

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. // CIVIL ACTION NO. 1:17CV181
(Judge Keeley)

MYLAN N.V., MYLAN GMBH,
MYLAN INC., and MYLAN
PHARMACEUTICALS INC.,

Defendants.

ORDER GRANTING DEFENDANTS' MOTION FOR EXPEDITED SCHEDULING
CONFERENCE [DKT. NO. 45] AND MOTION TO EXPEDITE [DKT. NO. 46]

The plaintiffs, Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie (collectively, "Sanofi"), commenced this second-filed Hatch-Waxman case on October 26, 2017, by filing a complaint against the defendants, Mylan N.V., Mylan GmbH, Mylan Inc., and Mylan Pharmaceuticals Inc. (collectively, "Mylan") (Dkt. No. 1). On November 1, 2017, the Court entered its First Order and Notice Regarding Discovery and Scheduling ("First Order"), setting a scheduling conference in this case for January 23, 2018 (Dkt. No. 21).

On November 22, 2017, however, Mylan moved for an expedited "scheduling conference for January 3, 2018 or at the Court's earliest convenience" (Dkt. No. 45). In support, Mylan avers that, on March 23, 2020, the insulin product at issue in this case will transition from being subject to approval under the Hatch-Waxman

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Act to being subject to approval under the Biologics Price Competition and Innovation Act ("BPCIA"). Id. at 1. If an Abbreviated New Drug Application ("ANDA") for a biological product is not approved by this date, the Food and Drug Administration ("FDA") will not approve the ANDA. The applicant will instead be required to seek approval under the BPCIA regulatory approval process (Dkt. No. 45-1 at 8). Accordingly, Mylan insists that an accelerated schedule is necessary "to obtain final regulatory approval before March 23, 2020" (Dkt. No. 45 at 2).

Sanofi opposes Mylan's motion, asserting that "the BPCIA transition date is irrelevant to this case because the 30-month stay will expire prior to the BPCIA transition date." Given that "the FDA will have full authority to approve the pending drug application prior to the transition date," Sanofi contends that "this lawsuit presents no impediment to FDA approval" (Dkt. No. 57 at 2). Despite its opposition, Sanofi notes that it will defer "to the Court's schedule and availability, as Sanofi will be prepared to participate in a scheduling conference whenever the Court deems appropriate." Id.

After reviewing the parties' arguments, and without otherwise deciding how the BPCIA transition date should affect the schedule

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or posture of this case,¹ the Court finds that good cause supports Mylan's request for an expedited scheduling conference. An expedited scheduling conference will permit the Court to hear argument on Sanofi's motion to stay and determine at the earliest possible time whether the looming BPCIA transition date affects this litigation. Therefore, the Court **GRANTS** Mylan's Motion Requesting an Expedited Scheduling Conference (Dkt. No. 45), as well as its Motion to Expedite Defendants' Motion Requesting an Expedited Scheduling Conference (Dkt. No. 46).

The Court thus **AMENDS** the dates and deadlines set forth in its First Order as follows:

INITIAL PLANNING MEETING:	December 18, 2017
REPORT FILING DATE:	December 22, 2017
SCHEDULING CONFERENCE DATE:	January 3, 2018
SCHEDULING CONFERENCE TIME:	10:00 A.M.
INITIAL DISCOVERY DISCLOSURES DUE DATE:	January 10, 2018

1. **INITIAL PLANNING MEETING:** Pursuant to Fed. R. Civ. P. 16 and 26(f) and LR 16.01(b), parties to this action shall meet in person or by telephone on or before **December 18, 2017**. At this

¹ The BPCIA transition date may also affect the resolution of Sanofi's pending motion to stay this case in favor of the first-filed case in the District of New Jersey (Dkt. No. 41).

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meeting, they shall discuss all matters required by Fed. R. Civ. P. 16 and 26(f) and LR 16.01(b). The parties shall also consider the benefits of early mediation and advise in their report whether they wish the Court to schedule the matter for early mediation.

2. **MEETING REPORT AND PROPOSED DISCOVERY PLAN**: Pursuant to Fed. R. Civ. P. 26(f) and LR 16.01(c), the parties shall submit a written report on the results of the initial discovery meeting on or before **December 22, 2017**. This report shall include the parties' report on those matters set forth in LR 16.01(b) and (c) and the parties' discovery plan as required by Fed. R. Civ. P. 26(f). The parties' report on their meeting shall be considered by this Court as advisory only. Parties and counsel are subject to sanctions as set forth in LR 37.01 for failure to participate in good faith in the development and submission of a meeting report and proposed discovery plan.

3. **SCHEDULING CONFERENCE/SCHEDULING ORDER**: Upon receipt of the meeting report and proposed discovery plan, the undersigned District Judge **WILL CONDUCT** a scheduling conference on **January 3, 2018, at 10:00 A.M.**, in the Clarksburg District Courtroom, Second Floor. See Fed. R. Civ. P. 16(b) and LR 16.01(d). (Please note that the Court conducts scheduling conferences in all cases.) The

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scheduling conference may be by telephone. If counsel elect to proceed by telephone, the Court directs lead counsel for the plaintiff to arrange the conference call and provide dial-in information to all parties and the Court, by email to **candace_levitsky@wvnd.uscourts.gov**, no later than **December 27, 2017**. If counsel elect to appear in person, counsel shall notify the Court, by email to **candace_levitsky@wvnd.uscourts.gov**, no later than **December 27, 2017**. The Court notifies the parties that any pending motions in the case that are fully briefed **WILL BE ADDRESSED** at the scheduling conference.

4. **INITIAL DISCOVERY DISCLOSURES**: Pursuant to LR 26.01(a), each party shall provide to every other party the initial discovery disclosures required under Fed. R. Civ. P. 26(a)(1) on or before **January 10, 2018**.

The Court directs the Clerk to transmit copies of this Order to counsel of record.

DATED: December 13, 2017.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE