IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

KALDEROS, INC., Plaintiff, v. UNITED STATES OF AMERICA, *et al.*, Defendants.	No. 21-cv-2608 (DLF)

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO STAY PROCEEDINGS

There is no dispute that this case implicates the same statutory interpretation given by this Court in *Novartis Pharmaceuticals Corp. v. Espinosa*, No. 1:21-cv-1479 (D.D.C.), and *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686 (D.D.C.). The Government has now appealed this Court's resolution of that statutory question to the D.C. Circuit. *See* Notice of Appeal, *Novartis Pharmaceuticals Corp. v. Espinosa*, No. 1:21-cv-1479 (D.D.C. Dec. 28, 2021), ECF No. 33; Notice of Appeal, *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686 (D.D.C. Dec. 28, 2021), ECF No. 33.[1] The D.C. Circuit has thus been squarely presented with the question whether the Health Resources and Services Administration ("HRSA") correctly determined in its May 2021 violation letters that the 340B statute prohibits drug manufacturers from imposing restrictive conditions on covered entities' access to 340B-priced drugs—the exact same question Kalderos urges this Court to once again address in this matter. Because the D.C. Circuit's decision in the *Novartis–United Therapeutics* appeal will have significant ramifications for this case, and may provide a rule of decision, a stay of further proceedings is amply justified.

Kalderos opposes Defendants' proposed stay, however. *See* ECF No. 24 ("Opp."). In doing so, it (i) points to irrelevant factual distinctions between this case and the *Novartis–United Therapeutics* appeal, while altogether ignoring the overlapping legal theories on which its claims depend; and (ii)

[1] As a result, Kalderos's argument that Defendants' stay motion is premature is moot. *See* Opp. at 6–8.

fails to grapple with the obvious fact that the denial of a stay and a favorable, expeditious decision from this Court would not materially impact Kalderos, since the harms it purportedly suffers are caused by the decisions of third-party drug manufacturers in the marketplace. But critically, Kalderos does *not* dispute that the D.C. Circuit's decision in *Novartis* and *United Therapeutics* will, in all likelihood, provide this Court and the parties with substantial guidance (if not a dispositive rule of decision) in properly and efficiently resolving the legal issues in this case. For the reasons explained in Defendants' stay motion and elaborated on below, the Court should stay this case pending resolution of the *Novartis–United Therapeutics* appeal.

1. As Defendants have explained, the *Novartis–United Therapeutics* appeal will ask the D.C. Circuit to review the correctness of this Court's order finding that HRSA's statutory interpretation, as set forth in the May 17, 2021 violation letters, is flawed. The merits of Kalderos's claims before this Court turn on precisely the same interpretive question. Kalderos does not dispute this; nor could it, as it is evident from the face of Kalderos's complaint that its claims rest on the same statutory question presented on appeal in *Novartis* and *United Therapeutics*. *See, e.g.*, Compl. ¶ 75 (acknowledging that "United Therapeutics … challenged the [same] agency[] determination" that "[t]his action challenges"); *see also id.* ¶¶ 73, 83, 87. Instead of acknowledging the substantial overlap between the legal theories in this case and those at issue in the *Novartis–United Therapeutics* appeal, Kalderos attempts to focus this Court's attention on marginal and irrelevant factual distinctions.[2] Specifically, Kalderos suggests that Defendants' proposed stay would be "inappropriate" because the D.C. Circuit in *Novartis* and *United Therapeutics* will not analyze the specific manufacturer-imposed restrictions that are allegedly necessary to facilitate the use of Kalderos's product, and will thus not "resolve Kalderos's case." *See* Opp. at 1–2, 9–12; *see also* Compl. ¶¶ 7, 60 (alleging that manufacturers would require covered entities to use Kalderos's product as a "condition" on all 340B purchases made by covered entities and dispensed through contract pharmacies); *id.* ¶ 79 (alleging that the utility of Kalderos's product

[2] Kalderos's current focus on immaterial factual differences between this case and *Novartis* and *United Therapeutics* is strikingly at odds with its prior concession that these cases "involve[] common issues of fact" sufficient to treat them as related cases pending in this Court. *See* Notice of Designation of Related Civil Cases Pending in This or Any Other United States Court, ECF No. 2 (Oct. 6, 2021).

depends on manufacturers' ability to "require covered entities to produce [the] claims data" necessary for the product to "function"). But that is both incorrect and beside the point, because HRSA's position is that manufacturers lack authority to impose such conditions at all.

As an initial matter, Kalderos's argument does not reflect the standard by which courts determine the propriety of a stay pending resolution of independent proceedings. Contrary to what Kalderos appears to suggest, to obtain a stay, Defendants need not demonstrate that the *Novartis–United Therapeutics* appeal is both factually and legally *identical* to this case. As the Supreme Court explained in *Landis v. N. Am. Co.*, 299 U.S. 248 (1936): "True, a decision in the cause then pending in New York may not settle every question of fact and law in suits by other companies, but in all likelihood it will settle many and simplify them all." *Id.* at 256. Following *Landis*, district courts have routinely issued stays to await the resolution of proceedings that will not dispose of all the factual or legal issues in the cases before them. *See, e.g.*, *Washington v. Trump*, No. C17-0141JLR, 2017 WL 2172020, at *2 (W.D. Wash. May 17, 2017) ("Where a stay is considered pending the resolution of another action, the court need not find that the two cases involve identical issues; a finding that the issues are substantially similar is sufficient to support a stay." (citing *Leyva v. Certified Grocers of Cal., Ltd.*, 593 F.2d 857, 863-64 (9th Cir. 1979)); *Monaghan v. Sebelius*, No. 12–15488, 2013 WL 3212597, at *1 (E.D. Mich. June 26, 2013) (staying proceedings despite "potential differences" between cases because "the factual circumstances and central legal issues in both cases are substantially similar to those in this case"); *Univ. of Colo. Health Mem'l Hosp. v. Burwell*, No. 14-cv-1220, 2017 WL 535246, at *12 (D.D.C. Feb. 9, 2017) ("Because many of the applicable issues may be resolved by the D.C. Circuit, and because the D.C. Circuit may otherwise provide instruction on the issues here, the Court finds a stay would serve the interests of judicial efficiency."); *Kiakombua v. Wolf*, 498 F. Supp. 3d 1, 21 (D.D.C. 2020) (noting that the court stayed consideration of cross-motions for summary judgment "pending the D.C. Circuit's decision in [a related case]" because that case "'presented threshold issues

concerning the meaning of various statutory terms under' [a relevant statute], and 'substantially similar questions of law arise in the context of the present dispute'" (citation omitted)).[3]

In any event, the merits of Kalderos's claims do not depend on the specific types of restrictions that manufacturers must allegedly impose in order to utilize its product.[4] In fact, in Kalderos's own words, it challenges and seeks to set aside HRSA's "absolute, unqualified position—*without regard to the specifics of any manufacturer or the nature of any condition*—that no condition of any kind may be required," a position allegedly set forth in HRSA's May 2021 violation letters. Opp. at 4 (emphasis added); *see also, e.g.*, Compl. ¶ 73 (challenging HRSA's determination "that *universally* purport[s] to prohibit *any* conditions of *any* kind" (emphasis added)). Kalderos claims that HRSA's "new" categorical "policy" exceeds statutory authority and is arbitrary and capricious because the agency's "reading of the [340B] statute reflected in its May 2021 letters conflicts with the statute's unambiguous terms." Compl. ¶ 87.

[3] Neither *Garcia v. Acosta*, 393 F. Supp. 3d 93 (D.D.C. 2019), nor *National Industries for the Blind v. Department of Veterans Affairs*, 296 F. Supp. 3d at 131 (D.D.C. 2017), are to the contrary. *Contra* Opp. at 9. In *Garcia*, the defendants sought a stay of proceedings pending issuance of a new agency rulemaking, not a binding decision on a central merits issue from the D.C. Circuit. 393 F. Supp. 3d at 110. The court denied the stay request after observing that (i) the anticipated date of the rulemaking had already passed, thus likely mooting the stay request; (ii) the plaintiffs would likely suffer "concrete harm in the near future"; and (iii) the contours of the rulemaking and its impact on the case remained uncertain. *Id.* In *National Industries for the Blind*, the defendants sought a stay of proceedings pending the Federal Circuit's non-binding resolution of a case involving some similar legal issues. 296 F. Supp. 3d at 136–140. The defendants in that case (unlike Defendants here) argued that the "first-filed rule" applied, which required them to show that the two cases involved the same parties and the same causes of action. *Id.* at 138–39. The court rejected the defendants' reliance on that rule because the Federal Circuit action involved different parties, different causes of action, and different requested remedies. *Id.* The court denied the stay request on the additional grounds that (i) the Federal Circuit action (unlike the *Novartis–United Therapeutics* appeal) involved a threshold jurisdictional issue that could preclude that court from reaching the common legal issue; and (ii) there was more than a fair possibility that, pending a stay, the plaintiffs (unlike Kalderos) would be subjected to significant, prolonged harm as a direct result of the challenged policy. *Id.* at 139–141.

[4] Kalderos refers throughout its opposition to "the Kalderos conditions" or the "conditions reflected in [its] model." *See, e.g.*, Opp. at 1–2, 9–11. To be clear, Kalderos cannot impose its "own specific conditions" on 340B-drug purchases, *see id.* at 15, because Kalderos is not in any way a participant in the 340B Program. Rather, Kalderos sells a product that purportedly requires third-party drug manufacturers to condition covered entities' access to 340B-priced drugs on their mandatory and continual use of Kalderos's product.

The merits of those claims thus depend not on the precise operation of any specific manufacturer-imposed restriction but on the validity of HRSA's statutory interpretation. And as Kalderos itself acknowledges, *see* Opp. at 9, this Court decided not to analyze the legality of the "specific conditions" imposed by the plaintiffs in *Novartis* and *United Therapeutics* because it concluded that HRSA's violation letters "contain legal reasoning that rests upon an erroneous reading of Section 340B"—namely, that "[t]he plain language, purpose, and structure of the statute do not prohibit [drug] manufacturers from imposing *any* conditions on their offers of 340B-priced drugs to covered entities." *Novartis* Op. at 20–21. Whether that decision was correct is directly at issue in the *Novartis*–*United Therapeutics* appeal.[5]

Accordingly, a stay of proceedings pending appeal in *Novartis* and *United Therapeutics* will conserve the parties' resources and ensure that any future district court proceedings are resolved in an efficient and economical manner. As already explained, *see* Mot. at 7–10, it is highly likely that the D.C. Circuit's decision in the *Novartis*–*United Therapeutics* appeal will simplify or possibly altogether eliminate issues that the parties would have to brief and the Court would have to decide if litigation were to continue at this time. Requiring the parties to litigate issues that are under review in parallel appellate proceedings and that the D.C. Circuit may soon resolve would be a tremendous waste of time and resources. It may also prove unnecessary for the parties to engage in motions practice to address threshold issues or "disputes over the proper scope of the administrative record," *see* Opp. at 13, once the D.C. Circuit provides guidance on the statutory issue that is central to Kalderos's claims.[6] In fact,

[5] Attempting to draw a distinction between this case and the *Novartis*–*United Therapeutics* appeal, Kalderos maintains that "what [it] seeks in this litigation is judicial consideration of the lawfulness of HRSA's policy as applied to Kalderos's circumstances, which are distinct from those in the *Novartis*/*UT* cases." Opp. at 16. But as already explained, that assertion is wildly at odds with the legal theories and relief requested in Kalderos's complaint. *See, e.g.*, Compl., Prayer for Relief (requesting that the Court "declar[e] that HRSA's new policy on manufacturer conditions is unlawful"; "vacat[e] HRSA's new policy on manufacturer conditions"; and "bar[] Defendants from taking any enforcement action based on HRSA's new policy on manufacturer conditions.").

[6] Kalderos suggests that it would be more efficient for the parties to brief and the Court to adjudicate a Rule 12 motion before the D.C. Circuit has a chance to resolve the same general statutory issue on which Kalderos's claims depend. *See* Opp. at 12–13. But that makes little sense. The D.C. Circuit's decision in *Novartis* and *United Therapeutics* may be pertinent to the threshold questions that the parties would likely address in a Rule 12 motion. For instance, if the D.C. Circuit were to agree

the parties may even be able to avoid further litigating this case once that fundamental legal issue is resolved on appeal.

Thus, contrary to Kalderos's contention, *see* Opp. at 8, Defendants' proposed stay would indeed avoid the clear hardship of litigating future proceedings in this Court without the benefit of the D.C. Circuit's guidance on a legal issue centrally important to this case—guidance that would likely clarify applicable standards, narrow the issues in dispute, and potentially eliminate the need for future proceedings. And by choosing to go forward with this litigation now, the Court may need to issue rulings that could conflict with the D.C. Circuit's ultimate decision in *Novartis* and *United Therapeutics*, requiring the Court and the parties to unravel and revisit the proceedings in this case. As courts have determined in similar circumstances, *see* Mot. at 5–7, the better course is to stay proceedings to await guidance from the D.C. Circuit, *see* 16 Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 3921.2 (3d ed. 2017) ("[T]he district court should—with help from the parties—consider the possibility that the issues framed on appeal may change the context of the matters presented for district-court action.").

2. Kalderos, on the other hand, makes no serious effort to show that it will suffer harm as a result of Defendants' proposed stay. *See* Opp. at 15–16. As explained, *see* Mot. at 10–11, there is no reason to think that another favorable ruling from this Court on the merits of HRSA's interpretation of third-party drug manufacturers' statutory obligations would have any appreciable impact on those manufacturers' willingness to impose new restrictive conditions on covered entities' access to 340B-priced drugs. And that is particularly true when those conditions would violate not only HRSA's longstanding statutory interpretation but also the interpretations adopted by two federal courts. *See* Mot. at 3–4, 10–11. Rather than grapple with this reality, Kalderos simply asserts, without support,

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with HRSA that the *340B statute itself* prohibits drug manufacturers from restricting covered entities' ability to purchase 340B-priced drugs, then it would be manufacturers' own *statutory obligations* and not HRSA's "policy" that would deter them from utilizing Kalderos's product, and thus any vacatur of HRSA's "policy" would not redress Kalderos's purported proprietary harms. In any event, appellate resolution of the statutory question at issue in this case may completely obviate the need for the parties to litigate and this Court to adjudicate those issues.

that a ruling in this case "would directly address the concerns of manufacturers who have declined to move forward with Kalderos's" product. *See* Opp. at 16. But for reasons already explained, that argument defies common sense. *See* Mot. at 10–11.[7]

CONCLUSION

The Court should stay further proceedings in this matter pending the D.C. Circuit's resolution of *Novartis* and *United Therapeutics*.

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Respectfully submitted,

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[7] Kalderos's contention that a stay would "prevent [it] from receiving expeditious judicial review" of HRSA's statutory interpretation ignores the fact that it waited nearly five months to challenge that interpretation while other entities litigated that same general issue.