IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

KNOWLEDGE ECOLOGY INTERNATIONAL, Plaintiff, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Case No. 8:18-cv-01130-PJM

DEFENDANTS' SUPPLEMENTAL BRIEF

Defendants, National Institutes of Health ("NIH"), National Cancer Institute ("NCI"), Francis S. Collins ("Collins"), and David Lambertson ("Lambertson," and together with NIH, NCI, Collins, and Lambertson, the "Defendants"), by their counsel, Robert K. Hur, United States Attorney for the District of Maryland, and Alan C. Lazerow, Assistant United States Attorney for that district, respectfully submit this *Supplemental Brief* (the "Supplemental Brief").

I. INTRODUCTION

In the two-count *Complaint for Declaratory, Injunctive, and Other Relief*, *see* ECF No. 1 (the "Complaint"), Knowledge Ecology International ("KEI" or the "Plaintiff") asserts that certain of Defendants' conduct was arbitrary and capricious: Defendants' failure to seek and obtain the antitrust advice of the Attorney General about NIH's grant of an exclusive license relating to certain cancer treatments to a large pharmaceutical company (the "Proposed License") (Count I); and Defendants' refusal to consider Plaintiff's appeal of NIH's rejection of certain comments Plaintiff provided on the Proposed License (Count II). In Defendants' *Motion to Dismiss*, see ECF No. 5 (the "Motion to Dismiss") and *Defendants' Reply to Plaintiff's Memorandum in Opposition to Defendants' Motion to Dismiss*, *see* ECF No. 10 (the "Reply"), Defendants argued Plaintiff lacked standing to sue for the requested relief,

and thus the Court lacked subject-matter jurisdiction over the Complaint under Rule 12(b)(1) of the Federal Rules of Civil Procedure (the "Rules").

After an October 15, 2018 hearing on the Motion to Dismiss, the Court entered an *Order*, *see* ECF No. 14 (the "Supplemental Briefing Order"), deferring ruling on the Motion to Dismiss and ordering "supplemental briefing on the applicability of the Administrative Procedures Act with respect to Plaintiff's entitlement, if any, to a hearing and to an appeal of their comments to NIH …." Supplemental Briefing Order, at p. 1. Consistent with the Supplemental Briefing Order, and in opposition to Plaintiff's *Supplemental Memorandum in Support of Plaintiff's Opposition to Defendants' Motion to Dismiss*, *see* ECF No. 16 ("Plaintiff's Supplemental Brief"), Defendants submit this Supplemental Brief.

As for Count II, the Court should dismiss or grant summary judgment in Defendants' favor on the claim for any one of three reasons. *First*, because NIH's decision whether to consider an appeal of a determination on the grant of a license, under 37 C.F.R. § 404.11(a)(3), is committed to agency discretion by law, Count II is unreviewable and the Court lacks subject-matter jurisdiction over the claim. *Second*, because whatever procedural harm Plaintiff suffered by NIH's refusal to consider an appeal is not tied to a concrete injury, Plaintiff lacks standing on Count II and the Court further lacks subject-matter jurisdiction over the claim. And *third*, even if the Court has subject-matter jurisdiction over Count II and the Court reaches the merits, NIH's refusal to consider Plaintiff's appeal was not arbitrary or capricious, and thus Defendants are entitled to summary judgment on the claim.

As for Count I—in which Plaintiff challenges the merits of NIH's grant of the Proposed License—and as Defendants explain in the Motion to Dismiss and the Reply, Plaintiff lacks both organizational and associational standing to sue. Defendants do not repeat those arguments here, but instead incorporate the standing arguments they made in the Motion to Dismiss and the Reply.

For these reasons, and as Defendants explain below, in the Motion, and in the Reply, the Court should (i) dismiss Count I for lack of subject-matter jurisdiction, and (ii) dismiss Count II for lack of subject-matter jurisdiction or enter summary judgment in Defendants' favor.

II. FACTS RELEVANT TO THE SUPPLEMENTAL BRIEFING

On January 4, 2018, James Love wrote to Collins and Lambertson to "express [KEI's] opposition to the [P]roposed [License]." Berkley Declaration[1,2] ¶ 6.[3] Mr. Love attached a five-page document outlining KEI's opposition to the Proposed License. *Id.*

On January 25, 2018, Lambertson responded to Mr. Love by email and attached NIH's response, explaining that "[w]hile your comments have been given full consideration, they do not persuade us that the [Proposed License] would be inconsistent with the regulations and, furthermore, advance public health." *Id.* ¶ 7.[4]

On February 14, 2018, Andrew Goldman—former counsel of record for KEI—emailed Collins and Lambertson asking about KEI's appeal rights and asked Collins and Lambertson to "let [KEI] know what formal procedures the NIH requires for these appeals …." *Id.* ¶ 8.[5] On February 26, 2018, Lambertson responded to Mr. Goldman, noting that under 37 C.F.R. § 404.11(a)(3), only "a

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[1] A copy of the Berkley Declaration was attached as Exhibit A to the Motion to Dismiss.

[2] Capitalized terms not otherwise defined are given the meanings ascribed to them in the Motion to Dismiss.

[3] A copy of the January 4, 2018 email from Mr. Love to Collins and Lambertson, with an attachment, was attached as Exhibit 1 to the Berkley Declaration.

[4] A copy of the January 25, 2018 email from Lambertson to Mr. Love, with an attachment, was attached as Exhibit 2 to the Berkley Declaration.

[5] A copy of the February 14, 2018 email from Mr. Goldman to Collins and Lambertson was attached as Exhibit 3 to the Berkley Declaration.

person who can demonstrate to the satisfaction of the agency that such person may be damaged by the action," can take an appeal, that NIH "determined that there is no likelihood that KEI will be damaged by the agency action," and that NIH "will not entertain an appeal of our decision." *Id.* ¶ 9.[6] Later on February 26, 2018, Mr. Goldman responded to Collins and Lambertson, attaching KEI's appeal. *Id.* ¶ 10.[7]

III. NIH'S APPEAL PROCEDURES RELATED TO LICENSING DETERMINATIONS

37 C.F.R. § 404.11 (titled "appeals") provides:

> (a) In accordance with procedures prescribed by the Federal agency, the following parties may appeal to the agency head or designee any decision or determination concerning the grant, denial, modification, or termination of a license:
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> (1) A person whose application for a license has been denied;
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> (2) A licensee whose license has been modified or terminated, in whole or in part; or
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> (3) A person who timely filed a written objection in response to the notice required by § 404.7(a)(1)(i) or § 404.7(b)(1)(i) and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action.
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> (b) An appeal by a licensee under paragraph (a)(2) of this section may include a hearing, upon the request of the licensee, to address a dispute over any relevant fact. The parties may agree to Alternate Dispute Resolution in lieu of an appeal.

Consistent with 37 C.F.R. § 404.11(a)'s reference to "procedures prescribed by the Federal agency," in Chapter No. 307 of the United States Public Health Service Technology Transfer Manual, NIH issued *Procedures for Handling Requests for Reconsideration and Appeals of Licensing Decisions* (the "Appeal

[6] A copy of the February 26, 2018 email from Lambertson to Mr. Goldman was attached as Exhibit 4 to the Berkley Declaration.

[7] A copy of the February 26, 2018 email from Mr. Goldman to Collins and Lambertson, with attachments, was attached as Exhibit 5 to the Berkley Declaration.

Procedures"). *See* Declaration of Mark L. Rohrbaugh, Ph.D., J.D. (the "Rohrbaugh Declaration")[8] ¶ 7; *see* Rohrbaugh Declaration, Exh. 1. The Appeal Procedures provide that "[t]he following person(s) may either request reconsideration by the Director, O[ffice of] T[echnology] T[ransfer] or may subsequently appeal to the Director, NIH":

> 1. A person whose application for a license to technology advertised as available has been denied;
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> 2. A licensee whose license has been modified or terminated in whole or in part; or
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> 3. A person who has timely filed a written objection in response to the notice published in the Federal Register as required by 37 C.F.R. § 404.7(a)(1)(I) or 37 C.F.R. § 404.7(b)(1)(I) and who can demonstrate to the satisfaction of the Director, OTT that such person may be damaged by the determination of the NIH.

Rohrbaugh Declaration, Exh. 1, at p. 1.

The first-level appeal is a request for reconsideration. *See id.* "A person/licensee may request reconsideration … by filing with the Director, OTT, a written request for reconsideration within thirty … days after … a response to a Written Objection is sent by the OTT to the person." *Id.* at pp. 1-2. "When the Director, OTT receives a request for reconsideration, he or she shall appoint an ad hoc committee," which may include "OTT Licensing Specialists … as well as other NIH employees," "to review the case and make recommendations regarding action to be taken." *Id.* at p. 2. The review committee makes recommendations to the Director, OTT, and "[w]ithin sixty … days of receiving the request for reconsideration, the Director, OTT shall send a final determination to the requesting party along with notice of the party's right to appeal the decision to the director." *Id.*

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[8] The Rohrbaugh Declaration is attached as **Exhibit A**.

The second-level appeal is an appeal to the Director, NIH. "Appellants shall not be entitled to an adversary hearing" on appeal.[9] To request an appeal, "[t]he Appellant shall file a written appeal to the Director, NIH … no later than thirty … days from the receipt of an adverse decision by the Director, OTT concerning a request for reconsideration." *Id.* "If the Director, NIH, deems it appropriate, he or she may appoint an individual or a committee which may include representatives from the OTT, OGC, and, if necessary, scientists with expertise in the particular field of technology, to review the administrative record." *Id.* The review committee makes recommendations to the Director, NIH, and "[w]ithin sixty … days of receiving the written appeal, the Director, NIH, shall send the final determination to the Appellant." *Id.* The Appeal Procedures provide that "[j]udicial review is available as the law permits." *See id.* at p. 3.

IV. ARGUMENT

A. THE DECISION WHETHER TO CONSIDER AN APPEAL[10] OF A LICENSING DETERMINATION, UNDER 37 C.F.R. § 404.11(a)(3), IS COMMITTED TO AGENCY DISCRETION BY LAW AND IS THUS UNREVIEWABLE

NIH's refusal to consider Plaintiff's appeal is "committed agency discretion by law" and not subject to challenge under the Administrative Procedure Act (the "APA"). *See* 5 U.S.C. § 701(a)(2); *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). Agency action is committed to agency discretion where

[9] This dovetails with 37 C.F.R. § 404.11(b), which provides that "[a]n appeal by a licensee under paragraph (a)(2) of this section may include a hearing, upon the request of the licensee, to address a dispute over any relevant fact." Thus, under section 404.11, the only class of appellants who *may* (but are not necessarily entitled to) receive a hearing are those "whose license has been modified or terminated, in whole or in part …." *See* 37 C.F.R. § 404.11(a)(2). The Appeal Procedures' provision that "[a]ppellants shall not be entitled to an adversary hearing" on an appeal accords with section 404.11's non-guarantee of a hearing.

[10] As discussed above, the Appeal Procedures provide for a two-level review: first, reconsideration to the Director, OTT; second, an appeal to the Director, NIH. Throughout this Supplemental Brief, Defendants reference NIH's refusal to consider Plaintiff's "appeal," which Defendants mean as NIH's refusal to allow Plaintiff the first-level reconsideration.

the applicable statutes and regulations provide "no meaningful standard against which to judge the agency's exercise of discretion." *Heckler*, 470 U.S. at 830; *see Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (holding agency action unreviewable "where 'statutes are drawn in such broad terms that in a given case there is no law to apply'") (quoting S. Rep. No. 752, 79th Cong., 1st Sess. 26 (1945)). "In other words, § 701(a)(2) encodes the principle that an agency cannot abuse its discretion, and thus violate § 706(2)(A), where its governing [law] confers such broad discretion as to essentially rule out the possibility of abuse." *Drake v. FAA*, 291 F.3d 59, 70 (D.C. Cir. 2002).

Pertinent here, courts have dealt with "whether the vehicle through which the agency is granted discretion in the first instance must be a statute." *Sheikh v. U.S. Dep't of Homeland Sec.*, 685 F. Supp. 2d 1076, 1087 (C.D. Cal. 2009). In examining this issue, courts have held "that a grant of agency discretion 'by law,' need not be statutory." *See id.*; *see Ngure v. Ashcroft*, 367 F.2d 975, 982-85 (8th Cir. 2004) (applying section 701(a)(2) to a series of "streamlining regulations" for immigration appeals); *Lunney v. United States*, 319 F.3d 550, 558 (2d Cir. 2003) (holding that, to demonstrate that a claim is not barred by section 701(a)(2), a plaintiff "must specify some statute *or regulation* that would limit the [agency]'s discretion in th[e] matter") (emphasis added); *Diebold v. United States*, 947 F.2d 787, 796 (6th Cir. 1991) (looking "to the regulations issued pursuant to … statutes as sources of law and examin[ing] whether they create 'law to apply'"); *see also Heckler*, 470 U.S. at 830 (Brennan, J., concurring) ("[T]he statutes or regulations at issue may well provide 'law to apply' under 5 U.S.C. §701(a)(2).").

Because the issue here is "whether a statute or regulation commits the challenged agency decision 'to agency discretion by law,'" *Target v. Training Int'l, Ltd. v. Lee*, 1 F. Supp. 3d 927, 941 (N.D. Iowa 2014), examination of the regulation that NIH cited in refusing Plaintiff's appeal—37 C.F.R. § 404.11—and its enabling statutes is appropriate.

i. 37 C.F.R. § 404.11's Enabling Statutes Provide the Court with No Law to Apply

In his February 26, 2018 email to Mr. Goldman, Lambertson explained that NIH was refusing to consider Plaintiff's appeal and cited 37 C.F.R. § 404.11. *See* Berkley Declaration ¶ 9. The enabling statutes for 37 C.F.R. § 404.11 are 35 U.S.C. §§ 207, 208, and 209. 35 U.S.C. § 208 simply provides that "[t]he Secretary of Commerce is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention … may be licensed on a nonexclusive, partially exclusive, or exclusive basis." *See* 71 Fed. Reg. 11510-01, 11514 (Mar. 8, 2006) (issuing final rule on the granting of licenses by federal agencies on federally owned inventions and revising 37 C.F.R. § 404.11). None of 35 U.S.C. §§ 207, 208, or 209 addresses the appeals of decisions on the grant, denial, modification, or termination of licenses, let alone provides any limits, requirements, or criteria that could serve as guideposts for NIH's decisions. *See, e.g.*, *Watervale Marine Co., Ltd. v. U.S. Dep't of Homeland Sec.*, 55 F. Supp. 3d 124, 143 (D.D.C. 2014) (holding agency's decision committed to agency discretion by law where "the statute … [is] devoid of any … limits, requirements, or criteria that provide any guideposts by which a court can measure the [agency]'s discretionary decision"); *see also Slyper v. Attorney General*, 827 F.2d 821, 824 (D.C. Cir. 1987) (holding an agency's decision committed to agency discretion by law where "the governing statute is devoid of guidance").[11]

[11] Congress knew how to provide guidance for appeals elsewhere in Chapter 18 of Title 35, also known as the Bayh-Dole Act—where 37 C.F.R. § 404.11's enabling statutes are housed and which generally deals with patent rights in inventions made with federal assistance. 35 U.S.C. § 203 involves "march-in" rights, which allow the funding agency, on its own initiative or at the request of a third party, effectively to ignore the exclusivity of a patent awarded under the Bayh-Dole Act and grant additional licenses of the patent. 35 U.S.C. § 203(b) deals with the appeal rights of those "adversely affected" by determinations on march-in rights, providing the who ("any contractor, inventor, assignee, or exclusive licensee adversely affected by a determination under this section"), the when ("at any time within sixty days after the determination is issued"), the what ("file a petition") and the where ("in the United States Court of Federal Claims") of such appeals. Congress's silence (in the same Act) on the appeal rights for those submitting comments to Federal Register notices about licensing determinations is telling.

ii. 37 C.F.R. § 404.11(a)(3) Provides NIH Unfettered Discretion Over Decisions Regarding Licensing Appeals

"[E]ven if the underlying statute does not include meaningful (or manageable) standards, 'regulations promulgated by an administrative agency in carrying out its statutory mandate can provide standards for judicial review.'" *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 246 (4th Cir. 2001) (quoting *CC Distribs., Inc. v. United States*, 883 F.2d 146, 154 (D.C. Cir. 1989)). As discussed above, 37 C.F.R. § 404.11(a) provides:

> (a) In accordance with procedures prescribed by the Federal agency, the following parties may appeal to the agency head or designee any decision or determination concerning the grant, denial, modification, or termination of a license:
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> (1) A person whose application for a license has been denied;
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> (2) A licensee whose license has been modified or terminated, in whole or in part; or
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> **(3) A person who timely filed a written objection in response to the notice required by § 404.7(a)(1)(i) or § 404.7(b)(1)(i) and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action**.

(Emphasis added). 37 C.F.R. § 404.11(a)(3), which provides that appeals of licensing decisions are available to those "who can demonstrate *to the satisfaction of the Federal agency* that such person may be damaged by the agency action" (emphasis added), gives unfettered discretion to NIH to determine who may appeal. Thus, such decisions are committed to NIH's discretion by law. Reported caselaw supports this conclusion.

In *Drake*, 291 F.3d at 59, appellant—a flight attendant—contended that the FAA neglected its statutory responsibilities in finding that appellant's airline-employer did not violate agency drug-testing regulations. *See id.* at 62. The statute at issue provided that the agency "may dismiss a complaint without a hearing when the Secretary [of Transportation] … *is of the opinion* that the complaint does not state facts that warrant an investigation or action." *See id.* (emphasis added); 49 U.S.C.

§ 46101(a)(3). In holding that the FAA's decisions were committed to agency discretion by law, the court noted that "the language of § 46101(a)(3), which set the terms for the FAA's decision to dismiss [appellant]'s complaint without a hearing, is highly discretionary." *Drake*, 291 F.3d at 71-72. The court emphasized that "a provision that allows the Administrator to act when she '*is of the opinion* that the complaint does not state facts that warrant an investigation' gives the FAA virtually unbridled discretion over such decisions," because "[t]he only reference point is the Administrator's own beliefs." *Id.* at 72. Thus, the court determined that it "has no meaningful standard against which to judge the agency's exercise of discretion," and refused to consider appellant's challenge to agency action. *See id.*

As in *Drake*, 37 C.F.R. § 404.11(a)(3)'s requirement that a commenter "demonstrate to the satisfaction of the Federal agency that [it] may be damaged" is "highly discretionary" and gives NIH "virtually unbridled discretion over such decisions," because "[t]he only reference point is the [agency]'s own beliefs." *See Drake*, 291 F.3d at 72. Thus, just as the D.C. Circuit did in *Drake*, this Court should hold that such highly-discretionary language commits NIH's decisions about licensing appeals, under 37 C.F.R. § 404.11(a)(3), to its discretion by law.

Michigan Department of State v. United States, 166 F. Supp. 2d 1228 (W.D. Mich. 2001), is also instructive. There, the State of Michigan challenged the decision of the United States Department of Health and Human Services to deny the state an exemption from a statute mandating that states collect social security numbers of driver's license applicants to improve child support collection, and claimed that denial violated the APA. *Id.* at 1231-32. 42 U.S.C. § 666(d) provides that "[i]f a State *demonstrates to the satisfaction of the Secretary* … that the enactment of any law … will not create the effectiveness and efficiency of the State child support enforcement program, the Secretary may exempt the state …." *Mich. Dep't of State*, 166 F. Supp. 2d at 1236 (emphasis added). In holding that section "701(a)(2)

applies and that DHHS's decision to deny Michigan an exemption is not reviewable," the district court highlighted that the statute's language that states must "demonstrate to the satisfaction of the Secretary" "indicates that Congress was placing the exemption decision solely within DHHS's discretion," and "[c]onsequently, the Court is not authorized to review DHHS's decision." *Id.* at 1236, 1237.

Both 42 U.S.C. § 666(d)—the statute at issue in *Michigan*—and 37 C.F.R. § 404.11(a)(3)—the regulation here—require challengers of agency action to "demonstrate to the satisfaction" of the pertinent agency. *Compare* 42 U.S.C. § 666(d) *with* 37 C.F.R. § 404.11(a)(3). Invoking identical language, the Court should hold, as the district court in *Michigan* did, that 37 C.F.R. § 404.11(a)(3) commits NIH's decisions about licensing appeals to its discretion by law. *See Speed Mining, Inc. v. Fed. Mine Safety & Health Review Comm'n*, 528 F.3d 310, 317 (4th Cir. 2008) (holding an agency's decision committed to its discretion by law where the pertinent statute provided that "*if the Secretary believes* that an operator has violated the Mine Act, the Secretary shall issue a citation to the operator") (cleaned up)[12] (emphasis added); *see also Angelex Ltd. v. United States*, 723 F.3d 500, 506-07 (4th Cir. 2013) (holding an agency's decision committed to its discretion by law where the pertinent statute provided that a certain "[c]learance may be granted upon the filing of a bond or other surety *satisfactory to the Secretary*") (emphasis added).

For these reasons, NIH's refusal to consider Plaintiff's appeal is committed agency discretion by law, and the Court lacks subject-matter jurisdiction over Count II. *See Madison-Hughes v. Shalala*, 80

[12] "'Cleaned up' is a new parenthetical used to eliminate unnecessary explanation of non-substantive prior alterations." *United States v. Seward*, 880 F.3d 883, 986 n.3 (8th Cir. 2018); *see also Yarls v. Bunton*, 905 F.3d 911 n.22 (5th Cir. 2018); *Arnold v. Dittmann*, 901 F.3d 830, 838 (7th Cir. 2018) *Am. Freedom Defense Initiative v. WMATA*, 901 F.3d 356, 369 n.6 (D.C. Cir. 2018); *Franks v. City of Santa Ana*, 735 F. App'x 305, 306 (9th Cir. 2018); *Gutierrez v. First Nat'l Bank of Am.*, No. 8:18-cv-00479, 2018 WL 4562959, at *3 (D. Md. Sept. 21, 2018) (Hazel, J.).

F.3d 1121, 1127 (6th Cir. 1996) ("[C]ourts do not have subject matter jurisdiction to review agency actions that are committed to agency discretion by law.") (internal quotation marks omitted).

B. BECAUSE WHATEVER PROCEDURAL HARM PLAINTIFF SUFFERED BY NIH'S REFUSAL TO CONSIDER PLAINTIFF'S APPEAL IS NOT TIED TO A CONCRETE INJURY, PLAINTIFF LACKS STANDING ON COUNT II

Plaintiff contends "that a decision taken without providing KEI the opportunity to file [an] appeal … is a violation of procedural rules …." Plaintiff's Supplemental Brief, at p. 18. Plaintiff asserts no harm—aside from a technical violation of 37 C.F.R. § 404.11(a)(3)—stemming from Defendants' refusal to consider Plaintiff's appeal. As Defendants explain below, even if 37 C.F.R. § 404.11(a)(3) does not commit NIH's decisions about licensing appeals to its discretion by law, such bare "procedural harm" cannot confer Plaintiff standing. Thus, the Court further lacks subject-matter jurisdiction over Count II. *See St. Croix Chippewa Indians of Wis. v. Salazar*, 384 F. App'x 7, 8 (D.C. Cir. 2010) (affirming "the district court's dismissal for lack of subject matter jurisdiction" where plaintiffs could not "identify an injury that follows the violation of a procedural right").

Plaintiff insists that "administrative standing and judicial standing are conceptually distinct." *Id.* at p. 12. That is a correct pronouncement of the law in a vacuum. But "*Lujan* [*v. Defenders of Wildlife*, 504 U.S. 555 (1992)] and the cases that have followed it reason that the right to participate in the proceedings of the agency does not give one the right to seek redress for the deprivation of that right in federal court …." *Bensman v. U.S. Forest Service*, 408 F.3d 945, 953 (7th Cir. 2005). Instead, "[p]laintiffs must show a separate concrete interest in order to assert a procedural injury …." *Sierra Club v. U.S. Def. Energy Support Ctr.*, No. 1:11-cv-00041, 2011 WL 3321296, at *4 (E.D. Va. July 29, 2011); *see Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) ("[D]eprivation of a procedural right

without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing."). Many authorities agree.[13]

> *Bensman* is on point. There, the Seventh Circuit began:
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> > [I]t is essential that we pause a moment and focus on the precise nature of the claim asserted by these plaintiffs. The plaintiffs' claim alleges a violation of the APA. The plaintiffs believe that the Forest Service arbitrarily and capriciously dismissed their appeals and therefore deprived them of their rights under the Appeals Reform Act … to file an appeal from the Service's initial determination and to have that appeal considered according to the terms of that statute. In essence, [the plaintiffs] challenge the Forest Service's refusal to consider their appeals; in their view, this refusal denied them rights that they believe Congress afforded them under the ARA as notice and comment participants. The injury that they assert is the Service's refusal to hear those appeals, an injury, they further submit, that the district court can remedy through the requested relief.

Bensman, 408 F.3d at 949 (internal citation omitted). The court noted that the plaintiffs there—like Plaintiff here—"asserted what might be called generically a 'procedural injury.'" *Id.* at 951. The court explained that it, "along with other circuits, has acknowledged that the denial of a 'procedural right, unconnected to a plaintiff's concrete harm, is not enough to convey standing.'" *Id.* at 952 (quoting *Heartwood, Inc. v. U.S. Forest Serv.*, 230 F.3d 947, 952 (7th Cir. 2000)). The court emphasized that

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[13] *See, e.g.*, *KERM, Inc. v. FCC*, 353 F.3d 57, 69 (D.C. Cir. 2004) ("That a petitioner participated in administrative proceedings before an agency does not establish that the petitioner has constitutional standing to challenge those proceedings in federal court."); *Hydro Invs., Inc. v. FERC*, 351 F.3d 1192, 1197 (D.C. Cir. 2003) ("Administrative agencies need not adjudicate only Article III cases and controversies, but federal courts must. If the petitioner has no Article III concrete interest in receiving the relief requested before the agency, … Congress has no power to grant a petitioner a right to seek judicial review of an agency's decision to deny him relief."); *Wilcox Elec., Inc. v. FAA*, 119 F.3d 724, 727-28 (8th Cir. 1997) (holding that federal courts "may review on appeal only those agency adjudications in which the parties to the agency proceeding would have had standing to bring an action in federal district court with respect to the matter in dispute if one lay there," and that "to hold otherwise, and deem any loss in an agency protest proceeding an injury of Article III dimensions, … would enable plaintiffs lacking Article III standing at the outset of their protests to bootstrap their way into a federal court"); *see also* CHARLES A. WRIGHT ET AL., FEDERAL PRACTICE & PROCEDURE § 3531.13 (3d ed. 2016) (noting that "[c]ountless numbers of government officials interact with untold numbers of people every day," and "[t]hat an official in some sense accords 'standing' in recognizing a person and engaging in official exchanges should not support standing to seek judicial review of whatever was said or not said, done or not done").

although "the procedural lapse … can be said to be personal to the plaintiffs," "unless the plaintiffs can show that the deprivation of this procedural right somehow is related to a discrete, substantive injury for which they may seek redress in federal court, they have no standing to seek redress of the procedural injury itself." *Bensman*, 408 F.3d at 953.

The court rejected the contention that "the ARA-granted right to participate in Forest Service decision-making is a concrete interest …." *Id.* Rejecting the "claimed participation injury," *Id.* at 955, the court explained:

> We cannot accept this argument. The right guaranteed by the ARA is, at bottom, simply a right to participate in agency deliberations. At least after *Lujan*, participation in agency proceedings is alone insufficient to satisfy judicial standing requirements. Because agencies are not constrained by Article III, they may permit persons to intervene in the agency proceedings who would not have standing to seek judicial review of the agency action. *Lujan* and the cases that have followed it reason that the right to participate in the proceedings of the agency does not give one the right to seek redress for the deprivation of that right in federal court when one does not have a sufficiently differentiated concrete interest in the agency proceedings to seek review of the agency's substantive decision in federal court.

Id. at 953 (cleaned up).

Here, as in *Bensman*, Plaintiff contends that NIH arbitrarily and capriciously refused to consider its appeal. But raising this bare "procedural harm" does not grant Plaintiff standing unless that harm is "somehow is related to a discrete, substantive injury for which [it] may seek redress in federal court …." *Bensman*, 408 F.3d at 953; *see Khan v. Children's Nat'l Health Sys.*, 188 F. Supp. 3d 524, 534 (D. Md. 2016) ("[A] 'bare procedural harm' … 'divorced from any concrete harm,' would not 'satisfy the injury-in-fact requirement' ….") (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1549 (2016)). Aside from the denial of an appeal itself, Plaintiff does not allege—in the Complaint or in Plaintiff's Supplemental Brief—any harm it suffered or will suffer from Defendants' refusal to consider its appeal. And as

Defendants explain in the Motion to Dismiss,[14] Plaintiff lacks organizational and associational standing because, among other reasons, it did not suffer an injury-in-fact. Thus, Plaintiff does not allege a "discrete, substantive injury for which [it] may seek redress in federal court," and thus Plaintiff lacks standing to assert what is a mere procedural harm. *See Bensman*, 408 F.3d at 953; *see also Brown v. R&B Corp. of Va.*, 267 F. Supp. 3d 691, 698 (E.D. Va. 2017) ("[A] 'bare' procedural violation that is essentially harmless because it presents no risk of harm to a substantive right is not sufficient to demonstrate a concrete injury."); *see also Fund Democracy, LLC v. SEC*, 278 F.3d 21, 27-28 (D.C. Cir. 2002) (holding that "[p]articipation in agency proceedings is alone insufficient to satisfy judicial standing requirements," and where appellant "has not shown any … concrete interest apart from the procedural injury").

The Court can contrast 37 C.F.R. § 404.11(a)(3), that applies to Plaintiff, and section 404.11(a)(1) and (2), which provide for appeals to "[a] person whose application for a license has been denied" and "[a] licensee whose license has been modified or terminated," respectively. A prospective licensee or licensee whose licensing rights NIH affects—either by denying an application or modifying or terminating an existing license—has a concrete interest in those licensing rights. If NIH refused such prospective licensees or licensees an appeal, NIH would be hard-pressed to argue that such licensees did not suffer a concrete harm separate from the appeal refusal. But one who merely comments on a proposed license—which section 404.11(a)(3) contemplates, assuming that commenter "can demonstrate to the satisfaction of [NIH] that such person may be damaged by the agency action"—does not necessarily suffer a concrete injury separate from the appeal refusal.

A practical point. As Defendants discuss above, the harm Plaintiff asserts here is the bare procedural harm it suffered from NIH's refusal to consider Plaintiff's appeal. Plaintiff does not and

[14] Defendants incorporate here their arguments in the Motion to Dismiss and the Reply.

could not credibly contend that NIH denied it a voice on NIH's grant of the Proposed License as a general matter. As further discussed above, on January 4, 2018, Mr. Love submitted five-pages of comments on the Proposed License in response to the Federal Register notice. *See* Berkley Declaration ¶ 6. On January 25, 2018, Lambertson responded to Mr. Love by email, attaching a response. *See id.* ¶ 7; Exh. 2. The response was more than a "thanks, but no thanks." Instead, Lambertson responded, in detail and point-by-by point, to Plaintiff's comments. *See id.*; Exh. 2. And although Plaintiff complains of NIH's refusal to consider Plaintiff's appeal, on February 26, 2018, Mr. Goldman emailed Plaintiff's appeal to Collins and Lambertson. *See id.* ¶ 10; Exh. 5. The appeal largely reiterated Plaintiff's original comments. Thus, NIH heard Plaintiff's voice and considered its comments about the Proposed License even if NIH refused to consider its appeal.

Finally, all the authorities that Plaintiff cites in Plaintiff's Supplemental Brief are distinguishable. In *Preservation of Los Olivos v. United States Department of Interior*, 635 F. Supp. 2d 1076, 1085 (C.D. Cal. 2008), like here, the court emphasized that "the precise injury at stake in this action is the [Interior Board of Indian Appeals]'s very refusal to hear the merits of Plaintiffs' appeal …." But unlike this case, "the declarations submitted by Plaintiffs establish that certain of their members have concrete environmental and economic interests" sufficient to grant them standing. *See id.* at 1086. And in *Los Olivos*, the Government did not dispute that the plaintiffs' asserted injuries "are cognizable injuries-in-fact under Article III …." *Id.* Again, here, Plaintiff does not assert any concrete injury stemming from NIH's refusal to consider Plaintiff's appeal, aside from the refusal itself. And on the merits of Plaintiff's contentions about NIH's grant of the Proposed License, as Defendants explain in the Motion to Dismiss and the Reply, Plaintiff lacks both organizational and associational standing because it suffered no injury-in-fact. Thus, *Los Olivos*, a case with plaintiffs who sufficiently alleged a

concrete injury separate from the denial of an appeal itself, is of no use to Plaintiff, which can make no such showing.

Ritchie v. Simpson, 170 F.3d 1092 (Fed. Cir. 1999), which Plaintiff also cites, involved a different question than the one here. In *Ritchie*, plaintiff filed oppositions to three trademarks, contending that the marks "constitute immoral and scandalous matter, thus precluding their registration under the law." *Id.* at 1093-94. The Trademark Trial and Appeal Board dismissed the oppositions, holding that plaintiff "did not have standing to oppose the registrations." *Id.* at 1093. The only issue before the court was "whether [plaintiff wa]s entitled to come before the Board and raise th[e] question" of whether the trademarks were immoral or scandalous. *Id.* at 1094. *Ritchie* thus involved *administrative* standing, not *Article III* standing. *Ritchie* stands for the uncontroversial proposition that "'case' and 'controversy' restrictions for standing do not apply to matters before administrative agencies and board …." *Id.* But whether one has standing before an administrative agency is a question different from whether a party refused a voice at the agency level may seek review of the refusal in an Article III court.[15,16] The parties in *Ritchie* asked the court to decide the former, not the latter, which is evident because the court did not apply *Lujan*, "the seminal standing opinion" under Article III. *See Constitution Party of Pa. v. Aichele*, 757 F.3d 347 (3d Cir. 2014).

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[15] For this reason, Plaintiff cannot rely on *Bromberg v. Carmel Self Service, Inc.*, a decision from the Trademark Trial and Appeal Board that only deals with administrative standing. *See* Plaintiff's Supplemental Brief, at p. 14.

[16] Plaintiff also relies on Judge Bazelon's concurring opinion in *Koniag, Inc. v. Andrus*, 580 F.2d 601 (D.C. Cir. 1978). Putting aside that Judge Bazelon's analysis is from a concurring opinion, even Judge Bazelon recognized that the question before the court was: "What [s]hould be the standards for determining standing *to appear before an agency*? *Id.* at 641 (Bazelon, J., concurring) (emphasis added). The issue here is, what are the standards for determining standing *to appear before an Article III court*? Even the majority opinion in *Koniag* recognized that there could be parties with administrative standing but without Article III standing. *See id.* at 606 ("[I]t does not follow … that a party must be [e]xcluded from participation before the agency if it does not have a sufficient interest to meet Article III requirements for judicial review.").

Because Plaintiff alleges mere procedural harm, Plaintiff lacks standing on Count II.

C. NIH'S REFUSAL TO CONSIDER PLAINTIFF'S APPEAL WAS NOT ARBITRARY OR CAPRICIOUS

On February 26, 2018, Lambertson emailed Mr. Goldman and explained, citing 37 C.F.R. § 404.11(a)(3), that NIH would "not entertain an appeal," as NIH "considered [KEI']s objection and determined that there is no likelihood that KEI will be damaged by agency action." Berkley Declaration ¶ 9; Exh. 4. In Plaintiff's Supplemental Brief, Plaintiff contends that "NIH abused its discretion and otherwise acted in an arbitrary and capricious manner when it refused to consider Plaintiff's February 26, 2018 appeal …." Plaintiff's Supplemental Brief, at p. 18. As Defendants explain below, even if 37 C.F.R. § 404.11(a)(3) does not commit NIH's decisions about licensing appeals to its discretion by law, and even if Plaintiff has standing to assert what is mere procedural harm, NIH did not act arbitrarily and capriciously in refusing the appeal.[17] Thus, to the extent the Court has subject-matter jurisdiction over Count II, Defendants are entitled to summary judgment on the claim. *See Noroozi v. Napolitano*, 905 F. Supp. 535, 541 (S.D.N.Y. 2012) ("The question whether an agency's decision is arbitrary and capricious is a legal issue amenable to summary disposition.") (cleaned up).

As this Court has explained:

> The APA provides that a reviewing court is bound to hold unlawful and set aside agency action for certain specified reasons, including whenever the challenged

[17] Although 5 U.S.C. § 706(2)(A) provides that a reviewing court can set aside an agency action that is either arbitrary and capricious or an abuse of discretion, "[t]his is the APA's 'catch-all' provision governing the scope and standards of review, and the courts rarely draw any meaningful distinctions between acts that are 'arbitrary, capricious, or an abuse of discretion.'" *See Eagle Broadcasting Grp., Ltd. v. FCC*, 563 F.3d 543, 551 (D.C. Cir. 2009). Instead, "'arbitrary, capricious, [or] an abuse of discretion' review under § 706(2)(A) is now routinely applied by the courts as one standard under the heading of 'arbitrary and capricious' review." *Id.*; *see Japanese Found. for Cancer Research v. Lee*, 773 F.3d 1300, 1304 n.3 (Fed. Cir. 2014) ("[W]e generally review agency decisions pursuant to the APA § 706(2)(A) using the terms 'abuse of discretion' and 'arbitrary and capricious' interchangeably, as indicated by the plain text of the statute.").

> act is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Review under the APA is highly deferential, however, and the agency action enjoys a presumption of validity and regularity. The party challenging an agency decision has the burden to demonstrate that the agency action was arbitrary or capricious.

Outdoor Amusement Bus. Ass'n, Inc. v. DHS, 334 F. Supp. 3d 697, 711 (D. Md. 2018). "The court is not empowered to substitute its judgment for that of the agency." *Holly Hill Farm Corp. v. United States*, 447 F.3d 258, 263 (4th Cir. 2006) (quoting *Citizens to Preserve Overton Park*, 401 U.S. at 416); *see Andreas-Myers v. NASA*, 8:16-cv-03410, 2017 WL 1632410, at *4 (D. Md. Apr. 28, 2017) (holding that a "court will not second guess an agency decision or question whether the decision made was the best one") (quoting *C&W Fish Co. v. Fox*, 931 F.2d 1556, 1565 (D.C. Cir. 1991)). Instead, agency action is arbitrary and capricious only if "the agency relies on factors that Congress did not intend it to consider, entirely ignores important aspects of the problem, explains its decision in a manner contrary to the evidence before it, or reaches a decision so implausible that it cannot be ascribed to a difference in view." *Bedford County Mem. Hosp. v. HHS*, 769 F.2d 1017, 1022 (4th Cir. 1985).

First, as Defendants explain above, under 37 C.F.R. § 404.11(a)(3), appeals are available to persons who comment on the Federal Register notices related to a license, but only where such persons "can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action." Lambertson relayed NIH's position to Mr. Goldman that it determined Plaintiff would not be harmed by the grant of the Proposed License. Berkley Declaration § 9; Exh. 4. That is, Plaintiff did not "demonstrate to the satisfaction" of NIH that it the Proposed License would damage it. As a result, NIH's refusal to consider Plaintiff's appeal comports with the plain language of 37 C.F.R. § 404.11(a)(3), and that refusal was thus not arbitrary and capricious. *See Clanton v. U.S. ex rel. USDA*, No. 1:13-cv-01063, 2015 WL 461648, at *5 (W.D. Ark. Feb. 4, 2015) (rejecting contention that agency action was arbitrary and capricious where that action was "consistent with the

regulation's plain meaning," and concluding "that the agency considered the relevant factors that the regulations ascribed for consideration, namely the plain language of the regulation").

Second, even putting aside the "demonstrate to the satisfaction of the … agency" language, NIH's determination that the Proposed License would not damage Plaintiff (and NIH's refusal to consider Plaintiff's appeal as a result) was not arbitrary and capricious. The only argument Plaintiff offers for why NIH abused its discretion by refusing to consider Plaintiff's appeal—a point on which Plaintiff bears the burden—is that "KEI is one of the few organizations that regularly files comments with the NIH on proposed exclusive licenses," and it has "a widely recognized expertise on intellectual [property] and particularly in licensing of government-funded intentions …." Plaintiff's Supplemental Brief, at p. 17. But the frequency with which a group comments on Federal Register notices and the expertise of a group in making such comments bears no relation to whether the agency action on which it is commenting will damage that group. Again, as Defendants explain in the Motion to Dismiss and the Reply, Plaintiff offers only unsupported and vague allegations about a general diversion of its time to this matter.[18] Given such vague and unsupported allegations, NIH did not act arbitrarily and capriciously in determining that the Proposed License would not damage Plaintiff and thus was not entitled to an appeal under 37 C.F.R. § 404.11(a)(3).

Third, even following Plaintiff's suggestion and applying Judge Bazelon's five-factor analysis from his concurring opinion in *Koniag*—which analysis has been applied in exactly one commercially-available opinion[19]—NIH's refusal to consider Plaintiff's appeal was not arbitrary and capricious. Under Judge Bazelon's formulation, agencies must consider "[t]he nature of the interest asserted by

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[18] Although the Complaint alleges harm to patients, taxpayers, and consumers generally, *see* Complaint ¶ 14, it contains no allegations about what harm KEI will suffer because of the Proposed License.

[19] *See Preservation of Los Olivos v. U.S. Dep't of Interior*, 635 F. Supp. 2d 1076, 1092 (C.D. Cal. 2008).

the potential participant" and "[t]he relevance of this interest to the goals and purposes of the agency." *Koniag, Inc.*, 580 F.2d at 616 (Bazelon, J., concurring). As for Plaintiff's asserted interest, Plaintiff's chief concern is how the Proposed License will affect the cost of cancer drug treatments to patients. *See* Complaint ¶ 1 (stating that the Proposed License "will result in the denial of affordable cancer treatments"); *id.* ¶ 4 (stating that NIH is "threatening access to th[ese] treatment[s], imposing unnecessary financial toxicity on patients that have access, and ignoring the public interest in having affordable cancer treatments"); Love Declaration ¶ 43 ("KEI is concerned that the license may grant an excessive term of exclusivity, … and that the prices will not be consistent with the obligations in the Bayh-Dole Act for making the invention available to the public on reasonable terms.") (internal quotation marks omitted). Indeed, KEI "works extensively on issues pertaining to access to affordable medicines …." Complaint ¶ 5. As for the relevance of this interest to the goals and purposes of the agency, however, NIH has repeatedly stated that it is not within the mission of NIH to control drug prices, as trying to do so could result in fewer partnerships with companies and fewer therapies to serve the public. *See* Rohrbaugh Declaration ¶ 6. Thus, Plaintiff would not be entitled to administrative standing even under Judge Bazelon's framework, and NIH did not act arbitrarily and capriciously in refusing to consider the appeal of an entity whose goals and interests do not align with NIH's. *See Koniag, Inc.*, 580 F.2d at 611 (Bazelon, J., concurring) ("[A]dministrative standing should be determined in light of the functions of an administrative agency, and whether a would-be participant would contribute to fulfilling those functions.").

Not only is this the first time a court has addressed whether NIH acted arbitrarily and capriciously in refusing to consider an appeal under 37 C.F.R. § 404.11(a)(3), this is the first time any party has asked for an appeal under 37 C.F.R. § 404.11(a)(3). *See* Rohrbaugh Declaration ¶ 8. Thus, this is the first time NIH has had to determine whether a commenter to a Federal Register notice is

"damaged" by NIH's licensing decision. Defendants contend that Plaintiff has not been "damaged by the agency action" under any definition of the phrase. But if the Court determines that the phrase is ambiguous, NIH asserts that "damage" under this regulation means damage sufficient to grant that party Article III standing. Thus, NIH contends that appeals under 37 C.F.R. § 404.11(a)(3) are available only to those who have Article III standing to assert whatever challenge that party has to a licensing decision in federal court. *See* Rohrbaugh Declaration ¶ 9.

Limiting administrative standing to those who have Article III standing is permissible. *See Envirocare of Utah, Inc. v. NRC*, 194 F.3d 72, 73 (D.C. Cir. 1999) ("Federal agencies *may*, and *sometimes do*, permit persons to intervene in administrative proceedings even though these persons would not have standing to challenge the agency's final action in federal court.") (emphasis added). Interpreting 37 C.F.R. § 404.11(a)(3) as providing appeals to only those with Article III standing fits with section 404.11(a)(1) and (2), which deal with the appeal rights of those whose license applications have been denied or whose licenses have been modified or terminated—parties who suffer sufficiently concrete injuries to satisfy the "injury in fact" prong of an Article III standing analysis. And providing appeals to only those with Article III standing is considerate of the agency's time in carrying out what is a detailed, two-step, appeal process. *See* Rohrbaugh Declaration, Exh. 1; *id.* ¶ 10. As Defendants discuss above, at the first-level reconsideration stage, the Director, OTT, "shall appoint an ad hoc review committee" of individuals who were not involved with the original licensing decision, which review committee "shall provide a recommendation to the Director, OTT within forty-five … days …." *Id.* at p. 2. At the second-level appeal stage, the Director, NIH may appoint a separate committee, and the Director, NIH must send the final determination to the appellant within "sixty … days of receiving the written appeal …." *Id.* The Appeal Procedures are thus a thorough two-step process involving senior-level NIH officials under a tight time frame, and providing appeals to every commenter to a

Federal Register notice would require a substantial diversion of high-level agency resources. *See* Rohrbaugh Declaration ¶ 10. Under *Auer v. Robbins*, 519 U.S. 452, 461 (1997), NIH's interpretation of its own regulation is entitled to deference because it is not "plainly erroneous or inconsistent with the regulation." *See also Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195, 208 (2011) (holding that courts "deter to an agency's interpretation of its own regulation," even where that interpretation is "advanced in a legal brief").

NIH reasonably determined that the Proposed License would not damage Plaintiff, and thus that NIH was not required to entertain an appeal. Although Plaintiff disagrees with this determination, mere disagreement with an agency decision does not rise to the level of an abuse of discretion or arbitrary and capricious conduct. Thus, even if the Court has subject-matter jurisdiction over Count II, Defendants are entitled to summary judgment on the claim. *See Labnet, Inc. v. U.S. Dep't of Labor*, 197 F. Supp. 3d 1159, 1173 (D. Minn. 2016) (holding that an agency action was not arbitrary or capricious where "plaintiffs merely disagree" with the agency decision).

D. PLAINTIFF LACKS STANDING TO SEEK JUDICIAL REVIEW OF THE MERITS OF NIH'S DECISION TO GRANT THE PROPOSED LICENSE, AND THAT ISSUE IS BEYOND THE SCOPE OF THE SUPPLEMENTAL BRIEFING

In opposing the Motion to Dismiss, Plaintiff asserted that it had standing to raise the merits of its claims. *See Plaintiff's Memorandum in Opposition to Defendants' Motion to Dismiss*, *see* ECF No. 9, at pp. 3-16. In the Supplemental Briefing Order, however, the Court ordered briefing only "on the applicability of the [APA] with respect to Plaintiff's entitlement, if any, to a hearing and to an appeal of their comments to NIH pertaining to the licensing of patents for a drug to Kite Pharma." *See* ECF No. 14, at p. 1. Although the Supplemental Briefing Order limits the briefing to NIH's refusal of an appeal, Plaintiff nevertheless argues that "the APA empowers this Court to review Defendants' actions, regardless of whether or not Defendants correctly determined that KEI was not entitled to

appeal the rejection of its Comments." Plaintiff's Supplemental Brief, at p. 11. More specifically, Plaintiff contends it has standing under 5 U.S.C. § 706, which allows reviewing courts to "decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action …." Plaintiff's Supplemental Brief, at p. 10.

If Plaintiff were correct, any plaintiff could challenge any agency action—irrespective of an Article III standing analysis—if that plaintiff asked the reviewing court to "decide … questions of law, interpret constitutional [or] statutory provisions, [or] determine the meaning or applicability of the terms of an agency action." *See id.* This is not the law. *See Valley Forge Christian College v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 487 n. 24 (1982) ("Neither the Administrative Procedure Act, nor any other congressional enactment, can lower the threshold requirements of standing under Art[icle] III."); *Motor Coach Indus., Inc. v. Dole*, 725 F.2d 958, 963 (4th Cir. 1984) (noting that the APA "has not displaced the analytical framework under which the constitutional [standing] determination is made"); *Aiken Cty. v. Bodman*, 509 F. Supp. 2d 548, 552-53 (D.S.C. 2007) ("A prerequisite for the exercise of a right to review under the APA is that the plaintiff must satisfy the minimum standing requirements of Article III.").

Thus, for Plaintiff to have a voice in this Court, it must satisfy the Article III standing requirements. Putting aside that the merits of NIH's decision to grant the Proposed License are beyond the scope of the Supplemental Briefing Order, for the reasons Defendants explain the Motion to Dismiss and the Reply, Plaintiff lacks both organizational and associational standing. That Plaintiff sues under the APA does not resurrect its claims.

V. CONCLUSION

The Court lacks subject-matter jurisdiction over Count II, both because NIH's determination whether to consider an appeal is committed to agency discretion by law, and because Plaintiff lacks

standing. And even if the Court has subject-matter jurisdiction over Count II, NIH's refusal to consider Plaintiff's appeal was not arbitrary and capricious, and thus Defendant is still entitled to summary judgment on the claim. Finally, as Defendants explain in the Motion to Dismiss and Reply, Plaintiff lacks standing on Count I of the Complaint. For these reasons, the Court should (i) dismiss Count I for lack of subject-matter jurisdiction, and (ii) dismiss Count II for lack of subject-matter jurisdiction or enter summary judgment in Defendants' favor.

Respectfully submitted,

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