UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS DEUTSCHLAND GMBH, and SANOFI WINTHROP INDUSTRIE, Plaintiffs, v. MYLAN N.V., MYLAN GMBH, MYLAN INC., and MYLAN PHARMACEUTICALS INC., Defendants.	Civ. No. 2:17-09105 (SRC-CLW)

JOINT PROPOSED DISCOVERY PLAN

Pursuant to Federal Rule of Civil Procedure 26(f), Local Civil Rule 26.1(b), and this Court's Order dated November 14, 2017 (ECF No. 13), Plaintiffs Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie (collectively, "Plaintiffs" or "Sanofi") and Defendants Mylan N.V., Mylan GmbH, Mylan Inc., and Mylan Pharmaceuticals Inc. (collectively, "Defendants")[1], by their undersigned attorneys, present the following Joint Discovery Plan to the Court.

1. Set forth the name of each attorney appearing, the firm name, address and telephone number and facsimile number of each, designating the party represented.

For Plaintiffs:

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[1] In compliance with the Court-ordered schedule, Defendants intend to participate in the Rule 16 Conference subject to and without waiver of their pending motion to dismiss for improper venue and lack of subject matter jurisdiction. Plaintiffs dispute the issues presented in Defendants' motion to dismiss and believe that venue in this Court is proper and that Defendants' motion should be denied in full, as will be set forth in Sanofi's forthcoming opposition brief.

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2. Set forth a brief description of the case, including the causes of action and affirmative defenses asserted.

Sanofi's Response:

This is a Hatch-Waxman action involving Sanofi's insulin glargine (rDNA origin) vial and pen injectable drug products, which are prescribed and sold in the United States under the trademarks Lantus® and Lantus® SoloSTAR®, respectively. Both products are indicated for the treatment of adults with type 2 diabetes and adults and pediatric patients (children 6 years and older) with type 1 diabetes for the control of high blood sugar. Sanofi alleges that Defendants have infringed one or more claims of U.S. Patent Nos. 7,476,652, 7,713,930, 7,918,833, 8,512,297, 8,556,864, 8,603,044, 8,679,069, 8,992,486, 9,011,391, 9,233,211, 9,408,979, 9,526,844, 9,533,105, 9,561,331, 9,604,008, 9,604,009, 9,610,409, and 9,623,189 (collectively the "patents-in-suit") by submitting Section 505(b)(2) New Drug Application No. 210605 to market follow-on versions of Sanofi's Lantus® vial product and Lantus® SoloSTAR® pen

injectable drug product prior to the expiration of the patents-in-suit. The "FDA mandated 30-month stay" in this action expires on March 18, 2020.

Sanofi seeks entry of judgment holding that Mylan has infringed the patents-in-suit, and among other things, the entry of an order pursuant to 35 U.S.C. 271(e)(4)(A), declaring that the effective date of any approval of Mylan's NDA No. 210605 shall be a date that is not earlier than the last date of the expiration of any of the patents-in-suit or any additional period of exclusivity to which Plaintiffs and/or the patents-in-suit are, or become, entitled.

Mylan has filed a motion to dismiss Sanofi's complaint for alleged improper venue, lack of subject matter jurisdiction, and failure to state a claim against the three Mylan entities that are not identified on Mylan's Notice Letter (Mylan NV, Mylan Inc., and Mylan Pharmaceuticals Inc.) leaving only Mylan GmbH, which Mylan agrees is a proper defendant (but contests venue for this entity).

Sanofi maintains that venue is proper and that each of the named Mylan entities is a proper defendant in this case. Notwithstanding Sanofi's position, in an effort to avoid undue motion practice and continue to move this case forward on the merits, Sanofi proposed a stipulation that would dismiss the non-Mylan GmbH entities in exchange for Mylan withdrawing its Motion to Dismiss and consenting to venue in New Jersey as to the Mylan GmbH entity. Sanofi's proposed stipulation would also require that the terminated Mylan entities cooperate in discovery and be bound by any relief issued by this Court as if they were named defendants. There would be no dispute as to proper defendants or subject matter jurisdiction of Sanofi's declaratory judgment claims, as the stipulation proposed by Sanofi would obviate those issues. Sanofi's proposed stipulation would thus serve to quickly resolve Mylan's motion and thereby expedite these proceedings. Mylan never responded to Sanofi's proposed stipulation.

Separately, in an effort to resolve the factual disputes presented in Mylan's Motion, Sanofi requested that Mylan consent to limited, expedited discovery on the issues raised therein while proceeding with discovery on the merits of the case in parallel, but Mylan refused to provide any such discovery. Accordingly, in Sanofi's response to Mylan's motion to dismiss, Sanofi intends to request this limited discovery in the event that the Court does not deny Mylan's motion outright. Permitting limited discovery is common practice in venue disputes post *TC-Heartland*, and Sanofi's requests will be narrowly tailored and specifically targeted at the factual issues raised by Mylan in its motion and declaration, namely, (i) Mylan's presence in New Jersey, (ii) the interconnectedness of the Mylan entities, and (iii) the proper defendants in this case. Sanofi's request will thus help the Court resolve the issues in dispute.

Sanofi has also commenced a second-filed "protective" suit against the same Mylan entities asserting the same patents and causes of action in the United States District Court for the Northern District of West Virginia. *Sanofi-Aventis U.S. LLC, et al. v. Mylan N.V., et al.*, No. 1:17-cv-00181 (N.D.W. Va.) ("West Virginia Action"). Sanofi filed the West Virginia Action because Sanofi had correctly anticipated that Mylan would move to dismiss this New Jersey action based on venue grounds. In particular, because FDA regulations provide that the aforementioned 30-month stay is lost if the corresponding patent action is dismissed, in the event that Mylan's motion to dismiss is successful, the 30-month stay would otherwise be lifted absent the existence of the second-filed West Virginia Action. *See* 21 C.F.R. § 314.107 (2016). Second-filed "protective" suits like the West Virginia Action are thus common in Hatch-Waxman litigation particularly again Mylan.

Sanofi has moved to stay the West Virginia Action to avoid duplicative parallel litigation, and Mylan has opposed a stay, arguing this Court will not resolve the litigation within the 30-month stay period (expiring no later than March 18, 2020). *See* Exhibit B, Mylan Opp. to Mtn. to

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