

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-R-2796)

Complainant

v.

Atty's Parti Expo, Inc.
d/b/a Parti Expo,

Respondent.

Docket No. T-16-1990

Decision No. TB2906

Date: July 6, 2018

DECISION

This case is before me on remand from the Department of Health and Human Services, Departmental Appeals Board, Appellate Division (“the Board”). I have complied with the Board’s instructions set forth in full on page 3 of this decision. After careful review and consideration of the entire the record as presently constituted, I sustain the determination of the Center for Tobacco Products (“CTP”) of the United States Food and Drug Administration (“FDA”) to impose a 30-day prohibition on the sale of tobacco products, No-Tobacco-Sale-Order (“NTSO”), against Respondent Atty’s Parti Expo, Inc. d/b/a Parti Expo. Accordingly, I again impose an NTSO against Respondent Parti Expo for a period of 30 calendar days, for five repeated violations of federal tobacco regulations over a period of 36 months.

I. Background and Procedural History

On September 26, 2016, CTP filed an administrative complaint against Respondent alleging that Respondent’s staff impermissibly sold tobacco products to minors and failed

to verify that tobacco product purchasers were of sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 301 et seq., and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140. The complaint likewise alleges that Respondent Parti Expo previously admitted to violations of regulations found at 21 C.F.R. pt. 1140.

On October 19, 2016, Respondent's counsel timely filed an Answer to Complaint and Request for Hearing ("Answer"). On November 15, 2016, I issued an Acknowledgment and Pre-Hearing Order ("APHO") that set out the deadlines for the parties' submissions in this case, and informal briefs for the parties to submit.

On April 7, 2017, CTP filed its pre-hearing exchange. CTP's pre-hearing exchange included an Informal Brief of Complainant, a list of proposed witnesses and exhibits, and twenty-five numbered exhibits. CTP's exhibits included the declarations of two witnesses. On May 1, 2017, Respondent filed its pre-hearing exchange. Respondent's pre-hearing exchange included an Informal Brief, a list of proposed witnesses and exhibits, and seven exhibits marked A-G. Respondent's exhibits included a document entitled "Johnny Atty Statement." Respondent described that statement in its proposed witness list as "Sworn Statement by Johnny Atty," and on the electronic docket as "Exhibit C-Sworn Statement by Johnny Atty."

On May 17, 2017, CTP filed a Motion to Exclude Evidence not Exchanged in Accordance with 21 C.F.R. §§ 17.25 and 17.37(b) ("Motion to Exclude Evidence"). In that motion, CTP asked that I exclude the testimony of two of Respondent's proposed witnesses, Muhsin Atty and Issam Atty, because Respondent failed to include their sworn statements with its exchange. On May 24, 2017, Respondent filed an opposition to CTP's motion.

Prehearing Conference and Hearing

On June 9, 2017, I held a pre-hearing conference in this case. During the prehearing conference, I explained that the sole purpose of a hearing under the applicable regulations was to allow for the cross-examination and re-direct of any witnesses who had provided sworn testimony in pre-hearing exchanges, and only if the opposing party elected to cross-examine the witness. Respondent's counsel communicated his desire to cross-examine only one of CTP's witnesses, Inspector Timothy Shafto, and declined to cross-examine Ms. Laurie Sternberg. CTP's counsel communicated her desire to cross-examine Mr. Johnny Atty.

During the prehearing conference, I also informed the parties of my ruling on the arguments presented in CTP's May 17, 2017 Motion to Exclude Evidence, and Respondent's May 24, 2017 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, I ruled that Mr. Johnny Atty was the only witness for Respondent eligible to appear at the hearing. On June 14, 2017, I

memorialized my ruling in an order scheduling a hearing and granting CTP's Motion to Exclude Evidence.

On August 17, 2017, I held a hearing in during which I admitted the parties' exhibits. Respondent's counsel cross-examined Inspector Shafto. *See* Hearing Transcript at 10-40. CTP then conducted a redirect examination of Inspector Shafto. *See* Hearing Transcript at 40-45. Although I administered the oath to Inspector Shafto and Mr. Atty, CTP's Counsel declined to cross-examine Mr. Atty.

On September 8, 2017, I informed the parties that the Court had received the transcript of the hearing, and set the deadline of October 5, 2017, for the parties' post-hearing brief submissions. Respondent filed a post-hearing brief ("Respondent's Post-hearing Brief").

Initial Decision and Appeal

On November 30, 2017, I issued an Initial Decision imposing a No-Tobacco-Sale Order against Respondent Parti Expo for a period of 30 consecutive calendar days, for five repeated violations of federal tobacco regulations over a period of 36 months. In the Initial Decision, I noted that Mr. Johnny Atty's statement is not, in fact, a "sworn statement," but rather, an offer to provide one. *See* Initial Decision at 3 n. 3. Accordingly, I declined to accord it the same weight as a written declaration that is "signed by a witness under penalty of perjury for false testimony." *Id.* at 9. Respondent appealed the Initial Decision.

On May 24, 2018, the Board issued a Remand of Administrative Law Judge Decision ("Remand Decision"). While the Board did not "reach the merits" of the Initial Decision, *see* Remand Decision at 1, the Board explained:

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. 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."

Remand Decision at 9 (footnotes omitted). On May 30, 2018, I issued an order allowing Respondent until June 8, 2018, to refile a statement of Johnny Atty, as specified in the

Remand Decision. On June 8, 2018, Respondent’s Counsel filed a Declaration of Johnny Atty, Co-Owner of Artty’s Parti Expo and the Johnny Atty Statement (“Atty Declaration”).

II. Issues

- A. Whether the Atty Declaration meets the requirements of 21 C.F.R. §§ 17.25(a), 17.37(b) and the November 15, 2016 APHO.
- B. Whether the evidence on the record, including the Atty Declaration, supports a finding that Respondent sold tobacco products to a minor and failed to verify that the tobacco product purchaser was of sufficient age on November 13, 2015, in violation of 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i).
- C. Whether the NTSO for a period of 30 calendar days is reasonable.

III. Analysis

A. Atty Declaration

I find that the June 8, 2018 Atty Declaration meets the requirements of 21 C.F.R. §§ 17.25(a), 17.37(b) and the November 15, 2016 APHO. At the prehearing conference and hearing, the court understood the Johnny Atty Statement to be a sworn declaration because it was described as “Exhibit C-Sworn Statement by Johnny Atty.” The court became aware of the oversight during a final review of the evidence on the record prior to issuing the decision and noted it in the Initial Decision. *See* Initial Decision at 3 n.3.

Under 21 C.F.R. § 17.25(a), “[a]t least 30 days before the hearing . . . the parties shall exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including written testimony.” Under 21 C.F.R. § 17.25(a). The regulations further provide:

Direct testimony shall be admitted in the form of a written declaration submitted under penalty of perjury. Any such written declaration must be provided to all other parties along with the last known address of the witness. Any prior written statements of witnesses proposed to testify at the hearing shall be exchanged as provided in §17.25(a).

21 C.F.R. § 17.37(b). My November 15, 2016 APHO contained instructions regarding a party’s submission of written direct testimony, including 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).

APHO ¶ 9. I find that the Atty Declaration appears to contain the same text as the statement currently in the record as Respondent Exhibit (Ex.) C. Because Respondent attached the statement to a declaration signed by Mr. Johnny Atty under penalty and perjury for false testimony, I hereby admit the Atty Declaration as written direct testimony in lieu of in-person testimony.¹ *See* APHO ¶ 9.

B. Alleged Violations and Evidence on the Record

After according the Atty Declaration the same weight as written direct testimony and weighing it against the other evidence of the record, I find that Respondent failed to provide sufficient evidence to refute CTP's evidence. The Board did not make a finding regarding my treatment of CTP's evidence or my determinations regarding the credibility or weight to be "accorded either party's evidence." Remand Decision at 9. Accordingly, the factual findings in the Initial Decision are incorporated herein and I will restate or refer to the Initial Decision as appropriate.

Current Allegations

This is the third enforcement complaint filed by CTP against Respondent. Respondent has conceded that the past violations occurred. Answer ¶¶ 12-14; Initial Decision at 4, 10, 11-12. The two prior complaints are administratively final and uncontested.

CTP alleges that Respondent committed five repeated violations of the Act and its implementing regulations over a 36-month period. *See* Complaint ¶ 1. CTP states that it did not include any repeated violations that occurred outside of the 36-month period or any violations of other Act sections that are not at issue in this case. *Id.* n.1.

Specifically, CTP alleged that at approximately 2:07 p.m. on November 13, 2015, at Respondent's business establishment, 15201 West 7 Mile Road, Detroit, Michigan 48235, an FDA commissioned inspector documented Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age. Complaint ¶ 10; *see* Informal Brief of Complainant at 3. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. *Id.*

Respondent's Rebuttal

Respondent denied the "allegations stated in the Complaint, including the latest alleged violation." Answer ¶¶ 1, 10, 15. Respondent also denied having violated the enumerated statutes "in a manner that authorizes the FDA to impose the NTSO." Answer ¶¶ 2-7.

¹ CTP declined to cross-examine Mr. Atty during the hearing and the Board did not require a new hearing. *See* Remand Decision at 9 n.9.

Respondent declined to admit or deny that an “FDA -commissioned inspector conducted an inspection of Parti Expo on [November 13, 2015], as no notification of inspection was provided that day, nor was any notice of violation.”² Answer ¶ 10. Respondent admits that it has been the subject of two prior CTP Civil Money Penalty (“CMP”) actions based on its violations of the Act; and appears to concede that the record is correct “regarding any past violations and previous settlements.” Answer ¶¶ 12-14.

Respondent has submitted the Atty Declaration for consideration “as rebuttal and counter evidence.” *See* Respondent’s Post-Hearing Brief ¶ VII. In the Atty Declaration, Mr. Atty testified that his business provides strict training to employees to prevent unlawful alcohol and tobacco sales and that his business has signs all over the store to reinforce this policy. Mr. Atty denies that the November 13, 2015 violations occurred because no one that worked in the store then or at the time of the statement has a beard. Mr. Atty testified that he requires the employees to shave their face clean at all times. Mr. Atty testified that he reviewed the footage and that he did not see the alleged transaction. Mr. Atty testified that he informed his attorney that the CTP could send someone to review the tapes. Mr. Atty testified that the video footage disappeared after about 60 days and that he would have preserved the video if he knew that CTP would seek to impose an NTSO. Mr. Atty stated that his attorney sent a response letter to CTP and that he followed up with his attorney for several months to find out if his attorney had heard from CTP. Mr. Atty testified that he received the current Complaint at the end of September 2016, almost a year “after the ticket.” Finally, Mr. Atty testified that the NTSO would permanently destroy his business and would embarrass them “in the community, where [they]” have operated for over 20 years.

After a careful review of the Atty Declaration, I find that it states the same arguments and defenses that Respondent already raised in its Answer, pre-hearing brief, Parti Expo Letter to FDA (“Respondent’s Ex. B”), and post-hearing brief. I thoroughly addressed the parties’ contentions in the Initial Decision. *See* Initial Decision at 5 -10. Mr. Atty’s main argument in rebuttal remains “that the current violations did not occur and thus, a 30-day NTSO is inappropriate.” Initial Decision at 6. As discussed in the Initial Decision, CTP offered the testimony of Inspector Shafto, an FDA-commissioned officer with the Michigan Department of Health and Human Services. *Id.* Inspector Shafto testified that on November 13, 2015, he, accompanied by a confidential state-contracted minor, conducted an undercover buy portion of a follow-up compliance check inspection at Parti Expo. *Id.* at 6-7. On August 17, 2017, Respondent’s counsel cross-examined Inspector Shafto about his written direct testimony (“Shafto Declaration”). *See id.* at 7. I

² As in the Initial Decision, I note a discrepancy between Respondent’s assertion that it did not receive any notice of violation, and Respondent’s later assertion that on December 2, 2015, it issued a response to CTP’s November 18, 2015 Notice of Compliance Check Inspection. *See* Answer at 4; Parti Expo Letter to FDA (“Respondent’s Ex. B”).

also noted that Respondent's counsel asked questions that were outside the scope of the Shafto Declaration. *Id.* at 7 n.8.

Inspector Shafto testified credibly during the hearing. While Respondent's counsel attempted to discredit Inspector Shafto's testimony, I am convinced that Inspector Shafto testified truthfully about his November 13, 2015 documented observations. *See* Initial Decision at 7-9. I find the Atty Declaration to be a reiteration of Respondent's arguments and defenses presented elsewhere on the record. I stand by the analysis, findings of fact, and NTSO penalty determination that I made in the Initial Decision. *See* Initial Decision at 7-12. Even after admitting the Atty Declaration into evidence and giving it the appropriate weight, I find that Respondent failed to rebut the sworn testimony of Inspector Shafto and CTP's corroborating evidence. Accordingly, I find that CTP has established that on November 13, 2015, Respondent Atty's Party Expo, Inc. d/b/a Parti Expo, sold tobacco products to a minor and failed to verify that the tobacco product purchaser was of sufficient age, and Respondent is therefore liable under the Act. For these and the reasons previously set forth in the November 30, 2017 Initial Decision, I find that an NTSO is an appropriate penalty.

IV. Conclusion

For these reasons, I hereby impose a No-Tobacco-Sale Order against Respondent Atty's Parti Expo, Inc. d/b/a Parti Expo, for a period of 30 consecutive calendar days. During this period of time, Respondent shall stop selling cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and covered tobacco products regulated under the Federal Food, Drug, and Cosmetic Act. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/
Catherine Ravinski
Administrative Law Judge