February 22, 2016

Patrick McCue, Ph.D.
Senior Licensing and Patenting Manager
Technology Advancement Office
The National Institutes of Diabetes and Digestive and Kidney Diseases
12A South Drive
Bethesda, MD 20892
via email: patrick.mccue@nih.gov

Dear Dr. McCue:

We are writing in regard to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) notice in the Federal Register concerning possible exclusive licenses for patents on 'Development of in vitro Diagnostics for the Detection of Diseases or Pathogenic Agents' using cyclopentane-peptide nucleic acids (PNA). [81 FR 8082]

The technology will be applied to diagnose communicable diseases and the NIH has already developed robust protocols to used cyclopentyl-PNA probes in the detection of Anthrax. The incorporation of a cyclopentane ring to PNA-based probes increases the sequence specificity of the diagnostic assays, thus requiring smaller samples and minimising contamination. Furthermore, the stability of such bonds also makes this technology practical for confirmatory tests. The properties of PNAs are optimal for uses in public health both as qualitative point-of-care rapid diagnostics or quantitative high-throughput epidemiological monitoring.

As per *35 U.S.C. 209(a)(2)*, in order "to bring the invention to practical application or otherwise promote the invention's utilization by the public," such diagnostic technology must be placed on the market on "reasonable terms." Accordingly, we ask that this exclusive commercialisation licence regarding federally-owned patent applications include provisions that ensure that the product is (a) not priced higher than other high-income countries and (b) that the prices are affordable enough that the products do not face restrictions on access by insurers and government payors.

Additionally, "A Federal agency shall normally grant a license under section 207(a)(2) to use or sell any federally owned invention in the United States only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States" [*35 U.S.C. 209(c)(1)*]. AltraTech, Ltd. is a

company incorporated in Ireland. We ask the NIDDK if the foreign owned firm will be manufacturing the products in the United States, and if not, we ask the licence contains terms that will assure that the diagnostic product be indeed manufactured in the United States.

The inherent stability of PNAs make them ideal for diagnostics practices outside of a laboratory setting and or where such resources may be limited. This is especially true in developing countries. Considering that AltraTech is seeking a worldwide territory for this license, we ask that they demonstrate how the product will be accessible in developing countries.

Cyclopentane-PNAs technology will have important applications for public health and our request address concerns that this technology, developed using public resources, be indeed reasonably accessible to the public.

Sincerely,

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