

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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**PLAINTIFF’S MEMORANDUM IN  
OPPOSITION TO DEFENDANTS’ MOTION TO DISMISS**

Plaintiff, Knowledge Ecology International (“KEI”), by and through its undersigned attorneys, hereby submits this 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 (“Mr. Lambertson” or collectively “NCI”, and, collectively with all of the above, “Defendants”); and, as reasons therefore, states:

**INTRODUCTION**

In January 2018, Defendants rejected Plaintiff’s substantive recommendations for public interest safeguards and declared that they would grant an exclusive license of critical CAR T cancer treatment technology to a large pharmaceutical corporation with a history of excessive pricing, including on one of

the only other two CAR T cancer treatments currently on the market. In February 2018, Defendants announced that they would proceed without providing Plaintiff the opportunity to set forth the arguments of why it merited an appeal under the statutes and regulations of the Bayh Dole Act.

Additionally, Defendants admitted to failing to abide by the black letter obligations of the Federal Property and Administrative Services Act with regard to seeking and obtaining antitrust advice from the Attorney General prior to disposing of federal property, including patents, to private interests.

As set forth in detail in the Complaint, both of these sets of actions constitute statutory and/or regulatory issues in their own right, in addition to being violations of relevant sections of the Administrative Procedure Act.

In response to KEI's Complaint attempting to call attention to their illegal actions, Defendants attempt to avoid these issues entirely by convincing the Court that KEI lacks standing to bring Defendants to task.

In so doing, Defendants erroneously insist that this Court is bound by a "functional equivalency" test that has yet to be accepted by the Fourth Circuit and that this Court must adhere to a rigid interpretation of the law of associational standing that the Supreme Court has never embraced and where other jurisdictions have shied away from such a formulaic approach. Furthermore, KEI can establish organizational standing because it has diverted a substantial amount of resources toward redressing the issues asserted in the Complaint, to the detriment of KEI's mission.

Contrary to Defendants' assertions, KEI's Complaint laid out a clear set of facts showing that it and the consumers, patients and taxpayers that it represents were injured by Defendants' unlawful acts; therefore, as discussed more fully *infra*, KEI's standing is sufficiently established and Defendants should be required to answer to this Court for their improper actions.

### ARGUMENT

All that a plaintiff must allege in order to establish standing is that it has: “(1) suffered an injury-in-fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Hutton v. Nat'l Bd. of Examiners in Optometry, Inc.*, No. 17-1506, 2018 WL 2927626, at \*4 (4th Cir. June 12, 2018) (quoting *Spokeo, Inc. v. Robins*, — U.S. —, 136 S.Ct. 1540, 1547, 194 L.Ed.2d 635 (2016)). This Court recently instructed that “[i]njury-in-fact is not Mount Everest.” *District of Columbia v. Trump*, 291 F.Supp.3d at 738 (quoting *Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286, 294 (3d Cir. 2005) (Alito, J.)).

“At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, [since] on a motion to dismiss [the court] presum[es] that general allegations embrace those specific facts that are necessary to support the claim.” *Lujan*, 504 U.S. at 561, 112 S.Ct. 2130 (citation and quotation marks omitted).

**I. KEI's Has Sufficient Indicia-of-Membership to Have Associational Standing Because Patients, Taxpayers, and Consumers Control KEI's Functions, Serve on KEI's Leadership, and Finance KEI's Activities.**

In support of their argument that Plaintiff lacks standing, Defendants rely in large part upon their assertion that KEI “apparently has no members;” however, as Defendants later acknowledge, the law is clear that associational standing is not limited to traditional membership organizations. (*Compare* Doc. No. 5-1, p.10 *with Hunt v. Washington Apple Advertising Comm’n*, 432 U.S. 333, 344 (1977).)

The proper test, as the Supreme Court stated in *Hunt* is whether the persons whose interests were affected “possessed all of the indicia of membership in an organization,” and the functions performed by the organization, which included engaging in “advertising, market research and analysis, public education campaigns, and scientific research” in support of the Washington apple industry. *Id.* at 334.

Following *Hunt*, courts have determined that organizations may have associational standing without members if the organization is the functional equivalent of a member organization. *Heap v. Carter*, 112 F.Supp.3d 402, 418-19 (E.D. Va. 2015) (citing *Washington Legal Found. V. Leavitt*, 477 F.Supp.2d 202, 208 (D.D.C. 2007) (adopting the ruling in *Hunt* as a rigid test: the organization “(1) serves a specialized segment of the community; (2) represents individuals that have all the indicia of membership, including (i) electing the entity’s leadership, (ii) serving in the entity, and (iii) financing the entity’s activities, and (3) its fortunes are tied closely to those of its constituency.”)

**A. KEI Meets the Functional Equivalency Test to Establish Associational standing.**

The record demonstrates that KEI is a well-respected nongovernmental organization: (i) with a long track record of working for a constituency of consumers, patients and taxpayers on issues relating to intellectual property and access to affordable medicines; (ii) that has leadership, including a Board of Directors, a Nobel prize-winning Board of Advisers, and staff, that are directly affected by such issues and who guide the work of KEI; and (iii) that receives feedback and guidance from its constituency via its IP-Health listserv and through regular meetings, and receives individual donations from its constituency.

Attempting to undermine these clear indicia of standing, Defendants assert rather flippantly that KEI “apparently often opines on the new costs of new medical technologies,” and that KEI lacks associational standing because it has not shown that the constituency that KEI “purports to ‘represent’ ... (i) elects KEI’s leadership (or even of what KEI’s leadership is comprised), (ii) serves activities and goings-on (whatever they may be), or (iii) finances KEI’s budget.” Defendants’ Memorandum in Support of Motion to Dismiss, p.11, 13. In fact, KEI meets this functional equivalency test for the reasons provided in the Complaint, and as further explained in the Declaration of James Packard Love (“Love Declaration”).

**i. KEI has a long history of representing patients and consumers on issues at the intersection of intellectual property and access to affordable medicines.**

As mentioned in the Complaint, KEI is an award-winning non-profit organization with a lengthy, well-established track record of public service on issues relating to intellectual property and public health. Complaint, ¶5. The organization

was founded by Director James Packard Love in 2006 upon a prestigious MacArthur Award for Creative & Effective Institutions, based largely upon Mr. Love's work at predecessor organizations the Consumer Project on Technology and the Taxpayer Assets Project. Love Declaration ¶13. At those organizations, Love did groundbreaking work in the field of access to medicines, including successfully negotiating a \$1/day price for a three-drug combination treatment for HIV/AIDS with the generic drug manufacturer Cipla in 2001 that is credited with making the medicines affordable for countries in Africa and other developing countries that were suffering through a horrendous crisis with the disease. Love Declaration, ¶19; *See also* Sarah Boseley, *Big Pharma's Worst Nightmare*, The Guardian, Jan. 26, 2016 (available at: <https://www.theguardian.com/society/2016/jan/26/big-pharmas-worst-nightmare>). Mr. Love is an internationally recognized expert in the field of access to medicines and intellectual property rights, and, through KEI or its predecessor organizations, has authored important materials for the World Health Organization ("WHO"), World Intellectual Property Organization ("WIPO"), UNITAID, and as an expert witness in compulsory licensing cases in South Africa and India. Love Declaration, ¶¶ 20-27.

As mentioned in the Complaint, under Mr. Love's direction KEI routinely works on issues pertaining to the licensing of federally-funded medical technologies. Complaint ¶5. Since 2015, Mr. Love and KEI have filed comments on over thirty proposed exclusive patent licenses, with most comments consistently focusing on "(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.” Love Declaration, ¶¶38-39.

Mr. Love and KEI have a specific and well-documented interest and expertise in issues regarding the expansion of access to affordable treatments for cancer and rare diseases. KEI is one of six partner organizations of the Union for Affordable Cancer Treatment, and is in official relations with the World Health Organization, working in collaboration to expand access to, and the affordability of, cancer treatments. *Id.* ¶¶61-62. Mr. Love has been asked to advise U.S. agencies and member states on issues relating to the pricing and affordability of drugs, vaccines, and new gene- and cell-based treatments such as the CAR T therapy at issue in this case, and has been invited to present at various WHO-sponsored meetings and roundtables on noncommunicable diseases (“NCDs”). *Id.* ¶64. KEI has special accreditation to participate in a series of meetings and negotiations relating to the United Nations High-Level Meetings on NCDs. *Id.* KEI is a member of the Transatlantic Consumer Dialogue (TACD), a coalition of sixty consumer groups in the United States and Europe, and Mr. Love is the elected U.S. co-chair of the TACD policy committee on intellectual property. *Id.*, ¶60.

In all meetings in these or other fora, KEI and Mr. Love are expected to represent the interests of the public as patients or persons who pay for health insurance. *Id.*

**ii. KEI's leadership and staff is directly affected by the underlying issues of the high prices of cancer medicines, and KEI's Board of Directors and Board of Advisers Guide the Work of KEI.**

The high price of cancer medicines directly affects KEI's staff, including both Mr. Love himself, who was treated for squamous cell carcinoma skin cancer, and Mr. Love's wife, Manon Ress, KEI's Director of Information Society Projects, who was diagnosed in 2010 with HER2+ breast cancer. Love Declaration, ¶¶ 29, 31. Ms. Ress is currently treated with an expensive, NIH-funded medicine sold by Roche as Kadcylla, for stage 4 HER2+ breast cancer patients. *Id.* Ms. Ress lost her mother to breast cancer in 2007, and has a sister who has been treated for breast cancer. *Id.* ¶ 30. Mr. Love has additionally lost a father to cancer, and has several other family members that currently have cancer, including his mother and two brothers. *Id.* ¶32. One brother "has been diagnosed and treated for diffuse large B cell lymphoma (DLBCL), one of the indications in the proposed license [by Defendants] to Gilead" of the CAR-T patents. *Id.*

In lieu of members, KEI has a Board of Directors, which manages the affairs of KEI as provided in Article 3 of the Bylaws, and a Board of Advisors that guide the direction of KEI's work. *Id.* ¶¶3-6. The Board of Directors currently consists of academics, established public advocates and attorneys, patients, consumers, and activists on issues regarding access to affordable medicines. *Id.* The Board of Directors elects the executive director of KEI and other officers at each annual meeting, per Article 5 of the Bylaws. *Id.*



The Board of Advisors consists of Joseph Stiglitz and Amartya Sen, two economists who have received the Nobel Memorial Prize in Economic Sciences, and, until his recent death, Sir John Sulston, who was awarded the The Nobel Prize in Physiology or Medicine in 2002. *Id.* ¶6.

**iii. KEI is further guided by its constituency via the subscribers to its IP-Health listserv, via regular meetings, and via individual donations from consumers and patients.**

The IP-Health listserv mentioned in the Complaint (¶5) with approximately 2400 subscribers consists of patients and consumers, as well as governmental and intergovernmental officials, journalists, advocates and activists and other members of civil society, and the list serves a two-way function — both providing a means for KEI to disseminate information broadly, as well as a means for others outside of KEI to inform KEI’s work. Love Declaration, ¶ 58. KEI also regularly convenes meetings and consultations on behalf of and together with its constituency, and is also regularly invited to meet with other groups to discuss the affordability of and access to federally funded medical inventions. *Id.* ¶65.

Furthermore, KEI is transparent with regard to its funding, which includes grants and research contracts from reputable foundations such as the Open Society Foundation and other organizations such as UNITAID, but also includes individual contributions from consumers and patients affected by the high prices of medical technologies. *Id.*, ¶ 59 (“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.”); *See also*

<https://www.keionline.org/about/who-funds-kei>. “If those constituents are dissatisfied with the direction the organization is taking, or with its advocacy efforts, they may then ‘vote with their pocketbooks’ and cease financial support for the organization.” *Citizens Coal Council* at 640. KEI is additionally funded by 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. Love Declaration, ¶59.

KEI has set forth clear facts establishing that Defendants flagrantly violated a variety of statutes and regulations and harmed KEI in ex-ante denying KEI the right of appeal before even permitting KEI to assert why it would merit the appeal, and in admitting to ignoring the black letter obligations of 40 U.S.C. § 559. These acts not only harmed KEI directly but also harmed and were an affront to the interests of consumers and patients and taxpayers in government accountability, and in lower prices for important cancer treatments — especially those funded by taxpayer dollars. KEI has established that it merits associational standing for all of the reasons described above, and this case should proceed.

**B. The Functional Equivalency Test Should Not Be Rigidly Applied.**

As this case appears to be the first time that the question of the functional equivalency doctrine has arisen in the District of Maryland, and the Court is not bound by the *Heap* decision, it is worth considering that the indicia-of-membership test is not a good fit for many non-member public interest organizations with non-voting constituencies. As Professor Coplan states:

Many public interest environmental organizations are organized as non-membership organizations, or other organizational forms in which the organization's constituency does not vote to select the board of directors or officers of the organization.<sup>1</sup> Typically, these organizations have a "self-perpetuating board of directors, in which the sitting board of directors elects both officers and new board members of the organization."<sup>2</sup> For these organizations, the question of whether membership voting rights are an essential element of representational standing assumes great importance. A few decisions, with varying results and rationales, have addressed the question of whether voting rights are essential to organizational standing.<sup>3</sup>

Karl Coplan, *Is Voting Necessary? Organizational Standing and Non-Voting Members of Environmental Advocacy Organizations*, 14 *Se. Envtl. L. J.* 47, 49 (2005). The article concludes "that voting rights should not be essential to the assertion of representational standing." *Id.*

As Prof. Coplan explains, there are many reasons why nongovernmental organizations would not be structured as traditional membership organizations, as is the case with Plaintiff. These reasons Coplan cites include, for example: added administrative burden; and the potential for "hostile takeover organized by institutions opposed to an organization's advocacy purpose," such as the 2004 proxy battle for control of the Sierra Club (noting that certain "advocacy organizations may be particularly vulnerable given the nature of the issues they take on and the finances available to the institutions they oppose."). *Coplan* at 56-57. Coplan quotes

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<sup>1</sup> See Charles H. Steen & Michael B. Hopkins, *Corporate Governance Meets the Constitution: A Case Study of Nonprofit Membership Corporations and Their Associational Standing Under Article III*, 17 *Rev. Litig.* 209, 211 (1998).

<sup>2</sup> See Robin Dimieri & Stephen Weiner, *The Public Interest and Governing Boards of Nonprofit Health Care Institutions*, 34 *Vand. L. Rev.* 1029, 1043 (1981) (discussing nonprofit corporation statutes).

<sup>3</sup> See Steen & Hopkins, *supra* note 2, at 221-51.

the ABA Section of Business Law, Nonprofit Governance and Management, 337-54 (V. Futter, ed. 2002):

For most nonprofits serving humanity, the current thinking is to cast as wide a net as possible to further the cause and to communicate electronically with members and nonmembers alike. Supporting a membership, however, is expensive. Cutting-edge nonprofits, particularly mission-driven organizations, will rethink the value of membership to gain the competitive advantage of serving society.

*Id.*

Thus, rigidly applying the functional equivalency doctrine oversimplifies a complex landscape of public interest organizations and does a disservice to many non-member NGOs that do vital work in the public service, but do not meet the requirements of the test to the t for one reason or another. It is important to note that *Hunt* is not clear as to whether that functional equivalency test was meant to be understood as the minimum requirement. *See* Coplan at p.55 (“[I]n *Hunt* and its progeny, the Supreme Court recognized representational standing for an organization without formal members as long as the traditional indicia of membership were present, but failed to spell out what the irreducible minimum of such indicia were... [and] which of these factors were the bare minimum necessary conditions to representative capacity.”).

There are, as Defendants noted, a variety of cases in various jurisdictions that suggest that the functional equivalency test requires some flexibility in analysis. “These cases illustrate that in this area, the decisions are fact specific, a definitive formal test has yet to be delineated, and most courts have heeded the warning in *Hunt* not to elevate form over substance.” *Citizens Coal Council v. Matt*

*Canestrone Contracting*, 40 F. Supp.3d 632, 638 (W.D. Pa. 2014) (denying motion to dismiss where associational standing granted and absence of voting rights found not dispositive). These include, for example: “P&A” cases such as *Oregon Advocacy Center v. Mink*, involving Protection and Advocacy Organizations charged with working on behalf of individuals with disabilities, wherein the Court found that mentally disabled constituents had sufficient indicia of membership even though the constituents did not alone choose leadership, and did not alone serve on the board, but where the organization sufficiently identified with and was subject to the influence of those it seeks to represent as to have a “personal stake in the outcome of the controversy.” 322 F.3d 1101 (9th Cir. 2003) (quoting *Baker v. Carr*, 369 U.S. 186, 204, 82 S.Ct. 691 (1962)); *See also* Kelsey McCowan Heilman, *The Rights of Others: Protection and Advocacy Organizations’ Associational Standing to Sue*, 157 U. Pa. L. Rev. 237 (2008). Other notable cases lend support to a flexible approach, such as *Friends of the Earth v. Chevron Chemical*, 129 F.3d 826 (5th Cir. 1997), where the Court rejected a formulaic approach to the indicia of membership test, and *U.S. Public Interest Research Group v. Bayou Steel*, Civ. A. No. 96–0432, slip op. at 5 (E.D.La. Sept. 15, 1997), wherein USPIRG was granted standing without members and without granting contributors voting rights.

**II. Plaintiff has Organizational Standing Because Defendant’s Acts Force KEI to Divert Significant Resources To the Frustration of its Mission**

Separate and apart from the fact that Defendants’ claims that Plaintiff lacks associational standing are contradicted by a fair application of the functional

equivalency test and the reasons described *supra*, Plaintiff's organizational standing is established by the substantial diversion of its limited resources toward redressing Defendants' actions, to the detriment of KEI's mission.

The Supreme Court has held that organizational standing may be found where the alleged wrong has caused the organization to "devote significant resources to identify and counteract" the wrong and frustrated the mission of the organization. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379, 102 S.Ct. 1114, 71 L.Ed.2d 214 (1982). The Court in that case held that the allegations made by a non-profit organization called Housing Opportunities Made Equal ("HOME") were sufficient to survive a motion to dismiss where the organization alleged that the defendants' racial steering practices caused HOME to divert significant resources and thereby frustrate its mission of assisting equal access to housing through counseling and other referral services. *Id.* "Such concrete and demonstrable injury to the organization's activities—with the consequent drain on the organization's resources—constitutes far more than simply a setback to the organization's abstract social interests." *Id.*

In *Equal Rights Center v. Equity Residential*, this Court similarly held that "an organization suffers an injury-in-fact sufficient to satisfy the first prong of the Article III standing analysis where the organization incurs expenditures in identifying and counteracting [the alleged harm] and those expenditures perceptibly impair the organization's ability to advance its mission." 798 F.Supp.2d 707, 720 (D. Md. 2011). As with the organization in *Havens Realty*, the Equal Rights Center

(“ERC”) was a nonprofit organization dedicated to fair housing practices through education, research, training, counseling, enforcement and advocacy. *Id.* at 712. ERC had alleged that Equity Residential, a housing company, had repeatedly violated the Fair Housing Act; relevant to the organizational standing question, the Court noted that Equity Residential’s acts had caused ERC to divert resources away from its mission, and that the lawsuit itself constituted a diversion of resources. *Id.* at 715.

As with *Havens Realty* and *Equal Rights Center*, KEI has diverted a substantial amount of its resources toward redressing the issues asserted in the Complaint, to the detriment of KEI’s mission as stated in the organization’s Articles of Incorporation:

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.

Love Declaration, ¶ 2. KEI is a small but effective nonprofit organization, with a staff of seven persons. *Id.*, ¶ 55. One of the seven is counsel, whose primary role is outside of litigation on a variety of time-intensive domestic and international policy and legal and regulatory issues on topics hewing to the issues described in the KEI Articles of Incorporation. *Id.*, ¶56. KEI has spent over 100 hours of time on the

underlying issues and related research and drafting for this litigation, beginning with the original comments submitted to Defendants up through this memorandum, and – but for the personal experiences of outside counsel that resulted in his willingness to accept this case without immediate remuneration – already would have incurred tens of thousands of additional dollars in expenses that would take away from its ability to fulfill its mission. *Id.*, ¶57. That time and eventual expenditure could have been used toward KEI’s mission of meaningfully educating the public and other constituencies, and of contributing to policy discourse and debate, on the issues described in the Articles of Incorporation. *Id.*

For these reasons, KEI should be deemed to have organizational standing.

### CONCLUSION

Plaintiff respectfully requests that Defendant’s Motion to Dismiss be DENIED.

\_\_\_\_\_/s/\_\_\_\_\_  
Andrew S. Goldman (Fed. Bar No. 18910)  
Knowledge Ecology International  
1621 Connecticut Ave NW, Suite 500  
Washington, D.C. 20009  
(202)332-2670  
[andrew.goldman@keionline.org](mailto:andrew.goldman@keionline.org)

\_\_\_\_\_/s/\_\_\_\_\_  
Daniel P. Doty (Fed. Bar No. 28247)  
The Law Office of Daniel P. Doty, P.A.  
5500 Harford Road, Suite 202  
Baltimore, MD 21214  
410-615- 0902



[ddoty@dotylawoffice.com](mailto:ddoty@dotylawoffice.com)

*Attorneys for Plaintiff*

DATED: June 25, 2018