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October 15, 2021

**VIA CM/ECF**

The Honorable Leonard P. Stark  
United States District Court for the District of Delaware  
J. Caleb Boggs Federal Building  
844 N. King Street  
Unit 26, Room 6124  
Wilmington, DE 19801-3555

**Re: *AstraZeneca Pharmaceuticals LP v. Becerra, et al., C.A. No. 21-27-LPS***

Dear Judge Stark:

We write on behalf of AstraZeneca to alert this Court of further developments relevant to the Court's disposition of the litigation.

On September 24, 2021, we informed the Court that "the National Association of Community Health Centers served on AstraZeneca an amended petition for declaratory and injunctive relief in [HRSA's] Administrative Dispute Resolution (ADR) process." D.I. 100 at 2. We advised the Court that "[a]ssignment of the amended petition to an ADR panel could happen at any time," and noted that, in accordance with this court's June 16, 2021 Memorandum Opinion, "such proceedings do not provide a meaningful venue for contesting Defendants' interpretation of the 340B statute." *Id.* at 3. Indeed, as this Court previously held: "If AstraZeneca (or another manufacturer) tries to raise the legal issue presented here in ADR proceedings, the result is preordained." D.I. 78 at 17.

HRSA has now informed us that four separate ADR petitions against AstraZeneca have been assigned to panels for formal proceedings. Upon receiving that news, AstraZeneca sent HRSA a letter on October 8, inquiring about (1) the composition of the panel or panels that will preside over the disputes; (2) whether and when AstraZeneca is required to respond to the petitions; (3) the rules governing the ADR proceedings, including whether AstraZeneca will be permitted to request a stay; and (4) whether the ADR panel or panels would enter an administrative stay of proceedings pending this Court's decision on the parties' fully briefed dispositive motions.

Given the temporal urgency, AstraZeneca asked for a response no later than yesterday, October 14. To date, however, the agency has provided no response. As we read the ADR regulations (which have never been interpreted or applied), AstraZeneca's responses to the ADR petitions could be due as soon as November 4.

Facing similar set of circumstances, Sanofi-Aventis, U.S., LLC—another 340B manufacturer litigating a similar case—filed a motion for an emergency administrative stay of the

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ADR proceedings pending disposition of the parties' summary judgment motions. The U.S. District Court for the District of New Jersey denied the motion, but stated that it "will render its decision on the pending summary judgment motions on or before November 5, 2021," the date by which it appears Sanofi will be required to respond to the ADR petition against it. The court's ruling is attached to this letter.

Respectfully submitted,

*/s/ Daniel M. Silver*

Daniel M. Silver (#4758)

cc: Counsel of Record (via Electronic Mail)

Enclosure

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

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

Defendants.

Civil Action No. 21-00634 (FLW)

**ORDER DENYING EMERGENCY  
ADMINISTRATIVE STAY**

**THIS MATTER** having been opened to the Court by Plaintiff Sanofi-Aventis, U.S., LLC, on an emergency motion to administratively stay, pending disposition of the parties' summary judgment motions, ECF Nos. 62, 68, Sanofi's "obligation under the Administrative Dispute Resolution ('ADR') Rule," ECF No. 101, at 1, in connection with an ADR petition filed by the National Association of Community Health Centers' ("NACHC") against Sanofi in the Department of Health and Human Services on August 31, 2021, which was then assigned to an ADR panel on October 5, 2021, ECF No. 101, at 4-5; it appearing that the Government opposes the motion, ECF No. 103; it appearing that the Court will render its decision on the pending summary judgment motions in this matter on or before November 5, 2021; it appearing that on November 5, 2021, Sanofi must file a response to NACHC's arbitration petition, and that Sanofi may request that the panel, to the extent permitted under the applicable regulations, stay the arbitration proceeding in light of this Court's timeline; it appearing that the Court having reviewed the parties' submissions in connection with the motion pursuant to Fed. R. Civ. P. 78, for the reasons set forth herein, and for good cause shown;

**IT IS** on this 14th day of October, 2021,

**ORDERED** that Sanofi's "Motion for an Emergency Motion for a Stay Pending Resolution of the Dispositive Motions and for an Immediate Interim Stay" is **DENIED**.

/s/ Freda L. Wolfson  
Hon. Freda L. Wolfson  
U.S. Chief District Judge