

JUN 11 1992

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

WATTANASIN	:	
	:	INTERFERENCE 102,648
V.	:	EXAMINER-IN-CHIEF:
	:	MICHAEL SOFOCLEOUS
PICARD ET AL	:	
	:	
V.	:	
	:	
FUJIKAWA ET AL	:	

FUJIKAWA ET AL MOTION TO ADD COUNTS,
37 CFR §1.633(c)

HONORABLE COMMISSIONER OF PATENTS AND TRADEMARKS
WASHINGTON, DC 20231
BOX INTERFERENCE

SIR:

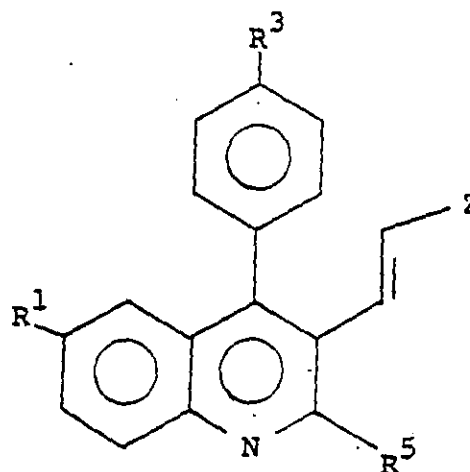
Pursuant to the provisions of the above Motion, the Senior Party hereby moves that the subject matter of this Interference be redefined by the addition of Counts 3 and 4, set forth below. As required by 37 CFR §1.637(c)(1)(ii) and (vi), this Motion is accompanied by an Amendment in Fujikawa's application involved herein, and a Request for Benefit as to the proposed Counts, and claims added by Amendment.

Fujikawa moves the following Counts be added to redefine the

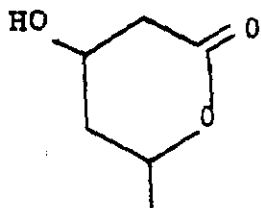
Interference.

Count 3

A compound of the formula:

wherein $R^1 = H$ $R^3 = F$ $R^5 = \text{cyclopropyl (c-Pr)}$ and Z is selected from the group

consisting of

 $-\text{CH}(\text{OH})-\text{CH}_2-\text{CH}(\text{OH})-\text{CH}_2-\text{COOH}$ $-\text{CH}(\text{OH})-\text{CH}_2-\text{CH}(\text{OH})-\text{CH}_2-\text{COONa}$ $-\text{CH}(\text{OH})-\text{CH}_2-\text{CH}(\text{OH})-\text{CH}_2\text{COO}1/2\text{Ca}$ $-\text{CH}(\text{OH})-\text{CH}_2-\text{CH}(\text{OH})-\text{CH}_2-\text{COOR}$, wherein R is C_{1-3} , alkyl and

lactone.

Count 4

A method of inhibiting cholesterol biosynthesis in a patient in need of said treatment comprising administering thereto a cholesterol synthesis inhibiting amount of a compound as defined by Count 3 in combination with a pharmaceutically acceptable carrier.

STATEMENT OF MATERIAL FACTS

1. The compounds embraced by Count 1 of the current Interference and the claims of the Senior and Junior Party thereto (Judgment against Picard et al having been rendered based on request for the same) designated as corresponding to the Count have utilities as inhibitors of biosynthesis of cholesterol (the synthesis, in vivo by animals, of cholesterol).

2. The method of inhibiting cholesterol biosynthesis in an animal in need of same by administration of the compounds of Count has been judged to be patentably distinct from Count 1, and constitutes separate Count 2 of this Interference.

3. The compounds of proposed Count 3, characterized by a cyclopropyl substituent at R⁵, exhibit unusually high activity in the inhibition of cholesterol biosynthesis. Page 3 of the Declaration of Kitahara.

4. In side-by-side comparisons with structural isomers of the proposed Count 3, varying only with respect to the identity of the R⁵ substituent, the n-propyl and isopropyl isomers exhibited dramatically reduced activity, whether measured in vivo or in vitro. The Declaration of Kitahara, see the tables attached thereto.

5. The unusually high activity exhibited by compounds of proposed Count 3 is not a function of the molecular weight of the substituent at R⁵. Analogous substituents, both lower and greater molecular weight, show lower activity, when the remainder of the molecule is the same. See the Kitahara Declaration, tables attached thereto.

6. There is nothing in the art that would suggest the enhanced activity conferred on the compounds of Count 1 when R⁵ is cyclopropyl and the remaining identities of Count 3 are observed.

One of ordinary skill in the art could not have predicted the differences between compounds of Count 3, and isomers thereof with respect to R⁵, on the basis of structure only. Kitahara Declaration, paragraph 5.

7. The Fujikawa application describes, and enablingly discloses, compounds within the scope of proposed Count 3, as well as providing a generic description of that Count.

8. The application of Wattanasin involved herein does not specifically identify cyclopropyl as a substituent at the R⁵ position (R in the claims of Wattanasin). This substituent is suitably identified as cycloalkyl C₃₋₇, however, and the application elsewhere identifies isopropyl and methyl as suitable substituents for this position. Thus, the identity of this substituent as cyclopropyl is reasonably conveyed to those of ordinary skill in the art by the application of Wattanasin.

REASONS IN SUPPORT OF THE DESIRED RELIEF

As set forth in MPP 2309.01, each Count must be drawn to a separate patentable invention. Separate counts to a species or

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