IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE MEDICINES COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 09-752 (ECR)
	)	
APP PHARMACEUTICALS, LLC and APP PHARMACEUTICALS, INC.	)	
	)	
Defendants.	)	

AMENDED COMPLAINT

Plaintiff The Medicines Company, by its undersigned attorneys, for its Complaint against defendants APP Pharmaceuticals, LLC and APP Pharmaceuticals, Inc. (collectively "APP") 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).

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, APP Pharmaceuticals, LLC is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173.

4. Upon information and belief, APP Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173.

5. Upon information and belief, APP Pharmaceuticals, LLC is a wholly-owned subsidiary of APP Pharmaceuticals, Inc. Upon information and belief, APP Pharmaceuticals, LLC is controlled and/or dominated by APP Pharmaceuticals, Inc.

6. Upon information and belief, APP Pharmaceuticals, LLC manufactures and distributes generic drugs for sale and use throughout the United States, including at the direction of, under the control of, and for the direct benefit of APP Pharmaceuticals, Inc. Upon information and belief, APP Pharmaceuticals, LLC acts as the agent for APP Pharmaceuticals, Inc. for purposes of regulatory submissions to the FDA seeking approval for certain generic drugs, including injectable generic drugs.

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over APP Pharmaceuticals, LLC. APP Pharmaceuticals, LLC has submitted to personal jurisdiction in this Court because, *inter alia*, it is a resident and citizen of the State of Delaware and has availed itself to the rights and benefits of the laws of Delaware by virtue of organizing in Delaware.

9. This Court has personal jurisdiction over APP Pharmaceuticals, Inc. APP Pharmaceuticals, Inc. has submitted to personal jurisdiction in this Court because, *inter alia*, it is a resident and citizen of the State of Delaware and has availed itself to the rights and benefits of the laws of Delaware by virtue of incorporating in Delaware.

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

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 for 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. Pursuant to 21 U.S.C. § 355(b)(1), the '727 patent is 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.

14. APP Pharmaceuticals, LLC prepared and submitted Abbreviated New Drug Application ("ANDA") No. 90-189 ("APP's ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) 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 ("APP's Proposed Product").

15. APP Pharmaceuticals, LLC sent The Medicines Company a notification purportedly pursuant to § 505(j)(2)(B)(ii) of the FDCA regarding APP's Proposed Product ("APP's Notice Letter").

16. 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" ("notice letter"). 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).

17. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), APP's Notice Letter contained an Offer of Confidential Access to APP's ANDA.

18. The Medicines Company requested access to APP's ANDA and samples of APP's Proposed Product.

19. APP did not respond to The Medicines Company's request and has not provided access to either APP's ANDA or APP's Proposed Product.

FIRST COUNT
(Infringement of the '727 Patent by APP)

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

21. Upon information and belief, APP Pharmaceuticals, LLC seeks FDA-approval for the manufacture and/or distribution of APP's Proposed Product.

22. Upon information and belief, APP Pharmaceuticals, LLC amended APP's ANDA to include 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 APP's Proposed Product before the expiration of the '727 patent.

23. Upon information and belief, APP will commercially manufacture, sell, offer for sale, and/or import APP's Proposed Product immediately upon FDA-approval. Upon information and belief, APP seeks immediate FDA-approval.

24. Upon information and belief, as of the date of APP's Notice Letter, APP 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 amendment of ANDA No. 90-189 with a paragraph IV certification to the '727 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of APP's Proposed Product before the expiration of the '727 patent is an act of infringement by APP Pharmaceuticals, LLC of one or more claims of the '727 patent under 35 U.S.C. § 271(e)(2)(A).

26. Upon information and belief, APP's commercial manufacture, use, sale, offer for sale and/or importation into the United States of APP's Proposed Product that is the subject of ANDA No. 90-189 will infringe one or more claims of the '727 patent.

27. Upon information and belief, APP 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.

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

SECOND COUNT

(Induced and/or Contributory Infringement of the '727 Patent by APP Pharmaceuticals, Inc.)

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

30. APP Pharmaceuticals, Inc. is jointly and severally liable for APP Pharmaceuticals, LLC's infringement of one or more claims of the '727 patent.

31. Upon information and belief, APP Pharmaceuticals, Inc. knowingly induced APP Pharmaceuticals, LLC to infringe and/or contributed to APP Pharmaceuticals, LLC's infringement of one or more claims of the '727 patent.

32. Upon information and belief, APP Pharmaceuticals, Inc. actively induced, encouraged, aided, or abetted APP Pharmaceuticals, LLC's preparation and submission of ANDA No. 90-189 and amendment with a paragraph IV certification to the '727 patent.

33. APP Pharmaceuticals, Inc.'s inducement, encouragement, aiding, or abetting of APP Pharmaceuticals, LLC's preparation and submission of ANDA No. 90-189 and amendment with a paragraph IV certification constitutes infringement of the '727 patent under 35 U.S.C. § 271(e)(2)(A). Further, APP Pharmaceuticals, Inc.'s commercial use, sale, offer for sale and/or importation of APP's Proposed Product would induce and/or contribute to APP Pharmaceuticals, LLC's infringement of the '727 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

34. Upon information and belief, APP Pharmaceuticals, Inc. has, continues to, and will actively induce, encourage, aid, or abet APP Pharmaceuticals, LLC's infringement of the '727 patent with knowledge that it is in contravention of The Medicines Company's rights.

35. Upon information and belief, APP Pharmaceuticals, Inc. is aware of the existence of the '727 patent and acted without a reasonable basis for believing that it would not be liable for inducing and/or contributing to APP Pharmaceuticals, LLC's infringement of the '727 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

36. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless APP Pharmaceuticals, Inc. 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. 90-189 with a paragraph IV certification amendment 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. 90-189 was an act of infringement of the '727 patent by APP Pharmaceuticals, LLC;

(c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A) and/or 35 U.S.C. § 271(a), 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. 90-189 prior to the expiration of the '727 patent, including any regulatory extensions, will constitute an act of infringement by APP Pharmaceuticals, LLC and APP Pharmaceuticals, Inc., individually and collectively;

(d) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), APP Pharmaceuticals, Inc. has and continues to induce and/or contribute to APP Pharmaceuticals, LLC's infringement of the '727 patent based on the submission to the FDA of ANDA No. 90-189 with a paragraph IV certification amendment 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. 90-189;

(e) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), APP Pharmaceuticals, Inc. would induce and/or contribute to APP Pharmaceuticals, LLC's infringement of the '727 patent based on 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. 90-189;

(f) 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. 90-189 shall be no earlier than the date on which the '727 patent expires including any regulatory extensions;

(g) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining APP Pharmaceuticals, LLC, APP Pharmaceuticals, Inc. and their 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. 90-189 until the expiration of the '727 patent including any regulatory extensions;

(h) A judgment awarding The Medicines Company damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if APP Pharmaceuticals, LLC and APP Pharmaceuticals, Inc. commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 90-189 that infringes the '727 patent;

(i) A judgment declaring that infringement of the '727 patent is willful if APP Pharmaceuticals, LLC and APP Pharmaceuticals, Inc. commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 90-189 that infringes the '727 patent;

(j) 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;

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

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