IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECORDATI RARE DISEASES INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
EXELA PHARMA SCIENCES, LLC, EXELA PHARMSCI, INC., and EXELA HOLDINGS, INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Recordati Rare Diseases Inc. ("Recordati") files this complaint for patent infringement against Defendants Exela Pharma Sciences, LLC, Exela PharmSci, Inc., and Exela Holdings, Inc., (collectively "Exela" or "Defendants") and, in support thereof, alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 8,415,337 ("the '337 patent"). This action relates to an Abbreviated New Drug Application ("ANDA") submitted by and/or for the benefit of Exela with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Recordati's NeoProfen® product that is sold in the United States.

PARTIES

2. Recordati is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 100 Corporate Drive, Lebanon, New Jersey, 08833. Recordati is engaged in the research, development, manufacture and sale of pharmaceutical products.

3. 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 1245 Blowing Rock Boulevard, Lenoir, North Carolina 28645.

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

5. 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.

6. Upon information and belief, defendant Exela Holdings, Inc. ("Exela Holdings") is the parent company of defendant Exela PharmSci.

7. 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 1245 Blowing Rock Boulevard, Lenoir, North Carolina 28645.

8. 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.

9. Upon information and belief, defendant Exela Pharma's primary business is marketing and selling pharmaceutical products, including generic versions of brand name prescription drug products, throughout the United States, including Delaware.

JURISDICTION AND VENUE

10. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

11. This Court has personal jurisdiction over Exela Pharma because, among other reasons, it is a Delaware corporation, has extensive contacts with the State of Delaware, and regularly does business in this district.

12. This Court has personal jurisdiction over Exela Holdings because, among other reasons, it is a Delaware corporation, has extensive contacts with the State of Delaware, and regularly does business in this district.

13. This Court has personal jurisdiction over Exela PharmSci because, among other reasons, it has extensive contacts with the State of Delaware, and regularly does business in this district. Together with Exela Pharma Sciences and Exela Holdings, Exela PharmSci has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Recordati, a Delaware corporation.

14. Upon information and belief, Exela Pharma, Exela PharmSci, and Exela Holdings have all previously consented to the personal jurisdiction of this Court and availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior Delaware action. *See Cadence Pharmaceuticals, Inc. v. Paddock Laboratories, Inc.*, Case No. 1:11-cv-00733, Answer, Defenses and Counterclaims of Defendants Exela Pharma Sciences, LLC, Exela PharmSci, Inc. and Exela Holdings, Inc. to Complaint (D.I. 21) at ¶¶ 19-24 and p. 29 (Oct. 17, 2011).

15. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

FACTUAL BACKGROUND

Recordati's NeoProfen® Product

16. NeoProfen® is an intravenous medication indicated to close a clinically significant patent ductus arteriosus (PDA) in premature infants. An NDA seeking approval to market NeoProfen® (NDA 21-903) was filed by Farmacon-IL, LLC on August 30, 2005 and approved by the FDA on April 13, 2006. Recordati is the current holder of NDA 21-903.

The '337 Patent

17. The '337 patent, entitled "Ibuprofen compositions and methods of making same," was duly and legally issued on April 9, 2013 to inventor Aravind Krishna. A true and correct copy of the '337 patent is attached hereto as Exhibit A. The '337 patent claims an improved ibuprofen lysine pharmaceutical composition and a process for preparing the same. The claims of the '337 patent are valid and enforceable. Recordati is the assignee of the '337 patent. The '337 patent expires on March 2, 2032.

18. The '337 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") with respect to NeoProfen®, 20 mg base/2ml (eq 10 mg base/ml).

Exela's ANDA Filings and Notice Letter

19. On information and belief, Exela submitted ANDA No. 20-2402 ("Exela's ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j). Exela is seeking approval from the FDA to market and sell ibuprofen lysine intravenous injection, 20 mg/ml (10 mg base/ml) ("Exela's generic ibuprofen lysine product"), as a generic version of Recordati's NeoProfen® product prior to the expiration of the '337 patent.

20. On or about June 5, 2014, Exela sent a "Notice of Paragraph IV Certification" letter to Recordati, the patent owner and holder of the NDA, notifying Recordati that it had submitted ANDA No. 20-2402 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of Exela's ibuprofen lysine product, a generic version of NeoProfen® 20 mg base/2ml (eq 10 mg base/ml), prior to the expiration of the '337 patent ("Exela's Notice Letter"). Recordati received Exela's Notice Letter on June 6, 2014.

21. Exela made, and included in its ANDA No. 20-2402, "Paragraph IV" certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '337 patent is invalid and/or will not be infringed by the commercial manufacture, use, or sale of Exela's generic ibuprofen lysine product.

22. Exela's Notice Letter purported to include an "Offer of Confidential Access" to Recordati of ANDA No. 20-2402. Under the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355 (c)(3)(D)(i)(III), restrictions to an Offer of Confidential Access must be consistent with protective orders entered in litigation for the purpose of protecting trade secrets and other confidential business information. Exela's Offer of Confidential Access restricted disclosure to outside counsel only and required that such counsel not be involved in patent prosecution, reexamination, reissue, or related proceedings without limitation as to time.

23. The proposed terms of Exela's Offer of Confidential Access were unreasonable and went beyond the scope of protecting trade secrets and other confidential business information. For example, Exela's Offer of Confidential Access did not allow Recordati's management—who do not engage in patent prosecution matters relating to NeoProfen® and who are crucial decision makers in the process of filing an infringement action—access to the necessary information with which to assess Exela's proposed generic copy of NeoProfen®.

Exela's proposed restrictions to other work performed by those having access to the ANDA were not directed and limited to the purpose of protecting trade secrets and other confidential business information. Therefore, Exela's Offer of Confidential Access was not reasonable in terms.

24. Exela's and Recordati's outside counsel diligently engaged in a series of discussions to attempt to reach agreement on the terms and conditions of the Offer of Confidential Access. The parties, however, were unable to come to an agreement. As a result, no outside counsel or member of Recordati's management has been able to review information concerning Exela's generic ibuprofen lysine product beyond that which is set forth in Exela's Paragraph IV Notice. Consequently, through no fault of its own, Recordati has not been able to analyze the basis, if any, for Exela's assertion that its proposed generic product as described in ANDA No. 20-2402 would not infringe the '337 Patent.

25. Exela's submission of ANDA No. 20-2402 to the FDA constitutes infringement of the '337 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale, and/or import of Exela's generic ibuprofen lysine product into the United States would infringe the '337 patent under 35 U.S.C. § 271(a)-(c).

26. This suit is being filed within 45 days of Recordati's receipt of Exela's Paragraph IV Notice Letter.

COUNT I: INFRINGEMENT OF THE '337 PATENT

27. Recordati incorporates each of the preceding paragraphs as if fully set forth herein.

28. Exela's submission of ANDA No. 20-2402 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Exela's generic ibuprofen lysine product

prior to the expiration of the ’337 patent constitutes infringement of one or more of the valid claims of the ’337 patent under 35 U.S.C. § 271(e)(2)(A).

29. Exela’s commercial manufacture, use, offer to sell, sale, or importation of its generic ibuprofen lysine product prior to the expiration of the ’337 patent, or its inducement of or contribution to such conduct, would further infringe the ’337 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

30. Exela’s filing of its ANDA, and its intention to engage in the commercial manufacture, use, offer to sell, sale, or importation of Exela’s generic ibuprofen lysine product upon receiving FDA approval, create an actual case or controversy with respect to infringement of the ’337 patent.

31. Upon FDA approval of Exela’s ANDA, Exela will infringe the ’337 patent by making, using, offering to sell, selling, or importing its generic ibuprofen lysine product in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

32. Unless Exela is enjoined from infringing the ’337 patent and/or actively inducing the infringement of the ’337 patent, Recordati will suffer irreparable injury. Recordati has no adequate remedy at law.

COUNT II: DECLARATORY JUDGMENT AS TO THE ’337 PATENT

33. Recordati incorporates each of the preceding paragraphs as if fully set forth herein.

34. Upon information and belief, Exela has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, sell, offer to sell,

and/or import Exela's generic ibuprofen lysine product into the United States prior to expiration of the '337 patent.

35. Upon information and belief, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), Exela's commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Exela's generic ibuprofen lysine product will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '337 patent.

36. Upon information and belief, Exela maintains, and Recordati denies, that the '337 patent is invalid or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Exela's generic ibuprofen lysine product. Accordingly, there is a real, substantial, and continuing justiciable case or controversy between Recordati and Exela regarding whether Exela's commercial manufacture, use, sale, offer for sale, or importation into the United States of Exela's generic ibuprofen lysine product according to ANDA No. 20-2402 will infringe one or more claims of the '337 patent. Recordati is thus entitled to a declaration that Exela's commercial manufacture, use, sale, offer for sale, and importation into the United States of Exela's generic ibuprofen lysine product according to ANDA No. 20-2402 will infringe one or more claims of the '337 patent.

PRAYER FOR RELIEF

WHEREFORE, Recordati requests entry of judgment in its favor and against Exela and prays that the Court:

A. Enter a declaratory judgment that: (1) a claim or claims of the '337 patent is infringed by the manufacture, use, sale, offer for sale or importation of Exela's generic ibuprofen lysine product; (2) that Exela's submission of Exela's ANDA No. 20-2402 is an act of

infringement of the ’337 patent; (3) that Exela’s making, using, offering to sell, selling, or importing Exela’s generic ibuprofen lysine product, and its inducement of such conduct by others, will infringe the ’337 patent;

B. Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Exela’s ANDA No. 20-2402, or any product or compound that infringes the ’337 patent, shall be a date which is not earlier than the expiration of the ’337 patent and any additional period of exclusivity to which Recordati is or becomes entitled;

C. Permanently enjoin Exela and its affiliates and subsidiaries, and each of its officers, agents, servants, and employees, from making, have made, using, offering to sell, selling, marketing, distributing, or importing Exela’s generic ibuprofen lysine product, or any product or compound that infringes the ’337 patent, and from inducing such conduct by others, until after expiration of the ’337 patent and any additional period of exclusivity to which Recordati is or may become entitled;

D. Award reasonable attorney fees, filing fees, and costs of suit incurred by Recordati in this action; and

E. Award such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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