

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

THE STATE OF IOWA, ex rel.)
THOMAS J. MILLER,)
ATTORNEY GENERAL)
99AG25112)
)
Plaintiff,)
)
vs)
)
GLAXOSMITHKLINE LLC)
)
and)
)
SB PHARMCO PUERTO RICO, INC,)
)
Defendants.)

PETITION

Equity No. CELE8819

INTRODUCTION

Plaintiff, the State of Iowa ex rel. Attorney General Thomas J. Miller, by Assistant Attorney General Layne M. Lindebak, brings this action complaining of Defendants Glaxosmithkline, LLC and SB Pharmco Puerto Rico, Inc., for violating the Iowa Consumer Fraud Act, Iowa Code section 714.16, as follows:

FILED
POLK COUNTY, IA
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IOWA DISTRICT COURT

JURISDICTION AND VENUE

1. This action is brought by the State of Iowa ex rel. Attorney General Thomas J. Miller, pursuant to the provisions of the Iowa Consumer Fraud Act, Iowa Code section 714.16.
2. This Court has jurisdiction over the Defendants pursuant to Iowa Code section 714.16, because the Defendants have transacted business within the State of Iowa at all times relevant to this Petition.

3. Venue for this action properly lies in Polk County, Iowa, pursuant to Iowa Code section 714.16(10), because Defendants transact business in Polk County, Iowa and/or some of the transactions out of which this action arose occurred in Polk County, Iowa.

PARTIES

4. The Attorney General of Iowa is charged, inter alia, with the enforcement of the Consumer Fraud Act, Iowa Code section 714.16(7).

5. 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 Iowa and nationwide by manufacturing, marketing, promoting, selling and distributing prescription drugs.

6. 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 engaged in business in Iowa by manufacturing prescription drugs that were sold in Iowa.

ADVERTISING AND SELLING MERCHANDISE IN IOWA

7. Iowa Code § 714.16(2)(a) applies to the sale, lease or advertisement of merchandise in the State of Iowa. Defendants were at all times relevant hereto, engaged in the advertisement and sale of merchandise in the State of Iowa to wit: advertising, soliciting, offering for sale and selling prescription drugs, and accepting monies from Iowa consumers for the same.

BACKGROUND

8. 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.

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

- a. Kytril is a sterile drug used to prevent nausea and vomiting caused by cancer chemotherapy and radiation therapy.
- b. Bactroban is an antibiotic ointment used to treat skin infections.
- c. Paxil CR is the controlled release formulation of the popular antidepressant drug, Paxil.
- d. Avandamet is a combination Type II diabetes drug.

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

11. 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 STATUTES

12. Iowa Code section 714.16(2)(a), states in relevant part as follows:

The act, use or employment by a person of an unfair practice, deception, fraud, false pretense, false promise, or misrepresentation, or the concealment, suppression, or omission of a material fact with intent that others rely upon the concealment, suppression, or omission, in connection with the lease, sale, or advertisement of any merchandise or the solicitation of contributions for charitable purposes, whether or not a person has in fact been misled, deceived, or damaged, is an unlawful practice.

13. As used in the Consumer Fraud Act, the term "person" includes:

any natural person or the person's legal representative, partnership, corporation (domestic and foreign), company, trust, business entity or association, and any agent, employee, salesperson, partner, officer, director, member, stockholder, associate, trustee or cestui que trust thereof.

Iowa Code section 714.16(1)(j).

14. Neither all nor any part of the application for injunctive relief herein has been previously been presented to or refused by any court or justice. Iowa R. Civ. P. 1.1504.

15. In an action by the state, no security shall be required of the state. Iowa R. Civ. P. 1.207.

VIOLATIONS OF LAW

IOWA CONSUMER FRAUD ACT

16. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs 1 through 11.

17. Defendants GSK and SB Pharmco, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of prescription drugs, have engaged in unfair, deceptive, or misleading practices in connection with the advertisement or sale of merchandise, conduct which is unlawful under Section 2 of the Iowa Consumer Fraud Act 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.

18. Defendants, in the course of engaging in the development, manufacture, promotion, sales, and interstate distribution of prescription drugs, have engaged in unfair, deceptive, or misleading practices in connection with the advertisement or sale of merchandise, conduct which is unlawful under Section 2 of the Iowa Consumer Fraud Act 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.

REMEDIES

19. Iowa Code § 714.16(7), in relevant part, provides:

If it appears to the attorney general that a person has engaged in, is engaging in, or is about to engage in a practice declared to be unlawful by this section, the attorney general may seek and obtain in an action in a district court a temporary restraining order, preliminary injunction, or permanent injunction prohibiting the person from continuing the practice or engaging in the practice or doing an act in furtherance of the practice. The court may make orders or judgments as necessary to prevent the use or employment by a person of any prohibited practices, or which are necessary to restore to any person in interest any moneys or property, real or personal, which have been acquired by means of a practice declared to be unlawful by this section, including the appointment of a receiver in cases of substantial and willful violation of this section.

. In addition to the remedies otherwise provided for in this subsection, the attorney general may request and the court may impose a civil penalty not to exceed forty thousand dollars per violation against a person found by the court to have engaged in a method, act, or practice declared unlawful under this section; provided, however, a course of conduct shall not be considered to be separate and different violations merely because the conduct is repeated to more than one person. In addition, on the motion of the attorney general or its own motion, the court may impose a civil penalty of not more than five thousand dollars for each day of intentional violation of a temporary restraining order, preliminary injunction, or permanent injunction issued under authority of this section. A penalty imposed pursuant to this subsection is in addition to any penalty imposed pursuant to section 537.6113. Civil penalties ordered pursuant to this subsection shall be paid to the treasurer of state to be deposited in the general fund of the state.

20. Iowa Code section 714.16(10) provides:

In an action brought under this section, the attorney general is entitled to recover costs of the court action and any investigation which may have been conducted, including reasonable attorneys' fees, for the use of this state.

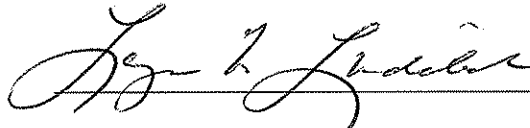
REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter an order:

- A. Issuing a permanent injunction prohibiting 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, as provided by Iowa Code section 714.16(7);
- B. Ordering Defendants to pay civil penalties of up to \$40,000 for each violation of the Consumer Fraud Act, as provided by Iowa Code section 714.16(7);
- C. Ordering Defendants to pay all costs, court costs, and attorney fees for the prosecution and investigation of this action, as provided by Iowa Code sections 714.16(10);
- D. Granting such other and further relief as the Court deems equitable and proper.

Respectfully submitted,

STATE OF IOWA ex rel.
ATTORNEY GENERAL
THOMAS J. MILLER



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