

legal principles, judicial review, if any, must await the conclusion of the administrative process.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

The CPSC is an independent regulatory agency established by Congress to “protect the public against unreasonable risks of injury associated with consumer products.” 15 U.S.C. § 2051(b)(1). Congress explained that “an unacceptable number of consumer products which present unreasonable risks of injury are distributed in commerce,” and that “the public should be protected against unreasonable risks of injury associated with consumer products.” *Id.* § 2051(a)(1), (3).

The Commission is charged with enforcing the Consumer Product Safety Act (“CPSA”), 15 U.S.C. §§ 2051-2089, among other statutes. The CPSA empowers the Commission to conduct investigations into the safety of consumer products to protect the public against unreasonable risks of injury. 15 U.S.C. §§ 2054(b)(1), 2065. The CPSA defines a “substantial product hazard” as

(1) a failure to comply with an applicable consumer product safety rule under this Act or a similar rule, regulation, standard, or ban under any other Act enforced by the Commission which creates a substantial risk of serious injury to the public, or (2) a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.

15 U.S.C. § 2064(a). If the Commission determines, after a hearing, that a product distributed in commerce presents a substantial product hazard, and certain other conditions are met, the Commission may order a manufacturer, distributor, or retailer of the product to cease distribution of the product and offer a refund to consumers, among other actions. 15

U.S.C. § 2064(c)-(d). A hearing to determine if a product presents a substantial product hazard must meet the requirements set forth in the APA, 5 U.S.C. § 554. 15 U.S.C. § 2064(f)(1).

The Commission has issued regulations at 16 C.F.R. part 1025 (“Rules of Practice for Adjudicative Proceedings”) governing adjudicative proceedings under the APA. After a hearing on the merits, the Administrative Law Judge (“ALJ”) “shall endeavor to file an Initial Decision with the Commission within sixty (60) days after the closing of the record or the filing of post-hearing briefs, whichever is later.” 16 C.F.R. § 1025.51(a). Next, “[t]he Initial Decision and Order shall become the Final Decision and Order of the Commission forty (40) days after issuance unless an appeal is noted and perfected or unless review is ordered by the Commission.” 16 C.F.R. § 1025.52. If the Commission issues a Final Decision and Order affecting a party’s rights or obligations, the party may then seek review in a federal district court under the APA. 5 U.S.C. § 704.

II. FACTUAL AND PROCEDURAL BACKGROUND

In 2009, Maxfield & Oberton Holdings, LLC (“M&O”), Plaintiff’s company, began importing and distributing aggregated masses of small, high-powered magnets under the brand name Buckyballs. Compl. ¶ 12, 14; Compl. Ex. 4 ¶ 1. M&O introduced a similar product, Buckycubes, to the market in October 2011. Compl. ¶ 28; Compl. Ex. 4 ¶ 20. On July 25, 2012, CPSC staff filed an administrative complaint against M&O (the “administrative complaint”) pursuant to sections 15(c) and (d) of the CPSA, 15 U.S.C. § 2064(c)-(d), alleging that Buckyballs and Buckycubes, imported and distributed by M&O, present a substantial product hazard and seeking a mandatory recall order. Compl. ¶ 47. CPSC staff subsequently filed administrative complaints against two other manufacturers of

substantively identical magnet sets, also seeking recall orders. Compl. ¶ 48. All three adjudicative proceedings against magnet manufacturers have been consolidated and are in the discovery stage.¹

The CPSC's administrative complaint alleges that, since 2009, CPSC has received reports of children ingesting Buckyballs. Compl. Ex. 4 at ¶ 45-50. Ingestion incidents can occur when children place single magnets or numerous magnets in their mouths and also when adolescents and teens use magnets to mimic piercings of the mouth, tongue, and cheek, and accidentally swallow the magnets. *Id.* ¶ 100, 101. The administrative complaint alleges that if two or more magnets are ingested and the magnetic forces pull the magnets together, they can pinch or trap the intestinal walls or other digestive tissue, possibly leading to tissue death, perforations, and fistulas. *Id.* ¶ 102. Ingestion of more than one magnet often requires medical intervention, including endoscopic and surgical procedures. *Id.* ¶ 103. Plaintiff recognizes that Buckyballs "may cause harm if ingested." Compl. ¶ 19. According to the administrative complaint, M&O sold more than 2.5 million sets of Buckyballs and more than 290,000 sets of Buckycubes in the United States as of July 2012. Compl. Ex. 4 ¶ 24-25.

On December 27, 2012, M&O filed a certificate of cancellation of its incorporation in Delaware and ceased business operations. *See* Compl. ¶ 56; Compl. Ex. 4 ¶ 14. On February 11, 2013, Commission staff sought leave to amend its administrative complaint to name Plaintiff, the founder and Chief Executive Officer of M&O, as a Respondent in the proceeding. Compl. Ex. 3. The ALJ granted CPSC's motion. Compl. Ex. 6. Plaintiff sought an interlocutory appeal of that decision, requesting review by the Commission, but the

¹ Separate from the adjudicative proceedings, the Commission has issued a notice of proposed rulemaking to regulate the sale of high-powered magnet sets in the future. *See* <http://www.regulations.gov/#!documentDetail;D=CPSC-2012-0050-0001>.

ALJ rejected that request and ordered the litigation to proceed with Plaintiff as a named Respondent. Compl. Ex. 7. Pursuant to that Order, the adjudicative proceeding is ongoing and is currently being litigated before the ALJ under Commission regulations at 16 C.F.R. part 1025. The ALJ has not yet issued an Initial Decision nor has the Commission issued a Final Decision or Order. *See* 16 C.F.R. part 1025, subpart F.

On November 12, 2013, Plaintiff filed a complaint in this Court alleging that the Commission's action in naming him as a Respondent was arbitrary and capricious, an abuse of discretion, and in excess of the Commission's statutory authority in violation of the APA. Compl. ¶ 103. Plaintiff further alleged that the Commission violated his First and Fifth Amendment rights. *Id.* ¶ 109. Plaintiff asks this Court to enjoin the Commission from proceeding against him in the ongoing administrative adjudication. *Id.* at 20.

ARGUMENT

I. STANDARD OF REVIEW

Under Rule 12(b)(1) of the Federal Rules of Civil Procedure, a plaintiff has the burden of proving subject matter jurisdiction. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); *Allen v. Wright*, 468 U.S. 737, 751 (1984); *Flast v. Cohen*, 392 U.S. 83, 95 (1968); *Friends for Ferrell Parkway, LLC v. Stasko*, 282 F.3d 315, 320 (4th Cir. 2002); *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999). A motion to dismiss under Rule 12(b)(1) should be granted "if the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." *Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991).

Moreover, declaratory relief is permitted only if jurisdiction otherwise exists. 28 U.S.C. § 2201 ("In a case of actual controversy within its jurisdiction . . . any court . . . may

declare the rights. . . .”); *Public Serv. Comm’n of Utah v. Wycoff Co.*, 344 U.S. 237, 242 (1952) (Declaratory Judgment Act “applies . . . only to ‘cases and controversies in the constitutional sense.’”) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937)); *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671-72 (1950).

II. THE COMMISSION HAS NOT TAKEN FINAL AGENCY ACTION AGAINST PLAINTIFF

Fourth Circuit law makes clear that APA claims based on non-final agency action must be dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure. *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 313 F.3d 852, 862 (4th Cir. 2002) (“we are of opinion and hold that there has not been final agency action under 5 U.S.C. §§ 702 and 704. The decision of the district court is remanded for dismissal on account of want of subject matter jurisdiction.”); *Invention Submission Corp. v. Rogan*, 357 F.3d 452, 454 (4th Cir. 2004) (“we conclude that because the PTO’s advertising campaign was not a final agency action . . . We must therefore vacate the district court’s order . . . for lack of subject matter jurisdiction.”); *Golden and Zimmerman, LLC v. Domenech*, 599 F.3d 426, 433 (4th Cir. 2010) (“we hold that the ATF’s publication of the 2005 edition of the Reference Guide and FAQ F13 did not constitute final agency action reviewable in court, and, accordingly, we affirm the district court’s order dismissing this case for lack of subject matter jurisdiction.”).

As noted above, Plaintiff is a Respondent in an ongoing CPSC adjudicative proceeding. Because that administrative proceeding has yet to conclude – discovery is not complete, the ALJ has made no initial decision on the merits, and the Commission has not issued any final decision – there has been no final agency action by the Commission. In

these circumstances, the Court lacks subject matter jurisdiction to review Plaintiff's claims under the APA. *See* 5 U.S.C. § 704 (authorizing judicial review of "final agency action").

Final agency action "mark[s] the 'consummation' of the agency's decisionmaking process" and is "one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (citations omitted); *see also Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992) ("The core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties."). Far from being consummated or completed, the administrative action Plaintiff wishes to challenge is still ongoing. No rights or obligations have been determined and Plaintiff has yet to suffer any legal consequences stemming from the CPSC's actions to date.

Indeed, it has long been established that filing an administrative complaint is not final agency action subject to judicial review under the APA. In *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232 (1980), the Federal Trade Commission ("FTC") filed an administrative complaint against Standard Oil Company of California ("Socal"), alleging violations of the FTC Act. Socal sought judicial review, claiming that the FTC had initiated the administrative action without sufficient evidence to believe that Socal was violating the Act. The Supreme Court held that the Commission's issuance of its complaint was not final agency action. 449 U.S. at 239. Rather, the complaint served "only to initiate the proceedings," *id.* at 242, and "had no legal force or practical effect upon Socal's daily business other than the disruptions that accompany any major litigation." *Id.* at 243. The Court reached this result even though the complaint was "definitive" on the question whether the Commission had "reason to believe" that Standard Oil was violating the FTC Act. *Id.* at

241. The complaint was only a determination that adjudicatory proceedings would commence. *Id.* Permitting judicial review of the FTC’s complaint, the Court held, would lead to “piecemeal review which at the least is inefficient and upon completion of the agency process might prove to have been unnecessary.” *Id.* at 242.

Plaintiff’s position before this Court is almost exactly that of *Socal* in *Standard Oil*. Like *Socal*, Plaintiff first sought to block the action against him at the administrative level. Having been unsuccessful there, Plaintiff, again like *Socal*, now asks a federal district court to intervene and declare that the filing of an administrative complaint against him is unlawful, a result the Supreme Court clearly foreclosed in *Standard Oil*. As in *Standard Oil*, the CPSC staff’s administrative complaint merely initiates a proceeding and has no independent legal force. Contrary to Plaintiff’s contention, the complaint represents the beginning of agency action, not its culmination, which is the prerequisite for judicial review. Indeed, Plaintiff concedes as much, referring to the CPSC action as an “on-going administrative proceeding” in which “the very question of whether M&O’s products are defective or hazardous is being adjudicated.” Compl. ¶ 48. As the ALJ himself pointed out, “if the undersigned finds the products do not present a substantial product hazard, no sanction will be imposed on Mr. Zucker in the final judgment.” Compl. Ex. 7 at 7. Thus, only after the merits have been adjudicated, and only if the Commission issues an order against Plaintiff, will Plaintiff’s rights and obligations be affected – and only then will final agency action have occurred.

In these circumstances, there is no merit to Plaintiff’s claim that the CPSC’s “decision to assert authority over [him] determined his legal rights or obligations and resulted in immediate legal consequences by forcing him to defend an unlawful adjudicative

proceeding,” thereby creating final agency action. Compl. ¶ 102. To the contrary, as the Supreme Court made clear in *Standard Oil*, the “burden of responding” to an administrative complaint, however substantial, does not make the agency action “final” for purposes of judicial review:

Socal does not contend that the issuance of the complaint had any such legal or practical effect, except to impose upon Socal the burden of responding to the charges made against it. Although this burden certainly is substantial, it is different in kind and legal effect from the burdens attending what heretofore has been considered to be final agency action.

Standard Oil, 449 U.S. at 242. See also *Reliable Automatic Sprinkler Co. v. CPSC*, 324 F.3d 726, 732 (D.C. Cir. 2003) (“If the Government brings an enforcement proceeding, such parties may defend themselves on the ground that the agency lacks jurisdiction, but they may not preemptively challenge the Government’s jurisdiction before the Government has taken any action to enforce the law against them.”); *Eastman Kodak Co. v. Mossinghoff*, 704 F.2d 1319, 1324-25 (4th Cir. 1983) (immediate judicial intervention would interfere with proper functioning of agency, burden courts, and “lead to piecemeal review which at least is inefficient, and may be unnecessary depending on the outcome of the . . . proceedings.”); *Mentor Graphics Corp. v. Rea*, No. 13-CV-518, 2013 WL 3874522 at *3 (E.D. Va. June 25, 2013) (“Even though Mentor Graphics is forced to participate in the inter partes proceedings, this fact does not render the PTAB’s decision final under the APA.”) (citing *Standard Oil*).

Because the CPSC has not finally determined Plaintiff’s legal rights or obligations, or otherwise consummated its ongoing adjudicative proceeding, there has been no final agency action and Plaintiffs’ complaint must be dismissed for lack of jurisdiction. See *Flue-Cured Tobacco*, 313 F.3d at 862; *Invention Submission Corp.*, 357 F.3d at 454; *Golden and Zimmerman, LLC*, 599 F.3d at 433.

III. PLAINTIFF'S CLAIMS ARE NOT RIPE

Both Article III of the U.S. Constitution and the APA, 5 U.S.C. § 704, require that the agency complete its decision-making process before a plaintiff seeks judicial review.² The ripeness doctrine serves “to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.” *Ohio Forestry Ass’n v. Sierra Club*, 523 U.S. 726, 732-33 (1998). “A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Texas v. United States*, 523 U.S. 296, 300 (1998) (citations and internal quotation marks omitted). As the D.C. Circuit has elaborated:

[T]he “usually unspoken element of the rationale” is this: “If we do not decide [the claim] now, we may never need to. Not only does this rationale protect the expenditure of judicial resources, but it comports with our theoretical role as the governmental branch of last resort. Article III courts should not make decisions unless they have to.

Nat’l Treasury Emps. Union v. United States, 101 F.3d 1423, 1431 (D.C. Cir. 1996) (citation omitted); *see also Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 386 (D.C. Cir. 2012); *Fourth Quarter Props. IV, Inc. v. City of Concord, N.C.*, 127 Fed. Appx. 648 (4th Cir. 2005) (upholding district court’s dismissal of claim for lack of ripeness under Rule 12(b)(1)).

² The doctrine of ripeness originates in Article III’s “case or controversy” requirement. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 341 (2006); *see also Nat’l Park Hospitality Ass’n v. Dep’t of Interior* 538 U.S. 803, 808 (2003). The APA likewise authorizes judicial review only with respect to “final agency action.” 5 U.S.C. § 704. Thus, the requirement of final agency action is both part of the Article III ripeness inquiry as well as an independent basis for dismissal under the APA. *See, e.g., Holistic Candles & Consumers Ass’n v. FDA*, 664 F.3d 940, 943 & n.4 (D.C. Cir. 2012).

To determine whether an agency decision is ripe for review, courts examine “both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.” *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). The fitness prong, in turn, depends upon (a) whether the claims raise purely legal questions, and (b) whether the challenge involves final agency action. *Id.* As discussed above, Plaintiff seeks to challenge agency action that is manifestly non-final. Nor does Plaintiff’s complaint raise purely legal issues. To the contrary, both the question of whether Buckyballs and Buckycubes are a substantial product hazard as well as the determination of Plaintiff Zucker’s individual liability are inherently fact-based inquiries. Thus, Plaintiff’s claims are demonstrably unfit for judicial decision.

Plaintiff also fails to establish that withholding judicial review now will cause him hardship – the second element of the ripeness test. Indeed, the only “hardship” Plaintiff will suffer in the absence of immediate review is that attendant to participating in the administrative process itself – hardship that the Supreme Court has long deemed insufficient to warrant judicial intervention. *See Standard Oil Co.*, 449 U.S. at 244. As the Court explained:

Socal also contends that it will be irreparably harmed unless the issuance of the complaint is judicially reviewed immediately. Socal argues that the expense and disruption of defending itself in protracted adjudicatory proceedings constitutes irreparable harm. As indicated above, we do not doubt that the burden of defending this proceeding will be substantial. But “the expense and annoyance of litigation is ‘part of the social burden of living under government.’” . . . As we recently reiterated: “Mere litigation expense, even substantial and unrecoupable cost, does not constitute irreparable injury.”

Id. (citations omitted); *see also Devia v. NRC*, 492 F.3d 421, 427-28 (D.C. Cir. 2007) (“In order to outweigh institutional interests in the deferral of review, the hardship to those

affected by the agency's action must be immediate and significant.") (citation omitted); *Eastman Kodak*, 704 F.2d at 1324-25 (rejecting claim that Kodak would "suffer serious hardship" absent immediate judicial review due to "trouble and expense" of relitigating issue all over again, noting that "the expense and annoyance of litigation is 'part of the social burden of living under government.'") (quoting *Standard Oil*, 449 U.S. at 244) (internal citation omitted).

Thus, in the absence of final agency action, Plaintiff's claims satisfy neither the fitness nor the hardship prongs of the ripeness test. The CPSC has not finally determined any legal rights or obligations, or otherwise consummated its adjudicative proceeding, and Plaintiff will suffer no cognizable hardship from deferring review until the conclusion of the ongoing administrative proceeding. Accordingly, Plaintiff's challenge is not ripe for review.

IV. PLAINTIFF'S COMPLAINT SHOULD BE DISMISSED BECAUSE IT IS AN ATTEMPT TO PRECLUDE AN ENFORCEMENT ACTION

Plaintiff's complaint must also be dismissed because it seeks to preemptively enjoin CPSC's ongoing enforcement action. Whether an enforcement action is simply contemplated or has already been filed, it is well-established that those subject to agency enforcement may not file a separate challenge, but must raise any defenses they have in the enforcement case itself. *See Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 598 (1950) (opportunity for court hearing in enforcement action "satisfies the requirements of due process."); *see also Myers v. Bethlehem Shipbuilding Corp.* 303 U.S. 41, 48 (1938) ("The District Court is without jurisdiction to enjoin [NLRB] hearings," in part because the Act provided for appropriate procedure before the Board). Thus, under *Ewing* and its progeny, courts lack jurisdiction to entertain preemptive challenges to enforcement such as that lodged by Plaintiff here. The rule articulated in *Ewing* precludes judicial interference with an agency's decision

to institute enforcement action, “whatever the precise context,” and has been “consistently and strictly observed” by the lower courts for over sixty years.³ *United States v. Alcon Labs.*, 636 F.2d 876, 881-82 (1st Cir. 1981). For this reason as well, Plaintiff’s claims must be dismissed for lack of jurisdiction.

³ See, e.g., *Great Plains Coop v. CFTC*, 205 F.3d 353, 355 (8th Cir. 2000) (no jurisdiction to enjoin administrative enforcement action prior to final agency decision); *Gen. Fin. Corp. v. FTC*, 700 F.2d 366, 368 (7th Cir. 1983) (target of investigation cannot sue the FTC to enjoin investigation, but must present claims in FTC’s affirmative case); *Southeastern Minerals, Inc. v. Harris*, 622 F.2d 758, 764 (5th Cir. 1980) (“in seeking to enjoin federal officials from interfering with the manufacturing and marketing of their product, the appellees necessarily sought pre-enforcement review of the FDA’s determination that probable cause existed to seize and initiate enforcement proceedings . . . , a review clearly proscribed by *Ewing*.”); *Pharmadyne Labs, Inc. v. Kennedy*, 596 F.2d 568, 570-71 (3d Cir. 1979) (no jurisdiction to enjoin seizure enforcement actions under *Ewing*); *Parke, Davis & Co. v. Califano*, 564 F.2d 1200, 1206 (6th Cir. 1977) (“it was an abuse of discretion to enjoin the FDA in the circumstances of this case where pending enforcement actions provided an opportunity for a full hearing before a court.”); *Holistic Candles & Consumers Ass’n v. FDA*, 770 F. Supp. 2d 156, 163 (D.D.C. 2011) (district court “may not review requests for injunctive or declaratory relief preventing the FDA from bringing enforcement actions against plaintiffs”), *aff’d on other grounds*, 664 F.3d 940); *Direct Mktg. Concepts, Inc. v. FTC*, 581 F. Supp. 2d 115, 117 (D. Mass. 2008) (“If this action is related to the enforcement action, then it must be dismissed as an impermissible attempt to enjoin an ongoing enforcement action. If the two actions are not related, then this action must be dismissed for failure to present a ripe claim for judicial adjudication.”); *Genendo Pharm. v. Thompson*, 308 F. Supp. 2d 881, 883 (N.D. Ill. 2003) (it “is well-settled that the district courts lack jurisdiction to enjoin enforcement proceedings.”).

CONCLUSION

For the foregoing reasons, Plaintiff's complaint should be dismissed for lack of subject matter jurisdiction.

Respectfully submitted,

STUART F. DELERY
Assistant Attorney General

MAAME EWUSI-MENSAH FRIMPONG
Deputy Assistant Attorney General

MICHAEL S. BLUME
Director

/s/ _____
PERHAM GORJI
Trial Attorney
Consumer Protection Branch
United States Department of Justice
P.O. Box 386
Washington, DC 20044
Telephone: 202-353-3881
Fax: 202-514-8742