

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
1 September 2005 (01.09.2005)

PCT

(10) International Publication Number
WO 2005/079761 A1

(51) International Patent Classification⁷: **A61K 9/20**,
9/14, 9/68, 9/28

(21) International Application Number:
PCT/US2005/005021

(22) International Filing Date: 16 February 2005 (16.02.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/783,118 17 February 2004 (17.02.2004) US
60/598,629 3 August 2004 (03.08.2004) US

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(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, IS, IT, LT, 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).

Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv)) for US only

Published:

— with international search report

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

(54) Title: COMPOSITIONS FOR DELIVERING HYPNOTIC AGENTS ACROSS THE ORAL MUCOSA AND METHODS OF
USE THEREOF

(57) Abstract: The present invention provides novel compositions for the delivery of a hypnotic agent across the oral mucosa. In particular, the buffer system in the compositions of the present invention raises the pH of saliva to a pH greater than about 7.8, thereby facilitating the substantially complete conversion of the hypnotic agent from its ionized to its un-ionized form. As a result, the dose of hypnotic agent is rapidly and efficiently absorbed by the oral mucosa with surprisingly low inter-subject variability. Furthermore, delivery of the hypnotic agent across the oral mucosa advantageously bypasses hepatic first pass metabolism of the drug and avoids enzymatic degradation of the drug within the gastrointestinal tract. Methods for using the compositions of the present invention for treating sleep disorders such as insomnia are also provided.



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