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(54) **Title:** HYDROPHOBIC INTERACTION CHROMATOGRAPHY FOR VIRAL CLEARANCE

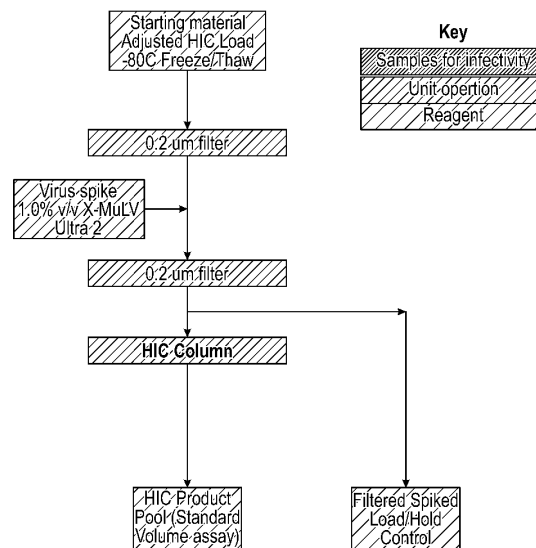


FIG. 1

(57) **Abstract:** The present application provides a method for characterizing and/or determining viral clearance capacity of hydrophobic interaction chromatography (HIC) including experimental design for multivariate analysis of viral clearance of HIC. The method provides understanding of the mechanism of the viral clearance using HIC by running a D-Optimal design of experiment including evaluations of multiple factors, such as pH, buffer concentration, column loading concentration, flow rate of column, or hydrophobic strength of the HIC column.

[Continued on next page]

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Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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