August 11, 2023

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

Dear Richard Girards,

These questions are in regard to the prospective license to EnZeta Immunotherapies, published August 11, 2023, 88 FR 54629.

1. Can you tell us how this relates to a similar Federal Register Notice published April 6, 2023, 88 FR 20544, regarding a company also named EnZeta, also for T-cell-based immunotherapies for solid tumors. We notice there is some overlap in the description of the intellectual property (see below). Is it the case that the NIH is no longer negotiating the earlier prospective license, or is expanding that license? In any case, why is the NIH now offering to what we assume is essentially the same company a different bundle of patent rights in an exclusive license? Was it really necessary to include more patents in the exclusive license than were proposed in April?

2. We cannot locate a web page for EnZeta and the company does not appear to have any SEC filings and a Google search of the term “EnZeta” turns up nothing connected to the company but the two Federal Register notices. A search of the Delaware Division of Corporations records notes that EnZeta, Inc. was incorporated May 13, 2022, having the registered agent "Business Filings Incorporated," and EnZeta Immunotherapies, Inc. was incorporated July 31, 2023, having the registered agent "Resident Agent." Has there been a change in ownership for the new entity?

3. What are you willing to tell us about the company, regarding its ownership or management or operations? For example:

a. Who is on the Board of Directors?
b. Who are the CEO or CFO or chief medical officers?
c. Does the company have a US address other than the registered agent in Delaware?
d. Are any of the owners, board members, or key employees former employees of the NIH?
e. Who are persons or entities that own more than 5 percent of the company?
f. Is there significant foreign ownership in EnZeta?

4. Will this company be treated as a start-up company by the NIH, eligible for a 1.5 percent royalty on the license?

5. 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?

6. Has EnZeta had discussions with the NIH regarding a waiver of US manufacturing requirements in 35 USC § 204?

7. What is the stage of development of the technology?

8. Has any US government agency funded or offered to fund any clinical trials related to this license?

9. Will the US government require that the prices for products using the licensed patents be available to the US public at prices no higher than a reference price for a set of other high-income countries with large economies? If not, why not?

10. Is the license term the same or shorter than the life of the patents, and if the same as the life of the patents, how has the NIH determined that a life of patent license term is "necessary reasonably necessary to provide the incentive for bringing the invention to practical application," a restriction in 35 USC § 209(a)(2), as compared to an exclusivity term-limited in time, such has been used in for past for licenses on NIH-owned patents, such as the ddI patent license?

11. What are the expected costs of the clinical trials needed to provide the FDA with sufficient evidence of the safety and efficacy of the therapy? If you don't have an exact number, what is the range of costs you have used in doing the Section 209 analysis regarding the "proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application"?

James Love
Knowledge Ecology International

ANNEX

August 11, 2023 Intellectual Property

E–010–2021: Enhanced Antigen Reactivity of Immune Cells Expressing a Mutant Non-Signaling CD3 Zeta Chain

1. United States Provisional Patent Application No. 63/113,428, filed 13 November 2020 (HHS Reference No. E–010–2021–0–US–01);

2. International Patent Application No. PCT/US2021/059109, filed 12 November 2021 (HHS Reference No. E–010–2021–0–PCT–02);

3. United States Patent Application No. 18/036,112, filed 09 May 2023 (HHS Reference No. E–010–2021–0–US–02);

4. European Patent Application No. 21824143.8, filed 30 March 2023 (HHS Reference No. E–010–2021–0–EP–01); and

5. any and all other U.S. and ex-U.S. patents and patent applications claiming priority to any one of the foregoing, now or in the future

April 6, 2023 Intellectual Property

Intellectual Property E–010–2021: Enhanced Antigen Reactivity of Immune Cells Expressing a Mutant Non–Signaling CD3 Zeta Chain

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2. International Patent Application No. PCT/US2021/059109, filed 12 November 2021 (HHS Reference No. E–010–2021–0–PCT–02); and

3. any and all other U.S. and ex-U.S. patents and patent applications claiming priority to any one of the foregoing, now or in the future.