Part 3
to
EXHIBIT J

35. The oligomer of claim 34 wherein the quinoxaline component is selected from the group consisting of a quinoxaline, a (2-imidozolin-2-ylamino) quinoxaline, a 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, derivatives thereof and mixtures thereof.

36. The oligomer of claim 34 wherein the quinoxaline component is a tartrate of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline.

37. The oligomer of claim 34 which is a dimer.

38. The oligomer of claim 35 which is a dimer.

39. The oligomer of claim 36 which is a dimer.

40. A composition comprising:

an alpha-2-adrenergic agonist component in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered;

an oxy-chloro component in an effective amount to at least aid in preserving the composition; and

a liquid carrier component,

wherein the composition is substantially free of cyclodextrins.

41. The composition of claim 40 wherein the alpha-2-adrenergic agonist component is selected from the group consisting of imino-imidazolines, imidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, derivatives thereof and mixtures thereof.

42. The composition of claim 40 wherein the

therapeutically active component includes a quinoxaline component.

43. The composition of claim 42 wherein the quinoxaline component is selected from the group consisting of quinoxaline, derivatives thereof, and mixtures thereof.

44. The composition of claim 40 which further includes a solubility enhancing component in an amount effective to increase the solubility of the alpha-2-adrenergic agonist component in the composition relative to the solubility of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component.

45. The composition of claim 44 wherein the solubility enhancing component is effective to increase the solubility in a biological environment of the alpha-2-adrenergic agonist component relative to the solubility in a biological environment of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component.

46. The composition of claim 44 wherein the solubility enhancing component comprises a polyanionic component.

1936

DECLARATION FOR PATENT APPLICATION

D-2892

As a below named inventor, I hereby declare that:

My residence post office address and citizenship are as stated below next to my name.
I believe I am the original first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS** the specification of which

(check one) [X] is attached hereto
[ ] was filed on
as US Application Serial Number or PCT International Application Number
and was amended on ___ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification,

including the claims, as amended by any amendment referred to above.
I acknowledge the duty to disclose information which is material to the patentability as defined in 37 CFR § 1.56.
I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed. **NONE**

Prior Foreign Application(s)			Priority Not Claimed
			[ ]
(Number)	(Country)	(Day/Month/Year Filed)	

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

60/218,200	July 14, 2000
(Application Number)	(Filing Date)

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s), or §365(c) of any PCT International application designation the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application. NONE

(Application Number)	(Filing Date)	(Status -patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: **Martin A. Voet, Reg. No. 25,208, Robert Baran, Reg. No. 25,806, Carlos A. Fisher, Reg. No. 36,510, Stephen Donovan, Reg. No. 33,433 and Frank J. Uxa, Reg. No. 25,612**

TOOT20 • 5T0Ti0G0

Address all telephone calls to Frank J. Uxa - Telephone: 949-450-1750
Address all correspondence to Frank J. Uxa
4 Venture, Suite 300
Irvine, CA 92618

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor (given name, family name) OREST OLEJNIK

Inventor's signature [signature] Date 7/9/01
Residence Coto de Coza, CA Citizenship U.S.A.
Post Office Address 5 Addington Place
Coto de Coza, CA 92679

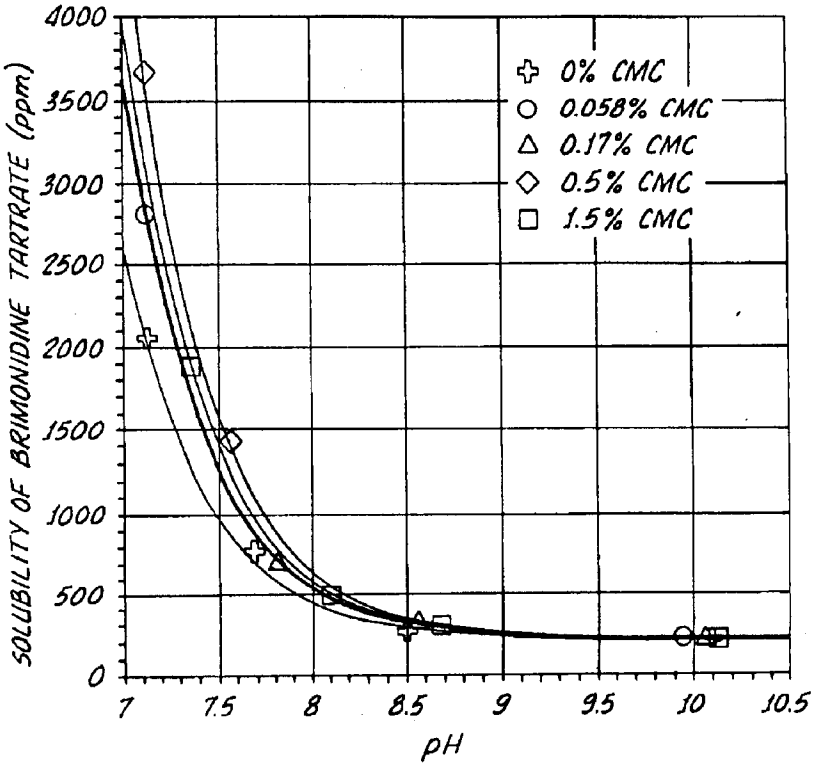
Full name of second inventor (given name, family name) EDWARD D.S. KERSLAKE

Inventor's signature [signature] Date 7/3/2001
Residence Charleston, MA Citizenship ~~U.S.A.~~ U.K
Post Office Address 30 Elm Street, #1
Charleston, MA 02129

26 MOUNT VERNON
CHARLESTOWN
MA, ~~80~~ 02129

PRINT OF DRAW
AS ORIGINALLY FILED

1/1



FILED UNDER SEAL

D-2892

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

In re application of: OLEJNIK ET AL	)	Group Art Unit: N/A
Serial No. N/A	)	Examiner: N/A
Dated: Submitted herewith	)	
For: COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS	)	

Express Mail Mailing Label No. EL608288434US

Date of Deposit: JULY 10, 2001

I hereby certify that the following documents as identified below are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and are addressed to the Assistant Commissioner for Patents, Box New App, Washington, D.C. 20231:

1. Application Transmittal Sheet;
2. Application Data Sheet;
3. New Application;
4. 1 Formal Drawing;
5. Declaration;
6. Recordation Cover Sheet with Assignment;
7. Return postcard.

The 7 above-identified documents are enclosed herewith.

Respectfully submitted,

Janet E. McGhee

Janet E. McGhee, Office of
Frank J. Uxa
Attorney for Applicant
Reg. No. 25,612
4 Venture, Suite 300
Irvine, CA 92618
(949) 450-1750
Facsimile (949) 450-1764

FJUxa/jm

07-13-01 A

S(5 10/97)

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No D-2892
Total Pages in this Submission

jc812 U.S. PTO 07/10/01

J1046 U.S. PTO 09/904018 07/10/01

TO THE COMMISSIONER FOR PATENTS
Box Patent Application
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 CFR 1.53(b) is a new utility patent application for an invention entitled:

COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS

and invented by:

OLEJNIK ET AL

If a CONTINUATION APPLICATION, *check appropriate box an supply the requisite information:*
[ ]**Continuation** [ ]**Divisional** [ ]**Continuation-in-part (CIP)** of prior application No.:

Enclosed are **Application Elements:**

[x] Filing Fee

[x] Specification having 40 page(s) and including the following:

- [x] Title of the Invention
- [X] Cross References to Related Applications *(if applicable)*
- [x] Background of the Invention
- [x] Brief Summary of the Invention
- [x] Description of the Drawings
- [x] Detailed Description
- [x] Claim(s) as Classified Below
- [x] Abstract of the Disclosure

[x] 1 Sheets of Drawings(s) (37 CFR 113) [X] Formal [ ] Informal

[x] Oath or Declaration [x] Executed [ ] Unexecuted
[ ] Copy from prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*

[x] Power of Attorney [x] Executed [ ] Unexecuted
[ ] Copy from prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*

[ ] Incorporation By Reference -- The entire disclosure of the prior application from which a copy of the oath or declaration is supplied under the above entry, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

[ ] Computer Program in Microfiche *(Appendix)*

Accompanying Application Parts

[x] Assignment Papers (cover sheets & documents(s))
[ ] The prior application is assigned of record to
[ ] Copy from prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*

[ ] 37 CFR 3.73(B) Statement *(when there is an assignee)*

[ ] English Translation Document *(if applicable)*

[ ] Information Disclosure .ment/PTO-1449 [ ] Copies of _ Cited Reference(s)
[ ] Preliminary Amendment
[x] Acknowledgment postcard
[ ] Copy from prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*
[x] Certificate of Mailing by Express Mail
[ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*

Fee Calculation and Transmittal

* *The filing fee is calculated on the basis of the claims existing in the prior application as amended by the accompanying preliminary amendment noted above.*

CLAIMS AS FILED					
For	**#Filed**	**#Allowed**	**#Extra**	**Rate**	**Fee**
Total Claims	46	- 20 =	26	X $18.00	$468.00
Independent Claims	6	- 3 =	3	X $80.00	$ 240.00
Multiple Dependent Claims	*(check if applicable)* [ ]				$ 0.00
				BASIC FEE	$710.00
OTHER FEE *(specify purpose) ASSIGNMENT RECORDATION FEE*					$ 40.00
(Applicant has small entity status under 37 CFR 1.9 and 1.27)				**SMALL ENTITY STATUS**	--
				TOTAL FILING FEE	$1458.00

[ ] A check in the amount of $ __ to cover the filing fee and the assignment fee is enclosed.
[x] The Commissioner is hereby authorized to charge and/or credit Deposit Account Number **01-0885** as described below.
  [x] Charge the amount of **$1458.00** as filing fee and assignment fee.
  [x] Credit any overpayment.
  [x] Charge any additional filing fees required under 37 CFR 1.16 and 1.17.

Respectfully Submitted,

Frank J. Uxa
Attorney for Applicants
Registration Number: 25,612

Stout, Uxa, Buyan & Mullins, LLP
4 VENTURE, SUITE 300, IRVINE, CA 92618
phone (949) 450-1750; *fax* (949) 450-1764

OIPE JC41 FEB 12 2002 PATENT & TRADEMARK OFFICE

RECEIVED FEB 15 2002 TECHNOLOGY CENTER 1600/2900

#2 1614

D-2892

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Olejnik et al.)
)
U.S. Serial No: 09/904,018)
)
Filed: July 10, 2001)
)
For: COMPOSITIONS CONTAINING)
ALPHA-2-ADRENERGIC AGONIST)
COMPONENTS)
)

Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicant wishes to call to the attention of the Examiner the copy of the co-pending application cited on the accompanying Form PTO-1449. A copy of the listed reference is enclosed herewith.

Because this IDS is being submitted before the mailing of the first Office Action on the merits, no fee is required. However, if any fee is deemed necessary, the Commissioner is hereby authorized to charge any necessary fee, or credit any overpayment, to Deposit Account No. 01-0885.

OIPE JC41 FEB 12 2002 PATENT & TRADEMARK OFFICE

D-2892

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No concession is made that this document is prior art, and applicant expressly reserves the right to antedate the document as may be appropriate. Applicant requests that this document be made of record in the above-identified application.

Respectfully Submitted

Date: 1/16/02

Frank J. Uxa
Attorney for Applicants
Registration No. 25,612
4 Venture, Suite 300
Irvine, CA 92618
(949) 450-1750
(949) 450-1764 Facsimile

FJUxa/jh

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal service as first class mail in an envelope addressed to:
Commissioner for Patents
Washington, D.C. 20231
on 1/16/02.

Jean F. Heuler

Sheet 1 of 1

Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION
(Use several sheets if necessary)

Docket Number (Optional) D-2892 | Application Number 09/904,018

Applicant OLEJNIK ET AL.

Filing Date July 10, 2001 | Group Art Unit 1614

U. S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	RULING DATE IF APPROPRIATE
	09/903,962	07/10/2001	Olejnik et al.			07/10/2001

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FEB 15 2002
TECH CENTER 1600/2900

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER Rachel W Bennett DATE CONSIDERED 1/8/03

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

1614
#13 D.A.
8-16-02

JC41 -2892
JIPE AUG 0 8 2002 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT

In application of:
Olejnik et al

Serial No. 09/904,018

Filed: July 10, 2001

For: COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS

Group Art Unit: 1614

Examiner: Unknown

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COPY OF PAPERS ORIGINALLY FILED

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on or before

July 31, 2002
Janet McGhee
Title Assistant
Date 7/31/02

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, DC 20231

Dear Sir:

Applicant wishes to call to the attention of the Examiner the documents cited on the accompanying Form PTO-1449. No concession is made that these documents are prior art, and applicant expressly reserves the right to antedate the documents as may be appropriate. This Supplemental Information Disclosure Statement is being filed before the first office action has been received from the Patent and Trademark Office in the above-identified application.

Respectfully submitted,

Frank J Uxa
Attorney for Applicant
Reg. No. 25,612
4 Venture, Suite 300
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(949) 450-1750
Facsimile (949) 450-1764

FJUxa/ac

Sheet 1 of 1

Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

OIPE AUG 0 8 2002 PATENT & TRADEMARK OFFICE

DOCKET NO: D-2892	APPLN. NO.: 09/904,018
APPLICANT: Olejnik et al.	
FILING DATE: 7/10 /01	GROUP ART: 1614

U. S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
VB	3 2 7 8 4 4 7	10/11/86	McNicholas			
VB	5 7 1 9 1 9 7	02/17/98	Kanios et al.			

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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
VB	0 0 1 2 1 3 7	03/09/00	International WIPO				
VB	0 0 1 9 9 8 1	04/13/00	International WIPO				

OTHER DOCUMENTS

EXAMINER: Rachel M. Bennett

DATE CONSIDERED: 1/8/03

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,018	07/10/2001	Orest Olejnik	D-2892	1779

7590 09/18/2002

Frank J. Uxa
Stout, Uxa, Buyan & Mullins, LLP
Suite 300
4 Venture
Irvine, CA 92618

EXAMINER	
BENNETT, RACHEL M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/904,018	OLEJNIK ET AL.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2002* .

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

U.S. Patent and Trademark Office
PTO-326 (Rev. 04-01) Office Action Summary Part of Paper No. 4

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-30, drawn to composition, classified in class 424, subclass 455.

II. Claims 31-33, drawn to complex, classified in class 514, subclass 249.

III. Claims 34-39, drawn to oligmer comprising monomer units, classified in class 514, subclass 1.

IV. Claims 40-46, drawn to a composition comprising oxychloro, classified in class 424, subclass 400.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Group I and Groups II & III are independent and distinct because the complex and oligomer of Groups II & III do not require a solubility enhancing component or an aqueous liquid carrier component as required by Group I.

The inventions of Group I and Group IV are independent and distinct because the composition of Group I does not require the preserving agent as required by Group IV.

The inventions of Group II and III are independent and distinct because the complex of Group II is not a dimmer as required by the oligomer of Group III.

The inventions of Group IV and Groups II & III are independent and distinct because the complex and oligmer of Groups II & III do not require an oxy-chloro component and a liquid carrier as required by the composition of Group IV.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. Because these inventions are distinct for the reasons given above and the search required for Group I and IV is not required for Group II and III, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 309-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett
September 16, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

OIPE JC117 SEP 23 2002 PATENT & TRADEMARK OFFICE

D-26992

GP/1614 RECEIVED SEP 25 2002 TECH CENTER 1600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

In application of:
Olejnik et al

Serial No. 09/904,018

Filed: July 10, 2001

For: COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS

Group Art Unit: 1614

Examiner: Unknown

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on or before September 19, 2002

Title

Date 9/19/02

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, DC 20231

Dear Sir:

Applicant wishes to call to the attention of the Examiner the documents cited on the accompanying Form PTO-1449. No concession is made that these documents are prior art, and applicant expressly reserves the right to antedate the documents as may be appropriate. This Supplemental Information Disclosure Statement is being filed before the first office action has been received from the Patent and Trademark Office in the above-identified application.

Respectfully submitted,

Frank J. Uxa
Attorney for Applicant
Reg. No. 25,612
4 Venture, Suite 300
Irvine, CA 92618
(949) 450-1750
Facsimile (949) 450-1764

FJUxa/ac

OIPE SEP 23 2002 PATENT & TRADEMARK OFFICE

Sheet 1 of 1

Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION
(Use several sheets if necessary)

DOCKET NO: D-2892 | APPLN. NO.: 09/904,818

APPLICANT: Olejnik et al.

FILING DATE: 7/10/01 | GROUP ART: 1614

RECEIVED SEP 25 2002 TECH CENTER 1600/2900

U. S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
RM	3 8 9 0 3 1 9	06/17/75	Danielwicz et al.			
	4 5 3 0 9 2 0	07/23/85	Nestor et al.			
	4 8 0 8 5 5 6	02/21/89	Portoghese			
	5 0 2 1 4 1 8	06/04/91	Gluchowski			
	5 2 0 2 1 2 8	04/13/93	Morella et al.			
	5 3 5 2 7 9 6	10/04/94	Hoeger et al.			
	5 4 5 9 1 3 3	10/17/95	Neufeld			
	5 7 0 3 0 7 7	12/30/97	Burke et al.			
	5 7 2 5 8 8 7	03/10/98	Martin et al.			
	5 8 1 4 6 3 8	09/29/98	Lee et al.			
	5 8 3 4 5 0 2	11/10/98	Cheng et al.			
RM	5 9 9 4 1 1 0	11/30/99	Moabach et al.			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
RM	2 0 4 8 3 1 5	02/09/92	Canada				
	0 6 0 9 9 6 1	08/10/94	European				
	94 / 1 6 6 8 5	08/04/94	~~International~~ WIPO				
	98 / 4 7 8 7 8	10/29/98	~~International~~ WIPO				
	99 / 4 3 2 9 9	09/02/99	~~International~~ WIPO				
RM	99 / 5 1 2 7 3	10/14/99	International				

OTHER DOCUMENTS

EXAMINER Rachel M. Bennett | **DATE CONSIDERED:** 1/8/03

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

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D-2892

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1615 #6 YC 11608

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT

In the application of: Olejnik

Group Art Unit: 1615

Serial No. 09/904,018

Examiner: Bennett, Rachel

Filed: July 10, 2001

For: COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on or

before OCTOBER 16, 2002

Title atty

Date 10/16/02

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is in response to the Examiner's communication mailed September 18, 2002.

Restriction has been required between Group I, claims 1 to 30, drawn to compositions; Group II, claims 31 to 33, drawn to complexes; Group III, claims 34 to 39, drawn to oligmer comprising monomers; and Group IV, claims 40 to 46, drawn to a compositions. Applicant elects the Group I claims. However, applicant traverses the restriction requirement.

Each of the present claims 1 to 46 involve an alpha-2-adrenergic agonist component and/or a quinoxaline component. Thus, each of the present claims is closely related. A search directed to one of the above-noted groups of claims would also be an effective search for the other groups of claims. Therefore, the Patent and Trademark Office is placed under no undue burden in considering all of the present claims in the above-identified application.

In view of the above, applicant requests that the restriction requirement be withdrawn.

Applicant respectfully requests early and favorable action in the above-identified application.

Respectfully submitted,

Frank J. Uxa
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FJU/jm

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Washington, D.C. 20231
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,018	07/10/2001	Orest Olejnik	D-2892	1779

7590 01/15/2003

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EXAMINER
BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/904,018	OLEJNIK ET AL.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b)

Status

1)☒ Responsive to communication(s) filed on *22 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *31-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 11, 13
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

U.S. Patent and Trademark Office
PTO-326 (Rev. 04-01) Office Action Summary Part of Paper No. 7

DETAILED ACTION

The examiner acknowledges receipt of Supplemental Information Disclosure Statement filed 9/23/02.

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that each of the present claims 1 to 46 involve an alpha-2-adrenergic agonist component and/or a quinoxaline component and therefore, each of the present claims is closely related. This is not found persuasive because while the claims are related, they are patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 47-52, 57-62 of copending Application No. 10/236566. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a composition

comprising 5-bromo-6-(2-imidozolin-2-ylamino) quinozaline tartate and 5-bromo-6-(2-imidozolin-2-ylamino) quinozaline in an ophthalmically acceptable formulation while Application 10/236566 claims a composition comprising a tartate of 5-bromo-6-(2-imidozolin-2-ylamino) quinozaline in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered and an aqueous liquid carrier component.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Specification

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1,7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7-8 are indefinite because Applicants do not clearly define "substantially unionized". Clarification is request.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke (US 5215991) and in further view of Remington's Pharmaceutical Sciences.

Burke discloses pharmaceutical compositions of alpha 2 agonists and Na+/H+ exchange inhibitors which are useful in lowering intraocular pressure (IOP) and treatment of intraocular hypertension (see abstract). Preferred imidazoline-derived alpha 2 agonists or pharmaceutically acceptable salts thereof are disclosed in col. 3 (see formula). The most preferred imidazoline-derived alpha 2 agonist compounds include 5-bromo-6-(2-imidazolidine-2-ylamino) quinoaxaline. Doses of alpha 2 agonist in an ophthalmic preparation effective, non-toxic amount of the agonist in a pharmaceutically acceptable liquid, gel, cream or aqueous or nonaqueous liquid suspension or solution are preferably from about 0.001% to about 1.0% weight/volume. Regardless of the preferred range stated herein, one can determine the most efficacious dose for a particular alpha 2 agonist by carrying out a dose response curve as is well known in the art (see col. 4 lines 34-44). Various buffers and means for adjusting pH may be used as long as the resulting preparation is ophthalmically acceptable. Burke does not disclose the solubility enhancing agent to be carboxymethylcellulose or the pH of the composition.

↳ see col. 5 & 6.

Remington discloses carboxymethylcellulose sodium as a known pharmaceutic aid for use as a suspending agent or viscosity-increasing agent (see page 1305).

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Burke by adding carboxymethylcellulose in order to achieve the desired viscosity as taught by Remington. Burke teaches topical ophthalmic preparations, for example ocular drops, gels or creams, are preferred because of ease of application, ease of dose delivery and fewer systemic side effects. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a suitable amount of

carboxymethylcellulose to achieve the desired viscosity in order to ease the application, as taught by Burke. Furthermore, Burke desires the formulation to ophthalmically acceptable. Thus, one of ordinary skill in the art would determine a pH that is suitable for a composition, which is administration into the eye.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett
January 9, 2003



Notice of References Cited	Application/Control No. 09/904,018	Applicant(s)/Patent Under Reexamination OLEJNIK ET AL.	
	Examiner Rachel M. Bennett	Art Unit 1615	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-US005215991A	06-1993	Burke	514/255
*	B	US-US005459133A	10-1995	Neufeld	514/211
	C	US-US 20020071874A1	06-2002	Olejnik et al	424/661
	D	US-US 20020010202 A1	01-2002	Garst	514/392
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Remington's Pharmaceutical Sciences, Eighteenth Edition, 1990, pages 1304-1305.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office
PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 7