IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF INDIANA INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, and LILLY USA, LLC

Plaintiffs,

v.

No. 1:21-cv-81-SEB-MJD

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

Defendants.

CONSENT MOTION TO MOFIFY SCHEDULE IN LIGHT OF RECENT DECISIONS

On June 3, 2021, this Court approved and entered the parties' proposal for an amended schedule for further proceedings and to set a hearing date on Plaintiffs' pending motion for preliminary injunction. ECF No. 110. Under that schedule, Defendants' final brief addressing all of Plaintiffs' claims and Plaintiffs' pending motion for preliminary injunction is due this Wednesday, June 23, 2021. Plaintiffs' final brief is due July 12, 2021, and the Court will hold a hearing on the pending motions on July 30, 2021.

Two recent judicial decisions could impact this Court's consideration of Plaintiffs' claims. First, on June 16, 2021, the court hearing a related case determined that the Advisory Opinion challenged in that litigation (and in this litigation) erred in concluding that the 340B statute unambiguously compelled the Advisory Opinion's conclusion. On Friday, June 18, 2021, the Advisory Opinion was withdrawn. *AstraZeneca v. Becerra*, No. 21-27-LPS (D. Del.), ECF No. 79. Defendants notified this Court of that development and the fact that withdrawal of the Opinion in no way affected HRSA's enforcement of the statute against Plaintiffs. *See* ECF No. 119.

This morning, June 21, 2021, the United States Supreme Court issued its decision in United

States v. Arthrex, No. 19-1434. (Slip opinion available at

https://www.supremecourt.gov/opinions/20pdf/19-1434_ancf.pdf.). That decision concerns the appointment of Administrative Patent Judges and has relevance to Plaintiffs' Article II challenge to the HHS final ADR Rule pending before this Court.

In light of these developments, in particular with regard to the need to assess the Supreme Court's decision in *Arthrex* and to ascertain how, if at all, it could impact this litigation, counsel for Defendants contacted counsel for Plaintiffs regarding a slight modification of the stipulated schedule. Specifically, Plaintiffs have consented to a short modification whereby Defendants will have two additional days, until June 25, 2021, to file their final brief, and Plaintiffs will receive a commensurate two-day modification such that their final brief shall be due July 14, 2021. Defendants believe that this modification is important to allow them adequately to consider the decisions in *Astra* and *Arthrex* and file one final, complete brief on all issues before the Court. Plaintiffs do not oppose this request. No other modifications are requested.

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

Dated: June 21, 2021

Respectfully submitted,

BRIAN D. NETTER Deputy Assistant Attorney General

MICHELLE R. BENNETT Assistant Branch Director

<u>/s/ Kate Talmor</u> KATE TALMOR RACHAEL WESTMORELAND JODY D. LOWENSTEIN Trial Attorneys U.S. Department of Justice Civil Division, Federal Programs Branch 1100 L Street, N.W. Washington, D.C. 20005 (202) 305-5267 Case 1:21-cv-00081-SEB-MJD Document 122 Filed 06/21/21 Page 3 of 3 PageID #: 6783

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PROPOSED ORDER

Upon consideration of Defendants' Consent Motion to Modify the Schedule, the Court hereby

GRANTS Defendants' motion.

- Defendants shall file their final brief on JUNE 25, 2021
- Plaintiffs shall file their final brief on JULY 14, 2021

SO ORDERED.

Dated: _____

Signed:_____ The Honorable Sarah Evans Barker

Order served on all counsel of record via ECF