



SAGITTARIUS IP

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European Patent Office
80298 Munich
GERMANY

Our Ref: STA-C-P1699EPD1

6 January 2023

Dear Sir/Madam

**Re: European Patent No. 3 147 295
“NEW AAV CAPSID PROTEINS FOR NUCLEIC ACID TRANSFER”
granted on 9 December 2020
based on European Application No. 16 196 258.4
in the name of The Board of Trustees of the Leland Stanford Junior
University**

Further to the Summons to Attend Oral Proceedings Pursuant to Rule 115(1) EPC dated 10 February 2022, we wish to first thank the Opposition Division (OD) for preparing the consolidated list of prior art and supporting documents, the numbering of which will be adhered to throughout the procedure.

In response to said Summons, we herein file the enclosed Written Submissions ahead of Oral Proceedings scheduled for 7 March 2023.

As an initial matter, we wish to re-iterate the argumentation made in our reply dated 24 January 2022 to the Notice of Opposition. In particular, we wish to highlight the large amount of published evidence previously provided which supports the advantageous properties of AAV-LK03.

Furthermore, regarding the further submissions from the Opponent filed late on 18 January 2022 in which the experimental report D10 was provided, the Guidelines for Examination at E-VI, 2 set out the considerations to be taken into account when deciding whether to admit facts, evidence or grounds not filed in due time which are: (i) they are not *prima facie* relevant; (ii) they have been filed at a late state of the procedure; and (iii) the reasons for belated submission are insufficient. We submit that D10 should not be admitted because it meets each of these considerations as follows. Similarly, D20 and D21 (filed with the opponent's submission of 14th July 2022) should also not be admitted because they are not *prima facie* relevant, they have been filed late, and the opponent has not given sufficient reasons for the late filing.

D10 is Not Prima Facie Relevant

The further submissions from the Opponent of 18 January 2022 and D10 are not *prima facie* relevant because the results presented therein cannot be relied upon since the purification method used in D10 is iodixanol gradient fractionation (see section 3.1 of D10). As mentioned at point 5.2 on page 6 of our reply dated 24 January 2022, this method is stated in D11 (comment from Mark A Kay) to be known to result in a high proportion of empty (and therefore non-functional) capsids. This is especially relevant

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