**UNITED STATES OF AMERICA**
**BEFORE FEDERAL TRADE COMMISSION**

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| In the Matter of<br><br>**Glaxo Wellcome plc,**<br>a corporation,<br><br>and<br><br>**SmithKline Beecham plc,**<br>a corporation. | ) | Docket No. C-3990 |

## COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that Respondent Glaxo Wellcome plc ("Glaxo"), a corporation subject to the jurisdiction of the Commission, has agreed to merge with Respondent SmithKline Beecham plc ("SB"), a corporation subject to the jurisdiction of the Commission, in violation of 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, 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. DEFINITIONS

1. "Commission" means the Federal Trade Commission.

4. “5HT-3 antiemetic drug” means any 5HT-3 receptor antagonist prescription pharmaceutical compound indicated for the prevention and treatment of nausea and vomiting associated with medical treatment, including chemotherapy, radiation therapy, or surgery.

5. “Second generation oral and intravenous antiviral drugs for the treatment of herpes” means oral and intravenous antiviral drugs, other than acyclovir, for use in the treatment of infections by the herpes simplex virus Type 1 (“HSV-1"), the herpes simplex virus Type 2 (“HSV-2"), and the herpes varicella zoster virus.

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herpes vaccines, OTC H-2 blockers, Topoisomerase I inhibitors, Drugs for the treatment of IBS, and Triptan drugs for the treatment of migraine headaches.

13. Respondent SB is a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom, with its office and principal place of business located at New Horizons Court, Brentford, Middlesex, TW8 9EP, England. SB, among other things, is engaged in the research, development, manufacturing and sale of human pharmaceutical products, including 5HT-3 antiemetic drugs, Second generation oral and intravenous antiviral drugs for the treatment of herpes, Topical prescription herpes antivirals, Ceftazidime, Prophylactic herpes vaccines, OTC H-2 blockers, Topoisomerase I inhibitors, Drugs for the treatment of IBS, and Triptan drugs for the treatment of migraine headaches.

14. Respondents are, and at all times relevant herein have been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and are corporations whose business is in, or affects commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

## III. THE PROPOSED MERGER

15. On January 17, 2000, the Boards of Glaxo and SB announced agreement to the terms of a merger to be effected by way of a scheme of arrangement of Glaxo and SB under section 425 of the Companies Act of 1985 ("Merger"). The value of the transaction is approximately $182 billion. On completion of the transaction, the current Glaxo shareholders will own approximately 58.75% of the shares of Glaxo SmithKline and current SB shareholders will own approximately 41.25% of the shares of Glaxo SmithKline.

## IV. THE RELEVANT MARKETS

16. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Merger are:

a. the research, development, manufacture and sale of 5HT-3 antiemetic drugs;

b. the research, development, manufacture and sale of Second generation oral and intravenous antiviral drugs for the treatment of herpes;

c. the research, development, manufacture and sale of Topical prescription herpes antivirals;

d. the research, development, manufacture and sale of Ceftazidime;

e. the research, development, manufacture and sale of Prophylactic herpes vaccines;

f. the research, development, manufacture and sale of OTC H-2 blockers;

g. the research, development, manufacture and sale of Topoisomerase I inhibitors;

h. the research, development, manufacture and sale of Drugs for the treatment of IBS; and

i. the research, development, manufacture and sale of Triptan drugs for the treatment of migraine headaches.

17. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Merger in the relevant lines of commerce.

## V. THE STRUCTURE OF THE MARKETS

18. The market for 5HT-3 antiemetic drugs is highly concentrated as measured by the Herfindahl-Hirschman Index ("HHI"). Glaxo and SB are the two leading suppliers of 5HT-3 antiemetic drugs in the United States. Glaxo and SB, respectively, have approximately 58% and 34% of the market, and the pre-merger HHI is 4584. As a result of the Merger, Glaxo SmithKline would have a 92% percent share of the market, and the post-merger HHI would be 8528, representing a 3944 point increase in the HHI.

19. The market for Second generation oral and intravenous antiviral drugs for the treatment of herpes is highly concentrated. Glaxo and SB are the only two suppliers of these drugs in the United States. No other company is presently manufacturing or selling drugs to compete with Glaxo and SB.

20. The market for Ceftazidime is highly concentrated as measured by the HHI. Glaxo and SB are the only two manufacturers of Ceftazidime in the United States, and two of the three firms with rights to market Ceftazidime in the United States. Glaxo and SB, respectively, have approximately 77% and 8% of the market, and the pre-merger HHI is 6218. As a result of the Merger, Glaxo SmithKline would have an 85% share of the market, and the post-merger HHI would be 7450, representing a 1232 point increase in the HHI.

21. The market for Topical prescription herpes antivirals is highly concentrated. Currently, SB's Denavir is the only topical prescription preparation approved by the FDA for the treatment of oral herpes. Until April of 2000, Glaxo was in the final stages of seeking FDA

approval of a creme formulation of Zovirex for the treatment of oral herpes, but after the announcement of the Merger, Glaxo withdrew the application for FDA approval, without prejudice to its refiling its NDA with the FDA. Glaxo's Zovirex creme could be on the market in less than one year. No other companies are working on a prescription topical treatments for oral herpes.

22. No company currently markets a prophylactic herpes vaccine. SB has the most advanced development effort toward a herpes vaccine. Glaxo has been developing a vaccine for HSV infection in conjunction with Cantab Pharmaceuticals plc. Glaxo had planned, with Cantab, to design Phase III clinical trials this year, exercising its option to do so pursuant to its contract with Cantab. Other firms that have undertaken efforts to develop a prophylactic herpes vaccine either have failed in their efforts or are far behind SB and Glaxo/Cantab, with vaccines that are only in pre-clinical stages of testing. Thus, Glaxo and SB are likely to be the first two competitors to reach the market with Prophylactic herpes vaccines.

23. The market for OTC H-2 blockers is highly concentrated as measured by the HHI. Glaxo and SB are two of the leading suppliers of OTC H-2 blockers in the United States. Glaxo and SB, respectively, have approximately 30% and 11% of the market, and the pre-merger HHI is 2990. As a result of the Merger, Glaxo SmithKline would have a 41% share of the market, and the post-merger HHI would be 3650, representing a 660 point increase in the HHI.

24. The market for Topoisomerase I inhibitors is highly concentrated. SB's drug Hycamptin is currently a leading second-line therapy for ovarian and non-small cell lung cancer ("non-SCLC") and SB is pursuing first-line indications for these cancers as well as second-line therapy for colorectal and other solid-tumor cancers. Glaxo presently maintains rights in a topoisomerase I inhibitor formulation being developed by Gilead Sciences, Inc. for ovarian, breast, non-SCLC and other solid tumor indications, including colorectal cancer. The only other topoisomerase I inhibitor on the market is Camptosar from Pharmacia, which is currently indicated as a second-line therapy for colorectal cancer. No other topoisomerase I inhibitors is in development.

25. Currently, there are no Drugs available for the treatment of irritable bowel syndrome. Though effective in treating IBS sufferers, Glaxo's Lotronex, the only FDA-approved treatment for IBS, was recently taken off the market by Glaxo because of concerns about serious side effects in some patients. However, Glaxo continues to conduct clinical trial for Lotronex. Alizyme plc, pursuant to a licensing agreement with SB, has been developing a drug called renzapride for the treatment of irritable bowel syndrome. If SB exercises the relevant options under its agreement with Alizyme, then SB and Alizyme would have one of only three drugs currently being developed to treat IBS.

26. The market for Triptan drugs for the treatment of migraine headaches is highly concentrated. Glaxo, with approximately 65% of sales, leads the market with its migraine medications Immitrex and Amerge. Only two other drugs in the triptan class are approved for the

treatment of migraine headaches – Zomig from AstraZeneca and Maxalt from Merck & Co., Inc. SB presently maintains rights in SB209509, a compound in development that is in the same triptan class as these four drugs. SB209509 is being developed by Vernalis Ltd. for the treatment of migraine headaches.

## VI. ENTRY CONDITIONS

27. Entry into each of the relevant markets identified in Paragraph 16 is unlikely and would not occur in a timely manner to deter or counteract the adverse competitive effects described in Paragraph 28, because of, among other things, the time and expense necessary to develop and gain FDA approval for such human pharmaceutical products.

## VII. EFFECTS OF THE MERGER

28. The effects of the Merger, if consummated, may be substantially to lessen competition and to tend to create a monopoly in the relevant markets in 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, in the following ways, among others:

a. by increasing the likelihood that the merged entity would increase prices and reduce innovation in the market for 5HT-3 antiemetic drugs, either unilaterally or through coordinated interaction;

b. by increasing the likelihood that the merged entity would increase prices in the market for Ceftazidime, either unilaterally or through coordinated interaction;

c. by increasing the likelihood that the merged entity would unilaterally increase prices and reduce innovation in the market for Second generation oral and intravenous antiviral drugs for the treatment of herpes;

d. by eliminating the only potential entrant in the market for Topical prescription herpes antivirals where SB is currently a monopolist;

e. by increasing the likelihood that the merged entity would forego or delay the development efforts of one of the Prophylactic herpes vaccines or, alternatively, eliminate price competition between the two prophylactic herpes vaccines if both were introduced in the market;

f. by increasing the likelihood that the merged entity would increase prices

and reduce innovation in the market for OTC H-2 blockers, either unilaterally or through coordinated interaction;

g. by increasing the likelihood that the merged entity would increase prices and reduce innovation in the market for Topoisomerase I inhibitors for the treatment of ovarian, non-SCLC, colorectal, and other solid tumor cancers, either unilaterally or through coordinated interaction;

h. by increasing the likelihood that the merged entity would increase prices and reduce innovation in the market for Drugs for the treatment of IBS; and

i. by increasing the likelihood that the merged entity would increase prices and reduce innovation in the market for Triptan drugs for the treatment of migraine headaches, either unilaterally or through coordinated interaction.

## VIII. VIOLATIONS CHARGED

29. The Merger Agreement described in Paragraph 15 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

30. The Merger described in Paragraph 15, 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 fifteenth day of December, 2000, issues its Complaint against said Respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: