

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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BRECKENRIDGE PHARMACEUTICAL, INC.,))
1141 South Rogers Circle, Suite 3))
Boca Raton, FL 33487))
))
Plaintiff,)	Civil Action No. _____
))
v.))
)	JURY TRIAL DEMANDED
CORNERSTONE BIOPHARMA, INC.,))
2000 Regency Parkway, Suite 255))
Cary, NC 27518))
))
J-MED PHARMACEUTICALS, INC.,))
9205 Pegasus Court))
Potomac, MD 20854))
Montgomery County))
))
and))
))
ALLAN M. WEINSTEIN,))
9205 Pegasus Court))
Potomac, MD 20854))
Montgomery County))
))
Defendants.))
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COMPLAINT

Breckenridge Pharmaceutical, Inc., by and through its attorneys, states as follows for its

Complaint against Defendants:

The Parties

1. Plaintiff Breckenridge Pharmaceutical, Inc. (“Breckenridge”) is a corporation organized and existing under the laws of the State of Florida, with its principal place of business at 1141 South Rogers Circle, Suite 3, Boca Raton, Florida, 33487.

2. Breckenridge is in the business of developing, marketing and selling pharmaceutical products to retailers, wholesalers, distributors, and other purchasers of such products nationwide.

3. Before introducing any new pharmaceutical product into the marketplace, Breckenridge invests significant resources to ensure that the formulation, testing, and manufacture of each of its products complies both with internal quality-control release standards as well as with all applicable U.S. Food and Drug Administration regulations, including current Good Manufacturing Practices. Breckenridge also conducts due diligence that includes the review and analysis of any intellectual property that may potentially be relevant to the introduction of a new pharmaceutical product.

4. Defendant Cornerstone BioPharma, Inc. (“Cornerstone”) is a corporation organized and existing under the laws of the State of Nevada, with a principal place of business at 2000 Regency Parkway, Suite 255, Cary, North Carolina, 27518.

5. Defendant J-Med Pharmaceuticals, Inc. (“J-Med”) is a corporation organized and existing under the laws of the State of Maryland, with a principal place of business at 9205 Pegasus Court, Potomac, Montgomery County, Maryland, 20854.

6. Defendant Allan M. Weinstein is an individual residing at 9205 Pegasus Court, Potomac, Montgomery County, MD 20854.

Jurisdiction And Venue

7. This is an action for a declaratory judgment pursuant to 28 U.S.C. § 2201, for the purpose of determining a case of actual controversy between the parties, as hereinafter more fully appears. Jurisdiction is proper under 28 U.S.C. § 1338(a) because the subject of the action is the invalidity and non-infringement of two United States patents, arising under an Act of Congress relating to patents, as well as the invalidity and non-infringement of a copyright, arising under the Copyright Act.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400, because Cornerstone regularly sells its products in this District, J-Med is incorporated in Maryland, and Allan M. Weinstein resides in Maryland.

STATEMENT OF FACTS

The Patents Licensed To Cornerstone By J-Med And/Or Allan M. Weinstein

9. United States Patent No. 6,651,816 (“the ’816 Parent Patent”), entitled “Antihistamine/ Decongestant Regimens for Treating Rhinitis,” issued on November 25, 2003, to Robert E. Weinstein as the inventor. A copy of the ’816 Parent Patent is attached as Exhibit A.

10. A continuation of the application which issued as the ’816 Parent Patent was filed on August 18, 2003. This continuation application issued on January 18, 2005, as United States Patent No. 6,843,372 (“the ’372 Child Patent”), entitled “Antihistamine/ Decongestant Regimens for Treating Rhinitis,” to Robert E. Weinstein as the inventor. A copy of the ’372 Child Patent is attached as Exhibit B.

11. The independent claims of the ’816 Parent Patent and the ’372 Child Patent are substantially the same, both claiming a “prepackaged therapeutic regimen” and a “method for rhinitis treatment.”

12. An earlier patent, United States Patent No. 6,270,796 (“the ’796 Patent”), also entitled “Antihistamine/ Decongestant Regimens for Treating Rhinitis,” issued on August 7, 2001 to Robert E. Weinstein as the inventor. A copy of the ’796 Patent is attached as Exhibit C.

13. As with the ’816 Parent Patent and the ’372 Child Patent, the two independent claims of the ’796 Patent also claim a “prepackaged therapeutic regimen” and a “method for rhinitis treatment.”

14. According to information available on the website of the United States Patent and Trademark Office (“USPTO”), the ’816 Parent Patent and the ’372 Child Patent have been assigned by the inventor Robert E. Weinstein to Allan M. Weinstein, while the ’796 Patent was assigned to J-Med, a corporation having same address shown for Allan M. Weinstein. Upon information and belief, Allan M. Weinstein has also assigned all or part of his ownership interest in the ’816 Parent Patent and the ’372 Child Patent to J-Med.

15. Cornerstone states on the labeling of its AlleRx Dose Pack and AlleRx PE products that they are licensed and protected under the ’796 Patent and the ’372 Child Patent, respectively. Upon information and belief, the ’816 Parent Patent is also licensed to Cornerstone by J-Med and/or Allan M. Weinstein.

The Patent Reexaminations By The USPTO

16. On July 7, 2006, a third party filed with the USPTO a request for reexamination of the ’796 Patent, which was granted on September 13, 2006, and assigned Reexamination No. 90/008,111.

17. On February 13, 2008, the USPTO issued a final rejection of all 18 claims in the ’796 Patent, finding that all were unpatentable as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103.

18. On June 13, 2008 a third party requested reexamination by the USPTO of the '372 Child Patent.

19. This request was granted and reexamination of the '372 Child Patent was ordered by the USPTO on August 21, 2008, and assigned Reexamination No. 90/009,182. (See Exhibit D.)

20. As stated in the order granting the request for reexamination, the USPTO has determined that “the combined references” submitted by the request “raise a substantial new question of patentability as to claims 1-14,” that is, all of the claims of the '372 Child Patent. *Id.* at ¶ 32.

Cornerstone’s Prior Litigation Concerning The '796 Patent

21. Cornerstone markets and sells certain prescription pharmaceutical products under various permutations of the name “AlleRx,” all of which are supplied as 10-day night and day dose packs.

22. The labeling for the original AlleRx Dose Pack product states: “This product is licensed and protected under U.S. Patent No. 6,270,796 issued 8/7/2001.”

23. After the USPTO ordered reexamination of the '796 Patent, Cornerstone and its licensor J-Med nonetheless asserted, *inter alia*, infringement of the '796 Patent against other competitors that marketed products with the same ingredients as its AlleRx Dose Pack product in 10-day dose packs: *Cornerstone BioPharma, Inc. and J-Med Pharmaceuticals, Inc. v. Preston, et al.*, no. 4:06-cv-00251-FL (E.D.N.C.), filed November 13, 2006; and *Cornerstone BioPharma, Inc. and J-Med Pharmaceuticals, Inc. v. Sovereign Pharmaceuticals, Ltd.*, no. 1:06-cv-01006-JAB-PTS (M.D.N.C.), filed November 16, 2006.

24. In April 2007, Breckenridge began selling a pharmaceutical product under the name “Allergy DN,” which contained a “day dose” of 120 mg pseudoephedrine HCl and 2.5 mg of

methscopolamine nitrate, and a “night dose” of 8 mg chlorpheniramine maleate and 2.5 mg methscopolamine nitrate, supplied in a 10-day treatment regimen in “dose packs.”

25. Cornerstone’s AlleRx Dose Pack contains the same active ingredients in the same amounts as Breckenridge’s Allergy DN, and is also supplied in 10-day dose packs.

26. After Cornerstone threatened to sue Breckenridge for, *inter alia*, infringement of the ’796 Patent, based on its sale of Allergy DN, Breckenridge filed a declaratory judgment action against Cornerstone and J-Med in this District, *Breckenridge Pharmaceutical, Inc. v. Cornerstone BioPharma, Inc., et al.*, civil action no. 8:07-cv-01004-DKC (the “Prior Breckenridge-Cornerstone Litigation”).

27. Cornerstone and J-Med filed a counterclaim for patent infringement in the Prior Breckenridge-Cornerstone Litigation, alleging that the “formulation of the ’796 Patent” is used in its AlleRx Dose Pack product, and that the claims of the ’796 Patent cover its pharmaceutical product marketed and sold as AlleRx Dose Packs.

28. Cornerstone and J-Med also counterclaimed for infringement of a copyright based on Breckenridge’s product information insert for its Allergy DN.

29. The Prior Breckenridge-Cornerstone Litigation was settled by a confidential settlement agreement negotiated among the parties, and the lawsuit was dismissed.

30. However, Cornerstone and J-Med rejected Breckenridge’s efforts to include in the settlement agreement products similar to certain additional Cornerstone AlleRx products, and refused to agree not to file another lawsuit against Breckenridge if and when it launched such products on the market.

31. Thereafter, Cornerstone and J-Med continued to aggressively enforce the ’796 Patent, filing yet another lawsuit against another competitor, alleging infringement of the ’796 Patent and

copyright infringement: *Cornerstone BioPharma, Inc. and J-Med Pharmaceuticals, Inc. v. Vision Pharma, LLC, et al.*, no. 5:07-cv-00389-F (E.D.N.C.), filed on October 8, 2007. However, this lawsuit has been stayed pending the outcome of the patentee's appeal of the final rejection by the USPTO in the reexamination of the '796 Patent.

The Current Dispute

32. On or about November 10, 2008, Breckenridge began selling a pharmaceutical product under the name "Allergy DN II," which contains a "day dose" of 4 mg chlorpheniramine maleate and 2.5 mg of methscopolamine nitrate, and a "night dose" of 8 mg chlorpheniramine maleate and 2.5 mg methscopolamine nitrate, supplied as a 10-day treatment regimen in "dose packs."

33. Cornerstone markets a pharmaceutical product under the name "AlleRx DF" which contains the same active ingredients in the same amounts as in Allergy DN II, and which is also supplied in 10-day "dose packs." The labeling of this product states "patent pending."

34. Also on or about November 10, 2008, Breckenridge began selling a pharmaceutical product under the name "Allergy DN PE," which contains a "day dose" of 40 mg phenylephrine HCl and 2.5 mg of methscopolamine nitrate, and a "night dose" of 10 mg phenylephrine HCl, 8 mg chlorpheniramine maleate, and 2.5 mg methscopolamine nitrate, supplied as a 10-day treatment regimen in "dose packs."

35. Cornerstone markets a pharmaceutical product under the name "AlleRx PE" which contains the same active ingredients in the same amounts as in Allergy DN PE, and which is also supplied in 10-day "dose packs."

36. The labeling of AlleRx PE states: "This product is licensed and protected under U.S. Patent No. 6,843,372 issued 1/18/2005."

37. Upon information and belief, based on the substantial similarity between the claims of '372 Child Patent and the claims of the '816 Parent Patent, Cornerstone will also assert that its AlleRx PE is licensed under and protected by the '816 Parent Patent.

38. The product information inserts for both AlleRx DF and AlleRx PE state that they are copyrighted.

39. Based on the foregoing, the totality of the circumstances shows that an actual and substantial controversy exists between the parties, having adverse legal interests, for reasons including but not limited to:

- Beginning in 2006, Cornerstone and its licensor have consistently sued companies which market products competing with Cornerstone's AlleRx products, alleging, *inter alia*, patent infringement (even after the USPTO had begun a reexamination of the asserted patent) and copyright infringement;
- In 2007, Cornerstone and its licensor specifically refused to agree not to file such a lawsuit against Breckenridge if and when Breckenridge introduced into the market products competing with additional Cornerstone AlleRx products;
- Breckenridge has now introduced products that compete directly with Cornerstone's AlleRx PE and AlleRx DF;
- Cornerstone's product labeling for these products indicates that the former is protected by the '372 Child Patent, that a patent is pending respecting the latter, and that the product information inserts of both are covered by a copyright; and

- Breckenridge maintains that it does not need a license to market its Allergy DN PE and Allergy DN II products, that they do not infringe any valid patent claim, and that their product information inserts do not infringe any valid copyright;

as a consequence of which, Breckenridge has a reasonable apprehension of a lawsuit by Cornerstone and its licensor.

40. Accordingly, there is an actual controversy between the parties that may be adjudicated by way of declaratory judgment pursuant to 28 U.S.C. § 2201.

COUNT I
Declaration of Invalidity of the '816 Patent

41. Breckenridge incorporates the allegations of the preceding paragraphs as though fully set forth herein.

42. The '816 Parent Patent is invalid for failure to comply with the statutory requirements of patentability under Title 35 of the United States Code and/or the requirements of Title 37 of the Code of Federal Regulations, including, without limitation, the requirements of 35 U.S.C. §§ 102 and 103, based on, without limitation, the prior art considered by the USPTO in the reexamination of the '372 Child Patent.

43. Accordingly, Breckenridge is entitled to a declaration that the '816 Parent Patent is invalid.

COUNT II
Declaration of Invalidity of the '372 Patent

44. Breckenridge incorporates the allegations of the preceding paragraphs as though fully set forth herein.

45. The '372 Child Patent is invalid for failure to comply with the statutory requirements of patentability under Title 35 of the United States Code and/or the requirements of Title 37 of the Code of Federal Regulations, including, without limitation, the requirements of 35 U.S.C. §§ 102 and 103 based on, without limitation, the prior art considered by the USPTO in the reexamination of the this patent.

46. Accordingly, Breckenridge is entitled to a declaration that the '372 Child Patent is invalid.

COUNT III
Declaration of Non-Infringement of the Patents-in-Suit

47. Breckenridge incorporates the allegations of the preceding paragraphs as though fully set forth herein.

48. Breckenridge's Allergy DN PE does not directly infringe any valid claim of the '816 Parent Patent or the '372 Child Patent, either literally or under the doctrine of equivalents; nor does Breckenridge, by its sale of Allergy DN PE, indirectly infringe by inducing infringement or contributing to infringement of any valid claim of the '816 Parent Patent or the '372 Child Patent.

49. Accordingly, Breckenridge is entitled to a declaration that its Allergy DN PE does not directly or indirectly infringe any valid claim of the '816 Parent Patent or the '372 Child Patent.

COUNT IV
Declaration of Invalidity of Asserted Copyright

50. Breckenridge incorporates the allegations of the preceding paragraphs as though fully set forth herein.

51. The product information inserts for Cornerstone's AlleRx DF and AlleRx PE that are the basis of Cornerstone's asserted copyright(s) constitute functional lists or descriptions of the ingredients contained in the products and the basic instructions necessary for proper use of the products, which do

not contain sufficiently original material to constitute original works of authorship under Section 102(a) of the United States Copyright Act, 17 U.S.C. § 102(a).

52. The product information inserts for Cornerstone's AlleRx DF and AlleRx PE that are the basis of Cornerstone's asserted copyright(s) constitute functional lists or descriptions of the ingredients contained in the products and the basic instructions necessary for proper use of the products, which constitute an idea, procedure, process, system, method of operation, concept, principle, or discovery not entitled to copyright protection pursuant to Section 102(b) of the United States Copyright Act, 17 U.S.C. § 102(b).

53. Accordingly, Breckenridge is entitled to a declaration that Cornerstone's asserted copyright is invalid.

COUNT V

Declaration of Non-Infringement of Asserted Copyright Based on Fair Use

54. Breckenridge incorporates the allegations of the preceding paragraphs as though fully set forth herein.

55. The product inserts for Cornerstone's AlleRx DF and AlleRx PE that are the basis of Cornerstone's asserted copyright(s) constitute functional lists or descriptions of the ingredients contained in the products and the basic instructions necessary for proper use of the products. Accordingly, Breckenridge's alleged copying and use of the information contained on those product inserts in order to fairly and accurately provide the same information to its customers regarding the content and use of its own product is a fair use under Section 107 of the United States Copyright Act, 17 U.S.C. § 102(b).

56. Accordingly, Breckenridge is entitled to a declaration that the product information inserts for Allergy DN II and Allergy DN PE do not infringe Cornerstone's asserted copyright(s).

WHEREFORE, Breckenridge requests that the Court:

- (a) Enter judgment declaring that United States Patent No. 6,651,816 is invalid;
- (b) Enter judgment declaring that United States Patent No. 6,843,372 is invalid;
- (c) Enter judgment declaring that Breckenridge's sale of Allergy DN PE does not directly or indirectly infringe any valid claim of United States Patent No. 6,651,816 or No. 6,843,372;
- (d) Enter an order enjoining Cornerstone, J-Med, Allan M. Weinstein and their privies from asserting either United States Patent No. 6,651,816 or No. 6,843,372 against Breckenridge and/or its privies based on Breckenridge's Allergy DN PE;
- (e) Enter judgment declaring invalid Cornerstone's asserted copyright(s) covering its product information inserts for AlleRx DF and AlleRx PE;
- (f) Enter judgment declaring that Breckenridge's alleged copying and use of the information contained on Cornerstone's product information inserts constitutes a fair use;
- (g) Enter an order enjoining Cornerstone, J-Med, Allan M. Weinstein and their privies from asserting that the product information insert for Breckenridge's Allergy DN II or Allergy DN PE infringe a copyright;
- (h) Declare this case exceptional and enter an order awarding attorneys' fees and expenses to Breckenridge pursuant to 35 U.S.C. § 285;
- (i) Enter an order granting Breckenridge the costs of this litigation; and
- (j) Enter an order granting Breckenridge such other and additional relief against Defendants as may be just and proper in the circumstances.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Breckenridge demands a trial by jury of all issues properly triable to a jury in this case.

Dated: November 10, 2008

/s/ Joseph L. Meadows

Joseph L. Meadows
CROWELL & MORING LLP
1001 Pennsylvania Avenue, N.W.
Washington, DC 20004
Phone: (202) 624-2500
Fax: (202) 628-5116
jmeadows@crowell.com

Of Counsel

Bruce D. DeRenzi
bderenzi@crowell.com
Jerry Canada
jcanada@crowell.com
C. Randolph Ross
rross@crowell.com
CROWELL & MORING LLP
153 East 53rd Street, 31st Floor
New York, NY 10022
Telephone: (212) 895-4200
Fax: (212) 895-4201

Teresa Stanek Rea
trea@crowell.com
Melissa M. Hayworth
mhayworth@crowell.com
CROWELL & MORING LLP
1001 Pennsylvania Avenue, N.W.
Washington, DC 20004
Phone: (202) 624-2500
Fax: (202) 628-5116

*Attorneys for Plaintiff
Breckenridge Pharmaceutical, Inc.*