

seeking review of the Commission's finding of violation as to the '577 and '668 patents. *Arista Networks, Inc. v. Int'l Trade Comm'n*, Appeal No. 17-2336. On August 3, 2017, the Federal Circuit consolidated the Arista and Cisco appeals. *Cisco Sys., Inc. v. Int'l Trade Comm'n*, Appeal No. 17-2289, Dkt. No. 20.

On August 25, 2017, Arista filed a motion with the Federal Circuit seeking to stay the Commission's remedial orders pending resolution of the appeal on the merits. On September 22, 2017, the Federal Circuit denied this request "subject to the condition that the product redesign on which Cisco relies to deny irreparable harm must be permitted to enter the country, without being blocked by the Commission order under review in this case, unless and until Commission proceedings are initiated and completed to produce an enforceable determination that such a redesign is barred by the order here under review or by a new or amended order." *Cisco Sys, Inc. v. ITC; Arista Networks, Inc. v. ITC*, Appeal Nos. 2017-2289, -2351, Order at 3 (Fed. Cir. Sept. 22, 2017).

On September 27, 2017, Cisco petitioned for a modification proceeding to determine whether Arista's redesigned switches infringe the patent claims that are the subject of the LEO and CDO issued in this investigation and for modification of the remedial orders to specify the status of these redesigned products.

On November 1, 2017, the Commission instituted the modification proceeding. 82 FR 50678 (Nov. 1, 2017). On November 7, 2018, the Commission issued a notice clarifying that OUII is not named as a party in the modification proceeding. 82 FR 52318 (Nov. 13, 2017).

On February 14, 2018, the Federal Circuit summarily affirmed the PTAB's decision finding the claims of the '668 patent unpatentable. *Cisco Systems, Inc. v. Arista Networks, Inc.*, Appeal No. 17-2384, Order (Feb. 14, 2018). The Court issued the mandate on March 23, 2018. *Id.*, Dkt. No. 54.

On March 23, 2018, the ALJ issued a recommended determination in the modification proceeding ("MRD"), finding that Arista's redesigned products infringe the relevant claims of the '668 patent but do not infringe the relevant claims of the '577 patent. MRD (Mar. 23, 2018). Also on March 23, 2018, the ALJ issued an order denying Arista's motion to stay the modification proceedings or to stay the remedial orders with respect to the '668 patent. Order No. 20 (Mar. 23, 2018).

On April 5, 2018, the Commission determined to modify the remedial orders to suspend enforcement of those orders with respect to the '668 patent. Notice (Apr. 5, 2018); Comm'n Order (Apr. 5, 2018).

On June 26, 2018, the Commission accepted the ALJ's recommended determination finding no infringement with respect to the '577 patent and determined to modify the remedial orders to exempt Arista's redesigned products that were the subject of the modification proceeding. The Commission also determined to suspend the modification proceeding as to the '668 patent. The '577 patent expired on June 30, 2018.

On August 27, 2018, the Federal Circuit granted a motion of the parties to voluntarily dismiss the consolidated appeal from the Commission's final determination on violation. *Cisco Sys., Inc.*, Appeal No. 17-2289, Dkt. No. 121 (Aug. 27, 2018).

On August 27, 2018, Cisco and Arista filed a joint motion to terminate the modification proceeding in its entirety pursuant to Commission Rule 210.21(b)(1) (19 CFR 210.21(b)(1)) based on a settlement agreement between the parties. The motion indicates that the Agreement fully resolves the disputed issues in the modification proceeding, that there are no other agreements, written or oral, express or implied, between them concerning the subject matter of this proceeding, and that the motion includes a public version of this Motion along with an accompanying public version of the Agreement. The motion also contends that termination of the modification proceeding will not adversely affect the public interest.

The Commission has determined to grant the joint motion and terminate the modification proceeding in its entirety. We note that only the '668 patent remains in the modification proceeding.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: September 14, 2018.

Lisa Barton,

Secretary to the Commission.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Sharon C. Worosilo, M.D., Decision and Order

On February 7, 2018, the Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Sharon C. Worosilo, M.D. (Registrant), who is registered in Somerset and East Brunswick, New Jersey. The Show Cause Order proposed to revoke Registrant's two DEA Certificates of Registration, Nos. BW8636219 and BW4026375, pursuant to 21 U.S.C. 824(a)(3), on the ground that she does not have authority to handle controlled substances in New Jersey, the state in which she is registered with the DEA, and to deny any applications for renewal or modification and any applications for any other DEA registrations. GX 2 (Order to Show Cause), at 1.

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Registrant is registered with the DEA as a practitioner authorized to handle controlled substances in schedules II through V under two DEA Certificate of Registrations: No. BW4026375 at the registered address of 49 Veronica Avenue, Somerset, New Jersey, and No. BW8636219, at the registered address of 620 Cranbury Road, Suite #115, East Brunswick, New Jersey. *Id.* at 2. The Order stated that both of Registrant's registrations were due to expire on May 31, 2018. *Id.*

Regarding the substantive grounds for the proceeding, the Show Cause Order specifically alleged that the New Jersey State Board of Medical Examiners issued an Order of Temporary Suspension "suspending [her] New Jersey medical license." "Consequently, the DEA must revoke [her] DEA registrations based on [her] lack of authority to handle controlled substances in the State of New Jersey." *Id.* at 2, citing 21 U.S.C. 824(a)(3) and 21 CFR 1301.37(b).

The Show Cause Order then notified Registrant of her right to request a hearing on the allegations, or to submit a written statement in lieu of a hearing, the procedure for doing either, and the consequence for failing to elect either option. *Id.* at 2, citing 21 CFR 1301.43. It also notified her of her right to submit a corrective action plan in accordance with 21 U.S.C. 824(c). *Id.* at 2-3.

On February 15, 2018, two DEA Diversion Investigators, accompanied by a Task Force Officer, personally served Registrant with the Order to Show

Cause at her residence at 1000 Avenue at Port Imperial, Number 706, Weehawken, New Jersey. GX 4 (Declaration of Service of Order to Show Cause) at 1–2.

On April 13, 2018, the Government submitted a Request for Final Agency Action (RFAA) and the evidentiary record to my Office. The Government represented that “Registrant has not requested a hearing and has not otherwise corresponded or communicated with DEA regarding the Order served on her, including the filing of any written statement in lieu of a hearing,” RFAA, at 1–2.

Based on the Government’s representation that more than 30 days have now passed since the date of service of the Show Cause Order and that Registrant has not submitted a request for a hearing or any other reply, I find that Registrant has waived her right to a hearing or to submit a written statement in lieu of a hearing. 21 CFR 1301.43(d). I therefore issue this Decision and Final Order based on relevant evidence contained in the record submitted by the Government. 21 CFR 1301.43(d) & (e). I make the following findings of fact.

Registrant is the holder of two DEA Registrations pursuant to which she is authorized to dispense controlled substances in schedules II–V as a practitioner at the registered address of 49 Veronica Avenue, Somerset, New Jersey (Registration No. BW4026375), and at the registered address of 620 Cranbury Road, Suite #115, East Brunswick, New Jersey (Registration No. BW8636219). GX 1 at 1–2.

On April 12, 2018, the Associate Chief of the DEA Registration and Program Support Section certified that both registrations were due to expire by their terms on May 31, 2018. *Id.* at 1–2. She further stated that “[Registrant] has no other pending or valid DEA registrations in New Jersey or in any other state.” *Id.* at 1–2. Pursuant to 5 U.S.C. 556(e), I take official notice of Registrant’s registration record with the Agency. *See also* 21 CFR 1316.59(e).¹

A review of Agency registration records shows that Registrant has not

filed any applications for renewal, nor has she filed a new application for a DEA Registration. Accordingly, I find that Registrant’s registrations expired on May 31, 2018, and that there is no application to act upon.

Having reviewed the record, I hold that this proceeding is now moot. DEA has long held that “if a registrant has not submitted a timely renewal application prior to the expiration date, then the registration expires and there is nothing to revoke.” *Donald Brooks Reece II, M.D.*, 77 FR 35054 (2012) (quoting *Ronald J. Riegel*, 63 FR 67132, 67133 (1998); *see also Thomas E. Mitchell*, 76 FR 20032, 20033 (2011), *Donald Kenneth Shreves, D.V.M.*, 83 FR 22518 (2018). Moreover, in the absence of an application (whether timely filed or not), there is nothing to act upon. Accordingly, because Respondent has allowed her registrations to expire and has not filed either a renewal or a new application, this case is now moot and will be dismissed.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that the Order to Show Cause issued to Sharon C. Worosilo, M.D., be, and it hereby is, dismissed. This Order is effective immediately.

Dated: September 12, 2018.

Uttam Dhillon,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 16–22]

Brian Thomas Nichol, M.D., Decision and Order

On March 14, 2016, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Brian Thomas Nichol, M.D. (Respondent), which proposed the revocation of his DEA Certificate of Registration No. BN4578057, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, at the registered address of 5106 McLanahan Drive, Suite B, North Little Rock, Arkansas. Administrative Law Judge Exhibit (ALJ Ex.) 1, at 1. As grounds for the proposed action, the Show Cause Order alleged that Respondent’s “registration would be inconsistent with the public interest.” *Id.* (citing 21 U.S.C.

823(f), 824(a)(4)). For the same reason, the Order also proposed the denial of any of Registrant’s “pending applications for renewal or modification of such registration, and . . . any applications for any other DEA registrations.” *Id.*

More specifically, the Show Cause Order set forth six independent reasons why the Government alleges that Respondent’s registration should be revoked. *Id.* at 1–3. The Show Cause Order first charged that Respondent’s “pre-signing of prescriptions for controlled substances violated [21] ¹ CFR 1306.05(a).” *Id.* at 2. The Order states that this charge is based on the allegation that in 2006, the Arkansas State Medical Board found that Respondent violated Arkansas and federal laws when (1) he “pre-signed controlled substance prescriptions, which [his] staff members, who were not authorized by law to issue such prescriptions, then issued to patients” and (2) he “[was] not present and [was] not consulted by [his] staff when such prescriptions were issued.” *Id.* at 1–2. The Order further alleged that in 2006, as a result of these findings, the Arkansas Board suspended Respondent’s medical license for six months. *Id.* at 2.

The Show Cause Order also set forth five charges of recordkeeping violations based on DEA’s July 4, 2014 “on-site inspection of [Respondent’s] registered location.” *Id.* *First*, the Order charged that Respondent “failed to maintain an initial inventory of all controlled substances in violation of 21 U.S.C. 827(a)(3) & 842(a)(5) and 21 CFR 1304.11(b).” *Id.* *Second*, the Order charged that he “failed to maintain complete and accurate dispensing records in violation of 21 U.S.C. 827(a)(3) & 842(a)(5) and 21 CFR 1304.21(a).” *Id.* at 2–3. *Third*, the Order charged that, during the on-site inspection, Respondent “could not provide a DEA–222 order form dated [January 16, 2014], for an order of oxycodone tablets, in violation of 21 U.S.C. [842](a)(5) and 21 CFR 1305.17(a).”² *Id.* at 3. *Fourth*, the Order

¹ Although the Order erroneously referenced Title 42 of the Code of Federal Regulations for this violation, Government counsel corrected the error during his Opening Statement at the administrative hearing when he made clear that Title 21 was the title that the Government had intended to allege. *See* Transcript (Tr.) 18. Respondent raised no objection based on the erroneous title reference, and I find that this error was merely a scrivener’s error and that Respondent had adequate notice of the charged violation.

² Although the Order erroneously referenced an August 28, 2013 DEA 222 form for this charge, the Government corrected the date of the allegedly missing DEA 222 form to January 16, 2014 in its

¹ Under the Administrative Procedure Act (APA), an agency “may take official notice of facts at any stage in a proceeding—even in the final decision.” U.S. Dept. of Justice, Attorney General’s Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA’s regulations, Respondent is “entitled on timely request to an opportunity to show to the contrary.” 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within 15 calendar days of service of this order which shall commence on the date this order is mailed.