1510196

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Maureen K. Ohlhausen
Terrell McSweeny

In the Matter of	)	
TEVA PHARMACEUTICAL INDUSTRIES LTD., a corporation;	)	**Docket No. C-**
and	)	
ALLERGAN PLC, a corporation.	)	

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Teva Pharmaceutical Industries Ltd. ("Teva") of the voting securities of certain entities (defined herein as "Allergan Generic Pharmaceutical Entities") and related assets from their ultimate parent entity Allergan plc ("Allergan") (Teva and Allergan hereinafter collectively referred to as "Respondents"), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Teva is a corporation organized, existing, and doing business under and by virtue of the laws of Israel with its principal nt05

B. “Allergan” means: Allergan plc; its directors, officers, employees, agents,

ehf. (APH4) (Iceland); Forest Laboratories UK Ltd. (United Kingdom of Great Britain and Northern Ireland); Forest Pharma BV (Netherlands); Axcan France (Invest) SAS (French Republic); Forest Tosara Ltd. (Republic of Ireland); and Actavis Holdco US, Inc. (Delaware).

K. "Allergan Generic Pharmaceutical Business" means:

1. the Allergan Generic Pharmaceutical Entities;
2. the respective directors, officers, employees, agents, representatives, successors, and assigns of each of the Allergan Generic Pharmaceutical Entities;
3. the assets acquired or to be acquired by Teva from Allergan pursuant to the Acquisition Agreement and referred to as Transferred Assets in Section 2.1(a) of the Acquisition Agreement; and
4. the Businesses related to all of the Allergan Generic Pharmaceutical Entities to the extent acquired by Teva.

L. "API Customer(s)" means any customer who has purchased any of the API Products from Respondent Teva during the period from January 1, 2013 until the Acquisition Date for the purposes of manufacturing any Product that is any of the following: (i) an API Finished Dosage Form Product, (ii) the Therapeutic Equivalent of an API Finished Dosage Form Product, (iii) in Development to become the Therapeutic Equivalent of an API Finished Dosage Form Product.

M. "API Product(s)" means, the following active pharmaceutical ingredients, individually and collectively:

1. Betamethasone Dipropionate;
2. Betamethasone Valerate;
3.

API Finished Dosage FPI Produ9-1(t)]TJ 5.42 0I P385 5.42 044heamop Espms

1. “Betamethasone Dipropionate Product(s)” means the Products manufactured, in

b. ANDA No. 074407, and any ANDA that relies on ANDA No. 074407 as the Reference Listed Drug. These Products are topically administered ointments that contain, as an active pharmaceutical ingredient, clobetasol propionate, at the following strength: 0.05%.

4. “Desonide Product(s)” means the Products manufactured, in Development, marketed, or sold pursuant to each of the following Applications: NDA No. 017010 and any ANDA that relies on NDA No. 017010 as the Reference Listed Drug. These Products are topically administered creams that contain, as an active pharmaceutical ingredient, desonide, at the following strength: 0.05%.

5. “Fluocinolone Product(s)” means the Fluocinolone Products as defined in Non-Public Appendix VI.

6. “Fluorouracil Product(s)” means the Fluorouracil Products as defined in Non-Public Appendix VI.

7. “Probenecid Product(s)” means the Products manufactured, in Development, marketed, or sold pursuant to each of the following Applications:

a. ANDA No. 084211, and any ANDA that relies on ANDA No. 084211 as the Reference Listed Drug. These Products are orally administered tablets that contain, as an active pharmaceutical ingredient, probenecid, at the following strengths: 500 mg; and

b. ANDA No. 084279, and any ANDA that relies on ANDA No. 084279 as the Reference Listed Drug. These Products are orally administered tablets that contain, as active pharmaceutical ingredients, colchicine and probenecid, at the following strengths: 0.5 mg colchicine and 500 mg probenecid.

8. “Triamcinolone Product(s)” means the Products manufactured, in Developmen8 0 Td ( )Tj Prtiin

O. "Application(s)" means all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. "Application" also includes an "Investigational New Drug Application" ("IND") filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.

P. "Armodafinil Product(s)" means the following: generic versions of the Products manufactured, in Development, marketed, or sold pursuant to the following Application: NDA No. 021875, and any supplements, amendments, or revisions to this NDA that are orally administered tablets containing, as an active pharmaceutical ingredient, armodafinil, at the following strength: 200 mg.

Q. "Armodafinil Supply Agreement" means the Armodafinil Supply Agreement between Cephalon, Inc. and Aurobindo Pharma USA, Inc. dated as of June 9, 2016, and all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreement. The Armodafinil Supply Agreement is contained in Non-Public Appendix III. The Armodafinil Supply Agreement that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective is a Remedial Agreement.

R. "Aurobindo" means Aurobindo Pharma Limited, a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of India with its principal executive offices located at Water Mark Building, Plot No. 11, Survey No. 9, Kondapur, Hitech City, Hyderabad – 500 084, Telangana, India. Aurobindo includes its United States subsidiary, Aurobindo Pharma USA, Inc., a Delaware corporation.

S. "Benzoyl Peroxide/Clindamycin Product Divestiture Agreement" means the Transfer of Agreement a.k.a. Letter Agreement by and between Perrigo UK Finco Limited Partnership (as successor in interest to Perrigo Netherland BV) and Barr Laboratories, Inc. dated as of June 9, 2016, and all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreement. The Benzoyl Peroxide/Clindamycin Product Divestiture Agreement is contained in Non-Public Appendix II.G. The Benzoyl Peroxide/Clindamycin Product Divestiture Agreement that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective is a Remedial Agreement.

T. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of a Product.

U. "Categorized Assets" means the following assets and rights of the specified Respondent (as that Respondent is identified in the definition of the Divestiture Product), as such assets and rights are in existence as of the date the specified Respondent signs the Agreement Containing Consent Orders in this matter and to be maintained by the Respondents in accordance with the Order to Maintain Assets until the Closing Date for each Divestiture Product:

1. all rights to all of the Applications related to the specified Divestiture Product;
2. all rights to all of the Clinical Trials related to the specified Divestiture Product;
3. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
4. all Product Approvals related to the specified Divestiture Product;
5. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
6. all Product Marketing Materials related to the specified Divestiture Product;
7. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
8.

c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the Respondents of any such cross-referencing that is discovered by a Respondent);

d. to seek cross-referencing from a customer of the specified Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;

e. to approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product except for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and except as may be required by applicable Law and except as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and

f. to approve any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondents prior to such notification(s) being disseminated to the customer(s);

id>BD2igsplihep-a

b. f

18. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process, and finished goods related to the specified Divestiture Product;

19. the quantity and delivery terms in all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;

20. at the option of the Acquirer of the specified Divestiture Product, the right to fill any or all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date; and

21. all of a Respondent's books, records, and files directly related to the foregoing;

provided, however, that "Categorized Assets" shall not include: (i) documents relating to a Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Monitor or the Acquirer of the specified Divestiture Product; (iv) information that is exclusively related to the Retained Products; (v) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Licensed Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of the specified Respondent

CC. "Contract Manufacture" means the following:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer (including, without limitation, for the purposes of Clinical Trials and/or commercial sales);
2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent of, and in the identical dosage strength, formulation, and presentation as, a Contract Manufacture Product on behalf of an Acquirer; or
3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

DD. "Contract Manufacture Product(s)" means the following Divestiture Products, individually and collectively:

1. Alendronate Products;
2. Carbidopa/Levodopa Products;

id(a)-

22. Modified Release Phentermine/Topiramate Products;

23. Nabumetone Products;

24. Nitrofurantoin Products;

25. Nortriptyline Products;

26. OC Desogestrel/Ethinyl Estradiol Azurette Products;

27. OC Desogestrel/Ethinyl Estradiol Caziant Products;

28. OC Drospirenone/Ethinyl Estradiol Zarah Products;

29. OC Estradiol Valerate/Estradiol Valerate/Dienogest Products;

30. OC Ethinyl Estradiol/Ethynodiol Zovia Products;

31. OC Ethinyl Estradiol/Levonorgestrel Products;

32. OC Ethinyl Estradiol/Levonorgestrel Levora Products;

33. OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Products;

34. OC Ethinyl Estradiol/Norethindrone Microgestin 1.5/30 Products;

35. OC Ethinyl Estradiol/Norethindrone Necon Products;

36. OC Ethinyl Estradiol/Norethindrone Tilia Fe Products;

37. OC Norethindrone Camila Products;

38. OC Norethindrone Errin Products;

39. Propranolol Products;

40. Tamoxifen Products;

41. Trimethoprim Products; and

42. and any ingredient, material, or component used in the manufacture of the foregoing Products including the active pharmaceutical ingredient(s), excipient(s), or packaging materials (including, without limitation, drug vials);

provided, however, that with the consent of the Acquirer of the specified Product, a Respondent may substitute a Therapeutic Equivalent form of such Product in performance of that Respondent's agreement to Contract Manufacture.

EE. "Development" means all preclinical and clinical drug development activities, including test method development and stability testing; toxicology; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals); Product Approval and registration; and regulatory

affairs related to the foregoing. "Develop" means to engage in Development.

FF. "Development Two Product Divestiture Agreements" means the "Development Two Product Divestiture Agreements" as defined in Non-Public Appendix IV.

GG. "Direct Cost" means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. "Direct Cost" to the Acquirer for its use of any of a Respondent's employees' labor shall not exceed the average hourly wage rate for such employee;

provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, "Direct Cost" means such cost as is provided in such Remedial Agreement for that Divestiture Product.

HH. "Divestiture Product(s)" means the following, individually and collectively:

1. "Acitretin Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 202552, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, acitretin, at the following strengths: 10 mg; 17.5 mg; 22.5 mg; 25 mg.

2. "Alendronate Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 075710, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, alendronate sodium, at the following strengths: EQ 5 mg Base; EQ 10 mg Base; EQ 35 mg Base; EQ 40 mg Base; EQ 70 mg Base.

3. "Benzoyl Peroxide/Clindamycin Product(s)" means the following: the Products manufactured, in Development, marketed, or sold pursuant to the following Application: ANDA No. 202440, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered gels and contain, as active pharmaceutical ingredients, benzoyl peroxide and clindamycin phosphate, at the following strength: 5% benzoyl peroxide and EQ 1% Base clindamycin phosphate. The holder of this ANDA is Perrigo.

4. "Budesonide INH Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to each of the following Applications:

a. ANDA No. 078404, and any supplements, amendments, or revisions to this ANDA. These Products are sterile suspensions administered by inhalation using a nebulizer containing as an active pharmaceutical ingredient, budesonide, at the following strengths: 0.25 mg/2ml; 0.5 mg/2ml; and

b. ANDA No. 202558, and any supplements, amendments, or revisions to this ANDA. These Products are sterile suspensions administered by inhalation using a nebulizer containing as an active pharmaceutical ingredient, budesonide, at the following strength: 1.0 mg/2ml.

5. "Buprenorphine/Naloxone Product(s)" the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are the subject of an ANDA or to be the subject of an ANDA that relies on NDA No. 022410 (Suboxone) or the Therapeutic Equivalent of Suboxone as the Reference Listed Drug. These Products are films administered

8. “Clonidine Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Barr) pursuant to the following Application: ANDA No. 079090, and any supplements, amendments, or revisions to this ANDA. These Products are transdermally administered by film (patch) for extended release and contain, as an active pharmaceutical ingredient, clonidine, at the following strengths: 0.1 mg/24-hours; 0.2 mg/24-hours; 0.3 mg/24-

a. ANDA No. 071134;

b. ANDA No. 071135; and

c. ANDA No. 071136;

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, diazepam, at the following strengths: 2 mg; 5 mg; 10 mg.

15. "Disopyramide Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to each of the following Applications:

a. ANDA No. 070173; and

b. ANDA No. 070174;

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, disopyramide phosphate, at the following strengths: EQ 100 mg Base; EQ 150 mg Base.

16. "Estazolam Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 074921, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, estazolam, at the following strengths: 1 mg; 2 mg.

17. "Estradiol Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 040114, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, estradiol, at the following strengths: 0.5 mg; 1 mg; 2 mg.

18. "Ethinyl Estradiol/Etonogestrel Vaginal Ring Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by

at the following strengths: 10 mg ezetimibe and 10 mg simvastatin; 10 mg ezetimibe and 20 mg simvastatin; 10 mg ezetimibe and 40 mg simvastatin; 10 mg ezetimibe and 80 mg simvastatin.

20. "Fentanyl Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 206329, and any supplements, amendments, or revisions to this ANDA. These Products are sublingually or buccally administered tablets containing, as an active pharmaceutical ingredient, fentanyl citrate, at the following strengths: EQ 0.1 mg Base; EQ 0.2 mg Base; EQ 0.4 mg Base; EQ 0.6 mg Base; EQ 0.8 mg Base.

21. "Fluocinonide Emulsified Product(s)" means the following: the Products manufactured, in Development, marketed, or sold pursuant to the following Application: ANDA No. 074204, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered creams containing, as an active pharmaceutical ingredient, fluocinonide (emulsified base), at the following strength: 0.05%. The holder of this ANDA is G & W Laboratories.

22. "Fluocinonide Product(s)" means the following: the Products manufactured, in Development, marketed, or sold pursuant to the following Application: ANDA No. 073085, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered creams containing, as an active pharmaceutical ingredient, fluocinonide, at the following strength: 0.05%. The holder of this ANDA is G & W Laboratories.

23. "Flutamide Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Ivax) pursuant to the following Application: ANDA No. 075780, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, flutamide, at the following strength: 125 mg.

24. "Glyburide/Metformin Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Ivax) pursuant to the following Application: ANDA No. 076345, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, glyburide and metformin hydrochloride, at the following strengths: 1.25 mg glyburide and 250 mg metformin; 2.5 mg glyburide and 500 mg metformin hydrochloride; 5 mg glyburide and 500 mg metformin.

25. "Griseofulvin Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Ivax) pursuant to the following Application: ANDA No. 065354, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered liquid suspensions containing, as an active pharmaceutical ingredient, griseofulvin (micro

size

30. “Injectable Methotrexate Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 203407, and any supplements, amendments, or revisions to this ANDA. These Products are administered by injection and contain, as an active pharmaceutical ingredient, methotrexate, at the following strength: 50 mg/2 ml; 250 mg/10 ml; 500 mg/20 ml; 1000 mg/40 ml (25 mg/1 ml).

31. “Injectable Paclitaxel Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are administered by intravenous infusion and contain, as an active pharmaceutical ingredient, paclitaxel (lyophilized -for injectable suspension), at the following strength: 100 mg/vial.

32. “Injectable Propofol Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 075102, and any supplements, amendments, or revisions to this ANDA. These Products are administered by injection and contain, as an active pharmaceutical ingredient, propofol, at the following strength: 10 mg/ml.

33. “Levalbuterol Product(s)” means the following: the Products manufactured, Td [(fg-2(ngr)-2(a To

active pharmaceutical ingredient, dexmethylphenidate hydrochloride, at the following strengths: 5 mg; 10 mg; 15 mg; 20 mg; 30 mg. The Modified Release Dexmethylphenidate Products also include the orally administered extended release capsules containing, as an active pharmaceutical ingredient, dexmethylphenidate hydrochloride, that are in Development at the following strengths: 25 mg; 35 mg.

40. "Modified Release Dextroamphetamine Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Barr) pursuant to the following Application: ANDA No. 076137, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered extended release capsules containing, as an active pharmaceutical ingredient, dextroamphetamine sulfate, at the following strengths: 5 mg; 10 mg; 15 mg.

41. "Modified Release Metformin/Saxagliptin Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are the subject of an ANDA or to be the subject of an ANDA that relies on NDA No. 200678 (Kombiglyze XR) or the Therapeutic Equivalent of Kombiglyze XR as the Reference Listed Drug. These Products are orally administered extended release tablets containing, as active pharmaceutical ingredients, metformin hydrochloride and saxagliptin hydrochloride, at the following strengths: 500 mg metformin hydrochloride and EQ 5 mg Base saxagliptin hydrochloride; 1 gm metformin hydrochloride and EQ 5 mg Base saxagliptin; 1 gm metformin hydrochloride and EQ 2.5 mg Base saxagliptin.

42. "Modified Release Methylphenidate CAP Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Applications:

    a. ANDA No. 078458,

    b. ANDA No. 200886;

    and any supplements, amendments, or revisions to this ANDA. These Products are orally administered extended release capsules containing, as an active pharmaceutical ingredient, methylphenidate hydrochloride, and that are the Therapeutic Equivalent of Ritalin LA (NDA No. 021284) at the following strengths: 10 mg; 20 mg; 30 mg; 40mg; 60 mg.

43. "Modified Release Methylphenidate TAB Product(s)" means the following: the Products manufactured, in Development, marketed, sold, that are the subject of an ANDA or to be the subject of an ANDA that relies on NDA No. 021121 (Concerta) or the Therapeutic Equivalent of Concerta as the Reference Listed Drug. These Products are orally administered extended release tablets containing, as an active pharmaceutical ingredient, methylphenidate hydrochloride, at the following strengths: 18 mg; 27 mg; 36 mg; 54 mg.

44. "Modified Release Mirtazapine Product(s)" means the following: the Products

manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 076901, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets (orally disintegrating) containing, as an active pharmaceutical ingredient,

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, nortriptyline hydrochloride at the following strengths: EQ 10 mg Base; EQ 25 mg Base; EQ 50 mg Base; and EQ 75 mg Base.

49. "OC Desogestrel/Ethinyl Estradiol Azurette Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 076916, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, desogestrel and ethinyl estradiol, at the following strengths: 0.15 mg desogestrel and 0.02 mg ethinyl estradiol; 0.01 mg ethinyl estradiol.

50. "OC Desogestrel/Ethinyl Estradiol Caziant Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 077182, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, desogestrel and ethinyl estradiol, at the following strengths: 0.1 mg desogestrel and 0.025 mg ethinyl estradiol; 0.125 mg desogestrel and 0.025 mg ethinyl estradiol; 0.15 mg desogestrel and 0.025 mg ethinyl estradiol.

51. "OC Drospirenone/Ethinyl Estradiol Zarah Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 090081, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, drospirenone and ethinyl estradiol, at the following strength: 3.0 mg drospirenone and 0.03 mg ethinyl estradiol.

52. "OC Estradiol Valerate/Estradiol Valerate/Dienogest Product(s)" means the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 202999, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, estradiol valerate and dienogest, at the following strengths: 3 mg estradiol valerate; 2 mg estradiol valerate and 2 mg dienogest; 2 mg estradiol valerate and 3 mg dienogest; 1 mg estradiol valerate.

53. "OC Ethinyl Estradiol/Ethynodiol Zovia Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 072721, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and ethynodiol diacetate, at the following strength: 0.035 mg ethinyl estradiol and 1 mg ethynodiol diacetate.

the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant the following Application: ANDA No. 078834, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, levonorgestrel and ethinyl estradiol, at the following strengths: 0.15 mg levonorgestrel and 0.03 mg ethinyl estradiol; 0.01 ethinyl estradiol.

65. "OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Lo Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant the following Application: ANDA No. 200407. These Products are orally administered tablets containing, as active pharmaceutical ingredients, levonorgestrel and ethinyl estradiol, at the following strengths: 0.1 mg levonorgestrel; 0.02 mg ethinyl estradiol; 0.01 mg ethinyl estradiol.

66. "OC Levonorgestrel/Ethinyl Estradiol Lutera Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 076625, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, levonorgestrel and ethinyl estradiol, at the following strength: 0.10 mg levonorgestrel and 0.02 mg ethinyl estradiol.

67. "OC Norethindrone Camila Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Barr) pursuant to the following Application: ANDA No. 076177, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, norethindrone, at the following strength: 0.35 mg.

68. "OC Norethindrone Errin Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Barr) pursuant to the following Application: ANDA No. 076225, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, norethindrone, at the following strength: 0.35 mg.

69. "Propranolol Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Pliva) pursuant to

e. ANDA No. 071976;

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, propranolol hydrochloride, at the following strengths: 10 mg; 20 mg; 40 mg; 60 mg; 80 mg.

70. "Ramelteon Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 091693, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, ramelteon, at the following strength: 8 mg.

71. "Rotigotine Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are the subject of an ANDA or to be the subject of an ANDA that relies on NDA No. 021829 (Neupro) or the Therapeutic Equivalent of Neupro as the Reference Listed Drug. These Products are transdermally administered by film (patch) for extended release and contain, as an active pharmaceutical ingredient, rotigotine, at the following strengths: 1 mg/24-hours; 2mg/24-hours; 3 mg/24-hours; 4 mg/24-hours; 6 mg/24-hours; 8 mg/24-hours.

72. "Tamoxifen Product(s)" means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to each of the following Applications:

a. ANDA No. 075797; and

b. ANDA No. 074858;

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, tamoxifen citrate at the following strengths: EQ 10 mg Base; and EQ 20 mg Base.

Development, marketed, or sold, pursuant to the following Application: ANDA No. 077361, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, trimipramine maleate, at the following strengths: EQ 25 mg Base; EQ 50 mg Base; EQ 100 mg Base

all assets related to the Business of Teva within the United States of America related to each of the Carbidopa/Levodopa Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Carbidopa/Levodopa Products.

8.

14. "Diazepam Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Diazepam Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Diazepam Products.

15. "Disopyramide Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Disopyramide Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Disopyramide Products.

16. "Estazolam Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Estazolam Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Estazolam Products.

17. "Estradiol Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Estradiol Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Estradiol Products.

18. "Ethinyl Estradiol/Etonogestrel Vaginal Ring Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Ethinyl Estradiol/Etonogestrel Vaginal Ring Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Ethinyl Estradiol/Etonogestrel Vaginal Ring Products.

19. "Ezetimibe/Simvastatin Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Ezetimibe/Simvastatin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Ezetimibe/Simvastatin Products

20. "Fentanyl Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Fentanyl Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Fentanyl Products; provided, however, "Fentanyl Product Assets" excludes Patents that are owned, controlled or held by Teva on or before the Closing Date related to the Retained Product Fentora® (NDA No. 021947), and such Patents are not included in the Product Licensed Intellectual Property related to the Fentanyl Product(s).

21. "Fluocinonide Emulsified Product Assets" means all rights, title, and interest in and to all assets related to the Business related to the Fluocinonide Emulsified Products to the extent that such rights are owned, controlled, or held by Allergan under the Amended and Restated Supply Agreement by and between Actavis Pharma Inc., Actavis Mid Atlantic LLC, and G&W Laboratories, Inc., dated as of December 19,

2014, as amended February 5, 2015. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.B.

22. "Fluocinonide Product Assets" means all rights, title, and interest in and to all assets related to the Business related to the Fluocinonide Products to the extent that such rights are owned, controlled, or held by Allergan under the Amended and Restated Supply Agreement by and between Actavis Pharma Inc., Actavis Mid Atlantic LLC, and G&W Laboratories, Inc., dated as of December 19, 2014, as amended February 5, 2015. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.A.

23. "Flutamide Product Assets" means all rights, title and interest in and to all assets related to the Business related to the Flutamide Products to the extent that such rights are owned, controlled, or held by Teva under the Supply and Distribution Agreement between Zenith Goldline Pharmaceutical Inc. and Cipla Limited, dated as of May 14, 2001, and all amendments, exhibits, attachments to the Supply and Distribution Agreement executed prior to the termination of this agreement. This agreement was submitted to the Commission by Respondent Teva and is contained in Non-Public Appendix II.D.

24. "Glyburide/Metformin Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Glyburide/Metformin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Glyburide/Metformin Products.

25. "Griseofulvin Product Assets" means all rights, title and interest in and to all assets related to the Business related to the Griseofulvin Products to the extent that such rights are owned, controlled, or held by Teva under the Development and Supply Agreement between Ivax Pharmaceutical, Inc. and Cipla Ltd., dated as of January 3, 2004, and all amendments, exhibits, attachments to the Development and Supply Agreement executed prior to the termination of this agreement. This agreement was submitted to the Commission by Respondent Teva and is contained in Non-Public Appendix II.D.

26. "Hydroxyzine Pamoate Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Hydroxyzine Pamoate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Hydroxyzine Pamoate Products.

27. "Imiquimod Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Imiquimod Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Imiquimod Products.

28. "Injectable Epirubicin Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America

related to each of the Injectable Epirubicin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Injectable Epirubicin Products.

29. "Injectable Fludarabine Product Assets" means all rights, title, and interest in and to all assets related to

36. "Modified Release Amphetamine Sulfate Product Assets" means all rights, title and interest in and to all assets related to the Business related to the Amphetamine Sulfate Products to the extent that such rights are owned, controlled, or held by Teva under the Adderall XR Distribution and Supply Agreement by and between Shire LLC and Teva Pharmaceuticals USA, Inc., dated as of November 8, 2013 and all amendments, exhibits, attachments to the Adderall XR Distribution and Supply Agreement executed prior to the termination of this agreement by Teva and its re-execution by an Acquirer. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.J.

37. "Modified Release Aspirin/Dipyridamole Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Modified Release Aspirin/Dipyridamole Product Assets, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Aspirin/Dipyridamole Products.

38. "Modified Release Clarithromycin Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Modified Release Clarithromycin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Clarithromycin Products.

39. "Modified Release Dexmethylphenidate Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Modified Release Dexmethylphenidate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Dexmethylphenidate Products.

40. "Modified Release Dextroamphetamine Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Modified Release Dextroamphetamine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Dextroamphetamine Products.

41. "Modified Release Metformin/Saxagliptin Product Assets" means all rights, title, and interes(i)-2317-1(f)9(o)1TJ 0.002 Tc -0.02(,)2iedl (sset)-1(s)5(r)-1e(l)4(at)-1(e)5 Tc -0.02(,)

Products, to the extent legally transferable, including, without limitation, the Produ t(A)3(sset)-1(s" m)9(ean)1(s al41(l)-0.9 (r)-1(i)-1(g)1(h)6(t)-1(s(is,)1(t)-1(i)-1(t)4(l)-1(e,)1

43. "Modified Release Methylphenidate TAB Product Assets" means all rights, title and interest in and to all assets related to the Business related to the Modified Release Methylphenidate TAB Products to the extent that such rights are owned, controlled, or held by Teva pursuant to the Strategic Alliance Agreement between Teva Pharmaceuticals Curacao N.V. and Impax Laboratories, Inc. dated as of June 27, 2001, and all amendments, exhibits, attachments to the Strategic Alliance Agreement to the extent related to the Methylphenidate TAB Products executed prior to the termination of this agreement as it pertains to the Methylphenidate TAB Products. This agreement was submitted to the Commission by Respondent Teva and is contained in Non-Public Appendix II.B.

44. "Modified Release Mirtazapine Product Assets" means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Modified Release Mirtazapine Products, to the

United States of America related to each of the OC Ethinyl Estradiol/Levonorgestrel Sronyx Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Levonorgestrel Sronyx Products which include all rights to the Sronyx® Product Trademark.

57. "OC Ethinyl Estradiol/Levonorgestrel Trivora Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Levonorgestrel Trivora Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Levonorgestrel Trivora Products which include all rights to the Trivora® OC ntvrii4(i)-1(

Tilia Fe Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Norethindrone Tilia Fe Products which include all rights to the Tilia® Product Trademark.

63. "OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Product Assets" means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Products which include all rights to the Low

68. “OC Norethindrone Errin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to OC Norethindrone Errin

76. "Development Divestiture Product Assets" means each of the Development Divestiture Product Assets as defined in Non-Public Appendix IV.

JJ. "Divestiture Product Core Employees" means the Product Research and Development Employees and the Product Manufacturing Employees related to each Contract Manufacture Product.

KK. "Divestiture Product License" means a perpetual, non-exclusive, fully paid-up, and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, held, or controlled by a Respondent:

1. to research and Develop the specified Divestiture Product(s) for marketing, distribution, or sale within the United States of America;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the United States of America;
3. to import or export the specified Divestiture Product(s) to or from the United States of America to the extent related to the marketing, distribution, or sale of the specified Divestiture Products in the United States of America; and
4. to have the specified Divestiture Product(s) made anywhere in the world for distribution or sale within, or import into the United States of America;

provided, however, that for any Product Licensed Intellectual Property or Product Manufacturing Technology that is the subject of a license from a Third Party entered into by a Respondent prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to that Respondent.

LL. "Divestiture Product Releasee(s)" means the following Persons:

1. the Acquirer for the assets related to a particular Divestiture Product;
2. any Person controlled by or under common control with that Acquirer;
3. Clinical Trial Research Organization Designee(s); and
4. any Manufacturing Designee(s), licensees, sublicensees, manufacturers, supplieto1( )5(l)-1(i)tur Re

OO. "Drug Master File(s)" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

PP. "Dr. Reddy's" means Dr. Reddy's Laboratories S.A., a corporation organized, existing, and doing business under and by virtue of the laws of the Swiss Confederation with its principal executive offices located at Elisabethenanlage 11, 4051 Basel, Switzerland.

QQ. "G & W Laboratories" means G & W Laboratories, a corporation organized, existing, and doing business under and by virtue of the laws of the State of New Jersey with its principal executive offices located at 111 Coolidge Street, South Plainfield, New Jersey 07080-3895.

RR. "Good Clinical Practices" means then-current standards, practices and promulgated or endorsed by (i) International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use; (ii) the FDA; and (iii) any applicable Laws for the country(ies) within which a Clinical Trial is being conducted.

SS. "Government Entity" means any Federal, state, local, or non-U.S. government; any court, legislature, government agency, or government commission; or any judicial or regulatory authority of any government.

TT. "Group A Product(s)" means the following Divestiture Products, individually and collectively:

1. Carbidopa/Levodopa Products;
2. Clonidine Products;
3. Clozapine Products;
4. Clozapine II Products;
5. Cyclosporine Products;
6. Cyclosporine LIQ Products;
7.

VV. “Group A Product Divestiture Agreements” means the following:

1. Asset Purchase Agreement between Teva Pharmaceutical Industries Ltd., Mayne Pharma LLC, and Mayne Pharma Inc., dated as of June 27, 2016;
2. Supply Agreement between Teva Pharmaceutical Industries Ltd. and Mayne Pharma Inc., attached to the preceding Asset Purchase Agreement;
3. Asset Purchase Agreement teTj /TT0 18Td ( )Tj [-2(o teTj /TT0 18Td ( )J [V..oM22m)2(

13. Modified Release Aspirin/Dipyridamole Products;
14. Modified Release Dexmethylphenidate Products;
15. Modified Release Methylphenidate TAB Products;
16. Modified Release Mirtazapine Products;
17. Nabumetone Products;
18. Nitrofurantoin Products; and
19. Propranolol Products.

XX. "Group B Product Assets" means the following Divestiture Product Assets, individually and collectively:

1. Acitretin Product Assets;
2. Alendronate Product Assets;
3. Budesonide INH Product Assets;
4. Buspirone Product Assets;
5. Desmopressin Product Assets;
6. Development One Product Assets;
7. Fluocinonide Emulsified Product Assets;
8. Glyburide/Metformin Product Assets;
9. Hydroxine Pamoate Product Assets;
10. Injectable Epirubicin Product Assets;
11. Levalbuterol Product Assets;
12. Metoclopramide Product Assets;
13. Modified Release Aspirin/Dipyridamole Product Assets

2. Supply Agreement between Teva Pharmaceutical Industries Ltd. and Impax Laboratories, Inc., attached to the preceding Asset Purchase Agreement;

3. Asset Purchase Agreement among Actavis Elizabeth LLC, Actavis Group PTC EHF, Actavis Holdco US, Inc., Actavis LLC, Actavis Mid Atlantic LLC, Actavis Pharma, Inc., Actavis South Atlantic LLC, Andrx LLC, Breath Ltd., The Rugby Group, Inc., Watson Laboratories, Inc. and Impax Laboratories, Inc., dated as of June 20, 2016;

4. Supply Agreement among Actavis Elizabeth LLC, Actavis Group PTC EHF, Actavis Holdco US, Inc., Actavis LLC, Actavis Mid Atlantic LLC, Actavis Pharma, Inc., Actavis South Atlantic LLC, Andrx LLC, Breath Ltd., The Rugby Group, Inc., Watson Laboratories, Inc. and Impax Laboratories, Inc., attached to the preceding Asset Purchase Agreement;

5. Termination of Agreements (Methylphenidate HCL ER) by and between Impax Laboratories, Inc. and Teva Pharmaceuticals USA, Inc., dated as of June 20, 2016; and

6. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group B Product Divestiture Agreements are contained in Non-Public Appendix II.B. The Group B Product Divestiture Agreements that have been approved by the Commission

3. Asset Purchase Agreement among Actavis Group PTC EHF, Actavis LLC and Sagent Pharmaceuticals, Inc., dated as of June 15, 2016;

4. Supply Agreement among Actavis Group PTC EHF, Actavis LLC and Sagent Pharmaceuticals, Inc. attached to the preceding Asset Purchase Agreement; and

5. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group C Product Divestiture Agreements are contained in Non-Public Appendix II.C. The Group C Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

CCC. "Group D Product(s)" means the following Divestiture Products, individually and collectively:

1. Flutamide Products;

2. Griseofulvin Products; and

3. Injectable Paclitaxel Products.

DDD. "Group D Product Assets" means the following Divestiture Product Assets, individually and collectively:

1. Flutamide Product Assets;

2. Griseofulvin Product Assets; and

3. Injectable Paclitaxel Product Assets.

EEE. "Group D Product Divestiture Agreements" means the following:

1. Buy-Back of Asset by and between Pharmachemie B.V. and Cipla Limited, dated as of June 9, 2016, that makes reference to the Development, License, Manufacture and Commercial Supply Agreement by and between Pharmachemie B.V. and Cipla Limited dated as of October 1, 2014.
2. Sale of ANDA Documentation and Termination of related Agreements (Griseofulvin OS Microcrystalline and Flutamine Capsules) between Teva Pharmaceuticals USA, Inc., Ivax Pharmaceuticals NV, LLC, and Cipla Limited, dated as of June 15, 2016; and
3. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group D Product Divestiture Agreements are contained in Non-Public Appendix II.D. The Group D Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

FFF. "Group E Product(s)" means the following Divestiture Products, individually and collectively:

1. Minocycline Products; and
2. Rotigotine Products.

GGG. "Group E Product Assets" means the following Divestiture Product Assets, individually and collectively:

1. Minocycline Product Assets; and
2. Rotigotine Product Assets.

HHH. "Group E Product Divestiture Agreements" means the following:

1.

The Group E Product Divestiture Agreements are contained in Non-Public Appendix II.E. The Group E Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

III. "Group F Product(s)" means the following Divestiture Products, individually and collectively:

1. Buprenorphine/Naloxone Products;
2. Ethinyl Estradiol/Etonogestrel Vaginal Ring Products;
3. Ezetimbe/Simvastin Products;
4. Imiquimod Products;
5. Modified Release Metformin/Saxagliptin Products;
6. Modified Release Phentermine/Topiramate Products;
7. Ramelteon Products; and
8. Tobramycin Products.

JJJ. "Group F Product Assets" means the following Divestiture Product Assets, individually and collectively:

1. Buprenorphine/Naloxone Product Assets;
2. Ethinyl Estradiol/Etonogestrel Vaginal Ring Product Assets;
3. Ezetimbe/Simvastin Product Assets;
4. Imiquimod Product Assets;
5. Modified Release Metformin/Saxagliptin Product Assets;
6. Modified Release Phentermine/Topiramate Product Assets;
7. Ramelteon Product Assets; and
8. Tobramycin Product Assets.

KKK. "Group F Product Divestiture Agreements" means the following:

1. Asset Purchase Agreement between Teva Pharmaceutical Industries Ltd. and Dr. Reddy's Laboratories S.A., dated as of June 10, 2016;
2. Supply Agreement between Teva Pharmaceutical Industries Ltd. and Dr. Reddy's Laboratories S.A., attached to the preceding Asset Purchase Agreement;
3. Asset Purchase Agreement between Watson Laboratories, Inc. and Dr. Reddy's ;

4. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group F Product Divestiture Agreements are contained in Non-Public Appendix II.F. The Group F Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

LLL. "High Volume Account(s)" means any retailer, wholesaler, or distributor whose annual or projected annual purchase amounts, in units or in dollars, of a Divestiture Product in the United States of America from a Respondent, was or was forecasted (prior to the contemplation of the Acquisition and subsequent divestiture) to be among the top twenty (20) highest such purchase amounts of that Respondent's total sales of that Divestiture Product to U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; (iv) for forecasts of purchases of the Divestiture Product

Prasco, LLC and dated as of June 16, 2016; and

2. Termination of Distribution and Supply Agreement by Teva Pharmaceuticals USA, Inc., accepted and agreed to by Shire LLC, dated as of June 16, 2016, that makes reference to the Adderall XR Distribution and Supply Agreement, by and between Shire LLC and Teva Pharmaceuticals USA, Inc., dated as of November 8, 2013, (and which is necessary to effect the divestiture to Prasco, LLC).

The Modified Release Amphetamine Sulfate

AAAA. "Pipeline External Manufacture Products" means, the following Divestiture Products, individually and collectively:

1. Budesonide INH Products (ANDA Number 202558);
2. Buprenorphine/Naloxone Products;
3. Cyclosporine Liquid Products;
4. Development Two Products;
5. Injectable Paclitaxel Products;
6. Fluocinonide Products;
7. Imiquimod Products;
8. Modified Release Dexmethylphenidate Products;
9. Ramelteon Products;
10. Rotigotine Products; and
11. Tobramycin Products.

BBBB. "Pipeline Internal Manufacture Products" means, the following Divestiture Products, individually and collectively:

1. Clozapine II Products;
2. Ethinyl Estradiol/Etonogestrel Vaginal Ring Products;
3. Ezetimibe/Simvastatin Products;
4. Fentanyl Products;
5. Injectable Methotrexate Products;
6. Modified Release Aspirin/Dipyridamole Products;
7. Modified Release Metformin/Saxagliptin Products;
8. Modified Release Phentermine/Topiramate Products;
9. OC Ethinyl Estradiol/Levonorgestrel Products; and
10. OC Estradiol Valerate/Estradiol Valerate/Dienogest Products.

CCCC. "Prasco" means Prasco LLC, a corporation organized, existing and doing business under and by virtue of the laws of the State of Ohio with its principal executive offices located at 6125 Commerce Court, Mason, Ohio 45040.

DDDD. "Product(s)" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.

EEEE. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents,

12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture,

HHHH. “Product Development Reports” means:

1. pharmacokinetic study reports related to the specified Divestiture Product;
2. bioavailability study reports (including Reference Listed Drug information) related to the specified Divestiture Product;
3. bioequivalence study reports (including Reference Listed Drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from, or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including m(s)4(t5iTa5 0 3s)-1(b)Tj [(i)-2(oe)-

16. analytical methods development records related to the specified Divestiture Product;

17. manufacturing batch records related to the specified Divestiture Product;

18. stability testing records related to the specified Divestiture Product;

19. change in control history related to the specified Divestiture Product; and

20. executed validation and qualification protocols and reports related to the specified Divestiture Product.

IIII. "Product Employee Information" means the following, for each Divestiture Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by a Respondent a co9(tu)tne co9(tu)tpg, f1hrrP1(l)-2(udrT1 1 7( )TD 400.001 Tw (nc)-11(l)-2(A)c-2(i)-2(pr)-2(nt

1. Patents;
2. Product Copyrights;
3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and
4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof.

have directly participated in any of the following: (i) defining the commercial manufacturing process, (ii) confirming that the manufacturing process is capable of reproducible commercial manufacturing, (iii) formulating the manufacturing process performance qualification protocol, (iv) controlling the manufacturing process to assure performance Product quality, (iv) assuring that during routine manufacturing the process remains in a state of control, (v) collecting and evaluating data for the purposes of providing scientific evidence that the manufacturing process is capable of consistently delivering quality Products, (vi) managing the operation of the manufacturing process, or (vii) managing the technological transfer of the manufacturing process to a different facility, of the Product Manufacturing Technology of the specified Divestiture Product

other similar materials related to the specified Divestiture Product.

OOOO.

VVVV. “Remedial Agreement(s)” means the following:

1. any agreement between a Respondent

3. Product Scientific and Regulatory Material;

for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.

YYYY.

1. designating employees of a Respondent knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery;

2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;

3. preparing and implementing a detailed technological transfer plan that contains, inter alia, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee;

4. permitting employees of the relevant Acquirer to visit the Respondent's facility from which the Divestiture Product will be transferred for the purposes of evaluating and learning the manufacturing process of such Divestiture Product and/or discussing the process with employees of Respondent involved in the manufacturing process (including, without limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, methods to ensure batch consistency), pharmaceutical development, and validation of the manufacturing of the Divestiture Product at the Respondent's facility; and

5. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:

    a. manufacture the specified Divestiture Product in the quality and quantities achieved by a Respondent, or the manufacturer and/or developer of such Divestiture Product;

    b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and

    c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

DDDDD. "Teva Limited License" means a non-exclusive and non-renewable license to Teva to the Product Intellectual Property, the Product Manufacturing Technology, the Product Marketing Materials, the content that is displayed on any Website (to the extent any

related to the marketing, distribution, or sale of these Products in the United States of America; and (iii) to use any Confidential Business Information related to the Modified Release Methylphenidate CAP Product(s), but solely as is necessary to give effect to this license. The Teva Limited License shall terminate on or before the date three (3) years after the Closing Date for the Modified Release Methylphenidate CAP Product(s).

The Teva Limited License is contained in Non-Public Appendix II.A. to this Order.

EEEEE. "Therapeutic Equivalent" means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.

FFFFF. "3M" means 3 M Company a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at 3M Center, St. Paul, Minnesota 55144.

GGGGG. "Trimipramine Product Divestiture Agreements" means Termination of the Asset Purchase Agreement and Master Supply Agreement by Actavis LLC, accepted and agreed to by Mikah Pharma LLC, dated as of May 25, 2016, that makes reference to both the Asset Purchase Agreement by and between Actavis LLC (assignee of Actavis Totowa LLC and Mikah Pharma LLC, dated as of June 16, 2010, as amended August 27, 2012, and the Supply and Distribution Agreement by and between Actavis LLC and Mikah Pharma LLC, dated as of November 21, 2011. The Trimipramine Product Divestiture Agreements are contained in Non-Public Appendix II.I. The Trimipramine Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

HHHHH. "Third Party(ies)" means any non-governmental Person other than the following: a Respondent; or an Acquirer of particular assets or rights pursuant to this Order.

IIIII. "United States of America" means the United States of America, and its territories, districts, commonwealths and possessions.

JJJJJ. "Website" means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by a Respondent; provided, however, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), except to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

KKKKK. "Zydus" means Zydus Worldwide DMCC, a corporation organized, existing and doing business under and by virtue of the rules and regulations of Dubai Multi Commodities Center Authority. "Zydus" also includes Zydus Pharmaceuticals (USA) Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey with its principal executive offices located at 73 Route 31 N, Pennington, New Jersey 08534. Zydus Pharmaceuticals (USA) Inc. is a step down subsidiary of Cadila Healthcare Limited.

Impax prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Impax is not an acceptable purchaser of any of the Group B Product Assets, then Respondents shall immediately rescind the transaction with Impax, in whole or in part, as directed by the Commission, and shall divest the relevant Group B Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Group B Product Assets to Impax prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Group B Product Assets to Impax (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

C. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group C Product Assets and grant the Divestiture Product Licenses related to the Group C Products, absolutely and in good faith, to Sagent pursuant to, and in accordance with, the Group C Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Sagent or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Group C Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Group C Product Assets to

D. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group D Product Assets and grant the Divestiture Product Licenses related to the Group D Products, absolutely and in good faith, to Cipla pursuant to, and in accordance with, the Group D

provided, however, that if Respondents

Allergan under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Trimipramine Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent Allergan has divested the Trimipramine Product Assets to Mikah Pharma prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Allergan that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Allergan, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Trimipramine Product Assets to Mikah Pharma (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

J. Not later than ten (10) days after the Acquisition Date, Respondent Teva shall divest the

directly with each of the relevant Third Parties.

M. Respondents shall:

1. submit to each Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;

2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:

   a. in good faith;

   b. in a timely manner, i.e., as soon as practicable, avoiding any delays in transmission of the respective information; and

   c. in a manner that ensures its completeness and accuracy and ..705 -1(s)-1(oen)6(su)finteeIn

P. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent Teva shall:

1. upon reasonable written notice and request from the Acquirer to Respondent Teva, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Supply Cost, for a period of time sufficient to allow the Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished dosage form drug product independently of Respondent Teva, and to secure sources of supply of the active pbef activecy r-1(n not)-2(i)-2(ce)-2(v)-T6(r)-1(c)5(v)-T6()(

4. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondent Teva's own use or

Divestiture Product for a period of at least four (4) years after the Closing Date at a price not to exceed the prices contained in the relevant binding letters of intent submitted by Respondent Teva to the Commission;

2. at the Acquirer's option, the quantity shall be for commercial quantities;

3. the manufacturing and delivery of the active pharmaceutical ingredient(s) by Respondent Teva to the Acquirer shall be in a timely manner;

4. in the event any pu

R. For each Acquirer, Respondent Teva shall designate employees of Respondent Teva knowledgeable about the marketing, distribution, warehousing, and sale (including administrative logistics of sales to the respective High Volume Accounts) related to each of the Divestiture Products to assist the Acquirer, in the transfer and integration of the Business related to the Divestiture Products into the Acquirer's business.

S. Respondents shall require, as a condition of continued employment post-divestiture of the Divestiture Product Assets, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of the Respondents (other than as necessary to comply with the requirements of this Order).

T. Not later than thirty (30) days after the Closing Date, each Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Each Respondent

2.

scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that this Paragraph does not require nor shall be construed to require a Respondent to terminate the employment of any employee or to prevent a Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year after the Closing Date, not: (i) directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or (ii) hire any Divestiture Product Employee;

provided, however, a Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing
Dr 12.915 rmnt

rs ont.515 -2(e)rrit (m)10(p)2(lo)2(f)5rrommnt
2.7920 Td ( )T5 EMC /H-(105 0 Td(")Tj --6.2pon /T001 Tw(V.1 Tf3 <2)-1(e).1(1.08 00( )58 0 T-1(r)]-1(v)-1(e)358 0 T

2. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in this Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses related to that Divestiture Product.

W. Respondents shall not, in the United States of America:

1. use any of the Product Trademarks related to Divestiture Products or any mark confusingly similar to the Product Trademarks as a trademark, tradename, or service mark except as may be necessary to sell stocks of Divestiture Products in existence as of the Acquisition Date;

2. attempt to register the Product Trademarks;

3. attempt to register any mark confusingly similar to the Product Trademarks;

4. challenge or interfere with an Acquirer's use and registration of the Product Trademarks acquired by that Acquirer; or

5. challenge or interfere with an Acquirer's efforts to enforce its trademark registrations for and trademark rights in the relevant Product Trademarks against Third Parties.

X. For each Acquirer of a Pipeline External Manufacture Product or Pipeline Internal Manufacture Product that requires a Clinical Trial(s) prior to receiving final FDA approval of the Application related to that Pipeline External Manufacture Product or Pipeline Internal Manufacture Product, as applicable, Respondents shall:

1. designate employees of the Respondents that have worked on or been involved in the planning of such Clinical Trial(s) who will be responsible for communicating directly with the Acquirer and/or its Clinical Research Organization Designee(s), and the Interim Monitor (if one has been appointed), for the purpose of effecting any transition agreed upon between the Respondents and the Acquirer for the purposes of ensuring the continued prosecution of such Clinical Trials in a timely manner;

2. coordinate with the Acquirer to prepare any protocols necessary to transfer the Clinical Trials to the Acquirer or the Acquirer's Clinical Research Organization Designee(s);

3. assist the Acquirer to prepare and implement any Clinical Plan(s) and Regulatory Package(s) for the Clinical Trial until either (i) the completion of the trial, or (ii) such other event as the Respondent and the Acquirer agree upon in a Remedial Agreement related to the Divestiture Product;

4. prepare and implement a detailed transfer plan that contains, inter alia, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such information related to such Clinical Trial(s) to the Acquirer and/or its Clinical Research Organization Designee(s); and

5. provide, in a timely manner, assistance and advice to enable the Acquirer and/or its

Clinical Research Organization Designee(s) to commence or continue such Clinical Trial in the same quality, scope, and pace as was planned or being achieved by the specified Respondent

Z. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America.

AA. For any patent infringement suit filed prior to the Closing Date in which a Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that a Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within t Clnna las of the Cl

provided, however

Teva that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Teva, or appoint a Divestiture Trustee, to effect such modifications to the manner of the supply of the Armodafinil Products with Aurobindo (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

B. Respondent Teva shall, in connection with any Remedial Agreement by Respondent Teva to supply the Armodafinil Products to an Acquirer,

1. not later than ten (10) days after the Acquisition Date, deliver, absolutely and in good faith, to that Acquirer sufficient commercial quantities of the Armodafinil Products in final dosage form and packaged for sale to the ultimate consumer/patient by the Acquirer (including all Acquirer approved packaging) in

penalty incurred by an Acquirer from a customer directly related to that Acquirer's inability to supply the Divestiture Product to that customer that was the result of

3. at the API Customer’s option, the quantity shall be for

B. Not later than ten (10) days from the Order Date, Respondent Teva shall notify each of the API Customers of their right to enter into a contract to purchase the API Products with Respondent Teva under the terms described in this Order. Such notifications shall be sent by certified mail with return receipt requested to (i) the employee(s) of the API Customer that have submitted the most recent purchase orders for the API Product to Respondent Teva, and (ii) the Chief Executive Officer and the General Counsel of the API Customer.

C. Not later than ten (10) days after a request by any API Customer to negotiate a contract with Respondent Teva to supply the API Products to that API Customer under the terms described in this Order, Respondent Teva shall notify the Commission of the request.

D. Not later than ten (10) days after the date of the execution of a contract with Respondent Teva to supply the API Products to an API Customer under the terms described in this Order, Respondent Teva shall submit a copy of that contract to the Commission.

E. The obligations in this Paragraph IV shall only apply to the supply of API Products to be used in the manufacture of API Finished Dosage Form Product(s) that will be marketed or sold in the United States of America.

F. The purpose of the provisions of this Order related to the supply of the API Products is to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner and to ensure that none of the API Customers are subjected to an unfair method of competition due to the Acquisition because of their reliance upon Respondent Teva as a source for their API Products.

V.

IT IS FURTHER ORDERED that:

A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Monitor") to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreements.

B. The Commission shall select the Monitor, subject to the consent of Respondent Teva, which consent shall not be unreasonably withheld. If Respondent Teva has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Teva of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.

C. Not later than ten (10) days after the appointment of the Monitor, Respondent Teva shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor each Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

D. If a Monitor is appointed, each Respondent shall consent to the following terms and

conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:

1. The Monitor shall have the power and authority to monitor each Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor

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.

H. Each Respondent shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by each Acquirer with respect to the performance of a Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by a Respondent of its obligations under the Order; provided, however, beginning ninety (90) days after Respondent Teva has filed its final report pursuant to Paragraph IX.C., and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Teva.

VI.

IT IS FURTHER ORDERED that:

A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver,

2. The Divestiture Trustee shall have one (1) year after th

VII.

IT IS FURTHER ORDERED

include in the Remedial Agreement(s) related to that Divestiture Product a representation

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by Respondent Teva to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and

2. a detailed description of the timing for the completion of such obligations.

D. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form

XII.

IT IS FURTHER ORDERED that Respondent Alle5(da-1(nt’v)-2)-1(p ob)-2RED

XIV.

IT IS FURTHER ORDERED that this Order shall terminate on the date ten (10) years after the Order Date.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED:

NON-PUBLIC APPENDIX I
ACQUISITION AGREEMENT
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II.A
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP A DIVESTITURE PRODUCTS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II.B
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP B DIVESTITURE PRODUCTS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II.C
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP C DIVESTITURE PRODUCTS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II.D
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP D DIVESTITURE PRODUCTS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II.E
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP E DIVESTITURE PRODUCTS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II.F
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP F DIVESTITURE PRODUCTS

NON-PUBLIC APPENDIX II.G.
AGREEMENTS RELATED TO THE DIVESTITURE
OF THE BENZOYL PEROXIDE/CLINDAMYCIN PRODUCTS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II.H
AGREEMENTS RELATED TO THE DIVESTITURE
OF THE DEVELOPMENT TWO PRODUCTS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II.I
AGREEMENTS RELATED TO THE DIVESTITURE
OF THE TRIMIPRAMINE PRODUCTS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX II.J
AGREEMENTS RELATED TO THE DIVESTITURE
OF THE MODIFIED RELEASE AMPHETAMINE SULFATE PRODUCTS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX III
ARMODAFINIL SUPPLY AGREEMENT
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX IV
DEVELOPMENT DIVESTITURE PRODUCTS
DEVELOPMENT DIVESTITURE PRODUCT ASSETS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX IV
DEVELOPMENT DIVESTITURE PRODUCTS
DEVELOPMENT DIVESTITURE PRODUCT ASSETS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX V
LETTERS OF INTENT RELATED TO THE PURCHASE OF THE ACTIVE PHARCEUTICAL INGREDIENTS USED IN CERTAIN DIVESTITURE PRODUCTS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]

NON-PUBLIC APPENDIX VI
API FINISHED DOSAGE FORM PRODUCTS:
FLUOCINOLONE PRODUCTS
FLUOROURACIL PRODUCTS
[Cover Page]
[Redacted From the Public Record Version, But Incorporated By Reference]