

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

CONSENT MOTION TO MODIFY SCHEDULE IN LIGHT OF RECENT DECISIONS

In light of two recent judicial decisions with relevance to this action, and to correct an inadvertent error by undersigned counsel, Defendants respectfully request this Court grant a slight modification of the schedule in this action. Undersigned counsel contacted counsel for Plaintiffs, and Plaintiffs consent to this request.

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. *AstraZeneca v. Becerra*, No. 21-27-LPS (D. Del.), ECF No. 79. That same day, Defendants filed their final brief in this matter, *see* ECF No. 89. Due to the timing of the *Astra* decision, Defendants were unable to address that opinion in their final brief before this Court.

The following day, June 17, 2021, this Court notified the parties (through its Law Clerk) that Defendants should file a five-page letter brief addressing the *Astra* decision by June 24, 2021, and that Plaintiff should respond in its reply brief due July 6, 2021.

On Friday, June 18, 2021, the Advisory Opinion that had been challenged in this litigation

and at-issue in the *Astra* decision was withdrawn. Defendants notified this Court of that development and the fact that HRSA's enforcement of the 340B statute was not based on the Opinion and thus withdrawal of the Opinion did not affect HRSA's enforcement of the statute against Plaintiff. *See* ECF No. 90. Later that evening, counsel for Plaintiff alerted undersigned counsel to the fact that Defendants' final brief, filed two days earlier, was overlength. Specifically, Defendants filed a 50-page brief, whereas the parties had stipulated, and the Court had entered, that the brief should not exceed 35 pages in 12-point, non-proportional font. *See* ECF Nos. 49, 82.

Undersigned counsel respectfully asks this Court to excuse the inadvertent filing of an overlength brief, and to allow counsel to correct her error. This case is one of several related challenges, with lengthy briefs due very close together in time. Defendants' final brief in a similar challenge, pending before the U.S. District Court for the Southern District of Indiana, has a page allotment of not more than 60 pages. Undersigned counsel unfortunately confused the page limitations and did not intend to disregard this Court's order.

Separately, this morning, June 21, 2021, the United States Supreme Court issued its decision in *United States v. Artbrex*, 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 Plaintiff's 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 *Artbrex* 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 that would permit counsel to simultaneously address the *Artbrex* and *Astra* decisions while correcting the page error. Specifically, Defendants request that they be permitted to file one final and corrected brief this Thursday, June 24, 2021, that (1) addresses the *Astra* decision, as this Court

has instructed, (2) addresses the Supreme Court's opinion in *Arthrex*, and (3) conforms to the correct page limitations. In light of the Court's order that Defendants should have 5 pages (in letter-brief form) to address the *Astra* decision, Defendants request that their page allotment be increased from 35 pages to 40 pages. Defendants believe that this modification (both to schedule and pages) 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

SO ORDERED.

Dated: 6/22/2021

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson
Chief Judge

/s/ Kate Talmor
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
kate.talmor@usdoj.gov
Attorneys for Defendants