28 August 2023

Richard T. Girards, Jr., Esq., MBA
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National Institutes of Health
NCI Technology Transfer Center
Via: richard.girards@nih.gov

Re: Prospective Grant of an Exclusive Patent License: Manufacture, Distribution, Sale and Use of T-Cell-Based Immunotherapies for Solid Tumors to a company named EnZeta Immunotherapies for which there is no public information, noticed in 88 FR 54629

Dear Richard Girards,

KEI objects to the grant of an exclusive license to the company EnZeta Immunotherapies about which there is no public information. Our comments today are in reference to the notice published in the Federal Register on August 11, 2023, 88 FR 54629.

1. **The NIH lack of transparency regarding the company or licensing terms**

On August 11, 2023, KEI emailed you with a list of questions about the proposed license and the company. A copy of that letter is available here: https://www.keionline.org/38976.

On August 17, 2023, you replied to our request for information, helpfully telling KEI that the technology was "early stage" and that the NIH is not aware of any federal funding of clinical trials. But the NIH refused to answer any questions about the terms of the license or the company itself, which has no web page, SEC filings or mentions in Google searches.

Our primary objection to the grant of the exclusive license regards the appalling secrecy surrounding the company and the licensing terms. The NIH is required to permit the public to comment on any proposed exclusive license, but makes this a sham procedure when the public has no information about the company and almost no information, outside of the field of use, on the proposed licensing terms.

2. **The Section 209 restrictions on the scope of rights**

Of course, we have no information on the terms of the license other than the field and geographic area of use. While NIH refuses to disclose the duration of the exclusive rights, from other conversations with Mark Rohrbaugh, it seems likely the NIH is offering a life of patent license, and royalties apparently are typically around 4 percent of less, and the response to our questions suggests the NIH is maintaining its investor friendly policy of allowing the licensee to price products at whatever the market will bear, even if those prices are far higher in the USA than in any other high income country. I'm guessing that the NIH will impose no obligations to make the benefits of the inventions available to the public on reasonable terms, or to ensure

that inventions are “broad accessibility for developing countries” in accordance with the PHS Licensing Policy, as set out in Chapter 300 (12/02/2010 version).

What then is the NIH doing to satisfy the requirement in 35 USC 209 to ensure that the “scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application . . . or otherwise to promote the invention’s utilization by the public”?

In the past, NIH owned inventions on AIDS drugs like DDI, licensed to BMS, or DDC, licensed to Hoffman La Roche, limited the number of years of exclusivity, because life of patent licenses were not necessary.

Unless the NIH comes up with some limit on the scope of exclusive rights, other than the field of use, the agency is acting contrary to the plain language of the statute, and for this reason, we oppose the license.

The NIH can satisfy the restrictions on the scope of exclusive rights in different ways, by limiting the prices charged to US residents, by limiting the years of exclusivity or tying the duration of exclusivity to revenue milestones, to mention three approaches that KEI has endorsed in the past and endorses for this license.

**3. Global access**

The August 17 letter from the NIH responded to our serious and morally significant questions about access in developing countries with an insulting reply.

KEI’s question 5 was:

> “The geographic scope of the proposed license is worldwide. What evidence do you have that EnZeta will be inclined or have the capacity to make the inventions available worldwide, including in developing countries? In particular, will the NIH include working and affordability conditions to give effect to the objective of “broad accessibility for developing countries,” a goal expressed in the United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy?”

The NIH response was:

> “Turning to KEI’s query 5, we have received confirmation that the proposed licensee intends - depending of course on the outcome on high-risk clinical trials, certain of which may implicate special local regulatory and/or other circumstances - to make one or more licensed inventions available both in the U.S. and exU.S. The remainder of your query 5 either calls for or inextricably implicates business confidential information that NIH is legally precluded from divulging.”

Does the NIH really think that “to make one or more licensed inventions available both in the U.S. and exU.S” say anything about “broad accessibility for developing countries”? More generally, does anyone in the federal government or the Congress for that matter, ever bother to audit the NIH to see how its licensing policy promotes or undermines “broad accessibility for developing countries”? Most of the world’s humanity live in developing countries. When the US government routinely agrees to trade agreements and UN resolutions to promote “access to medicine for all,” the NIH has an obligation to address this.

4. **Transparency more generally, including implementation of WHA72.8**

The NIH leadership has yet to take measures to implement the norms the US agreed to at the World Health Assembly on “Improving the transparency of markets for medicines, vaccines, and other health products,” set out in the 2019 resolution WHA72.8. The US government, under President Trump, actively supported this norm. Among the norms are those in Paragraphs 1(1), 1(2) and 1(3), which read:

> 1. URGES Member States in accordance with their national and regional legal frameworks and contexts:
> (1) to take appropriate measures to publicly share information on the net prices2 of health products;
> (2) to take the necessary steps, as appropriate, to support dissemination and enhanced availability of, and access to, aggregated results data and, if already publicly available or voluntarily provided, costs from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval, while ensuring patient confidentiality;
> (3) to work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;

In the past, the NIH has cited 35 US 209(d)(2) and 209(f) as justification for the secrecy of the utilization and utilization efforts by licensees. To the extent the statute is a barrier to greater transparency, the leadership of the NIH should inform the Congress and propose appropriate amendments to Section 209.

Sincerely

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