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File Name: 20a0321p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

VAPOR TECHNOLOGY ASSOCIATION,

Plaintiff,

VAPOR STOCKROOM, LLC,

Plaintiff-Appellant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR, II, Secretary of Health and Human Services; STEPHEN HAHN, M.D., Commissioner of the Food and Drug Administration,

Defendants-Appellees.

No. 20-5199

Appeal from the United States District Court
for the Eastern District of Kentucky at Lexington.
No. 5:19-cv-00330—Karen K. Caldwell, District Judge.

Argued: August 8, 2020

Decided and Filed: October 5, 2020

Before: ROGERS, KETHLEDGE, and NALBANDIAN, Circuit Judges.

COUNSEL

ARGUED: Eric N. Heyer, THOMPSON HINE LLP, Washington, D.C., for Appellant. Lindsey Powell, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. **ON BRIEF:** Eric N. Heyer, THOMPSON HINE LLP, Washington, D.C., Robert P. Johnson, THOMPSON HINE LLP, Cincinnati, Ohio, for Appellant. Lindsey Powell, Joshua Revesz, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees.

The court delivered a PER CURIAM opinion. ROGERS, J. (pp. 10–11), delivered a separate concurring opinion.

OPINION

PER CURIAM. Vapor Stockroom challenges the Food and Drug Administration's (FDA) current enforcement guidance timetable for when e-cigarette manufacturers must file premarket tobacco applications to remain on the market. The challenged timetable was set by the District Court for the District of Maryland in an injunction issued by that court in separate litigation regarding the FDA's 2017 enforcement guidance. Vapor Stockroom contends that the FDA's remedial brief and an attached declaration submitted by an FDA official to the Maryland district court motivated that court to impose the challenged deadline for application submissions, which significantly accelerated the original FDA deadline. The company alleges that the FDA's brief and declaration constituted a final agency action that violated the Administrative Procedure Act (APA). However, the Maryland court's injunction was independent from the FDA's brief and declaration. Vapor Stockroom therefore lacks Article III standing to obtain judicial review of the remedial brief and attached declaration, because the alleged injury is the result of the Maryland court's independent action, not the challenged FDA filings. For similar reasons, the company's request for injunctive relief against enforcement proceedings is without merit because the allegedly unauthorized court submissions do not form a plausible legal basis for an injunction against subsequent, independently caused FDA enforcement proceedings.

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA) to regulate tobacco products and to empower the FDA to conduct the regulation. Pub. L. No. 111-31, 123 Stat. 1776 (2009). The statute recognized the FDA as the primary federal regulatory authority regarding the manufacture, marketing, and distribution of tobacco products. *Id.* § 3(1), 123 Stat. at 1781. The Act applies to "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," and also authorizes the Secretary of Health and Human Services (HHS) to subject through regulation any other tobacco product to the statute's requirements. 21 U.S.C. § 387a(b). The Secretary carries out this responsibility through the FDA. *See id.* § 393(d)(2).

Manufacturers of new tobacco products that were not on the market as of February 15, 2007 or that were modified after that date must obtain premarket authorization prior to marketing their products. *Id.* § 387j(a). The TCA contains multiple pathways for tobacco manufacturers to seek authorization to market their products. *See* 21 U.S.C. §§ 387j(a)(2)(A)(i)–(ii), 387j(b)–(c), 387e(j)(1), 387e(j)(3). The relevant path here is the premarket tobacco application, in which a manufacturer may file a premarket application that contains information regarding the product's health risks, a statements of the product's ingredients, the product's manufacturing information, and samples of the product and its proposed labeling. 21 U.S.C. § 387j(b)–(c). A tobacco product that is marketed without the appropriate authorization can face civil and criminal enforcement action by the FDA. 21 U.S.C. §§ 331(a)–(c), 332, 334, 387b(6).

In May 2016, the FDA promulgated the "Deeming Rule," which deemed cigars, pipe tobacco, and electronic nicotine delivery systems (e-cigarettes)[1] to be tobacco products subject to the TCA. 81 Fed. Reg. 28,974, 28,982–84 (May 10, 2016). When the Deeming Rule took effect in August 2016, as many as 25,000 products already on the market became subject to, and would suddenly be in violation of, 21 U.S.C. § 387j(a). Vapor Stockroom, which manufactures nicotine-containing e-liquids for e-cigarettes, thus became subject to the TCA's premarket authorization requirements pursuant to the Deeming Rule. The FDA announced that it would stagger compliance periods for deemed tobacco products that were already on the market on the effective date of the Deeming Rule, during which time the FDA would not bring enforcement actions against the manufacturers of newly-regulated tobacco products for failure to obtain premarket authorization. 81 Fed. Reg. at 28,977–78. This was intended to allow time for manufacturers of newly deemed products to come into compliance. Originally, the FDA required premarket tobacco applications to be submitted by August 8, 2018. *Id.* at 29,010–11, 29,106. In May 2017, the FDA extended the compliance period by three months. 82 Fed. Reg. 22,338, 22,340 (May 15, 2017). Finally, the FDA issued new guidance in August 2017 that extended the compliance period to August 8, 2022 for most e-cigarettes. The FDA issued the August 2017 guidance without going through notice and comment.

[1]We use the term "e-cigarettes" to refer to all electronic nicotine delivery systems, which includes "vaping" products, as well as components and parts, such as e-liquids. *See* 81 Fed. Reg. at 29,028.

In 2018, several physicians and public health organizations filed suit against the FDA and HHS in the United States District Court for the District of Maryland under the APA, alleging that the FDA's August 2017 guidance was procedurally and substantively invalid. *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 468–69 (D. Md. 2019) (*AAP I*). The Maryland district court concluded that the August 2017 guidance was inconsistent with the TCA and was therefore unlawful. *Id.* at 491–98. The Maryland court also determined that the August 2017 guidance was a legislative rule, rather than an interpretive rule, that required notice and comment under the APA. *Id.* Accordingly, the Maryland court granted summary judgment in favor of the plaintiffs. *Id.* at 498. Because the compliance deadlines in the Deeming Rule and the May 2017 guidance had passed during the litigation, the court asked the parties to submit additional briefing on the appropriate remedy. *Id.*

The plaintiffs in the Maryland case urged the court to direct the FDA to require all covered manufacturers to file premarket applications within 120 days of the court's order. *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 481–82 (D. Md. 2019) (*AAP II*). On the other hand, the Government argued that the court should simply remand to the FDA to allow the agency to develop a new course of action consistent with the court's opinion. *Id.* at 484–85; The Government also stated that, should the court (over the Government's opposition) order that the premarket applications be submitted by a certain date, then "under no circumstances should it set that deadline sooner than 10 months from the date of its decision." The Government asserted that although a ten-month deadline would "perhaps not [be] the date[] that the FDA would select if permitted to exercise its own discretion, such a deadline would at least reduce the expected abrupt and massive market exit; avoid flooding the FDA with thousands of premarket applications on a nearly immediate basis; and allow the agency at least some time to prepare and review applications much more quickly than it had anticipated." The Government submitted a declaration from the Director of the FDA's Center for Tobacco Products, Mitchell Zeller, with its brief to the Maryland court. Director Zeller asserted it was his "firm belief that plaintiffs' proposed 120-day submission deadline creates a genuine risk of migration from potentially less harmful [e-cigarette] products back to combustible tobacco products," which is a "public health outcome that should be avoided if at all possible." Further, Director Zeller stated that, "[i]f the

Court nevertheless finds it necessary to enter an injunction requiring the submission of premarket applications by a date certain, it should not set a deadline sooner than 10 months from now."

Ultimately, on July 12, 2019, the Maryland district court issued its remedy opinion, imposing a ten-month deadline. The court concluded that it had the authority to impose a deadline for FDA action because the case presented extraordinary circumstances of a rising public health crisis of youth e-cigarette use. *AAP II*, 399 F. Supp. 3d at 486. The court "agreed with [the Government] that the ten-month deadline for applications would be more reasonable than the four-month deadline, allowing sufficient time for application submissions that present the information that the FDA needs to assess the e-cigarette products, while not delaying longer than necessary." *Id.* Accordingly, the court entered an injunction that ordered the FDA to require that premarket applications be filed within ten months of the court's order. *Id.* at 487. The deadline therefore became May 12, 2020. However, the court declined to require the FDA to take enforcement action against manufacturers who did not file a premarket application by this date. *Id.* Instead, the court left such enforcement decisions to the FDA's discretion. *Id.* The court also allowed the FDA to exempt manufacturers from the filing requirements "for good cause on a case-by-case basis." *Id.*

Subsequently, the Government and various industry groups that had intervened or sought to intervene in district court appealed the Maryland court's summary judgment and remedy orders. However, while the appeal was pending, the FDA issued new guidance in January 2020, which replaced the August 2017 guidance. The 2020 guidance stated that the FDA intended to prioritize enforcement of the TCA's premarket-review requirements for e-cigarettes beginning on May 12, 2020. The 2020 guidance explained that the FDA chose the May 12, 2020 date "[b]ecause of FDA's concerns regarding youth use of [e-cigarette] products, as well as other ongoing health concerns regarding vaping more generally," and noted that the FDA chose the date "independently of the court order" in *AAP*. Before the Fourth Circuit ruled on the appeal, the FDA also asked the Maryland district court to alter its injunction in light of the global pandemic caused by the COVID-19 virus to provide the tobacco manufacturers with more time to comply with the TCA's premarket-review requirements. The district court amended its injunction to require the premarket-review applications to be submitted by September 9, 2020,

rather than by May 12, 2020. Order, *AAP*, No. 8:18-cv-883 (D. Md. Apr. 22, 2020). Following the Maryland court's extension of the deadline, the FDA revised the 2020 guidance to change its May 12, 2020 deadline to September 9, 2020. 85 Fed. Reg. 23,973 (Apr. 30, 2020). Given the intervening issuance of the 2020 guidance, which replaced the challenged August 2017 guidance, the Fourth Circuit ruled on May 4, 2020 that the industry groups' appeal was moot and dismissed the FDA's appeal at the agency's request. *In re Cigar Ass'n of Am.*, 812 F. App'x 128, 132, 136 (4th Cir. 2020).

Shortly after the Maryland court issued its injunction and while the appeal was pending in the Fourth Circuit, Vapor Stockroom and Vapor Technology Association, which is a trade organization that represents the e-cigarette industry, filed this suit in the Eastern District of Kentucky on August 14, 2019. Vapor Stockroom and Vapor Technology Association allege that the FDA violated the APA and the Constitution's Due Process Clause by "proposing an abbreviated ten-month deadline" as an alternative in the Government's remedial brief and accompanying declaration from Director Zeller to the Maryland district court. The complaint sought a declaration "that FDA's proposal and/or enforcement of the ten-month (i.e., May 2020) deadline constitutes unlawful agency action" under the APA, and "violates the procedural due process rights" of the plaintiffs. The complaint also sought an injunction to require the FDA to "refrain from taking enforcement action based on the failure of a vapor product manufacturer to submit a complete[d] PMTA [premarket tobacco application] by May 11, 2020." Plaintiffs moved for a preliminary injunction, and the Government filed a motion to dismiss the complaint and a motion to transfer the case to the District of Maryland. While these motions were pending, the FDA issued new guidance in January 2020, as discussed above. Upon being notified that the FDA had issued new guidance, Vapor Stockroom and Vapor Technology Association advised the court that they intended "to file a motion for leave to file an amended complaint to include new counts" addressing the 2020 guidance. But the district court granted the Government's motion to dismiss on January 16, 2020 before the plaintiffs actually sought leave to amend their complaint.

The district court concluded that Vapor Stockroom and Vapor Technology Association lacked standing because they failed to establish that their alleged injuries are causally connected

to the challenged Government action. The court determined that "it was the District Court for the District of Maryland, and not the FDA, which set the deadline that gives rise to the Plaintiffs' alleged injuries." Thus, the court concluded that the alleged injuries are the result of the Maryland district court's orders in the *AAP* litigation, which are independent actions by a third party not before the Kentucky district court.

Further, the court rejected the plaintiffs' argument that the FDA motivated the Maryland court to impose the ten-month deadline by proposing this timeline in its remedial brief and attached declaration. First, the court examined the Government's remedial brief to the Maryland court and assessed that the brief primarily argued for the Maryland court to simply remand to the FDA, rather than to enforce a specific deadline. The court noted that the government proposed a ten-month deadline, but that it only did so as an argument in the alternative. Second, and more importantly in the district court's view, the court rejected the notion that courts are "motivated" by parties to rule in a certain manner.

Accordingly, the district court dismissed the case for lack of standing. Because the court granted the Government's motion to dismiss, it denied as moot the Government's motion to transfer and the plaintiffs' motion for a preliminary injunction.

Vapor Stockroom now appeals the district court's decision to dismiss the case. Vapor Stockroom also asks this court to preliminarily enjoin the FDA from taking enforcement action against it because it alleges it faces immediate irreparable harm after the compliance deadline date, which is now September 9, 2020. Vapor Technology Association has not appealed the district court's decision.

Vapor Stockroom lacks standing to obtain judicial review of the FDA's remedial brief and attached declaration in the Maryland district court under the APA. Vapor Stockroom alleges that the FDA's proposal of a ten-month deadline to the Maryland court caused it to be injured. Vapor Stockroom contends that the FDA's proposal led the Maryland court to adopt the accelerated ten-month deadline, which Vapor Stockroom asserts that it is unprepared to meet. Vapor Stockroom further alleges that it has not received sufficient guidance on what to include in its premarket tobacco application. Thus, Vapor Stockroom contends that the FDA's conduct

has caused the company current and impending financial harm because it will not be able to submit an acceptable application by the compliance deadline. But the alleged injuries arising from the new deadline are not caused by the challenged actions of the FDA.

Vapor Stockroom's alleged injuries are the result of the Maryland district court's injunction, not the FDA's conduct. The Supreme Court has articulated that for a plaintiff to have standing, "there must be a causal connection between the injury and the conduct complained of—the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (alterations in original) (quoting *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41–42 (1976)). The Maryland court's injunction was not an action by the FDA—it was an action taken by the court itself. The Maryland court is an independent third party that is not part of the present suit. Vapor Stockroom cannot sue the FDA to attack the Maryland court's decision.

Further, the FDA's remedial brief and attached declaration were not a motivating factor in the Maryland court's decision. In *Parsons v. U.S. Department of Justice*, 801 F.3d 701 (6th Cir. 2015) (*Parsons I*), we acknowledged that "the allegation that a defendant's conduct was a motivating factor in the third party's injurious actions satisfies the requisite standard" to establish the causation prong of the standing analysis. *Id.* at 714. Although courts are aided by the parties' briefings, a court's resolution of a contested issue is ultimately guided by the court's own view of the law, the facts, or the exercise of discretion.

Also, this case is readily distinguishable from our opinion in *Parsons I*. In *Parsons I*, we determined that the plaintiffs, members of a group known as the Juggalos, had standing to sue the Department of Justice (DOJ) based on DOJ's designation of the group as a gang, despite the fact that local law enforcement officers were the ones who directly caused the plaintiffs' alleged injuries. *Parsons I*, 801 F.3d at 714. We concluded that the Juggalos alleged "that the injurious third-party actions were motivated by the DOJ gang designation," which satisfied the causation prong of the standing analysis. *Id.* But the relationship between federal and local law enforcement agencies is quite distinct from the relationship between courts and litigants. Local law enforcement agencies may feel compelled to follow the lead of federal law enforcement and

take action pursuant to information provided by federal law enforcement. But courts are not similarly beholden to litigants.

Finally, Vapor Stockroom's argument that its injury is fairly traceable to the FDA's 2020 guidance fails because Vapor Stockroom never challenged the 2020 guidance in its complaint. As discussed above, Vapor Stockroom indicated that it intended to amend its complaint to challenge the 2020 guidance, but it failed to do so before the district court dismissed the case. We therefore decline to address Vapor Stockroom's arguments regarding the 2020 guidance, which have been raised for the first time on appeal. *See Frazier v. Jenkins*, 770 F.3d 485, 497 (6th Cir. 2014).[2]

Accordingly, the district court properly determined that Vapor Stockroom did not have standing to pursue its APA claim for judicial review because the threat to Vapor Stockroom of enforcement proceedings against it cannot be fairly traced back to the submission of litigation documents.

For the foregoing reasons, we affirm the judgment of the district court.

[2]Vapor Stockroom can presumably still file a new complaint to challenge the 2020 guidance if it desires, as a district court's dismissal for lack of jurisdiction is presumed to be without prejudice and the district court here did not specify otherwise. *Pratt v. Ventas, Inc.*, 365 F.3d 514, 522 (6th Cir. 2004).

CONCURRENCE

ROGERS, Circuit Judge, concurring. It is necessary to add that Vapor Stockroom's request for injunctive relief to prevent the FDA from taking enforcement action against it is without merit. Generally speaking—one could say that it is almost a truism—an injunction to the benefit of a plaintiff is not warranted where the alleged harm is not caused by the allegedly unlawful action, or where the sought relief is not lawfully owed to the plaintiff. For the same reasons that Vapor Stockroom lacks standing to obtain judicial review of the litigation submissions of the FDA, there is no legal basis to support an injunction against threatened FDA enforcement action. The alleged illegality of the litigation submissions is so factually independent that it does not legally support the requested injunction.

It may seem strange that the same break in the causal chain creates an Article III case-or-controversy hurdle with respect to the challenge to the FDA's litigation submission, but only a merits hurdle with respect to the request for injunctive relief against FDA enforcement. But Article III goes fundamentally to whether a plaintiff will benefit from the relief sought, and not to whether there is a legal basis for ordering the relief sought. Stated differently, a plaintiff meets the injury-in-fact requirement for Article III standing even if the plaintiff brings a totally frivolous lawsuit, as long as the plaintiff is asking for relief from an injury that is, in the words of *Lujan*, "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." 504 U. S. at 560 (internal quotations omitted).

Perhaps an example would be useful. If plaintiff P sues to challenge the denial to stranger A of a certain Government benefit, P lacks standing, where the denial to A does not affect P, and a grant to A would not benefit P. But if P sues the same Government agency to challenge the denial to P of the same (concrete and particularized, actual not conjectural) benefit, and makes only the irrelevant argument that the agency's denial to A was illegal, then although P has Article III standing, and there is a case or controversy, P has simply not stated a claim.

In addition, to the extent that Vapor Stockroom's injunction argument seeks to have us overturn the Maryland district court's judgment, that argument is frivolous.