

infringement of claim 1 of the '295 patent. The Final ID included a recommended determination ("RD") on remedy and bonding that recommended issuance of a limited exclusion order directed to the three remaining respondents and a cease and desist order directed to Summit. *See* Final ID at 73–87.

On May 16, 2024, the Commission determined to review the Final ID in part. 89 FR 45012–15 (May 22, 2024). The Commission determined not to review the Final ID's findings with respect to claim construction, infringement, and the technical prong of the domestic industry requirement. *Id.* at 45013. On July 23, 2024, the Commission determined to supplement the Final ID and to reverse-in-part Order No. 19 and remand the investigation to the CALJ for further proceedings with respect to the written description requirement. *See* Comm'n Notice (July 23, 2024); Comm'n Op. (July 23, 2024); Remand Order (July 23, 2024).

On remand, the parties agreed that a live hearing was unnecessary and the CALJ set a procedural schedule for the submission of evidence and the parties' briefing and extended the target date to February 10, 2025. Order No. 23 (Aug. 1, 2024), *unreviewed by* Comm'n Notice (Aug. 27, 2024). The parties conducted additional expert discovery and the CALJ admitted the resulting evidence into the record. Order No. 24 (Sept. 3, 2024).

On November 8, 2024, the CALJ issued the Remand ID finding that claim 1 of the '295 is not invalid for lack of written description under 35 U.S.C. 112. OUII filed a petition for review on November 21, 2024. Respondents filed a petition for review on November 29, 2024. West filed a response to OUII's petition for review on November 29, 2024. West filed a response to Respondents' petition for review on December 6, 2024.

On December 20, 2024, the Commission determined to review the Remand ID in its entirety. On review, the Commission has determined to take no position with respect to certain statements in the Remand ID.¹ Specifically, the Commission takes no position on the second sentence of the last paragraph on page 5 continuing to page 6 ("The Commission concluded that OUII. . .") and the subsequent citations ("*Id.* at 18. . .; *see also*; . . .; *but cf.* . . ."); and the Commission takes no position on the second sentence in the first full paragraph on page 7 ("Because OUII. . ."). The

Commission has determined to affirm the remainder of the Remand ID. Because the Commission previously determined not to review the finding on summary determination with respect to the economic prong of the domestic industry requirement and the findings in the Final ID with respect to claim construction, infringement, and the technical prong of the domestic industry requirement, the Commission has determined that there has been a violation of section 337 with respect to infringement of claim 1 of the '295 patent.²

For remedy, the Commission has determined to issue a limited exclusion order prohibiting further importation of infringing products by the three remaining respondents and a cease and desist order against Respondent Summit. The Commission has determined that the public interest factors do not counsel against issuing remedial orders. The Commission has determined that bond should be set in the amount of zero percent (0%) (*i.e.*, no bond).

The Commission vote for this determination took place on February 3, 2025.

This action is taken under the authority of 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: February 3, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–02336 Filed 2–6–25; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Massoud Amini, M.D.; Decision and Order

On February 23, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Massoud Amini, M.D., of Woodland Hills, California. (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 3. The OSC proposed the revocation of Registrant's DEA Certificate of Registration No. BA6612142, alleging that Registrant's registration should be revoked because Registrant is "currently without authority to handle controlled

substances in California, the state in which [he is] registered with DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The OSC notified Registrant of his right to file with DEA a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 2.¹ "A default, unless excused, shall be deemed to constitute a waiver of the [registrant's] right to a hearing and an admission of the factual allegations of the [OSC]." 21 CFR 1301.43(e).

Further, "[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67." *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

¹ Based on the Government's submissions in its RFAA dated April 18, 2024, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the Declaration from a DEA Diversion Investigator (DI) indicates that on February 29, 2024, the DI successfully served the OSC via email to Registrant's registered email address, as the DI's email was not returned undeliverable. RFAAX 2, at 2; *Mohammed S. Aljanaby, M.D.*, 82 FR 34552, 34552 (2017) (finding that service by email satisfies due process where the email is not returned as undeliverable and other methods have been unsuccessful).

The DI made several other attempts to serve Registrant with the OSC, but they were unsuccessful. On February 27, 2024, the DI attempted personal service at Registrant's last known forwarding address. RFAAX 2, at 2. The DI left a copy of the OSC at the address and asked the current residents to give the documents to Registrant. *Id.* Also on this date, the DI called and texted Registrant via a telephone number provided by the current residents and received no response. *Id.* On February 29, 2024, the DI attempted to contact Registrant by his registered phone number and left her contact information with an acquaintance of Registrant who answered the phone. *Id.* at 2–3. On March 1, 2024, the DI sent the OSC via certified mail to four addresses associated with Registrant, including Registrant's registered address. *Id.* at 3. Attachment C. According to the DI, all four mailings were returned unable to forward. *Id.* at 3. The DI also contacted the Medical Board of California in attempting service, but the Board was unable to provide a current address. *Id.* at 3.

In sum, the Agency finds that Registrant was successfully served the OSC by email and the DI's efforts to serve Registrant by other means were "reasonably calculated, under all the circumstances, to apprise [Registrant] of the pendency of the action." *Jones v. Flowers*, 547 U.S. 220, 226 (2006) (quoting *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950)). Therefore, due process notice requirements have been satisfied.

¹ Commissioner Schmidlein stepped down from the Commission on January 31, 2025.

² Commissioner Kearns respectfully dissents from the Commission's decision and has filed a separate opinion explaining his views.

I. Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted. According to the OSC, effective January 12, 2024, the Medical Board of California revoked Registrant's California medical license. RFAAX 1, at 2. According to California's online records, of which the Agency takes official notice, Registrant's California medical license remains revoked.² California DCA License Search, <https://search.dca.ca.gov/> (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice medicine in California, the state in which he is registered with DEA.

II. Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under 21 U.S.C. 823 "upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." With respect to a practitioner, DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, D.O.*, 76 FR 71371, 71372 (2011), *pet. for rev. denied*, 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, D.O.*, 43 FR 27616, 27617 (1978).³

² Under the Administrative Procedure Act, an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), "[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary." Accordingly, Registrant may dispute the Agency's finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at dea.addo.attorneys@dea.gov.

³ This rule derives from the text of two provisions of the Controlled Substances Act (CSA). First, Congress defined the term "practitioner" to mean "a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice." 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's

According to California statute, "dispense" means "to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery." Cal. Health & Safety Code section 11010 (West 2024). Furthermore, a "practitioner" means a person "licensed, registered, or otherwise permitted, to distribute, dispense, conduct research with respect to, or administer, a controlled substance in the course of professional practice or research in [the] state." *Id.* section 11026(c).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in California. As discussed above, a physician must be a licensed practitioner to dispense a controlled substance in California. Thus, because Registrant currently lacks authority to practice medicine in California and, therefore, is not currently authorized to handle controlled substances in California, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BA6612142 issued to Massoud Amini, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Massoud Amini, M.D., to renew or modify this registration, as well as any other pending application of Massoud Amini, M.D., for additional registration in California. This Order is effective March 10, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed

registration. Congress directed that "[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(g)(1). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper, D.O.*, 76 FR 71371, 71372; *Sheran Arden Yeates, D.O.*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci, D.O.*, 58 FR 51104, 51105 (1993); *Bobby Watts, D.O.*, 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton, D.O.*, 43 FR 27617.

on January 31, 2025, by Acting Administrator Derek Maltz. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025-02342 Filed 2-6-25; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 24-47]

Herold Pierre-Louis, P.A.; Decision and Order

On May 21, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Herold Pierre-Louis, P.A., of Tucson, Arizona (Respondent). OSC, at 1, 3. The OSC proposed the revocation of Respondent's DEA Certificate of Registration No. MP7845766, alleging that Respondent's DEA registration should be revoked because Respondent is "without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of Arizona, the state in which [he is] registered with DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

On May 30, 2024, Respondent requested a hearing and filed an Answer to the OSC. On June 10, 2024, the Government filed a Motion for Summary Disposition, to which Respondent did not respond.¹ On June 27, 2024, Administrative Law Judge Paul E. Soeffing (the ALJ) granted the Government's Motion for Summary Disposition and recommended the revocation of Respondent's registration, finding that because Respondent lacks state authority to handle controlled substances in Arizona, the state in which he is registered with DEA, "there is no other fact of consequence for this tribunal to decide." Order Granting the

¹ On June 17, 2024, Respondent filed a Motion to Continue Show Cause Hearing to request a continuance on the instant proceedings, which the Administrative Law Judge denied.