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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
17 March 2005 (17.03.2005)

PCT

(10) International Publication Number
WO 2005/023328 A2

(51) International Patent Classification[7]: A61M

(21) International Application Number:
PCT/US2004/019118

(22) International Filing Date: 14 June 2004 (14.06.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/497,702	26 August 2003 (26.08.2003)	US
60/550,197	3 March 2004 (03.03.2004)	US

(71) Applicant *(for all designated States except US)*: **BECTON DICKINSON AND COMPANY** [US/US]; 1 Becton Drive, Franklin Lakes, NJ 07417-1880 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **PETTIS, Ronald, J.** [US/US]; 101 Langdale_Place, Cary, NC 27513 (US). **HARVEY, Alfred** [US/US]; 1204 Queensbury Circle, Durham, NC 27713 (US). **CAMPBELL, Robert** [US/US]; 607 Phar Lap Lane, Bahama, NC 27503 (US). **MIKSZTA, John** [US/US]; 3205 Lochinvar Drive, Durham, NC 27705 (US). **BRITTINGHAM, John** [US/US]; 21 Davis Drive, RTP, NC 27709 (US).

(74) Agents: **CORUZZI, Laura, A.** et al.; Jones Day, 222 East 41st Street, New York, NY 10017-6702 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2005/023328 A2

(54) Title: METHODS FOR INTRADERMAL DELIVERY OF THERAPEUTICS AGENTS

(57) Abstract: The present invention relates to methods and devices for delivering one or more biologically active agents, particularly therapeutic agents, the intradermal compartment of a subject's skin. The present invention provides an improved method of delivery of biologically active agents, such as therapeutic agents, through lymphatic vasculature accessed by intradermal delivery. Therapeutic agents to be delivered in accordance with the present invention include, but are not limited ton antineoplastic agents, chemotherapeutic agents, antibodies, antibiotics, anti-angiogenesis agents, anti-inflammatory agents, and immunotherapeutic agents. Therapeutic agents delivered in accordance with the present invention have improved bioavailability, including improved systemic distribution and improved delivery to particular tissues. Therapeutic agents, delivered in accordance with the methods of the invention have an improved clinical utility and therapeutic efficacy relative to other drug delivery methods, including intraperitoneal, intramuscular and subcutaneous delivery. The methods of the present invention provide benefits and improvements over convention drug delivery methods including dose sparing, increased drug efficacy, reduced side effects, reduced metastatic potential and prolonged survival.