

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Atty's Parti Expo, Inc., d/b/a Parti Expo
Docket No. A-18-22
Decision No. 2871
May 24, 2018

REMAND OF
ADMINISTRATIVE LAW JUDGE DECISION

Atty's Parti Expo, Inc., d/b/a Parti Expo (Parti Expo or Respondent) appeals the November 30, 2017 initial Decision of an Administrative Law Judge (ALJ) imposing a 30-calendar-day No-Tobacco-Sale Order (NTSO) against Parti Expo for five repeated violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq., and its implementing regulations, over a period of 36 months. *Atty's Parti Expo, Inc., d/b/a Parti Expo*, DAB TB2263 (2017) (ALJ Decision or Decision). The ALJ issued her Decision following a hearing on an administrative complaint (Complaint) filed by the Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) in which CTP alleged that during an FDA inspection on November 13, 2015, Respondent's staff 1) sold a package of cigarettes to a person younger than 18 years of age and 2) did not verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. The Complaint also alleged that Respondent admitted to previously selling tobacco products to a minor on March 1, 2014, July 31, 2014, and April 18, 2015 and to failing to verify the age of a purchaser via photographic identification on March 1, 2014 and July 31, 2014. The ALJ concluded that the evidence of record supported the allegations in the Complaint and provided a basis for imposition of an NTSO. We do not reach the merits of the ALJ Decision because, for reasons explained below, we conclude it is necessary to remand the Decision to the ALJ for further proceedings consistent with our decision.

Applicable Law

The Act prohibits “the doing of any . . . act” with respect to a tobacco product “held for sale . . . after shipment in interstate commerce” that results in the product being “misbranded” and authorizes the FDA to impose certain remedies against any person who intentionally violates that prohibition. 21 U.S.C. §§ 331(k), 333. A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under section 387f(d) of the Act. *Id.* § 387c(a)(7)(B). Congress authorized the Secretary of Health & Human Services (Secretary) to adopt regulations that impose “restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and

the advertising and promotion of, the tobacco product” as appropriate to protect public health. *Id.* § 387f(d). Congress also directed the Secretary to establish CTP within the FDA to implement the tobacco products provisions of the Act. 21 U.S.C. § 387a(e). The regulations adopted by the Secretary provide that “[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age.” They also require retailers “to verify by means of photographic identification containing the bearer’s date of birth that no purchaser of the [tobacco] products is younger than 18 years of age,” except that “[n]o such verification is needed for any person over the age of 26[.]” 21 C.F.R. §§ 1140.14(a)(1) and (a)(2)(i).¹

CTP may impose civil money penalties (CMPs) against “any person who violates a requirement of [the Act] which relates to tobacco products” 21 U.S.C. § 333(f)(9). CTP also may impose an NTSO (alone or in addition to a CMP) when it finds “that a person has committed repeated violations of restrictions promulgated under section 387f(d) . . . at a particular retail outlet” *Id.* § 333(f)(8). “Repeated violations” is defined as “at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation. . . .” Act § 103(q)(1)(a); *See also* FDA Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers: Guidance for Industry (December 2016) at 3, 5-6, *available at* <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf>.

A person is entitled to a hearing before an NTSO is entered. 21 U.S.C. § 333(f)(8). The Act does not specify the duration of an NTSO but does specify the factors that must be considered in determining the length of an NTSO: “the nature, circumstances, extent, and gravity of the . . . violations and, with respect to the violator, . . . , effect on ability to continue to do business[;] any history of prior such violations[;] the degree of culpability[;] and such other matters as justice may require.” *Id.* §333(f)(5)(B). CTP policy guidelines establish 30 calendar days as the maximum NTSO duration for a first NTSO. *See* Determination Guidance for Tobacco Retailers (August 2015) at 4, *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf>.

The CMP hearing regulations permit a retailer to appeal a CMP by requesting a hearing before a “presiding officer” who is “an [ALJ] qualified under 5 U.S.C. 3105.” 21 C.F.R. §§ 17.3(c), 17.9(a). CTP initiates a case before the ALJ by serving a Complaint on the retailer (21 C.F.R. § 17.5) and filing it with the Civil Remedies Division (CRD) of the Departmental Appeals Board (DAB). The retailer (the respondent in the administrative

¹ At the time of the FDA inspections at issue here, these regulations were codified at 21 C.F.R. 1140.14(a) and (b). Effective August 8, 2016, the regulations were recodified to the sections to which we cite without any substantive change. 81 FR 28,973, 28,974, 29,103; *see* <https://federalregister.gov/a/2016-10685>.

appeal proceedings) requests a hearing by filing an answer to the complaint within 30 days but may request one 30-day extension. *Id.* § 17.9(a), (c). If the respondent does not file an answer within the prescribed time, the ALJ “shall assume the facts alleged in the Complaint to be true” and enter a default judgment “if such facts establish liability under the relevant statute” *Id.* § 17.11(a). Assuming a timely answer, the case proceeds to hearing before the ALJ according to the procedures set forth in 21 C.F.R. Part 17.

A respondent dissatisfied with an ALJ decision may appeal that decision (which the regulations refer to as the “initial decision”) to the DAB. 21 C.F.R. §§ 17.45, 17.47. The Board “may decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion), or reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined by” the ALJ. *Id.* § 17.47(j).

Case Background²

1. The Complaint and the Hearing

On September 23, 2016, CTP served a Complaint (dated September 21, 2016) on Parti Expo at its place of business, 15201 W. 7 Mile Road, Detroit, MI 48235. The Complaint sought to impose an NTSO as a remedy for five repeated violations of FDA’s tobacco regulations over a period of 36 months. ALJ Decision at 2; CRD Docket (Dkt.) Entry 1 and 1a. The Complaint alleged that on November 13, 2015, an FDA-commissioned inspector inspected Parti Expo and found the following violations of the Act and regulations: 1) impermissibly selling tobacco products to a minor in violation of 21 C.F.R. § 1140.14(a)(1) and 2) failing to verify the purchaser was 18 years of age or older by means of photo identification containing a date of birth in violation of 21 C.F.R. § 1140.14(a)(2)(i). ALJ Decision at 1-2; CRD Dkt. Entry 1, ¶ 10. The Complaint specifically alleged that during the inspection, “a person younger than 18 years of age was able to purchase a package of Newport Box 100s on November 13, 2015 at approximately 2:07 PM” and that “the minor’s identification was not verified before the sale, as detailed above, on November 13, 2015, at approximately 2:07 PM.” *Id.* CTP filed a copy of the Complaint with the CRD to initiate the proceedings leading to this appeal. ALJ Decision at 2; CRD Dkt. Entry 1.

In addition to charging Parti Expo with the alleged violations found on the November 13, 2015 inspection, the Complaint noted that the CRD had closed two prior CMP actions involving complaints filed by CTP after Parti Expo admitted to the allegations in those

² The factual findings stated here are taken from the ALJ Decision and the administrative record. We make no new findings of fact, and the facts stated are undisputed unless we indicate otherwise.

complaints and paid the agreed upon CMPs.³ ALJ Decision at 2, citing Complaint ¶¶ 1, 10, 13-15. These prior actions involved one original violation and two repeated violations of the regulation prohibiting sale of tobacco products to a minor and one original violation and one repeated violation of failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth. *Id.*

On October 19, 2016, Parti Expo, through counsel, filed an Answer denying the allegations in the Complaint but admitting the previous case history. ALJ Decision at 2. CRD Dkt. Entries 3 and 3a-f. On November 15, 2016, the ALJ issued an Acknowledgment and Pre-hearing Order (APHO) which acknowledged receipt of the Answer and specified (among other things) the following:

A party must exchange as a proposed exhibit the complete written direct testimony of any proposed witness. Generally, I will accept that witness' written direct testimony as a statement in lieu of in-person testimony. A witness statement must be submitted in the form of a written declaration that is signed by the witness under penalty of perjury for false testimony. *See* 21 C.F.R. § 17.25(a), 17.37(b).

CRD Dkt. Entry 5. On January 9, 2017, CTP moved for a protective order in response to a discovery request filed on December 28, 2016 by Parti Expo. ALJ Decision at 2, n.2; CRD Dkt. Entries 7, 8, 9. Respondent filed objections to the motion, but the ALJ granted the protective order. ALJ Decision at 2, n.2; CRD Dkt. Entries 11-16. On April 7, 2017, CTP filed a prehearing brief, an exhibit and witness list and 25 exhibits numbered 1-25; exhibits 24 and 25 were sworn declarations containing the written direct testimony of CTP's two proposed witnesses. ALJ Decision at 2; CRD Dkt. Entries 17 and 17a-z. On May 1, 2017, Parti Expo filed its prehearing brief, an exhibit and witness list, and seven exhibits marked A-G, which included – as Respondent (R.) Exhibit (Ex.) C – a document titled “Johnny Atty Statement” that was described on Parti Expo's witness and exhibit list as “Sworn Statement by Johnny Atty.” ALJ Decision at 2-3; CRD Dkt. Entries 18 and 18a-h. Parti Expo's witness list proposed two additional witnesses for whom Parti Expo submitted no written statements. CRD Dkt. Entry 18; *see also* ALJ Decision at 3 (noting that “Respondent's exhibits included a written statement of one witness, Mr. Johnny Atty.”).

³ The prior violations occurred on March 1, 2014 (sale to a minor and failure to verify age); July 31, 2014 (same) and April 18, 2015 (sale to a minor), but CTP only sent a warning letter for the violations that occurred on March 1, 2014 and did not count the violations from that date when calculating the total five repeated violations within a 36-month period. *See* Complaint ¶¶ 1 (and the table that follows), 15.

CTP filed a motion asking the ALJ to exclude two witnesses proposed by Parti Expo. ALJ Decision at 3; CRD Dkt. Entry 20. CTP noted that Parti Expo's list of proposed witnesses included Mr. Atty and two other proposed witnesses but then stated,

However, Respondent has provided Complainant the written testimony of only one of these three proposed witnesses, the declaration of Johnny Atty. *See* Dkt. 18d [Parti Expo Ex. C]. For the other two proposed witnesses . . . Respondent briefly described what such witnesses may testify about, *see* Dkt. 18b, but has not provided the complete written testimony of these proposed witnesses

Motion to Exclude Evidence Not Exchanged in Accordance with 21 C.F.R. §§ 17.25 and 17.37(b) (Motion to Exclude) at 3. Referring to CTP's Motion to Exclude, the ALJ stated, "In that motion, CTP asked that I exclude the testimony of two of Respondent's proposed witnesses because Respondent failed to include their sworn statements with its exchange." ALJ Decision at 3.

The ALJ held a pre-hearing conference on June 9, 2017. The order summarizing the conference states:

During the prehearing conference call, I explained that the sole purpose of a hearing under the applicable regulations is to allow for the cross-examination and re-direct of any witnesses who have provided sworn testimony in pre-hearing exchanges, and only if the opposing party elects to cross-examine the witness... [Respondent's counsel] communicated his intent to stipulate to [CTP's Senior Regulatory Counsel's] statements. [CTP counsel] communicated her desire to cross-examine Respondent's only witness who provided written testimony under oath as part of the exchange, Mr. Johnny Atty.

Order Scheduling In-Person Telephone Hearing and Granting CTP's Motion to Exclude Evidence Not Exchanged In Accordance With 21 C.F.R. §§ 17.25 and 17.37(b) (Pre-hearing Conference Order) at 1-2; *see* CRD Dkt. Entry 24. In the Pre-hearing Conference Order the ALJ also granted CTP's Motion to Exclude, stating as follows:

During the prehearing conference call, I informed the parties of my ruling on the arguments presented in CTP's . . . Motion to Exclude Evidence, and Respondent's . . . Opposition. I noted that Respondent's exchange only included written testimony under oath from one witness, Johnny Atty, the third co-owner of the business, and none from the two other co-owners who were named on Respondent's witness list. Accordingly, Mr. Johnny Atty is the only witness for Respondent eligible to appear at the hearing. For these reasons CTP's Motion to Exclude Evidence is GRANTED.

Id. at 2.

The ALJ held a hearing on August 17, 2017, at which she admitted the parties' exhibits⁴ and heard cross-examination and re-direct testimony from CTP's witness, the FDA inspector who conducted the November 13, 2015 inspection at Parti Expo. ALJ Decision at 3. CTP's counsel decided not to cross-examine Johnny Atty. *Id.* Parti Expo filed a post-hearing brief.

2. The ALJ Decision

The ALJ found "an abundance of evidence" to support the Complaint allegations that on November 13, 2015, Parti Expo violated 21 C.F.R. §§ 1140.14(a)(1) and (a)(2)(i) by selling tobacco products to a minor and failing to verify that the purchaser of the tobacco products was of sufficient age to lawfully make the purchase.⁵ ALJ Decision at 9. Based on these findings and on Parti Expo's admission to the prior repeated violations, the ALJ concluded that CTP had a basis to impose an NTSO under 21 U.S.C. § 333(f)(8). In reaching her conclusion, the ALJ found that Parti Expo "ha[d] failed to provide sufficient evidence to rebut CTP's allegation." *Id.*

In the Decision, the ALJ relied heavily on the direct and cross-examination testimony of the FDA inspector, who she found "testified credibly and comprehensively about his observations during the November 13, 2015, inspection at which he observed Respondent selling tobacco products to Minor 433." ALJ Decision at 7 (citing Hearing Transcript at 15-37, 45; Shafto [the inspector's name] Declaration, CTP Ex. 24; Narrative Report, CTP Ex. 9⁶); *see also id.*, at 8-9 (discussion of the inspector's testimony). In particular, the ALJ found that the inspector "testified credibly regarding the description of the employee" and that "Respondent failed to support its argument that no employee matches this description." *Id.* at 9.

⁴ With its appeal to the Board, Parti Expo submitted a document entitled "Affidavit of Johnny Atty" that differed in some respects (including the title) from the "Johnny Atty Statement" submitted to the ALJ and admitted to the record as Respondent exhibit C. During oral argument, which the Board held at Mr. Atty's request on March 15, 2018, the Presiding Board Member ruled that the "Affidavit of Johnny Atty" would not be considered by the Board since it was not part of the record before the ALJ. Transcript of Oral Argument at 5-6. The Presiding Board Member, "[o]n the other hand, . . . recognize[d] the presence" in the record of the document entitled "Johnny Atty Statement" but emphasized that this recognition was "no[t] [a] determination regarding the dispute about the document" by herself or the other panel members hearing the appeal. *Id.* Counsel for Parti Expo did not challenge the Presiding Board Member's ruling.

⁵ On page 9 of the Decision, the ALJ stated the date of the inspection as November "15," 2015, but this is clearly a typographical error. *See* ALJ Decision at 2, 5, 6, 7, 10, 12; Complaint ¶10. Since there is no dispute that inspection occurred on November 13, 2015, the error would not be material in any event.

⁶ The ALJ's citation to CTP exhibit 9 as the inspector's narrative report is not correct. The narrative report (by the inspector) she cites is in CTP Exhibit 18. Again, this appears to be a typographical error that is not material since there is no dispute that the narrative report is in the record as CTP exhibit 18.

Without some corroborating evidence[,] for example, a written policy that all employees must be clean shaven in effect **during the time period at issue**, or footage of the employee in question on that day, this assertion does not hold water. Moreover, Respondent should have maintained the video footage of the date and time specified in the November 18, 2015 Notice of Compliance Check Inspection.

Id. The ALJ noted Parti Expo’s request in its post-hearing brief that the ALJ give Johnny Atty’s statement “proper attention as rebuttal and counter evidence.” *Id.*, citing Respondent’s Post-hearing Brief ¶ VII. In his statement, Mr. Atty challenged the inspector’s description of the employee as having a beard, “because,” Mr. Atty stated, “we require everyone who works for us to shave their face clean at all times.” R. Ex. C. Earlier in the Decision, the ALJ had noted that this statement “is not, in fact, a ‘sworn statement,’ but[,] rather, an offer to provide one. *See* Mr. Johnny Atty’s statement, (“Exhibit C”) at 2 (‘I am willing to testify to this under oath and under penalty of perjury if necessary.’)” ALJ Decision at 3, n.3. Now, the ALJ rejected Parti Expo’s request to give the statement “proper attention as rebuttal and counter evidence.” *Id.* at 9. Explaining her rejection, the ALJ (citing the earlier footnote) “reiterate[d] that Mr. Atty’s statement is not a declaration under oath.” *Id.* at 9. She then stated that “[b]ecause Mr. Atty’s statement does not constitute a written declaration that is signed by the witness under oath, I cannot accord it such weight.” *Id.* The ALJ went on to conclude, “Even if I were to consider Mr. Atty’s statement and the fact that CTP did not raise an objection to the statement, the evidence in support of CTP’s allegations is overwhelming. Moreover, Respondent’s counsel should have complied with the APHO requirement if he wanted Mr. Atty’s statement to be accorded the same weight as a sworn declaration.” *Id.*

Standard of review

“The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.” 21 C.F.R. § 17.47(k).

Analysis

We do not review the ALJ Decision on the merits at this time because Parti Expo has alleged a procedural error that we conclude is harmful and needs to be addressed by the ALJ on remand.⁷ Parti Expo argues that the ALJ Decision “improperly minimizes the value and weight of Johnny Atty’s sworn statement, while affording full weight and credibility to that of the inspector, despite the Complainant’s refusal to cross-examine him after requiring him to appear at the hearing.” Respondent’s Appeal and Post-Hearing

⁷ For the same reason, we do not address the additional arguments made by Parti Expo on appeal.

Brief (Appeal Br.) In Support at 1; *see also* Appeal Br. at 2 (asserting that the ALJ’s finding in footnote 3 of the ALJ Decision that Mr. Atty’s statement was merely an offer to provide a sworn statement, not itself a sworn statement, “is not reflective of [the ALJ’s Prehearing Conference Order] and is not stated anywhere in that opinion that was subject to a contentious dispute over who can testify at the hearing”). As we indicated above, the ALJ concluded that “Mr. Atty’s statement [R. Ex. C] does not constitute a written declaration that is signed by the witness under oath[.]” and for that reason, she could not accord the statement “the same weight as a sworn declaration.” ALJ Decision at 9. Parti Expo argues that the ALJ’s conclusion is inconsistent with her treatment of the same statement during the pre-hearing process. Parti Expo points to the ALJ’s acknowledgment in the Decision that, “[d]uring the prehearing conference,” she granted CTP’s motion to exclude all of Respondent’s witnesses except for Mr. Atty because “Respondent’s exchange only included ‘written testimony under oath from one witness, Johnny Atty, the third co-owner of the business and none from the two other co-owners who were named on Respondent’s witness list.’” Appeal Br. at 2, citing ALJ Decision at 3. Parti Expo argues, in effect, that the ALJ’s exclusion of its other two witnesses and the language “written testimony under oath from one witness, Johnny Atty” shows that the ALJ communicated to the parties that she regarded Johnny Atty’s statement as a sworn statement, and the parties proceeded to hearing with that understanding. Parti Expo also cites the fact that CTP’s counsel did not object to the statement and expressed a desire to cross-examine Mr. Atty at the hearing – although CTP ultimately did not do so – and the fact that the statement “was accepted for the record.” *Id.* Based on these facts, Parti Expo asserts that prior to the hearing, “[I]t was understood that Mr. Atty’s statement was a sworn statement under oath.” *Id.* Parti Expo argues, in effect, that the ALJ’s inconsistent treatment of the Johnny Atty statement prejudiced its ability to present its case and, in particular, its ability to counter the testimony of the FDA inspector relied on by the ALJ in the Decision. Parti Expo also appears to suggest that CTP’s decision at the hearing to not cross-examine Mr. Atty compounded the prejudice to Parti Expo by depriving it of an opportunity to provide in-person testimony on cross-examination which would have effectively removed any question about the statement’s qualifications as evidence.

We conclude that the record supports Parti Expo’s position that the ALJ’s treatment of the statement as unsworn in her decision is inconsistent with her treatment of the same statement as “written testimony under oath” before the hearing. We also note that the ALJ continued to treat the statement as sworn written testimony during the hearing. She referred to Mr. Atty’s statement as “a statement under oath” and swore in Mr. Atty in anticipation that CTP would cross-examine him, although ultimately CTP chose not to do so. Hearing Transcript at 7, 9, 45. Given these record facts, it was reasonable for Parti Expo to assume that in the Decision, the ALJ would treat Mr. Atty’s statement as written direct testimony and weigh that testimony against the other evidence of record, including the written direct testimony and cross-examination testimony of the FDA inspector. Yet, the ALJ acknowledged that she did not do this when she stated in the Decision, “Because

Mr. Atty's statement does not constitute a written declaration that is signed by the witness under oath, I cannot accord it such weight." ALJ Decision at 9.

We conclude that the ALJ's inconsistent treatment of the Atty statement was harmful error because it "affect[ed] the substantial right" of Parti Expo to a fair hearing and it would "be inconsistent with substantial justice" for the Board to decline to act to remedy this error. 21 C.F.R. § 17.48. Accordingly, we have decided to remand the case to the ALJ with instructions to provide Parti Expo with an opportunity to refile a statement of Johnny Atty (with the same text as the statement currently in the record as Respondent exhibit C) that complies with 21 C.F.R. §§ 17.25(a), 17.37(b) and the ALJ's APHO.⁸ Assuming Parti Expo uses this opportunity, the ALJ shall then determine whether the refiled statement meets the requirements of 21 C.F.R. §§ 17.25(a), 17.37(b) and the ALJ's APHO. If the ALJ concludes that the refiled statement does meet those requirements, she shall conduct such further proceedings as necessary to reach a decision that treats the statement as written direct testimony, weighs it against the other evidence of record and is otherwise consistent with "substantial justice."⁹

In remanding, we make no finding as to whether the ALJ's conclusion that the Atty statement currently in the record (R. Ex. C) does not constitute a sworn statement meeting the requirements of 21 C.F.R. §§ 17.25(a) and 17.37(b) was legally sound or whether the ALJ had a basis for rejecting the statement or taking other action based on the failure of Parti Expo or its counsel to comply with the ALJ's APHO. Nor should our remand be construed as an opportunity for Mr. Atty to change the content of his statement, as opposed to its form. We also make no finding regarding the ALJ's treatment of CTP's evidence or her determinations regarding the credibility or weight to be accorded either party's evidence.

In reaching our decision, we considered whether the harm to Parti Expo could have been cured by the ALJ's statement that, "[e]ven if I were to consider Mr. Atty's statement and the fact that CTP did not raise an objection to the statement, the evidence in support of

⁸ We are cognizant that while 21 C.F.R. § 17.47 specifically addresses "remand [of] any [CMP] determined by the presiding officer . . . ," it does not mention remand in the context of an initial decision imposing an NTSO. On the other hand, the regulations do not prohibit remand in the context of cases involving lawful remedies other than CMPs or, for that matter, for reasons other than the reason identified in section 17.47. We conclude that authority to remand as necessary to assure that proceedings are consistent with the "substantial justice" standard in 21 C.F.R. § 17.48, a standard consistent with principles of jurisprudence generally, is implicit in section 17.47.

⁹ Since CTP declined to cross-examine Mr. Atty at a time when the record shows that CTP and the ALJ treated his then statement of record as properly sworn written direct testimony, we find no reason to instruct the ALJ to give CTP an opportunity to conduct cross-examination on the new statement, should the ALJ admit it as written direct testimony (and assuming no change in content). However, the ALJ is free to conduct whatever proceedings she deems necessary to assure substantial justice.

CTP's allegations is overwhelming." ALJ Decision at 9. We concluded that the statement was insufficient to cure the harm. The ALJ's statement indicates that the ALJ considered only the evidence supporting CTP's allegations – which she found "overwhelming" – instead of weighing that evidence against Mr. Atty's statement. Indeed, the ALJ's finding that Mr. Atty's statement was not a properly sworn statement was, in essence, a finding that his statement did not qualify as evidence (in the form of written direct testimony) and, thus, could not be weighed against the other evidence of record. This other evidence of record included the testimony of the FDA inspector, which substantially influenced the ALJ Decision, and some of which Mr. Atty attempted to challenge in his statement.

Conclusion

We conclude that the ALJ's determination in her Decision not to accord Johnny Atty's statement (R. Ex. C) "the same weight as a sworn declaration," under the circumstances here, was an error that adversely affected Parti Expo's fundamental right to a fair hearing, inasmuch as the ALJ's treatment of the same statement prior to and during the hearing gave Parti Expo reason to believe that the statement would be accorded such weight, and we remand the Decision for further proceedings consistent with our decision, including the instructions stated above.

/s/
Christopher S. Randolph

/s/
Leslie A. Sussan

/s/
Sheila Ann Hegy
Presiding Board Member