

3:16 cr 225 (AWT)

UNITED STATES OF AMERICA v. SHEFFIELD PHARMACEUTICALS, LLC
CASE NO. 16CR225(AWT)
United States District Court
District of Connecticut
FILED AT HARTFORD

DEFERRED PROSECUTION AGREEMENT

12/13/2016
 Roberta D. Tabora, Clerk

1. Sheffield Pharmaceuticals, LLC, known until 2014 as Faria Limited, LLC ("Company"), by its undersigned attorney and pursuant to authority granted by its Board of Directors, and the United States Attorney's Office for the District of Connecticut (the "Office"), enter into this Deferred Prosecution Agreement (the "Agreement"). Except as specifically provided below, the Agreement shall be in effect for a period of seven (7) years from the date that it is fully executed by both parties.
2. Sheffield is a manufacturer of over-the-counter pharmaceutical creams, ointments, and health-and-beauty products, and operates a factory at 170 Broad Street in New London, Connecticut. Sheffield and its predecessors have operated this factory continuously since 1850. From at least April 2004 through May 2011, Sheffield discharged untreated industrial wastewater to the New London publicly owned treatment works ("POTW") without the required environmental permit, and without a wastewater pretreatment system, as required by federal and state law.
3. On July 8, 2014, Thomas H. Faria, Sheffield's former chief executive officer and president, pleaded guilty to knowingly violating the requirements imposed in a pretreatment program approved under the Clean Water Act, 33 U.S.C. § 1319(c)(2)(A). In pleading guilty, Mr. Faria acknowledged that, under his leadership from at least April 2004 to May 2011, (a) Sheffield operated without a Connecticut Department of Energy and Environmental Protection ("CT DEEP") permit and a wastewater treatment system in violation of Connecticut's pretreatment program as approved by the U.S. Environmental Protection Agency ("EPA"); and (b) that Mr. Faria, as Sheffield's chief executive officer and president, knowingly committed these violations of the Clean Water Act.
4. Per the terms of his plea agreement in *United States v. Thomas H. Faria*, Case No. 3:14CR149(AWT), Mr. Faria resigned from his position as president and chief executive officer of Sheffield, and relinquished his seat on the board of directors on March 7, 2014. On May 13, 2014, by written amendment to Sheffield's Operating Agreement, his 38% equity interest in Sheffield was converted to non-voting shares.
5. The Office has informed Sheffield that it will file, either on or shortly after the date this Agreement is fully executed, an Information in the United States District Court for the District of Connecticut charging Sheffield with knowingly violating the requirements imposed in a pretreatment program approved under the Clean Water Act, 33 U.S.C. § 1319(c)(2)(A). Sheffield and the Office agree that upon filing of the Information, this Agreement shall be publicly filed in the United States District Court for the District of Connecticut.
6. In light of Sheffield's efforts to date, as discussed below, and its willingness (a) to acknowledge responsibility for knowingly violating the requirements imposed in a pretreatment program approved under the Clean Water Act, 33 U.S.C. § 1319(c)(2)(A), from

April 2004 to May 2011; (b) to continue its cooperation with the Office and other governmental regulatory agencies, specifically the EPA and CT DEEP; (c) to conduct business operations in compliance with all applicable environmental laws; and (d) to consent to the payment of \$1 million as set forth in Appendix A, the Office shall recommend to the Court that the prosecution of Sheffield pursuant to the filed Information be deferred for a period of seven (7) years from the filing date of the Information. However, if the Court declines to defer prosecution for any reason, this Agreement shall be null and void, the Office will withdraw the Information, and the parties will revert to their pre-Agreement positions.

7. Sheffield has undertaken significant reforms to ensure its compliance with environmental laws and regulations since its Clean Water Act violations were detected on April 20, 2011. On or about May 27, 2011, Sheffield submitted a draft permit application to CT DEEP. In July 2011, Sheffield installed a wastewater pretreatment system at its factory to pretreat its industrial wastewater prior to its discharge to the New London POTW. On September 13, 2013, the CT DEEP approved Sheffield's pretreatment permit to discharge industrial wastewater to the New London POTW.
8. Sheffield has cooperated with this Office and the EPA in its investigation of the company and Mr. Faria, including the voluntary production of internal company documents.
9. As part of this Agreement, Sheffield admits, accepts, and acknowledges responsibility for the facts set forth in the Statement of Facts attached as Appendix B ("Statement of Facts") and fully incorporated by reference in this Agreement.
10. Sheffield agrees that in the event that future criminal proceedings are brought by the Office in accordance with this Agreement, Sheffield will not contest the admissibility of the Statement of Facts in any such proceedings. Nothing in this Agreement shall be construed as an acknowledgment by Sheffield that the Agreement, including the Statement of Facts, is admissible or may be used in any proceeding other than in a proceeding brought by the Office.
11. Sheffield expressly agrees that it shall not, through its present or future attorneys, Board of Directors, agents, officers or employees, make any public statement contradicting any statement contained in the Statement of Facts or its acknowledgement herein that failing to comply with the Clean Water Act is a serious matter. Any such contradictory public statement by Sheffield, its present or future attorneys, Board of Directors, agents, officers or employees, shall constitute a breach of this Agreement and Sheffield would thereafter be subject to prosecution pursuant to the terms of this Agreement. In the event that the Office determines such breach has occurred, the Office shall notify Sheffield in writing of the public statement made by any such person that in whole or in part contradicts a statement contained in the Statement of Facts. Once notified, Sheffield may avoid breach of this Agreement by publicly repudiating such statement within twenty-four (24) hours after such notification by the Office. This paragraph is not intended to apply to any statement by any former Sheffield employee, officer or director, or any Sheffield employee, officer or director testifying in any proceeding in an individual capacity and not on behalf of Sheffield.

12. Sheffield agrees that its continuing cooperation during the term of this Agreement shall include, but not be not limited to, the following:
 - a. Sheffield shall not engage in, or attempt to engage in, any criminal conduct in the District of Connecticut;
 - b. Sheffield shall conduct business operations in compliance with all federal, state, and local environmental laws and cooperate fully with all environmental regulatory agencies, including the EPA and CT DEEP; and
 - c. If requested by the Office during this Agreement's term, Sheffield shall meet with the Office within ten business days after the Office has provided written notice, to address any deficiencies or non-compliance of this Agreement.
13. Should the Office determine that during the term of this Agreement, Sheffield knowingly and materially breached this Agreement, Sheffield shall, in the discretion of the Office, be subject to prosecution for any federal crimes of which the Office has knowledge, including any crimes relating to the matters set forth in the Statement of Facts. Sheffield agrees that a material breach will include a failure to abide by the terms stated above in subparagraphs 12(a) and 12(b) of this Agreement.
14. Sheffield shall expressly waive all rights to a speedy trial pursuant to the Sixth Amendment of the United States Constitution, Title 18, United States Code, Section 3161, Federal Rule of Criminal Procedure 48(b), and any applicable Local Rules of the United States District Court for the District of Connecticut, for the period that this Agreement is in effect.
15. Sheffield agrees to waive the statute of limitations with respect to any crimes relating to the violations set forth in the Information that would otherwise expire during the term of this Agreement. This waiver is knowing and voluntary, and in express reliance on the advice of Sheffield's counsel.
16. This Agreement expires seven (7) years after the date of its execution by all parties, or on the date that the last payment referred to in Appendix A is fully made, whichever is earlier, provided that Sheffield has complied with all terms of this Agreement, including all payment terms stated in Appendix A. The Office agrees that if Sheffield is in full compliance with all of its obligations under this Agreement, including its payment obligations outlined in Appendix A, the Office will seek to dismiss with prejudice the Information referenced in paragraph 5, within ten days of the expiration of the Agreement.
17. Sheffield agrees that if it sells or merges all or substantially all of its business operations as they exist as of the date of this Agreement, to or into a single purchaser or group of affiliated purchasers during the term of this Agreement, Sheffield shall include in any contract for sale or merger a provision binding the purchaser/successor to the obligations described in this Agreement. In such case, with the Office's written approval, Sheffield may be released from any future obligations pursuant to this Agreement.

18. The CT DEEP has also, or will shortly hereafter, file a complaint ("Complaint") against Sheffield in Superior Court for the State of Connecticut ("Superior Court"), Judicial District of Hartford, alleging that Sheffield is responsible for violating §§ 22a-430 and 22a-430b of the Connecticut General Statutes, as well as Paragraphs 5(b)(1)(A) and 5(c)(1)(A) of the CT DEEP's Industrial Stormwater General Permit. In the Complaint, the CT DEEP seeks a civil penalty and injunctive relief in the form of a prohibitory injunction, in connection with Sheffield's environmental violations, pursuant to §§ 22a-430 and 22a-438 of the Connecticut General Statutes. In accordance with the terms of this Agreement, Sheffield also agrees to enter into a Stipulation for Judgment to resolve the Complaint in Superior Court.
19. This Agreement constitutes the full and complete agreement between Sheffield and the Office and supersedes any previous agreement between them. No additional promises, agreements, or conditions have been entered into other than those set forth in this Agreement, and none will be entered into unless in writing and signed by the Office, Sheffield's counsel, and a duly authorized representative of Sheffield. It is understood that the Office may permit exceptions to or excuse particular requirements set forth in this Agreement at the written request of Sheffield, but any such permission shall be in writing.

AGREED TO:

FOR THE UNITED STATES:

DEIRDRE M. DALY
UNITED STATES ATTORNEY
DISTRICT OF CONNECTICUT



HAROLD H. CHEN
Assistant U.S. Attorney

Date

12/13/16

FOR SHEFFIELD PHARMACEUTICALS, LLC:



JEFFREY DAVIS
Chief Executive Officer
Sheffield Pharmaceuticals, LLC

Date

12/13/16



DOUGLAS A. COHEN, ESQ.
Attorney for Sheffield Pharmaceuticals, LLC

Date

12/13/16

APPENDIX A – TERMS OF SHEFFIELD’S \$1 MILLION PAYMENT

Pursuant to this Agreement, Sheffield shall make a total payment of \$1 million as specified below. No part of the \$1 million payment shall be considered tax deductible by Sheffield.

The first payment of \$50,000 shall be made in 2017 no later than one year after the month and day on which this Agreement is fully executed. The second payment of \$100,000 shall be made in 2018 no later than two years after the month and day on which this Agreement is fully executed. These first two payments (totaling \$150,000) shall be made payable to the Clerk of Court of the United States District Court for the District of Connecticut, and should reference the case number assigned to this matter.

The five remaining annual payments for 2019, 2020, 2021, 2022, and 2023 shall be made payable to the appropriate third-party, grant-making entity, as directed by the United States Attorney’s Office for the District of Connecticut, to fund beneficial environmental projects in coastal Connecticut. At least 30 days before such payment is due, the United States Attorney’s Office for the District of Connecticut will identify the third-party, grant-making entity to which Sheffield shall make payment, with the exception of the 2020 payment.¹ Such third-party, grant-making entities must be financially trustworthy and have indicia of responsible financial management, including clear legal authority to receive such monies; internal accounting and self-auditing procedures; experience in handling the amount of money to be received; formal procedures for auditing selected projects; and separation of community service funds from operating expenses. In addition, such entities must have procedures that will guarantee a fair and inclusive project selection process, and have appropriate safeguards to ensure that community service funds will not be used for improper purposes. Finally, the third-party, grant-making entities shall make periodic reports to the parties and the Court.

In considering which third-party, grant-making entities shall receive the five annual payments for 2019, 2020, 2021, 2022, and 2023, the United States Attorney shall consult with the Connecticut Office of the Attorney General and the Connecticut Department of Energy and Environmental Protection (“CT DEEP”). As noted in the chart below, Sheffield shall make the annual payments for 2019, 2020, 2021, 2022, and 2023 no later than the day before the month and day on which this Agreement is fully executed.

PAYMENT YEAR	AMOUNT
2017	\$50,000
2018	\$100,000
2019	\$150,000

¹ The 2020 payment shall be made payable to the CT DEEP’s Supplemental Environmental Project (“SEP”) Account, in accordance with the terms of the Stipulation for Judgment to be filed with the Superior Court for the State of Connecticut. If the Superior Court for the State of Connecticut fails to enter the fully signed Stipulation for Judgment as a final judgment in resolution of the CT DEEP’s Complaint, the United States Attorney’s Office for the District of Connecticut will identify the entity to which Sheffield shall make payment for the 2020 installment.

2020	\$150,000
2021	\$150,000
2022	\$200,000
2023	\$200,000

Per paragraphs 6 and 13 of this Agreement, the failure to make any of the seven annual payments between 2017 and 2023 pursuant to the above terms shall constitute a material breach of this Agreement. Such breach shall subject Sheffield to prosecution for any federal offenses of which the United States Attorney's Office for the District of Connecticut has knowledge, including any criminal matters set forth in the Statement of Facts. Per paragraph 16, Sheffield may elect to make any or all of these payments prior to their due date.

APPENDIX B – STATEMENT OF FACTS

Sheffield Pharmaceuticals, LLC, formerly known as Faria Limited, LLC (“Sheffield” or the “company”), is a limited liability company operating a factory at 170 Broad Street in New London, Connecticut, that manufactures a wide range of over-the-counter pharmaceutical creams, ointments, and health-and-beauty products.

The Clean Water Act (“CWA”) at Title 33, United States Code, Section 1251 *et seq.*, prohibits the discharge of pollutants to waters of the United States, except in a manner consistent with the National Pollutant Discharge Elimination System (“NPDES”) permitting program set forth in Section 1342 of the CWA. Under the NPDES permitting program, all publicly owned sewage-treatment systems, commonly known as publicly owned treatment works (“POTWs”), that discharge to waters of the United States must obtain and comply with discharge permits. Such discharge permits often require the development and implementation of a POTW pretreatment program to treat industrial waste at the factory before the industrial waste reaches the POTW. Among other things, the purpose of such pretreatment programs is to prevent introducing pollutants into a POTW that may pass through the POTW, may interfere with the POTW’s operation, or may otherwise be incompatible with the POTW.

The CWA authorizes the U.S. Environmental Protection Agency (“EPA”) to approve states to administer the NPDES permit program. To receive EPA approval, the state must develop a state pretreatment program that, among other things, incorporates POTW pretreatment program conditions into permits issued to POTWs; requires compliance by POTWs with these incorporated permit conditions; and requires compliance by industrial users with pretreatment standards. A state with an approved state pretreatment program may assume responsibility for implementing the POTW pretreatment program in lieu of requiring the POTW to develop a pretreatment program.

In 1979, the State of Connecticut (“Connecticut”) made a formal request to the EPA that Connecticut be approved to administer the NPDES program and to assume responsibility for implementing the POTW pretreatment program in lieu of requiring the POTW to develop a pretreatment program. In its application for pretreatment program approval dated March 27, 1979, the Connecticut Department of Environmental Protection (“CT DEP”) stated, “The Department is committed to achievement of its own and the national goals of fishable swimmable waters and elimination of the discharge of pollutants. The treatment of industrial wastes prior to discharge to POTWs is a necessary and significant program element in achievement of those goals.” In 1981, the EPA approved Connecticut’s pretreatment program, including the request to operate a state-wide pretreatment program. The CT DEP merged with the Connecticut Department of Public Utility Control in July 2011 to form the Connecticut Department of Energy and Environmental Protection (“CT DEEP”). The CT DEP and its successor entity will be referred to herein collectively as CT DEEP.

Connecticut’s pretreatment program prohibits the discharge of industrial wastewater to POTWs without a CT DEEP permit. The failure to obtain a CT DEEP permit prior to discharging industrial wastewater to a POTW constitutes a violation of a requirement of a pretreatment program approved under Title 33, United States Code, Section 1342(b)(8).

The CT DEEP tailors wastewater permits for industrial users based on, among other things, the type and quantity of industrial wastewater being discharged by the facility. When applying for a wastewater permit from CT DEEP, an industrial facility must characterize and quantify the pollutants contained in its wastewater based on actual wastewater samples. A CT DEEP permit allows an industrial facility to discharge pollutants to the POTW only within the specific conditions and numeric limitations for pollutants mandated by the permit. Furthermore, CT DEEP permits impose on the industrial facility the obligation to sample and analyze its wastewater regularly, and to report the results to the CT DEEP each month in a Discharge Monitoring Report (“DMR”). The CT DEEP relies upon the sampling data provided in these monthly DMRs to determine whether the industrial facility is complying with the discharge permit’s parameters.

The City of New London Water Pollution Control Facility, together with its public sewer system, constitutes a POTW (“New London POTW”) within the meaning of the CWA and Connecticut’s pretreatment program, and as approved by the EPA. The New London POTW discharges to the Thames River in southeastern Connecticut.

From in or about 1986 to July 2011, Sheffield discharged untreated industrial wastewater from its New London manufacturing operations to the New London POTW without a permit and in violation of Connecticut’s pretreatment program as approved by the EPA. During this entire time period, Sheffield lacked a pretreatment system at its factory to treat its industrial wastewater prior to discharge to the New London POTW, performed no regular monitoring of its discharges of industrial wastewater, and submitted no monthly DMRs to the CT DEEP.

In or about April 2003, Thomas H. Faria became the president and chief executive officer of Sheffield, and assumed day-to-day management and control over the company. In or about April 2003, Mr. Faria learned from Sheffield employees that the company was discharging pollutants in its industrial wastewater, including compounds such as zinc oxide, without the required permit. Mr. Faria also learned that in order to obtain a permit from CT DEEP, Sheffield would have to install a wastewater pretreatment system that would pretreat its industrial wastewater prior to discharging it to the New London POTW.

On May 27, 2003, a manager on the Sheffield production floor, who is now the company’s current chief executive officer, sent the following e-mail message, which was copied to Mr. Faria and states in pertinent part: “I strongly suggest we engage an environmental consultant to study this issue. There are several firms that specialize in just this type of permitting. In my experience I have never heard of an industry not needing a discharge permit to discharge into the sanitary sewer. This could potentially be very damaging to the company if it is discovered we are discharging to the sewer without the proper permits and monitoring.”

On April 5, 2005, the same manager sent directly to Mr. Faria the following e-mail message and attached a proposal prepared by an environmental consultant to bring Sheffield into compliance with the CWA and the CT DEEP:

“You need to understand a couple of things.

- 1) We are out of compliance with the Clean Water Act. We may continue on for years this way, however once it is recognized we are discharging to the

New London POTW and not meeting the pretreatment standards it will mean an immediate shutdown of discharge due to the type of industry we are. Shutdown of our discharge will mean shutting down the factory unless we contract to have our discharge taken away to a disposal facility. This might never happen, or it could happen tomorrow. All it takes is one serious problem at the New London POTW after which the state starts taking a look upstream.

- 2) Criminal penalties could also be levied, and as officers of the company this burden will fall upon you. In my opinion this is probably a slim possibility, but the option exists to the state. But, remember that article I showed you in which [Company X] in Stafford Springs exceeded pretreatment standards when discharging to the local POTW. Multi million dollar fines and criminal prosecution did happen.

I can't stress strongly enough that this should become the top priority in the project list. We need to take immediate action to get this treatment system set up and our permitting completed. To follow the letter of the law we should immediately discontinue all discharge to the New London POTW until this permitting is in place."

Under Mr. Faria's leadership and with his knowledge, Sheffield hired between 2004 and 2007 at least four environmental consulting firms to advise the company regarding its discharge of industrial wastewater to the New London POTW. The consultants of these firms informed Sheffield that its discharge of industrial wastewater to the public sewage treatment system, without a pretreatment system or CT DEEP permit, was illegal. Despite having knowledge of its legal obligations, Sheffield violated the CWA from at least April 2004 to May 2011.

On April 20, 2011, the CT DEEP conducted an unannounced inspection of Sheffield's facility. After finding that the company had no wastewater discharge permits but was discharging industrial wastewater to the New London POTW, the CT DEEP inspector issued a Notice of Violation and cited Sheffield for discharging manufacturing and laboratory wastewater without a permit.

On or about May 27, 2011, Sheffield submitted a permit application to CT DEEP, so that Sheffield could discharge industrial wastewater from its New London facility into the New London POTW in a lawful fashion. In July 2011, Sheffield installed a wastewater pretreatment system at its factory to pretreat the pollutants contained in its industrial wastewater prior to its discharge to the New London POTW.

On July 8, 2014, Mr. Faria, as president and chief executive officer of Sheffield, admitted to knowingly violating and causing to be violated a requirement imposed in a pretreatment program approved under section 1342(a)(3) and 1342(b)(8) of Title 33, United States Code—that is, the discharge of industrial wastewater into the New London publicly owned treatment works without a permit—in violation of Title 33, United States Code, Section 1319(c)(2)(A), from April 2004 to May 2011.