IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

SOMPONG WATTANASIN

Junior Party,[1]

v.

YOSHIHIRO FUJIKAWA, MIKIO SUZUKI, HIROSHI IWASAKI,
MITSUAKI SAKASHITA and MASAKI KITAHARA

Senior Party.[2]

Patent Interference No. 102,648

Before CALVERT, Vice Chief Administrative Patent Judge, and SOFOCLEOUS and DOWNEY, Administrative Patent Judges.

SOFOCLEOUS, Administrative Patent Judge.

FINAL DECISION

The subject matter of this interference relates to a method of inhibiting cholesterol biosynthesis using novel mevalonolactones. These compounds inhibit the enzyme, ß-hydroxy-ß-methyl-glutaryl-CoA reductase (HMG-CoA), which controls a key step in the biosynthesis of cholesterol, by catalyzing the conversion of the substrate HMG-CoA to mevalonate, an

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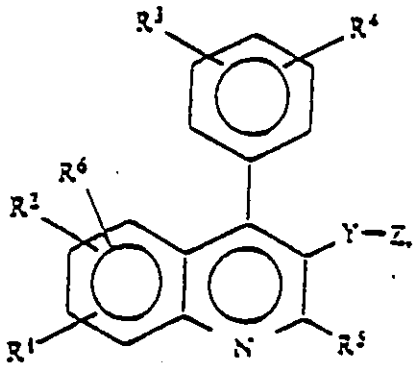
[1] Application 07/498,301 filed March 23, 1990. Accorded the benefit of U.S. Application 07/318,773 filed March 3, 1989, now abandoned. Assignor to Sandoz Pharmaceuticals Corporation.

[2] Application 07/233,752 filed August 19, 1988. Accorded the benefit of Japan Applications 207224 filed August 20, 1987, 193606 filed August 3, 1988 and 15585 filed January 26, 1988. Assignors to Nissan Chemical Industries Ltd.

intermediate of cholesterol. The count of this interference is as follows:

Count 3

A method of inhibiting cholesterol biosynthesis in a patient in need of said treatment comprising administering a cholesterol synthesis inhibiting amount of a compound of the formula:



wherein R^1, R^2, R^3, R^4 and R^6 are independently

hydrogen,

C_{1-6} alkyl,

C_{1-6} cycloalkyl,

C_{1-3} alkoxy,

n-butoxy,

i-butoxy,

sec-butoxy,

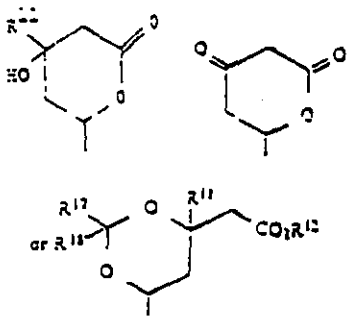
R^7R^8N- (wherein R^7 and R^8 are independently hydrogen or C_{1-3} alkyl),

trifluoromethoxy,
difluoromethoxy,
fluoro,
chloro,
bromo,
phenyl,
phenoxy,
benzyloxy,
hydroxy,
hydroxymethyl,
$-O(CH_2)_\alpha OR^{19}$ (wherein R^{19} is hydrogen or C_{1-3}alkyl and α is 1, 2 or 3),
or when located at the ortho position to each other, R^3 and R^4 together optionally form $-CH=CH-CH=CH-$;

R^5 is hydrogen,
C_{1-6} alkyl,
C_{2-3} alkenyl,
C_{3-6} cycloalkyl,
phenyl substituted by R^9 (wherein R^9 is hydrogen, C_{1-4}alkyl, C_{1-3}alkoxy, fluoro, chloro, bromo or trifluoromethyl),
phenyl-$(CH_2)_m$- (wherein m is 1, 2 or 3), $-(CH_2)_nCH(CH_3)$-phenyl or phenyl-$(CH_2)_nCH(CH_3)$- (wherein n is 0, 1 or 2).

Y is
$-CH_2-$,
$-CH_2CH_2-$,
$-CH=CH-$,
$-CH_2-CH=CH-$, or
$-CH=CH-CH_2-$;

Z is



or $-Q-CH_2WCH_2-CO_2R^{12}$ (where R^{12} is hydrogen or R^{14});

Q is $-CH(OH)-$.
$-C(O)-$, or
$-C(OR^{13})_2-$;

W is $-C(R^{11})(OH)-$ (where R^{11} is hydrogen or C_{1-3} alkyl),
$-C(O)-$, or
$-C(OR^{13})_2-$;

the two R^{13} are independently primary or secondary C_{1-6} alkyl; or two R^{13} together form $-(CH_2)_2-$ or $-(CH_2)_3-$;

R^{14} is physiologically hydrolyzable alkyl or M (wherein M is NH_4, sodium, potassium, 1/2 calcium or a hydrate of lower alkylamine, di-lower alkylamine or tri-lower alkylamine); and

R^{17} and R^{18} are independently hydrogen or C_{1-3} alkyl;

as defined in combination with pharmaceutically acceptable carrier.

Wattanasin's claims 8 and 9 and Fujikawa et al.'s (Fujikawa's) claims 35, 37 and 38 correspond to the count. No question of interference-in-fact or separate patentability of claims under 37 CFR 1.633(b) and (c)(4) has been raised.

This interference was initially declared with three parties on two counts. Count 1 was directed to compounds per se; count 2, to a method of administering the compounds to inhibit cholesterol biosynthesis. The intermediate party, Picard et al., U.S. Patent No. 4,761,419, filed a request for adverse judgment and judgment was entered against it. During the motion period, Fujikawa filed, inter alia, a preliminary motion (Paper No. 15) to add two proposed counts to this interference, which motion was denied by the administrative patent judge (APJ). As a result of the APJ's Decision on Preliminary Motions, method count 3 was substituted for count 2 and Interference No. 102,975 was declared on a count directed to compounds per se. Times for taking testimony were set. Wattanasin presented testimony in order to establish priority of invention within the meaning of 35 U.S.C. 102(g). Fujikawa took cross-examination and presented rebuttal testimony. Both parties filed briefs and appeared, through counsel, at final hearing.

The briefs raise the following issues:

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