David E. De Lorenzi
Lisa H. Wang
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Telephone No.: (973) 596-4500
Facsimile No.: (973) 596-0545

Edgar H. Haug (ehaug@flhlaw.com)
Porter F. Fleming (pfleming@flhlaw.com)
Angus Chen (achen@flhlaw.com)
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
Telephone: (212) 588-0800
Facsimile: (212) 588-0500

Attorneys for Plaintiff
The Medicines Company

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

THE MEDICINES COMPANY, Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. _____ ***DOCUMENT ELECTRONICALLY FILED***

COMPLAINT

Plaintiff The Medicines Company, through its attorneys, files this Complaint against defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") 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 Exhibit A) and 7,598,343 ("the '343 patent") (attached as Exhibit B).

THE PARTIES

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

3. Upon information and belief, defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, with a principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

4. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

5. Upon information and belief, Apotex Corp. is an agent, affiliate, or subsidiary of Apotex Inc., including for Abbreviated New Drug Application ("ANDA") No. 204876 ("Apotex's ANDA").

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Apotex.

8. Upon information and belief, Apotex has a continuous and systematic business presence within this judicial district and/or substantial events giving rise to acts of infringement have occurred and/or will occur within this judicial district, including but not limited to: (i) the preparation of and/or contribution to the submission and/or filing of ANDA No. 204876 under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j))

seeking approval to market a 250 mg/vial bivalirudin drug product for intravenous injection ("Apotex's Product") before the expiration of the '727 and '343 patents; and/or (ii) making, using, selling, offering for sale, and/or importing Apotex's Product.

9. Apotex has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction and/or by asserting counterclaims in other civil actions initiated in this jurisdiction. (*See, e.g., Otsuka Pharmaceutical Co., Ltd. v. Apotex Corp. et al.*, Civil Action No. 12-05645 (D.N.J.) (ECF No. 27); *Meda Pharmaceuticals Inc. v. Apotex Inc., et al.*, Civil Action No. 12-00361 (D.N.J.) (ECF No. 25); *Novartis Pharmaceuticals Corp. v. Apotex Inc. et al.*, Civil Action No. 12-05574 (D.N.J.) (ECF No. 12)).

10. Upon information and belief, Apotex'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.

11. Upon information and belief, Apotex has derived revenue from generic drug products distributed and/or sold in the State of New Jersey.

12. Upon information and belief, Apotex has registered with the New Jersey Department of Health and Senior Services as: (i) a business or firm engaging in the wholesale distribution of drugs under N.J.A.C. 8:21 Subchapter 3A and/or; (ii) a drug manufacturing business or a wholesale nonprescription drug business under N.J.S.A. 24:6B-1.

13. Upon information and belief, Apotex's "Registration Number" with the New Jersey Department of Health and Senior Services is 5003192.

14. Upon information and belief, Apotex has and continues to avail itself of the laws of the State of New Jersey, including but not limited to N.J.A.C. 8:21 Subchapter 3A

and/or N.J.S.A. 24:6B-1.

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

16. Upon information and belief, (i) Apotex 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) substantial events giving rise to acts of infringement have occurred and/or will occur within this judicial district, including in connection with Apotex's preparation of and/or contribution to the submission and/or filing of ANDA No. 204876 under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to market Apotex's Product before the expiration of 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, among other things, for 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. In accordance with 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. Upon information and belief, Apotex filed its ANDA with the FDA under § 505(j) of the FDCA seeking approval to engage in the manufacture, use, sale, offer for sale, and/or importation of Apotex's Product before the expiration of the '727 and '343 patents.

22. Upon information and belief, Apotex Inc. sent The Medicines Company a letter purporting to include a notice of certification for the '727 and '343 patents under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. 505(j)(2)(B)(ii) of the FDCA regarding Apotex's Product ("Apotex's Notice Letter").

23. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification must "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).

24. Apotex's Notice Letter did not contain a detailed statement or include the factual and legal basis for asserting that Apotex's Product does not infringe each claim of the '727

and ’343 patents.

FIRST COUNT
(Infringement of the ’727 Patent by Apotex – ANDA No. 204876)

25. The Medicines Company repeats and incorporates by reference each paragraph above.

26. Upon information and belief, Apotex seeks FDA-approval for the manufacture, use, sale, offer for sale, and/or importation of Apotex’s Product that is the subject of ANDA No. 204876.

27. Upon information and belief, Apotex’s ANDA includes a paragraph IV certification to the ’727 patent to obtain approval to engage in the manufacture, use, sale, offer for sale, and/or importation of Apotex’s Product before the expiration of the ’727 patent.

28. Upon information and belief, Apotex will manufacture, sell, offer for sale, and/or import Apotex’s Product upon FDA-approval, including within this judicial district.

29. Upon information and belief, as of the date of Apotex’s Notice Letter for Apotex’s ANDA, Apotex 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).

30. The inclusion of a paragraph IV certification to the ’727 patent in Apotex’s ANDA for the purpose of obtaining approval to engage in the manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex’s Product before the expiration of the ’727 patent is an act of infringement by Apotex 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).

31. Upon information and belief, Apotex’s manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex’s 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).

32. Apotex admits that Apotex's Product infringes the '727 patent because, among other things, Apotex's Notice Letter does not provide a basis - let alone a detailed factual and legal basis - for noninfringement of each claim of the '727 patent. Specifically, Apotex's Notice Letter does not provide a detailed factual and legal basis for noninfringement of claims 1-10 and 17 of the '727 patent.

33. Upon information and belief, Apotex 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.

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

SECOND COUNT

(Infringement of the '343 Patent by Apotex – ANDA No. 204876)

35. The Medicines Company repeats and incorporates by reference each paragraph above.

36. Upon information and belief, Apotex seeks FDA-approval for the manufacture, use, sale, offer for sale, and/or importation of Apotex's Product that is the subject of ANDA No. 204876.

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

38. Upon information and belief, Apotex will manufacture, sell, offer for sale, and/or import Apotex's Product upon FDA-approval, including within this judicial district.

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

40. The inclusion of a paragraph IV certification to the '343 patent in Apotex's ANDA for the purpose of obtaining approval to engage in the manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's Product before the expiration of the '343 patent is an act of infringement by Apotex 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).

41. Upon information and belief, Apotex's manufacture, use, sale, offer for sale, and/or importation into the United States of Apotex's 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).

42. Apotex admits that Apotex's Product infringes the '343 patent because, among other things, Apotex's Notice Letter does not provide a basis - let alone a detailed factual and legal basis - for noninfringement of each claim of the '343 patent. Specifically, Apotex's Notice Letter does not provide a detailed factual and legal basis for noninfringement of claims 1-11 of the '343 patent.

43. Upon information and belief, Apotex 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.

44. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless Apotex 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, under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204876 with a paragraph IV certification to obtain approval for the manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 204876 was an act of infringement of the '727 patent by Apotex directly and/or by inducement;

(c) A judgment declaring that, under 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 manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 204876 before the expiration of the '727 patent, including any regulatory extensions, will constitute an act of infringement by Apotex directly and/or by inducement;

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

(e) A judgment declaring that, under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204876 with a paragraph IV certification to obtain approval for the manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 204876 was an act of infringement of the '343 patent by Apotex directly and/or by inducement;

(f) A judgment declaring that, under 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 manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 204876 before the expiration of the '343 patent, including any regulatory extensions, will constitute an

act of infringement by Apotex directly and/or by inducement;

(g) An order under 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the product that is the subject of ANDA No. 204876 shall be no earlier than the date on which the '727 and '343 patents expire including any regulatory extensions;

(h) A judgment under 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Apotex and all Apotex 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 manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 204876 until the expiration of the '727 and '343 patents including any regulatory extensions;

(i) In accordance with 35 U.S.C. §§ 271(e)(4)(C) and 284, a judgment awarding The Medicines Company damages or other monetary relief if Apotex manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 204876 that infringes the '727 and '343 patents;

(j) A judgment declaring that infringement of the '727 and '343 patents is willful if Apotex manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 204876 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; and

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

Dated: May 1, 2013

s/ David E. De Lorenzi
David E. De Lorenzi
Lisa H. Wang
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Telephone No.: (973) 596-4500
Facsimile No.: (973) 596-0545

Edgar H. Haug (ehaug@flhlaw.com)
Porter F. Fleming (pfleming@flhlaw.com)
Angus Chen (achen@flhlaw.com)
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151
Telephone: (212) 588-0800
Facsimile: (212) 588-0500

Attorneys for Plaintiff
The Medicines Company