

**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

**NOTICE OF JOINT MOTION FOR ENTRY OF  
DECLARATORY JUDGMENT AND INJUNCTION**

PLEASE TAKE NOTICE that, pursuant to Local Civil Rule 79.4, the parties jointly move for the entry of a declaratory judgment and injunction implementing the judgment of the U.S. Court of Appeals for the Third Circuit as set forth in the attached proposed order. In support of this motion, the parties submit the following:

1. On May 25, 2021, Plaintiff Sanofi-Aventis U.S., LLC (“Sanofi”) filed the operative complaint in this case, asserting claims under the Administrative Procedure Act. Dkt. 78. As relevant here, Sanofi challenged two actions taken by Defendants, namely (1) Advisory Opinion 20-06 issued by Defendant General Counsel of the United States Department of Health and Human Services (“HHS”) on December 30, 2020, and (2) the Violation Letter issued by Defendant Health Resources and Services Administration to Sanofi on May 17, 2021. *See id.* ¶¶ 131-83.

2. On November 5, 2021, the district court (Wolfson, C.J.) entered final

judgment denying as moot the parties' cross-motions for summary judgment concerning the Advisory Opinion and granting in part and denying in part the parties' cross-motions for summary judgment concerning the Violation Letter. Dkt. 111 (order); Dkt. 110 (opinion). Sanofi appealed and Defendants cross-appealed to the U.S. Court of Appeals for the Third Circuit.

3. On January 30, 2023, the Third Circuit issued an opinion and judgment affirming in part and reversing in part the district court's decision. Dkt. 117-2 (opinion); Dkt. 115 (judgment). As relevant here, the Third Circuit held that (i) Sanofi's challenge to the Advisory Opinion was "not moot" because Defendants could be "enjoin[ed] ... from reverting to the Advisory Opinion's interpretation of Section 340B [of the Public Health Service Act, 42 U.S.C. § 256b]," Dkt. 117-2 at 12; (ii) the Advisory Opinion and Violation Letter "are unlawful," *id.* at 18; and (iii) Section 340B does not require delivery of discounted drugs to an unlimited number of contract pharmacies nor prohibit or deem unlawful the manufacturers' specific policies on delivery to contract pharmacies as addressed in the Third Circuit's opinion, *id.* at 13, 18. The Third Circuit further instructed the district court to "enjoin the agency from enforcing against these three drug makers its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies" and "enter declaratory relief to that effect." Dkt. 115 at 2; *see* Dkt. 117-2 at 18.

4. On April 25, 2023, the Third Circuit issued its mandate. Dkt. 117 at 3.

5. On April 28, 2023, pursuant to Local Civil Rule 79.4, the prevailing party was directed to submit an order implementing the Third Circuit's mandate.

6. On May 1, 2023, this case was reassigned to this Court for all further proceedings.

7. Having met and conferred, the parties now jointly move for entry of a declaratory judgment and injunction as set forth in the attached proposed order. Pursuant to Local Civil Rule 7.1(d)(4), the parties respectfully submit that a separate brief is not necessary because they agree that the requested relief implements the Third Circuit's mandate.

Dated: May 12, 2023

Respectfully submitted,

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*s/ Kate Talmor*

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