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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 April 2023 (13.04.2023)

WIPO | PCT

(10) International Publication Number
WO 2023/057444 A1

(51) International Patent Classification:
A61K 9/127 (2006.01) *A61K 9/51* (2006.01)
A61K 9/19 (2006.01) *A61K 31/7105* (2006.01)

(21) International Application Number:
PCT/EP2022/077571

(22) International Filing Date:
04 October 2022 (04.10.2022)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
21306387.8 05 October 2021 (05.10.2021) EP

(71) Applicant: **SANOFI** [FR/FR]; 46 avenue de la Grande Armée, 75017 PARIS (FR).

(72) Inventors: **PERAL, Florent**; c/o SANOFI, Patent Department, 54 rue la Boétie, 75008 PARIS (FR). **WOINET, Bertrand**; c/o SANOFI, Patent Department, 54 rue la Boétie, 75008 PARIS (FR). **BOUTRY, Etienne**; c/o SANOFI, Patent Department, 54 rue la Boétie, 75008 PARIS (FR).

(74) Agent: **CABINET NONY**; 11 rue Saint-Georges, 75009 PARIS (FR).

(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, 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, SK, SM, 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))*
— *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))*
— *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

WO 2023/057444 A1

(54) Title: METHODS FOR FREEZING AND FREEZE-DRYING LIPID NANOPARTICLES (LNPs) AND LNPs OBTAINED WITH THE SAME

(57) Abstract: The present invention relates to a method for freezing or freeze-drying lipid nanoparticles (LNPs) comprising at least a nucleic acid and, at least, as lipid components, a cationic ionizable lipid, a neutral lipid, and a steroid alcohol, or an ester thereof. The method comprises the steps of providing a liquid composition comprising said LNPs, spraying the composition of step a) in conditions suitable for obtaining liquid droplets, and freezing the liquid droplets obtained at step b) to obtain frozen LNPs. The method may also comprise a step of drying the frozen LNPs obtained to obtain freeze-dried LNPs. The invention also relates to frozen and freeze-dried LNPs.