UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA

THE MEDICINES COMPANY, Plaintiff, v. EXELA PHARMA SCIENCES, LLC, EXELA PHARMSCI, INC., and EXELA HOLDINGS, INC., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiff The Medicines Company, through its attorneys, files this Complaint against defendants Exela Pharma Servies, LLC, Exela Pharmsci, Inc. and Exela Holdings, Inc., (collectively, "Exela" or "Defendants"), and 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 Nos. 7,582,727 ("the '727 patent") (attached as Ex. A) and 7,598,343 ("the '343 patent") (attached as Ex. B).

THE PARTIES

2. Plaintiff The Medicines Company is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 8 Sylvan Way, Parsippany, New Jersey 07054.

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 1325 William White Place NE, 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 19978 Palmer Classic Parkway, Ashburn, Virginia 20147.

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 develops and manufactures generic drugs, including injectable drug products, for sale and use throughout the United States.

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over Exela.

12. Upon information and belief, Exela has a continuous and systematic business presence within this judicial district and substantial events giving rise to acts of infringement have occurred and/or will occur within this judicial district, including but not limited to the preparation of and/or contribution to the submission and/or filing of ANDA No. 206230 under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to market before the expiration of the '727 and '343 patents a bivalirudin drug product that infringes the '727 and/or '343 patents.

13. Upon information and belief, Exela's business includes developing, manufacturing, distributing, and/or selling generic drug products for sale and use throughout the United States, including for sale and use within this judicial district.

14. Upon information and belief, Exela has derived revenue from generic drug products distributed and/or sold in the State of North Carolina.

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

16. Upon information and belief, Exela (i) operates a permanent business location within this judicial district and can, therefore, be found in this judicial district and is a resident of this judicial district, and/or (ii) on information and belief, substantial events giving rise to acts of infringement have occurred and/or will occur within this judicial district, including but not limited to the preparation of and/or contribution to the submission and/or filing of ANDA No. 206230 under § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) seeking approval to market before the expiration of the '727 and '343 patents a bivalirudin drug product that infringes the '727 and/or '343 patents.

FACTS AS TO ALL COUNTS

17. The Medicines Company is the owner of New Drug Application ("NDA")

N020873, which was approved by the FDA for the manufacture and sale of Angiomax®. Angiomax® is the trade name for bivalirudin, 250 mg/vial, for intravenous injection, which is indicated for, *inter alia*, use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty.

18. The '727 patent, entitled "Pharmaceutical formulations of bivalirudin and processes of making the same," was duly and legally issued on September 1, 2009, to The Medicines Company upon assignment from Gopal Krishna and Gary Musso. The '727 patent is generally directed to bivalirudin compositions.

19. The '343 patent, entitled "Pharmaceutical formulations of bivalirudin and processes of making the same," was duly and legally issued on October 6, 2009, to The Medicines Company upon assignment from Gopal Krishna and Gary Musso. The '343 patent is generally directed to bivalirudin compositions.

20. Pursuant to 21 U.S.C. § 355(b)(1), the '727 and '343 patents are listed in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering The Medicines Company's Angiomax® product.

21. On information and belief, Exela prepared, submitted, and/or filed Exela's ANDA to the FDA under § 505(j) of the FDCA seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic bivalirudin, 250 mg/vial, for intravenous injection ("Exela's Proposed Product") before the expiration of the '727 and '343 patents.

22. On information and belief, Exela sent The Medicines Company a purported notice of paragraph IV certifications for the '727 and '343 patents pursuant to §

505(j)(2)(B)(ii) of the FDCA regarding Exela's Proposed Product ("Exela's Notice Letter").

23. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder and the holder of the NDA for the drug that is claimed by the patent(s) or a use of which is claimed by the patent(s) of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

FIRST COUNT

(Infringement of the '727 Patent by Exela – ANDA No. 206230)

24. The Medicines Company repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

25. On information and belief, Exela seeks FDA-approval for the manufacture, use, sale, offer for sale and/or importation of Exela's Proposed Product that is the subject of ANDA No. 206230.

26. On information and belief, Exela's ANDA includes a paragraph IV certification to the '727 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Exela's Proposed Product before the expiration of the '727 patent.

27. On information and belief, Exela will commercially manufacture, sell,

offer for sale, and/or import Exela's Proposed Product upon FDA-approval, including within this judicial district.

28. On information and belief, as of the date of Exela's Notice Letter for Exela's ANDA, Exela 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).

29. The inclusion of a paragraph IV certification to the '727 patent in Exela's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Exela's Proposed Product before the expiration of the '727 patent is an act of infringement by Exela of one or more claims of the '727 patent directly and/or indirectly in a cooperative venture under 35 U.S.C. § 271(e)(2)(A).

30. On information and belief, Exela's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Exela's Proposed Product will infringe one or more claims of the '727 patent directly under 35 U.S.C. § 271(a) and/or indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

31. On information and belief, Exela is aware of the existence of the '727 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '727 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

32. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless Exela is preliminarily and permanently enjoined by this Court.

SECOND COUNT

(Infringement of the '343 Patent by Exela – ANDA No. 206230)

33. The Medicines Company repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

34. On information and belief, Exela seeks FDA-approval for the manufacture, use, sale, offer for sale and/or importation of Exela's Proposed Product that is the subject of ANDA No. 206230.

35. On information and belief, Exela's ANDA includes a paragraph IV certification to the '343 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Exela's Proposed Product before the expiration of the '343 patent.

36. On information and belief, Exela will commercially manufacture, sell, offer for sale, and/or import Exela's Proposed Product upon FDA-approval, including within this judicial district.

37. On information and belief, as of the date of Exela's Notice Letter for Exela's ANDA, Exela 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).

38. The inclusion of a paragraph IV certification to the '343 patent in Exela's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Exela's Proposed Product before the expiration of the '343 patent is an act of infringement by Exela of one or more claims of the '343 patent directly and/or indirectly in a cooperative venture under 35 U.S.C. § 271(e)(2)(A).

39. On information and belief, Exela's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Exela's Proposed Product will infringe one or more claims of the '343 patent directly under 35 U.S.C. § 271(a) and/or indirectly in a cooperative venture under 35 U.S.C. § 271(b) and/or (c).

40. Upon information and belief, Exela is aware of the existence of the '343

patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '343 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

41. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless Exela is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 206230 with a paragraph IV certification to obtain approval for 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. 206230 was an act of infringement of the '727 patent by Exela directly and/or by inducement;

(b) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), 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. 206230 prior to the expiration of the '727 patent, including any regulatory extensions, will constitute an act of infringement by Exela directly and/or by inducement;

(c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 206230 with a paragraph IV certification to obtain approval for 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. 206230 was an act of infringement of the '343 patent by Exela directly and/or by inducement;

(d) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. §

271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), 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. 206230 prior to the expiration of the '343 patent, including any regulatory extensions, will constitute an act of infringement by Exela directly and/or by inducement;

(e) An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 206230 shall be no earlier than the date on which the '727 and '343 patents expire, including any regulatory extensions;

(f) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Exela and all Exela 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 to sale and/or importation in the United States of the product that is the subject of ANDA No. 206230 until the expiration of the '727 and '343 patents, including any regulatory extensions;

(g) A judgment awarding The Medicines Company damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Exela receives FDA approval and commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 206230 that infringes the '727 and '343 patents;

(h) A judgment declaring that infringement of the '727 and '343 patents is willful if Exela receives FDA approval and commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 206230 that infringes the '727 and/or the '343 patents;

(i) A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding The Medicines Company its attorneys' fees and costs;

(j) Such other and further relief as this Court may deem just and proper.

This the 25th day of April, 2014.

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