Part 3
to
EXHIBIT K

10/299,358

Sheet 2 of 2

Form PTO-1449

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

DOCKET NO: D-2892DIV | APPLN. NO.: N/A

APPLICANT: Olejnik et al.

FILING DATE: Herewith | GROUP ART: N/A

U. S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
RB	3 2 7 8 4 4 7	10/11/66	McNicholas			
	5 7 1 9 1 9 7	02/17/98	Kenios et al.			
RB	09 / 9 0 3 9 6 2	07/10/01	Olejnik et al.			

other ref.

FOREIGN PATENT DOCUMENTS

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

OTHER DOCUMENTS

EXAMINER Rachel Bennett

DATE CONSIDERED: 2/27/03

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.

10299386.111902

D-2892DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

2

In re application of:
OLEJNIK ET AL

Serial No. N/A

Dated: Submitted herewith

For: COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS

Group Art Unit: N/A
(Prior: 1615)

Examiner: N/A
(Prior: Bennett, R.)

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, DC 20231

Sir:

Please amend the above-identified application as follows:

IN THE SPECIFICATION:

On page 1, before the first sentence, add the following paragraph:

--This application is a division of application Serial No.: 09/904,018, filed July 10, 2001, which application claims the benefit of U.S. Provisional Application Serial No. 60/218,200 filed July 14, 2002, the disclosure of each of these applications is hereby incorporated herein in its entirety by reference.--

IN THE CLAIMS:

Cancel claims 1 to 39, without prejudice.

Add new claims 40 to 46 as follows.

40. (New Claim) 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. (New claim) 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.

A2 cont.

42. (New claim) The composition of claim 40 wherein the therapeutically active component includes a quinoxaline component.

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

44. (New claim) 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. (New claim) 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.

A

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A2 cancel

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

REMARKS

Claims 1 to 39 have been canceled, without prejudice. New claims 40 to 46 have been added and are directed to embodiments for which patent protection is sought.

Applicant requests early and favorable action 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

10299586.111902

DOCKET NO.: D-2892DIV

THE ENCLOSED PATENT APPLICATION OF OLEJNIK ET AL IS BEING FILED IN ACCORDANCE WITH SECTION 37 CFR 1.10 BY EXPRESS MAIL AND SHOULD BE ACCORDED A FILING DATE OF:

November 19, 2002

SEE THE EXPRESS MAIL CERTIFICATE ATTACHED TO THE APPLICATION.

10299386.111902

D-2892DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

In re application of: OLEJNIK ET AL	)	Group Art Unit: N/A
	)	(Prior: 1615)
Serial No. N/A	)	
	)	Examiner: N/A
Dated: Submitted herewith	)	(Prior: Bennett, R.)
	)	
For: COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS	)	

Express Mail Mailing Label No. EV059890633

Date of Deposit: November 19, 2002

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. Preliminary Amendment;
4. Copy of Application;
5. 1 Formal Drawing;
6. Copy Declaration;
7. Copy of Assignment Recordation Cover Sheet and Assignment;
8. Information Disclosure Statement and PTO 1449; and
9. Acknowledgment Postcard

The 9 above-identified documents are enclosed herewith.

Respectfully submitted,

Janet C. 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/ac

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.
10/299,386	11/19/2002	Orest Olejnik	D-2892DIV	4927

33197 7590 03/13/2003

STOUT, UXA, BUYAN & MULLINS LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

EXAMINER
BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/13/2003

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

PTO-90C (Rev. 07-01)

Office Action Summary	Application No. 10/299,386	Applicant(s) OLEJNIK ET AL.	
	Examiner Rachel M. Bennett	Art Unit 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 *19 November 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) *40-46* 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) *40-46* 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) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The examiner acknowledges receipt of Preliminary Amendment A filed 11/19/02.

Specification

Double Patenting

1. 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).

2. Claims 40-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 47-66 of copending Application No. 10/236566. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim an alpha –2-adrenergic agonist with an oxy-cholo component.

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

3. Claims 40-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 of copending Application No. 09/903962. Although the conflicting claims are not identical, they are not

patentably distinct from each other because both applications claim an alpha –2-adrenergic agonist with an oxy-cholo component.

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

Claim Rejections - 35 USC § 112

4. 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.

5. Claims 40-46 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. Applicants do not clearly define "substantially free of cyclodextrins" in the claims or the specification. Clarification is requested.

Claim Rejections - 35 USC § 103

6. 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.

7. Claims 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke (US 5215991) in further view of Beck et al. (US .6358935).

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. Benzalkonium choride may be used as a preservative. Vehicles include carboxy methyl cellulose. Burke does not disclose the preservative to be a chlorite component.

Beck discloses compositions including a liquid medium, a cylodextrin component and a preservative component which has a reduced tendency of being complexed with the cyclodextrin component. The clycodextrin component can be in an amount as little as 0.1%. In one embodiment, the preservative component is a chlorite component. Active compounds, such as pharmaceutically active components or drugs, preferably are included in the compositions (see abstracts). For example, the present compositions may include a pharmaceutically effective in providing a therapeutic effect when administered to the eyes of a human or animal. The preservative employed is preferably ophthalmically acceptable at the concentration employed so that the human or animal is effectively treated without significant harm caused by the presence of the preservative (see col. 1). Preferably, the preservative component has in increased or greater preservative efficacy in the composition relative to an identical amount (w/v) of benzalkonium chloride.

Absent unexpected results, 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 substituting the preservative, chlorite as taught by Beck for the benzalkonium choride because of the expectation of increased or greater preservative efficacy as taught by Beck.

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
March 3, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice of References Cited	Application/Control No. 10/299,386	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-US006358935B1	03-2002	Beck et al.	514/58
	C	US-			
	D	US-			
	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	
	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.

OIPE JC175 JAN 21 2003 PATENT & TRADEMARK OFFICE

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D-8892DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT

In the application of:

OLEJNIK ET AL.

Serial No. 10/299,386

Filed: November 19, 2002

For: COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS

Group Art Unit: 1615

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

January 15, 2003

Janet McGee

Title Assist.

Date 1/15/03

REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Please issue a corrected Filing Receipt in the above-identified application to read as follows with regard to the APPLICANT:

Please change applicant's city name from "Coto de Coza" to --Coto de Caza--.

Therefore, applicant requests that a corrected filing receipt be issued, as set forth above, to properly identify the applicant's city.

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

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Commissioner for Patents
Washington, DC 20231
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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
10/299,386	11/19/2002	1614	740	D-2892DIV	1	7	1

CONFIRMATION NO. 4927

33197
STOUT, UXA, BUYAN & MULLINS LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

17361

FILING RECEIPT

OC000000009282947

Date Mailed: 12/23/2002

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

CAZA

Orest Olejnik, Coto de Coza, CA;
Edward D.S. Kerslake, Charlestown, MA;

Assignment For Published Patent Application

Allergan Sales, Inc., Irvine, CA;

Domestic Priority data as claimed by applicant

This application is a DIV of 09/904,018 07/10/2001 which claims benefit of 60/218,200 07/14/2000

Foreign Applications

If Required, Foreign Filing License Granted: 12/20/2002

Projected Publication Date: 04/03/2003

Non-Publication Request: No

Early Publication Request: No

Title

Compositions containing alpha-2-adrenergic agonist components

RECEIVED DEC 30 2002 Stew

Preliminary Class
514

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

OIPE JC37
MAR 17 2003
PATENT & TRADEMARK OFFICE

MAR 19 2003
TECH CENTER 1600/2900

PTO/SB/122 (10-01)
Approved for use through 10/31/2002. OMB 0651-0035
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CHANGE OF CORRESPONDENCE ADDRESS
Application

Address to:
Commissioner for Patents
Washington, D.C. 20231

Application Number	10/299,386
Filing Date	November 19, 2002
First Named Inventor	Olejnik
Art Unit	1615
Examiner Name	NA
Attorney Docket No.	D-2892 DIV

4/ Change of address

Please change the Correspondence Address for the above-identified application to:

☐ Customer Number _____ → _____
OR *Customer Number* *Customer Number Bar Code*

Bet 6-24-03

☒ Firm or Individual Name	Carlos A. Fisher				
Address	Allergan, Inc. 2525 Dupont Drive				
City	Irvine	State	CA	Zip	92627
Country	US				
Telephone	714-246-4920	Fax	714-246-4249		

This form cannot be used to change the data associated with a Customer Number. To change the data associated with an existing Customer Number use "Request for Customer Number Data Change" (PTO/SB/124).

I am the:

☐ Applicant/Inventor.

☐ Assignee of record of the entire interest.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☒ Attorney or Agent of record.

☐ Registered practitioner named in the application transmittal letter in an application without an executed oath or declaration. See 37 CFR 1.33(a)(1). Registration Number _____

Typed or Printed Name	Frank J. Uxa
Signature	Frank J. Uxa
Date	March 10, 2003

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

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

March 10, 2003
Janet McGhee
Title Assist.
Date 3/10/03

OIPE JUN 16 2003 JC22 PATENT & TRADEMARK OFFICE

41

#Gp1626

DOCKET NO. 17361 DIV (AP)
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of Olejnik, et al.

Serial No: 10/299,386

Filed: November 19, 2002

For: COMPOSITIONS CONTAINING ALPHA-2-ADRNERGIC AGONIST COMPONENTS

Group Art Unit: 1626

Examiner: Bennett, R.

5/B e/m 6-13-03

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JUN 18 2003
TECH CENTER 1600/2900

Bet 6-24-03

REPLY TO OFFICE ACTION

This communication is in Reply to the Office Action mailed March 13, 2003. Applicants have carefully studied the Office Action, and respectfully request reconsideration of the claim rejections in light of the claim amendments and comments which follow.

CERTIFICATE OF MAILING
I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL WITH SUFFICIENT POSTAGE IN AN ENVELOPE ADDRESSED TO THE: MAIL STOP AMENDMENT-FEE, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 ON 6/13/2003
Signature of Person Making Deposit: Bonnie Ferguson (BONNIE FERGUSON) Date: 6/12/03

13

AMENDMENTS TO THE CLAIMS

1-39 (Cancelled)

~~40.~~ (Currently amended) A therapeutically effective ophthalmic 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; and
a solubility enhancing component other than a cyclodextrin 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
~~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.~~ (Previously added) The composition of claim ~~40~~ wherein the alpha-2-adrenergic component is selected from the group consisting of imino-imidazolines, inidazolines, imidazoles, azepines, thiazines, oxazolines, guanidines, catecholamines, derivatives thereof, and mixtures thereof.

~~42.~~ (Previously added) The composition of claim ~~40~~ wherein the therapeutically active component includes a quinoxaline component.

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

~~44.~~ (Currently amended) The composition of claim ~~40~~ ~~which further includes a~~ wherein said 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~~ comprises an anionic polymer.

45. (Currently amended) The composition of claim ~~44~~ 42 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. (Currently amended) The composition of claim ~~44~~ 42 wherein the solubility enhancing component comprises ~~a polyanionic component~~ an anionic polymer.

47. (New) The composition of claim 42 wherein said solubility enhancing component comprisers an anionic polymer.

48. (New) The composition of claim 40 which further comprises an effective amount of a preservative.

49. (New) The composition of claim 45 which further comprises an effective amount of a preservative.

REMARKS

The Applicants are in receipt of the Office Action dated March 13, 2003. Following a careful review, the Applicants have the following comments.

Correspondence Address

Kindly note the change of correspondence address filed March 10, 2003. The new correspondence address is:

Carlos A. Fisher
Allergan. Inc.
Legal Department
Mail Stop T2-7
2525 Dupont Dr.
Irvine, CA 92612

Provisional Obviousness Type Double Patenting Rejections

Applicants herewith have filed a Terminal Disclaimer over 1) any patent issuing from US Patent Application Serial No. 10/236,566 and 2) issued United States Patent 6,562,873 (which issued from Serial No. 09/903,962). Thus, the provisional double patenting rejections are now thought to be moot.

35 USC §112

The Examiner rejected claims 40-46 as being allegedly indefinite due to use of the term "substantially free of cyclodextrins". Applicants have now amended claim 40 to state that the solubility enhancing component is other than a cyclodextrin. Thus, this rejection is now thought to be moot.

35 USC 103

The Examiner has rejected claims 40-46 as allegedly unpatentable over Burke (US Patent No. 5,215,991) in view of Beck (US Patent 6,358,935). Applicants respectfully traverse this rejection.

B

The claims have now been amended to set forth the invention in a preferred embodiment thereof. Thus, as now claimed, the invention comprises a therapeutically effective ophthalmic composition containing an alpha -2- adrenergic receptor agonist and a solubility enhancing component.

The Examiner points out that Burke discloses compositions comprising a combination of alpha 2 agonists and Na+/H+ exchanges inhibitors for the treatment of high IOP. These combinations may be in liquid form, either suspensions or solutions. Burke discloses that the combinations claimed may optionally be formulated using various vehicles, including carboxymethyl cellulose, various tonicity agents, and various preservatives, including benzalkonium chloride.

The Examiner also cites Beck for the proposition that an oxychoro component may be used in an ophthalmic formulation. Applicants have amended the claims to remove the necessity for a preservative, this reference is no longer thought to be applicable.

Applicants respectfully maintain that for all its discussion of possible formulations, nothing in Burke discloses or suggests the use of a solubility enhancing component in combination with an alpha adrenergic agonist. The present application, which also discloses the advantages of using such a component (such as greater flexilibity with the concentration and pH at which such composition is formlated, is, to the Applicants' knowledge, the first reference to do so.

For these reasons, the Applicants respectfully request reconsideration and withdrawal of the pending rejections.

If there is a fee, please charge deposit account 01-0885.

Date: 12/13/03 By: Carlos A. Fisher

Carlos A. Fisher
Reg. No. 36,510
ALLERGAN SALES, INC.

Please direct all correspondence to:

Carlos A. Fisher (T2-7H)
Attorney of Record
ALLERGAN, INC.
2525 Dupont Drive
Irvine, CA 92612
Telephone: 714/246-4920
Fax: 714/246-4249

B

OIPE
JUN 16 2003
PATENT & TRADEMARK OFFICE

DOCKET NO. 17361DIV(AP)
PATENT

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6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of Olejnik et al

Serial No: 10/299,386

Filed: November 19, 2002

For: COMPOSITIONS CONTAINING ALPHA-2-AGONIST ADRENERGIC AGONIST COMPONENTS

Group Art Unit: 1615

Examiner: Bennett, R.

Commissioner of Patents
Washington, D.C. 20231

TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER BOTH AN ISSUED PATENT AND A PENDING PATENT APPLICATION

Dear Sir:

The owner, ALLERGAN, INC., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 USC 154 and 156 and 173, as may be presently shortened by any terminal disclaimer, of 1) any patent issuing on co-pending United States Patent Application No.10/236,566 and on 2) issued United States Patent 6,562,873. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it, any patent issuing from the above-identified patent application, and the above-identified patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 USC 154 to 156 and 173 of either 1) any patent issuing from United States Patent Application No. 10/236,566, or 2) issued United States Patent 6,562,873 as presently shortened by any terminal disclaimer, in the event that one

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or both of the latter: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminal disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

The undersigned is an attorney of record.

Date: 6/13/03

By: Carlos A. Fisher

Carlos A. Fisher
Reg. No. 36,510

ALLERGAN SALES, LLC

X Please charge the terminal disclaimer fee under 37 CFR 1.20(d) to Account No. 01-0885. A duplicate of this terminal disclaimer is enclosed.

Please direct all future correspondence to:

Carlos A. Fisher (T2-7H)
Attorney of Record
ALLERGAN, INC.
2525 Dupont Drive
Irvine, CA 92612
Telephone: 714/246-4920
Fax: 714/246-4249

Notice of Allowability	Application No. 10/299,386	Applicant(s) OLEJNIK ET AL.	
	Examiner Rachel M. Bennett	Art Unit 1615	

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment B and Terminal Disclaimer filed 6/16/03*.
2. ☒ The allowed claim(s) is/are *40-49*.
3. ☒ The drawings filed on *19 November 2002* are accepted by the Examiner.
4. ☐ 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 the:
      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)).

   * Certified copies not received: _____.
5. ☒ 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.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☐ CORRECTED DRAWINGS must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. ____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
2☐ Notice of Informal Patent Application (PTO-152)
3☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
4☐ Interview Summary (PTO-413), Paper No.____.
5☐ Information Disclosure Statements (PTO-1449), Paper No. ____.
6☐ Examiner's Amendment/Comment
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8☐ Examiner's Statement of Reasons for Allowance
9☐ Other

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
CENTER 1600

U.S. Patent and Trademark Office
PTO-37 (Rev. 04-03) Notice of Allowability Part of Paper No. 7

DETAILED ACTION

The examiner acknowledges receipt of Amendment B filed 6/16/03.

Terminal Disclaimer

1. The terminal disclaimer filed on 6/16/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of co-pending application 10/236566 and US Pat. 6,562,873 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

2. Claims 40-49 are allowed.

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.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
CENTER 1600

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 08/04/2003

CARLOS A. FISHER
ALLERGAN, INC.
2525 DUPONT DRIVE
IRVINE, CA 92627

EXAMINER	
BENNETT, RACHEL M	
ART UNIT	**CLASS-SUBCLASS**
1615	424-078040

DATE MAILED: 08/04/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/299,386	11/19/2002	Orest Olejnik	D-2892DIV	4927

TITLE OF INVENTION: COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$300	$1600	11/04/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
A, If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (REV. 05-03) Approved for use through 04/30/2004.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
Alexandria, Virginia 22313-1450
Fax **(703)746-4000**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

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CARLOS A. FISHER
ALLERGAN, INC.
2525 DUPONT DRIVE
IRVINE, CA 92627

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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/299,386	11/19/2002	Orest Olejnik	D-2892DIV	4927

TITLE OF INVENTION: COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$300	$1600	11/04/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
BENNETT, RACHEL M	1615	424-078040

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

☐ Issue Fee
☐ Publication Fee
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) (Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE(S)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/299,386	11/19/2002	Orest Olejnik	D-2892DIV	4927

7590 08/04/2003

CARLOS A. FISHER
ALLERGAN, INC.
2525 DUPONT DRIVE
IRVINE, CA 92627

EXAMINER	
BENNETT, RACHEL M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/04/2003

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.

PTOL-85 (REV. 05-03) Approved for use through 04/30/2004.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/299,386	11/19/2002	Orest Olejnik	D-2892DIV	4927

7590 08/04/2003

CARLOS A. FISHER
ALLERGAN, INC.
2525 DUPONT DRIVE
IRVINE, CA 92627
UNITED STATES

EXAMINER	
BENNETT, RACHEL M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/04/2003

Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003: Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: http://www.uspto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (REV. 05-03) Approved for use through 04/30/2004.

OIPE JC17
Aug 8, 2003
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PART B - FEE(S) TRANSMITTAL

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Commissioner for Patents
Alexandria, Virginia 22313-1450
Fax (703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

7590 08/04/2003

CARLOS A. FISHER
ALLERGAN, INC.
2525 DUPONT DRIVE
IRVINE, CA 92627

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

Bonnie Ferguson (Depositor's name)
(Signature)
8/12/2003 (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/299,386	11/19/2002	Orest Olejnik	D-2892DIV	4927

TITLE OF INVENTION: COMPOSITIONS CONTAINING ALPHA-2-ADRENERGIC AGONIST COMPONENTS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1300	$300	$1600	11/04/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
BENNETT, RACHEL M	1615	424-078046

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Frank J. Uxa
2 Carlos A. Fisher
3 Martin A. Voet

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Allergan, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Irvine, California USA

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☒ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:
☒ Issue Fee
☒ Publication Fee
☒ Advance Order - # of Copies 10

4b. Payment of Fee(s):
☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number 01-0885 (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) Carlos A Fisher (Date) 8/12/03

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

08/18/2003 KHERNE1 00000094 010885 10299386
01 FC:1501 1300.00 DA
02 FC:8001 30.00 DA
03 FC:1504 300.00 DA

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10299386.111902

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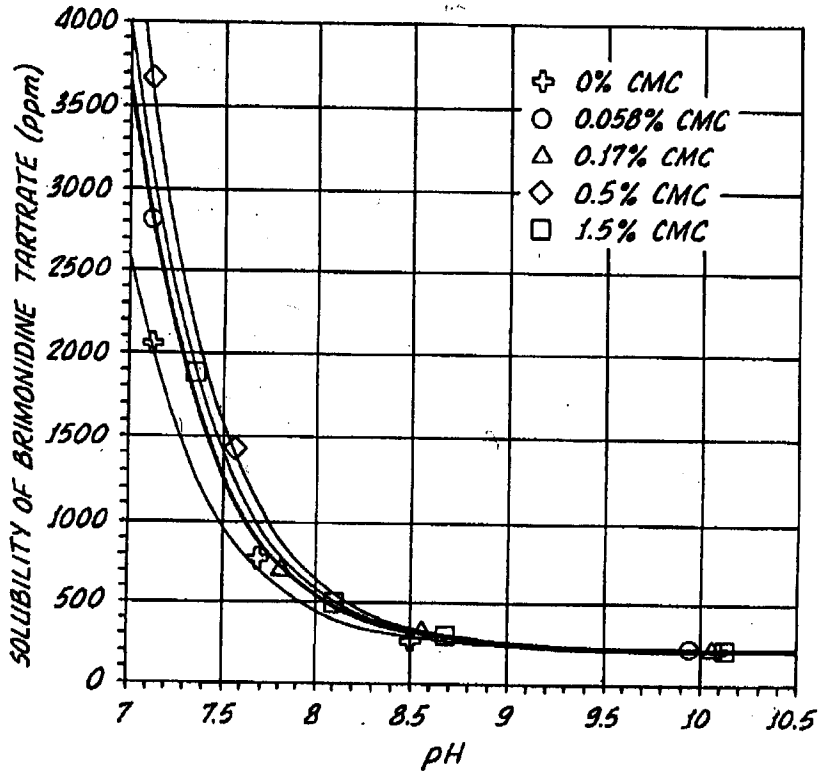
FIG. 1



CLAIMS ONLY

SERIAL NO.	FILING DATE

APPLICANT(S)

CLAIMS

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT			*		*		*	
	IND.	DEP.	IND.	DEP.	IND.	DEP.		IND.	DEP.	IND.	DEP.	IND.	DEP.
1							51						
2							52						
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37							87						
38							88						
39							89						
40	1						90						
41		1					91						
42		1					92						
43		1					93						
44		1					94						
45		1					95						
46		1					96						
47							97						
48							98						
49							99						
50							100						
TOTAL IND.	1						TOTAL IND.						
TOTAL DEP.	6						TOTAL DEP.						
TOTAL CLAIMS	7						TOTAL CLAIMS						

* MAY BE USED FOR ADDITIONAL CLAIMS OR ADMENDMENTS

FORM PTO-2022 (1-98)

U.S.DEPARTMENT OF COMMERCE
Patent and Trademark Office

*U.S. GPO: 1998-443-593/69152

PATENT APPLICATION FEE DETERMINATION RECORD
Effective October 1, 2001

Application or Docket Number: 10299374

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	7	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	7 minus 20=	* 0
INDEPENDENT CLAIMS	1 minus 3 =	* 0
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	370.00	OR	BASIC FEE	740.00
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL		OR	TOTAL	740

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 10	Minus	** 20	=
Independent	* 1	Minus	*** 3	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X42=		OR	X84=	
+140=		OR	+280=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875 (Rev. 8/01)

☆U.S. GPO:2001 483-124 / 59197

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AGN0221786