BEFORE THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ADMINISTRATIVE DISPUTE RESOLUTION PANEL

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, *Petitioner*, v. SANOFI-AVENTIS U.S. LLC and ASTRAZENECA PLC, *Respondents*	Nos. 210112-2

ORDER GRANTING MOTIONS TO DISMISS

On March 28, 2022, Respondents Sanofi-Aventis U.S. LLC (Sanofi) and AstraZeneca PLC separately moved this Panel to dismiss Petitioner National Association of Community Health Centers (NACHC)'s claims. Petitioner filed an opposition to those motions on May 18, 2022, and the Respondents separately replied on July 1, 2022. The motions are, therefore, fully briefed.

For the reasons set forth below, this Panel grants the Sanofi and AstraZeneca motions, and the matter is dismissed without prejudice.

A. Standard for Dismissal Based on Collateral Estoppel

In their motions, Respondents raise the judicial doctrine of collateral estoppel, arguing that Petitioner's claims are barred because "once a court has decided an issue of fact or law necessary to its judgment, that decision is conclusive in a subsequent suit based on a different cause of action involving a party to the prior litigation." AstraZeneca Mot. to Dismiss at 12; *United States v. Mendoza*, 464 U.S. 154, 158 (1984). The undersigned will begin by noting that this Panel's proceedings are governed by the Federal Rules of Civil Procedure, including pleading requirements contained in Rules 8, 10, and 11. 42 C.F.R. § 10.23(b), 10.21(a). Pursuant to Rule 8, Petitioner must make a "short and plain statement of a claim showing that the pleader is entitled to relief," and Respondents may raise "estoppel" as an affirmative defense. Federal Rules of Civil Procedure 8(a)(2), 8(c)(1).

Under the doctrine of collateral estoppel—also referred to as issue preclusion—a party is barred from relitigating an issue when: (1) the same "issue of fact or law" is involved in both the prior and current action; (2) the issue was "actually litigated" in the prior action; (3) the issue was "actually…determined" in the prior action by a "final" and "valid" judgment; and (4) determination on the issue was "essential to the judgment" of the prior action. Restatement (Second) of Judgments § 27; *see also New Hampshire v. Maine*, 532 U.S. 742, 748-749 (2001). The rationale for the doctrine of collateral estoppel, like the doctrine of res judicata, is to "relieve parties of the cost and vexation of multiple lawsuits, conserve judicial resources, and, by preventing inconsistent decisions, encourage reliance on adjudication." *Allen v. McCurry*, 449 U.S. 90, 94 (1980).

The collateral estoppel doctrine applies equally to administrative agencies as to courts. The Supreme Court has stated that "issue preclusion is not limited to those situations in which the same issue is before two courts," but also includes situations "where a single issue is before a

court and an administrative agency." *B & B Hardware, Inc. v. Hargis Indus., Inc.*, 575 U.S. 138, 148 (2015). Where an "agency proceeding follows after a judicial determination," the agency "may wish, or be required, to honor the judgment by precluding readjudication of common issues." 18B Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 4475 (Wright & Miller).[1] This makes sense, as the same rationale given for judicial adoption of the doctrine can apply to agencies. Agencies should not spend resources re-adjudicating disputes already decided by courts well-equipped to handle them—not to mention the potential separation of powers concerns raised by an agency decision running counter to a federal court order.

To determine *who* can be barred by collateral estoppel, courts have traditionally considered a judgment binding only on "parties and persons in 'privity' with a party." 18A Wright & Miller § 4448. Exceptions to that rule exist, including that a nonparty may be bound if their interests were "adequately represented" by a party to the prior action, like in the case of class actions. *Taylor v. Sturgell*, 553 U.S. 880 (2008). Further, while federal courts once followed the "doctrine of mutuality"—which stated that only the parties involved in the prior action could invoke collateral estoppel in the current action—this was later abandoned. 18A Wright & Miller § 4464. The Supreme Court first endorsed the use of nonmutual estoppel in *Blonder-Tongue Laboratories v. University of Illinois*, finding that "[p]ermitting repeated litigation of the same issue" wasted defendants' "time and money" and could reflect "the aura of the gaming table" rather than a court system. 402 U.S. 313, 329 (1971). In the eyes of the Court, nonparties to an action can be estopped as long as they had a "full and fair opportunity to

[1] One issue with this variety of preclusion is that it may be denied if the burden of persuasion in the agency proceeding is lower than the burden used in the prior judicial proceeding. *See, e.g.*, *Polcover v. Secretary of Treasury*, 477 F.2d 1223, 1231–1232 (D.C. Cir. 1973); *Young & Co. v. Shea*, 397 F.2d 185 (5th Cir. 1968). However, in this case, the ADR Panel makes determinations based on the same "preponderance of the evidence" standard used in most civil proceedings. 42 C.F.R. § 10.24(a).

litigate" the issue. *Id.*; *see also* Restatement (Second) of Judgments § 29. This is based on the "deep-rooted historic tradition that everyone should have his own day in court." *Richards v. Jefferson County*, 517 U.S. 793, 798 (1996). The Supreme Court later spelled out several considerations for courts to determine if "full and fair opportunity" was given, including whether estoppel incentivizes plaintiffs to take a "wait and see" attitude, whether the estopped party may not have litigated the issue as aggressively in the first action, whether the procedural rules of the prior court were more restrictive, and whether past inconsistent judgments would make it unfair to give conclusory effect to any one in particular. *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322 (1979).[2]

Relevant to the dispute at hand, an action brought against the government may bind private nonparties and preclude them from bringing future action. Government litigation on an issue could preclude relitigation by private individuals asserting "common public rights" who were adequately "represented by the State." *City of Tacoma v. Taxpayers of Tacoma*, 357 U.S. 320, 340–341 (1958). To determine if the private individual or company is estopped, courts may ask if the statutory scheme at issue "contemplate[s] enforcement of private interests both by a public agency and the affected parties." Restatement (Second) of Judgments § 85; *see, e.g.*, *Southwest Airlines Co. v. Texas International Airlines, Inc.*, 546 F.2d 84, 100 (5th Cir. 1977). If the statute does not contemplate a private right of action—as the Supreme Court held in regard to the 340B statute in *Astra USA, Inc. v. Santa Clara County*—a court would likely find that the government litigation is preclusive. 563 U.S. 110, 117 (2011). When the government is "charged

[2] In *Parklane*, the Court defined two types of collateral estoppel: "defensive" and "offensive." *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 326 n.4 (1979). Defensive collateral estoppel, which the Respondents invoke here, is "when a defendant seeks to prevent a plaintiff from relitigating an issue the plaintiff has previously litigated unsuccessfully in another action against the same or a different party." *Id.* Offensive collateral estoppel is when "the plaintiff seeks to foreclose the defendant from litigating an issue the defendant has previously litigated unsuccessfully in an action with another party." *Id.* The Court stated that lower courts should treat offensive collateral estoppel "differently," since it may raise more issues of fairness and actually increase the total amount of litigation. *Id.* at 329.

with representing private interests […] [p]reclusion by representation—privity—is then appropriate." 18A Wright & Miller § 4458.1; *see also* Restatement (Second) of Judgments § 41(1)(d) (1982) (stating that a nonparty to an action is nonetheless "bound by" a judgment if an "official or agency invested by law with authority to represent" them was a party).

B. Application of the Standard

This Panel will begin by applying the collateral estoppel standard to the present dispute. *First*, the same "issue of fact or law" is involved here and in the final judgment of a federal district court. *See AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-27, 2022 WL 484587 (D. Del. Feb. 16, 2022); *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021). In coming to that judgment, the U.S. District Court for the District of Delaware asked whether the "unambiguous text of the 340B statute" compelled the U.S. Department of Health & Human Services' (HHS) position that drug manufacturers are required to offer discounted drugs to covered entities (like Petitioners' members) that use contract pharmacies, "without any limit on the number of contract pharmacies per covered entity." *AstraZeneca*, 543 F. Supp. 3d at 53. The court clearly answered no—the statute's text did not compel that position. *AstraZeneca*, 2022 WL 484587 at *2. Based on this reading, the court vacated HHS' Advisory Opinion and May 17 Violation Letter. *Id.* at *6. Here, Petitioner argues that AstraZeneca and Sanofi's "refusal to provide covered outpatient drugs at the 340B ceiling price to . . . covered entities for drugs dispensed to such entities' patients via contract pharmacies" constitutes a violation of the 340B statute. Am. Pet. ¶ 5. As Respondents point out, the Petition relies expressly on the vacated May 17 Letter. Am. Pet. ¶ 17. And while the facts of Petitioners' claims against AstraZeneca and Sanofi vary, the court's judgment on the ambiguity of the statute is broad enough to cover both situations, so the doctrine of collateral estoppel applies equally to both Respondents.

Second, the issue was "actually litigated" in the federal court, through extensive judicial proceedings that included oral argument and briefing by amici (including Petitioner). *AstraZeneca*, No. 1:21-cv-27 (D. Del. Mar. 11, 2022); AstraZeneca Mot. to Dismiss at 14.

Third, the issue was "actually…determined" through a "final" and "valid" judgment. On March 11, 2022, the court issued an order and final judgment to vacate both the Advisory Opinion and the May 17 letter. *AstraZeneca*, No. 1:21-cv-27 (D. Del. Mar. 11, 2022), ECF No. 115. It did so based on two memorandum opinions. The first considered "the merits of AstraZeneca's claims" to conclude that the government's reading of the 340B statute in its Advisory Opinion was "not compelled by the unambiguous text of the statute." *AstraZeneca*, 2022 WL 484587 at *2 (citing *AstraZeneca*, 543 F. Supp. 3d 47). That opinion denied the government's motion for failure to state a claim while leaving open the precise relief available. *AstraZeneca*, 543 F. Supp. 3d at 62. HHS then voluntarily withdrew the Advisory Opinion before the court could grant relief. *AstraZeneca*, 2022 WL 484587 at *2. In the second opinion, the court noted that the Advisory Opinion had since been "vacated and set aside" and then vacated the May 17 letter on similar grounds, given the "logical application of the reasoning in the Court's previous memorandum opinion to the Violation Letter." *Id.* at 7.

Although Petitioner argues that the court's judgments were not "final," this is incorrect. The court's judgment was binding on HHS, and a judgment's "preclusive effect is generally immediate, notwithstanding any appeal." *Coleman v. Tollefson*, 575 U.S. 532, 135 (2015). A judgment typically becomes final for res judicata or collateral estoppel purposes "when the district court disassociates itself from the case." *Clay v. United States*, 537 U.S. 522, 527 (2003). Thus, the "federal rule" is that "collateral estoppel may be applied to a trial court finding even while the judgment is pending on appeal." *S. Pac. Commc'ns Co. v. Am. Tel. & Tel. Co.*, 740

F.2d 1011, 1018 (D.C. Cir. 1984); *see also Huron Holding Corp. v. Lincoln Mine Operating Co.*, 312 U.S. 183, 189 (1941) (expressing that an appeal "does not—until and unless reversed—detract from [a judgment's] decisiveness and finality"); 18A Wright & Miller § 4433 (stating that "the preclusive effects of a lower court judgment cannot be suspended simply by taking an appeal that remains undecided"); Restatement (Second) of Judgments § 13 cmt. f (1982).

Fourth, a determination on the issue was "essential to the judgment" of the court. The court based its holding on HHS' "legally flawed reading" of the 340B statute. *AstraZeneca*, 2022 WL 484587 at *4. While the court acknowledged in its second opinion that the agency's failure to acknowledge a change in position "provides an independent basis for the Court to award AstraZeneca relief," that argument was not central to its holding, nor was it relied upon in the court's first opinion—on the basis of which the Advisory Opinion was vacated. *AstraZeneca*, 2022 WL 484587 at *9, *5 n.6; *see generally AstraZeneca*, 543 F. Supp. 3d 47. Instead, the court rested its reasoning on the legal argument that the 340B statute did not impose a duty on manufacturers to provide discount pricing for multiple contract pharmacy sales. *AstraZeneca*, 543 F. Supp. 3d at 61. In the words of the court: "[t]he *only issue* before the Court is whether Congress has spoken clearly and unambiguously on this arrangement. It has not." *Id.* at 62 (emphasis added). The Petitioner here is asking for precisely the opposite of what the district court held, *viz.*, a decision from this Panel that the 340B statute *does* require manufacturers to provide discount pricing for multiple contract pharmacy sales. Am. Pet. ¶ 5. Statutory interpretation of the 340B statute—the same interpretation that Petitioner asks this Panel to independently conduct—was clearly "essential" to the court's holding. Addressing that same issue here would be thus clearly duplicative of the court's analysis.

Finally, the federal court judgment is binding on Petitioner. The Supreme Court has held that "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 117 (2011). The Court further stated that a "third-party suit to enforce an HHS-drug manufacturer agreement" is "in essence a suit to enforce the statute itself." *Id.* at 118. NACHC, lacking its own private right of action under the 340B program, could not sue manufacturers in district court alongside the government. *Id.* Thus, the 340B statute did not "contemplate enforcement of private interests both by a public agency and the affected parties," and the government's suit may preclude a private suit. Restatement (Second) of Judgments § 85. Petitioner's interests were certainly well-represented by the government in federal court: the government defended what Petitioner saw as "a plain reading of the 340B statute." Brief of Amici Curiae NACHC et al., No. 1:21-cv-27 (D. Del. Mar. 11, 2022), ECF No. 59 at 2. Thus, the Petitioner is precluded from raising the issue here.

C. Conclusion

For the above reasons, this Panel dismisses Petitioner's claims. In doing so, the undersigned offer no opinion on any other arguments that the parties raised and see no need to touch upon them.[3] As the federal court that precludes our consideration of this dispute aptly put it, 340B disputes such as these "implicate[] a number of important issues of public policy, including funding for healthcare facilities across the country and access to care – especially for

[3] The Panel is not addressing Respondents' arguments that the claims are moot, since they do not raise subject-matter jurisdiction concerns for an Article I tribunal. Further, while this Panel may be able to apply standing and mootness requirements on prudential grounds, *Outlaw v. United States*, 104 Fed.Cl. 226 (2012), it is not subject to the "case and controversies" requirement of Article III, the constitutional source of the mootness doctrine. U.S. Const. art. III § 2; *see also DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). The Panel is also not weighing in on Respondents' arguments that Petitioner's claims were insufficiently pled. The Panel does not need to resolve that issue here as we dismiss on alternate grounds.

low-income individuals[.]" *AstraZeneca*, 2022 WL 484587 at *1. Nevertheless, this Panel—no less than a federal district court—is bound by our duty to follow the law. In this dispute, we are plainly precluded from deciding upon the very issue on which the Petitioner's claims rest. That said, given that the issue is currently pending before the Third Circuit, this Panel dismisses the Petition without prejudice to allow Petitioner to raise it with us again should it be able to do so in the future.

It is so ordered this 10th day of August, 2022.

Glenn Clark
ADR Panel Member

Sean R. Keveney
ADR Panel Member

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