IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

THE MEDICINES COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. _____
	)	
MYLAN INC., MYLAN PHARMACEUTICALS INC., and and BIONICHE PHARMA USA, LLC,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff The Medicines Company, by its undersigned attorneys, for its Complaint against defendants Mylan Inc., Mylan Pharmaceuticals Inc., and Bioniche Pharma USA, LLC (collectively "Mylan"), herein alleges 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 Exhibit A hereto) and 7,598,343 ("the '343 patent") (attached as Exhibit B hereto).

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. On information and belief, Defendant Mylan Inc. is an entity organized and existing under the laws of the State of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania, 15317.

4. On information and belief, Defendant Mylan Pharmaceuticals Inc. is an entity organized and existing under the laws of the State of West Virginia with principal place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia, 26505, and it is a wholly owned subsidiary of Defendant Mylan Inc.

5. On information and belief, Defendant Bioniche Pharma USA, LLC ("Bioniche") is an entity organized and existing under the laws of the State of Illinois with a principal place of business at 272 E. Deerpath No. 304, Lake Forest, Illinois, 60045, and is a wholly owned subsidiary of Defendant Mylan Inc.

6. On information and belief, Defendant Bioniche operates a business within this judicial district involved in the manufacturing of injectable pharmaceutical preparations.

7. On information and belief, Mylan manufactures and distributes generic drugs, including injectable drugs, for sale and use throughout the United States, including within this judicial district.

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Mylan because it (i) has a continuous and systematic business presence in Illinois, including within this judicial district and/or (ii) substantial events giving rise to acts of infringement occurred within this judicial district, including but not limited to the preparation of and/or contribution to the submission of Abbreviated New Drug Application ("ANDA") No. 202471 ("Mylan's ANDA") 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 '343 patents.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b) because Mylan (i) operates permanent business locations within this judicial district and can therefore be found in this judicial district and is a resident of this judicial district, and/or (ii) substantial events giving rise to acts of infringement occurred within this judicial district, including but not limited to the preparation of and/or contribution to Mylan's ANDA seeking approval to market before the expiration of the '727 and '343 patents a bivalirudin drug product that infringes the '727 and '343 patents.

FACTS AS TO ALL COUNTS

11. The Medicines Company is the owner of New Drug Application ("NDA") No. 20-873, 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.

12. 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.

13. 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.

14. 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.

15. Mylan prepared and submitted Mylan'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 ("Mylan's Proposed Product") before the expiration of the '727 and '343 patents.

16. On information and belief, Defendant Bioniche was involved in the development of Mylan's Proposed Product and/or the preparation and submission of Mylan's ANDA.

17. On information and belief, and as set forth in a July 2010 press release, Mylan's acquisition of Defendant Bioniche provides Mylan "an immediate entry into the North American injectables market."

18. Mylan sent The Medicines Company a notification for the '727 and '343 patents purportedly pursuant to § 505(j)(2)(B)(ii) of the FDCA regarding Mylan's Proposed Product ("Mylan's Notice Letter").

19. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder 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 Mylan – ANDA No. 202471)

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

21. Upon information and belief, Mylan seeks FDA-approval for the manufacture, use, sale, offer for sale and/or importation of Mylan's Proposed Product that is the subject of ANDA No. 202471.

22. Upon information and belief, Mylan'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 Mylan's Proposed Product before the expiration of the '727 patent.

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

24. Upon information and belief, as of the date of Mylan's Notice Letter for Mylan's ANDA, Mylan 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 '727 patent in Mylan's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Mylan's Proposed Product before the expiration of the '727 patent is an act of infringement by Mylan of one or more claims of the '727 patent under 35 U.S.C. § 271(e)(2)(A), directly and by inducement.

26. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Mylan's Proposed Product will infringe one or more claims of the '727 patent.

27. Mylan admits that Mylan's Proposed Product infringes at least claims 1-10, and 17 of the '727 patent because Mylan's Notice Letter does not include a paragraph IV certification asserting non infringement of those claims.

28. Upon information and belief, Mylan 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.

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

SECOND COUNT

(Infringement of the '343 Patent by Mylan – ANDA No. 202471)

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

31. Upon information and belief, Mylan seeks FDA-approval for the manufacture, use, sale, offer for sale and/or importation of Mylan's Proposed Product.

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

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

34. Upon information and belief, as of the date of Mylan's Notice Letter for Mylan's ANDA, Mylan 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).

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

36. Upon information and belief, Mylan's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Mylan's Proposed Product will infringe one or more claims of the '343 patent.

37. Mylan admits that Mylan's Proposed Product infringes at least claims 1-11 of the '343 patent because Mylan's Notice Letter does not include a paragraph IV certification asserting non infringement of those claims.

38. Upon information and belief, Mylan 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.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment declaring that the ’727 patent is valid and enforceable;

(b) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 202471 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. 202471 was an act of infringement of the ’727 patent by Mylan directly and by inducement;

(c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), and/or 35 U.S.C. § 271(b), 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. 202471 prior to the expiration of the ’727 patent, including any regulatory extensions, will constitute an act of infringement by Mylan directly and by inducement;

(d) A judgment declaring that the ’343 patent is valid and enforceable;

(e) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 202471 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. 202471 was an act of infringement of the ’343 patent by Mylan directly and by inducement;

(f) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), and/or 35 U.S.C. § 271(b), 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. 202471 prior to the expiration of the ’343 patent, including any regulatory extensions, will constitute an act of

infringement by Mylan directly and by inducement;

(g) 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. 202471 shall be no earlier than the date on which the ’727 and ’343 patents expire including any regulatory extensions;

(h) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Mylan 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 to sale and/or importation in the United States of the product that is the subject of ANDA No. 202471 until the expiration of the ’727 and ’343 patents including any regulatory extensions;

(i) A judgment awarding The Medicines Company damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Mylan commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202471 that infringes the ’727 and ’343 patents;

(j) A judgment declaring that infringement of the ’727 and ’343 patents is willful if Mylan commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 20-873 that infringes the ’727 and/or the ’343 patents;

(k) 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;

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

Respectfully submitted,

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