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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THE MEDICINES COMPANY, Plaintiff, v. SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMACEUTICAL INDUSTRIES INC., and CARACO PHARMACEUTICAL LABORATORIES, LTD., Defendants.	Civil Action No. _____ ***DOCUMENT ELECTRONICALLY FILED***

COMPLAINT

Plaintiff The Medicines Company, by its undersigned attorneys, for its Complaint against defendants Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries Inc., and Caraco Pharmaceutical Laboratories, Ltd. (collectively "Sun" or "Defendants"), 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 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 Sun Pharma Global FZE ("Sun FZE") is an entity organized and existing under the laws of the United Arab Emirates with a principal place of business at Executive Suite # 43, Block Y, SAIF Zone, P.O. Box # 122304, Sharjah, United Arab Emirates.

4. On information and belief, Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") is an entity organized and existing under the laws of India, with a principal place of business at Acme Plaza, Andheri-Kurla Road, Andheri (E), Mumbai, 400 059, India.

5. On information and belief, Sun FZE is an agent, affiliate or subsidiary of Sun Ltd. On information and belief, Sun Ltd. conducts business through and with Sun FZE.

6. On information and belief, Sun Pharmaceutical Industries Inc. ("Sun Inc."), is an entity organized and existing under the laws of the State of Michigan with a principal place of business at 270 Prospect Plains Road, Cranbury, NJ 08512.

7. On information and belief, Sun Inc. is registered to do business in New Jersey, including manufacturing and distribution of pharmaceutical products, with an authorized agent at 830 Bear Tavern Road, West Trenton, NJ 08628.

8. On information and belief, Sun Inc. is an agent, affiliate or subsidiary of Sun Ltd and/or Sun FZE. On information and belief, Sun Ltd. and/or Sun FZE conduct business through and with Sun Inc.

9. On information and belief, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is an entity organized and existing under the laws of the State of Michigan with a principal place of business at 1150 Elijah McCoy Drive, Detroit, MI 48202.

10. On information and belief, Caraco is registered to do business in New Jersey, including distribution of pharmaceutical products, with an authorized agent at 820 Bear Tavern Road, West Trenton, NJ 08628.

11. On information and belief, Sun Ltd. owns a majority interest in Caraco.

12. On information and belief, Caraco is an agent, affiliate or subsidiary of Sun Ltd. On information and belief, Sun Ltd. and/or Sun FZE conduct business through and with Caraco.

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

JURISDICTION AND VENUE

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

15. This Court has personal jurisdiction over Sun because Defendants (i) have a continuous and systematic business presence within 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. 203381 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.

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b) because one or more Defendants (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. 203381 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 '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, Sun prepared, submitted, and/or filed Sun'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 ("Sun's Proposed Product") before the expiration of the '727 and '343 patents.

22. On information and belief, Sun Ltd. filed and holds a drug master file ("DMF") for bivalirudin active pharmaceutical ingredient with the United States Food and Drug Administration ("FDA").

23. On information and belief, Sun 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 Sun's Proposed Product ("Sun's Notice Letter").

24. 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).

25. Sun's Notice Letter did not contain any detailed statement or factual and legal basis that Sun's Proposed Product does not infringe the '727 and '343 patents.

FIRST COUNT

(Infringement of the '727 Patent by Sun – ANDA No. 203381)

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

27. On information and belief, Sun seeks FDA-approval for the manufacture, use, sale, offer for sale and/or importation of Sun's Proposed Product that is the subject of ANDA No. 203381.

28. On information and belief, Sun'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 Sun's Proposed Product before the expiration of the '727 patent.

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

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

31. The inclusion of a paragraph IV certification to the '727 patent in Sun'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 Sun's Proposed Product before the expiration of the '727 patent is an act of infringement by Sun 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).

32. On information and belief, Sun's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sun'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).

33. Sun admits that Sun's Proposed Product infringes the '727 patent because, *inter alia*, Sun's Notice Letter does not provide a basis—let alone a detailed factual and legal basis—for non-infringement of any claim of the '727 patent.

34. On information and belief, Sun 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.

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

SECOND COUNT

(Infringement of the '343 Patent by Sun – ANDA No. 203381)

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

37. On information and belief, Sun seeks FDA-approval for the manufacture, use, sale, offer for sale and/or importation of Sun's Proposed Product.

38. On information and belief, Sun'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 Sun's Proposed Product before the expiration of the '343 patent.

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

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

41. The inclusion of a paragraph IV certification to the '343 patent in Sun'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 Sun's Proposed Product before the expiration of the '343 patent is an act of infringement by Sun 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).

42. On information and belief, Sun's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Sun'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).

43. Sun admits that Sun's Proposed Product infringes the '343 patent because, *inter alia*, Sun's Notice Letter does not provide a basis—let alone a detailed factual and legal basis—for non-infringement of any claim of the '343 patent.

44. Upon information and belief, Sun 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.

45. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless Sun 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. 203381 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. 203381 was an act of infringement of the '727 patent by Sun directly and/or by inducement;

(c) 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. 203381 prior to the expiration of the '727 patent, including any regulatory extensions, will constitute an act of infringement by Sun directly and/or 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. 203381 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. 203381 was an act of infringement of the '343 patent by Sun directly and/or by inducement;

(f) 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. 203381 prior to the expiration of the '343 patent, including any regulatory extensions, will

constitute an act of infringement by Sun directly and/or 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. 203381 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 Sun and all Sun 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. 203381 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 Sun commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 203381 that infringes the '727 and '343 patents;

(j) A judgment declaring that infringement of the '727 and '343 patents is willful if Sun commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 203381 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.

Dated: November 21, 2011

SAIBER LLC
Attorneys for Plaintiff
The Medicines Company

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CERTIFICATION PURUSANT TO LOCAL CIVIL RULE 11.2

The Medicines Company, by its undersigned counsel, hereby certifies pursuant to Local Civil Rule 11.2 that the patents in suit here are the subjects of the following related action pending in this Court before the Honorable Peter G. Sheridan, U.S.D.J.: *The Medicines Company v. Dr. Reddy's Laboratories Ltd., et al.*; Docket No. 3:11-cv-02456-PGS-DEA.

Dated: November 21, 2011

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Attorneys for Plaintiff
The Medicines Company

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CERTIFICATION PURUSANT TO LOCAL CIVIL RULE 201.1

Under Local Civil Rule 201.1, The Medicines Company, by its undersigned counsel, hereby certifies that, in addition to monetary damages greater than $150,000, The Medicines Company seeks injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: November 21, 2011

SAIBER LLC
Attorneys for Plaintiff
The Medicines Company

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