Michael R. Griffinger
Lisa H. Wang
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Telephone No.: (973) 596-4500
Facsimile No.: (973) 596-0545

Of Counsel:
Edgar H. Haug
Jason A. Lief
Angus Chen
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
Telephone No.: (212) 588-0800
Facsimile No.: (212) 599-0500

Attorneys for Plaintiffs
Cornerstone Therapeutics Inc., Cornerstone BioPharma, Inc., and EKR Therapeutics, LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CORNERSTONE THERAPEUTICS INC., CORNERSTONE BIOPHARMA, INC., and EKR THERAPEUTICS, LLC,	)	
Plaintiffs,	)	Civil Action No. _____
v.	)	
SANDOZ INC.	)	***Document electronically filed.***
Defendant.	)	

COMPLAINT

Plaintiffs Cornerstone Therapeutics Inc., Cornerstone BioPharma, Inc., and EKR Therapeutics, LLC ("EKR") (collectively "Cornerstone"), by its undersigned attorneys, for its Complaint against defendant Sandoz Inc. ("Sandoz") herein, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 7,612,102 ("the '102 patent") (attached as Exhibit A hereto), United States Patent No. 7,659,291 ("the '291 patent") (attached as Exhibit B hereto), United States Patent No. 8,455,524 ("the '524 patent") (attached as Exhibit C hereto), and United States Patent No. 7,659,290 ("the '290 patent") (attached as Exhibit D hereto) (collectively "the Patents-in-Suit").

THE PARTIES

2. Plaintiff Cornerstone Therapeutics Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518.

3. Plaintiff Cornerstone BioPharma, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518.

4. Plaintiff EKR (formerly known as EKR Therapeutics, Inc.) is a wholly-owned subsidiary of Cornerstone Therapeutics Inc., organized and existing under the laws of the State of Delaware, having a place of business at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518.

5. Upon information and belief, Sandoz is a corporation organized and existing under the laws of the State of Colorado, having its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

6. Upon information and belief, Sandoz develops, manufactures, and distributes generic drugs throughout the United States, including in New Jersey.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and/or 35 U.S.C. § 271.

8. This Court has personal jurisdiction over Sandoz because, *inter alia*: (i) Sandoz maintains a principal place of business in this judicial district; (ii) Sandoz has committed, induced, or contributed to acts of patent infringement in this judicial district; (iii) Sandoz resides and is doing business in this judicial district and maintains continuous and systematic contacts with this judicial district; (iv) Sandoz is registered as a drug manufacturer and wholesale drug distributor in the State of New Jersey under the registration number 5003732; (v) Sandoz has consented to the jurisdiction of this Court in numerous prior actions; and (vi) Sandoz has availed itself of the rights, benefits, and privileges of this Court by asserting claims and counterclaims in numerous prior actions in this judicial district.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

FACTS AS TO ALL COUNTS

10. EKR is the current owner of New Drug Application ("NDA") No. 19-734, approved by the U.S. Food and Drug Administration ("FDA") for the manufacture and sale of Cardene® I.V. Premixed Injection, 0.1 mg/mL and 0.2 mg/mL. Cardene® I.V. is a nicardipine hydrochloride premixed injection for intravenous administration indicated for the short-term treatment of hypertension when oral therapy is not feasible or not desirable.

11. The '102 patent, titled "Pre-mixed, Ready-to-Use Pharmaceutical Compositions" was duly and legally issued on November 3, 2009. The '102 patent is generally directed to pharmaceutical compositions comprising nicardipine hydrochloride.

12. The '291 patent, titled "Methods of Treatment with Pre-Mixed, Ready-to-Use Pharmaceutical Compositions" was duly and legally issued on February 9, 2010. The '291

patent is generally directed to methods of treatment with pharmaceutical compositions comprising nicardipine hydrochloride.

13. The ’524 patent, titled “Methods of Treatment with Pre-mixed, Ready-to-Use Pharmaceutical Compositions” was duly and legally issued on June 4, 2013. The ’524 patent is generally directed to methods of treatment with pharmaceutical compositions comprising nicardipine hydrochloride.

14. The ’290 patent, titled “Methods of Preparing Pre-Mixed, Ready-to-Use Pharmaceutical Compositions” was duly and legally issued on February 9, 2010. The ’290 patent is generally directed to methods of preparing pharmaceutical compositions comprising nicardipine hydrochloride. The ’290 patent issued from U.S. Patent Application No. 12/407,551, a division of U.S. Patent Application No. 11/788,076 which issued as the ’102 patent.

15. The Patents-in-Suit all claim priority to U.S. Provisional Application No. 60/793,074, filed on April 18, 2006. EKR has been assigned, and currently owns, all rights, title, and interest in the Patents-in-Suit.

16. Pursuant to 21 U.S.C. § 355(b)(1), the ’102 patent, the ’291 patent and the ’524 patent are listed in FDA’s publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “*Orange Book*”) as covering Cardene® I.V. Premixed Injection.

17. Upon information and belief, Sandoz prepared, submitted, and filed Abbreviated New Drug Application No. 203978 (“Sandoz’s ANDA”) to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of

generic Nicardipine HCl Intravenous Injection 0.1 mg/ml in sodium chloride and 0.2 mg/ml in sodium chloride ("Sandoz's Generic Products").

18. Sandoz sent a letter to Cornerstone Therapeutics Inc., Cornerstone BioPharma, Inc., and EKR Therapeutics, LLC purporting to provide notification that Sandoz's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") with regard to the '102, '291, and '524 patents ("Sandoz's Notice Letter").

19. Sandoz's Notice Letter does not provide non-infringement contentions for any claim of the '102, '291, or '524 patents.

FIRST COUNT

(Infringement of the '102 Patent by Sandoz)

20. Cornerstone repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

21. Upon information and belief, Sandoz seeks FDA approval for the manufacture, marketing, sale, and/or distribution of Sandoz's Generic Products.

22. Upon information and belief, Sandoz included a paragraph IV certification to the '102 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Generic Products before the expiration of the '102 patent.

23. Upon information and belief, Sandoz will commercially manufacture, sell, offer for sale, and/or import Sandoz's Generic Products upon, or in anticipation of, FDA approval and before the expiration of the '102 patent.

24. Upon information and belief, as of the date of Sandoz's Notice Letter, Sandoz was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

25. The inclusion of a paragraph IV certification to the '102 patent in ANDA No. 203978 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Generic Products before the expiration of the '102 patent is an act of direct and/or indirect infringement (including induced and/or contributory infringement) by Sandoz of one or more claims of the '102 patent under 35 U.S.C. § 271(e)(2)(A).

26. Upon information and belief, Sandoz's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Generic Products that are the subject of ANDA No. 203978 will infringe one or more claims of the '102 patent under 35 U.S.C. § 271 *et seq.*, including § 271(a), § 271(b), and/or § 271(c).

27. Upon information and belief, Sandoz was and is aware of the existence of the '102 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '102 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

28. Sandoz's infringement of the '102 patent has caused and will cause Cornerstone to suffer irreparable harm. Sandoz's infringement will continue unless enjoined by the Court. Cornerstone has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Sandoz from infringing the '102 patent.

SECOND COUNT
(Infringement of the '291 Patent by Sandoz)

29. Cornerstone repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

30. Upon information and belief, Sandoz seeks FDA approval for the manufacture, marketing, sale, and/or distribution of Sandoz's Generic Products.

31. Upon information and belief, Sandoz included a paragraph IV certification to the '291 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Generic Products before the expiration of the '291 patent.

32. Upon information and belief, Sandoz will commercially manufacture, sell, offer for sale, and/or import Sandoz's Generic Products upon, or in anticipation of, FDA approval and before the expiration of the '291 patent.

33. Upon information and belief, as of the date of Sandoz's Notice Letter, Sandoz was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

34. The inclusion of a paragraph IV certification to the '291 patent in ANDA No. 203978 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Generic Products before the expiration of the '291 patent is an act of direct and/or indirect infringement (including induced and/or contributory infringement) by Sandoz of one or more claims of the '291 patent under 35 U.S.C. § 271(e)(2)(A).

35. Upon information and belief, Sandoz's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Generic Products that are the subject of ANDA No. 203978 will infringe one or more claims of the '291 patent under 35 U.S.C. § 271 *et seq.*, including § 271(b) and/or § 271(c).

36. Upon information and belief, Sandoz was and is aware of the existence of the '291 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '291 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

37. Sandoz's infringement of the '291 patent has caused and will cause Cornerstone to suffer irreparable harm. Sandoz's infringement will continue unless enjoined by the Court. Cornerstone has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Sandoz from infringing the '291 patent.

THIRD COUNT
(Infringement of the '524 Patent by Sandoz)

38. Cornerstone repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

39. Upon information and belief, Sandoz seeks FDA approval for the manufacture, marketing, sale, and/or distribution of Sandoz's Generic Products.

40. Upon information and belief, Sandoz included a paragraph IV certification to the '524 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Generic Products before the expiration of the '524 patent.

41. Upon information and belief, Sandoz will commercially manufacture, sell, offer for sale, and/or import Sandoz's Generic Products upon, or in anticipation of, FDA approval and before the expiration of the '524 patent.

42. Upon information and belief, as of the date of Sandoz's Notice Letter, Sandoz was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

43. The inclusion of a paragraph IV certification to the '524 patent in ANDA No. 203978 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Generic Products before the expiration of the '524 patent is an act of direct and/or indirect infringement (including induced and/or contributory

infringement) by Sandoz of one or more claims of the '524 patent under 35 U.S.C. § 271(e)(2)(A).

44. Upon information and belief, Sandoz's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Generic Products that are the subject of ANDA No. 203978 will infringe one or more claims of the '524 patent under 35 U.S.C. § 271 *et seq.*, including § 271(b) and/or § 271(c).

45. Upon information and belief, Sandoz was and is aware of the existence of the '524 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '524 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

46. Sandoz's infringement of the '524 patent has caused and will cause Cornerstone to suffer irreparable harm. Sandoz's infringement will continue unless enjoined by the Court. Cornerstone has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Sandoz from infringing the '524 patent.

FOURTH COUNT

(Infringement of the '290 Patent by Sandoz)

47. Cornerstone repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

48. Upon information and belief, Sandoz seeks FDA approval for the manufacture, marketing, sale, and/or distribution of Sandoz's Generic Products.

49. Upon information and belief, Sandoz seeks FDA approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Generic Products before the expiration of the '290 patent.

50. Upon information and belief, Sandoz will commercially manufacture, sell, offer for sale, and/or import Sandoz's Generic Products upon, or in anticipation of, FDA approval and before expiration of the '290 patent.

51. Upon information and belief, the submission and/or filing of ANDA No. 203978 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Sandoz's Generic Products before the expiration of the '290 patent is an act of direct and/or indirect infringement (including induced and/or contributory infringement) by Sandoz of one or more claims of the '290 patent under 35 U.S.C. § 271(e)(2)(A).

52. Upon information and belief, Sandoz's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Generic Products that are the subject of ANDA No. 203978 before the expiration of the '290 patent will infringe one or more claims of the '290 patent under 35 U.S.C. § 271 *et seq.*, including § 271(a), § 271(b), § 271(c) and/or § 271(g).

53. Upon information and belief, Sandoz was and is aware of the existence of the '290 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '290 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

54. Sandoz's infringement of the '290 patent has caused and will cause Cornerstone to suffer irreparable harm. Sandoz's infringement will continue unless enjoined by the Court. Cornerstone has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Sandoz from infringing the '290 patent.

PRAYER FOR RELIEF

WHEREFORE, Cornerstone respectfully requests the following relief:

i. A judgment declaring that the '102 patent is valid and enforceable;

ii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 203978 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Sandoz's Generic Products was an act of infringement of the '102 patent by Sandoz;

iii. A judgment declaring that, pursuant to 35 U.S.C. § 271 *et seq.*, including § 271(e)(2)(A), § 271(a), § 271(b) and/or § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sandoz's Generic Products prior to the expiration of the '102 patent, including any regulatory extensions, will constitute an act of infringement by Sandoz;

iv. An order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and/or 283, the effective date of any approval of Sandoz's Generic Products shall be no earlier than the date on which the '102 patent expires including any regulatory extensions;

v. A judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and/or 283, preliminarily and permanently enjoining Sandoz 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, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 203978 until the expiration of the '102 patent including any regulatory extensions;

vi. A judgment awarding Cornerstone damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and/or 284, if Sandoz commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 203978 that infringes the '102 patent;

vii. A judgment declaring that infringement of the ’102 patent is willful if Sandoz commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 203978 that infringes the ’102 patent;

viii. A judgment declaring that the ’291 patent is valid and enforceable;

ix. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 203978 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Sandoz’s Generic Products was an act of infringement of the ’291 patent by Sandoz;

x. A judgment declaring that, pursuant to 35 U.S.C. § 271 *et seq.*, including § 271(e)(2)(A), § 271(b) and/or § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Sandoz’s Generic Products prior to the expiration of the ’291 patent, including any regulatory extensions, will constitute an act of infringement by Sandoz;

xi. An order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and/or 283, the effective date of any approval of Sandoz’s Generic Products shall be no earlier than the date on which the ’291 patent expires including any regulatory extensions;

xii. A judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and/or 283, preliminarily and permanently enjoining Sandoz 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, sale, offer for sale, and/or importation into the United States of the product that is the subject of ANDA No. 203978 until the expiration of the ’291 patent including any regulatory extensions;

xiii. A judgment awarding Cornerstone damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and/or 284, if Sandoz commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 203978 that infringes the '291 patent;

xiv. A judgment declaring that infringement of the '291 patent is willful if Sandoz commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 203978 that infringes the '291 patent;

xv. A judgment declaring that the '524 patent is valid and enforceable;

xvi. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 203978 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Sandoz's Generic Products was an act of infringement of the '524 patent by Sandoz;

xvii. A judgment declaring that, pursuant to 35 U.S.C. § 271 *et seq.*, including § 271(e)(2)(A), § 271(b) and/or § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Sandoz's Generic Products prior to the expiration of the '524 patent, including any regulatory extensions, will constitute an act of infringement by Sandoz;

xviii. An order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and/or 283, the effective date of any approval of Sandoz's Generic Products shall be no earlier than the date on which the '524 patent expires including any regulatory extensions;

xix. A judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and/or 283, preliminarily and permanently enjoining Sandoz 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, sale, offer for sale, and/or importation into the United States of the product that is the subject of ANDA No. 203978 until the expiration of the '524 patent including any regulatory extensions;

xx. A judgment awarding Cornerstone damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and/or 284, if Sandoz commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 203978 that infringes the '524 patent;

xxi. A judgment declaring that infringement of the '524 patent is willful if Sandoz commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 203978 that infringes the '524 patent;

xxii. A judgment declaring that the '290 patent is valid and enforceable;

xxiii. A judgment declaring that, pursuant to 35 U.S.C. § 271 *et seq.*, including § 271(e)(2)(A), § 271(a), § 271(b), § 271(c) and/or § 271(g), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Sandoz's Generic Products prior to the expiration of the '290 patent, including any regulatory extensions, will constitute an act of infringement by Sandoz;

xxiv. An order that, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281 and/or 283, the effective date of any approval of Sandoz's Generic Products shall be no earlier than the date on which the '290 patent expires including any regulatory extensions;

xxv. A judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281 and/or 283, preliminarily and permanently enjoining Sandoz 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, sale, offer for sale, and/or importation into the

United States of the product that is the subject of ANDA No. 203978 until the expiration of the '290 patent including any regulatory extensions;

xxvi. A judgment awarding Cornerstone damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and/or 284, if Sandoz commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 203978 that infringes the '290 patent;

xxvii. A judgment declaring that infringement of the '290 patent is willful if Sandoz commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 203978 that infringes the '290 patent;

xxviii. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Cornerstone its attorneys' fees and costs;

xxix. Such other and further relief as this Court may deem just and proper.

Of Counsel:

Edgar H. Haug
Jason A. Lief
Angus Chen
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
Telephone No.: (212) 588-0800
Facsimile No.: (212) 599-0500

Dated: September 25, 2013

Respectfully submitted,

By: s/ Michael R. Griffinger

Michael R. Griffinger
Lisa H. Wang
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Telephone No.: (973) 596-4500
Facsimile No.: (973) 596-0545

Attorneys for Plaintiffs
Cornerstone Therapeutics Inc., Cornerstone BioPharma, Inc., and EKR Therapeutics, LLC