UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

December 14, 2023

CO87-VV-005

MEMORANDUM

TO: Office of the Secretary

FROM: Jason E. Kearns, Commissioner

SUBJECT: Complaint of R.J. Reynolds Tobacco Company and R.J. Reynolds Vapor Company Concerning Certain Disposable Vaporizer Devices and Components and Packaging Thereof (Docket No. 3700)

I agree with my colleagues' decision today to institute an investigation into certain alleged violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), based on the above filed complaint. I write separately, however, because I would also investigate the allegations under section 337(a)(1)(A) based on false advertising under the Lanham Act "that Disposable Vapes are Authorized and/or 'Allowed' for Sale in U.S." Compl. ¶¶ 120-36 ("Authorization Claims"). I also write separately to explain why, in my view, it is appropriate to deny institution as to the allegation based on unfair competition and unfair acts through violations of Customs laws and regulations. Compl. ¶¶ 326-348 ("Customs Claims").

Authorization Claims

The majority finds that the Authorization Claims are precluded by the Food, Drug and Cosmetic Act ("FDCA"), and that the Food and Drug Administration ("FDA") is charged with the administration of the FDCA. This rationale is expounded upon in a letter submitted by the FDA requesting that the Commission decline institution based on the Authorization Claims. EDIS ID No. 807175 ("FDA Letter"). I respectfully disagree.

The FDA has analogized the Authorization Claims in this case to the claims that were denied institution by the Commission in *Certain Synthetically Produced, Predominantly EPA*

Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form, Dkt. No. 3427 (Oct. 27, 2017), *aff'd sub nom. Amarin Pharma, Inc. v. ITC*, 923 F.3d 959 (Fed. Cir. 2019) ("*Amarin*"). I recognize that in *Amarin*, the court held that Lanham Act allegations "based entirely on violations of the FDCA . . . are precluded . . . at least where the FDA has not yet provided guidance as to whether violations of the FDCA occurred." 923 F.3d at 965. In *Amarin*, the underlying issue that the Commission would have needed to resolve was whether the respondents misrepresented their accused products as dietary supplements (which do not require premarket approval), rather than drugs (which do require prior FDA approval). The question of whether the omega-3 products qualified as dietary supplements or drugs was squarely within the expertise of the FDA.

No such expertise of the FDA is required to assess the Authorization Claims here. As acknowledged by the FDA, the accused vapes products require premarket authorization, and the Complaint alleges that those products are on the market without that authorization. The only question that the Commission would need to resolve is whether the proposed respondents have misrepresented their authorization status through the labels they have placed on those products. The Commission has previously instituted section 337 investigations based on similar Lanham Act claims. *See Certain Products Containing Tirzepatide and Products Purporting to Contain Tirzepatide*, 337-TA-1377 (instituted investigation that included allegation based on false and misleading advertising that confuses consumers about FDA approval); *Certain Clidinium Bromide*, Inv. No. 337-TA-1109 (same); *Certain Potassium Chloride Powder Products*, Inv. No. 337-TA-1013 (same).

The FDA letter further suggests "the Commission would need to determine if the [accused] product is marketed to youth or lacks adequate restrictions on youth access." FDA Letter at 5. Although the Complaint does allege that the accused products "i) [] do not have a timely filed premarket tobacco product application pending with FDA, or a marketing denial order that has been stayed by FDA or a court, (ii) [] are marketed toward youth, *and/or* (iii) the manufacturer of the product has failed to take (or is failing to take) adequate measures to prevent youth access" (Compl. ¶ 127 (emphasis added)) as alternative reasons why the products are "unlawful," Complainants have clarified that they "do **not** contend that proof that the accused products are marketed towards youth, or that the manufacturer of the product has failed to take (or is failing to take) adequate measures to prevent youth access, is necessary to establish the accused products are 'unlawfully on the market.'" EDIS ID No. 809498 (Complainants' response to Commission's letter seeing clarification regarding Authorization Claims).

Moreover, while the FDA's own enforcement priorities have focused on unauthorized youth-marketed or youth-accessible products, the FDA has also made clear that its enforcement "guidance does not in any way alter the fact that it is illegal to market any new product without premarket authorization." *See* Ctr. for Tobacco Prods., *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)* at 3 (Apr. 2020), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market (Compl. Ex. 8). Thus, leaving aside whether a determination that the accused products are marketed towards youth or lack adequate restrictions on youth access is uniquely within the FDA's expertise, the Commission need not make such a determination to evaluate the Authorization Claims.

The Supreme Court has recognized that "[t]he Lanham Act and the FDCA complement each other in major respects," and thus claims based on false or misleading labeling of products that are also subject to FDA regulations are not necessarily precluded. *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 114 (2014). Consistent with this recognition, courts have held that Lanham claims based on misrepresentation of FDA approval status are not precluded by the FDCA. *See Azurity Pharm., Inc. v. Edge Pharma, LLC*, 45 F.4th 479, 501 (1st Cir. 2022) (finding no FDCA preclusion and distinguishing *Amarin*, where the Lanham Act claim merely alleges a violation of the "plain text" of a "clear" requirement in the statute); *Belcher Pharms., LLC v. Hospira, Inc.*, 1 F.4th 1374, 1381 (11th Cir. 2021) (finding that "the FDCA does not categorically preclude Lanham Act claims" where "[t]he only question at issue here is whether Hospira's package inserts falsely imply that its epinephrine products or the package insert claims that go along with them are FDA-approved. Nothing in the FDCA prohibits a competitor from bringing that kind of claim."); *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 939 (8th Cir. 2005) (holding that, under the "primary jurisdiction" doctrine, a Lanham Act claim was permissible based on a false assertion of FDA approval of an animal feed product because "[t]he question of whether Pennfield's BMD *has been* approved as safe and effective is much different from the question of whether Pennfield's BMD *should be* approved as safe and effective, and it is only the latter that requires the FDA's scientific expertise" (emphasis added)). In *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924-25 (9th Cir. 2010), which was followed by the Federal Circuit in *Amarin*, the court noted "[i]f, for example, it was clear that an affirmative statement of approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued for injuries suffered by a competitor as a result of a false assertion that approval had been granted." That is precisely the allegation presented in the complaint.

I recognize there are certain unique aspects to the Authorization Claims, but none of those justify a denial of institution in my view. First, as noted by the FDA, the allegedly misleading statement on the accused products ("Sale Only Allowed in the United States") is required to be placed *verbatim* on the labels and packaging of all tobacco products sold in the United States by the FDCA. FDA Letter at 4 (citing 21 U.S.C. § 387t(a)). The FDA contends "[i]f *all* tobacco products—authorized or not—must bear the word 'allowed,' then under Complainants' theory, every one that is not in fact 'allowed' by FDA is apparently false or misleading under the Lanham Act." *Id.* Whether the label on the accused products is actually false or misleading is a question on the merits that should be fully evaluated based on a complete record after institution. Indeed, placing a government-required label on unauthorized products may be even more problematic insofar as it might give a false impression of the safety of those products. At this preliminary stage, however, I do not consider that mandatory labeling requirement as somehow sanctioning otherwise unauthorized products that, at least arguably, mislead purchasers into believing they are in fact allowed for sale in the United States, which is the crux of the allegation here.

Second, the FDA notes that the Authorization Claims would require the Commission to determine whether an accused product has a marketing application before the FDA, but this is "a fact that FDA is required to keep confidential unless the manufacturer has publicly revealed it." FDA Letter at 5. At this point, there is nothing to suggest that any of the accused products have a pending premarket application. But to the extent that any of the proposed respondents wish to raise that as a possible defense, it is of course possible for the Commission to keep that

information confidential within the confines of a protective order entered in an instituted investigation. And, in any event, this does not strike me as a reason to not even initiate an investigation.

Third, I respect the FDA's expertise concerning the health and safety of these products and recognize the FDA's stated policy reasons against the immediate enforcement of the FDCA towards unauthorized Electronic Nicotine Delivery Systems (ENDS) products, i.e., to strike a balance between the risk those products pose to youth and the potential benefit of those products in helping adults transition from combustible cigarettes. FDA Letter at 2. However, given the mandatory language in section 337(b)(1), I do not believe the Commission has discretion to deny institution of an otherwise cognizable claim based merely on the FDA's policy justifications for its enforcement priorities. *See* 19 U.S.C. § 1337(b)(1) ("The Commission *shall* investigate any alleged violation of this section on complaint under oath or upon its initiative.") (emphasis added); *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1354 (2018) ("The word 'shall' generally imposes a nondiscretionary duty."). Instead, the Commission should consider those policy reasons as part of its statutorily required public interest analysis after institution.

Customs Claims

I agree with the Commission's decision not to institute a section 337 investigation based on the Customs Claims. I find the nature of the allegations and the potential remedy encompassed by the Customs Claims to be distinguishable from the Authorization Claims discussed above. In particular, these claims are based on allegations that certain accused products have been misclassified under the Harmonized Tariff Schedule of the United States (HTSUS). As noted by U.S. Customs and Border Protection (CBP), CBP is responsible for classifying merchandise imported into the United States and has the sole authority to bring enforcement action for violations of the Customs laws. *See* EDIS ID No. 807525 (CBP Letter). For example, CBP may initiate an administrative action under 19 U.S.C. § 1592 to recover penalties and lost revenue for alleged violations of the Customs laws. Unlike with the Lanham Act, private parties do not have a separate cause of action under the Customs laws. Whether a complainant can link an alleged unlawful act to a private right of action under that law is one factor to consider (although it is unclear whether it should be dispositive or how much weight it should carry) in assessing whether there is a cognizable cause of action under section 337. CBP further notes that the remedy of an exclusion order directing CBP to exclude goods that are misclassified would be inconsistent with 19 U.S.C. § 1592(d). Taking all this into account, I find that the Customs Claims are not cognizable under section 337(a)(1)(A).