27 JUN 2005 2005041587

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 July 2004 (29.07.2004)

PCT

(10) International Publication Number
WO 2004/062561 A3

(51) International Patent Classification[7]: A61K 9/00, 31/4468, A61P 25/04

(21) International Application Number: PCT/GB2004/000057

(22) International Filing Date: 12 January 2004 (12.01.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0300531.1 10 January 2003 (10.01.2003) GB

(71) Applicant (*for all designated States except US*): **WEST PHARMACEUTICAL SERVICES DRUG DELIVERY & CLINICAL RESEARCH CENTRE LIMITED** [GB/GB]; Albert Einstein Centre, Nottingham Science & Technology Park, University Boulevard, Nottingham NG7 2TN (GB).

(72) Inventors; and

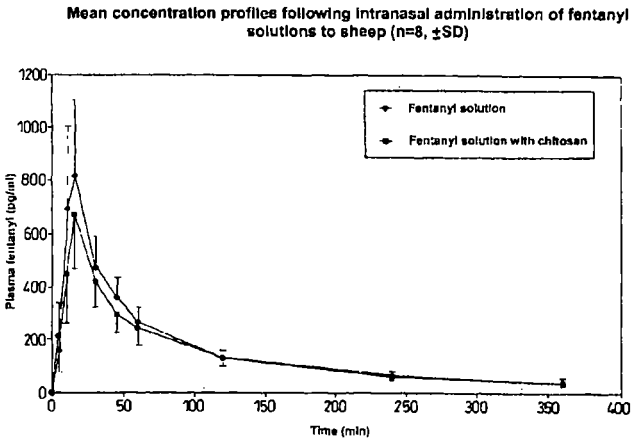
(75) Inventors/Applicants (*for US only*): **CASTILE, Jonathan, David** [GB/GB]; West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited, Albert Einstein Centre, Nottingham Science & Technology Park, University Boulevard, Nottingham NG7 2TN (GB). **WATTS, Peter, James** [GB/GB]; West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited, Albert Einstein Centre, Nottingham Science & Technology Park, University Boulevard, Nottingham NG7 2TN (GB). **LAFFERTY, William, Columbus, Ian** [GB/GB]; 28 Nanpantan Road, Loughborough, Leicestershire LE11 3SU (GB). **SMITH, Alan** [GB/GB]; West Pharmaceutical Services Drug Delivery & Clini, cal Research Centre Limited, Albert Einstein Centre, Nottingham Science & Technology Park, University Boulevard, Nottingham NG7 2TN (GB).

(74) Agent: **CROWHURST, Charlotte**; Eric Potter Clarkson, Park View House, 58 The Ropewalk, Nottingham NG1 5DD (GB).

(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,

[Continued on next page]

(54) Title: PHARMACEUTICAL COMPOSITIONS COMPRISING FENTANYL FOR INTRANASAL DELIVERY



(57) Abstract: This invention provides a composition for the intranasal delivery of fentanyl or a pharmaceutically acceptable salt thereof to an animal, which comprises an aqueous solution of (i) fentanyl or a pharmaceutically acceptable salt thereof and (ii) a pharmaceutically acceptable additive selected from (a) a pectin and (b) a poloxamer and chitosan or a salt or derivative thereof; provided that when the composition comprises a pectin it is substantially free of divalent metal ions; and which, in comparison to a simple aqueous solution of fentanyl administered intranasally at the same dose, provides a peak plasma concentration of fentanyl (C_{max}) that is from 10 to 80% of that achieved using a simple aqueous solution of fentanyl administered intranasally at an identical fentanyl dose.

WO 2004/062561 A3

162162

ACTION