IN THE UNITED STATES PATENT AND TRADEMARK OFFICE IN RE APPLICATION OF: YOSHIHIRO FUJIKAWA ET AL

FILED: HEREWITH

FOR: QUINOLINE TYPE MEVALONOLACTONES

#### REQUEST FOR PRIORITY, 35 U.S.C. \$120

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

SIR:

Full benefit of the filing date of U.S. Application Serial No. 07/233,752, filed AUGUST 19, 1988, is claimed pursuant to the provisions of 35 U.S.C. §120. Applicants further claim any right to priority from any earlier filed applications to which they may be entitled pursuant to the provisions of 35 U.S.C. §119.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon Registration No.: 24,618

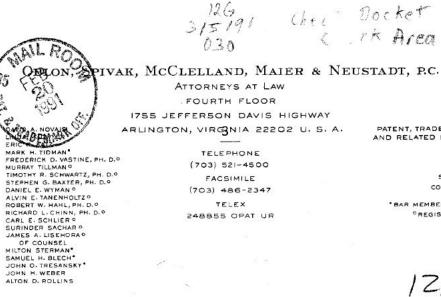
Steven B. Kelber Registration No.: 30,073 Attorneys of Record

Fourth Floor 1755 South Jefferson Davis Highway Arlington, Virginia 22202 703-521-5940

Docket: 49-146-0 CONT

3/8/91 2 40

NORMAN F. OBION MARVIN J. SPIVAK C.IRVIN MCCLELLAND GREGORY J. MAIER ARTHUR I. NEUSTADT ROBERT C. MILLER RICHARD D. KELLY JAMES D. HAMILTON ECKHARD D. KELLY JAMES D. HAMILTON ECKHARD D. KELLY JAMES D. HAMILTON ECKHARD D. KELST CHARLES L. GHOLZ VINCENT J. SUNDERDICK\* WILLIAM E. BEAUMONT STEVEN B. KELBER\* STUART D. OWORK ROBERT F. GNUSE JEAN-FAUL LAVALLEYE, PH. D. JEFFREY H. KAUFMAN BRIAN D. ANDERSON\* ROBERTA S. BREN\*



PATENT, TRADEMARK AND COPYRIGHT LAW AND RELATED FEDERAL AND ITC LITIGATION

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IRVING MARCUS 1919-1982 STANLEY P. FISHER COUNSEL TO THE FIRM \*BAR MEMBERSHIP OTHER THAN VIRGINIA "REGISTERED PATENT AGENT

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#### DOCKET NO.: 49-146-0 CONT

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

IN RE APPLICATION OF: YOSHIHIRO FUJIKAWA ET AL SERIAL NUMBER: 07/631,092 FILED: DECEMBER 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES

SIR:

Attached hereto for filing are the following papers:

SECOND PRELIMINARY AMENDMENT AND UNEXCUTED RULE 132 DECLARATION

Our check in the amount of \$ -0- is enclosed covering any required fees. In the event of any variance between the amount enclosed and the Patent Office Charges, please charge or credit the difference to our Deposit Account No. 15-0030. A duplicate copy of this letter is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon Registration No.: 24,618

4S Steven B. Kelber 30,073 Registration No.:

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NORMAN F. OBLON MARVIN J. SPIVAK C.IRVIN MCCLELLAND GREGORY J. MAIER ARTHUR I. NEUSTADT ROBERT C. MILLER RICHARD D. KELLY JAMES D. HAMILTON ECHARDE D. KUESTERS ROBERT T. POUS DAVID J. KERA CHARLES L. GHOLZ VINCENT J. SUNDERDICK\* WILLIAM E. BEAUMONT STEVEN B. KELBER\* STUART D. OWORK ROBERT F. GNUSE JEAN-PAUL LAVALLEYE, PH. D. JEFFREY H. KAUFMAN BRIAN D. ANDERSON\* ROBERTA S. BREN\*

OBLON SPITAR, MCCLELLAND, MAIER & NEUSTADT, P.C. Attorneys at Law FOURTH FLOOR 1955 JEFFERSON DAVIS HIGHWAY 2U199 ARLINGTON, VIRGINIA 22202 U. S. A.

DAVID ANOVAIS LINDA M. DWYER' RECE.R. KATE MARK H. TIDMAN' FREDERICE D. WASTINE, PH. D.O MURAY TILLMAN' TIMOTHY R. SCHWARTZ, PH. D.O DANIEL E. WYMAN' ALVIN E. TANENHOLTZ ' ROBERT W. HAHL, PH. D.O CARL E. SCHLER O SURINDER SACHAR' JAMES A. LISEMORA' OF COUNSEL MILTON STERMAN' SAMUEL H. BLECH' JOHN D. RESANSKY' JOHN H. WEBER ALTON D. ROLLINS

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TELEPHONE (703) 521-4500 FACSIMILE (703) 486-2347 TELEX 248855 OPAT UR PATENT, TRADEMARK AND COPYRIGHT LAW AND RELATED FEDERAL AND ITC LITIGATION IRVING MARCUS 1919-1982 STANLEY P. FISHER COUNSEL TO THE FIRM BAR MEMBERSHIP OTHER THAN VIRGINIA REGISTERED PATENT AGENT

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#### DOCKET NO.: 49-146-0 CONT

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

IN RE APPLICATION OF: YOSHIHIRO FUJIKAWA ET AL SERIAL NUMBER: 07/631,092 FILED: DECEMBER 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES

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SIR:

, \* <sup>\*</sup>

Attached hereto for filing are the following papers:

PRELIMINARY AMENDMENT AND UNEXCUTED RULE 132 SECOND DECLARATION

Our check in the amount of \$ -0- is enclosed covering any required fees. In the event of any variance between the amount enclosed and the Patent Office Charges, please charge or credit the difference to our Deposit Account No. 15-0030. A duplicate copy of this letter is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon Registration No.: 24,618

Steven B. Kelber

Registration No.: 30,073

≠5/PreC. V.V. 19 Mar 1991



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:	:	121
YOSHIHIRO FUJIKAWA ET AL	:	GROUP ART UNIT: 129
SERIAL NUMBER: 07/631,092		EXAMINER: Richer
FILED: DECEMBER 19, 1990	:	
FOR: QUINOLINE TYPE MEVALONOLAC	TONES	9

#### SECOND PRELIMINARY AMENDMENT

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

SIR:

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Prior to prosecution on the merits, entry of the following amendments is respectfully requested.

#### IN THE CLAIMS:

Claim 41, line 6, please delete "-COOH, COONa, COOR" and insert therefore \_\_\_ -CH(OH)-CH<sub>2</sub>-CH(OH)-CH<sub>2</sub>-COOH, -CH(OH)-CH<sub>2</sub>-CH(OH)-CH<sub>2</sub>-COONa, -CH(OH)-CH<sub>2</sub>-CH(OH)-CH<sub>2</sub>-COOR ] --.

#### **REMARKS:**

Applicants have amended independent Claim 41, to correct

inadvertent typographical errors in the original Preliminary Amendment. No new matter is introduced thereby, the original disclosure appearing, e.g., in Claim 2 of the application as filed.

Upon entry, the claims are believed in conformance with the requirements of Title 35, and in condition for examination on the merits. The same is respectfully requested, in light of the Declaration submitted herewith. Applicants are submitting at this time, an unexecuted Declaration, an executed Declaration will be submitted when available.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon Registration No.: 24,618

Steven B. Kelber Registration No.: 30,073 Attorneys of Record

Fourth Floor 1755 South Jefferson Davis Highway Arlington, Virginia 22202 703-521-5940

# IN THE UNEQUED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:	:	
YOSHIHIRO FUJIKAWA ET AL	:	GROUP ART UNIT: 129
SERIAL NUMBER: 07/631,092		EXAMINER:
FILED: DECEMBER 19, 1990	:	20
FOR: QUINOLINE TYPE MEVALONOLAC	TONES	

# DECLARATION UNDER 37 CFR \$1.132

# HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

SIR:

I, YOSHIHIRO FUJIKAWA, do hereby declare and state that:

 I am a named co-inventor in the above-captioned patent application, an employee of Nissan Chemical Industries, Limited, and a citizen and resident of Japan.

I am familiar with the above-captioned patent application,
 and Claims 41 - 45 presented by Amendment therein.

3. To demonstrate the unobvious superiority of the subject matter claimed in Claims 41 - 45, comparatives tests were

conducted, demonstrating the importance and unobvious superiority conferred on these compounds by the selection of the cyclopropyl substituent. These are described as follows:

Data was obtained with regard to the following compound having

the formu		OH OH CO2Na			
	QQI	<sub>R</sub> 5		TEST METHOD	
Compound	<u>R<sup>5</sup></u>	Compound No.	Test A <u>Evaluation</u>	Test B <u>Evaluation</u>	Test C Evaluation
Compound * of this Invention	c-Pr	I-520	4.2 x 10 <sup>-9</sup>	17.5 x 10 <sup>-9</sup>	55% (0.05 mg/kg)
Reference** Compound	i-Pr	I-51	10 x 10 <sup>-9</sup>	100 x 10 <sup>-9</sup>	65% (0.2 mg/kg)
Reference** Compound	* CS-514	CS-514	9.0 x 10 <sup>-9</sup>	350 x 10 <sup>-9</sup>	55% 10.0 mg/km

Given at page 71 of the specification Given at page 41 of the specification Given at page 33 of the specification

#### Test A: Inhibition of cholesterol biosynthesis from acetate in vitro Inhibition . 6

This test was carried out as described on pages 28 - 29 of the specification. The above numerical values indicate  $IC_{50}$  (molar

concentration).

#### Test B: <u>Inhibition of cholesterol</u> <u>biosynthesis in culture cells</u>

This test was carried out as described on pages 29 to 30 of the specification. The above numerical values indicate  $IC_{50}$  (molar concentration).

# Test C: <u>Inhibition of cholesterol</u> <u>biosynthesis in vivo</u>

This test was carried out as described on pages 30 to 31 of the specification. The above numerical values indicate inhibition percent and the numerical values in parenthesis indicate "administration amounts" (mg/kg).

In tests A and B, CS-514 is an optical isomer, and was administered in an amount of 1.25 mg. However, the other compounds are racemic compounds, and were administered in double amounts, i.e., 2.50 mg.

4. Based on the data reported above, it can be determined that the compounds of this invention exhibit unobvious superiority, and in particular, sharply enhanced inhibition of cholesterol

biosynthesis, in in vitro, culture cell, and in vivo testing, when compared with referenced compounds of the prior art, and compounds having an identical structure save for the selection of cyclopropyl, as opposed to isopropyl substituent, for R<sup>5</sup>. This enhanced activity could not be predicted on the basis of structure, or information available to those of ordinary skill in the art as of the effective filing date of this application.

All statements made herein of my own knowledge are true, and all statements made on information and belief are believed true. I am aware that willful false statements and the like are punishable by fine, imprisonment or both, 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the above-captioned patent application and any patent issuing thereon.

FURTHER, I SAYETH NOT.

DATE:

YOSHIHIRO FUJIKAWA

Sawai Ex 1003 Page 122 of 175

#6 GP # Oblon, Spivak, McClelland, Maier & Neustadt, p.c. ATTORNEYS AT LAW FOURTH FLOOR 1755 JEFFERSON DAVIS HIGHWAY DAVID A. NOVAIS LINDA M. DWYER\* ERIC R. KATZ MARK H. TIDMAN' ALAN HOLLER LAURA TERLIZZI' FREDERICK D. VASTINE, PH.D.° MURRAY TILLMAN' TIMOTHY R. SCHWARTZ, PH.D.° STEPHEN G. BAXTER, PH.D.° STEPHEN G. BAXTER, PH.D.° CARLE. WYMAN' ROBERT W. HAHL, PH.D.° RICHARD L. CHINN, PH.D.° CARLE. SCHLIER\* SURINOER SACHAR' JAMES A. LISEHORA' ANDREW D. FORTNEY, PH.D.° MARC R. LABGOLO, PH.D.° OF COUNSEL MILTON STERMAN' SAMUEL H. BLECK' JOHN H. WEBER ALTON D. ROLLINS PATENT, TRADEMARK AND COPYRIGHT LAW AND RELATED FEDERAL AND ITC LITIGATION NORMAN F. OBEAN MARVIN J. SPIVAR C. IRVIN MCCLELLAND GREGORY J. MAIER ARTHUR I. NEUSTADT ROBERT C. MILLER RICHARD D. KELLY JAMES D. HAMILTON ECKHARD H. KUESTERS ROBERT J. POUS DAVID J. KERA CHARLES L. GHOLZ VINCENT J. SUNDERDICK\* WILLIAM E. BEAUMONT STEVEN B. KELBER\* STUART D. DWORK ROBERT F. GNUSE JEAN-PAUL LAVALLEYE, PH. D. JEFFREY H. KAUFMAN BRIAN D. ANDERSON\* ROBERTA S. BREN\* WILLIAM B. WALKER\* ARK ARLINGTON, VIRGINIA 22202 U.S.A. IRVING MARCUS TELEPHONE 1919-1982 (703) 521-4500 STANLEY P. FISHER FACSIMILE COUNSEL TO THE FIRM (703) 486-2347 WEST COAST OFFICE TELEX 2021 THE ALAMEDA, SUITE 110 248855 OPAT UR SAN JOSE, CALIFORNIA 95126 TELEPHONE (408) 345-3890 FACSIMILE (408) 345-3898 BAR MEMBERSHIP OTHER THAN VIRGINIA REGISTERED PATENT AGENT DOCKET NO.: 49-146-0 CONT 2 HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231 IN RE APPLICATION OF: 3/15/51 YOSHIHIRO FUJIKAWA ET AL SERIAL NUMBER: 07/631,092 FILED: DECEMBER 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES SIR: 630 Attached hereto for filing are the following papers: EXCUTED RULE 132 DECLARATION where

Our check in the amount of \$ -0- is enclosed covering any required fees. In the event of any variance between the amount enclosed and the Patent Office Charges, please charge or credit the difference to our Deposit Account No. 15-0030. A duplicate copy of this letter is enclosed.

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#### Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon Registration No.: 24,618

Steven B. Kelber Registration No.: 30,073

#### Oblon, Spivak, McClelland, Maier & Neustadt, p.c. ATTORNEYS AT LAW FOURTH FLOOR

1755 JEFFERSON DAVIS HIGHWAY

ARLINGTON, VIRGINIA 22202 U.S.A.

DAVID A. NOVAIS LINDA M. OWYER" ERIC R. KATZ MARK H. TIDMAN" ALAN HOLLER LAURA TERLIZI" MEDERICK D. VASTINE, PH. D." MURRAY TILLMAN" TIMOTHY R. SCHWARTZ, PH. D." STEPHEN G. BAXTER, PH. D." STEPHEN G. BAXTER, PH. D." DANIEL E. WYMAN" ROBERT W. MAHL, PH. D." CARL E. SCHLIER" SURINDER SACHAR" JURINDER SACHAR" JURINDER SACHAR" JOHN O. FORTHER, PH. D." MARC R. LØBOLD, PH. D." MARC R. LØBOLD, PH. D." MARC R. LØBOLD, PH. D." D'COUNSEL MILTON STERMAN" SAMUEL H. BLECH" JOHN O. TRESANSK" JOHN N. WEERR ALTON D. ROLLINS KERA L. GHOL J. SUNDERL E. BEAUMONT B. KELBER\* D. DWORK HANGHUSE AUL LAYARLEYE, PH. D. CYHI, KAUFMAN ANDERSON BREMO DOCKET NO.: 49-146-0 CONT

TELEPHONE (703) 521-4500 FACSIMILE (703) 486-2347 TELEX 248855 OPAT UR

IRVING MARCUS 1919-1982 STANLEY P. FISHER COUNSEL TO THE FIRM

PATENT, TRADEMARK AND COPYRIGHT LAW AND RELATED FEDERAL AND ITC LITIGATION

WEST COAST OFFICE 2021 THE ALAMEDA, SUITE 110 SAN JOSE, CALIFORNIA 95126 TELEPHONE (408) 345-3890 FACSIMILE (408) 345-3898

BAR MEMBERSHIP OTHER THAN VIRGINIA REGISTERED PATENT AGENT

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HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS ARK MASHINGTON, DC 20231

IN RE APPLICATION OF: YOSHIHIRO FUJIKAWA ET AL SERIAL NUMBER: 07/631,092 FILED: DECEMBER 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES

SIR:

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NORMAN F. OBLON MARVIN J. SPIVAK C. IRVIN MCCLELLAND GREGORY J. MAIER ARTHUR I. NEUSTADT ROBERT C. MILLER RICHARD D. KELLY JAMES O. HAMILTON ECKHARD H. KUESTERS ROBERT T. POUS CHARLES L. GHOLZ VINCENT J. SUNDEROICK<sup>4</sup> WILLIAM E. BEAUMONT

22

Attached hereto for filing are the following papers:

**EXCUTED RULE 132 DECLARATION** 

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Respectfully submitted,

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon Registration No.: 24,618 tet 1

Steven B. Kelber Registration No.: 30,073

#6

APR IN THE UNITED STATES PATENT AND TRADEMARK OFFICE IN RE APPLICATION OF: YOSHIHIRO FUJIKAWA ET AL SERIAL NUMBER: 07/631,092 FILED: DECEMBER 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES

#### SUBMISSION OF EXECUTED DECLARATION

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

SIR:

Applicants submit herewith the executed Declaration of Kitahara in the above-captioned patent application. The Declaration is identical to that submitted with the Preliminary Amendment of February 20, 1991, save for the fact that the name of the Declarant has been changed from Fujikawa to Kitahara. The content of the Declaration, particularly the demonstration of unobvious impact of the substuent of  $R^5$  as cyclopropyl, to which all pending claims are limited, is clearly made out by the Declaration. Entry and consideration is respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon Registration No.: 24,618

Steven B. Kelber Registration No.: 30,073 Attorneys of Record

Fourth Floor 1755 South Jefferson Davis Highway Arlington, Virginia 22202 703-521-5940

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION OF: YOSHIHIRO FUJIKAWA ET AL SERIAL NUMBER: 07/631,092 FILED: DECEMBER 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES

GROUP ART UNIT: 129 **EXAMINER:** 

#6

4/25/91

0109

#### DECLARATION UNDER 37 CFR \$1.132

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

SIR:

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1

Ι. Masaki Kitahara , do hereby declare and state that:

I am a named co-inventor in the above-captioned patent 1. application, an employee of Nissan Chemical Industries, Limited, and a citizen and resident of Japan.

2. I am familiar with the above-captioned patent application, and Claims 41 - 45 presented by Amendment therein.

To demonstrate the unobvious superiority of the subject 3. matter claimed in Claims 41 - 45, comparatives tests were conducted, demonstrating the importance and unobvious superiority conferred on these compounds by the selection of the cyclopropyl substituent. These are described as follows:

Data was obtained with regard to the following compound having F. C

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2 z <sup>2</sup>	ÓÓ	R <sup>5</sup>		TEST METHOD	
Compound	<u>R<sup>5</sup></u>	Compound No.	Test A <u>Evaluation</u>	Test B <u>Evaluation</u>	Test C <u>Evaluation</u>
Compound * of this Invention	c-Pr	1-520	4.2 x 10 <sup>-9</sup>	17.5 x 10 <sup>-9</sup>	55% (0.05 mg/kg)
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Given at page 71 of the specification Given at page 41 of the specification Given at page 33 of the specification ...

the formula:

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#### Test A: Inhibition\_ of cholesterol biosynthesis from acetate in vitro , t.'

This test was carried out as described on pages 28 - 29 of the specification. The above numerical values indicate  $IC_{50}$  (molar

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### Test C: <u>Inhibition of cholesterol</u> biosynthesis in vivo

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In tests A and B, CS-514 is an optical isomer, and was administered in an amount of 1.25 mg. However, the other compounds are racemic compounds, and were administered in double amounts, i.e., 2.50 mg.

4. Based on the data reported above, it can be determined that the compounds of this invention exhibit unobvious superiority, and in particular, sharply enhanced inhibition of cholesterol

biosynthesis, in in vitro, culture cell, and in vivo testing, when compared with referenced compounds of the prior art, and compounds having an identical structure save for the selection of cyclopropyl, as opposed to isopropyl substituent, for R<sup>5</sup>. This enhanced activity could not be predicted on the basis of structure, or information available to those of ordinary skill in the art as of the effective filing date of this application.

All statements made herein of my own knowledge are true, and all statements made on information and belief are believed true. I am aware that willful false statements and the like are punishable by fine, imprisonment or both, 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the above-captioned patent application and any patent issuing thereon.

FURTHER, I SAYETH NOT.

DATE: \_\_\_\_\_April 9, 1991

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Masahi Kitahara

The states of th	UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office Address : COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231
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OBLON, SPIVAC, MC CLELLAND, Maier & Neustadt Fourth Floor	RICHTER, J
1755 JEFFERSON DAVIS HIGHWAY ARLINGTON, VA 22202	1201
	12/16/91
	an and a start and a start and a start of the start of th
This application has been examined Responsive to communicat	tion filed on This action is made final.
A shortened statutory period for response to this action is set to expire	month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application	
	N:
Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTIC	
<ol> <li>Notice of References Cited by Examiner, PTO-892.</li> <li>Notice of Art Cited by Applicant, PTO-1449.</li> </ol>	<ol> <li>Notice re Patent Drawing, PTO-948.</li> <li>Notice of Informal Patent Application, Form PTO-152</li> </ol>
<ol> <li>Notice of References Cited by Examiner, PTO-892.</li> <li>Notice of Art Cited by Applicant, PTO-1449.</li> <li>Information on How to Effect Drawing Changes, PTO-1474.</li> </ol>	
<ol> <li>Notice of References Cited by Examiner, PTO-892.</li> <li>Notice of Art Cited by Applicant, PTO-1449.</li> </ol>	4. Notice of Informal Patent Application, Form PTO-152
1.       Notice of References Cited by Examiner, PTO-892.         3.       Notice of Art Cited by Applicant, PTO-1449.         5.       Information on How to Effect Drawing Changes, PTO-1474.         Part II SUMMARY OF ACTION         1.       Claims	A. Notice of Informal Patent Application, Form PTO-152     6 are pending in the application.
1.       Notice of References Cited by Examiner, PTO-892.         3.       Notice of Art Cited by Applicant, PTO-1449.         5.       Information on How to Effect Drawing Changes, PTO-1474.         Part II SUMMARY OF ACTION         1.       Claims	A. Notice of Informal Patent Application, Form PTO-152     6are pending in the application.    are withdrawn from consideration.
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1.       Notice of References Cited by Examiner, PTO-892.         3.       Notice of Art Cited by Applicant, PTO-1449.         5.       Information on How to Effect Drawing Changes, PTO-1474.         Part II SUMMARY OF ACTION         1.       Claims         Of the above, claims         2.       Claims         3.       Claims	A.      Notice of Informal Patent Application, Form PTO-152     6.      are pending in the application.     are withdrawn from consideration.     have been cancelled.     are allowed.     are rejected.
1.       Notice of References Cited by Examiner, PTO-892.         3.       Notice of Art Cited by Applicant, PTO-1449.         5.       Information on How to Effect Drawing Changes, PTO-1474.         Part II SUMMARY OF ACTION         1.       Claims         Of the above, claims         2.       Claims         3.       Claims         4.       Claims         5.       Claims	A.      Notice of Informal Patent Application, Form PTO-152     6.      are pending in the application.     are withdrawn from consideration.     have been cancelled.     are allowed.     are rejected.
1.       Notice of References Cited by Examiner, PTO-892.         3.       Notice of Art Cited by Applicant, PTO-1449.         5.       Information on How to Effect Drawing Changes, PTO-1474.         Part II SUMMARY OF ACTION         1.       Claims         Of the above, claims         2.       Claims         3.       Claims         4.       Claims         5.       Claims	A.      Notice of Informal Patent Application, Form PTO-152     6.      are pending in the application.     are withdrawn from consideration.     have been cancelled.     are allowed.     are rejected.     are rejected.     are objected to.     are subject to restriction or election requirement.
1.       Notice of References Cited by Examiner, PTO-892.         3.       Notice of Art Cited by Applicant, PTO-1449.         5.       Information on How to Effect Drawing Changes, PTO-1474.         Part II SUMMARY OF ACTION         1.       Claims         Of the above, claims         2.       Claims         3.       Claims         4.       Claims         5.       Claims         6.       Claims	A.      Notice of Informal Patent Application, Form PTO-152     6.      are pending in the application.     are withdrawn from consideration.     have been cancelled.     are allowed.     are rejected.     are rejected.     are objected to.     are subject to restriction or election requirement.
1.       Notice of References Cited by Examiner, PTO-892.         3.       Notice of Art Cited by Applicant, PTO-1449.         5.       Information on How to Effect Drawing Changes, PTO-1474.         Part II SUMMARY OF ACTION         1.       Claims         Of the above, claims         2.       Claims         3.       Claims         4.       Claims         5.       Claims         6.       Claims         7.       This application has been filed with informal drawings under 37 (         8.       Formal drawings are required in response to this Office action.	A.      Notice of Informal Patent Application, Form PTO-152     6.      are pending in the application.     are withdrawn from consideration.     are withdrawn from consideration.     have been cancelled.     are allowed.     are rejected.     are rejected.     are objected to.     are subject to restriction or election requirement. C.F.R. 1.85 which are acceptable for examination purposes.
1. □       Notice of References Cited by Examiner, PTO-892.         3. □       Notice of Art Cited by Applicant, PTO-1449.         5. □       Information on How to Effect Drawing Changes, PTO-1474.         Part II SUMMARY OF ACTION         1. □       Claims         3. □       Claims         2. □       Claims         3. □       Claims         4. □       Claims         5. □       Claims         6. □       Claims         7. □       This application has been filed with informal drawings under 37 (         8. □       Formal drawings are required in response to this Office action.         9. □       The corrected or substitute drawings have been received on	4.       Notice of Informal Patent Application, Form PTO-152         6.
1.       Notice of References Cited by Examiner, PTO-892.         3.       Notice of Art Cited by Applicant, PTO-1449.         5.       Information on How to Effect Drawing Changes, PTO-1474.         Part II SUMMARY OF ACTION         1.       ✓ Claims         2.       Claims         3.       Claims         3.       Claims         3.       Claims         4.       ✓ Claims         5.       Claims         6.       Claims         7.       This application has been filed with informal drawings under 37 C         8.       Formal drawings are required in response to this Office action.         9.       The corrected or substitute drawings have been received on	4.       Notice of Informal Patent Application, Form PTO-152         6.
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EXAMINER'S ACTION

#### Serial No. 07/631092

Art Unit 1201

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

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.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 36-40 are rejected under 35 U.S.C. § 103 as being unpatentable over applicants admission.

Applicants admit that optical isomers as well as compounds differing only in the selection of cyclopropyl are already known in the art. A declaration has been submitted in support of unobviousness. The claimed compounds would have been obvious to one of ordinary skill because isomers are prima facie obvious. The declaration will overcome the rejection when signed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Johann Richter whose telephone number is (703) 308-4532.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

RICHTER:mp December 17, 1991

JOHANN RICHTER EXAMINER Kichler ART

NORMAN SCOBLON MARVIN SEVAK C. IRVIN MCLEVAND GREGORY J. MCRI HAL MARVIN J. MCRI HAL MCCONTROLOGICA RECORPT J. MCRI HAL RICHARD D. KELLY JAMES D. HAMILTON ECKHARD H. KUESTERS ROBERT T. POUS DAVID J. KERA CHARLES L. GHOLZ VINCENT J. SUNDERDICK<sup>4</sup> WILLIAM E. BEAUMONT STUYEN B. KELBER<sup>4</sup> STUART D. OWORK ROBERT F. GRUSE JEAN-FAUL LAVALLEYE, PH. D. JEFFREY H. KAUFMAN BRIAN D. ANDERSON<sup>4</sup> ROBERTS J. BREN<sup>4</sup> WILLIAM B. WALKER<sup>4</sup> TIMOTY R. SCHWARTZ, PH. D. RICHARD H. STERN<sup>4</sup> JOHN H. WEBER

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. Attorneys at Law FOURTH FLOOR PATEN IN M. ZOLTICK I755 JEFFERSON DAVIS HIGHWAY IS R. DALEY ARLINGTON, VIRGINIA 22202 U.S.A. EN P. WEIHROUCH ARLINGTON, VIRGINIA 22202 U.S.A.

ALAN HOLLER MARTIN M. ZOLTICK WARTIN M. ZOLTICK WARTIN M. ZOLTICK WARLE. SCHLIER DENNIS R. DALEY STEVEN P. WEIHROUCH BILLIE MUNRO<sup>5</sup> P. JAY HINES<sup>5</sup> FREDERICK D. VASTINE, PH. D.<sup>6</sup> MURRAY TILLMAN<sup>6</sup> STEPHEN G. BAXTER, PH. D.<sup>6</sup> ROBERT W. HAHL, PH. D.<sup>6</sup> RICHARD L. CHINN, PH. D.<sup>6</sup> SURINDER SACHAR<sup>7</sup> JAMES A. LISEHORA<sup>8</sup> ANDREW D. FORTNEY, PH. D.<sup>6</sup> RICHARD A. NEIFELD, PH. D.<sup>6</sup> RICHARD A. NEIFELD, PH. D.<sup>6</sup> KENNETH G. WELLS<sup>6</sup> KAREN I. KRUPEN, PH. D.<sup>6</sup> CF COUNSEL

TELEPHONE (703) 521-4500 FACSIMILE (703) 486-2347 TELEX 248855 OPAT UR PATENT, TRADEMARK AND COPYRIGHT LAW AND RELATED FEDERAL AND ITC LITIGATION WEST COAST OFFICE 2021 THE ALAMEDA, SUITE 110 SAN JOSE, CALIFORNIA 95126 TELEPHONE (408) 345-3890 FACSIMILE (408) 345-3898 \*BAR MEMBERSHIP OTHER THAN VIRGINIA \*REGISTERED PATENT AGENT

DAVID A. NOVAIS

KRA WARTZ, PH. D. OF COUNSEL KRN MILTON STERMAN SAMUEL H. BLECH JOHN O. TRESANSKY S ALTON D. ROLLINS R JOHN H.O. CLARKE

DOCKET NO.: 49-146-0 CONT

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

IN RE APPLICATION OF: YOSHIHIRO FUJIKAWA ET AL SERIAL NUMBER: 07/631,092 FILED: DECEMBER 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES

#### SIR:

Attached hereto for filing are the following papers:

RESPONSE; COPY OF EXECUTED RULE 132 DECLARATION COPY OF DATE-STAMPED FILING RECEIPT (4/22/91) PETITION FOR EXTENSION OF TIME WITH FEE

Our check in the amount of \$ 810.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the abovenoted documents, including any fees required under 37 CFR 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

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Norman F. Oblon Registration No.: 24,618

Steven B. Kelber Registration No.: 30,073 Attorneys of Record

I. NEUSTA C. MILLER D. KELLY HAMILTO D. H. KUES T. POUS AHOLZ

OBLON, SPIVAR, MCCLELLAND, MAIER & NEUSTADT, P.C. ATTORNEYS AT LAW FOURTH FLOOR 1755 JEFFERSON DAVIS HIGHWAY ARLINGTON, VIRGINIA 22202 U.S.A. TELEPHONE (703) 521-4500

ALAN HOLLER MARTIN M. ZOLTICK CARL E. SCHLIER DENNIS R. DALEY STEVEN P. WEIHROUCH BILLIE MUNRO<sup>®</sup> P. JAY HINES<sup>®</sup> FREDERICK D. VASTINE, PH.D.<sup>®</sup> MURRAY TILLMAN<sup>®</sup> STEPHEN G. BAXTER, PH.D.<sup>®</sup> ROBERT W. HAHL, PH.D.<sup>®</sup> RICHARD L. CHINN, PH.D.<sup>®</sup> SURINDER BACHAR<sup>®</sup> JAMES A. LISEHORA<sup>®</sup> ANDREW D. FORTNEY, PH.D.<sup>®</sup> RICHARD L. JUSHORA<sup>®</sup> ANDREW D. FORTNEY, PH.D.<sup>®</sup> RICHARD A. NEIFELD, PH.D.<sup>®</sup> RICHARD A. NEIFELD, PH.D.<sup>®</sup> XERNETH G. WELLS<sup>®</sup> KAREN I. KRUPEN, PH.D.<sup>®</sup>

FACSIMILE (703) 486-2347 TELEX 248855 OPAT UR PATENT, TRADEMARK AND COPYRIGHT LAW AND RELATED FEDERAL AND ITC LITIGATION WEST COAST OFFICE OZI THE ALAMEDA, SUITE 110 SAN JOSE, CALIFORNIA SBIES TELEPHONE (408) 345-3890 FACSIMILE (408) 345-3898 BAR MEMBERSHIP OTHER THAN VIRGINIA REGISTERED PATENT AGENT

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DAVID A. NOVAIS

OF COUNSEL MILTON STERMAN SAMUEL H. BLECH JOHN O. TRESANSKY ALTON D. ROLLINS JOHN H.O. CLARKE

DOCKET NO.: 49-146-0 CONT

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS 20231 WASHINGTON, DC

IN RE APPLICATION OF: YOSHIHIRO FUJIKAWA ET AL SERIAL NUMBER: 07/631,092 FILED: DECEMBER 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES

SIR:

Attached hereto for filing are the following papers:

RESPONSE; COPY OF EXECUTED RULE 132 DECLARATION COPY OF DATE-STAMPED FILING RECEIPT (4/22/91) PETITION FOR EXTENSION OF TIME WITH FEE

Our check in the amount of \$ 810.00 is attached covering any required fees. In the event any variance exists between the is attached covering amount enclosed and the Patent Office charges for filing the abovenoted documents, including any fees required under 37 CFR 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, MCCLELLAND,

MAIER & NEUSTADT, P.C. Norman F. Oblon

24,618 Registration No.:

Steven B. Kelber Registration No.: 30,073 Attorneys of Record

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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RE APPLICATION OF:

YOSHIHIRO FUJIKAWA ET AL SERIAL NUMBER: 07/631,092 FILED: DECEMBER 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES GROUP ART UNIT: 129 EXAMINER: RICHTER 3

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR \$1.136

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

SIR:

It is hereby requested that a THREE-MONTH extension of time for responding to the Office Action of DECEMBER 18, 1991, be granted until JUNE 18, 1992.

The required fee of \$810.00 is enclosed herewith by check and further charges may be made against the Attorney of Record's Deposit Account No. 15-0030. A duplicate copy of this Petition is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Oblon Norman F.

Registration No.: 24,618

Steven B. Kelber 30,073 Registration No.: Attorneys of Record

Fourth Floor 1755 South Jefferson Davis Highway Arlington, Virginia 22202 703-521-5940

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RE APPLICATION OF: : YOSHIHIRO FUJIKAWA ET AL GROUP ART UNIT: 129 : SERIAL NUMBER: 07/631,092 : EXAMINER: RICHTER FILED: DECEMBER 19, 1990 : FOR: QUINOLINE TYPE MEVALONOLACTONES

#### PETITION FOR EXTENSION OF TIME UNDER 37 CFR \$1.136

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

SIR:

49-146-0 CONT

It is hereby requested that a THREE-MONTH extension of time for responding to the Office Action of DECEMBER 18, 1991, be granted until JUNE 18, 1992.

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Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MATER & NEUSTADT, P.C.

Norman F. Oblon Registration No.: 24,618

Steven B. Kelber Registration No.: Attorneys of Record 30,073

Fourth Floor 1755 South Jefferson Davis Highway Arlington, Virginia 22202 703-521-5940

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: : YOSHIHIRO FUJIKAWA ET AL : SERIAL NUMBER: 07/631,092 : FILED: DECEMBER 19, 1990 : FOR: QUINOLINE TYPE MEVALONOLACTONES

GROUP ART UNIT: 129 EXAMINER: RICHTER

#### RESPONSE

# HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

SIR:

Responsive to the outstanding Office Action issued December 18, 1991, withdrawal of the rejection of Claims 36-40, all claims pending, as obvious over applicants' admission is respectfully requested, in light of the executed Declaration pursuant to Rule 132 already of record.

In the outstanding Office Action, the Examiner rejected all claims over applicants' admission, but was kind enough to indicate that the Declaration submitted in support of unobviousness would overcome the rejection, when the Declaration was signed. Prior to issuance of the Office Action, the executed Declaration was filed, a copy of the Declaration being submitted herewith. This executed Declaration was filed April 22, 1991, as confirmed by the datestamped filing receipt, also enclosed herewith. It appears that the executed Declaration was not made part of the file prior to the issuance of the Office Action some eight months later. In any event, withdrawal of the rejection for obviousness, and allowance of the claims presented, is respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

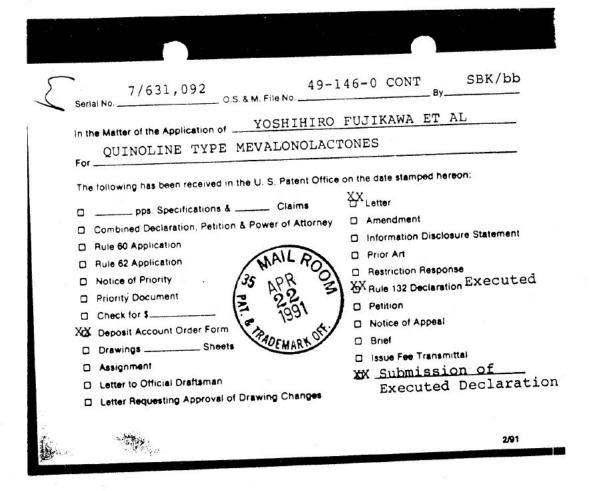
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Norman F. Oblon Registration No.: 24,618

Steven B. Kelber Registration No.: 30,073 Attorneys of Record

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:	:	
YOSHIHIRO FUJIKAWA ET AL	:	GROUP ART UNIT: 129
SERIAL NUMBER: 07/631,092	•	EXAMINER:
FILED: DECEMBER 19, 1990	:	
FOR: QUINOLINE TYPE MEVALONOLAG	TONES	

#### DECLARATION UNDER 37 CFR \$1.132

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

SIR:

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I, Masaki Kitahara , do hereby declare and state that:

1. I am a named co-inventor in the above-captioned patent application, an employee of Nissan Chemical Industries, Limited, and a citizen and resident of Japan.

I am familiar with the above-captioned patent application,
 and Claims 41 - 45 presented by Amendment therein.

 To demonstrate the unobvious superiority of the subject matter claimed in Claims 41 - 45, comparatives tests were conducted, demonstrating the importance and unobvious superiority conferred on these compounds by the selection of the cyclopropyl substituent. These are described as follows:

Data was obtained with regard to the following compound having

the formu	la:	OH CO2Na			
	OLOL	R <sup>5</sup>		TEST METHOD	
Compound	<u>R<sup>5</sup></u>	Compound No.	Test A <u>Evaluation</u>	Test B <u>Evaluation</u>	Test C <u>Evaluation</u>
Compound * of this Invention	c-Pr	1-520	4.2 x 10 <sup>-9</sup>	17.5 x 10 <sup>-9</sup>	55% (0.05 mg/kg)
Reference** Compound	i-Pr	I-51	10 x 10 <sup>-9</sup>	100 x 10 <sup>-9</sup>	65% (0.2 mg/kg)
Reference** Compound	*	CS-514	9.0 x 10 <sup>-9</sup>	350 x 10 <sup>-9</sup>	55% 10.0 mg/km

Given at page 71 of the specification Given at page 41 of the specification Given at page 33 of the specification

the formula:

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# Inhibition of cholesterol biosynthesis from acetate in vitro Test A:

This test was carried out as described on pages 28 - 29 of the specification. The above numerical values indicate  $IC_{50}$  (molar

concentration).

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# Test B: <u>Inhibition of cholesterol</u> <u>biosynthesis in culture cells</u>

This test was carried out as described on pages 29 to 30 of the specification. The above numerical values indicate  $IC_{50}$  (molar concentration).

#### Test C: <u>Inhibition of cholesterol</u> <u>biosynthesis in vivo</u>

This test was carried out as described on pages 30 to 31 of the specification. The above numerical values indicate inhibition percent and the numerical values in parenthesis indicate "administration amounts" (mg/kg).

In tests A and B, CS-514 is an optical isomer, and was administered in an amount of 1.25 mg. However, the other compounds are racemic compounds, and were administered in double amounts, i.e., 2.50 mg.

4. Based on the data reported above, it can be determined that the compounds of this invention exhibit unobvious superiority, and in particular, sharply enhanced inhibition of cholesterol

> Sawai Ex 1003 Page 142 of 175

biosynthesis, in in vitro, culture cell, and in vivo testing, when compared with referenced compounds of the prior art, and compounds having an identical structure save for the selection of cyclopropyl, as opposed to isopropyl substituent, for R<sup>5</sup>. This enhanced activity could not be predicted on the basis of structure, or information available to those of ordinary skill in the art as of the effective filing date of this application.

All statements made herein of my own knowledge are true, and all statements made on information and belief are believed true. I am aware that willful false statements and the like are punishable by fine, imprisonment or both, 18 U.S.C. \$1001, and that such willful false statements may jeopardize the validity of the above-captioned patent application and any patent issuing thereon.

FURTHER, I SAYETH NOT.

DATE: April 9, 1991

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Masaki Kitahara



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

092 31 FILING DATE L NUMBER

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FIRST NAMED APPLICANT ATTORNEY DOCKET NO.

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PAPER NUMBER
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Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents.

All claims are allowable. However, due to a potential interference, *ex parte* prosecution is SUSPENDED FOR A PERIOD OF SIX MONTHS FROM THE DATE OF THIS LETTER.

Upon expiration of the period of suspension, applicant should make an inquiry as to the status of the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Richter whose telephone number is (703) 308-4532.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JOHANN RICHTON PRIMARY EXAMINER GROUP 120

1-Patent Application File Copy

PTOL-90 (REV. 6/84)

Serial No. 07/631,092 Art Unit 1201

Richter:1b September 08, 1992

JOHANN RICHTEH PRIMARY EXAMINER GROUP 120 TOROLORICHLEX

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NORMAN F. CLA MARVIN J. SPILEL MARVIN J. SPILEL MARVIN MCGLEL GREGORY J. MAIER DENN ARTHUR I. NEUSTADT ROBERT C. MILLER P. JA RICHARD D. KELLY JOBEN D. KELLY JOBEN D. KELLY GOBERT F. POUS GAVID J. XERA ROBERT F. POUS CHARLES L. GHOZ MURING VINCENT J. SUNDERDICK' ROBERT F. GNUSE STLART D. DWORK MARD JEAN-PAUL LAVALLEYE, PH. D. RICH JEAN-PAUL LAVALLEYE, PH. D. RICH JOHN H. XELER' NOBERT S. BRCN MILLIAM B. WALKER' RICH STEMEN S. BARN MILLIAM B. MALKER' RICH STEMEN S. BARN MILLIAM B. MALKER' RICH STEMEN S. BARN MILLIAM B. WALKER' RICH STEMEN S. BARN MILLIAM B. WALKER' MILLIAM B. WALKER' MICH STEMEN S. BARN MILLIAM B. STEPHEN SAM

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Attorneys at Law FOURTH FLOOR 1755 JEFFERSON DAVIS HIGHWAY ARLINGTON, VIRGINIA 22202 U.S.A.

TELEPHONE

DBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.

(703) 413-3000 FACSIMILE (703) 413-2220 TELEX 248855 OPAT UR

DOCKET NO.: 49-146-0 CONT

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PATENT, TRADEMARK AND COPYRIGHT LAW AND RELATED FEDERAL AND ITC LITIGATION WEST COAST OFFICE 2021 THE ALAMEDA, SUITE 110 SAN JOSE, CALIFORNIA 95126 TELEPHONE (408) 345-3890 FACSIMILE 1408) 345-3898 \*BAR MEMBERSHIP OTHER THAN VIRGINIA °REGISTERED PATENT AGENT

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HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

IN RE APPLICATION OF: YOSHIHIRO FUJIKAWA ET AL SERIAL NUMBER: 07/631,092 FILED: DECEMBER 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES

SIR:

Attached hereto for filing are the following papers:

#### STATUS INQUIRY

, S

Our check in the amount of  $\frac{0}{2}$  is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 CFR 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAR, McCLELLAND, MAIER NEWSTADT, P.C. Ŋ

Norman F. Oblon Registration No.: 24,618

Steven B. Kelber Registration No.: 30,073 Attorneys of Record

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. ATTORNEYS AT LAW NORMAN F. OBLON MARVIN J. SPIVAK C. IRVIN MCCLELLAND GREGORY J. MAIER ARTHUR I. NEUSTADT ROBERT C. MILLER RICHARD D. KELLY JAMES D. HAMILTON ECKHARD H. KUESTERS ROBERT T. POUS DAVID J. KERA CHARLES L. GHOIZ VINCENT J. SUNDERDICK<sup>1</sup> WILLIAM E. BEAUMONT STEVEN B. KELBER<sup>2</sup> STUART D. DWORK ROBERT F. GNUSE JEAN-PAUL LAVALLEYE, PH.O. JEFFREY H. KAUFMAN BRIAN D. ANDERSON<sup>1</sup> ROBERT S. BREN WILLIAM B. WALKER<sup>2</sup> INMOTH F. SCHWARTZ, PH.O. RICHARD H. STERN<sup>1</sup> JOHN H. WEBER STEPHEN G. BAXTER, PH.D. DAVID A. NOVAIS MARTIN M. ZOLTICK CARL E. SCHLER DENNIS R. DALEY STEVEN P. WEIHROUCH P. JAY HINES JOSEPH T. LEONE BARRY P. MILLER SUBINDER SACHAR JARES J. KULBASKI FREDERICK D. VASTINE, PH. D.\* MURRAY TILLMAN\* ROBERT W. HAHL, PH. D.\* RICHARD K. CHINN, PH. D.\* MACK. ABGOLO, PH. D.\* MICHARD A. NEIFELD, PH. D.\* MICHARD B. GRIFFIS\* RICHARD L. TREANOR, PH. D.\* PATENT, TRADEMARK AND COPYRIGHT LAW AND RELATED FEDERAL AND ITC LITIGATION ARUNGTON, VIRGINIA 22202 U.S.A. 1993 TELEPHONE FADEL FOST 413-3000 FACSIMILE WEST COAST OFFICE · PIL: 2021 THE ALAMEDA, SUITE 110 SAN JOSE. CALIFORNIA 95126 TELEPHONE (408) 345-3890 FACSIMILE (703) 413-2220 408-345-3898 TELEX BAR MEMBERSHIP OTHER THAN VIRGINIA 248855 OPAT UR "REGISTERED PATENT AGENT MILTON STERMAN" SAMUEL H. BLECH" JOHN O. TRESANSKY" ALTON D. ROLLINS JOHN H.O. CLARKE" DOCKET NO.: 49-146-0 CONT **93 HAR** 

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

IN RE APPLICATION OF: YOSHIHIRO FUJIKAWA ET AL SERIAL NUMBER: 07/631,092 FILED: DECEMBER 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES

SIR:

Attached hereto for filing are the following papers:

#### STATUS INQUIRY

Our check in the amount of  $\frac{0}{0}$  is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 CFR 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAR, MCCLELLAND, MAIER NEWSTADT, P.C. X

Norman F. Oblon Registration No.: 24,618

Steven B. Kelber Registration No.: 30,073 Attorneys of Record

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49-146-0 CONT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: . YOSHIHIRO FUJIKAWA ET AL : GROUP ART UNIT: 129 SERIAL NUMBER: 07/631,092 EXAMINER: RICHTER : FILED: DECEMBER 19, 1990 : FOR: QUINOLINE TYPE MEVALONOLACTONES 93 MAR 17 PM

#### STATUS INQUIRY

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

SIR:

Further to the Notice of Suspension issued on September 9, 1992 (Paper No. 10), the six-month suspension period now having expired on March 9, 1993, applicants respectfully request written notification as to the current status of the above-captioned application.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon

Registration No.: 24,618

Steven B. Kelber Registration No.: Attorneys of Record 30,073

Fourth Floor 1755 South Jefferson Davis Highway Arlington, Virginia 22202 703-413-3000



UNITED STATE: EPARTMENT OF COMMERCE Patent and Trademark Office ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 #12/5/17/93 CB

May 17, 1993

In re application of Yoshihiro Fujikawa, Et al

Serial Number: 07/631,092 : Filed: December 19, 1990 : For: QUINOLINE TYPE MEVALONO- : ACTONES :

DECISION ON PETITION RE SUSPENSION

Action in this application is further suspended for six months from the date of this letter due to a pending Interference.

Upon expiration of the period of suspension, applicant(s) should again make an inquiry as to the status of the application. Manual of Fatent Examining Procedure, Section 709; 37 C.F.R. 1.103.

here Toth Non E John F. Terapane

Director Patent Examining Group 120 Organic Chemistry

OBLON, SPIVACK, MCCLELAND, MAIER & NEUSTADT 4th Floor 1755 Jefferson Davis Hwy., Arlington, VA 22202



#### UNITED STATES DI RTMENT OF COMMERCE Patent and Tradem. Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS Weshington, D.C. 20231

SERIAL NUMBER	FILING DATE	FILING DATE FIRST NAMED APPLICANT			
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	SPIVAC, MC C NEUSTADT	LELIGNU,	ART UNIT	PAPER NUMBER	
1755 JE	FFERSON DAVI		1201	13	
ARLING	TON, VA 2220	2	DATE MAILED:	04/19/94	

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents.

Action in this application is further suspended for six months from the date of this letter due to a possible interference.

Upon expiration of the period of suspension, applicants should again make an inquiry as to the status of the application. Manual of Patent Examining Procedure Section 709; 37 C.F.R. 1.103.

John F. Terapane Director, Group 1200 Organic Chemistry

-90 (REV. 6/84)

1-Patent Application File Copy



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

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	12#1/0313	SPRINGE	MINER
OBLON, SPIVAC, MC CLELLA Maier % neustadt		ART UNIT	PAPER NUMBER
FOURTH FLOOR 1755 JEFFERSON DAVIS HIG ARLINGTON, VA. 20000	HWAY	DATE MAILED:	14
ARLINGTON, VA 22202			03/13/95

Please find below a communication from the EXAMINER in charge of this application.

**Commissioner of Patents** 

631092

Action in this application is further suspended for six months from the date of this letter due to a possible interference.

Upon expiration of the period of suspension, applicants should again make an inquiry as to the status of the application. Manual of Patent Examining Procedure Section 709; 37 CFR 1.103.

Lehard W. Fisle

PTOL-90 (Rev. 6/84)

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Richard V. Fisher, Director Patent Examining Group 1200 Organic Chemistry

1 - PATIENT APPLICATION FILE COPY



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

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FOURTH F 1755 JEFI	LOOR FERSON DAVIS	HIGHMAY	1281	15
- ARLINGTO	M, VA 22202		DATE MAILED:	

12/15/95

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Action in this application is further suspended for six months from the date of this letter due to a possible interference.

Upon expiration of the period of suspension, applicants should again make an inquiry as to the status of the application. Manual of Patent Examining Procedure Section 709; 37 CFR 1.103.

APPROVED HCHAPPOLY MSHER icher

Richard **PRECTOR GROUP**, 1200 irector Patent Examining Group 1200 Organic Chemistry

, \* <sup>1</sup>

PTOL-90 (Rev. 6/84)

**1 - PATENT APPLICATION FILE COPY** 



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

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT		ATTORNEY DOCKET NO
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MAIER & N Fourth FL				16
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FICL TING LENA	, VA 22202			09/18/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

PTOL-90 (Rev. 6/84)

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**1-PATENT APPLICATION FILE COPY** 



#### UNITED STATES C ... RTMENT OF COMMERCE Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

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			DATE MAILED:		

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents.

Action in this application is further suspended for six months from the date of this letter due to a possible interference.

Upon expiration of the period of suspension, applicants should again make an inquiry as to the status of the application. Manual of Patent Examining Procedure Section 709; 37 CFR 1.103.

Richard V. Fisher, Director Patent Examining Group 1200 Organic Chemistry

SUBSTITUTE PTOL-90

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1997 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Yoshihiro FUJIKAWA, et al. SERIAL NUMBER: 07/631,092 FILED: December 19, 1990 FOR: QUINOLINE TYPE MEVALONOLACTONES

: GROUP: 1201 : EXAMINER: Springer

1072 9

:

#### STATUS REQUEST

Honorable Commissioner of Patents & Trademarks Washington, D.C. 20231 SIR:

The undersigned respectfully requests the status of the above-captioned application.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

11 61

Norman F. Oblon Attorney of Record Registration No. 24,618

Registration Number 27,295

1755 Jefferson Davis Highway Suite 400 Arlington, Virginia 22202 (703) 413-3000



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

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/631,092	12/19/90	Fuji Kawa d	tal. 49-146-0-CON
			EXAMINER STOCKTON, L.
			1613 18
			10
	INTERVI	EW SUMMARY	DATE MAILED:
All participants (applicant, applican	t's representative, PTO personnel	):	
(1) Mr. Steven Ke	Iber	(3) Mr. Tsuc	hina
(2) Mr. Masuda		(4) Mr. Joho	
Date of Interview_Sept.	24, 1998	(5) Laura L	. Stockton
Type: Telephonic Persona			ə).
Exhibit shown or demonstration co	nducted: 🗆 Yes 🕅 No If yes, t	prief description:	
Claim(s) discussed: <u>ALL</u> Identification of prior art discussed: Description of the general nature of <u>OMC NDD L</u>	f what was agreed to if an agreem	ent was reached, or any oth	er comments: The claims
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( A fuller description, if necessary, a must be attached. Also, where no attached.)	and a copy of the amendments, if a copy of the amendments which we	available, which the examine buld render the claims allowa	r agreed would render the claims allowable ble is available, a summary thereof must be
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IS NOT WAIVED AND MUST INCL action has are ready been filed, AF SUBSTANCE OF THE INTERVIEW	UDE THE SUBSTANCE OF THE PLICANT IS GIVEN ONE MONTH V.	INTERVIEW. (See MPEP S I FROM THIS INTERVIEW I	I RESPONSE TO THE LAST OFFICE ACTION ection 713.04). If a response to the last Office DATE TO FILE A STATEMENT OF THE
rejections and requirements	that may be present in the last Of ponse requirements of the last Of	ice action, and since the cla	plete response to each of the objections, ms are now allowable, this completed form effeved from providing a separate record of
Examiner Note: You must sign this	form unless it is an attachment to	another form.	/ Y Handra
FORM PTOL-413 (REV.1-96)		70	und - Judge

	07/631,092	Applicant(s	Yoshihiro Fujik	kawa et al.	
Interview Summary	Examiner Laura L. Stockton		Group Art Unit 1613		
Il participants (applicant, applicant's representative	, PTO personnel):		i i	4	
1) Laura L. Stockton	(3)				
2) Mr. Steven B. Kelber {Registry Number 30,073}	(4)		-		
bate of Interview Sep 28, 1998					
ype: 🛛 Telephonic 🗌 Personal (copy is given t	to 🗌 applicant 🗌 ap	plicant's rep	presentative).		
xhibit shown or demonstration conducted: 🗌 Ye	es 🛛 No. If yes, brief d	escription:			
greement 🛛 was reached. 🗌 was not reached.					
laim(s) discussed: 10	¥8				
dentification of prior art discussed:					
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07/631,092 12/19/90 FUJIKAWA	Y 49-146-0-CON
	EXAMINED
OBLON, SPIVAC, MC CLELLAND,	
MAIER & NEUSTADT Fourth Floor	STOCKTON, L
1755 JEFFERSON DAVIS HIGHWAY Arlington va 22202	1613 201
and a second	DATE MAILED:
	09/30/98
This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS	e 4 <sup>18</sup>
NOTICE OF ALLOWA	2017237220170128
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate	CLOSED in this application. If not included herewith (or e communication will be mailed in due course.
This communication is responsive to	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
X The allowed claim(s) Fare 36 - 40 now renumbered	claims 1-5, respectively
The drawings filed on are acceptable.	
Acknowledgement is made of a claim for foreign priority under 35 U.S.C. §	19(a)-(d).
$X$ All $\square$ Some* $\square$ None $~$ of the CERTIFIED copies of the priority docum	nents have been
received.	
received in Application No. (Series Code/Serial Number)723	3,752
$\square$ received in this national stage application from the International Bureau (I	PCT Rule 17.2(a)).
*Certified copies not received:	· · · · · · · · · · · · · · · · · · ·
Acknowledgement is made of a claim for domestic priority under 35 U.S.C.	
A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the req FROM THE "DATE MAILED" of this Office action. Failure to timely comply will re time may be obtained under the provisions of 37 CFR 1.136(a).	uirements noted below is set to EXPIRE <b>THREE MONTHS</b> sult in ABANDONMENT of this application. Extensions of
Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL A declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQU	PPLICATION, PTO-152, which discloses that the oath or JIRED.
Applicant MUST submit NEW FORMAL DRAWINGS	
because the originally filed drawings were declared by applicant to be infor	mal.
including changes required by the Notice of Draftperson's Patent Drawing F	Review, PTO-948, attached hereto or to Paper No
including changes required by the proposed drawing correction filed on by the examiner.	, which has been approved
including changes required by the attached Examiner's Amendment/Comm	ent.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) sh The drawings should be filed as a separate paper with a transmittal letter	
Note the attached Examiner's comment regarding REQUIREMENT FOR THE	
Any response to this letter should include, in the upper right hand corner, the APF If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE B/ ALLOWANCE should also be included.	PLICATION NUMBER (SERIES CODE/SERIAL NUMBER). ATCH NUMBER and DATE of the NOTICE OF
Attachment(s)	
Notice of References Cited, PTO-892	
Information Disclosure Statement(s), PTO-1449, Paper No(s).	
Notice of Draftsperson's Patent Drawing Review, PTO-948	P Paul
Notice of Informal Patent Application, PTO-152	Laura L. Stockton
X Interview Summary, PTO-413	Laure L. Stockton
X Examiner's Amendment/Comment	Data + Examina
Examiner's Comment Regarding Requirement for Deposit of Biological Mat	erial Patent Examiner Art Unit 1613
EXAMINE S GRAUTING OF TREASURE TO ANOWARCH	

Sawai Ex 1003 Page 158 of 175

#### Application/Control Number: 07/631,092

Page 2

Art Unit: 1613

#### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Steven B. Kelber on September 28, 1998.

2. The application has been amended as follows:

Abstract:

See attached.

Application/Control Number: 07/631,092 Art Unit: 1613

3. The following is an examiner's statement of reasons for allowance. This invention relates to mevalonolactone derivatives having a quinoline ring. The closest prior art of record {U.S. Pat. 5,753,675} generically teach the instant claimed compounds. However, the executed Declaration submitted June 18, 1992 {Paper No. 9} was persuasive in showing that the instant claimed compounds have unexpected results {also see Paper No.7}. Therefore, the instant claimed compounds were found unobvious over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Page 3

Application/Control Number: 07/631,092

Page 4

Art Unit: 1613

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or 305-3592.

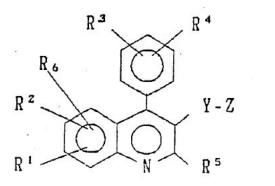
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Laura L. Stockton Patent Examiner Art Unit 1613, Group 1610 Technology Center 1

September 28, 1998

## ABSTRACT

Described herein are mevalonolactone derivatives having a quinoline ring of formula (I)



(I)

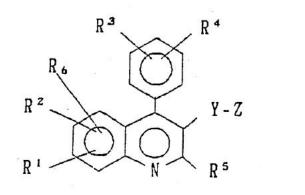
wherein the  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^4$ ,  $R^5$ , Y and Z variables are described therein.

631092

(I)

### ABSTRACT

Described herein are mevalonolactone derivatives having a quinoline ring of formula (I)



wherein the  $\mathbb{R}^1$ ,  $\mathbb{R}^2$ ,  $\mathbb{R}^3$ ,  $\mathbb{R}^4$ ,  $\mathbb{R}^5$ , Y and Z variables are described therein.

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	Notice of Refe	rences Cited	Examiner Laura L. Stor	Examiner Group Art Un Laura L. Stockton 1613		Page 1 of 1	
		U.	S. PATENT DOCUMENTS				
	DOCUMENT NO.	DATE	NAME			CLASS	SUBCLASS
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U. S. Patent and Trademark Office PTO-892 (Rev. 9-95)

Notice of References Cited

Part of Paper No. 20



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

#### NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM/2/1930 CREON, SPIVAC, MC CLELLAND, MAJER & NEUSTADJ FOUNTH FLOOR 1755 JEFFERSON DAVIS HIGHWAY

ARLINGTUN VA 22202

APPLIC	ATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	0	ATE MAILED
	077634,092	: 12719.	190 has	STOCKTON, L	1613	0973079
First Named Applicant	FUIKAWA	i ,	Yu.c	SHIHIRC		

ATTY'S DOCKET NO.	CLASS-SUBCL	ASS BATCH NO.	APPLN		SMALL ENTITY	FEE DUE	DATE DUE
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#### THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

# THE ISSUE FEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. <u>THIS STATUTORY PERIOD CANNOT BE EXTENDED.</u>

#### HOW TO RESPOND TO THIS NOTICE:

<ol> <li>Review the SMALL ENTITY status shown above.</li> <li>If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:</li> </ol>	If the SMALL ENTITY is shown as NO:	
A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or	A. Pay FEE DUE shown above, or	

B. If the status is the same; pay the FEE DUE shown above.

- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give application number and batch 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.

PATENT AND TRADEMARK OFFICE COPY

PTOL-85 (REV. 10-96) Approved for use through 06/30/99. (0651-0033)

\*U.S. GPO: 1998-437-639/80023

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First Named Applicant FLUTEAU	IA,	YOS	HIRO			
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:	:	
YOSHIHIRO FUJIKAWA ET AL	:	GROUP ART UNIT: 129
SERIAL NO.: 07/233,752	:	EXAMINER: SPRINGER
FILED: AUGUST 19, 1988	:	
FOR: QUINOLINE TYPE MEVA- LONOLACTONES	:	

#### AMENDMENT

# HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS WASHINGTON, DC 20231

SIR:

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Supplementing the decision finding all claims allowable reflected in the Interview Summary Sheet of August 27, 1990, and pending the Declaration of Interference referred to in the Interview Summary Sheet, applicants respectfully request entry of the following amendment.

#### IN THE CLAIMS:

Please cancel Claim 10.

#### REMARKS:

Applicants have cancelled Claim 10 of the above-captioned patent application, the subject matter of which is being pursued in a divisional application, filed simultaneously herewith. Applicants have discovered that the subject matter of Claim 10, and related subject matter, exhibits unobvious and distinguishing properties, with respect to the genus circumscribed by the remaining claims of the above-captioned application, as well as the claims of the patent with which an Interference is to be declared. Accordingly, that claim will be pursued in a separate application.

Applicants look forward to the Declaration of Interference in the above-captioned application.

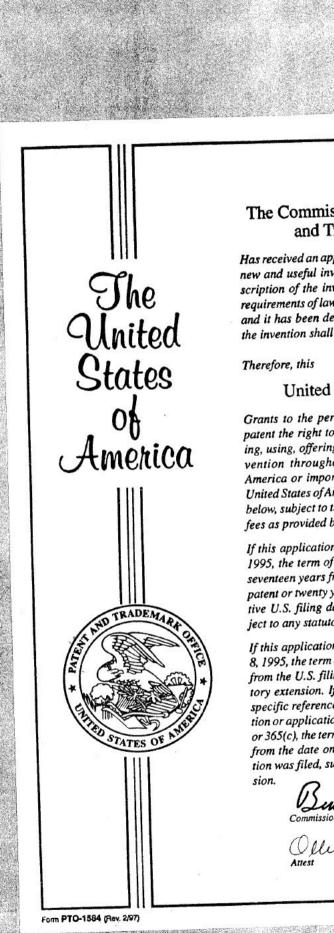
Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon Registration No.: 24,618

Steven B. Kelber Registration No.: 30,073 Attorneys of Record

Fourth Floor 1755 South Jefferson Davis Highway Arlington, Virginia 22202 703-521-5940



#### PTO UTILITY GRANT Paper Number

#### The Commissioner of Patents and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

## United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

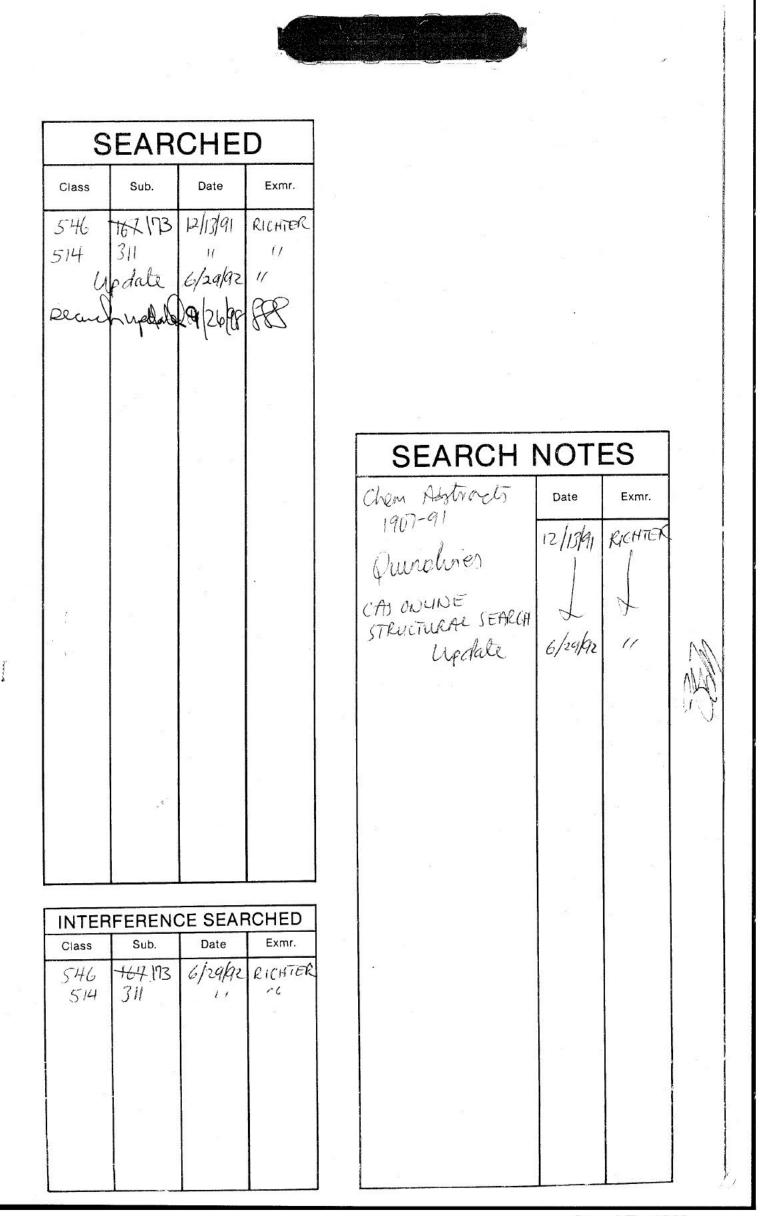
If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to an statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory exten-

Buce Lehman commissioner of Patents and Trademarks Ollie M. Auson

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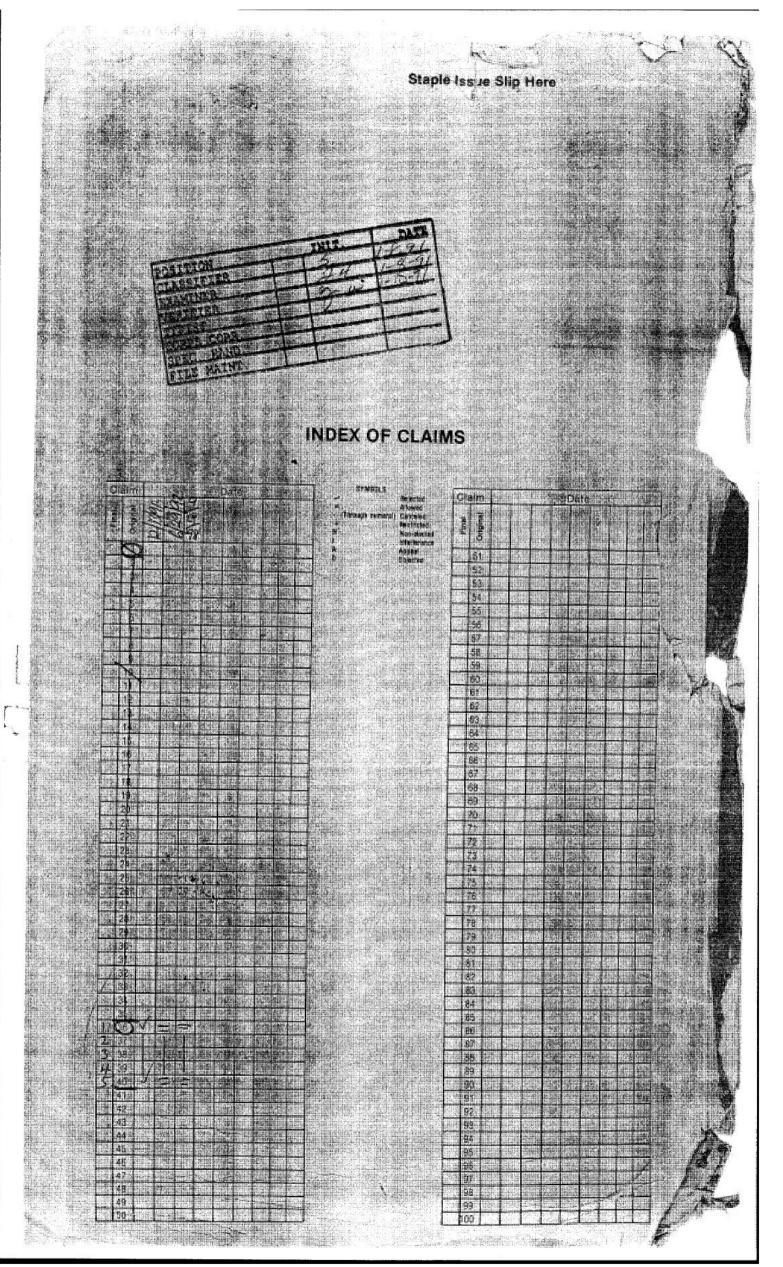


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