

Exhibit A
(Rohrbaugh Declaration)

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

DECLARATION OF MARK L. ROHRBAUGH, PH.D., J.D.

I, Mark L. Rohrbaugh, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I am the Special Advisor for Technology Transfer to the Office of the Director, National Institutes of Health (“NIH”), an agency of the U.S. Department of Health and Human Services.
2. Through its technology transfer program, NIH makes patents and other intellectual property owned by the United States available to public and private companies, through the granting of exclusive and non-exclusive licenses to use that technology.
3. The Bayh-Dole Act requires a Notice of Intent to grant an exclusive or partially exclusive license to be published at least fifteen days before the license is granted.
4. Since 2016, NIH has published over fifty-one notices of its intent to license potential human therapeutics and vaccines on an exclusive basis in the Federal Register.
5. Knowledge Ecology International (“KEI”) has submitted written objections or comments to at least thirty-four of fifty-one proposed licenses.
6. Most of KEI’s objections request that the NIH impose, through its license agreements, price controls on therapeutics and vaccines covered by the licensed patents. NIH has repeatedly


stated that it is not within the mission of the NIH to control drug prices, and that trying to do so would result in fewer partnerships with companies and fewer therapies developed to serve the public health. Nevertheless, almost every objection to the proposed NIH licenses by KEI are based on a demand to impose such price controls in its license agreements, taxing NIH resources to respond to questions that have already been repeatedly asked and answered.

7. 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 Procedures”). A true and correct copy of the Appeal Procedures is attached as Exhibit 1.

8. NIH has heard objections to proposed licenses from companies that were denied a license in favor of another applicant. However, this is the first time any party has asked for an appeal under 37 C.F.R. § 404.11(a)(3). 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.

9. 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. NIH believes this contention is consistent with the Appeal Procedures’ provision that “[j]udicial review is available as the law permits.” Appeal Procedures, Exh. 1, at p. 3.

10. The Appeal Procedures are a detailed, two-step, appeal process involving senior-level NIH officials under a tight time frame. Providing appeals to every commenter to a Federal Register notice would require a substantial diversion of high-level agency resources, as the first-level of review—and sometimes the second—requires technology transfer staff who were not involved in the initial license application to review the entire record.

 1/8/19

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer

Exhibit 1
(Appeal Procedures)

**United States Public Health Service
Technology Transfer Manual
Chapter No. 307**

NIH Procedures for Handling Requests for
Reconsideration and Appeals of Licensing Decisions

A. PURPOSE

This Manual Chapter describes the basis for appealing a decision of the Office of Technology Transfer (OTT) concerning the grant, denial, modification, or termination of a license for any invention administered by the National Institutes of Health (NIH), Department of Health and Human Services (DHHS) and establishes procedures for processing, reviewing, and responding to requests for reconsideration and appeals. All previous procedures are superseded.

B. BACKGROUND

The OTT has been delegated the authority to make any decision or determination concerning the grant, denial, modification, or termination of any license for any invention in the custody and control of the NIH. 37 CFR § 404.11 requires Federal agencies to establish procedures under which certain parties may appeal decisions or determinations relating to the licensing of government-owned inventions by that agency. The decision and determination of the OTT is final unless the procedures for reconsideration and appeal set forth below are initiated.

C. POLICY

The following person(s) may either request reconsideration by the Director, OTT or may subsequently appeal to the Director, NIH, any determination by the OTT granting, denying, terminating or modifying an NIH-administered license:

- 1 A person whose application for a license to technology advertised as available has been denied;
- 2 A licensee whose license has been modified or terminated in whole or in part; or
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.

D. PROCEDURES

1. Requests for Reconsideration

- a. A person/licensee may request reconsideration of a determination by the Director, OTT granting, denying, terminating, or modifying a license by filing with the Director, OTT a

written request for reconsideration within thirty (30) calendar days after the notice of denial, termination or modification or a response to a Written Objection is sent by the OTT to the person. The request for reconsideration shall concisely state the grounds for reconsideration and include copies of all pertinent documents. The Director, OTT may require submission of additional information or documentation.

- b. 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).
- c. The review committee shall provide a recommendation to the Director, OTT within forty-five (45) days after the request for reconsideration is received by the OTT.
- d. Within sixty (60) calendar 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.

2. Appeals

- a. A person/licensee who has received an adverse determination on a request for reconsideration may appeal such determination to the Director, NIH. Appellants shall not be entitled to an adversary hearing. The Appellant shall file a written appeal to the Director, NIH, with two copies to the Director, OTT, no later than thirty (30) calendar days from the receipt of an adverse decision by the Director, OTT concerning a request for reconsideration. The appeal shall concisely state the grounds for appeal and include copies of all pertinent documents. The appeal must include concise arguments as to why the decision of the Director, OTT, should be rejected or modified. Upon review of the appeal, the Director, NIH, or his or her designee, may require submission of additional information or documentation.
- b. 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 including all documents submitted in support of the appeal.
- c. The review committee shall submit a written recommendation to the Director, NIH, or his or her designee, within forty-five (45) days after the written appeal is received by the NIH. If no review committee is appointed, the individual acting on behalf of the Director, NIH, shall review all documents and submit a written recommendation to the Director, NIH, or his order designee, within forty-five (45) calendar days after the written appeal is received by the NIH.
- d. Within sixty (60) calendar days of receiving the written appeal, the Director, NIH, shall send the final determination to the Appellant. The decision of the Director, NIH, or his

or her designee, shall constitute a final decision by the agency.

e. Judicial review is available as the law permits.

E. EFFECTIVE DATE

The policy and procedures set forth in this Manual Chapter are effective immediately upon issuance.

F. ADDITIONAL INFORMATION

For more information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057.