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,) REDACTED -
Defendant) PUBLIC VERSION

STIPULATION AND AGREEMENT TO NARROW ISSUES IN THE LITIGATION AND IPR PROCEEDINGS AND COVENANT NOT TO SUE

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Plaintiff Cubist Pharmaceuticals, Inc. ("Plaintiff") and Defendant Fresenius Kabi USA, LLC ("Defendant"), by their undersigned counsel, stipulate and agree as follows:

WHEREAS Defendant submitted Abbreviated New Drug Application No. 206077 (together with any amendments or supplements thereto, "Defendant's ANDA") to obtain approval from the FDA to engage in the commercial manufacture, use and/or sale of the generic daptomycin injectable product described therein ("Defendant's 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. 21572 for CUBICIN® injectable, IV (infusion), 500 mg/vial, which contains the active ingredient daptomycin;

WHEREAS Plaintiff has asserted in *Cubist Pharmaceuticals, Inc.*, v. Fresenius Kabi USA, LLC, C.A. No. 14-914-GMS (D. Del.) ("this Litigation") that the filing of Defendant's ANDA infringes (directly or indirectly) and/or the commercial manufacture, use, offer for sale,



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

WHEREAS at issue in this Litigation is whether the asserted claims of the '967, '689, '238, and '342 Patents are invalid;

WHEREAS Defendant 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 are as follows (referred to hereinafter as the "IPR Petitions"):

- IPR2015-00227: challenging the validity of claims 1-7, 12-28, and 32-45 of the '967 Patent;
- IPR2015-00223: challenging the validity of claims 1-5 and 10-57 of the '689 Patent;
- IPR2015- 01566: challenging the validity of claims 1-54 of the '342 Patent;
- IPR2015-01570: challenging the validity of claims 3-7, 21-25, 27-33, 35-44, 48-52, 61-63, 66, 85, 87-89, 92-109, 113, 115-121, 123-151, 153-159, 161-162, 164-167, 175-184, and 189-190 of the '238 Patent;
- IPR2015-01571: challenging the validity of claims 1-19, 21-44, 48-51, 53, 92-107, 112-146, 151-167, 176-177, 179, and 183-189 of the '238 Patent; and
- IPR2015-01572: challenging the validity of claims 20, 45-47, 49-52, 54-91, 108-111, 147-150, 168-175, 182-183, and 190-192 of the '238 Patent; and



WHEREAS Plaintiff and Defendant 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 Defendant;

Now, THEREFORE, Plaintiff and Defendant, by their undersigned counsel, subject to the approval of the Court, hereby provide as follows:









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