IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
HOSPIRA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Cubist Pharmaceuticals, Inc., by its attorneys, alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Defendant Hospira, Inc. of New Drug Application ("NDA") No. 203797 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of CUBICIN® prior to the expiration of U.S. Patent Nos. 6,468,967; 6,852,689; RE39,071; 8,058,238; and 8,129,342.

PARTIES

2. Plaintiff Cubist Pharmaceuticals, Inc. ("Cubist") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 65 Hayden Avenue, Lexington, Massachusetts.

3. Upon information and belief, Defendant Hospira, Inc. ("Hospira") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 275 North Field Drive, Lake Forest, Illinois.

4. Hospira manufactures and sells various generic drug products and regularly conducts business throughout the United States, including in the State of Delaware.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America and this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

7. Hospira is subject to personal jurisdiction in Delaware because, among other things, it has submitted itself to the jurisdiction of courts in Delaware by virtue of its incorporation under Delaware law. Hospira is also subject to personal jurisdiction in Delaware because, among other things, Hospira manufactures, markets, and sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware.

BACKGROUND

8. CUBICIN® (daptomycin for injection) is an intravenous bactericidal antibiotic approved by the FDA for the treatment of complicated skin and skin structure infections caused by certain Gram-positive microorganisms, such as *Staphylococcus aureus,* including methicillin-resistant strains, also known as MRSA. CUBICIN® is also approved for the treatment of *S. aureus* bloodstream infections (bacteremia), including right sided infective endocarditis caused by MRSA.

9. Cubist sells CUBICIN® in the United States pursuant to a New Drug Application that has been approved by the FDA.

10. United States Patent No. 6,468,967 ("the '967 patent"), entitled "Methods for Administration of Antibiotics" (Exhibit A hereto), was duly and legally issued on October 22, 2002. The '967 patent, which is owned by Cubist, will expire on September 24, 2019.

11. United States Patent No. 6,852,689 ("the '689 patent"), entitled "Methods for Administration of Antibiotics" (Exhibit B hereto), was duly and legally issued on February 8, 2005. The '689 patent, which is owned by Cubist, will expire on September 24, 2019.

12. United States Patent No. RE39,071 ("the RE'071 patent"), entitled "Anhydro-and Isomer-A-21978C Cyclic Peptides" (Exhibit C hereto), was duly and legally issued on April 18, 2006. The RE'071 patent, which is owned by Cubist, will expire on June 15, 2016.

13. United States Patent No. 8,058,238 ("the '238 patent"), entitled "High Purity Lipopeptides" (Exhibit D hereto), was duly and legally issued on November 15, 2011. The '238 patent, which is owned by Cubist, will expire on November 28, 2020.

14. United States Patent No. 8,129,342 ("the '342 patent"), entitled "High Purity Lipopeptides" (Exhibit E hereto), was duly and legally issued on March 6, 2012. The '342 patent, which is owned by Cubist, will expire on November 28, 2020.

15. CUBICIN®, or its use, is covered by one or more claims of the '967, '689, RE'071, '238, and '342 patents, which have been listed in connection with CUBICIN® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations,* referred to as the "Orange Book."

16. By letter dated August 10, 2012 (the "Notice Letter"), Hospira notified Cubist that it had submitted an NDA to the FDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act along with a certification under Section 505(b)(2)(A)(iv) ("Paragraph

IV"), requesting approval to market Daptomycin for Injection, 350 mg/vial, a generic version of CUBICIN® ("Hospira's 505(b)(2) Product"). The FDA assigned NDA No. 203797 to the application.

17. In the Notice Letter, Hospira alleged that the '967, '689, RE'071, '238, and '342 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Hospira's 505(b)(2) Product.

18. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 6,468,967

19. Plaintiff incorporates each of the proceeding paragraphs 1-18 as if fully set forth herein.

20. The use of Hospira's 505(b)(2) Product is covered by one or more claims of the '967 patent.

21. Hospira had knowledge of the '967 patent when it submitted its NDA to the FDA.

22. Hospira's submission of NDA No. 203797 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Hospira's 505(b)(2) Product before the expiration of the '967 patent is an act of infringement of the '967 patent.

23. The commercial manufacture, use, offer for sale, sale and/or importation of Hospira's 505(b)(2) Product would infringe one or more claims of the '967 patent.

24. Upon information and belief, use of Hospira's 505(b)(2) Product in accordance with and as directed by Hospira's proposed labeling for that product would infringe one or more claims of the '967 patent.

25. Upon information and belief, Hospira intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Hospira's 505(b)(2) Product with its proposed labeling immediately and imminently upon approval of NDA No. 203797.

26. Upon information and belief, Hospira will actively induce infringement of the '967 patent when its NDA is approved, and plans and intends to, and will do so immediately and imminently upon approval.

27. Upon information and belief, Hospira knows that its 505(b)(2) Product and its proposed labeling are especially made or adapted for use in infringing the '967 patent, and that its 505(b)(2) Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Hospira plans and intends to, and will, contribute to the infringement of the '967 patent immediately and imminently upon approval of NDA No. 203797.

28. The foregoing actions by Hospira constitute and/or would constitute infringement of the '967 patent, active inducement of infringement of the '967 patent, and/or contribution to the infringement by others of the '967 patent.

29. Upon information and belief, Hospira acted without a reasonable basis for believing that it would not be liable for infringing the '967 patent, actively inducing infringement of the '967 patent, and/or contributing to the infringement by others of the '967 patent.

30. Unless Hospira is enjoined from infringing the ’967 patent, actively inducing infringement of the ’967 patent, and/or contributing to the infringement by others of the ’967 patent, Cubist will suffer irreparable injury. Cubist has no adequate remedy at law.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 6,852,689

31. Plaintiff incorporates each of the proceeding paragraphs 1-30 as if fully set forth herein.

32. The use of Hospira’s 505(b)(2) Product is covered by one or more claims of the ’689 patent.

33. Hospira had knowledge of the ’689 patent when it submitted its NDA to the FDA.

34. Hospira’s submission of NDA No. 203797 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Hospira’s 505(b)(2) Product before the expiration of the ’689 patent is an act of infringement of the ’689 patent.

35. The commercial manufacture, use, offer for sale, sale and/or importation of Hospira’s 505(b)(2) Product would infringe one or more claims of the ’689 patent.

36. Upon information and belief, use of Hospira’s 505(b)(2) Product in accordance with and as directed by Hospira’s proposed labeling for that product would infringe one or more claims of the ’689 patent.

37. Upon information and belief, Hospira intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Hospira’s 505(b)(2) Product with its proposed labeling immediately and imminently upon approval of NDA No. 203797.

38. Upon information and belief, Hospira will actively induce infringement of the ’689 patent when its NDA is approved, and plans and intends to, and will do so immediately and imminently upon approval.

39. Upon information and belief, Hospira knows that its 505(b)(2) Product and its proposed labeling are especially made or adapted for use in infringing the ’689 patent, and that its 505(b)(2) Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Hospira plans and intends to, and will, contribute to the infringement of the ’689 patent immediately and imminently upon approval of NDA No. 203797.

40. The foregoing actions by Hospira constitute and/or would constitute infringement of the ’689 patent, active inducement of infringement of the ’689 patent, and/or contribution to the infringement by others of the ’689 patent.

41. Upon information and belief, Hospira acted without a reasonable basis for believing that it would not be liable for infringing the ’689 patent, actively inducing infringement of the ’689 patent, and/or contributing to the infringement by others of the ’689 patent.

42. Unless Hospira is enjoined from infringing the ’689 patent, actively inducing infringement of the ’689 patent, and/or contributing to the infringement by others of the ’689 patent, Cubist will suffer irreparable injury. Cubist has no adequate remedy at law.

COUNT III

INFRINGEMENT OF U.S. PATENT NO. RE39,071

43. Plaintiff incorporates each of the proceeding paragraphs 1 - 42 as if fully set forth herein.

44. Hospira’s 505(b)(2) Product is covered by one or more claims of the RE’071 patent.

45. Hospira's submission of NDA No. 203797 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Hospira's 505(b)(2) Product before the expiration of the RE'071 patent is an act of infringement of the RE'071 patent.

46. The commercial manufacture, use, offer for sale, sale and/or importation of Hospira's 505(b)(2) Product would infringe one or more claims of the RE'071 patent.

47. Upon information and belief, Hospira intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Hospira's 505(b)(2) Product with its proposed labeling immediately and imminently upon approval of NDA No. 203797.

48. The foregoing actions by Hospira constitute and/or would constitute infringement of the RE'071 patent.

49. Unless Hospira is enjoined from infringing the RE'071 patent, Cubist will suffer irreparable injury. Cubist has no adequate remedy at law.

COUNT IV

INFRINGEMENT OF U.S. PATENT NO. 8,058,238

50. Plaintiff incorporates each of the proceeding paragraphs 1 - 49 as if fully set forth herein.

51. Hospira's 505(b)(2) Product is covered by one or more claims of the '238 patent.

52. Hospira's submission of NDA No. 203797 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Hospira's 505(b)(2) Product before the expiration of the '238 patent is an act of infringement of the '238 patent.

53. The commercial manufacture, use, offer for sale, sale and/or importation of Hospira's 505(b)(2) Product would infringe one or more claims of the '238 patent.

54. Upon information and belief, Hospira intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Hospira's 505(b)(2) Product with its proposed labeling immediately and imminently upon approval of NDA No. 203797.

55. The foregoing actions by Hospira constitute and/or would constitute infringement of the '238 patent.

56. Unless Hospira is enjoined from infringing the '238 patent, Cubist will suffer irreparable injury. Cubist has no adequate remedy at law.

COUNT V

INFRINGEMENT OF U.S. PATENT NO. 8,129,342

57. Plaintiff incorporates each of the proceeding paragraphs 1 - 56 as if fully set forth herein.

58. Hospira's 505(b)(2) Product is covered by one or more claims of the '342 patent.

59. Hospira's submission of NDA No. 203797 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Hospira's 505(b)(2) Product before the expiration of the '342 patent is an act of infringement of the '342 patent.

60. The commercial manufacture, use, offer for sale, sale and/or importation of Hospira's 505(b)(2) Product would infringe one or more claims of the '342 patent.

61. Upon information and belief, Hospira intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Hospira's 505(b)(2) Product with its proposed labeling immediately and imminently upon approval of NDA No. 203797.

62. The foregoing actions by Hospira constitute and/or would constitute infringement of the ’342 patent.

63. Unless Hospira is enjoined from infringing the ’342 patent, Cubist will suffer irreparable injury. Cubist has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court grant the following relief:

(a) A judgment that Hospira’s submission of NDA No. 203797 was an act of infringement of the ’967, ’689, RE’071, ’238, and ’342 patents, and that Hospira’s manufacture, use, offer to sell, sale, or importation of Hospira’s 505(b)(2) Product prior to the expiration of the ’967, ’689, RE’071, ’238, and ’342 patents will infringe, actively induce infringement, and/or contribute to the infringement of the ’967, ’689, RE’071, ’238, and ’342 patents;

(b) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Hospira’s NDA No. 203797, or any product or compound that infringes the ’967, ’689, RE’071, ’238, and ’342 patents, shall not be earlier than the expiration of the ’967, ’689, RE’071, ’238, and ’342 patents;

(c) An Order permanently enjoining Hospira, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Hospira’s 505(b)(2) Product, or any product or compound that infringes the ’967, ’689, RE’071, ’238, and ’342 patents, or inducing or contributing to the infringement of the ’967, ’689, RE’071, ’238, and ’342 patents until after the expiration of the ’967, ’689, RE’071, ’238, and ’342 patents;

(d) A declaration that this is an exceptional case and an award of attorneys’ fees to plaintiff pursuant to 35 U.S.C. § 285;

(e) Plaintiffs reasonable costs of suit incurred; and

(f) Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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