IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, 1100 New York Avenue, N.W., Suite 725W Washington, D.C. 20005

Civil Action No. 1:17-cv-2645 (EGS)

Plaintiff,

v.

ALEX M. AZAR, In His Official Capacity as Secretary of Health and Human Services, U.S. Department of Health and Human Services 200 Independence Ave., S.W. Washington, D.C. 20201

Defendant.

NOTICE OF SUPPLEMENTAL AUTHORITY

Plaintiff the American Clinical Laboratory Association respectfully submits the Supreme Court's recent decision in *SAS Institute Inc. v. Iancu*, No. 16-969 (U.S. S. Ct. Apr. 24, 2018), as supplemental authority in support of its motion for summary judgment and in opposition to defendant's motion for summary judgment. A copy of the decision is attached as Exhibit A.

In SAS, the Supreme Court considered whether the Patent Trial and Appeal Board, when it initiates an inter partes review, must resolve all of the claims raised by petitioner in a case or may choose to limit its review to only some of them. The decision addressed the Board's contention that the Court lacked jurisdiction to consider the appeal because 35 U.S.C. § 314(d) states that the "determination by the [Board] whether to institute an inter partes review under this section shall be final and nonappealable." Op. 12 (citing statute). The Board argued that this provision "foreclos[es] judicial review of any legal question bearing on the institution of inter

partes review—including whether the statute permits" the Board to limit review to only certain claims. *Id*.

The Supreme Court rejected this argument. Noting that there is a "strong presumption" in favor of judicial review, the Court emphasized that there must be "clear and convincing indications" that Congress meant to foreclose review. Op. 13. The Court concluded that the statutory bar on review "does not 'enable the agency to act outside its statutory limits." *Id.* (citation omitted). Instead, "if a party believes the [Board] has engaged in 'shenanigans' by exceeding its statutory bounds, judicial review remains available consistent with the Administrative Procedure Act, which directs courts to set aside agency action 'not in accordance with law' or 'in excess of statutory jurisdiction, authority, or limitations." *Id.* (quoting 5 U.S.C. § 706(2)(A), (C)). Accordingly, because the petitioner was not challenging the Board's decision whether to institute an inter partes review, but instead was claiming that the Board had "exceeded [its] statutory authority by limiting the review to fewer than all of the claims [petitioner] challenged," nothing withdrew the Court's power to ensure that the Board's review "proceeds in accordance with the law's demands." Op. 14.

This decision is relevant to the jurisdictional arguments raised in this case, which are addressed in ACLA's opening brief (ECF Nos. 13, 31-1) at pages 19 to 23, and in its reply/opposition brief (ECF No. 29) at pages 3 to 19.

Respectfully submitted,

/s/ DRAFT DRAFT DRAFT

Mark D. Polston
D.C. Bar No. 431233
Ashley C. Parrish
D.C. Bar No. 464683
KING & SPALDING LLP
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006

Telephone: (202) 737-0500 Facsimile: (202) 626-3737 mpolston@kslaw.com aparrish@kslaw.com

Attorneys for Plaintiff American Clinical Laboratory Association

Dated: May ____, 2018