IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

JUDGE HOLWELL

GLAXO GROUP LIMITED	'07 CIV 6012
Plaintiff,	Civil Action No.
v.	**COMPLAINT FOR PATENT INFRINGEMENT**
CYPRESS PHARMACEUTICAL, INC.	
Defendant.	

Plaintiff Glaxo Group Limited for its Complaint against defendant Cypress Pharmaceutical, Inc. avers and alleges as follows:

THE PARTIES

1. Plaintiff Glaxo Group Limited ("Glaxo") is a company organized and existing under the laws of England and Wales and having a registered office at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 ONN, Middlesex, England.

2. Defendant Cypress Pharmaceutical, Inc. ("Cypress") is a Mississippi corporation that applied for, and was granted, authorization to do business in New York. A true and correct copy of Cypress' "Entity Information" from the New York Department of State website is attached as Exhibit A.

JURISDICTION AND VENUE

3. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 271 *et seq.* and 21 U.S.C. § 355.

4. Jurisdiction and venue are proper in this judicial district pursuant to 28 U.S.C. §§ 1331, 1338(a) and 1391(c).

5. Personal jurisdiction over Cypress is available in this judicial district. Cypress selected New York County on its "Application for authority" to do business in New York as the "county...in which its office is to be located." Cypress designated the New York Secretary of State as its "agent upon whom process against it may be served." New York Business Corporation Law §§ 1304(a)(5) and (a)(6), respectively. New York County (Manhattan) is within the Southern District of New York.

PATENT INFRINGEMENT PURSUANT TO 35 U.S.C. § 271(e)(2)

6. On November 26, 1991, United States Patent No. 5,068,249 ("the '249 patent") entitled "Aqueous Ranitidine Compositions Stabilized with Ethanol" was duly and legally issued. Since that date, Glaxo Group Limited has been and remains the assignee and owner of the '249 patent.

7. The '249 patent covers a pharmaceutical composition which is an aqueous formulation for oral administration of an effective amount of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation comprising a stabilizing effective amount of ethanol and having a pH in the range of 6.5 – 7.5. The '249 patent expires on November 26, 2008. A true and correct copy of the '249 patent is attached to this Complaint as Exhibit B.

8. SmithKline Beecham Corporation is the holder of the approved New Drug Application ("NDA") No. 19-675 under Section 505(b) of the Federal Food, Drug and Cosmetic Act (hereinafter the "Act"), codified at 21 U.S.C. § 355(b), for

Ranitidine Hydrochloride Oral Syrup, 15mg/ml, (the "approved drug product"), which is covered by the '249 patent.

9. Glaxo has qualified for pediatric exclusivity for its approved drug product. *See* Section 505A of the Act, 21 U.S.C. § 355a. The grant of pediatric exclusivity by the United States Food and Drug Administration ("FDA") attaches 6 months of exclusivity to the patent protection already afforded by the '249 patent to Glaxo's approved drug product. During this additional 6 month period, or until May 26, 2009, the FDA may not make effective the approval of an abbreviated new drug application "for which a certification has been submitted under subsection ... (j)(2)(A)(vii) (IV) of section 505" of the Act, also known as a paragraph IV certification. Section 505A (b)(2)(B) of the Act, 21 U.S.C. § 355a (b)(2)(B).

10. Cypress has filed or has caused to be filed with the FDA Abbreviated New Drug Application No. 78-779, (the "ANDA"), requesting FDA approval to market a generic version of the approved drug product prior to the expiration of Glaxo's '249 patent and attendant pediatric exclusivity. The manufacture, use or sale of Cypress' generic Ranitidine Oral Syrup, 15 mg/ml, prior to the expiration of the '249 patent and attendant pediatric exclusivity, would be an infringement of the '249 patent claims.

11. The Cypress ANDA submission contains a paragraph IV certification under Section 505(j)(2)(A)(vii)(IV) of the Act (21 U.S.C. § 355(j)(2)(A)(vii)(IV)). FDA approval of the ANDA cannot be made effective until at least May 26, 2009, 6 months after the '249 patent expires, because Glaxo was granted pediatric exclusivity. Section 505A (b)(2)(B) of the Act, 21 U.S.C. § 355a (a)(2)(B).

12. On or about May 14, 2007, Glaxo received from Cypress the statutorily required written notice of Cypress' ANDA submission requesting FDA marketing approval to manufacture, use or sell Ranitidine Oral Syrup, 15 mg/ml, prior to the expiration of the '249 patent. *See* Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355 (j)(2)(B)(ii); *see also* 21 CFR § 314.95(c). In its written notice, Cypress alleges that "no valid claim of the '249 patent will be infringed" by its proposed generic version of Glaxo's approved drug product, but Cypress does not provide a factual and legal basis for any non-infringement allegation.

13. Cypress also ignored Glaxo's May 16, May 29 and June 7, 2007 requests for information regarding the formulation and composition of Cypress' proposed generic version of Glaxo's approved drug product. Consequently, Cypress has not provided any information to Glaxo to support any non-infringement allegation.

14. Cypress, by filing its ANDA and requesting FDA marketing approval for generic Ranitidine Oral Syrup, 15 mg/ml, prior to expiration of the '249 patent and attendant pediatric exclusivity period, has infringed the claims of the '249 patent under 35 U.S.C. § 271(e)(2), and such infringement will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Glaxo prays for a Judgment:

A. Finding that defendant has infringed the claims of United States Patent No. 5,068,249;

B. Ordering that the effective date of any approval of defendant's Abbreviated New Drug Application No. 78-779 under Section 505(j) of the Federal Food,

Drug and Cosmetic Act, 21 U.S.C. § 355(j), for Ranitidine Oral Syrup, 15 mg/ml, and its use be not earlier than the expiration date of United States Patent No. 5,068,249, including any additional period of FDA-authorized exclusivity;

C. Awarding plaintiff preliminary and final injunctions enjoining defendant and its officers, agents, servants, employees and privies from infringement of United States Patent No. 5,068,249; and

D. Awarding plaintiff its costs, expenses, and reasonable attorneys' fees and such other and further relief as this Court may deem just and proper.

Dated: June 25, 2007

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