IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

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.	Civil Action No. 1:17-CV-181-IMK

INITIAL PLANNING MEETING REPORT AND DISCOVERY PROPOSALS

I. INITIAL PLANNING MEETING

Pursuant to Fed. R. Civ. P. 16 and 26(f), Local Rule 16.01(b) and (c), and the Court's December 13, 2017 Order Granting Defendants' Motion for Expedited Scheduling Conference [Dkt. No. 45] and Motion to Expedite [Dkt. No. 46] (Dkt. No. 60) ("Order"), the parties, by and through their undersigned counsel, jointly submit this report of the parties' initial planning meeting, which was held by telephone on December 18, 2017. The following persons participated in the initial planning teleconference:

- Attorneys from Simmerman Law Office, PLLC and Weil, Gotshal & Manges LLP participated on behalf of Plaintiffs Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie (collectively, "Plaintiffs" or "Sanofi"); and
- Attorneys from Robinson & McElwee PLLC and Wilson Sonsini Goodrich & Rosati P.C. participated on behalf of Defendants Mylan N.V., Mylan GmbH, Mylan Inc., and Mylan Pharmaceutical Inc. (collectively, "Defendants").

The parties attach, for the Court's consideration, a chart summarizing the parties' respective scheduling proposals for this action (Exhibit A). Pursuant to the Court's Order, a scheduling conference is set for January 3, 2018.

Sanofi's Statement:

A. Introduction

This is a second-filed "protective" Hatch-Waxman action in which Sanofi asserts 18 patents against Mylan. Sanofi's identical first-filed action is proceeding in the District Court for the District of New Jersey—Sanofi's state of incorporation. *See Sanofi-Aventis U.S. LLC, et al. v. Mylan N.V., et al.*, No. 2:17-09105 (SRC-CLW) (the "New Jersey Action"). This second-filed "protective" suit names the same Mylan entities and asserts the same patents and causes of action as the New Jersey Action. To avoid duplicative, parallel litigation, Sanofi has moved to stay[1] this second-filed action in view of its first-filed New Jersey Action, which is already well underway. Indeed, discovery is open, and the parties participated in the Rule 16 conference in New Jersey on December 19, where the magistrate judge adopted a schedule for the New Jersey Action and expressly acknowledged the date of expiration of the 30-month stay and its importance to the case. Moreover, two of the patents at issue in this case have also been asserted by Sanofi against Merck in the District of New Jersey, and thus, coordinating claim construction will be more efficient in New Jersey rather than here. *See Sanofi-Aventis U.S. LLC, et al. v. Merck Sharp & Dohme Corp.*, No. 2:17-cv-05914 (D.N.J.). In fact, the magistrate judge in the New Jersey Action has already ordered briefing deadlines for claim construction that will allow for a consolidated claim construction hearing in both cases. Because the New Jersey cases will likely have common issues of claim construction and validity, judicial economy will be better

[1] Mylan has responded to Sanofi's motion, Sanofi has replied, and thus, Sanofi's motion is ripe for resolution.

served through adjudication in New Jersey, as a stay will avoid the obvious risk of inconsistent rulings here. In summary, Sanofi maintains that this case should be stayed in view of (i) its preference to proceed in its home state of New Jersey, (ii) the overlapping legal issues pending in the Merck litigation in New Jersey, and (iii) to avoid the waste of judicial and party resources from litigating both cases at the same time.

B. Case Overview

By way of background, both cases involve 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 in both cases 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 in both cases, 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.

C. Motion to Stay

Sanofi filed this second action because Sanofi had correctly anticipated that Mylan would move to dismiss the New Jersey Action based on venue grounds.[2] 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 this second-filed case. *See* 21 C.F.R. § 314.107 (2016). Second-filed "protective" suits like this action are thus common in Hatch-Waxman litigation, particularly against Mylan. Stays of second-filed suits are likewise common in suits against Mylan in this District. *See, e.g.*, D.I. 42 at 4 n. 2 (listing stayed cases involving Mylan).

But Mylan has opposed a stay, contending that the New Jersey Court will not resolve the litigation within the 30-month stay period (expiring no later than March 18, 2020). As explained in Sanofi's reply brief, however, the New Jersey Court is well-equipped to adjudicate the case in the timeframe of the 30-month stay, and the New Jersey Action has already progressed further than this case. Indeed, as mentioned above, at the Rule 16 conference in the New Jersey Action, the magistrate judge emphasized the District's extensive experience with Hatch-Waxman cases and the importance of the date of expiration of the 30-month stay. Mylan cites statistics concerning the average time to trial in New Jersey and West Virginia, but those are for *all* civil cases, not Hatch-Waxman cases subject to the 30-month stay. Indeed, Judge Chesler—the presiding Judge over the New Jersey Action—has presided over fifty Hatch-Waxman cases and has been instrumental in the development of rules to timely adjudicate Hatch-Waxman cases within the 30-month stay time period.

[2] Plaintiffs dispute the issues presented in Defendants' motion to dismiss and believe that venue in New Jersey is proper and that Defendants' motion should be denied in full.

Mylan also opposes the stay because Mylan believes it will be prejudiced if it does not obtain final FDA approval prior to March 23, 2020, which is the "transition date" on which the FDA will begin to apply new approval procedures for insulin glargine drug products.[3] But as Sanofi explained in its reply, the 30-month stay expires no later than March 18, 2020, in advance of the "transition date," so this patent litigation will thus not preclude FDA final approval prior to the transition date. Indeed, nothing prevents Mylan from working with the FDA now (while the stay is pending) on any regulatory issues to ensure timely final approval of its application prior to the transition date. Assuming that Mylan is diligent in doing so, as of the expiration of the stay (prior to the transition date), there will be no patent barriers to FDA approval. In short, there are regulatory steps that Mylan can and should take while the stay is pending to ensure timely approval of its NDA irrespective of this lawsuit or any patent barriers.

D. Related Litigation

Sanofi further advises the Court that claim terms of certain of the patents-in-suit have been construed in two orders from Plaintiffs' prior suit against Eli Lilly & Company in the District of Delaware. *See Sanofi-Aventis U.S. LLC v. Eli Lilly & Co.*, No. 14-113-RGA-MPT, 2015 U.S. Dist. LEXIS 5946 (D. Del. Jan 20, 2015); *id.* at 2015 U.S. Dist. LEXIS 57877 (D. Del. Apr. 27, 2015). Claim terms of certain of the patents-in-suit are also anticipated to be construed in Plaintiffs' current suit against Merck Sharp & Dohme Corp. ("Merck") in the District of Delaware where claim construction briefing has been completed and a *Markman* hearing was conducted on November 6, 2017, *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 16-812-RGA-MPT (D. Del.). And as mentioned above, Sanofi anticipates that claim terms will be construed for two of the patents-in-suit in the Merck litigation pending in the District of New

[3] The new procedures were established by the Biologics Price Competition and Innovation Act ("BPCIA").

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