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SUPERIOR COURT OF NJ
MERCER VICINAGE
CIVIL DIVISION

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Division of Law
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By: Lorraine K. Rak (035771985)
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SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION, MERCER COUNTY
DOCKET NO. MER-C-

CHRISTOPHER S. PORRINO, Attorney General of
the State of New Jersey, and SHARON M. JOYCE,
Acting Director of the New Jersey Division of
Consumer Affairs,

Plaintiffs,

v.

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC.,

Defendants.

Civil Action

COMPLAINT

1. Plaintiffs Christopher S. Porrino, Attorney General of the State of New Jersey ("Attorney General"), with offices located at 124 Halsey Street, Fifth Floor, Newark, New Jersey, and Sharon M. Joyce, Acting Director of the New Jersey Division of Consumer Affairs ("Director"), with offices located at 124 Halsey Street, Seventh Floor, Newark, New Jersey (collectively, "Plaintiffs"), bring this action against Defendant Boehringer Ingelheim Pharmaceuticals, Inc. for violating the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq.

(“CFA”).

2. Plaintiffs bring this action pursuant to the CFA, N.J.S.A. 56:8-1 et seq., in the public interest, to protect the public’s health, safety and welfare and pursuant to their general statutory and common law authority powers and duties. Plaintiffs have reason to believe that the above-named Defendant has violated and/or is continuing to violate the CFA. Plaintiffs also have reason to believe that this action is in the public interest.

3. Upon interest and belief, Plaintiffs allege as follows:

JURISDICTION AND VENUE

4. This Court has jurisdiction over Boehringer Ingelheim Pharmaceuticals, Inc. pursuant to the CFA, because Boehringer Ingelheim Pharmaceuticals, Inc. has transacted business within the State of New Jersey (“New Jersey”) at all times relevant to this Complaint.

5. Venue for this action properly lies in Mercer County pursuant to R. 4:3-2(b) because Boehringer Ingelheim Pharmaceuticals, Inc. transacts business in Mercer County and/or some of the transactions out of which this action arose occurred in Mercer County.

PARTIES

6. The Attorney General is charged with enforcing the CFA, which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce. The Director is charged with administering the CFA on behalf of the Attorney General. Pursuant to N.J.S.A. 56:8-8, 8-11, 8-13 and 8-19, the Attorney General and Director may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the CFA and to secure such equitable and other relief as may be appropriate in each case.

7. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”) is a Delaware corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut

06877. At all relevant times, BIPI did business in New Jersey by marketing, promoting, and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

ADVERTISEMENT AND SALE OF MERCHANDISE

8. The CFA, N.J.S.A. 56:8-1(a), defines “advertisement” as:

... the attempt directly or indirectly by publication, dissemination, solicitation, indorsement or circulation or in any other way to induce directly or indirectly any person to enter or not enter into any obligation or acquire any title or interest in any merchandise or to increase the consumption thereof . . .

9. The CFA, N.J.S.A. 56:8-1(c), defines “merchandise” as “any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale.”

10. The CFA, N.J.S.A. 56:8-1(e), defines “sale” as “any sale, rental or distribution, offer for sale, rental or distribution or attempt directly or indirectly to sell, rent or distribute.”

11. BIPI was at all times relative hereto, engaged in the advertisement and sale of merchandise in New Jersey by marketing, promoting and selling the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent.

ALLEGATIONS

Aggrenox

12. 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.

13. Aggrenox’s main competitor was Plavix, which the FDA approved in 1997.

14. 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”).

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

16. 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 evidence to substantiate those claims.

Micardis

17. 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).

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

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

20. 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.

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

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

23. To increase sales, BIPI created marketing messages that lacked substantiation in an effort to distinguish Micardis from the competition.

24. 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 evidence to substantiate that claim.

25. 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 evidence to substantiate those claims.

Atrovent and Combivent

26. 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.

27. 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.

28. 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 evidence to support that claim.

29. 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 evidence to support that claim.

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

COUNT I

VIOLATION OF THE CFA BY DEFENDANT (UNCONSCIONABLE COMMERCIAL PRACTICES AND DECEPTION)

31. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 30 as if more fully set forth herein.

32. The CFA, N.J.S.A. 56:8-2, prohibits:

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. . .

33. Defendant, in the course of engaging in the marketing, promotion and sale of the prescription drugs Micardis, Aggrenox, Atrovent and Combivent, has engaged in the advertisement or sale of merchandise through unconscionable commercial practices and deception in violation of the CFA, specifically by representing that the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent have sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have.

34. Each unconscionable commercial practice and act of deception by Defendant constitutes a separate violation of the CFA, N.J.S.A. 56:8-2.

COUNT II

VIOLATION OF THE CFA BY DEFENDANT (KNOWING OMISSIONS OF MATERIAL FACT AND/OR MISREPRESENTATIONS)

35. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 34

as if more fully set forth herein.

36. Defendant, in the course of engaging in the marketing, promotion and sale of the prescription drugs Micardis, Aggrenox, Atrovent and Combivent, has engaged in the advertisement or sale of merchandise through knowing omissions of material fact and/or misrepresentations in violation of the CFA, specifically by making omissions and misrepresentations about the prescription drugs Micardis, Aggrenox, Atrovent and Combivent.

37. Each knowing omission of material fact and/or misrepresentation by Defendant constitutes a separate violation of the CFA, N.J.S.A. 56:8-2.

PRAYER FOR RELIEF

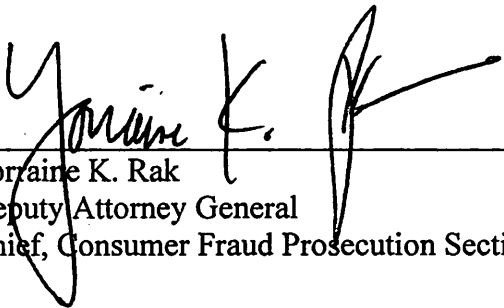
WHEREFORE, based upon the foregoing allegations, Plaintiffs respectfully request that the Court enter judgment against Defendant:

- (a) Finding that the acts and omissions of Defendant constitute multiple instances of unlawful practices in violation of the CFA, N.J.S.A. 56:8-1 et seq.;
- (b) Permanently enjoining and restraining Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in deceptive or misleading conduct, acts, or practices in the marketing, promotion and sale of the prescription drugs Micardis, Aggrenox, Atrovent, and Combivent in violation of the CFA, N.J.S.A. 56:8-1 et seq., including, but not limited to, the acts and practices alleged in this Complaint, as authorized by N.J.S.A. 56:8-8;
- (c) Directing Defendant to restore to any affected person, whether or not named in this Complaint, any money or real or personal property acquired by means of any alleged practice herein declared to be unlawful and found to be unlawful, as authorized by N.J.S.A. 56:8-8;
- (d) Directing Defendant to pay the maximum statutory civil penalties for each and every violation of the CFA, in accordance with N.J.S.A. 56:8-13;
- (e) Directing Defendant to pay costs and fees, including attorneys' fees, 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

- (f) Granting such other relief as the interests of justice may require.

CHRISTOPHER S. PORRINO
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: _____


Lorraine K. Rak
Deputy Attorney General
Chief, Consumer Fraud Prosecution Section

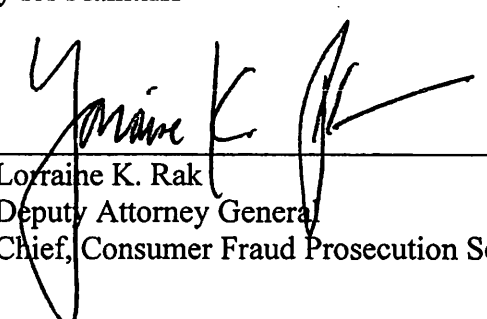
Dated: December 20, 2017
Newark, New Jersey

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 CFA, N.J.S.A. 56:8-1 et seq., 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 Defendant, but have no direct information that any such actions involve consumer fraud allegations. 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 certify that there is no other party who should be joined in this action at this time.

CHRISTOPHER S. PORRINO
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: _____

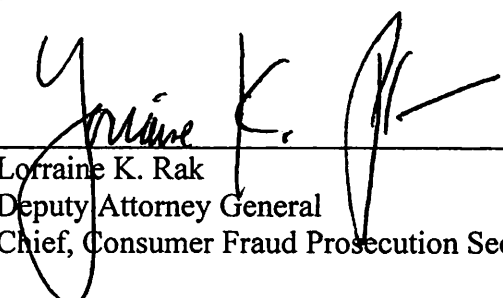

Lorraine K. Rak
Deputy Attorney General
Chief, Consumer Fraud Prosecution Section

Dated: December 20, 2017
Newark, New Jersey

RULE 1:38-7(c) CERTIFICATION OF COMPLIANCE

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 Rule 1:38-7(b).

CHRISTOPHER S. PORRINO
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

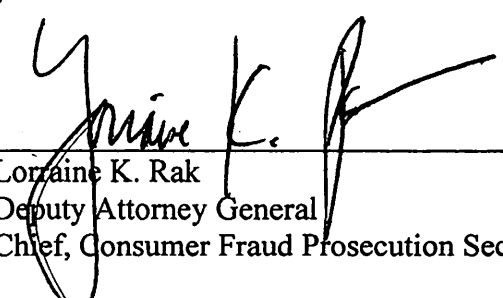
By: 
Lorraine K. Rak
Deputy Attorney General
Chief, Consumer Fraud Prosecution Section

Dated: December 20, 2017
Newark, New Jersey

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Deputy Attorney General Lorraine K. Rak is hereby designated as trial counsel for the Plaintiffs in this action.

CHRISTOPHER S. PORRINO
ATTORNEY GENERAL OF NEW JERSEY
Attorney for Plaintiffs

By: 
Lorraine K. Rak
Deputy Attorney General
Chief, Consumer Fraud Prosecution Section

Dated: December 20, 2017
Newark, New Jersey