

UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

MMJ BIOPHARMA CULIVATION
INC.,

Plaintiff,

v.

MERRICK GARLAND, *et al.*

Defendants.

Civil Action No.
1:24-cv-127-WES-PAS

**DEFENDANTS' MOTION AND SUPPORTING MEMORANDUM OF LAW
TO DISMISS ALL CLAIMS WITH PREJUDICE UNDER FEDERAL
RULES OF CIVIL PROCEDURE 12(b)(1) AND (6)
OR, IN THE ALTERNATIVE, RULE 56**

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Plaintiff MMJ Biopharma Cultivation Inc. (“MMJ”) asks this Court to stop an administrative proceeding before a Drug Enforcement Administration (“DEA”) Administrative Law Judge (“ALJ”) on the ground that the removal restrictions that apply to DEA ALJs are unconstitutional. Upon receiving an Order to Show Cause (“OTSC”) from the DEA—which triggered the adjudicatory phase of the ongoing administrative proceeding below—MMJ asked for a hearing before the ALJ. Despite its current constitutional objection, MMJ actively litigated the merits of claims before that ALJ and moved to stay the proceeding only after the ALJ had issued orders adverse to MMJ. MMJ then successfully sought to stay that proceeding while litigating its constitutional objection here. Despite its concerns over the ALJ’s removal protections and their alleged effect on the exercise of Executive power, MMJ does not and cannot allege that either the President or the Attorney General has sought to remove the ALJ presiding over MMJ’s case. Regardless, the ALJ removal protections are constitutional because ALJs make only recommendations to the final decisionmaker on MMJ’s application—the Administrator—whom the President may remove at will. MMJ also asks this Court to declare that MMJ “has met its burden for issuance” of a registration to make marijuana for research purposes—a conclusion that must first follow the administrative process that MMJ has shut down and that must be made, in the first instance, by the Administrator.

The Defendants¹ ask this Court to dismiss all of MMJ’s claims with prejudice for three reasons, the first two of which avoid the constitutional issue MMJ alleges.

First, under Federal Rule of Civil Procedure 12(b)(1), this Court lacks subject-matter jurisdiction to make any declaration about the merits of MMJ’s

¹ MMJ has sued the United States, the U.S. Department of Justice, and the DEA as well as three individuals in their official capacities: Merrick B. Garland, the U.S. Attorney General; Anne Milgram, the DEA Administrator; and Teresa A. Wallbaum, the DEA ALJ presiding over the adjudicatory phase of MMJ’s administrative proceeding. ECF 15 at 1 & ¶¶ 19-24, 77. This brief refers to them collectively as the Defendants.

application for a registration to make marijuana. The Controlled Substances Act (“CSA”) governs such registrations. Under the CSA, Congress expressly limits judicial review to only final agency actions and only in the U.S. Courts of Appeals for the D.C. Circuit or, because MMJ wants to make marijuana in Rhode Island, the First Circuit. Even if the Court had subject-matter jurisdiction to issue a declaration on MMJ’s application, that matter is not ripe for judicial review as there has been no final agency action. Regardless, the Amended Complaint lacks sufficient allegations that MMJ qualifies for a registration, which may be granted only if it were in the “public interest.” Thus, the Amended Complaint fails to allege sufficient facts to state a claim for a registration as a matter of law and the request for this relief should, under Rule 12(b)(6), be dismissed.

Second, MMJ has failed to allege that the contested ALJ removal restrictions caused any cognizable, much less irreparable, harm. MMJ’s sole allegation of harm is having to appear in “an unconstitutional proceeding led by an unconstitutional decisionmaker.” ECF 15 ¶ 88. That might establish jurisdiction for this Court to hear MMJ’s constitutional claim notwithstanding the CSA’s otherwise exclusive administrative and judicial review scheme. *Axon Enter. Inc. v. Fed. Trade Comm’n*, 598 U.S. 175 (2023). But, under the Supreme Court’s decision in *Collins v. Yellen*, 594 U.S. 220 (2021)—and decisions by the Second, Fourth, Fifth, Sixth, Ninth, and Tenth Circuits applying *Collins*—such an alleged constitutional defect (if proven) is severable, poses no harm by itself, cannot invalidate the ALJ’s decisionmaking, and fails to state any constitutional claim. MMJ’s allegation of harm is also implausible. When the underlying administrative proceeding had advanced to the ALJ stage, MMJ requested an ALJ hearing and, despite its constitutional objection, actively litigated the merits of its application before that ALJ. Whether under either Rule 12 or 56, the Court should dismiss MMJ’s claims.

Finally, if the Court reaches the constitutional issue, it should find the ALJ removal restrictions constitutional and dismiss the Amended Complaint. MMJ alleges that DEA ALJs are subject to two layers of removal protection—first, because the Merit Services Protection Board (“MSPB”) must find any ALJ removal was for “good cause”; and second, because MSBP members may be removed only for “inefficiency, neglect of duty, or malfeasance in office.” MMJ further contends that these protections interfere with the President’s obligations to “take care that the laws be faithfully executed.” U.S. Const. art. II, § 3; *id.* § 1.

Given the structure of the CSA and the implementing regulations adopted by the Executive branch, these protections pose no threat to Executive power nor any separation-of-powers problem, and thus do not violate the Constitution. Under the CSA, the use of ALJs in any DEA adjudication is a matter of discretion invested in the Attorney General—and, by lawful delegation, the Administrator. They *chose* by regulation to delegate the first level of adjudication to ALJs who are subject to statutory removal protection. Moreover, the presiding ALJ makes only recommendations. The Administrator will consider those recommendations and then decide whether to grant or deny MMJ’s application. Because the Administrator enjoys no statutory removal protection, there is no separation-of-powers problem.

STANDARD OF REVIEW

“Although dismissals under Rules 12(b)(1) and 12(b)(6) are conceptually distinct, the same basic principles apply in both situations.” *Harper v. Rettig*, 46 F.4th 1, 5 (1st Cir. 2022) (cleaned up).² The Court (a) must ignore allegations comprising only “legal labels or conclusions or [that] merely rehash cause-of-action elements”;

² This brief uses the parenthetical “(cleaned up)” where undersigned counsel omitted from quotations: (a) internal quotation marks, (b) other changes typically indicated by brackets or ellipses, and (c) citations. The purpose is to declutter the brief while noting immaterial alterations. *See generally* Jack Metzler, *Cleaning Up Quotations*, 18 J. App. Prac. & Process 143 (2017), <https://lawrepository.ualr.edu/cgi/viewcontent.cgi?article=1405&context=appellatepracticeprocess>.

(b) must take allegations of “non-conclusory, non-speculative facts as true and draw all reasonable inferences in the plaintiff’s favor”; and (c) may “consider information attached to or incorporated into the complaint and facts susceptible to judicial notice.” *Id.*

Federal Rule of Civil Procedure 12(b)(1) compels dismissal when the Court lacks subject-matter jurisdiction, which MMJ must establish. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). Courts “presume they lack jurisdiction unless the contrary appears affirmatively from the record.” *Renne v. Geary*, 501 U.S. 312, 316 (1992) (cleaned up).

Rule 12(b)(6) compels dismissal of complaints that do not allege a plausible legal and factual bases for relief. *See, e.g., Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 561-562 (2007); *id.* at 557 (describing pleadings containing only “naked assertion[s]” without “further factual enhancement” as deficient).

Federal Rule of Civil Procedure 56(a) compels summary judgment when the movants show there is no genuine dispute as to any material fact such that they are entitled to judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). The Defendants, as the moving parties, bear “initial responsibility of informing the district court of the basis for [their] motion, and identifying those portions of [the record] which [they] believe[] demonstrate[] the absence of a genuine issue of material fact.” *Vigeant v. United States*, 462 F. Supp. 2d 221, 226 (D.R.I. 2006) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). Once they have done so, the burden shifts to MMJ, which, to defeat summary judgment, “must show that there is sufficient evidence for a jury to find for [it] on each essential element of [its] claims.” *Id.*

BACKGROUND AND MMJ'S ALLEGATIONS

The Controlled Substances Act and its regulatory framework

The CSA criminalizes making “controlled substances,” including marijuana. 21 U.S.C. § 841(a)(1) (criminal prohibition); 21 U.S.C. § 812(b)(1) (defining Schedule I qualifications); 21 U.S.C. § 812, Schedule I(c)(10) (listing marijuana); 21 C.F.R. § 1308.11(d)(23) (same).

The CSA carves out exceptions to these criminal prohibitions, and delegates decisionmaking about them to the Attorney General or “to any officer or employee of the Department of Justice.” 21 U.S.C. § 871(a). The President appoints and may remove the Attorney General at will. 28 U.S.C. § 503; *see also, e.g., Collins v. Yellen*, 594 U.S. 220, 248 (2021) (“When a statute does not limit the President’s power to remove an agency head, the Court generally presumes that the officer serves at the President’s pleasure.”). The Attorney General delegated his functions under the CSA to the Administrator, his subordinate, whom the President also directly appoints and may remove at will. Reorganization Plan No. 2 of 1973, § 5(a); 28 C.F.R. §§ 0.100(c), 0.102; *Collins*, 594 U.S. at 248. For clarity, the Defendants generally refer to the Administrator, even as the CSA refers to the Attorney General and the Administrator has delegated some of her authority under CSA regulations to her subordinates. 28 C.F.R. § 0.104 & app. § 7(a).

Most relevant to MMJ’s allegations here are two parameters Congress set forth about who may issue registrations—that is, documented exceptions to the CSA’s criminal prohibitions—and on what basis. First, only the Administrator may issue registrations. 21 U.S.C. § 822; 21 U.S.C. §§ 823(c)(1)(C) & (c)(2); 21 C.F.R. § 1301.31. Second, to issue a registration, the Administrator must decide it would be “consistent with the public interest.” 21 U.S.C. § 823(a); 21 C.F.R. § 1301.31; ECF 15 ¶ 25. In making this public-interest determination, the Administrator must

consider six factors. 21 U.S.C. § 823(a).³ MMJ's pleading does not allege what those factors are or any facts that show that MMJ has satisfied them.⁴

If the Administrator intends to deny an application, the CSA and its corresponding regulations require specific procedures, which necessarily precede the Administrator's final decision. Only three of those procedural steps are relevant here. First, the Administrator must issue to the applicant an order to show cause "why registration should not be denied, revoked, or suspended." 21 U.S.C. § 824(c)(1); 21 C.F.R. § 1301.37(a). Second, the order triggers an applicant's right to request (or waive) an administrative hearing over which an ALJ presides (which is also referred to informally as the "OTSC proceeding"). 21 C.F.R. §§ 1316.42(f) & (g), 1316.47, 1316.49, 1316.52. Third, at the end of that proceeding, the ALJ issues "recommended" findings of fact, conclusions of law, and decision(s), which are then presented to the Administrator. 21 C.F.R. § 1316.65(a).⁵

³ The factors include the applicant's: (1) maintenance of effective controls against unlawful diversion; (2) compliance with State and local law; (3) promotion of technical manufacturing advances; (4) conviction record related to controlled substances; (5) industry and diversion-control experience; as well as (6) "such other factors as may be relevant to and consistent with the public health and safety." 21 U.S.C. §§ 823(a)(1)-(6).

⁴ MMJ's amended pleading includes substantial, additional characterizations of other CSA provisions and regulations as well as allegations about its own and the DEA's conduct in the underlying, incomplete regulatory proceeding. ECF 15 ¶¶ 25-75. Defendants do not dissect those allegations because they are extraneous to MMJ's constitutional objection.

⁵ The full text of 21 C.F.R. Section 1316.65(a) ("Report and record") reads (emphases added):

- (a) As soon as practicable after the time for the parties to file proposed findings of fact and conclusions of law has expired, the presiding officer [*i.e.*, the ALJ] shall prepare a report containing the following:
 - (1) His **recommended** rulings on the proposed findings of fact and conclusions of law;
 - (2) His **recommended** findings of fact and conclusions of law, with the reasons therefore; and
 - (3) His **recommended** decision.

Only after this preceding process is complete does the Administrator issue a final order. 21 C.F.R. § 1316.67. That step has not occurred in this case because MMJ filed this action, *see generally* ECF 15, and the ALJ below stayed OTSC proceedings. Defs.’ Statement of Undisputed Facts ¶ 11 (hereafter, “Defs. SOF”). No law requires the Administrator to defer in any way to the ALJ’s recommendations on any issue. *See generally* 21 U.S.C. §§ 822, 823; 21 C.F.R. § 1316.69.

Congress expressly limited judicial review of administrative decisionmaking under the CSA to only “final” determinations. 21 U.S.C. § 877. Only two courts may review final agency action under the CSA: the U.S. Court of Appeals for the D.C. Circuit or the federal appellate court “for the circuit in which” a rejected applicant’s “principal place of business is located,” *id.*, which—in MMJ’s case—would be the First Circuit, ECF 15 ¶ 18.

The presiding ALJ’s interim, advisory assessment of MMJ’s application

MMJ alleges the following about the OTSC proceeding:

- MMJ received an OTSC on October 31, 2023, *e.g.*, ECF 15 ¶¶ 2, 18, 62, 76;
- MMJ requested a hearing before a DEA ALJ, *id.* ¶¶ 76-78;
- “[I]nitial ALJ hearings” occurred remotely, *id.* ¶ 18; and
- After MMJ’s request for an ALJ hearing but “prior to any hearing taking place”—by which Defendants suspect that MMJ means only that the full merits hearing had not yet occurred and not that there were no ALJ hearings at all—MMJ now “objects to the Constitutionality of the proceeding,” *id.* ¶ 78.

The Defendants ask the Court to take judicial notice of the following facts concerning the “initial ALJ hearings” or, in the alternative, to consider them under Federal Rule of Civil Procedure 56 (as explained in Section II below).

- In the OTSC proceeding, the ALJ issued 13 orders. Defs. SOF ¶ 2.
- At least two orders included substantive rulings. The first issued December 19, 2023, and adopted as factual findings various admissions by MMJ in its request for an ALJ hearing / answer to the OTSC as well as the parties’ joint stipulations. Defs. SOF ¶¶ 3-5.

- The second substantive order issued February 2, 2024; granted the DEA’s motion for summary disposition; and made several legal conclusions as well as factual findings. Defs. SOF ¶¶ 6-8.
- The ALJ then set the full merits hearing for April 10-12, 2024. Defs. SOF ¶ 9.
- The parties thereafter submitted briefs on the DEA’s motion in limine to exclude certain witness testimony at the hearing, which the ALJ granted in part on March 19, 2024. Defs. SOF ¶ 10.
- One day after filing this action in this Court, and only five days before the full merits hearing, MMJ moved to stay the OTSC proceeding, which the ALJ granted. Defs. SOF ¶ 11.
- The first time that MMJ raised its constitutional objections in the administrative process was in its motion to stay. Defs. SOF ¶ 12.

MMJ’s Amended Complaint

MMJ alleges that the circumstances on which the ALJ could be removed from office violate the Constitution—namely, that:

- The ALJ may be removed only for “good cause” by the MSPB, 5 U.S.C. § 7521;
- Members of the MSPB may be removed by the President only for “inefficiency, neglect of duty, or malfeasance in office,” 5 U.S.C. § 1202(d);⁶ and
- This “arrangement impedes the President’s Article II executive authority” and frustrates his “duty to faithfully execute laws by independently assessing whether good cause exists to remove inferior officers,” such as ALJs.

ECF 15 ¶¶ 2, 4, 7-10, 12, 83-86. MMJ does not allege that the President or the Attorney General wants to remove the ALJ or that they are displeased with her performance. MMJ’s sole allegation of harm is its continuing participation in an allegedly unconstitutional proceeding “in and of itself.” *Id.* ¶¶ 16, 88, 89.

MMJ’s Complaint does not explicitly set forth any causes of action in the two listed “Counts,” which seek two types of relief. Count One asks this Court to enjoin the underlying DEA administrative proceeding “until a constitutionally valid system is in place.” *Id.* ¶¶ 87-90 & at 18 (Prayer for Relief ¶(b)). Count Two asks this Court to declare unconstitutional the removal provisions that apply to DEA ALJs.

⁶ In some spots, MMJ inadvertently alleges a different, and inaccurate, standard (“good cause”) for removing MSPB members. ECF 15 ¶¶ 11, 84.

Id. ¶¶ 91-92. MMJ also asks for relief concerning an utterly separate, nonconstitutional issue: that the Court review the OTSC itself and “find[] that MMJ met its burden for issuance of the manufacturer registration under applicable law.” *Id.* at 18 (Prayer for Relief ¶ (c)).

ARGUMENT

I. **MMJ’s request for declaratory relief that MMJ qualifies for a registration to make marijuana fails.**

For two reasons, this Court lacks subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1) to grant MMJ’s request for “review of the DEA’s Order to Show Cause, and finding that MMJ met its burden for issuance of the manufacturer registration under applicable law[.]” ECF 15 at 18 (Prayer for Relief ¶ (c)). First, this Court has no role under the CSA to make such determinations. Congress entrusted this role first to the Administrator and then to the federal appellate courts. Second, even if MMJ sought this relief from the proper court, there is no final agency action and MMJ’s request is not ripe. This Court also should dismiss this request for relief under Federal Rule of Civil Procedure 12(b)(6). MMJ has failed to allege any facts that could show that MMJ’s application for a registration would be in the public interest, as the CSA requires.

What reinforces all three preceding points is the Amended Complaint’s failure to plead a cause of action that could support such relief. The only relief to which MMJ could ever be entitled, given its sole focus on the alleged unconstitutionality of ALJs’ removal restrictions, would be the invalidation of those restrictions (and only if they were unconstitutional, which they are not). *See, e.g., Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 508 (2010) (hereinafter “*Free Enterprise*”); *Decker Coal Co. v. Pehringer*, 8 F.4th 1123, 1331 (9th Cir. 2021) (citing *Free Enterprise*). Because no amendment could cure all of these problems, the Court

should dismiss with prejudice MMJ's request that the Court declare that MMJ has met the requirements for a registration.

A. The Court lacks subject-matter jurisdiction to declare that MMJ has met its burden to qualify for a registration to make marijuana.

The CSA does not authorize this Court to review the substance of the underlying agency action at all, much less the OTSC. The CSA empowers judicial review of only final agency action and only by one of two federal appellate courts:

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

21 U.S.C. § 877. The Amended Complaint concedes that there is no final agency action here by contesting the constitutionality of ongoing administrative proceedings, not a final order. ECF 15 ¶¶ 13, 14, 16, 90 & at 18-19 (Prayer for Relief ¶¶ (a)-(c) (seeking relief prior to a final determination by the ALJ)).

For this reason alone, the Court should find that MMJ's Amended Complaint has failed to allege any basis for the Court to issue any declaration about MMJ's registration eligibility. *John Doe, Inc. v. Drug Enforcement Admin.*, 484 F.3d 561, 565 (D.C. Cir. 2007) (affirming district court order dismissing challenge to DEA agency action given courts of appeals' exclusive jurisdiction under 21 U.S.C. § 877) ("When judicial review is sought under the [Administrative Procedures Act ("APA")], for example, the requirement of final agency action is not jurisdictional. But when, as here, review is sought under a specific statute prescribing finality as a prerequisite of judicial review, it is.") (cleaned up); *id.* at 568 ("As a matter of practice almost all cases challenging DEA decisions under the CSA have been filed

directly in the courts of appeals pursuant to 21 U.S.C. § 877.”) (cleaned up); *see also Woods v. U.S. Drug Enforcement Admin.*, 283 F. Supp. 3d 649, 660 (W.D. Tenn. 2017) (granting defendant’s motion for summary judgment given court’s lack of subject-matter jurisdiction) (“No gap exists between final agency action under the APA and final determinations, findings, and conclusions under the CSA.”) (cleaned up).

Even if MMJ had alleged final agency action, such a claim is not properly brought before this Court. MMJ is required to bring such a claim before one of two federal appellate courts. 21 U.S.C. § 877.

MMJ cannot rely on the Supreme Court’s recent decision in *Axon Enterprise, Inc. v. Federal Trade Commission*, 598 U.S. 175 (2023), to circumvent CSA Section 877. *Axon* may allow MMJ to bring certain structural constitutional challenges in this Court, rather than await final agency action and challenge such action in the Courts of Appeals under the CSA. *Id.* at 175, 191, 192, 195. It does not apply to MMJ’s statutory claim seeking a declaration that it is entitled to a registration. *See, e.g., Leachco, Inc. v. Consumer Prod. Safety Comm’n*, 103 F.4th 748, 758-59 (10th Cir. 2024), *pet. for cert. filed*, No. 24-156 (U.S. Aug. 9, 2024).

B. Because there is no final agency action on MMJ’s application for a registration, MMJ’s request for a declaration that it qualifies for a registration is not ripe.

Even if this Court otherwise had subject-matter jurisdiction to make a declaration about MMJ’s registration qualifications, the Court should decline to hear that issue under the ripeness doctrine. *See, e.g., Downing/Salt Pond Partners, L.P. v. Rhode Island & Providence Plantations*, 643 F.3d 16, 17 (1st Cir.) (evaluating ripeness challenges under R. 12(b)(1)), *cert. denied*, 565 U.S. 977 (2011).

“Ripeness is a justiciability doctrine” whose purpose is to prevent “courts from ‘entangling themselves in abstract disagreements over administrative policies’ and from improperly interfering in the administrative decision-making process.” *City of Fall River v. Fed. Energy Regulatory Comm’n*, 507 F.3d 1, 6 (1st Cir. 2007)

(quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967)). “The burden to prove ripeness is on the party seeking jurisdiction.” *Labor Relations Div. of Constr. Indus. of Mass., Inc. v. Healey*, 844 F.3d 318, 326 (1st Cir. 2016) (affirming dismissal of pre-enforcement judicial review on ripeness grounds). Courts apply a two-part test to determine whether a case is ripe for review, and both favor dismissal of MMJ’s request for a declaration about its registration qualifications.

First, a court must consider whether the case is fit for judicial review—that is, “whether the matter involves uncertain events which may not happen at all, and whether the issues involved are based on legal questions or factual ones.” *City of Fall River*, 507 F.3d at 6 (declining to review agency’s conditional project approval for lack of ripeness) (cleaned up). This case lacks a complete administrative record for the Court to make any substantive decision about MMJ’s qualifications for a registration. In the OTSC proceeding, the parties presented issues of fact and law awaiting interim, advisory resolution by the ALJ. Defs. SOF ¶¶ 3, 6 & Exs. A, B. The Amended Complaint echoes many of those (disputed) issues. *E.g.*, ECF 15 ¶¶ 63-75 (concerning bona fide supply agreements). Their validity, however, must be resolved first by the ALJ and then by the Administrator. The disputes that MMJ identifies in its Amended Complaint may persist or may be resolved to its satisfaction (and thus never percolate to any court) upon completion of the OTSC proceeding. 21 U.S.C. § 824(c)(1); *City of Fall River*, 507 F.3d at 6 (“[A] claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.”).

The doctrines of ripeness and administrative exhaustion are distinct. *Williamson Planning Comm’n v. Hamilton Bank*, 473 U.S. 172, 192 (1985). But the two doctrines are “complementary” and “designed to prevent unnecessary or untimely judicial interference in the administrative process.” *John Doe, Inc.*, 484 F.3d at 567; *cf. Portela-Gonzalez v. Sec’y of the Navy*, 109 F.3d 74, 79 (1st Cir. 1997)

(“Disregarding available administrative processes thrusts parties prematurely into overcrowded courts and weakens an agency’s effectiveness by encouraging end-runs around it.”). This rationale applies even more so here, where MMJ seeks to displace the decisionmaking entrusted in the first instance not to the Judiciary but to a principal officer of the Executive branch who has yet to decide the issues on which MMJ seeks a declaration.

Second, a court must consider the hardship to both parties, but there is no hardship to MMJ when it may challenge final agency action, only if adverse, to the D.C. or First Circuits. *See City of Fall River*, 507 F.3d at 7.

C. Because the Amended Complaint fails to allege sufficient facts that granting a registration to MMJ would be in the public interest, MMJ’s request for a declaration that it has met that requirement should be dismissed under Rule 12(b)(6).

MMJ has not only failed to cite a legal basis for this Court’s subject-matter jurisdiction. It also has failed to allege any facts at all relevant to the CSA’s six public-interest factors that the Administrator must weigh—and that this Court, in turn, would be reviewing, if it had subject-matter jurisdiction—to decide whether MMJ “met its burden” for a registration. 21 U.S.C. § 823(a). The Amended Complaint does not enumerate those six factors. It lacks any allegations about how MMJ satisfies them. The Amended Complaint thus fails the basic requirements of notice pleading. *See, e.g., Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557, 561-62 (2007).

“Public interest” appears only twice in the Amended Complaint—both times merely uttering the standard alone. ECF 15 ¶¶ 25, 90. The Amended Complaint also includes two conclusory allegations about DEA’s investigation. Neither satisfies MMJ’s burden to allege facts that, if assumed to be true, could establish that granting its application would be in the public interest. First, MMJ alleges that “all DEA questions were satisfactorily answered, all security system and protocols were reviewed, and MMJ demonstrated that all security and diversion conditions were in

compliance with the regulations.” *Id.* ¶ 51. But to allege that a “system and protocols” was merely “reviewed” falls far short of alleging what that system and those protocols actually were and whether and how they allegedly satisfy the public interest. This allegation otherwise presents mere legal conclusions and omits some of Section 823(a)’s six public-interest factors. Second, MMJ alleges that it “made every attempt to comply with the government’s ever-increasing and ever-convoluted demands,” *id.* ¶ 65, which is similarly insufficient.

II. Because MMJ failed to allege that ALJ removal protections caused MMJ any cognizable harm—and it is undisputed that MMJ has suffered no cognizable harm—its claims must be dismissed.

To prevail on a removal challenge, MMJ must do more than simply allege a constitutional violation. MMJ must allege *actual* harm arising from the removal protections it challenges. *See, e.g., Collins v. Yellen*, 594 U.S. 220, 258 n.24 (2021) (rejecting argument that unconstitutional removal protections voided agency action); *id.* at 261, 263, 267 (Thomas, J., concurring); *id.* at 283 (Kagan, J. concurring with the majority’s analysis of harm and remedy); *id.* 284 n.1 (Sotomayor, J.; same). And, because the Amended Complaint lacks any such allegations, this Court should dismiss this case with prejudice.

What must MMJ have pleaded to overcome a Rule 12 motion? The Supreme Court posited two scenarios, neither of which MMJ could ever plausibly allege: (a) that the President had tried, and failed, to remove the ALJ because he lacked “‘cause’ for removal”; or (b) that the President had stated publicly that he was displeased with the ALJ and would have removed her “if the [contested] statute did not stand in the way.” *Id.* at 259-60. Justice Kagan explained why such allegations are necessary:

Granting relief in any other case would, contrary to usual remedial principles, put the plaintiffs in a better position than if no constitutional violation had occurred. . . . When an agency decision would not capture a President’s

attention, his removal authority could not make a difference—and so no injunction should issue.

Id. at 274-75 (cleaned up).

MMJ makes only one, insufficient allegation of harm: “being subject to this illegitimate proceeding,” “in and of itself.” ECF 15 ¶¶ 16, 88, 89. MMJ does not allege that the President or the Attorney General has tried to remove the ALJ or is displeased with her performance or that she (or even MMJ’s application) has even captured their attention.

The only federal appellate courts to have decided similar issues have done one of two things—and both are fatal to MMJ’s claims. Most found no constitutional violation or that the party in MMJ’s shoes failed to allege any cognizable harm:

- *Leachco, Inc. v. Consumer Prod. Safety Comm’n*, 103 F.4th 748, 749, 756 (10th Cir. 2024) (affirming denial of preliminary-injunction motion), *pet. for cert. filed*, No. 24-156 (U.S. Aug. 9, 2024); *id.* at 753 (“Leachco has failed to show under prevailing law that its mere subjection to administrative proceedings before an agency whose officials possess unconstitutional removal protections, alone, constitutes irreparable harm.”).⁷
- *K & R Contractors, LLC v. Keene*, 86 F.4th 135, 149 (4th Cir. 2023) (denying petition for review of ALJ order based on constitutional challenge to ALJ removal provisions given absence of any allegation of cognizable harm).
- *Consumer Fin. Prot. Bureau v. Law Offices of Crystal Moroney, P.C.*, 63 F.4th 174, 179-80 (2d Cir. 2023) (affirming order enforcing civil investigative demand (CID); rejecting challenge to CFPB Director authority to issue CID based on allegedly unconstitutional removal provision), *cert. denied*, ___ U.S. ___, No. 22-1233, 2024 WL 2709347 (May 28, 2024).
- *Cnty. Fin. Servs. Ass’n of Am. v. Consumer Fin. Prot. Bureau*, 51 F.4th 616, 631-32 (5th Cir. 2022) (affirming summary judgment for agency; concluding that “promulgating Director’s insulation from removal did not render [regulations] void ab initio”), *rev’d & remanded on other grounds*, 601 U.S. 416

⁷ See also *Leachco*, 103 F.4th at 758:

Axon does not help *Leachco* establish irreparable harm because *Axon* did not address the issue of irreparable harm, or any other issue regarding entitlement to injunctive relief. The Court in *Axon* only addressed whether the petitioners, who were respondents in administrative enforcement actions before the SEC and FTC, could initially bring collateral challenges in federal district court to the constitutionality of those agencies’ structure.

(2024);⁸ *id.* at 633 (“Applying *Collins*’s framework, we conclude the Plaintiffs fail to show that the Act’s removal provision inflicted a constitutional harm.”).

- *Calcutt v. FDIC*, 37 F.4th 293, 310, 313-17 (6th Cir. 2022) (denying petition for review of ALJ order; rejecting contention that removal protections of FDIC and ALJ were unconstitutional), *rev’d & remanded on other grounds*, 598 U.S. 623 (2023); *id.* at 310 (“As the Court recently explained in *Collins v. Yellen*, even if an agency’s structure unconstitutionally shields officers from removal, a party challenging the agency’s action is not entitled to relief unless that unconstitutional provision inflicts compensable harm. *Calcutt* has not demonstrated that the removal protections of the FDIC Board or the FDIC ALJs caused such harm to him.”) (cleaned up).

And even in the rare instance in which a federal appellate court has found removal provisions unconstitutional, the court found those provisions to be severable, severed those provisions, affirmed the underlying administrative action, and denied an injunction. *Kaufmann v. Kijakazi*, 32 F.4th 843, 846, 848-50 (9th Cir. 2022) (affirming order denying Social Security disability benefits, despite holding that statutory provision affording removal protection to Commissioner of Social Security violated separation of powers).⁹

Finally, to merit the injunction that MMJ seeks, it must establish that, absent this relief, it would be irreparably harmed by having to appear before an unconstitutionally protected ALJ. As a matter of law, such an alleged constitutional violation by itself cannot constitute irreparable harm. *E.g.*, *Leachco*, 103 F.4th at 750. Underscoring the absence of irreparable harm, there can be no dispute that appearing before an the ALJ here, even if she were unconstitutionally protected from removal (which is not the case), caused MMJ no harm.

⁸ In invalidating SEC ALJ removal provisions, the Fifth Circuit did not reach the same remedial result in *Jarkesy v. Securities & Exchange Commission*, 34 F.4th 446, 463-65 (5th Cir. 2022), *aff’d on other grounds*, 603 U.S. ___, No. 22–859, slip op. (U.S. June 27, 2024). Instead, it vacated the SEC’s judgment on other grounds, and acknowledged the likely application of *Collins* if the removal issue had been the only basis of its decision. *Id.* at 463 n.17.

⁹ Here, similarly, even if the removal provisions were unconstitutional (which they are not), and even if MMJ had alleged any harm resulting from that provision (which it has not and cannot), the removal provisions would still be severable.

Instead, while the ALJ presided over the OTSC proceeding, MMJ remained silent about its constitutional objection. Before its eleventh-hour objection to the ALJ's removal protections:

- MMJ submitted merits briefing to the ALJ. Defs. SOF ¶ 6.
- The ALJ made two substantive rulings on facts and law, one in the nature of summary judgment and in the DEA's favor. Defs. SOF ¶¶ 3-8.
- The ALJ also granted in part the DEA's motion to exclude testimony from witnesses MMJ had designated. Defs. SOF ¶ 10.¹⁰

The Defendants do not emphasize the preceding procedural history to invite this Court's review of its underlying merits. *See* Section I *above*. Instead, the Defendants emphasize this history because they further expose the hollowness of MMJ's claim of irreparable harm, which is necessary for any injunction to issue.

Even if the DEA ALJ removal protections were unconstitutional, MMJ has not alleged and cannot prove that the statutory removal protections that apply to DEA ALJs caused MMJ any cognizable harm. The Court should therefore dismiss the Amended Complaint.

III. Because the ALJ removal protections are constitutional, MMJ has failed to allege any viable claims.

Although the Court need not reach the question of whether the ALJs' removal protections are constitutional,¹¹ if it does, the Court should hold that they are. Congress created ALJs by enacting the APA in 1946. Pub. L. No. 79-404 § 11, 60 Stat. 237, 244 (1946). ALJs were "[s]ubject to the civil-service" and were "removable by the agency in which they are employed only for good cause established and

¹⁰ The Defendants ask the Court to take judicial notice of these facts or, in the alternative, consider them under Rule 56.

¹¹ *See, e.g., Ashwander v. Tenn. Valley Auth.*, 297 U.S. 288, 347 (1936) (Brandeis, J., concurring) ("If a case can be decided on either of two grounds, one involving a constitutional question, the other a question of statutory construction or general law, the Court will decide only the latter.") (cleaned up); *K & R Contractors, LLC v. Keene*, 86 F.4th 135, 148 (4th Cir. 2023) (citing *Ashwander*) (denying petition for review of ALJ order based on constitutional challenge to ALJ removal provisions given lack of allegations of cognizable harm).

determined by the Civil Service Commission.” *Id.* Section 7521(a) of Title 5 codified that provision, which now allows ALJ removal “only for good cause established and determined by the” MSPB. The President may remove MSPB members “only for inefficiency, neglect of duty, or malfeasance in office.” 5 U.S.C. § 1202(d). This longstanding structure gives ALJs a “qualified right of decisional independence,” *Nash v. Califano*, 613 F.2d 10, 15 (2d Cir. 1980), and is designed to rebut allegations that ALJs might be an agency’s “mere tools.” *Ramspeck v. Fed. Trial Exam’rs Conference*, 345 U.S. 128, 131 (1953).

Article II of the Constitution empowers the President to appoint “lesser officers” and “[t]hat power . . . includes the ability to remove” them. *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 591 U.S. 197, 213 (2020). Just as the “power to remove” is “an incident of the power to appoint,” “the power of Congress to regulate removals” is “incidental to the exercise of its constitutional power to vest appointments.” *Myers v. United States*, 272 U.S. 52, 161 (1926); *see United States v. Perkins*, 116 U.S. 483, 485 (1886). The key inquiry in removal cases is whether Congress has “interfere[d] with the President’s exercise of the ‘executive power’ and his constitutionally appointed duty to ‘take care that the laws be faithfully executed’ under Article II.” *Morrison v. Olson*, 487 U.S. 654, 689 (1988) (cleaned up; quoting U.S. Const. art. II §§ 1, 3).

There has been no Congressional interference that could invalidate DEA ALJ removal restrictions. First, the Supreme Court has recognized that Congress may regulate removals of inferior officers. *Perkins*, 116 U.S. at 484-85 (upholding restriction on Secretary of the Navy’s power to remove a naval officer); *Morrison*, 487 U.S. at 685-96 (upholding restriction on Attorney General’s power to remove independent counsel).

Second, the Supreme Court has also recognized that the scope of the President’s constitutional power to remove and control adjudicators—and MMJ concedes

that is all that DEA ALJs do, ECF 15 ¶¶ 81-82—differs from the scope of his power to remove and control other executive officers. For example, in *Morrison*, the Court observed that tenure protection may be “necessary to the proper functioning” of “an official performing ‘quasi-judicial’ functions.” 487 U.S. at 691 n.30; *see also Wiener v. United States*, 357 U.S. 349, 355-56 (1958) (holding that Congress could limit the President’s power to remove members of the War Claims Commission, an “adjudicatory body,” because of “the intrinsic judicial character of the task with which the Commission was charged”); *Humphrey’s Executor v. United States*, 295 U.S. 602, 629 (1935) (finding it “plain under the Constitution that illimitable power of removal is not possessed by the President in respect of officers” charged with “quasi-judicial” duties).

Third, Congress enacted the removal protections that apply to ALJs generally. But Congress did not impose ALJ adjudication as part of the CSA. 21 U.S.C. § 824(c)(1). Instead, by the power delegated to the Attorney General and, in turn, the Administrator, the Executive branch chose to have ALJs with removal protections¹² to conduct interim, advisory functions. 21 C.F.R. §§ 1316.42(f) & (g), 1316.47, 1316.49, 1316.52. The same principal officers, subject to removal by the President at will, could just as easily change this structure—diminishing any separation-of-powers concerns. *Decker Coal Co. v. Pehringer*, 8 F.4th 1123, 1133-34 (9th Cir. 2021) (rejecting constitutional challenge to removal restrictions applied to Department of Labor ALJs); *see also Calcutt v. FDIC*, 37 F.4th 293, 310, 319 (6th Cir. 2022) (“Even if

¹² The MSPB’s involvement does not, “by itself, put any additional burden on the President’s exercise of executive authority”; rather, it simply “ensure[s] that an [ALJ] is removed only in accordance with” the good-cause standard prescribed by Congress and, here, chosen by the Executive branch in the regulatory choices it has made to implement the CSA. *See Morrison*, 487 U.S. at 693 n.33. Just as the Attorney General’s decision to fire an “inferior officer” for good cause was allowable in *Morrison*, even though it was subject to judicial review, so is the same decision to fire a DEA ALJ for good cause allowable even though it may be reviewed by the MSPB. *Id.* at 663-64, 686-93.

relief were available, we doubt Calcutt could establish a constitutional violation from [FDIC] ALJ removal restrictions. . . . [F]or-cause protections of ALJs are distinguishable [from those invalidated in *Free Enterprise*] because agencies can choose not to use ALJs in adjudications. . . .”), *rev’d & remanded on other grounds*, 598 U.S. 623 (2023).

Fourth, even if Congress had imposed these removal protections in the CSA, the President still has ample tools to hold his subordinates accountable. DEA ALJs have only an interim, advisory function. Once the ALJ in MMJ’s case makes her recommendations, the Administrator is utterly free to accept, reject, or otherwise modify them in her final order. And the Administrator—the decisionmaker who matters here—is removable by the President at will. *Decker*, 8 F.4th at 1134; *id.* at 1135 (“ALJs are judges who make decisions that are subject to vacatur by people without tenure protection. With this structure, the President continues to enjoy an ‘ability to execute the laws’”) (quoting *Free Enter.*, 561 U.S. at 496); *Calcutt*, 37 F.4th at 319 (same).

Moreover, in circumstances limiting Executive power more than the regulatory choices the Executive branch made under the CSA, the Ninth Circuit rejected a constitutional challenge to ALJ removal protections. In *Decker*, the Ninth Circuit held that the President had sufficient control over ALJs to satisfy the separation of powers because, although the ALJs were removable only for good cause, the ALJs’ decisions were reviewable by an administrative appellate board whose members served at the pleasure of the Secretary of Labor, who in turn was removable at will by the President. *Decker*, 8 F.4th at 1133-35. And, adopting that reasoning, the Tenth Circuit found the same removal protections challenged here constitutional. *Leachco*, 103 F.4th at 763-65. Under the CSA, Executive control over DEA ALJs and DEA decisionmaking is both broader and more direct than in *Decker* and, thus, constitutional.

MMJ's Amended Complaint nevertheless seeks to invalidate the DEA ALJ removal protections based on *Free Enterprise*. ECF 15 ¶¶ 8, 84. But *Free Enterprise* did not consider any of the preceding arguments. And, on its own terms, it does not render DEA ALJ removal protections unconstitutional for at least three more reasons.¹³ First, *Free Enterprise* invalidated the “highly unusual,” “sharply circumscribed,” “novel,” and “rigorous” removal standards and procedures that applied to a particular set of officers—members of the Public Company Accounting Oversight Board (“PCAOB”). 561 U.S. at 496, 505. The Court expressly distinguished that context from the one here—namely, where the “‘ordinary’ dual for-cause standard” applies. *Id.* at 502-03. The removal standard that applies to DEA ALJs—“good cause”—is, moreover, the one that gives the President the *most* removal authority. *Collins v. Yellen*, 594 U.S. 220, 255 (2021). Second, *Free Enterprise* “did not broadly declare all two-level for-cause protections for inferior officers unconstitutional.” *See Decker*, 8 F.4th at 1132; *Free Enter.*, 561 U.S. at 506-07. Instead, it expressly reserved judgment concerning the removal protections that apply to ALJs. 561 U.S. at 507 n.10. Finally, the Court stressed the historical novelty of the PCAOB itself, *id.* at 505-06, as well as its broad policymaking powers, as contrasted from ALJs’ “purely recommendatory powers,” *id.* at 507 n.10, which ALJs have employed, with the essentially the same protections, for nearly 80 years.

CONCLUSION

For the reasons set forth above, the Defendants respectfully request that the Court dismiss MMJ's Amended Complaint with prejudice.

¹³ For its failure to credit these arguments or the ways that DEA ALJs differ from SEC ALJs, the Fifth Circuit's decision in *Jarkesy* that the removal protections that apply to SEC ALJs are unconstitutional similarly cannot extend to DEA ALJs. *Jarkesy v. Secs. & Exchange Comm'n*, 34 F.4th 446, 463-65 (5th Cir. 2022), *aff'd on other grounds*, 603 U.S. ___, No. 22-859, slip op. (U.S. June 27, 2024).

Local Civil Rule 7(c) Statement

The Defendants ask the Court to schedule oral argument on their motion.

Dated: September 9, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on September 9, 2024, I filed the foregoing document through this Court's Electronic Case Filing (ECF) system, thereby serving it upon all registered users in accordance with Federal Rule of Civil Procedure 5(b)(2)(E) and Local Rule Gen 304.

/s/ Kevin Bolan

KEVIN BOLAN

Assistant United States Attorney