The Commission therefore determines that the maximum allowable charge for the year 2009 will be $11.00.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. E8–30830 Filed 12–24–08: 8:45 am]

BILLING CODE 6750–01–S

FEDERAL TRADE COMMISSION

[File No. 081 0224]

Teva Pharmaceutical Industries Ltd. and Barr Pharmaceuticals, Inc; Analysis of Agreement Containing Consent Orders 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 or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 19, 2008

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to ''Teva-Barr, File No. 081 0224,'' to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room 135-H, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Comments containing confidential material must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with Commission Rule 4.9(c). 16 CFR 4.9(c) (2005).[1] The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments that do not contain any nonpublic information may instead be filed in electronic form by following the instructions on the web-based form at (*http://secure.commentworks.com/ftc-TevaBarr*). To ensure that the Commission considers an electronic comment, you must file it on that web-based form.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC website, to the extent practicable, at *www.ftc.gov.* As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at (*http://www.ftc.gov/ftc/privacy.shtm*).

FOR FURTHER INFORMATION CONTACT: Stephanie C. Bovee, FTC Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, (202) 326-2083.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 of the Commission Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order 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 December 19, 2008), on the World Wide Web, at (*http://www.ftc.gov/os/2008/12/index.htm*). A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before the date specified in the **DATES** section.

Analysis of Agreement Containing Consent Order 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 Barr Pharmaceuticals Inc. (''Barr'') that is designed to remedy the anticompetitive effects of the acquisition of Barr by Teva. Under the terms of the proposed Consent Agreement, the companies would be required to assign and divest to Watson Pharmaceuticals (''Watson'') Teva's rights and assets necessary to manufacture and market generic: (1) chlorzoxazone tablets; (2) deferoxamine injection; (3) fluoxetine weekly capsules; (4) carboplatin injection; and (5) metronidazole tablets. The Consent Agreement also requires the companies to assign and divest to Watson all of Barr's rights and assets necessary to manufacture and market generic: (1) metoclopramide hydrochloride (''HCl'') tablets; (2) cyclosporine liquid; (3) cyclosporine capsules; (4) desmopressin acetate tablets; (5) epoprostenol sodium (freeze-dried powder) injection (''epop''); (6) flutamide capsules; (7) glipizide/metformin HCl tablets; (8) mirtazapine orally disintegrating tablets (''ODT''); (9) tamoxifen citrate tablets; and (10) tetracycline HCl capsules. In addition, the proposed Consent Agreement requires the companies to divest Teva's rights and assets necessary to manufacture and market generic trazodone HCl tablets and thirteen oral contraceptive products to Qualitest Pharmaceuticals (''Qualitest'').

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (''Order'').

Pursuant to an Agreement and Plan of Merger dated July 18, 2008, Teva proposes to acquire all of the issued and outstanding shares of Barr for approximately $7.4 billion, plus the assumption of $1.5 billion of net debt, for approximately $8.9 billion. The Commission's Complaint alleges 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

[1] The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

U.S.C. § 45, by lessening competition in the U.S. markets for the manufacture and sale of the following generic pharmaceutical products: (1) tetracycline HCl capsules; (2) chlorzoxazone tablets; (3) desmopressin acetate tablets; (4) metoclopramide HCl tablets; (5) carboplatin injection; (6) tamoxifen citrate tablets; (7) metronidazole tablets; (8) trazodone HCl tablets; (9) glipizide/metformin HCl tablets; (10) cyclosporine liquid; (11) cyclosporine capsules; (12) flutamide capsules; (13) mirtazapine ODT; (14) deferoxamine injection; (15) epop; (16) weekly fluoxetine capsules; and (17) thirteen generic oral contraceptive markets (collectively, the ''Products''). The proposed Consent Agreement will remedy the alleged violations by replacing the lost competition that would result from the acquisition in each of the markets.

The Products and Structure of the Markets

The proposed acquisition of Barr by Teva would strengthen Teva's worldwide position in generic pharmaceuticals and provide Teva with a stronger pipeline of generic products.

The transaction would reduce the number of competing generic suppliers in each of the relevant markets. The number of generic suppliers has a direct and substantial effect on generic pricing as each additional generic supplier can have a competitive impact on the market. Generic pharmaceutical customers are not likely to switch to the equivalent branded product because they are priced significantly higher than the generic products. After more than one generic product is introduced, competition among the generic competitors drives pricing, and the branded product's pricing largely becomes competitively irrelevant.

In the markets for generic tetracycline HCl tablets, chlorzoxazone tablets, and desmopressin acetate tablets, Teva and Barr are the only companies manufacturing and selling products in the United States. Tetracycline HCl is an old, broad-spectrum antibiotic used now primarily for the treatment of acne and rosacea. Chlorzoxazone is a centrally acting muscle relaxant used to treat muscle spasms. Desmopressin acetate is a synthetic replacement for an antidiuretic hormone that reduces urine production during sleep and is used to treat bed-wetting in children. Because Teva and Barr are the only suppliers of these generic products in the United States, the proposed acquisition creates a monopoly in each of these markets.

In the generic tamoxifen citrate and cyclosporine liquid markets, the proposed acquisition reduces the number of competitors from three to two. Tamoxifen citrate is a selective estrogen receptor modulator that is used in the treatment of breast cancer. Cyclosporine is an immunosuppressant drug used to prevent the rejection of transplanted organs. Combined, Teva and Barr, currently account for 73 percent of the generic tamoxifen citrate market and 55 percent of the generic cyclosporine liquid market.

Teva's proposed acquisition of Barr would reduce the number of competitors from four to three in the following generic markets: (1) metoclopramide HCl tablets; (2) carboplatin injection; (3) metronidazole tablets; (4) trazodone HCl tablets; (5) cyclosporine capsules; (6) flutamide capsules; (7) glipizide/metformin HCl tablets; (8) deferoxamine injection; and (9) mirtazapine ODT. The structure of each of these markets is as follows:

- Metoclopramide HCl is a dopamine receptor antagonist used to treat nausea and vomiting as well as gastroesophageal reflux disease (''GERD''). In the generic metoclopramide HCl market, Teva and Barr are two of only four suppliers supplying all dosage forms of metoclopramide HCl. Qualitest and Mutual/URL Pharmaceuticals (''Mutual'') are the remaining two suppliers. A combined Teva and Barr would possess 82 percent of the overall generic metoclopramide HCl market based on current sales.
- Carboplatin, the generic version of Bristol-Myers Squibb Company's (''BMS'') Paraplatin®, is a chemotherapy drug used to treat a variety of cancers, mainly ovarian, lung, head and neck cancers. Teva and Barr are two of the leading suppliers of generic carboplatin injection with a combined market share of 60 percent. APP Pharmaceuticals and Bedford Laboratories (''Bedford'') are the two remaining suppliers in the generic carboplatin injection market with 11 percent and 29 percent of the market, respectively.
- Metronidazole is an anti-infective used in the treatment of a variety of bacterial infections. Barr is the market leader in the generic metronidazole market with 50 percent market share. Teva is close behind with 39 percent of the market. Mutual and Amneal Pharmaceuticals are the only other suppliers with 4 percent and 1 percent of the market, respectively. Therefore, the proposed acquisition combines two of the most competitively significant suppliers of generic metronidazole, resulting in a combined market share of 89 percent.
- Trazodone is an antidepressant with a sedative effect. In the generic trazodone market, the proposed acquisition would result in a combined market share of 75 percent. Apotex Group is the only other competitively significant supplier with 22 percent of the market. The fourth supplier—Watson—has had limited success in this market, having captured only a 3 percent market share to date.
- Cyclosporine is an immunosuppressant drug used to prevent the rejection of transplanted organs. In the generic cyclosprine capsules market, Teva and Barr have roughly equal market shares and their post-acquisition market share would be 41 percent. Abbott Laboratories is the market leader with 51 percent of the market. The fourth supplier—Sandoz Inc. (''Sandoz'')— represents approximately 8 percent of the market.
- Flutamide is an anti-androgen drug used to treat prostate cancer. Teva, Barr, Par Pharmaceutical Companies (''Par''), and Sandoz are the four suppliers of generic flutamide. Sandoz is the market leader with 34 percent of the market. Teva has 28 percent of the market, Par has 24 percent, and Barr has 14 percent. Consequently, the proposed acquisition would result in a combined market share of 42 percent.
- Glipizide/Metformin, the generic version of BMS's Metaglip®, is commonly prescribed as a first line treatment for diabetes. Mylan Pharmaceuticals (''Mylan''), Sandoz, Teva, and Barr are the four suppliers of generic glipizide/metformin. Sandoz is the market leader with 37 percent. Barr and Teva have roughly equal market shares of 25 and 26 percent, respectively. The fourth supplier—Mylan—has the smallest market share with 12 percent. Thus, Teva's proposed acquisition of Barr would result in a post acquisition market share of 51 percent.
- Deferoxamine, the generic version of Novartis International AG's Desferal®, is a chelating agent used to remove excess iron from the body. In the generic deferoxamine market, a combined Teva and Barr would possess 16 percent of the market. Hospira Inc. is the market leader with 73 percent market share. The remaining supplier—Bedford—is a small competitor as reflected by its 11 percent share of the market. Although the combined share of Teva and Barr is only 16 percent, the proposed

transaction would combine two of only four companies offering generic deferoxamine injection in the United States. As discussed in Effects, below, the number of suppliers is the driving factor for prices in generic markets.

- Mirtazapine is an antidepressant used to treat moderate to severe depression. Only four companies currently supply generic mirtazapine in the United States—Teva, Barr, Prasco Laboratories (''Prasco''), and Aurobindo Pharma (''Aurobindo''). Prasco is the market leader with a 49 percent market share. Barr has 26 percent of the market, and Teva has 10 percent of the market. Aurobindo is the smallest competitor with only 8 percent of the market. Hence, the proposed acquisition would result in a combined market share of 36 percent.

In two product markets—epop and fluoxetine weekly capsules—the proposed acquisition would eliminate important and significant future competition. Epop is used to treat severe primary pulmonary hypertension. Epop is a new generic market and Teva is currently the only generic epop supplier. Barr has an epop product in development. Fluoxetine weekly capsules are a widely-prescribed antidepressant. Both Teva and Barr have generic products in development for the fluoxetine weekly capsules market. There are few firms that are capable of, and interested in, entering these markets.

Oral contraceptives are pills taken by mouth to prevent ovulation and pregnancy. They are the most common method of reversible birth control, used by 82 percent of women in the United States at some point during their reproductive years.

The thirteen oral contraceptive markets include two markets where both Teva and Barr participate, ten markets where Barr participates and Teva has a product in development and one market where both Teva and Barr have products in development. The two markets where both Barr and Teva currently participate—generic Ortho-Cyclen® and generic Ortho Tri-Cyclen®—are already highly concentrated. A combined Teva and Barr would have 68 percent of the generic Ortho-Cyclen® market and 51 percent of the generic Ortho Tri-Cyclen® market. Watson is the only other supplier in each of these markets.

Barr also competes in ten oral contraceptive markets where Teva is developing a competing product. These markets include generic products that are equivalent to Ortho-Cept®, Mircette®, Triphasil®, Alesse®, OrthoNovum® 1-35, OthroNovum® 7/7/7, Loestrin® FE (1mg/.02 mg & 1.5 mg/.03 mg), Loestrin® FE (1mg/.2 mg), Loestrin® FE 24, and Ovcon® 35. In each of these relevant markets, Teva is one of a limited number of firms capable of developing a generic oral contraceptive product that would compete in each of these markets, and is well-positioned to enter the markets in a timely manner. Both Teva and Barr are developing generic products equivalent to Ortho Tri-Cyclen® Lo 28 and are two of a limited number of firms with this product in development.

Entry

Entry into the markets for the manufacture and sale of the Products would not be timely, likely or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and Food and Drug Administration (''FDA'') drug approval requirements takes at least two years. Entry would not be likely because many of the relevant markets are relatively small and in decline, so the limited sales opportunities available to a new entrant would likely be insufficient to warrant the time and investment necessary to enter.

Effects

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of each of the generic markets listed above. In generic pharmaceutical markets, pricing is heavily influenced by the number of competitors that participate in a given market. Here, the evidence shows that the prices of the generic pharmaceutical products at issue decrease with the entry of each additional competitor.

Evidence gathered during the investigation confirms that pricing for the generic pharmaceutical products at issue in the transaction is driven by the number firms that compete in the markets. Customers consistently state that the price of a generic pharmaceutical decreases with the entry of the second, third and even fourth competitor. The evidence also indicates that the presence of four significant competitors allows customers to negotiate lower prices than is the case where there are fewer firms. The proposed transaction would eliminate one of at most four competitors in each of the relevant markets and would cause significant anticompetitive harm to consumers in the U.S. markets by eliminating actual, direct, and substantial competition between Teva and Barr and by increasing the likelihood that customers will pay higher prices.

The competitive concerns can be characterized as both unilateral and coordinated in nature. The homogenous nature of the products involved, the minimal incentives to deviate, and the relatively predictable prospects of gaining new business all indicate that the firms in the market will find it profitable to coordinate their pricing. The impact that a reduction in the number of firms would have on pricing can also be explained in terms of unilateral effects, as the likelihood that the merging parties would be the first and second choices in a significant number of bidding situations is enhanced where the number of firms participating in the market decreases substantially.

The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the relevant product market. Pursuant to the Consent Agreement, Teva and Barr are required to divest certain rights and assets related to the Products to a Commission-approved acquirer no later than ten days after the acquisition. Specifically, the proposed Consent Agreement requires that Teva divest the oral contraceptive products and trazodone to Qualitest and that Teva/Barr divest the remainder of the Products to Watson.

The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed acquirer of divested assets must not itself present competitive problems.

Qualitest and Watson are well-positioned to manufacture and market their respective acquired Products and to compete effectively in those markets. Both Qualitest and Watson develop, manufacturer, sell, and distribute generic pharmaceuticals within the United States. Moreover, the divestitures to both companies do not present competitive problems of their own because neither competes in those markets. With their resources, capabilities, strong reputation, and experience marketing generic products, the two companies are expected to replicate the competition that would be lost with the proposed acquisition.

If the Commission determines that either Watson or Qualitest is not acceptable acquirer of the assets to be

divested, or that the manner of the divestitures is not acceptable, the parties must unwind the sale and divest the assets within six months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six months, the Commission may appoint a trustee to divest the Products.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Teva and Barr to provide transitional services to enable the Commission-approved acquirers to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Teva or Barr. Most of the oral contraceptive products had been divested to Teva pursuant to a Commission Order in the matter of *Watson Pharmaceuticals, Inc./Andrx Corporation*, Docket No. C-4172 (October 31, 2006). This proposed D&O does not relieve Watson of any of its obligations pursuant to the Commission Order issued in the above referenced Watson/Andrx matter.

The Commission has appointed William Rahe of Quantic Regulatory Services, LLC (''Quantic'') to oversee the asset transfer and to ensure Teva's and Barr's compliance with all of the provisions of the proposed Consent Agreement. Mr. Rahe is a senior consultant at Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires Teva and Barr to file reports with the Commission periodically until the divestitures and transfers are accomplished.

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.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. E8–30831 Filed 12–24–08: 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60 days.

Proposed Project: Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law—OMB No. 0990–NEW—Office of the Secretary.

Abstract: The proposed information collection is contained in the Final Rule entitled, ''Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law.'' The purpose of this collection is to ensure, by requiring written certification of compliance similar to other, existing certifications currently made by funding recipients and applicants, that recipients of Department funds are aware of and comply with the legal obligations imposed on them by the Church Amendments (42 U.S.C. 300a–7), Public Health Service Act section 245 (42 U.S.C. 238n) and the Weldon Amendment (Consolidated Appropriations Act, 2008, Pub. L. 110–161 Div. G section 508(d), 121 Stat. 1844, 2209). We estimate the universe and number of entities that would be required to certify to be 571,947. The act of certification consists of reviewing the certification language, reviewing relevant entity policies and procedures, and reviewing files before signing. Although some entities may need to sign a certification statement more than once, we assume that the entity will only carefully review the language, procedures and their files before signing the initial statement each year.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Hospitals (less than 100 beds)	2403	1	30/60	1202
Hospitals (less than 100 beds)	1129	1	30/60	565
Hospitals (200–500 beds)	1160	1	30/60	580
Hospitals (more than 500 beds)	244	1	30/60	122
Nursing Homes (less than 50 beds)	2388	1	30/60	1194
Nursing Homes (50–99 beds)	5819	1	30/60	2910
Nursing Homes (99—199 beds)	6877	1	30/60	3439
Nursing Homes (more than 200 beds)	1037	1	30/60	519
Physicians Offices	234200	1	30/60	117100
Offices of Other Health Care Practitioners	115378	1	30/60	57689
Outpatient Care Centers	26901	1	30/60	13451