

VT SUPERIOR COURT  
WAHSINGTON UNIT  
CIVIL DIVISION

2017 DEC 20 P 1:58

STATE OF VERMONT  
SUPERIOR COURT  
WAHSINGTON UNIT

FILED

STATE OF VERMONT, )  
 )  
 ) Plaintiff, )  
 )  
 v. )  
 )  
 BOEHRINGER INGELHEIM )  
 PHARMACEUTICALS, INC., )  
 )  
 ) Defendant. )  
 )  
 )

CIVIL DIVISION

Docket No. 729-12-17Wncw

**CONSUMER PROTECTION COMPLAINT**

NOW COMES the State of Vermont, through Thomas J. Donovan, Jr., Attorney General of the State of Vermont, and brings this action against Boehringer Ingelheim Pharmaceuticals, Inc. for violating the Vermont Consumer Protection Act, 9 V.S.A. §§ 2451, *et seq.* ("Consumer Protection Act"), as follows:

**I. JURISDICTION AND VENUE**

1. This action is brought for and on behalf of the State of Vermont, by Thomas J. Donovan, Jr., Attorney General of the State of Vermont, pursuant to the provisions of the Vermont Consumer Protection Act.

2. The Vermont Attorney General is authorized, under the Vermont Consumer Protection Act, 9 V.S.A. §2458, to sue to enforce the Act's prohibitions on unfair and deceptive acts and practices in commerce.

3. This Court has personal jurisdiction over BIPI pursuant to the Consumer Protection Act because BIPI has transacted business within the State of Vermont at all times relevant to this Complaint.

4. Venue for this action properly lies in Washington County because Boehringer Ingelheim Pharmaceuticals, Inc. transacts business in Washington County and/or some of the transactions out of which this action arose occurred in Washington County.

## II. PARTIES

5. Plaintiff, State of Vermont, through its Attorney General, Thomas J. Donovan, Jr., is charged with enforcing the Consumer Protection Act, which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce. Pursuant thereto, the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the Consumer Protection Act, and to secure such equitable and other relief as may be appropriate in each case.

6. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”) is a Delaware corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, CT 06877. At all relevant times, BIPI did business in Vermont by marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

## 7. III. FACTUAL BACKGROUND

### A. Aggrenox

8. Aggrenox (a combination of aspirin and dipyridamole) is an antiplatelet drug and was approved by the U.S. Food and Drug Administration (FDA) in 1999 to reduce the risk of secondary stroke in patients who have had a transient ischemic attack (TIA), which is sometimes referred to as a “mini stroke”, or stroke due to a blood clot.

9. Aggrenox's main competitor was Plavix, which the FDA approved in 1997.

10. Plavix had an indication to reduce the risk of secondary stroke following a TIA or stroke due to a blood clot; however, it also had indications to treat a broader range of secondary clot related events, including myocardial infarction and peripheral artery disease (PAD), which is also referred to as peripheral vascular disease (PVD).

11. BIPI represented that Aggrenox was superior to Plavix and Plavix/aspirin combinations, when in fact, BIPI did not have the requisite evidence to substantiate those claims.

12. BIPI also represented that Aggrenox was effective "below the neck" to treat myocardial infarction (heart attack), congestive heart failure, and PAD/PVD, when in fact, BIPI did not have the requisite evidence to substantiate those claims.

#### **B. Micardis**

13. Micardis (telmisartan) belongs to a class of drugs called angiotensin receptor blockers (ARBs) and is indicated to treat hypertension (high blood pressure) and to reduce cardiovascular risk in patients unable to take angiotensin-converting-enzyme inhibitors (ACE inhibitors).

14. The FDA approved Micardis in 1998 as the fourth ARB on the market.

15. At that time, the hypertension market was already dominated by Diovan, Cozaar, and Avapro.

16. Initial sales for Micardis were poor, in part, because BIPI had no comparative data proving Micardis was superior to any of the existing hypertension drugs.

17. Both Cozaar and Avapro received additional indications for treatment of renal nephropathy among diabetics, which distinguished them from other hypertension drugs, including Micardis.

18. Similarly, there was data suggesting that Cozaar was effective against prevention of secondary myocardial infarction.

19. To increase sales, BIPI created marketing messages that lacked competent and reliable scientific substantiation in an effort to distinguish Micardis from the competition.

20. BIPI represented that Micardis best protects consumers from the “Early Morning Risk” of strokes or cardiac events due to rising blood pressure for patients at the end of a dosing interval for hypertension drugs, when in fact, BIPI did not have the requisite evidence to substantiate that claim.

21. BIPI also represented that Micardis could treat the constellation of symptoms popularly known as “Metabolic Syndrome”, protected the kidneys, and prevented heart attacks and strokes, when in fact, BIPI did not have the requisite evidence to substantiate those claims.

### **C. Atrovent and Combivent**

22. Both Atrovent (ipratropium bromide) and Combivent (ipratropium bromide and albuterol) are bronchodilators indicated to treat bronchospasms (airway narrowing) associated with chronic obstructive pulmonary disease (COPD) and contain albuterol plus a drug belonging to a class called anticholinergics.

23. Atrovent is approved as a first line treatment; however, Combivent is only approved for use when a person continues to have evidence of bronchospasm when using a regular aerosol bronchodilator.

24. BIPI represented Combivent could be used as a first line treatment for bronchospasms associated with COPD, when in fact, Combivent is not indicated as a first line treatment and BIPI did not have the requisite evidence to support that claim.

25. BIPI also represented that both Atrovent and Combivent could be used at doses that exceed the maximum dosage recommendation in the product labeling, when in fact, BIPI did not have the requisite evidence to support that claim.

26. BIPI further represented that anticholinergics were essential for treatment of COPD, when in fact, BIPI did not have the requisite evidence to support that claim.

#### **IV. VIOLATIONS OF LAW**

27. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding Paragraphs 1 through 25.

28. BIPI engaged in unfair and deceptive trade practices in commerce, in violation of Vermont Consumer Protection Act, 9 V.S.A. §2453(a), by making the misrepresentations and omissions described above about the prescription drugs Micardis, Aggrenox, Atrovent, and Combiven. These misrepresentations were likely to mislead consumers and affect their decisions to purchase 5-hour ENERGY® products. The meaning ascribed to Defendants' claims herein is reasonable given the nature of those claims.

29. Defendants also engaged in unfair and deceptive trade practices in commerce, in violation of Vermont Consumer Protection Act, 9 V.S.A. §2453(a) to the extent that those statements were not substantiated by competent and reliable scientific evidence.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, State of Vermont, respectfully requests judgment in its favor and the following relief:

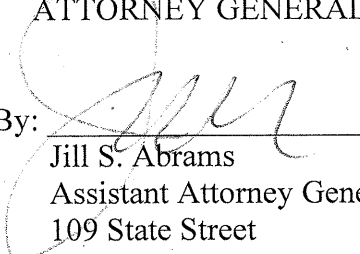
- A. A judgment determining that BIPI has violated the Consumer Protection Act;
- B. A permanent injunction enjoining and restraining BIPI, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive acts or practices in the marketing, promotion, and sale of the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent, pursuant to the Consumer Protection Act;
- C. Ordering BIPI to pay civil penalties of up to \$10,000 for each and every violation of the Consumer Protection Act;
- D. Awarding investigative and litigation costs and fees to the State of Vermont; and
- E. Such other and further relief as the Court deems equitable and proper.

Dated: December 20, 2017

Respectfully submitted,

STATE OF VERMONT

THOMAS J. DONOVAN, JR.  
ATTORNEY GENERAL

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