IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 14-914-GMS
	)	
FRESENIUS KABI USA, LLC,	)	
	)	
Defendant.	)	

DEFENDANT FRESENIUS KABI USA, LLC'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Defendant Fresenius Kabi USA, LLC ("Fresenius"), by its attorneys, hereby responds to the allegations of Plaintiff Cubist Pharmaceuticals, Inc. ("Cubist") (D.I. 1) 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.

ANSWER:

Fresenius admits that the Complaint contains averments of patent infringement that arise under the patent laws of the United States, but denies that those averments have merit. Fresenius further admits that it has filed ANDA No. 206077 with the FDA seeking approval to manufacture and sell Daptomycin Intravenous Injection, 500 mg prior to the expiration of U.S.

Patent Nos. 6,468,967, 6,852,689, 8,058,238, and 8,129,342. To the extent that there are further averments in paragraph 1 not addressed by the foregoing, Fresenius denies them.

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.

ANSWER:

Upon information and belief, Fresenius admits that Cubist is registered as a Delaware corporation, and has a principal place of business at 65 Hayden Avenue, Lexington, Massachusetts. Fresenius is without information sufficient to form a belief as to the truth of the remaining averments in paragraph 2 and therefore denies them.

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.

ANSWER:

Admitted.

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 conducts business throughout, the United States, including in Delaware.

ANSWER:

Fresenius admits that it filed ANDA No. 206077 for Daptomycin Intravenous Injection, 500 mg. Paragraph 4 contains legal conclusions to which no response is required. To the extent that there are further averments in paragraph 4 not addressed by the foregoing, Fresenius denies them.

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.

ANSWER:

Paragraph 5 contains conclusions of law for which no response is required. To the extent that a response is required, Fresenius admits that this court has subject matter jurisdiction based upon the statutes cited solely for claims asserted against Fresenius under 35 U.S.C. § 271(e)(2)(A).

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

ANSWER:

Paragraph 6 contains conclusions of law to which no response is required. To the extent a response is required, Fresenius does not contest venue solely for the limited purposes of this particular action.

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.

ANSWER:

Paragraph 7 contains conclusions of law for which no response is required. To the extent that a response is required, Fresenius does not contest personal jurisdiction solely for the limited purposes of this particular action. To the extent that there are further averments in paragraph 7 not addressed by the foregoing, Fresenius denies them.

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.

ANSWER:

Fresenius admits that the current, approved package insert for CUBICIN® states that it is indicated for "[c]omplicated skin and skin structure infections (cSSSI) caused by susceptible

isolates of the following Gram-positive bacteria: *Staphylococcus aureus* (including methicillin-resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* subsp. *equisimilis*, and *Enterococcus faecalis* (vancomycin-suceptible isolates only)." Fresenius further admits that the FDA label for CUBICIN® states that it is indicated for "*Staphylococcus aureus* bloodstream infections (bacteremia), including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates." To the extent that there are further averments in paragraph 8 not addressed by the foregoing, Fresenius denies them.

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

ANSWER:

Upon information and belief, admitted.

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.

ANSWER:

Fresenius admits that the '967 patent indicates on its face that it was issued on October 22, 2002, and that the '967 patent is titled "Methods for Administration of Antibiotics," but denies that the '967 patent was duly and legally issued. Fresenius also admits that what purports to be a copy of the '967 patent was attached as Exhibit A to the Complaint. Fresenius further admits that the '967 patent indicates on its face that it is assigned to Cubist Pharmaceuticals,

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