

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

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UNITED STATES OF AMERICA,

Plaintiff,

v.

Civil No 3:20-cv-01178

TAPI PUERTO RICO, INC.,

Defendant.

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**STIPULATION OF SETTLEMENT AND ORDER**

WHEREAS, Plaintiff United States of America, on behalf of the United States Environmental Protection Agency (“EPA”), has filed a complaint in this action, concurrently with the lodging of this Stipulation of Settlement and Order (“Stipulation”), alleging that TAPI Puerto Rico, Inc. (“Defendant”) violated various provisions 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 its pharmaceutical manufacturing facility in Guayama, Puerto Rico (the “Facility”).

WHEREAS, the Complaint alleges, inter alia, that Defendant, at the Facility, failed to comply with the CAA’s provisions governing the emission of hazardous air pollutants (“HAPs”) from its pharmaceutical production process and hazardous waste equipment, in violation of Sections 112, 502 and 504 of the CAA, 42 U.S.C. §§ 7412, 7661a, and 7661c and EPA’s implementing regulations; discharged wastewater to the local publicly owned treatment works without abiding by its industrial discharge permit requirements, in violation of Section 307 of the

CWA, 33 U.S.C. § 1317, and EPA's implementing regulations; stored hazardous waste in tanks, containers and an aeration basin either without a RCRA permit or in violation of its permit, failed to comply with its RCRA permit record-keeping obligations, failed to meet the permit exemptions for its less than 90-day storage tanks, and failed to comply with its RCRA permit obligation to minimize risk of releases of hazardous waste, all in violation of Section 3005 of RCRA, 42 U.S.C. § 6925, and EPA's implementing regulations; and failed to timely submit a Toxic Release Inventory report form to EPA for calendar years 2010 and 2011, in violation of Section 313 of EPCRA, 42 U.S.C. § 11023, and EPA's implementing regulations.

WHEREAS, Defendant ceased active manufacturing operations at the Facility in or about April 2016 and has represented that it will not restart such operations in the future.

WHEREAS, Defendant does not admit any liability to the United States arising out of the actions, omissions or occurrences alleged in the Complaint.

WHEREAS, the Parties recognize, and the Court by entering this Stipulation finds, that this Stipulation has been negotiated by the Parties in good faith and will avoid litigation between the Parties and that this Stipulation is fair, reasonable, and in the public interest.

NOW, THEREFORE, before the taking of any testimony, without the adjudication or admission of any issue of fact or law except as provided in Section I, and with the consent of the Parties, IT IS HEREBY ADJUDGED, ORDERED, AND STIPULATED as follows:

#### I. JURISDICTION AND VENUE

1. This Court has jurisdiction over the subject matter of this action, pursuant to 28 U.S.C. §§ 1331, 1345, and 1355, 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), and Section 325(c)(4) of EPCRA, 42 U.S.C. § 11045(c)(4). Venue lies in

this judicial 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 the Facility is located in this judicial district and the violations alleged herein occurred within this judicial district.

2. For purposes of this Stipulation, or any action to enforce this Stipulation, Defendant consents to the Court's jurisdiction over this Stipulation, and any such action, and over Defendant, and consents to venue in this judicial district.

3. For purposes of this Stipulation, Defendant agrees that the Complaint states claims upon which relief may be granted 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), and Section 325(c)(4) of EPCRA, 42 U.S.C. § 11045(c)(4).

## II. APPLICABILITY

4. The obligations of this Stipulation apply to and are binding upon the United States and upon Defendant and any successors, assigns, or other entities or persons otherwise bound by law.

## III. DEFINITIONS

5. Whenever the terms set forth below are used in this Stipulation, the following definitions shall apply:

“Complaint” shall mean the complaint filed by the United States in this action;

“Day” shall mean a calendar day unless expressly stated to be a business day. In computing any period of time under this Stipulation, where the last day would fall on a Saturday, Sunday, or federal holiday, the period shall run until the close of business of the next business day;

“Defendant” shall mean TAPI Puerto Rico, Inc.;

“EPA” shall mean the United States Environmental Protection Agency and any of its successor departments or agencies;

“Effective Date” shall have the definition provided in Section VIII.

“Facility” shall mean Defendant’s pharmaceutical manufacturing facility located in Guayama, Puerto Rico, which ceased active manufacturing operations in or about April 2016;

“Paragraph” shall mean a portion of this Stipulation identified by an arabic numeral;

“Parties” shall mean the United States and Defendant;

“Section” shall mean a portion of this Stipulation identified by a roman numeral;

“Stipulation” shall mean this Stipulation of Settlement and Order; and

“United States” shall mean the United States of America, acting on behalf of EPA.

#### IV. CIVIL PENALTY

6. Within 60 Days after the Effective Date, Defendant shall pay the sum of \$539,784 as a civil penalty, together with interest accruing from the date on which the Stipulation is lodged with the Court, at the rate specified in 28 U.S.C. § 1961 as of the date of lodging.

7. Defendant shall pay the civil penalty due by FedWire Electronic Funds Transfer ("EFT") to the U.S. Department of Justice account, in accordance with instructions provided to Defendant by the Financial Litigation Unit (“FLU”) of the United States Attorney’s Office for the District of Puerto Rico after the Effective Date. The payment instructions provided by the FLU will include a Consolidated Debt Collection System (“CDCS”) number, which Defendant shall use to identify all payments required to be made in accordance with this Stipulation. The FLU will provide the payment instructions to:

Helen E. Tamarin  
Senior Manager Business Finance  
400 Interpace Parkway, Building A  
Parsippany, NJ 07054  
Telephone: 973-265-3529  
helen.tamarin@tevapharm.com

-and-

Gail S. Port  
Proskauer Rose LLP  
Eleven Times Square  
New York, NY 10036-8299  
Telephone: 212-969-3243  
gport@proskauer.com

on behalf of Defendant. At the time of payment, Defendant shall send notice that payment has been made: (i) to EPA via email at cinwd\_acctsreceivable@epa.gov and via regular mail at EPA Cincinnati Finance Office, 26 W. Martin Luther King Drive, Cincinnati, Ohio 45268; and (ii) to the United States and EPA via the email and regular mail addresses set forth in Section VII. Such notice shall state that the payment is for the civil penalty owed pursuant to the Stipulation in United States v. TAPI Puerto Rico, Inc. (D.P.R.) and shall reference the civil action number, CDCS Number and DJ No. 90-5-2-1-11448.

8. Defendant shall not deduct any civil or stipulated penalties paid under this Stipulation in calculating its federal income tax.

9. If Defendant fails to pay the civil penalty required to be paid under Paragraph 6 when due, Defendant shall pay a stipulated penalty of \$1,000 per Day for each Day that the payment is late. Defendant shall pay such stipulated penalty within 30 Days of receiving the United States' written demand. Defendant shall pay such stipulated penalty in the manner set forth and with the confirmation notices required by Paragraph 7, except that the transmittal letter shall state that the payment is for stipulated penalties. If Defendant fails to pay stipulated penalties according to the

terms of this Stipulation, Defendant shall be liable for interest on such stipulated penalties, as provided for in 28 U.S.C. § 1961, accruing as of the date payment became due. Interest under 28 U.S.C. § 1961 shall accrue on any unpaid civil penalty or stipulated penalty that is due to be paid until such payment is made. Nothing in this Paragraph shall be construed to limit the United States from seeking any remedy otherwise provided by law for Defendant's failure to pay the civil penalty or any stipulated penalty due hereunder.

V. EFFECT OF SETTLEMENT/RESERVATION OF RIGHTS

10. This Stipulation resolves the civil claims of the United States for the violations alleged in the Complaint filed in this action through the date of lodging of this Stipulation.

11. In any subsequent administrative or judicial proceeding initiated by the United States for injunctive relief, civil penalties, and/or other appropriate relief relating to the Facility, Defendant shall not assert, and may not maintain, any defense or claim based upon the principles of waiver, res judicata, collateral estoppel, issue preclusion, claim preclusion, claim-splitting, or other defenses based upon any contention that the claims raised by the United States in the subsequent proceeding were or should have been brought in the instant case, except with respect to claims that have been specifically resolved pursuant to Paragraph 10.

12. Defendant is responsible for achieving and maintaining complete compliance with all applicable federal, State, and local laws, regulations, and permits. Defendant's compliance with this Stipulation shall be no defense to any action commenced pursuant to any such laws, regulations, or permits, except as set forth herein.

13. This Stipulation does not limit or affect the rights of Defendant or of the United States against any third parties, not party to this Stipulation, nor does it limit the rights of third parties, not party to this Stipulation, against Defendant, except as otherwise provided by law.

14. This Stipulation shall not be construed to create rights in, or grant any cause of action to, any third party not party to this Stipulation.

VI. COSTS

15. The Parties shall bear their own costs of this action, including attorneys' fees, except that the United States shall be entitled to collect the costs (including attorneys' fees) incurred in any action necessary to collect any portion of the civil penalty or any stipulated penalties due hereunder but not timely paid by Defendant.

VII. NOTICES

16. Unless otherwise specified in this Stipulation, whenever notifications, submissions, or communications are required by this Stipulation, they shall be made in writing and addressed as follows:

As to the United States by email: eescdcopy.enrd@usdoj.gov  
Re: DJ # 90-5-2-1-11448

As to the United States by mail: EES Case Management Unit  
Environment and Natural Resources Division  
U.S. Department of Justice  
P.O. Box 7611  
Washington, D.C. 20044-7611  
Re: DJ # 90-5-2-1-11448  
-and-

Donald G. Frankel  
Senior Counsel  
Environmental Enforcement Section  
United States Department of Justice  
408 Atlantic Avenue  
Suite 236  
Boston, MA 02110

As to EPA by mail: Nancy Rodriguez, Chief  
Multimedia Permits and Compliance Branch  
Caribbean Environmental Protection Division  
U.S. Environmental Protection Agency  
City View Plaza II Building, 7th Floor,  
48 Road 165  
Guaynabo, PR 00968

As to EPA by email: rodriguez.nancy@epa.gov

As to Defendant by mail: Kirsten Bauer, Esq.  
Senior Vice President & General Counsel, NA and  
TGO  
400 Interpace Parkway  
Parsippany, NJ 07054  
-and-  
Gail S. Port  
Proskauer Rose LLP  
Eleven Times Square  
New York, NY 10036-8299

As to Defendant by email: kirsten.bauer@tevapharm.com  
-and-  
gport@proskauer.com

17. Any Party may, by written notice to the other Parties, change its designated notice recipient or notice address or email address provided above.

#### VIII. EFFECTIVE DATE

18. The Effective Date of this Stipulation shall be the date upon which this Stipulation is entered by the Court or a motion to enter the Stipulation is granted, whichever occurs first, as recorded on the Court's docket.

#### IX. PUBLIC PARTICIPATION

19. This Stipulation shall be lodged with the Court for a period of not less than 30 Days for public notice and comment. The United States reserves the right to withdraw or withhold its

consent if the comments regarding the Stipulation disclose facts or considerations indicating that the Stipulation is inappropriate, improper, or inadequate. Defendant consents to entry of this Stipulation without further notice and agrees not to withdraw from or oppose entry of this Stipulation by the Court or to challenge any provision of the Stipulation, unless the United States has notified Defendant in writing that it no longer supports entry of the Stipulation.

20. If for any reason the Court should decline to approve this Stipulation in the form presented, this agreement is voidable at the sole discretion of either Party and the terms of the agreement may not be used as evidence in any litigation between the Parties.

#### X. MODIFICATION

21. The terms of this Stipulation may be modified only by a subsequent written agreement signed by both Parties. Where the modification constitutes a material change to this Stipulation, it shall not be effective without approval of the Court.

#### XI. SIGNATORIES/SERVICE

22. Each undersigned representative of Defendant and the Deputy Section Chief of the Environmental Enforcement Section of the Environment and Natural Resources Division of the United States Department of Justice certifies that he or she is fully authorized to enter into the terms and conditions of this Stipulation and to execute and legally bind the Party he or she represents to this document.

23. This Stipulation may be signed in counterparts, and its validity shall not be challenged on that basis. Defendant agrees to accept service of process by mail with respect to all matters arising under or relating to this Stipulation and to waive the formal service requirements set forth in Rules 4 and 5 of the Federal Rules of Civil Procedure and any applicable Local Rules of this Court including, but not limited to, service of a summons.

Defendant need not file an answer to the Complaint in this action unless or until the Court expressly declines to approve or enter this Stipulation.

## XII. INTEGRATION

24. This Stipulation constitutes the final, complete, and exclusive agreement and understanding among the Parties with respect to the settlement embodied in the Stipulation and supersedes all prior agreements and understandings, whether oral or written, concerning the settlement embodied herein. The Parties acknowledge that there are no representations, agreements, or understandings relating to the settlement other than those expressly contained in this Stipulation.

## XIII. FINAL JUDGMENT

25. This Stipulation shall be considered an enforceable judgment for purposes of post-judgment collection of any past due but unpaid amounts in accordance with Rule 69 of the Federal Rules of Civil Procedure, the Federal Debt Collection Procedure Act, 28 U.S.C. §§ 3001–3308, and other applicable federal authority.

26. Upon approval and entry of this Stipulation by the Court, this Stipulation shall constitute a final judgment of the Court as to the United States and Defendant.

Dated and entered this \_\_\_ day of \_\_\_\_\_, 2020

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UNITED STATES DISTRICT JUDGE

**FOR THE UNITED STATES OF AMERICA**

Dated: 3/24/20

/s/ Ellen M. Mahan  
ELLEN M. MAHAN  
Deputy Section Chief  
Environmental Enforcement Section  
Environment & Natural Resources Division  
United States Department of Justice

Dated: 4/8/20

/s/ Donald G. Frankel  
DONALD G. FRANKEL  
Senior Counsel  
Environmental Enforcement Section  
Environment & Natural Resources Division  
United States Department of Justice  
408 Atlantic Avenue  
Suite 236  
Boston, MA 02110  
617-748-3512

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District of Puerto Rico

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Chief, Civil Division  
U.S. Attorney's Office  
District of Puerto Rico  
Torre Chardon Suite 1201  
350 Carlos Chardon Avenue  
San Juan, PR 00918  
787-766-5656

**FOR THE U.S. ENVIRONMENTAL PROTECTION AGENCY**

Dated: 4/3/20

*/s/ Eric Schaaf*  
ERIC SCHAAF  
Regional Counsel  
EPA Region II  
290 Broadway  
New York, NY 10007

**FOR DEFENDANT TAPI PUERTO RICO, INC.**

Dated: March 9, 2020

  
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Kirsten E. Bauer  
SVP & FC, NA-T&O