IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA

EXELA PHARMA SCIENCES, LLC, Plaintiffs, v. CORNERSTONE THERAPEUTICS INC., CORNERSTONE BIOPHARMA, INC., and EKR THERAPEUTICS, LLC Defendants.	)	Civil Action No. 5:13-cv-111

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Exela Pharma Sciences, LLC ("Exela"), for its Declaratory Judgment Complaint against Defendants EKR Therapeutics, LLC ("EKR"), Cornerstone Therapeutics Inc. ("CTI"), Cornerstone BioPharma, Inc. ("CBI") (collectively "Defendants") states and alleges as follows:

NATURE OF THE ACTION

1. This is a declaratory judgment action for noninfringement and invalidity arising under the patent laws of the United States, Title 35, United States Code, and the federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This action involves United States Patent No. 7,659,290 ("the '290 patent") (attached as Exhibit A hereto).

THE PARTIES

2. Plaintiff Exela Pharma Sciences, LLC ("Exela") is an entity organized under the laws of the State of Delaware and has a principal place of business at 1325 William White Place NE, Lenoir, North Carolina 28645.

3. On information and belief, Defendant EKR is organized under the laws of the State of Delaware and has a principal place of business at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518.

4. On information and belief, Defendant CTI is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518.

5. On information and belief, Defendant CBI is a corporation organized and existing under the laws of the State of Nevada and has a principal place of business at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518.

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over EKR, CTI and CBI because, among other things:

(a) each maintains its principal place of business in North Carolina;

(b) on information and belief, each does business in North Carolina, including conducting sales activities and selling products into this District; and

(c) on information and belief, each has continuous and systematic contacts with North Carolina, including conducting sales activities and selling products into this District.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because, among other things, a substantial part of the events giving rise to the claim occurred in this judicial district.

FACTS AS TO ALL COUNTS

10. On information and belief, EKR is the current owner of New Drug Application No. 19-734 ("EKR's NDA"). EKR's NDA has been approved by the FDA for the manufacture and sale of Cardene® I.V. Premixed Injection ("Cardene®"). Cardene® is indicated for the short-term treatment of hypertension when oral therapy is not feasible or not desirable. Cardene® is the trade name for nicardipine hydrochloride premixed injection.

11. In connection with EKR's NDA, Defendants identified United States Patent No. 7,612,102 ("the '102 patent") and United States Patent No. 7,659,291 ("the '291 patent") as applicable to Cardene®. Accordingly, the '102 and '291 patents are listed for Cardene® in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, which is commonly known as the Orange Book.

12. The '102 patent is generally directed to a nicardipine hydrochloride premixed injection formulation and the '291 patent is generally directed to a method of treatment using a nicardipine hydrochloride premixed injection formulation.

13. On information and belief, EKR is also the assignee and owner of the '290 patent. The '290 patent is entitled "Methods of Preparing Pre-Mixed, Ready-to-Use Pharmaceutical Compositions." The '290 patent generally relates to a process for making nicardipine hydrochloride premixed injection. The '290 patent is not listed in the Orange Book because patents covering processes for making a drug are not eligible for inclusion in the Orange Book.

14. Exela submitted Supplemental New Drug Application No. 22276 ("Exela's sNDA") to the FDA under 21 U.S.C. § 355(b)(2). Exela's sNDA seeks approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of a generic nicardipine

hydrochloride injectable formulation ("Exela's Product") before the expiration of the patents listed in the Orange Book for Cardene®.

15. In connection with its sNDA and pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), Exela filed paragraph IV certifications to the '102 and '291 patents, certifying that the '102 and '291 patents are invalid, unenforceable and/or will not be infringed by Exela's Product.

16. On June 10, 2013, Exela sent a letter to CTI and EKR pursuant 21 U.S.C. § 355(b)(3)(B)(i) notifying them that Exela submitted sNDA No. 22276 to the FDA with paragraph IV certifications to the '102 and '291 patents.

17. On July 24, 2013, Defendants brought an action against Exela in the United States District Court for the District of Delaware alleging infringement the '102 and '291 patents under 35 U.S.C. § 271(a), (b), (c) and (e), *Cornerstone Therapeutics, Inc. et al. v. Exela Pharma Sciences, LLC et al*., Case No. 13-cv-01275 ("Delaware Action"), based on Exela's sNDA. Defendants did not assert infringement of the '290 patent in the Delaware Action.

18. The '291 patent and the '290 patent issued from divisional applications of the '102 patent. The three patents share a common specification and claim priority to the same provisional application, U.S. Provisional Application Serial Number 60/793,074, filed on April 18, 2006.

19. On August 9, 2013, Exela is filing a motion to transfer the Delaware Action to this district pursuant to 28 U.S.C. § 1404(a).

20. Upon a final judgment that the '102 and '291 patents are invalid, unenforceable and/or not infringed by Exela's Product, the FDA can approve Exela's sNDA. Once Exela's sNDA is approved, there are no regulatory barriers preventing Exela from commercially marketing the Exela Product.

21. However, unless Exela obtains a similar judgment of invalidity, unenforceability and/or noninfringement with respect to the '290 patent, Exela faces infringement liability from the '290 patent upon marketing the Exela Product. Only a declaratory judgment of invalidity, unenforceability and/or noninfringement from this Court will provide Exela with certainty with respect to the '290 patent and allow Exela to compete in the nicardipine market free from potential infringement liability.

COUNT I

Declaratory Judgment of Noninfringement of the '290 Patent

22. Exela realleges and incorporates by reference the allegations of Paragraphs 1-21.

23. This Declaratory Judgment Action arises under the Patent Laws of the United States, 35 U.S.C. § 1, et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '290 patent will not be infringed by the manufacture, use or sale of Exela's Product.

24. A present, genuine and justiciable controversy exists between Defendants and Exela regarding, among other things, the issue of whether the manufacture, use, or sale of Exela's Product would infringe one or more claims of the '290 patent.

25. The manufacture, use or sale of Exela's Product would not infringe the claims the '290 patent.

26. Exela is entitled to a declaration that the manufacture, use or sale of the Exela Product would not infringe the claims of the '290 patent.

COUNT II

Declaratory Judgment of Invalidity of the '290 Patent

27. Exela realleges and incorporates by reference the allegations of Paragraphs 1-26.

28. This Declaratory Judgment Action arises under the Patent Laws of the United States, 35 U.S.C. § 1, et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that one or more claims of the '290 patent are invalid.

29. A present, genuine and justiciable controversy exists between Defendants and Exela regarding, among other things, the issue of whether one or more claims of the '290 patent are invalid.

30. One or more claims '290 patent are invalid at least for failure to comply with one or more statutory requirements of patentability of Title 35 of the United States Code, including at least §§ 102 and 103.

31. More specifically and without limitation, the claims of the '290 patent are invalid under §102 or § 103 in view of one or more of the following prior art references:

(a) United States Patent No. 5,164,405

(b) Linden et al., "Ready-to-Use Injection Preparation versus Conventional Reconstituted Admixtures," Pharmacoeconomics 2002, 20(8): 529-536.

(c) Schmitt et al., "Ready to Use Injectable Paracetamol: Easier, Safer, Lowering Workload and Costs," EJHP 2003, 6: 96-102;

(d) Baaske et al., "Stability of nicardipine hydrochloride in intravenous solutions," Am. J. Health Syst. Pharm 1996, 53(15): 1701-1705;

(e) Martens et al., "Sorption of various drugs in polyvinyl chloride, glass and polyethylene-line infusion containers," Am. J. Pharmacy 1990, 47:369-373; and

(f) Griffin and D'Arcy, A Manual of Adverse Drug Interactions, Elsevier 1997.

PRAYER FOR RELIEF

WHEREFORE, Exela prays for judgment against Defendants as follows:

A. Declaring that the ‘290 patent is not infringed by Exela;

B. Declaring that the claims of the ‘290 patent are invalid;

C. Declaring that this case is exceptional under 35 U.S.C. § 285 and awarding Exela its attorneys’ fees, costs and expenses in this action; and

D. Awarding such other and further relief as this Court may deem just and equitable.

s/ Rodrick J. Enns
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