



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Kathryn Ardizzone
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Subject: Comments Submitted in Response to Federal Register Notice 2020-13137 (85 FR 36872), entitled
“Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies
for Cancer”

Dear Ms. Ardizzone:

Thank you for providing us with your comments regarding the above-referenced notice (“Notice”). As you indicated, your comments were submitted on behalf of two organizations and we kindly request that you share our response with both parties.

Prior to posting the Notice, the NCI determined that the prospective licensee was qualified, both technically and financially, to be granted an exclusive license to the Government’s intellectual property in the specified fields of use. 37 C.F.R. § 404.7(a)(1)(i) provides an opportunity for public comment and possible objection to the proposed license.

NCI considered all written objections timely received in response to the Notice and has since determined that the requirements specified in 37 C.F.R. § 404.7(a)(1)(ii)(A-C) and 37 C.F.R. § 404.7(a)(1)(iii) have been satisfied.

The technologies described in the Notice will be applied in the development of certain companion diagnostics and T cell therapies for the treatment of cancers expressing RAS with G12D or G12V mutations. Considering, for example, the magnitude of investment required to develop such products and the overall probability of success, a degree of exclusivity is an appropriate incentive to the commercial partner. Moreover, any exclusive license executed pursuant to the Notice would be limited to the narrow fields of use specified in the same. The purposeful limitations contained in these fields of use will allow for additional companies utilizing distinct technical approaches to further license the Government’s rights. This strategy helps to create robust competition in the therapeutic space occupied by these technologies and increases the likelihood that products embodying the inventions secure regulatory approval and becomes available to the public.

Sincerely,

A handwritten signature in black ink that reads "Andrew Burke".

Andrew Burke, Ph.D.
Senior Technology Transfer Manager