IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
STRIDES, INC. and AGILA SPECIALTIES PRIVATE LIMITED,	)	
	)	
	)	
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 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.

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.

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.

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.

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, marketing, 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.

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.

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

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.).

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.

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.

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

12. 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.

13. 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.

14. 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.

15. 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.

16. 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."

17. By letter dated August 26, 2013 (the "Notice Letter"), Defendants notified Cubist that they had submitted to the FDA ANDA No. 205037 for Daptomycin for Injection, 500mg/vial, a generic version of CUBICIN® ("Strides's ANDA Product").

18. In the Notice Letter, Defendants stated that their 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 Strides's ANDA Product.

19. 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

20. Plaintiff incorporates each of the proceeding paragraphs 1 – 19 as if fully set forth herein.

21. The use of Strides's ANDA Product is covered by one or more claims of the '967 patent.

22. Defendants had knowledge of the '967 patent when they submitted their ANDA to the FDA.

23. Defendants' submission of ANDA No. 205037 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Strides's ANDA Product before the expiration of the '967 patent is an act of infringement of the '967 patent.

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

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

26. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of Strides's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 205037.

27. Upon information and belief, Defendants will actively induce infringement of the '967 patent when their ANDA is approved, and plan and intend to, and will do so, immediately and imminently upon approval.

28. Upon information and belief, Defendants know that Strides's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '967 patent, and that Strides's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to the infringement of the '967 patent immediately and imminently upon approval of ANDA No. 205037.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.