



(51) International Patent Classification:

A61K 9/00 (2006.01) A61K 39/12 (2006.01)
A61K 9/08 (2006.01) A61P 31/14 (2006.01)
A61K 39/00 (2006.01)

(21) International Application Number:

PCT/US2023/062530

(22) International Filing Date:

14 February 2023 (14.02.2023)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/310,437 15 February 2022 (15.02.2022) US
22163647.5 22 March 2022 (22.03.2022) EP

(71) Applicant: **TAKEDA VACCINES, INC.** [US/US]; 75
Sidney Street, Cambridge, Massachusetts 02139 (US).

(72) Inventors: **BRONSON, Sean**; c/o Takeda Vaccines, Inc.,
75 Sidney Street, CAMBRIDGE, Massachusetts 02139
(US). **SHOEMAKER, Scott**; c/o Takeda Vaccines, Inc., 75
Sidney Street, Cambridge, Massachusetts 02139 (US).

(74) Agent: **FOX, Harold H.**; 1440 New York Ave NW, Suite
200, Washington, District of Columbia 20005 (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, CV, CZ, DE, DJ, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE,
KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU,
LY, MA, MD, 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, CV,
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, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI,

(54) Title: DENGUE VACCINE BATCH MIXING PROCESS

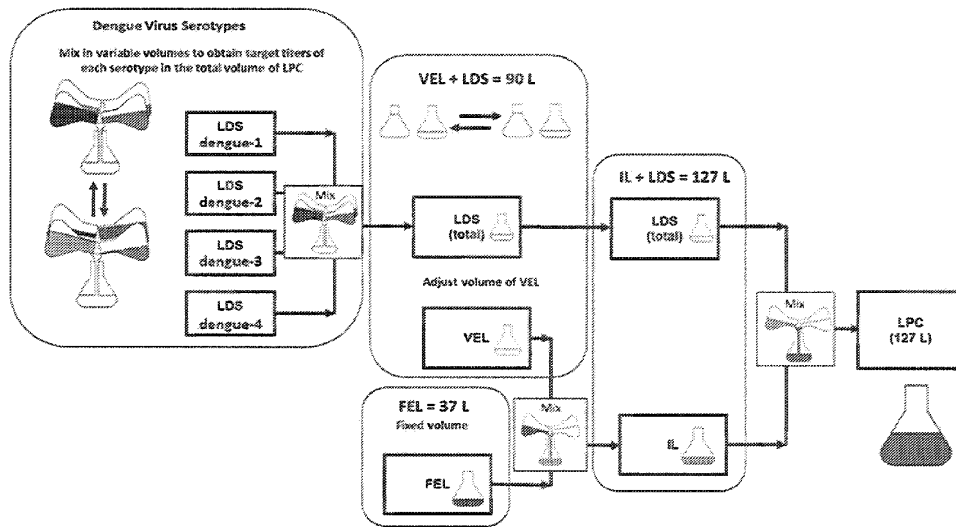


FIG. 1

(57) Abstract: The present invention relates to a batch mixing process for preparing a liquid pharmaceutical composition (LPC) comprising at least one biological active agent and at least one adjustable excipient, wherein the at least one biological active agent has a target concentration in the LPC ($^T[A_i]_{LPC}$) and the at least one adjustable excipient has a target concentration in the LPC ($^T[E_x]_{LPC}$).

[Continued on next page]

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

Declarations under Rule 4.17:

- *as to the identity of the inventor (Rule 4.17(i))*

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*
- *with sequence listing part of description (Rule 5.2(a))*