ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Teva Pharmaceutical Industries Ltd. and Allergan plc
File No. 151-0196, Docket No. C-4589

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 d (se8)Tj EMC /L

-

- 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

- **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[1]

[1] 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.

The fifteen downstream pharmaceutical mar[1wC ts

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 in

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