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LUCAS COUNTY

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COMMON PLEAS COURT
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IN THE COMMON PLEAS COURT OF LUCAS COUNTY, OHIO

CI0201103928

STATE OF OHIO *ex rel.*)
MICHAEL DEWINE)
ATTORNEY GENERAL)
30 E. Broad Street, 14th Floor)
Columbus, Ohio 43215)

CASE NO.

JUDGE

Mandros

Plaintiff,)

**COMPLAINT FOR DECLARATORY
JUDGMENT, INJUNCTIVE RELIEF,
AND CIVIL PENALTY**

v.)

GLAXOSMITHKLINE, LLC)
1 Franklin Plaza)
Philadelphia, Pennsylvania 19102)

And)

SB PHARMCO PUERTO RICO, INC.)
Rd. 172, Km 9.2, Bo. Certenejas)
Cidra, PR 00739)

JURISDICTION AND VENUE

1. Michael DeWine, Attorney General of Ohio, having reasonable cause to believe that violations of Ohio's consumer protection laws have occurred, brings this action in the public interest and on behalf of the State of Ohio under the authority vested in him by R.C. 1345.01 *et seq.* (the Ohio Consumer Sales Practices Act).

2. The actions of the Defendants GlaxoSmithKline, LLC and SB Pharmco Puerto Rico, Inc.,

(hereinafter “Defendants”), hereinafter described, have occurred in the State of Ohio, in Lucas County and other counties in Ohio and, as set forth below, are in violation of the Consumer Sales Practices Act, R.C. 1345.01 *et seq.*

3. Jurisdiction over the subject matter of this action lies within this Court pursuant to R.C. 1345.04 of the Consumer Sales Practices Act.

4. This Court has venue to hear this case pursuant to Ohio Civ. R. 3(B)(1)-(3) in that some of the transactions complained of herein, and out of which this action arose, occurred in Lucas County.

5. The Ohio Attorney General is the proper party to commence these proceedings under the authority provided him under R.C. 1345.07.

DEFENDANTS

6. 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 Lucas County, Ohio and other counties in Ohio by developing, manufacturing, promoting, selling, and distributing prescription drugs.

7. Defendant SB PharmCo Puerto Rico, Inc. (“SB PharmCo”) was a corporation organized under the laws of the Commonwealth of Puerto Rico with a principal place of business at Rd. 172, Km 9.2, Bo. Certenejas, Cidra, PR 00739. SB PharmCo was an indirect subsidiary of Glaxo Smith Kline plc, a British corporation with a principal place of business in Brentford, Middlesex, England. SB Pharmco was dissolved effective July 3, 2008 but continues to exist under operation of law for three years for purposes of litigation, prosecution, and settlement of its affairs. Together with GSK, SB Pharmco operated and managed a manufacturing facility located in Cidra, Puerto Rico. SB PHARMCO transacts business in Lucas County, Ohio and

other counties in Ohio by developing, manufacturing, promoting, selling, and distributing prescription drugs.

8. Defendant GSK is a “supplier” as that term is defined in R.C. 1345.01(C) as GSK was, at all times relevant herein, engaged in the business of effecting consumer transactions by developing, manufacturing, promoting, selling, and distributing prescription drugs in Lucas County and other counties in the State of Ohio for purposes that were primarily personal, family or household within the meaning specified in R.C. 1345.01(A) and (D).

9. Defendant SB Pharmco is a “supplier” as that term is defined in R.C. 1345.01(C) as SB Pharmco was, at all times relevant herein, engaged in the business of effecting consumer transactions by developing, manufacturing, promoting, selling, and distributing prescription drugs in Lucas County and other counties in the State of Ohio for purposes that were primarily personal, family or household within the meaning specified in R.C. 1345.01(A) and (D).

DEFENDANTS’ MANUFACTURING PRACTICES

10. In or around January 2001, Defendants’ Cidra manufacturing facility became one of the Defendants’ 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.

11. 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.

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

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

14. Paxil CR is the controlled release formulation of the popular antidepressant drug, Paxil.
15. Avandamet is a combination Type II diabetes drug.
16. When these drugs are sold to consumers, there is an implied representation that they are unadulterated.
17. 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 processes used to produce these lots were substandard.

APPLICABLE STATUTES

18. R.C. 1345.02(A) of the Consumer Sales Practices Act states as follows:

No supplier shall commit an unfair or deceptive act or practice in connection with a consumer transaction. Such an unfair or deceptive act or practice by a supplier violates this section whether it occurs before, during or after the transaction.

19. R.C. 1345.02(B)(1) and (2) of the Consumer Sales Practices Act state as follows:

(B) Without limiting the scope of division (A) of this section, the act or practice of a supplier in representing any of the following is deceptive:

- (1) That the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits that it does not have;
- (2) That the subject of a consumer transaction is of a particular standard, quality, grade, style, prescription, or model, if it is not;...

COUNT I

UNFAIR AND DECEPTIVE ACTS AND PRACTICES

20. Plaintiff incorporates by reference, as if completely rewritten herein, the allegations set forth in Paragraphs 1 through 19.
21. Defendants, in the course of engaging in the development, manufacture, promotion, sales,

and interstate distribution of prescription drugs, misrepresented that they had sponsorship, approval, performance characteristics, accessories, uses, or benefits that they did not have by making written and oral representations about prescription drugs when the Defendants knew the written and oral representations were not true as a result of the manner in which the prescription drugs were manufactured. Such representations are deceptive acts or practices in violation of R.C. 1345.02(A) and R.C. 1345.02(B)(1) of the Ohio Consumer Sales Practices Act.

COUNT II

UNFAIR AND DECEPTIVE ACTS AND PRACTICES

22. Plaintiff incorporates by reference, as if completely rewritten herein, the allegations set forth in Paragraphs 1 through 19.

23. Defendants, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of prescription drugs, misrepresented that they were of a particular standard, quality or grade and such misrepresentations are deceptive acts or practices in violation of the Ohio Consumer Sales Practices Act.

24. Defendants committed unfair or deceptive acts or practices in violation of the Ohio Consumer Sales Practices Act, R.C. R.C. 1345.02(A) and 1345.02(B)(2) by misrepresenting that the prescription drugs were of a particular standard, quality or grade when they were not.

PRAYER FOR RELIEF


WHEREFORE, Plaintiff respectfully requests that this Court:

- A. Adjudge and decree that Defendants have engaged in acts or practices in violation of the Ohio Consumer Sales Practices Act, R.C. 1345.01 *et seq.*, as previously set forth.
- B. Permanently enjoin and restrain the Defendants from engaging in deceptive and unfair practices set forth herein and from violating the Ohio Consumer Sales Practices Act.

- C. Adjudge and decree that the Defendants are liable to the State for the reasonable costs and expense of the investigation and prosecution of the Defendants' actions.
- D. Assess, fine and impose upon Defendants a civil penalty pursuant to R.C. 1345.07(D) of Twenty-Five Thousand Dollars (\$25,000.00) for each unfair or deceptive act or practice alleged herein.
- E. Order that all costs in this cause be taxed against Defendants.
- F. Grant Plaintiff such other and further relief as the Court deems just, equitable and appropriate.

Respectfully submitted,

MICHAEL DEWINE
Attorney General of Ohio



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