

July 2, 2018

Karen Surabian  
Licensing and Patenting Manager  
Technology Transfer and Intellectual Property Office  
National Institute of Allergy and Infectious Diseases  
[karen.surabian@nih.gov](mailto:karen.surabian@nih.gov).

Re: Prospective Grant of Exclusive Patent Commercialization License:  
Streptococcus Pneumonia PSAA Peptide for Treatment of Sepsis and  
Infection to The University of Liverpool, located in Liverpool, UK

Dear Karen Surabian,

These are the KEI comments relating the proposed exclusive license to inventions identified in the federal notice 83 FR 28002.

1. The license should prohibit the licensee from charging more for any drug, vaccine, medical device or any other health technology using the invention than the median price charged in the seven countries with the largest gross domestic product (GDP), that also have a per capita income of at least 50 percent of the United States, as measured by the World Bank Atlas Method.
2. The license should not be exclusive in any country with a per capita income less than 30 percent of the United States per capita income, as measured by the World Bank Atlas method.
3. The license should include an obligation to make an annual report to the NIH that would be available to the public on the research and development (R&D) costs associated with the development of any product that uses the invention, including reporting separately and individually the outlays on each clinical trial. This type of information should be made available to the public in order to ensure that the terms of the licenses over NIH-owned inventions can be evaluated, in light of the requirements of 35 USC 209. Indeed, the most relevant information regarding 35 USC 209 is that the expected costs of bringing an invention to practical application, and the data collected from license holders, is important evidence and should be available and considered.
4. To guarantee that the scope of the license is sufficiently narrow, as required under 35 USC 209, the exclusivity of the license in the United States should be reduced by one year for every \$500 million in revenue equivalents, earned after the first \$1 billion, where revenue equivalent is defined as global cumulative

sales, plus market entry rewards plus government grants or tax credits, for the product or products using the invention.

The Federal Register notice would have been more informative if we knew more about the extent of NIH or other government agency funding in this area, and also if there are plans for the NIH, BARDA or any other U.S. government agency to continue to support the development of products based upon this invention. We do note that 32 administering institutes or other government agencies that report grants in the NIH RePORT database have funded more than \$1 billion in research grants for streptococcus pneumonia or streptococcus pneumoniae.

Sincerely



Luis Gil Abinader  
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#### Annex: Government funding of research in NIH RePORT database

(Funding data available only for NIH, CDC, FDA, and ACF)

**July 2, 2018 Text Search:** "streptococcus pneumonia" "streptococcus pneumoniae" (or), **Search in:** Projects **Admin IC:** All, **Fiscal Year:** All Fiscal Years

Administering Agency	projects	Project funding	sub projects	Sub Project funding
NIAID	1,569	\$589,508,807	104	\$43,190,320
NIGMS	265	\$102,398,204	25	\$3,488,408
NHLBI	234	\$86,247,316	55	\$17,791,985
NIDCD	205	\$68,803,279	12	\$1,439,957
NIA	101	\$21,227,109	6	\$975,142
NIDCR	75	\$20,234,993	5	\$782,428
NICHD	67	\$27,311,146	17	
NEI	58	\$18,749,443		
FDA	56			
NIAAA	40	\$8,062,504	26	\$4,259,685
NIEHS	31	\$11,977,092	17	\$5,018,550
VA	29			

FIC	26	\$3,949,321		
NCI	26	\$6,875,593	6	\$4,763,834
NIDA	22	\$4,787,617		
NINDS	19	\$5,108,633	4	
AHRQ	19			
NIAMS	17	\$6,115,167	5	\$403,020
NIMH	17	\$3,290,727		
NIDDK	15	\$3,824,942	1	\$147,712
CID	14	\$14,828,991		
NIMHD	11	\$3,471,409	3	\$1,029,828
NIBIB	7	\$1,447,386		
NCRR	6	\$4,445,858	112	\$3,336,220
NCIRD	6	\$3,934,512		
NHGRI	4	\$1,855,111	1	\$233,333
OD	4	\$2,938,501		
NCCIH	4	\$1,200,391		
CLC	3			
CIT	2			
NIADDK	1	\$162,792		
ODCDC			3	\$650,465
Totals	2,953	\$1,022,756,844	402	\$87,510,887