

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
21 April 2022 (21.04.2022)



(10) International Publication Number
WO 2022/081938 A1

(51) International Patent Classification:
G01N 31/16 (2006.01)

(21) International Application Number:
PCT/US2021/055116

(22) International Filing Date:
15 October 2021 (15.10.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/093,124 16 October 2020 (16.10.2020) US
63/144,744 02 February 2021 (02.02.2021) US
63/251,465 01 October 2021 (01.10.2021) US

(71) Applicant: AMGEN INC. [US/US]; One Amgen Center Drive, Thousand Oaks, CA 91320-1799 (US).

(72) Inventor: SOTO, Robert, Joseph; c/o Amgen Inc., One Amgen Center Drive, Legal Dept-Patent Operations, Mail Stop 28-5-A, Thousand Oaks, CA 91320-1799 (US).

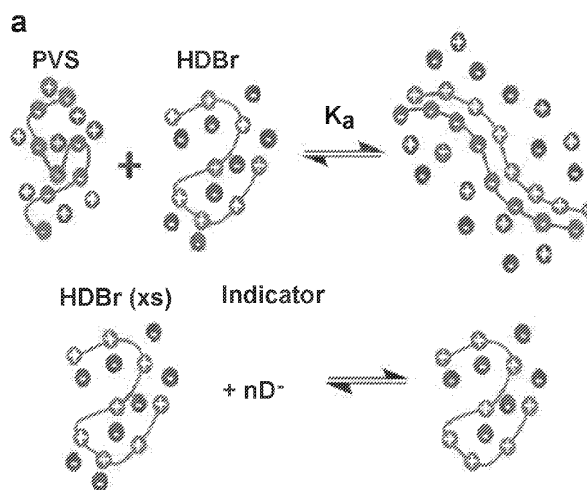
(74) Agent: MERKEL, William, K.; Marshall, Gerstein & Borun LLP, 233 S. Wacker Drive, 6300 Willis Tower, Chicago, IL 60606-6357 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,

(54) Title: TITRATION METHODS FOR DETECTING POLYVINYL SULFONATE (PVS) IN BUFFERS

FIG. 3



(57) Abstract: The disclosure provides methods, including automated methods, to detect levels of polyanions such as polyvinyl sulfonates in fluids such as buffers by complexometric or titration-based techniques. Such polyanionic compounds have been shown to inhibit enzymes involved in PCR that confounds efforts to monitor the purity of proteins obtained from cell culture, such as biologics and biosimilars.

[Continued on next page]

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*