



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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*Via email only*

January 11, 2019

Mr. James Love  
Knowledge Ecology International  
1621 Connecticut Avenue NW, Suite 500  
Washington, DC 20009

IN RE: Prospective Grant of an Exclusive Patent License: “Multifunctional RNA Nanoparticles and Methods of Uses” and “RNA/DNA Hybrid Nanoparticles Modified with Single Stranded RNA Toeholds and Uses Thereof”, Noticed at Federal Register / Vol. 83, No. 245 / Friday, December 21, 2018

Dear Mr. Love:

Thank you for your emails dated December 25, 2018 (two emails) and January 07, 2019 (two emails) with your comments regarding the above-referenced Federal Register Notice of the proposed [Startup Exclusive Evaluation License](#) the National Cancer Institute intends to grant to Sixfold Biosciences Inc., a U.S.-based startup company.

With respect to your comment regarding the grant of an exclusive license for use of the technologies in gene-editing or drug delivery, the NIH has determined that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied in view of the applicant's intentions, plans and abilities to bring the invention to the point of practical application. We believe that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the field of use as specified. Our long experience in licensing these technologies, supplemented as it always is by responses to our license notices and our understanding of the commercial market in this particular field, persuade us that exclusivity is necessary to incentivize investment in this technology. This incentive is especially important in a situation like this one, where commercial interest in the invention has been low and only small companies who are willing to take greater risks can be expected to request a license. The advertised field of use is no greater than necessary and will be narrowed to a few gene-editing targets and specified aptamers upon execution of the follow on Exclusive Commercialization License. The field of use will also be term limited. NCI does not have the commercial expertise nor resources to develop early stage inventions and must rely on the private sector to bring its technologies to the marketplace so that they can be used by the public. In our judgment, this license will tend to increase market competition of drug delivery agents and gene-editing therapeutics, advancing therapeutic options and public health in general, because this is only one of many potentially viable therapeutics that address the indication or use this core technology.

Importantly, additional fields of use covered by the patent claims are still available for licensing. These include methods for hybridizing proteins and imaging agents, which are additional applications that we may be able to license to competent applicants, further increasing competition in the marketplace. NCI intends to continue marketing the technologies by promptly advertising the additional uses to attract additional licensees. The NCI would be happy to send KEI a copy or link to the abstract when published.

With respect to your request for unpublished patent applications, all relevant patent application information for this technology appears to be publicly available and can be found at the USPTO Public Pair or WIPO databases and attached herein for your convenience.

- E-765-2013:
  - o <http://appft1.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PG01&p=1&u=/netahtml/PTO/srchnum.html&r=1&f=G&l=50&s1=20170121708.PGNR.&OS=DN/20170121708&RS=DN/20170121708>
  - o <https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2015042101>
- E-078-2016:
  - o [https://patentscope.wipo.int/search/en/detail.jsf;jsessionid=DCC77A39E9F573EE8B954C152AA85F4F.wapp2nA?docId=WO2017139758&recNum=201&office=&queryString=&prevFilter=%26fq%3DOF%3AWO%26fq%3DICF\\_M%3A%22C12N%22&sortOption=%E5%85%AC%E5%B8%83%E6%97%A5%E9%99%8D%E5%BA%8F&maxRec=40468](https://patentscope.wipo.int/search/en/detail.jsf;jsessionid=DCC77A39E9F573EE8B954C152AA85F4F.wapp2nA?docId=WO2017139758&recNum=201&office=&queryString=&prevFilter=%26fq%3DOF%3AWO%26fq%3DICF_M%3A%22C12N%22&sortOption=%E5%85%AC%E5%B8%83%E6%97%A5%E9%99%8D%E5%BA%8F&maxRec=40468)

With respect to your comment about the company's employee profiles, the company is a U.S. based startup company incorporated in Delaware. Other companies working in the same space have been directly contacted regarding this matter and have declined to apply for a license to this technology and have submitted no comments objecting to this intent to grant.

The public comment period is now closed. We have considered all your comments and will consider all comments prior to negotiating the proposed license.

Sincerely,

Jasmine Yang, Ph.D.  
Senior Technology Transfer Manager  
NCI Technology Transfer Center