

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.)

**STIPULATION TO NARROW ISSUES IN THE LITIGATION,
COVENANT NOT TO SUE, AND SETTLEMENT OF IPR PROCEEDINGS**

Plaintiff Cubist Pharmaceuticals, Inc. (“Plaintiff”) and Defendants Agila Specialties Inc. (f/k/a Strides, Inc.) and Agila Specialties Private Limited (collectively, “Defendants”), by their undersigned counsel, stipulate and agree as follows:

WHEREAS Defendants submitted Abbreviated New Drug Application No. 205037 (“Defendants’ ANDA”) to obtain approval from the FDA to engage in the commercial manufacture, use and/or sale of generic daptomycin injectable, IV (infusion), 500 mg/vial (“Defendants’ ANDA Product”);

WHEREAS Plaintiff represents that it owns Patent No. 6,468,967 (the “967 Patent”), Patent No. 6,852,689 (the “689 Patent”), Patent No. 8,058,238 (the “238 Patent”), and Patent No. 8,129,342 (the “342 Patent”);

WHEREAS Plaintiff represents that it holds approved New Drug Application No. 21-572 for Cubicin® injectable, IV (infusion), 500 mg/vial, which contains the active ingredient daptomycin;

WHEREAS Plaintiff has asserted in *Cubist Pharmaceuticals Inc., v. Strides, Inc. et al*, C.A. No. 13-1679-GMS (D. Del) (“this Litigation”) that the filing of Defendants’ ANDA

infringes (directly or indirectly) and/or the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product would infringe (directly or indirectly) the '967, '689, '238, and '342 Patents;

WHEREAS at issue in this Litigation is whether the filing of Defendants' ANDA infringes (directly or indirectly) and/or the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Product would infringe (directly or indirectly) claims 1-45 of the '967 Patent, claims 1-57 of the '689 Patent, claims 1-192 of the '238 Patent, or claims 1-54 of the '342 Patent;

WHEREAS at issue in this Litigation is whether claims 1-45 of the '967 Patent, claims 1-57 of the '689 Patent, claims 1-192 of the '238 Patent, or claims 1-54 of the '342 Patent are invalid;

WHEREAS Defendant Agila Specialties Inc. and Mylan Pharmaceuticals Inc. filed *inter partes* review petitions with the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (the "PTAB") challenging the validity of certain claims of the '967, '689, '238, and '342 Patents, the *inter partes* review petitions filed by Defendant Agila Specialties Inc. and Mylan Pharmaceuticals Inc. are as follows (referred to hereinafter as the "IPR Petitions"):

- IPR2015-00131: challenging the validity of claims 1-17 and 20-45 of the '967 Patent;
- IPR2015-00132: challenging the validity of claims 1-12, 14-18, 21-30, 32,33, and 36-57 of the '689 Patent;
- IPR2015-00140: challenging the validity of claims 1-54 of the '342 Patent;
- IPR2015-00141: challenging the validity of claims 1-7, 49, 52-65, 93, 108-111, 125-138, and 147-150 of the '238 Patent;
- IPR2015-00142: challenging the validity of claims 8-9, 49-51, 85-92, 105-107, 113-124, 144-146, 151-162, and 164-175 of the '238 Patent;

- IPR2015-00143: challenging the validity of claims 37-42, 48, 139-143; 66-84, 94-104, 112, and 163 of the '238 Patent; and
- IPR2015-00144: challenging the validity of claims 10-48, 139-143, and 176-192 of the '238 Patent;

WHEREAS, for the sole purpose of this stipulation and agreement, hereinafter the term “Defendants” includes Mylan Pharmaceuticals in its capacity as a co-petitioner with Agila Specialties Inc. in the filing of the IPR Petitions; and

WHEREAS Plaintiff and Defendants seek to narrow the issues in dispute in this Litigation and before the PTAB and thereby reduce the effort and judicial resources expended by the Delaware District Court and the PTAB and reduce the time and expense consumed by Plaintiff and Defendants;

Now, THEREFORE, Plaintiff and Defendants, by their undersigned counsel, hereby provide as follows:

1. Without prejudice to any claim or defense Defendants have in this Litigation, Defendants agree to request that the IPR Petitions be withdrawn or terminated by contacting the PTAB within one (1) business day of execution of the present Stipulation to request leave to file a motion to withdraw or terminate each IPR Petition and filing such motion within two (2) business days of PTAB approval to file; and Defendants further stipulate and agree not to file, maintain, join, or support another challenge to any claims of the ‘238, ‘342, ‘967, or ‘689 patents in the U.S. Patent Office;
2. Plaintiff agrees to join or not oppose the request to withdraw/terminate the IPR Petitions;
3. Defendants stipulate and agree as follows:

a. Defendants consent to the entry of a judgment finding that the commercial manufacture, use, sale, offer for sale, or importation of Defendants' ANDA Product would infringe claims 91, 98 and 187 of the '238 Patent, claims 23 and 53 of the '342 Patent, claims 16-17 and 34-35 of the '967 Patent, and claims 51-52 of the '689 Patent to the extent that such claims are not found to be unenforceable or invalid pursuant to a final and non-appealable decision.

b. Defendants consent to the entry of a judgment finding the submission of Defendants' ANDA to the FDA to have infringed claims 91, 98 and 187 of the '238 Patent, claims 23 and 53 of the '342 Patent, claims 16-17 and 34-35 of the '967 Patent, and claims 51-52 of the '689 Patent to the extent that such claims are not found to be unenforceable or invalid pursuant to a final and non-appealable decision.

4. Plaintiff stipulates and agrees to limit the asserted claims against Defendants (or their successors and/or assigns) in this Litigation to claims 91, 98 and 187 of the '238 Patent, claims 23 and 53 of the '342 Patent, claims 16-17 and 34-35 of the '967 Patent, and claims 51-52 of the '689 Patent;

5. Plaintiff covenants not to sue or otherwise hold Defendants (or their successors and assigns) liable for infringement of claims 1-15, 18-33, and 36-45 of the '967 Patent, claims 1-50 and 53-57 of the '689 Patent, claims 1-90, 92-97, 99-186, and 188-192 of the '238 Patent, and claims 1-22, 24-52, and 54 of the '342 Patent (collectively the "Unasserted Claims") based on: (1) the filing of Defendants' ANDA or (2) Defendants' manufacture, importation into the United States, sale, offer for sale and/or use of Defendants' ANDA Product.

6. Defendants stipulate and agree to dismiss from this Litigation and, with respect to Defendants' ANDA Product, not reassert in any action: (a) Defendants' Affirmative

Defenses with respect to the Unasserted Claims; (b) Defendants' Counterclaims directed to a declaratory judgment of non-infringement relating to: (1) the filing of Defendants' ANDA or (2) Defendants' manufacture, importation into the United States, sale, offer for sale and/or use of Defendants' ANDA Product; and (c) Defendants' Counterclaims directed to a declaratory judgment of invalidity of the Unasserted Claims.

7. Plaintiff and Defendants agree that the claims or defenses not specifically addressed herein are not prejudiced or otherwise affected by this stipulation and agreement.

8. Plaintiff and Defendants agree that this stipulation and agreement is binding on their respective successors and assigns.

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