



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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**DATE:** February 26, 2019

**RE:** KEI Comments in regards to 84 FR 2555, “*Prospective Grant of an Exclusive Patent License: “Virus-Like Particles Vaccines Against Human Polyomaviruses, BK Virus (BKV) and JC Virus (JCV)”*” notice, Prospective Exclusive License Grant to BioE Holding Inc.

Dear Mr. Abinader,

Thank you for your comments regarding the Intent to Grant an Exclusive License notice referenced above in Federal Register 84 FR 2555. Prior to posting a notice for a proposed grant of an exclusive license, the NIH determines that the criteria set forth in 37 CFR 404.4(a)(1)(ii-iii) has been satisfied with respect to granting the organization an exclusive license to the Government’s intellectual property in the fields of use as specified.

Our answers and responses to your questions and comments are as follows. As indicated in the Notice, the parent company is Biological E Ltd and a link to their publicly available website is provided herein (<http://www.biologicale.com/>). In regards to the patent estate that covers this technology, both of the IP families listed in the Notice are already at the national stage and the listing in the Notice represents a complete description of the patent family. The technology is a core research interest of the inventor’s laboratory; however, it is not the only technology that is being researched. NIH has not determined how much funding went into this particular research project. Information on funding of NIH laboratories can be found at <https://projectreporter.nih.gov/reporter.cfm>. The technology is current at the pre-clinical stage and clinical trials have not been entered. This is the reason that we have sought a commercial partner through this prospective license. In regards to your other comments, we will take them under consideration.

Best regards,

Kevin W. Chang, Ph.D.  
Senior Technology Transfer Manager