

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF PUERTO RICO

_____)	
UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No.
)	
TAPI PUERTO RICO, INC.,)	
)	
Defendant.)	
_____)	

COMPLAINT

Plaintiff, the United States of America, by the authority of the Attorney General of the United States and through the undersigned attorneys, acting at the request of the Administrator of the United States Environmental Protection Agency (“EPA”), files this Complaint and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action against TAPI Puerto Rico, Inc. (“TAPI”) for violations of the Clean Air Act (“CAA”), 42 U.S.C. §§ 7401 *et seq.*, the Clean Water Act (“CWA”), 33 U.S.C. §§ 1251 *et seq.*, the Resource Conservation and Recovery Act (“RCRA”), 42 U.S.C. §§ 6901 *et seq.*, and the Emergency Planning and Community Right-to-Know Act (“EPCRA”), 42 U.S.C. §§ 11001 *et seq.*, at TAPI’s former pharmaceutical manufacturing facility in Guayama, Puerto Rico (the “Facility”). The United States seeks civil penalties for TAPI’s violations of each of these statutes, as well as their implementing permits and regulations.

2. TAPI failed to comply with the CAA’s regulations governing the emission of hazardous air pollutants (“HAPs”) from its pharmaceutical production equipment and from its

hazardous waste incinerators, in violation of Sections 112, 502 and 504 of the CAA, 42 U.S.C. §§ 7412, 7611a and 7661c and EPA's implementing regulations. TAPI discharged wastewater to the local publicly owned treatment works without abiding by its industrial discharge permit requirements, violating Section 307 of the CWA, 33 U.S.C. § 1317, and EPA's implementing regulations. TAPI stored hazardous waste in tanks, containers and aeration basins subject to its RCRA permit in violation of the permit and failed to meet the permit exemptions for its less than 90-day storage tanks, in violation of Section 3005 of RCRA, 42 U.S.C. § 6925, and EPA's implementing regulations. Finally, TAPI failed to timely submit a Toxic Release Inventory report to EPA for calendar years 2010 - 2011, violating Section 313 of EPCRA, 42 U.S.C. § 11023, and EPA's implementing regulations.

JURISDICTION AND VENUE

3. Jurisdiction is vested in this Court pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Section 309(b) of the CWA, 33 U.S.C. § 1319(b), Section 3008(a)(1) and (g) of RCRA, 42 U.S.C. §§ 6928(a)(1) and (g), Section 325(c)(4) of EPCRA, 42 U.S.C. § 11045(c)(4), and 28 U.S.C. §§ 1331, 1345, and 1355.

4. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1395(a), 33 U.S.C. § 1319(b), and 42 U.S.C. §§ 6928(a) and (g), 7413(b), and 11045(b)(3), because TAPI is located in this District and the violations alleged herein occurred within this District.

DEFENDANT

5. TAPI is a for-profit corporation incorporated in Puerto Rico.

DESCRIPTION OF THE FACILITY

6. The Facility is located at State Road # 3, Km 143, Guayama, Puerto Rico. TAPI shut down active manufacturing operations at the Facility in or about April 2016. Prior to shutting down the Facility in 2016, TAPI operated four manufacturing areas at the Facility. The Facility primarily manufactured Levetiracetam, an anti-convulsion medication used to treat epilepsy. Other products that were manufactured at the Facility included Amlodipine Besylate (blood pressure medication), Eszopiclone (insomnia treatment), Ibandronate Acid (osteoporosis treatment), and Lisinopril (blood pressure medication). The Facility also had a research and development area and small-volume laboratories.

7. The Facility's pharmaceutical manufacturing process consisted of chemical production operations that produced drugs and medications. These operations included chemical synthesis (producing a drug's active ingredient) and chemical formulation (producing a drug in its final form). Air emissions of hazardous air pollutants ("HAPs") occurred as a result of breathing and withdrawal losses from chemical storage tanks, venting of process vessels, leaks from piping and equipment used to transfer HAP compounds (equipment leaks), and volatilization from wastewater streams.

8. The Facility had two hazardous waste incinerators which burned organic and aqueous hazardous waste.

9. The Facility also discharged pollutants from its secondary wastewater treatment plant via a pipe that connects to the public sewer system that leads to the Puerto Rico Aqueduct and Sewer Authority ("PRASA") publicly owned treatment works, the Guayama Pretreatment Wastewater Regional Plant, which is authorized to discharge effluent into Las Mareas Bay.

10. The Facility generated more than 1,000 kilograms per month of hazardous waste. Pursuant to its RCRA permit, the Facility was authorized to manage one hazardous waste container storage area and eight hazardous waste tank systems at its Facility. The Facility also had nine tanks that stored hazardous waste that were exempt from RCRA's permitting requirements, but only if they stored hazardous waste for less than 90 days and met certain other requirements of the RCRA regulations.

11. Naphthalene is a listed toxic chemical under the EPCRA regulations. The Facility used over 10,000 lbs. of naphthalene in each of the calendar years 2010-2011.

12. At all times relevant to this action, TAPI owned and operated the Facility.

CLEAN AIR ACT

Statutory Background

13. The CAA was enacted to protect and enhance the quality of the nation's air resources so as to promote the public health and welfare. Section 101(b)(1) of the CAA, 42 U.S.C. § 7401(b)(1).

14. Section 112(b) of the CAA, 42 U.S.C. § 7412(b), establishes a list of HAPs.

15. Section 112(c) of the CAA, 42 U.S.C. § 7412(c), directs EPA to publish a list of all categories and subcategories of major sources and area sources of HAPs.

16. Section 112(d) of the CAA, 42 U.S.C. § 7412(d), directs EPA to promulgate regulations establishing emission standards for each category or subcategory of major and area sources of HAPs. Emission standards promulgated pursuant to Section 112 of the CAA are commonly known as National Emission Standards for Hazardous Air Pollutants ("NESHAPs"). NESHAPs promulgated under the CAA, as amended in 1990, are sometimes known as "MACT"

standards, because Section 112(d) of the CAA, as amended in 1990, directs EPA to promulgate emission standards based on the maximum achievable control technology.

17. Section 112(i)(3) of the CAA, 42 U.S.C. § 7412(i)(3), provides that after the effective date of any emission standard, limitation or regulation promulgated pursuant to Section 112 and applicable to a source, no person may operate such source in violation of such standard, limitation or regulation.

18. Section 112(f)(4) of the CAA, 42 U.S.C. § 7412(f)(4), prohibits the emission of any air pollutant to which a standard under Section 112 applies from any stationary source in violation of such standard without first obtaining a waiver from EPA.

19. Title V of the Act, 42 U.S.C. §§ 7661–7661f, establishes an operating permit program for certain sources in order to ensure that all applicable requirements for compliance with the CAA are set forth in a single permit.

20. Section 502(a) of the CAA, 42 U.S.C. § 7661a(a), provides that after the effective date of any permit program approved or promulgated pursuant to Title V of the Act, it shall be unlawful for any person to violate any requirement of a permit issued under Title V of the Act, or to operate a Title V affected source except in compliance with a permit issued by a permitting authority under Title V of the Act.

21. Pursuant to Section 502(b) of the CAA, EPA promulgated 40 C.F.R. § 70, State Operating Permit Program regulations.

22. Section 502(d) of the CAA required each state (including the Commonwealth of Puerto Rico) to develop, and submit to the Administrator, a permit program meeting the requirements of Title V of the Act, including the requirements of the State Operating Permit Program regulations.

Environmental Quality Board Air Permitting Program

23. Pursuant to Section 502(d)(1) of the Act, the Commonwealth of Puerto Rico developed and submitted the Puerto Rico Title V Operating Permit Program, to meet the requirements of Title V of the Act and the requirements of 40 C.F.R. § 70.

24. Pursuant to Section 112(1) of the CAA, 42 U.S.C. § 7412(1), the Puerto Rico Environmental Quality Board (“EQB”) developed and submitted to the Administrator for approval a program for the implementation and enforcement of emission standards and other requirements for air pollutants subject to Section 112 of the CAA. (Pursuant to a statute that was enacted August 2, 2018, EQB has become a part of the Puerto Rico Department of Natural and Environmental Resources, but will be referred to herein as EQB since the operative facts alleged in this case took place prior to that date).

25. EPA granted final full approval of the Puerto Rico Title V Operating Permit Program and approved the EQB CAA § 112(1) delegation request on February 26, 1996. *See* 61 Fed. Reg. 7073 (Feb. 26, 1996); 40 C.F.R. Part 70, Appendix A. EPA approved delegation to EQB of all CAA § 112 MACTs, pursuant to Subpart E of 40 C.F.R. Part 63 (Approval of State Programs and Delegation of Federal Authorities).

26. Pursuant to Section 502(e) of the CAA, EPA maintains its authority to enforce permits issued by EQB.

NESHAP for Pharmaceuticals Production

27. Pursuant to Section 112 of the CAA, 42 U.S.C. § 7412, EPA, on September 21, 1998, promulgated the NESHAP for Pharmaceuticals Production (“Pharmaceutical MACT”), 40 C.F.R. §§ 63.1250–63.1261.

28. EPA developed the Pharmaceutical MACT to significantly reduce HAP emissions from pharmaceutical facilities. National Emission Standards for Hazardous Air Pollutants for Source Categories: Pharmaceuticals Production, 63 Fed. Reg. 50280, 50284 (1998).

29. Pursuant to 40 C.F.R. § 63.1250(a), except as provided by 40 C.F.R. § 63.1250(d), an “affected source” is a pharmaceutical manufacturing operation, as defined in 40 C.F.R. § 63.1251, that: (A) manufactures a pharmaceutical product, as defined in 40 C.F.R. § 63.1251; (B) is located at a plant site that is a major source of HAPs, as defined in Section 112(a) of the CAA; and (C) processes, uses or produces any HAP.

30. Section 112(a)(1) of the CAA, 42 U.S.C. § 7412(a)(1), defines “major source” as any stationary source that emits or has the potential to emit, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants.

31. Pursuant to 40 C.F.R. § 63.2, “potential to emit” is defined as the maximum capacity of a stationary source to emit a pollutant under its physical and operational design. Any physical or operational limitation on the capacity of the stationary source to emit a pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation or the effect it would have on emissions is federally enforceable.

32. Pursuant to 40 C.F.R. § 63.1250(f)(1), an owner or operator of an existing affected source at the time the Pharmaceutical MACT was promulgated was required to comply with the provisions of the Pharmaceutical MACT no later than October 21, 2002, unless an extension was granted in accordance with 40 C.F.R. § 63.1250(f)(6)(i).

33. Pursuant to 40 C.F.R. § 63.6(c)(5), except as provided in 40 C.F.R. § 63.6(b)(7), the owner or operator of an area source (a non-major source) that increases its potential to emit hazardous air pollutants such that the source becomes a major source is subject to the

Pharmaceutical MACT standards for existing area sources and must comply with such standards by the date set forth in the relevant standard or, if no such date is set forth, a period of time that is equivalent to the compliance period specified in the Pharmaceutical MACT for existing sources in existence at the time the Pharmaceutical MACT became effective, unless the addition of equipment or operations meets the definition of new affected source in the relevant standard.

34. Pursuant to 40 C.F.R. § 63.6(b)(7), when an area source becomes a major source by the addition of equipment or operations that meet the definition of a new affected source, the portion of the existing facility that is a new affected source must comply with the Pharmaceutical MACT standards for new sources upon startup. Under 40 C.F.R. § 63.1250(f)(2), the owner or operator of a new or reconstructed affected source must comply with the provisions of the Pharmaceutical MACT applicable to new sources on April 29, 2000 or upon startup, whichever is later.

35. Under 40 C.F.R. § 63.1250(b), a new affected source includes (a) a source for which construction or reconstruction commenced after April 2, 1997 and the Pharmaceutical MACT was in effect and (b) a pharmaceutical manufacturing process unit (“PMPU”) dedicated to manufacturing a single product that has the potential to emit ten tons per year of any HAP for which construction commenced after April 2, 1997 or reconstruction commenced after October 21, 1999.

36. Pursuant to 40 C.F.R. § 63.1250(a)(2), an owner or operator of an affected source shall report to the permitting authority, as part of an operating permit application or as otherwise specified by the permitting authority, the source’s Pharmaceutical MACT applicability determination.

37. Pursuant to 40 C.F.R. § 63.9(b), the owner or operator of an affected source that has an initial startup before the effective date of the Pharmaceutical MACT and that increases its potential to emit such that the source becomes a major source is required to submit a notification to EQB within 120 days after the source becomes a major source.

38. An owner or operator of an affected source must comply with the storage tank standards of 40 C.F.R. § 63.1253.

39. An owner or operator of an affected source must comply with the process vents standards of 40 C.F.R. § 63.1254.

40. An owner or operator of an affected source must comply with the requirements of 40 C.F.R. § 63.1255 related to equipment leaks with respect to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems.

41. An owner or operator of an affected source must comply with the general wastewater requirements and the maintenance wastewater standards required by 40 C.F.R. § 63.1256.

42. Pursuant to 40 C.F.R. § 63.1258(a), an owner or operator of an affected source, using a control device to comply with the Pharmaceutical MACT, must conduct an initial compliance demonstration in which it establishes maximum or minimum operating parameters, as appropriate.

43. Pursuant to 40 C.F.R. § 63.1258(b), except as specified in 40 C.F.R. § 63.1258(b)(1)(i), an owner or operator of an affected source must, for each control device, install and operate monitoring devices and operate them within the established parameter levels to ensure continuous compliance with the applicable Pharmaceutical MACT emission standards.

44. An owner or operator of an affected source must comply with the recordkeeping requirements mandated by 40 C.F.R. § 63.1259.

45. Pursuant to 40 C.F.R. § 63.1260(f), an owner or operator of an affected source must submit a notification of compliance status report, as specified in 40 C.F.R. § 63.9(h). This must include, among other things, descriptions of monitoring devices, monitoring frequencies, and the values of monitored parameters established during the initial compliance determinations, including data and calculations to support the levels established.

46. Pursuant to 40 C.F.R. § 63.1260(g), an owner or operator of an affected source must prepare and submit to EPA periodic reports in accordance with 40 C.F.R. §§ 63.1260(g)(1) and (2).

Title V

47. Title V of the CAA, 42 U.S.C. §§ 7661–7661f, establishes an operating permit program for certain sources, including “major sources.” The purpose of Title V is to ensure that all “applicable requirements” for compliance with the Act are collected in one place.

48. Section 502(a) of the CAA, 42 U.S.C. § 7661a(a), provides, among other things, that after the effective date of any permit program approved or promulgated under Title V of the CAA, it is unlawful for any person to operate a source subject to Title V except in compliance with a permit issued by a permitting authority under Title V.

49. For major sources, the permitting authority shall include in the permit all applicable requirements for all relevant emissions units in the major source. 40 C.F.R. § 70.3(c)(1).

50. Under 40 C.F.R. § 70.5(b) and Rule 602(b) of the Regulation for the Control of Atmospheric Pollution of the Commonwealth of Puerto Rico (“RCAP”), all Title V permit

applicants have an ongoing duty to supplement or correct operating permit applications if they are deficient or incorrect. This duty includes providing additional information as necessary to address any requirements that become applicable to the source after the date it files a complete application but prior to release of a draft permit.

NESHAP for Hazardous Waste Combustors

51. Pursuant to Section 112 of the CAA, 42 U.S.C. § 7412, EPA, on September 30, 1999, promulgated the NESHAP for Hazardous Waste Combustors (“HWC MACT”), 40 C.F.R. §§ 63.1200-63.1221, which sets forth the standards applicable to the operation of hazardous waste combustors, among other sources.

52. While NESHAPS generally apply only to major sources, the HWC MACT applies to “area sources” as well.

53. The HWC MACT, at 40 C.F.R. § 63.1206(a)(ii), established that existing sources must comply with the emission standards under §§ 63.1219, 63.1220, and 63.1221 and the other applicable requirements of 40 C.F.R. §§ 63.1200-1221 no later than the compliance date, October 14, 2008, unless the Administrator granted the source an extension of time under § 63.6(i) or § 63.1213.

54. The HWC MACT, at 40 C.F.R. § 63.1206(b), established that, *inter alia*, failure to comply with the operating requirements is failure to ensure compliance with the emission standards of 40 C.F.R. §§ 63.1200-1221.

55. The HWC MACT, at 40 C.F.R. § 63.1206(c)(3)(i), established that upon the compliance date, a facility must operate the hazardous waste incinerator with a functioning system that immediately and automatically cuts off the hazardous waste feed, except as provided 40 C.F.R. § 63.1206(c)(3)(viii), when (A) any of the following are exceeded: operating

parameter limits specified under § 63.1209; an emission standard monitored by a Continuous Emission Monitoring System (“CEMS”); or the allowable combustion chamber pressure; (B) the span value of any Continuous Monitoring System (“CMS”) detector, except a CEMS, is met or exceeded; (C) there is a malfunction of a CMS monitoring an operating parameter limit specified under § 63.1209 or an emission level; or (D) any component of the automatic waste feed cutoff system fails.

56. Pursuant to 40 C.F.R. § 63.10(d)(5)(i), if actions taken by an owner or operator of a hazardous waste combustor during a startup or shutdown (and the startup or shutdown causes the source to exceed any applicable emission limitation in the relevant emission standards), or during a malfunction of the hazardous waste combustor, are consistent with the procedures specified in the source’s startup, shutdown and malfunction report, the owner or operator must set forth such information in the startup, shutdown and malfunction report required to be submitted on a semi-annual basis.

57. Pursuant to 40 C.F.R. § 63.1209(j), the owner or operator of a hazardous waste combustor must establish limits on the maximum pumpable and total hazardous waste feed rate for each location where hazardous waste is fed and must comply with the limits on an hourly rolling average basis.

Enforcement Provisions

58. Sections 113(a)(3) and (b) of the CAA, 42 U.S.C. § 7413(a)(3) and (b), authorize the EPA Administrator to bring a civil action for civil penalties and/or for injunctive relief against any person who has violated or is in violation of any requirement or prohibition of Title I of the CAA (which includes Section 112 of the CAA) or any requirement or prohibition of any rule promulgated, issued, or approved under Title I of the CAA.

59. Section 113(b) of the CAA, 42 U.S.C. § 7413(b), and 40 C.F.R. § 19.4, establish maximum civil penalties for violations of Section 113(b) of the CAA. The maximum civil penalty per day per violation of Section 113(b) of the CAA is \$37,500 for the violations alleged below occurring after January 12, 2009 through November 2, 2015 and on or before November 2, 2015 and \$101,439 for the violations alleged below occurring after November 2, 2015.

First CAA Claim for Relief – Violation of Pharmaceutical MACT Standards

60. Paragraphs 1 through 59 are incorporated herein by reference.

61. In or about January 2012, TAPI implemented a project at the Facility intended to increase the Facility's capacity to produce Levetiracetam ("2012 Project"). The 2012 Project involved process equipment modifications to facilitate a reduction in batch step cycle times. The Facility also adjusted the underlying process steps.

62. At least as of the completion of the 2012 Project, the Facility had the potential to emit at least ten tons per year of acetonitrile, which is a HAP. Therefore, from at least January 2012, the Facility was a "major source" of HAPs under Section 112(a)(1) of the Act, 42 U.S.C. § 7412(a)(1) and was therefore an "affected source" under the meaning of 40 C.F.R. § 63.1250.

63. The Facility was required to submit a notification to EQB indicating that it had the potential to emit over ten tons/year of acetonitrile by no later than May 2012, 120 days from completion of the 2012 Project.

64. The Facility was required to come into compliance with the Pharmaceutical MACT requirements no later than February 2015, three years from completion of the 2012 Project.

65. During the period of time from at least February 2015 to at least April 2016, when the Facility shut down its active pharmaceutical manufacturing operations, TAPI violated the requirements of the Pharmaceutical MACT as follows:

- a. TAPI failed to comply with the storage tanks standards set forth at 40 C.F.R. § 63.1253.
- b. TAPI failed to comply with the process vents standards set forth at 40 C.F.R. § 63.1254.
- c. TAPI failed to comply with the equipment leak standards set forth at 40 C.F.R. § 63.1255.
- d. TAPI failed to comply with the wastewater standards set forth at 40 C.F.R. § 63.1256.
- e. TAPI failed to conduct an initial compliance demonstration to establish maximum or minimum operating parameters for its control devices to indicate compliance with the Pharmaceutical MACT, as required by 40 C.F.R. § 63.1258(a).
- f. For each control device, TAPI failed to install and operate monitoring devices and operate the control devices within established parameter levels to ensure continuous compliance with the applicable Pharmaceutical MACT emission standards, as required by 40 C.F.R. § 63.1258(b).
- g. TAPI failed to comply with the Recordkeeping requirements set forth at 40 C.F.R. § 63.1259.
- h. TAPI failed to comply with the reporting requirements set forth at 40 C.F.R. § 63.1260.

66. TAPI violated Section 112(i)(3) of the CAA, 42 U.S.C. § 7412(i)(3), and the requirements of the Pharmaceutical MACT, and each violation of these requirements subjects TAPI to liability.

67. Pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 40 C.F.R. Part 19, TAPI is liable for civil penalties for each day of violation.

Second CAA Claim for Relief – Title V Violations

68. Paragraphs 1 through 67 are incorporated herein by reference.

69. In 2005, TAPI submitted a Title V permit application related to its hazardous waste incinerators. The permit application was revised in April 2007. EQB did not approve the permit or issue a draft permit prior to the shut-down of TAPI's active manufacturing operations.

70. TAPI violated Sections 502(a) and 504(a) of the CAA, 42 U.S.C. §§ 7661a(a) and 7661c(a), 40 C.F.R. § 70.5(b), and Rule 602(b) of the RCAP, by failing to submit an amendment to its Title V operating permit application for the Facility indicating that the Facility was subject to the Pharmaceutical MACT requirements.

71. TAPI violated Sections 502(a) and 504(a) of the CAA, 42 U.S.C. §§ 7661a(a) and 7661c(a), and the Title V implementing regulations including 40 C.F.R. § 70.5, and each violation of these requirements subjects TAPI to liability

72. Pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), and 40 C.F.R. § 19, TAPI is liable for civil penalties for the violations alleged above.

Third CAA Claim for Relief – Violations of the Hazardous Waste Combustor MACT Standards

73. The waste feed rates for hazardous waste combustors at the Facility were exceeded during unsuccessful start-up events on June 2, 2011 and June 5, 2011, but such

unsuccessful start-ups were not reported in the SSM sections of the semi-annual Hazardous Waste Combustor MACT reports filed by TAPI.

74. A malfunction of the automatic waste feed cutoff system caused an exceedance of the organic waste feed rate for the Trane 1 Hazardous Waste Combustor for a period of about 6.6 hours on December 18, 2011, during an automatic waste feed cutoff system monthly test.

75. Pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 40 C.F.R. Part 19, TAPI is liable for civil penalties for each day of violation.

CLEAN WATER ACT

Statutory Background

76. Congress enacted the CWA in 1972 “to restore and maintain the chemical, physical and biological integrity of the Nation’s waters.” 33 U.S.C. § 1251(a).

77. Section 301(a) of the CWA, 33 U.S.C. § 1311(a), prohibits any person from discharging any pollutant except in compliance with, *inter alia*, Section 402.

78. Section 402(a) of the CWA, 33 U.S.C. § 1342(a), establishes a system for the issuance of National Pollutant Discharge and Elimination System (“NPDES”) permits for discharges from point sources of pollutants to waters of the United States.

79. Section 402 of the CWA, 33 U.S.C. § 1342, authorizes EPA and the States (including the Commonwealth of Puerto Rico) (subsequent to EPA approval) to administer the NPDES Permit Program, including issuing NPDES permits allowing for the discharge of pollutants from a point source into navigable waters.

CWA Pretreatment Program

80. Section 402(b)(8) of the CWA, 33 U.S.C. § 1342(b)(8), along with Section 307(b) of the CWA, 33 U.S.C. § 1317(b), establishes the National Pretreatment Program to regulate

discharges from industries to publicly owned treatment works (“POTWs”) as a component of the NPDES Permitting Program. The National Pretreatment Program requires industrial and commercial dischargers to treat or control pollutants in their wastewater before discharging to POTWs. EPA has chosen to promulgate pretreatment standard regulations pursuant to 33 U.S.C. §§ 1311(b) and 1314(b).

81. The National Pretreatment Program embodies three fundamental objectives: 1) prevent the introduction of pollutants into a POTW that will interfere with its operation; 2) prevent the introduction of pollutants into a POTW that will pass through the treatment works into waters of the United States; and 3) improve opportunities to recycle and reclaim municipal and industrial wastewaters and sludge. 40 C.F.R. § 403.2. In turn, these goals protect drinking water supplies, extend the life of the nation’s wastewater infrastructure, and protect worker safety.

82. Section 307(d) of the CWA, 33 U.S.C. § 1317(d), prohibits the owner or operator of any source from discharging pollutants or otherwise operating that source in violation of any applicable pretreatment standard or prohibition as set forth in Section 307 of the CWA, 33 U.S.C. § 1317, and the implementing regulations. This prohibition includes discharging pollutants from a source into a POTW in violation of the applicable pretreatment standards for that source.

83. Pursuant to Section 307 of the CWA, 33 U.S.C. § 1317, EPA promulgated the General Pretreatment Regulations for Existing and New Sources of Pollution at 40 C.F.R. Part 403 and established the “responsibilities of Federal, State, and local government, industry and the public to implement National Pretreatment Standards to control pollutants which pass through or interfere with treatment processes [in POTWs].” 40 C.F.R. § 403.1(a).

84. On September 26, 1985, the EPA Administrator authorized the Puerto Rico Aqueduct and Sewer Authority (“PRASA”) to administer a NPDES pretreatment program pursuant to the aforementioned statutory and regulatory provisions.

TAPI’s Industrial Discharge Permit

85. Under its delegated permitting authority, PRASA issued Industrial Discharge Permit No. GDA-98-507-038 to TAPI on October 21, 2011 (the “Pretreatment Permit”). The Pretreatment Permit was effective from November 25, 2011 through October 31, 2016.

86. The Pretreatment Permit required, *inter alia*, that TAPI “operate and maintain [its] facilities to ensure compliance with this permit” (Section III, General Condition C); and included nine minimum items in its operation and maintenance manual (Section III, General Condition C.1).

Enforcement Provisions

87. Section 309 of the CWA, 33 U.S.C. § 1319, establishes EPA’s enforcement authority against any person (including any corporation) who violates any condition or limitation contained in a pretreatment permit. Section 309(b) authorizes EPA to commence a civil action for appropriate relief, including a permanent or temporary injunction, for any violation of a pretreatment permit.

88. Section 309(d) of the CWA, 33 U.S.C. § 1319(d), and 40 C.F.R. § 19.4, establish maximum civil penalties for violations of pretreatment permits. The maximum civil penalty per day per violation of a pretreatment permit is \$32,500 for violations alleged below occurring after January 12, 2009 through December 6, 2013 and \$37,500 for the violations alleged below occurring after December 6, 2013 through November 2, 2015 and \$55,800 for the violations alleged below occurring after November 2, 2015.

CWA Claim for Relief – Violations of Pretreatment Permit

89. Paragraphs 1 through 88 above are re-alleged and incorporated herein by reference.

90. TAPI is a “person” within the meaning of Section 502(5) of the CWA, 33 U.S.C. §1362(5).

91. TAPI is an “owner” and/or “operator” of a “facility” subject to regulation as a “point source” under the NPDES program. 40 C.F.R. § 122.2; Section 502(14) of the CWA, 33 U.S.C. § 1362(14).

92. TAPI “discharge[s]” wastewater resulting from its manufacturing processes from the Facility into the PRASA POTW, a “treatment works” within the meaning of Section 212(2)(a) of the CWA, 33 U.S.C. §1292(2)(a), which is publicly owned. Wastewater or industrial waste is a “pollutant” within the meaning of Section 502(6) of the CWA, 33 U.S.C. § 1362(6). The Facility was a “source” within the meaning of Section 306(a)(3) of the CWA, 33 U.S.C. §1316(a)(3), and an “Industrial User” within the meaning of 40 C.F.R. § 403.3(j). The PRASA POTW is authorized to discharge effluent into the Caribbean Sea, a water of the United States within the meaning of Section 502(7) of the CWA, 33 U.S.C. § 1362(7).

93. TAPI violated its Pretreatment Permit as follows:

a. Failure to “operate and maintain [TAPI’s] facilities to ensure compliance with” the Pretreatment Permit, as required by Section III.C of the Pretreatment Permit, because:

1) tank V-476 had corroded to the point that EPA observed wastewater leaking from a hole in the tank during EPA’s February 2013 inspection of the Facility, and TAPI personnel could not say how long the tank had been leaking before the inspection; 2) equalization tanks A, B, and C had large cracks in them that threatened to leak wastewater; 3) equalization tank A contained oil

during the inspection, and TAPI personnel said oil had been in the tank for approximately 3 years; 4) equalization tanks overflowed in July 2011; 5) TAPI was operating effluent tank V-431 without level controls to prevent overflows of wastewaters during the inspection; 6) as of February, 2013, TAPI had failed to implement several of an engineering consultant's recommendations for corrective actions to improve the operation of the wastewater treatment plant, including failing to increase the pH in the aeration basin to enhance ammonia removal, failing to implement microscopic observation as a process control to improve the WWTP's operations, and failing to add four new surface aerators to the aeration basin to increase the oxygen transfer rate; and

b. Failure to include one of the nine minimum items required by Section III.C.1 of the Pretreatment Permit in TAPI's operation and maintenance manual; specifically, TAPI's operation and maintenance manual, at the time of the inspection, did not contain adequate "[p]rocedures for detection of problems and corrective actions."

94. TAPI violated the Pretreatment Permit and each violation of these requirements subjects TAPI to liability under Section 309(d) of the CWA, 33 U.S.C. § 1319(d).

95. Pursuant to Section 309(b) and (d) of the CWA, 33 U.S.C. § 1319(b) and (d), TAPI is liable for civil penalties, with respect to the violations alleged above.

RESOURCE CONSERVATION AND RECOVERY ACT

Statutory and Regulatory Background

96. RCRA establishes a comprehensive program to be administered by EPA for regulating the generation, transportation, treatment, storage, and disposal of hazardous waste. RCRA aims to reduce the generation of hazardous waste and ensure that hazardous waste

nevertheless generated is “treated, stored, or disposed of so as to minimize the present and future threat to human health and the environment.” 42 U.S.C § 6902.

97. Section 3002 of RCRA, 42 U.S.C. § 6922, and the regulations promulgated thereunder at 40 C.F.R. § 262, establish standards applicable to generators of hazardous waste.

98. Section 3005 of RCRA, 42 U.S.C. § 6925, prohibits the treatment, storage, or disposal of hazardous waste except in accordance with RCRA’s permitting regime set forth in 40 C.F.R. § 270.

99. Pursuant to 40 C.F.R. § 262.34(a), generators of hazardous waste may accumulate hazardous waste on-site in tanks and containers for up to 90 days without a permit provided they comply with all applicable conditions set forth in that provision, including: 1) maintaining containment areas free of cracks or gaps (under 40 C.F.R. § 265.193(e)(1), as referenced by 40 C.F.R. § 262.34(a)(1)(ii)); 2) providing a secondary containment area for each tank; 3) marking the date on which each period of accumulation begins on each container; and 4) labeling each tank and container with the words “Hazardous Waste.”

TAPI’s RCRA Permit

100. EPA issued a RCRA permit to TAPI in January 2008 that was effective for ten years (“RCRA Permit”). The RCRA Permit authorized TAPI to manage one hazardous waste container storage area and eight hazardous waste tank systems.

101. Pursuant to Condition V.F.3 of the RCRA Permit, at least once each operating day TAPI was required to inspect the specific components of its hazardous waste tank system, including: the construction materials and the area immediately surrounding the externally accessible portion of the tank system—including the secondary containment system—to detect

erosion or signs of releases of hazardous waste and, for the secondary containment coating, to look for wear, deterioration, and coverage.

102. Pursuant to Condition V.F.4 of the RCRA Permit, TAPI was required to document compliance with the aforementioned inspection requirements and place this documentation in the Facility's operating record.

103. Pursuant to Condition II.A of the RCRA Permit, TAPI was required to maintain and operate the facility to minimize the possibility of a fire, explosion or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

Enforcement Provisions

104. Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), authorizes the Administrator of EPA to commence a civil action against any person that has violated or is in violation of Subtitle C of RCRA in the United States district court in which the violation occurred for appropriate relief, including temporary or permanent injunction.

105. Section 3008(g) of RCRA, 42 U.S.C. § 6928(g), and 40 C.F.R. § 19.4, establish maximum civil penalties for violations of the hazardous waste regulations and hazardous waste permits issued under RCRA. The maximum civil penalty per day per violation is \$37,500 for the violations alleged below occurring after January 12, 2009 through November 2, 2015 and \$75,867 for the violations alleged below occurring after November 2, 2015.

First RCRA Claim for Relief – Failure to Obtain a RCRA Permit

106. Paragraphs 1 through 105 are incorporated herein by reference.

107. During the relevant period of time, TAPI was a "person" within the meaning of Section 1004(15) of RCRA, 42 U.S.C. § 6903(15).

108. During the relevant period of time, TAPI was a “generator” of hazardous waste within the meaning of 40 C.F.R. § 260.10.

109. The Facility, at all times relevant to this action, was used for treating, storing, or disposing of “hazardous waste” within the meaning of Section 1004(5) of RCRA, 42 U.S.C. § 6903(5), and 40 C.F.R. § 260.10.

110. At the time of EPA’s February 2013 inspection of the Facility, TAPI failed to maintain the secondary containment areas for hazardous waste tanks V-308, V-333, V-825, and V-826 (which were not covered by the RCRA Permit) free of cracks or gaps as required by 40 C.F.R. § 265.193(e)(1), as referenced by 40 C.F.R. § 262.34(a)(1)(ii). As a result, four of TAPI’s hazardous waste tanks failed to meet all the conditions set forth in 40 C.F.R. § 262.34 to qualify for the RCRA permitting 90-day exemption. Having failed to meet these conditions, TAPI was storing hazardous waste in tanks without a permit in violation of Section 3005 of RCRA, 42 U.S.C. § 6925, and 40 C.F.R. § 270.1(c).

111. TAPI’s treatment/disposal of listed hazardous waste at its aeration basin without a permit violated Section 3005 of RCRA, 42 U.S.C. § 6925. TAPI routed hazardous waste from the hazardous waste tanks systems to the scrubber (S-405), which discharged “blowdown” wastewaters to the Facility’s aeration basin through the wastewater treatment unit. Although the wastewater treatment unit itself was exempt from permitting, the aeration basin, which constituted a surface impoundment under 40 C.F.R. § 260.10, was not.

112. TAPI’s conduct described in Paragraphs 110 and 111 violated Section 3005 of RCRA, 42 U.S.C. § 6925, and 40 C.F.R. § 270.1(c), and each violation of these requirements subjects TAPI to liability.

113. Pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, TAPI is liable for civil penalties for each day of violation.

Second RCRA Claim for Relief – Violations of TAPI’s RCRA Permit

114. Paragraphs 1 through 113 are incorporated herein by reference.

115. During EPA’s February 2013 inspection of the Facility, TAPI provided EPA with the daily tank inspection records from November 1, 2012, through February 11, 2013.

116. TAPI’s daily tank inspection reports failed to provide adequate information concerning inspection of secondary containment, in violation of TAPI’s RCRA Permit Module V.F.4.

117. TAPI’s daily tank inspection records showed that TAPI did not record twenty-six daily inspections for certain of its RCRA-permitted hazardous waste tanks during the period of time from November 1, 2012 to February 11, 2013, in violation of TAPI’s RCRA Permit Module V.F.4.

118. Based on information obtained during EPA’s February 2013 inspection of the Facility, TAPI failed to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water, which could threaten human health or the environment. This violated TAPI’s RCRA Permit Condition II.A, including, but not limited to, the following deficiency: a hazardous waste accumulation tank (V-825) that TAPI personnel said had been out of service for at least one-and-a-half years was releasing residual spent solvent from its transfer piping onto the concrete pad.

119. TAPI violated Section 3005 of RCRA, 42 U.S.C. § 6925, and each violation of these requirements subjects TAPI to liability.

120. Pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928, TAPI is liable for civil penalties for each day of violation.

EMERGENCY PLANNING AND COMMUNITY RIGHT-TO-KNOW ACT

Statutory Background

121. Congress enacted the Emergency Planning and Community Right-to-Know Act (“EPCRA”) in 1986 to help local communities protect public health, safety, and the environment from chemical hazards. 42 U.S.C. §§ 11001-11050. The statute aims to provide the public with information regarding the presence of hazardous chemicals in their communities, and establish emergency planning and notification requirements to protect the public and emergency responders in the event of a release of hazardous chemicals.

Toxic Chemical Release Reporting Requirements

122. Section 313(a) of EPCRA, 42 U.S.C. § 11023(a), as implemented by 40 C.F.R. § 372.30, provides that an owner or operator of a facility that meets the statutory and regulatory criteria is required to submit annually to the Administrator of EPA and to the State (including the Commonwealth of Puerto Rico) in which the facility is located, no later than July 1st of each year, a toxic chemical release inventory reporting form (“Form R”) for each toxic chemical listed under 40 C.F.R. § 372.65 that was manufactured, processed, or otherwise used at the facility during the preceding calendar year in quantities exceeding the thresholds established under EPCRA Section 313(f) and 40 C.F.R. §§ 372.25 and 372.26.

123. Section 313(b) of EPCRA, 42 U.S.C. § 11023(b), and 40 C.F.R. § 372.22 provide that the requirements of Section 313(a) and 40 C.F.R. § 372.30 apply to an owner and operator of a facility that has 10 or more full-time employees; that is, *inter alia*, in Standard Industrial Classification major group codes 20 through 39; and that manufactures, processes, or otherwise

uses one or more toxic chemicals listed under Section 313(c) of EPCRA and 40 C.F.R. § 372.65 in quantities in excess of the applicable thresholds established under EPCRA Section 313(f) and 40 C.F.R. §§ 372.25 and 372.28.

124. Section 313(c) of EPCRA, 42 U.S.C. § 11023(c), establishes a list of toxic chemicals at 40 C.F.R. § 372.65 that are subject to toxic chemical release reporting requirements.

125. EPCRA Section 313(f), 42 U.S.C. § 11023(f), and 40 C.F.R. § 372.25 set threshold amounts of releases for the purposes of reporting toxic chemicals including, *inter alia*, 10,000 pounds of the chemical used for the applicable calendar year for a chemical that is “otherwise used” at a facility.

Enforcement Provisions

126. Section 325(c) of EPCRA, 42 U.S.C. § 11045(c), establishes civil, administrative, and criminal penalties for noncompliance with mandatory provisions of the act.

127. Section 325(c)(4) of EPCRA, 42 U.S.C. § 11045(c)(4), authorizes the Administrator of EPA to commence a civil action to assess and collect a civil penalty against any person that has violated or is in violation of EPCRA’s reporting requirements in the United States district court in which the person from whom the penalty is sought resides or in which such person’s principal place of business is located.

128. Section 325(c)(1) of EPCRA, 42 U.S.C. § 11045(c)(1), and 40 C.F.R. § 19.4, establish maximum civil penalties for violations of Section 313 of EPCRA, 42 U.S.C. § 11023. The maximum civil penalty per day per violation is \$37,500 for the violations alleged below.

EPCRA Claim for Relief – Violations of Toxic Chemical Release Reporting Requirements

129. Paragraphs 1 through 128 above are re-alleged and incorporated herein by reference.

130. During the relevant period of time, TAPI was a “person” within the meaning of Section 329(7) of EPCRA, 42 U.S.C. § 11049(7).

131. During the relevant period of time, TAPI was an owner and operator of a “facility” as that term is defined by Section 329(4) of EPCRA, 42 U.S.C. § 11049(4), and by 40 C.F.R. § 372.3.

132. During the years 2010 and 2011, the Facility had ten or more “full time employees” as that term is defined by 40 C.F.R. § 372.3.

133. The Facility had SIC Code 2834 (Pharmaceutical Preparations), which falls within a major group or industry listed in Section 313(b) of EPCRA and 40 C.F.R. § 372.22, and NAICS Code 325412 (Pharmaceutical Preparation Manufacturing), which is a primary NAICS subsector or industry code listed in 40 C.F.R. § 372.23(b).

134. During the relevant period of time, the Facility manufactured (including imported), processed, or otherwise used naphthalene, a chemical listed under 40 C.F.R. § 372.65, in excess of 10,000 pounds, its threshold as set forth in 40 C.F.R. § 372.30(a).

135. Because the Facility (a) had ten or more full time employees, (b) was in a covered SIC Code, and (c) manufactured, processed, or otherwise used naphthalene in excess of its regulatory threshold, TAPI was required to submit annually to the Administrator of EPA and to the Commonwealth of Puerto Rico, no later than July 1st of each year, a toxic chemical release inventory reporting form (“Form R”) for the chemical for the previous calendar year. Section 313(a) of EPCRA, 42 U.S.C. § 11023, and 40 C.F.R. § 372.30.

136. TAPI submitted the required TRI Form R report for naphthalene for calendar year 2010 on July 16, 2013, more than two years late; and for calendar year 2011 on July 16, 2013, more than one year late.

137. TAPI's failure to submit timely TRI Form R reports for naphthalene to EPA and the Commonwealth of Puerto Rico for calendar years 2010 and 2011 constitute failures to comply with Section 313 of EPCRA, 42 U.S.C. § 11023, and with 40 C.F.R. Part 372.

138. Pursuant to Section 325(c)(4) of EPCRA, 42 U.S.C. § 11045(c)(4), TAPI is liable for civil penalties for the violations alleged above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the United States of America, respectfully requests that this Court:

1. Order TAPI to pay civil penalties for each violation of the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act, and the Emergency Planning and Community Right-to-Know Act;
2. Award the United States its costs in this action; and
3. Grant the United States such other and further relief as the Court deems just and proper.

Respectfully submitted,

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/s/ Donald G. Frankel

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