

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
GREENSBORO DIVISION

CORNERSTONE BIOPHARMA, INC.,	:	
and J-MED PHARMACEUTICALS, INC.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Civil Action No.: _____
	:	
	:	
SOVEREIGN PHARMACEUTICALS, LTD.,	:	COMPLAINT
	:	AND DEMAND FOR
	:	JURY TRIAL
Defendant.	:	
	:	

Plaintiffs, Cornerstone BioPharma, Inc. ("Cornerstone") and J-Med Pharmaceuticals, Inc. ("J-Med"), by and through their counsel, for their Complaint against Defendant Sovereign Pharmaceuticals, Ltd. ("Sovereign"), allege on personal knowledge as to their actions, and upon information and belief as to the actions of others, as follows:

NATURE OF THIS ACTION

1. This action arises under the patent laws of the United States, 35 U.S.C. § 1 et seq. Among other things, Plaintiffs seek injunctive relief.

JURISDICTION AND VENUE

2. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, and 1338(a).

3. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and/or 1400.

THE PARTIES

4. 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, and is doing business in this District.

5. J-Med is a corporation organized and existing under the laws of the State of Maryland with a principal place of business at 229 Berkeley Street, Boston, Massachusetts 02116.

6. Defendant Sovereign is, upon information and belief, a corporation organized and existing under the laws of the Texas, having a principal place of business at 7590 Sand St., Ft. Worth, TX 76118, and is doing business in this District.

BACKGROUND FACTS

7. Respiratory disease strikes millions of Americans each year. More than thirty million people in the U.S. have reportedly been diagnosed with allergic rhinitis, while many more suffer from allergic rhinitis but have never been diagnosed. Several medicines used to treat respiratory disease work well but have compliance or side effect issues that make them difficult to use. Cornerstone seeks to improve such medicines. Its prescription AlleRx products for respiratory illness reflect its stated mission of "making good medicines better."

8. Cornerstone's AlleRx products are designed to treat allergic rhinitis and symptoms of the common cold. Cornerstone and/or J-Med own and control the use of patent rights in connection with the manufacturing, sale and marketing of its prescription products, including AlleRx.

9. J-Med is the owner and assignee of United States Patent No. 6,270,796 ("the '796 patent"), entitled "Antihistamine/Decongestant Regimens for Treating Rhinitis" (Exhibit A).

Cornerstone is the exclusive licensee of the formulation of the '796 patent used in the AlleRx products.

10. The '796 patent concerns a prepackaged therapeutic regimen for the treatment of rhinitis through the use of antihistamines and/or decongestants. The claims of the '796 patent cover the AlleRx product marketed and sold in this District by Cornerstone.

11. The package insert of Cornerstone's AlleRx Dose Pack product contains a notice that expressly states that it is covered by the '796 patent (Exhibit B) pursuant to 35 U.S.C. §287. A copy of the notice as it appears on the package insert is reproduced below:

Distributed by Cornerstone Biopharma, Inc., Cary, NC 27518.

This product is licensed and protected under U.S. Patent No. 6,270,796 issued 8/7/2001.

12. Upon information and belief, Everton Pharmaceuticals, LLC ("Everton") is a limited liability company organized and existing under the laws of the State of North Carolina, having a principal place of business at 50010 Governors Drive, Suite 193, Chapel Hill, North Carolina 27517, and is doing business in this District.

13. Upon information and belief, Everton sells and/or offers to sell a product named AllePak in this District.

14. Upon information and belief, Everton and/or others have made public claims that the AllePak products are "equivalent" to Cornerstone's AlleRx products and have the "same formulation and dosing" as AlleRx products.

15. Cornerstone's patented day/night AlleRx 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.

16. Upon information and belief, the day/night AllePak product contains identical active ingredients at identical doses, supplied in the same 10-day treatment regimen and in the same day/night formulations. Like Cornerstone's patented product, the AllePak product 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.

17. Upon information and belief, Sovereign makes the AllePak products on behalf of Everton. The Material Safety Data Sheet for the AllePak products marketed, sold and/or offered for sale by Everton indicates that Sovereign is the manufacturer of such products.

18. Upon information and belief, through such activities Sovereign has infringed and continues to infringe, contribute to and/or induce the infringement of one or more claims of the '796 patent in violation of Cornerstone's intellectual property rights.

19. Neither Defendant nor Everton (nor others working together with Defendant or Everton) has a license or permission to use or practice the inventions claimed in the '796 patent.

COUNT I

INFRINGEMENT OF THE '796 PATENT

20. Cornerstone and J-Med reallege and incorporate the allegations in Paragraphs 1 through 19 above as if fully set forth herein.

21. The '796 patent, entitled "Antihistamine/Decongestant Regimens for Treating Rhinitis," was duly and legally issued on August 7, 2001.

22. Upon information and belief, Defendant, by engaging in unauthorized commercial manufacture, use, sale, offers for sale, or importation into the United States of the AllePak products, has committed or is continuing to commit acts of direct, and/or induced infringement,

either literally or under the doctrine of equivalents, of one or more valid and enforceable claims of the '796 patent.

23. Upon information and belief, Defendant was aware of the existence of the '796 patent since before it began its infringing activities, making the acts of patent infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

24. The acts of infringement set forth above will cause Cornerstone and J-Med to suffer immediate and irreparable injury unless enjoined by the Court. Cornerstone and J-Med have no adequate remedy at law and are entitled to preliminary and permanent injunctive relief prohibiting Defendant from infringing the '796 patent, and, after trial, to recover any damages proven to have been caused by reason of Defendant's acts of infringement.

COUNT II

INDUCED INFRINGEMENT OF THE '796 PATENT

25. Cornerstone and J-Med reallege and incorporate the allegations in Paragraphs 1 through 24 above as if fully set forth herein.

26. Upon information and belief, Defendant has actively, willfully and unlawfully induced the infringement, either literally or under the doctrine of equivalents, of one or more valid and enforceable claims of the '796 patent by another.

27. The acts of infringement set forth above will cause Cornerstone and J-Med to suffer immediate and irreparable injury unless enjoined by the Court. Cornerstone and J-Med have no adequate remedy at law and are entitled to preliminary and permanent injunctive relief prohibiting Defendant from inducing the infringement of the '796 patent, and, after trial, to recover any damages proven to have been caused by reason of Defendant's acts of inducing infringement.

COUNT III

CONTRIBUTORY INFRINGEMENT OF THE '796 PATENT

28. Cornerstone and J-Med reallege and incorporate the allegations in Paragraphs 1 through 27 above as if fully set forth herein.

29. To the extent Sovereign does not perform every step or element required by the claims of the '796 patent, upon information and belief, Sovereign's activities or their results constitute a material part of the claimed invention. Upon information and belief Sovereign knowingly conducts such activities, which are especially designed for infringement by another.

30. Upon information and belief, Defendant has actively, knowingly, intentionally and/or willfully contributed to the unlawful infringement, either literally or under the doctrine of equivalents, of one or more valid and enforceable claims of the '796 patent by another.

31. The acts of infringement set forth above will cause Cornerstone and J-Med to suffer immediate and irreparable injury unless enjoined by the Court. Cornerstone and J-Med have no adequate remedy at law and are entitled to preliminary and permanent injunctive relief prohibiting Defendant from contributing to the infringement of the '796 patent, and, after trial, to recover any damages proven to have been caused by reason of Defendant's acts of contributory infringement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment in their favor as follows:

- A. Declare that the making, using, selling, and/or offering to sell the AllePak products has infringed and will continue to infringe one or more valid and

enforceable claims of the '796 patent directly or indirectly, either literally or under the doctrine of equivalents;

- B. Declare that the Defendant's infringement of the '796 patent was willful;
- C. Preliminarily and permanently enjoin the Defendant and its officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of AllePak products until the expiration of the '796 patent;
- D. Preliminarily and permanently enjoin Defendant and its officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from inducing others to engage in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of AllePak products until the expiration of the '796 patent;
- E. Preliminarily and permanently enjoin Defendant and its officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from contributing to the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States of AllePak products by another until the expiration of the '796 patent;
- F. Award Cornerstone and J-Med treble damages or other monetary relief for Defendant's willful infringement of the '796 patent;

- G. Award Cornerstone and J-Med damages or other monetary relief for Defendant's inducement of infringement of the '796 patent;
- H. Award Cornerstone and J-Med damages or other monetary relief for Defendant's contribution to the infringement of the '796 patent by another;
- I. Award Cornerstone and J-Med their attorneys' fees, costs and expenses; and
- J. Award Cornerstone and J-Med such other and further relief as the Court deems just and proper.

Demand for Jury Trial

Plaintiff demands a trial by jury of all issues triable of right by jury.

This the 16th day of November, 2006.

Attorneys for Plaintiffs
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J-MED PHARMACEUTICALS, INC

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