# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA WESTERN DIVISION No. 5:07-CV-00389-F

CORNERSTONE BIOPHARMA, INC. and	)
J-MED PHARMACEUTICALS, INC.,	)
Plaintiffs,	) )
v.	) FIRST AMENDED COMPLAINT
VISION PHARMA, LLC	) )
SANDER BUSMAN, THOMAS	)
DESTEFANO, MICHAEL MCALOOSE	)
and NEXGEN PHARMA, INC.,	)
	)
Defendants.	)

Pursuant to Rule 15(a) of the Federal Rules of Civil Procedure, and prior to the service of a responsive pleading herein, plaintiffs Cornerstone BioPharma, Inc. and J-Med Pharmaceuticals, Inc., complaining of defendants Vision Pharma, LLC, Sander Busman, Thomas DeStefano, Michael McAloose, and Nexgen Pharma, Inc., hereby allege as follows for their First Amended Complaint in this action:

#### NATURE OF ACTION

- 1. This action arises under the patent laws of the United States, 35 U.S.C. § 1, et seq., the Copyright Act of 1976, 17 U.S.C. § 101, et seq., Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and the common law.
- 2. Plaintiff Cornerstone BioPharma, Inc. ("Cornerstone") markets patented prescription medicines for the treatment of respiratory illness. Cornerstone's AlleRx<sup>TM</sup> Dose Pack product is a ten-day or thirty-day prepackaged therapeutic regimen for temporary relief of symptoms associated with allergic rhinitis. AlleRx<sup>TM</sup> Dose Pack is covered by one or more

claims of U.S. Patent No. 6,270,796 (the "'796 Patent"), entitled "Antihistamine/Decongestant Regimens for Treating Rhinitis," issued August 7, 2001. The '796 Patent has been assigned to and is owned by plaintiff J-Med Pharmaceuticals, Inc. ("J-Med"). The '796 Patent is exclusively licensed by J-Med to Cornerstone.

- 3. In contravention of plaintiffs' rights under the '796 Patent and other intellectual property rights, defendant Vision Pharma, L.L.C. ("Vision") has launched and is now selling in the United States an unauthorized generic version of AlleRx<sup>TM</sup> Dose Pack known as "VisRx." VisRx contains the same active ingredients in the same dosages as AlleRx<sup>TM</sup> Dose Pack. Like AlleRx<sup>TM</sup> Dose Pack, VisRx comes in ten-day and thirty-day treatment regimens with day/night formulations. The product informational insert for VisRx is almost a word-for-word copy of Cornerstone's copyrighted product informational insert for AlleRx<sup>TM</sup> Dose Pack. Vision recently applied to list VisRx in one or more national databases of pharmaceutical products as a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack. These databases are widely used by pharmacists, health care providers and others, including in North Carolina and specifically in this judicial district, in selecting and dispensing prescription drugs. VisRx has been sold and dispensed in North Carolina and in this judicial district.
- 4. VisRx is manufactured for Vision by defendant Nexgen Pharma, Inc. ("Nexgen"), a contract manufacturer of pharmaceutical products.
- 5. Due to the violations of plaintiffs' patent and other intellectual property rights described herein, plaintiffs seek in this action injunctive relief, actual damages, consequential damages, treble damages, costs, attorneys' fees, and other equitable and monetary relief.

#### **PARTIES**

- 6. Plaintiff Cornerstone BioPharma, Inc. is a corporation organized under the laws of the State of Nevada with its principal place of business located in Cary, North Carolina.
- 7. Plaintiff J-Med Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Maryland with its principal place of business located in Potomac, Maryland.
- 8. Upon information and belief, defendant Vision Pharma, LLC is a limited liability company organized under the laws of the State of New Jersey with its principal place of business located in Wall, New Jersey.
- 9. Defendant Sander Busman is an individual who, upon information and belief, is a member of Vision. Busman is Vision's President and Chief Executive Officer.
- 10. Defendant Thomas DeStefano is an individual who, upon information and belief, is a member of Vision. DeStefano is Vision's Executive Vice President of Sales and Marketing.
- 11. Defendant Michael McAloose is an individual who, upon information and belief, is a member of Vision. McAloose is Vision's Chief Financial Officer and Chief Operating Officer.
- 12. Upon information and belief, defendant Nexgen Pharma, Inc. is a corporation organized under the laws of the State of California with its principal place of business located in Irvine, California.

#### JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction over this action and the claims asserted herein pursuant to 28 U.S.C. § 1331, 1332(a) and 1338(a) and (b) and 1367. Plaintiffs and defendants are citizens of different States, and the amount in controversy, exclusive of interest and costs, exceeds \$75,000.

- 14. This Court may exercise personal jurisdiction over Vision based upon its substantial business activities in and/or affecting North Carolina. VisRx has been sold and dispensed in North Carolina and in this judicial district. Vision's other generic pharmaceutical products also are regularly sold and offered for sale in North Carolina and in this judicial district. Vision places its generic pharmaceutical products, including VisRx, into the stream of commerce with the expectation that those products will be sold and offered for sale throughout the United States, including within North Carolina and within this judicial district. Vision's application to list VisRx in a national database of pharmaceutical products was done with the expectation that the information would be used nationwide by pharmacists and others for dispensing decisions, including in North Carolina and specifically in this judicial district.
- 15. This Court may exercise personal jurisdiction over Busman, DeStefano and McAloose based upon their substantial business activities in and/or affecting North Carolina. Upon information and belief, Busman, DeStefano and McAloose are responsible for and have actively directed, managed, controlled, approved, participated in, and carried out the placement of Vision's pharmaceutical products, including VisRx, into the stream of commerce with the expectation that those products will be sold and offered for sale throughout the United States, including within North Carolina and within this judicial district. Upon information and belief, they have actively directed, managed, controlled, approved, participated in and carried out Vision's infringing activities described herein and have done so with knowledge of Vision's intellectual property rights, acting with willful disregard therefor. Further, upon information and belief, they actively directed, managed, controlled, approved, participated in and carried out Vision's application to list VisRx in one or more national databases of pharmaceutical products

with the expectation that the information would be used nationwide by pharmacists and others for dispensing decisions, including in North Carolina and specifically in this judicial district.

- 16. This Court may exercise personal jurisdiction over Nexgen based upon its substantial business activities in and/or affecting North Carolina. Upon information and belief, Nexgen manufactured VisRx for Vision with the expectation that it would be sold and offered for sale throughout the United States, including within North Carolina and within this judicial district. VisRx has been sold and dispensed in North Carolina and in this judicial district. Upon information and belief, Nexgen manufactures other pharmaceutical products with the expectation that those products will be sold and offered for sale throughout the United States, including within North Carolina and within this judicial district. Such products manufactured by Nexgen are regularly sold and offered for sale in North Carolina and in this judicial district. Also, Nexgen has encapsulated balsalizide as Colazal® under contract with Salix Pharmaceuticals, Inc., which is based in Morrisville, North Carolina.
  - 17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

#### FACTUAL BACKGROUND

# AlleRx<sup>TM</sup> Dose Pack

18. Respiratory disease strikes millions of Americans each year. More than 30 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. Cornerstone's AlleRx<sup>TM</sup> products for treatment of respiratory illness reflect its stated mission of "making good medicines better."

- 19. Cornerstone's AlleRx<sup>TM</sup> Dose Pack product is a prepackaged ten-day or thirty-day therapeutic regimen for temporary relief of symptoms associated with allergic rhinitis containing a day dose of 120 mg pseudoephedrine HCl and 2.5 mg methscopolamine nitrate and a night dose of 8 mg chlorpheniramine maleate and 2.5 mg methscopolamine nitrate.
- 20. Cornerstone and/or J-Med own and control the use of patent and other intellectual property rights in connection with the manufacturing, marketing and sale of AlleRx<sup>TM</sup> Dose Pack. J-Med is the assignee and owner of U.S. Patent No. 6,270,796 (the "796 Patent"), entitled "Antihistamine/Decongestant Regimens for Treating Rhinitis," issued August 7, 2001. A copy of the '796 Patent is attached as Exhibit A. The '796 Patent describes, *inter alia*, an invention concerning a prepackaged therapeutic regimen for the temporary relief of symptoms associated with rhinitis through the use of antihistamines and/or decongestants.
- 21. Cornerstone is the exclusive licensee of the '796 Patent and has the right to prosecute actions for infringement thereof.
- 22. One or more claims of the '796 Patent cover the AlleRx<sup>TM</sup> Dose Pack product marketed and sold in this judicial district by Cornerstone.
- 23. The product informational insert that Cornerstone distributes inside the box for AlleRx<sup>TM</sup> Dose Pack, a copy of which is attached hereto as Exhibit B, contains a specific notice stating that AlleRx<sup>TM</sup> is covered by the '796 Patent. The notice contained in the AlleRx<sup>TM</sup> product informational insert states as follows:

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.

24. The AlleRx<sup>TM</sup> product informational insert is the product of expense, effort, creativity, and originality on the part of Cornerstone's predecessor in interest.

- 25. The AlleRx<sup>TM</sup> Dose Pack product informational insert is original with Cornerstone's predecessor in interest and constitutes copyrightable subject matter under the laws of the United States.
- 26. The AlleRx<sup>TM</sup> Dose Pack product informational insert and the copyright therein have been assigned to Cornerstone. Cornerstone is and, at all times relevant to the matters alleged herein, was the sole owner of all right, title and interest in and to the AlleRx<sup>TM</sup> Dose Pack product informational insert and the copyright therein.
- 27. Cornerstone has duly and lawfully registered the copyright in the AlleRx<sup>TM</sup> Dose Pack product informational insert with the U.S. Copyright Office, which has issued to Cornerstone Certificates of Registration Nos. TX 6-452-085 and TX 6-591-925.

# The Deliberate and Unauthorized Copying of Cornerstone's AlleRx<sup>TM</sup> Dose Pack and Insert

- 28. Vision has launched and is now selling in the United States a pharmaceutical product under the name "VisRx." VisRx has been sold and dispensed in North Carolina and in this judicial district. Upon information and belief, Busman, DeStefano and McAloose have actively managed, directed, controlled, approved, participated in and carried out Vision's launch of VisRx and the marketing and sale of VisRx.
- 29. In papers that Vision filed with the United States Patent and Trademark Office in July 2007 seeking trademark registration for the term "VisRx," Vision identified VisRx as a "pharmaceutical preparation for the relief of symptoms associated with allergic rhinitis, vasomotor rhinitis and the common cold."
- 30. VisRx actually is an unauthorized generic version of AlleRx<sup>TM</sup> Dose Pack. Like AlleRx<sup>TM</sup> Dose Pack, VisRx is a prepackaged ten-day or thirty-day therapeutic regimen for the temporary relief of symptoms associated with rhinitis containing a day dose of 120 mg

pseudoephedrine HCl and 2.5 mg methscopolamine nitrate and a night dose of 8 mg

chlorpheniramine maleate and 2.5 mg methscopolamine nitrate. The active ingredients and

dosages used in VisRx are the same as the active ingredients and dosages used in AlleRx<sup>TM</sup> Dose

Pack. As with AlleRx<sup>TM</sup> Dose Pack, VisRx is supplied in ten-day and thirty-day treatment

regimens with day/night formulations.

31. Vision has applied to list VisRx as a generic equivalent or other substitute for

AlleRx<sup>TM</sup> Dose Pack in one or more national pharmaceutical databases widely used by

pharmacists, health care providers and others in selecting and dispensing prescription drugs.

Upon information and belief, Vision seeks to list VisRx as a generic equivalent or other

substitute for AlleRx<sup>TM</sup> Dose Pack in order to encourage substitution of VisRx for AlleRx<sup>TM</sup>

Dose Pack based upon VisRx's lower retail price. Upon information and belief, Busman,

DeStefano and McAloose have actively managed, directed, controlled, approved, participated in,

and carried out Vision's application to list VisRx as a generic equivalent or other substitute for

AlleRx<sup>TM</sup> Dose Pack in one or more national pharmaceutical databases.

32. Upon information and belief, Vision has not performed testing to support a claim

that VisRx is, in fact, a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack.

33. Vision has engaged Nexgen, a contract manufacturer of pharmaceutical products,

to manufacture VisRx. The product informational insert for VisRx specifically identifies

Nexgen as the manufacturer of VisRx as follows:

Manufactured for:

Vision Pharma, LLC

Wall, NJ 07719

www.visionpharma.com

Manufactured by:

Nexgen Pharma, Inc.

Irvine, CA 92614

A copy of the VisRx informational product insert is attached as Exhibit C. Upon information

and belief, Nexgen has collaborated with and provided substantial assistance to Vision in the

production of VisRx, thereby enabling Vision to offer VisRx for sale. Upon information and

belief, Busman, DeStefano and McAloose have actively managed, directed, controlled,

approved, participated in and carried out Vision's engagement of Nexgen to manufacture VisRx.

34. Vision does not have a license or permission to use or practice the inventions

claimed in the '796 Patent.

35. Busman, DeStefano and McAloose do not have a license or permission to use or

practice the inventions claimed in the '796 Patent.

36. Nexgen does not have a license or permission to use or practice the inventions

claimed in the '796 Patent.

37. Upon information and belief, Vision was aware of the '796 Patent when it

arranged for VisRx to be manufactured and when it began to offer VisRx for sale.

Notwithstanding its knowledge of the '796 Patent, Vision is continuing to sell VisRx and to offer

VisRx for sale as of the date of this First Amended Complaint.

38. Upon information and belief, Busman, DeStefano and McAloose were aware of

the '796 Patent when they managed, directed, controlled, approved, participated in and carried

out Vision's engagement of Nexgen to manufacture VisRx. Upon information and belief,

Busman, DeStefano and McAloose also were aware of the '796 Patent when they managed,

directed, controlled, approved, participated in and carried out Vision's sale and offer of VisRx

for sale. Notwithstanding their knowledge of the '796 Patent, Busman, DeStefano and

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McAloose are continuing to manage, direct, control, approve, participate in and carry out Vision's sale and offer of VisRx for sale as of the date of this First Amended Complaint.

- 39. The product informational insert that Vision has prepared and that it is distributing with VisRx is almost a word-for-word copy of the copyrighted product informational insert for AlleRx<sup>TM</sup> Dose Pack. Upon information and belief, Vision would not offer VisRx for sale unaccompanied by a product informational insert such as the one it has largely copied from Cornerstone. Upon information and belief, Vision has had access to and has copied Cornerstone's product informational insert for its AlleRx<sup>TM</sup> Dose Pack product, which includes a specific reference to the '796 Patent. Upon information and belief, Busman, DeStefano and McAloose actively directed, managed, controlled, approved, participated in and carried out Vision's unauthorized copying of Cornerstone's copyrighted AlleRx<sup>TM</sup> product informational insert.
- 40. Vision does not have a license or permission to copy, distribute or use Cornerstone's copyrighted AlleRx<sup>TM</sup> Dose Pack product informational insert or to create derivative works based thereon.
- 41. Busman, DeStefano and McAloose do not have a license or permission to copy, distribute or use Cornerstone's copyrighted AlleRx<sup>TM</sup> Dose Pack product informational insert or to create derivative works based thereon.

# FIRST CLAIM FOR RELIEF INFRINGEMENT OF THE '796 PATENT (VISION, BUSMAN, DESTEFANO AND MCALOOSE)

42. Cornerstone and J-Med repeat and reallege as if fully set forth here each and every allegation set forth above in paragraphs 1 through 41, inclusive.

- 43. Upon information and belief, Vision has directly infringed and is directly infringing, either literally or under the doctrine of equivalents, one or more valid claims of the '796 Patent by manufacturing, using, selling, and offering VisRx for sale in the United States.
- 44. Upon information and belief, Vision has actively induced and is actively inducing infringement, either literally or under the doctrine of equivalents, of one or more valid claims of the '796 Patent by encouraging others to manufacture, use, sell, and offer VisRx for sale in the United States.
- 45. Upon information and belief, Busman, DeStefano and McAloose have actively induced and are actively inducing infringement, either literally or under the doctrine of equivalents, of one or more valid claims of the '796 Patent by actively directing, managing, controlling, approving, participating in and carrying out Vision's manufacture, use, sale and offer of VisRx for sale in the United States and by encouraging others to manufacture, use, sell and offer VisRx for sale in the United States.
- 46. Cornerstone and J-Med have suffered significant harm as a direct and proximate result of infringement of the '796 Patent by Vision, Busman, DeStefano and McAloose. Such damage will continue in the future unless Vision, Busman, DeStefano and McAloose are enjoined from further infringement of the '796 Patent. Cornerstone and J-Med do not have an adequate remedy at law to redress all of the injuries they have sustained by reason of Vision's, Busman's, DiStefano's and McAloose's unlawful activities.
- 47. Upon information and belief, Vision, Busman, DeStefano and McAloose have engaged in the acts of infringement alleged herein with knowledge of the '796 Patent and with willful and deliberate disregard therefor, making this an exceptional case under 35 U.S.C. § 285

and entitling Cornerstone and J-Med to recover from Vision, Busman, DeStefano and McAloose enhanced damages and reasonable attorneys' fees.

# SECOND CLAIM FOR RELIEF INFRINGEMENT OF THE '796 PATENT (NEXGEN)

- 48. Cornerstone and J-Med repeat and reallege as if fully set forth here each and every allegation set forth above in paragraphs 1 through 47, inclusive.
- 49. Upon information and belief, Nexgen has directly and/or contributorily infringed, either literally or under the doctrine of equivalents, one or more valid claims of the '796 Patent by manufacturing VisRx and by providing same to Vision for sale and distribution in the United States.
- 50. Upon information and belief, Nexgen has actively induced and is actively inducing infringement, either literally or under the doctrine of equivalents, of one or more valid claims of the '796 Patent by manufacturing VisRx and by providing same to Vision for sale and distribution in the United States.
- 51. Cornerstone and J-Med have suffered significant harm as a direct and proximate result of Nexgen's infringement of the '796 Patent. Such damage will continue in the future unless Nexgen is enjoined from further infringement of the '796 Patent. Cornerstone and J-Med do not have an adequate remedy at law to redress all of the injuries they have sustained by reason of Nexgen's unlawful activities.
- 52. Upon information and belief, Nexgen has engaged in the acts of infringement alleged herein with knowledge of the '796 Patent and with willful and deliberate disregard therefor, making this an exceptional case under 35 U.S.C. § 285 and entitling Cornerstone and J-Med to recover from Nexgen enhanced damages and attorneys' fees.

# THIRD CLAIM FOR RELIEF COPYRIGHT INFRINGEMENT (VISION, BUSMAN, DESTEFANO AND MCALOOSE)

- 53. Cornerstone and J-Med repeat and reallege as if fully set forth here each and every allegation set forth above in paragraphs 1 through 52, inclusive.
- 54. Upon information and belief, by copying the product informational insert for AlleRx<sup>TM</sup> Dose Pack and by distributing its knock-off product informational insert for VisRx, Vision has infringed and is infringing, directly, contributorily and/or vicariously, Cornerstone's registered copyright in its AlleRx<sup>TM</sup> Dose Pack product informational insert in violation of 17 U.S.C. § 501.
- 55. Upon information and belief, Vision has actively induced, and is actively inducing, infringement of Cornerstone's registered copyright in its AlleRx<sup>TM</sup> product informational insert in violation of 17 U.S.C. § 501.
- 56. Upon information and belief, by actively directing, managing, controlling, approving, participating in and carrying out Vision's copying of the product informational insert for AlleRx<sup>TM</sup> Dose Pack and Vision's distribution of its knock-off product informational insert for VisRx, Busman, DeStefano and McAloose have infringed and are infringing, directly, contributorily and/or vicariously, and have actively induced and are actively inducing infringement of Cornerstone's registered copyright in its AlleRx<sup>TM</sup> product informational insert in violation of 17 U.S.C. § 501.
- 57. As a direct and proximate result of the infringement of Cornerstone's registered copyright in the AlleRx<sup>TM</sup> Dose Pack product informational insert by Vision, Busman, DeStefano and McAloose, Cornerstone has suffered significant harm. Such harm to Cornerstone will continue in the future unless Vision, Busman, DeStefano and McAloose are enjoined from further infringement of Cornerstone's registered copyright in the AlleRx<sup>TM</sup> Dose Pack product

informational insert. Cornerstone does not have an adequate remedy at law to redress all of the injuries it has sustained by reason of Vision's, Busman's, DeStefano's and McAloose's unlawful activities.

58. Upon information and belief, the infringement of Cornerstone's registered copyright in its AlleRx<sup>TM</sup> Dose Pack product informational insert by Vision, Busman, DeStefano and McAloose has been and is willful, deliberate and intentional.

# FOURTH CLAIM FOR RELIEF UNFAIR COMPETITION (15 U.S.C. 1125(a)) (VISION, BUSMAN, DESTEFANO AND MCALOOSE)

- 59. Cornerstone and J-Med repeat and reallege as if fully set forth here each and every allegation set forth above in paragraphs 1 through 58, inclusive.
- 60. Upon information and belief, Vision's application to list VisRx in one or more national pharmaceutical databases as a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack constitutes unfair competition and false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), because all necessary testing required to support a claim that VisRx is a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack has not been performed.
- 61. Upon information and belief, Busman, DeStefano and McAloose have actively managed, directed, controlled, approved, participated in, and carried out Vision's application to list VisRx as a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack in one or more national pharmaceutical databases. Upon information and belief, at the time that they did so, they knew that all necessary testing required to support a claim that VisRx is a generic equivalent or other substitute for AlleRx<sup>TM</sup> had not been performed.

62. As a direct and proximate result, Cornerstone and J-Med have suffered significant harm. Such harm will continue in the future unless Vision, Busman, DeStefano and McAloose are enjoined from listing VisRx as a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack and are enjoined from otherwise claiming that VisRx is a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack without performing all necessary testing required to support such claim. Cornerstone and J-Med do not have an adequate remedy at law to redress all of the injuries they have sustained by reason of Vision's, Busman's, DeStefano's and McAloose's unlawful activities.

### FIFTH CLAIM FOR RELIEF STATE LAW UNFAIR COMPETITION (VISION, BUSMAN, DESTEFANO AND MCALOOSE)

- 63. Cornerstone and J-Med repeat and reallege as if fully set forth here each and every allegation set forth above in paragraphs 1 through 62, inclusive.
- 64. Upon information and belief, Vision's application to list VisRx in one or more national pharmaceutical databases as a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack is false and misleading because, upon information and belief, testing to support a claim that VisRx is a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack has not been performed. Such activity by Vision constitutes state law unfair competition.
- 65. Upon information and belief, at the time that Busman, DeStefano and McAloose actively managed, directed, controlled, approved, participated in, and carried out Vision's application to list VisRx as a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack in one or more national pharmaceutical databases, they knew that all necessary testing required to support a claim that VisRx is a generic equivalent or other substitute for AlleRx<sup>TM</sup> had not been performed.

- 66. As a direct and proximate result, Cornerstone and J-Med have suffered significant harm. Such harm will continue in the future unless Vision, Busman, DeStefano and McAloose are enjoined from listing VisRx as a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack in national pharmaceutical databases and are enjoined from otherwise claiming that VisRx is a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack without performing testing to support such claim.
- 67. Cornerstone and J-Med do not have an adequate remedy at law to redress all of the injuries they have sustained by reason of Vision's, Busman's, DeStefano's and McAloose's unlawful activities.
- 68. Vision's false and misleading statements and representations to one of more national pharmaceutical databases, which were actively managed directed, controlled, approved, participated in, and carried out by Busman, DeStefano and McAloose, were made with malice, or willfully and wantonly, entitling Plaintiffs to punitive damages under applicable state law.

WHEREFORE, Cornerstone and J-Med respectfully request:

- a. That the Court enter judgment in favor of Cornerstone and J-Med and against Vision, Busman, DeStefano and McAloose on the First Claim for Relief set forth in the Complaint;
- That the Court enter judgment in favor of Cornerstone and J-Med and against
   Nexgen on the Second Claim for Relief set forth in the Complaint;
- c. That the Court enter an order preliminarily and permanently enjoining Vision and Nexgen, and their officers, directors, agents, servants, employees, attorneys, representatives, successors and assigns, and all persons or entities in active

- concert or participation or privity with any of them, from further infringement of the '796 Patent;
- d. That the Court enter an order preliminarily and permanently enjoining Vision, Busman, DeStefano, McAloose and Nexgen, and their officers, directors, agents, servants, employees, attorneys, representatives, successors and assigns, and all persons in active concert or participation or privity with any of them, from further inducement of infringement of the '796 Patent;
- e. That the Court award Cornerstone and J-Med damages or other monetary relief for infringement of the '796 Patent by Vision, Busman, DeStefano, McAloose and Nexgen;
- f. That the Court find that the infringement of the '796 Patent by Vision, Busman, DeStefano, McAloose and Nexgen was willful and award Cornerstone and J-Med treble damages pursuant to 35 U.S.C. § 284;
- g. That the Court enter an order requiring Vision and Nexgen to recall from distribution all of their products that infringe, or induce or contribute to infringement of the '796 Patent and that the Court order the impoundment and destruction of all such products, together with all other products in their possession, custody or control that infringe, or induce or contribute to infringement of the '796 Patent;
- h. That the Court enter judgment in favor of Cornerstone and against Vision,
  Busman, DeStefano and McAloose on the Third Claim for Relief;
- i. That the Court enter an order preliminarily and permanently enjoining Vision,
  Busman, DeStefano and McAloose, and their respective officers, directors,

- agents, servants, employees, attorneys, representatives, successors and assigns, and all persons or entities in active concert or participation or privity with any of them, from further infringement of the copyright in Cornerstone's AlleRx<sup>TM</sup> Dose Pack product informational insert;
- j. That the Court enter an order declaring that the infringement of Cornerstone's copyright in the AlleRx<sup>TM</sup> Dose Pack product informational insert by Vision, Busman, DeStefano and McAloose was willful;
- k. That the Court award Cornerstone damages for infringement by Vision, Busman,
  DeStefano and McAloose of its copyright in the AlleRx<sup>TM</sup> Dose Pack product
  informational insert and that Vision, Busman, DeStefano and McAloose be
  ordered to disgorge all profits and other gains attributable to their infringement or,
  in the alternative, that the Court award Cornerstone statutory damages;
- 1. That the Court enter an order requiring Vision to recall from distribution all items that infringe Cornerstone's copyright in the AlleRx<sup>TM</sup> Dose Pack product informational insert and that the Court order the impoundment and destruction of all such items, together with all other items in Vision's possession, custody or control that infringe Cornerstone's copyright in the AlleRx<sup>TM</sup> Dose Pack product informational insert;
- m. That the Court enter judgment in favor of Cornerstone and J-Med and against
   Vision, Busman, DeStefano and McAloose on the Fourth and Fifth Claims for
   Relief set forth in the Complaint;
- n. That the Court enter an order preliminarily and permanently enjoining Vision,
  Busman, DeStefano, McAloose, and their respective officers, directors, agents,

servants, employees, attorneys, representatives, successors and assigns, and all persons or entities in active concert or participation or privity with any of them, from engaging in false or misleading advertising in connection with VisRx, including but not limited to claiming to national pharmaceutical databases and others that VisRx is a generic equivalent or other substitute for AlleRx<sup>TM</sup> Dose Pack without performing testing to support such claim;

- o. That the Court award Cornerstone and J-Med damages or other monetary relief, including punitive damages, for Vision's, Busman's, DeStefano's, and McAloose's false advertising/representations and unfair competition in violation of applicable state law;
- p. That the Court award Cornerstone and J-Med their attorneys' fees, costs and expenses as allowed by law;
- q. That the Court award Cornerstone and J-Med pre-judgment and post-judgment interest as allowed by law; and
- r. That the Court grant Cornerstone and J-Med such other and further relief as the Court may deem just and proper.

#### **DEMAND FOR JURY TRIAL**

Cornerstone and J-Med hereby demand a trial by jury as to all issues in this case so triable.

#### /s/ Robert J. Morris

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Attorneys for Plaintiffs

#### CERTIFICATE OF SERVICE

I hereby certify that, on the 19<sup>th</sup> day of November, 2007, I electronically filed the foregoing First Amended Complaint with the Clerk of Court using the CM/ECF system, which will send notification to the attorneys of record for Vision Pharma, LLC and Nexgen Pharma, Inc. as follows:

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