IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND (SOUTHERN DIVISION)

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KNOWLEDGE ECOLOGY INTERNATIONAL,

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Plaintiff

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v.

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NATIONAL INSTITUTES OF HEALTH, *et al.*,

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Defendants

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REPLY TO DEFENDANTS' SUPPLEMENTAL BRIEF

Plaintiff, Knowledge Ecology International ("KEI"), by and through its undersigned attorneys, hereby submits this reply to the Supplemental Brief filed by Defendants National Institutes of Health ("NIH") and Francis Collins in his official capacity with NIH ("Mr. Collins" or, collectively, "NIH"), and National Cancer Institute ("NCI") and David Lambertson in his official capacity with NCI ("Dr. Lambertson" or collectively "NCI", and, collectively with all of the above, "Defendants"); and, states:

Defendants argue that their refusal to consider Plaintiff's appeal is not subject to challenge under the Administrative Procedure Act (the "APA"). This argument simply ignores a key fact undisputed by Defendants: NIH refused the appeal even before it was filed. Thus, the question in this case is not whether the phrase "to the satisfaction of the Federal agency" gives the NIH some discretion to decide which appeals should move forward and which should not; the question is

whether NIH can completely and unilaterally deprive the Plaintiff of a procedural right that is available under 37 C.F.R. § 404.11(a)(3).

Defendants cite *Drake v. F.A.A.,* 291 F.3d 59 (D.C. Cir. 2002) in support of the argument that the NIH had discretion to deprive KEI of its right to an appeal. Again, Defendants' discussion on whether the phrase "to the satisfaction of the Federal agency" grants the NIH some discretion to decide which appeals can move forward, and on the extent of such discretion, only would have been relevant if the decision to refuse the appeal had been made after the appeal was filed, and had been based on the information available on the record, including the appeal itself, which did not happen in this case. [1]

Even if Defendants' discussion about the extent of its discretion to refuse an appeal were relevant, this case is distinguishable from those cited in their discussion. For example, in *Drake*, the FAA dismissed the complaint after it was

[1] In fact, Defendants' Supplemental Brief, at pp.5-6 admits that NIH's own procedures require two levels of appeal, the first of which requires the NIH director to create an ad hoc committee to consider that appeal:

> **When the Director**, OTT **receives a request for reconsideration**, **he or she shall appoint an ad hoc review committee to review the case and make recommendations** regarding action to be taken. The committee may include OTT Licensing Specialists (but not the Licensing Specialist who made the original decision that is at issue) as well as other NIH employees (e.g. scientists, Technology Development Coordinators or attorneys from the Office of the General Counsel).

(*See* NIH Procedure Manual Chap. 307) (emphasis added).

Defendants effectively concede in footnote 10 that NIH never provided such an ad hoc committee; in fact, Defendant never even provided Plaintiff with a copy of the NIH Procedure Manual or otherwise made it publicly available until after this Court ordered supplemental briefing. Thus, Plaintiff had no way of even knowing that such a committee should have been provided.

filed and determined, based on the facts stated in the complaint, that an investigation or action was not warranted. *Id.* at 71. ("Here, the agency determined that no hearing was necessary because the facts stated in Drake's complaint were insufficient to warrant further action.") The discretion exercised by the FAA related to whether the facts stated in the complaint warranted an investigation or action, not relative to whether the FAA could preemptively deprive Drake of its right to file a complaint.[2]

Defendants' argument that a federal agency can refuse an appeal even before the appeal is filed – and without following its own procedures in violation of the *Accardi* doctrine[3] – eviscerates the procedural right provided under 37 C.F.R. § 404.11(a)(3). Simply put, 37 C.F.R. § 404.11(a)(3) does not grants the NIH absolute and unreviewable discretion to eliminate the availability of an appeal to whichever appellants it chooses.[4]

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[2] Defendants also cite *Michigan Department of State v. United States,* 166 F. Supp. 2d 1228 (W.D. Mich. 2001). This case is distinguishable as it relates to whether the phrase "demonstrates to the satisfaction of the Secretary" gives the Secretary some discretion, not to whether an agency can preemptively deprive a prospective appellant a procedural right recognized under a regulation. Similarly, *Angelex Ltd. v. United States,* 723 F.3d 500, 506-07 examined whether the Coast Guard had discretion to grant clearance to a vessel that petitioned for such clearance. Again, the discretion examined in that case was related to the Coast Guard decision to deny clearance, not whether they can entirely deprive a vessel from requesting such clearance. *Speed Mining, Inc. v. Fed. Mine Safety & Health Review Comm'n,* 528 F.3d 310, 317 is distinguishable for the same reasons.

[3] *Accardi v. Shaughnessy,* 347 U.S. 260 (1954)

[4] Although it is true that courts will "accord substantial deference to an agency's final action and presume it valid, 'the arbitrary-and-capricious standard does not reduce judicial review to a rubber stamp of agency action.' " *Ergon-W. Va., Inc. v.*

The remainder of Defendants' arguments are essentially a re-hash of their claim that Plaintiffs lack organizational and associational standing, and Plaintiffs only briefly respond with the following points pertinent to claims made in Defendants' Supplemental Brief:

The concrete and specific injury alleged by Plaintiff is the unjustified and unexplained, ex ante denial of the right to an appeal as provided under 37 C.F.R. § 404.11, and the denial of legal and factual information required to exercised that right to appeal, thereby depriving Plaintiff of a procedural means that it was entitled to and that it would have used to advance its advocacy mission on its own behalf and on behalf of patients, taxpayers, and consumers against the grant of exclusive patent licenses that are not a "reasonable and necessary" incentive to induce innovation, as provided under 35 U.S. Code § 209.

U.S. Envtl. Prot. Agency, 896 F.3d 600, 609 (4th Cir. 2018) (*quoting Friends of Back Bay v. U.S. Army Corps of Eng'rs,* 681 F.3d 581, 587 (4th Cir. 2012)). Courts must conduct a "searching and careful review to determine whether the agency's decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Sierra Club v. U.S. Dep't of the Interior,* 899 F.3d 260, 270 (4th Cir. 2018) (internal quotation marks omitted) (*citing Marsh v. Or. Nat. Res. Council,* 490 U.S. 360, 378 (1989)). An agency must "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983) (*quoting Burlington Truck Lines, Inc. v. United States,* 371 U.S. 156, 168 (1962)). A rule is arbitrary and capricious if the agency has "entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency." *Id.* Review of an agency decision "is based on the administrative record and the basis for the agency's decision must come from the record." *Nat'l Ass'n of Home Builders v. Norton,* 340 F.3d 835, 840–41 (9th Cir. 2003).

The Love Declaration submitted by Plaintiff summarizes the credentials that KEI and Mr. Love have on intellectual property issues in general, and in particular on licensing of government-funded and government-owned inventions. The credentials that KEI and Mr. Love have on these issues are not being disputed by Defendants. *See* October 15, motion hearing ("We are not here arguing that KEI is not qualified to speak on these issues. They appear to be qualified to speak on these issues [...]").

The Supplemental Love Declaration, attached hereto as **Exhibit 1**, responds to some of the claims submitted in the Supplemental declaration filed by Defendants, and further demonstrates how, as part of its mission, KEI has been conducting evidence-based research concerning the patent licensing practices of federal agencies; sharing information about these patent licensing practices with elected government officials, other patient groups, academics, consumers, and members of the general public; and engaging directly with federal agencies throughout several advocacy methods, including filing comments with objections and suggestions regarding proposed exclusive patent licenses.

This injury meets the criteria of a "procedural injury" for the purpose of standing: (1) the NIH violated the procedural rules provided under 37 C.F.R. § 404.11; (2) these rules protect KEI's concrete interests in filing public comments and conducting advocacy against the grant of exclusive patent licenses when they are not "reasonable and necessary" to induce innovation; and (3) it is reasonably probable that the NIH's actions will threaten KEI's concrete interests.

CONCLUSION

By depriving KEI of its right to an appeal, Defendants denied KEI a means to conduct its advocacy mission on its own behalf that it is entitled to use under 37 C.F.R. § 404.11 on behalf of patients, taxpayers, and consumers against the grant of exclusive patent licenses that are not a "reasonable and necessary" incentive to induce innovation, as provided under 35 U.S. Code § 209 and 37 C.F.R. § 404.

This conduct threatened a concrete interest protected under 35 U.S. Code § 209 and 37 C.F.R. § 404, which prohibits the grant of exclusive patent licenses over government-owned inventions if this license is not a "reasonable and necessary" incentive to induce innovation; and imposes an obligation over federal agencies to seek comments and observations from parties like KEI in order to ensure that the intended policy goals of 35 U.S. Code § 209 and 37 C.F.R. § 404 are being met.

Plaintiff respectfully requests that Defendant's Motion to Dismiss be DENIED.

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