IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Honorable R. Brooke Jackson

Civil Case No. 17-CV-2645-RBJ

ZEN MAGNETS, LLC,

Plaintiff,

v.

U.S. CONSUMER PRODUCT SAFETY COMMISSION,

Defendant.

MOTION FOR AND MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Zen Magnets, LLC ("Zen"), through counsel, and pursuant to Rule 56, F.R.C.P., requests summary judgment on all of the claims in the Complaint (Doc. 1) and as grounds therefor relies on the following Statement of Undisputed Facts, Memorandum of Points and Authorities, memoranda, pleadings, records,[1] and files in this action.

I. STATEMENT OF UNDISPUTED FACTS

1. In 2012, the U.S. Consumer Product Safety Commission ("CPSC" or "the Commission") initiated an administrative enforcement action against Zen and several other firms selling small rare earth magnets ("SREMs").[2] The products at issue in this proceeding are coated magnetic

[1] The administrative record ("AR") will be cited to by the docket number, followed by "AR" and the index document number as provided by the Commission. If more than one document exists under the index number, a parenthetical will be provided to indicate the document being cited.

[2] The CPSC consolidated its docket numbers 12-1 and 12-2, stating that "Buckyballs, Buckycubes and Zen Magnets are referred to herein as the 'Subject Products'." 12-1AR7 at 2. *See also* 12-2AR9 at 1 (noting that both CPSC Dockets 12-1 against Buckyballs 12-2 against Zen involved "high-powered, small rare earth magnets.").

spheres, roughly 5mm in diameter, sold by Zen as "Zen Magnets" and "Neoballs." These SREMs have been defined as the "Subject Products" in the proceedings before the Commission.

2. According to the CPSC, "because SREMs are functionally identical, and brands are indistinguishable, the physical characteristics of SREMs that give rise to a risk of injury are shared by all brands." 12-2AR163 (FDO) at 23; *see also id*. at 23-25.

3. On October 3, 2014, the Commission voted 4-0 to commence a rulemaking, and subsequently to promulgate a magnet safety rule (the "Rule"). Chairman Buerkle[3] abstained from the vote. At the time the Rule was promulgated, Plaintiff was the only U.S. firm selling SREMs subject to the rule. 79 Fed. Reg. 59962, 59962-59963 (Oct. 3, 2014).

4. The CPSC promulgated the Rule two months before the hearing on the parallel administrative proceeding, Docket 12-2. The CPSC made regulatory findings regarding SREMs, including those sold by Zen, in the categories of: the use and utility of SREMs; the degree and nature of the risk of injury the Rule was designed to eliminate; the need for the SREMs and the probable effect of the Rule on the utility, cost, or availability of the SREMs to meet that need; that no feasible safety standard or warning would adequately protect the public from the risk associated with SREMs; and that the benefits of the Rule bear a reasonable relationship to its costs. *See* 79 Fed. Reg. at 59986, 59980-59982; 12-2AR141 at 20-22.

5. Both the rulemaking and administrative adjudication also considered the degree and nature of the risk of injury posed by the Subject Products. Identical incident reports, National Electronic Injury Surveillance System ("NEISS") data, and estimates based on that NEISS data were used to establish both the need for the Rule, *see* 79 Fed. Reg. at 59987, as well as the

[3] Acting Chairman Buerkle will be referred to as "Chairman Buerkle" in this memorandum.

Commission's attempt to prove the existence of a substantial product hazard in the administrative adjudication. *See* 12-2AR26 at ¶¶ 56-59, 61, 63, 113; 79 Fed. Reg. at 59987-59988, 59962, 59964-59965; 12-2AR141 at 17-19.

6. Plaintiff petitioned the Tenth Circuit to vacate the Rule and on November 22, 2016, the Court granted Zen's petition, vacating the Rule. *See Zen Magnets, LLC v. CPSC*, 841 F.3d 1141 (10th Cir. 2016).

7. On October 20, 2014, Plaintiff filed a motion to dismiss the administrative proceeding before Administrative Law Judge ("ALJ") Dean C. Metry, arguing that three Commissioners and then-Chairman Kaye[4] had already exhibited bias and if Zen were to prevail at the hearing, any appeal would violate its Fifth Amendment rights. 12-2AR123.

8. Judge Metry denied Plaintiff's motion on November 19, 2014, because he did not believe he had the jurisdiction to rule on the motion and also deemed the matter unripe, saying: "[i]n the event there is an appeal, this prejudgment issue is more appropriately raised to the Commission and, if need be, upon further appeal to the federal courts." 12-2AR134.

9. ALJ Metry heard the evidence on the administrative complaint for three weeks in December 2014, issuing his Initial Decision and Order ("IDO") on March 25, 2016. 12-2AR141.

10. Complaint Counsel filed its notice of intent to appeal the IDO pursuant to 16 C.F.R. § 1025.53, and perfected its appeal by filing its Appeal Brief on May 4, 2016, *id*. at § 1025.53(b). 12-2AR142, 143.

11. Three commissioners made pre-decisional public statements about the Subject Products.

[4] Then-Commissioner Mohorovic did not take part in the consideration of the FDO.

12. Commissioner Adler stated:

> First, it's impossible [to put] warnings on the magnets themselves. So many adults have never fully appreciated the extremely hazardous nature of high-powered magnets and as we heard sometimes adults never read or have access to the warnings on the boxes. * * *

12-2AR144 (memo) at 14-15.

> [T]he conclusion that I reach is that if these magnet sets remain on the market irrespective of how strong the warnings on the boxes in which they're sold or how narrowly they are marketed to adults, children will continue to be at risk of debilitating harm or death from this product.

Id.

13. Then-Chairman Kaye stated: "Mr. [Qu] this is what I would like to leave you with. I hope your dreaming will continue and that inspiration will strike again and that there is a path forward that secures for you that elusive childhood wonder but in a way that can endure." *Id*. at 14.

> We all have fears in life. Every single one of us. For me, the biggest without any question, is something tragic happening to one of my boys. Every night, EVERY NIGHT, long after we have put them to bed, I sneak back into their rooms to kiss them one more time. As I do that, I feel tremendous gratitude they are alive and well, and that I am so blessed to have the privilege of hearing in the dark of their rooms the soothing and rhythmic sound of their breathing. I hug them tight, trying not to wake them, all the while knowing that, as long as I might hang on that particular evening, that moment is rather fleeting. And I also know each night that there is certainly no guarantee I will have even one more night to hold onto them tight.
>
> As a parent and as the Chairman of the CPSC, I hurt so much for [AC's] family. I was so deeply moved that [AC's] mother, brothers, grandmother, aunt, and cousin took the time to drive from Ohio to attend the Commission's vote. I will always think of [AC] when it comes to this rule and the action the Commission has approved, and I am so deeply sorry for [AC's] family's loss.

Id. at 20-21. Then-Chairman Kaye also applauded a recent decision against Zen by a District Court:

> Today's decision puts the rule of law and the safety of children above the profits sought by Zen Magnets," said Chairman Elliot F. Kaye for CPSC. "Far too many children have been rushed into hospital emergency rooms to have multiple, highpowered magnets surgically removed from their stomachs. Young children have suffered infections and one child tragically died from swallowing loose magnets that often look like candy. The ruling is a major victory for the safety of consumers.

Id. at 21.

14. Commissioner Robinson stated:

> I would quickly learn that the problem was however that *however they were marketed* that these were items that were being swallowed by young children and ingested by teenagers and were causing some very, very serious injuries and even deaths.

Id. at 12. So I was really struck with how this hidden hazard was something that as I say however marketed that this was something that needed to be addressed." *Id*.

> High-powered magnets are responsible for horrific, long-term, and life threatening injuries in infants and children estimated to be in the thousands[.] * * * The CPSC exists to address just such dangerous products." * * * "I congratulate the parties on reaching this resolution. I hope, as a result, families who own Buckyballs will return the dangerous product as per the directions in the settlement and all companies and individuals will stop sale of Buckyballs in this country. I also hope that the publicity of this settlement and the accompanying Buckyballs recall and stop sale will lead to a significant decrease in injuries to high-powered magnets." (*Id*.) * * * [I]f anything I think that with the data that we had even though it made a compelling case for this being an unreasonable risk of injury it was understated so the risk was even higher.

Id. at 24.

15. Chairman Buerkle, on the other hand, stated:

> I reluctantly conclude that my colleagues should be disqualified from hearing this appeal. Based on the findings that they have made in the rulemaking, I believe they have already made up their minds that small, rare earth magnets should not be in the hands of the public under any circumstances. I also believe that all of [my colleagues] have made public statements that could cause a "disinterested observer" to conclude that they have "in some measure adjudged the facts as well the law of a particular case in advance of hearing it." *Cinderella II*, 425 F.2d at 591. I am not convinced that this test should apply only to statements made outside of official

> agency functions, or even that statements made in a speech to a trade association should be deemed "unrelated to official agency functions." Majority Opinion at 6. Nevertheless, even if the proper test for disqualification is that the mind of a decision maker is "irrevocably closed," I regret to say that the statements made by my colleagues suggest nothing less.

12-2AR155 (dissent).

> The enforcement case against Zen Magnets is an administrative adjudication subject to special trial-type procedures such as witness testimony and cross examination, which don't apply in ordinary rulemaking. The Administrative Procedure Act (APA) also establishes "separation of functions" safeguards for adjudications. The Commissioners, as possible future decisionmakers, are not allowed to receive or make contacts with either of the parties individually, including our own CPSC staff attorneys who are prosecuting the case. 5 U.S.C. § 557(d). These safeguards help prevent bias and promote fairness.
>
> While such an adjudication is pending, Commissioners are routinely cautioned to avoid making statements, or even asking questions, that may suggest a prejudgment of the matter. To issue a final rule outlawing the very same product that is the subject of the adjudication would seem to be the ultimate prejudgment.
>
> The situation here is particularly unusual in that the only magnet sets that are practically affected by the new standard are those already involved in the adjudication. There is a close identity between the products affected by the rule and those potentially affected by the adjudication. In the usual case, a standard would sweep more broadly, but the agency's prior enforcement efforts have left Zen Magnets as the only firm still selling magnet sets in the United States.
>
> Some have suggested that finalizing the magnet standard poses no prejudgment problem because the standard will apply only prospectively, *i.e.*, after the effective date, while a decision in the enforcement case—if favorable to the CPSC staff--would operate retroactively (*i.e.*, resulting in a recall of magnet sets already in the market). This view is oversimplified, because if the enforcement case is decided against the respondent, it will also have prospective effect, prohibiting any further distribution of the only magnets sets currently being sold. *See* 15 U.S.C. § 2064(c)(1); Preamble at 4 (in the administrative enforcement case, CPSC staff sought "an order that the firm cease distribution and importation of the products.").
>
> Some have suggested that issuing a final rule would not be prejudicial in this instance because the criteria for promulgating a mandatory standard are different from the criteria necessary to justify a recall. In this case, the differences are more apparent than real. To obtain an involuntary recall, the staff must prove that the magnet sets constitute a "substantial product hazard." 15 U.S.C. § 2064(d). That

> term is defined in the CPSA to mean a product that creates "a substantial risk of injury to the public," either because of a failure to comply with an applicable standard or because of a defect. 15 U.S.C. § 2064(a). To promulgate a mandatory standard, the Commission must make a number of specific findings, of which one is that the rule "is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product." 15 U.S.C. § 2058(f)(3). While it may be possible to imagine an "unreasonable risk of injury" that is not also a "substantial risk of injury," there is at the least a very substantial degree of overlap between the two.

Doc. 1, Ex. 10 (cited in 12-2AR144 (memo)) (footnotes omitted).

16. After Complaint Counsel perfected its appeal, Plaintiff filed a motion to stay the appeal pending the disposition of its contemporaneously filed Motion to Disqualify the Commission or Some of its Members. 12-2AR144, 145. The Commission issued an order denying Plaintiff's Motion for Stay, 12-2AR152, and motion to disqualify, 12-2AR155, with Chairman Buerkle filing a separate dissent in which she concluded that, because of the statements made by her colleagues and the regulatory actions they had taken, they "should be disqualified from hearing this appeal." 12-2AR155 (dissent).

17. On June 7, 2017, the Commission heard oral arguments regarding Complaint Counsel's appeal, and the Agency issued its Final Decision and Order on ("FDO") October 26, 2017. Acting Chairman Buerkle filed a separate opinion concurring in part and dissenting in part.

18. The FDO set aside the IDO and its findings in full. 12-2AR163 (FDO) at 54 ¶ 1.

19. The FDO compels Zen to "cease from manufacturing for sale, offering for sale, distributing in commerce, or importing into the customs territory of the United States, the Subject Products." *Id.* at ¶ 2.

II. STANDARD OF REVIEW

Zen Magnets asserts the CPSC violated its right to due process. "The question of whether a constitutional violation has occurred is reviewed de novo." *U.S. v. Dowlin*, 408 F.3d 647, 659 (10th Cir. 2005) (citing *U.S. v. Ramone*, 218 F.3d 1229, 1234 (10th Cir. 2000)).

Zen also argues that the CPSC's actions, findings, and conclusions were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, 5 U.S.C. § 706(2)(A); contrary to Plaintiff's constitutional rights, *id*. at § 706(2)(B); in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, *id*. at § 706(2)(C); and unsupported by substantial evidence, *id*. at § 706(2)(E). The Court shall hold unlawful and set aside agency action, findings, and conclusions found to be unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court. 5 U.S.C. § 706(2)(F); *see also id*. at § 706(2)(A)-(E).

Summary judgment is appropriate when there are no genuine issues of material fact. Rule 56, F.R.C.P. The Tenth Circuit generally prohibits summary judgment motions to dispose of administrative appeals, *Olenhouse v. Commodity Credit Corp*., 42 F.3d 1560, 1579 (10th Cir. 1994). Here, the factual record is undisputed, *Biodiversity Legal Found. v. Babbitt*, 146 F.3d 1249, 1252 (10th Cir. 1998), and Zen's due process claim is a question of law that is reviewed de novo. As such, a summary judgment motion is appropriate. *See Bacchus Ind., Inc. v. Arvin Ind., Inc*., 939 F.2d 887, 891 (10th Cir. 1991); *cf. Daughetry v. Thompson*, 322 F.3d 1249, 1254, 1256 (10th Cir. 2003) (summary judgment appropriate when standard of review is de novo). Where cross-motions for summary judgment are filed, the court views each motion separately, and the denial of one does not require the granting of the other. *U.S. Airways, Inc., v. O'Donnell*, 627 F.3d 1318,

1324 (10th Cir. 2010). Zen is entitled to judgment as a matter of law, as requested in the Complaint.

III. ARGUMENT

A. Commission Findings and Commissioner Statements Showed Bias and Prejudgment.

A "fair trial in a fair tribunal is a basic requirement of due process." *In re Murchison*, 349 U.S. 133, 136 (1955). "This applies to administrative agencies which adjudicate as well as to courts." *Withrow v. Larkin*, 421 U.S. 35, 46-47 (1975) (citing *Gibson* v. *Berryhill*, 411 U.S. 564, 579 (1973)). An administrative hearing "must be attended, not only with every element of fairness but with the very appearance of complete fairness." *Cinderella II*, 425 F.2d at 591 (quoting *Texaco, Inc. v. FTC*, 336 F.2d 754, 760 (D.C. Cir. 1964), *vacated and remanded on other grounds*) (quotation marks omitted). *See also Amos Treat & Co. v. SEC*, 306 F.2d 260, 267 (D.C. Cir. 1962) ("[A]n administrative hearing of such importance and vast potential consequences must be attended . . . with the very appearance of complete fairness. Only thus can the tribunal conducting a quasi-adjudicatory proceeding meet the basic requirement of due process.").

While the Commission is free to alert the public to suspected violations of law, it may neither prejudge cases, *nor even give the appearance* that the case has been prejudged and that "the ultimate determination of the merits will move in predestined grooves." *Cinderella II*, 425 F.2d at 591 (emphasis added); *accord Kennecott Copper Corp. v. FTC*, 467 F.2d 67, 80 (10th Cir. 1972). Though various tests have been applied by other circuits to determine whether a showing of bias and prejudgment has been made,[5] under any standard, and to any independent observer,

[5] *See e.g. Cinderella II*, 435 F.2d at 491; *FTC v. Cement Inst.*, 333 U.S. 683, 701 (1948); *NEC Corp. v. U.S.*, 151 F.3d 1361, 1373 (Fed. Cir. 1998) (a petitioner can prevail on a claim of prejudgment if the decisionmaker's mind is "irrevocably closed" on a disputed issue).

the FDO majority's conduct and statements show their irrevocably closed minds, bias and prejudgment.

The core issue in both the administrative proceeding and the rule making was whether the Subject Products should remain on the market. In September 2014, the majority of commissioners answered in the negative,[6] finding that irrespective of how they were sold, the Subject Products would endanger the lives of children if made available for sale. 12-2AR144 (memo) at 14-15; Statement of Undisputed Facts ("SOF") ##12-15. That the magnets sold by Zen are the same as those covered by the rule is not in question. *See e.g.* 79 Fed. Reg. at 59962-59963; SOF #3. Both proceedings also sought prospective relief, barring Zen from selling the Subject Products in the future. *See* SOF #19; fn. 6, *supra*.

In their order denying Zen's motion to disqualify, the majority attempted to distinguish the magnets subject to the rulemaking from Zen's own products. 12-2AR155 at 12. The order also said that statements made by Commissioner Adler regarding SREMs "did not refer to the Subject Products." 12-2AR155 at 19. These arguments are unavailing as they are patently absurd and intellectually dishonest. The CPSC knew the Subject Products were subject to the Rule, 79 Fed. Reg. at 59968, and every commissioner understood that fact, *see* 12-2AR155 at 16. The CPSC

[6] While the Tenth Circuit did not reach the issue of whether the rule "banned" the Subject Products, the Commission has acknowledged that the Rule barred Zen from selling its products. *See* P.I. Hearing Tr. 01/04/2018, 64:11-12; *see also* CPSC-2012-0050; Public Hearing on Safety Standard for Magnet Sets (Oct. 22, 2013), CPSC-2012-0050-2597; *id.* at 28:9-10) ("This proposed rule would effectively ban very small, highly powerful rare earth magnets"); *id*. at 44:18-19) ("it really is a ban except its [sic] being cast in terms of a rule"); *id*. at 13:5-6 ("The safety standard proposal would prohibit current magnet sets"); CPSC-2012-0050-0494 ("a ban under section 8 may have the same immediate effect as a standard promulgated under section 7 and 9").

also believed that all SREMs are indistinguishable, fungible[7] objects, where the dangers of one brand of SREMs are necessarily shared by all others. *See* 12-2AR163 (FDO) at 21 n.18; *id*. at 34, 41, 23; SOF #2; 12-1AR7 at 2. The majority's beliefs are further reinforced by their prior positions that marketing, branding, and warnings could not possibly curb the ingestion hazard. 12-2AR163 (FDO) at 30-34. Why would the FDO's majority decide to not use data from the rulemaking in the administrative proceeding if the two proceedings were actually unrelated?

Moreover, at the time that the Commission promulgated the Rule, Zen was the only firm whose products were actually subject to the rule. *See* SOF #3; *Zen Magnets, LLC v. CPSC*, 841 F.3d 1141, 1146 (10th Cir. 2016) ("Zen is the only remaining importer and distributor of the magnet sets targeted by the final rule."). Therefore, when the CPSC decided to promulgate the rule, it necessarily made factual and legal findings regarding the Subject products. *See* 15 U.S.C. § 2058(f)(1), (3); SOF ##4-5. That same conclusion was reached by Chairman Buerkle, who stated that "outlawing the very same product that is the subject of the adjudication would seem to be the ultimate prejudgment." 12-2AR144 (memo) at 5; SOF #15. Zen agrees with Chairman Buerkle's assessment, and maintains that if nothing else, the CSPC's promulgation of the rule at least gave the reasonable appearance that the commissioners had prejudged the ultimate questions of law and fact at issue in the appeal.

Both the administrative adjudication and rulemaking addressed the use and utility of the Subject Products. *See* 79 Fed. Reg. at 59987-59988; 12-2AR141 at 20-22; 12-2AR163 (FDO) at 36-38. While the ALJ found that the magnets' "usefulness outweighs the risk of injury associated

[7] While the Department of Justice made an argument to the contrary before Judge Arguello, the CPSC has since conceded that "Once these magnets are separated from their container, they're fungible." P.I. Hearing Tr. 01/04/2018, 70:24-25; SOF #2.

with the product," 12-2AR141 at 28, the CPSC had already necessarily rejected such a finding by promulgating a rule it deemed necessary to address an unreasonable risk of injury, even considering the magnets' benefits vis-à-vis their costs. *See* SOF ##4-5.

The rulemaking and administrative adjudication also considered the degree and nature of the risk of injury posed by the Subject Products. Identical incident reports, National Electronic Injury Surveillance System ("NEISS") data, and estimates based on that NEISS data were used to establish both the need for the rule and the existence of a substantial product hazard. *See* 12-2AR26 (Ex. B) at ¶¶ 56-59, 61, 63, 113; Testimony of Kathleen Stralka, Dec. 8, 2014 to Dec. 9, 2014; 79 Fed. Reg. at 59987-59988, 59962, 59964-59965. *See also* 12-2AR141 at 17-19 (discussing the nature of the risk of injury); CC-18, CC-18.1 to 18.95 (incident reports and CPSC investigations); CC-40 (NEISS records from 2009 through 2013); R-111 (NEISS data from 2009 through 2013); R-117, R-117A (summary charts of ingestion incidents).

In the administrative adjudication, the ALJ assessed the data and determined that "the nature of the risk of injury which the product presents is negligible when accompanied by proper warnings and appropriate age restrictions." 12-2AR141 at 19. That finding was expressly prejudged by Commissioner Adler. *See* 12-2AR144 (memo) at 14-15; SOF #12. The ALJ also found that "[t]he number of SREM ingestions is relatively insignificant when compared to the number of SREMs in the market." 12-2AR141 at 5, ¶ 16. Again, in the rulemaking, the Commission concluded differently, finding that there were, conservatively, 2,900 ingestion incidents involving the Subject Products between January 1, 2009 and December 31, 2014 (using

the same NEISS data admitted in CC-40), which the Commission deemed to present an unreasonable risk of injury to the public. 79 Fed. Reg. at 59962, 59967, 59987-59988.[8]

Another critical question of fact and law in the administrative adjudication was whether the design, marketing, and warnings could make the Subject Products safe for sale to the public. But, the Commission had already decided that no warning or marketing scheme could address the risks posed by the Subject Products. *See e.g.* SOF ##12-14. The Commission, again, therefore prejudged this question of law and fact that came before it on appeal.

The ALJ also found that the evidence adduced at the hearing suggested that Zen's warnings were effective: "It is more than a reasonable inference that little evidence exists of injury resulting from use of Respondent's product because Respondent's warnings sufficiently deter ingestion." 12-2AR141 at 16. Once again, the Commission addressed these issues in the rulemaking and concluded that no warning could possibly be effective in reducing the risk posed by the magnets. 79 Fed. Reg. at 59970-59971, 59975-59976; SOF ##12, 14. Having done so, three members of the Commission plainly and objectively prejudged this issue.

The Commission's regulatory findings and factual analyses in the rulemaking make clear its conclusion that the Subject Products should not be available to consumers. *See* SOF ##12-13. Zen agrees with Chairman Buerkle's assessment that the Commission's actions and statements constitute "the ultimate prejudgment," and that their minds were irrevocably closed. SOF #15.

[8] In the hearing before the ALJ, Complaint Counsel heavily relied on the NEISS data to show the danger posed by Zen's products. At oral argument on appeal, Complaint Counsel disavowed the use of NEISS data for injury estimates. Even though Zen had been repeatedly told by the CPSC that the administrative adjudication was unrelated to the rulemaking, the FDO expressly ignored this part of the administrative record for injury estimates, but opted to use it to show the population exposed to the risk of injury – ignoring the record when it did not suit the Commission's predetermined narrative, and looking to the record when it did. 12-2AR163 (FDO) at 29 n.28.

The Commission was free to initiate a rulemaking and administrative action simultaneously.[9] However, the Commission's actions in the rulemaking combined with the public comments by the majority, as well as the systematic, systemic, and legally inconsistent attacks on Zen in various fora all lead to the conclusion that the ultimate determination of the merits was only going to move in predestined grooves. *Cinderella II*, 425 F.2d at 591; *Bakalis v. Golembeski*, 35 F.3d 318, 326 (7th Cir. 1994) (running controversy between the plaintiff and the board showed that board had prejudged issue).

The FDO majority's pre-decisional public statements evincing their bias against Zen are found in SOF ##12-14. Zen does not assert that the commissioners need to be without independent thought or void of opinions. But the commissioners are required to be neutral and avoid behavior that would indicate their minds were irrevocably closed or that they were otherwise incapable of judging this particular controversy fairly on the basis of its own circumstances. *See Hortonville Joint School Dist. No. 1 v. Hortonville Educ. Assn.*, 426 U.S. 482, 493 (1976). As members of the CPSC, the commissioners will come into contact with information regarding the products they regulate, and will naturally form opinions about such products. In this case, however, the statements show that three commissioners had concluded that the magnets were dangerous and cannot remain on the market long before the issue was presented to them on appeal. *See* SOF ##12-14. Such statements are not permissible.

[9] Zen is unaware of any congressional mandate requiring the Commission to undertake regulatory and adjudicatory action at the same time. *See e.g. Pangburn v. Civil Aeronautics Bd.*, 311 F.2d 349, 355-356 (1st Cir. 1962) (Congressional mandate to investigate accidents and decide appeals from revocation or suspension orders).

Commissioner Adler's statement (SOF #12), for example, has more than just the appearance of prejudgment; it is precisely prejudgment. And Commissioner Robinson's belief that the magnets pose more than an "unreasonable risk" of injury, and are also a "dangerous product," states her conclusion that the magnets are in fact dangerous.[10] But the ALJ found exactly the opposite.[11] Commissioner Robinson even incorrectly opined that ingestion of the Subject Products had resulted in multiple deaths, something directly refuted by the record. *See* 12-2AR163 (FDO) at 23. It was therefore unsurprising that the FDO found that the risk posed by Plaintiff's products could not be mitigated by appropriate age warnings or recommendations. *Id*. at 46.

The majority of the Commissioners were biased and/or prejudged issues of law and fact as a matter of law. In *NEC Corp. v. United States*, the Federal Circuit adopted a demanding test for a finding of bias and prejudgment when an agency is tasked by Congress with the duty to both investigate and then judge. 151 F.3d 1361, 1371 (Fed. Cir. 1998). *See also Withrow v. Larkin*, 421 U.S. 35, 46-47 (1975). In *NEC*, the agency was absolved of wrongdoing when the offending decisionmaker was replaced before the agency ruled:

> Our conclusion that NEC has failed to establish an invalidating prejudgment on the part of the government officials involved is not a statement that the conduct of these officials is to be emulated. But for the fortuitous intervention at the final stages of the process of a different decision maker the outcome could well have been different. Thus NEC is not without grounds for feeling aggrieved.

[10] Zen has not questioned the fact that ingesting the Subject Products can result in injury. However, the question of whether the Subject Products were dangerous due to a defect was at issue in the administrative adjudication.

[11] "The record supports a finding that these products are not intended for ingestion and *the nature of the risk of injury from an un-ingested SREM is nil*." 12-2AR141 at 17-18. "[T]he nature of the risk of injury which the product presents is negligible when accompanied by proper warnings and appropriate age restrictions." *Id*. at 19.

NEC, 151 F.3d at 1376. Zen does not argue that the Commission could not sit in judgment of the appeal because it was the Commission who investigated the administrative case against Zen. Rather, the facts common to both the administrative proceeding and the promulgation of the Rule, together with the published statements prove the commissioners' irrevocably closed minds and bias. It is uncontested here that the same commissioners who promulgated the Rule also made statements about the Subject Products prior to engaging in the appellate process as judges.

In *FTC v. Cement Inst.*, 333 U.S. 683 (1948), the Supreme Court reasoned that because commissioners had expressed opinion that the respondent was in violation of the law, it did not necessarily mean that that their minds were irrevocably closed. *Id*. at 701. But here, the CSPC's members did not opine that Zen was in violation of the law. Rather, the commissioners opined on an ultimate issue of fact AND law that ultimately came before them: that Zen should not be allowed to sell the Subject Products, regardless of how they are sold to consumers. *See* SOF ##12-15. That is nothing other than prejudgment and evidence of irrevocably closed minds.

Staton v. Mayes, 552 F.2d 908 (10th Cir. 1977) is a case more aligned with the case at bar. In *Staton*, bias was shown when three of five school board members made statements prior to the hearing regarding whether the superintendent should be fired. *Id*. at 914. The Tenth Circuit found that "statements on the merits by those who must make factual determinations on contested fact issues of alleged incompetence and willful neglect of duty, where the fact finding is critical . . . left no room for a determination that there was a decision by a fair tribunal, with the appearance of fairness." *Id.* at 914-15. That is precisely what happened in Zen's case.

The questions before the ALJ were whether the Subject Products were dangerous, whether the warnings were adequate, whether the products were defective, and ultimately whether Zen

could continue to sell its products. 12-2AR163 (FDO) at 4-5. Long before the Commission acted as a decisionmaking body to rule on the ALJ's decision, a majority of its members had already concluded that no warnings could possibly be adequate; that the magnets were dangerous no matter how they were sold; and that the product had to be removed from the market. 12-2AR144 (memo) at 14-15; SOF ##12-14. These were not policy statements; they were conclusions about the merits of the case that the Commission would later hear on appeal. *See Staton*, 552 F.2d at 914.

But it is not only Zen who believes that the CPSC was biased. Chairman Buerkle also believed that each of her fellow commissioners who participated in the FDO were biased and had irrevocably closed minds, and should therefore not hear the appeal: "[E]ven if the proper test for disqualification is that the mind of a decision maker is 'irrevocably closed,' I regret to say that the statements made by my colleagues suggest nothing less." 12-2AR155 (dissent). Zen agrees. Issuing a rule that functionally banned the Subject Products and commenting that the adjudicated products were hazardous to children and must be taken off the market does not leave any room for minds to be changed. The majority of commissioners therefore gave a reasonable appearance of having prejudged the case. *Kennecott Copper*, 467 F.2d at 80 (noting that showing a "slight commitment" could be considered to be stepping over the line). Here, the risk of unfairness was also "intolerably high" under the circumstances. *Mangels v. Pena*, 789 F.2d 836, 838 (10th Cir. 1986) (quoting *Withrow*, 421 U.S. at 58)); *see also Bakalis*, 35 F.3d at 326 (running controversy between the plaintiff and the board showed that board had prejudged issue).

Even if the Court finds that only one member of the Commission who voted to overturn the ALJ's findings was biased, the entire process was tainted. As the D.C. Circuit explained: "Litigants are entitled to an impartial tribunal whether it consists of one man or twenty and there

is no way which we know of whereby the influence of one upon the others can be quantitatively measured." *Cinderella II*, 425 F.2d at 592 (citing *Berkshire Employees Assn. of Berkshire Knitting Mills v. NLRB*, 121 F.2d 235, 239 (3rd Cir. 1941) and *American Cyanamid Co. v. FTC*, 363 F.2d 757 (1966)).

Because the majority of the commissioners had engaged in prejudgment and evinced biased, irrevocably closed minds, Zen was not able to receive a fair hearing before the CPSC sitting as an appellate body, in violation of the Fifth Amendment to the U.S. Constitution.

B. The Commission's Final Decision and Order was Arbitrary, Capricious, an Abuse of Discretion, or Otherwise not in Accordance with the Law.

Pursuant to 5 U.S.C. § 706(2)(A), a reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." While the Court is not to substitute its judgment for that of the agency, the "agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Assn. of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983) (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U. S. 156, 168 (1962)); *see also Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1574 (10th Cir. 1994).

1. The CPSC's Reading of its Defect Regulation was Arbitrary and Capricious.

Complaint Counsel's case was premised not on the misuse of the Subject Products, but on the theory that the products had a design defect "because when the products are used as intended, they create a risk of injury." Tr. 12/9/14, 1225:14-18. But Zen's evidence showed that only the misuse of the Subject Products can even possibly result in injury. 12-2AR141 at 10. Presumably, that is why the CPSC chose to find in its FDO that a product can be defective "solely" and

"entirely" because it is foreseeable that it could be misused. 12-2AR163 (FDO) at 11. To support its position that a defect is *something* that is caused *solely* and *entirely* as a result of misuse, FDO at 11, the CPSC cites to 16 C.F.R. § 1115.4(d), which provides an example of a defective drill "***because*** of the inadequate warnings and instructions." (Emphasis added.) In that example, the drill was misused *because* it contained a defective warning; it was not defective *because* it was misused. *Id*. No deference is owed to the CPSC's reading of the regulation because it is plainly erroneous and inconsistent with the regulation. *See Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945); *Udall v. Tallman*, 380 U.S. 1, 16-17 (1965); *see also Bowen v. Georgetown Univ. Hospital*, 488 U.S. 204, 213 (1988) ("Deference to what appears to be nothing more than an agency's convenient litigating position would be entirely inappropriate.").

The CPSC also alleges that "Congress implicitly approved of the Commission's definition of defect by incorporating such language in the 2008 Consumer Product Safety Improvement Act," 12-2AR163 (FDO) at 13 n. 11. Contrary to the Commission's strained inference, there is no evidence that Congress has ever adopted the Commission's "definition" of defect. In fact, the opposite appears to be the case. The Commission states in the FDO that a *draft* version of the CPSA defined the term "use" to include "reasonably foreseeable misuse." *Id*. at 13 [emphasis added]. But, as Chairman Buerkle noted, "the fact that Congress considered and rejected such a definition tends to cut against the majority's position here, rather than support it." 12-2AR163 (dissent) at 3. *See also District of Columbia v. Heller*, 554 U.S. 570, 590 (2008) ("It is always perilous to derive the meaning of an adopted provision from another provision deleted in the drafting process.").

Zen acknowledges that the last paragraph of 15 C.F.R. § 1115.4 lists the foreseeability of consumer misuse to be one of the factors to consider in determining whether the product contains a defect. 12-2AR163 (FDO) at 11. However, even as the majority concedes, "the factors listed in § 1115.4 do not present a separate basis for a defect finding." 12-2AR163 (FDO) at 8 n.6.

For purposes of this litigation, Zen adopts Chairman Buerkle's analysis of the CPSC's defect regulation, found at 12-2AR163 (dissent) at 2-5. The CPCS's defect regulation does not define "use" to include the misuse of products. Holding otherwise would render all products capable of being misused to be deemed "defective" for purposes of the CPSA. Such a holding would also render 16 C.F.R. § 1115.4 superfluous. The majority's reading of 16 C.F.R. § 1115.4 is facially flawed, and resulted in the Commission contorting and contradicting itself in order to arrive at the predetermined conclusion that it desired.

2. The CPSC's Design Defect Finding was Arbitrary and Capricious and was not Supported by Substantial Evidence.

The FDO implicitly and necessarily found that the Subject Products contained an inherent design defect because the magnets are separable. 12-2AR163 (FDO) at 39. However, Complaint Counsel did not meet their burden of establishing that any design defect exists. *See* 16 C.F.R. § 1025.43(b)(1). That the Subject Products are separable is not in question; that is part of their operation. But Complaint Counsel submitted no evidence whatsoever that the magnets were defective *because* they could be separated. For that reason, the ALJ wrote: "The Agency submitted absolutely no evidence that separation, alone, creates any threat to any individual and that any consumer has ever been harmed by an un-ingested, liberated SREM." 12-2AR141 at 7.

The FDO cites to testimony from Dr. Paul Frantz as evidence of a *design* defect. *See* 12-2AR163 (FDO) at 16. Dr. Frantz was retained as a human factors expert by Complaint Counsel

to "comment on the implications of [the] warnings." *Id.* at n.14. But that testimony was *not* admitted to show that there existed a design defect, but whether the products' warnings were effective. Zen's counsel objected to Dr. Frantz opining on the design of the products, as that was not within Dr. Frantz's expertise and not for what Dr. Frantz was endorsed pursuant to Rule 702, F.R.E. The ALJ admitted his testimony for a limited purpose: "Yeah, I think in the context of how that relates to his warning, it is within his expertise and is helpful to me. With that understanding of his testimony, I will overrule the objection, and I will take the answer." Tr. 12/2/14, 344:21-345:4.

Apart from Dr. Frantz's testimony, which was only admitted for a limited purpose (unrelated to design defect), the record contains no evidence that the Subject Products are defective in their design, and the FDO cites to no other evidence in the record. Therefore, the FDO's finding that the Subject Products are defective in their design is arbitrary and capricious, and is unsupported by *substantial* evidence. *See* 5 U.S.C. § 706(2)(A), (E); *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938); *Honeyville Grain, Inc. v. NLRB*, 444 F.3d 1269, 1277 (10th Cir. 2006).

3. The CPSC's Finding of Defective Warnings was Arbitrary and Capricious.

The FDO faults Judge Metry for "draw[ing] comparisons between Buckyballs' lack of warnings and attributable incidents, and [Zen's] affirmative warnings concerning the ingestion hazard and relative absence of incidents." 12-2AR163 (FDO) at 34. The FDO also charges that Zen submitted no evidence to support the ALJ's conclusion that the warnings were effective, and did not present "actual evidence concerning what conclusions, if any, could be drawn from the [incident, or NEISS] data." *Id.* Such statements, however, ignore the NEISS data and ingestion

incident reports submitted by the CPSC's own Complaint Counsel, which showed that Zen's products might have been involved in two ingestion incidents, which is about 0.0069% of the alleged ingestions that took place. That fact is certainly probative of whether Zen's warnings were effective. *See* 12-2AR153 at 18-22. And, even though the CPSC said it was not going to use the NEISS data for injury estimates in the FDO, 12-2AR163 (FDO) at 29 n.28, it nonetheless maintained that "hundreds of incidents were introduced as evidence" in refuting Zen's argument that its warnings were ineffective, *id*. at 34. Not only is this an arbitrary treatment of the record, it is further evidence of the CPSC's bias against Zen.

4. The CPSC Applied a Definition of Defect that is Contrary to its Own Regulations.

Rather than expressly define "defect" in its regulations, the CPSC chose to promulgate a regulation describing what, at minimum, a defect must include, *i.e.*, a fault, flaw, or irregularity that causes, weakness, failure, or inadequacy in form or function, providing examples to guide the public, and listing a number of factors for manufacturers to consider when their product presents a potential risk of injury but requires that potential to function adequately. 16 C.F.R. § 1115.4. Complaint Counsel, however, "submitted absolutely no evidence" related to how Plaintiff's products were defective pursuant to the commonly understood, dictionary definition of that word, as the Commission's regulations require. *See* 12-2AR141 at 7-8.

Zen is not challenging the CPSC's adopted definition of defect in 16 C.F.R. § 1115.4. Rather, Zen is challenging the CPSC's application of its regulation to the case at bar. Here, the CPSC did not follow its rules,[12] but applied a new, post hoc definition of "defect" that runs counter

[12] *See Reuters Ltd. v. F.C.C.*, 781 F.2d 946, 950 (D.C. Cir. 1986) ("*Ad hoc* departures from those rules, even to achieve laudable aims, cannot be sanctioned").

to its existing regulations.[13] The crux of Zen's argument is not that the Commission has "defined" a defect improperly in its regulations, but that in the FDO the CPSC failed to apply to Zen's products the definition of defect that it has already promulgated. The CPSC may promulgate a new regulation explaining what the definition of "defect" is, but it was not free to do so in the administrative adjudication against Zen. *See* 5 U.S.C. § 553.

CPSC regulations plainly require that, "[a]t a minimum, defect includes the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function." 16 C.F.R. § 1115.4. The regulation then provides examples of how products might be defective, explaining the process for making such determinations. The CPSC "acknowledged" this in the FDO, but then failed to heed its own rules.

To support its position that a defect is *something* that is caused *solely* and *entirely* as a result of misuse, FDO at 11, the CPSC cites to § 1115.4(d), which, again, does not contemplate a finding of defect based entirely on a consumer's ability to misuse the product. The FDO ultimately found that "the Commission has the authority to find that a product is defective based solely on reasonably foreseeable misuse of a consumer product." 12-2AR163 (FDO) at 11. This conclusion has no foundation in the Commission's regulations, and in adopting and applying this standard, the majority wholly failed to consider the plain, dictionary definition of "defect," as required by its regulations.

CONCLUSION

Complaint Counsel did not meet its evidentiary burden of proving Zen's products present a substantial product hazard in the administrative adjudication held by Judge Metry. However,

[13] The CPSC's error is explained in greater detail in Doc. 2 and Doc. 2, Ex. 3 at 2-5.

because of the majority's predetermined conclusion that Zen's products pose a substantial product hazard, the FDO made legal and factual findings unsupported by the record and contrary to the Commission's own regulations, as recognized by the FDO dissent. It was this prejudgment and bias that also rendered the CPSC appellate process unfair and violated Zen's Fifth Amendment rights as a matter of law.

WHEREFORE, for the foregoing reasons, Zen respectfully requests that the Court enter judgment in favor of Zen Magnets and vacate the CPSC Final Decision and Order, leaving intact Judge Metry's Findings and Order as if affirmed by the CPSC, and for all other relief allowed by law, including recovery of Zen's fees and costs consistent with 16 C.F.R § 1025.7 and the Equal Access to Justice Act (EAJA), 5 U.S.C. § 504.

RESPECTFULLY SUBMITTED,

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CERTIFICATE OF SERVICE

I hereby certify that I have served a copy of this Reply on counsel for the Government, Mr. Roger Gural, Trial Attorney, United States Department of Justice, Consumer Protection Branch via ECF to Roger.Gural@usdoj.gov on this 27th day of February 2018

S/ David C. Japha

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