



Issue Date: 27 February 2020

CASE NO.: 2019-CPS-00001

In the Matter of:

TANYA SANDROCK,
Complainant,

vs.

ARCHER DX,
Respondent.

**ORDER GRANTING MOTION FOR SUMMARY DECISION,
DISMISSING COMPLAINT, AND VACATING HEARING**

This case was filed by Complainant under the employee protection provisions of the Consumer Product Safety Improvement Act of 2008, 15 U.S.C. § 2087 (CPSIA or the “Act”). Complainant is self-represented. Respondent is represented by attorney, John B. Greer.

I. PROCEDURAL BACKGROUND

Complainant filed a complaint on June 26, 2019, with the Department of Labor Occupational Safety and Health Administration (OSHA). Complainant alleged that Respondent terminated her employment in retaliation for voicing concerns about inaccurate data related to a developmental medical device. She alleged that Respondent ignored her concerns about the data and provided their medical device data to the FDA, which also concluded that Respondent’s data was inaccurate. Respondent terminated Complainant’s employment for being insubordinate, after she apparently refused to lead a meeting as directed by management and said she did not want to work for a certain director any longer. *See* OSHA Decision, July 18, 2019¹. The Secretary of Labor, acting through OSHA, determined that Complainant’s activity was taken in regard to a medical device, but that medical devices are not “consumer products” under the Act, and therefore OSHA had no jurisdiction. *Id.* Her complaint was dismissed.

¹ This document is attached to Respondent’s Motion for Summary Decision as Exhibit A.

On September 20, 2019², Complainant filed a request for hearing before an Administrative Law Judge (ALJ) (the “Request for Hearing”). Complainant stated, “This objection is a complaint that medical devices and drug development industry employees are excluded from OSHA 15 U.S.C. § 2087(V)(A)(2)(h) whistleblower protection laws. The FDA covers drugs and devices; however, the agency focuses on product safety investigation not whistleblower complaints with respect to the employee. The FDA complaint form related to reporting is found at [link and phone number omitted]. This is a citizen complaint to review the following and reverse dismissal of the initial complaint . . .” The matter was assigned to me, and I issued a *Notice of Hearing and Pre-Hearing Order* on October 15, 2019. The hearing was scheduled for March 5, 2020, in Salt Lake City, Utah, and a pre-hearing conference was scheduled for February 27, 2020.

On December 30, 2019, I received a letter from Complainant (which was dated December 22, 2019) in which she requested removal of ArcherDX from the case. On January 6, 2020, Respondent filed a *Response to Complainant’s Letter Dated December 22, 2019, “Requesting Removal of ArcherDX from the Case”*. Respondent stated it had no objection to being removed from the case as long as it meant that Ms. Sandrock’s complaint would be dismissed. Respondent also indicated it would be filing a motion for summary decision.

On January 17, 2020, Respondent filed a *Motion for Summary Decision* (the “Motion”). Respondent argues that, because the complaint concerns a medical device which is not governed by the CPSIA, OSHA does not have jurisdiction to investigate the complaint and the ALJ does not have jurisdiction to consider the complaint. On February 6, 2020, I issued an *Order to Show Cause Regarding Summary Decision*, which was served on Complainant by email from my legal assistant. This order explained summary decision motions and set a deadline for filing opposition papers to the Motion. In addition, the order informed Complainant that I was denying her request to remove ArcherDX from the case, without prejudice, so I could effectively adjudicate the Motion for Summary Decision.

Complainant replied the same day directly to that email.³ She stated that she “requested whistleblower protection through the intelligence community” and is therefore “unable to comment further on the nature of the dispute with the labor department.” She stated her “hope that you will grant the case to proceed further with respect to this inquiry without my involvement.” Complainant argued that ArcherDX products are analogous to a genetic test, “23 and me”, which she alleges is a consumer product. She also argued that even if the product at issue “were a medical device, scientists should be protected.” I consider the email as a response by Complainant to the Motion (the “Response”), while noting that Complainant submitted no evidence, in the form of documents or declarations, in support of her argument.

² This document is dated August 12, 2019, but the date of receipt by the Office of Administrative Law Judges is used as the date of filing.

³ It did not appear that Complainant had copied Respondent’s counsel or otherwise served Respondent with her email. On February 11, 2020, I issued a *Notice of Ex Parte Filing and Order Setting Pre-Hearing Conference*, attaching a copy of the email exchange between my legal assistant and Complainant.

On February 6, 2020, Respondent filed a *Motion to Compel and for Sanctions and Request for an Immediate Hearing*. In light of this Decision and Order, this motion is moot, and it is unnecessary for me to rule on it. By letter dated and received February 12, 2020, Complainant informed me that she would not participate in the “meeting” on March 5, 2020, and will leave the decision in my hands. On February 21, 2020, I held a telephonic pre-hearing conference at which Mr. Greer appeared but Complainant did not. Mr. Greer informed me that he had received email correspondence from Complainant indicating she did not intend to participate, and the conference was then closed. To date, I have received no further filings or communication from Complainant.

II. LEGAL STANDARDS

A. Summary Decision

Under OALJ Procedural Rules, an administrative law judge (“ALJ”) shall grant a motion for summary decision if the pleadings, affidavits, evidence obtained by discovery, or other evidence show that there is no genuine issue of material fact and that the moving party would prevail as a matter of law. 29 C.F.R. § 18.72; *see also* Fed. R. Civ. P. 56(c). The moving party bears the initial burden to show the absence of a genuine issue of material fact and entitlement to judgement as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party presents such evidence, the burden shifts to the non-moving party to show that a genuine issue of material fact remains. *Id.* at 330. In doing so, the non-moving party “may not rest upon mere allegations or denials of his pleading, but ... must set forth specific facts showing that there is a genuine issue for trial.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). The moving party must show that there is not enough evidence of an essential element for the non-moving party to carry its ultimate burden of persuasion at trial. *Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Cos., Inc.*, 210 F.3d 1099, 1002-03 (9th Cir. 2000).

B. Whistleblower Protection under CPSIA

The whistleblower protection provisions of the CPSIA apply to an employee who provides information to the employer, federal government, or a state attorney general relating to a violation, or an act or omission which the employee reasonably believes to be a violation, of the Act or any other act enforced by the Consumer Product Safety Commission. 15 U.S.C. § 2087(a)(1). The Act applies to “consumer products,” which is defined as “any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation or otherwise”. 15 U.S.C. § 2052(a)(5). Specifically excluded from this definition are “drugs, devices, or cosmetics (as such terms are defined in sections 201 (g), (h), and (i) of the Federal Food, Drug, and Cosmetic Act [FDCA]. . .” 15 U.S.C. § 2052(a)(5)(H). Medical devices which are covered by the FDCA are therefore not “consumer products” to which the CPSIA applies.

III. ANALYSIS

Respondent has established that the concerns Complainant relayed to her employer were related to a medical device. Complainant's original complaint to OSHA indicates that she "raised concerns with the doctor and patient (medical device – companion diagnostic) that the company was not being truthful." Motion, Exhibit B. The OSHA Decision indicates that Complainant alleged Respondent retaliated against her for voicing concerns to management about "inaccurate data related to a developmental medical device that Respondent was seeking fast track approval from the Food and Drug Administration (FDA)." Motion, Exhibit A. When she was employed by Respondent, Complainant primarily worked on the early stage development of an IVD companion diagnostic test or device, which is regulated by the FDA. Motion, Exhibit D (Affidavit of Ming-Chou Lee, Ph.D.). Dr. Lee does not specifically attest that it was this particular device about which Complainant was concerned, and I draw no such inference.

Nevertheless, the evidence is sufficient to show that Complainant's activity was taken in relation to a medical device for which Respondent was seeking FDA approval. Respondent argues that this device falls within the FDCA's definition of "device," at 21 U.S.C. § 321 (h), thereby excluding it from the definition of "consumer product" under CPSIA. Motion, pp. 9-10. This argument is persuasive and well-supported by the evidence.

Complainant does not present any evidence to establish that a genuine issue of material fact still remains. In her Request for Hearing, Complainant makes a "complaint that medical devices and drug development industry employees are excluded from OSHA [CPSIA] whistleblower protection laws." That complaint, regardless of its merit, does not alter the fact that Complainant's activity was taken in relation to a medical device. To the extent that Complainant is requesting me to extend of the CPSIA whistleblower protection to encompass medical devices which are subject to the FDCA, I decline to do so.

In her Response to the Motion for Summary Decision, Complainant argues that ArcherDX products are analogous to a genetic test, which could be a consumer product. She offers no evidence on which a reasonable fact-finder could conclude that an IVD companion diagnostic device, or any other ArcherDX product, is analogous to a genetic test directly available to consumers. The argument of analogy is not persuasive.

Complainant also argued in her Response that, even if the product at issue "were a medical device, scientists should be protected." Whether scientists are generally afforded adequate whistleblower protections is not an issue I can decide here. As Complainant's activity in informing her employer of inaccurate data was related to a medical device, I can only decide that the whistleblower protections of CPSIA do not apply to her in this case.

IV. CONCLUSION

The device which was the subject of the concerns Complainant voiced to her employer is not a "consumer product" within the meaning of the CPSIA. Accordingly, Complainant's complaint of retaliation does not fall within the whistleblower protections of the CPSIA. There

is no genuine issue as to any material fact, and Respondent is entitled to judgment as a matter of law.

Respondent's Motion for Summary Decision is GRANTED. Complainant's complaint is DISMISSED. All dates are VACATED.

SO ORDERED.

SUSAN HOFFMAN
Administrative Law Judge