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To: Sury Vepa, Ph.D., J.D. Senior Licensing and Patenting Manager Office of Strategic Alliances Via: sury.vepa@nih.gov

## RE: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Metarrestin and Its Analogs for the Treatment of Metastatic Cancers (88 FR 18324)

Knowledge Ecology International (KEI) submits the following comments on the Prospective Grant of an Exclusive Patent License: Development and Commercialization of Metarrestin and Its Analogs for the Treatment of Metastatic Cancers (<u>88 FR 18324</u>). The technology is to be licensed to Oncala Bio Inc. in Bend, OR, a company which returns no results in a Google search, save links to this Federal Register notice. A search of the Oregon Business Registry for "Oncala Bio" or "Oncala" yields no results, as does a search of US SEC company filings.

As KEI has noted in regards to other prospective exclusive licenses to companies with a dearth of public information, the Federal Register notice is intended to solicit public comment on the prospective license, and yet in instances such as this the public has no information on the company set to receive the license. How is the public supposed to offer comments on the capacity of a company to bring a technology to market, assess its interest in this technology, or other matters with a staggering lack of transparency?

While KEI is denied the ability to comment on Oncala Bio as a licensee and steward of publicly developed technologies through the lack of transparency of the Federal Register notice, KEI would ask the NIH to include in its license with Oncala Bio the following:

- A requirement in the license that prices for products using the license not exceed the median prices charged in the seven countries with the largest GDP and at least 50 percent of US per capita income. In this regard, we note that the U.S. government negotiated international reference pricing agreements with both Merck and Pfizer for COVID-19 therapeutics.
- A limit in the geographic scope of the exclusive nature of the license to countries with at least 30 percent of US per capita income.
- Terms in the license which abide by the transparency norms in resolution WHA72.8, which were supported by the US government, including by requiring in the license every transparency element referred to in the resolution.