IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ACTAVIS LLC,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Cubist Pharmaceuticals LLC, 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 Actavis LLC ("Actavis" or "Defendant") of Abbreviated New Drug Application ("ANDA") No. 208503 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; 8,058,238; and 8,129,342.

PARTIES

2. Plaintiff Cubist Pharmaceuticals LLC ("Cubist" or "Plaintiff") is a company 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 Actavis is a Delaware company, with its principal place of business in Parsippany, New Jersey.

4. Upon information and belief, defendant Actavis engages in or collaborates in the development, manufacturing, marketing, and sale of generic copies of branded pharmaceutical

products, including daptomycin for injection. On information and belief, defendant Actavis imports, distributes, manufactures, markets, and/or sells generic versions of branded drugs in, and regularly conducts business throughout, the United States, including in 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. Actavis is subject to personal jurisdiction in Delaware because it is a Delaware company and has continuous and systematic contacts with the State of Delaware. Upon information and belief, Actavis, directly or indirectly, purposefully offers to sell, sells, markets, distributes, and/or manufactures goods, including generic pharmaceutical products, for sale in the United States and Delaware; derives substantial revenue from things used or consumed in Delaware; regularly does business and solicits business in Delaware; and has admitted, consented to, and/or not objected to jurisdiction in this Court, including, for example, in *Cephalon Inc. v. Actavis LLC*, C.A. No. 14-122-GMS (D. Del).

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. 8,058,238 ("the '238 patent"), entitled "High Purity Lipopeptides" (Exhibit C hereto), was duly and legally issued on November 15, 2011. The '238 patent, which is owned by Cubist, will expire on November 28, 2020.

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

14. CUBICIN®, or its use, is covered by one or more claims of the '967, '689, '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."

15. By letter dated November 18, 2015 (the "Notice Letter"), Defendant notified Cubist that it had submitted to the FDA ANDA No. 208503 for Daptomycin Injection (500mg), a generic version of CUBICIN® ("Actavis's ANDA Product").

16. In the Notice Letter, Defendant stated that its ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '967, '689, '238, and '342

patents and alleged that the ’967, ’689, ’238, and ’342 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Actavis’s ANDA Product.

17. On December 8, 2014, the United States District Court for the District of Delaware entered an order in *Cubist Pharmaceuticals, Inc. v. Hospira, Inc.*, C.A. No. 12-367-GMS (consolidated), which, in relevant part, held certain claims of the ’967, ’689, ’238, and ‘342 patents invalid.

18. On November 12, 2015, the United States Court of Appeals for the Federal Circuit issued an opinion in *Cubist Pharmaceuticals, Inc. v. Hospira, Inc.*, Nos. 2015-1197, 2015-1204, and 2015-1259, in which it affirmed the District Court’s decision.

19. Because Cubist believes the judgment of invalidity is incorrect, on December 14, 2015, Cubist filed a combined petition for panel rehearing and rehearing en banc in the United States Court of Appeals for the Federal Circuit, in which it requested reconsideration of certain issues in the appeal. No mandate in the appeal has issued.

20. 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

21. Plaintiff incorporates each of the preceding paragraphs 1 –20 as if fully set forth herein.

22. The use of Actavis’s ANDA Product is covered by one or more claims of the ’967 patent.

23. Defendant had knowledge of the ’967 patent when it submitted its ANDA to the FDA.

24. Defendant's submission of ANDA No. 208503 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Actavis's ANDA Product before the expiration of the '967 patent was an act of infringement of the '967 patent.

25. The commercial manufacture, use, offer for sale, sale and/or importation of Actavis's ANDA Product would infringe one or more claims of the '967 patent.

26. Upon information and belief, use of Actavis's ANDA Product in accordance with and as directed by Defendant's proposed labeling for that product would infringe one or more claims of the '967 patent.

27. Upon information and belief, Defendant intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Actavis's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208503.

28. Upon information and belief, Defendant will actively induce infringement of the '967 patent when its ANDA is approved, and plan and intends to, and will do so, immediately and imminently upon approval.

29. Upon information and belief, Defendant knows that Actavis's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '967 patent, and that Actavis's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to the infringement of the '967 patent immediately and imminently upon approval of ANDA No. 208503.

30. The foregoing actions by Defendant 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.

31. Upon information and belief, Defendant 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.

32. Unless Defendant 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

33. Plaintiff incorporates each of the preceding paragraphs 1 – 32 as if fully set forth herein.

34. The use of Actavis’s ANDA Product is covered by one or more claims of the ’689 patent.

35. Defendant had knowledge of the ’689 patent when it submitted its ANDA to the FDA.

36. Defendant’s submission of ANDA No. 208503 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Actavis’s ANDA Product before the expiration of the ’689 patent was an act of infringement of the ’689 patent.

37. The commercial manufacture, use, offer for sale, sale and/or importation of Actavis’s ANDA Product would infringe one or more claims of the ’689 patent.

38. Upon information and belief, use of Actavis's ANDA Product in accordance with and as directed by Defendant's proposed labeling for that product would infringe one or more claims of the '689 patent.

39. Upon information and belief, Defendant intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Actavis's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208503.

40. Upon information and belief, Defendant will actively induce infringement of the '689 patent when its ANDA is approved, and plans and intends to, and will do so, immediately and imminently upon approval.

41. Upon information and belief, Defendant knows that Actavis's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '689 patent, and that Actavis's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to the infringement of the '689 patent immediately and imminently upon approval of ANDA No. 208503.

42. The foregoing actions by Defendant 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.

43. Upon information and belief, Defendant 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.

44. Unless Defendant 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. 8,058,238

45. Plaintiff incorporates each of the preceding paragraphs 1 – 44 as if fully set forth herein.

46. Actavis’s ANDA Product is covered by one or more claims of the ’238 patent.

47. Defendant’s submission of ANDA No. 208503 for the purpose of the obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Actavis’s ANDA Product before the expiration of the ’238 patent was an act of infringement of the ’238 patent.

48. The commercial manufacture, use, offer for sale, sale and/or importation of Actavis’s ANDA Product would infringe one or more claims of the ’238 patent.

49. Upon information and belief, Defendant intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Actavis’s ANDA Product immediately and imminently upon approval of ANDA No. 208503.

50. The foregoing actions by Defendant constitute and/or would constitute infringement of the ’238 patent.

51. Unless Defendant is enjoined from infringing the ’238 patent, Cubist will suffer irreparable injury. Cubist has no adequate remedy at law.

COUNT IV
Infringement of U.S. Patent No. 8,129,342

52. Plaintiff incorporates each of the preceding paragraphs 1 – 51 as if fully set forth herein.

53. Actavis's ANDA Product is covered by one or more claims of the '342 patent.

54. Defendant's submission of ANDA No. 208503 for the purpose of the obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Actavis's ANDA Product before the expiration of the '342 patent was an act of infringement of the '342 patent.

55. The commercial manufacture, use, offer for sale, sale and/or importation of Actavis's ANDA Product would infringe one or more claims of the '342 patent.

56. Upon information and belief, Defendant intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Actavis's ANDA Product immediately and imminently upon approval of ANDA No. 208503.

57. The foregoing actions by Defendant constitute and/or would constitute infringement of the '342 patent.

58. Unless Defendant are 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 Defendant's submission of ANDA No. 208503 was an act of infringement of the '967, '689, '238, and '342 patents, and that Defendant's manufacture, use, offer to sell, sale, or importation of Actavis's ANDA Product prior to the expiration of the '967,

'689, '238, and '342 patents, will infringe, actively induce infringement, and/or contribute to the infringement of the '967, '689, '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 Actavis's ANDA No. 208503, or any product or compound that infringes the '967, '689, '238, and '342 patents, shall not be earlier than the expiration of the '967, '689, '238 and '342 patents;

(c) An Order permanently enjoining Defendant, and its affiliates and subsidiaries, and each of its officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Actavis's ANDA Product, or any product or compound that infringes the '967, '689, '238, and '342 patents, or inducing or contributing to the infringement of the '967, '689, '238, and '342 patents until after the expiration of the '967, '689, '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) Plaintiff's reasonable costs of suit incurred; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiff
Cubist Pharmaceuticals LLC

OF COUNSEL:

William F. Lee
Lisa J. Pirozzolo
Emily Whelan
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

December 29, 2015