IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
CRANE PHARMACEUTICALS 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 Crane Pharmaceuticals LLC ("Crane" or "Defendant") of Abbreviated New Drug Application ("ANDA") No. 206005 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.

3. Upon information and belief, defendant Crane is a company organized and existing under the laws of the State of Delaware.

4. Upon information and belief, following any FDA approval of ANDA No. 206005, defendant Crane will make, use, offer to sell, and/or sell the generic products that are the

subject of ANDA No. 206005 throughout the United States, including in the State of Delaware, and/or import such generic products into the United States.

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. Crane is subject to personal jurisdiction in Delaware because it is a Delaware company and has continuous and systematic contacts with the State of Delaware. Moreover, Crane has committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Cubist, a Delaware corporation, which sells CUBICIN® throughout the United States, including 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. 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 December 29, 2015 (the "Notice Letter"), Defendant notified Cubist that it had submitted to the FDA ANDA No. 206005 for daptomycin injectable, IV (infusion), 500 mg/vial, a generic version of CUBICIN® ("Crane'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 Crane'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 (the "Federal Circuit") issued an opinion in *Cubist Pharmaceuticals, Inc. v. Hospira, Inc.*, Nos. 2015-1197, 2015-1204, and 2015-1259, affirming the District Court's decision. On December 14, 2015, Cubist filed a combined petition for panel rehearing and rehearing en banc in the Federal Circuit, in which it requested reconsideration of certain issues in the appeal. On January 22, 2016, the Federal Circuit denied Cubist's petition for rehearing, and on January 29, 2016, the Federal Circuit issued a mandate in this appeal.

19. Because Cubist believes the judgment of invalidity is incorrect, Cubist intends to petition the Supreme Court of the United States for a writ of certiorari to review the judgment of the Federal Circuit in this case.

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 Crane'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. 206005 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Crane’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 Crane’s ANDA Product would infringe one or more claims of the ’967 patent.

26. Upon information and belief, use of Crane’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 Crane’s ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 206005.

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 Crane’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’967 patent, and that Crane’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. 206005.

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