



September 3, 2019

Ms. Michelle G. Bulls
Director
Office of Policy for Extramural Research Administration (OPERA)
National Institutes of Health

Via E-mail: MICHELLE.BULLS@NIH.GOV

Dear Ms. Bulls,

I am writing to request an investigation into apparent non-disclosure of federal funding for several patents assigned to the Trustees of the University of Pennsylvania.

KEI has been investigating federal funding of certain gene therapies. In this instance, we are writing in regards to seven patents that were issued to the same three inventors and assigned to the Trustees of the University of Pennsylvania that do not disclose federal funding.

The three inventors are:

- Gao Guang-ping,
- James M. Wilson, and
- Mauricio Alvira.

All seven patents that did not report federal funding are related to adeno-associated virus (AAV) sequences. The patent numbers, filing dates and patent titles are listed in Table 1.

Table 1: Seven patents related to AAV sequences with the same three inventors and no federal funding disclosures.

Patent	Filing Date	Title	Inventors
10,308,958	2017-06-27	Method of detecting and/or identifying adeno-associated virus (AAV) sequences and isolating novel sequences identified thereby	Gao; Guangping(Westborough, MA), Wilson; James M.(Philadelphia, PA), Alvira; Mauricio R.(Philadelphia, PA)
10,041,090	2014-12-02	Method of detecting and/or identifying adeno-associated virus (AAV) sequences and isolating novel sequences identified thereby	Gao; Guangping(Westborough, MA), Wilson; James M.(Glen Mills, PA), Alvira; Mauricio R.(Philadelphia, PA)
9,790,472	2012-10-03	Method of detecting and/or identifying adeno-associated virus (AAV) sequences and isolating novel sequences identified thereby	Gao; Guangping(West Borough, MA), Wilson; James M.(Glen Mills, PA), Alvira; Mauricio R.(Philadelphia, PA)
8,906,675	2007-11-14	Adeno-associated virus (AAV) sequences and isolating novel sequences identified thereby	Gao; Guangping(Rosemont, PA), Wilson; James M.(Glen Mills, PA), Alvira; Mauricio R.(Philadelphia, PA)
8,524,446	2010-12-08	Method for detecting adeno-associated virus	Gao; Guangping(West Borough, MA), Wilson; James M(Glen Mills, PA), Alvira; Mauricio R.(Philadelphia, PA)
7,235,393	2003-04-22	Method for direct rescue and amplification of integrated viruses from cellular DNA of tissues	Gao; Guangping(Rosemont, PA), Wilson; James M.(Gladwyne, PA), Alvira; Mauricio R.(Philadelphia, PA)
7,198,951	2003-07-26	Adeno-associated virus (AAV) serotype 9 sequences, vectors containing same, and uses therefor	Gao; Guangping(Rosemont, PA), Wilson; James M.(Gladwyne, PA), Alvira; Mauricio(Philadelphia, PA)

The seven which do not disclose federal funding in the U.S. PTO database or in the NIH RePORTER database, can be compared to the following ten patents in Table 2 that have the same three inventors and also pertain to AAV sequences, but do report federal funding in the patents.

Table 2: Ten patents relating to AAV sequences with the same three inventors and federal funding disclosures.

Patent	Filing date	Title	Government Rights in Patent	Inventors
10,301,650	2015-02-08	Adeno-associated virus (AAV) serotype 8 sequences, vectors containing same, and uses therefor	DK047757 and HL059407 awarded by the National Institutes of Health.	Gao; Guangping, Wilson; James M., Alvira; Mauricio R.
10,266,846	2016-10-20	Adeno-associated virus (AAV) serotype 8 sequences, vectors containing same, and uses therefor	DK047757 and HL059407 awarded by the National Institutes of Health.	Gao; Guangping, Wilson; James M., Alvira; Mauricio R.
9,677,089	2016-03-30	Adeno-associated virus (AAV) serotype 8 sequences, vectors containing same, and uses therefor	P30 DK 47757-09, NIDDKD P01 HL 59407-03 NHLBI	Gao; Guangping, Wilson; James M., Alvira; Mauricio R.
9,587,250	2015-01-16	Adeno-associated virus (AAV) serotype 8 sequences, vectors containing same, and uses therefor	P30 DK 47757-09 NIDDKD P01 HL 59407-03 NHLBI.	Gao; Guangping, Wilson; James M., Alvira; Mauricio R.
9,493,788	2015-01-16	Adeno-associated virus (AAV) serotype 8 sequences, vectors containing same, and uses therefor	P30 DK 47757-09 NIDDKD P01 HL 59407-03 NHLBI.	Gao; Guangping, Wilson; James M., Alvira; Mauricio R.
8,962,332	2013-09-13	Adeno-associated virus (AAV) serotype 8 sequences, vectors containing same, and uses therefor	P30 DK 47757-09 NIDDKD, P01 HL 59407-03 NHLBI	Gao; Guangping, Wilson; James M., Alvira; Mauricio R.
8,962,330	2007-10-31	Adeno-associated virus (AAV) serotype 8 sequences, vectors containing same, and uses therefor	P30 DK 47757-09 NIDDKD P01 HL 59407-03 NHLBI	Gao; Guangping, Wilson; James M., Alvira; Mauricio R.
8,318,480	2007-10-31	Adeno-associated virus (AAV) serotype 8 sequences, vectors containing same, and uses therefor	P30 DK 47757-09, NIDDKD P01 HL 59407-03, NHLBI.	Gao; Guangping, Wilson; James M., Alvira; Mauricio R.
7,790,449	2007-09-06	Adeno-associated virus (AAV) serotype 8 sequences, vectors containing the same, and uses therefor	In February 19, 2019 Certificate of Correction: DK-047757 and HL-059407	Gao; Guangping, Wilson; James M., Alvira; Mauricio R.
7,282,199	2003-04-25	Adeno-associated virus (AAV) serotype 8 sequences, vectors containing same, and uses therefor	In March 5, 2019 Certificate of Correction: DK-047757 and HL-059407	Gao; Guangping, Wilson; James M., Alvira; Mauricio R.

In addition, there are three other patents that have the same title as the patents in Table 2 and have the same three inventors, plus a fourth inventor (Luk H. Vandenberghe), and which also disclose federal funding involving the same two grants.

Table 3: Three patents related to AAV sequences with the same three inventors as in Table 1 and 2, plus Luk Vandenberghe, with disclosures of federal funding.

Patent	Filing date	Title	Government Rights in Patent	Inventors
10,265,417	2006-08-03	Adeno-associated virus (AAV) clades, sequences, vectors containing same, and uses therefor	P30 DK47757 NIDDK and P01 HL59407 NHLBI awarded by the National Institutes of Health.	Wilson; James M., Gao; Guangping, Alvira; Mauricio R., Vandenberghe; Luc H.
9,737,618	2015-07-20	Adeno-associated virus (AAV) clades, sequences, vectors containing same, and uses therefor	P30 DK47757 NIDDK and P01 HL59407 NHLBI awarded by the National Institutes of Health.	Wilson; James M., Gao; Guangping, Alvira; Mauricio R., Vandenberghe; Luk H.
7,906,111	2004-09-30	Adeno-associated virus (AAV) clades, sequences, vectors containing same, and uses therefor	P30 DK47757 NIDDK and P01 HL59407 NHLBI awarded by the National Institutes of Health.	Wilson; James M., Gao; Guangping , Alvira; Mauricio R. , Vandenberghe; Luc H.

The two grants disclosed in Tables 2 and 3 covered a span of 26 years and involved more than \$63 million in public funds (see Table 4).

Table 4: Two NIH grants identified on the Penn AAV patents in Tables 2 and 3.

Funding agency	Grant #	First to last year	Cumulative NIH funding
NIDDK	P30 DK 047757	1993 to 2017	\$26,335,057
NHLBI	P01 HL 059407	1999 to 2019	\$36,864,829

Also, we note that James Wilson is listed as the principal investigator for 109 projects and 90 subprojects at Penn involving \$105.5 million in NIH funding from seven different NIH institutes/centers, from 1992 to 2019, indicating that public funding has played a significant role in supporting his research.

We would like to speak with you or the appropriate contact in your office about this and other related cases of non-disclosures of federal funding in patents.

Sincerely

A handwritten signature in blue ink that reads "James Love". The signature is written in a cursive style with a large, looping initial "J".

James Love
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