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SUPERIOR COURT OF NEW JERSEY  
CHANCERY DIVISION  
MERCER COUNTY  
DOCKET NO. C-41-11

PAULA T. DOW, Attorney General of the  
State of New Jersey, and THOMAS R.  
CALCAGNI, Acting Director of the New  
Jersey Division of Consumer Affairs,

Plaintiffs,

vs.

GLAXOSMITHKLINE LLC and SB  
PHARMCO PUERTO RICO, INC.,

Defendants.

Civil Action

COMPLAINT

Plaintiffs Paula T. Dow, Attorney General of the State of New Jersey ("Attorney General"), with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, and Thomas R. Calcagni, Acting Director of the New Jersey Division of Consumer Affairs ("Acting Director"), with offices located at 124 Halsey Street, Seventh Floor, Newark, New Jersey, bring this action complaining of Defendants GLAXOSMITHKLINE LLC and SB PHARMCO

PUERTO RICO, INC. for violating the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. (“CFA”) as follows:

### JURISDICTION AND VENUE

1. This action is brought by the Attorney General and the Acting Director, pursuant to pursuant to their authority under the CFA, specifically N.J.S.A. 56:8-8, 56:8-11, 56:8-13 and 56:8-19.

2. Venue for this action properly lies in Mercer County, New Jersey, pursuant to R. 4:3-2, because Defendants transact business in the county and/or some of the transactions out of which this action arose occurred in the county and it is a county in which at least one of the parties reside.

### PARTIES

3. The Attorney General is charged with the responsibility of enforcing the CFA and all regulations promulgated thereunder (the “CFA Regulations”), N.J.A.C. 13:45A-1.1 et seq. The Acting Director is charged with the responsibility of administering the CFA and the CFA Regulations on behalf of the Attorney General.

4. Defendant GLAXOSMITHKLINE LLC (“GSK”) is a Delaware corporation with a principal place of business at 1 Franklin Plaza, Philadelphia, Pennsylvania 19102. GSK transacts business in New Jersey by developing, manufacturing, promoting, selling, and distributing prescription drugs.

5. Defendant SB PHARMCO PUERTO RICO, INC. (“SB PHARMCO”) is a corporation with a principal place of business at Rd. 172, Km 9.2, Bo. Certenejas, Cidra, PR 00739. SB PHARMCO is a wholly-owned subsidiary of GSK. Together with GSK, SB PHARMCO operates and manages a manufacturing facility located in Cidra. SB PHARMCO

transacts business in New Jersey by developing, manufacturing, promoting, selling, and distributing prescription drugs.

6. SB PHARMCO and GSK are collectively referred to as "Defendants".

#### **COMMERCE**

7. The New Jersey Consumer Fraud Act defines "merchandise" as "any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale." N.J.S.A. 56:8-1(c).

8. Defendants, at all times relative hereto, offered merchandise to consumers in the State of New Jersey ("New Jersey") by developing, manufacturing, promoting, selling, and distributing prescription drugs.

#### **DEFENDANTS' MANUFACTURING PRACTICES**

9. In or around January 2001, Defendants' Cidra manufacturing facility became one of their largest manufacturing facilities worldwide and a major supplier of prescription drugs to the United States. Defendants were responsible for making a complex portfolio of drugs, including pills, creams, ointments, and injectables at the Cidra facility.

10. Among other drugs manufactured at the Cidra facility, Defendants made the following drugs available for distribution to the United States: Kytril, Bactroban, Paxil CR, and Avandamet.

11. Kytril is a sterile drug used to prevent nausea and vomiting caused by cancer chemotherapy and radiation therapy.

12. Bactroban is an antibiotic ointment used to treat skin infections.

13. Paxil CR is the controlled release formulation of the popular antidepressant drug, Paxil.

14. Avandamet is a combination Type II diabetes drug.

15. When these drugs are sold to consumers, there is an implied representation that they are unadulterated.

16. Between 2001 and 2004, Defendants manufactured and put into the stream of commerce certain lots of Kytril, Bactroban, Paxil, and Avandamet that were adulterated because the manufacturing process used to produce these lots were substandard.

#### APPLICABLE STATUTE

17. The CFA focuses on commercial deception in consumer transactions and provides, in pertinent part:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice . . . .

[N.J.S.A. 56:8-2.]

18. As such, “the word ‘unconscionable’ must be interpreted liberally so as to effectuate the public purpose of the CFA.” Associates Home Equity Svcs., Inc. v. Troup, 343 N.J. Super. 254, 278 (App. Div. 2001).

19. Under New Jersey law, “an affirmative misrepresentation is ‘one which is material to the transaction and which is a statement of fact, found to be false, made to induce the buyer to make the purchase.’” Mango v. Pierce-Coombs, 370 N.J. Super. 239, 251 (App. Div. 2004).

20. “When the alleged consumer fraud violation consists of an affirmative act, intent

is not an essential element and the plaintiff need not prove that the defendant intended to commit an unlawful act.” Cox v. Sears Roebuck & Co., 138 N.J. 2, 17-18 (1994) (citing Kugler v. Romain, 58 N.J. 522, 543-44 (1973)).

## COUNT I

### **VIOLATION OF THE CFA BY DEFENDANTS (UNCONSCIONABLE COMMERCIAL PRACTICES)**

21. Plaintiffs reallege and incorporate each and every allegation contained in the preceding Paragraphs 1 through 20.

22. Defendants, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of prescription drugs, have engaged in a course of trade or commerce which constitutes unconscionable commercial practices, and is therefore unlawful under the CFA. Defendants misrepresented the nature of prescription drugs despite their knowledge that the representations were not true as a result of the manner in which the prescription drugs were manufactured.

23. Each unconscionable commercial practice and/or misrepresentation by Defendants constitutes a separate violation under the CFA, N.J.S.A. 56:8-2.

## COUNT II

### **VIOLATION OF THE CFA BY DEFENDANTS (FALSE PROMISES AND/OR MISREPRESENTATIONS)**

24. Plaintiffs reallege and incorporate each and every allegation contained in the preceding Paragraphs 1 through 23.

25. Defendants, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of prescription drugs, have made false promises and/or misrepresentations, and have therefore violated CFA by:

- a. Representing the prescription drugs had sponsorship, approval characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have as a result of the manner in which the prescription drugs were manufactured; and
- b. Creating a likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of the prescription drugs as a result of the manner in which the prescription drugs were manufactured.

26. Each unconscionable commercial practice and/or misrepresentation by

Defendants constitutes a separate violation under the CFA, N.J.S.A. 56:8-2.

### REMEDIES

27. N.J.S.A. 56:8-8 provides, in pertinent part:

Whenever it shall appear to the Attorney General that a person has engaged in, is engaging in or is about to engage in any practice declared to be unlawful by this act he may seek and obtain in a summary action in the Superior Court an injunction prohibiting such person from continuing such practices or engaging therein or doing any acts in furtherance thereof . . . . The court may make such orders or judgments as may be necessary to prevent the use or employment by a person of any prohibited practices . . . .

28. N.J.S.A. 56:8-13 provides, in pertinent part:

Any person who violates any of the provisions of the act to which this act is a supplement shall, in addition to any other penalty provided by law, be liable to a penalty of not more than \$10,000 for the first offense and not more than \$20,000 for the second and each subsequent offense.

29. N.J.S.A. 56:8-11 provides that “[i]n any action or proceeding brought under the provisions of this act, the Attorney General shall be entitled to recover costs for the use of the State.”

30. N.J.S.A. 56:8-19 provides that “[i]n all actions under this section, including those brought by the Attorney General, the court shall also award reasonable attorneys’ fees, filing fees and reasonable costs of suit.”

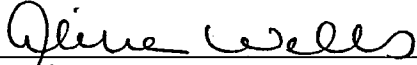
**PRAYER FOR RELIEF**

WHEREFORE, based upon the foregoing allegations, the Plaintiffs respectfully request that the Court enter judgment against Defendants:

- (a) Finding that the acts of Defendants constitute multiple instances of unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 et seq.;
- (b) Permanently enjoining Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair, deceptive or misleading conduct;
- (c) Assessing the maximum statutory civil penalties against Defendants, jointly and severally, for each and every violation of the CFA, in accordance with N.J.S.A. 56:8-13;
- (d) Directing the assessment of costs and fees, including attorneys' fees, against Defendants, jointly and severally, for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56:8-11 and N.J.S.A. 56:8-19; and
- (e) Granting such other relief as the interests of justice may require.

Respectfully submitted,

PAULA T. DOW  
ATTORNEY GENERAL OF NEW JERSEY  
Attorney for Plaintiffs

By:   
Alina Wells  
Deputy Attorney General

Dated: June 23, 2011  
Newark, New Jersey

**RULE 4:5-1 CERTIFICATION**

I certify, to the best of my information and belief, that the matter in controversy in this action involving the aforementioned violations of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. ("CFA") is not the subject of any other action pending in any other court of this State. I am aware that private actions have been brought against the Defendants, but have no direct information that any such actions involve violations of the CFA and Advertising Regulations. I further certify that the matter in controversy in this action is not the subject of a pending arbitration proceeding in this State, nor is any other action or arbitration proceeding contemplated. I also certify that there is no other party who should be joined in this action at this time.

PAULA T. DOW  
ATTORNEY GENERAL OF NEW JERSEY  
Attorney for Plaintiffs

By: Alina Wells  
Alina Wells  
Deputy Attorney General

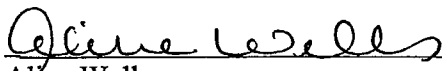
Dated: June 23, 2011  
Newark, New Jersey



**RULE 1:38-7(c) CERTIFICATION**

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with R. 1:38-7(b).

PAULA T. DOW  
ATTORNEY GENERAL OF NEW JERSEY  
Attorney for Plaintiffs

By:   
Alina Wells  
Deputy Attorney General

Dated: June 23, 2011  
Newark, New Jersey

**DESIGNATION OF TRIAL COUNSEL**

Pursuant to R. 4:25-4, Alina Wells, Deputy Attorney General, is hereby designated as trial counsel on behalf of Plaintiffs in this action.

PAULA T. DOW  
ATTORNEY GENERAL OF NEW JERSEY  
Attorney for Plaintiffs

By: Alina Wells  
Alina Wells  
Deputy Attorney General

Dated: June 23, 2011  
Newark, New Jersey