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FEDERAL TRADE COMMISSION

[File No. 151 0196]

Teva Pharmaceutical Industries Ltd. and Allergan plc; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders -- embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before August 29, 2016.

ADDRESSES: Interested parties may file a comment at https://ftcpublic.commentworks.com/ftc/tevaallerganconsent online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "In the Matter of Teva Pharmaceutical Industries Ltd. and Allergan plc, File No. 151-0196, C-4589- Consent Agreement" on your comment and file your comment online at https://ftcpublic.commentworks.com/ftc/tevaallerganconsent by following the instructions on the web-based form. If you prefer to file your comment on paper, write "In the Matter of Teva Pharmaceutical Industries Ltd. and Allergan plc, File No. 151-0196, C-4589- Consent Agreement" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to

the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Michael Moiseyev (202-326-3106), Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for July 27, 2016), on the World Wide Web, at http://www.ftc.gov/os/actions.shtm.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 29, 2016. Write "In the Matter of Teva Pharmaceutical Industries Ltd. and Allergan plc, File No. 151-0196, C-4589- Consent Agreement" on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at http://www.ftc.gov/os/publiccomments.shtm. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or

foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at https://ftcpublic.commentworks.com/ftc/tevaallerganconsent by following the instructions on the web-based form. If this Notice appears at http://www.regulations.gov/#!home, you also may file a comment through that website.

If you file your comment on paper, write "In the Matter of Teva Pharmaceutical Industries Ltd. and Allergan plc, File No. 151-0196, C-4589- Consent Agreement" on your

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at http://www.ftc.gov to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before August 29, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at http://www.ftc.gov/ftc/privacy.htm.

Analysis of Agreement Containing Consent Orders to Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Teva Pharmaceutical Industries Ltd. ("Teva") and Allergan plc ("Allergan"), which is designed to remedy the anticompetitive effects resulting from Teva's proposed acquisition of Allergan's generic pharmaceutical business. The proposed Consent Agreement requires the parties (1) to divest rights and assets related to pharmaceutical markets for one or more strengths of seventy-nine pharmaceutical products and (2) provide certain Teva active pharmaceutical ingredient ("API") customers that market one or more of fifteen pharmaceutical products with the option to enter into long-term API supply contracts.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order ("Order").

On July 26, 2015, Teva proposed to acquire Allergan's generic pharmaceutical business for approximately $40.5 billion. The Commission alleges in its Complaint that the proposed acquisition, if consummated, would violate 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, by lessening current or future competition in pharmaceutical markets for one or more strengths of ninety-four pharmaceutical products in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

I. The Products and Structure of the Markets

a. Horizontal Competition in Pharmaceutical Markets

Generic drugs are chemically and therapeutically equivalent to branded drugs. When a physician prescribes a particular branded drug, a pharmacy may only dispense that branded drug or its generic equivalent, which is "AB-rated" to the branded product. State laws permit or require pharmacies to automatically substitute the generic equivalent for the prescribed branded drug unless a physician expressly states not to do so.

The 1984 Hatch-Waxman Act provides the statutory framework for the Food and Drug Administration ("FDA") to approve generic drugs. Under Hatch-Waxman, a generic drug

manufacturer can rely on an already-approved branded drug's safety and efficacy data in its own application—called an Abbreviated New Drug Application ("ANDA")—to the FDA, substantially lowering the research and development cost of the generic drug. Upon FDA approval, a generic drug typically launches at a discount to the branded drug's price. When there is only one generic drug on the market, the branded drug usually competes with the generic drug on price, either directly or through an authorized generic version. As subsequent generic drugs launch, a generic-only market typically forms, with competition among generics driving pricing. When multiple generic drugs are available, customers usually substitute between the generics only—not the branded drug—and solicit bids exclusively from generic drug suppliers.

Teva's proposed acquisition of Allergan's generic pharmaceutical business will lessen current or future competition by reducing the number of current or future suppliers in the pharmaceutical markets for one or more strengths of seventy-nine pharmaceutical products. Those markets fall into three categories: (1) current competition between Teva and Allergan; (2) future competition between Teva and Allergan in an existing generic market; and (3) future competition between Teva and Allergan in a future generic market (*i.e.*, the generic market has not yet formed and only the branded drug is on the market). Absent a remedy, the proposed acquisition would reduce the number of suppliers in each market as indicated below.

- **Current Competition between Teva and Allergan, 2-to-1 Supplier Consolidation**
    - Armodafinil Oral Tablet, 200 mg
    - Desogestrel/Ethinyl Estradiol Oral Tablet, 0.025/0.1 mg then 0.025/0.125 mg then 0.025/0.15 mg (AB-rated to Cyclessa)
    - Estazolam Oral Tablet, 1 mg

- Estazolam Oral Tablet, 2 mg
- Ethinyl Estradiol/Ethynodiol Diacetate Oral Tablet, 0.035/1mg (AB-rated to Demulen 1/35)
- Ethinyl Estradiol/Norethindrone Oral Tablet, 0.035/1mg (AB-rated to Tri-Norinyl 28-Day)
- Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.02/0.03/0.035/1/1/1 mg (AB-rated to Estrostep FE)
- Metoclopramide HCl Oral Tablet, 5 mg
- Trimipramine Maleate Oral Capsule, 25 mg
- Trimipramine Maleate Oral Capsule, 50 mg
- Trimipramine Maleate Oral Capsule, 100 mg

- **Current Competition between Teva and Allergan, 3-to-2 Supplier Consolidation**
  - Budesonide Inhalation Suspension, 0.25 mg/2 mL
  - Budesonide Inhalation Suspension, 0.5 mg/2 mL
  - Clarithromycin Extended Release Oral Tablet, 500 mg
  - Clonidine HCl Extended Release Transdermal Film, 0.1 mg/24 hr
  - Clonidine HCl Extended Release Transdermal Film, 0.2 mg/24 hr
  - Clonidine HCl Extended Release Transdermal Film, 0.3 mg/24 hr
  - Cyclosporine Oral Solution, 100 mg/mL

- Desmopressin Acetate Oral Tablet, 0.1 mg
- Desogestrel/Ethinyl Estradiol/Ethinyl Estradiol Oral Tablet, 0.15/0.02 mg/0.01 mg (AB-rated to Mircette)
- Disopyramide Phosphate Oral Capsule, 100 mg
- Disopyramide Phosphate Oral Capsule, 150 mg
- Estradiol Oral Tablet, 0.5 mg
- Estradiol Oral Tablet, 1 mg
- Estradiol Oral Tablet, 2 mg
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.1mg (AB-rated to Levlite-28)
- Ethinyl Estradiol/Levonorgestrel Oral Tablet 0.03/0.04/0.03/0.05/0.075/0.125 mg (AB-rated to Triphasil-28)
- Ethinyl Estradiol/Norethindrone Oral Tablet, 0.035/0.5mg (AB-rated to Modicon 28)
- Ethinyl Estradiol/Norgestrel Oral Tablet, 0.03/0.3mg (AB-rated to Lo/Ovral-28)
- Fludarabine Lyopholized Vial Injection, 50 mg
- Fluocinonide Topical Cream, 0.05%
- Flutamide Oral Capsule, 125 mg
- Griseofulvin Microcrystalline Oral Liquid Suspension, 125 mg/5 mL

- Metoclopramide HCl Oral Tablet, 10 mg
- Mirtazapine Oral Disintegrating Tab, 15 mg
- Mirtazapine Oral Disintegrating Tab, 30 mg
- Mirtazapine Oral Disintegrating Tab, 45 mg
- Nabumetone Oral Tablet, 500 mg
- Nabumetone Oral Tablet, 750 mg
- Nortriptyline HCl Oral Capsule, 10 mg
- Nortriptyline HCl Oral Capsule, 25 mg
- Nortriptyline HCl Oral Capsule, 50 mg
- Nortriptyline HCl Oral Capsule, 75 mg
- Tamoxifen Citrate Oral Tablet, 10 mg
- Tamoxifen Citrate Oral Tablet, 20 mg
- Trimethoprim Oral Tablet, 100 mg

- **Current Competition between Teva and Allergan, 4-to-3 Supplier Consolidation**
  - Acitretin Oral Capsule, 17.5 mg
  - Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 5 mg
  - Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 10 mg

- Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 15 mg
- Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 20 mg
- Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 25 mg
- Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 30 mg
- Carbidopa/Levodopa Oral Tablet, 10/100 mg
- Carbidopa/Levodopa Oral Tablet, 25/100 mg
- Carbidopa/Levodopa Oral Tablet, 25/250 mg
- Cyclosporine Oral Capsule, 25 mg
- Cyclosporine Oral Capsule, 100 mg
- Desmopressin Acetate Oral Tablet, 0.2 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 5 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 10 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 20 mg
- Dextroamphetamine Sulfate Extended Release Oral Capsule, 5 mg
- Dextroamphetamine Sulfate Extended Release Oral Capsule, 10 mg

- Dextroamphetamine Sulfate Extended Release Oral Capsule, 15 mg
- Diazepam Oral Tablet, 2 mg
- Diazepam Oral Tablet, 5 mg
- Diazepam Oral Tablet, 10 mg
- Epirubicin Injection Vial 50 mg/25 mL
- Epirubicin Injection Vial 200 mg/100 mL
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.01/0.1mg (AB-rated to Lo Seasonique)
- Ethinyl Estradiol/Norethindrone Acetate Oral Tablet, 0.02/1mg (AB-rated to Loestrin 21 1/20)
- Ethinyl Estradiol/Norethindrone Acetate Oral Tablet, 0.03/1.5mg (AB-rated to Loestrin 21 1.5/30)
- Glyburide/Metformin HCl Oral Tablet, 1.25/250 mg
- Glyburide/Metformin HCl Oral Tablet, 2.5/500 mg
- Glyburide/Metformin HCl Oral Tablet, 5/500 mg
- Hydroxyzine Pamoate Oral Capsule, 25 mg
- Hydroxyzine Pamoate Oral Capsule, 50 mg
- Levalbuterol HCl Inhalation Solution, 0.0103%
- Levalbuterol HCl Inhalation Solution, 0.0210%

- Levalbuterol HCl Inhalation Solution, 0.042%
- Minocycline HCl Oral Capsule, 50 mg
- Minocycline HCl Oral Capsule, 75 mg
- Minocycline HCl Oral Capsule, 100 mg
- Nitrofurantoin Oral Capsules, 50 mg
- Nitrofurantoin Oral Capsules, 100 mg
- Propofol Injection Emulsion, 10 mg/mL 20 mL vial
- Propofol Injection Emulsion, 10 mg/mL 50 mL vial
- Propofol Injection Emulsion, 10 mg/mL 100 mL vial
- Propranolol HCl Oral Tablet, 10 mg
- Propranolol HCl Oral Tablet, 20 mg
- Propranolol HCl Oral Tablet, 40 mg
- Propranolol HCl Oral Tablet, 80 mg

- **Current Competition between Teva and Allergan, 5-to-4 Supplier Consolidation**
  - Acitretin Oral Capsule, 10 mg
  - Acitretin Oral Capsule, 25 mg
  - Alendronate Sodium Oral Tablet, 35 mg
  - Buspirone HCl Oral Tablet, 15 mg

- Clozapine Oral Tablet, 25 mg
- Clozapine Oral Tablet, 100 mg
- Drospirenone/Ethinyl Estradiol Oral Tablet, 3/0.03 mg (AB-rated to Yasmin-28)
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.1 mg (AB-rated to Alesse-28)
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.03/0.15 mg (AB-rated to Nordette)
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.03/0.01/0.15 mg (AB-rated to Seasonique)
- Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.02/1 mg (AB-rated to Loestrin FE 1/20)
- Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.03/1.5 mg (AB-rated to Loestrin FE 1.5/30)
- Norethindrone Oral Tablet, 0.35 mg (AB-rated to Micronor 28)
- Norethindrone Oral Tablet, 0.35 mg (AB-rated to Nor-QD)

- **Future Competition between Teva and Allergan in an Existing Generic Market, 3-to-2 Supplier Consolidation**
  - Budesonide Inhalation Suspension, 1 mg/2 mL
  - Fluocinonide Cream Emulsified Base 0.05%

- Methylphenidate HCl Extended Release Capsule, 20 mg
- Methylphenidate HCl Extended Release Capsule, 30 mg
- Methylphenidate HCl Extended Release Capsule, 40 mg

- **Future Competition between Teva and Allergan in an Existing Generic Market, 4-to-3 Supplier Consolidation**
  - Aspirin/Dipyridamole Extended Release Oral Capsule 25/200 mg

- **Future Competition between Teva and Allergan in an Existing Generic Market, 5-to-4 Supplier Consolidation**
  - Benzoyl Peroxide/Clindamycin Phosphate Gel, 5%/1%
  - Clozapine Oral Tablet, 200 mg
  - Methotrexate Injection, 25 mg/mL in 2 mL vial
  - Methotrexate Injection, 25 mg/mL in 10 mL vial
  - Methylphenidate HCl Extended Release Tablet, 18 mg
  - Methylphenidate HCl Extended Release Tablet, 27 mg
  - Methylphenidate HCl Extended Release Tablet, 36 mg
  - Methylphenidate HCl Extended Release Tablet, 54 mg
  - Tobramycin Inhalant Solution, 300 mg/5 mL

- **Future Competition between Teva and Allergan in a Future Generic Market, 2-to-1 Supplier Consolidation**

- Methylphenidate HCl Extended Release Capsule, 10 mg
- Ramelteon Tablet, 8 mg

- **Future Competition between Teva and Allergan in a Future Generic Market, 3-to-2 Supplier Consolidation**
  - Buprenorphine/Naloxone Buccal Film, 12/3 mg
  - Buprenorphine/Naloxone Buccal Film, 4/1 mg
  - Ethinyl Estradiol/Etonogestrel Vaginal Ring 0.015mg/24hr; 0.012mg/24hr
  - NAB Paclitaxel Injectable Suspension, 100 mg/vial
  - Phentermine HCl/Topiramate Extended Release Capsule, 11.25/69 mg
  - Phentermine HCl/Topiramate Extended Release Capsule, 15/92 mg
  - Phentermine HCl/Topiramate Extended Release Capsule, 3.75/23 mg
  - Phentermine HCl/Topiramate Extended Release Capsule, 7.5/46 mg
  - Rotigotine Transdermal Patch, 1 mg
  - Rotigotine Transdermal Patch, 2 mg
  - Rotigotine Transdermal Patch, 3 mg
  - Rotigotine Transdermal Patch, 4 mg
  - Rotigotine Transdermal Patch, 6 mg
  - Rotigotine Transdermal Patch, 8 mg

- **Future Competition between Teva and Allergan in a Future Generic Market, 4-to-3 Supplier Consolidation**
    - Buprenorphine/Naloxone Buccal Film, 2/0.5 mg
    - Buprenorphine/Naloxone Buccal Film, 8/2 mg
    - Dienogest/Estradiol Valerate and Estradiol Valerate Oral Tablet, 3 mg, 2/2 mg, 3/2 mg, 1 mg (AB-rated to Natazia)
    - Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.15 mg; 0.025/0.15 mg; 0.03 mg/0.15 mg; 0.01 mg (AB-rated to Quartette)
    - Ezetimibe/Simvastatin Tablets, 10/10 mg
    - Ezetimibe/Simvastatin Tablets, 10/20 mg
    - Ezetimibe/Simvastatin Tablets, 10/40 mg
    - Ezetimibe/Simvastatin Tablets, 10/80 mg
    - Imiquimod Topical Cream, 3.75%
    - Four pipeline products[2]

[2] Teva's and Allergan's independent development projects for two overlapping pharmaceutical products are not public, and their existence is confidential business information. But for the proposed acquisition, certain strengths of the Teva and Allergan products would likely compete in four future markets. To preserve the confidentiality of these development programs, the specific future markets in which these products would compete are not identified in this document, and references to these products have been redacted from the public version of the Complaint.

- **Future Competition between Teva and Allergan in a Future Generic Market, 5-to-4 Supplier Consolidation**
    - Dexmethylphenidate HCl Extended Release Oral Capsule, 25 mg
    - Dexmethylphenidate HCl Extended Release Oral Capsule, 35 mg
    - Fentanyl Buccal Tablet, 100 mcg
    - Fentanyl Buccal Tablet, 200 mcg
    - Fentanyl Buccal Tablet, 400 mcg
    - Fentanyl Buccal Tablet, 600 mcg
    - Fentanyl Buccal Tablet, 800 mcg
    - Metformin HCl/Saxagliptin Extended Release Tablet, 500/5 mg
    - Metformin HCl/Saxagliptin Extended Release Tablet, 1000/2.5 mg
    - Metformin HCl/Saxagliptin Extended Release Tablet, 1000/5 mg

b. API Supply and Competition in Pharmaceutical Markets

APIs are central inputs in the manufacture of finished dose form pharmaceutical products. API supply sources must be designated in a drug's FDA marketing authorization. Switching to a non-designated API source requires a drug maker to supplement its New Drug Application or ANDA, a process that can take as long as two years or even more. Consequently, a generic drug manufacturer's API supply options are limited to the sources qualified under its ANDA. If only one API supplier is qualified under an ANDA, the ANDA holder has no immediate recourse if its designated API supplier elects to raise its prices or refuse to supply.

Teva is world's largest API supplier and supplies API to Allergan's competitors in a number of generic markets. The proposed acquisition may lessen current or future competition in fifteen pharmaceutical products markets by creating the incentive and ability for Teva to foreclose rival suppliers of fifteen newly acquired Allergan pharmaceutical products by withholding supply of the following eight Teva API products:

- Betamethasone dipropionate API;
- Betamethasone valerate API;
- Clobetasol propionate API;
- Desonide API;
- Fluocinolone API;
- Fluorouracil API;
- Probenecid API; and
- Triamcinolone acetonide API.

The fifteen downstream pharmaceutical markets in which competition would be lessened as a result of the acquisition are:

- Betamethasone dipropionate augmented ointment, 0.05%;
- Betamethasone dipropionate cream, 0.05%;
- Betamethasone dipropionate lotion, 0.05%;
- Betamethasone dipropionate ointment, 0.05%;

- Betamethasone valerate cream, 0.1%;
- Betamethasone valerate ointment, 0.1%;
- Clobetasol propionate shampoo, 0.05%;
- Clobetasol propionate ointment, 0.05%;
- Desonide cream, 0.05%;
- Probenecid tablets, 500 mg;
- Probenecid/colchicine tablets, 500 mg/0.5 mg;
- Nystatin/triamcinolone acetonide cream, 100,000 units/gm/0.1%;
- Nystatin/triamcinolone acetonide ointment, 100,000 units/gm/0.1%; and
- Two pipeline products.[3]

II. Entry

Entry into these pharmaceutical markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. Introducing generic pharmaceutical products is costly and lengthy due to drug development times and regulatory requirements, including approval by the FDA. Additionally, it can take up to two years for an API manufacturer to qualify as a new API supplier for a generic

[3] Allergan has not yet made public the development of two pharmaceutical products that would likely compete with products for which Teva supplies API. To preserve the confidentiality of these Allergan development programs, the specific markets in which these likely future products would compete are not identified in this document, and references to these products have been redacted from the public version of the Complaint.

pharmaceutical product, leaving the generic pharmaceutical product with no alternative to its existing qualified API supplier or suppliers.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm by eliminating current or future competition in markets for one or more strengths of seventy-nine pharmaceutical products where the parties currently sell or are developing generic drugs. In each of these markets, Teva and Allergan are two of a limited number of current or likely future suppliers in the United States. Customers and competitors have observed that the price of generic pharmaceutical products decreases with new entry even after several suppliers have entered the market. Removal of an independent generic pharmaceutical supplier from the relevant markets in which Teva and Allergan currently compete would result in significantly higher prices post-acquisition. Similarly, the elimination of a future independent competitor would prevent the price decreases that are likely to result from the firm's entry. Thus, absent a remedy, the proposed acquisition would likely result in significantly higher prices for these generic drugs.

Additionally, the proposed acquisition likely would cause competitive harm in markets for fifteen pharmaceutical products in which Teva supplies API for a generic pharmaceutical product that currently competes or will compete in the near future with an Allergan generic pharmaceutical product. Those generic pharmaceutical markets already have or will have a limited number of competitors, some of which are supplied API by Teva. Teva has the ability to foreclose these competitors by denying them API from their only approved source. Post-acquisition, Teva would have the incentive to foreclose one or more competitors because the lost

API sales would be less than the recouped profits on additional sales gained from the foreclosed competitor(s) and the increased prices. Such foreclosure would harm consumers because market concentration and price would result in significantly higher prices.

IV. The Consent Agreement

The remedy reflected in the proposed Consent Agreement would eliminate the likely anticompetitive effects of the proposed acquisition by requiring the parties to divest rights and assets related to the pharmaceutical products in each relevant market. The acquirers are: Mayne Pharma Group Ltd. ("Mayne"), Impax Laboratories, Inc. ("Impax"), Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's"), Sagent Pharmaceuticals, Inc. ("Sagent"), Cipla Limited ("Cipla"), Zydus Worldwide DMCC ("Zydus"), Mikah Pharma LLC ("Mikah"), Perrigo Pharma International D.A.C. ("Perrigo"), Aurobindo Pharma USA, Inc. ("Aurobindo"), Prasco LLC ("Prasco"), and 3M Company ("3M") (collectively, the "Acquirers"). The parties must divest the products no later than ten days after the acquisition.

The Commission's goal in evaluating possible acquirers of divested assets is to maintain the competitive environment that existed prior to the acquisition. The Commission thoroughly reviewed the assets to be divested, the transitional services to be provided by Teva, and the capabilities and plans of each Acquirer. The interim monitors, who will oversee the divestiture process, have worked closely with Commission staff to ensure the viability of the divestiture and anticipate logistical and technical challenges. Additionally, Teva—in conjunction with the Acquirers, Allergan, and interim monitors—has prepared a comprehensive divestiture plan to guide the process of transferring the divested products to their new proposed owners. If the Commission determines that an Acquirer is not acceptable, or that the manner of the divestitures

is not acceptable, the parties must unwind the sale or release of rights to that Acquirer and divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the products if the parties fail to divest the products as required.

The proposed Consent Agreement contains provisions to help ensure the divestitures are successful. The parties must take all action to maintain the economic viability, marketability, and competitiveness of the divestiture products until they are divested. The parties must provide transitional services to the Acquirers to assist them in establishing independent manufacturing capabilities. These transitional services include technical assistance to manufacture the divestiture products in substantially the same manner and quality employed or achieved by the parties, as well as advice and training from knowledgeable employees. The goal of the transitional services is to ensure that the acquirers will be able to operate independently of the parties in the manufacture and sale of the divested products. The proposed Consent Agreement also requires the parties to supply product to the Acquirers so that the Acquirers can market them independently while the parties transfer the associated technology to the production facilities of the Acquirer or its chosen third-party manufacturer(s). The Consent Agreement allows sufficient time to complete the manufacturing transfers, and for products in development, to gain FDA approval before completing manufacturing transfers. To ensure that the buyers of divestiture products for which Teva or Allergan supply API will have access to adequate supplies of reasonably priced API until they are able to qualify alternative suppliers, the proposed Consent Agreement requires Teva to supply API for up to four years after closing at prices not to exceed those set forth in binding letters of intent, recently executed by Teva and the buyers.

Nothing in the Consent Agreement precludes the buyers from sourcing other divestiture product inputs from Teva on a negotiated basis.

In addition, to address the anticompetitive effects likely to arise in the fifteen pharmaceutical markets where Teva supplies API to Allergan competitors, the Consent Agreement requires Teva to give API customers in those markets the option of entering into long-term API supply contracts. Teva must notify each affected API customer of the option to enter a contract within ten days of consummating the proposed acquisition, and such customers may exercise their options at any point up to three years after the date of the Consent Agreement. Any such API supply contracts executed pursuant to the option shall be renewable for up three years after the date of the Consent Agreement, which will give the customers sufficient time to qualify alternative API suppliers if they wish to do so.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Statement of the Federal Trade Commission In the Matter of Teva Pharmaceuticals Industries Ltd. and Allergan plc

The Commission has accepted a proposed consent order in connection with Teva Pharmaceutical Industries Ltd.'s proposed acquisition of the generic pharmaceutical business of Allergan plc. We believe the consent order remedies the anticompetitive effects that would otherwise likely result from this transaction by requiring the divestiture of nearly 80 drug products to buyers that appear well positioned to replicate the competition that would have occurred absent the merger. The consent order includes a number of safeguards to help achieve our remedial goals.

Both Teva and Allergan are global pharmaceutical companies that are among the largest suppliers of generic pharmaceuticals in the United States. Teva is currently the largest generic drug company in the United States, with an overall generic market share of approximately 13%; Allergan is third, accounting for approximately 9% of generic sales.[1] Although this merger combines two large sellers of generic drugs, the generic pharmaceutical industry as a whole remains relatively unconcentrated. Over two hundred firms sell generic drugs in the United States and the five largest suppliers account only for about half of overall generic sales. Following this transaction, the combined firm will likely have a 22% share of industry-wide sales across all generic product markets.

Despite the industry's relatively low concentration, the Commission appreciates that the price, quality, and availability of generic pharmaceutical products have a significant impact on American consumers' daily lives and on healthcare costs nationwide. We therefore looked closely at every possible aspect of this transaction that could result in competitive harm. We examined not only particular product overlaps but also whether the combination between Teva and Allergan would result in other adverse consequences to competition. Our comprehensive investigation included the review of extensive documents from the merging parties and other industry players as well as interviews with dozens of customers and more than 50 competitors. We concluded that the substantial divestitures required by the consent order resolve the competitive concerns resulting from the transaction.

The Complaint and Remedy

As detailed in our complaint, we have reason to believe that, absent a remedy, the transaction would likely substantially reduce competition in 79 markets for pharmaceutical

[1] This market share data is based on 2014 IMS gross sales data.

products, including oral contraceptives, steroidal medications, mental health drugs, and many other products. These markets include individual strengths of pharmaceutical products where Teva and Allergan currently offer competing products as well as products where there would likely be future competition absent the merger because one or both of the parties are developing competing products.[2] To remedy the likely anticompetitive effects in each of the relevant markets, the consent order requires the divestiture of the products and related assets to specific acquirers that the Commission has closely vetted and approved. Where at least one dosage strength raised a competitive concern, we required Teva to divest all strengths. These divestitures, and the other relief contained in the proposed consent order, are designed to maintain competition in the relevant markets.

In settling this case, we rely on the Commission's extensive experience with divestitures in the pharmaceutical industry, including prior divestitures involving Teva and Allergan and have structured the divestitures in a way to minimize potential risks. This includes breaking the divested products into smaller packages to ease the load on any single buyer and requiring Teva to divest the easier-to-divest product of the overlapping products whenever possible. We also undertook an extensive review process to ensure that the divestiture buyers are acceptable and have the resources they need to compete successfully in the relevant markets. The buyers have identified third-party contract research organizations or contract manufacturers they intend to use

[2] In addition to selling finished pharmaceutical products, Teva and Allergan also sell active pharmaceutical ingredients (API) to many third-party drug manufacturers, including parties that will now compete with the merged entity. Where the number of competitors in the finished product market is limited, the Commission determined that this vertical relationship could raise competitive concerns in markets for finished drug products by creating the incentive and ability for Teva to raise prices or withhold supply where third parties source from the merged firm. To address these concerns, the order requires Teva to provide affected customers with the option of entering into long-term API supply contracts to ensure that they have an adequate supply of API until they are able to qualify alternative suppliers.

and provided us with executed contracts. We involved interim monitors early in the divestiture negotiation process to ensure a smooth divestiture process and harmonize Teva's technological transfer plans with those of the acquirors of the divested assets. And we are requiring Teva to dedicate a full-time organization to implement the technology transfers and other measures necessary to effectuate the divestitures.

Other Potential Theories of Harm

In assessing whether the combination of the parties' generic businesses would harm competition or create a firm with a greater ability to engage in anticompetitive conduct, we evaluated three additional potential theories of harm beyond individual product overlaps.

First, we considered whether the merger would likely lead to anticompetitive effects from the bundling of generic products. Although both Teva and Allergan have broad generic drug portfolios today, the evidence did not show that the breadth of their portfolios significantly affects their ability to win business in individual drug product markets. Nor have they been able to use their portfolios to foreclose smaller competitors. Even with one of the broadest generic product portfolios in the industry, Teva's overall share of U.S. generic prescriptions has steadily declined from 2010 to 2015, and the share of total prescriptions filled by the five largest generic suppliers has similarly fallen during this period. Generic sales occur at the individual product level, and customers sometimes even break up purchases by specific strengths to obtain more favorable pricing. As a result, smaller firms with much smaller portfolios compete head-to-head against larger generic firms and are the leading suppliers in the markets for many individual generic treatments. Additionally, purchasers actively seek to diversify their supplier base by

sourcing from smaller suppliers. On the facts here, we concluded that anticompetitive effects arising from the merged company's portfolio of products are unlikely to occur.

Second, we examined whether the merger would likely decrease incentives to challenge the patents held by brand-name pharmaceutical companies and bring new generic drugs to market. The regulatory framework governing generic pharmaceuticals, the Hatch-Waxman Act, provides specific procedures for identifying and resolving patent disputes related to new generic drugs. Under the Hatch-Waxman Act, a company seeking to introduce a new generic drug may file what is commonly known as a "Paragraph IV challenge" to a brand-name pharmaceutical product's patent. This filing triggers a process, including potential litigation, to resolve patent issues surrounding the proposed generic product's entry into the marketplace.

We considered whether the merger would likely result in fewer or less effective Paragraph IV challenges, but the evidence did not support such a conclusion. A major incentive to file Paragraph IV challenges is the 180-day exclusivity period awarded to the first generic drug that the Food and Drug Administration approves in a market. The financial rewards associated with this "first-to-file" exclusivity period provide a strong incentive for generic drug companies of all sizes to challenge brand drug patents and litigate against brand drug companies. Indeed, first-to-file Paragraph IV challenges are not concentrated among a small group of firms. To the contrary, many firms, including small ones, have been active and successful first filers. In 2014, for example, twenty-five different companies were the first to file Paragraph IV challenges. For eight of those companies, that was their very first Paragraph IV challenge. Thus, while Teva and Allergan have actively filed Paragraph IV challenges, we found no evidence that either one has been better positioned to win the first-to-file race or that they have substantially greater incentives or ability to succeed in Paragraph IV challenges than many other

generic companies. Nor did we see evidence that a merger between the two would diminish the combined firm's incentive to continue to pursue Paragraph IV challenges.

Finally, we analyzed whether the proposed transaction might dampen incentives to develop new generic products. For example, certain types of generic drugs are especially difficult to develop. For the most part, however, the parties' in-house technical capabilities to develop complex generic drugs do not overlap. And to the extent that there are complex products for which both companies have engaged in development efforts, we found that there are a number of other firms with similar capabilities such that the transaction would not substantially lessen competition. Moreover, generic firms, including the merging parties, often partner with third parties (e.g., specialized contract development and manufacturing organizations) to obtain the technical capability to develop complex generic drugs. These types of partnership options will remain after the merger. The consent order addresses individual markets where the merger was likely to harm competition, including markets for difficult-to-develop products that are currently in the parties' pipelines.

Conclusion

We therefore concluded that the proposed merger is unlikely to produce anticompetitive effects beyond the markets discussed above. That conclusion is necessarily limited to the facts of this case. Another set of facts presented by a different transaction might lead us to find that there are competitive concerns that extend beyond markets for individual pharmaceutical products.

The extensive investigation and detailed consent order reflect the Commission's dedication to ensuring that pharmaceutical markets, including generic markets, remain competitive. We will continue to take enforcement actions, where appropriate, to ensure that any

merger or acquisition complies with the antitrust laws and does not undermine competition in the pharmaceutical industry.

By direction of the Commission.

Donald S. Clark,
Secretary.

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