UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1

In the Matter of:	)	
	)	
Professional Contract Sterilization, Inc.,	)	
40 Myles Standish Boulevard,	)	
Taunton, MA 02780	)	Docket No. CAA-01-2022-0059
	)	
Proceeding under Section 113	)	
of the Clean Air Act	)	
	)	

RESPONDENT'S OPPOSITION TO COMPLAINANT'S MOTION FOR ACCELERATED DECISION ON LIABILITY AND MOTION TO STRIKE AFFIRMATIVE DEFENSES

Respondent, Professional Contract Sterilization, Inc. ("PCS" or "Respondent") respectfully submits its Opposition to the United States Environmental Protection Agency, Region 1 ("EPA" or "Complainant") Motion for Accelerated Decision on Liability and to Strike Affirmative Defenses (the "Motion"). For the reasons set forth below, Complainant's Motion should be denied.

I. Background

On June 28, 2022, 2022, EPA filed a civil administrative Complaint against PCS. The Complaint alleges that PCS violated the Clean Air Act ("CAA"), 42 U.S.C. §7401 et seq., on two instances. Specifically, the Complaint alleges that PCS failed to respond to EPA's Information Collection Request Letter and failed to submit a Performance Test Plan to EPA in violation of Section 114(a) of the CAA, 42 U.S.C. § 7414(a).

On or about July 28, 2022, Respondent filed its Answer to the Complaint. In its Answer, PCS denied liability for the alleged Section 114(a) violations and raised 10 affirmative defenses.

Of note, PCS's First, Second, Third, Sixth, and Tenth Affirmative Defenses challenged EPA's proposed penalties of $60,391 for Count 1 and $40,260 for Count II of the Complaint.

In its Prehearing Exchange filed on January 6, 2023, PCS acknowledged that it did not respond to the EPA's Clean Air Act ("CAA") Section 114 Information Request and Section 114 Testing Requirement by their respective deadlines but did not admit to any purported violation of the CAA. Indeed, the Prehearing Exchange detailed with reference to the affidavits of Michael Burns and Gary Cranston, and associated exhibits, how representations made by EPA staff and its agents caused PCS to understand that any untimely submittal of information to EPA's ICR and/or request for a test plan would not result in violation of the CAA so as to justify penalization. PCS's Prehearing Exchange also provided significant information in support of its First, Second, Third, Sixth, and Tenth Affirmative Defenses, including, but not limited to, the expert report of Jonathan Shefftz detailing PCS's inability to pay the proposed penalties and an affidavit of PCS's President, Gary Cranston, providing information regarding PCS's operations which support penalty mitigation pursuant to Section 113(e) of the CAA.

II. Standard of Review

Pursuant to Rule 22.20(a) of the Consolidated Rules of Practice, the Presiding Officer may render an accelerated decision as to all or any part of the proceeding at any time "if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law." 40 C.F.R. § 22.20(a). These standards are akin to motions for summary judgment in federal practice that are rendered if the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," show that there is no genuine issue of any material fact and that the moving party is entitled to a judgment as a matter of law. In the Matter of Gerald Strubinger, et. al., Docket No. CWA-3-2001-001, 2002 EPA ALJ LEXIS 50, at *3-4 (Aug. 22, 2002) (citing Fed. R. Civ. P. 56(c)).

The burden of showing that no genuine issue of material fact exists is on the party moving for summary judgment. Adickes v. S. H. Kress & Co., 398 U.S. 144, 157 (1970). In considering such a motion, the tribunal must construe the evidentiary material and reasonable inferences drawn therefrom in the light most favorable to the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1985). Summary judgment on a matter is inappropriate when contradictory inferences may be drawn from the evidence. Rogers Corp. v. EPA, 275 F.3d 1096, 1103 (D.C. Cir. 2002).

A party responding to a motion for accelerated decision must produce some evidence which places the moving party's evidence in question and raises a question of fact for an adjudicatory hearing. In the Matter of Strong Steel Products, Docket Nos.RCRA-05-2001-0016, CAA-05-2001-0020, and MM-05-2001-0006, 2002EPA ALJ LEXIS 57 at *22-23 (ALJ, September 9, 2002). This evidence, however, need not be in the form of affidavits nor be in a form that would be admissible at trial in order to avoid summary judgment. Celotex Corp. v. Catrett, 477 U.S. 317, 323-324 (1986). Even if a judge believes that summary judgment is technically proper upon review of the evidence in a case, sound judicial policy and the exercise of judicial discretion permit a denial of such a motion for the case to be developed fully at trial. See Roberts v. Browning, 610 F.2d 528, 536 (8th Cir.1979).

Because motions to strike are not addressed in the applicable procedural rules (40 C.F.R. Part 22), Federal court practice as established by the Federal Rules of Civil Procedure (FRCP) are commonly looked to for guidance. In the Matter of Strong Steel Prods., LLC, 2003 EPA ALJ LEXIS 191, *25-26. FRCP 12(f) provides that a "court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent or scandalous matter." Section 22.15(b) of the Consolidated Rules of Practice does not require a respondent's answer to include

the specific facts in support of the defense, but merely the "circumstances or arguments which are alleged to constitute the grounds" for the defense and “the basis for opposing any proposed relief.” Similarly in Federal court, FRCP 8(b) merely requires that "a party shall state in short and plain terms the party's defenses."

III. Argument

a. The Motion for Accelerated Decision on Liability Should be Denied Because there is an Issue of Material Fact as to Whether PCS Violated Section 114 of the Clean Air Act.

EPA’s repeated representations that PCS would not be penalized for responding to its Section 114 Information Collection Requests (ICRs) after the sixty (60) day deadline creates a genuine issue of material fact as to whether Respondent violated the Clean Air Act so as to support Count 1 of the Complaint and proposed associated penalty. As detailed in PCS Prehearing Exchange and the affidavits of Michael Burns (RX 2) and Gary Cranston (RX 10), in September 2021, during the heart of the worst pandemic in American history which has and continues to significantly adversely impact PCS’s business, EPA sent PCS a voluminous Information Collection Request (ICR) which the EPA estimated would take PCS approximately 108 hours to complete. See Respondent’s Prehearing Exchange, Section VI; Affidavit of Michael Burns, PE, TURP dated January 5, 2023, RX 2, ¶¶ 5-6; Affidavit of Gary Cranston dated January 6, 2023, RX 10, ¶¶ 3-4. Despite the constraints that COVID-19 had placed on the EtO industry as a whole, and PCS’s business in particular, EPA only provided 60 days for PCS to provide responses to the ICR. RX 10, p. 8. Ultimately, it took approximately 120 hours for PCS’s staff and consultants to respond to the ICR. RX 10, ¶ 7. Importantly, these requests were explained to the EtO industry as an effort by EPA to take into consideration public comments on new EtO regulation rather than a mandatory requirement of all companies. RX 10, ¶ 5. Nevertheless, from the time it received

the ICR, PCS endeavored in good faith to respond in a timely fashion. RX 10, ¶ 6. As its efforts progressed, PCS recognized that it would not be able to provide all the information requested in the ICR before the November 19, 2021 deadline and timely requested an extension. RX 2, ¶9, RX 5, RX 10, ¶¶ 8-9. EPA denied PCS's reasonable and timely extension request as an apparent matter of policy. RX 2, ¶9, RX 10, ¶¶ 8-9. But, in a conference call between PCS's consultant Michael Burns of Occupational Health and Safety and Steve Fruh and Charlene Spells of EPA's Fuels and Incineration Group, Mr. Fruh and Ms. Spells represented to Mr. Burns that PCS would not be penalized for an untimely submittal. See Respondent's Prehearing Exchange, Section VI. This representation was subsequently reinforced and reiterated by Jeremy (Jerry) Guo, an outside consultant from RTI International, hired by the EPA to review responses to the ICR. Id. These statements and representations indicate that, irrespective of the deadline, EPA did not consider an untimely response to the ICR as a violation of the Clean Air Act so as to justify penalization; and repeatedly represented same to PCS. Accordingly, these statements and representations create a genuine issue of material fact as to whether PCS violated the Clean Air Act and Complainant's Motion for Accelerated Decision on Liability should be denied.

Similarly, Complainant's Motion for Accelerated Decision as to Count 2 of the Complaint should be denied where there is a genuine issue of material fact as to whether PCS's production of a Proposed Test Plan - 31 days after the May 7, 2022 deadline - is a violation of the CAA where the EPA's subsequent actions in requiring PCS to submit at least three more iterations of the test plan demonstrate that the deadline was arbitrary. Indeed, the process of evaluating necessary components of a Test Plan is a time consuming process that has taken over 7 months to date for PCS to work in good faith with EPA which has provided extensive comments and modification to the Test Plan protocol. This circumstance is not a unique one. PCS's good faith efforts to comply

with the Section 114 request and the parties ongoing efforts to agree on a Test Plan undermines a finding that a violation of the CAA has occurred and, therefore, EPA's Motion for Accelerated Decision as to Count 2 should be denied.

b. Complainant's Motion to Strike Respondent's First, Second, Third, Sixth, or Tenth Affirmative Defenses Should be Denied Where they have been Properly Pled, Supported by Facts, and are Relevant to Mitigation of the Proposed Penalties.

Complainant's Motion to Strike PCS's First, Second, Third, Sixth, or Tenth Affirmative Defenses[1] should be denied where PCS has demonstrated with its Answer, Pre-Hearing Exchange, and this Opposition that these defenses are properly pled, supported by facts, and are relevant to mitigation of the proposed penalties. In the Matter of Strong Steel Prods., LLC, 2003 EPA ALJ LEXIS 191, *25-26 (E.P.A. October 27, 2003) (refusing to strike Affirmative Defenses where respondent supported them in Prehearing Exchange and Opposition to Accelerated Decision); see also In the Matter of Goodman Oil Co., 2001 EPA ALJ LEXIS 152, *40 (E.P.A. August 22, 2001) (refusing to strike Affirmative Defenses to the extent they "may be relevant to mitigation of a penalty).

CAA 113(e) requires that the EPA shall, when assessing a penalty, "take into consideration...the size of the business, the economic impact of the penalty on the business, the violator's full compliance history and good faith efforts to comply, the duration of the violation as established by credible evidence..., payment by the violator of penalties previously assessed for the same violation, the economic benefit of noncompliance, and the seriousness of the violation." Section 22.15(b) of the Consolidated Rules of Practice does not require PCS's Answer to include the specific facts in support of the defense, but merely the "circumstances or arguments which are alleged to constitute the grounds" for the defense and "the basis for opposing any proposed relief."

[1] Respondent will waive the Fourth, Fifth, Seventh, Eighth, and Ninth Affirmative Defenses asserted in its Answer.

As detailed below, PCS has met its burden to survive Complainant's Motion to Strike relative to the following Affirmative Defenses:

First Affirmative Defense: "Respondent has created no danger to health and public safety or human welfare, nor any danger to the environment."

The absence of "actual harm," is clearly relevant to the "seriousness of the violation" which is a factor considered for the civil penalty assessed against Respondent pursuant to Section 113(e) of the CAA. Here, where the alleged violations in the Complaint concern clerical inaction, the fact that no "actual harm" is alleged in Complainant's Complaint, Pre-Hearing Exchange, or Motion supports a finding of penalty mitigation. This is particularly relevant when the Respondent has presented evidence of its inability to pay the proposed civil penalty. RX 1, RX 10. For these reasons, Respondent requests that Complainant's Motion to Strike Respondent's First Affirmative Defense be denied. In the Matter of Strong Steel Prods., LLC, 2003 EPA ALJ LEXIS 191, *25-26 (refusing to strike Affirmative Defenses where respondent supported them in Prehearing Exchange and Opposition to Accelerated Decision); see also In the Matter of Goodman Oil Co., 2001 EPA ALJ LEXIS 152, *40 (refusing to strike Affirmative Defenses to the extent they "may be relevant to mitigation of a penalty).

Second Affirmative Defense: "The absence of harm has not adequately been considered as a mitigating factor in connection with the penalty assessment."

As noted above, the absence of harm is relevant to the consideration of the proposed civil penalty under Section 113(e) of the CAA. Both Count I and Count II concern purely administrative violations against a first-time offender. The absence of harm resulting from these administrative violations is relevant to and should be considered in the mitigation of the assessed penalties. For these reasons, Respondent requests that Complainant's Motion to Strike Respondent's Second Affirmative Defense be denied. In the Matter of Strong Steel Prods., LLC, 2003 EPA ALJ LEXIS

191, *25-26 (refusing to strike Affirmative Defenses where respondent supported them in Prehearing Exchange and Opposition to Accelerated Decision); see also In the Matter of Goodman Oil Co., 2001 EPA ALJ LEXIS 152, *40 (refusing to strike Affirmative Defenses to the extent they "may be relevant to mitigation of a penalty).

Third Affirmative Defense: "Any and all alleged acts or omissions concerning Respondent's compliance with Section 114 of the Clean Air Act, 42 U.S.C. §7414(a) have not resulted in any economic benefit to Respondent."

As stated in Respondent's Answer, Section VI of its Prehearing Exchange, and detailed in Jonathan Shefftz's Report (RX 1), Respondent has received no economic benefit from the alleged failure to provide information detailed in Count 1 or Count 2 of the Complaint. It is undisputed that Respondent has incurred the time and expense to provide the responses to the ICR and Performance Test Plan as requested by EPA. The fact that the Respondent does not have the financial ability to pay the proposed penalties is further evidence that it received no economic benefit from the alleged Section 114 violations. RX 1. This information is relevant under Section 113(e) to the penalty assessment. For these reasons, Respondent requests that Complainant's Motion to Strike Respondent's Third Affirmative Defense be denied. In the Matter of Strong Steel Prods., LLC, 2003 EPA ALJ LEXIS 191, *25-26 (refusing to strike Affirmative Defenses where respondent supported them in Prehearing Exchange and Opposition to Accelerated Decision); see also In the Matter of Goodman Oil Co., 2001 EPA ALJ LEXIS 152, *40 (refusing to strike Affirmative Defenses to the extent they "may be relevant to mitigation of a penalty).

Sixth Affirmative Defense: "The proposed penalty is excessive, inappropriate and unwarranted, and Complainant has not provided adequate explanation as to how the penalty amount was calculated."

There is clearly an issue of material fact as to whether the proposed penalty is excessive and/or unsupported by EPA's proposed penalty calculation. Respondent contends that Section

113(e) of the CAA and the CAA Civil Penalty Policy ("Penalty Policy") as amended by EPA's Penalty Inflation Adjustment Memorandum ("Inflation Adjustment Memo") do not support the level of penalty levied against it. See 42 U.S.C. § 7413(e); CX 1; CX 2. CAA 113(e) requires that the EPA shall, when assessing a penalty, "take into consideration...the size of the business, the economic impact of the penalty on the business, the violator's full compliance history and good faith efforts to comply, the duration of the violation as established by credible evidence..., payment by the violator of penalties previously assessed for the same violation, the economic benefit of noncompliance, and the seriousness of the violation." As detailed in Respondent's Prehearing Exchange, there are many factors that suggest mitigation of the proposed penalty under Section 113(e) including the fact that Respondent is a small business with few employees, that its business continues to be adversely impacted by the COVID-19 Pandemic, it has no history of non-compliance, it derived no economic benefit from the alleged violations, the alleged violations did not result in actual harm, and that it is not able to pay the proposed penalty. See Respondent's Prehearing Exchange, Sections VI, VII, RX 1. Importantly, Section VII of Complainant's Prehearing Exchange provides nothing but a vague reference to the framework upon which penalties are assessed under Section 113 and the Penalty Policy and wholly fails to explain what factors were deemed relevant in this present case, what monetary value was apportioned thereto, and what mitigating factors, if any, were considered in assessing the penalties. For these reasons, Respondent requests that Complainant's Motion to Strike Respondent's Sixth Affirmative Defense be denied. In the Matter of Strong Steel Prods., LLC, 2003 EPA ALJ LEXIS 191, *25-26 (refusing to strike Affirmative Defenses where respondent supported them in Prehearing Exchange and Opposition to Accelerated Decision); see also In the Matter of Goodman Oil Co., 2001 EPA ALJ

LEXIS 152, *40 (refusing to strike Affirmative Defenses to the extent they "may be relevant to mitigation of a penalty).

Tenth Affirmative Defense: "Complainant's penalty assessment constitutes an abuse of discretion."

As discussed above relative to PCS's Ninth Affirmative Defense, there is clearly an issue of material fact as to whether the proposed penalty is excessive and/or unsupported by EPA's proposed penalty calculation. The lack of factual or legal support for EPA's proposed penalty supports a finding that it abused its discretion. For these reasons, Respondent requests that Complainant's Motion to Strike Respondent's Sixth Affirmative Defense be denied. In the Matter of Strong Steel Prods., LLC, 2003 EPA ALJ LEXIS 191, *25-26 (refusing to strike Affirmative Defenses where respondent supported them in Prehearing Exchange and Opposition to Accelerated Decision); see also In the Matter of Goodman Oil Co., 2001 EPA ALJ LEXIS 152, *40 (refusing to strike Affirmative Defenses to the extent they "may be relevant to mitigation of a penalty).

IV. Conclusion

For the reasons stated above, Respondent requests that Complainant's Motion for Accelerated Decision on Liability and Motion to Strike Respondent's First, Second, Third, Sixth, or Tenth Affirmative Defenses be denied. In the alternative, if it is determined that Respondent has inadequately pled its First, Second, Third, Sixth, or Tenth Affirmative Defenses, then Respondent requests that it be allowed to correct the technical deficiency. In the Matter of Strong Steel Prods., LLC, 2003 EPA ALJ LEXIS 191, *25-26 (E.P.A. October 27, 2003).

Respectfully submitted,

Robert Fasanella

2/21/2023
Date

Counsel for Respondent

CERTIFICATE OF SERVICE

I hereby certify that the forgoing Opposition to Complainant's Motion for Accelerated Decision on Liability and Motion to Strike Affirmative Defenses, dated February 21, 2023, was sent this day to the following parties in the matter indicated below.

Original by OALJ E-Filing System to:

Mary Angeles, Headquarters Hearing Clerk
U.S. Environmental Protection Agency
Office of Administrative Law Judges
https://yosemite.epa.gov/OA/EAB-ALJ_Upload.nsf

Copy by Electronic Mail to:

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Dated: February 21, 2023

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