

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Crim. No. 17-82 (RHK)

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	PLEA AGREEMENT AND
)	SENTENCING STIPULATIONS
CHRISTOPHER BARRY,)	
)	
Defendant.)	

The United States of America and Christopher Barry (hereinafter referred to as the “defendant”) agree to resolve this case on the terms and conditions that follow. This plea agreement binds only the defendant and the United States Attorney’s Office for the District of Minnesota. This agreement does not bind any other United States Attorney’s Office or any other federal or state agency.

1. **Charges.** The defendant agrees to plead guilty to Count One of the Criminal Information, charging him with Theft of Trade Secrets in violation of 18 U.S.C. § 1832.

2. **Factual Basis.** The Defendant admits the following facts and, where the defendant lacks direct knowledge, the defendant acknowledges that the government has sufficient evidence to prove beyond a reasonable doubt the following facts, all of which constitute the factual basis for this plea:

Beginning in about 2007 and continuing until on or about May 1, 2015, defendant Christopher BARRY was employed at Lutonix, Inc. (“Lutonix”). Lutonix is a wholly-

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owned subsidiary of C.R. Bard Inc. that develops, manufactures, and sells drug coated balloon (“DCB”) medical products. Lutonix was founded in 2007, and was purchased by C.R. Bard in December 2011. Lutonix is based in New Hope, Minnesota, and also has a manufacturing facility located in Glens Falls, New York.

Lutonix’s Trade Secrets

Lutonix’s primary product is a proprietary DCB called the Lutonix 035 DCB, an angioplasty balloon catheter, whose balloon component is coated with the drug paclitaxel (among other ingredients). The catheter is inserted into a patient in order to help keep arteries open and restore blood flow in the event of a blockage. The Lutonix 035 DCB was the first DCB approved by the U.S. Food and Drug Administration (“FDA”), and obtained such approval in October 2014.

The Lutonix 035 DCB technology is extremely valuable. Most of Lutonix’s sales in 2015, which totaled more than \$50 million, were derived from the 035 DCB. Furthermore, the Lutonix 035 DCB is a “platform technology,” one that can be adapted for numerous other medical applications, further enhancing its value to the company. Lutonix spent approximately seven years bringing this product to market, a process that involved a lengthy research and development phase, multiple clinical studies, extensive testing, and significant time refining a manufacturing and quality assurance process.

There are multiple aspects of the process used by Lutonix to create the 035 DCB that are proprietary to Lutonix and not generally known to the public, including but not limited to: (1) the formula of how the components are combined, including the ratio of

both active ingredients and excipients, which give the 035 DCB its unique properties; (2) the manufacturing process, which involves a series of proprietary steps through which the 035 DCB derives its unique properties; and (3) the testing methodology used by Lutonix to identify defects and remediate any issues, as well as the results of that testing methodology.

The following files (among others) stored on Lutonix's computer systems contained proprietary information related to Lutonix 035 DCB and constitute trade secrets within the meaning of 18 U.S.C. § 1832:

a. *File 1 – Design Input Requirements.* A blueprint-type document for Lutonix's design of a new version of the 035 drug-coated balloon which outlines various design requirements such as what sizes of the balloon might be manufactured; how much drug should coat each balloon; descriptions of claims that Lutonix hopes to make about the product and its uses; and test methods.

b. *File 2 – Design Input Summary.* A document discussing all of the design inputs outlined in File 1 but in greater, and more technical, detail. This document serves as a blueprint of product specifications while also providing details about what the customer wants to see in the product and why.

c. *File 3 – Coating Solution Preparation.* Work instructions for operators that show the manufacturing steps for how to prepare the proprietary coating solution, including mixing details such as the order that ingredients are added, for the 035 DCB.

d. **File 4 – Coating Solution Formula.** The formula Lutonix uses to create its proprietary coating solution, including the weights of each ingredient for the volume of solution being created, which along with File 3 provides a complete set of instructions for preparing the drug coating solution for the 035 DCB.

e. **File 5 – Evaluation of the Dissolution Methods.** A document that describes the performance of possible manufacturing failures specific to the Lutonix formulation and references the name of a specific confidential ingredient for the 035 DCB.

f. **File 6 – Paclitaxel Polymorphic Form Study with a Dissolution Method.** Study performed by Lutonix to establish uniformity in the manufacturing processes for the 035 DCB.

Lutonix has implemented multiple measures to protect and maintain the confidentiality of its trade secrets, including: requiring all employees to sign confidentiality and non-disclosure agreements; implementing policies identifying company confidential information; prohibiting employee disclosure of trade secrets; restricting access to office workspaces; and establishing safeguards against electronic and other disclosures of trade secrets.

Christopher Barry's Employment at Lutonix

BARRY was employed by Lutonix as the Vice President of Research & Development. In this role, BARRY was responsible for all research and development, quality assurance, and manufacturing activities for the company. BARRY worked with the Chief Technology Officer in the design, formulation, and establishment of a "Quality

System”—designed to ensure compliance with all regulatory guidelines and policies—for the company; worked with key component suppliers to establish long term supply contracts; hired a team to bring products to commercialization; and helped to establish a manufacturing structure to support R&D activities and future scale up for commercialization. BARRY was directly involved in the development of the confidential process for coating the Lutonix 035 DCB with the paclitaxel drug.

Urotronic

L.W. is a former employee of Lutonix who in or about December 2014 formed a start-up medical device company named Urotronic. H.H. is a principal of Urotronic and L.W.’s primary business partner. In or about December 2014, L.W. and H.H. (through Urotronic) began attempting to develop drug-coated balloons for urological applications.

In or about February 2015, BARRY began a series of conversations with L.W. and H.H. about their plans for developing Urotronic’s business. While talking with L.W. and H.H. about Urotronic, BARRY attempted to avoid specifically discussing job opportunities for himself at Urotronic. However, as a result of these conversations with L.W. and H.H., BARRY began considering joining Urotronic if he decided to leave Lutonix. Ultimately, as described below, in about May 2015, BARRY left Lutonix and accepted employment as CEO of Urotronic.

Defendant’s Theft of Trade Secrets

In April 2015, BARRY had several conflicts with Lutonix’s President, with whom he had a contentious relationship. Specifically, on April 7, 2015, and again on April 14,

2015, BARRY and Lutonix's President had heated disagreements about how to conduct certain internal business meetings. As a result of these conflicts, BARRY decided to leave his employment with Lutonix. As BARRY was planning to leave Lutonix, he—without seeking or obtaining authorization from Lutonix—took numerous trade secret files belonging to Lutonix so that he could utilize information in those files in connection with his next job.

On April 9, 2015, between 12:06 p.m. and 1:58 p.m., BARRY downloaded at least 47 documents—including multiple trade secret files—from Lutonix's cloud-storage platform (named "Grand Avenue") and saved them to his Lutonix-issued computer. BARRY later transferred the trade secret files from his Lutonix computer to a USB Device and then to a personal portable hard drive.

On April 15, 2015, between 3:26 p.m. and 4:35 p.m., BARRY downloaded another approximately 25 documents—including **File 5** and **File 6**, among other files containing Lutonix trade secrets—from Grand Avenue and saved them to his Lutonix computer. Later that same day, between 9:08 p.m. and 9:52 p.m., while at home, BARRY downloaded at least 48 documents—including **File 1**, **File 2**, **File 3**, and **File 4**, among other files containing Lutonix trade secrets—from Grand Avenue and saved them to his Lutonix computer. BARRY later transferred the trade secret files to a USB Device and then to a personal portable hard drive. BARRY intended to and did take these trade secret files in order to use and reference certain information in those files in his next job. That same evening, at approximately 10:00 p.m., BARRY drafted his letter of resignation to Lutonix.

On April 16, 2015, BARRY tendered his resignation to Lutonix. BARRY informed Lutonix that he was leaving the workforce, and had no specific plans for future employment. During the two weeks that BARRY continued working at Lutonix after notifying Lutonix of his intention to resign, BARRY downloaded additional trade secret files.

On April 28 and April 30, 2015, BARRY downloaded at least 19 documents—including files containing Lutonix trade secrets—from Grand Avenue and saved them to his Lutonix computer. BARRY later transferred the trade secret files to a USB Device and then to his personal portable hard drive. BARRY's last day at Lutonix was May 1, 2015.

Defendant's New Job

On May 15, 2015, BARRY accepted the position of CEO at Urotronic. During his employment with Urotronic, BARRY transferred files—including numerous files containing Lutonix trade secrets—he stole from Lutonix from his portable hard drive onto his Urotronic work computer. Additionally, while BARRY was employed at Urotronic, he shared several procedural documents containing Lutonix trade secrets with other Urotronic employees.

Estimate of Losses

The defendant acknowledges and agrees that Lutonix incurred approximately \$533,842 in investigative and legal fees and costs in order to fully detect and remediate the defendant's criminal conduct.

3. **Waiver of Indictment.** The defendant agrees to waive indictment by a grand jury on this charge and to consent to the filing of a criminal information. The defendant further agrees to execute a written waiver of the defendant's right to be indicted by a grand jury on this offense.

4. **Waiver of Pretrial Motions.** The defendant understands and agrees that had defendant been charged by indictment, he would have had certain rights to file pre-trial motions in this case, including a motion to dismiss based on improper venue or jurisdiction. As part of this plea agreement, and based upon the concessions of the United States within this plea agreement, the defendant knowingly, willingly, and voluntarily gives up the right to file pre-trial motions in this case.

5. **Statutory Penalties.** The defendant understands that the maximum statutory penalty for violation of 18 U.S.C. § 1832 is as follows:

- a. a term of imprisonment of up to 10 years;
- b. a criminal fine of up to \$250,000.00;
- c. a term of supervised release of up to three years;
- d. a special assessment of \$100.00, which is payable to the Clerk of Court prior to sentencing; and
- e. the costs of prosecution (as defined in 28 U.S.C. § 1918(b) and 1920).

6. **Revocation of Supervised Release.** The defendant understands that, if he were to violate any condition of supervised release, he could be sentenced to an additional

term of imprisonment up to the length of the original supervised release term, subject to the statutory maximums set forth in 18 U.S.C. § 3583.

7. **Guideline Calculations.** The parties acknowledge that the defendant will be sentenced in accordance with 18 U.S.C. § 3551, et seq. The parties also acknowledge that the Court will consider the United States Sentencing Guidelines to determine the appropriate sentence and stipulate to the following guideline calculations:

a. **Base Offense Level.** The parties agree and stipulate that appropriate Guidelines section for Count 1 is § 2B1.1, and the base offense level is 6. (U.S.S.G. § 2B1.1(a)(2)).

b. **Specific Offense Characteristics.**

(1) **Loss.** The parties agree that, based on the facts available to the government, the loss resulting from the offense of conviction is between \$250,000 and \$550,000, and therefore the base offense level should be increased by 12 levels. (U.S.S.G. § 2B1.1(b)(1)(G)).

c. **Chapter Three Adjustments.**

(1) **Abuse of Trust.** The parties agree that the defendant abused a position of private trust in a manner that significantly facilitated the commission or concealment of the offense, and therefore the offense level should be increased by 2 levels. (U.S.S.G. § 3B1.3).

(2) **Acceptance of Responsibility.** In exchange for the defendant's plea and provided that the defendant does not falsely deny any offense or relevant conduct, the government agrees to recommend that the defendant receive a 2-level reduction for acceptance of responsibility and to make any appropriate motions with the Court. However, the defendant understands and agrees that this recommendation is conditioned upon the following: (i) the defendant testifies truthfully during the change of plea hearing, (ii) the defendant cooperates with the Probation Office in the pre-sentence investigation, (iii) the defendant commits no further acts inconsistent with acceptance of responsibility, and (iv) the defendant complies with this

agreement, fully identifies all assets and makes good faith efforts to make restitution to his victims. (U.S.S.G. § 3E1.1). The defendant timely notified the government of his intent to plead guilty, and therefore the government will make a motion to reduce the offense level by an additional 1 point pursuant to U.S.S.G. § 3E1.1(b).

- d. Other Enhancements/Adjustments. The parties agree that, based on the information available at this time, there are no other applicable enhancements or adjustments to the offense level.
- e. Criminal History Category. Based on information available at this time, the parties believe that the defendant's criminal history category is I. This does not constitute a stipulation, but a belief based on an assessment of the information currently known. Defendant's actual criminal history and related status will be determined by the Court based on the information presented in the Presentence Report and by the parties at the time of sentencing.
- f. Guideline Range. If the adjusted offense level is 17, and the criminal history category is I, the Sentencing Guidelines range is **24-30 months** of imprisonment.
- g. Fine Range. If the adjusted offense level is 17, the fine range is \$10,000 to \$95,000. (U.S.S.G. § 5E1.2(c)(3)).
- h. Supervised Release. The Sentencing Guidelines require a term of supervised release of up to three years. (U.S.S.G. § 5D1.2).
- i. Departures and Sentencing Recommendations. The parties reserve the right to make motions for departures or variances from the applicable guideline.

8. **Discretion of the Court**. The foregoing stipulations are binding on the parties, but do not bind the Court. The parties understand that the Sentencing Guidelines are advisory and their application is a matter that falls solely within the Court's discretion. The Court may make its own determination regarding the applicable guideline factors and the applicable criminal history category. The Court may also depart from the applicable

guidelines. If the Court determines that the applicable guideline calculations or the defendant's criminal history category is different from that stated above, the parties may not withdraw from this agreement, and the defendant will be sentenced pursuant to the Court's determinations.

9. **Special Assessments.** The Guidelines require payment of a special assessment in the amount of \$100.00 for each felony count of which the defendant is convicted. U.S.S.G. § 5E1.3. The defendant agrees to pay the special assessment prior to sentencing.

10. **Restitution.** Defendant understands and agrees that the Mandatory Restitution Act, 18 U.S.C. § 3663A, applies and that the Court is required to order the defendant to pay the maximum restitution to the victims of his crimes as provided by law. The defendant agrees that he will pay \$533,842 in restitution to Lutonix, representing the approximate amount of investigative and legal fees and costs that Lutonix incurred to fully detect and remediate the defendant's criminal conduct.

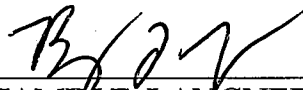
11. **Waiver of Appeal and Collateral Attack.** The defendant understands that 18 U.S.C. § 3742 affords the defendant the right to appeal the sentence imposed in this case. Acknowledging this right, and in exchange for the concessions made by the United States in this plea agreement, the defendant hereby waives all rights conferred by 18 U.S.C. § 3742 to appeal defendant's sentence, unless the sentence exceeds 12 months' imprisonment. The defendant expressly waives the right to petition under 28 U.S.C. § 2255, except for a post-conviction attack based on a claim of ineffective assistance of

counsel. The defendant has discussed these rights with the defendant's attorney. The defendant understands the rights being waived, and the defendant waives these rights knowingly, intelligently, and voluntarily.

12. **Complete Agreement.** This Plea Agreement, along with any agreement signed by the parties before entry of plea, is the entire agreement and understanding between the United States and the defendant.

Date: *May 9, 2017*

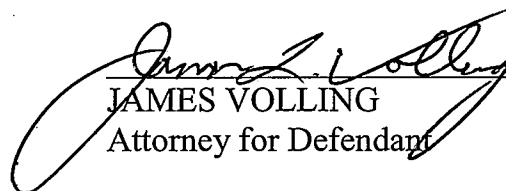
GREGORY G. BROOKER
Acting United States Attorney

BY: 
BENJAMIN F. LANGNER
Assistant U.S. Attorney

Date: *May 9, 2017*


CHRISTOPHER BARRY
Defendant

Date: *May 9, 2017*


JAMES VOLLING
Attorney for Defendant