IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE MEDICINES COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
HOSPIRA, INC.	)	
	)	
Defendant.	)	
	)	

COMPLAINT

Plaintiff The Medicines Company, by its undersigned attorneys, for its Complaint against defendant Hospira, Inc. ("Hospira") 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) 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. Upon information and belief, Hospira is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

4. Upon information and belief, Hospira manufactures and distributes generic drugs, including injectable drugs, for sale and use throughout the United States.

JURISDICTION AND VENUE

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

6. This Court has personal jurisdiction over Hospira. Hospira 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.

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

FACTS AS TO ALL COUNTS

8. 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, which is indicated for, *inter alia*, use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty.

9. 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.

10. 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.

11. 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.

12. Hospira prepared and submitted Abbreviated New Drug Application ("ANDA") Nos. 90-811 and 90-816 (collectively "Hospira's ANDAs") 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 ("Hospira's Proposed Products").

13. For each of Hospira's ANDAs, Hospira sent The Medicines Company a notification for the '727 and '343 patents purportedly pursuant to § 505(j)(2)(B)(ii) of the FDCA regarding Hospira's Proposed Products ("Hospira's Notice Letters").

14. 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).

15. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), Hospira's Notice Letters each contained an Offer of Confidential Access to Hospira's ANDAs.

16. The Medicines Company requested access to Hospira's ANDAs.

FIRST COUNT

(Infringement of the '727 Patent by Hospira – ANDA No. 90-811)

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

18. Upon information and belief, Hospira seeks FDA-approval for the manufacture and/or distribution of Hospira's proposed product that is the subject of ANDA No. 90-811 ("Hospira's 90-811 Product").

19. Upon information and belief, Hospira amended its ANDA No. 90-811 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 Hospira's 90-811 Product before the expiration of the '727 patent.

20. Upon information and belief, Hospira will commercially manufacture, sell, offer for sale, and/or import Hospira's 90-811 Product immediately upon FDA-approval.

21. Upon information and belief, as of the date of Hospira's Notice Letter for its ANDA No. 90-811, Hospira 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).

22. The amendment of ANDA No. 90-811 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 Hospira's 90-811 Product before the expiration of the '727 patent is an act of infringement by Hospira of one or more claims of the '727 patent under 35 U.S.C. § 271(e)(2)(A).

23. Upon information and belief, Hospira's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Hospira's 90-811 Product will infringe one or more claims of the '727 patent.

24. Upon information and belief, Hospira 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.

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

SECOND COUNT

(Infringement of the '343 Patent by Hospira – ANDA No. 90-811)

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

27. Upon information and belief, Hospira seeks FDA-approval for the manufacture and/or distribution of Hospira's 90-811 Product.

28. Upon information and belief, Hospira amended its ANDA No. 90-811 to include 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 Hospira's 90-811 Product before the expiration of the '343 patent.

29. Upon information and belief, Hospira will commercially manufacture, sell, offer for sale, and/or import Hospira's 90-811 Product immediately upon FDA-approval.

30. Upon information and belief, as of the date of Hospira's Notice Letter for its ANDA No. 90-811, Hospira 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 amendment of ANDA No. 90-811 with a paragraph IV certification to the '343 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Hospira's 90-811 Product before the expiration of the '343 patent is an act of infringement by Hospira of one or more claims of the '343 patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief, Hospira's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Hospira's 90-811 Product will infringe one or more claims of the '343 patent.

33. Upon information and belief, Hospira 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.

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 Hospira is preliminarily and permanently enjoined by this Court.

THIRD COUNT

(Infringement of the '727 Patent by Hospira – ANDA No. 90-816)

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

36. Upon information and belief, Hospira seeks FDA-approval for the manufacture and/or distribution of Hospira's proposed product that is the subject of ANDA No. 90-816 ("Hospira's 90-816 Product").

37. Upon information and belief, Hospira amended its ANDA No. 90-816 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 Hospira's 90-816 Product before the expiration of the '727 patent.

38. Upon information and belief, Hospira will commercially manufacture, sell, offer for sale, and/or import Hospira's 90-816 Product immediately upon FDA-approval.

39. Upon information and belief, as of the date of Hospira's Notice Letter for its ANDA No. 90-816, Hospira 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 amendment of ANDA No. 90-816 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 Hospira's 90-816 Product before the expiration of the '727 patent is an act of infringement by Hospira of one or more claims of the '727 patent under 35 U.S.C. § 271(e)(2)(A).

41. Upon information and belief, Hospira's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Hospira's 90-816 Product will infringe one or more claims of the '727 patent.

42. Upon information and belief, Hospira 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.

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

FOURTH COUNT

(Infringement of the '343 Patent by Hospira – ANDA No. 90-816)

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

45. Upon information and belief, Hospira seeks FDA-approval for the manufacture and/or distribution of Hospira's 90-816 Product.

46. Upon information and belief, Hospira amended its ANDA No. 90-816 to include 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 Hospira's 90-816 Product before the expiration of the '343 patent.

47. Upon information and belief, Hospira will commercially manufacture, sell, offer for sale, and/or import Hospira's 90-816 Product immediately upon FDA-approval.

48. Upon information and belief, as of the date of Hospira's Notice Letter for its ANDA No. 90-816, Hospira 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).

49. The amendment of ANDA No. 90-816 with a paragraph IV certification to the '343 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of Hospira's 90-816 Product before the expiration of the '343 patent is an act of infringement by Hospira of one or more claims of the '343 patent under 35 U.S.C. § 271(e)(2)(A).

50. Upon information and belief, Hospira's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Hospira's 90-816 Product will infringe one or more claims of the '343 patent.

51. Upon information and belief, Hospira 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.

52. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless Hospira 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. 90-811 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. 90-811 was an act of infringement of the '727 patent by Hospira;

(c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 90-816 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. 90-816 was an act of infringement of the '727 patent by Hospira;

(d) 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. 90-811 prior to the expiration of the '727 patent, including any regulatory extensions, will constitute an act of infringement by Hospira;

(e) 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. 90-816 prior to the expiration of the '727 patent, including any regulatory extensions, will constitute an act of infringement by Hospira;

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

(g) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 90-811 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. 90-811 was an act of infringement of the '343 patent by Hospira;

(h) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 90-816 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. 90-816 was an act of infringement of the '343 patent by Hospira;

(i) 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. 90-811 prior to the expiration of the '343 patent, including any regulatory extensions, will constitute an act of infringement by Hospira;

(j) 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. 90-816 prior to the expiration of the '343 patent, including any regulatory extensions, will constitute an act of infringement by Hospira;

(k) 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. 90-811 shall be no earlier than the date on which the '727 and '343 patents expire including any regulatory extensions;

(l) 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. 90-816 shall be no earlier than the date on which the '727 and '343 patents expire including any regulatory extensions;

(m) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Hospira and its 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. 90-811 until the expiration of the '727 and '343 patents including any regulatory extensions;

(n) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Hospira and its 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. 90-816 until the expiration of the '727 and '343 patents including any regulatory extensions;

(o) A judgment awarding The Medicines Company damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Hospira commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 90-811 that infringes the '727 and '343 patents;

(p) A judgment awarding The Medicines Company damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Hospira commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 90-816 that infringes the '727 and '343 patents;

(q) A judgment declaring that infringement of the '727 and '343 patents is willful if Hospira commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 90-811 that infringes the '727 and/or the '343 patents;

(r) A judgment declaring that infringement of the '727 and '343 patents is willful if Hospira commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 90-816 that infringes the '727 and/or the '343 patents;

(s) 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;

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

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Dated: August 19, 2010

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