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

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KNOWLEDGE ECOLOGY INTERNATIONAL
1621 Connecticut Ave NW #500 *
Washington, D.C. 20009

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Plaintiff

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v.

*

NATIONAL INSTITUTES OF HEALTH
9000 Rockville Pike *
Bethesda, Maryland 20892

*

and

*

FRANCIS COLLINS, in his official
capacity as director of the *
National Institutes of Health
9000 Rockville Pike *
Bethesda, Maryland 20892

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and

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NATIONAL CANCER INSTITUTE
9609 Medical Center Drive *
Bethesda, MD 20892

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And

*

DAVID LAMBERTSON, in his official
capacity as Senior Technology *
Transfer Manager of the
National Cancer Institute *
9609 Medical Center Drive
Bethesda, MD 20892 *

Defendants *

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COMPLAINT FOR DECLARATORY,
INJUNCTIVE, AND OTHER RELIEF

INTRODUCTION

1. This civil action seeks declaratory, injunctive, and other relief in order to rectify Defendants' waste of taxpayer funds that will result in the denial of affordable cancer treatments for patients who would benefit from immunotherapy treatments because Defendants improperly granted an exclusive license for key technology that underpins the newest and most promising cancer therapies to a multi-billion dollar pharmaceutical behemoth.

2. Specifically, Plaintiff Knowledge Ecology International challenges the Defendant National Institutes of Health's ("NIH") exclusive license of a federally-owned and federally-funded cancer treatment technology from the Defendant National Cancer Institute ("NCI") to Kite Pharma, Inc. ("Kite"), a wholly owned subsidiary of multi-billion dollar company Gilead Sciences, Inc. ("Gilead").

3. The technology in question pertains to chimeric antigen receptor ("CAR") T-cell therapies (sometimes referred to as "CAR T") — immunotherapy frequently thought of as the "frontier" of cancer treatment for being among the newest and most promising cancer therapies. Yet the only two CAR T cancer therapies currently on the market, including one by Gilead, have been priced at extraordinarily high prices approaching a half million dollars per treatment

(significantly more expensive than the median price of a new home, which is typically financed over 30 years), with total expenses for treatment potentially much higher, in spite of the fact that the manufacturing costs have been reported to be as low as $15,000. These high costs place severe burdens on patients, consumers, taxpayers, payers, and health budgets.

4. In disregard of federal law, the NIH has indicated its intention to proceed with this license, failed to seek and obtain antitrust review by the Attorney General prior to execution of the license, and denied KEI's right of appeal. In so doing, the NIH and the NCI have mismanaged taxpayer funds at a time when high drug prices are a leading concern both within the United States and abroad, thereby threatening access to this treatment, imposing unnecessary financial toxicity on patients that have access, and ignoring the public interest in having affordable cancer treatments.

PARTIES

5. Plaintiff KNOWLEDGE ECOLOGY INTERNATIONAL ("KEI") is an award-winning nonprofit organization that works extensively on issues pertaining to access to affordable medicines and related intellectual property concerns. In 2006, KEI was the recipient of the MacArthur Foundation's MacArthur Award for Creative and Effective Institutions. The organization is based in Washington, D.C. and maintains a satellite office in Geneva, Switzerland. KEI conducts research, writing, and advocacy in the public interest on behalf of patients, taxpayers, and consumers, including on the licensing of federally-funded and/or federally-owned

medical technologies, and comments frequently on proposed exclusive licenses by the federal government including those by NIH. KEI frequently testifies before federal and state government on these and other drug pricing issues at the intersection of intellectual property and health, and additionally advocates for the public interest internationally on these issues as an accredited non-state actor of the World Health Organization, and a participant in many ongoings at the World Intellectual Property Organization, among other fora. KEI's work is frequently written about in the press, including the *New York Times*, *Washington Post*, and other publications both within the United States and abroad. KEI maintains multiple email lists on these and other public health issues for patients, taxpayers, and consumers, academics, and other interested persons, including the "IP-Health" listserv of approximately 2400 subscribers. KEI brings this action on its own behalf and on behalf of the adversely affected patients and taxpayers that the organization represents.

6. Defendant NATIONAL INSTITUTES OF HEALTH is part of the Department of Health and Human Services, and is the primary governmental agency responsible for biomedical and public health research.

7. Defendant FRANCIS COLLINS is sued in his official capacity as the Director of the NIH.

8. Defendant NATIONAL CANCER INSTITUTE is the institute within the NIH responsible for cancer research and is listed as the licensee of the CAR technology at issue.

9. Defendant DAVID LAMBERTSON is sued in his official capacity as the Senior Technology Transfer Manager of the National Cancer Institute.

JURISDICTION AND VENUE

10. This action arises under, and alleges violation of, federal law and regulations including the Federal Property and Administrative Services Act ("FPASA"), 40 U.S.C. §§ 101 *et seq*., the Administrative Procedure Act ("APA"), 5 U.S.C. § 701–706, and 37 C.F.R. § 404.11.

11. Jurisdiction over this action is conferred by 28 U.S.C. § 1331 regarding the federal question, and 5 U.S.C. § 702 and 704 regarding APA jurisdiction to review agency actions. The requested relief is proper under 28 U.S.C. §§ 2201 (declaratory relief); 2202 (injunctive relief); and 2412 (costs and fees).

12. Defendants made a final action reviewable under the APA when they committed to proceed with the exclusive license of the CAR T technology at issue and denied Plaintiff's right of appeal without explanation.

13. Defendants made a final action reviewable under the APA when they proceeded with the exclusive license without complying with the requirements of 40 U.S.C. § 559 regarding the obligation to seek and obtain the antitrust advice of the Attorney General on whether the disposal of federally-owned patents to a private interest would tend to create or maintain a situation inconsistent with antitrust law.

14. The requested relief would redress actual, concrete injuries to Plaintiff and the patients, taxpayers and consumers Plaintiff represents, caused by the

failure to adhere to statutory and regulatory requirements designed to protect the public interest, and by the determination to proceed with an exclusive license for the life of the patent without the expectation of effective safeguards against excessive pricing or barriers to access.

15. Plaintiff has submitted comments to the NIH and has exhausted all available administrative remedies.

16. Venue is properly vested in this Court under 28 U.S.C. §1391(e) because defendants are officers or employees of the United States, and a substantial part of the events or omissions giving rise to the claim occurred in Maryland. Defendant NIH maintains its headquarters in Maryland at 9000 Rockville Pike, Bethesda, Maryland 20892.

STATUTORY AND REGULATORY FRAMEWORK

Administrative Procedure Act (5 U.S.C. §§ 701–706)

17. The Administrative Procedure Act, 5 U.S.C. §§ 701–706, authorizes courts to review final agency actions and hold unlawful and set aside final agency actions, findings, and conclusions that are arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A). The APA also authorizes a reviewing court to compel agency action that is unlawfully withheld. 5 U.S.C. § 706(1). The APA provides a cause of action to challenge any final agency action taken pursuant to any statute where the action is made reviewable by that statute, or where there is no other adequate remedy in a court. 5 U.S.C. § 704.

18. Federal Property and Administrative Services Act (40 U.S.C. §§ 101 *et seq.*)

19. The FPASA governs the management and disposal of federal property. 40 U.S.C. § 101.

20. "Property" is defined within the statute to mean "any interest in property" except for the public domain, certain lands and minerals, naval vessels, and government records. 40 U.S.C. § 102(9).

21. Under the FPASA, Executive Branch agencies may not dispose of property to a private interest "until the agency has received the advice of the Attorney General on whether the disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law." 40 U.S.C. § 559(b)(1).

22. This obligation applies to the license of federally-owned patents, as the exception for personal property with estimated fair market value of less than $3 million does not apply to patents, processes, techniques or inventions. 40 U.S.C. § 559(b)(2); *see also* 41 CFR 102-75.270 ("antitrust laws must be considered in any case in which there is contemplated a disposal to any private interest of . . . (b) Patents, processes, techniques, or inventions, irrespective of cost").

23. The FPASA explicitly requires transmittal of notice to the Attorney General of the intention to dispose of the property, "including probable terms and conditions," with a copy sent to the Administrator of General Services. 40 U.S.C. § 559(c)(1-2). Upon receipt, the Attorney General is required to respond within a

reasonable time, not later than 60 days, with advice as to the antitrust implications of the proposed disposition. 40 U.S.C. § 559(d).

24. Neither the Secretary of Health and Human Services nor the Director of the National Institutes of Health, nor the executive department and agency that they represent, are listed among those whose authority may not be impaired via the limitations of the FPASA in 40 U.S.C. § 113.

The Bayh-Dole Act (35 U.S.C. §§ 200 *et seq.*)

25. The Bayh-Dole Act governs the license of federally-owned and federally-funded technology. 35 U.S.C. §§ 200 *et seq.*; *see also* 37 C.F.R. 404.1-14.

26. The stated policy and objective of the Bayh-Dole Act contains clear reference to the need "to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions. . . ." 35 U.S.C. § 200.

27. The Bayh-Dole Act does not contain any provision creating an exception to the requirements of 40 U.S.C. § 559.

28. The Bayh-Dole Act does contain a provision allowing a license only where the license "will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws." 35 U.S.C. § 209(a)(4).

29. Prior to executing any non-exclusive or exclusive license, the NIH is required to provide public notice and opportunity for comment at least fifteen days prior to the grant of the license. 35 U.S.C. § 209(e).

Regulations on the Licensing of Government Owned Inventions (37 C.F.R. Part 404)

30. The federal regulations in 37 C.F.R. Part 404 prescribe the terms, conditions, and procedures for the license of federally-owned inventions. 37 C.F.R. § 404.1.

31. These regulations provide a right of appeal to specified parties "in accordance with procedures prescribed by the Federal Agency" with regard to "any decision or determination concerning the grant, denial, modification, or termination of a license." 37 C.F.R. § 404.11(a).

32. The right of appeal is granted to "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." 37 C.F.R. § 404.11(a)(3).

Equal Access to Justice Act (28 U.S.C. § 2412)

33. The Equal Access to Justice Act authorizes the payment of attorney's fees to a prevailing party in an action against the United States absent a showing by the government that its position in the underlying litigation "was substantially justified." 28 U.S.C. § 2412.

FACTUAL AND PROCEDURAL BACKGROUND

34. The problem of high prices for drugs and CAR T treatments stems in large part from rights granted to patent holders to exclude competition via patents and related exclusive rights, coupled with insufficient enforcement of safeguards against excessive pricing.

35. Numerous studies find significant decreases on the prices of drugs when patent terms expire and competition is allowed. Some recent studies estimate the decrease in prices following competition from manufacturers of generic drugs at 70 to 95 percent.

36. The high prices of patented cancer medicines and treatments in particular, including those utilizing CAR T technology, create severe hardships on patients, consumers, taxpayers, payers and health budgets.

37. CAR T technology for the treatment of human cancers is considered a "gene therapy" or "immunotherapy" because the technology works by actually drawing blood from the patient's body, removing T-cells, using a disarmed virus to genetically engineer chimeric antigen receptors on the surface of those cells that allow for the cells to attach to cancerous tumor cells, and then reinjecting those modified cells into the patient.

38. This type of immunotherapy has demonstrated great promise as a treatment for cancer, in some cases effectively eradicating the cancer altogether.

39. In 2017, the U.S. Food and Drug Administration approved the first two drugs that utilize CAR T immunotherapy: (1) tisagenlecleucel, marketed by Novartis as Kymriah, for the treatment of acute lymphoblastic leukemia ("ALL"); and (2) axicabtagene ciloleucel, marketed by Kite/Gilead as Yescarta, for the treatment of B-cell lymphomas in patients whose cancer has progressed after receiving at least two prior treatment regimens.

40. Kite was purchased by Gilead in October 2017 for $11.9 billion and is now a wholly owned subsidiary of Gilead.

41. Novartis set the price for Kymriah at $475,000 for a course of treatment.

42. Gilead set the price for Yescarta at $373,000 for a course of treatment.

43. Both Kymriah and Yescarta benefitted from substantial federal subsidy of the research and development costs, including in the basic CAR T science supporting these treatments.

44. The high price of these treatments bears no relationship to the cost of manufacture, which has been estimated to be as low as $15,000 by pioneering CAR T researcher Dr. Carl June.

45. The total costs of treatment for CAR T immunotherapy per patient, including the costs of continued management for potentially harmful side effects, is expected to be significant, and the combined fiscal impact of the high cost for the initial treatment and the associated care has a negative impact on decisions by reimbursement entities and thus is constaining access.

46. The high prices of these CAR T therapies for cancer has prompted concern and outrage by patients, doctors, consumers, taxpayers, and public interest groups.

47. 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 to Kite of patents for CAR T technology for the treatment of human cancer. 82 Fed. Reg. 60406-7 (Dec. 20, 2017).

48. The Notice specifically referred to "United States Provisional Patent Application No. 62/241,896, filed 15 October 2015 and entitled "Anti-CD30 Chimeric Antigen Receptors" [HHS Reference No. E–016–2018/0–US–01]; PCT Patent Application PCT/US2016/ 056262, filed 10 October 2016 and entitled "Anti-CD30 Chimeric Antigen Receptors" [HHS Reference No. E–016– 2018/0–PCT–02]; and U.S. and foreign patent applications claiming priority to the aforementioned applications." (Collectively, the "CAR T Technology").

49. The Notice additionally specified that the CAR T Technology would provide treatment for rare cancers "including Hodgkin lymphoma (HL), Non-Hodgkin's Lymphoma (NHL), diffuse large B cell lymphoma (DLBCL), peripheral T cell lymphoma not otherwise specified (PTCL–NOS), anaplastic large cell lymphoma (ALCL), and angioimmunoblastic T cell lymphoma (AITL)."

50. The Notice provided a window for public comment on the proposed exclusive license that closed on January 4, 2018, spanning two national holidays.

51. On January 4, 2018, KEI submitted written comments to the NIH in response to the Notice ("Comments"), objecting to the exclusivity of the license and requesting the inclusion of public interest safeguards in any license to be executed.

52. In its Comments, KEI identified the ongoing, federally-funded Phase 1 Clinical Trial for the CAR T Technology by its ClinicalTrials.gov identifier, NCT03049449, and noted that given the early stage of the clinical trials and the fact

that the patents had not yet even been granted, the proposed exclusive license was premature and unwise for the NIH to create a monopoly on this NIH-funded invention, prior to evaluating the Phase 1 trial evidence and the costs of moving the technology forward to FDA approval.

53. KEI's Comments also made additional suggestions for contractual protections that are consistent with the obligations in and requirement of the Bayh-Dole Act that should be included to protect U.S. residents against excessive prices and barriers to access.

54. On Jan. 25, 2018, Defendant Lambertson sent an email to KEI acknowledging receipt of KEI's comments, rejecting all of KEI's substantive suggestions and objections, and stating that ". . . NCI intends to proceed with the negotiation of the proposed exclusive license. . . ."

55. On Feb. 13, 2018, KEI sent an email to NIH and Defendant Lambertson asking whether NIH, under 40 U.S.C. § 559, requests and obtains advice advice of the Attorney General with respect to antitrust laws prior to transferring patents and related rights from the NIH to private interests.

56. On Feb. 14, 2018, KEI sent an email to Defendants Lambertson and Collins notifying them of the intent to appeal, and requesting that NIH provide its procedures for such an appeal. As noted in this email, the procedures are not available on the NIH website as of the date of this filing. In that email, KEI noted that the link to what appears to potentially be the NIH procedures for appeal is broken.

57. On Feb. 15, 2018, NIH replied to KEI's inquiry of Feb. 13th to say that the NIH does not follow the requirements of 40 U.S.C. § 559 in its patent licensing activities.

58. On Feb. 26, Defendant Lambertson, prior to having received or viewed the KEI appeal itself, emailed KEI in response to the email of Feb. 14, ignoring the request for the NIH appeal procedures, and stating that, "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."

59. There is no statutory basis for KEI to further appeal the determination of Defendants to proceed with the exclusive license, and no other remedy available.

CAUSES OF ACTION

I. Violation of the Federal Property and Administrative Services Act and 5 U.S.C. 706(2)(A)

Defendants' Failure to Seek and Obtain the Antitrust Advice of the Attorney General is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance With Law

60. Plaintiff realleges and incorporates all preceding paragraphs of this Complaint.

61. 40 U.S.C. § 559 creates a black letter obligation for all federal agencies, including NIH, to seek and obtain the antitrust advice of the Attorney General prior to the disposal of federal property to private interests.

62. 41 CFR 102-75.270 clarifies that 40 U.S.C. § 559 applies to the disposal of patents.

63. The license of federally-owned patents in the CAR T Technology to Gilead constitutes a disposal of federal property to private interests.

64. Defendants by admission have violated the black letter obligations of the FPASA in neglecting to seek and obtain the antitrust advice of the Attorney General with regard to the license of the CAR T Technology to Kite.

65. The failure to do so is a violation of 40 U.S.C. § 559 and applicable regulations, and constitutes agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law under 5 U.S.C. § 706(2)(A), or that is illegal agency action under 5 U.S.C. § 706(1).

II. Violation of 37 C.F.R. § 404.11 and 5 U.S.C. 706(2)(A)

Defendants' Refusal to Provide the Right of Appeal to KEI is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance With Law

66. Plaintiff realleges and incorporates all preceding paragraphs of this Complaint.

67. 37 C.F.R. § 404.11 provides a right of appeal on any determination concerning the grant of a license, in accordance with procedures prescribed by the federal agency, to any party that has timely submitted comments and who can demonstrate to the satisfaction of the agency that the party may be damaged by the agency action.

68. Defendants have not made such procedures readily available to the public, and have refused to provide such procedures upon request.

69. Defendants have refused to entertain the rightful appeal of KEI without explanation, without stating what Defendants require to demonstrate to

their satisfaction that KEI and the parties KEI represents may be damaged by the license, and prior to even seeing the appeal itself.

70. In ex-ante denying Plaintiff the right of appeal, Defendants' action constitutes a violation of 37 C.F.R. § 404.11, as well as an agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law under 5 U.S.C. § 706(2)(A), or that is illegal agency action under 5 U.S.C. § 706(1).

CONCLUSION

71. NIH's failure to adhere to the black letter law with regard to seeking and obtaining antitrust advice from the Attorney General prior to granting Gilead a license for a second CAR T treatment covering large B-cell lymphoma is an abdication of its obligations to the public and creates a high likelihood, given Gilead's past track record of high prices, of anti-consumer behavior.

72. The refusal of the NIH to grant the right of appeal to KEI is an affront to patients, taxpayers, and consumers who would otherwise have no voice in the licensing process, and who will be damaged by the higher prices stemming from an exclusive license of CAR T technology without limitation or restriction.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully request that the Court:

A. Declare that Defendants violated FPASA and applicable regulations by committing to proceed with an exclusive license of NCI technology without seeking and obtaining the antitrust advice of the Attorney General, and in so doing

committed agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A), or that is illegal agency inaction under 5 U.S.C. § 706(1);

B. Declare that Defendants violated regulations on the licensing of federally-owned inventions at 37 C.F.R. § 404.11 in ex-ante denying Plaintiff the right of appeal, and in so doing committed agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A), or that is illegal agency inaction under 5 U.S.C. § 706(1);

B. Invalidate the exclusive license of the NCI CAR technology to Kite;

C. Enter appropriate preliminary and permanent injunctive relief to ensure that Defendants comply with FPASA and specifically to ensure that Defendants and their agents take no further actions toward proceeding with the challenged license until they have complied with FPASA and granted KEI the right of appeal;

E. Award Plaintiff the costs of this action including expenses, expert witness fees, and reasonable attorney fees under 28 U.S.C. § 2412; and

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

Respectfully submitted this 19 day of April, 2018:

_____/s/_____

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