

FILED
U.S. DISTRICT COURT
DISTRICT OF MARYLAND

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

FILED
U.S. DISTRICT COURT
DISTRICT OF MARYLAND
BY _____

 BRECKENRIDGE PHARMACEUTICAL, INC.,)
 1141 South Rogers Circle, Suite 3)
 Boca Raton, FL 33487)
)
 Plaintiff,)
)
 v.)
)
 CORNERSTONE BIOPHARMA, INC.,)
 2000 Regency Parkway, Suite 255)
 Cary, NC 27518)
)
 and)
)
 J-MED PHARMACEUTICALS, INC.,)
 9205 Pegasus Court)
 Potomac, MD 20854)
)
 Defendants.)

Civil Action No. _____

DKC07CV1004

JURY TRIAL DEMANDED

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. 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.

3. 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, MD 20854.

Jurisdiction And Venue

4. 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 alleged non-infringement and invalidity of a United States patent, arising under an Act of Congress relating to patents, and under 28 U.S.C. § 1332(a) because of diversity of citizenship.

5. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400, because Cornerstone regularly sells its products in this District, and J-Med is incorporated in Maryland and thus a citizen of this District.

STATEMENT OF FACTS

The Patent at Issue

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

7. The two independent claims of the ’796 patent claim a “prepackaged therapeutic regimen” and a “method for rhinitis treatment.”

8. On July 7, 2006, a third party filed with the United States Patent and Trademark Office (“PTO”) a request for reexamination of the ’796 patent. On September 13, 2006, the PTO ordered such reexamination.

9. On March 7, 2007, the PTO issued a non-final rejection of all 18 claims in the ’796 patent.

The Prior Litigation

10. J-Med has asserted in prior litigation that it is the owner and assignee of the ’796 patent. *See, e.g., Cornerstone BioPharma, Inc. and J-Med Pharmaceuticals, Inc. v. David M. Preston, et al.*, Civil Action NO. 4:06-cv-00251, filed November 14, 2006, in the United States District Court for the Middle District of North Carolina, and *Cornerstone BioPharma, Inc. and J-Med Pharmaceuticals, Inc. v. Sovereign Pharmaceuticals, Ltd.*, Civil Action No. 1:06-cv-01006, filed November 16, 2006, in the United States District Court for the Middle District of North Carolina (collectively, the “Prior Litigation”).

11. Cornerstone asserted in the Prior Litigation that it is the exclusive licensee “of the formulation of the ’796 patent.”

12. Cornerstone markets and sells certain prescription pharmaceutical products under various permutations of the name “AlleRx.”

13. Cornerstone asserted in the Prior Litigation that the “formulation of the ’796 patent” is used in its AlleRx products, and that the claims of the ’796 patent cover its pharmaceutical product marketed and sold as AlleRx “dose packs.” This product contains 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 ten-day treatment regimen.

14. Cornerstone also asserted in the Prior Litigation that its goal is to improve the medicines available to the “millions of Americans” who are struck each year with respiratory diseases by “making good medicines better,” and that it has expended “millions of dollars” in advertising and promoting such products.

15. Cornerstone does not allude to the fact that millions of Americans would be helped if such medicines were available to them at a lower price, as would be the case if there were competition in the sale of such medicines.

16. Instead, in spite of their knowledge that the '796 patent was undergoing reexamination and might soon be rendered invalid, and in order to exclude competitors from the marketplace, Cornerstone and J-Med sued the defendants in the Prior Litigation for patent infringement, based on the defendants' manufacture and marketing of a product marketed as “AllePak,” which also 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 ten-day treatment regimen.

The Current Dispute

17. On or about April 18, 2007, Breckenridge began selling a pharmaceutical product under the name of “Allergy DN.”

18. As with the AlleRx dose packs sold by Cornerstone, and as with the AllePak sold by the defendants in the prior litigation, Breckenridge's Allergy DN also contains 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 ten-day treatment regimen.

19. On April 19, 2007, Craig Collard, the president of Cornerstone, contacted Breckenridge and informed it that Cornerstone was aware of Breckenridge's Allergy DN product, and that if Breckenridge were to market this product, Cornerstone will enforce the '796 patent by initiating legal proceedings against Breckenridge for infringement of the '796 patent.

20. In the Fall of 2006, Cornerstone and J-Med made similar statements to the defendants in the Prior Litigation, demanding that they discontinue selling the product marketed as AllePak, and thereafter commenced the Prior Litigation. Thus, Cornerstone and J-Med have demonstrated that they will in fact follow up their "cease and desist" warnings with actual lawsuits asserting infringement of the '796 patent.

21. Moreover, as the Federal Circuit recently ruled, "where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise."¹

22. Cornerstone has asserted that it has the right to file a lawsuit to enforce the '796 patent against Breckenridge's Allergy DN, and Breckenridge contends that it has the right to market its Allergy DN and that such activity will not infringe any valid claims of the '796 patent.

23. 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.

¹ *Sandisk Corp. v. STMicroelectronics, Inc.*, ___ F.3d ___, 2007 WL 881008, *7 (Fed. Cir. Mar. 26, 2007).

COUNT I
Declaration of Invalidity

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

25. The '796 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.

26. The '796 patent is invalid for the reasons set forth in the March 7, 2007 non-final rejection issued by the PTO.

27. Accordingly, Breckenridge is entitled to a declaration that the '796 patent is invalid.

COUNT II
Declaration of Non-Infringement

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

29. Breckenridge's Allergy DN does not infringe the claims of the '796 patent, either literally or under the doctrine of equivalents; nor does Breckenridge, by its sale of Allergy DN, induce infringement or contribute to infringement of the '796 patent.

30. Accordingly, Breckenridge is entitled to a declaration that its Allergy DN does not infringe the '796 patent.

WHEREFORE, Breckenridge requests that the Court:

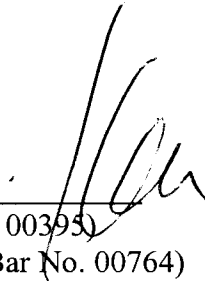
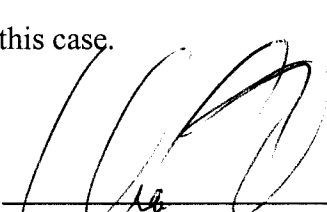
- (a) Enter judgment declaring that the '796 patent is invalid;

- (b) Enter judgment declaring that Breckenridge's sale of Allergy DN does not infringe the '796 patent;
- (c) Enter an order enjoining Cornerstone, J-Med, and their privies from asserting the '796 patent against Breckenridge and/or its privies;
- (d) Declare this case exceptional and enter an order awarding attorneys' fees and expenses to Breckenridge pursuant to 35 U.S.C. § 285;
- (e) Enter an order granting Breckenridge the costs of this litigation; and
- (f) 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: April 19, 2007



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