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

Re: Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer, to Paz Pharmaceuticals, LLC

Date: July 7, 2020

Dear Richard Girards,

I read with interest the Federal Register notice, 85 FR 37464, regarding a proposed exclusive license to Paz Pharmaceuticals, LLC. I was unable to find a web site for the company. Some searches using Google.Com or Bing.Com suggest the company's offices are 3003 34th St NW Washington, DC 20008, which is a residence, where Irving W. Wainer has been registered to vote. A LinkedIn entry identifies Irving Wainer as a Senior Researcher at the National Institutes of Health, at the National Institute on Aging, although, I'm not sure this is current. Is it? In any event, Wainer is also the lead inventor for the US granted patents in the proposed license, including:

- 8,703,826,
- 9,522,871
- 9,908,841
- 10,308,591, and
- 10,562,843.

I have not checked the several patent applications, but I am assuming that Wainer is also among the inventors.

Basically, Irving W. Wainer is the lead inventor for the licensed inventions, and did so while working as an employee of the NIH. Wainer appears to be the principal in Paz Pharma, and is in the process of setting up a company that still has no public web site (we assume this is not the company: https://www.paz-pharma.com/) or other visible presence, and despite its lack of a track record as a company, is seeking exclusive worldwide rights to the inventions for:

> "The development, manufacture, distribution, sale and use for the treatment of cancer of one or more of fenoterol and its analogues, either in combination or not in combination with one or more other therapeutic agents."

(PAZ Pharmaceuticals appears to be only one of the companies that Wainer has been associated with, as it relates to NIH funded inventions. Wainer was also the chief scientific officer for Mitchell Woods Pharmaceuticals, a company that received at least two earlier NIH exclusive patent licenses.)

While I am disappointed that you were not willing to answer most of Ms. Ardizonne's questions, thank you for sharing that while research into fenoterol for the field of use is relatively early stage, there have been several trials involving fenoterol and its analogues for a variety of other indications.

As is unfortunately often the case, there is really nothing in the notice to explain why Paz Pharmaceuticals is considered qualified for an exclusive license on this portfolio of patents, or what the terms of the license might look like, other than it will be "worldwide" and be related to the treatment of cancer. We don't know the years of exclusivity, or the royalties involved.

I'm guessing that you or more generally Director Francis Collins thinks the statutory requirement for public notice and comment is an inconvenient formality that does not require the NIH to provide any details relevant to whether or not the exclusive license was needed, who the company is (since it has almost no visible public presence), or any of the terms of the license. Of course, this was not always the case, and indeed, in the first 15 years of the Bayh-Dole Act, the NIH was considerably more forthcoming in terms of transparency as regards its licensing practices.

The fact that the licensee will be a company that gives as its address the residence of the NIH employee who was the lead inventor, raises a question of self dealing or conflicts of interest. Is Dr. Wainer still with the NIH, and if not, when did he leave? And does the NIH acknowledge that when licensing patents to its own employees, it should be more rather than less transparent?

I would suggest than when the NIH hands over exclusive worldwide rights to a portfolio of cancer treatment patents to an NIH employee (current or former), on secret terms, there is a potential for abuses, the most benign being a failure to drive a hard bargain on the license terms, including the requirement in 35 USC 209 that the agency limit the scope of exclusivity to that which is reasonably necessary.

One area, elaborated below in more detail, concerns the geographic area of exclusivity. Even if you give the licensee exclusive rights to every country in Europe, North America, Japan, Australia and China, where collectively most of the global GDP resides, there is no serious argument that India and other low and moderate income countries in Asia, all of Africa, and most of Latin America, would be an issue with the licensee if the NIH excluded them from the exclusivity. On the other, it is obvious, as demonstrated every day and every year, that drug companies with monopolies on cancer drugs underserve developing countries, to such extremes that patients don't have access or experience extreme fiscal hardships in gaining access. This is not some hypothetical argument, it is the real world, and if you don't know it, it is because you don't want to know.

NIH licensing policies have generally been very responsive to investor and inventor interests, and not at all concerned about the extreme global disparities in access for cancer treatments. This is appalling for a taxpayer funded institution.

I will close by making these suggestions, in the event that the NIH proceeds with the licenses,

KEI requests that the NIH includes the following provisions to protect the public's interest in NIH-funded technology:

1. **Geographic scope of exclusivity.** If the NIH decides to grant exclusive rights to the subject invention, it should limit exclusivity to the European Union, Japan and other high-income countries, but not the United States, so that countries that did not fund the R&D underlying the inventions would bear the costs of the exclusivity, while the U.S. residents would not. The NIH should also limit exclusivity in moderate and lower income countries, where the monopoly is likely to have an adverse impact on access with almost no benefit in terms of the incentives for the company.

2. **Price discrimination.** Any medical technology using the patented invention should be available in the United States at a price that does not exceed the median price in the seven largest economies by GDP that have at least 50 percent of the GNI per capita as the United States, using the World Bank Atlas method. This is a modest safeguard.

3. **Low and middle income countries.** The exclusive licenses should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide something that will give effect to the policy objective in the "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy," which states the following: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

4. **Global registration and affordability.** The licenses should require the licensee to disclose the steps that each will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

5. **Medicines Patent Pool.** The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the

medical technology from competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.

6. **Years of exclusivity.** We propose the licenses reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddI case. We propose that the exclusivity of the licenses be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the licenses could be reduced by one year for every $500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]"

7. **Transparency of R&D outlays.** The licensees should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We note that this is not a request to see a company business plan or license application. We are asking that going forward the company be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application." Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

In any case please notify KEI if a license is actually granted to Paz Pharma, so we can request a copy under the FOIA.

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