UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

THE MEDICINES COMPANY, Plaintiff, v. SAGENT PHARMACEUTICALS, INC. Defendant.	Civil Action No. _____

COMPLAINT

Plaintiff The Medicines Company, through its attorneys, files this Complaint against defendant Sagent Pharmaceuticals, Inc. ("Sagent") and 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 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. On information and belief, Defendant Sagent Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1901 N. Roselle Road, Schaumburg, IL 60195.

JURISDICTION AND VENUE

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

5. This Court has personal jurisdiction over Sagent.

6. Upon information and belief, Sagent 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. 091602 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.

7. Upon information and belief, Sagent'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.

8. Upon information and belief, Sagent has derived revenue from generic drug products distributed and/or sold in the State of Illinois.

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

10. Upon information and belief, Sagent (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. 091602 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

11. 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.

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. In a July 2, 2015 opinion in *The Medicines Company v. Hospira Inc.*, Nos. 14-1469, 14-1504 (Fed. Cir.), the Court of Appeals for the Federal Circuit held that asserted claims 1-3, 7-10, and 17 of the '727 patent and claims 1-3 and 7-11 of the '343 patent are invalid under the on-sale bar. The Federal Circuit has not yet issued a mandate. The Federal Circuit opinion did not address unasserted claims 4-6, 11-16, and 18-19 of the '727 patent and unasserted claims 4-6 and 12-20 of the '343 patent.

15. On July 31, 2015, The Medicines Company submitted a petition for panel rehearing and rehearing en banc in the above appeal. On August 24th, the Federal Circuit invited

a response from Hospira, Inc. to the petition for rehearing en banc. Hospira's response is due on or before September 8, 2015.

16. 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.

17. On information and belief, Sagent prepared, submitted, and/or filed Sagent'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 ("Sagent's Proposed Product") before the expiration of the '727 and '343 patents.

18. Sagent 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 Sagent's Proposed Product ("Sagent's Notice Letter").

19. 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 the 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 Sagent – ANDA No. 091602)

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

21. On information and belief, Sagent seeks FDA-approval for the manufacture, use, sale, offer for sale and/or importation of Sagent's Proposed Product that is the subject of Sagent's ANDA.

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

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

24. On information and belief, as of the date of Sagent's Notice Letter for Sagent's ANDA, Sagent 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. Sagent's submission of its ANDA No. 091602 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 Sagent's Proposed Product before the expiration of the '727 patent is an act of infringement by Sagent of one or more claims of the '727 patent under 35 U.S.C. §271(e)(2)(A).

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

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

SECOND COUNT

(Infringement of the '343 Patent by Sagent – ANDA No. 091602)

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

29. On information and belief, Sagent seeks FDA-approval for the manufacture, use, sale, offer for sale and/or importation of Sagent's Proposed Product that is the subject of Sagent's ANDA.

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

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

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

33. Sagent's submission of its ANDA No. 091602 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 Sagent's Proposed Product before the expiration of the '343 patent is an act of infringement by Sagent of one or more claims of the '343 patent under 35 U.S.C. §271(e)(2)(A).

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

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 Sagent 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. 091602 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. 091602 was an act of infringement of the '727 patent by Sagent;

(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. 091602 prior to the expiration of the '727 patent, including any regulatory extensions, will constitute an act of infringement by Sagent;

(c) A judgment declaring that, pursuant to 35 U.S.C. §271(e)(2)(A), the submission to the FDA of ANDA No. 091602 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. 091602 was an act of infringement of the '343 patent by Sagent;

(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. 091602 prior to the expiration of the '343 patent, including any regulatory extensions, will constitute an act of infringement by Sagent;

(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. 091602 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 Sagent and all Sagent 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. 091602 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 Sagent receives FDA approval and commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 091602 that infringes the '727 and '343 patents;

(h) A judgment declaring that infringement of the '727 and '343 patents is willful if Sagent receives final FDA approval and commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 091602 that infringes the '727 and/or the '343 patents;

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

This the 26th day of August, 2015.

Of Counsel

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