Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Safeway Inc. d/b/a Safeway Fuel Store 4404
Docket No. A-16-65
Decision No. 2694
May 17, 2016

REMAND TO ADMINISTRATIVE LAW JUDGE

The Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) appealed the Order Dismissing Complaint issued by an Administrative Law Judge (ALJ) on March 22, 2016. CTP's Complaint sought assessment of a $250 civil money penalty (CMP) against Safeway Inc. d/b/a Safeway Fuel Store 4404 (Respondent) for violating the tobacco regulations promulgated by FDA under the Federal Food, Drug, and Cosmetic Act. CTP contends that, once Respondent failed to file a timely answer to the Complaint, the ALJ was required to issue an initial decision assessing the CMP without further proceedings. Instead, the ALJ ultimately dismissed the Complaint with prejudice based on his findings that CTP did not provide adequate proof of service of the Complaint on Respondent and failed to submit a motion for issuance of a default judgment, after being instructed by the ALJ to do both.

For the reasons explained below, we conclude that the ALJ did not exceed his authority by requiring that CTP establish that the Complaint was properly served or by requiring CTP to move for default judgment. However, we further conclude that the ALJ abused his discretion in dismissing the Complaint with prejudice because we find that the sanction was not reasonably related to the conduct for which it was imposed. Accordingly, we reverse the dismissal and remand to the ALJ for further proceedings.

Legal Background

The regulations at 21 C.F.R. Part 17 "set forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA" under various authorities, including section 303(f) of the Federal Food, Drug, and Cosmetic Act, which "authorizes civil money penalties for any person who violates a requirement of the Family Smoking Prevention and Tobacco Control Act which relates to tobacco products." 21 C.F.R. § 17.1(j). The "Center with principal jurisdiction over the matter," in this case, CTP, "shall begin all administrative civil money penalty actions by serving on the respondent(s) a complaint. . . ." 21 C.F.R. § 17.5(a). Section 17.7 of 21 C.F.R., titled "Service of complaint," reads as follows:

> (a) Service of a complaint may be made by:
> (1) Certified or registered mail or similar mail delivery service with a return receipt record reflecting receipt; or
> (2) Delivery in person to:
> (i) An individual respondent;
> (ii) An officer or managing or general agent in the case of a corporation or unincorporated business.
> (b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date or service, may be made by:
> (1) Affidavit or declaration under penalty of perjury of the individual serving the complaint by personal delivery;
> (2) A United States Postal Service or similar mail delivery service return receipt record reflecting receipt; or
> (3) Written acknowledgment of receipt by the respondent or by the respondent's counsel or authorized representative or agent.

The regulations require a respondent to answer the complaint within 30 days of service of the complaint or request, within that period, an extension of time to file the answer. 21 C.F.R. § 17.9(a), (c); *see also* 21 C.F.R. § 17.30(c) (providing that when a document has been served by mail, "an additional 5 days will be added to the time permitted for any response").

Section 17.11 of 21 C.F.R., titled "Default upon failure to file an answer," reads in relevant part as follows:

> (a) If the respondent does not file an answer within the time prescribed in § 17.9 and if service has been effected as provided in § 7.7, the presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing:
> (1) The maximum amount of penalties provided for by law for the violations alleged; or
> (2) The amount asked for in the complaint, whichever amount is smaller.

In addition, section 17.32 of 21 C.F.R., titled "Motions," states in relevant part, "Any application to the presiding officer for an order or ruling shall be by motion." 21 C.F.R. § 17.32(a).

Section 17.35, titled "Sanctions," authorizes the presiding officer to sanction a party for certain failures or misconduct. 21 C.F.R. § 17.35(a). Sanctions "shall reasonably relate to the severity and nature of the failure or misconduct." 21 C.F.R. § 17.35(b)(3).

Case Background[1]

In a Complaint dated October 5, 2015, CTP requested "that an order assessing a civil money penalty against Respondent in the amount of $250 be entered. . . ." Administrative Record (AR) 1, at 4. As proof of service, CTP provided a UPS "Proof of Delivery" notice sent on 10/14/2015 at 11:19 a.m. to "Dear Customer." The notice shows that a shipment identified only by the UPS tracking number was delivered on 10/12/2015 at 9:02 a.m. to Pleasanton, CA, signed for by "Eric," and left at "Receiver." AR 2.

In a February 3, 2016 Procedural Order, the ALJ stated that this notice "does not set forth all the information required to demonstrate proof of service of the complaint," citing 21 C.F.R. § 17.7. AR 3. The ALJ also stated: "Aside from the prayer for relief in the complaint, no application to the administrative law judge has been made requesting relief (21 C.FR. § 17.32). CTP may file a motion for default if it believes Respondent is in default." *Id*. Finally, the ALJ stated that, "[u]ntil 21 C.F.R. Part 17 is complied with in its entirety, this matter will not proceed." *Id*.

On March 9, 2016, the ALJ issued an Order to Show Cause incorporating the Procedural Order by reference and stating that no response to the Procedural Order had been received. The Order to Show Cause imposed a deadline for compliance and "described more fully . . . the Complainant's responsibilities to the Court." AR 5, at 1. The Order to Show Cause stated in part:

> The PROCEDURAL ORDER noted that the documents available at the date of the Order did not demonstrate proper service of the complaint. There is no evidence (for example, an authenticated certificate of service; an affidavit attesting to placing a specific complaint in a specific mailing envelope; a certified receipt number on an individual complaint) linking a specific complaint to a specific respondent. The Complainant may not rely upon any sort of presumption of administrative regularity in this regard, as the Respondent's due process rights hang in the balance.

[1] The procedural background is based on undisputed facts in the Order Dismissing Complaint and in the administrative record, which was provided to the Board by FDA's Division of Dockets Management. The index that accompanied the administrative record is attached to this decision. The last two items on the index, CTP's notice of appeal and brief, are not part of the record for the Order Dismissing Complaint but rather are part of the record of this appeal.

> A Court is not an extension of the "enforcement arm" of the Food and Drug Administration: the Court's function, consistent with the Administrative Procedure Act, is to adjudicate disputes and to ensure the parties receive notice and an opportunity to be heard. It is therefore not the part of the Court to move toward a resolution of a case absent some request to do so by a party before the Court. . . . . the Court is not empowered to act on its own motion.

Id. The ALJ proceeded to order CTP to show cause "why the Complaint should not be dismissed with prejudice in accordance with 21 C.F.R. § 17.35." AR 5, at 2. The ALJ also stated: "If the Complainant believes it has demonstrated the requisite proper service, it shall move for a default judgment. . . . Failure to do so will be construed as an abandonment of the complaint and will result in a dismissal with prejudice. 21 C.F.R. § 17.35." *Id*. Finally, the ALJ stated: "Failure to comply with this ORDER in any particular will result in a dismissal with prejudice." *Id*.

In its response to the Order to Show Cause, CTP took the position, which it also takes on appeal, that dismissal is not warranted because "service was effected consistent with the controlling regulation" and "there is no requirement that CTP file a motion seeking a default order" before an ALJ issues an initial decision imposing a CMP. AR 7, at 1. CTP also noted that, on February 11, 2016, in response to the Procedural Order, it filed a UPS "Delivery Notification." *Id*. at 2. The Delivery Notification is dated February 4, 2016 and provides further information in response to an inquiry from CTP. In particular, it shows a shipment consisting of "1 parcel" addressed to "Safeway Inc. Attn: William Harris, 5918 Stoneridge Mall Rd, Pleasanton, CA 94588"," with the same tracking number as on the 10/14/15 Proof of Delivery, was delivered on 10/12/15 at 9:02 a.m. and "signed for by Eric[.]" AR 4.

Standard of Review

The standard of review on a disputed issue of law is whether the initial decision is erroneous. 21 C.F.R. § 17.47(k). We review an ALJ's imposition of a sanction for abuse of discretion. *See, e.g., Guardian Care Nursing & Rehab. Ctr*., DAB No. 2260, at 3 (2009), citing *Osceola Nursing & Rehab. Ctr.*, DAB No. 1708 (1999).

Discussion

1. The ALJ did not err in requiring further evidence that the Complaint was properly served on Respondent.

CTP argues principally that, in requiring further evidence that the Complaint was properly served, the ALJ ignored the provisions of 21 C.F.R. § 17.7(b) allowing proof of service by a "United States Postal Service or similar mail delivery service return receipt record reflecting receipt[.]" Notice of Appeal at 2; *see also* Appeal Br. at 8-17.

According to CTP, the UPS Proof of Delivery and UPS Delivery Notification it filed in this case "comply with the plain requirements" of that regulation. Notice of Appeal at 2. CTP notes specifically that the UPS Delivery Notification "states the name and address of the person on whom the delivery was made, the manner of service (UPS), and the date of service," as required by that regulation. Appeal Br. at 10. CTP argues that, contrary to what the ALJ found, section 17.7(b) does not require that CTP provide evidence of what was in the parcel delivered to Respondent. According to CTP, there is "a presumption of regularity that ministerial steps, such as putting a complaint in a UPS parcel, were taken in accordance with the requirements of the law." Notice of Appeal at 3; *see also* Appeal Br. at 11 (citing court cases).

These arguments have no merit. It is true that section 17.7 does not expressly require that the proof of service state that what was served was the complaint. However, since the regulation is titled "Service of *complaint*" (emphasis added), it is implicit in the regulation that the proof of service must relate to the relevant complaint. As the ALJ found, neither of the UPS notices provided by CTP shows "that it was the complaint against the Respondent, and not . . . any other printed matter, that went into the envelope handled by the commercial courier." Order Dismissing Complaint at 2-3 (unnumbered). As the ALJ pointed out, once the content of what was in the package was questioned, multiple options existed to establish that the service was of the complaint in this matter, as required by the regulation. While the ALJ **might** have inferred that from the UPS notices filed by CTP, nothing in the regulations **required** him to draw that inference or precluded him from seeking more evidence to support it before cutting off statutory rights to a hearing.

Furthermore, while a presumption of regularity may indeed attach to performance of a ministerial task by a government office in accordance with regular practices, the ALJ could reasonably require CTP to show a factual basis for applying that presumption here, e.g., that CTP had a regular process for preparing complaints for mailing by UPS that provided a reasonable assurance that the parcel to which a proof of mailing such as the one at issue here referred contained the complaint. CTP does not suggest that it proffered any such evidence.

We also find no merit in CTP's other arguments. CTP argues that the ALJ failed to defer to CTP's interpretation of section 17.7, and in effect found it invalid, when he required CTP to prove more than what CTP says is required under controlling regulations regarding service. Appeal Br. at 12. Contrary to what CTP argues, however, the ALJ did not read section 17.7 as imposing requirements for service beyond those described by CTP. Instead, the ALJ simply required additional evidence to show that those requirements were met. Thus, he did not interpret the regulatory requirements differently than CTP did or find them invalid.

CTP also asserts that the "Board has upheld FDA's service regulation as valid and expressly held that it does not require personal service." Appeal Br. at 9, citing *Korangy Radiology Associates, P.A. t/a Baltimore Imaging Centers*, DAB No. 1996 (2005) (finding "no authority for the proposition that the statute requires the FDA to have a notice process that 'restricts delivery' to Dr. Korangy personally"). However, *Korangy* is not on point because the ALJ here did not require evidence of personal service.

Finally, CTP points out that it served Respondent in this case in the same manner "as in virtually every case CTP has filed under 21 C.F.R. Part 17 since the beginning of the tobacco civil money penalty enforcement program in 2012." Appeal Br. at 8. The presiding officers in those cases were ALJs located at the Departmental Appeals Board. Even assuming that the proof of service in those cases was the same as that proffered here, the fact that those ALJs did not question whether service was properly effected does not deprive the ALJ here of discretion to require further proof that it was.[2]

Thus, the ALJ did not err in concluding that CTP did not establish proper service of the Complaint on Respondent.

2. The ALJ did not err in concluding that in the absence of a motion for a default judgment, he was not required to issue an initial decision assessing a CMP against Respondent.

CTP argues that in concluding that he was not required to issue a default judgment even if the Complaint were properly served, the ALJ ignored the default regulation at 21 C.F.R. § 17.11. According to CTP, this regulation "plainly states that so long as service has been properly effected under 21 C.F.R. § 17.7, a timely answer has not been filed, and the facts alleged in the complaint, which must be assumed to be true, establish liability, the presiding officer 'shall' enter a default against the respondent, imposing [a penalty]." Notice of Appeal at 3; *see also* Appeal Br. at 4-5, 17-20. CTP asserts that the word "shall" "creates a mandatory duty to act" under these circumstances since section 17.11 "requires no additional procedures." Appeal Br. at 18. CTP argues that since the

[2] We note that another ALJ did infer in two cases that a complaint was properly served where the UPS notice was for an address other than the address identified in the complaint as the address of the respondent's establishment but the package was addressed to the respondent and someone signed for it. *JMG Food Inc. d/b/a Country Mar / Mobil*, DAB CR3412, n.1 (2014) and *Two Farms, Inc. d/b/a Royal Farms Store 34*, DAB CR3316, n.1 (2014). In both cases, however, the ALJ noted that his initial order setting procedures was sent to both addresses (stating in *JMG* that neither order was returned as improperly addressed), as further evidence establishing that service of the complaint to the second address was valid.

Complaint here was properly served and Respondent did not timely file an answer or request for an extension of time, the ALJ "exceeded his authority by ordering CTP to file a motion for default under 21 C.F.R. § 17.32, and sanctioning CTP by dismissing this case when it did not do so." Notice of Appeal at 3-4.

CTP's reliance on section 17.11 is misplaced, even if CTP is correct that the word "shall" mandates the issuance of a default judgment when a respondent fails to answer a properly served complaint. The ALJ explicitly found that there was no proof of proper service, which the regulation itself provides is a prerequisite to the issuance of a default judgment. Moreover, CTP points to nothing in section 17.11 that precludes a presiding officer from requiring any other procedural steps prior to issuing a default judgment even though the regulation authorizes issuance of a default judgment sua sponte. Section 17.19(b) of 21 C.F.R. empowers the presiding officer, among other things, to "[r]egulate the course of the hearing and the conduct of the parties;" "[w]aive, suspend, or modify any rule in this part if the presiding officer determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law;" and "[e]xercise such other authority as is necessary to carry out the responsibilities of the presiding officer under this part." 21 C.F.R. § 17.19(b)(8), (17), (19). The ALJ's decision to require CTP to file a motion for a default judgment prior to his issuing a default judgment is well within this broad authority and is not inconsistent with the provisions of section 17.11 even though the regulation does not require such a motion.

CTP further argues that "because there is a regulation directly addressing default, the separate provision . . . . requiring parties to file motions with the presiding officer seeking an order or ruling, 21 C.F.R. § 17.32, is inapplicable in the default context." Appeal Br. at 19 (citing cases for the principle that a specific statute takes precedence over a more general one). Contrary to what this argument suggests, the ALJ did not need to rely on section 17.32 to require CTP to file a motion for a default judgment in view of his broad authority under section 17.19(b). In any event, CTP's argument that the ALJ could not properly rely on section 17.32 to require such a motion is based on a misapplication of the principle of statutory construction on which it relies. That principle generally applies where two provisions are inconsistent. *See, e.g., Howard v. Pritzker*, 775 F.3d 430, 438 (D.C. Cir. 2015) ("[I]t is a commonplace of statutory construction that the specific governs the general,". . . , and this is ordinarily true where two statutes irreconcilably conflict[.]") The regulatory provisions here are not necessarily in conflict. The regulation on default judgments does not specify that the ALJ shall act without requiring any application prior to issuing a default judgment, so it is not necessarily inconsistent with that regulation for the ALJ to rely on the requirement in section 17.32 that "[a]ny application to the presiding officer for an order or ruling shall be by motion."

CTP also points out that "other ALJs have routinely entered default judgments under 21 C.F.R. § 17.11 against respondents who fail to file timely answers without requiring motions by the complainant." Appeal Br. at 19. However, the practice of the other ALJs does not deprive the ALJ here of discretion to require CTP to file a motion for a default judgment.

Finally, CTP asserts that requiring it to file a motion for a default judgment "opens another opportunity for briefing before default may be entered" and prevents it from accomplishing its goal of "protecting young people from tobacco products" by "swiftly and efficiently initiating action against those who disregard their statutory obligations." Appeal Br. at 25. It is not clear that the procedure required by the ALJ would significantly delay the imposition of a CMP since, as the ALJ pointed out, in the absence of a motion, cases ripe for a default judgment would have to await the ALJ taking the initiative to identify them. In any event, we have no basis for finding that any delay would be so significant that it would be an abuse of discretion for the ALJ to require CTP to move for a default judgment.

Thus, the ALJ did not err in concluding that he need not issue an initial decision assessing the CMP against Respondent in the absence of a motion by CTP for a default judgment.

3. The ALJ abused his discretion in dismissing CTP's Complaint with prejudice.

Section 17.35(a)(1) authorizes the presiding officer to sanction a party for "[f]ailing to comply with an order, . . . rule, or procedure governing the proceeding;" "[f]ailing to prosecute or defend an action;" or "[e]ngaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing." Section 17.35(c)-(e) lists specific sanctions that may be imposed for particular misconduct although it does not limit the presiding officer's authority to impose sanctions for other conduct. 21 C.F.R. § 17.35(b); *see also* 60 Fed. Reg. 38,612, 38,620 (July 27, 1995) (preamble to final CMP regulation rejecting comment that "urged FDA . . . to limit sanctions"). The regulation requires that any sanction "shall reasonably relate to the severity and nature of the failure or misconduct." 21 C.F.R. § 17.35(b).

The ALJ concluded that given CTP's "inability to provide adequate proof of service of the complaint, and given its willful refusal to move for the ruling to which it believes itself entitled," dismissal with prejudice is appropriate. Order Dismissing Complaint at 5. As explained below, we find that what the ALJ acknowledged is a "drastic remedy" (*id.*) is not reasonably related to the severity and nature of the conduct for which it was imposed.

We note first that the regulations list dismissal of an action as a possible sanction "[i]f a party fails to prosecute. . . an action[.]" 21 C.F.R. § 17.35(e). However, we conclude that this provision provides no authority for the dismissal because CTP intended to prosecute the action it initiated by filing the Complaint seeking assessment of a CMP against Respondent. In response to the ALJ's order to show cause why the Complaint should not be dismissed with prejudice, CTP argued that it had complied with the regulatory requirements for service and that the regulations require an ALJ to issue a default judgment where the respondent has been properly served and has failed to timely file an answer to the complaint. Thus, in CTP's view, it had already fully prosecuted the matter. While CTP might have been able to provide further proof of service that satisfied the ALJ and certainly could have filed a motion for default, it is apparent that CTP refused to do so in order to test its interpretation of the regulations on appeal, if necessary, by incurring the consequences the ALJ warned would ensue, but that CTP did not fail to prosecute due to any neglect or inaction on its part.

We further note that the regulations list as a possible sanction where a party "refuses to obey an order of the presiding officer" the exclusion of the party from participation in the hearing, or, "[i]n the case of repeated refusal," "grant[ing] judgment to the opposing party." 21 C.F.R. § 17.35(d). By dismissing the Complaint with prejudice, the ALJ in effect granted judgment to Respondent. The ALJ may have regarded section 17.35(d) as authorizing the dismissal since he characterized the action for which he imposed the sanction as "deliberately flout[ing] a legal procedural order of the ALJ." Order Dismissing Complaint at 1. However, even if this regulation applies here, and we make no finding in that regard, we conclude that dismissal was not warranted because that sanction is not reasonably related to the severity and nature of the conduct for which it was imposed.

The "reasonably related" requirement also appears in a provision of the Social Security Act that applies to CMP proceedings involving nursing facilities and authorizes the official conducting a hearing to impose sanctions for certain conduct by a party. In prior decisions involving a dismissal pursuant to this authority, the Board has looked for guidance to cases analyzing dismissals pursuant to Rule 41(b) of the Federal Rules of Civil Procedure, which vests district courts with discretion to dismiss an action "[i]f the plaintiff fails to prosecute or to comply with [the Federal Rules] or a court order." In *Osceola Nursing & Rehabilitation Center*, for example, the Board stated:

> A review of Rule 41(b) cases demonstrates that, while the appellate courts acknowledge the importance of a district court's ability to manage its own docket, they repeatedly declare that dismissal is a remedy to be used with great caution: "Rule 41(b) dismissals are a 'harsh remedy' that are 'appropriate only in extreme circumstances.'" *Spencer v. Doe*, 139 F.3d 107,112 (2nd Cir. 1998) (citations

> omitted); "Dismissal with prejudice is an extreme sanction and should be used only in cases of willful disobedience of a court order or . . . persistent failure to prosecute a complaint." *Rodgers v. University of Missouri*, 135 F.3d 1216, 1219 (8th Cir. 1998); . . . Dismissal should be used "as a weapon of last, rather than first, resort." *Meade v. Grubbs*, 841 F.2d 1512, 1520 (10th Cir. 1988).

Osceola at 11-12.

Applying these standards here, we conclude that the sanction of dismissal is not reasonably related to the severity and nature of the conduct on which it was based. As discussed above, we find no failure to prosecute. Further, since CTP could not test the ALJ's interpretation of the regulations without declining to provide further proof of service or to file a motion for a default judgment, we do not believe that conduct constituted the type of "willful disobedience of a court order" to which the cited caselaw refers. Moreover, contrary to the cited caselaw, the ALJ used dismissal with prejudice as a weapon of first, not last, resort. The regulatory history makes clear that the purpose of the sanctions is to provide a "means of compelling the parties to adhere to the orders and rulings of the presiding officer" so as to enable the presiding officer to "manage proceedings effectively." 60 Fed. Reg. at 38,620. This purpose could have been achieved by less severe measures, including dismissing the Complaint without prejudice, thus permitting CTP to either request that this case be reopened to allow it to meet the ALJ's requests for adequate proof of service of this Complaint or initiate new proceedings by serving a new complaint on Respondent. We note that in another case an ALJ dismissed without prejudice a complaint as to one of the two respondents where the only UPS notice CTP provided as proof of service was addressed to the other respondent. *FFJ Inc. d/b/a Dellwood Market and Fuad Ali d/b/a Dellwood Market*, DAB CR3191 (2014).

Furthermore, while we share the ALJ's concern that Respondent be provided due process including an opportunity for a hearing to the full extent provided by statute and regulation, we view dismissal with prejudice as a particularly inappropriate remedy where it precludes the assessment of a CMP against a party alleged to have violated a federal statute intended, as CTP pointed out, to protect public health, especially that of young people. This respondent's hearing rights can be preserved without infringing on public health concerns.

Accordingly, we conclude that the ALJ abused his discretion in dismissing CTP's Complaint with prejudice.

Conclusion

For the foregoing reasons, we reverse the ALJ's dismissal with prejudice and remand the case to the ALJ for further proceedings consistent with this decision. The ALJ shall provide CTP another opportunity to demonstrate proper service of the Complaint by proffering evidence demonstrating that the UPS delivery notices indeed related to mailing of the Complaint. Should CTP fail or refuse to submit such evidence, a reasonable sanction would be dismissal without prejudice, allowing CTP to initiate new proceedings by serving a new complaint on Respondent.

/s/
Sheila Ann Hegy

/s/
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/s/
Leslie A. Sussan
Presiding Board Member