

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

BERKEY INTERNATIONAL, LLC,

Plaintiff,

v.

ENVIRONMENTAL PROTECTION AGENCY,
et al.,

Defendants.

CIVIL NO. 24-1106 (CVR)

OPINION AND ORDER¹

INTRODUCTION

Plaintiff Berkey International, LLC (“Plaintiff” or “Berkey”) is a Puerto Rico based manufacturer of water filtration systems. Defendants are the Environmental Protection Agency (“EPA”), its Administrator Michael S. Regan, and Christine Tokarz (“Tokarz”) and David Cobb (“Cobb”), EPA personnel (collectively, “Defendants”). The present case arises from challenges to a Stop Sale, Use, or Removal Order (“SSURO”) issued by Defendants to Plaintiff’s water filter manufacturing business. Plaintiff challenges the agency’s actions, alleging the EPA failed to comply with notice and comment rules and acted in an arbitrary and capricious manner, in violation of the Administrative Procedure Act. Plaintiff seeks a finding that the EPA exceeded its authority in this matter, vacatur of the SSURO, and damages therefrom.

PROCEDURAL BACKGROUND

Plaintiff filed the present Complaint, together with an application for a temporary

¹ This Opinion and Order is limited to the evidentiary rulings related to Plaintiff’s Motion for Preliminary Injunction. As such, it serves as the basis for the Opinion and Order to be issued separately denying Plaintiff’s preliminary injunction request.

Berkey International, LLC v. Environmental Protection Agency, et al.
Opinion and Order
Civil 24-1106 (CVR)
Page 2

restraining order, and a preliminary and temporary injunction. (Docket No 1). The Court denied the motion for a temporary restraining order, ordered Plaintiff to serve Defendants, and set a hearing for the preliminary injunction petition. (Docket No. 12). Before the hearing was held, the parties proposed that witness testimony be offered via declarations and evidence already on the record, but the proposal proved unworkable because Defendants opposed certain evidence being offered by Plaintiff. In the end, the parties agreed that the Court would consider the evidence on the record without the need for a hearing and each party would have the opportunity to express their positions in writing. (Docket No. 58).

The EPA submitted the administrative record pertaining to the case. (Docket No. 57). Defendants filed their objections to Plaintiff's exhibits and declarations. (Docket No. 59). Plaintiff responded with a Second Supplemental Declaration and additional exhibits. (Docket Nos. 60, 61 and 62). Defendants replied to Plaintiff's objections and to the additional filings. (Docket No. 64).

OBJECTIONS TO THE EVIDENCE PRESENTED

In support of Plaintiff's petition for injunctive relief and in lieu of live testimony, Plaintiff submitted a Declaration of Mr. Shepherd ("Shepherd I") (Docket No. 1, Exhibit A), a Declaration of Ms. Susan Spaar ("Ms. Spaar"; the "Spaar Declaration") (Docket No. 1-B), a Supplemental Declaration of Mr. Shepherd ("Shepherd II") (Docket No. 55), a Second Supplemental Declaration of Mr. Shepherd ("Shepherd III") (Docket No. 60), and a host of documentary evidence accompanying each declaration. The EPA submitted only the administrative record it used to issue the SSURO and no testimony. (Docket No. 57-3).

Berkey International, LLC v. Environmental Protection Agency, et al.

Opinion and Order

Civil 24-1106 (CVR)

Page 3

To succeed in seeking a preliminary injunction, the movant must establish the following four (4) elements, to wit: 1) the movant is likely to succeed on the merits of the case; 2) the movant will suffer irreparable harm in the absence of an injunction; 3) the balance of equities tips in the movant's favor, and 4) the injunction is in the public interest. Brox v. Woods Hole, Martha's Vineyard & Nantucket S.S. Auth., 83 F.4th 87, 91 (1st Cir. 2023).

Defendants objected to certain testimony and exhibits, and offered both general and specific objections. As to general objections, regarding the likelihood of success on the merits prong of the analysis, Defendants objected to evidence that was not in the administrative record. As to the remaining factors necessary to obtain injunctive relief, Defendants offered objections to evidence of harm suffered by entities other than Plaintiff as irrelevant; certain testimony in the Shepherd declarations that was not based on personal knowledge; and improper attempts to consider certain documents as "business records" under Fed. R. Evid. 902(11) and 803(6). As to specific objections, Defendants objected to evidence related to the efficacy of Berkey products versus competitors' products; evidence regarding lost sales to non-parties, including Berkey competitors; testimony alleging lost market share/loss of goodwill; evidence regarding counterfeit competitors; evidence regarding enforcement actions not taken against others; and the entirety of the Spaar Declaration.

In sum, Defendants objected to the following:

1. As to the issue of the likelihood of success on the merits: all of Plaintiff's exhibits

Berkey International, LLC v. Environmental Protection Agency, et al.

Opinion and Order

Civil 24-1106 (CVR)

Page 4

except numbers 17², 24, and 33, and testimony related to those exhibits.

2. As to the remaining preliminary injunction factors: Exhibits 2, 6, 11-12, 19-23, 27-32, 35, and 41- 42, and testimony related to those exhibits.

3. As to Shepherd I: ¶¶4-5, ¶6, n.1, ¶10, ¶24, ¶¶27-28, ¶30, ¶31 (second sentence), ¶32 (first sentence), ¶33, ¶¶36-42, ¶¶44-46³ (first set), ¶¶43-46 (second set), ¶47, ¶49 (first two sentences), ¶50 (first sentence), ¶51, ¶55 (last two sentences), ¶56 (first three sentences), ¶¶57-59, ¶62, ¶¶64-65, and evidence related to that testimony.

4. As to Shepherd II: ¶¶ 5-6, ¶¶9-12, ¶13 (last sentence), ¶¶15-17, ¶21, ¶23, ¶26, ¶¶30-32, ¶37 (third sentence), ¶39, ¶41 (first two sentences), ¶42 (first sentence), ¶43 (last two sentences), and evidence related to that testimony.

5. As to Shepherd III: ¶¶ 5-6, ¶16.

6. As to the Spaar Declaration: in its entirety.

As an initial matter, regarding the first prong of the preliminary injunction analysis, issue of the likelihood of success on the merits, Defendants proffer that it must be proven based only on the administrative record the EPA used, citing to Camp v. Pitts, 411 U.S. 138, 93 S.Ct 1241 (1973). Under this precedent, Defendants' position is that the Court should only consider the totality of the record the EPA considered in rendering its decision on this first element, and nothing more. Thus, Defendants contend that the Court cannot consider any of Plaintiff's exhibits filed at Docket No. 62 (or testimony relating thereto) except Exhibit 17 (SSURO issued to James Enterprises), Exhibit 24

² This numbering is in line with Plaintiff's Exhibit and Witness List filed with the Court at Docket No. 62.

³ There is paragraph numbering mistake in the Shepherd I declaration. On page 11, it contains paragraph numbers 43-46, and on pages 12 and 13, it renubers several paragraphs again as numbers 43-46. The Court distinguishes them as the "first set" and the "second set."

Berkey International, LLC v. Environmental Protection Agency, et al.

Opinion and Order

Civil 24-1106 (CVR)

Page 5

(SSURO issued to Berkey International), and Exhibit 33 (Notice 2000-1, Pesticide Registration Notice dated March 3, 2000), because these three (3) documents are in the administrative record.

Plaintiff argues in opposition that the cases cited by Defendants suggest the opposite, and contain examples where new evidence can be considered, for instance where, as here, the agency has acted in bad faith. Plaintiff proffers that, in insisting the use of its own record, the EPA can hide its actions by creating an inadequate administrative record, and public policy requires all relevant evidence to be considered. Therefore, Plaintiff asks the Court to do just that.

“[W]hen reviewing an agency’s decision under the arbitrary and capricious standard, ‘the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.’” City of Taunton, Massachusetts v. United States Env’t Prot. Agency, 895 F.3d 120, 126 (1st Cir. 2018) (quoting Camp, 411 U.S. at 142, 93 S.Ct. at 1244). The Court of Appeals for the First Circuit has recognized several exceptions to the rule against record supplementation, for example, where there is a strong showing of bad faith. Housatonic River Initiative v. United States Env’t Prot. Agency, New England Region, 75 F.4th 248, 278-79 (1st Cir. 2023); Town of Winthrop v. FAA, 535 F.3d 1, 14 (1st Cir. 2008). The Court can also supplement the record “to facilitate our comprehension of the record or the agency’s decision,” particularly when “highly technical, environmental matters” are at issue or when the agency has “fail[ed] to explain administrative action as to frustrate effective judicial review.” City of Taunton, 895 F.3d at 127 (cleaned up). Supplementation of an administrative record is the exception, not the rule, so Plaintiff must establish that

Berkey International, LLC v. Environmental Protection Agency, et al.

Opinion and Order

Civil 24-1106 (CVR)

Page 6

supplementation is appropriate and make a strong showing that the EPA acted in bad faith. Town of Norfolk v. U.S. Army Corps of Eng'rs, 968 F.2d 1438, 1458-59 (1st Cir. 1992). The decision of whether to supplement an agency record is discretionary and rests with the reviewing court. Town of Winthrop, 535 F.3d at 14.

As candidly argued by Defendants, Plaintiff has made no formal motion to supplement the administrative record, and failed to demonstrate that any of its additional exhibits should be included therein. Instead, Plaintiff simply argues that the EPA's bad faith justifies the inclusion of extra record material and essentially brings nothing in support thereof. The Court finds that Plaintiff has not made the required "strong showing" of bad faith for the Court to consider additional evidence for this prong of the preliminary injunction analysis. Town of Norfolk, 968 F.2d at 1458; *see, e.g.* Dist. Hosp. Partners, L.P. v. Burwell, 786 F.3d 46, 55 (D.C. Cir. 2015) ("conclusory statements" in brief "fall far short" of high threshold needed to evidence bad faith). For this reason, on the likelihood of success on the merits prong, the Court must limit itself to using the agency's administrative record.

The parties do agree, however, that the Court can consider non-record evidence for the remaining three (3) prongs of the preliminary injunction test. Thus, the Court will consider only the administrative record for purposes of the likelihood of success on the merits prong, and will consider some of the evidence supplied by Plaintiff for the remaining prongs of the preliminary injunction test. Friends of Animals v. United States Bureau of Land Mgmt., 548 F.Supp.3d 39, 56-57 (D.D.C. 2021).

Additionally, the Court will afford the parties some leniency at this juncture regarding the rules of evidence. Asseo v. Pan American Grain Co., Inc., 805 F.2d 23, 26

Berkey International, LLC v. Environmental Protection Agency, et al.

Opinion and Order

Civil 24-1106 (CVR)

Page 7

(1st Cir. 1986) (“Affidavits and other hearsay materials are often received in preliminary injunction proceedings. The dispositive question is not their classification as hearsay but whether, weighing all the attendant factors, including the need for expedition, this type of evidence was appropriate given the character and objectives of the injunctive proceeding.”); Westernbank Puerto Rico v. Kachkar, Civil No. 07-1606 (ADC), 2009 WL 2871160, at *21 (D.P.R. Sept. 1, 2009) (“[T]he Rules of Evidence do not apply strictly to preliminary injunction submissions” and the court has broad discretion in deciding what evidence to consider in connection with a motion for preliminary injunction).

Considering these holdings, Defendants’ objections to Plaintiff’s documentary and testimonial evidence are GRANTED IN PART AND DENIED IN PART as explained below.

DISCUSSION OF THE OBJECTIONS

A. Documentary Evidence.

In relation to the documentary evidence to be considered in the likelihood of success on the merits analysis, the Court sustained Defendants’ objection and only considered the administrative record. Consequently, the Court only considered the following:

- Exhibit 17 (SSURO issued to James Enterprises).
- Exhibit 24 (SSURO issued to Berkey International).
- Exhibit 33 (Pesticide registration Notice 2000-1 dated March 6, 2000), which formed a part of said record.

As to the remaining preliminary injunction factors, the Court overruled Defendants’ objections as to the following exhibits:

Berkey International, LLC v. Environmental Protection Agency, et al.

Opinion and Order

Civil 24-1106 (CVR)

Page 8

-
- Exhibit 2 (Microbiological Challenge Study dated 2009-10-01).
 - Exhibit 31 (reputation damage example in global marketplace).
 - Exhibits 41-42 (evidence of competitors' filters containing silver).

These are all matters that Mr. Shepherd, as President of Berkey International and trustee for the trust that owns Berkey International, has knowledge of and is qualified to testify about by virtue of his position. However, the Court declines to declare him an expert as suggested by Plaintiff. Moreover, this information is readily available to the public on the internet.

The Court sustained Defendants' objections as to the remainder of Plaintiff's exhibits, as it found they pertained to other matters that were not relevant to the narrow issue being decided by the Court, they lacked foundation or were otherwise inadmissible hearsay under the Rules of Evidence. See Fed. R. Evid. 401; Fed. R. Evid 402; Fed. R. Evid. 803(6); Fed. R. Evid. 902(11) and Fed. R. Evid. 1006.

B. Testimonial Evidence.

Plaintiff offered the three (3) Shepherd Declarations, as well as the Spaar Declaration. Keeping in mind that at the preliminary injunction stage more relaxed standards of evidence are applied, the following rulings were made:

Shepherd I: The Court overruled Defendants' objections as to:

- ¶¶ 4-5 (how filters function and Berkey's efforts after hurricane María).
- ¶10 (EPA considered Berkey filters a pesticide device).
- ¶31 (second sentence, lack of EPA notices regarding guidance as to reclassification of water filters as pesticides).
- ¶32 (first sentence, Berkey came into compliance with EPA regulations).

Berkey International, LLC v. Environmental Protection Agency, et al.

Opinion and Order

Civil 24-1106 (CVR)

Page 9

-
- ¶33 (Berkey changed website to reflect it was treated article).
 - ¶36-39 (damages due to issuance of SSURO).
 - ¶¶44-46 (first set; damages due to SSURO).
 - ¶49 (first two sentences, opinion that Berkey is a treated article or pesticide device but not pesticide).
 - ¶50 (first sentence, EPA first published standard for purifiers in 1986).
 - ¶51 (silver in Berkey filters does not leach into water).
 - ¶56 (first three sentences, EPA relied in statements made by European websites for Berkey's SSURO).
 - ¶57 (comments about EPA Pesticide registration notice).
 - ¶62 (Berkey dealer Beroux breached contract with Berkey and made its own filter).

The Court once again found that the testimony offered pertained to matters that that Mr. Shepherd, as President of Berkey International, has personal knowledge of and was qualified to testify about in that capacity.

The Court sustained Defendants' objections regarding the following:

- ¶6, n.1 (comment from EPA contact regarding agency consideration of water filters as pesticides after 2022).
- ¶24 (SSUROs issued to other vendors).
- ¶27 (Vendor B removed pathogen claims from packaging it made for Berkey and SSURO lifted).
- ¶28 (Amazon restricted sale of Berkey products).

Berkey International, LLC v. Environmental Protection Agency, et al.

Opinion and Order

Civil 24-1106 (CVR)

Page 10

-
- ¶30 (phone conversation with EPA contact regarding reclassification of filters as pesticides).
 - ¶¶39-42 (market loss to counterfeit items).
 - ¶¶43-46 (second set, phone calls between EPA and agents for New Millenium Concepts, Ltd. (“NMCL” agents)).
 - ¶47 (opinions about EPA vendetta).
 - ¶55 (last two sentences, EPA is targeting Berkey and has not gone against other filter manufacturers).
 - ¶58 (impropriety of EPA crossing regions).
 - ¶59 (phone call with co-Defendant Tokarz).
 - ¶¶64-65 (opinion that EPA has problems, other lawsuits against the EPA, letter to EPA regarding modernization of FIFRA regulations).

The Court sustained these objections for the same reasons stated before, as the testimony is not relevant, lacked foundation or was inadmissible hearsay under the Rules of Evidence. See Fed. R. Evid. 401; Fed. R. Evid 402; Fed. R. Evid. 803(6); Fed. R. Evid. 902(11).

Shepherd II: The Court overruled Defendants’ objections to the following testimony, based on Mr. Shepherd’s personal knowledge:

- ¶¶5-6 (use of Berkey filers after Hurricane María, reincorporation of prior statement).
- ¶¶9-12 (EPA’s inspection of NMCL container in April 2022, efforts to change packaging to solve EPA issues).

Berkey International, LLC v. Environmental Protection Agency, et al.

Opinion and Order

Civil 24-1106 (CVR)

Page 11

- ¶13 (last sentence, EPA has not issued SSURO to other manufacturers whose filters contain silver).
- ¶¶ 15-16 (other competitors use silver).
- ¶17 (never seen EPA regulate silver containing filters before 2022).
- ¶21 (third-party testing and reviews about Berkey filters).
- ¶23 (EPA's only solution to this issue is filter registration as pesticide).
- ¶26 (Berkey test results show silver does not leach into water).
- ¶30 (Berkey is a registered trademark and information about other lawsuits).
- ¶37 (third sentence, harm as to facilities in Puerto Rico).
- ¶39 (product vacuum created competition for Berkey).

The Court sustained Defendants' objections as to the following:

- ¶31 (options as to counterfeit manufacturers).
- ¶32 (case filed to stop Ukrainian counterfeiters).
- ¶41 (first sentence, opinion as to EPA's actions; second sentence, efforts at compliance after April 2022 NMCL container inspection).
- ¶42 (first sentence, opinion as to EPA demands as non-negotiable).
- ¶43 (last two sentences, opinion about EPA's unequal treatment).

See Fed. R. Evid. 401; Fed. R. Evid 402; Fed. R. Evid. 803(6); Fed. R. Evid. 902(11)(relevancy, lack of foundation, and hearsay).

Shepherd III: The Court overruled Defendants' objections as to:

- ¶ 5 (regularly conducted activity records).
- ¶6 (explanation about Ms. Spaar's qualifications).
- ¶16 (Berkey sales).

Berkey International, LLC v. Environmental Protection Agency, et al.

Opinion and Order

Civil 24-1106 (CVR)

Page 12

See Fed. R. Evid. 401; Fed. R. Evid. 402; Fed. R. Evid. 803(6); Fed. R. Evid. 902(11)(relevancy, lack of foundation, and hearsay).

Spaar's Declaration: The Court accepts the Spaar Declaration in its entirety except some of its exhibits as explained below. The Court finds that her statement is based on personal knowledge as former bookkeeper and account manager for Berkey International. NMCL is licensed to manufacture and sells Berkey water filters, and Spaar was a General Partner at said entity as well. The Court is cognizant that the Spaar Declaration contains details and information about the EPA's initial action in stopping an NMCL container in April 2022, and has attached as an exhibit the SSURO issued to third party James Enterprises, which culminated in the issuance of the SSURO to Plaintiff herein.⁴ Ms. Spaar was also directly and personally involved in the efforts undertaken with the EPA's investigation of Berkey filters in April 2022, and was involved with the EPA to change the Berkey packaging to make it compliant. In fact, the initial investigation in April 2022, which came about because of the EPA inspecting a NMCL container in Colorado with Berkey filters, eventually culminated in the present claim. Therefore, to the extent that both Plaintiff and NMCL are involved in the manufacturing and marketing of Berkey water filters and in the facts that gave rise to this cause of action, the Court will consider some of the documents attached to the Spaar Declaration, to the extent they were not already covered in Defendants' documentary objections.

The Court therefore overrules Defendants' objections as to the following Spaar Declaration exhibits:⁵

⁴ The SSURO issued to James Enterprises is contained in the EPA's administrative record.

⁵ Once again, these numbers coincide with the Exhibit List submitted by Plaintiff at Docket No. 62.

Berkey International, LLC v. Environmental Protection Agency, et al.

Opinion and Order

Civil 24-1106 (CVR)

Page 13

- Exhibit 14 (email thread with co-Defendant Tokarz).
- Exhibit 15 (co-Defendant Tokarz EPA closeout letter).
- Exhibit 18 (co-Defendant Tokarz email seeking documents).

The Court sustains Defendants' objections to all other documents attached to the Spaar Declaration, on the same basis as before, to wit, relevancy, lack of foundation, and hearsay. See Fed. R. Evid. 402; Fed. R. Evid. 803(6); and Fed. R. Evid. 902(11).

IT IS SO ORDERED.

In San Juan, Puerto Rico, on this 24th day of July 2024.

S/CAMILLE L. VELEZ-RIVE
CAMILLE L. VELEZ RIVE
UNITED STATES DISTRICT JUDGE