UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

SWISHER INTERNATIONAL, INC.,

Plaintiff,

v. Case No. 3:21-cv-764-BJD-JBT

UNITED STATES FOOD AND DRUG ADMINISTRATION, JANET WOODCOCK, in her official capacity as Acting Commissioner of Food and Drugs, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,

Defendants.
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ORDER

THIS CAUSE is before the Court on Plaintiff's Motion for an Emergency Preliminary Injunction (Doc. 2), Defendants' Response (Doc. 27), Plaintiff's Reply (Doc. 37); and Defendants' Motion to Transfer (Doc. 32) and Plaintiff's Response (Doc. 39).[1] The Court has also considered the Campaign for Tobacco-Free Kids's amicus curiae brief (Doc. 33).

[1] The Court refers to Defendants collectively as the FDA.

A. Background

Plaintiff, Swisher International, Inc., contends the facts culminating to this case began in May 2016, "when the FDA adopted the 'Deeming Rule.'" (Doc. 1; Complaint ¶ 2). The Deeming Rule "subjected cigars to the requirements of the Tobacco Control Act" (the "TCA" or the "Act"). Id. The TCA is formally known as the Family Smoking Prevention and Tobacco Control Act, which amended the Federal Food, Drug, and Cosmetic Act "to establish a comprehensive regulatory scheme for tobacco products." Cigar Ass'n of Am. v. United States Food & Drug Admin., 5 F.4th 68, 73 (D.C. Cir. 2021) (internal quotations omitted) (the "Cigar Association" case or "CAA").[2] "It regulates 'all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco,' as well as 'any other tobacco products' that the FDA 'by regulation deems to be subject to the Tobacco Control Act.'" Id. (quoting 21 U.S.C. § 387a).[3] Congress did not initially include cigars under the auspices of the TCA.

Among the TCA requirements is one that requires "new tobacco product[s]"—defined as any tobacco product not commercially marketed in the United States as of February 15, 2007, or any tobacco product available

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[2] The Court refers to the docket entries in the CAA case as "CAA Doc. xx."

[3] The "Deeming Provision" is that portion of the statute conferring authority to the FDA to subject non-enumerated tobacco products to the TCA.

by February 25, 2007 that experienced any modification—undergo "premarket review." 21 U.S.C. § 387j(a) and (b). Of the available paths to obtain premarket authorization, Swisher sought compliance by submitting substantial equivalence reports for its cigars. To accommodate cigars already on the market and in light of the TCA's requirements, the FDA promised to withhold enforcement until manufacturers were afforded a reasonable opportunity to comply with the TCA. Complaint ¶ 3. More specifically, the FDA announced it would accept substantial equivalence reports for 18 months from the effective date of the Deeming Rule and for 12 additional months beyond the submission deadline to allow for review of the reports. 81 Fed. Reg. at 29,011.

Over the years that followed, Swisher complied with the FDA's instructions and spent millions of dollars to obtain premarket review and to prevent its products from being subject to any enforcement action. Complaint ¶ 4. After receiving millions of applications, the FDA was unable to meet its own deadlines to review substantial equivalence reports and extended these deadlines beyond 2021 and, for certain products, allowed them to remain on the market until the FDA rendered a final decision (known as the "August 2017 Guidance"). Am. Acad. of Pediatrics v. Food & Drug Admin., 379 F. Supp. 3d 461, 468 (D. Md. 2019) (the "AAP"

case); (Doc. 27.2 at 7). However, the court in the AAP case explained that such an indefinite suspension of enforcement action while unreviewed and new tobacco products remained on the market was tantamount to "postmarket review," which contravened Congress's direction to the FDA to conduct premarket review. Id. at 492. The court vacated the FDA's "August 2017 Guidance" on this point and required new guidance subject to notice and comment.

To date, nearly all Swisher's cigar products remain in administrative limbo awaiting premarket review. Complaint ¶ 5. Complicating Swisher's situation further, Swisher alleges the FDA is now "threatening to bring enforcement actions against Swisher and other companies for selling products that are stuck in [a] regulatory quagmire." Id. In response, Swisher brings this suit, wherein it asserts the following eight counts:

Count I: The "Deeming Provision" of the TCA that grants the FDA the authority to enact the Deeming Rule is an unconstitutional delegation of legislative authority (Complaint at 31-32);

Count II: The Deeming Rule violates the appointment clause because Leslie Kux issued the Rule while she was the FDA's Associate Commissioner for Policy and was not appointed by the president or confirmed by the senate (Id. at 32);

Count III: The FDA's attempts to ratify the Deeming Rule were unlawful because they failed to comply with the APA's notice-and-comment requirements, were arbitrary and capricious, contrary to law, and procedurally improper (Id. at 33);

Count IV: The Deeming Rule exceeds the FDA's authority because the TCA does not allow the FDA to deem cigars subject to the TCA (Id. at 34);

Count V: The Deeming Rule was arbitrarily and capriciously applied to cigars because there was a lack of notice and comment, a lack of an administrable plan for obtaining FDA approval, was contrary to APA requirements, and failed to weigh costs and benefits (Id. at 34-35);

Count VI: The FDA failed to timely act on Swisher's substantial-equivalence reports (Id. at 36-37);

Count VII: The FDA is essentially banning Swisher cigars contrary to the TCA by refusing to act on Swisher's substantially-equivalence reports when that failure to act is accompanied by the FDA's threat of enforcement (Id. at 37-38);

Count VIII: The FDA's threatened enforcement against Swisher is unlawful (Id. at 38-39).

B. Discussion

1. Motion for Preliminary Injunction

In addition to the relief sought in the Complaint, Swisher seeks an emergency preliminary injunction that either bars the FDA from enforcing the TCA against Swisher's cigars or, "[a]t a minimum" bars enforcement while Swisher's substantial equivalence reports are pending and for 30 days after any order finding that the product(s) are not substantial equivalent. (Doc. 2 at 25). Swisher's Motion focuses on its claims that the Deeming Rule is invalid and that the FDA's threatened action against Swisher's products pending premarket approval is unlawful. Swisher and the FDA agreed that Swisher's Motion can be resolved without an evidentiary hearing. (Doc. 24).

"For a district court to grant a preliminary injunction, the movant must establish:

> (1) a substantial likelihood of success on the merits of the underlying case, (2) the movant will suffer irreparable harm in the absence of an injunction, (3) the harm suffered by the movant in the absence of an injunction would exceed the harm suffered by the opposing party if the injunction issued, and (4) an injunction would not disserve the public interest."

Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242, 1246-47 (11th Cir. 2002); see also Fed. R. Civ. P. 65. A preliminary

injunction is a drastic and extraordinary remedy which should not be granted unless the movant can clearly establish each of the four elements. America's Health Ins. Plans v. Hudgens, 742 F.3d 1319, 1329 (11th Cir. 2014).

"The burden of persuasion on all of the four requirements . . . is at all times upon the [movant]." Canal Auth. of Fla. v. Callaway, 489 F.2d 567, 573 (5th Cir. 1974).[4] The failure to establish an element, such as a substantial likelihood of success on the merits, will warrant denial of the request for preliminary injunctive relief and obviate the need to consider the remaining prerequisites. See Pittman v. Cole, 267 F.3d 1269, 1292 (11th Cir. 2001) (citing Church v. City of Huntsville, 30 F.3d 1332, 1342 (11th Cir. 1994)); see also Del Monte Fresh Produce Co. v. Dole Food Co., 148 F. Supp. 2d 1326, 1339 n.7 (S.D. Fla. 2001) ("Because Del Monte has not met the first requirement, it is not necessary to discuss the remaining elements required for a preliminary injunction.").

In deciding whether a party has made the requisite showing for entry of a preliminary injunction, "[a] district court may rely on affidavits and hearsay materials which would not be admissible evidence for a

[4] In Bonner v. City of Prichard, Ala., 661 F.2d 1206, 1207 (11th Cir. 1981), the Eleventh Circuit adopted as binding precedent decisions of the former Fifth Circuit rendered prior to October 1, 1981.

permanent injunction, if the evidence is appropriate given the character and objectives of the injunctive proceeding." Levi Strauss & Co. v. Sunrise Int'l Trading Inc., 51 F.3d 982, 985 (11th Cir. 1995) (internal quotation marks and citation omitted). The Court is mindful that "[p]reliminary injunctions are, by their nature, products of an expedited process often based upon an underdeveloped and incomplete evidentiary record." Cumulus Media, Inc. v. Clear Channel Commc'ns, Inc., 304 F.3d 1167, 1171 (11th Cir. 2002).

The Court first considers whether Plaintiffs established that absent a preliminary injunction it will suffer irreparable harm. "A showing of irreparable injury is the sine qua non of injunctive relief." Siegel v. LePore, 234 F.3d 1163, 1176 (11th Cir. 2000) (internal quotations omitted); see also Snook v. Tr. Co. of Georgia Bank of Savannah, 909 F.2d 480, 486 (11th Cir. 1990) (affirming denial of preliminary injunctive relief after finding that there was a substantial likelihood of the plaintiffs' success on the merits of their case because the injury that would occur could be remedied). This analysis takes place on two fronts. To start, the Court considers what harm occurs if Swisher's cigars are subject to the Deeming Rule and second, what harm, if any, occurs absent injunctive relief. For the sake of argument, the Court accepts Swisher's contention that FDA enforcement

action against Swisher's products could cause it ruin for which there could be no remedy.

Swisher's fear that the FDA would begin enforcing the TCA against Swisher's products is rooted in a June 11, 2021 FDA Webinar that announced the FDA "generally continues to defer enforcement of premarket authorization requirements until Sept. 9, 2021 . . . ." (Doc. 2 at 9-10 (citing Deemed Product Review: A Conversation with the Center for Tobacco Products Office of Science - 06/11/2021 - 06/11/2021 | FDA); (see also Doc. 2 at 1) ("The exigency is the result of the FDA's recent, explicit threat to enforce the TCA against Swisher and others beginning on September 10, 2021, after years of promises that the FDA would not do so until the company had a meaningful opportunity to get its cigars through the FDA's complex 'premarket review' process.")). Swisher also focuses on the following excerpt, "But broadly speaking, it's important to remind everyone if products are not authorized by September 9th of 2021 and you knock them off the market at that time, they risk FDA enforcement." Id. Tr. 37. Finally, Swisher cites to the FDA's failure to respond to an inquiry letter. (Doc. 2 at 10).

As to the first cited excerpt, Swisher only offers language that the FDA will continue deferment until September 9, 2021, not that it will

begin enforcement on September 10, 2021. Regarding the second cited passage, Swisher omits language giving context to the risk-of-enforcement comment. The lack of complete context impacts how one reads the FDA's remarks. See City of Cleburne v. Cleburne Living Ctr., Inc., 473 U.S. 432, 468–69 (1985) ("A sign that says 'men only' looks very different on a bathroom door than a courthouse door."). (Marshall, J., concurring in the judgment in part and dissenting in part). The FDA's remark was made in response to a question and specifically prefaced by a disclaimer that the FDA was "not planning to discuss it outside of the scope of [the webinar]. **BUT** FDA does have the discretion to defer enforcement action against that particular product on a case-by-case basis after the one-year period for review comes to an end this coming September." Webinar Tr. 37 (emphasis added). Thus, even construing the first excerpt as a threat of enforcement, the risk of enforcement would be accompanied by case-by-case review and companies could obtain continued deferment.

To be sure, in its Response, the FDA provided a letter to Swisher (after this case was filed) stating it "has no intention of initiating an enforcement action" against "any of the product implicated by this lawsuit" and further, if that changed, the FDA would "send a warning letter" and grant Swisher a 60-day response period before any enforcement action is

taken. (Doc. 27 at 11); (Doc. 27.1 at 2-3; August 12, 2021 FDA Letter to Swisher (emphasis added)). The FDA's letter makes clear that it has no intention to bring enforcement action against Swisher's products and it makes clear that Swisher is not facing any enforcement action, and if that changed, Swisher would have at least 60 days to renew its request for a preliminary injunction before any harm could be realized. Swisher admits as much in its reply. Reply at 5 (arguing the harm of a post September 9, 2021 enforcement actions will "put[ ] the parties and the Court right back in the same emergency posture re-litigating the same issues").

These facts place the instant case in a separate category than those upon which Swisher relies. First, there is a question of whether the FDA's comments that prompted Swisher's concern regarding enforcement provide a sufficient basis for this Court to preliminarily enjoin the FDA. For its part, Swisher cites to U.S. Army Corps of Engineers v. Hawkes Co., 578 U.S. 1129 (2016) for the proposition that it need not wait for the FDA to "drop the hammer" before it can wage a meritorious pre-enforcement challenge. Reply at 6. Hawkes Co, resolved whether the Army Corps of Engineers' "jurisdictional determination" ("JD") that water of the United

States existed on the appellant's property was a final agency action.[5] The Court started its analysis by asking whether the approved JD "clearly mark[ed] the consummation of the Corp's decision making process . . . ." Hawkes Co 578 U.S. at 1129 (quotations omitted). The Court next asked whether the JD's issuance gave "rise to direct and appreciable legal consequences . . . ." Id.

As to the first question, the Court found the issuance of the approved JD, unlike a preliminary JD, consummated the Corp's decisionmaking because it was issued after extensive fact finding, valid for five years, and typically not revisited. Id. The second question was also answered in the affirmative because the approved JD finding the presence of United States' water meant appellant could not avail itself of the protections afforded by the Clean Water Act's safe harbor provision. Id.

Comparing the facts in Hawkes to the facts Swisher presents leaves the Court unconvinced that an off-the-cuff remark in a webinar restating a possibility announced and created by the court in AAP represents the FDA's decision-making.[6] Moreover, the statements did not create or

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[5] The Court described two types of JDs: "preliminary" and "approved." Id. at 1129. The JD at issued was approved. Id.

[6] Swisher stated in its opening that the predicate act justifying the current "exigency" was the June 2021 Webinar. To the extent Swisher claims the Deeming Rule, the lack of ruling on its premarket applications, or the FDA's failure to agree to not enforce the September 10, 2021 deadline are the relevant acts (or non-acts), Swisher knew of their

diminish Swisher's legal rights. If anything affected Swisher's rights, it was the decision in AAP to vacate the FDA's guidance that gave Swisher exactly what it now asks this Court to do. While an actual enforcement action would certainly demonstrate a final agency decision, there is no credible reason to believe one is forthcoming, or that if one does come, that the Court could not, if appropriate, enjoin the FDA while resolving the merits of this case. If the Court were to enjoin the FDA [now], such an injunction would be premature and merely advisory because no final agency action has occurred. See Fla. Med. Ass'n, Inc. v. Dep't of Health, 947 F. Supp. 2d 1325, 1354 (M.D. Fla. 2013) (holding that an injunction against possible future agency action would "constitute an impermissible advisory opinion") (Howard, J.).

Swisher's reliance on Wollschlaeger v. Governor, Fla., 848 F.3d 1293 (11th Cir. 2017) and Socialist Workers Party v. Leahy, 145 F.3d 1240 (11th Cir. 1998) ("SWP") do nothing to alter the Court's decision. In SWP, the

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existence for many months, if not years and therefore, these acts cannot serve as basis for the Court's emergency action. The same is true for Swisher's failure to address the ruling in AAP. The risk of enforcement dates to 2019. The 2021 Webinar merely parrots the status established more than two years prior. Moreover, given the numerous failed challenges to the Deeming Rule it also does not appear meritorious. Similarly, the Court is not convinced that it is likely to require a timetable by which the FDA must process Swisher's claims after considering the factors in Telecommunications Rsch. & Action Ctr. v. F.C.C., 750 F.2d 70, 80 (D.C. Cir. 1984), or that the FDA is violating some notion of fair notice.

Eleventh Circuit considered an appeal where the district court rejected a challenge to a Florida statute that required political parties to submit bonds to maintain minor party status on Florida ballots on the basis that the challenge was not ripe. Socialist Workers Party, 145 F.3d at 1241-42. Because Florida had not enforced the statute, the court analyzed whether appellants had demonstrated that: "(1) [they were] threatened with application of the statute; (2) application is likely; or (3) there is a credible threat of application." Id. at 1245. The court held appellants made the requisite showing because state officials declared that appellant must comply with the statute and "unambiguously threatened revocation of plaintiff-appellants' minor party status after the previous Secretary of State also attempted to apply the bonding requirement to [ ]appellants . . . ." Id. at 1247.

Wollsclaeger also involved a challenge to a Florida statute, but this time the statute involved, among other things, a prohibition against medical providers inquiring about their patients' firearm ownership. Wollschlaeger, 848 F.3d at 1300-01. The Court considered whether appellants "alleged an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution." Id. at 1304 (quotations and

alteration omitted). The court cautioned that the fear of disciplinary action must be objectively reasonably. Id. (citing A.C.L.U v. The Fla. Bar, 999 F.2d 1486, 1492 n.13 (11th Cir. 1993)). Following the statute's enactment, the medical providers engaged in "self-censorship" and thus a harm was immediately realized. Id. at 1305. Moreover, the statute's language required enforcement and resultant disciplinary action. Id.

Unlike the appellants in Wollsclaeger, Swisher is not yet injured. It has not shuttered its business nor will it on September 10, 2021. The FDA is not required to take enforcement action and not required to assess sanctions. Unlike the appellants in SWP, Swisher has not been "unambiguously" threatened by the FDA and there is no history of the FDA threatening Swisher for marketing products still under premarket review.[7] Not only has the FDA indicated a willingness to defer any enforcement action, but it attempted to issue guidance affirmatively delaying such action. The FDA's reticence to take enforcement action in light of the backlog of applications is clear. It repeatedly extended the enforcement deadline; the current deadline exists merely as a possibility, and exists

[7] Even though the appellants in SWP prevailed in overturning a judgment against them, they were previously denied a temporary restraining order and preliminary injunction for that same conduct and that denial was upheld on appeal. SWP, 145 F.3d at 1243 (11th Cir. 1998).

only because of AAP. The deadline is not sufficiently likely to be accompanied by imminent enforcement action, when considered along with the FDA's letter and past actions, to justify injunctive relief. The possibility that Swisher will suffer irreparable harm is not enough; Swisher must show that it is likely to suffer irreparable harm absent injunctive relief. See Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 22, (2008) ("We agree with the Navy that the Ninth Circuit's 'possibility' standard is too lenient. Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is likely in the absence of an injunction."). Swisher has failed to make that showing.

Similarly, Swisher's claims regarding the FDA's decision to usher cigars under the TCA's regulations cannot have caused Swisher future irreparable harm. The TCA requires premarket authorization, which Swisher claims to have spent millions of dollars obtaining. The harm inuring from the Deeming Rule, if any, would be compliance with the premarket requirements, which Swisher has, by its own terms, already suffered.

All of that is to say Swisher filed this suit after learning it may be subject to FDA enforcement action beginning September 10, 2021 for products it markets and for which it submitted timely premarket

applications. Certainly, such enforcement, appears on its face, as unjust, contrary to principals of due process, and potentially ruinous to Swisher. But that is not what is happening. The FDA has clarified its remarks and no injunctive action is needed to keep Swisher from the harms it claims it would suffer absent injunctive relief.[8]

2. Motion to Transfer

The FDA seeks asks the Court to transfer this case to United States District Court for the District of Columbia for consolidation with the Cigar Association case pursuant to the first-to-file rule, or alternatively, 28 U.S.C. §1404(a).

a. First filed case

When a party has competing or parallel actions in different courts, the first court to have the action filed is expected to hear the case. See Collegiate Licensing Co. v. Am. Cas. Co. of Reading, 713 F.3d 71, 78 (11th Cir. 2013). A strong presumption favors the forum where the first suit is

[8] Swisher relies on demands from one of its customers to certify certain compliance with 21 U.S.C. § 387j. (Docs. 41.2 and 41.3). Certainly, this customer is entitled to its prerogatives but its insistence on a certain course of action does not justify injunctive relief because "there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." See DiMaio v. Democratic Nat. Comm., 520 F.3d 1299, 1302 (11th Cir. 2008) (internal quotations omitted). Equally damning to Swisher's reliance on this customer's actions is that an injunction would not preserve the status quo given the passage of the deadline given by the customer.

filed if there are duplicative actions with overlapping issues and parties. See Manuel v. Convergys Corp., 430 F.3d 1132, 1135 (11th Cir. 2005). To justify an exception to the first-to-file rule, the opposing party must demonstrate compelling circumstances to maintain the action in another court. Id. In circumstances that fall under the "first-to-file" rule, a district court may stay, transfer, or dismiss a "duplicative later-filed action." Glasgo v. Uber Techs., Inc., Case No. 8:19-cv-97-T-33AAS, 2019 WL 1998326, at *1 (M.D. Fla. May 3, 2019).

A court considers the following when determining whether the first-to-file rule applies: (1) the chronology of the two actions; (2) similarity of the parties; and (3) similarity of the issues. See 15 U.S.C. § 77e(a),(c); Glasgo, 2019 WL 1998326, at *1; Poertner v. Gillette Co., 2012 WL 12898875, at *1 (M.D. Fla. July 9, 2012). The primary purpose of the rule "is to conserve judicial resources and avoid conflicting rulings." Allstate Ins. Co. v. Clohessy, 9 F. Supp. 2d 1314, 1316 (M.D. Fla. 1998).

The Cigar Association Case was filed on July 15, 2016, which is approximately five years prior to this case being filed. Cigar Ass'n of Am. v. United States Food & Drug Admin., Case No. 1:16-cv-1460-APM (D.D.C. July 15, 2016). Cigar Association of America ("CAA"), one of the plaintiffs in the Cigar Association Case, initially represented that is "is a national

trade group representing cigar manufacturers, importers, distributors, and major suppliers to the industry. CAA has member companies from all sectors of the industry . . . ." (CAA Doc. 1 ¶ 9; CAA Complaint). CAA continues making this representation to this day. (CAA Doc. 236 ¶ 9; Fourth Amended Complaint). CCA also classified its standing as being derivative from its members and their interest to ensure "that any regulation of cigars . . . is consistent with statutory and constitutional requirements." Id. ¶¶ 12-13. It is undisputed that Swisher is a member of CAA. Central to Cigar Association case is the plaintiffs' challenge to the FDA's Deeming Rule, and the case remains ongoing. See Cigar Ass'n of Am., 5 F.4th at 72.

There is persuasive authority that members of a trade association should be bound to judgments and actions brought by their trade association. See W. Coal Traffic League v. I.C.C., 735 F.2d 1408, 1411 (D.C. Cir. 1984) (R. B. Ginsburg, J); Aluminum Co. of Am. v. I.C.C., 761 F.2d 746, 751 (D.C. Cir. 1985) (Scalia, J). The issues featured in the CAA case, like those featured in this action, all originate from the Deeming Rule. For example, Paragraphs 78 through 81 of the Fourth Amended Complaint in CAA criticizes the FDA's decision to regulate cigars and argues the premarket authorization process deadlines will deny cigar manufactures

an opportunity to show that their products are substantially equivalent to a predicate product. (CAA Doc. 236 at 25-26). Further, Swisher's sought relief, which is tantamount to a collateral attack on the AAP decision, was already considered and rejected by the court in CAA. Cigar Ass'n of Am. v. U.S. Food & Drug Admin., 411 F. Supp. 3d 1, 3 (D.D.C. 2019) (holding "the AAP court's decision is the cause of Plaintiffs' claimed harm, not any agency action" and an order that essentially resurrects the August 2017 Guidance "would be tantamount to permitting a collateral attack on the AAP court's order"). While the wording in the cases' claims differ, at their heart is a challenge, mounted by cigar manufacturers, to the FDA's application and enforcement of the TCA to cigars.

It is true that Swisher's "catch-22" claim is not a feature issue in the CAA case like it is here—that is to say—the FDA's failure to act on premarket applications coupled with a threat of enforcement against products on the market without premarket approval. Yet, these issues affect all cigar manufacturer's equally, or at least, Swisher has not shown itself to be in a position different from the plaintiffs in CAA. "Under the first-to-file rule, it is not any particular claim but 'the overall content of each suit' that controls . . . ." En Fuego Tobacco Shop LLC v. United States Food & Drug Admin., No. 4:18-CV-00028, 2018 WL 11247716, at *3 (E.D.

Tex. July 30, 2018). Regardless, the issue of enforcement is insufficient to cause a new district court to begin anew in a case involving issues litigated and subject to litigation in the CAA case filed some five years prior by a trade association to which Swisher belongs.

These facts distinguish this case from those Swisher cites. For example, the court in Google Inc. v. Rockstar Consortium U.S. LP, No. C 13-5933 CW, 2014 WL 1571807 (N.D. Cal. Apr. 17, 2014) declined to transfer its case pursuant to the first-to-file rule. The basis of the court's decision on this point were the lack of privity and substantial similarity between a manufacturer and customer. Id. at 9. The court also indicated, in dicta, that transfer may have otherwise been appropriate but for a unique exception found in patent law dubbed the "customer-suit exception." Id. The customer-suit exception cannot apply to this non-patent case, nor is the relationship between Swisher and CAA fairly categorized as one of manufacturer and customer.

Equally inapposite is Swisher's reliance on Young v. Trump, No. 20-CV-07183-EMC, 2020 WL 7319434 (N.D. Cal. Dec. 11, 2020), appeal dismissed sub nom. Young v. Biden, No. 21-15233, 2021 WL 3507648 (9th Cir. Mar. 16, 2021), a case where the court declined to transfer its case after finding "no overlap between named plaintiffs," which is not the case

here. Collegiate Licensing Co., 713 F.3d at 78, like Young, also held transfer pursuant to the first-to-file rule was inappropriate, for among other things, there being "no relationship" between the relevant insurers, and the second-filed case was the first-filed case once intervention was considered. Id. at 77; see also Schwanke v. JB Med. Mgmt. Sols., Inc., No. 5:16-CV-597-OC-30PRL, 2017 WL 78727, at *3 (M.D. Fla. Jan. 9, 2017) (declining to transfer case where the plaintiff's case could not have arisen from the facts giving rise to the purported first-filed case by operation of the class definition removing the plaintiff from the class).

Swisher's strongest argument against transfer is that the CAA case's focus is on premium cigars. (See CAA Doc. 181 at 3).[9] However, the relief sought in CAA benefited Swisher as much as it did the plaintiffs in CAA. Had the CAA court declared the deeming rule to be arbitrary and capricious, or held that it was promulgated in violation of the Appointments Clause, Swisher would have been the beneficiary of the court's ruling. Further such a ruling would have come at the behest of a trade organization representing that the case was brought, in part, on Swisher's behalf. It would be incongruent to now find that Swisher is not

[9] Judge Mehta specifically noted the CAA plaintiffs challenged certain FDA action as it pertained "as to all cigars" as opposed to only premium cigars. (CAA Doc. 181 at 12).

also bound to litigate its claims before that same court, especially where the relief it seeks at least partially runs counter to some of the that court's rulings. Finally, while Swisher argues it accepts the AAP court's ruling as a "given" it is the very process from which Swisher seeks relief regardless of its impact on various iterations of tobacco through the Deeming Rule.

b. 28 U.S.C. § 1404(a)

In considering whether to transfer a case pursuant to § 1404(a), the district court must determine whether "the convenience of parties and witnesses, in the interest of justice" suggest the transfer of a case to another district or division. To determine whether the circumstances of a case warrant transfer, the court evaluates a number of factors. They include:

> (1) the convenience of the witnesses; (2) the location of relevant documents and the relative ease of access to sources of proof; (3) the convenience of the parties; (4) the locus of operative facts; (5) the availability of process to compel the attendance of unwilling witnesses; (6) the relative means of the parties; (7) a forum's familiarity with the governing law; (8) the weight accorded a plaintiff's choice of forum; and (9) trial efficiency and the interests of justice, based on the totality of the circumstances.

Manuel v. Convergys Corp., 430 F.3d 1132, 1135 (11th Cir. 2005). Under section 1404(a), a trial court has broad discretion in determining whether a

transfer is appropriate. Brown v. Connecticut Gen. Life Ins. Co., 934 F.2d 1193, 1197 (11th Cir. 1991).

It is the party seeking the transfer who bears the burden of establishing that a case should be transferred to the suggested forum in the interests of convenience and justice. See In re Ricoh Corp., 870 F.2d 570, 573 (11th Cir. 1989) ("[T]he burden is on the movant to establish that the suggested forum is more convenient."). Moreover, "[i]n determining the propriety of transfer, the Court must give considerable weight to Plaintiff's choice of forum." Response Reward Sys., L.C. v. Meijer, Inc., 189 F. Supp. 2d 1332, 1339 (M.D. Fla. 2002) (internal citations omitted); see also In re Ricoh Corp., 870 F.2d at 573 ("[F]ederal courts traditionally have accorded a plaintiff's choice of forum considerable deference."). "Only if the Plaintiff's choice is clearly outweighed by considerations of convenience, cost, judicial economy, and expeditious discovery and trial process should this Court disregard the choice of forum and transfer the action." Id.; see also Robinson v. Giarmarco & Bill, P.C., 74 F.3d 253, 260 (11th Cir. 1996) ("The plaintiff's choice of forum should not be disturbed unless it is clearly outweighed by other considerations.").

Swisher's chosen venue was Florida, but the Court is skeptical as to why Swisher waited until after the CAA case proceeded for so long to bring

this case, and why the case would be brought in a court not yet apprised as to the controversy surrounding the Deeming Rule.[10] Swisher's choice on this matter invites conflicting rulings from the federal courts and will result in duplicative efforts. True enough, Swisher and this Court have a legitimate and acute interest in litigating on their home-turf. However, that interest is not so great to outweigh the nation's interest in regulation of potentially dangerous products and adhering to a uniform body of law. To hold otherwise would do anything but conserve judicial resources, where a case exists as developed as CAA. Because the FDA is headquartered in the District of Columbia, the case could have been brought there. The location of witnesses, and records seems to have minimal value here owing to this case being one based on an administrative record.

Neither forum is convenient for all parties or witnesses, but the District of Columbia certainly is closer to the relevant events, witnesses, and evidence. More importantly, the Court is moved to transfer this case owing to the District of Columbia's familiarity with this case and the efficiency and consistency to be achieved through its transfer.

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[10] The Court is not persuaded that the FDA's remark in the Webinar as opposed to the AAP court's decision prompted Swisher's fear that the FDA might take enforcement action.

Accordingly, after due consideration, it is

ORDERED:

1. Plaintiff's Motion for an Emergency Preliminary Injunction (Doc. 2) is **DENIED**.
2. Defendants' Motion to Transfer (Doc. 32) is **GRANTED**.
3. The Clerk of the Court shall transfer this case to the United States District Court for the District of Columbia.

DONE and **ORDERED** in Jacksonville, Florida this 7th day of September, 2021.

BRIAN J. DAVIS
United States District Judge

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Copies furnished to:

Counsel of Record