



(51) International Patent Classification:

C12M 1/00 (2006.01) C12P 21/02 (2006.01)
C07K 1/14 (2006.01) C12M 1/36 (2006.01)

(21) International Application Number:

PCT/US2020/018463

(22) International Filing Date:

16 February 2020 (16.02.2020)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/806,448 15 February 2019 (15.02.2019) US

(71) Applicants: JUST-EVOTEC BIOLOGICS, INC.

[US/US]; 401 Terry Avenue North, Seattle, WA 98109 (US). **MERCK SHARP & DOHME CORP.** [US/US]; 126 East Lincoln Avenue, Rahway, NJ 07065 (US).

(72) Inventors: VANDIVER, Michael, Wayne;

10325 Ne 153rd Place, Bothell, WA 98011 (US). **GEFROH, Eva, Fan;** 8122 126th Place Se, Newcastle, WA 98056 (US). **MCCOY, Rebecca, Eileen;** 7524 S 135th St., Seattle, WA 98178 (US). **PIPER, Robert, James;** 405 Mt. McKinley Drive SW, Issaquah, WA 98027 (US). **BROWER, Mark, A.;** 2000 Galloping Hill Road, Kenilworth, NJ 07033 (US). **PINTO, Nuno, J. Dos Santos;** 2000 Galloping Hill Road, Kenilworth, NJ 07033 (US). **NAPOLI, William, N.;** 278 Old Connecticut Path, Mayland, MA 01778 (US).

STRAUGHN, Rachel, Y.; 2530 E. Madison Street, Unit C, Seattle, WA 98112 (US). **CONNELL-CROWLEY, Lisa, A.;** 8311 Roosevelt Way Ne, Seattle, WA 98115 (US). **MC-CLURE, Megan, J.;** 920 1st Avenue North, Apt. 412, Seattle, WA 98109 (US).

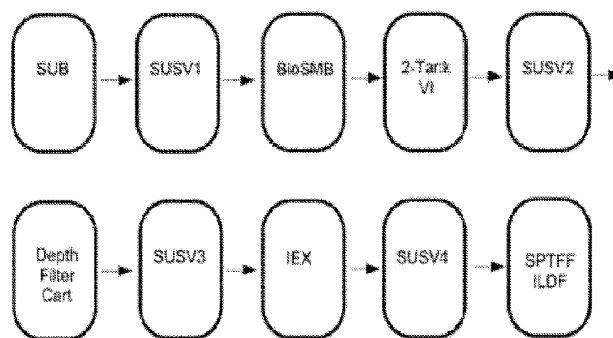
(74) Agent: **STEINBERG, Nisan A.;** 5307 Wilkinson Avenue, Unit 14B, Valley Village, CA 91607 (US).

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

(54) Title: AUTOMATED BIOMANUFACTURING SYSTEMS, FACILITIES, AND PROCESSES

FIG. 22



(57) Abstract: Disclosed are a process and an automated facility for manufacturing a purified protein of interest using one or more single-use perfusion bioreactors, one or more single-use surge vessels and one or more chromatography systems. The protein of interest can be a recombinant or naturally occurring protein and/or a therapeutic or other medically useful protein. For example, the disclosed process and automated facility are useful for manufacturing a purified protein drug substance.

[Continued on next page]

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))*

Published:

- *with international search report (Art. 21(3))*
- *with amended claims (Art. 19(1))*