictly.³⁰ In response to the alleged unfair treatment, the company filed a challenge against the United States under Chapter 11 of NAFTA.³¹

Specifically, Apotex alleges that by enforcing the import alert against the Etobicoke and Toronto manufacturing plants, “the United States accorded [Apotex] treatment less favorable than that afforded to U.S. investors in like circumstances regarding the establishment, acquisition, expansion, management, conduct, operation and sale of investments in the form of authorizations to sell pharmaceutical products and other investments in the U.S.”³² Apotex claims that U.S.-owned rivals were afforded more favorable treatment by the FDA, citing a U.S.-owned pharmaceutical plant in Israel as an example.³³ Apotex alleges that such favorable treatment violates NAFTA Article 1102, which states in part that “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.”³⁴

II. UNITED STATES INSTITUTES CAFTA-DR ACTION AGAINST GUATEMALA FOR ALLEGED LABOR LAW VIOLATIONS

In August 2011, the Office of the United States Trade Representative announced that the United States would request an arbitral panel under the CAFTA-DR to evaluate claims that Guatemala was failing to enforce its own labor rights laws (as required by the free trade agreement) and Guatemala’s lack of a satisfactory response to the allegations.³⁵ Since then, the two CAFTA-DR signatory countries have been engaged in informal negotiations but have failed to resolve the dispute.³⁶ The formal request for a decision from the CAFTA-DR Free Trade Commission is

29. Jeff Gray, *Apotex Challenges U.S. Import Ban under NAFTA*, *GLOBE AND MAIL*, Mar. 15, 2012, at B3.

30. *Id.*

31. *Id.*

32. Apotex Request for Arbitration, *supra* note 24, ¶ 69 (citing NAFTA Article 1102).

33. Flavelle, *supra* note 1; *see also* Apotex Request for Arbitration, *supra* note 24, ¶ 69.

34. Apotex Request for Arbitration, *supra* note 24, ¶ 25.

35. Press Release, U.S. Trade Representative Ron Kirk Announces Next Step in Labor Rights Enforcement Case against Guatemala (Aug. 9, 2011), *available at* <http://www.ustr.gov/about-us/press-office/press-releases/2011/august/us-trade-representative-ron-kirk-announces-next-ste>.

36. *See U.S., Guatemala Take Another Stab at Resolving CAFTA Labor Fight*, 29 *INSIDE U.S. TRADE* 50 (2011).

the first labor case brought by the United States against another party to one of its free trade agreements.³⁷

A. HISTORY OF THE DISPUTE

In July 2010, the United States formally requested that Guatemala respond to allegations that it was violating its own labor rights laws.³⁸ CAFTA-DR, which governs free trade between the United States and the Central American nations, along with the Dominican Republic, requires that each nation enforce its own labor laws adequately.³⁹ The request referred back to an April 2008 filing by the United States' American Federation Labor-Congress of Industrial Organizations and six Guatemalan labor rights organizations.⁴⁰ That filing claimed that Guatemala was failing to enforce its own laws regarding "the right of association, the right of workers to organize and bargain collectively, and acceptable conditions of work."⁴¹ Further, labor rights leaders in Guatemala claimed that they were systematically excluded from discussions regarding labor rights between the Guatemalan government and the United States.⁴²

Since the submission and subsequent investigation by the United States, the U.S. Trade Representative and the U.S. Departments of Labor and State examined Guatemalan compliance with the requisite that it enforces those laws relating to labor rights. Consultations between the agencies and the Guatemalan government took place in 2010, and the United States requested a meeting of the Free Trade Commission in 2011.⁴³ Although negotiations have continued, the governments of the United States and Guatemala have been unable to reach agreement regarding "an adequate enforcement plan" for the labor rights guaranteed by Guatemala's labor laws.⁴⁴ In light of this failure, the United States has moved on to requesting an arbitral panel to evaluate the violations.

According to an AFL-CIO official, if the complaint were fully adjudicated and Guatemala were found to have violated its own labor laws, the nation "could be assessed a maximum fine of \$15 million, which it would pay to itself to address the underlying problems."⁴⁵ Failure to pay the

37. Amy Tsui, *USTR Takes Next Step Against Guatemala in CAFTA-DR Labor Law Enforcement Case*, 28 INT'L TRADE REP. 824 (2011).

38. Rossella Brevetti, *U.S. Seeks Arbitration Panel in Labor Case Against Guatemala Brought Under CAFTA-DR*, 28 INT'L TRADE REP. 1322 (2011).

39. *Id.*

40. See John Crook, *Contemporary Practice of the United States Relating to International Law: Settlement of Disputes: United States Initiates CAFTA-DR Labor Law Arbitration Against Guatemala*, 105 AM. J. OF INT'L LAW 812 (2011).

41. See *id.* at 813.

42. Matthew Walter, *U.S. Leans on Guatemala to Enforce Trade Pact*, CHRISTIAN SCI. MONITOR (July 13, 2011), <http://www.csmonitor.com/World/Americas/2011/0713/US-leans-on-Guatemala-to-enforce-trade-pact>.

43. See Crook, *supra* note 40, at 813 (noting that the Commission met on June 7, 2011 and stating that the Commission is composed of members from each of the member countries).

44. *Id.*

45. Tsui, *supra* note 37.

fine and address the violations, if the tribunal found Guatemala to be in violation, could result in trade sanctions by the United States.⁴⁶

B. GUATEMALA'S RESPONSE

In December 2011, Guatemalan Economic Minister Luis Velasquez announced that the two countries were informally negotiating to “find an alternative route to resolv[e] the labor dispute without resorting to a panel.”⁴⁷ Guatemala had previously agreed to fourteen of the seventeen points raised by the United States to resolve the dispute and bring Guatemala into compliance with its own labor regulations.⁴⁸

One of the three remaining disputes was for Guatemala to “hire and train 100 additional labor inspectors,” which Velasquez indicated that the country was now ready to do.⁴⁹ The two remaining issues “involve returning to the labor ministry the power to sanction employers for non-compliance with labor laws and requiring businesses operating under a special law promoting the growth of ‘maquilas’ to post a bond that would compensate workers in the event the business closes.”⁵⁰

Guatemala claims that returning the power to sanction employers to the labor ministry would violate the country’s constitution because the power is vested in the country’s labor courts.⁵¹ Velasquez said that it would continue to negotiate to resolve the two remaining issues, but noted that the country would not “propose improvements or changes to the constitution.”⁵² The nation also claims that it would be unfair to require the bonding for certain maquilas retroactively, and has not proposed an alternative arrangement for either of these two disputed issues.⁵³ A U.S. Trade Representative spokeswoman said that the United States believed that the steps it is requesting of Guatemala “could be taken in a manner consistent with Guatemala’s constitution and its laws, and, were Guatemala to take such steps, we believe they could lead to resolution of this matter.”⁵⁴

Guatemala also alleges that the United States did not have grounds under CAFTA 16.2 to bring the action because it did not show that the outstanding issues alleged by the United States actually affected trade between the countries.⁵⁵ Article 16.2 of the CAFTA-DR agreement states that a party “shall not fail to effectively enforce its labor laws, through a sustained or recurring course of action or inaction, in a manner

46. *Id.*

47. See U.S., *Guatemala Take Another Stab at Resolving CAFTA Labor Fight*, *supra* note 36.

48. *Id.*

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

53. *Id.*

54. *Id.*

55. *Id.*

affecting trade between the parties.”⁵⁶ Guatemala claims that even if the issues alleged by the United States are true, they have not affected trade between the two countries.⁵⁷

56. Dominican Republic-Central America-United States Free Trade Agreement art. 16.2, Aug. 23, 2010, 75 FR 51869, USTR-2010-0023.

57. *See U.S., Guatemala Take Another Stab at Resolving CAFTA Labor Fight, supra* note 36.

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