UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY
Lilly Corporate Center
893 Delaware Street
Indianapolis, Indiana 46225

and

LILLY USA, LLC
1500 South Harding Street
Indianapolis, Indiana 46221,

Plaintiffs,

v.

NORRIS COCHRAN, in his official capacity as Acting Secretary of HHS
Office of the Secretary
200 Independence Avenue, SW
Washington, D.C. 20201,

DANIEL J. BARRY, in his official capacity as Acting General Counsel of HHS
Office of the General Counsel
200 Independence Avenue, SW
Washington, D.C. 20201,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, SW
Washington D.C. 20201,

DIANA ESPINOSA, in her official capacity as Acting Administrator of HRSA
5600 Fishers Lane
Rockville, Maryland 20852,

and

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane
Rockville, Maryland 20852,

Defendants.

No. 1:21-cv-81-SEB-MJD

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PLAINTIFFS' REPLY IN SUPPORT OF
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

The 340B ADR Rule provides a textbook illustration of the wisdom behind the safeguards built into the Constitution and the Administrative Procedure Act. After a decade of inaction, the government bowed to "public outcry" (Opp. 9) and promulgated an "Advisory Opinion" that both reversed a longstanding and recently reaffirmed agency policy and imposed extra-statutory burdens on politically unpopular drug manufacturers. It also issued a defective ADR regulation, based on a stale record, without accounting for intervening factual and legal developments. The result is an adjudication scheme overseen by agency employees who are neither accountable nor impartial, in violation of Articles II and III of the Constitution. The government's efforts to defend the Rule in this Court make its defects worse, not better. The government's opposition ignores the Rule's text and pretends its plain words do not mean what they say, but cannot refute Lilly's constitutional claims. Nevertheless, those *post hoc* editing efforts do succeed in rendering the ADR Rule even more incoherent, arbitrary, and capricious than it was before. Bedrock principles of administrative law preclude the government from defending a defective rule with explanations that are at war with its text and stated justifications. A preliminary injunction is warranted.

ARGUMENT

I. Lilly Is Likely To Succeed On The Merits.

A. The ADR Rule Violates Article II of the Constitution.

Lilly is likely to succeed in its claim that the ADR Rule violates the Appointments Clause of Article II. The government concedes (Opp. 13) that ADR panelists' broad suite of powers—"indeed, nearly all the tools of federal trial judges"—makes them "'Officers of the United States,' subject to the Appointments Clause." *Lucia v. SEC*, 138 S. Ct. 2044, 2048, 2053-55 (2018). But the government denies that the ADR panelists are ***principal*** officers who must be appointed by the President with the advice and consent of the Senate. The government is wrong.

ADR panelists' authority to make significant final decisions for the Executive Branch bears all the traditional hallmarks of principal-officer power. Under the express terms of the 340B statute and the ADR Rule, ADR panel decisions are the "final" word of the Executive Branch, "binding on the parties," and "precedential" within HHS. 42 U.S.C. § 256b(d)(3)(C); 42 C.F.R. § 10.24(d). Those precedential decisions cannot be modified or undone by any superior officer within the Executive Branch, not even by the Secretary himself; only "a court of competent jurisdiction" can set them aside. *Id.* That suffices to make panelists principal officers, *see* PI Mem. 17-18, so the Rule violates Article II by vesting panelists' appointment in the Secretary.

None of the government's attempts to resist that straightforward conclusion is persuasive. The government says that "'the line between principal and inferior officers' turns on supervision by a higher authority, not on the 'exercise of significant authority.'" Opp. 14 (quoting *Edmond v. United States*, 520 U.S. 651, 662-66 (1997)). That is wrong. As the Supreme Court explained just last year, the line between principal and inferior turns on far more than just "whether the officer's work is 'directed and supervised'" by a higher authority within Article II; it also depends on "factors such as the nature, scope, and duration of an officer's duties." *Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2199 n.3 (2020) (quoting *Edmond*, 520 U.S. at 661, 663); *Edmond*, 520 U.S. at 667 (Souter, J., concurring) ("Having a superior officer is necessary for inferior officer status, but not sufficient."). Here, "the nature, scope, and duration of [ADR panelists'] duties" make clear that they are principal officers for purposes of Article II: Most important, because panelists may "render a final decision on behalf of the United States," *Edmond*, 520 U.S. at 665 (majority op.); *see* 42 U.S.C. § 256b(d)(3)(C); 42 C.F.R. § 10.24, they are principal officers under Article II.

But even if the government were right that principal-officer status hinged only on "supervision by a higher authority," Opp. 14, no such supervision exists here. By statute, ADR

panelists issue "a final agency decision" on behalf of the United States that is "binding upon the parties involved." 42 U.S.C. § 256b(d)(3)(C); *see* 42 C.F.R. § 10.24. Critically, they may do so without "permi[ssion] … by other Executive officers." *Edmond*, 520 U.S. at 665. That fact distinguishes this case from *Edmond*, where the Court held Coast Guard judges to be inferior officers because their decisions ***were*** subject to review by superior Senate-confirmed Article II officials. *See id.* The government buries this critical point in a footnote, *see* Opp. 14 n.4, but *Edmond* makes clear that that distinction makes all the difference. The Court emphasized that without this power of review within the Executive Branch—which is lacking here—supervision of the judges was "not complete." 520 U.S. at 664. Instead, "[w]hat is significant is that the judges of the Court of Criminal Appeals have no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers." *Edmond*, 520 U.S. at 665.

The government promises to cite "numerous persuasive decisions establish[ing] that," contrary to *Edmond*, "the absence of direct review of an officer's ***decisions*** does not render that officer a principal." Opp. 14 n.4. But the government cites no such case, because none exists. To the contrary, the Supreme Court has routinely reaffirmed the critical distinction underlying *Edmond*. For instance, the Supreme Court held in *Free Enterprise Fund v. PCAOB* that PCAOB members are inferior officers because the SEC's "oversight authority" included the ability to "approv[e] ***and alter***[]" PCAOB decisions. 561 U.S. 477, 486, 510 (2010) (emphasis added). And in *Department of Transportation v. Association of American Railroads*, Justice Alito made clear that when—as here—an officer is empowered to make final, binding determinations on behalf of an agency that are not reversible by any other Article II officer, the officer is a principal officer. 575 U.S. 43, 64 (2015) (Alito, J., concurring) ("[I]t looks like the arbitrator would be making law without supervision—again, it is 'binding arbitration.' … ***As to that 'binding' decision, who is***

the supervisor? Inferior officers can do many things, but ***nothing final should appear in the Federal Register unless a Presidential appointee has at least signed off on it***." (emphasis added)).

The D.C. Circuit cases the government cites are to the same effect. On remand in *American Railroad*, for example, the D.C. Circuit followed Justice Alito's lead and held the challenged law unconstitutional because—just as the ADR Rule does vis-à-vis panelists—it permitted arbitrators to render "final," "binding" decisions, but did not "provide any procedure by which the arbitrator's decision is reviewable." *Assoc. of Am. R.Rs. v. U.S. Dep't of Transp.*, 821 F.3d 19, 39 (D.C. Cir. 2016). The D.C. Circuit confirmed this approach just last week, holding that USDA ALJs are inferior officers because, unlike here or in *American Railroads*, "the Secretary" has authority to "step in and act as final appeals officer in any case," which means—unlike here—that the "ALJ's decision" is not necessarily the agency's final word. *Fleming v. USDA*, --- F.3d ---, 2021 WL 560743, at *8 (D.C. Cir. Feb. 16, 2021). But here, just like the arbitrators in *American Railroads*, ADR panelists render "final agency decision[s]" that by statute are not only "binding upon the parties," 42 U.S.C. § 256b(d)(3)(C), but "appealable only to courts of the Third Branch," *Edmond*, 520 U.S. at 665; *see* 42 C.F.R. § 10.24(d) (ADR panel decisions are "final," "precedential," and "binding" "unless invalidated by an order of a court of competent jurisdiction"). The government again buries this problem below the line, Opp. 17 n.5, but it is no less fatal to its case.

Ignoring this precedent, the government seeks refuge in *Intercollegiate Broadcasting System, Inc. v. Copyright Royalty Board*, 684 F.3d 1332 (D.C. Cir. 2012), but that case provides no help to the government either. The government claims that the copyright royalty judges in *Intercollegiate* were deemed inferior officers because their "decisions" were not reviewable "by any other Executive Branch officer." Opp. 15. In reality, *Intercollegiate* held that, as designed, CRJs "***are principal officers***" precisely because—"unlike the judges in *Edmond*," but exactly like

ADR panelists here—the determinations "***are final for the executive branch***" and "not reversible … by any other officer or entity within the executive branch." 684 F.3d at 1340 (emphasis added). The court so held, moreover, even though the Register of Copyrights could "review[] ***and correct***[] any legal errors in the CRJs' determinations." *Id.* at 1338-39 (emphasis added). The conclusion that ADR panelists are principal officers is thus *a fortiori* of *Intercollegiate*, as ADR panels' statutorily "final," "binding" "agency decisions" are not reviewable or correctible by anyone within the Executive Branch in any way. *See* 42 U.S.C. § 256b(d)(3)(C); 42 C.F.R. § 10.24(d).

In short, instead of "numerous persuasive decisions," Opp. 14 n.4, no authority supports the government's claim that an agency adjudicative officer is inferior when—as here—that officer's final, binding decisions cannot be reviewed or set aside by another Executive officer.

The government's last defense is to argue that ADR panel decisions can be supervised through roundabout means. According to the government, the Secretary can remedy the Rule's constitutional defect by (1) "rescind[ing]" its delegation of authority to panels and "adjudicat[ing] these matters personally," or (2) revising the Rule and exercising "at will" removal power as in *In re Grand Jury Investigation*, 916 F.3d 1047 (D.C. Cir. 2019). Opp. 16-17. Neither "fix" works.

First, the HHS Secretary cannot solve the Article II problem by personally adjudicating ADR disputes. For starters, that is not what the 340B statute or the actual ADR Rule contemplate. The Rule specifies where ADR panelists will come from (HRSA, CMS, and the HHS Office of General Counsel) and who will appoint them (the Secretary). *See* 42 C.F.R. § 10.20; 85 Fed. Reg. 80,632, 80,634 (Dec. 14, 2020). Under that regulation, the HHS Secretary is not a panelist, and neither is any other principal officer properly appointed by the President. That dooms the government's argument. Lilly is challenging the actual ADR Rule—not some hypothetical future

regulation. Nor could the Secretary rescind the ADR Rule with the stroke of a pen; a policy reversal along the lines the government posits here would require shepherding an entirely new rule through the APA's notice-and-comment process, an achievement that eluded HHS for ***a decade*** the last time around. See *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

In any case, the government's solution would still violate Article II, since it would still allow the Secretary, rather than the President, to make a principal-officer appointment. By giving ADR panels authority to issue "a final agency decision," 42 U.S.C. § 256b(d)(3)(C)—*i.e.*, what Justice Alito explained in *American Railroads* must be done by a principal officer: The statute's express terms make clear that the position of ADR panelist is necessarily a principal-officer position, so it must be filled by a principal officer appointed by the President—or no one at all. *See Weiss v. United States*, 510 U.S. 163, 170 (1994) (because military trial judge's powers were those of an officer, all those currently "serving as military judges must be appointed pursuant to the Appointments Clause"). But by vesting panel appointments only in the Secretary, the ADR Rule "allows the President no formal role at all in the selection of the particular individuals who will actually serve in those positions," which "disregard[s] the special treatment the Constitution requires for the appointment of principal officers," including allowing the Senate to "adequately focus" on the role in which a nominee may actually serve. *Id.* at 591 (Souter, J., concurring).

Second, the argument that the Secretary has plenary removal power over ADR panelists, *see* Opp. 17-18, fares no better. That is again contrary to the text of the ADR Rule, which says that "individuals serving on a 340B ADR Panel may be removed for cause." 85 Fed. Reg. at 80,634; *see also* 42 C.F.R. § 10.20(a)(ii) ("For each case, the HRSA Administrator shall … [r]emove an individual from a 340B ADR Panel for cause."). If the government is right that panelists are actually subject to at-will removal by the HRSA Administrator's direct superior, then

the Rule's express limitation to removal only "for cause" is utterly illusory—and a defense that depends on turning an agency rule into nonsense is not a winning one.[1]

In all events, plenary removal authority would not suffice to make ADR panelists inferior officers. To be sure, the power to remove an officer may be a "powerful tool for control." *Edmond*, 520 U.S. at 664. That is why the D.C. Circuit found it a sufficient remedy to sever the limitations on removability in *Intercollegiate*; there, the Register of Copyrights had the authority to "review[] ***and correct***[]" CRJs' decisions. 684 F.3d at 1338-39 (emphasis added). But that is not the case here. And, contrary to the government's suggestion, the Supreme Court has never held that an officer is inferior just because he can be removed. Rather, the Court has made clear that removal power suffices to render an officer inferior only when that power is buttressed by or tantamount to the power to review, modify, or otherwise undo the officer's decisions. *Edmond* drew that precise distinction: The Judge Advocate General had unfettered power to remove the Coast Guard judges "without cause," but that ***did not suffice*** to make them inferior officers; his oversight powers were "not complete" because he "ha[d] no power to reverse decisions." 520 U.S. at 664. It was only because the Article II officers on the Court of Appeals for the Armed Forces ***did*** have that power that the Coast Guard judges were inferior officers. *Id.* That makes eminent sense, since even plenary power to remove would thus not permit a superior to correct or reverse decisions already made: "The firing of judges does not, in itself, vacate their decisions." Gary Lawson, *Appointments and Illegal Adjudications: The America Invents Act through a Constitutional Lens*,

[1] That is particularly true given that this argument belies everything the government says to justify its decision to eschew independent, impartial ALJs (in favor of existing agency employees likely to hold positions consistent with HHS policy). *See* pp. 21-22, *infra*. The government cannot defend an agency action by assuring on the one hand that ADR panelists will be fully "objective[]" and impartial adjudicators, Opp. 32, yet touting on the other the "Secretary's ability to remove an individual from a panel, or from the Board, at will—with or without a conflict of interest," Opp. 18.

26 GEO. MASON L. REV. 26, 61 (2018). And, here, making ADR panelists removable at will would not make them inferior officers because their decisions cannot be undone by the Secretary.

That also distinguishes this case from *In re Grand Jury Investigation*, where removal effectively allowed control of the removed officer's decisions. There, the Attorney General not only could remove the Special Counsel at will, but could unilaterally rescind the Special Counsel's entirely-regulatory authority, terminate an investigation, and discharge the grand jury. That is not the case here. Even a removed ADR panelist's decisions would remain the agency's final word, "precedential and binding on the parties involved[,] unless invalidated by an order of a court of competent jurisdiction." 42 C.F.R. § 10.24(d); *see* 42 U.S.C. § 256b(d)(3)(C); *see also Free Enter. Fund*, 561 U.S. at 544 (Breyer, J., dissenting) (doubting "that courts will always be able to cure [an Article II] defect merely by severing an offending removal provision"); Lawson, *supra*, at 61 (concluding that the "power to fire [ALJs] does not constitute the kind of formal control over their decisions that makes them inferior rather than principal officers" where—as here—"their decisions are the final (nonpresidential) word on the exercise of executive power").

Thus, the government's creative attempts to avoid the Rule's obvious Appointments Clause defects fail. But to the extent this Court has any doubt about the inadequacy of the government's severance-and-removal gambit, the proper course would be to enjoin the ADR Rule pending the Supreme Court's resolution of *Arthrex, Inc. v. Smith & Nephew, Inc.*, 141 S. Ct. 551 (2020), in which the efficacy of the same proposed remedy (vis-à-vis administrative patent judges) is directly at issue. *See* Ex. A (PTO order staying numerous proceedings pending *Arthrex*).

B. The ADR Rule Violates Article III of the Constitution.

Lilly is also likely to succeed in showing that the ADR Rule violates Article III. The ADR Rule grants to administrative adjudicators the very core of the "judicial Power." *See Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 221 (1995). Even the government admits that "Article III

prevents Congress from 'withdraw[ing] from judicial cognizance any matter which, from its nature, is the subject of a suit at the common law.'" Opp. 22 (quoting *Stern v. Marshall*, 564 U.S. 462, 484 (2011)). Under the Rule, an aggrieved entity (either a covered entity or a manufacturer) can file what the rule describes as an "action" for "monetary damages or equitable relief." 42 C.F.R. § 10.21(a). Yet such actions are heard not by a court, but by a "340B ADR Panel," which has exclusive "jurisdiction" over any such "action." *Id.* § 10.21(b), (c). That is unconstitutional, as the Supreme Court has long held that an "action" between private parties for "monetary damages or equitable relief" is the type of suit that only courts can adjudicate. *See Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 55-56 (1989); *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284 (1856); *see also* 3 W. Blackstone, *Commentaries* *2, *138-39 (1765).

The government's contrary arguments are meritless—but they are also telling. In an attempt to save the Rule from constitutional infirmity, the government has effectively rewritten its text and insisted upon unusual definitions of common terms. The government's lead Article III arguments are thus better described as tacit admissions of the Rule's defects as written—defects that cannot be cured *ex post* in a legal brief. The government separately denies that any private rights are at stake in disputes between manufacturers and covered entities because, among other things, a federal statutory program is implicated. Numerous Supreme Court cases hold otherwise.

1. The ADR Rule cannot be salvaged by changing its text in litigation.

Federal agencies cannot fix legally defective regulations by offering "*post hoc* rationalizations for agency action" in a legal brief that have no basis in the rule. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983). On the contrary, "an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Id.*; *see SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947) ("We may not supply a reasoned basis for the agency's action that the agency itself has not given."); *Phila. Gas Works v. FERC*, 989 F.2d 1246,

1250 (D.C. Cir. 1993) ("under *Chenery I*, FERC, not we (or FERC's appellate lawyers), must adopt" the "grounds … FERC's counsel suggest[s]"). The government flouts that principle.

The government first contends that ADR panel "decisions" are nothing like common-law courts" because they "are not self-effectuating," but instead "must be 'submit[ted] … to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities.'" Opp. 20 (alterations in original) (quoting 42 C.F.R. § 10.24(e)). But the statute and the Rule are clear that only a court has any power to modify a panel's "decision based on its review and evaluation of the evidence." 42 C.F.R. § 10.24(b); *see* 85 Fed. Reg. at 80,634-642; 42 U.S.C. § 256b(d)(3)(C). While the Rule does authorize HRSA, following a panel decision, to take "appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities," 42 C.F.R. § 10.24(e), it does not authorize HRSA to ***modify*** panel decisions; it merely provides a mechanism for ***further*** enforcement. After all, panel decisions—including the decision to award money damages (and how much) and/or equitable relief (and what kind)—are "binding on the parties involved unless invalidated by an order of a court of competent jurisdiction," 42 C.F.R. § 10.24(d). The Rule does not say they are binding "once approved by HRSA."

The government next asserts that "Lilly is incorrect that an ADR Panel has authority to issue binding judgments for money damages." Opp. 28. The text of the Rule, however, says this: "Any covered entity or manufacturer may initiate ***an action for monetary damages*** … against a manufacturer or covered entity, as the case may be, by filing a written petition for relief"; filing such a petition initiates "***a proceeding for damages***"; exclusive "jurisdiction to entertain any [such] petition" rests with a "340B ADR Panel"; and the panel's "decision constitutes a final agency decision that is precedential and binding on the parties involved." 42 C.F.R. §§ 10.21 (emphasis added), 10.24; *see also id.* § 10.21(e) ("In a proceeding ***for damages***, the Petitioner must still

introduce evidence sufficient to support ***its claim for damages*** even though the merits have been resolved through default." (emphasis added)); 42 U.S.C. § 256b(d)(3)(C).

The government's novel interpretation of the term "equitable relief" is even more remarkable. The Rule states that panels may award "equitable relief," full stop. 42 C.F.R. § 10.21(a); *see also* 85 Fed. Reg. at 80,633. Normally, when a term "is obviously transplanted from another legal source," as "equitable relief" plainly is, "it brings the old soil with it." *Taggart v. Lorenzen*, 139 S. Ct. 1795, 1801 (2019) (citation omitted). Here, that includes the quintessential form of equitable relief: an injunction. *See Mertens v. Hewitt Assocs.*, 508 U.S. 248, 256 (1993); Dan. B. Dobbs, LAW OF REMEDIES: DAMAGES EQUITY RESTITUTION 9 (2d ed. 1993). But the government's brief, without citing any provision of the regulation, announces that "the 'equitable relief' contemplated in the Rule means an order determining whether a manufacturer or covered entity has violated the statute—not a self-executing, judicial-style remedy." Opp. 20. What the government is describing is called a declaratory judgment, or perhaps a "cease-and-desist letter," and the government offers no explanation why HHS would choose to use the term "equitable relief" to describe it. The confusion is heightened by the fact that the Rule separately tells ADR panels to apply "the Federal Rules of Civil Procedure," 42 C.F.R. § 10.23(b), which authorize courts to issue "preliminary injunction[s]" and "restraining order[s]," Fed. R. Civ. P. 65. While Lilly is pleased to have the government concede that ADR panels lack such powers, *see* Opp. 21, one would not know that from the Rule the agency adopted; nor is there any way to tell ***which*** provisions of the Federal Rules of Civil Procedure the government thinks do and do not apply.[2]

[2] Lilly was not the only one surprised by the government's reading of "equitable relief." A group of covered entities recently petitioned the panel for a self-styled "Preliminary Injunction," "to employ its equitable authority under 42 C.F.R. § 10.21(a) to compel drug manufacturers … to immediately make their covered outpatient drugs available to FQHC covered entities at or below

The point of all the government's creative editing is to make it ***look like*** ADR panels are not adjudicating private rights, but no one should be fooled. For example, the government asserts that ADR panels actually cannot "command[] one private party to convey its property to another." Opp. 19 (quoting PI Mem. 21). But the text of the Rule gives panels precisely that authority, vesting them with "jurisdiction to resolve all issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility." 85 Fed. Reg. at 80,636; *see also* 42 C.F.R. § 10.21(b), (c). It also authorizes ADR panels to determine that an entity (*e.g.*, a contract pharmacy) is covered by the statute; to determine that a manufacturer's refusal to sell to such entity at 340B prices violates "statutory requirements" (Opp. 19); and to issue "precedential and binding" judgments that the manufacturer is legally required to do just that.

That is the definition of unconstitutional adjudication of private rights outside Article III. The Supreme Court's decision in *Oil States Energy Services v. Greene's Energy Group*, 138 S. Ct. 1365 (2018), could not be clearer on this point: The Court upheld a non–Article III tribunal only because that tribunal "does not make any binding determination regarding 'the liability of [one party] to [another] under the law as defined." *Id.* at 1378. But making binding determinations regarding the liability of one private party to another ***is exactly what ADR panels do***.

As a failsafe, the government claims that it "make[s] no difference" to Article III what vast common-law powers ADR panels enjoy. Opp. 21. That is wrong. The Supreme Court has made crystal clear that the suite of powers exercised by an administrative tribunal is directly relevant to the degree of infringement on the judicial power—and that the suite of powers exercised by ADR panels is well over the constitutionally permissible line. *See CFTC v. Schor*, 478 U.S. 833, 851

340B ceiling prices when shipped to a contract pharmacy." *Nat'l Ass'n of Cmty. Health Ctrs. v. Eli Lilly & Co.*, Petition No: 210112-2 (filed Jan. 13, 2021).

(1986). Here, the Rule authorizes ADR panels to resolve claims by a private party that it is entitled to another private party's property below cost, to issue money-damages judgments for past failures to convey that property, and to use the official rules that govern federal-court proceedings. And it does this while simultaneously limiting Article III courts' review—even though the Supreme Court deems constitutionally suspect administrative schemes that allow federal-court review of agency decisions only under the deferential APA standard that applies here. *See, e.g.*, *id.* at 853. By these devices, the Rule removes any meaningful "control by Article III judges over the interpretation, declaration, and application of federal law," and usurps the "constitutional role of the judiciary." *United States v. Johnston*, 258 F.3d 361, 368 (5th Cir. 2001) (quoting *Pacemaker Diagnostic Clinic, Inc. v. Instromedix, Inc.*, 725 F.2d 537, 544 (9th Cir. 1984) (en banc) (Kennedy, J.)).

2. Lilly's property rights are traditional private rights.

More ambitiously, the government claims that, because a federal statute is implicated here, Lilly has no private rights at stake requiring Article III adjudication at all—even though Lilly asserts that its preexisting common-law right to dispose of its property has not been abrogated by the 340B statute vis-à-vis contract pharmacies. Specifically, the government says "it matters not" to the Constitution "that the dispute may arise between private parties" because (it says) the whole 340B Program is tied to a federal statute. Opp. 22. That is both wrong and dangerous.

The government's position is based on a misreading of the Supreme Court's decision in *Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568 (1985). In that case, a non–Article III tribunal was allowed to adjudicate disputes between private parties when ***neither of them*** had any asserted private rights at stake. *Union Carbide* arose in the context of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), under which pesticide registrants generally were required to submit to the EPA data regarding the safety and efficacy of their products. By submitting the data, the registrant extinguished any common-law property right it might have had.

See id. at 584. The EPA could then use the first registrant's data to evaluate a second registrant's application. *Id.* FIFRA created a novel scheme under which the second registrant would owe registrant 1 compensation if the EPA used its data to approve registrant 2's application; in such a case, the statute required binding arbitration of disputes between registrants. *Id.* And because each party's rights were wholly created by FIFRA, the Supreme Court held that Congress could require such disputes over public rights to be adjudicated outside Article III. *Id.* at 584; *see also* Caleb Nelson, *Adjudication in the Political Branches*, 107 COLUM. L. REV. 559, 606-08 (2007).

The private-rights claims at issue here bear no resemblance to the bilateral public-rights claims at issue in *Union Carbide*. Lilly's right to sell its property at its chosen price derives from the common law, not a federal statute; and no one is claiming any novel right to compensation for how ***the government*** uses one private party's data to benefit another (as was the case in *Union Carbide*). *Cf.* Br. for the United States, *Union Carbide*, No. 84-497, 1985 WL 669974, at *13 (U.S. Jan. 11, 1985) ("[D]ata compensation disputes under FIFRA were unknown to the common law and are wholly a matter of recently created federal statutory rights."). To be sure, a contract pharmacy may assert that it is entitled to obtain Lilly's property at a discount pursuant to the 340B statute. But Lilly contends otherwise—and if Lilly is correct, then its common-law rights will stand and can be vindicated in a common-law court. Seeking proper compensation for a private-property transaction is hardly an instance where "it depends upon the will of congress whether a remedy in the courts shall be allowed at all." *Stern*, 564 U.S. at 488-89 (citation omitted).

These differences between the *Union Carbide* scheme and the scheme created under the ADR Rule provide reason enough to reject the government's contentions. But there is more.

The government argues that *Astra U.S.A., Inc. v. Santa Clara County*, 563 U.S. 110 (2011), "confirms" that the ADR Rule's procedures comport with the Constitution. Opp. 25. But *Astra*—

which did not discuss Article III at all—does no such thing. The question in *Astra* was whether the PPA contract manufacturers sign to participate in the 340B program creates a private right of action. In rejecting that claim, the Court observed in passing that the statute contemplates ADR procedures. 563 U.S. at 121-22; *see Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001) But noting that Congress required HHS to set up ADR procedures is obviously not an opinion on the merits of the ADR procedures that HHS promulgated ***nine years later***. *See Glover v. United States*, 531 U.S. 198, 205 (2001) (the Court ordinarily only decides questions directly presented).

The government next switches gears from over-reading Supreme Court decisions to ignoring them. The government's erroneous assertion that a non–Article III tribunal can adjudicate all claims so long as they are related to a regulatory scheme would render incomprehensible the Supreme Court's decision in *Granfinanciera*—a case the government does not even acknowledge. *Granfinanciera* held that a fraudulent-conveyance claim that ***arose under a federal statute***, 11 U.S.C. § 548(a)(2), could not be adjudicated by a non–Article III forum because such claims entail deciding how much one private party owes another separate and apart from the bankruptcy priority regime. 492 U.S. at 34-35. Private-rights claims like these "possess a long line of common-law forebears" and must be heard by tribunals that comply with constitutional guarantees, ***even when created by statute***. *Id.* at 51-52. So too here: Even though the claims arise in the context of a statutory scheme, the claims by definition are a dispute between private parties implicating private-property rights and therefore must be heard in court.[3]

[3] In ignoring *Granfinanciera*, the government also ignores the Supreme Court's related teachings that actions to enforce legal rights for damages invoke the right to a jury trial, even when the issues arise in the context of a federal statutory scheme. *See Granfinanciera*, 492 U.S. at 36; *see also Curtis v. Loether*, 415 U.S. 189, 195 (1974) (holding that "a jury trial must be available" for "damages action[s] under [the Civil Right Act]" because such claims "involve[] rights and remedies of the sort typically enforced in an action at law"). *A fortiori*, adjudication of such issues requires an exercise of the "judicial Power" of Article III. *See Granfinanciera*, 492 U.S. at 53-54.

The government's theory also contradicts the Supreme Court's decision in *Stern*, which interpreted the bankruptcy court's ability to enter final judgments under a statutory provision that explicitly gave it jurisdiction over "all core proceedings arising under title 11, or arising in a case under title 11," including "counterclaims by [a debtor's] estate against persons filing claims against the estate." 28 U.S.C. § 157(b)(1), (2)(C). Notwithstanding that a state-law counterclaim for tortious interference "is a 'core proceeding' under the plain text of" the statute, *Stern*, 564 U.S. at 475, the Court held that allowing a bankruptcy court (a non–Article III tribunal) to enter final judgment on such claims would "raise[] serious constitutional concerns," *id.* at 477. Like the fraudulent-conveyance claim in *Granfinanciera* (and the claims for damages here), the state-law claim in *Stern* was "not a matter that can be pursued only by grace of the other branches, one that historically could have been determined exclusively by those branches [or one that] depend[ed] upon the will of Congress." *Id.* at 493 (citations and alterations omitted). Thus, the bankruptcy court could not adjudicate the state-law claim because it concerned private rights, even though it was permitted by statute and easily satisfies the government's integral-to-a-regulatory-scheme test.

The government's theory would do similar damage to the Supreme Court's decision in *Oil States*, on which it heavily relies. *Oil States* began by expressly stating that patents are public rights that did not exist at common law, and are thus purely creatures of statute. 138 S. Ct. at 1374. On the government's theory here, that also should have been the ***end*** of the case: If the grant of a patent is closely tied to a regulatory scheme, then surely the reconsideration of a patent is too. But the Supreme Court disagreed. Instead, the Court found it necessary to discuss at length the historical pedigree of patent reconsiderations by the executive and to engage in a lengthy analysis of how patent reconsiderations, separate and apart from patent grants, "fall[] on the public-rights

side of the line." *Id.* at 1374, 1377. The government cannot point to any similar long-established practice of the Executive Branch adjudicating anything like the disputes at issue here.

Indeed, the government's argument would suggest that even ***damages suits for patent infringements*** could be adjudicated by Executive Branch employees, since they, like 340B disputes, ultimately depend on a federal statutory scheme. But that is obviously not the case. Indeed, *Oil States* made clear that its holding did not mean that patent infringement actions could be adjudicated in a non–Article III forum. *See* 138 S. Ct. at 1379. And even the government's own briefs in *Oil States* conceded that, unlike patent cancellation, infringement actions were traditionally resolved by juries. *See* Br. for the Federal Respondent, No. 16-712, 2017 WL 4805230, at *17-18 (U.S. Apr. 28, 2017); *see also Oil States*, 138 S. Ct. at 1379. And Article III's touchstone is whether "a suit is made of 'the stuff of the traditional actions at common law tried by the courts at Westminster in 1789.'" *Stern*, 564 U.S. at 484 (citation omitted).

As these cases all make clear, the nature of the rights in dispute does indeed feature prominently in the assessment of whether the Constitution requires adjudication by an Article III court. These same cases also place beyond doubt the conclusion that ADR claims for money damages squarely fit that bill. Prior to the enactment of the 340B program, Lilly had the right to sell its drugs at whatever price the market allowed. The 340B statute did not create that "substantive federal right," Opp. 24 (citation omitted); it only impaired a pre-existing, independent common-law right by essentially placing ***restrictions*** on making sales for one-fifth of the Nation's population. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1806 (2019). Thus, at least to the extent they implicate sales to contract pharmacies and other entities not covered by the statute, such disputes remain "quintessentially" common-law suits with "a long line of common-law forebears." *Granfinanciera*, 492 U.S. at 34, 51. They concern "matter[s] which, from [their]

nature, [are] the subject of a suit at the common law." *Murray's Lessee*, 59 U.S. at 284. As the Supreme Court has made clear, "[t]he 'experts' in the federal system at resolving [such claims] are the Article III courts, and it is with those courts that [they] must stay." *Stern*, 564 U.S. at 494.

C. The ADR Rule Violates the APA.

1. Because the agency formally withdrew the NRPM from consideration, it was required to undergo notice and comment again before promulgating any final rule, but failed to do so. The government's lead argument to the contrary is that withdrawing the NRPM from the Unified Agenda did not amount to "a permanent termination," because (it says) "the termination of rulemakings" becomes official "only after a formal notice of withdrawal is published in the Federal Register." Opp. 27. That is not the law. The APA does not specify that withdrawal must occur through the Federal Register, *see* 5 U.S.C. § 553, and "courts are not free to impose upon agencies specific procedural requirements that have no basis in the APA," *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385 (2020) (citation omitted). That likely explains why none of the cases the government cites, Opp. 27, actually stands for the proposition that publication in the Federal Register is the exclusive means by which an agency can terminate a rulemaking, nor was the issue of withdrawal in dispute in ***any*** of them. The government cited no case approving HHS's tactics as a legitimate means of continuing the rulemaking process, and Lilly is aware of none.

The relevant question, then, is whether the agency's public-facing actions would lead a reasonable regulated entity to conclude that the agency had withdrawn the rulemaking. *See Ctr. for Auto Safety v. NHTSA*, 710 F.2d 842, 844-45 (D.C. Cir. 1983); *see also Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007) ("the object" of the APA is "fair notice"). The answer is "yes." The agency permanently removed the NPRM from the Unified Agenda in 2017 and took no further action. The consequence of that decision was that the NPRM was publicly

declared to be a "Completed Action," *see* HHS/HRSA, *View Rule, RIN: 0906-AA90* (Spring 2017), https://bit.ly/2ZydLLo, a status reserved for "rulemakings that are being Withdrawn or ending their lifecycle with a regulatory action that completes the rulemaking," HHS/HRSA, *About the Unified Agenda*, https://bit.ly/2OYh3FZ (last visited Feb. 23, 2020). Agency officials also told the public that, because "many of the issues that would arise for dispute are only outlined in guidance" the agency understood to be legally unenforceable, it had no plans to issue an ADR rule. PI Mem. 10 (citation omitted). And when it finally promulgated the final ADR Rule, the agency assigned the Rule a brand-new RIN. *See* HHS/HRSA, *View Rule, RIN: 0906-AB26* (Fall 2020), https://bit.ly/37yERqm. Taken together, these actions speak as loudly as any formal publication in the Federal Register—as even the proposed intervenors in this case have admitted. *See* AHA et al.'s Mem. in Support of Mot. to Intervene at 5 ("the proposed ADR regulation (which had been withdrawn)"). The agency withdrew the NPRM and made it abundantly clear that no rulemaking was forthcoming. The final ADR Rule therefore lacked proper notice and comment.

Even if the NRPM were properly withdrawn, the final Rule is not a logical outgrowth of the NPRM. The government's only response to the fact that the NPRM in no way presaged the award of monetary damages is to repeat its *ipse dixit* that the Rule does not actually allow for such actions, despite the plain language of 42 C.F.R. § 10.21(a), which permits aggrieved parties to file "action[s] for monetary damages." That is no response at all. The law is clear that "[i]f a final rule deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal." *See Public Citizen, Inc. v. Mineta*, 427 F. Supp. 2d 7, 14 (D.D.C. 2006). The government cannot evade that requirement by telling a reviewing court, through its lawyers, that none of the departures from its original proposal has any meaning.

The government does not even pretend that the NPRM foreshadowed the final rule's requirement that ADR panel decisions would be "precedential"—which provides HRSA with a backdoor means of doing what courts have said it may not do: adopt "binding rules that carry the force of law." *PhRMA v. HHS*, 138 F. Supp. 3d 31, 48 (D.D.C. 2015); *see PhRMA v. HHS*, 43 F. Supp. 3d 28, 39 (D.D.C. 2014). Instead, the government says Lilly should somehow have "divine[d]" that the agency would depart from the NPRM by giving agencies the power to issue binding ***and*** precedential judgments. *Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1299 (D.C. Cir. 2000). But "binding on the parties" and "precedential for the agency" mean different things. A "precedential" decision establishes how future disputes will be resolved and greatly increases the burdens placed on a regulated entity to conform its affairs to the conduct of others. And while "binding decisions" are at least contemplated by the statute, 42 U.S.C. § 256b(d)(3)(C), ***precedential*** decisions are not. Lilly thus had no reason to believe, in the wake of the agency's silence, that its powers would be broadened in such a fashion. That violates the logical outgrowth test. *See, e.g.*, *Ctr. for Biological Diversity v. Everson*, 435 F. Supp. 3d 69 (D.D.C. 2020) ("the proposed rule contains no reference to the Polar Bear Memo"); *D.C. v. USDA*, --- F. Supp. 3d ---, 2020 WL 6123104, at *10 (D.D.C. Oct. 18, 2020) ("No reference to extended unemployment benefits … was made in the [ANRPM] for the Final Rule."); *Council Tree Commc'ns, Inc. v. FCC*, 619 F.3d 235, 256-57 (3d Cir. 2010) (option was not mentioned in NPRM).

2. Lilly is equally likely to prevail on its substantive APA claims. The government offers several arguments attempting to salvage the rule, each of which fails.

First, the government claims that it simply could not have "predict[ed]" Lilly's constitutional concerns. Opp. 31. That is not a response. In the ADR Rule, as with every rule, the agency must "consider" all "important aspect[s] of the problem" to be addressed. *State Farm*,

463 U.S. at 43. Constitutional deficiencies cutting to the core of the entire adjudicative scheme certainly meet that criterion. And it should go without saying that an agency cannot ignore its overriding obligation to promulgate only constitutional rules. *See, e.g.*, *Alpine PCS, Inc. v. United States*, 878 F.3d 1086, 1097 (Fed. Cir. 2018). The agency had an independent obligation to ensure that, when creating this novel adjudicative body, it did so in keeping with current Supreme Court precedent and other constitutional developments. Because the agency completely failed to grapple with this vitally important aspect of the problem, the ADR Rule is arbitrary and capricious.

Second, the government moves from throwing up its hands to trying to point the finger, claiming Lilly "waived" any constitutional claims "by failing to raise [them] during the comment period." Opp. 31. That argument is, to borrow a word, brazen. Lilly objected to the lack of impartiality and accountability for ADR panelists in response to the original NRPM. *See* Ex. M to Am. Compl. More important, the availability of "monetary damages" and "equitable relief" appeared ***for the first time in the final Rule***, as did the power to issue "precedential decisions." Those proposals were not subject to notice and comment, and Lilly had no obligation to guess that the agency would alter the NPRM in a way that ran afoul of the Constitution.

Third, the government's response to Lilly's concerns over panelists' impartiality is self-defeating. In the APA section of its brief, the government insists that "HHS established multiple procedures and safeguards 'to ensure fairness and objectiveness" in the ADR process," including "remov[al] from a panel 'for cause.'" Opp. 32 (citation omitted). But that flies in the face of the government's purported remedy for its Appointments Clause problem—namely, its contention that unbeknownst to an ordinary reader of the ADR Rule, the Secretary can now remove panelists *at will*. *See* note **Error! Bookmark not defined.**, *supra*. The government cannot have it both ways: It cannot insist that ADR panelists need not be ALJs because they will not be influenced by "policy

positions or other objectives outside of the limited facts of the dispute at issue," Opp. 32, while arguing that their removal protections are mere window dressing that the Secretary can ignore (including, *e.g.*, if they do not agree with his policy goals). Either the government is correct about removal or correct about procedural safeguards ensuring "impartiality"; it cannot be right about both.

Fourth, the government's appeals to agency expertise as justification for the panel structure are baseless. As Lilly explained and as the statute and Rule make clear, the bulk of panelists' tasks involve activities analogous to common-law judging, not agency expertise. PI Mem. 31. Yet the government simply repeats the tautology that expertise is required because it says so, without pointing to any difference between the 340B program and, *e.g.*, other labyrinthine Medicare programs adjudicated by HHS ALJs. Such *ipse dixit* is not enough. And it makes no effort to justify having panels with two non-lawyers apply the Federal Rules of Civil Procedure and Evidence and render "precedential" decisions. By regurgitating the paltry reasoning contained in the Rule, the government has done nothing to establish "a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43.

II. Absent A Preliminary Injunction, Lilly Will Suffer Irreparable Harm.

The government claims a violation of "the constitutional separation of powers" causes no irreparable harm because it does not implicate an "individual right." Opp. 36 (emphasis omitted). The Supreme Court begs to differ: "The entitlement to an Article III adjudicator ***is*** '***a personal right***.'" *Wellness Int'l Network, Ltd. v. Sharif*, 135 S. Ct. 1932, 1944 (2015) (emphasis added) (quoting *Schor*, 478 U.S. at 848). That is because "[t]he structural principles secured by the separation of powers protect the individual," not just the branches from each other. *Bond v. United States*, 564 U.S. 211, 222 (2011); *see also Clinton v. City of New York*, 524 U.S. 417, 449-50 (1998) (Kennedy, J., concurring) (rejecting the contention that structural constitutional

violations "do[] not threaten the liberties of individual[s]"); *PHH Corp. v. CFPB*, 881 F.3d 75, 194 (D.C. Cir. 2018) (Kavanaugh, J., dissenting) ("[T]he Constitution's separation of powers is not solely or even primarily concerned with preserving the powers of the branches," but is "primarily designed to protect individual liberty"), *dissent adopted by Seila Law v. CFPB*, 140 S. Ct. 2183 (2020). The government's lead argument is thus squarely foreclosed by precedent, and its reliance on out-of-circuit cases rather than those of the Seventh Circuit and this Court is wholly unavailing.

Nor can the government brush aside the significant economic harm the ADR process will inflict on Lilly. Indeed, courts regularly conclude that being forced to litigate in an improper forum constitutes irreparable harm even when the claims at issue do not arise under the Constitution. *See, e.g.*, *Gen. Protecht v. Leviton*, 651 F.3d 1355, 1364-65 (Fed. Cir. 2011); *Qualcomm Inc. v. Broadcom Corp.*, 2006 WL 8455598, at *5 (S.D. Cal. Feb. 13, 2006). The government admits, as it must, that "courts in this district have found that irreparable injury may occur where a party is unable to recover economic losses from the Government." Opp. 37. That should be the end of the matter; given the government's admitted sovereign immunity in this context, *see* PI Mem. 33-34, every dollar this unconstitutional regime costs Lilly will be a dollar Lilly can never get back.

Unable to dispute that reality, the government asserts that any economic harm here is too "speculative" because (it claims) such harm is based on the mere "conclusory statement" that Lilly will "be forced to expend enormous resources" as a result of the ADR process. Opp. 37. Lilly's showing of economic harm is not based on a conclusory statement, but instead on the ***evidence*** Lilly submitted in support of its motion. That evidence shows that covered entities have ***already*** filed ADR petitions against it, *see* Ex. D to PI Mem., and includes a sworn statement by a Lilly executive that "***hundreds*** of covered entities have threatened legal action against Lilly" and that these threats include covered entities' "intent to seek reimbursement of these losses through

administrative action"—*i.e.*, the ADR process—"including applicable fees and costs." Ex. G to PI Mem at 3-4. In essence, the government's position is that a litigant must detail down to the dollar the costs of harms that have not yet occurred. That is not the law.

III. The Balance Of Harms And Public Interest Favor Granting The Injunction.

The government argues that because "Congress required HHS to promulgate regulations 'establishing and implementing a binding ADR process,'" enjoining enforcement of the regulations the agency dilatorily promulgated "would cause injury to the agency and to the public interest." Opp. 38 (quoting 85 Fed. Reg. at 80,633). While that might be true if the regulations were valid, they are not. *See* Part I, *supra*. And as the Seventh Circuit has made clear, there is no harm to the government "when it is prevented from enforcing an unconstitutional [law]." *Joelner v. Vill. of Wash. Park*, 378 F.3d 613, 620 (7th Cir. 2004); *see also Does v. City of Indianapolis*, 2006 WL 2927598, at *11 (S.D. Ind. Oct. 5, 2006). That general rule is all the more obviously applicable here, since the government has not even constituted the ADR panels.

The government next insists that Lilly's decision to no longer fulfill every "order[] placed by covered entities using contract pharmacies"—which followed from the explosion of contract pharmacies and the well-documented abuse that has ushered in[4]—has harmed "healthcare providers" and the patients they serve. Opp. 38. There is a reason, however, that the government cites no facts to support that charge: No facts support it. As Lilly has consistently explained, it continues to provide (and will continue to provide) every discount to which a covered entity is entitled. And it has. Since its new distribution plan went into effect, Lilly is not aware of a single instance in which a covered entity was charged more than the 340B price—and Lilly assuredly

[4] *See* Am. Compl. ¶¶ 69, 75-76 (citing HHS OIG testimony and a GAO report detailing the scale of the problem). The GAO reported a 1,438% increase in the number of contract pharmacy arrangements post-2010, from 1,300 in 2010 to nearly 20,000 in 2017. *Id.* ¶ 49.

would have heard about it if that had occurred. On the flip side, as Lilly has also consistently explained, its new distribution policy is not even a blanket prohibition. Rather, Lilly continues to provide full 340B discounts to contract pharmacies whenever a covered entity lacks an in-house retail pharmacy, whenever a contract pharmacy is wholly owned by a covered entity, and whenever a covered entity agrees that its designated contract pharmacy will pass on the entire discount to patients purchasing insulin at the pharmacy counter. The government's suggestion that Lilly has harmed "low-income patients amidst a global pandemic" (Opp. 38) lacks any foundation.

Finally, the government claims that what really "upended the status quo" is ***not*** the government's ten-years-too-late promulgation of the ADR Rule, but rather Lilly's post-contract-pharmacy-explosion decision to operate its program in the manner the program worked from 1992 to 2010. Opp. 38. That charge is ironic given its source. The government failed to issue any ADR regulation for a decade, despite a clear congressional command. It went out of its way to tell the public last March that it had no plans to issue an ADR rule absent additional congressional authority. It then suddenly promulgated a final Rule without providing any notice or opportunity to comment. And as recently as last July, it reaffirmed that its longstanding guidance allowing covered entities to use contract pharmacies ***did not impose an obligation on manufacturers*** to offer contract pharmacies 340B discounts. *See* Am. Compl. ¶ 94. But then it admits succumbed to "the public outcry" (Opp. 9) and issued a formal opinion in December imposing just such an obligation on manufacturers, a politically unpopular class. In short, while the government's efforts to deflect blame fail, they do highlight why it is critical that the claims covered entities wish to have decided by ADR panels are instead adjudicated by an impartial decisionmaker.

CONCLUSION

The motion for preliminary injunction should be granted.

Dated: February 23, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on **February 23, 2021**, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

/s/ Andrea Roberts Pierson
Andrea Roberts Pierson

Exhibit A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE
PATENT TRIAL AND APPEAL BOARD

GENERAL ORDER IN CASES REMANDED UNDER
ARTHREX, INC. V. SMITH & NEPHEW, INC.,
941 F.3D 1320 (FED. CIR. 2019)

GENERAL ORDER

Before SCOTT R. BOALICK, *Chief Administrative Patent Judge*.

BOALICK, *Chief Administrative Patent Judge*.

The United States Patent and Trademark Office ("Office") has received from the United States Court of Appeals for the Federal Circuit ("Federal Circuit") numerous Orders that rely on the Federal Circuit's decision in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019). Those Orders have already vacated more than 100 decisions by the Patent Trial and Appeal Board ("Board"), and more such Orders are expected. The Orders instruct the Board to conduct further proceedings on remand before newly-designated Board panels.

Several parties in Board matters that have been subject to such Orders have informed the Office that they intend to seek review of the pertinent Order by the Supreme Court of the United States ("Supreme Court"). Meanwhile, in accordance with the Board's Standard Operating Procedure 9 ("SOP 9"), parties are contacting the Board to schedule teleconferences with the appropriate Board panel in their proceeding. To avoid burdening the

Office and the parties until all appellate rights have been exhausted, I exercise my discretion to: (1) suspend the requirements in SOP 9 in cases remanded by the Federal Circuit under *Arthrex*; and (2) hold all such cases in administrative abeyance until the Supreme Court acts on a petition for certiorari or the time for filing such petitions expires.

ORDER

It is therefore ORDERED that the following matters are held in abeyance:

1. App. Ser. No. 95/001,679
2. App. Ser. No. 95/001,754
3. App. Ser. No. 95/001,792
4. App. Ser. No. 95/001,851
5. CBM2017-00064
6. CBM2017-00065
7. CBM2017-00066
8. CBM2017-00067
9. CBM2018-00034
10. IPR2014-01235
11. IPR2015-00249
12. IPR2015-01046
13. IPR2015-01047
14. IPR2016-00693
15. IPR2016-00957
16. IPR2016-01542
17. IPR2016-01621
18. IPR2016-01622

19. IPR2016-01756
20. IPR2017-01218
21. IPR2017-00058
22. IPR2017-00116
23. IPR2017-00198
24. IPR2017-00275
25. IPR2017-00350
26. IPR2017-00351
27. IPR2017-00352
28. IPR2017-00353
29. IPR2017-00524
30. IPR2017-00901
31. IPR2017-00950
32. IPR2017-00951
33. IPR2017-00952
34. IPR2017-01048
35. IPR2017-01049
36. IPR2017-01050
37. IPR2017-01256
38. IPR2017-01391
39. IPR2017-01392
40. IPR2017-01393
41. IPR2017-01405
42. IPR2017-01406
43. IPR2017-01409
44. IPR2017-01410

45. IPR2017-01500
46. IPR2017-01707
47. IPR2017-01714
48. IPR2017-01735
49. IPR2017-01736
50. IPR2017-01737
51. IPR2017-01797
52. IPR2017-01798
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54. IPR2017-01800
55. IPR2017-01801
56. IPR2017-01802
57. IPR2017-01919
58. IPR2017-02131
59. IPR2017-02132
60. IPR2017-02136
61. IPR2017-02138
62. IPR2017-02158
63. IPR2018-00522
64. IPR2018-00864
65. IPR2018-00044
66. IPR2018-00187
67. IPR2018-00200
68. IPR2018-00205
69. IPR2018-00206
70. IPR2018-00207

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79. IPR2018-00342
80. IPR2018-00343
81. IPR2018-00369
82. IPR2018-00374
83. IPR2018-00375
84. IPR2018-00404
85. IPR2018-00458
86. IPR2018-00486
87. IPR2018-00529
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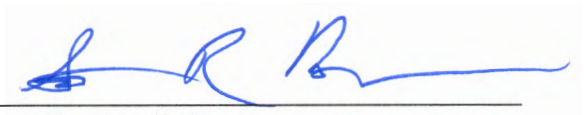
89. IPR2018-00599
90. IPR2018-00680
91. IPR2018-00870
92. IPR2018-00871
93. IPR2018-00872
94. IPR2018-00873
95. IPR2018-00874
96. IPR2018-00875

97. IPR2018-00998
98. IPR2018-00999
99. IPR2018-01000
100. IPR2018-01004
101. IPR2018-01005
102. IPR2018-01066
103. IPR2018-01205

It is further ORDERED that any other matters remanded by the Federal Circuit under *Arthrex* will be held in abeyance.



Scott R. Boalick
Chief Administrative Patent Judge