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

KNOWLEDGE ECOLOGY INTERNATIONAL 1621 Connecticut Ave NW Suite 500 Washington, DC 20009 *Plaintiff,* v. NATIONAL INSTITUTES OF HEALTH 9000 Rockville Pike Bethesda, MD 20892 *Defendant.*	Case No. 8:20-cv-02825

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Knowledge Ecology International (KEI) brings this action under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, for injunctive, declaratory, and other appropriate relief, seeking the release of records improperly withheld from KEI by the National Institutes of Health (NIH) with respect to three FOIA requests. As grounds therefore, Plaintiff alleges as follows:

JURISDICTION AND VENUE

1. Jurisdiction over this action is conferred by 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

2. Venue is properly vested in this Court under 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. §1391(e).

3. Plaintiff has constructively exhausted all administrative remedies and is entitled to judicial review over this matter, as Defendant has failed to provide responsive records or issue a final response to the requests at issue within the deadline established by the FOIA.

PARTIES

4. Plaintiff Knowledge Ecology International (KEI) is a nonprofit organization that works on issues pertaining to access to affordable medicines, access to knowledge and related intellectual property concerns. KEI submitted the FOIA requests at issue.

5. Defendant National Institutes of Health (NIH) is a component of the Department of Health and Human Services, and is an agency of the U.S. government within the meaning of 5 U.S.C. §552(f). The NIH has possession, custody, and control over the records sought. It is headquartered in Bethesda, Maryland.

STATEMENT OF FACTS

Request No. 47589—Dr. Francis Collins' Correspondence with the Pharmaceutical Industry

6. On February 20, 2018, KEI submitted a FOIA request to the NIH seeking:

> the correspondences of the National Institutes of Health (NIH) Director, Dr. Francis Collins, with persons representing pharmaceutical or biomedical companies, the trade associations PhRMA or BIO, university technology transfer offices, the Foundation for the National Institutes of Health, banks or other entities that make investments in biomedical companies.

7. The request states that KEI is entitled to a full waiver of fees, as KEI does not have a commercial interest in the responsive records and the records will contribute to the public's understanding of government activities.

8. The request reasonably describes the records sought.

9. On March 5, 2018, the NIH sent KEI an email stating that the request did not "reasonably describe the records sought".

10. Between March 7, 2018 and April 17, 2018, KEI engaged in a dialogue with the NIH about the scope of the request.

11. By email dated April 16, 2018, KEI Director James Love informed the NIH that KEI "would like to start with" Collins' correspondence with the following entities or individuals:

a. The Foundation for the NIH;

b. Biotechnology Innovation Organization;

c. The Pharmaceutical Research and Manufacturers of America;

d. Members of the Accelerating Medicines Partnership;

e. Gilead;

f. Roche;

g. Genentech;

h. Novartis;

i. The Biden Cancer Initiative (including Joe Biden and staff);

j. Charles Sawyer;

k. Carl Icahn; and

l. Patrick Soon-Shion.

12. On April 17, 2018, the NIH sent KEI an email stating that KEI's April 16, 2018 email "sufficiently clarified" the scope of the FOIA request.

13. The April 17, 2018 email stated further that the NIH "consider[ed] the scope [of the request] to be set, as [NIH] will not conduct rolling searches based on new terms."

14. On May 11, 2018, the NIH sent an email to KEI attaching a letter from the NIH to KEI. The letter formally acknowledged KEI's FOIA request, as "perfected" on April 16, 2018, and assigned it Case Number 47589.

15. The May 11, 2018 letter proposed that the NIH conduct a search using a "reduced scope", with new parameters that were neither proposed nor agreed to by KEI.

16. The letter stated further, "we are not addressing your request for a fee waiver at this time."

17. On July 16, 2019, KEI sent an email to the NIH attaching a letter from KEI. The letter stated that KEI did not agree to the proposed narrowing of the request and asked the NIH to produce responsive records within 20 business days.

18. On September 9, 2019, the NIH sent KEI an email stating that the NIH accepted KEI's "July 16th, 2019 letter indicating that [KEI] d[id] not agree with the proposed scope" offered by the NIH in its May 11, 2018 letter, and that the NIH "will move forward with" the request as narrowed in KEI's April 16, 2018 email.

19. As of the date of this Complaint, the NIH has not provided responsive records, a final determination for the request, a timeframe for a response, or a determination regarding KEI's fee waiver request.

20. KEI has constructively exhausted all administrative remedies with regard to its FOIA request assigned Case No. 47589.

FOIA Request No. 53325—Intramural Recordkeeping Procedures

21. KEI has submitted several FOIA requests to the NIH seeking records disclosing the budget and cost of certain NIH intramural clinical trials, which are clinical trials administered by the NIH.

22. The NIH has not provided KEI with records of the budgets or total costs of any of the intramural clinical trials for which records were requested by KEI, for the majority of the requests.

23. In failing to provide KEI with records of the total costs of its intramural clinical trials, the NIH has asserted on multiple occasions that it does not maintain a record of the costs of its intramural clinical trials.

24. On September 25, 2019, KEI submitted a FOIA request to the NIH seeking "all documents referring to the National Institutes of Health (NIH)'s procedures for maintaining records of budgets and/or expenses associated with NIH intramural clinical trials."

25. The request states that KEI is entitled to a full waiver of fees, as KEI does not have a commercial interest in the responsive records and the records will contribute to the public's understanding of government activities.

26. On December 27, 2019, the NIH acknowledged the request and assigned it Case Number 53325, at the NIH FOIA Public Portal.

27. On April 27, 2019, the "status" for the request was updated as "Assigned for Processing" at the NIH FOIA Public Portal.

28. As of the date of this Complaint, the "status" for the request is still listed as "Assigned for Processing" at the NIH FOIA Public Portal.

29. On Monday, May 18, 2020, KEI emailed the NIH FOIA office (nihfoia@mail.nih.gov) asking for an update on the request.

30. As of the date of this Complaint, the NIH has not responded to the May 18, 2020 email seeking a status update.

31. On June 2, 2020, KEI forwarded the May 18, 2020 email to the NIH FOIA office, stating "Please acknowledge [the May 18, 2020] email and advise as to how NIH will proceed."

32. As of the date of this Complaint, the NIH has not responded to the June 2, 2020 email seeking a status update.

33. As of the date of this Complaint, the NIH has not provided responsive records, a final determination for this request, a timeframe for a response, or a determination regarding KEI's request for a full waiver of fees.

34. KEI has constructively exhausted all administrative remedies with regard to Request No. 53325.

FOIA Request No. 54587—Dr. Mark Rohrbaugh's Correspondence about KEI

35. The Bayh-Dole Act, 35 U.S.C. §§ 200-212, limits the authority of federal agencies to grant exclusive licenses to federally-owned inventions.

36. Among other limits, federal agencies may grant an exclusive license to a federally owned invention "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[.]"

35 U.S.C. § 209(a)(1).

37. In addition to the requirement that exclusivity be a reasonable and necessary incentive, a federal agency may grant an exclusive license only if the agency "finds that . . . the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application [.]" 35 U.S.C. § 209(a)(2).

38. Section 209(e) of the Bayh-Dole Act sets forth the procedural requirements governing exclusive licenses to federally-owned inventions.

39. Before a federal agency may grant such a license, it must notify the public of its intent to grant the license, provide at least 15 days for the public to submit comments, and consider all timely-submitted comments. 35 U.S.C. § 209(e).

40. Since 2015, KEI has submitted more than 60 comments on proposed NIH exclusive licenses. Before submitting these comments, KEI researched the proposed license terms, licensees, and subject inventions, in order to assess whether or not the licenses comply with the Bayh-Dole Act and other applicable laws and regulations. Because certain information pertinent to the legality of the licenses was not publicly available, KEI submitted questions about the licenses to the NIH technology transfer official designated as the point of contact.

41. The NIH has declined to answer the majority of the questions asked by KEI, on the purported basis that those questions have already been addressed in response to questions about prior, unrelated licenses.

42. The questions that the NIH fails to answer for pending exclusive patent licenses, even though asked for the first time with respect to the particular license pending at the time, include inquiries concerning what analysis was conducted by the NIH in concluding that exclusivity is a necessary incentive and how the NIH determined that the scope of exclusivity was not greater than reasonably necessary to provide the incentive necessary to bring the subject invention to practical application.

43. On at least one occasion, Dr. Mark Rohrbaugh, Special Advisor for Technology Transfer with the NIH, has advised an NIH technology transfer official responsible for a prospective grant of an exclusive patent license not to answer KEI's questions regarding the license.

44. On June 18, 2020, KEI submitted a FOIA request to the NIH seeking all correspondence to and from Dr. Rohrbaugh that mention and/or concern:

a. Knowledge Ecology International or KEI;

b. James Love;

c. Andrew Goldman; or

d. Kathryn Ardizzone.

45. The request states that KEI is entitled to a full waiver of fees, as KEI does not have a commercial interest in the responsive records and the records will contribute to the public's understanding of government activities.

46. On June 18, 2020, the NIH acknowledged the request and assigned it Case Number 54587.

47. As of the date of this Complaint, the NIH has not provided responsive records, a final determination for this request, a timeframe for a response, or a determination regarding KEI's request for a full waiver of fees.

48. KEI has constructively exhausted all administrative remedies with regard to this request.

COUNT I

49. KEI realleges the foregoing paragraphs as if stated herein.

50. KEI properly submitted Request No. 47589 seeking records within the custody and control of the NIH and a fee waiver.

51. KEI has a statutory right under the FOIA to the responsive records and a full waiver of fees.

52. The NIH failed to provide responsive records.

53. The NIH failed to grant the request for a full waiver of fees.

54. There is no legal basis for the NIH's failure to disclose the responsive records and its failure to grant a full waiver of fees.

COUNT II

55. KEI realleges the foregoing paragraphs as if stated herein.

56. KEI properly submitted Request No. 53325 seeking records within the custody and control of the NIH and a fee waiver.

57. KEI has a statutory right under the FOIA to the responsive records and a full waiver of fees.

58. The NIH failed to provide responsive records.

59. The NIH failed to grant the request for a full waiver of fees.

60. There is no legal basis for the NIH's failure to disclose the responsive records and its failure to grant a full waiver of fees.

COUNT III

61. KEI realleges the foregoing paragraphs as if stated herein.

62. KEI properly submitted Request No. 54587 seeking records within the custody and control of the NIH and a fee waiver.

63. KEI has a statutory right under the FOIA to the responsive records and a full waiver of fees.

64. The NIH failed to provide responsive records.

65. The NIH failed to grant the request for a full waiver of fees.

66. There is no legal basis for the NIH's failure to disclose the responsive records and its failure to grant a full waiver of fees.

REQUESTED RELIEF

WHEREFORE, Plaintiff respectfully request that the Court:

A. Declare that the NIH's failure to provide KEI with timely and full responses to KEI's FOIA requests described above, including its failure to make a timely determination and produce all records requested, is in violation of the FOIA;

B. Order the NIH to produce, within 20 days of the Court's order and at no cost, all non-exempt responsive records and *Vaughn* indexes of any responsive records withheld under a claim of exemption;

C. Enjoin the NIH from continuing to withhold responsive records;

D. Award KEI its reasonable costs, litigation expenses, and attorneys' fees incurred in prosecuting this civil action under the FOIA, 5 U.S.C. § 552(a)(4)(E); and

E. Grant such other relief as the Court deems just and proper.

Dated: September 29, 2020

/s/ *Kathryn Ardizzone*
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