UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Civil Action No. 3:21-cv-634

PLAINTIFF'S REPLY IN SUPPORT OF EMERGENCY MOTION FOR A STAY PENDING RESOLUTION OF THE DISPOSITIVE MOTIONS

The government's attempt to fault Sanofi for seeking emergency relief is revisionist history. The government joined a motion to hold in abeyance Sanofi's motion to preliminarily enjoin the Administrative Dispute Resolution ("ADR") Rule after the court in Lilly's case granted identical relief—which eliminated the need for this Court to rule at that time. ECF 46. The government's now-public emails validate Sanofi's understanding that the Lilly preliminary injunction would prevent HRSA from moving forward with NACHC's joint ADR petition against Sanofi, Lilly, and AstraZeneca. ECF 101-3, at 75. But then, in August, the government offered *ex parte* instructions to NACHC on how to file a new ADR petition against Sanofi to circumvent that preliminary injunction—which has now resulted in Sanofi facing, for the first time, an impending deadline to respond to an ADR petition. *Id.* The government trumpets that this is Sanofi's third request for emergency relief, but that

merely reflects the government's repeated disregard for the judicial process despite the Lilly injunction and now-fully briefed dispositive motions in this and other courts regarding the ADR Rule's validity as well as manufacturers' rights and obligations under Section 340B.

The government's procedural objections to Sanofi's stay motion do not withstand scrutiny. First, the government tries to fault Sanofi for having "sat on the sidelines for months." ECF 103, at 5. But the government's emails confirm that Sanofi was correct to ask the Court to hold its motion for a preliminary injunction in abeyance. After the Lilly court granted identical relief, Sanofi's irreparable harm was no longer as imminent, and Sanofi—which was the defendant in just one ADR petition, which also named Lilly—did not want to ask the Court to rule on important constitutional questions unless necessary. *See Hassan v. City of New York*, 804 F.3d 277, 301 & n.12 (3d Cir. 2015) (constitutional questions should not be addressed absent "necessity" (quotation omitted)). Sanofi thus asked the Court to hold its preliminary injunction motion in abeyance, because Sanofi believed that the preliminary injunction in Lilly's case would prevent the government from adjudicating the joint petition. ECF 46, at 1–2. Indeed, the parties filed a *joint* motion seeking this relief, in which the government did not object to Sanofi's express reservation of the right to renew its preliminary injunction motion should circumstances change. *Id.* at 2. Sanofi's understanding of the implication of the Lilly ruling was correct, as HRSA subsequently told NACHC in *ex parte* communications that "HRSA will not take any

further action related to NACHC's current petition at this time" because of the Lilly preliminary injunction. ECF 101-3, at 75.[1] Even if the government had been quietly setting up the ADR process behind the scenes, there was never a need for the Court to grant emergency relief to Sanofi after the Lilly court's ruling—until now, when a petition against Sanofi is actually moving forward and a deadline is imminent.

Second, the government criticizes Sanofi for not waiting to see whether the ADR Panel would grant an administrative stay of its deadline to answer the ADR petition. ECF 103, at 7–8. But Sanofi made that request over a week ago, and Sanofi is *still* waiting for the ADR Panel's answer—all while the clock on Sanofi's response deadline continues to tick. On October 5, HRSA invited Sanofi to submit questions to the ADR Panel. ECF 101-2. On October 6, after conferring with the government, Sanofi asked the ADR Panel three questions, including asking for a stay of Sanofi's deadline to answer the ADR Petition. ECF 101-4. HRSA acknowledged Sanofi's questions and forwarded them to the ADR Panel, *see* Exhibit E (attached to this reply), but the ADR Panel has yet to respond to Sanofi's questions. Moreover,

[1] The government claims that "there is no impropriety" in how HRSA instructed NACHC to file a new petition against Sanofi. ECF 103, at 6. But *ex parte* communications in agency adjudicatory proceedings are no less a violation of due process than *ex parte* communications in a judicial proceeding. *See Sierra Club v. Costle*, 657 F.2d 298, 400 (D.C. Cir. 1981) ("Where agency action resembles judicial action, … the insulation of the decisionmaker from *ex parte* contacts is justified by basic notions of due process to the parties involved."). The government's claim that HRSA was acting as a regulator, ECF 103, at 6 n.2, ignores HRSA's integral role in the adjudicatory process, *see* 42 C.F.R. §§ 10.20(a) (HRSA establishes the ADR panel), 10.21(a) (HRSA receives ADR claims and reviews them for completeness), 10.24(e) (HRSA can take "appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities").

neither HRSA nor the ADR Panel has communicated that Sanofi's request was procedurally improper—*i.e.*, that it needed to be made in a formal motion, as the government now implies. Nor, for that matter, would anything in the ADR Rule support procedurally denying Sanofi's request. After all, Sanofi's questions for the ADR Panel were made at HRSA's invitation and the government's prompting.

Finally, analogizing to the Court's decision not to stay Sanofi's June 1 response deadline for HRSA's May 17 letter, the government argues that Sanofi's ADR response deadline "is not the type of agency action appropriate for a stay." ECF 103, at 9. But Sanofi did not even claim to be facing irreparable harm from the June 1 deadline; its request to stay that deadline instead sought deference to this Court's process. That consideration is important here, too, but now Sanofi is being forced to participate in an unconstitutional proceeding that inflicts irreparable harm and for which its damages are unrecoverable due to the government's sovereign immunity, thus warranting a stay in this instance. ECF 101-1, at 11–13. The Court should not permit the government to compel Sanofi's participation in an unconstitutional adjudicatory proceeding until the Court has an opportunity to decide whether the ADR Rule is legally valid. To spare Sanofi from suffering irreparable harm, the Court should grant a stay or, in the alternative, grant (in whole or in part) Sanofi's motion for a preliminary injunction of the ADR Rule.

Dated: October 14, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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Counsel for Plaintiff
Sanofi-Aventis U.S. LLC

EXHIBIT E

Shumate, Brett A.

From: 340B ADR <340BADR@hrsa.gov>
Sent: Thursday, October 7, 2021 11:58 AM
To: Shumate, Brett A.; 340B ADR
Cc: Talmor, Kate (CIV); Muttreja, Rajeev; Citera, Toni-Ann; mfreedus@ftlf.com
Subject: RE: 340B ADR ID 210112-2

** External mail **

Thank you for your email. The questions have been forwarded to the 340B ADR panel assigned to this petition (ADR ID 210112-2).

The Office of Pharmacy Affairs
Health Resources and Services Administration
Email: 340BADR@hrsa.gov

From: Shumate, Brett A. <bshumate@jonesday.com>
Sent: Wednesday, October 6, 2021 7:42 PM
To: 340B ADR <340BADR@hrsa.gov>
Cc: Talmor, Kate (CIV) <Kate.Talmor@usdoj.gov>; Muttreja, Rajeev <rmuttreja@jonesday.com>; Citera, Toni-Ann <tcitera@JonesDay.com>; mfreedus@ftlf.com
Subject: 340B ADR ID 210112-2

Dear 340B ADR Panel,

As you may know, Sanofi-Aventis USA, LLC ("Sanofi") has challenged the validity of HHS's ADR Rule in the U.S. District Court for the District of New Jersey. *Sanofi-Aventis U.S., LLC v. HHS*, No. No. 3:21-cv-634 (D.N.J.). The parties in that litigation are now waiting for Chief Judge Wolfson to rule on the validity of the ADR Rule as well as on whether Section 340B requires Sanofi to provide 340B-priced drugs to contract pharmacies. Sanofi and the government have filed competing dispositive motions that have been fully briefed since July 2021.

On October 5, 2021, HRSA notified undersigned counsel that "[t]he 340B Administrative Dispute Resolution (ADR) petition (ADR ID 210112-2) has been assigned to a 340B ADR panel for review. Please direct questions to 340BADR@hrsa.gov."

On October 6, 2021, undersigned counsel conferred with Kate Talmor, DOJ's litigation counsel, regarding HRSA's October 5 notice.

Ms. Talmor responded that Sanofi should ask the 340B ADR Panel about Sanofi's deadline to respond to the ADR petition, but HRSA would not (or could not) agree to an administrative stay of Sanofi's obligation to respond to the ADR petition. In light of Ms. Talmor's response, Sanofi respectfully requests that the ADR Panel answer the following questions:

1. Does Sanofi currently have an obligation to respond to the ADR petition?

2. If the ADR Panel expects Sanofi to file a response, what is the date by which the Sanofi must provide its written response to the ADR petition?

3. If the ADR Panel believes that Sanofi must file a response, will the ADR Panel enter an administrative stay of Sanofi's obligation to respond to the ADR petition until the court enters final judgment on the parties' pending and fully briefed dispositive motions (and toll Sanofi's response deadline until 30 days after the court rules)?

We believe that an administrative stay of the ADR proceeding would be the most efficient and desirable way to proceed in light of the pending litigation challenging the validity of the ADR Rule and addressing the scope of Sanofi's rights and obligations under Section 340B. *See* 42 C.F.R. § 10.23(a) ("The 340B ADR Panel will determine, in its own discretion, the most efficient and practical form of the ADR proceeding."); *id*. § 10.23(d) ("The 340B ADR Panel may issue additional instructions or guidance as may be necessary or desirable governing the conduct of ADR proceedings."). Chief Judge Wolfson's judgment will be binding on HHS—including on this ADR Panel. If Chief Judge Wolfson decides that the ADR Rule is unlawful, this ADR proceeding could not lawfully continue. Similarly, Chief Judge Wolfson could reject HHS's interpretation of Section 340B—which is the same position that is advanced in the ADR petition. Neither the parties nor the ADR Panel should expend time and resources participating in an ADR proceeding that could be significantly affected (if not terminated) by an imminent court decision.

Sanofi respectfully requests a response from the ADR Panel no later than **4:00 PM EST on October 7, 2021**, so that Sanofi may seek emergency relief from the court if the ADR Panel is unwilling to grant an administrative stay of Sanofi's obligation to respond to the ADR petition.

Thank you for your consideration of these questions. By submitting these administrative questions to the ADR Panel, Sanofi does not agree to participate in the ADR proceeding or waive any argument that the ADR Rule is unlawful.

Counsel for HHS and NACHC are copied on this email.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 14, 2021, a copy of Plaintiff's Reply in Support of Emergency Motion for a Stay Pending Resolution of the Dispositive Motions was filed with the Clerk of the Court by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: October 14, 2021

s/ Jennifer L. Del Medico

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