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

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF EMERGENCY MOTION FOR A STAY PENDING RESOLUTION OF THE DISPOSITIVE MOTIONS AND FOR AN IMMEDIATE INTERIM STAY

Plaintiff Sanofi-Aventis U.S., LLC ("Sanofi") respectfully requests that the Court enter an emergency order temporarily relieving Sanofi of its obligation under the Administrative Dispute Resolution ("ADR") rule to imminently respond to a pending ADR petition until this Court enters final judgment on the parties' dispositive motions. Defendants notified Sanofi two days ago that a new ADR petition filed against Sanofi "has been assigned to a 340B ADR panel for review"—which, under the ADR Rule, appears to require that Sanofi respond to the petition by November 4, 2021. *See* Exhibit A. Remarkably, Defendant HRSA *invited* this new ADR petition to be filed against Sanofi through *ex parte* communications for the open purpose of circumventing the preliminary injunction of the ADR Rule that Judge Barker granted to the manufacturer Eli Lilly ("Lilly") earlier this year. Absent emergency relief from

this Court—relief similar to but narrower than Judge Barker's order preliminarily enjoining the entire ADR Rule —Sanofi will be compelled to participate in an unconstitutional administrative process, even though the ADR Rule establishing that process is currently being reviewed by this Court in the parties' fully briefed dispositive motions. Alternatively, the Court should grant (in whole or in part) Sanofi's motion for a preliminary injunction of the ADR Rule—which is fully briefed and currently being held in abeyance by the Court for this precise situation. Counsel for Defendants stated that Defendants will oppose this motion.

BACKGROUND

One of the three agency actions being challenged in this case is Defendants' ADR Rule, which empowers panels of employees in the Department of Health & Human Services to wield full judicial authority when adjudicating claims that drug manufacturers have overcharged for or imposed conditions on 340B-priced drugs delivered to contract pharmacies.

As the Court may recall, on February 2, 2021, Sanofi initially moved for a preliminary injunction of the ADR Rule on the grounds that it violates Articles II and III of the Constitution. ECF 19. In that motion, Sanofi explained that it faced imminent irreparable harm from being haled into an unconstitutional administrative process to respond to an ADR petition filed by the National Association of Community Health Centers ("NACHC") jointly against Sanofi, Lilly, and AstraZeneca. ECF 19-1, at 27–31.

On March 21, 2021, after Judge Barker in the U.S. District Court for the Southern District of Indiana granted Lilly's motion for a preliminary injunction against the ADR Rule, and after Sanofi and Defendants agreed on an expedited briefing schedule for dispositive motions in this action, Sanofi requested that "the Court hold in abeyance its motion for a preliminary injunction pending notification from Sanofi that a ruling on that motion is necessary." ECF 46, at 2. At that time, there was no need for this Court to rule on Sanofi's motion, because the preliminary injunction in the Lilly case prevented Defendants from moving forward with NACHC's joint ADR petition against Sanofi, Lilly, and AstraZeneca. However, Sanofi "expressly reserve[d] the right to request that the Court rule on its motion for a preliminary injunction, should it prove necessary in light of developments with regard to any ADR proceeding against Sanofi." *Id.* The Court granted Sanofi's request and agreed that Sanofi's motion for a preliminary injunction would be "held in abeyance and ADMINISTRATIVELY TERMINATED." ECF 49, at 2. The Court then adopted the parties' proposed expedited schedule for briefing competing dispositive motions on Sanofi's claims. The parties' dispositive motions have been fully briefed since July 6.

All this time, NACHC's joint ADR petition lay dormant—as that petition named Lilly (as well as Sanofi and AstraZeneca) as a defendant, and Judge Barker had granted Lilly a preliminary injunction against the ADR Rule. But on August 5, 2021—approximately one month after briefing was complete on the dispositive

motions in this action—HRSA invited NACHC to work around the preliminary injunction. Specifically, HRSA sent an *ex parte* communication to NACHC inviting a new ADR petition against Sanofi and AstraZeneca that omitted the corresponding claims against Lilly, so that the ADR proceedings could proceed notwithstanding Judge Barker's preliminary injunction. *See* Exhibit B, at 75. HRSA instructed NACHC on how to submit this new ADR petition so as not to run afoul of the preliminary injunction in Lilly's case. HRSA's *ex parte* communication to NACHC read in full:

> On March 16, 2021, a federal district judge in the U.S. District Court for the Southern District of Indiana preliminarily enjoined HHS from implementing or enforcing the ADR final rule against Eli Lilly and Company and Lilly USA (collectively, Lilly). At this time HRSA is not able to move ahead with any ADR process involving Lilly. If you still wish to continue with your petition as it is currently submitted, you may do so, but HRSA will not take any further action related to NACHC's current petition at this time. If you would like to resubmit a petition that excludes claims against Lilly, NACHC may resubmit a new petition to 340BADR@hrsa.gov.

Id. Following HRSA's guidance, NACHC filed an amended ADR petition against Sanofi and AstraZeneca on August 31, 2021. *See id.* at 3–14.[1]

[1] This is not the only time Defendants have not deferred to this Court's proceedings. As the Court may recall, on May 17, 2021, during the midst of briefing summary judgment in this case, HRSA sent Sanofi a letter threatening Sanofi with enforcement actions, including civil monetary penalties ("CMPs"), if Sanofi continued to operate its 340B integrity initiative. Sanofi subsequently amended its complaint to include a challenge to that letter, the validity of which is now before the Court in the pending dispositive motions. And, more recently, on September 22, 2021, HRSA referred Sanofi to the HHS Office of the Inspector General for potential imposition of CMPs, all because Sanofi has continued to operate its integrity initiative while awaiting judicial resolution of manufacturers' rights and obligations under Section 340B. *See* Exhibit D.

On October 5, 2021, HRSA notified Sanofi that NACHC's ADR petition "has been assigned to a 340B ADR panel for review." Exhibit A. Under the ADR Rule, "the respondent must file with the 340B ADR Panel a written response to the Petition as set forth in Rule 12 or 56." 42 C.F.R. § 10.21(f). Sanofi "will have 30 days to submit a written response to the 340B ADR Panel." 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,639 (Dec. 14, 2020). Although the ADR Rule is not a model of clarity, Sanofi's deadline to respond to the ADR petition appears to be November 4, 2021. Sanofi now seeks to stay its obligation to respond to the ADR petition by the ADR Rule's deadline in deference to the prior-pending proceedings in this Court.

Counsel for Sanofi conferred with counsel for Defendants about this motion. Counsel for Defendants stated that Sanofi should ask the 340B Panel about Sanofi's deadline to respond to the ADR petition, but that HRSA would not (and could not) agree to stay Sanofi's obligation to respond to the ADR petition. Counsel for Defendants also stated that Defendants will oppose this motion. Sanofi then asked the ADR Panel to stay Sanofi's obligation to respond to the ADR petition until this Court enters final judgment on the parties' pending and fully briefed dispositive motions. *See* Exhibit C. Sanofi requested a response from the ADR Panel by 4:00 pm ET on October 7. *Id.* As of this filing, the ADR Panel has not responded to Sanofi's request for a stay of its obligation to respond to the pending ADR petition, but the

clock is ticking on Sanofi's response to the pending ADR petition under the ADR Rule.

ARGUMENT

The Court should stay the ADR Rule's requirement that Sanofi imminently respond to a pending ADR petition that Defendants invited to be filed against Sanofi through *ex parte* contacts to circumvent the preliminary injunction in Lilly's case. Such modest relief will spare Sanofi from suffering the irreparable harm of being compelled to participate in an unconstitutional administrative process caused by Defendants' enforcement of the ADR Rule against Sanofi. This limited request for relief from a portion of the ADR Rule would not require the Court to preliminarily enjoin the entire ADR Rule, but instead would merely relieve Sanofi from having to participate in the ADR proceeding while allowing the Court to review the validity of the ADR Rule in an orderly fashion.

I. Section 705 of the APA Authorizes the Court to Stay Sanofi's Obligation to Respond to the Pending ADR Petition.

Section 705 of the Administrative Procedure Act ("APA") authorizes this Court to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings" "[o]n such conditions as may be required and to the extent necessary to prevent irreparable injury." 5 U.S.C. § 705. Judicial authority under this provision to stay agency action pending review is well established. *See, e.g.*, *Chrysler Corp. v.*

Schlesinger, 565 F.2d 1172, 1192 (3d Cir. 1977) ("Interim relief can, of course, be ordered on the authority of 5 U.S.C. [§] 705."), *vacated on other grounds*, 441 U.S. 281 (1979); *In re GTE Serv. Corp.*, 762 F.2d 1024, 1026 (D.C. Cir. 1985) (Section 705 supplies "statutory authority to stay agency orders pending review in this court"); 33 Fed. Prac. & Proc. § 8386 (2d ed. Apr. 2021 update) (same). Even Defendants agree that § 705 authorizes this Court to grant emergency relief in the form of a stay pending review. ECF 79, at 5. Indeed, under § 705, courts regularly stay final rules in full—relief that significantly exceeds the modest relief sought here. *See, e.g.*, *Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016) (staying a final rule "in its entirety" nationwide); *Dist. of Columbia v. U.S. Dep't of Agric.*, 444 F. Supp. 3d 1, 48, 55 (D.D.C. 2020) (staying a final rule nationwide).

Sanofi's request for relief falls squarely within the terms of § 705. The "agency action" that Sanofi seeks to stay under § 705 is the portion of the ADR Rule requiring Sanofi to respond to the pending ADR petition. *See* 42 C.F.R. § 10.21(f) ("Upon receipt of service of petition, the respondent must file with the 340B ADR Panel a written response to the Petition as set forth in Rule 12 or 56."); 85 Fed. Reg. at 80,639 (stating that "the opposing party (or Respondent) will have 30 days to submit a written response to the 340B ADR Panel"). And this request seeks a measured remedy that is "necessary and appropriate" to prevent Sanofi from being compelled to participate in an ADR proceeding by "preserv[ing] status or rights pending conclusion of the review" of the ADR Rule in this Court. 5 U.S.C. § 705.

In similar situations, courts have regularly granted such relief to prevent an agency from conducting enforcement proceedings on the basis of an unlawful rule or other unlawful action. *See, e.g.*, *Casa de Md., Inc. v. Wolf*, 486 F. Supp. 3d 928, 970–71, 973–74 (D. Md. 2020) (explaining that § 705 "operates broadly to allow … a Court to suspend enforcement or enjoin [a rule's] application" and that a § 705 stay may operate as "a suspension of the case [or, presumably, a rule] or some designated proceedings within it"); *KindHearts for Charitable Humanitarian Dev., Inc. v. Geithner*, 676 F. Supp. 2d 649, 651, 654, 657 (N.D. Ohio 2009) (explaining that "[c]ourts reviewing agency action may, under 5 U.S.C. § 705, stay agency action from being completed or acted upon pending conclusion of the review process" and ordering that an agency could not proceed with an "ongoing administrative proceeding" against the plaintiff); *Branstad v. Glickman*, 118 F. Supp. 2d 925, 945 (N.D. Iowa 2000) (relying on § 705 to stay an agency enforcement action pending judicial review of agency determinations underlying the enforcement action).

Even if there were any doubt about the applicability of § 705, the Court clearly has the power to preliminarily enjoin the ADR Rule in whole or in part. *See* Fed. R. Civ. P. 65(a). Sanofi's motion for a preliminary injunction is fully briefed and currently being held in abeyance—just in case Defendants were to force Sanofi into an ADR proceeding, which has now occurred. ECF 19. That motion provides the Court with an alternative procedural vehicle to prevent Sanofi from suffering irreparable harm caused by the Defendants' enforcement of the ADR Rule.

II. The Court Should Stay Sanofi's Obligation to Respond to the Pending ADR Petition.

The Court should grant Sanofi temporary relief from the ADR Rule—whether under § 705 or Rule 65. As this Court previously explained, "a stay under section 705 requires the movant to establish each of the four traditional preliminary-injunction factors." ECF 83, at 6. A party seeking such a stay thus "must establish, by a clear showing: (1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief." *Id.* For the reasons Sanofi explained in its motion for a preliminary injunction and motion for summary judgment, ECF 19-1, 68-1, 94, all four factors weigh in favor of staying the ADR Rule's requirement that Sanofi imminently respond to the pending ADR petition until the Court can review the validity of the ADR Rule.

A. Sanofi Is Likely to Succeed on the Merits of Its Challenge to the ADR Rule.

Sanofi is likely to succeed on the merits of its claim that the ADR Rule is unlawful. In the ADR Rule, HHS established an unconstitutional administrative process authorizing unaccountable bureaucrats to resolve private disputes between manufacturers and covered entities through binding judgments, money damages, and injunctions—all without the defendants' consent. Sanofi has already briefed this matter at length. *See* ECF 68-1, at 56–80; ECF 94, at 36–44. In short:

First, HHS issued the ADR Rule in violation of the APA's notice-and-comment requirement, as Judge Barker has already held. *See Eli Lilly & Co. v. Cochran*, No. 21-cv-00081, 2021 WL 981350, at *10 (S.D. Ind. Mar. 16, 2021). Although HHS gave notice of a rule regarding ADR proceedings in 2016, HHS withdrew that notice in early 2017—but then issued the ADR Rule without warning during the last month of the prior Administration, and without going through the notice-and-comment process again. ECF 68-1, at 57–60; ECF 94, at 42–44.

Second, the ADR Rule violates Article II of the Constitution—as confirmed by the Supreme Court's recent decision in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021)—because the members of the ADR Panels are principal officers under the Appointments Clause, which means they must be appointed by the President and confirmed by the Senate. ECF 68-1, at 60–68; ECF 94, at 36–40. But the ADR Rule requires neither, instead installing in this role agency employees who are not Senate-confirmed and, worse, are protected by for-cause removal restrictions and thus not even politically accountable. Moreover, no Senate-confirmed agency employee has authority to review the ADR Panel's judgment.

Third, the ADR Rule violates Article III by granting these unaccountable bureaucrats the power to issue final judgments for money damages and equitable relief in order to resolve disputes concerning manufacturers' private rights to hold and alienate property. ECF 68-1, at 68–77; ECF 94, at 40–42. The Constitution reserves this authority to Article III courts.

B. Sanofi Will Suffer Irreparable Harm Absent a Stay of Its Obligation To Respond To The Pending ADR Petition.

Absent a stay of its imminent deadline to respond to the pending ADR petition, Sanofi will suffer irreparable harm by being forced to submit to an ADR process that violates the Constitution's structural protections. *See* ECF 19-1, at 27–31. "Harm is presumed" for a violation of the Constitution's structural protections (such as Article III and the Appointments Clause), because those provisions "safeguard[]" "individual liberty." *Cirko ex rel. Cirko v. Comm'r of Soc. Sec.*, 948 F.3d 148, 154 (3d Cir. 2020) (presuming plaintiff suffered harm as a result of alleged Appointments Clause violation); *see also Bond v. United States*, 564 U.S. 211, 222 (2011) ("Separation-of-powers principles … protect the individual."). And because the Constitution's structural protections safeguard individual rights, a violation of those protections—such as "subjection to an unconstitutionally constituted decisionmaker"—is "in itself a constitutional injury sufficient to warrant injunctive relief." *United Church of the Med. Ctr. v. Med. Ctr. Comm'n*, 689 F.2d 693, 701 (7th Cir. 1982); *see also Valley v. Rapides Par. Sch. Bd.*, 118 F.3d 1047, 1056 (5th Cir. 1997) (holding reputational injury, "not to mention the egregious and constitutionally infirm hearing [plaintiff] was subject to, sufficient to satisfy irreparable injury"); *Atl. Coast Demolition & Recycling, Inc. v. Bd. of Chosen Freeholders of Atl. Cnty.*, 893 F. Supp. 301, 309 (D.N.J. 1995) (holding "a violation of rights under the dormant Commerce Clause constitutes the 'irreparable harm' necessary for a plaintiff to avoid denial of a preliminary injunction").

When a party is haled before an unconstitutional tribunal, "[t]he injury is the submission itself; the [tribunal's] decision may also result in injury, but it is a separate, distinct one." *Hammond v. Baldwin*, 866 F.2d 172, 176 (6th Cir. 1989). Indeed, Sanofi may in the future suffer significant financial and other injury as a result of improper ADR panel decisions. But in the meantime, being forced to submit to unconstitutional proceedings itself imposes irreparable injury by depriving Sanofi of the liberty interests that the Constitution's structural provisions protect. *See United Church of the Med. Ctr.*, 689 F.2d at 701; *Ironridge Glob. IV, Ltd. v. SEC*, 146 F. Supp. 3d 1294, 1317 (N.D. Ga. 2015) (holding in Appointments Clause case that "Plaintiffs will be irreparably harmed if this injunction does not issue because if the SEC is not enjoined, Plaintiffs will be subject to an unconstitutional administrative proceeding").

Moreover, Sanofi's injury is imminent, because its irreparable constitutional injuries "will occur before a trial on the merits can be had" in this action. *BP Chems. Ltd. v. Formosa Chem. & Fibre Corp.*, 229 F.3d 254, 263 (3d Cir. 2000). The ADR Rule appears to require Sanofi to respond to the pending ADR petition by November 4, 2021. Plus, Sanofi additionally faces the threat of HHS enforcement action, including the threat of crippling civil monetary penalties and the potential loss of its ability to participate in Medicare. *See* 42 U.S.C. § 256b(d)(1)(B)(vi) (authorizing HHS to impose civil monetary penalties in the amount of $5,000 per day); *Am. Express Travel Related Servs. Co. v. Sidamon-Eristoff*, 755 F. Supp. 2d 556, 614 (D.N.J. 2010) (Wolfson, J.) (noting "threat of prosecution" in finding irreparable harm). Indeed, HRSA has

already referred Sanofi to the Office of Inspector General for a determination of whether CMPs are appropriate. Exhibit D.

The government's sovereign immunity underscores the irreparable nature of Sanofi's injuries. *See, e.g.*, *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2021 WL 3783142, at *4 (2021) (finding irreparable harm where there was "no guarantee of eventual recovery" of plaintiffs' financial losses from HHS rule). No matter what damages Sanofi incurs in defending itself before the ADR panel or as a result of the ADR panel's orders—all under a cloud of constitutional doubt—it cannot recover a dime from the government. "[E]conomic injury caused by federal agency action is unrecoverable because the APA's waiver of sovereign immunity does not extend to damages claims." *Dist. of Columbia*, 444 F. Supp. at 34; *see also* 5 U.S.C. § 702 (waiving sovereign immunity under the Administrative Procedure Act only where the plaintiff is "seeking relief other than money damages"). As this Court has previously recognized, such harm is irreparable by definition. *Am. Express Travel Related Servs. Co.*, 755 F. Supp. 2d at 614, *aff'd*, *N.J. Retail Merchs. Ass'n v. Sidamon-Eristoff*, 669 F.3d 374, 388 (3d Cir. 2012) (affirming preliminary injunction where plaintiffs "would not be entitled" to recover funds from the government if a law "is later found to be unconstitutional" due to sovereign immunity).

C. The Equities and Public Interest Favor a Stay of Sanofi's Obligation to Respond to the ADR Petition.

The equities and public interest also weigh in favor of modest relief staying Sanofi's imminent deadline to respond to the pending ADR petition. These two factors "merge when the government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Because the ADR Rule is unlawful, the equities straightforwardly favor Sanofi. As this Court has itself stated, "in the context of a motion for preliminary injunction, the Government does not have an interest in the enforcement of an unconstitutional law, and the public interest is not served by the enforcement of an unconstitutional law." *Am. Express Travel Related Servs. Co.*, 755 F. Supp. 2d at 614–15; *see also N.J. Retail Merchs. Ass'n*, 669 F.3d at 388–89; *Ala. Ass'n of Realtors*, 2021 WL 3783142, at *4 (explaining that "our system does not permit agencies to act unlawfully even in pursuit of desirable ends"). Sanofi stands to suffer irreparable harm if it is forced to participate in an unconstitutional ADR proceeding, but granting Sanofi the modest relief requested in this motion—a limited stay of the ADR Rule's requirement that Sanofi respond to the pending ADR petition, but only until this Court resolves the pending dispositive motions—would harm no one. The equities thus support Sanofi's request for a stay pending the Court's review of the ADR Rule.

Indeed, the parties have been proceeding on an expedited basis—with the government specifically inviting Sanofi to challenge HRSA's May 17 letter in this

Court[2]—in order to secure judicial resolution of both the ADR Rule's validity as well as whether Section 340B requires manufacturers to provide discounted drugs to contract pharmacies. The ADR proceedings cannot reasonably go forward until clarity is provided on what the statute requires and whether the ADR Rule is lawful. Defendants' end run around Judge Barker's preliminary injunction by inviting ADR proceedings against Sanofi—which Defendants manufactured through an *ex parte* invitation—is an affront to the judicial process and a recipe for chaos that a stay would easily avoid.

CONCLUSION

Sanofi respectfully requests that the Court stay the portion of the ADR Rule requiring Sanofi to respond to the pending ADR petition until the Court enters final judgment on the parties' dispositive motions. In addition, Sanofi respectfully requests that the Court enter an immediate interim stay of Sanofi's deadline to respond to the pending ADR petition until the Court resolves the present motion for a stay. In the alternative, Sanofi respectfully requests that the Court grant (in whole or in part) Sanofi's motion for a preliminary injunction of the ADR Rule.

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[2] *See* ECF 72-1, at 6 n.1 (reporting the government's position: "Defendants … believe that, should Sanofi wish the Court to review HRSA's recent letter, it promptly should amend its complaint and the parties should file short supplemental briefs regarding any additional claims Sanofi presents.").

Dated: October 7, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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