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**D E C I S I O N**  
**of 3 February 2004**

**Case Number:** W 0016/03 - 3.3.2

**Application Number:** PCT/EP 01/08733

**Publication Number:** -

**IPC:** A61K 31/44

**Language of the proceedings:** EN

**Title of invention:**  
Drugs for sex dysfunctions

**Applicant:**  
NICOX S.A.

**Opponent:**  
-

**Headword:**  
Sex dysfunctions/NICOX S.A.

**Relevant legal provisions:**  
PCT Art. 17(3)a  
PCT R. 40

**Keyword:**  
"Insufficient reasoning"

**Decisions cited:**  
G 0001/89, W 003/93

**Catchword:**  
-



Case Number: W 0016/03 - 3.3.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 3 February 2004

**Applicant:**

NICOX S.A.  
Via G.B. Morgani 2  
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**Representative:**

SAMA PATENTS

**Decision under appeal:**

Protest according to Rule 40.2(c) of the Patent  
Cooperation Treaty made by the applicants  
against the invitation (payment of additional  
fees) of the European Patent Office  
(International Searching Authority) dated ???.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** J. Riolo  
B. Günzel

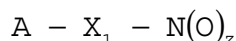
### Summary of Facts and Submissions

I. The applicant filed an international patent application PCT/EP 01/08733 comprising a set of 11 claims, the independent claim of which read as follows:

Claim 1:

"1. Use for the treatment of sex dysfunctions of one or more of the following classes of drugs:

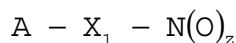
A) salified and non salified nitric oxide donor drugs, of formula



wherein the meaning of the terms appearing in the formula is as defined hereunder;

C) nitrate salts of compounds inhibiting phosphodiesterases;

in the compounds of general formula:



z is an integer and is 1 or 2, preferably 2;

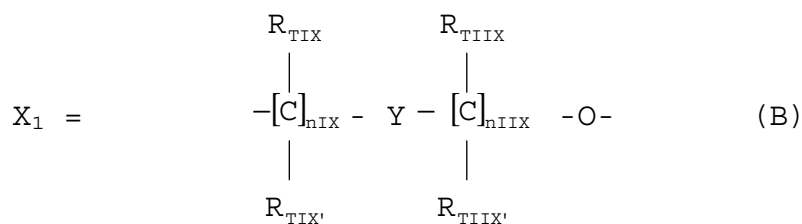
A = R(COX<sub>u</sub>)<sub>t</sub> and wherein t is an integer 0 or 1;

u is 0

or 1;

X = 0, NH, NR<sub>1c</sub> wherein R<sub>1c</sub> is a linear or branched C<sub>1</sub>-C<sub>10</sub> alkyl;

X<sub>1</sub> is the following bivalent linking group:



wherein:

nIX is an integer in the range 0-3;

nIIX is an integer in the range 1-3;

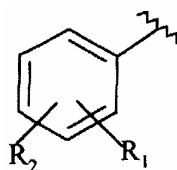
R<sub>TIIX</sub>, R<sub>TIIX'</sub>, R<sub>TIIIX</sub>, R<sub>TIIIX'</sub>, equal to or different from each other are H or a linear or branched C<sub>1</sub>-C<sub>4</sub> alkyl;

Y is an heterocyclic ring containing one or two nitrogen atoms, optionally one oxygen or sulphur atom, said saturated, unsaturated or aromatic ring having 5 or 6 atoms;

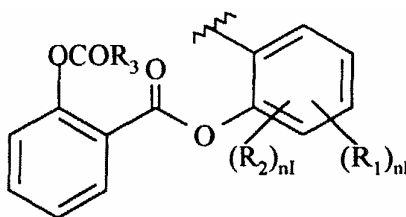
R of the radical A of formula A - X<sub>1</sub> N(O)<sub>z</sub> is selected from the following groups:

Group I) wherein t = 1 and u = 1

Ia)



Ib)



wherein:

R<sub>1</sub> is the OCOR<sub>3</sub> group; wherein R<sub>3</sub> is methyl, ethyl or a linear or branched C<sub>3</sub>-C<sub>5</sub> alkyl, or the residue of an heterocycle having only one ring having 5 or 6 atoms which can be aromatic, partially or totally hydrogenated, containing one or more

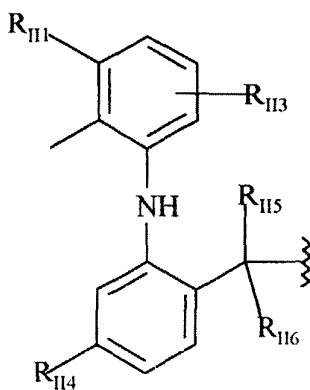
hetero-atoms independently selected from O, N and S;

R<sub>2</sub> is hydrogen, hydroxy, halogen, linear or branched C<sub>1</sub>-C<sub>4</sub> alkyl, linear or branched C<sub>1</sub>-C<sub>4</sub> alkoxy; a linear or branched C<sub>1</sub>-C<sub>4</sub> perfluoroalkyl, for example trifluoromethyl; nitro, amino, mono- or di-(C<sub>1-4</sub>) alkylamino;

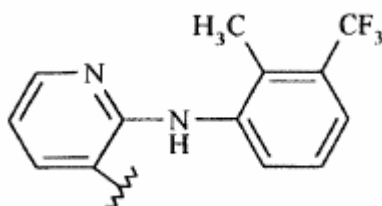
nI is an integer 0 or 1;

group II) wherein t = 1, u = 1

IIa)



IIb)



wherein:

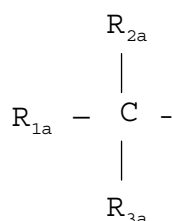
R<sub>II5</sub> is H, linear or branched when possible C<sub>1</sub>-C<sub>3</sub> alkyl; R<sub>II6</sub> has the same meaning as R<sub>II5</sub>, or when R<sub>II5</sub> is H it can be benzyl;

R<sub>III1</sub>, R<sub>II2</sub> and R<sub>II3</sub> can independently be hydrogen, linear or branched when possible C<sub>1</sub>-C<sub>6</sub> alkyl, or

linear or branched when possible C<sub>1</sub>-C<sub>6</sub> alkoxy, or Cl, F, Br;

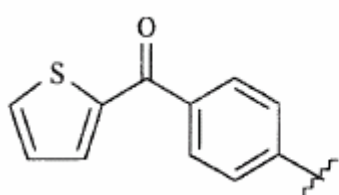
R<sub>II4</sub> is R<sub>III1</sub> or bromine;

IIb) is the residue of the 2-[(2-methyl-3-(trifluoromethyl)phenyl]amino]-3-pyridincarboxylic] acid and when the -COOH group is present it is known as flunixin; group III) wherein t = 1, u = 1 and R is

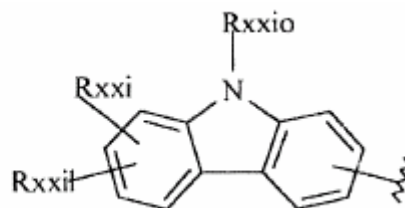


wherein:

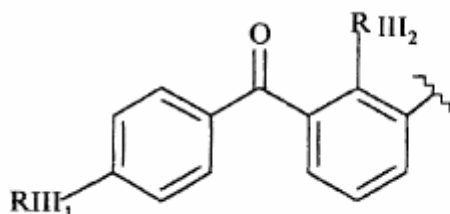
R<sub>2a</sub> and R<sub>3a</sub> are H, linear or branched when possible, substituted or not, C<sub>1</sub>-C<sub>12</sub> alkyl or allyl, with the proviso that if one of the two is allyl the other is H; preferably R<sub>2a</sub> is H, C<sub>1</sub>-C<sub>4</sub> alkyl, R<sub>3a</sub> is H; R<sub>1a</sub> is selected from



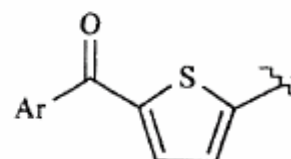
(II)



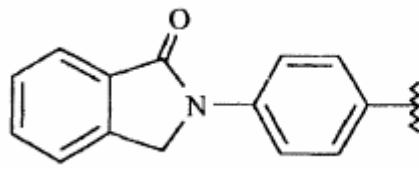
(XXI)



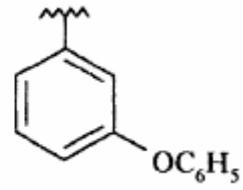
(IV)



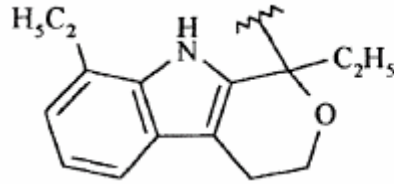
(XXXV)



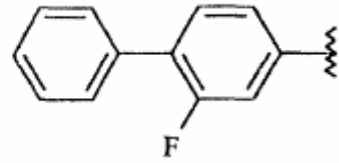
(VI)



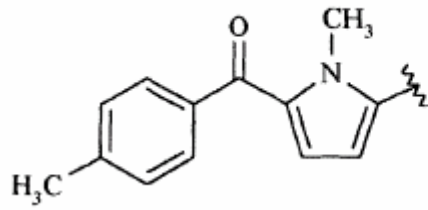
(VII)



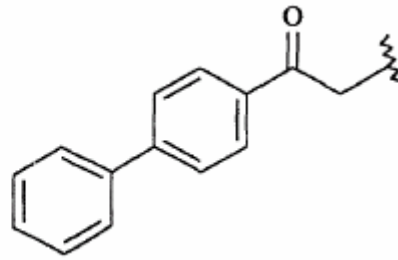
(VIII)



(IX)

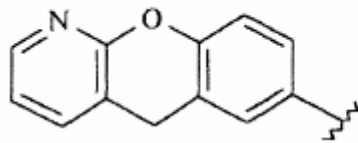


(X)

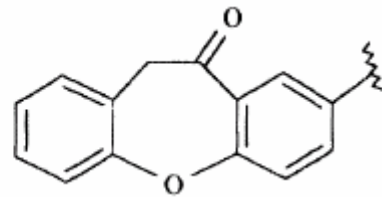


(III)

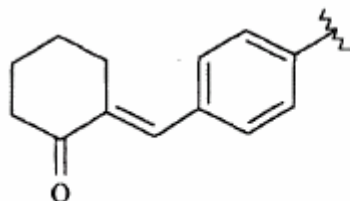
IIID) R<sub>1a</sub> corresponds to the following formulas:



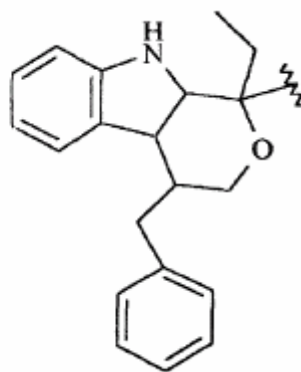
(IIIa)



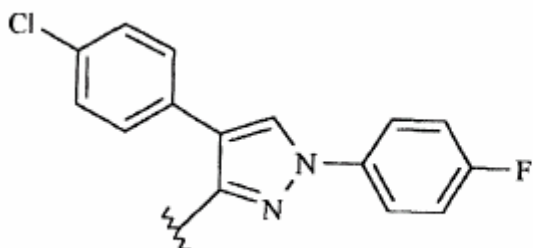
(XXX)



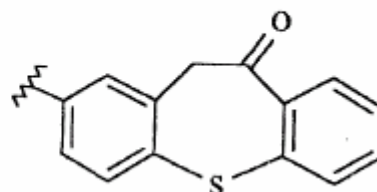
(XXXI)



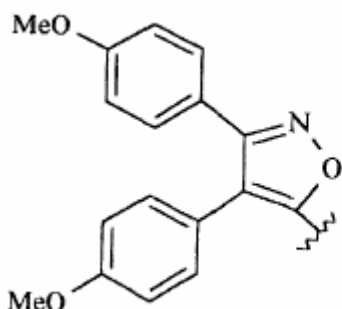
(XXXII)



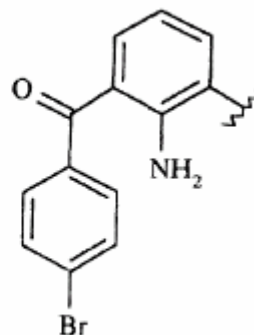
(XXXIII)



(XXXVI)



(XXXVII)



(XII)

wherein the meanings are the following:

- when  $R_{1a}$  is as defined in formula (IV), Ketoprofen residue:  $R_{III1}$  is H,  $SR_{III3}$  wherein  $R_{III3}$  contains from 1 to 4 carbon atoms, linear or branched when possible;  $R_{III2}$  is H, hydroxy;



- when R<sub>1a</sub> is as defined in formula (XXI), carprofen residue: R<sub>xxio</sub> is H, linear or branched when possible alkyl from 1 to 6 carbon atoms, C<sub>1</sub>-C<sub>6</sub> alkoxy carbonyl linked to a C<sub>1</sub>-C<sub>6</sub> alkyl, C<sub>1</sub>-C<sub>6</sub> carboxyalkyl, C<sub>1</sub>-C<sub>6</sub> alkanoyl, optionally substituted with halogens, benzyl or halobenzyl, benzoyl or halobenzoyl;  
R<sub>xxi</sub> is H, halogen, hydroxy, CN, C<sub>1</sub>-C<sub>6</sub> alkyl optionally containing OH groups, C<sub>1</sub>-C<sub>6</sub> alkoxy, acetyl, benzyloxy, SR<sub>xxi2</sub> wherein R<sub>xxi2</sub> is C<sub>1</sub>-C<sub>6</sub> alkyl; C<sub>1</sub>-C<sub>3</sub> perfluoroalkyl; C<sub>1</sub>-C<sub>6</sub> carboxyalkyl optionally containing OH groups, NO<sub>2</sub>, amino; sulphamoyl, dialkyl sulphamoyl with C<sub>1</sub>-C<sub>6</sub> alkyl or difluoroalkylsulphonyl with C<sub>1</sub>-C<sub>3</sub> alkyl;  
R<sub>xxi1</sub> is halogen, CN, C<sub>1</sub>-C<sub>6</sub> alkyl containing one or more OH groups, C<sub>1</sub>-C<sub>6</sub> alkoxy, acetyl, acetamido, benzyloxy, SR<sub>III3</sub> being R<sub>III3</sub> as above defined, C<sub>1</sub>-C<sub>6</sub> perfluoroalkyl, hydroxy, C<sub>1</sub>-C<sub>6</sub> carboxyalkyl, NO<sub>2</sub>, amino, mono- or di-alkyl-amino C<sub>1</sub>-C<sub>6</sub>; sulphamoyl, di-alkyl sulphamoyl C<sub>1</sub>-C<sub>6</sub>, or di-fluoroalkylsulphamoyl as above defined; or R<sub>xxi</sub> together with R<sub>xxi1</sub> is an alkylen dioxy C<sub>1</sub>-C<sub>6</sub>;
- when R<sub>1a</sub> is as defined in formula (XXXV) tiaprofenic acid residue:  
Ar is phenyl, hydroxyphenyl optionally mono or polysubstituted with halogen, alkanoyl and alkoxy C<sub>1</sub>-C<sub>6</sub>, trialkyl C<sub>1</sub>-C<sub>6</sub>, preferably C<sub>1</sub>-C<sub>3</sub>, cyclopentyl, cyclohexyl, cycloheptyl, heteroaryl, preferably tienyl, furyl optionally containing OH, pyridyl;
- when R<sub>1a</sub> is as defined in formula (II), suprofen residue, wherein R<sub>3a</sub> is H, R<sub>2a</sub> is methyl and X = O;

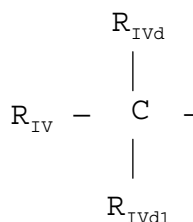
- when  $R_{1a}$  is as defined in formula (VI), R is the residue of indoprofen when  $R_{2a} = H$  and  $R_{3a} = CH_3$ ; of indobufen when  $R_{2a}$  is equal to H and  $R_{3a} = C_2H_5$ ; X = O;
- when  $R_{1a}$  is as defined in formula (VIII), R is the etodolac residue when  $R_{2a} = R_{3a} = H$  and X = O;
- when  $R_{1a}$  is as defined in formula (VII), R is the fenoprofen residue when  $R_{3a} = H$ ,  $R_{2a} = CH_3$  and X = O;
- when  $R_{1a}$  is as defined in formula (III), R is the fenbufen residue when  $R_{2a} = R_{3a} = H$  and X = O;
- when  $R_{1a}$  is as defined in formula (IX), R is the flurbiprofen residue when  $R_{3a} = H$ ,  $R_{2a} = CH_3$ , X = O;
- when  $R_{1a}$  is as defined in formula (X) R is the tolmetin residue when  $R_{2a} = R_{3a} = H$ , X = O;

in group IIID)  $R_{1a}$  corresponds to the following formulas:

- IIIa), when  $R_{2a} = H$  and  $R_{3a} = CH_3$  the pranoprofen residue is obtained:  $\alpha$ -methyl-5H-[1]benzopyran-[2,3-b]pyridin-7-acetic acid; the preferred compound has  $R_{2a} = H$ ,  $R_{3a} = CH_3$ , u = 1 and X = O:
- (XXX), when  $R_{2a} = H$  and  $R_{3a} = CH_3$  the bermoprofen residue is obtained: dibenz[b,f]oxepin-2-acetic acid;
- (XXXI), when  $R_{2a} = H$  and  $R_{3a} = CH_3$ , R is the radical of the CS-670 compound: 2-[4-(2-oxo-1-cyclohexyliden methyl) phenyl]propionic acid;
- (XXXII), when  $R_{2a} = R_{3a} = H$  the Pemedolac residue is obtained;
- (XXXIII), when  $R_{2a} = R_{3a} = H$  the pirazolac residue is obtained: 4-(4-chlorophenyl)-1-(4-fluoro phenyl)-3-pyrazolic acid;

- (XXXVI), when  $R_{2a} = H$ ,  $R_{3a} = CH_3$  the zaltoprofen residue is obtained; when the residue is saturated with an hydroxyl or amino group, or with the carboxylic function the compounds are known as dibenzothiepine derivatives;
- (XXXVII), when  $R_{2a} = R_{3a} = H$  the mofezolac residue is obtained: 3,4-di(p-methoxyphenyl)isoxazol-5-acetic acid;
- (XII), when  $R_{2a} = R_{3a} = H$  the bromfenac residue is obtained: 2-amino-3-(4-bromobenzoyl)benzeneacetic acid;

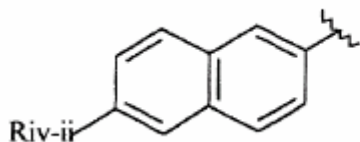
in group IV) wherein  $t = 1$ ,  $u = 1$ , R is



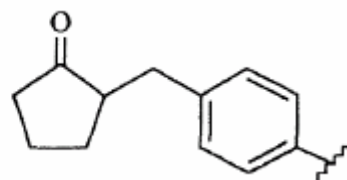
wherein:

$R_{IVd}$  and  $R_{IVd1}$  are at least one H and the other a linear or branched  $C_1$ - $C_6$ , preferably  $C_1$  and  $C_2$  alkyl, or difluoroalkyl with the alkyl from 1 to 6 carbon atoms,  $C_1$  is preferred, or  $R_{IVd}$  and  $R_{IVd1}$  form together a methylene group;

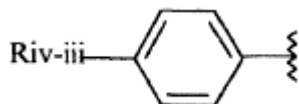
$R_{IV}$  has the following meaning:



(II)



(X)



(III)

wherein the compounds of group IV) have the following meanings:

- in formula (II):

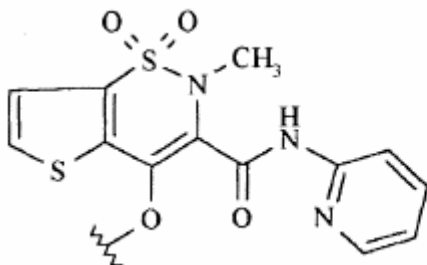
R<sub>iv-ii</sub> is C<sub>1</sub>-C<sub>6</sub> alkyl, C<sub>3</sub>-C<sub>7</sub> cycloalkyl, C<sub>1</sub>-C<sub>7</sub> alkoxyethyl, C<sub>1</sub>-C<sub>3</sub> trifluoroalkyl, vinyl, ethynyl, halogen, C<sub>1</sub>-C<sub>6</sub> alkoxy, difluoroalkoxy, with C<sub>1</sub>-C<sub>7</sub> alkyl, C<sub>1</sub>-C<sub>7</sub> alkoxyethyl, alkylthio methoxy with C<sub>1</sub>-C<sub>7</sub> alkyl, alkyl methylthio with C<sub>1</sub>-C<sub>7</sub> alkyl, cyano, difluoromethylthio, phenyl- or phenylalkyl substituted with C<sub>1</sub>-C<sub>3</sub> alkyl.

- formula (X) loxoprofen residue;

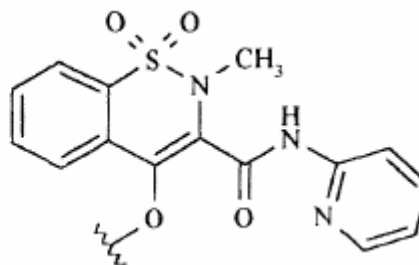
- in formula (III):

R<sub>iv-iii</sub> is a C<sub>2</sub>-C<sub>5</sub> alkyl, optionally branched when possible, C<sub>2</sub> and C<sub>3</sub> alkyloxy, allyloxy, phenoxy, phenylthio, cycloalkyl from 5 to 7 carbon atoms, optionally substituted in position 1 by a C<sub>1</sub>-C<sub>2</sub> alkyl;

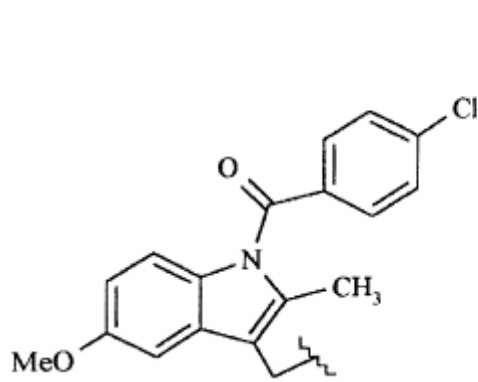
Group V)



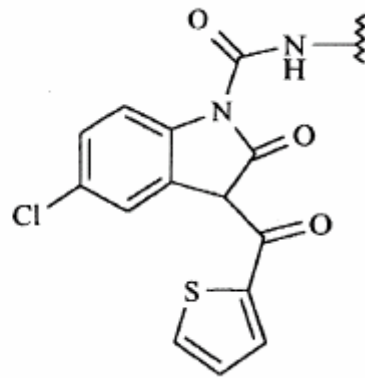
(VII)



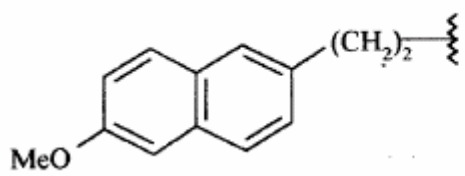
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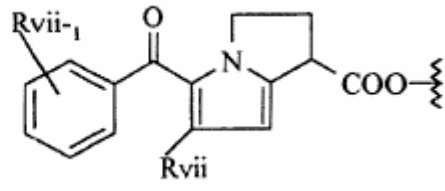
(IV)



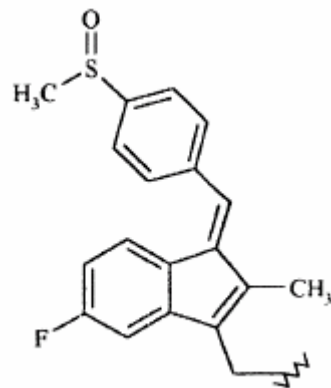
(V)



(III)

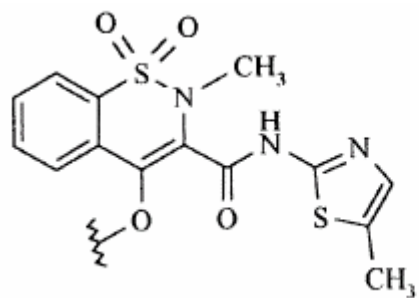


(II)

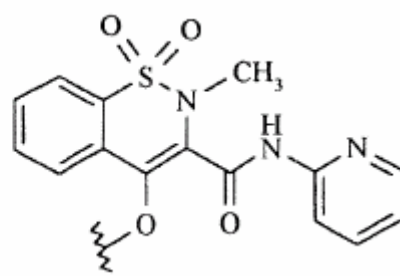


(LX)

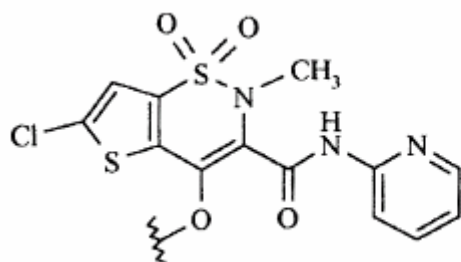
Group VE)



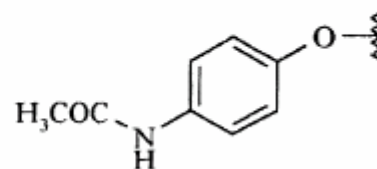
(X)



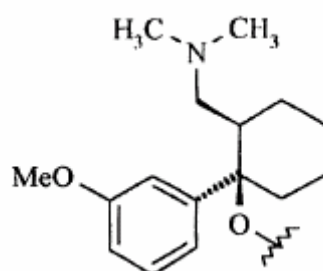
(XI)



(XIII)



(XXXX)



(XXXXI)

In group V) :

- when R is formula (II),  $R_{vii}$  is H or a linear or branched  $C_1$ - $C_4$  alkyl;  
 $R_{vii-1}$  is  $R_{vii}$  or a linear or branched  $C_1$ - $C_4$  alkoxy;  
 Cl, F, Br; the position of  $R_{vii-1}$  being ortho, or meta, or para;
- when R is formula (V)  
 of which the residue of the known tenidap has been indicated;
- when R is formula (V)  $A = R$  and  $t = 0$ ,
- when R is formula (VII),  $A$  is RCO,  $t = 1$   $u = 0$  or  
 $A$  is R and  $t = 0$ ;
- when R is formula (IX),  $A = R$  and  $t = 0$ , or  $A =$   
 RCO with  $t = 1$  and  $u = 0$ ;
- when R is formula (III)  $A = RCOO$ ,  $t = 1$  and  $u = 0$   
 or 1; or  $t = 0$  and  $A = R$ ;
- when R is formula (IV)  $A = RCOO$ ,  $t = 1$  and  $u = 1$ ;

- when R is formula (LX) and in  $(COX_u)_t$   $u = t = 1$  and X is oxygen, the precursor compound is sulindac;
- when R is formula (X) it is the meloxicam residue;
- when R is formula (XI) the residue is known as ampiroxicam when the termination is  $-CH(CH_3)OCOC_2H_5$ ;
- when R is formula (XIII) and the valence is saturated with H, the residue derives from lornoxicam;
- when R is formula (XXXX) and the valence is saturated with H the compound is known as paracetamol;
- when R is formula (XXXXI) and the valence is saturated with H the compound is known as tramadol."

Claims 2 to 11 relate to preferred embodiments of the claimed use.

II. By the communication dated 22 January 2003, the European Patent Office, acting as an International Searching Authority (ISA), invited the applicant pursuant to Article 17(3)(a) and Rule 40.1 PCT to pay 18 additional search fees.

Referring to documents (1) (WO 00/12076), (2) (Helund et al. The Journal of Urology, 1994, 151, 1107-1113) and (3) (US-A-6077841), the ISA found that the use in the treatment of sex dysfunctions of compounds comprising the structural element NO and also the use of nitrate salts of compounds inhibiting phosphodiesterase was known from the prior art documents (1) to (3), and inferred from this finding that there was lack of unity, the claims covering 19 different groups of inventions:

Group 1: claims 1, 7-11 (partially), 2-5 in as far as they relate to the use of compounds of formula A-X1-N(O)<sub>z</sub> in relation to the treatment of sex dysfunctions.

Group 2: claims 1, 6-11 (partially), 2-5 in as far as they relate to the use of nitrate salt of compound C1 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 3: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C2 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 4: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C3 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 5: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C4 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 6: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C5 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 7: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C6 as defined in claim 6 in relation to the treatment of sex dysfunctions.



Group 8: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C7 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 9: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C8 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 10: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C9 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 11: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C10 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 12: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C11 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 13: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C12 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 14: claims 1, 6-11 (partially), 2-5 in as far as they relate to the use of nitrate salt of compound C13 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 15: claims 1, 6-11 (partially), 2-5 in as far as they relate to the use of nitrate salt of compound C14 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 16: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C15 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 17: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C16 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 18: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C17 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Group 19: claims 1, 6-11 (partially), in as far as they relate to the use of nitrate salt of compound C18 as defined in claim 6 in relation to the treatment of sex dysfunctions.

Claim 6 reads:

"6. Use according to claims 1-5, wherein the nitrate salts of the compounds inhibiting the

phosphodiesterase are selected from the following:

(C1) 1-[4-ethoxy-3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazol[4,3-d]-pyrimidin-5-yl)-phenyl]sulphonyl-4-methyl-piperazine (Sildenafil), (C2) 2-(2-propoxyphenyl)-8-azapurin-6-one (Zaprinast), (C3) 2,6-bis-(diethanolamino)-4,8-dipiperidine pyrimido [5,4-d]-pyrimidine (dipyridamol), (C4) 6-chloro-4-(1,3-dioxaindan-5-yl)methylamino-2(4-carboxy-1-piperidinyl)-quinazoline, (C5) N-(phenyl methyl)-1-ethyl-1H-pyrazol-[3,4-b]-quinolin-4-amine, (C6) 1-(2-chlorobenzyl)-3-isobutyryl-2-propyl-6-amino carbonyl-indol, (C7) 1-benzyl-6-chloro-2-[1-[3-(imidazol-1-yl)propyl]indol-5-yl-amino carbonyl]benzimidazol, (C8) 2-(1-imidazolyl)-5-(phenyl)-4-(1,3-dioxaindan-5-yl) methyl aminopyrimidine, (C9) 6-ethynyl-4-(2-methoxyethyl)amino-2-(1-imidazolyl)quinazoline, (C10) 1-cyclopentyl-3-ethyl-6-(2-propoxyphenyl)pyrazol [3,4-d]pyrimidin-4-one, (C11) 1-cyclopentyl-3-ethyl-6-(4-methoxybenzyl)-pyrazol-[3,4-d]-pyrimidin-4-one, (C12) 1,3-dimethyl-6-(2-propoxy-5-methansulphonamidophenyl)-1,5-dihydro pyrazol [3,4-d]-pyrimidin-4-one, (C13) (6R, 12aR)-2,3,6,7,12, 12a-hexahydro-2-methyl-6-(1,3-dioxan-5-yl)pyrazine [2',1':6,1] pyrido [3,4-b]indol-1,4-dione, (C14) 1-propyl-3-methyl-6-[2-propoxy-5-[(4'-methyl-1-pyrazinyl)sulphonamido] phenyl]-1,5-dihydropyrazol[3,4-d]pyrimidin-4-one, (C15) 3-(4-amino carbonyl-1-piperidinyl)-6-cyan-8-(3-chloro-4-methoxy-phthalazine, (C16) 2-(1-imidazolyl)-4-(1,3-dioxaindan-5-yl) methylamino-7,8-dihydro-5H-thiopyran[3,2-d]pyrimidine, (C17) 1-Cyclopentyl-3-ethyl-6-(3-ethoxypyrid-4-yl)-1H-

pyrazolo [3, 4-d]pyrimidin-4-one, (C18) 1-[3-[1-[(4-Fluorophenyl) methyl]-7,8-dihydro-8-oxo-1H-imidazo[4,5-g]quinazolin-6-yl]-4-propoxyphenyl]carboxamide."

III. By its reply faxed 19 February 2003, the applicant paid one additional search fee under protest pursuant to Rule 40.2(c) PCT.

In support of the protest, the applicant argued in its "Statement under Rule 40.2(c)" that documents (1) to (3) did not disclose whether the use of the claimed compounds has a more advantageous therapeutic profile than sildenafil citrate (ie reduced effect on systemic pressure) as required and shown by the claimed invention according to the description of the application (page 2, lines 19-21 and page 25, table 1), so that claims 1 to 11 complied with the requirement of unity of invention.

IV. In a prior review pursuant to Rule 40.2(e) PCT dated 23 June 2003, the ISA found the invitation to pay additional fees to be justified and invited the applicant to pay the protest fee. In substance the Review Panel also considered that, in the light of documents (1) to (3), the presence of the structural element NO in compounds to be used for sexual dysfunction was already known.

V. By a letter of 10 July 2003, the applicant paid the protest fee according to Rule 40.2(e) PCT.

## Reasons for the Decision

1. *General requirements of protest proceedings pursuant to Rule 40.2 PCT*
  - 1.1 Pursuant to Rule 40.2 PCT, the Board must examine the protest and, to the extent that it finds the protest justified, shall order the total or partial reimbursement to the applicant of the additional fees.
  - 1.2 According to the established practice of the Boards of Appeal, the examination in protest proceedings has to be carried out in the light of the reasons given by the ISA in its invitation to pay additional fees under Rule 40.2 PCT and the applicant's submissions in support of the protest. The Board cannot investigate of its own motion whether an objection relating to non-unity of invention might be justified for other reasons not considered in the ISA's invitation to pay additional fees (see W 3/93, OJ EPO 1994, 931).
  - 1.3 A complete and comprehensive reasoning in the ISA's invitation to pay additional fees is therefore mandatory. The necessity of setting out "a logically presented, technical reasoning containing the basic considerations behind the finding of lack of unity in accordance with Annex B to the Administrative Instructions" is underlined in the PCT Search Guidelines (see Chapter VII, 2(a), WIPO, edition 1998) which are binding on the EPO when acting as an ISA and on the Boards of Appeal when deciding on protests against the charging of additional fees (see G 1/89, OJ EPO 1991, 155, point 6).

2. *Sufficiency of reasoning in the ISA invitation*

2.1 In the present case, the ISA's invitation to pay additional fees is based on the allegation that documents (1) to (3) disclose all the features of the invention. This allegation has been contested by the applicant in its above-mentioned "Statement" under Rule 40.2(c) PCT. Therefore, the Board has to examine the relevance of the prior art identified.

2.2 Although documents (1) to (3) disclose the presence of the structural element NO in compounds to be used for sexual dysfunction ((1), page 4, line 11 to page 6, line 28 and page 79, line 27 to page 83, line 28; (2), summary; (3), column 6, line 14 to column 7, line 33), these documents are silent about any **reduced effect on systemic pressure**.

In the absence of any element in the ISA's invitation showing that the compounds described in documents (1) to (3) nevertheless intrinsically possess this particular property and/or that the skilled person reading document (1) to (3) would be aware of that, the Board can only conclude that this functional feature of **reduced effect on systemic pressure** was either not disclosed in documents (1) to (3) or overlooked by the ISA when analysing the features of the invention.

As a matter of fact, the reasoning in the invitation to pay further fees does not consider the above-mentioned aspect (ie a feature relating to an advantageous and surprising technical property, which the compounds are deemed to possess) at all and the communication of the Review Panel also merely states that "the only common

feature between [the compounds recited in claim 1] is the presence of the structural element NO, covalently bound or not, and this particular feature is anticipated by [(2) and (1)]" without any comment or explanation as to the technical common effect achieved by the selected compounds of **reduced effect on systemic pressure**.

As stressed by the applicant in its letter dated 21 February 2003 (page 2, paragraphs 2, 3 and 4 and page 4, paragraphs 4 and 6) and as apparent from the application, this aspect is however a key feature of the claimed invention and, consequently, of the common inventive concept (see, page 1, line 23 to page 2, line 23 and example F1 together with table 1).

This aspect should therefore have been dealt with in the reasoning of lack of unity of the invention. In the absence of such a reference, the objection raised does not comply with the requirements of Rule 40.1 PCT which stipulates that the invitation to pay additional fees "shall specify the reasons for which the international application is not considered as complying with the requirement of unity of invention", in that it is not sufficiently reasoned (see W 17/99 dated 13 January 2000).

- 2.3 The Board therefore finds the applicant's protest entirely justified so that the additional fee and the protest fee must be refunded in accordance with Rule 40.2(e) PCT.

3. The Board is however not competent to judge the protest as far as references to groups 3 to 19 are concerned since no search fees have been paid for these subject-matters.

**Order**

**For these reasons it is decided that:**

The additional search fee and the protest fee are to be reimbursed.

The Registrar:

The Chairman:

A. Townend

U. Oswald