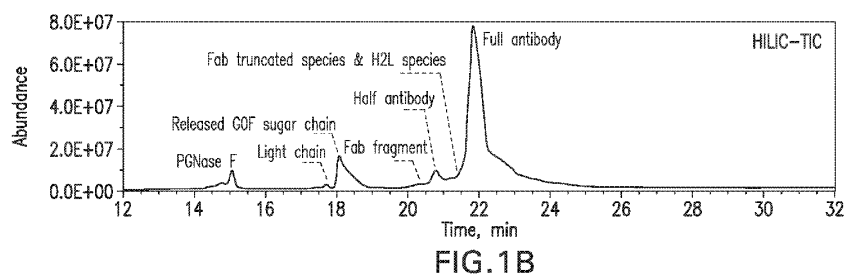
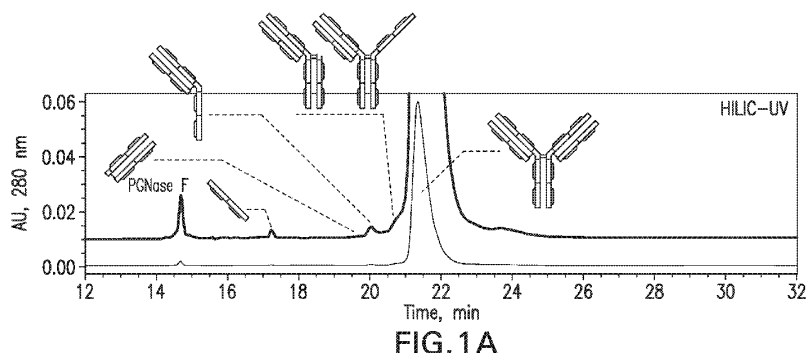




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- (71) **Applicant: REGENERON PHARMACEUTICALS, INC.** [US/US]; 777 Old Saw Mill River Road, Tarrytown, New York 10591-6706 (US).
- (72) **Inventor: WANG, Shunhai;** 777 Old Saw Mill River Road, Tarrytown, New York 10591-6707 (US).
- (74) **Agent: VORNDRAN, Charles;** Promenade, Suite 3100, 1230 Peachtree Street, N.E., Atlanta, Georgia 30309 (US).
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(54) **Title:** SYSTEM AND METHOD FOR CHARACTERIZING DRUG PRODUCT IMPURITIES



(57) **Abstract:** Systems and methods for characterizing low molecular weight (LMW) protein drug product impurities are provided. One embodiment uses hydrophilic interaction chromatography (HILIC) coupled to mass spectrometry analysis. After removal of the N-linked glycans from the protein drug product, for example an antibody drug product, the elution of LMW impurities from the HILIC column was determined by the size of the molecular weight species. In some embodiments, the HILIC separation is performed under denaturing conditions, making the detection of LMW forms using this method highly comparable to both SDS-PAGE and CE-SDS methods. LMW drug product impurities include, but are not limited to light chain, half antibody, H2L, H2, HL, HC, peptide backbone-truncated species, and combinations thereof.

[Continued on next page]

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