

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA)	
)	Criminal No.: 16-508
v.)	
)	Filed:
JASON T. MALEK,)	
)	Violation: 15 U.S.C. § 1
Defendant.)	TWO COUNTS
)	

PLEA AGREEMENT

The United States of America and Jason T. Malek (“defendant”) hereby enter into the following Plea Agreement pursuant to Rule 11(c)(1)(B) of the Federal Rules of Criminal Procedure (“Fed. R. Crim. P.”):

RIGHTS OF DEFENDANT

- I. The defendant understands his rights:
 - (a) to be represented by an attorney;
 - (b) to be charged by Indictment;
 - (c) to plead not guilty to any criminal charge brought against him;
 - (d) to have a trial by jury, at which he would be presumed not guilty of the charge and the United States would have to prove every essential element of the charged offense beyond a reasonable doubt for him to be found guilty;
 - (e) to confront and cross-examine witnesses against him and to subpoena witnesses in his defense at trial;
 - (f) not to be compelled to incriminate himself;
 - (g) to appeal his conviction, if he is found guilty; and
 - (h) to appeal the imposition of sentence against him.

AGREEMENT TO PLEAD GUILTY AND WAIVE CERTAIN RIGHTS

2. The defendant knowingly and voluntarily waives the rights set out in subparagraphs 1(b)-(g) above. The defendant also knowingly and voluntarily waives the right to file any appeal, any collateral attack, or any other writ or motion, including but not limited to an appeal under 18 U.S.C. § 3742 or a motion under 28 U.S.C. § 2241 or 2255, that challenges the sentence imposed by the Court if that sentence is consistent with or below the sentencing recommendations in Paragraph 9 of this Plea Agreement, regardless of how the sentence is determined by the Court. This agreement does not affect the rights or obligations of the United States as set forth in 18 U.S.C. § 3742(b). Nothing in this paragraph, however, will act as a bar to the defendant perfecting any legal remedies he may otherwise have on appeal or collateral attack respecting claims of ineffective assistance of counsel or prosecutorial misconduct. The defendant agrees that there is currently no known evidence of ineffective assistance of counsel or prosecutorial misconduct. Consistent with Fed. R. Crim. P. 11(b)(1)(O), the defendant recognizes that if he is not a citizen of the United States pleading guilty may have consequences with respect to his immigration status, including removal from the United States, denial of citizenship, and denial of admission to the United States in the future. Pursuant to Fed. R. Crim. P. 7(b), the defendant will waive indictment and plead guilty to a two-count Information to be filed in the United States District Court for the Eastern District of Pennsylvania. Count One of the Information will charge the defendant with participating in a conspiracy to suppress and eliminate competition by allocating customers, rigging bids, and fixing and maintaining prices for doxycycline hyclate sold in the United States, from in or about April 2013 and continuing until at least December 2015, in violation of the Sherman Antitrust Act, 15 U.S.C. § 1. Count Two of the Information will charge the defendant with participating in a conspiracy to suppress

and eliminate competition by allocating customers and fixing and maintaining prices for glyburide sold in the United States, from in or about April 2014 and continuing until at least December 2015, in violation of the Sherman Antitrust Act, 15 U.S.C. § 1.

3. The defendant will plead guilty to the criminal charges described in Paragraph 2 above pursuant to the terms of this Plea Agreement and will make a factual admission of guilt to the Court in accordance with Fed. R. Crim. P. 11, as set forth in Paragraph 4 below. The United States agrees that at the arraignment, it will stipulate to the release of the defendant on his personal recognizance, pursuant to 18 U.S.C. § 3142, pending the sentencing hearing in this case.

FACTUAL BASIS FOR OFFENSE CHARGED

4. Had this case gone to trial, the United States would have presented evidence sufficient to prove the following facts:

(a) During the periods relevant to Count One and Count Two described below, the defendant was Senior Vice President, Commercial Operations, and President of Company A, an entity organized and existing under the laws of Delaware and with its principal place of business in Eatontown, New Jersey. During the relevant periods, Company A was a generic pharmaceutical company engaged in the acquisition, licensing, production, marketing, sale, and distribution of generic pharmaceutical products, including doxycycline hyclate and glyburide, and was engaged in the sale of those drugs in the United States. Company A is a subsidiary of and conducts the U.S. commercial operations of Company B, a generic pharmaceutical company headquartered in Pune, India. Doxycycline hyclate is a generic antibiotic used to treat a variety of bacterial infections. Glyburide is a generic drug used in the treatment of diabetes. During the relevant periods, Company A produced and distributed doxycycline hyclate in delayed-

release tablet form in three dosage strengths; Company A produced and distributed glyburide in tablet form in four dosage strengths. During the relevant periods, the parties agree that the affected volume of commerce, based on Company A's sales of doxycycline hyclate and glyburide in the United States, totaled approximately \$1.6 million after excluding certain sales pursuant to United States Sentencing Guidelines ("U.S.S.G.," "Sentencing Guidelines," or "Guidelines") §1B1.8.

(b) For purposes of this Plea Agreement, the "relevant period" for Count One is that period from in or about April 2013 and continuing until at least December 2015. During the relevant period, the defendant participated in a conspiracy with other persons and entities engaged in the production and sale of generic pharmaceutical products, including doxycycline hyclate, the primary purpose of which was to allocate customers, rig bids, and fix and maintain prices of doxycycline hyclate sold in the United States. In furtherance of the conspiracy, the defendant and his co-conspirators, including individuals the defendant supervised at Company A and reported to at Company B, engaged in discussions, and attended meetings with co-conspirators involved in the production and sale of doxycycline hyclate. During such discussions and meetings, agreements were reached to allocate customers, rig bids, and fix and maintain the prices of doxycycline hyclate sold in the United States.

(c) For purposes of this Plea Agreement, the "relevant period" for Count Two is that period from in or about April 2014 and continuing until at least December 2015. During the relevant period, the defendant participated in a conspiracy with other persons and entities engaged in the production and sale of generic pharmaceutical products, including glyburide, the primary purpose of which was to allocate customers and fix and

maintain prices of glyburide sold in the United States. In furtherance of the conspiracy, the defendant and his co-conspirators at Company A, including individuals the defendant supervised, engaged in discussions and attended meetings with co-conspirators involved in the production and sale of glyburide. During such discussions and meetings, agreements were reached to allocate customers and fix and maintain the prices of glyburide sold in the United States. The defendant was a manager or supervisor in the conspiracy, which involved at least five participants.

(d) During the relevant periods, doxycycline hyclate and glyburide sold by one or more of the conspirator firms, and equipment and supplies necessary to the production and sale of doxycycline hyclate and glyburide, as well as payments for doxycycline hyclate and glyburide, traveled in interstate and foreign commerce. The business activities of Company A and co-conspirators in connection with the production and sale of doxycycline hyclate and glyburide that were the subject of this conspiracy were within the flow of, and substantially affected, interstate and foreign trade and commerce.

(e) Acts in furtherance of the conspiracies described in Count One and Count Two were carried out within the Eastern District of Pennsylvania. Doxycycline hyclate, the subject of the conspiracy described in Count One, and glyburide, the subject of the conspiracy described in Count Two, were sold by one or more conspirators to customers in this District. In addition, the conspiratorial meetings and discussions described above took place in the United States and elsewhere, and at least one of these discussions relevant to Count Two involved a co-conspirator that has its principal place of business in this District.

ELEMENTS OF THE OFFENSE

5. The elements of the charged offense are that:
- (a) the conspiracy described in the Information existed at or about the time alleged;
 - (b) the defendant knowingly became a member of the conspiracy; and
 - (c) the conspiracy described in the Information either substantially affected interstate and foreign commerce in goods or services or occurred within the flow of interstate and foreign commerce in goods and services.

POSSIBLE MAXIMUM SENTENCE

6. The defendant understands that the statutory maximum penalty which may be imposed against him upon conviction for a violation of Section One of the Sherman Antitrust Act is:

- (a) a term of imprisonment for ten (10) years (15 U.S.C. § 1);
- (b) a fine in an amount equal to the greatest of (1) \$1 million, (2) twice the gross pecuniary gain the conspirators derived from the crime, or (3) twice the gross pecuniary loss caused to the victims of the crime by the conspirators (15 U.S.C. § 1; 18 U.S.C. § 3571(b) and (d)); and
- (c) a term of supervised release of three (3) years following any term of imprisonment. If the defendant violates any condition of supervised release, the defendant could be required to serve up to two (2) years in prison (18 U.S.C. § 3559(a)(3); 18 U.S.C. § 3583(b)(2) and (e)(3); and U.S.S.G. §5D1.2(a)(2)).

7. In addition, the defendant understands that:

- (a) pursuant to U.S.S.G. §5E1.1 or 18 U.S.C. § 3663(a)(3) or 3583(d), the Court may order him to pay restitution to the victims of the offense; and

(b) pursuant to 18 U.S.C. § 3013(a)(2)(A), the Court is required to order the defendant to pay a \$100.00 special assessment per count upon conviction for the charged crime.

SENTENCING GUIDELINES

8. The defendant understands that the Sentencing Guidelines are advisory, not mandatory, but that the Court must consider, in determining and imposing sentence, the Guidelines Manual in effect on the date of sentencing unless that Manual provides for greater punishment than the Manual in effect on the last date that the offense of conviction was committed, in which case the Court must consider the Guidelines Manual in effect on the last date that the offense of conviction was committed. The parties agree there is no *ex post facto* issue under the November 2016 Guidelines Manual. The Court must also consider the other factors set forth in 18 U.S.C. § 3553(a) in determining and imposing sentence. The defendant understands that the Court will make Guidelines determinations by applying a standard of preponderance of the evidence. The defendant understands that although the Court is not ultimately bound to impose a sentence within the applicable Guidelines range, its sentence must be reasonable based upon consideration of all relevant sentencing factors set forth in 18 U.S.C. § 3553(a). Pursuant to U.S.S.G. §1B1.8, the United States agrees that self-incriminating information not previously known to the United States that the defendant provides to the United States pursuant to this Plea Agreement will not be used to expand the scope of the charged conduct, to increase the volume of affected commerce attributable to the defendant, or in determining the defendant's applicable Guidelines range, except to the extent provided in U.S.S.G. §1B1.8(b).

SENTENCING AGREEMENT

9. Pursuant to Fed. R. Crim. P. 11(c)(1)(B) and subject to the full, truthful, and continuing cooperation of the defendant, as defined in Paragraph 17 of this Plea Agreement, the United States agrees that it will recommend that the following Sentencing Guidelines should apply:

(a) The parties jointly recommend to the Court that for Counts One and Two (15 U.S.C. § 1) the Guidelines should be calculated as follows:

(1) Base Offense Level, U.S.S.G. §2R1.1(a)	12
(2) Volume of commerce attributable to the defendant in excess of \$1,000,000, U.S.S.G. §2R1.1(b)(2)(A)	+ 2
(3) Defendant’s role as a manager or supervisor of criminal activity involving five or more participants, U.S.S.G. §3B1.1(b)	<u>+ 3</u>
(4) Offense Level Total	17
(5) Fine, calculated as one to five percent of the volume of commerce, but not less than \$20,000, U.S.S.G. §2R1.1(c)(1):	\$20,000.00

(b) The United States agrees to recommend to the Court that the defendant receive a two-level downward adjustment for acceptance of responsibility, and an additional one-level downward adjustment if the Court determines the offense level prior to the acceptance-of-responsibility adjustment to be 16 or higher. U.S.S.G. §3E1.1(a)-(b). However, should the United States obtain or receive evidence or information prior to sentencing that, in its sole discretion, it determines to be credible and materially in conflict with this provision, then the United States will no longer be bound by this provision;

(c) The United States and the defendant are not aware of any information that would cause the defendant's Criminal History Category to be higher than I. The parties understand that the defendant's Criminal History Category is determined by the Court; and

(d) Subject to the foregoing provisions, the parties agree to recommend jointly to the Court that the defendant's adjusted offense level for the offenses to which he is pleading guilty be 14. The applicable Guidelines imprisonment range for offense level 14 is 15 to 21 months.

10. Subject to the full, truthful, and continuing cooperation of the defendant, as defined in Paragraph 17 of this Plea Agreement, and prior to sentencing in this case, the United States will fully advise the Court and the Probation Office of the fact, manner, and extent of the defendant's cooperation and his commitment to prospective cooperation with the United States' investigation and prosecutions, all material facts relating to the defendant's involvement in the charged offense, and all other relevant conduct. To enable the Court to have the benefit of all relevant sentencing information, the United States will request, and the defendant will not oppose, that sentencing be postponed until his cooperation is complete.

11. If the United States determines that the defendant has provided substantial assistance in its investigations or prosecutions of federal criminal law in the pharmaceutical industry, and has otherwise fully complied with all of the terms of this Plea Agreement, it will file a motion, pursuant to U.S.S.G. §5K1.1, advising the sentencing judge of all relevant facts pertaining to that determination and requesting that the Court sentence the defendant in light of the factors set forth in U.S.S.G. §5K1.1(a)(1)-(5). The defendant acknowledges that the decision as to whether he has provided substantial assistance in any investigations or prosecutions and has

otherwise complied with the terms of this Plea Agreement is within the sole discretion of the United States. It is understood that, should the United States determine that the defendant has not provided substantial assistance in any investigations or prosecutions, or should the United States determine that the defendant has violated any provision of this Plea Agreement, such a determination will release the United States from any obligation to file a motion pursuant to U.S.S.G. §5K1.1, but will not entitle the defendant to withdraw his guilty plea once it has been entered. The defendant further understands that, whether or not the United States files a motion pursuant to U.S.S.G. §5K1.1, the sentence to be imposed on him remains within the sole discretion of the sentencing judge. The defendant is free to recommend or argue for any specific sentence to the Court.

12. The parties agree to recommend jointly that there exists no aggravating or mitigating circumstance of a kind, or to a degree, not adequately taken into consideration by the U.S. Sentencing Commission in formulating the Sentencing Guidelines justifying a departure pursuant to U.S.S.G. §5K2.0.

13. The parties agree not to seek at the sentencing hearing any Guidelines adjustment for any reason that is not set forth in this Plea Agreement. The defendant understands that all party recommendations as to Sentencing Guidelines application and ultimate sentence are merely recommendations; all decisions as to Sentencing Guidelines application and ultimate sentence in this case will be made by the Court.

14. Pursuant to Fed. R. Crim. P. 11(c)(1)(B) and subject to the full, truthful, and continuing cooperation of the defendant, as defined in Paragraph 17 of this Plea Agreement, the United States agrees that it will recommend, as the appropriate disposition of this case, that the Court impose a sentence consistent with Paragraphs 9, 10, and 11 of this Plea Agreement. In

light of the availability of civil causes of action, which potentially provide for a recovery of a multiple of actual damages, the sentencing recommendations do not include a restitution order for the offense charged in the Information.

15. The defendant understands that the Court will order him to pay a \$100 special assessment per count pursuant to 18 U.S.C. § 3013(a)(2)(A) in addition to any fine imposed.

16. The United States and the defendant understand that the Court retains complete discretion to accept or reject the agreed upon Guidelines calculations provided for in Paragraph 9 of this Plea Agreement or other sentencing recommendations made by the parties pursuant to this Agreement. The defendant understands that, as provided in Fed. R. Crim. P. 11(c)(3)(B), if the Court does not impose either party's sentencing recommendation provided for in this Agreement, he nevertheless has no right to withdraw his plea of guilty.

DEFENDANT'S COOPERATION

17. The defendant will cooperate fully and truthfully with the United States in the prosecution of this case, the current federal investigation of violations of federal antitrust and related criminal laws involving the production and sale of generic pharmaceutical products in the United States, any federal investigation resulting therefrom, and any litigation or other proceedings arising or resulting from any such investigation to which the United States is a party (collectively "Federal Proceeding"). Federal Proceeding includes, but is not limited to, an investigation, prosecution, litigation, or other proceeding regarding obstruction of, the making of a false statement or declaration in, the commission of perjury or subornation of perjury in, the commission of contempt in, or conspiracy to commit such offenses in, a Federal Proceeding. The full, truthful, and continuing cooperation of the defendant will include, but not be limited to:

(a) producing all documents, including claimed personal documents, and other materials, wherever located, not protected under the attorney-client privilege or the work-product doctrine, in the possession, custody, or control of the defendant, that are requested by attorneys and agents of the United States in connection with any Federal Proceeding;

(b) making himself available for interviews, not at the expense of the United States, upon the request of attorneys and agents of the United States in connection with any Federal Proceeding;

(c) responding fully and truthfully to all inquiries of the United States in connection with any Federal Proceeding, without falsely implicating any person or intentionally withholding any information, subject to the penalties of making a false statement or declaration (18 U.S.C. §§ 1001, 1623), obstruction of justice (18 U.S.C. § 1503, *et seq.*), or conspiracy to commit such offenses;

(d) otherwise voluntarily providing the United States with any material or information not requested in (a) - (c) of this paragraph and not protected under the attorney-client privilege or work-product doctrine that he may have that is related to any Federal Proceeding; and

(e) when called upon to do so by the United States in connection with any Federal Proceeding, testifying in grand jury, trial, and other judicial proceedings fully, truthfully, and under oath, subject to the penalties of perjury (18 U.S.C. § 1621), making a false statement or declaration in grand jury or court proceedings (18 U.S.C. § 1623), contempt (18 U.S.C. §§ 401-402), and obstruction of justice (18 U.S.C. § 1503, *et seq.*).

GOVERNMENT'S AGREEMENT

18. Subject to the full, truthful, and continuing cooperation of the defendant, as defined in Paragraph 17 of this Plea Agreement, and upon the Court's acceptance of the guilty plea called for by this Plea Agreement and the imposition of sentence, the United States agrees that it will not bring further criminal charges against the defendant for any act or offense committed before the date of signature of this Plea Agreement that was undertaken in furtherance of an antitrust conspiracy involving the production or sale in the United States of doxycycline hyclate, glyburide, or those generic pharmaceutical products enumerated in Attachment A (filed under seal) ("Relevant Offense"). The United States further agrees that it will not bring criminal charges against the defendant for obstruction of justice related to the Relevant Offense committed prior to September 27, 2015. The nonprosecution terms of this paragraph do not apply to (a) any acts of perjury or subornation of perjury (18 U.S.C. §§ 1621-22), making a false statement or declaration (18 U.S.C. §§ 1001, 1623), obstruction of justice (18 U.S.C. § 1503, *et seq.*) committed on or after September 27, 2015, contempt (18 U.S.C. §§ 401-402), or conspiracy to commit such offenses; (b) civil matters of any kind; (c) any violation of the federal tax or securities laws or conspiracy to commit such offenses; or (d) any crime of violence. The nonprosecution terms of this paragraph also do not apply to conduct involving any corporate entity in which the defendant has or had an ownership interest other than Companies A and B.

19. The defendant understands that he may be subject to suspension or debarment action by state or federal agencies other than the United States Department of Justice, Antitrust Division, based upon the conviction resulting from this Plea Agreement, and that this Plea Agreement in no way controls what action, if any, other agencies may take. However, the Antitrust Division agrees that, if requested, it will advise the appropriate officials of any

governmental agency considering such action of the fact, manner, and extent of the cooperation of the defendant as a matter for that agency to consider before determining what action, if any, to take. The defendant nevertheless affirms that he wants to plead guilty regardless of any suspension or debarment consequences of his plea.

REPRESENTATION BY COUNSEL

20. The defendant has reviewed all legal and factual aspects of this case with his attorney and is fully satisfied with his attorney's legal representation. The defendant has thoroughly reviewed this Plea Agreement with his attorney and has received satisfactory explanations from his attorney concerning each paragraph of this Plea Agreement and alternatives available to the defendant other than entering into this Plea Agreement. After conferring with his attorney and considering all available alternatives, the defendant has made a knowing and voluntary decision to enter into this Plea Agreement.

VOLUNTARY PLEA

21. The defendant's decision to enter into this Plea Agreement and to tender a plea of guilty is freely and voluntarily made and is not the result of force, threats, assurances, promises, or representations other than the representations contained in this Plea Agreement and Attachment A. The United States has made no promises or representations to the defendant as to whether the Court will accept or reject the recommendations contained within this Plea Agreement.

VIOLATION OF PLEA AGREEMENT

22. The defendant agrees that, should the United States determine in good faith, during the period that any Federal Proceeding is pending, that the defendant has failed to provide full, truthful, and continuing cooperation, as defined in Paragraph 17 of this Plea Agreement, or

has otherwise violated any provision of this Plea Agreement, the United States will notify counsel for the defendant in writing by personal or overnight delivery, email, or facsimile transmission and may also notify counsel by telephone of its intention to void any of its obligations under this Plea Agreement (except its obligations under this paragraph), and the defendant will be subject to prosecution for any federal crime of which the United States has knowledge including, but not limited to, the substantive offenses relating to the investigation resulting in this Plea Agreement. The defendant agrees that, in the event that the United States is released from its obligations under this Plea Agreement and brings criminal charges against the defendant for any Relevant Offense, the statute of limitations period for such offense will be tolled for the period between the date of signature of this Plea Agreement and six (6) months after the date the United States gave notice of its intent to void its obligations under this Plea Agreement.

23. The defendant understands and agrees that in any further prosecution of him resulting from the release of the United States from its obligations under this Plea Agreement because of the defendant's violation of this Plea Agreement, any documents, statements, information, testimony, or evidence provided by him to attorneys or agents of the United States, federal grand juries, or courts, and any leads derived therefrom, may be used against him. In addition, the defendant unconditionally waives his right to challenge the use of such evidence in any such further prosecution, notwithstanding the protections of Fed. R. Evid. 410.

ENTIRETY OF AGREEMENT

24. This Plea Agreement and Attachment A constitute the entire agreement between the United States and the defendant concerning the disposition of the criminal charges in this

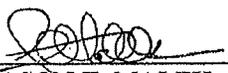
case. This Plea Agreement cannot be modified except in writing, signed by the United States and the defendant.

25. The undersigned attorneys for the United States have been authorized by the Attorney General of the United States to enter this Plea Agreement on behalf of the United States.

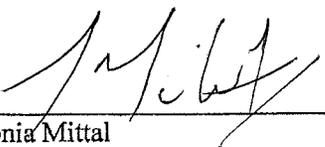
26. A facsimile or PDF signature will be deemed an original signature for the purpose of executing this Plea Agreement. Multiple signature pages are authorized for the purpose of executing this Plea Agreement.

DATED: 12/09/2016

Respectfully submitted,

BY: 

JASON T. MALEK
Defendant

BY: 

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Joseph C. Folio III
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