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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.,)) PUBLIC VERSION)
a corporation;)
and) Docket No. C-4589
ALLERGAN PLC,)
a corporation.)
	_)

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Teva Pharmaceutical Industries Ltd. ("Teva"), a corporation subject to the jurisdiction of the Commission, has made an offer to acquire the voting securities of certain entities and related assets from Allergan plc ("Allergan"), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate 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, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

- 1. Respondent Teva is a corporation organized, existing, and doing business under and by virtue of the laws of Israel with its principal executive offices located at 5 Basel Street, P.O. Box 3190, Petach Tikva 4951033, Israel, and its United States address as follows: General Counsel, Teva Pharmaceutical Industries Ltd., c/o Teva North America, 425 Privet Road, Horsham, Pennsylvania 19044.
- 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 offices located at Clonshaugh Business and Technology Park, Coolock Dublin, D17 E400, Ireland, and



its United States address as follows: Chief Legal Officer, Allergan plc, Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

II. THE PROPOSED ACQUISITION

3. On July 26, 2015, Teva proposed to acquire Allergan's generic pharmaceutical business for approximately \$40.5 billion (the "Acquisition").

III. THE RELEVANT PRODUCT MARKETS

- 4. U.S. Food and Drug Administration ("FDA") marketing approvals for generic pharmaceutical products are based on establishing bioequivalence to already approved drugs. When such bioequivalence is demonstrated by *in vivo* or *in vitro* studies, the FDA designates such generic drugs as "AB-rated" to the branded product, which allows for automatic substitution of the generic equivalent for the branded drug when the drug is dispensed at the pharmacy. Where only one AB-rated generic drug is approved, it competes against the branded drug. Where multiple AB-rated generic drugs are approved, they compete against each other in a "generic" market, which typically does not include the branded product. Generic drugs that are AB-rated to different branded drugs are not substitutable, even if they contain the same active ingredients in the same proportions in the same dosage form. For the purposes of this Complaint, relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of the following finished dosage form pharmaceutical products:
 - a. generic acitretin capsules;
 - b. generic alendronate sodium tablets;
 - c. generic amphetamine asparte/amphetamine sulfate/dextroamphetamine saccharate/dextroamphetamine sulfate extended release tablets;
 - d. armodafinil tablets;

f.

i.

- e. generic aspirin/dipyridamole extended release capsules;
- g. generic benzoyl peroxide/clindamycin phosphate topical gel;
- h. generic budesonide inhalation suspension;
- j. generic buprenorphine HCl/naloxone HCl buccal film;
- k. generic buspirone hydrochloride tablets;



- 1. generic carbidopa/levodopa tablets;
- m. generic clarithromycin extended release tablets;
- n. generic clonidine HCl transdermal film;
- o. generic clozapine tablets;
- p. generic cyclosporine capsules;
- q. generic cyclosporine oral solution;
- r. generic desmopressin acetate tablets;
- s. generic desogestrel/ethinyl estradiol tablets (AB-rated to Cyclessa);
- t. generic desogestrel/ethinyl estradiol and ethinyl estradiol tablets (AB-rated to Mircette);
- u. generic dexmethylphenidate HCl extended release capsules;
- v. generic dextroamphetamine sulfate extended release capsules;
- w. generic diazepam tablets;
- x. generic dienogest/estradiol valerate and estradiol valerate tablets (AB-rated to Natazia);
- y. generic disopyramide phosphate capsules;
- z. generic drospirenone/ethinyl estradiol tablets (AB-rated to Yasmin-28);
- aa. generic epirubicin injection;
- bb. generic estazolam tablets;
- cc. generic estradiol tablets;
- dd. generic ethinyl estradiol/ethynodiol diacetate tablets (AB-rated to Demulen 1/35);
- ee. generic ethinyl estradiol/etonogestrel vaginal rings;
- ff. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Alesse-28);
- gg. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Levlite-28);



- hh. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Lo Seasonique);
- ii. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Nordette);
- jj. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Seasonique);
- kk. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Triphasil-28);
- ll. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Quartette);
- mm. generic ethinyl estradiol/norethindrone tablets (AB-rated to Modicon-28);
- nn. generic ethinyl estradiol/norethindrone tablets (AB-rated to Tri-Norinyl 28-Day);
- oo. generic ethinyl estradiol/norethindrone acetate tablets (AB-rated to Loestrin 21 1/20);
- pp. generic ethinyl estradiol/norethindrone acetate tablets (AB-rated to Loestrin 21 1.5/30);
- qq. generic ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Estrostep FE);
- rr. generic ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Loestrin FE 1/20);
- ss. generic ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Loestrin FE 1.5/30);
- tt. generic ethinyl estradiol/norgestrel tablets (AB-rated to Lo/Ovral);
- uu. generic ezetimibe/simvastatin tablets;
- vv. generic fentanyl buccal tablets;
- ww. generic fludarabine injection;
- xx. generic fluocinonide cream;
- yy. generic fluocinonide cream, emulsified base;
- zz. generic flutamide capsules;
- aaa. generic glyburide/metformin HCl tablets;



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;

Ill. 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 tamoxifen citrate tablets;



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