IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
FRESENIUS KABI USA, LLC,	)	
	)	
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 Defendant Fresenius Kabi USA, LLC's filing of Abbreviated New Drug Application ("ANDA") No. 206077 seeking approval from the U.S. Food and Drug Administration ("FDA") 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, Inc. 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 Fresenius is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

4. Upon information and belief, defendant Fresenius 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 Fresenius imports, distributes, manufactures, markets, and/or sells generic versions of branded drugs in, and regularly conduct 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. Defendant Fresenius is subject to personal jurisdiction in Delaware because it is a Delaware corporation and has continuous and systematic contacts with the State of Delaware. Upon information and belief, Fresenius, 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; and regularly does business and solicits business in Delaware. Fresenius has also repeatedly and purposely availed itself of this forum by filing numerous complaints in this Court over the past two years.

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 May 29, 2014 (the "Notice Letter"), Fresenius notified Cubist that it had submitted ANDA No. 206077 to the FDA for Daptomycin for Injection, 500mg/vial, a generic version of CUBICIN® ("Fresenius's ANDA Product").

16. In the Notice Letter, Fresenius 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 Fresenius’s ANDA Product.

17. 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

18. Plaintiff incorporates each of the proceeding paragraphs 1–17 as if fully set forth herein.

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

20. Fresenius had knowledge of the ’967 patent when it submitted its ANDA to the FDA.

21. Fresenius’s submission of ANDA No. 206077 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Fresenius’s ANDA Product before the expiration of the ’967 patent is an act of infringement of the ’967 patent.

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

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

24. Upon information and belief, Fresenius intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Fresenius's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 206077.

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

26. Upon information and belief, Fresenius knows that Fresenius's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '967 patent, and that Fresenius's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius plans and intends to, and will, contribute to the infringement of the '967 patent immediately and imminently upon approval of ANDA No. 206077.

27. The foregoing actions by Fresenius constitute and/or would constitute infringement of the '967 patent, active inducement of infringement of the '967 patent, and/or contributory infringement of the '967 patent.

28. Upon information and belief, Fresenius 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 of the '967 patent.

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