

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman
Maureen K. Ohlhausen
Terrell McSweeney

In the Matter of)	
)	
TEVA PHARMACEUTICAL INDUSTRIES LTD.,)	PUBLIC VERSION
a corporation;)	
)	
and)	Docket No. C-4589
)	
ALLERGAN PLC,)	
a corporation.)	
)	

COMPLAINT

2. Respondent Allergan is a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland with its principal executive office located at Clonshaugh Business and Technology Park, Coolock Dublin, D17 E400, Ireland.

hh. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Lo Seasonique);

- bbb. generic griseofulvin microcrystalline liquid suspension;
- ccc. generic hydroxyzine pamoate capsules;
- ddd. generic imiquimod topical cream;
- eee. generic levalbuterol HCl inhalation solution;
- fff. generic metformin HCl/saxagliptin extended release tablets;
- ggg. generic methotrexate injection;
- hhh. generic methylphenidate HCl extended release tablets;
- iii. generic methylphenidate HCl extended release capsules;
- jjj. generic metoclopramide HCl tablets;
- kkk. generic minocycline capsules;
- lll. generic mirtazapine oral disintegrating tablets;
- mmm. generic NAB paclitaxel injection;
- nnn. generic nabumetone tablets;
- ooo. generic nitrofurantoin capsules;
- ppp. generic norethindrone tablets (AB-rated to Micronor 28);
- qqq. generic norethindrone tablets (AB-rated to Nor-QD);
- rrr. generic nortriptyline HCl capsules;
- sss. generic phentermine HCl/topiramate extended release capsules;
- ttt. generic propofol injection emulsion;
- uuu. generic propranolol HCl tablets;
- vvv. generic ramelteon tablets;
- www. generic rotigotine transdermal patch;
- xxx. generic t

yyy. generic tobramycin inhalation solution;

zzz. generic trimethoprim tablets; and

aaaa. trimipramine maleate capsules.

5. Additional relevant lines of commerce in which to analyze the effects of the Acquisition, for the purposes of this Complaint, are the development, manufacture, distribution, and sale of the following FDA-approved, finished dosage form pharmaceutical products:

a. betamethasone dipropionate augmented ointment;

b. betamethasone dipropionate cream;

c. betamethasone dipropionate lotion;

d. betamethasone dipropionate ointment;

e. betamethasone valerate cream;

f. betamethasone valerate ointment;

g. clobetasol propionate shampoo;

h. clobetasol propionate o(t)-o2(opi)-2(bc.6(nt)-2(;)]TJ 19.965 0 Td ()Tj93MC /P <</MC6D 37

IV. THE RELEVANT GEOGRAPHIC MARKETS

6. With respect to the lines of commerce set forth in Paragraphs 4 and 5, the United States is

- r. Desmopressin acetate tablets are used to treat bedwetting, clotting disorders, and a form of diabetes that causes excessive urination. Three firms supply 0.1 mg generic desmopressin acetate tablets: Allergan, Teva, and Glenmark Pharmaceuticals Ltd. (“Glenmark”). The Acquisition would reduce the number of firms supplying the 0.1 mg strength market from three to two. Four firms supply 0.2 mg generic desmopressin acetate tablets: Allergan, Teva, Glenmark, and Mylan. The Acquisition would reduce the number of suppliers of the 0.2 mg

- x. Dienogest/estradiol valerate and estradiol valerate tablets (AB-rated to Natazia)

- ff. Ethinyl estradiol/levonorgestrel tablets (AB-rated to Alesse-28) are oral contraceptives used to prevent pregnancy. Five firms supply generic Alesse-28: Allergan, Teva, Endo, Lupin, and Sandoz. Allergan sells its product as a branded generic under the name Lutera. The Acquisition would reduce the number of suppliers from five to four.
- gg. Ethinyl estradiol/levonorgestrel tablets (AB-rated to Levlite-28) are oral contraceptives used to prevent pregnancy. Three firms have ANDAs approved for generic Levlite-28: Allergan, Teva, and Mylan. Allergan sells its product as a branded generic under the name Sronyx. The Acquisition would reduce the number of suppliers from three to two.
- hh. Ethinyl estradiol/levonorgestrel tablets (AB-rated to Lo Seasonique) are oral contraceptives used to prevent pregnancy. Teva owns the branded product and markets an authorized generic. Allergan and Lupin market generic products, which compete directly with Teva's authorized generic. Allergan sells its product as a branded generic under the name Amethia Lo. Accounting for expected entry, the Acquisition would reduce the number of suppliers from four to three.
- ii. Ethinyl estradiol/levonorgestrel tablets (AB-rated to Nordette) are oral contraceptives used to prevent pregnancy. There are five competitively significant suppliers of generic Nordette: Allergan, Teva, Sandoz, Glec8(o S)1(e)-115 Td [(sd r

mm. Ethinyl estradiol/norethindrone tablets (AB-rated to Modicon-28) are oral contraceptives used to prevent pregnancy. Allergan, Teva, and Mylan market generic Modicon-28. Allergan sells its product as a branded generic under the name Necon.

product as a branded generic under the name Low-Ogestrel.

bbb. G

- iii. Methylphenidate HCl extended release capsules are used to treat ADHD. Teva and Allergan are two of a limited number of suppliers likely to enter the market

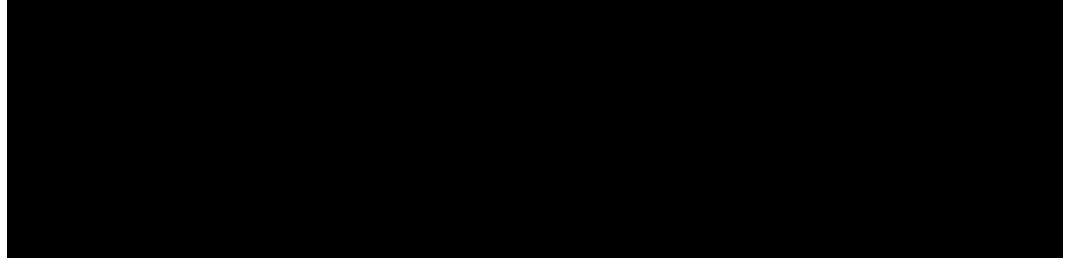
ppp. Norethindrone tablets (AB-rated to Micronor 28) are oral contraceptives used to prevent pregnancy. Five firms supply generic Micronor 28: Teva, Glenmark, Lupin, Mylan, and Allergan.

8. The structures of the relevant product markets set forth in Paragraph 5 are described below:

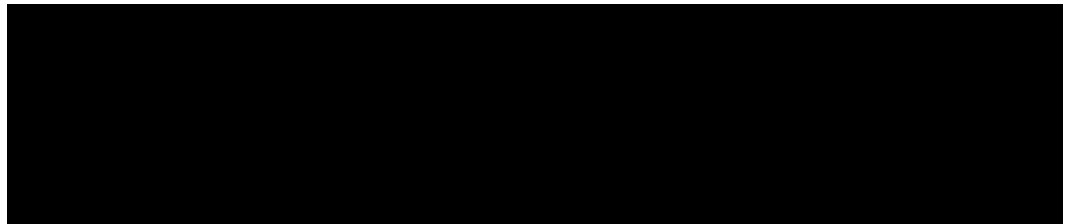
- a. Betamethasone dipropionate augmented ointment is a very high potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of betamethasone dipropionate API to manufacturers of FDA-approved betamethasone dipropionate augmented ointment. While other API suppliers are capable of manufacturing betamethasone dipropionate API, most of Teva's betamethasone dipropionate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- b. Betamethasone dipropionate cream is a medium potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of betamethasone dipropionate API to manufacturers of FDA-approved betamethasone dipropionate cream. While other API suppliers are capable of manufacturing betamethasone dipropionate API, most of Teva's betamethasone dipropionate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- c. Betamethasone dipropionate lotion is a medium potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of betamethasone dipropionate API to manufacturers of FDA-approved betamethasone dipropionate lotion. While other API suppliers are capable of manufacturing betamethasone dipropionate

- e. Betamethasone valerate cream is a medium potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of betamethasone valerate API to manufacturers of FDA-approved betamethasone valerate cream. While other API suppliers are capable of manufacturing betamethasone valerate API, most of Teva's betamethasone valerate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- f. Betamethasone valerate ointment is a medium potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of betamethasone valerate API to manufacturers of FDA-approved betamethasone valerate ointment. While other API suppliers are capable of manufacturing betamethasone valerate API, most of Teva's betamethasone valerate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- g. Clobetasol propionate shampoo is a very high potency corticosteroid indicated for the treatment of scalp psoriasis. Teva is an important supplier of clobetasol propionate API to manufacturers of FDA-approved clobetasol propionate shampoo. While other API suppliers are capable of manufacturing clobetasol propionate API, most of Teva's clobetasol propionate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- h. Clobetasol propionate ointment is a very high potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of clobetasol propionate API to manufacturers of FDA-approved clobetasol propionate ointment. While other API suppliers are capable of manufacturing clobetasol propionate API, most of Teva's clobetasol propionate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- i. Desonide cream is a low potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of desonide API to manufacturers of FDA-approved desonide cream. While other API suppliers are capable of manufacturing desonide API, most of Teva's desonide API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.

j.



k.



- l. Probenecid tablets are used in the treatment of chronic gout or gouty arthritis. Teva is an important supplier of probenecid API to manufacturers of FDA-approved probenecid tablets. While other API suppliers are capable of manufacturing probenecid API, most of Teva's API is manufactured in the United States.

- o. Nystatin/triamcinolone acetonide ointment is used to treat fungal skin infections. Teva is an important supplier of triamcinolone API to manufacturers of FDA-approved nystatin/triamcinolone acetonide ointment. While other API suppliers are capable of manufacturing triamcinolone acetonide API, most of Teva's triamcinolone acetonide API customers cannot easily switch suppliers because a drug manufacturer must use API from a source designated in its ANDA.

VI. ENTRY CONDITIONS

9. Entry into the relevant markets listed in Paragraph 4 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the

diazepam tablets;

- b. by eliminating future competition between Teva and Allergan and reducing the number of likely future competitors in the markets for (1) generic aspirin/dipyridamole extended release capsules; (2) [REDACTED]; (3) generic benzoyl peroxide/clindamycin phosphate topical gel; (4) generic budesonide inhalation suspension; (5) [REDACTED]; (6) generic buprenorphine HCl/naloxone HCl buccal film; (7)

VIII. VIOLATIONS CHARGED

12. The Acquisition described in Paragraph 3, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this