

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

No. 3:21-CV-634

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

Defendants.

**DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE,
FOR SUMMARY JUDGMENT**

TABLE OF CONTENTS

BACKGROUND	3
I. STATUTORY AND REGULATORY BACKGROUND.....	3
II. PHARMACEUTICAL COMPANIES UNILATERALLY RESTRICT ACCESS TO 340B DISCOUNTS FOR SAFETY-NET PROVIDERS.....	9
III. PHARMACEUTICAL COMPANIES SUE TO PREVENT HHS's ENFORCEMENT OF THE 340B STATUTE.....	12
STANDARD OF REVIEW.....	13
ARGUMENT.....	14
I. THE COURT LACKS JURISDICTION TO REVIEW THE GENERAL COUNSEL'S LEGAL ADVICE.....	15
A. The Advisory Opinion Does Not Constitute Final Agency Action	16
B. Sanofi's Attempt to Upend the Settled Operation of the 340B Program is Time-Barred.....	19
II. EVEN IF THE GENERAL COUNSEL'S LEGAL ADVICE WAS REVIEWABLE, SANOFI'S CLAIMS FAIL.....	24
A. Notice-and-Comment Rulemaking is Not Required Because the Advisory Opinion Is An Interpretive Rule	24
B. Sanofi Fails to State a Claim that the AO Violates HHS' Good Guidance Rule.....	26
C. Sanofi Fails To State A Claim On The Merits Because Lilly's Obligation to Offer Discounted Drugs To Covered Entities Is Imposed By the 340B Statute Itself	27
III. THE ADMINISTRATIVE-DISPUTE RESOLUTION MECHANISM MANDATED BY CONGRESS WAS LAWFULLY ESTABLISHED.....	31
A. ADR Board Members Are Lawfully Appointed Inferior Officers	31
B. The ADR Process Does Not Infringe the Power of the Judiciary	39
C. The Secretary Fully Complied with Notice-And-Comment Requirements in Promulgating the ADR Rule.....	46
1. HHS did not terminate the ADR Rulemaking in advance of issuing the final rule.....	46
2. The ADR Rule is a logical outgrowth of the NPRM.....	48

D.	The ADR Rule is Substantively Compliant with the APA.....	50
	CONCLUSION	53

TABLE OF AUTHORITIES

Cases

<i>Am. Hosp. Ass'n v. Dep't of Health & Hum. Servs.</i> , 2021 WL 616323 (N.D. Cal. Feb. 17, 2021).....	11
<i>Am. Med. Ass'n v. United States</i> , 887 F.2d 760 (7th Cir. 1989)	50
<i>Appalachian States Low-Level Radioactive Waste Comm'n v. O'Leary</i> , 93 F.3d 103 (3d Cir. 1996)	25
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	13
<i>Astra USA, Inc. v. Santa Clara Cty.</i> , 563 U.S. 110 (2011).....	6, 45
<i>Beard v. Braunstein</i> , 914 F.2d 434 (3rd Cir. 1990)	43
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	13
<i>Bennett v. Spear</i> , 520 U.S. 154 (1997).....	16, 18
<i>Biggerstaff v. FCC</i> , 511 F.3d 178 (D.C. Cir. 2007)	21
<i>CFTC v. Schor</i> , 478 U.S. 833 (1986).....	44
<i>Chao v. Rothermel</i> , 327 F.3d 223 (3d Cir. 2003)	24
<i>Cierco v. Lew</i> , 190 F. Supp. 3d 16 (D.D.C. 2016)	47
<i>City of Portland v. EPA</i> , 507 F.3d 706 (D.C. Cir. 2007)	51
<i>Clayton Cty., Ga. v. FAA</i> , 887 F.3d 1262 (11th Cir. 2018)	17
<i>Commonwealth of Pennsylvania v. HHS</i> , 80 F.3d 796 (3rd Cir. 1996)	34, 36, 38

...

<i>Council Tree Commc 'ns, Inc. v. FCC,</i> 619 F.3d 235 (3d. Cir. 2010)	48
<i>Crowell v. Benson,</i> 285 U.S. 22 (1932).....	44
<i>Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.,</i> 710 F.2d 842 (D.C. Cir. 1983)	47
<i>DaimlerChrysler Corp. v. Cuno,</i> 547 U.S. 332 (2006).....	13
<i>Diliberti v. United States,</i> 817 F.2d 1259 (7th Cir. 1987)	19, 20
<i>Edison Elec. Inst. v. OSHA,</i> 411 F.3d 272 (D.C. Cir. 2005)	21
<i>Edmond v. United States,</i> 520 U.S. 651 (1997).....	<i>passim</i>
<i>FCC v. Prometheus Radio Proj.,</i> (<i>Prometheus</i>), 141 S. Ct. 1150 (2021).....	31, 50
<i>Free Enter. Fund v. Pub. Co. Acc't Oversight Bd.,</i> 561 U.S. 477 (2010).....	33, 37, 38
<i>Golden and Zimmerman, LLC v. Domenech,</i> 599 F.3d 426 (4th Cir. 2010)	17, 18
<i>Herr v. U.S. Forest Svc.,</i> 803 F.3d 809 (6th Cir. 2015)	19
<i>In re Grand Jury Invest.,</i> 916 F.3d 1047 (D.C. Cir. 2019)	35, 36, 38
<i>Indep. Equip. Dealers Ass'n ("IEDA") v. EPA,</i> 372 F.3d 420 (D.C. Cir. 2004)	16, 17, 18, 20
<i>Indus. & Fin. Mkts. Ass'n v. U.S. Commodity Futures Trading Comm'n,</i> 67 F. Supp. 3d 373 (D.D.C. 2014)	52
<i>Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.,</i> 684 F.3d 1332 (D.C. Cir. 2012)	34, 37, 38
<i>Int'l Union, United Mine Workers of Am. v. U.S. Dep't of Labor,</i> 358 F.3d 40 (D.C. Cir. 2004).....	47

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.