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Issue Date: 29 August 2018

Case No.: 2014-FDA-00001

In the Matter of:

JAMES BYRON,
Complainant,

v.

I.E.H. LABORATORIES,
Respondent.

ORDER DENYING RESPONDENT'S MOTION FOR SUMMARY DECISION, ENTERING AND APPROVING CONFIDENTIALITY STIPULATION, GRANTING RESPONDENT'S MOTION TO SEAL ITS MOTION FOR SUMMARY DECISION, AND GRANTING RESPONDENT'S MOTION TO SEAL ITS REPLY

Procedural Posture

This matter arises under the employee protection provisions of the Food, Drug, and Cosmetic Act ("FDCA"), added by Section 402 of the Food and Safety Modernization Act of 2011 ("FSMA"), codified at 21 U.S.C. § 399d, and the implementing regulations at 29 C.F.R. § 1987.

In October 2011, James Byron ("Complainant") filed a complaint with the Occupational Safety and Health Administration ("OSHA") alleging that I.E.H. Laboratories ("I.E.H." or "Respondent") retaliated against him for raising concerns about Respondent's food testing practices. In August 2013, OSHA dismissed the complaint upon finding that there was insufficient evident to establish a violation of Section 402.

In October 2013, Complainant requested a hearing before the Office of Administrative Law Judges ("OALJ"). On December 24, 2013, I issued a Notice of Assignment and Pre-Hearing Order in this matter. On February 24, 2014, Respondent filed its Motion to Dismiss.[1] On July 30, 2014, I issued a Decision and Order Granting Respondent's Motion to Dismiss and Denying Motion for Attorney's Fees ("First D. & O.") based on my finding that Section 402 of the FSMA whistleblower provision did not cover entities such as Respondent.

[1] I treated Respondent's February 2014 Motion to Dismiss as a motion for summary decision.

Complainant then appealed to the Administrative Review Board ("ARB"). On September 28, 2016, the ARB issued a Decision and Order ("ARB D. & O."), in which it disagreed with my finding that Section 402 did not cover Respondent. The ARB concluded that Section 402 covers Respondent "in this case because the testing in question was performed on samples of food to detect public health threats arising during the manufacturing, processing or importation process." ARB D. & O. at 10. Moreover, contrary to my First D. & O., the ARB concluded that "FSMA Section 202 does not provide a separate means [apart from Section 402] to address retaliation against whistleblowers in testing laboratories. . . and does not prevent retaliation against an employee for making such a complaint." *Id*. at 9. Accordingly, the ARB remanded this matter to me for further proceedings consistent with its opinion.

On May 1, 2017, I received from Respondent I.E.H.'s Motion for Summary Decision ("Motion"); a Motion to Seal its Motion for Summary Decision and Corresponding Exhibits ("Motion to Seal"); a Stipulation of Confidentiality between Complainant and Respondent ("Confidentiality Stipulation"); and a Declaration of Bradley L. Crowell in Support of I.E.H.'s Motion for Summary Decision ("Crowell Declaration"). In its Motion, Respondent seeks dismissal on the basis that Complainant did not engage in a protected activity under the FSMA. Motion at 18. Alternatively, Respondent argues that even had Complainant engaged in a protected activity, it has demonstrated by clear and convincing evidence that I.E.H. would have terminated Complainant absent the protected activity. *Id*. at 26.

On June 5, 2017, I received Complainant's Opposition to Respondent's Motion for Summary Decision ("Opposition"). Complainant attached a Declaration of James Byron ("Declaration") to his Opposition. In his Opposition, Complainant argues, *inter alia*, that the ARB already effectively ruled that Complainant engaged in a protected activity and that summary decision in this matter is inappropriate because the reasonableness of Complainant's belief is a disputed issue of fact that cannot be determined without a hearing.

On July 10, 2017, I received from Respondent I.E.H.'s Reply in Support of its Motion for Summary Decision ("Reply"); a Motion to Seal the Reply in Support of I.E.H.'s Motion for Summary Decision ("Motion to Seal Reply"); the declaration of Bradley Crowell in Support of I.E.H.'s Reply in Support of its Motion for Summary Decision; and Exhibits A through C to I.E.H.'s Reply in Support of its Motion for Summary Decision ("Reply Exh. A-C"). Respondent's Reply asserts, *inter alia*, that courts routinely grant summary decision based on a finding that a complainant lacked a reasonable belief, and argued that the ARB did not decide whether Complainant engaged in a protected activity.

On July 11, 2018, I issued a notice to the parties concerning the Supreme Court's decision in *Lucia v. SEC*, 585 U.S. ___ (2018), and asked them "to advise me whether they waive a potential constitutional challenge to my authority to act in this matter." By letter received July 30, 2018, counsel for Respondent waived any such challenge. By fax received August 11, 2018, counsel for Complainant stated, "… I see no basis on which to either waive or challenge the constitutionality of your authority. Therefore, we decline any such gratuitous waiver." As both parties were informed of *Lucia* and neither party challenged my authority to

act in this matter, I proceed to rule on the Motion, the Motion to Seal, and the Confidentiality Stipulation.

Issues

The issues presented in this Motion for Summary Decision are: (1) whether the ARB D. & O. effectively precluded the arguments set forth in Respondent's Motion; if not, (2) whether Respondent met its burden to prove that no genuine dispute of material fact remained as to Complainant's alleged protected activity; and if not, (3) whether Respondent met its burden to prove that it would have fired Complainant absent Complainant's involvement in a protected activity.

Applicable Legal Standards

I. FSMA Section 402

The only reported case discussing the applicable standard for a cause of action regarding whistleblower retaliation under FSMA Section 402, codified at 29 U.S.C. § 399d, is *Chase v. Brothers Intern. Food Corp. See Chase v. Brothers Intern. Food Corp*, 3 F.Supp.3d 49, 53-54, (W.D.N.Y. 2014). In *Chase*, the court reasoned that a standard for stating an FSMA retaliation claim could be developed based on the language of the FSMA statute "combined with the well-known standard for stating a claim of retaliation under other laws such as the anti-discrimination provisions of Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, and the Age Discrimination in Employment Act." *Id*. at 53. The court found that "to state a claim for retaliation under the FSMA, a plaintiff must establish (1) participation in a protected activity under the FSMA known to the defendant; (2) an employment action disadvantaging the plaintiff or action that would dissuade a reasonable worker from exercising rights under the FSMA, and (3) a causal connection between the protected activity and adverse action." *Id*. at 54.

Upon review of OSHA's own proposed regulations, I note that OSHA repeatedly referred to the FSMA provisions as "analogous" to those of SOX when discussing the relevant standards with which to evaluate FSMA whistleblower retaliation claims. *See* Procedures for Handling Retaliation Complaints Under Section 402 of the FDA Food Safety Modernization Act, 81 Fed. Reg. 22530-01, 22532-33 (April 18, 2016) (codified at 29 C.F.R. Part 1987) (analogizing the "reasonable belief" standard in the FSMA to the SOX standard set out in *Sylvester*, 2011 WL *2165854 (ARB May 25, 2011)).

The ARB has adopted a three-pronged test with which it analyzes SOX claims. To succeed in a SOX claim for whistleblower retaliation, a complainant must establish "that: (1) he or she engaged in an activity or conduct that the SOX protects; (2) the respondent took some unfavorable personnel action against him or her; and (3) the protected activity was a contributing factor in the adverse personnel action." *Sylvester v. Parexel Int'l LLC*, ARB 07-123, 2011 WL 2165854 at *7 (ARB Mary 25, 2011); see *Dietz v. Cypress Semiconductor Corp.*, ARB No. 15-017, 2016 WL 1389927 at *4 (ARB Mar. 30, 2016); *Folger v. SimplexGrinnell, LLC*, ARB No. 15-021, 2016 WL 866116 at *1, n. 3 (ARB Feb. 18, 2016).

Based on the persuasive authority from *Chase* in adopting a three-pronged test formulated from the "well-known standard" of anti-discrimination provisions, and upon review of OSHA's own statements analogizing the elements of the FSMA to those of SOX retaliation claims, I find that the ARB's three-pronged standard for SOX claims is largely applicable to retaliation claims under the FSMA. *See* 21 U.S.C. § 399d; Procedures for Handling Retaliation Complaints Under Section 402 of the FDA Food Safety Modernization Act, 81 Fed. Reg. 22530-01, 22532-33 (April 18, 2016) (codified at 29 C.F.R. pt. 1987); *Chase v. Brothers Intern. Food Corp.*, 3 F.Supp.3d 49, 53-54, (W.D.N.Y. 2014); *Sylvester v. Parexel Int'l LLC*, ARB 07-123, 2011 WL 2165854 at *7 (ARB Mary 25, 2011); *Dietz v. Cypress Semiconductor Corp.*, ARB No. 15-017, 2016 WL 1389927 at *4 (ARB Mar. 30, 2016); *Folger v. SimplexGrinnell, LLC*, ARB No. 15-021, 2016 WL 866116 at *1, n. 3 (ARB Feb. 18, 2016).

Accordingly, I find that to establish a prima facie case for whistleblower retaliation under the FSMA, a complainant must show that: (1) he or she engaged in an activity or conduct protected by the FSMA; (2) the employer took some adverse personnel action against him or her; and (3) the protected activity was a contributing factor in the adverse personnel action.

II. Summary Decision

Pursuant to 29 C.F.R. § 18.72, an administrative law judge ("ALJ") may enter a summary decision "if the movant shows that there is no genuine dispute as to any material fact. . . ." 29 C.F.R. § 18.72. The ARB has held "that a 'genuine issue' exists if a fair-minded fact-finder (the ALJ in whistleblower cases) could rule for the nonmoving party after hearing all the evidence, recognizing that in hearings, the testimony is tested by cross-examination and amplified by exhibits and presumably more context." *Franchini v. Argonne Nat'l Lab*., ARB No. 11-006, ALJ No. 2009-ERA-014, slip op. at 6 (ARB Sept. 26, 2012); ARB D. & O. at 3. When considering a motion for summary decision, the ALJ must view the evidence in the light most favorable to the non-moving party. *Franchini*, ARB No. 11-006, slip op. at 6.

Discussion

In its Motion, Respondent moves for summary decision on the basis that Complainant did not engage in a protected activity under the FSMA.[2] Motion at 18. Alternatively, Respondent argues that it would have terminated Complainant regardless of whether Complainant engaged in a protected activity. *Id*. at 26. As Respondent is the moving party, it bears the burden to show that "there is no genuine dispute as to any material fact. . . ." 29 C.F.R. § 18.72.

I. The ARB D. & O. Does Not Preclude the Arguments Presented in Respondent's Motion

Complainant opposes Respondent's Motion for Summary Decision by arguing that the ARB, by granting jurisdiction to hear Complainant's appeal, effectively ruled that Complainant engaged in a protected activity. Opposition at 3. Complainant provides no authority in support

[2] Respondent limited its analysis of whether Complainant engaged in a protected activity to Complainant's August 2011 email exchange with Dr. Samadpour. Motion at 19-20, n. 10.

of his assertion that "pleading subject matter jurisdiction and protected activity is often the same thing, as it is in this case. . . ." *Id*. at 3.

As with the ARB, my authority to issue a decision in this matter is governed by 29 C.F.R. Part 1987, Subpart A. *See* 29 C.F.R. 1987; ARB D. & O. at 3, n.3. As discussed above, to establish a prima facie case for whistleblower retaliation under the FSMA, a complainant must show, *inter alia*, that he or she engaged in an activity or conduct protected by the FSMA. I reject Complainant's argument that merely bringing an issue before an adjudicator establishes an element of the claim on the merits. Moreover, the ARB did not address the alleged protected activity in this matter; rather, it expressly identified the "sole issue on appeal" to be "whether the FSMA whistleblower provision protects I.E.H. whistleblowers who raise concerns about its testing of food samples to check for threats to public health." ARB D. & O. at 2.

Accordingly, I find that the ARB did not issue any ruling regarding whether Complainant engaged in protected activity.

Complainant's Opposition also argues that the ARB "limited the availability of summary decision as to Complainant's protected activity in objecting to 'perceived' violations of food safety 'standards." Opposition at 6-8. Complainant notes that the ARB placed a "steep burden" on the employer to prove that summary decision is warranted. *Id*. at 7.

After I issued my First D. & O. in this matter, the regulation governing the burden of proof for summary decisions was amended. *Compare* 29 C.F.R. § 18.40(d) (2012) *with* 29 C.F.R. § 18.72(a) (2015). As the ARB stated, "[t]he amendment makes clear that the movant has a heavy burden to establish that there is no genuine issue of material fact." ARB D. & O. at 3, n. 5. The ARB clarified that, "[u]pon remand, failure to meet that burden under the new regulations should result in a denial of the motion for summary judgment." *Id*. at 3, n. 5.

I find that the availability of summary decision in this matter is limited to the extent that successful motions must satisfy the heavy burden of proof required by the 2015 amendments to the regulation, at 29 C.F.R. § 18.72(a).

Accordingly, I find that the ARB D. & O. did not preclude Respondent from making the arguments presented in its Motion for Summary Decision.

<u>II. Respondent Has Not Met Its Burden to Prove that No Genuine Dispute of Material Fact Remains</u>

Respondent argues for summary decision on the ground that Complainant did not engage in a protected activity. Respondent asserts that Complainant did not engage in a protected activity because Complainant's email to Dr. Samadpour did not "relate in an understandable way" to one of the provisions of relevant law. Motion at 20 (*citing Wiest v. Lynch*, 710 F.3d 121, 134 (3d Cir. 2013)).[3] Although Respondent acknowledges that Complainant was "not required

[3] Respondent cites to *Wiest* in support of its argument that Complainant could not have a subjectively reasonable belief because Complainant's email did not "relate in an understandable way" to one of the provisions of relevant law. Motion at 20 (citing *Wiest*, 710 F.3d at 134). However, the requirement from *Wiest* that an intra-corporate

to cite to a specific violation of law to engage in a protected activity," *id*. at 22, it asserts that Complainant must do more than express mere business concerns. *Id*. Respondent argues that Complainant's email exchange with Dr. Samadpour did not rise to the level of protected activity because Complainant "did not provide any information to IEH regarding conduct he subjectively believed violated the FDCA." *Id*.

In *Wiest*, the Third Circuit held that the appropriate standard for determining whether a complainant's conduct constituted a protected activity was the ARB's "reasonable belief test," set forth in *Sylvester*. *See Wiest*, 710 F.3d at 137 (citing *Sylvester v. Parexel Int'l LLC*, ARB 07-123, 2011 WL 2165854). To satisfy the reasonable belief test, a complainant must have both a subjectively and objectively reasonable belief that a respondent's conduct violated relevant law. *Sylvester*, 2011 WL 2165854 at *11-12.

a. Subjectively Reasonable Belief

Determining whether Complainant had a reasonable belief requires a fact based inquiry into the subjective and objective components of his belief. *Rhinehimer v. U.S. Bancorp Investments, In.c*, 787 F.3d 797, 811 (6th Cir. 2015). The subjective component of the reasonable belief test "is satisfied if the employee actually believed that the conduct complained of constituted a violation of relevant law." *Rhinehimer*, 787 F.3d at 811 (citing *Nielsen v. AECOM Tech. Corp.*, 762 F.3d 214, 221 (2d Cir. 2014)); *Beacom*, 825 F.3d at 380; *Sylvester*, 2011 WL 2165854 at *12.

i. Complainant's Knowledge

Respondent argues that Complainant's knowledge "that IEH agreed to submit its study results to the FDA for approval" eliminated any reasonable belief that Complainant may have had that the results violated relevant law. Motion at 20. Respondent also asserts that Complainant could not have actually believed Respondent violated relevant law because "Dr. Samadpour informed [Complainant] that his proposed validation study was not required by AOAC [guidance]."[4] *Id*. at 21.

Complainant asserts that he held a reasonable belief that Respondent violated relevant food safety laws and standards. *See* Declaration at 8-11. Complainant explains that his interactions with other employees, his own observations, and his industry experience formed the foundation of this belief. *See id*. at 6-11. In particular, Complainant alleges that two I.E.H. employees independently raised concerns about Respondent's testing practices to him.

Complainant explains that Dr. Sidhu, Respondent's Vice President of Business Development & Pharmaceutical Microbiology, told him that a scientist in one of Respondent's

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communication must "relate in an understandable way" to a provision of relevant law goes to establishing employer's knowledge, contained within the element of causation, rather than to the reasonableness of Complainant's belief. *See Wiest*, 710 F.3d at 134 ("*[I]n order for an employer to 'know or suspect* that the whistleblower-plaintiff is engaged in protected conduct ... the plaintiff's intra-corporate communications [must] relate in an understandable way to one of the stated provisions of federal law []'" (emphasis added) (internal citation omitted)).

[4] Respondent notes that the AOAC guidance is "more rigorous than the FDA guidance." Motion at 21.

labs "had attempted to manipulate the validation protocol and data to support the desired outcome rather than perform an objective test and analysis of the data." *Id*. at 6. Complainant states that Dr. Sidhu disclosed this concern to Dr. Samadpour, but that "Dr. Samadpour was dismissive of the concerns and declined to take any disciplinary action against the scientist." *Id*. at 6.

Complainant also describes an interaction with Mr. VanArsdale, a Business Development Manager for Respondent, in which Mr. VanArsdale expressed concern to Complainant about Respondent's testing procedure at its Carol Stream, Illinois lab. *Id*. at 6. According to Complainant, Mr. VanArsdale told him that Respondent's Carol Stream lab engaged in improper listeria testing by "pooling groups of five collected samples into a single composite sample prior to performing the PCR test so that only one test would have to be performed." *Id*. at 6. Complainant alleges that Respondent's practice of pooling food samples prior to testing "had not been calibrated and validated." *Id*. at 6. Complainant also notes that Respondent's "customers have been involved in food recalls associated with listeria." *Id*. at 7.

Complainant states that Mr. VanArsdale also expressed concern about Respondent's "Process Control Test." *Id*. at 7. According to Complainant, Mr. VanArsdale was concerned about the Process Control Test because Respondent's testing methodology had not been validated for the purpose for which it was being used. *Id*. at 7.

Finally, Complainant explains his personal observations which contributed to his belief that Respondent violated relevant food safety laws. *See id*. at 8-11. Complainant states that "in [his] experience when validating a testing method, use of multiple studies was the industry norm." *Id*. at 10-11. Complainant states that "[b]ased on [his] knowledge of AOAC and similar industry standards, [he] concluded that [Respondent's] protocol fell short of any acceptable industry standard, and would be insufficient to meet FDA standards, gain FDA acceptance, and assure that the test would produce accurate and reliable results when used." *Id*. at 10.

Upon consideration of a motion for summary decision, I must view the evidence presented in the light most favorable to the non-moving party, which is Complainant. *See Franchini*, ARB No. 11-006, slip op. at 6. I find that Complainant raised multiple allegations of insufficient testing practices, any of which may serve as an independent basis for actually believing that Respondent violated relevant law. Furthermore, Complainant alleged concern about the legal sufficiency of Respondent's testing practices, not merely the test results being submitted to the FDA addressed by Dr. Samadpour's email.

Based on my review of the evidence, and recognizing that not all evidence has yet been presented, I find that a fair-minded finder of fact could rule for Complainant upon further development of the record. Accordingly, I find that the subjective reasonableness of Complainant's belief is a genuine issue of material fact, which remains in dispute.

ii. Communication of Reasonableness to Employer

Next, Respondent argues that Complainant did not have a subjectively reasonable belief because Complainant failed to communicate such a belief to Respondent prior to being terminated. Motion at 22.

In support of this argument, Respondent relies in part on dicta from the U.S. District Court for the District of Minnesota, which stated that a "[plaintiff] must submit some evidence that, at the time of the complaints, he held this belief." Motion at 22 (citing *Beacom v. Oracle*, 2015 WL 2339558 at *5 (D. Minn. Mar. 11, 2015)). *Beacom*, however, was appealed to the Eighth Circuit, where the dicta upon which Respondent relied was not affirmed.[5]

Respondent also relies in part on a finding by the U.S. District Court for the Eastern District of Pennsylvania that "[i]n order to determine whether an employee made a protected communication, a court must look to what the employee actually communicated to the employer at the time the alleged [] violation occurred." Motion at 22 (citing *Wiest v. Lynch*, No. 10-3288, 2011 WL 2923860 at *5 (E.D. Pa. July 21, 2011)). However, on appeal, the Third Circuit clarified that whether the employer had reason to suspect that the communication constituted protected activity is distinct from whether the communication was in fact protected. *See Wiest*, 710 F.3d at 134 ("[I]n order for an employer to 'know or suspect that the whistleblower-plaintiff is engaged in protected conduct. . . the plaintiff's intra-corporate communications [must] relate in an understandable way to one of the stated provisions of federal law [in § 806]'. . . . [However], whether an employee's communication is indeed 'protected activity' under § 806 is distinct from whether the employer had reason to suspect that the communication was protected") (internal citations omitted).

Instead, as discussed above, the Third Circuit in *Wiest* held that the "reasonable belief test" from *Sylvester* was the appropriate test with which to analyze whether a complainant's conduct constituted protected activity. The ARB in *Sylvester* expressly rejected requiring "the complainant [to have] actually communicated the reasonableness of those beliefs to management. . ." for the purpose of determining the reasonableness of complainant's belief. *Sylvester*, 2011 WL 2165854 at *12.

Complainant nonetheless asserts that he communicated his concerns regarding Respondent's testing practices both to Ms. Cantera and to Dr. Samadpour. *See* Declaration at 9-11. Moreover, in his Declaration, Complainant explained the interactions and observations that formed the basis of his belief that Respondent violated relevant law. *See id*. at 9-11. Complainant argued that, ultimately, the reasonableness of his belief turns on credibility, "which cannot be resolved without a hearing." Opposition at 10 (citing *Prioleau v. Sikorsky Aircraft Corp.*, ARB No. 10-060, ALJ No. 2010-SOX-003, slip op. at 7-8 (ARB Nov. 9, 2011)). Complainant argues that the fact intensive nature of the reasonableness determination in this matter renders it inappropriate for me to find, as a matter of law, that no genuine issue of material fact remains as to the subjective reasonable of Complainant's belief. *Id*. at 9-10.

[5] The Eighth Circuit conducted a *de novo* review affirming the judgment below. It did not, however, discuss, restate, or affirm the dicta upon which Respondent relied.

For the purpose of determining protected activity, I find that Complainant was not required to show he actually communicated the reasonableness of his belief to Respondent. Even were such a showing required, however, I would find that the facts alleged, when construed in the light most favorable to Complainant, could lead a fair-minded fact finder to rule for Complainant upon further development of the record. Accordingly, I find that Respondent has failed to show that no genuine issue of material fact remains as to whether Complainant held a subjectively reasonable belief.

b. Objectively Reasonable Belief

An objectively reasonable belief is satisfied if "a reasonable person in [Complainant's] position, with the same training and experience, would have believed" that Respondent violated relevant law. *Beacom v. Oracle Am., Inc.*, 825 F.3d 376, 380 (8th Cir. 2016) (citing *Rhinehimer*, 787 F.3d at 811). "The issue of objective reasonableness should be decided as a matter of law only when '[n]o reasonable person could have believed' that the facts amounted to a violation" of relevant law. *Livingston v. Wyeth, Inc.*, 520 F.3d 344, 361 (4th Cir. 2008) (Michael, J., dissenting)) (internal brackets in original); *see also Rhinehimer*, 787 F.3d at 811; *Sylvester*, 2011 WL 2165854 at *12. In a motion for summary decision, the moving party bears the burden to prove that no genuine dispute as to any material fact remains.

i. Lack of Scientific Training

Respondent argues that Complainant's lack of scientific training precluded him from forming an objectively reasonable belief that Respondent violated an area of relevant law. Motion at 24 ("Mr. Byron has no training or experience in microbiology (or any science degree), and could not reasonably believe that he was able to better understand and design a proper validation study. . . compared to those with the requisite education, training and experience in validations study design. . .") (internal parentheses in original).

Respondent suggests that Complainant should have conducted research prior to reporting his concerns to Dr. Samadpour. *See id*. at 14, 24-25. Respondent conceded, however, that Complainant "cited to his previous experience with other companies" regarding validation study design. *Id*. at 15. Nonetheless, "Dr. Samadpour disregarded Mr. Byron's opinion on the subject of validation study design because Mr. Byron did not have the technical or scientific background to opine on the design of a validation study." *Id*. at 16 (citing M. Samadpour Dep. Tr. at 30:1 – 31:25, attached as Ex. 1).

Complainant asserts that his lack of scientific knowledge did not preclude him from forming an objectively reasonable belief that Respondent violated relevant law. *See* Opposition at 3-4, n.2. There is no requirement in the FSMA that a complainant undergo independent research to form an objectively reasonable belief. Moreover, an objectively reasonable belief is not dependent upon having scientific training; instead, whether Complainant held an objectively reasonable belief depends upon whether a reasonable person "with the same training and experience [as Complainant], would have believed" that Respondent violated relevant law. *See Beacom*, 825 F.3d at 380.

Complainant explains that, based on his experience with industry standards and his own observations at I.E.H., he believed that Respondent's proposed testing practices were inconsistent with industry norms and in violation of relevant law. Declaration at 7-11, ¶¶ 16-18, 20-26. Additionally, as discussed above, Complainant alleged that two employees at I.E.H. informed him of separate instances of misconduct in testing practices, which he believed violated industry standards, norms, or the FDA. *See id*. at 6-12, ¶¶ 13-15, 23.

Complainant, by asserting that he observed testing practices inconsistent with industry norms, and by asserting that two other I.E.H. employees also expressed concern about Respondent's practices, alleged facts in support of an objectively reasonable belief that Respondent violated relevant law. Upon review of the evidence presented, I find that a fair-minded fact finder could rule for Complainant upon further development of the record. Accordingly, I find that Respondent has not met its burden to prove that no genuine dispute of material fact remains.

ii. Lack of Follow Up

Next, Respondent argues that Complainant did not hold an objectively reasonable belief because a reasonable person "would have followed up on his concerns." Motion at 25. Respondent states that if Complainant "really believed the study design was improper, he would have conducted his own research on the topic and replied to Dr. Samadpour with support for his statement (or at least have responded to say he thought it was inaccurate)." *Id*. at 25 (parentheses in original). In support of its argument, Respondent notes that Complainant "still cannot explain how the validation study allegedly violated the AOAC guidance of the FDCA. . . ." *Id*. at 25.

There is no provision of the FSMA that requires a complainant to follow up after his initial communication to an employer. Additionally, a complainant's "reasonable, but mistaken, belief that employer's conduct" violated relevant law, may still form the basis of a protected activity. *See Sylvester*, 2011 WL 2165854 at *14 (citing *Halloum v. Intel Corp.*, ARB No. 04-068, ALJ No. 2003-SOX-007, slip op. at 6).

Even though no provision of the FSMA requires follow up, Complainant asserts that he did follow up with Dr. Samadpour regarding his concerns. Complainant explains that Dr. Samadpour responded to his first email about validation testing, but did not respond to Complainant's second email in which he "objected" to the proposed validation study. *Id*. at 10-11. Complainant also states that he made multiple phone calls to Dr. Samadpour, but that he did not receive responses. *Id*. at 11.

Furthermore, Complainant alleges facts in support of a finding that objectively reasonable people may not pursue or follow up on concerns with Dr. Samadpour. Specifically, Complainant describes Dr. Samadpour's management style as "arbitrary" and "rash," Declaration at 12, ¶ 30, and suggested that such a management style discouraged employees from reporting their concerns. As discussed above, Complainant states that Dr. Samadpour was dismissive of Dr. Sidhu's report of serious misconduct by a scientist. Complainant also posits that Mr. VanArsdale did not report his concerns about testing methodology to Dr. Samadpour in order to

avoid "Dr. Samadpour's wrath." *Id*. at 7. Nonetheless, Complainant asserts that he emailed Dr. Samadpour regarding testing validation practices.

Based on my review of the facts alleged, I find that a fair-minded finder of fact could find for Complainant upon further development of the record. Accordingly, I find that a genuine dispute remains as to Complainant's objective reasonableness.

c. Genuine Disputes of Fact Remain as to Protected Activity

For the reasons discussed above, I find that genuine disputes of material fact remain regarding both Complainant's subjective and objective reasonableness. Whether Complainant's belief that Respondent committed a violation of relevant law was subjectively and objectively reasonable is material to determining whether Complainant engaged in a protected activity under the FSMA. If "reasonable minds could disagree about whether the employee's belief was objectively reasonable, the issue cannot be decided as a matter of law." *Sylvester* at *13 (quoting *Livingston*, 520 F.3d 344 (Michael, J., dissenting) (internal citations omitted)). Moreover, "an employee need not establish the reasonableness of his or her belief as to each element of the violation." *Rhinehimer*, 787 F.3d at 812. Rather, the "reasonableness of the employee's belief will depend on the totality of the circumstances known (or reasonably albeit mistakenly perceived) by the employee at the time of the complaint, analyzed in light of the employee's training and experience." *Id.* at 812 (citing *Livingston*, 520 F.3d at 361).

Accordingly, I find that Respondent has not satisfied its burden of proof for summary decision to show that no genuine disputes remain as to Complainant's alleged protected activity.

<u>III. Respondent Has Not Met Its Burden to Prove that It Would Have Fired Complainant Absent Complainant's Involvement in a Protected Activity</u>

Respondent argues that, even if Complainant engaged in a protected activity, this matter should be summarily denied because Respondent would have terminated Complainant regardless of Complainant's involvement in a protected activity.

Under the analogous SOX framework, whistleblower claims are subject to a burden-shifting framework. *Rhinehimer*, 787 F.3d at 805; *Feldman v. Law Enforcement Associates Corp.*, 752 F.3d 399, 344 (4th Cir. 2014). When a plaintiff has established a prima facie case for retaliation, the employer may then seek to avoid liability by meeting the high burden of proving the affirmative defense "by clear and convincing evidence that the employer would have taken the same personnel action in the absence of the protected activity." *Rhinehimer*, 787 F.3d at 805 (quoting *Feldman*, 752 F.3d at 345); see *Palmer v. Canadian Nat'l Railroad Co.*, ARB No. 16-035, 2016 WL 5868560 at *12.

Respondent, in support of its affirmative defense, characterizes Complainant as a mere salesman and pointed to unsatisfactory sales as evidence that it would have terminated Complainant regardless of his participation in an alleged protected activity. Motion at 2, 26-28. Complainant disputes this characterization as a mere salesperson. Opposition at 5, n. 3. Complainant states that it was undisputed that his title at I.E.H. was "Vice President of

International Business Development and Technology Transfer." *Id*. at 5, n.3. Complainant also assert that "no set sales volume was a term or condition of his employment." *Id*. Moreover, Complainant notes that his experience in sales, marketing, strategic planning, and fostering loyal and highly performing sale teams all contributed to Respondent's decision to hire Complainant. *Id*. (citing Respondent's Motion). Complainant characterizes his employment responsibilities as including strategic planning and team building, as opposed to generating sales. *Id*.

The contrasting characterizations of Complainant's responsibilities at I.E.H. preclude me from finding that unsatisfactory sales records were sufficient to prove by clear and convincing evidence that Respondent would have terminated Complainant regardless of the alleged protected activity. Accordingly, I find that Respondent has not met its burden to prove by clear and convincing evidence that it would have terminated Complainant regardless of the alleged protected activity.

Conclusions

In this Motion for Summary Decision, Respondent, as the moving party, bears the burden to show that there is "no genuine dispute as to any material fact. . . ." *See* 29 C.F.R. § 18.72. Upon my review and consideration of the Motion, I view the evidence presented in the light most favorable to the non-moving party. *See Franchini*, ARB No. 11-006, slip op. at 6.

First, I reject Complainant's argument that the ARB D. & O. precluded respondent from disputing that Complainant engaged in a protected activity, and I find that the ARB D. & O. did not prevent Respondent from raising the arguments presented in its Motion for Summary Decision. Second, I find that genuine disputes of material fact remain as to whether Complainant held a subjectively and objectively reasonable belief that Respondent violated relevant law. Respondent, thus, fails to meet its burden of proof for summary decision on the ground that Complainant did not engage in protected activity. Third, I find that Respondent has not met its burden to prove by clear and convincing evidence that it would have fired Complainant regardless of any protected activity. For the reasons discussed above, I find that genuine disputes of material fact also remain in this matter, and as such, Respondent has not met its burden for summary decision.

Accordingly, Respondent's Motion for Summary Decision is **DENIED.**

ORDER ENTERING AND APPROVING CONFIDENTIALITY STIPULATION

Respondent submitted a Stipulation of Confidentiality between Complainant and Respondent ("Confidentiality Stipulation") attached to its Motion for Summary Decision. The Confidentiality Stipulation describes, *inter alia*, the type of documents that may be marked confidential by the parties, and describes the procedure for identification, use, and access of such materials for the purpose of this litigation.

The Confidentiality Stipulation is signed by counsel for both parties, and I find no reason to modify or disproved the Stipulations as written. Accordingly, the Confidentiality Stipulation is **ENTERED** and **APPROVED** pursuant to my authority at 29 C.F.R. § 18.83.

ORDER GRANTING RESPONDENT'S MOTIONS TO SEAL

Attached to Respondent's Motion for Summary Decision, was a Motion to Seal Respondent's Motion for Summary Decision and Corresponding Exhibits ("Motion to Seal").

Additionally, Respondent submitted a Reply in Support of I.E.H.'s Motion for Summary Decision ("Reply"). Attached to this Reply, I received from Respondent a Motion to Seal the Reply in Support of I.E.H.'s Motion for Summary Decision ("Motion to Seal Reply"); the declaration of Bradley Crowell in Support of I.E.H.'s Reply in Support of its Motion for Summary Decision; and Exhibits A through C to I.E.H.'s Reply in Support of its Motion for Summary Decision ("Reply Exh. A-C").

Although my authority pursuant to 29 C.F.R. § 18.85 permits me to seal privileged, sensitive, or classified materials from public access, the parties are advised that my authority is limited by the Freedom of Information Act ("FOIA"), among other statutes and limitations pertaining to public access to agency records. *See* 29 C.F.R. § 18.85(b)(2).

Respondent's Motion to Seal asserts that the identified documents contain confidential commercial and financial information. Upon my review of the record, I agree with Respondent's characterization of the identified documents. Accordingly, Respondent's Motion to Seal is **GRANTED** pursuant to my authority at 29 C.F.R. § 18.85. Additionally, I find that the identified documents fall within exemption 4 of FOIA. *See* 5 U.S.C. § 552(b)(4).

Upon submitting its Reply, Respondent submitted an additional Motion to Seal Reply on similar grounds. Based on my review of the record, I agree with Respondent's characterization that the identified documents contain confidential commercial and financial information. Accordingly, Respondent's Motion to Seal Reply is **GRANTED** pursuant to my authority at 29 C.F.R. § 18.85.

ORDER

Based on the foregoing:

1. Respondent's Motion for Summary Decision is **DENIED**;

2. The parties' Confidentiality Stipulation is **ENTERED** and **APPROVED**;

3. Respondent's Motion to Seal its Motion for Summary Decision and Corresponding Exhibits is **GRANTED**;

4. Respondent's Motion to Seal the Reply in Support of I.E.H's Motion for Summary Decision is **GRANTED**; and

5. The parties shall meet and confer and shall jointly provide me three potential dates for the hearing of this matter starting in January 2019 (but not including the weeks of January

21, February 19, April 8, or May 13) an agreed city for the location of the hearing, and an agreed estimated length of the hearing.

SO ORDERED.

PAUL R. ALMANZA
Associate Chief Administrative Law Judge