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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Declaration of James Packard Love

I, James Packard Love, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. My name is James Packard Love. I am the Director of Knowledge Ecology International, Incorporated (KEI), a 501c3 nonprofit organization. KEI was incorporated in 2006 in Washington, DC., and I am also one of the original incorporators and, in practical terms, the founder.
2. The Articles of Incorporation for KEI set out its purposes, and include this paragraph:

> "The Corporation is organized and will be operated exclusively for charitable, educational, and scientific purposes. Specifically, the Corporation will perform research, educate the public and other constituencies, and contribute to policy discourse and debate on issues relating to intellectual property, innovation, economics, international trade, consumer protection, law, and access to knowledge and the fruits of knowledge, including without limitation issues related to the public domain, freely licensed knowledge resources, knowledge resources that are available by custom, access to medical inventions including essential medicines, technologies and business or social systems that are used to manage knowledge resources, modes of stimulating and financing knowledge resources, and related

technological, legal and social aspects of the management of knowledge."

3. Under Article 3 of KEI's Bylaws, KEI's work is guided by a Board of Directors and Board of Advisors.
4. The Board of Directors for KEI has five members, and, per section 3 manages the affairs of KEI. The Chair is Sakiko Fukuda-Parr, a Professor of International Affairs at The New School, New York. Sakiko was recently a member of the UN Secretary-General's High-Level Panel on Access to Medicines. Previously she was, for 10 years, the editor of the UNDP Human Development Report. Tim Hubbard is Professor of Bioinformatics and Head of Department of Medical and Molecular Genetics at King's College London and is Director of Bioinformatics for King's Health Partners/King's College London. Rohit Malpani is a Special Advisor for the Initiative for Medicines, Access and Knowledge, and previously was Director of Policy and Analysis at Médecins sans Frontières' (MSF) Access Campaign. Eric Sawyer was one of the original co-founders of Act Up, and has a long history working for non-profit and UN organizations addressing HIV/AIDS. Rishab Aiyer Ghosh is a software developer, academic researcher and entrepreneur, now working for Apple Computers.
5. The Board of Directors holds an annual meeting and, under Article 5 of the Bylaws, elects the Executive Director and other officers.
6. KEI has a Board of Advisors. Its members include two economists who received the Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel, including Professor Joseph Stiglitz and Amartya Sen. A previous member of the KEI Board of Advisors, before his untimely death, was Sir John Sulston, who was awarded the The Nobel Prize in Physiology or Medicine in 2002.
7. In 1981, I was awarded a Masters in Public Administration (MPA) from the J.F.K. School of Government at Harvard University. In 1985, I earned a Masters in Public Affairs from the Woodrow Wilson School of Public and International Affairs at Princeton University, through the program on economic policy analysis.
8. Prior to my employment at KEI I was Director of Economic Studies at the Center for Study of Responsive Law (CSRL), where I was also tasked with running the Taxpayer Assets Project (TAP) and later the Consumer Project on Technology (CPTech).

9. KEI itself can be described as a spin-off of the work done through TAP and CPTech at the CSRL, into a separate organization with its own governance structure.
10. Prior to the working at the CSRL, I was Senior Economist for the Frank Russell Company, then a large pension funding consulting firm, where my primary duties included advising the pension fund clients IBM, DEC and Shell, and contributing to the design of a portfolio reporting system for the extensive real estate holdings owned by the IBM Pension Fund.
11. Prior to working at the Frank Russell Company, I worked as a Lecturer at the Business School at Rutgers University where I taught microeconomics, as a Lecturer and Researcher at Princeton University, and as a researcher for the National Bureau of Economic Research where I conducted studies of the impact of movements in exchange rates on U.S. manufacturing employment.
12. Earlier, I lived in Alaska, where I held a variety of jobs, including Special Assistant for the Commissioner of the Alaska Department of Revenue, a researcher and advisor to the Alaska State Legislature, the Executive Director of the Alaska Public Interest Research Group, the Executive Director of Open Door Clinic (a free medical clinic), and other jobs, including in the commercial fishing industry.
13. In 2006, KEI received one of the first MacArthur Awards for Creative & Effective Institutions, based largely upon the work done earlier at the CSRL through the CPTech and TAP projects. In announcing the award, the MacArthur Foundation said, "KEI promotes balanced intellectual property policies in U.S. law and in international agreements and norms. It supports providing reasonable benefits and incentives to creators and owners, while making essential knowledge and goods accessible and affordable to the broadest possible public. It is an effective broker and guide in this increasingly complex debate and one that is sought out worldwide."[1]
14. In 2007, I received the Public Knowledge IP3 Award for my work on intellectual property policy.[2]
15. In 2013, I was awarded the EFF Pioneer Award for my work on the WIPO Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled. My work on the Marrakesh Treaty began in 2008, when Dr. Manon Ress of KEI collaborated with the World Blind Union (WBU) and the Daisy Consortium to convene an

[1] https://www.macfound.org/maceirecipients/24/

[2] https://www.publicknowledge.org/press-release/public-knowledge-presents-fourth-ip3-awards-wu-lov

experts group to draft a proposed treaty on copyright exceptions for persons who are blind or have other disabilities. I edited the work of the experts group, and this became the original negotiating text for the treaty. I spent five years working on the treaty, which was concluded at a Diplomatic Conference on June 28, 2013. The Marrakesh treaty is currently signed by 91 countries plus the European Union. As of June 24, 2018, 39 countries have ratified the treaty. The U.S. Senate Committee on Foreign Relations unanimously recommended ratification on May 22, 2018.

16. In 2015, I was a joint winner of the Joe A. Callaway Award for Civic Courage for work expanding access to patented medicines.
17. I have been a consultant or expert on intellectual property rights for a number of international bodies, including the World Health Organization (WHO), the United Nations Development Program (UNDP), the World Intellectual Property Organization (WIPO), The United Nations Conference on Trade and Development (UNCTAD), the United Nations Human Rights Council, the World Bank, the Global Fund to Fight AIDS, Tuberculosis and Malaria (TGF) and UNITAID.
18. I have been invited to testify before the U.S. Congress on numerous occasions on issues related to intellectual property rights, access to knowledge and the regulation of businesses, including on several occasions on the pricing of drugs developed with federal funding.
19. In January 2001, I negotiated a $1 per day price for a three drug combination treatment for HIV/AIDS with the generic drug manufacturer Cipla.
20. In 2001, I was a consultant to the Department of Health in South Africa, during a trial concerning the South Africa Medicines Act.
21. A November 16, 2001 Wall Street Journal editorial, “Doha Hurrah,” credited the Consumer Project on Technology (CPTech) as one of the primary drivers of the World Trade Organization (WTO) Doha Declaration on TRIPS and Public Health.
22. In 2002, I proposed the creation of a collective management system for patents on HIV drugs, and spent several subsequent years working to advance the proposal. In 2010, the Medicines Patent Pool was created, and now provides open patent licenses to generic manufacturers for nearly all of the best drugs for HIV/AIDS in more than 110 countries.
23. In 2003, was the consultant to the Republic of South Africa Competition Commission in the Hazel Tau case regarding excessive pricing of patented medicines for HIV. This case enabled the licensing of a first line treatment for HIV throughout sub-Saharan Africa.

24. I am the author of the 2005 WHO/UNDP Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies.
25. In 2012 I was a pro-bono expert in a compulsory licensing case in India, on the issue of whether or not Bayer's cancer drug Nexavar was reasonably affordable in India. This was the first post-TRIPS Agreement compulsory licensing patent case in India, and greatly expanded access to the drug.
26. In 2014, I was the author of a report for the World Intellectual Property Organization (WIPO) titled, "Alternatives to the Patent System that are used to Support R&D Efforts, Including both Push and Pull Mechanisms, with a Special Focus on Innovation-Inducement Prizes and Open Source Development Models."
27. In 2018, I was appointed as an expert to a World Health Organization Cancer Medicines Working Group, tasked with making recommendations for changes in the WHO Essential Medicine List.
28. In recent years, I have focused much of my efforts on the challenges of expanding access to drugs for cancer and rare diseases.
29. Manon Anne Ress, my wife, is the Director of Information Society Projects at KEI. In 2010, she was diagnosed with HER2+ breast cancer. Manon's cancer has metastasized, and she is currently being treated with trastuzumab emtansine (T-DM1), an NIH-funded invention that is sold by Roche under the trade name Kadcyla. Our research shows that NIH has failed to require declaration of government funding in three T-DM1 patents.
30. Manon's mother was diagnosed with cancer and died from the cancer in 2007, while living with us. Manon's sister has also been treated for breast cancer.
31. Subsequent to Manon's diagnosis for cancer, I was diagnosed and treated for squamous cell carcinoma skin cancer, and I continue to be monitored for recurrences.
32. My father died of stomach cancer in 1990. My mother currently has breast cancer. One of my brothers has been treated for colon cancer. Another brother has been diagnosed and treated for diffuse large B cell lymphoma (DLBCL), one of the indications in the proposed license to Gilead, and he has also recently been diagnosed with prostate cancer.
33. In 2014, I co-founded the Union for Affordable Cancer Treatment (UACT), with my wife Manon Anne Ress. UACT is a membership organization devoted to making treatments for cancer more affordable, and also encouraging governments to develop new incentives for investment in research and development for medical technologies that are delinked from high prices.
34. Since 1991, I have been involved in several efforts to improve access to NIH-funded medical inventions, as well as to improve the transparency of the

licensing and commercial development of inventions. This began with a request from now-Senator Ron Wyden, then a member of the House of Representatives, to evaluate the NIH methodology for determining a reasonable price for the cancer drug paclitaxel (then named taxol, before BMS sought a trademark for the generic name), which lead to an investigation into the federal government's role in financing the R&D for all new cancer drugs registered by the FDA from 1955 to 1993, and then to investigations of the commercialization of several NIH-funded drugs for rare diseases and for HIV/AIDS.

35. I have been directly involved in several NIH march-in requests concerning the obligation in the Bayh-Dole Act to make inventions "available to the public on reasonable terms," including 2004 cases involving ritonavir, a treatment for HIV/AIDS, and latanoprost, a treatment for glaucoma, a 2012 case involving ritonavir and several other drugs, a 2016 march-in case involving enzalutamide, a treatment for prostate cancer, and a 2017 request regarding patents on daclizumab as a treatment for multiple sclerosis. I also provided advice to lawyers for Joseph M. Carik, Anita Hochendoner, and Anita Bova regarding a 2010 march-in case motivated by critical and life threatening shortages of Fabrazyme.
36. I have also been involved, through CPTech and KEI, in several requests to the federal government to use its royalty-free rights in NIH-funded drugs to obtain more affordable versions of drugs and to expand access to several drugs, including ones that treat HIV, cancer and multiple sclerosis.
37. Beginning in 2017, KEI has provided evidence to the NIH that inventors have failed to file required disclosures of NIH funding of several patented inventions related to the products Spinraza (nusinersen), Sovaldi (sofosbuvir) and combinations that involve sofosbuvir, Juxtapid (lomitapide), Rydapt (midostaurin), Exondys 51 and Vizamyl (flutemetamol F 18). In several of these cases KEI asked the NIH to take title to the patents (a remedy permitted by the funding agreements) as a remedy to the non-disclosure, and as leverage to counter the excessive pricing of the technologies.
38. Since 2015, KEI has filed comments with the NIH on more than 30 proposed exclusive patent licenses. Many of these comments are available here: https://www.keionline.org/nih-licenses.
39. KEI's comments on proposed exclusive patent licenses have generally focused on three issues, (1) standards to protect against excessive or discriminatory pricing, (2) provisions to protect or expand access in developing countries, and (3) requests for transparency of R&D investments, prices and revenues related to the commercialization of products using the inventions.

40. In the case of the Gilead/Kite license for the CAR T/ CD30 patents, KEI has several concerns. We have been skeptical that an exclusive license is needed, particularly since the NIH has already funded, and is conducting a phase 1 trial with 77 patients. For comparison, the safety and efficacy of the Novartis CAR T treatment marketed as Kymriah were demonstrated in one multicenter clinical trial of 63 patients.[3] The safety and efficacy of Yescarta were established in a multicenter clinical trial involving approximately 100 patients.[4]
41. The NIH has rejected our proposal that they delay the licensing of the CAR T/CD30 patents until the NIH has at least preliminary results from the current Phase 1 trial.
42. The NIH refused to tell KEI how much money it was spending on the Phase 1 trial, a fact that would have been useful in determining if an exclusive license was reasonably necessary, and perhaps more important, if the scope of rights granted were sufficiently limited.
43. KEI is concerned that the license may grant an excessive term of exclusivity, given the investments actually needed for FDA approval, and that the prices will not be consistent with the obligations in the Bayh-Dole Act for making the invention "available to the public on reasonable terms."
44. KEI is also concerned about the extensive patent thickets that are occurring in the CAR T area, and the huge costs of obtaining licenses from patent holders, and how those will impact the development of competitive treatments. Among the most critical patents that create barriers for the development of new treatments are inventions that were funded by the NIH.
45. It is increasingly expensive to acquire the rights to patents for CAR T therapies.
46. Gilead/Kite have already obtained significant patent rights from the NIH for the Yescarta CAR T therapy. Kite licensed patents from the NIH, and Gilead paid $11.9 billion in order to acquire Kite, in 2017.[5]
47. In 2018, Celgene acquired 90 percent of Juno Therapeutics for $9 billion,[6] a company with two unapproved candidates for CAR T treatments.

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[3] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm574058.htm

[4] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm581216.htm

[5] http://www.gilead.com/news/press-releases/2017/10/gilead-sciences-completes-acquisition-of-kite-pharma-inc

[6] https://www.bloomberg.com/news/articles/2018-01-22/celgene-to-buy-juno-for-9-billion-signaling-cancer-aspirations

48. The NIH proposed license to Gilead/Kite would give the company a monopoly over another set of inventions developed by the NIH for CAR T therapy. The consolidation of NIH-owned CAR T patents with Gilead raises concerns regarding competition for CAR T services that the NIH has failed to analyze.
49. Gilead has complex relationships with other companies that are potential competitors for CAR T therapies. For example, Gilead reported on its March 31, 2018 10-Q report to the Securities and Exchange Commission (SEC) that Gilead has entered into "a clinical trial collaboration with Pfizer, Inc. (Pfizer) to evaluate the safety and efficacy of the investigational combination of Yescarta and Pfizer's utomilumab, a fully humanized 4-1BB agonist monoclonal antibody, in patients with refractory large B-cell lymphoma."
50. Gilead is currently engaged in litigation with the Memorial Sloan Kettering Cancer Center and Celgene over patents that involve axicabtagene ciloleucel (Gilead trade name Yescarta). Those lawsuits may involve a settlement with Celgene, a potential competitor for the CAR T treatments for the cancers involved in the proposed NIH license to Gilead/Kite.[7]
51. The Centers for Medicaid and Medicare initial decisions on the reimbursement for the Gilead CAR T treatment Yescarta was $395,380 with a co-payment charge to patients of $79,076.
52. The high prices for Yescarta and Kymriah have been a significant barrier for patients seeking third party reimbursements.
53. In the experience of KEI, the NIH is not concerned about the prices of treatments based upon NIH licensed or funded patented inventions, taking the positions that any price satisfies the obligation to make inventions available on "reasonable terms." KEI is also of the opinion that the NIH routinely licenses patents for the full patent term, rather than a shorter period, as is required by 35 U.S.C. § 209, when the longer term is not reasonable and necessary to induce investments in the commercial development.
54. The NIH has acknowledged in email to KEI that it does not seek and obtain advice from the Antitrust Division of the U.S. Department of Justice (DOJ) when granting exclusive licenses, as is required by 40 U.S.C. § 559, and KEI is of the opinion that such a review is not only mandated by law but would be useful in that it would bring a more independent agency in to examine the impact of the transaction on monopolization of CAR T treatments.
55. KEI currently has a staff of seven full-time employees.

[7] March 31, 2018, SEC 10-Q Report.

56. Of those seven employees, our counsel is tasked with our litigation in this case, but more typically is tasked with a multifaceted primary role involving domestic and international legal and policy issues, liaising with other civil society, governmental, and intergovernmental organizations, and many other activities in furtherance of KEI's mission.
57. KEI has devoted well over 100 hours of its time on this case, from the initial comments through the current state of litigation, causing it to divert its limited resources to the detriment of the organization's mission, and away from various other mission-specific efforts towards which KEI might be directing its energy. Counsel, in particular, has been forced to dedicate a significant amount of his time to this litigation that has prevented him from assisting on his other KEI activities.
58. KEI maintains its "IP-Health" listserv of approximately 2400 subscribers, including many consumers and patients, on topics directly relevant to KEI's mission, and uses the listserv both to inform the subscribers of KEI's work as well as to receive feedback, suggestions and other information that help to guide KEI's work.
59. KEI receives funding from several U.S. based private foundations, and occasionally from intergovernmental organizations like UNITAID, as well as from other organizations and individuals. Our ability to obtain funding to advance KEI's mission depends in large measure on how well we represent patient interests in matters concerning intellectual property rights. Last year our third largest donor was the Kaiser Foundation Health Plan & Hospitals, a non-profit organization that is also the largest managed care organization in the United States, with 12.2 million members.
60. KEI is a member of the Transatlantic Consumer Dialogue (TACD), an organization created in September 1998 by 60 consumer groups in the United States and Europe. The TACD secretariat is provided by Consumers International. I am currently the U.S. co-chair of the TACD policy committee on intellectual property, elected by the U.S. members of TACD. There are currently 27 U.S. organizations in TACD, listed on this web page: http://tacd.org/about-tacd/member-list/. There are also 50 member organizations from Europe in TACD.
61. KEI is one of the six partner organizations for the Union for Affordable Cancer Treatment (UACT), listed on this web page: http://cancerunion.org/about/partners/. KEI is also a member of the Civil Society Coalition (CSC), and several other coalitions which are engaged in advocacy to make medical technologies more affordable.

62. KEI is in official relations with WHO, working in collaboration to expand access to and the affordability of cancer treatments.
63. KEI has permanent accreditation as an observer at the World Intellectual Property Organization (WIPO), and is an accredited observer at the World Trade Organization.
64. KEI has received accreditation to participate in a series of meetings and negotiations relating to the United Nations high-level meeting on the prevention and control of non-communicable diseases (NCDs). The prevention and control of NCDs includes treatments for cancer, and I have been asked to advise U.S. agencies and member states on issues relating to the pricing and affordability of drugs, vaccines and the new gene and cell treatments like CAR T. I was invited to present at a WHO dialogue on R&D financing for prevention and control of noncommunicable diseases on April 11, 2018, in Copenhagen, Denmark, and at a "WHO Meeting of the minds on personalised medicine and opportunities for the prevention and control of noncommunicable diseases," in Saint Petersburg, Russian Federation, on May 14, 2018. I am an invited expert on drug prices for a WHO-sponsored "Roundtable on noncommunicable diseases - strengthening the role and contribution of the private sector" held at Chatham House, London, United Kingdom, on June 26 and 27, 2018. KEI has special accreditation for a "civil society hearing" on July 5, 2018, at the UN Headquarters in New York. In all of the NCD meetings, I have been expected to represent the interests of the public as patients or persons who pay for health insurance.
65. KEI regularly convenes or co-convenes meetings and consultations on behalf of and together with its constituency, and also is regularly invited to meet with other groups to discuss the affordability of and access to federally funded medical inventions. These meetings include, for example, the May 23, 2018 side event on at the World Health Assembly on the WHO's Roadmap on Access to Medicines and Vaccines, organized with Knowledge Ecology International (KEI) and Stichting Health Action International (HAI), and the panel on government funded inventions at the June 27-29, 2018 Affordable Medicines Now Conference organized by the Treatment Action Group (TAG), Public Citizen, and the O'Neill Institute for National and Global Health Law at Georgetown University.

James Packard Love
Director, Knowledge Ecology International (KEI)
June 24, 2018