

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CORNERSTONE THERAPEUTICS INC.,)	
CORNERSTONE BIOPHARMA, INC., and)	
EKR THERAPEUTICS, LLC,)	
)	
Plaintiffs,)	C.A. No. 13-1275-GMS
v.)	
)	
EXELA PHARMA SCIENCES, LLC,)	
EXELA PHARMSCI, INC., and EXELA)	
HOLDINGS, INC.,)	
)	
Defendants.)	

FIRST AMENDED COMPLAINT

Plaintiffs Cornerstone Therapeutics Inc., Cornerstone BioPharma, Inc., and EKR Therapeutics, LLC (“EKR”) (collectively “Cornerstone”), by its undersigned attorneys, for its Complaint against defendants Exela Pharma Sciences, LLC, Exela PharmSci, Inc., and Exela Holdings, Inc. (collectively “Exela”) 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, defendant Exela Pharma Sciences, LLC (“Exela Pharma”), is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 1325 William White Place NE, Lenoir, North Carolina 28645.

6. Upon information and belief, defendant Exela Pharma is a wholly-owned subsidiary of Exela PharmSci, Inc. (“Exela PharmSci”).

7. Upon information and belief, defendant Exela PharmSci is an entity organized and existing under the laws of the Commonwealth of Virginia, with a principal place of business at 19978 Palmer Classic Parkway, Ashburn, Virginia 20147.

8. Upon information and belief, defendant Exela Holdings, Inc. (“Exela Holdings”) is the parent company of defendant Exela PharmSci.

9. Upon information and belief, defendant Exela Holdings is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 19978 Palmer Classic Parkway, Ashburn, Virginia 20147.

10. Upon information and belief, defendant Exela Pharma and defendant Exela PharmSci act at the direction of, under the control of, and for the direct benefit of Exela Holdings and are controlled and/or dominated by Exela Holdings.

11. Upon information and belief, defendant Exela Pharma develops and manufactures generic drugs, including injectable drug products, for sale and use throughout the United States.

12. Upon information and belief, defendant Exela PharmSci develops generic pharmaceutical products for distribution and sale in the United States. Exela PharmSci admitted that it develops generic pharmaceutical products for distribution and sale in the United States in *Exela PharmSci, Inc. v. Allergan, Inc.*, C.A. No. 1:07-cv-00338-TSE-TCB (E.D.Va.).

JURISDICTION AND VENUE

13. 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.

14. This Court has personal jurisdiction over Exela Pharma by virtue of, *inter alia*, its incorporation and residence in the State of Delaware.

15. This Court has personal jurisdiction over Exela PharmSci because, *inter alia*: (i) together with Exela Pharma and Exela Holdings, Exela PharmSci has committed, induced, or contributed to acts of patent infringement that have and will harm two Delaware corporations—Cornerstone Therapeutics Inc. and EKR; (ii) Exela PharmSci is doing business in Delaware and maintains continuous and systematic contacts with this judicial district, including through its wholly-owned subsidiary Exela Pharma; (iii) Exela PharmSci has submitted to the jurisdiction of this Court in at least one prior Delaware action (*Cadence Pharmaceuticals, Inc., et al. v. Exela PharmSci, Inc., et al.*, 1:11-cv-00733-LPS); and (iv) Exela PharmSci has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior

Delaware action (*Cadence Pharmaceuticals, Inc., et al. v. Exela PharmSci, Inc., et al.*, 1:11-cv-00733-LPS).

16. This Court has personal jurisdiction over Exela Holdings by virtue of, *inter alia*, its incorporation and residence in the State of Delaware.

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

FACTS AS TO ALL COUNTS

18. 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. Cardene[®] I.V. Premixed Injection is the trade name for nicardipine hydrochloride premixed injection, 0.1 mg/mL in 4.8% dextrose, 0.1 mg/mL in 0.86% sodium chloride, 0.2 mg/mL in 5% dextrose, and 0.2 mg/mL in 0.83% sodium chloride for intravenous administration and is indicated for the short-term treatment of hypertension when oral therapy is not feasible or not desirable.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. Upon information and belief, Exela Pharma, Exela PharmSci, and Exela Holdings worked in concert to prepare, submit, and file Supplemental New Drug Application No. 22276 ("Exela's sNDA") to the FDA under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(b)(2)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic nicardipine hydrochloride ready-to-use ("RTU") injectable formulations containing 0.1 mg/mL and 0.2 mg/mL nicardipine hydrochloride in 0.9% sodium chloride ("Exela's Products").

26. Exela sent a letter to Cornerstone Therapeutics Inc./EKR Therapeutics purporting to provide notification that the Exela sNDA contains certifications under 21 U.S.C. § 355(b)(2)(A)(iv) (a "paragraph IV certification") with regard to the '102 and '291 patents ("Exela's '102 and '291 Patent Notice Letter").

27. Exela sent a letter to Cornerstone Therapeutics Inc./EKR Therapeutics purporting to provide notification that the Exela sNDA contains a paragraph IV certification with regard to the '524 patent ("Exela's '524 Patent Notice Letter").

FIRST COUNT

(Infringement of the '102 Patent by Exela)

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

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

30. Upon information and belief, Exela 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 Exela's Products before the expiration of the '102 patent.

31. Upon information and belief, Exela will commercially manufacture, sell, offer for sale, and/or import Exela's Products upon, or in anticipation of, FDA approval.

32. Upon information and belief, as of the date of Exela's '102 and '291 Patent Notice Letter, Exela was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c)(6).

33. The inclusion of a paragraph IV certification to the '102 patent in sNDA No. 22276 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Exela's Products before the expiration of the '102 patent is an act of direct and/or indirect infringement (including induced and/or contributory infringement) by Exela of one or more claims of the '102 patent under 35 U.S.C. § 271(e)(2)(A).

34. Upon information and belief, Exela's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Exela's Products that are the subject of sNDA

No. 22276 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).

35. Upon information and belief, Exela 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.

36. Exela's infringement of the '102 patent has caused and will cause Cornerstone to suffer irreparable harm. Exela'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 Exela from infringing the '102 patent.

SECOND COUNT

(Infringement of the '291 Patent by Exela)

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

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

39. Upon information and belief, Exela 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 Exela's Products before the expiration of the '291 patent.

40. Upon information and belief, Exela will commercially manufacture, sell, offer for sale, and/or import Exela's Products upon, or in anticipation of, FDA approval.

41. Upon information and belief, as of the date of Exela's '102 and '291 Patent Notice Letter, Exela was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c)(6).

42. The inclusion of a paragraph IV certification to the '291 patent in sNDA No. 22276 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Exela's Products before the expiration of the '291 patent is an act of direct and/or indirect infringement (including induced and/or contributory infringement) by Exela of one or more claims of the '291 patent under 35 U.S.C. § 271(e)(2)(A).

43. Upon information and belief, Exela's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Exela's Products that are the subject of sNDA No. 22276 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).

44. Upon information and belief, Exela 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.

45. Exela's infringement of the '291 patent has caused and will cause Cornerstone to suffer irreparable harm. Exela'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 Exela from infringing the '291 patent.

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

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

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

48. Upon information and belief, Exela 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 Exela's Products before the expiration of the '524 patent.

49. Upon information and belief, Exela will commercially manufacture, sell, offer for sale, and/or import Exela's Products upon, or in anticipation of, FDA approval.

50. Upon information and belief, as of the date of Exela's '524 Patent Notice Letter, Exela was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c)(6).

51. The inclusion of a paragraph IV certification to the '524 patent in sNDA No. 22276 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Exela's Products before the expiration of the '524 patent is an act of direct and/or indirect infringement (including induced and/or contributory infringement) by Exela of one or more claims of the '524 patent under 35 U.S.C. § 271(e)(2)(A).

52. Upon information and belief, Exela's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Exela's Products that are the subject of sNDA No. 22276 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).

53. Upon information and belief, Exela 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.

54. Exela's infringement of the '524 patent has caused and will cause Cornerstone to suffer irreparable harm. Exela'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 Exela from infringing the '524 patent.

FOURTH COUNT

(Infringement of the '290 Patent by Exela)

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

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

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

58. Upon information and belief, Exela will commercially manufacture, sell, offer for sale, and/or import Exela's Products upon, or in anticipation of, FDA approval.

59. Upon information and belief, the submission and/or filing of sNDA No. 22276 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Exela's Products before the expiration of the '290 patent is an act of direct and/or indirect infringement (including induced and/or contributory infringement) by Exela of one or more claims of the '290 patent under 35 U.S.C. § 271(e)(2)(A).

60. Upon information and belief, Exela's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Exela's Products that are the subject of sNDA No. 22276 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).

61. Upon information and belief, Exela 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.

62. Exela's infringement of the '290 patent has caused and will cause Cornerstone to suffer irreparable harm. Exela'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 Exela 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 sNDA No. 22276 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 Exela's Products was an act of infringement of the '102 patent by Exela;
- 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 Exela's Products prior to the expiration of the '102 patent, including any regulatory extensions, will constitute an act of infringement by Exela;
- 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 Exela's 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 Defendants and their 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 sNDA No. 22276 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 Exela commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of sNDA No. 22276 that infringes the '102 patent;

vii. A judgment declaring that infringement of the '102 patent is willful if Exela commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of sNDA No. 22276 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 sNDA No. 22276 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 Exela's Products was an act of infringement of the '291 patent by Exela;

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 Exela's Products prior to the expiration of the '291 patent, including any regulatory extensions, will constitute an act of infringement by Exela;

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 Exela's 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 Defendants and their 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 sNDA No. 22276 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 Exela commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of sNDA No. 22276 that infringes the '291 patent;

xiv. A judgment declaring that infringement of the '291 patent is willful if Exela commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of sNDA No. 22276 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 sNDA No. 22276 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 Exela's Products was an act of infringement of the '524 patent by Exela;

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 Exela's Products prior to the expiration of the '524 patent, including any regulatory extensions, will constitute an act of infringement by Exela;

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 Exela's 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 Defendants and their 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 sNDA No. 22276 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 Exela commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of sNDA No. 22276 that infringes the '524 patent;

xxi. A judgment declaring that infringement of the '524 patent is willful if Exela commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of sNDA No. 22276 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 Exela's Products prior to the expiration of the '290 patent, including any regulatory extensions, will constitute an act of infringement by Exela;

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 Exela's 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 Defendants and their 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 sNDA No. 22276 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 Exela commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of sNDA No. 22276 that infringes the '290 patent;

xxvii. A judgment declaring that infringement of the '290 patent is willful if Exela commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of sNDA No. 22276 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.

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Dated: August 19, 2013

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