

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND  
HUMAN SERVICES, *et al.*,

Defendants.

No. 3:21-CV-634

**JOINT SCHEDULING MOTION**

The parties in the above-captioned action have conferred and respectfully request that the Court hold in abeyance the motion for a preliminary injunction filed by Plaintiff Sanofi-Aventis U.S. LLC (“Sanofi”), *see* Dkt. 19, and enter a stipulated schedule changing the default response date for Defendants’ response to Plaintiff’s complaint and setting hearing and briefing dates for further motions to resolve this action.

On February 2, 2021, Sanofi amended its complaint to challenge the Department of Health & Human Services’ (“HHS”) Administrative Dispute Resolution (“ADR”) Rule and moved for a preliminary injunction seeking to enjoin the ADR Rule’s enforcement. *See* Dkts. 17, 19. On Friday, March 12, 2021, the Court canceled the oral argument that had been scheduled for March 19, 2021, and indicated that the “motion will be decided on the papers and an opinion will soon follow.” *See* ECF No. 45.

On March 16, 2021, a district court in the Southern District of Indiana entered an order granting Eli Lilly’s motion to preliminarily enjoin the ADR Rule as to Eli Lilly. *See* Dkt. 81, Order Granting Plaintiffs’ Motion for Preliminary Injunction; Dkt. 82, Preliminary Injunction, *Eli Lilly &*

*Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Mar. 16, 2021).

On March 17, 2021, this Court directed the parties via email to file supplemental briefing related to Count IV of Plaintiff's Amended Complaint, *see* ECF No. 17 at ¶¶ 102-09, which alleges that Defendants' ADR Rule failed to comply with the Administrative Procedure Act ("APA"), and also to address the reasoning set forth in the order granting a preliminary injunction of that same rule by the *Eli Lilly* court. Plaintiff's supplemental brief is due March 26, 2021, and Defendants' supplemental brief is due April 5, 2021. Meanwhile, Defendants' responsive pleading currently is due Monday, March 22, 2021.

Sanofi requests that, in light of the parties' agreement to brief the merits of Sanofi's claims in an expedited fashion and the *Eli Lilly* decision, the Court hold in abeyance its motion for a preliminary injunction pending notification from Sanofi that a ruling on that motion is necessary. Sanofi expressly reserves the right to request that the Court rule on its motion for a preliminary injunction, should it prove necessary in light of developments with regard to any ADR proceeding against Sanofi. In light of Sanofi's request, the parties request that the Court vacate the March 17, 2021 supplemental briefing order to allow the parties to address the *Eli Lilly* decision in their forthcoming dispositive motions.

Plaintiff's complaint includes constitutional challenges and claims under the APA regarding two discrete issuances of the U.S. Department of Health and Human Services ("HHS"). As such, the parties agree that Plaintiff's claims should be decided on the basis of administrative records produced by the agency, and that this action most efficiently can be decided through cross-motions presenting pure questions of law. To that end, the agency has been working diligently to produce the administrative records to Plaintiff in advance of filing Defendants' forthcoming motion to dismiss or, in the alternative, for summary judgment. Accordingly, the parties have conferred and respectfully request that the Court adopt the following schedule for additional proceedings in this

case:

- Defendants will produce the administrative record of HHS's General Counsel's Advisory Opinion on **March 23, 2021**
- Defendants will produce the administrative record of HHS's newly promulgated Administrative Dispute Resolution rule on **April 6, 2021**
- Defendants will move to dismiss for lack of subject-matter jurisdiction and failure to state a claim or, in the alternative, for summary judgment on **April 19, 2021**
- Plaintiff will oppose Defendants' motion to dismiss and cross-move for summary judgment on **May 10, 2021**
- Defendants will reply in support of their motion to dismiss and oppose Plaintiffs' cross-motion for summary judgment on **May 31, 2021**
- Plaintiff will reply in support of its motion for summary judgment on **June 14, 2021**
- Hearing on the parties' motions to be held **June 21, 2021**, or at the Court's soonest availability thereafter.

The parties respectfully suggest that this schedule will enable them fully to develop and present argument for the Court in the most efficient manner possible on the complex constitutional and administrative-law issues raised by Plaintiff's complaint. To that end, the parties request two additional, slight modifications to this Court's Local Rules.

First, considering the number and complexity of Plaintiff's claims, the parties believe that additional pages are required adequately to address the issues presented. The parties thus request that the Court allow each side 60 pages in 12-point, non-proportional font (80 pages in 14-point font) for their opening briefs, and 30 pages in 12-point, non-proportional font (40 pages in 14-point font) for their reply briefs. Second, because this case presents claims which should be decided as questions of law on the basis of the administrative record produced by the agency, the parties respectfully request that they be excused from providing a statement of material facts not in dispute, *see* Local Civ. Rule 56.1, on the ground that there are no disputed material facts.<sup>1</sup> Instead,

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<sup>1</sup> While the parties do not anticipate disputed factual issues, Sanofi reserves its rights because it has not yet received the administrative records for the Advisory Opinion or the ADR Rule.

Defendants will provide the Court with the full administrative records, and the parties will cite in their briefs to those portions of the administrative record on which they rely.

The parties appreciate the Court's consideration and respectfully request entry of the attached proposed order.

Dated: March 21, 2021

Respectfully submitted,

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/s/ Kate Talmor

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