

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC., )  
)  
Plaintiff, )  
)  
v. ) C.A. No. 13-1679-GMS  
)  
STRIDES, INC. and AGILA )  
SPECIALTIES PRIVATE LIMITED, )  
)  
Defendants. )

**DEFENDANTS' STRIDES, INC.'S AND AGILA SPECIALTIES PRIVATE LIMITED'S  
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO  
PLAINTIFF'S COMPLAINT**

Defendants Strides, Inc. ("Strides") and Agila Specialties Private Limited ("Agila")  
(collectively, "Defendants") hereby respond to the complaint filed by plaintiff Cubist  
Pharmaceuticals, Inc. ("Cubist" or "Plaintiff") as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, that arises out of the filing by Defendants Strides, Inc. ("Strides") and Agila Specialties Private Limited ("Agila") (collectively, "Defendants") of Abbreviated New Drug Application ("ANDA") No. 205037 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.

**ANSWER:**

Defendants admit that the Complaint contains averments of patent infringement that arise under the patent laws of the United States, but deny that those averments have merit. Defendants further admit that they have filed ANDA No. 205037 with the 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. To the extent that there are further averments in paragraph 1 not addressed by the foregoing, Defendants deny those averments.

**THE 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.

**ANSWER:**

Upon information and belief, Defendants admit that Cubist has a place of business at 65 Hayden Avenue, Lexington, Massachusetts. Defendants are without information sufficient to form a belief as to the truth of the remaining averments in paragraph 2 and therefore deny them.

3. Upon information and belief, defendant Strides is a New Jersey corporation, with its principal place of business at 201 South Main Street, Suite #3, Lambertville, NJ 08530.

**ANSWER:**

Admitted.

4. Upon information and belief, defendant Agila is a corporation organized under the laws of India, with its principal place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore 560076 India.

**ANSWER:**

Admitted.

5. Upon information and belief, defendant Strides is the U.S. agent for defendant Agila. Upon information and belief, defendants Strides and Agila are wholly owned subsidiaries of Strides Arcolab Ltd. that act in concert with respect to collaborating in the development, manufacturing, and sale of generic copies of branded pharmaceutical products, including daptomycin for injection. On information and belief, defendants Strides and Agila import, distribute, manufacture, market, and/or sell generic versions of branded drugs in, and regularly conduct business throughout, the United States, including in Delaware.

**ANSWER:**

Defendants admit that at the time of the filing of ANDA No. 205037, Strides filed the ANDA on behalf of (alternatively, as the U.S. agent for) Agila. Paragraph 5 contains legal conclusions to which no response is required. To the extent that there are further averments in paragraph 5 not addressed by the foregoing, Defendants deny these averments.

**JURISDICTION AND VENUE**

6. 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:**

Admitted.

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

**ANSWER:**

Defendants do not contest venue by this Court in this civil action.

8. Defendants are subject to personal jurisdiction in Delaware because of their continuous and systematic contacts with Delaware. Upon information and belief, Defendants directly or indirectly purposefully offer to sell, sell, market, distribute, and/or manufacture goods, including generic pharmaceutical products, for sale in the United States and Delaware; derive substantial revenue from things used or consumed in Delaware; regularly do business and solicit business in Delaware; and have admitted, consented to, and/or not objected to jurisdiction in this Court, including, for example, in *Aventis Pharma S.A. et al. v. Strides, Inc. et al.*, C.A. No. 11-1121-GMS (D. Del.) and *Senju Pharmaceutical Co., Ltd. et al. v. Strides, Inc. et al.*, C.A. No. 13-851-SLR (D. Del.).

**ANSWER:**

Defendants do not contest personal jurisdiction by this Court in this civil action. To the extent that there are further averments in paragraph 8 not addressed by the foregoing, Defendants deny those averments.

9. Alternatively, Agila is subject to personal jurisdiction in Delaware pursuant to Fed. R. Civ. P. 4(k)(2). Agila has contacts with the United States through, among other things, its having filed an ANDA with the FDA through its agent corporation, Strides, and its importation, distribution, manufacture, marketing, and/or sale of generic versions of branded drugs in the United States.

**ANSWER:**

Defendants do not contest personal jurisdiction by this Court in this civil action. To the extent that there are further averments in paragraph 9 not addressed by the foregoing, Defendants deny those averments.

**BACKGROUND**

10. 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:**

Defendants admit that the FDA label for CUBICIN® states that it is indicated for “[c]omplexed skin and skin structure infections (cSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant isolates) *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* subsp. *equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible isolates only).” Defendants further admit 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 10 not addressed by the foregoing, Defendants deny those averments.

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