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

*

KNOWLEDGE ECOLOGY INTERNATIONAL,

*

Plaintiff

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v.

*

NATIONAL INSTITUTES OF HEALTH, *et al.*,

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Defendants

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* * * * * * * * * * *

SUPPLEMENTAL MEMORANDUM IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

Pursuant to the Court's October 16, 2018 Order directing supplemental briefing on the applicability of the Administrative Procedure Act to the issues in this case (Doc. No. 14; entered 10.17.18), Plaintiff, Knowledge Ecology International ("KEI"), by and through its undersigned attorneys, hereby submits this Supplemental Memorandum in Opposition to the Motion to Dismiss (Doc. No. 5) 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:

PERTINENT HISTORY[1]

On December 20, 2017, NIH posted a notice of intent in the Federal Register (the "Notice") regarding the proposed grant of a worldwide exclusive license of patents for critical emerging technology for the treatment of human cancer ("CAR-T" technology) to Kite Pharma, Inc. ("Kite"), a wholly owned subsidiary of multi-billion dollar company Gilead Sciences, Inc. ("Gilead"). 82 Fed. Reg. 60406-7 (Dec. 20, 2017). (*See* Complaint, ¶47.)[2]

On January 4, 2018, Plaintiff timely submitted written comments to NIH in response to the Notice (the "Comments"). The Comments, *inter alia*, objected to the exclusivity of the license and requested the inclusion of public interest safeguards in any license to be executed. (*See* Complaint, ¶ 51.) A copy of KEI's written comments and cover e-mail are attached hereto as **Exhibit 1**.[3] Defendants concede that KEI was entitled to submit the Comments. (*See* Transcript of October 15, 2018 Hearing, at p.38, ll. 9 – 15.)

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[1] Unless otherwise specifically noted, all of the facts herein are taken from the Complaint (Doc. No. 1), documents submitted with Defendants' Motion to dismiss (Doc. No. 5), or documents submitted in support of Plaintiff's Response in Opposition thereto (Doc. No. 9).

[2] The nature and importance of CAR-T technology, the inappropriateness of awarding such technology to Kite, as well as the details of the Notice, are set forth in the Complaint; including, at Paragraphs 34 – 39, 40 – 46, and 47 – 50, respectively.

[3] Each of the documents attached to this Supplemental Memorandum were submitted within the exhibits to Defendants' Motion to Dismiss (Doc. No. 5-2) and are separately included herewith for the convenience of the Court.

On January 25, 2018, Defendants responded to KEI's Comments in an e-mail with an attached letter under NCI's letterhead and signed by Dr. Lambertson; stating, *inter alia*:

> In conclusion, NCI has determined that your objection did not raise an issue that would preclude the grant of the proposed exclusive license, and the NCI intends to proceed with the negotiation of the proposed exclusive license, the terms of which have not yet been negotiated. All of the regulations and statutes governing the grant of an exclusive license have been adhered to during the evaluation of the Kite license application.

(*See* January 25, 2018 letter, attached hereto as **Exhibit 2**; Complaint, ¶ 54.)

On February 14, 2018, KEI responded to Dr. Lambertson's decision by requesting that NIH disclose its appeals process because the link on the NIH website that purported to provide the process was not functional, and stating:

> It is our understanding that under 37 CFR 404.11, there is a right of appeal of "any decision or determination concerning the grant, denial, modification, or termination of a license." Knowledge Ecology International timely filed its comments on this particular proposed license and qualifies for the right of appeal under subsection (a)(3) as a public interest organization representing patients and taxpayers that will be damaged by the agency action.
>
> Please let us know what formal procedures the NIH requires for these appeals, as I did not see relevant guidelines or policies any on the NIH website. If there are none, we will follow up this email with a document detailing the arguments of our appeal.

(*See* February 14, 2018 e-mail, attached hereto as **Exhibit 3**; Complaint ¶ 56.)

On February 26, 2018, Dr. Lambertson, ignoring the request to provide the NIH appeal procedures, responded by refusing to consider KEI's appeal; stating:

> As you noted, 37 CFR 404.11 (a)(3) permits an appeal for a person who can demonstrate to the satisfaction of the agency that such person may be damaged by the action.
>
> We have considered your objection and determined that there is no likelihood that KEI will be damaged by the agency action. Accordingly, we will not entertain an appeal of our decision.

(*See* February 26, 2018 4:06PM e-mail, attached hereto as **Exhibit 4**; Complaint ¶ 58.)

Approximately twenty minutes later, KEI responded to Dr. Lambertson's e-mail:

> We are in receipt of your email of a few minutes ago wherein you state that you have considered our standing to appeal and determined that we do not meet the requirements, in spite of not having yet seen our appeal. We would request that you at least consider our finalized document before making your determination on this point.

(*See* February 26, 2018 4:24PM e-mail, attached hereto as **Exhibit 5**.) KEI attached to its e-mail an eleven-page formal appeal letter, which set forth in detail the statutory and other bases for KEI's objections to the exclusive license and requested a hearing. (*See* February 26, 2018 letter, attached hereto as **Exhibit 6**.)

Defendants never responded to KEI's February 26, 2018 communications.

PERTINENT LEGAL FRAMEWORK

The licensing of government-owned inventions such as the CAR-T technology at issue in this case is governed primarily by 35 U.S.C. §§ 200 – 212 (sometimes referred to as the "Bayh–Dole Act" and 37 C.F.R. Part 404.[4]

In pertinent part, 35 U.S.C. § 209 states:

> (a)Authority.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if—
>
> (1) granting the license is a reasonable and necessary incentive to—
>
> (A) call forth the investment capital and expenditures needed to bring the invention to practical application; or
> (B) otherwise promote the invention's utilization by the public;
>
> (2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;
>
> (3) the applicant makes a commitment to achieve practical application of the invention within a reasonable time, which time may be extended by the agency upon the applicant's request and the applicant's demonstration that the refusal of such extension would be unreasonable;

[4] Other provisions governing such licenses include, for example, 40 U.S.C. § 559, which requires executive agencies to obtain advice from the Attorney General prior to disposing of federal property to a private interest. Defendants' failure to follow this statute and implementing regulations was one of the bases upon which KEI objected to the issuance of the exclusive license underlying this case.

> (4) granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; and
>
> (5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.
>
> * * *
>
> (e)Public Notice.—
>
> **No exclusive or partially exclusive license may be granted under section 207(a)(2) unless public notice** of the intention to grant an exclusive or partially exclusive license on a federally owned invention **has been provided in an appropriate manner at least 15 days before the license is granted**, **and the Federal agency has considered all comments received before the end of the comment period in response to that public notice**. This subsection shall not apply to the licensing of inventions made under a cooperative research and development agreement entered into under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).
>
> * * *

(emphasis added.) *See also* 37 C.F.R. § 404.7 (setting forth the criteria an agency must consider before granting exclusive, co-exclusive, or partially-exclusive licenses for government inventions).

37 C.F.R. § 404.11, which governs appeals, states:

> (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:

> (1) A person whose application for a license has been denied;
> (2) A licensee whose license has been modified or terminated, in whole or in part; or
> (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**.
>
> (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.

(emphasis supplied.)

Neither Section 209 nor Part 404 set forth specific procedures governing judicial review of the licensing agency's decisions; therefore, such review is governed by the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701 *et seq*. (*See* 5 U.S.C. § 701(a) ("This chapter applies, according to the provisions thereof, except to the extent that — (1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law.")).

In pertinent part, the APA provides:

5 U.S.C. § 702 - Right of review

> **A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof**. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the

ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: Provided, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

5 U.S.C. § 704 - Actions reviewable

Agency action made reviewable by statute and **final agency action for which there is no other adequate remedy in a court are subject to judicial review**. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

5 U.S.C. § 706 - Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

> (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right, power, privilege, or immunity;
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance of procedure required by law;
>
> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
>
> (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.
>
> In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

(emphasis supplied.)

ANALYSIS

Defendants' position in this case has consistently reflected their view that not only is judicial review of decisions in cases such like this only available to parties who are directly and financially harmed by an agency's failure to comply with the stringent requirements of the Bayh-Dole Act, but also that administrative appeals are likewise foreclosed to all but this select group. That is simply not the law. In addition to the fact that such interpretation would effectively render 37 C.F.R. § 404.11(a)(3) meaningless, this position is at odds with both the Administrative Procedure Act and the fundamental requirements of due process.

I. JUDICIAL REVIEW OF DEFENDANTS' DECISION TO GRANT AN EXCLUSIVE LICENSE TO KITE IS REVIEWABLE UNDER THE APA.

The APA specifically provides for judicial review of final agency action not only "reviewable by statute," but also any "**final agency action for which there is no other adequate remedy in a court are subject to judicial review**." 5 U.S.C. § 704 (emphasis supplied). Such judicial review includes the requirements that the reviewing court "**decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action**" and, additionally, "hold unlawful and set aside agency action, findings, and conclusions found to be— (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706 (emphasis supplied).

In this case, a simple comparison of the mandatory requirements provided by 35 U.S.C. § 209 with the agency's January 25, 2018 decision demonstrates that the

decision clearly does not comply with the requirements of the Bayh-Dole Act and, additionally, fails to comply with other statutory requirements, such as 40 U.S.C. § 559, which requires executive agencies to obtain advice from the Attorney General prior to disposing of federal property to a private interest.

Therefore, 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.

II. DEFENDANTS' REFUSAL TO CONSIDER PLAINTIFF'S APPEAL IS ITSELF REVIEWABLE UNDER THE ADMINISTRATIVE PROCEDURE ACT AND SUBJECT TO REVERSAL BY THE COURT.

Defendants not only failed to follow the Bayh-Dole Act's strictures, but also flatly refused to consider Plaintiff's appeal – even before such appeal had been submitted. (*Compare, e.g.,* February 26, 2018 4:06PM e-mail declaring that NIH "w[ould] not entertain an appeal of [Defendants'] decision" *with* February 26, 2018 4:24 e-mail noting that Defendants had made this decision "in spite of not having yet seen [KEI's] appeal.")

In so doing, Defendants appear to have taken the position that standing to file an administrative appeal under 37 C.F.R. § 404.11 is functionally equivalent to judicial standing. In other words, Defendants' proposition seems to be that a party has to meet all the restrictive requirements for judicial standing in order to benefit from an administrative appeal, and because they now argue that Plaintiff lacks judicial standing, that somehow also justifies, *ex post*, their denial of an administrative appeal by Defendants. (*See, e.g.,* October 15, 2018 Tr. p. 39, ll. 15 –

24) ("And it would make sense that what's meant by damage by an agency action would be folks who have standing in the constitutional sense. Because that's the way these things percolate up through the court system, that there's an administrative level of review, and then cases go to court. That would be an appropriate time to cut that off, folks who aren't going to make it to court anyways.")

A. ADMINISTRATIVE STANDING AND JUDICIAL STANDING ARE CONCEPTUALLY DISTINCT.

What Defendants' position fails to recognize is the well-established principle that "judicial and administrative standing are conceptually distinct […]" *Koniag, Inc., Vill. of Uyak v. Andrus,* 580 F.2d 601, 613 (D.C. Cir. 1978). "[A]bsent a specific justification for invoking judicial standing decisions [there is] no basis for interjecting the complex and restrictive law of judicial standing into the administrative process." *Id.* As the United States Court of Appeals, Fourth Circuit, as previously stated, federal agencies "are not restricted to adjudication of matters that are 'cases and controversies' within the meaning of Article III of the *Constitution." N. Carolina Utilities Comm'n v. F.C.C.,* 537 F.2d 787, 791 (4th Cir. 1976).

Instead of Article III, the "starting point" for determining whether a party is properly before an agency is "the statute that confers standing before that agency." *Ritchie v. Simpson,* 170 F.3d 1092, 1095 (Fed. Cir. 1999).

In *Pres. of Los Olivos v. U.S. Dep't of Interior,* 635 F. Supp. 2d 1076, 1090 (C.D. Cal. 2008), the plaintiffs challenged the Interior Board of Indian Appeals

(IBIA)'s refusal to hear the merits of their appeal as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The United States District Court, C.D. California, found that the IBIA's action was erroneous under the APA, explaining: "[IBIA'S] error was in apparently assuming, without any explanation, that the concepts rooted in constitutional and prudential limitations on federal courts should be applied without regard to the IBIA's regulations." *Id.*

In the case before this Court, Defendants failed to provide any specific justification or explanation of the legal basis they used to deny, ex ante, Plaintiff's right of appeal under 37 C.F.R. § 404.11, incurring in an action that is considered "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" under 5 U.S.C. § 706(2)(A).

Although Defendants relied on the phrase "damaged by the agency action", provided under 37 C.F.R. § 404.11, to deny KEI'S right to an appeal, Defendants themselves seem to recognize that the concept of "damaged by the agency action" does not appear to be one that have been widely examined by the Courts in the context of administrative standing cases. See October 15, 2018, motion hearing ("I can represent to the Court that I tried to lift mountains to look into whatever the analog to legislative research is for regulatory research into what was meant by damage by agency action, and there simply is none, at least that I could uncover"). There does not seem to be any reason to assume, without justification, that the

phrase "damaged by the agency action" can be used to mechanically invoke the complex and restrictive law of judicial standing.

Some Courts have examined the term "damaged" as a requisite for determining standing to appear before an administrative agency in the context of trademark law. 15 U.S.C. § 1063(a) states that "[a]ny person who believes that he would be damaged by the registration of a mark upon the principal register . . . may, upon payment of the prescribed fee, file an opposition in the Patent and Trademark Office."

The administrative agencies and Courts that have decided standing issues for the purpose of trademark oppositions under 15 U.S.C. § 1063(a) have done so in a way that is far less restrictive than standing in the constitutional sense, and, therefore, far less restrictive than the criteria that the Defendants now seem to be suggesting, ex post, that applies to 37 C.F.R. § 404.11. For example, in *Bromberg v. Carmel Self Service, Inc.,* 198 USPQ 176 (Trademark Tr. & App. Bd.1978), the Trademark Trial and Appeal Board granted standing to two persons who were members of the largest segment of the general public, women. The registration at issue was for the mark, ONLY A BREAST IN THE MOUTH IS BETTER THAN A LEG IN THE HAND, for restaurant services. *See id.* at 177. The Trademark Trial and Appeal Board explained that "the fact that opposers have not based their claim of damage on their involvement in a commercial activity is not fatal to the question of standing." *Id.*

In *Ritchie v. Simpson,* 170 F.3d 1092, 1096–97 (Fed. Cir. 1999), the United States Court of Appeals, Federal Circuit examined whether William B. Ritchie was entitled to appear before the Trademark Trial and Appeal Board; that is, whether Mr. Ritchie had "standing" to oppose a registration. Mr. Ritchie alleged, inter alia, that he would be "damaged" by the registration of certain marks because these marks disparage his values, especially those values relating to his family. In addition, in his notice of opposition, Mr. Ritchie described himself as a "family man" who believed that the "sanctity of marriage requires a husband and wife who love and nurture one another," and as a member of a group that could be potentially damaged by marks that he alleged were synonymous with wife-beater and wife-murderer. Mr. Ritchie alleged that the marks are scandalous because they would "attempt to justify physical violence against women."

The Trademark Trial and Appeal Board dismissed Mr. Ritchie's opposition due to lack of standing but the Court of Appeals, Federal Circuit, decided that the Board "erred by requiring the opposer in this case to somehow show that his interest is not shared by any substantial part of the general population. On the contrary, the purpose of the opposition proceeding is to establish what a substantial composite of the general public believes. The limitation placed upon standing in this case by the Board undermines this very purpose." *Ritchie v. Simpson,* 170 F.3d 1092, 1096–97 (Fed. Cir. 1999). The United States Court of Appeals, Federal Circuit, also said that "[i]n no case has this court ever held that one must have a

specific commercial interest, not shared by the general public, in order to have standing as an opposer." *Id.*

In *Koniag*, Judge Bazelon suggested that a functional analysis of administrative standing is appropriate when the language of the governing regulation, as the phrase "damaged by the agency action" in this case, is broad. "Such an analysis would examine the nature of the asserted interest, the relationship of [the proponent of standing's] interest to the functions of the agency, and whether an award of standing would contribute to the attainment of these functions." *Koniag, Inc., Village of Uyak v. Andrus,* 580 F.2d 601, 614–15(D.C.Cir.1978). Judge Bazelon outlined five factors that would go into a functional analysis: (1) The nature of the interest asserted by the potential participant. (2) The relevance of this interest to the goals and purposes of the agency. (3) The qualifications of the potential participant to represent this interest. (4) Whether other persons could be expected to represent adequately this interest. (5) Whether special considerations indicate that an award of standing would not be in the public interest.

B. DEFENDANTS ABUSED THEIR DISCRETION IN DENYING PLAINTIFF'S RIGHT TO APPEAL

35 U.S. Code § 209 and 37 C.F.R. § 404 imposes several obligations to federal agencies that intent to grant exclusive licenses over government-owned inventions, including an explicit directive prohibiting the grant of exclusive licenses (or its characteristics, including the term, field of use, geographical scope, and licensee) are not a reasonable and necessary incentive to induce innovation; as well as the

obligation to seek public comments under the notice-and-comment procedure mandated by 35 U.S. Code § 209 and 37 C.F.R. § 404.11. As submitted by the Plaintiff in the Love Declaration, KEI has filed comments with the NIH on more than 30 proposed exclusive licenses and has an internationally recognized expertise on intellectual property issues and particularly on licensing of government-funded inventions. KEI is one of the few organizations that regularly files comments with the NIH on proposed exclusive licenses under 35 U.S. Code § 209, and frequently is the only organization that file these types of comments on proposed licenses. Other parties potentially interested in an specific license, such as patients of a rare disease acting in their individual capacity or medical practitioners acting in their individual capacity, do not tend to file these types of comments before the NIH and is unreasonable to expect that they will file these comments on a regular basis considering that the notice-and-comment procedure is subject to a short deadline of 15 days from the day the notice was published in the Federal Register, and examining and commenting on these license require a high level of technical expertise on intellectual property. Depriving KEI -an organization with a widely recognized expertise on intellectual and particularly in licensing of government-funded inventions- of its right to an appeal does not advances the administrative goals and purposes that the NIH is required to follow under 35 U.S. Code § 209 and 37 C.F.R. § 404.11. There does not seem to be any special considerations, economic or otherwise, that indicate that depriving KEI of this right to an appeal would

advance the public interest. On the contrary, depriving KEI of an appeal undermined the policy goals of 35 U.S. Code § 209 and 37 C.F.R. § 404.11.

Considering these facts, if the NIH had used, for instance, the five factors Judge Bazelon suggested in *Koniag* to determine whether KEI had administrative standing to exercise a right of appeal under 37 C.F.R. § 404.11, the NIH would have likely found that KEI had administrative standing under 37 C.F.R. § 404.11.

Plaintiff does not dispute that 37 C.F.R. § 404.11 gave Defendants some level of discretion to determine whether a person seeking an appeal will be "damaged by the agency action"; nor Plaintiff is asking this Court to impose an specific interpretation of the phrase "damaged by the agency action." Plaintiff argues that a decision taken without providing KEI the opportunity to file the appeal and without any explanation of which criteria was used to determine that KEI will not be "damaged by the agency action" is a violation of procedural rules pursuant to 37 C.F.R. § 404.11 and 5 U.S.C. § 701–706.

CONCLUSION

For the foregoing reasons and those stated on the record and in Plaintiff's Opposition to Defendants' Motion to Dismiss, Plaintiff respectfully requests that Defendant's Motion to Dismiss be DENIED, and that the Court either order the Parties to proceed on the merits of Plaintiff's claim; or, in the alternative, hold 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 and,

accordingly, set aside the agency's action and remand this matter to the agency for consideration on the merits of the appeal.

_____/s/_____
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