

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
22 February 2007 (22.02.2007)

PCT

(10) International Publication Number
WO 2007/021805 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/US2006/031153

(22) International Filing Date: 10 August 2006 (10.08.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/707,662 12 August 2005 (12.08.2005) US

(71) Applicant (for all designated States except US):
DRUGTECH CORPORATION [US/US]; 300 Delaware
Avenue, Suite 1270, Wilmington, DE 19801 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **BORTZ, Jonathan**
[US/US]; 8117 Stanford Avenue, St. Louis, MO 63130
(US). **RILEY, Thomas, C.** [US/US]; 5536 Wooded Creek
Drive, St. Charles, MI 63304 (US).

(74) Agent: **FORBERS, James, C.**; **HARNESS, DICKEY &**
PIERCE, P.L.C., 7700 Bonhomme, Suite 400, St. Louis,
MO 63105 (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, HN, HR, HU, ID, IL, IN, IS, JP,
KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT,
LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA,
NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC,
SD, SE, SG, SK, SL, SM, SY, 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, 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, LV, 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).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a
patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the
earlier application (Rule 4.17(iii))

Published:

- without international search report and to be republished
upon receipt of that 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: ESTROGEN COMPOSITIONS AND THERAPEUTIC METHODS OF USE THEREOF

(57) Abstract: A pharmaceutical composition comprises at least one estrogenic compound, the composition being adapted for ap-
plication in a unit dose amount to a vulvovaginal surface and having at least one nonlipoidal internal phase and at least one lipoidal
external phase that is bioadhesive to the vulvovaginal surface, wherein the at least one estrogenic compound is present in an amount
of about 5 to about 1000 µg estradiol equivalent per unit dose of the composition, and upon application of the composition to the vul-
vovaginal surface the at least one estrogenic compound is released over a period of about 3 hours to about 30 days. The composition
is useful for vulvovaginal administration to treat atrophic vaginitis or a disorder associated therewith, for example in a menopausal
or postmenopausal woman. A method for treating a hypoestrogenism-related condition of the urogenital system of a female patient
comprises intravaginal administration of at least one estrogenic compound according to a treatment regimen wherein a series of com-
positions releasing a progressively increasing daily amount of the at least one estrogenic compound is administered over a period of
at least about 1 month.

WO 2007/021805 A2