

# Exhibit A

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

_____		)
FEDERAL TRADE COMMISSION		)
600 Pennsylvania Avenue, N.W.		)
Washington, D.C. 20580		)
		)
Plaintiff,		)
v.		)
		)
CEPHALON, INC.		)
41 Moores Road		)
Frazer, Pennsylvania 19355		)
		)
Defendant.		)
_____		)

Civil Action No. 2:08-cv-2141-MSG

**[PROPOSED] STIPULATED REVISED ORDER FOR PERMANENT INJUNCTION  
AND EQUITABLE MONETARY RELIEF**

Plaintiff, the Federal Trade Commission ("Commission"), filed its Complaint for Injunctive Relief, subsequently amended as Plaintiff Federal Trade Commission's First Amended Complaint for Injunctive Relief, ("Complaint"), in this matter pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission, Cephalon, Inc. ("Cephalon") and Teva Pharmaceutical Industries Ltd. ("Teva") reached an agreement to resolve this case through settlement, and without trial or final adjudication of any issue of fact or law, and stipulated to entry of a Stipulated Order for Permanent Injunction and Equitable Monetary Relief ("Original Order") to resolve all matters in dispute in this action. The Commission, Cephalon and Teva now stipulate to entry of a Stipulated Revised Order for Permanent Injunction and Equitable Monetary Relief ("Revised Order") in settlement of the Commission's claims against Teva Pharmaceuticals USA in *FTC v. AbbVie Inc.*, Nos. 18-2621,

18-2748, 18-2758 (3d Cir.); Actavis in *Federal Trade Commission v Actavis*, Civ. Action No. 09-cv-955 (N.D. Ga.); and Watson in *FTC v. Allergan PLC*, Civ. Action No. 17-cv-00312 (N.D. Cal.).

**THEREFORE, IT IS ORDERED** as follows:

**DEFINITIONS**

For purposes of this Revised Order, the following definitions apply:

1. "Commission" means the United States Federal Trade Commission.
2. "Actavis" means Actavis Holdco US, Inc.
3. "Cephalon" means Cephalon, Inc.
4. "Watson" means Watson Laboratories, Inc.
5. "Cephalon Group" means Cephalon, any joint venture, subsidiary, division, group, or affiliate Controlled (for clarity, currently or in the future) by Cephalon that engages in Commerce in the United States, their successors and assigns, and the respective directors, officers, employees, agents and representatives acting on behalf of each.
6. "Teva" means Teva Pharmaceutical Industries Ltd.
7. "Teva Pharmaceuticals USA" means Teva Pharmaceuticals USA, Inc.
8. "Teva US Entities" means any joint venture, subsidiary, division, group, or affiliate Controlled (for clarity, currently or in the future) by Teva that engages in Commerce in the United States, including Cephalon, Teva Pharmaceuticals USA, Actavis, and Watson.
9. "Teva Group" means Teva, Teva US Entities, their successors and assigns, and the respective directors, officers, employees, agents, and representatives acting on behalf of each.
10. "Cephalon Parties" mean Cephalon, Cephalon Group, Teva and Teva Group.

11. "505(b)(2) Application" means an application filed with the United States Food and Drug Administration pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 § 355(b)(2).
12. "ANDA" means an Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j).
13. "Authorized Generic" means a Drug Product that is manufactured pursuant to an NDA and promoted, offered for sale, sold or distributed in the United States under a name other than the proprietary name identified in the NDA.
14. "Brand/Generic Settlement" means any agreement or understanding that settles a Patent Infringement Claim in or affecting Commerce in the United States.
15. "Brand/Generic Settlement Agreement" means a written agreement that settles a Patent Infringement Claim in or affecting Commerce in the United States.
16. "Branded Subject Drug Product" means a Subject Drug Product Marketed in the United States under the proprietary name identified in the NDA for the Subject Drug Product.
17. "Commerce" has the same definition as in 15 U.S.C. § 44.
18. "Contingent Supply Agreement" means a Supply Agreement that terminates within 30 days after the Generic Filer, after good faith commercially reasonable efforts, (i) has final FDA approval for its ANDA or 505(b)(2) Application for the Generic Subject Drug Product and (ii) can manufacture commercial quantities of the Generic Subject Drug Product,

*provided, however, the Generic Filer may take delivery of and Market quantities of Authorized Generic ordered prior to termination of the Contingent Supply Agreement*

so long as the total quantity of Authorized Generic delivered to the Generic Filer following termination of the Contingent Supply Agreement: (i) does not exceed the total quantity needed by the Generic Filer (as reflected in forecasts provided to the NDA Holder prior to termination of the Contingent Supply Agreement) during the 8 months following (x) termination of the Contingent Supply Agreement, if termination occurs after the Generic Entry Date or (y) the Generic Entry Date, if termination occurs before the Generic Entry Date; and (ii) is delivered within 8 months of termination of the Contingent Supply Agreement.

19. "Control" or "Controlled" means the holding of more than fifty percent (50%) of the common voting stock or ordinary shares in, or the right to appoint more than fifty percent (50%) of the directors of, or any other arrangement resulting in the right to direct the management of, the said corporation, company, partnership, joint venture or entity.
20. "Drug Product" means a finished dosage form (e.g., tablet, capsule, or solution), as defined in 21 C.F.R. § 314.3(b), that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.
21. "Exclusion Period" means the 60-day period starting 30 days before executing a Brand/Generic Settlement Agreement and ending 30 days after executing the Brand/Generic Settlement Agreement.
22. "Fully Allocated Manufacturing Cost" means the sum of the following:
  - a. Direct costs incurred to produce (or acquire) the Subject Drug Product or materials, as consistently applied in accordance with past practice and in the ordinary course of business, including but not limited to (x) acquisition costs or (y) if applicable, materials, labor, manufacturing costs, packaging, labeling,

testing, quality control, storage, insurance, and product maintenance, and determined in accordance with GAAP;

- b. The cost to ship the Subject Drug Product or materials to the Generic Filer; and
- c. Administrative expenses and overhead expenses directly related to the production of the Subject Drug Product or materials as allocated in accordance with past practice and in the ordinary course of business,

*provided that*, if administrative expenses and overhead expenses are not allocated to the Subject Drug Product in the ordinary course of business, for this definition, these expenses shall be allocated as a proportion of the NDA Holder's COGS of the Subject Drug Product to the NDA Holder's total COGS, excluding administrative expenses and overhead expenses. To illustrate, overhead expenses and administrative expenses shall be allocated proportionately, by determining the ratio of the Subject Drug Product's COGS (excluding administrative expenses and overhead expenses) to the NDA Holder's total COGS for the relevant manufacturing site (again excluding administrative expenses and overhead expenses), multiplied by the administrative expenses and overhead expenses for the same manufacturing site. In this provision COGS refers to the NDA Holder's cost of goods sold, determined in accordance with GAAP, as consistently applied in accordance with past practice and in the ordinary course of business.

- 23. "Generic Entry Date" means the date in a Brand/Generic Settlement Agreement, whether certain or contingent, on or after which a Generic Filer is authorized by the NDA Holder to begin manufacturing, importing, using or Marketing the Generic Subject Drug Product.

24. "Generic Filer" means a party to a Brand/Generic Settlement who controls an ANDA or 505(b)(2) Application for the Subject Drug Product or has the exclusive right under such ANDA or 505(b)(2) Application to distribute the Subject Drug Product.
25. "Generic Party" means the Generic Filer, its parents, and any joint venture, subsidiary, division, group, or affiliate Controlled (for clarity, currently or in the future) by the Generic Filer or its parent, and their successors and assigns.
26. "Generic Product" means a Drug Product manufactured under an ANDA or a 505(b)(2) Application.
27. "Generic Subject Drug Product" means the Generic Product that is the subject of the Patent Infringement Claim being resolved by the Brand/Generic Settlement.
28. "Market," "Marketed" or "Marketing" means the promotion, offering for sale, sale, or distribution of a Drug Product.
29. "Materials Agreement" means provisions in, or incorporated into, a Brand/Generic Settlement Agreement providing for the supply of materials to a Generic Party by an NDA Party for securing and/or maintaining regulatory approval, or manufacturing and Marketing by the Generic Filer of the Subject Drug Product, including the terms and conditions of any such supply.
30. "Materials Price" means the total actual per-unit price charged by the NDA Holder for materials provided through a Materials Agreement, including any transfer price and royalty or profit-share payments to be made by the Generic Filer, net of any discounts, allowances, rebates, or other reductions.
31. "Minor Purchase Order" means an ordinary course purchase order for Drug Products, their ingredients, or related equipment or supplies that does not exceed \$1,000,000,

*provided that* the \$1,000,000 limit referenced in this definition shall be increased (or decreased) as of January 1 of each year by an amount equal to the percentage increase (or decrease) from the previous year in the annual average Producer Price Index for Pharmaceutical preparations - WPU0638 published by the Bureau of Labor Statistics of the United States Department of Labor, or its successor.

32. "NDA" means a New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), including all changes or supplements thereto which do not result in the submission of a new NDA.

33. "NDA Holder" means a party to a Brand/Generic Settlement that controls the NDA for the Subject Drug Product or has the exclusive right to distribute the Branded Subject Drug Product in the United States.

34. "NDA Party" means the NDA Holder, its parents, and any joint venture, subsidiary, division, group, or affiliate Controlled (for clarity, currently or in the future) by the NDA Holder or its parent, their successors and assigns.

35. "No-AG Commitment" means any agreement with, or commitment or license to, a Generic Party that prohibits, prevents, restricts, requires a delay of, or imposes a condition precedent upon the research, development, manufacture, regulatory approval, or Marketing of an Authorized Generic of the Subject Drug Product,

*provided, however,* that agreement by the Generic Party to pay royalties to the NDA Party for the right to Market the Generic Subject Drug Product or an Authorized Generic of the Subject Drug Product, including agreement on the terms and conditions governing payment of such royalties, shall not be considered a No-AG Commitment.



36. “Original Order” means the Order for Permanent Injunction and Equitable Monetary Relief entered in this matter on June 17, 2015, at Docket No. 405.
37. “Patent Infringement Claim” means any allegation threatened in writing or included in a complaint filed with a court of law, that a Generic Product may infringe any U.S. Patent held by, or exclusively licensed to, an NDA Holder.
38. “Payment by the NDA Party to the Generic Party” means a transfer of value, other than a No-AG Commitment, by an NDA Party to a Generic Party (including, but not limited to, money, goods, or services), regardless of whether the Generic Party purportedly transfers value in return, where such transfer is either expressly contingent on entering a Brand/Generic Settlement Agreement or agreed to during the Exclusion Period. However, Payment by the NDA Party to the Generic Party does not include:
- a. compensation for saved future litigation expenses in litigation involving a Patent Infringement Claim that does not exceed x) the maximum limit (as defined in this paragraph) minus y) the value of Minor Purchase Orders (i) that were placed or confirmed during the Exclusion Period and (ii) do not qualify as the continuation or renewal of a pre-existing agreement, as set forth in Paragraph 38(f) below. The maximum limit was \$7,000,000 when the Original Order was entered on June 17, 2015 and, as required by the Original Order and this Revised Order, has increased (or decreased) – and, going forward, shall continue to increase (or decrease) – on January 1 of each year by an amount equal to the percentage increase (or decrease) from the previous year in the annual average Producer Price Index for Legal Services (Series Id. PCU5411--5411--) published by the Bureau of Labor Statistics of the United States Department of Labor, or its successor;

- b. the right to Market, as of an agreed upon Generic Entry Date: (i) Generic Product(s) in the United States under an ANDA or 505(b)(2) Application (x) that is controlled by the Generic Filer and was not transferred to the Generic Filer by the NDA Holder, or (y) to which the Generic Party has a license from a party other than the NDA Holder; or (ii) an Authorized Generic of the Subject Drug Product, regardless of whether the Generic Filer must pay for the right to Market or the terms and conditions governing such payment;
- c. an agreement to settle or resolve a different litigation claim, so long as that separate agreement independently complies with the terms of this Revised Order;
- d. a Qualified Materials Agreement or Qualified Supply Agreement;
- e. Minor Purchase Orders placed or confirmed during the Exclusion Period that do not exceed a cumulative maximum, which is initially \$4,000,000 and shall increase (or decrease) on January 1 of each year by an amount equal to the percentage increase (or decrease) from the previous year in the annual average Producer Price Index for Pharmaceutical preparations - WPU0638 published by the Bureau of Labor Statistics of the United States Department of Labor, or its successor;
- f. continuation or renewal of a pre-existing agreement so long as (i) the pre-existing agreement was entered at least 90 days before the relevant Brand/Generic Settlement Agreement, (ii) the terms of the renewal or continuation, including the duration and the financial terms, are substantially similar to those in the pre-existing agreement, and (iii) entering the continuation or renewal is not expressly contingent on agreeing to the relevant Brand/Generic Settlement;

- g. provisions to facilitate, by means other than the transfer of goods or money, the Generic Filer's ability to secure or maintain final regulatory approval, or commence or continue the Marketing, of a Generic Product, by, *inter alia*, providing covenants, waivers, permissions, releases, dismissals of claims, and/or authorizations; or
  - h. waiver or limitation of a claim for damages or other monetary relief based on prior Marketing of the Generic Subject Drug Product, but only if the NDA Holder and the Generic Filer do not agree, and have not agreed, to another Brand/Generic Settlement for a different Drug Product during the Exclusion Period.
39. "Qualified" as referring to a Materials Agreement or a Supply Agreement means a Materials Agreement or Supply Agreement that meets all of the following conditions:
- a. the price is above the Fully Allocated Manufacturing Cost, meaning
    - i) if the Agreement is a Materials Agreement, the Materials Price charged by an NDA Party for materials provided through the Materials Agreement is at or above the Fully Allocated Manufacturing Cost incurred by the NDA Party per unit of the relevant materials, or
    - ii) if the Agreement is a Supply Agreement, the Supply Price charged by an NDA Party for the Authorized Generic of the Subject Drug Product is at or above the Fully Allocated Manufacturing Cost incurred by the NDA Party per unit of the Authorized Generic of the Subject Drug Product provided under the agreement;
  - b. the Brand/Generic Settlement Agreement containing or incorporating the Materials Agreement or Supply Agreement is the only Brand/Generic Settlement Agreement that the NDA Party and the Generic Party have entered, or agreed to enter, during the Exclusion Period;

- c. within 14 days after signing the Brand/Generic Settlement Agreement containing or incorporating the Materials Agreement or Supply Agreement, the Cephalon Parties submit to the Monitor a full and complete copy of the Brand/Generic Settlement Agreement, including any Materials Agreement and/or Supply Agreement;
- d. within 14 days after the NDA Holder provides to the Generic Filer the Materials Price or Supply Price, as applicable, the Cephalon Parties submit to the Monitor notification of the relevant Materials Price or Supply Price;
- e. within 30 days after beginning supply under the relevant Materials Agreement or Supply Agreement, the NDA Holder submits to the Monitor:
  - i) if a Materials Agreement, a verified written statement containing (i) the Fully Allocated Manufacturing Cost per unit for the materials and (ii) a detailed breakdown of the Fully Allocated Manufacturing Cost for the materials, stated separately by cost component and on a per-unit basis; and
  - ii) if a Supply Agreement, a verified written statement containing (i) the Fully Allocated Manufacturing Cost per unit for the relevant Authorized Generic of the Subject Drug Product and (ii) a detailed breakdown of the Fully Allocated Manufacturing Cost for the Authorized Generic of the Subject Drug Product, stated separately by cost component and on a per-unit basis; and
- f. if the NDA Party is not a Cephalon Party, the Materials Agreement or Supply Agreement, as applicable, requires the NDA Party to (i) provide the notification required by subsection (e) above and cooperate with any reasonable request by the Monitor or staff of the Commission for documents and information to determine

the relevant Fully Allocated Manufacturing Cost, including without limitation and subject to any demonstrated legally recognized privilege, providing the Monitor reasonable access to personnel, books, documents, records kept in the ordinary course of business;

*provided that*, notwithstanding subsections (e) and (f) above, a Materials Agreement or Supply Agreement in which a Cephalon Party is a Generic Party shall also be considered a Qualified Agreement if it complies with subsections (a) to (d) above *and*:

- i) if a Materials Agreement, the Cephalon Parties submit to the Monitor within 30 days of beginning to receive the materials, a verified written statement containing (i) the Cephalon Parties' best estimate of what would be the Fully Allocated Manufacturing Cost per unit for the materials if manufactured or sourced by the Generic Party, including a separate estimate of each cost component on a per-unit basis, and (ii) a description of the terms and conditions of any agreement(s), offer(s), purchase order(s) or price quote(s) a Cephalon Party has entered into or received for supply of the materials in connection with manufacture of the Subject Drug Product and other facts and circumstances, if any, that the Cephalon Parties deem relevant to understanding such terms and conditions; and
- ii) if a Supply Agreement, it is a Contingent Supply Agreement and the Cephalon Parties submit to the Monitor within 30 days of beginning to receive the Authorized Generic, a verified written statement containing (i) the Cephalon Parties' best estimate of what would be the Fully Allocated Manufacturing Cost per unit for the Subject Drug Product if manufactured by a Generic Party and (ii) a detailed breakdown of that best estimate, including an estimate of each cost component on a per-unit basis.

40. "Subject Drug Product" means the Drug Product for which one or more Patent Infringement Claims are settled under a given Brand/Generic Settlement. For purposes of this Revised Order, the Drug Product of the NDA Holder and the Generic Filer to the same Brand/Generic Settlement shall be considered to be the same Subject Drug Product.
41. "Supply Agreement" means provisions in, or incorporated into, a Brand/Generic Settlement Agreement providing for the supply of the Subject Drug Product to the a Generic Party by an NDA Party for the Marketing by the Generic Party of an Authorized Generic on or after the Generic Entry Date, including the terms and conditions of any such supply.
42. "Supply Price" means the total actual per-unit price charged by the NDA Holder for supply provided through a Supply Agreement, including any transfer price and royalty or profit-share payments to be made by the Generic Filer, for the right to sell an Authorized Generic of the Subject Drug Product, net of any discounts, allowances, rebates or other reductions.
43. "U.S. Patent" means any patent issued by the United States Patent and Trademark Office, including all renewals, derivations, divisions, reissues, continuations, continuations-in part, modifications or extensions thereof.

#### FINDINGS

1. This Court has jurisdiction over the parties and the subject matter of this action. Teva has stipulated that, for purposes of this Revised Order alone, the Court has personal jurisdiction over Teva.
2. Venue for this matter is proper in this Court under Sections 5(a) and 13(b) of the FTC Act, 15 U.S.C. §§ 45(a), 53(b).

3. The Cephalon Parties admit the facts necessary to establish the personal and subject matter jurisdiction of this Court to enter and enforce the Original Order and this Revised Order.
4. The Commission and Cephalon agreed to stipulate to entry of the Original Order to resolve the litigation *FTC v. Cephalon, Inc.*, 08-cv-2141 (E.D. Pa.).
5. The Commission and the Cephalon Parties now have agreed to stipulate to entry of this Revised Order to resolve the litigations *FTC v. AbbVie Inc.*, Nos. 18-2621, 18-2748, 18-2758 (3d Cir.), *Federal Trade Commission v Actavis.*, Civ. Action No. 09-cv-955 (N.D. Ga.), *FTC v. Allergan PLC*, Civ. Action No. 17-cv-312 (N.D. Cal.); and *Endo Pharmaceuticals Inc. v. FTC*, Civ. Action No. 16-cv-5599 (E.D. Pa.).
6. The Cephalon Parties waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of the actions identified in Finding No. 5 through the date of this Revised Order, and agree to bear their own costs and attorney fees in those actions.
7. The Cephalon Parties waive all rights to appeal or otherwise challenge or contest the validity of this Revised Order.
8. This Revised Order does not constitute any evidence against the Cephalon Parties, or an admission of liability or wrongdoing by the Cephalon Parties in any case or other proceeding. This Revised Order shall not be used in any way, as evidence or otherwise, in any case or other proceeding; *provided that*, nothing in this provision prevents the Commission from using this Revised Order in any proceeding regarding enforcement or modification of this Revised Order, or as otherwise required by law.

9. Entry of the Revised Order satisfies the requests for relief made by the FTC in its complaints in the foregoing actions and is in the public interest.

#### STIPULATIONS

1. Teva stipulates that, in return for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Teva agrees to be fully bound by the terms of this Revised Order.
2. Teva stipulates that it will not object to the Commission's right to seek relief under this Revised Order against Teva to the same extent the Commission can seek relief against Cephalon (or Cephalon's successors and assigns). Teva does not otherwise waive its right to contest any enforcement action against it.
3. For purposes of this Revised Order alone, Teva does not contest personal jurisdiction of this Court over Teva. Teva is an Israeli company with its principal place of business at 5 Basel Street, Petah Tikva, 49131, Israel.
4. Teva stipulates that it is the ultimate corporate parent of Cephalon, Teva Pharmaceuticals USA, Actavis, and Watson.
5. Teva stipulates that venue for this matter is proper in this Court under Sections 5(a) and 13(b) of the FTC Act, 15 U.S.C. §§ 45(a), 53(b).
6. Teva stipulates that all stipulations herein are made on behalf of, and include, Teva and Teva Group.
7. The Cephalon Parties stipulate that they shall comply with the provisions of this Revised Order pending its entry by the Court.



8. Watson stipulates that, upon entry of this Revised Order, it will not file – or, if already filed, will voluntarily dismiss within one day of the entry of this Revised Order – any appeal of the order dismissing the action *Endo Pharmaceuticals Inc. v. FTC*, Civ. Action No. 16-cv-5599 (E.D. Pa.), with the parties agreeing to bear their own costs.
9. The Commission stipulates that, within one day of the entry of this Revised Order, the Commission will file motions for voluntary dismissals with prejudice of its claims against Teva Pharmaceuticals USA in *FTC v. AbbVie Inc.*, Nos. 18-2621, 18-2748, 18-2758 (3d Cir.); Actavis and Allergan Finance, LLC in *Federal Trade Commission v Actavis.*, Civ. Action No. 09-cv-955 (N.D. Ga.); and Watson in *FTC v. Allergan PLC*, Civ. Action No. 17-cv-00312 (N.D. Cal.) in the forms provided in Exhibit 1.
10. The Commission and the Cephalon Parties stipulate that upon entry of the Revised Order, the Commission and the Cephalon Parties each release the other from any and all claims, causes of actions and demands, including any claim for attorney fees, costs, sanctions or other expenses that are in existence as of the date of entry of the Revised Order in any of the following actions: *FTC v. AbbVie Inc.*, Nos. 18-2621, 18-2748, 18-2758 (3d Cir.); *Federal Trade Commission v Actavis.*, Civ. Action No. 09-cv-955 (N.D. Ga.); *FTC v. Allergan PLC*, Civ. Action No. 17-cv-00312 (N.D. Cal.); *Endo Pharmaceuticals Inc. v. FTC*, Civ. Action No. 16-cv-5599 (E.D. Pa.); and *Federal Trade Commission v. Endo Pharmaceuticals Inc.*, Civ. Action No. 16-cv-1440 (E.D. Pa.).
11. The Commission and the Cephalon Parties stipulate that the Original Order will remain in full force and effect until entry of the Revised Order. The Commission further stipulates that it releases the Cephalon Parties from claims for violation of the Original Order that are based on conduct that does not also violate the Revised Order, including claims

related to entry of a Supply Agreement or Material Agreement where the pricing in the relevant agreement is consistent with the pricing requirements (price at or above cost) for a Qualified agreement under the Revised Order.

## ORDER

### I. Prohibited Agreements

**IT IS ORDERED** that

- A. From the date the Revised Order is signed by Teva, the Cephalon Parties are prohibited from, together or separately, entering into any Brand/Generic Settlement that includes:
1. a Payment from an NDA Party to a Generic Party and an agreement by the Generic Filer not to research, develop, manufacture or Market the Subject Drug Product for any period of time; or
  2. a No-AG Commitment and an agreement by the Generic Filer not to research, develop, manufacture or Market the Subject Drug Product for any period of time,  
*provided, however,* that any agreement entered into by an entity prior to that entity becoming part of the Cephalon Parties is not subject to the terms of this Revised Order;  
*provided further,* that the Cephalon Parties may enter into any written agreement that receives the prior approval of the Commission. Within 30 days of receiving a request for prior approval under this paragraph, the Director of the Bureau of Competition (or his or her designee) shall consider the request in good faith and shall notify the requesting party in writing whether Commission staff believes the relevant agreement raises issues under Section 5 of the FTC Act and

the reasons for such a belief, or this Revised Order shall be deemed not to preclude the requesting party from entering into the subject written agreement.

B. Nothing in this Revised Order shall prohibit the Cephalon Parties from purchasing, merging with, or otherwise acquiring or being acquired by any party with which a Cephalon Party has entered a Brand/Generic Settlement.

C. In the event of a material change in the law governing the antitrust implications of Brand/Generic Settlements, the Commission will consider, in good faith, modifications to this Revised Order proposed by the Cephalon Parties.

## II. Equitable Monetary Relief

IT IS FURTHER ORDERED that

A. Under the Original Order, the Cephalon Parties paid, for purposes of settlement only (no portion of the payment was made in lieu of treble damages, fines, penalties, punitive damages or forfeitures), One Billion and Two Hundred Million Dollars (US\$ 1,200,000,000) as equitable monetary relief, to be used for a settlement fund ("Settlement Fund") in accordance with the terms of the Original Order, including the Settlement Fund Disbursement Agreement, attached to the Original Order as Exhibit A. Those terms of the Original Order, and the Settlement Fund Disbursement Agreement, shall continue to govern in regards to the administration and disposition of the Settlement Fund.

### III. Monitor

IT IS FURTHER ORDERED that:

- A. The Commission may appoint a Monitor to ensure that any Materials Agreement or Supply Agreement that the Cephalon Parties assert is a Qualified Materials Agreement or Qualified Supply Agreement complies with the definition of Qualified. The Commission shall select the Monitor, subject to the consent of the Cephalon Parties, which consent shall not be unreasonably withheld. If the Cephalon Parties have not opposed, in writing, including the reasons for opposing, the selection of any proposed Monitor within 14 days after notice by the staff of the Commission to the Cephalon Parties of the identity of any proposed Monitor, the Cephalon Parties shall be deemed to have consented to the selection of the proposed Monitor.
- B. The Monitor shall serve, without bond or other security, at the expense of the Cephalon Parties, on such reasonable and customary terms and conditions to which the Monitor and the Cephalon Parties agree and that the Commission approves.
- C. The Monitor's duties and responsibilities shall include the following:
1. the Monitor shall have the power and authority to perform his/her duties under this Paragraph. The Monitor shall exercise his/her power and authority and carry out his/her duties and responsibilities in a manner consistent with the purposes of this Revised Order and in consultation with the Commission;
  2. the Monitor shall have authority to employ, at the expense of the Cephalon Parties, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities; and

3. Thirty days after the Cephalon Parties have submitted to the Monitor information described in definition 38 (Qualified) regarding a Materials Agreement or Supply Agreement, the Monitor shall provide the Commission with a written report describing the facts relevant to determining whether the agreement is a Qualified Materials Agreement or a Qualified Supply Agreement.

D. The Cephalon Parties shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities under this Revised Order, including but not limited to, the following:

1. the Cephalon Parties shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to perform his/her duties as provided in this paragraph;
2. subject to any demonstrated legally recognized privilege, the Cephalon Parties shall provide the Monitor full and complete access to personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request to perform his/her duties under this paragraph;

3. the Cephalon Parties shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel, and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor; and

4. the Cephalon Parties may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Cephalon Parties' materials and information received in connection with the performance of the Monitor's duties,

*provided, however,* such agreement shall not restrict the Monitor from providing any information to the Commission or require the Monitor to report to the Cephalon Parties the substance of communications to or from the Commission or any party to a Brand/Generic Settlement Agreement other than the Cephalon Parties.

E. The Commission may require that the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.

F. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate.

G. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of the Cephalon Parties, which consent shall not be unreasonably withheld. If the Cephalon Parties have not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within fourteen (14) days after notice by the staff of the Commission to the Cephalon Parties of the identity of any proposed substitute Monitor, the Cephalon Parties shall be deemed to have consented to the selection of the proposed substitute Monitor.

#### IV. Reporting Requirements

**IT IS FURTHER ORDERED** that:

- A. The Cephalon Parties shall submit to the Commission a verified written report setting forth in detail the manner and form in which the Cephalon Parties have complied and are complying with this Order:
1. Within 60 days after entry of this Revised Order, although such report need only address whether any Supply Agreements and/or Materials Agreements executed by the Cephalon Parties after the Original Order was entered, but before this Revised Order was entered, are consistent with this Revised Order's pricing requirements (price at or above cost) for a Qualified Agreement; and
  2. On June 17, 2019, and annually thereafter until this Revised Order expires.

B. The Cephalon Parties shall include with each verified written report required by this provision:

1. A copy of any additional agreement, other than a Minor Purchase Order, with a party to a Brand/Generic Settlement to which a Cephalon Party is also a signatory if:
  - a. the relevant Brand/Generic Settlement Agreement includes an agreement by the Generic Filer not to research, develop, manufacture, or Market the Subject Drug Product for any period of time, and
  - b. the relevant additional agreement was entered during a 150-day period starting 75 days before entering the Brand/Generic Settlement Agreement and ending 75 days after entering the Brand/Generic Settlement Agreement,

*provided that*, the Cephalon Parties do not need to provide any additional agreement that they submitted to the Commission with a prior verified written report required by this provision, and *provided further that*, as concerns Brand/Generic Settlement Agreements that were entered into after the Original Order was entered but before the Cephalon parties submitted to the Commission their most recent verified written report under that Original Order, on June 15, 2018, the Cephalon Parties do not need to provide any additional agreement that they would not have been required to submit to the Commission under the Original Order; and



2. A description of information provided to the Monitor since submission of the most recent prior verified written report, and, if not previously submitted to the Monitor, information sufficient to show that any agreement Cephalon contends should be considered a Qualified Supply Agreement or Qualified Materials Agreement meets the pricing requirements (price at or above cost) for a Qualified agreement,

*provided that*, Cephalon Parties do not need to provide materials they submitted to the Commission with a prior verified written report required by this provision.

C. No information or documents obtained by the means provided in this Paragraph shall be divulged by the Commission to any person other than an authorized representative of the Commission, except in the course of a legal proceeding regarding enforcement or modification of this Revised Order, or as otherwise required by law.

D. This Revised Order does not alter the reporting requirements of the Cephalon Parties pursuant to Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

#### V. Change of Corporate Control

IT IS FURTHER ORDERED that

A. The Cephalon Parties shall notify the Commission at least 30 days prior to any proposed dissolution, acquisition, merger, or consolidation of Teva that might affect compliance obligations arising out of this Revised Order by submitting to the Commission appropriate notification.

B. No information or documents submitted to the Commission pursuant to this Paragraph shall be divulged by the Commission to any person other than an authorized representative of the Commission, except in the course of a legal proceeding regarding enforcement or modification of this Revised Order, or as otherwise required by law.

#### VI. Access to Information

**IT IS FURTHER ORDERED** that

A. For the purpose of determining or securing compliance with this Revised Order, subject to any legally recognized privilege, and upon written request with reasonable notice to the Cephalon Parties, the Cephalon Parties shall permit any duly authorized representative of the Commission:

1. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy, at the Cephalon Parties' expense, non-privileged books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of the Cephalon Parties reasonably related to this Revised Order; and
2. Upon reasonable notice to the Cephalon Parties, to interview a reasonable number of officers, directors, or employees of the Cephalon Parties, who may have counsel present, regarding any such matters.

B. No information or documents obtained by the means provided in this Paragraph shall be divulged by the Commission to any person other than an authorized representative of the Commission, except in the course of a legal proceeding regarding enforcement or modification of this Revised Order, or as otherwise required by law.

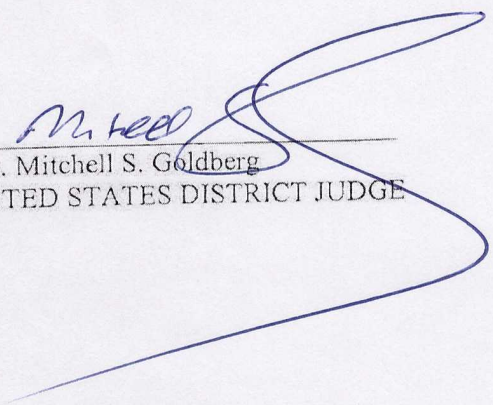
**VII. Retention of Jurisdiction**

IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Revised Order.

**VIII. Expiration of Revised Order**

IT IS FURTHER ORDERED that this Revised Order shall expire 10 years after the date it is entered.

SO ORDERED this 21<sup>st</sup> day of Feb., 2019.

  
\_\_\_\_\_  
Hon. Mitchell S. Goldberg  
UNITED STATES DISTRICT JUDGE

***SO STIPULATED AND AGREED:***

FOR PLAINTIFF FEDERAL TRADE COMMISSION:

Markus H. Meier

Date: 2/13/19

Markus H. Meier  
Assistant Director  
Health Care Division  
Bureau of Competition  
Federal Trade Commission

FOR TEVA PHARMACEUTICAL INDUSTRIES LTD.:

\_\_\_\_\_

Date: \_\_\_\_\_

Michael McClellan  
Executive Vice President, Chief Financial Officer

\_\_\_\_\_

Date: \_\_\_\_\_

Dov Bergwerk  
Senior VP & General Counsel—Corporate & Company Secretary

\_\_\_\_\_

Date: \_\_\_\_\_

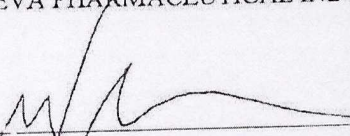
Jay P. Lefkowitz, P.C.  
Kirkland & Ellis LLP  
COUNSEL FOR TEVA PHARMACEUTICAL INDUSTRIES LTD.


*SO STIPULATED AND AGREED:*

FOR PLAINTIFF FEDERAL TRADE COMMISSION:

\_\_\_\_\_ Date: \_\_\_\_\_  
 Markus H. Meier  
 Assistant Director  
 Health Care Division  
 Bureau of Competition  
 Federal Trade Commission

FOR TEVA PHARMACEUTICAL INDUSTRIES LTD.:

  
 \_\_\_\_\_ Date: 2/12/2019  
 Michael McClellan  
 Executive Vice President, Chief Financial Officer

  
 \_\_\_\_\_ Date: 2/12/2019  
 Dov Bergwerk  
 Senior VP & General Counsel—Corporate & Company Secretary

LEGAL AFFAIRS  
BS

\_\_\_\_\_ Date: \_\_\_\_\_  
 Jay P. Lefkowitz, P.C.  
 Kirkland & Ellis LLP  
 COUNSEL FOR TEVA PHARMACEUTICAL INDUSTRIES LTD.

**SO STIPULATED AND AGREED:**

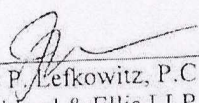
FOR PLAINTIFF FEDERAL TRADE COMMISSION:

\_\_\_\_\_  
Date: \_\_\_\_\_  
Markus H. Meier  
Assistant Director  
Health Care Division  
Bureau of Competition  
Federal Trade Commission

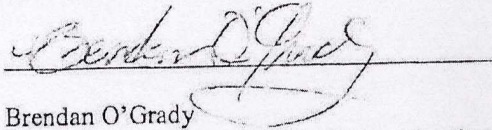
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Senior VP & General Counsel—Corporate & Company Secretary

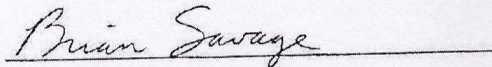
  
\_\_\_\_\_  
Date: 2/12/19  
Jay P. Lefkowitz, P.C.  
Kirkland & Ellis LLP  
COUNSEL FOR TEVA PHARMACEUTICAL INDUSTRIES LTD.

FOR CEPHALON, INC.:



Date: 2/12/2019

Brendan O'Grady  
Executive Vice President, North America Commercial



Date: 2/12/2019

Brian Savage  
General Counsel, US Generics

LEGAL AFFAIRS  
BS

\_\_\_\_\_  
Mark A. Ford  
Wilmer Cutler Pickering Hale and Dorr LLP  
COUNSEL FOR CEPHALON, INC.

Date: \_\_\_\_\_

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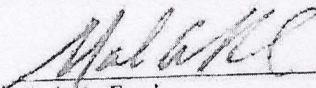
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\_\_\_\_\_ Date: \_\_\_\_\_

Brian Savage  
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