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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Supplemental Declaration of James Packard Love

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

1. I have submitted a previous declaration on June 25, 2018, which provides background on my role at Knowledge Ecology International (KEI) and my qualifications.

2. I submit this declaration in order to respond to certain comments provided in the January 8, 2019 declaration by Mark L. Rohrbaugh, on behalf of the National Institutes of Health (NIH).

3. In paragraphs 4 and 5 of his declaration, Mr. Rohrbaugh notes that KEI has "submitted written objections or comments to at least thirty-four of fifty-one proposed licenses" noticed by the NIH since 2016. To provide more context, KEI has frequently joined in comments that involve several parties that share concerns over NIH licensing practices. Since 2016, the KEI comments have included joint submissions that involved one or more of following parties:

- Health Action International (HAI),
- Health GAP,
- The Interfaith Center on Corporate Responsibility (ICCR),
- Médecins Sans Frontières (MSF), also known as Doctors Without Borders,
- People of Faith for Access to Medicines (PFAM),
- Public Citizen,

- Social Security Works,
- T1 International,
- Union for Affordable Cancer Treatment (UACT),
- Universities Allied for Essential Medicines (UAEM),
- Professor Brook K. Baker, Northeastern University School of Law, and
- Dean Baker, senior economist at the Center for Economic and Policy Research.

4. Most of the comments referred to by Mr. Rohrbaugh in paragraph 5 of his declaration are publicly available at this URL: https://www.keionline.org/nih-licenses.

5. In paragraph 6 of his declaration, Mr. Rohrbaugh describes "most of KEI's objections" as requests for "price controls," and he claims that it is "not within the mission of the NIH to control drug prices" because "to do so would result in fewer partnerships with companies and fewer therapies developed to serve the public health." Mr. Rohrbaugh describes our comments as "a demand" and complains that we are "taxing NIH resources to respond to questions that have already been repeatedly asked and answered."

6. It was misleading for Mr. Rohrbaugh to describe KEI's nuanced comments simply as a "demand" for price controls, and was also misleading to imply that KEI is requesting the NIH to undertake actions that are outside of its mission. It is true that KEI and the ten other groups and two individuals that have filed comments in the past have raised concerns regarding the pricing of the NIH licensed technologies, but what Mr. Rohrbaugh does not explain is the nature of the requests in these comments, nor does he provide important context.

7. The requests by KEI and other groups and individuals have relied upon 35 USC § 200, the Policy and Objective of the Bayh-Dole Act, which directs funding agencies to " protect the public against. . . unreasonable use of inventions," and 35 USC § 201(f), which provides a rarely enforced obligation on funding agencies and patent holders to ensure that the benefits of licensed inventions are "available to the public on reasonable terms," as a statutory requirement for achieving "practical application" of the inventions. The Bayh-Dole Act makes access and reasonable terms conditions of licensing the patented inventions, and these are not something the current leadership of the NIH can neglect simply because they favor licensing practices that ignore both.

8. The most common request that KEI and others have made to the NIH is that US residents not face prices higher than the license holder charges in foreign countries with high per-capita incomes and large economies. This is a request that the patent holder not discriminate against US residents, and not a requirement for a specific price. In 2017 the US Department of Defense was directed by a US Senate Committee to implement such a requirement for biomedical research that it funds.

9. In some comments, KEI and others have asked the NIH to consider other licensing conditions, such as the condition that prices not exceed the value of a product by an independent health assessment, or that the prices not constitute a barrier to access. These have been examples of safeguards that would address the obligation to ensure that the benefits of the inventions are available to the public on reasonable terms.

10. In addition to asking the NIH to consider provisions that concern the pricing of products or services like the chimeric antigen receptor T-cell (CAR T) technologies, KEI has asked the NIH to limit the number of years for the exclusivity granted in the licenses. KEI has recognized that exclusive licenses will be necessary in some cases to induce investments in R&D, but question the policy of the NIH to automatically grant life of patent licenses, as opposed to a shorter term. The request by KEI and others to limit the number of years of exclusive rights is not a novel issue. In the past, the NIH has limited the number of years of exclusivity, when a shorter period was sufficient. One such case involved ddI, a drug for the treatment of HIV.

11. The NIH experience with ddI is described in a September 2003 publication found on the NIH website titled, "Videx® Expanding Possibilities: A Case Study," which can be accessed here:
https://www.ott.nih.gov/sites/default/files/documents/pdfs/VidexCS.pdf.

According to the NIH:

> The technology transfer challenge was to negotiate a license that would provide a strong incentive for a drug company to make the significant investment necessary for the rapid development of a new drug while ensuring the long-term public health benefits. This balance was struck by offering a license that was initially exclusive, but which could became non-exclusive early, prior to the expiration of the NIH patents. . . .

> NIH exercised its prerogative to have the license become nonexclusive in October 2001."

12. The approach in the ddI license was consistent with the requirements in 35 USC § 209(a)(2) for funding agencies to limit scope of rights in exclusive licenses, specifically so "that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public."

13. In the present case, involving a license of CAR T technologies to Gilead, KEI was aware that, like the ddI case, the NIH had already funded much of the development work on the therapy. In fact, the NIH had initiated a trial with more than 70 patients for the licensed technology in 2017. KEI had asked the NIH for the budget of the trial, in order to evaluate the investments necessary to complete the development process, noting that the first two CAR T therapies approved by the US FDA had relied upon evidence from 63 and 100 patients, respectively. The NIH refused to provide information about the cost of the trial it was conducting and fully funding.

14. KEI also objected to the timing of the exclusive license, coming before the NIH had obtained any public results from the trial it was conducting. In our view, the NIH would have far more leverage in setting the terms of the license, including the number of years of exclusive rights, if the conducted and funded trial had a positive result. This was not a request for "price controls," but rather a request to comply with the restrictions on exclusive rights that are central to the Bayh-Dole right provisions set out in 35 USC § 209 on "Licensing federally owned inventions."

15. One possible mechanism proposed by KEI in the Gilead CAR T licensing case was to reduce the term of exclusivity if Gilead's revenues from the therapy exceeded certain benchmarks. Alternatively, the NIH could follow the approach taken in the ddI case, and provide an option to make the license non-exclusive, after a certain number of years. (KEI has asked the NIH for information about its practices as regards the number of years that licenses are exclusive; but, NIH has been non-responsive to KEI's requests, including an October 17, 2018 request under the Freedom of Information Act.)

16. The issue of the term of the license is important for several reasons. Even if the NIH does not want to interfere with the pricing of a product or a service like CAR T, it can satisfy the requirements of 35 USC § 209(a)(2) by limiting the number of years the license is exclusive.

17. In addition to requests that the NIH address concerns about pricing practices, including the discrimination against U.S. residents for NIH funded technologies, KEI and other parties have raised other issues, often specific to the particular technology being licensed, and its stage of maturity in development. One such area of concern are the provisions in the license relating to access to inventions in developing countries. Indeed, among the groups that have joined in various comments on NIH licenses, Health Action International (HAI), Health Gap, the Interfaith Center on Corporate Responsibility (ICCR), Médecins Sans Frontières (MSF), People of Faith for Access to Medicines (PFAM), Public Citizen, T1 International, the Union for Affordable Cancer Treatment (UACT) and Universities Allied for Essential Medicines (UAEM) have all been concerned about NIH licensing practices in developing countries.

18. In the Gilead CAR T license, KEI asked the NIH to protect patients in countries with per capita incomes that are less than one third of U.S. per capita income. KEI:

> (a) noted the NIH has filed an application in the WIPO PCT to protect the invention in 199 countries, including most countries in Sub-Saharan Africa, and many countries classified by the United Nations as a least developed country; and,
>
> (b) asked that the NIH exclude from the exclusive license any country with a per capita income that is less than one third the per capita income of the United States, or include requirements that products in such countries be affordable.

19. The NIH cannot argue that access to treatments in developing countries is outside its mission. The "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy", states the following:

> "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

The NIH has cited this policy to KEI in replies to our requests, but in many licensing cases we have reviewed, the NIH has ignored the policy objective set out in the PHS manual, and enters into licenses that are excessively broad in regard to the geographic area of exclusivity and provides no conditions on affordability in developing countries. This is relevant in the present case, where the first two CAR T treatments approved by the FDA, one by Novartis and one by Gilead, are for now only being made available in high income countries, and at prices that few can afford.

20. KEI has also frequently asked the NIH to include various requirements for transparency in licenses, in regard to the pricing and access, as well as for the private sector outlays for research and development expenses related to the licensed technology.

21. In the present dispute, the comments on the Gilead CAR T license addressed several issues, including the following:

a. It is premature to grant an exclusive license to Gilead, given the fact that the NIH is currently conducting and funding a large Phase 1 trial.

b. If the NIH grants an exclusive license to Gilead, it should include clear safeguards in the license to protect US residents from excessive prices and access barriers. Among the suggested provisions were:

    1. The company should not discriminate against US residents by charging higher prices in the US than in other high income countries with large economies.
    2. The price should not constitute an unreasonable barrier to access in the US.
    3. The price should not be higher than CAR T treatments of similar efficacy, taking into account differences in patient populations, if the cumulative revenue per indication is less than $300 million.
    4. The price should not increase faster than the rate of inflation as measured by the consumer price index, unless the increase can be justified by a need to earn a reasonable profit on the risk-adjusted investments in research and development.
    5. When the cumulative global revenue for the product exceeds a particular benchmark, the monopoly should end.

c. If a license is granted to Gilead, the NIH should protect patients in countries with per capita incomes that are less than one third of US per capita income, by either limiting the exclusive rights to countries that have at least one third US per capita income (as measured by the World Bank Atlas method GNI per capita), or by including requirements that treatments in such countries be affordable.

The NIH was also asked to include in its license to Gilead provisions that would require transparency with regards to R&D outlays, and specifically, require the disclosure to the public of the actual R&D costs for the commercializing licensed inventions, along with all public sector R&D subsidies, such as the federal R&D and orphan drug tax credits.

22. It is true that KEI and other parties have often repeated some proposals for terms in licenses, such as the request that companies not price discriminate against US residents. However, the comments on every license have differed from earlier comments, either by addressing the unique context of a specific proposed license, by raising different issues, or by proposing different approaches to public interest safeguards. If the NIH sees the comments as "taxing NIH resources to respond to questions that have already been repeatedly asked and answered," that says to me that they are not reading the actual comments, and in effect are suggesting that anything proposed by KEI has been answered before KEI even offers the comment or before the NIH receives and dismisses the comment.

23. One can appreciate how the NIH would reject any one of the specific suggestions that KEI and others have offered on various licenses. However, it is astonishing if every single comment is rejected in every licensing case, and that the NIH does not see the statutes that limit the use of exclusive licenses or even the PHS's own licensing manual as having more operational impact on its licensing decisions.

24. In paragraph 10 of his declaration, Mr. Rohrbaugh states "Providing appeals to every commenter to a Federal Register notice would require a substantial diversion of high-level agency resources." This is highly speculative. KEI has only appealed one licensing decision, and KEI would not be in court if the NIH had not rejected the administrative appeal before it was even received by the NIH.

25. Finally, it is important to emphasize that KEI is very supportive of the NIH mission, and is impressed with the skill and dedication of the NIH staff, including the NIH senior management. One can appreciate the importance of the NIH mission regarding advancing biomedical science, and still ask the NIH to comply with statutes that require inventions be made "available to the public on reasonable terms" as required by 35 USC § 201(f), and to insist that exclusive rights for federally-owned inventions be limited to cases where exclusive rights are both reasonably necessary and that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application" as are required by 35 USC § 209(a).

Dated: February 6, 2019

James Packard Love
Director, Knowledge Ecology International (KEI)