

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

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
20 January 2011 (20.01.2011)

PCT

(10) International Publication Number
WO 2011/006877 A1

(51) International Patent Classification:

A61L 2/00 (2006.01) *A61L 2/08* (2006.01)
A61L 2/20 (2006.01) *B65B 55/08* (2006.01)
B65B 55/10 (2006.01)

(21) International Application Number:

PCT/EP2010/060011

(22) International Filing Date:

13 July 2010 (13.07.2010)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

09165456.6 14 July 2009 (14.07.2009) EP

(71) Applicant (for all designated States except US): **NOVARTIS AG** [CH/CH]; Lichtstrasse 35, CH-4056 Basel (CH).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **SIGG, Jürgen** [DE/CH]; c/o Novartis Pharma AG, Postfach, CH-Basel (CH).

(74) Agent: **SPINNER, David, Richard**; Novartis Pharma AG, Patent Department, CH-4002 Basel (CH).

(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, BR, BW, BY, BZ,

CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, 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, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, 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, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

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))

(54) Title: SURFACE DECONTAMINATION OF PREFILLED CONTAINERS IN SECONDARY PACKAGING

(57) Abstract: Methods and systems for the terminal sterilization and surface decontamination of prefilled containers containing sensitive drug products, such as biotech drug products that are otherwise temperature or radiation sensitive, and thus not suitable for terminal sterilization by classical methods involving steam or gamma rays. The methods and systems are especially suited for prefilled containers in secondary packaging. Methods include terminal sterilization by exposing prefilled containers in secondary packaging to tunable-beta radiation and further include terminal sterilization by exposing prefilled containers to controllable vaporized-hydrogen peroxide, including application of measures to reduce or prevent diffusion of vaporized-hydrogen peroxide into prefilled containers.



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