IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE MEDICINES COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD.	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff The Medicines Company, by its undersigned attorneys, for its Complaint against defendants Teva Parenteral Medicines, Inc. ("Teva Parenteral"), Teva Pharmaceuticals USA, Inc. ("Teva USA") and defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") (collectively "Defendants" or "Teva") 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 No. 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, Teva Ltd. is a corporation organized and existing under the laws of Israel, with a principal place of business at 5 Basel Street, Petah Tikva, Israel. Upon information and belief, Teva Ltd. is in the business of developing, manufacturing, marketing, and selling generic drugs throughout the world, including throughout the United States including the State of Delaware.

4. Upon information and belief, Teva USA is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

5. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd. Upon information and belief, Teva USA is controlled and/or dominated by Teva Ltd. Upon information and belief, Teva Ltd. and Teva USA have at least one officer and/or director in common.

6. Upon information and belief, Teva USA 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 Teva Ltd. Upon information and belief, Teva USA acts as the U.S. agent for Teva Ltd. for purposes of regulatory submissions to the U.S. Food and Drug Administration ("FDA") seeking approval for generic drugs. Upon information and belief, Teva USA acts as the U.S. sales and marketing agent for Teva Ltd. for generic drugs.

7. Upon information and belief, Teva Parenteral is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 19 Hughes, Irvine, California 92618.

8. Upon information and belief, Teva Parenteral is a wholly-owned subsidiary of Teva USA. Upon information and belief, Teva Parenteral is controlled and/or dominated by Teva USA and/or Teva Ltd.

9. Upon information and belief, Teva Parenteral 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 Teva USA and Teva Ltd. Upon information and belief, Teva Parenteral acts as the agent for Teva USA and Teva Ltd. for purposes of regulatory submissions to the FDA seeking approval for certain generic drugs, including injectable generic drugs. Upon information and belief, Teva Parenteral manufactures and supplies certain generic drugs, including injectable generic drugs, to Teva USA, which acts as the U.S. sales and marketing agent for Teva Parenteral.

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over Teva Ltd. because, *inter alia*, of its continuous and systematic contacts with the State of Delaware by virtue of directly and/or through its wholly-owned subsidiaries, manufacturing, marketing and selling drugs throughout the United States, including the State of Delaware, and therefore has availed itself of the privilege of conducting business within the State of Delaware.

12. This Court has personal jurisdiction over Teva USA. Teva USA 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.

13. This Court has personal jurisdiction over Teva Parenteral. Teva Parenteral 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.

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

FACTS AS TO ALL COUNTS

15. 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.

16. 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.

17. 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.

18. Teva Parenteral prepared and submitted Abbreviated New Drug Application ("ANDA") No. 90-748 ("Teva'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 ("Teva's Proposed Product").

19. Teva Parenteral sent The Medicines Company a notification purportedly pursuant to § 505(j)(2)(B)(ii) of the FDCA regarding Teva's Proposed Product ("Teva's Notice Letter").

20. 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).

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

22. The Medicines Company requested access to Teva's ANDA and samples of Teva's Proposed Product.

23. Teva refused to provide The Medicines Company access to either Teva's ANDA or Teva's Proposed Product.

FIRST COUNT

(Infringement of the '727 Patent by Teva Parenteral, Teva USA and Teva Ltd.)

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

25. Upon information and belief, Teva Parenteral seeks FDA-approval for the manufacture and/or distribution of Teva's Proposed Product.

26. Upon information and belief, Teva Parenteral amended Teva'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 Teva's Proposed Product before the expiration of the '727 patent.

27. Upon information and belief, Teva Parenteral, Teva USA and/or Teva Ltd. will commercially manufacture, sell, offer for sale, and/or import Teva's Proposed Product immediately upon FDA-approval. Upon information and belief, Teva Parenteral, Teva USA and Teva Ltd. expect to receive final FDA-approval on or about September 23, 2010.

28. Upon information and belief, as of the date of Teva's Notice Letter, Teva Parenteral, Teva USA and Teva Ltd. were 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).

29. The amendment of ANDA No. 90-748 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 Teva's Proposed Product before the expiration of the '727 patent is an act of infringement by Teva Parenteral of one or more claims of the '727 patent under 35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief, Teva Parenteral's, Teva USA's and/or Teva Ltd.'s commercial manufacture, use, sale, offer for sale and/or importation into the United States of Teva's Proposed Product that is the subject of ANDA No. 90-748 will infringe one or more claims of the '727 patent.

31. Upon information and belief, Teva Parenteral, Teva USA and Teva Ltd. are 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, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

32. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless Teva Parenteral, Teva USA and Teva Ltd. are preliminarily and permanently enjoined by this Court.

SECOND COUNT

(Induced and/or Contributory Infringement of the '727 Patent by Teva USA and Teva Ltd.)

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

34. Teva USA and Teva Ltd. are jointly and severally liable for Teva Parenteral's infringement of one or more claims of the '727 patent.

35. Upon information and belief, Teva USA and Teva Ltd. knowingly induced Teva Parenteral to infringe and/or contributed to Teva Parenteral's infringement of one or more claims of the '727 patent.

36. Upon information and belief, Teva USA and Teva Ltd. actively induced, encouraged, aided, or abetted Teva Parenteral's preparation and submission of ANDA No. 90-748 and amendment with a paragraph IV certification.

37. Teva USA's and Teva Ltd.'s inducement, encouragement, aiding, or abetting of Teva Parenteral's preparation and submission of ANDA No. 90-748 and amendment with a paragraph IV certification constitutes infringement of the '727 patent under 35 U.S.C. § 271(e)(2)(A). Further, Teva USA's and/or Teva Ltd.'s commercial use, sale, offer for sale and/or importation of Teva's Proposed Product would induce and/or contribute to Teva Parenteral's infringement of the '727 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

38. Upon information and belief, Teva USA and Teva Ltd. have, continue to, and will actively induce, encourage, aid, or abet Teva Parenteral's infringement of the '727 patent with knowledge that it is in contravention of The Medicines Company's rights.

39. Upon information and belief, Teva USA and Teva Ltd. are 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 Teva Parenteral's infringement of the '727 patent, making the acts of infringement set forth above deliberate and willful, thus rendering this case "exceptional" under 35 U.S.C. § 285.

40. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless Teva USA and Teva Ltd. are 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. 90-748 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. 90-748 was an act of infringement of the '727 patent by Teva Parenteral;

(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. 90-748 prior to the expiration of the '727 patent, including any regulatory extensions, will constitute an act of infringement by Teva Parenteral, Teva USA and Teva Ltd., individually and collectively;

(d) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Teva USA and Teva Ltd. have and continue to induce and/or contribute to Teva Parenteral's infringement of the '727 patent based on the submission to the FDA of ANDA No. 90-748 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. 90-748;

(e) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Teva USA and Teva Ltd. would induce and/or contribute to Teva Parenteral'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. 90-748;

(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. 90-748 shall be no earlier than the date on which the '727 patent expires including any regulatory extensions;

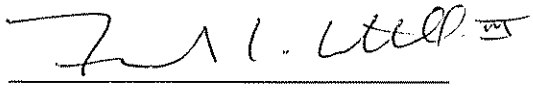
(g) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Teva Parenteral, Teva USA, Teva Ltd., their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 90-748 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 Teva Parenteral, Teva USA and/or Teva Ltd. commercially manufacture, use, sell, offer to sell and/or import any product that is the subject of ANDA No. 90-748 that infringes the '727 patent;

(i) A judgment declaring that Teva Parenteral's, Teva USA's and Teva Ltd.'s infringement of the '727 patent based on ANDA No. 90-748 was willful;

(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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