

**UNITED STATES DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

In the Matter of

**Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT**

**Docket No. 22-15**

**ORDER DENYING MINDSTATE’S MOTION FOR ADMINISTRATIVE PROTECTIVE ORDER**

On April 26, 2022, this tribunal held a status conference. During the status conference, Kykeon Biotechnologies Inc. (Mindstate) requested a protective order to allow for the submission of confidential and trade secret information in support of its response to the Government’s Motion to Dismiss in Part, in which the Government alleged that Mindstate lacks standing in this matter. The Government represented that it was not opposed to a limited protective order. As I indicated at the status conference, this tribunal lacks the authority to issue such a protective order.

On April 28, 2022, Mindstate filed the instant Motion for Administrative Protective Order (Motion for Protective Order), arguing that this tribunal has authority to issue an administrative protective order under 21 C.F.R. § 1316.52 (which grants the tribunal power necessary to achieve the ends of conducting a fair hearing); 5 U.S.C. § 556(c) (which sets forth the powers of the presiding official); and past Agency practice. Mot. for Protective Order at 1-2.

The authority of the Administrative Law Judge at administrative hearings is authorized and circumscribed by the Administrative Procedure Act (APA). 5 U.S.C. § 556(c). The authority and enumerated powers vested by the APA in the Administrative Law Judge flow “without the necessity of express agency delegation [and] an agency is without power to withhold such powers from [the Administrative Law Judge].” U.S. Dep’t of Justice, Attorney General’s Manual on the Administrative Procedure Act 74 (1947). The APA affords the presiding officer at an administrative hearing significant control over the course of the hearing and specified prehearing procedures, as well as authority to “take other action authorized by agency rule consistent with this subchapter.” 5 U.S.C § 556(c)(11). The authorities granted to the presiding Administrative

Law Judge are powerful, but none are inherent. Authority to issue a protective order in administrative proceedings is not within the powers specifically enumerated in the APA, and thus, can only exist to the extent it is “authorized by agency rule consistent with [the APA].” *Id.*

Neither does 21 C.F.R. § 1316.52 provide this tribunal clear authority to issue a protective order. That regulation, entitled “Presiding officer,” outlines the powers of the Administrative Law Judge. Notably, Mindstate relies upon the introductory language, which provides simply that: “The presiding officer shall have the duty to conduct a fair hearing.” The subsequent list of enumerated powers does not expressly identify issuing a protective order as one of the “necessary powers” to achieve a fair trial. *See* 21 C.F.R. § 1316.52. While that list is admittedly not exhaustive, the enumerated powers relate to providing a fair hearing, and nothing in that list suggests this tribunal has the power to issue the requested protective order.

Finally, Mindstate points to other instances in which the Agency has agreed to protective orders and occasions in which agreements were honored by Administrative Law Judges. Mot. for Protective Order at 2. But the fact that the Government may bind itself by entering into a non-disclosure agreement with a party, or even that the Agency has acknowledged or accepted those agreements, does not mean that this tribunal has authority to issue a protective order, especially in the present circumstances.<sup>1</sup> At the status conference, the tribunal raised the Agency’s decision in *Holiday CVS, LLC, d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62346 (2012), in which the Administrator concluded that a protective order between the two parties—and accepted by the Administrative Law Judge—“cannot bind the Administrator.” *Id.* at 62348 (internal punctuation omitted). Mindstate claims that *Holiday CVS* merely stands for the proposition “that information submitted as confidential under a protective order cannot bind the Administrator’s ability to publish such information in a final decision.” Mot. for Protective Order at 2. But *Holiday CVS* also noted that, while other Agency decisions had acknowledged or accepted protective orders, they did not establish any legal basis for doing so. *Holiday CVS*, 77 Fed. Reg. at 62347. The same is true for the cases cited by Mindstate—while they acknowledge or accept protective orders, none identify the source of this tribunal’s power to issue one.

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<sup>1</sup> The fact that, within the rulemaking context, “DEA permitted commenters to submit ‘CONFIDENTIAL BUSINESS INFORMATION’ to permit the submission of confidential business information without making that information publicly available,” *see* Mot. for Protective Order at 2 (quoting 87 Fed. Reg. 2376, 2377 (2022)), does not convey such authority on this tribunal.

Given the absence of any clear authority under 5 U.S.C. § 556(c) or 21 C.F.R. § 1316.52, this tribunal concludes that it lacks the power to issue a protective order in this matter. Accordingly, Mindstate's Motion for Administrative Protective Order is herein **DENIED**.

Dated: April 29, 2022

TERESA  
WALLBAUM  
TERESA A. WALLBAUM  
Administrative Law Judge

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Date: 2022.04.29  
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## CERTIFICATE OF SERVICE

This is to certify that the undersigned, on April 29, 2022, caused a copy of the foregoing to be delivered to the following recipients:

- (1) John E. Beerbower, Esq., Counsel for the Government, via email at John.E.Beerbower@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov;
- (2) David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net;
- (3) John T. Hunter, Esq., Counsel for Jason Wallach and Hamilton Morris, via email at john@hljdefense.com;
- (4) Matt Baggott, Tactogen Inc., via email at matt@tactogen.com;
- (5) Dillian DiNardo, Kykeon Biotechnologies Inc., via email at dillan@mindstate.design;
- (6) Graham Pechenik, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at graham@calyxlaw.com;
- (7) Matthew C. Zorn, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at mzorn@yettercoleman.com; and
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**ANIAYAH  
BECKFORD**  
Aniayah S. Beckford,  
Staff Assistant to Judge Wallbaum

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