

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROBERT D. DILLARD, SANJI HAGISHITA
and MITSUAKI OHTANI

Appeal No. 1997-2184
Application 08/278,441¹

ON BRIEF

Before METZ, WARREN and SPIEGEL, **Administrative Patent Judges**.
METZ, **Administrative Patent Judge**.

DECISION ON APPEAL

This is an appeal from the examiner's refusal to allow claims 1, 3 through 7, 10, 11, 14 and 17 through 19. Claims 2, 8, 9, 12 13, 15 and 16 are claims directed to the previously

¹ Application for patent filed July 21, 1994.

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non-elected invention, 37 C.F.R. § 1.142(b), and, accordingly, form no issue in this appeal.

THE INVENTION

The appealed subject matter is directed to a genus of compounds which may be broadly characterized as indene-1-acetamides. According to appellants, the compounds are useful for the general treatment of conditions induced or maintained by overproduction of the enzyme human non-pancreatic secretory phospholipase A₂ or "**sPLA₂**". Such conditions include septic shock, adult respiratory distress syndrome, pancreatitis, trauma, bronchial asthma, allergic rhinitis and rheumatoid arthritis.

Claims 1, 11 and 14 are believed to be adequately representative of the appealed subject matter and are reproduced below for a more facile understanding of appellants' invention.

Claim 1. An indene-1-acetamide compound or a pharmaceutically acceptable salt, solvate or prodrug derivative thereof; wherein said compound is represented by the formula (I);

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wherein;

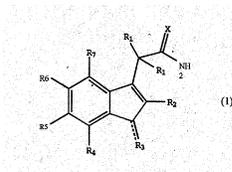
X is oxygen or sulfur;

each R_1 is independently hydrogen, C_1 - C_3 alkyl, or halo;

R_3 is selected from groups (a), (b) and (c) where;

(a) is C_7 - C_{20} alkyl, C_7 - C_{20} alkenyl, C_7 - C_{20} alkynyl, carbocyclic radical, or heterocyclic radical, or

(b) is a
with one or
selected
substituent



member of (a) substituted
more independently
non-interfering
s; or

(c) is the group $-(L)-R_{80}$; where, $-(L)-$ is a divalent linking group of 1 to 12 atoms and where R_{80} is a group selected from (a) or (b);

R_2 is hydrogen, halo, C_1 - C_3 alkyl, C_3 - C_4 cycloalkyl, C_3 - C_4 cycloalkenyl, $-O-(C_1-C_2$ alkyl), $-S-(C_1-C_2$ alkyl),

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or a non-interfering substituent having a total of 1 to 3 atoms other than hydrogen;

R₆ and R₇ are independently selected from hydrogen, a non-interfering substituent, or the group, -(L_a)-(acidic-group); wherein -(L_a)-, is an acid linker having an acid linker length of 1 to 10; provided, that at least one of R₆ and R₇ must be the group, -(L_a)-(acidic group); and

R₄ and R₅ are each independently selected from hydrogen, non-interfering substituent, carbocyclic radical, carbocyclic radical substituted with non-interfering substituents, heterocyclic radical, and heterocyclic radical substituted with non-interfering substituents.

Claim 11. A pharmaceutical formulation comprising the indene-1-acetamide as claimed in Claim 1 together with a pharmaceutically acceptable carrier or diluent therefor.

Claim 14. A method of treating a mammal to alleviate the pathological effects of septic shock, adult respiratory distress syndrome, pancreatitis, trauma, bronchial asthma, allergic rhinitis, and rheumatoid arthritis; wherein the method comprises administration to said mammal of at least one indene-1-acetamide as claimed in Claim 1 in an amount sufficient to inhibit sPLA₂ mediated release of fatty acid and to thereby inhibit or prevent the arachidonic acid cascade and its deleterious products.

OPINION

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Claims 1, 3 through 7, 11 and 14 are rejected as failing to comply with 35 U.S.C. § 112, second paragraph. Claims 1, 3 through 7, 10, 11, 14 and 17 through 19 stand rejected as being unpatentable under 35 U.S.C. § 103 from Girard or Shen et al. (either 3,888,902 or 3,954,852), any considered alone. We reverse.

THE REFERENCES

The references of record which are being relied on as evidence of obviousness are:

Shen et al. (Shen '902)	3,888,902	June 10, 1975
Shen et al. (Shen '852)	3,954,852	May 4, 1976
Girard et al. (Girard)	5,093,356	March 3, 1992

THE REJECTION UNDER 35 U.S.C. § 112

In rejecting appellants' claims under this section of the statute, it is incumbent upon the examiner to factually establish that one having ordinary skill in the art would not have been able to ascertain the scope of protection defined by the claims when read, not in a vacuum, but in light of the supporting specification. In re Moore, 439 F.2d 1232, 1234, 169 USPQ 236, 238 (CCPA 1971); In re Hammack, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970). Thus, the examiner bears the initial burden of establishing a *prima facie* case of

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failing to comply with the second paragraph of the statute.

Here, the examiner has merely announced that he does not understand what substituents are intended by the terminology used in the claims, that is, the examiner does not understand what are the "non-interfering substituents" R_6 and R_7 .

Moreover, although the examiner does not precisely reference the exact claim term to which he objects, the examiner expresses his concerns by stating at page 3 of his Answer

"[w]hat are the numbers 1-10 for La? What linker groups are intended? Are 1-10 oxygens, sulfur, carbon, nitrogen, Se, P, Ge, Pb also intended? Thus, the claims are indefinite."

Neither expressed ground serves as a basis for sustaining either rejection.

As we have stated above, the question to be resolved is whether the hypothetical person of ordinary skill in the relevant art, having read appellants' specification, would have been able to determine the scope of appellants' invention. Appellants have stated that the meaning intended for the term "non-interfering substituent" was a substituent which does not interfere with the compounds' **SPLA**, inhibiting properties (see page 5 of the brief). Considered with the list

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found on page 5, line 29 through page 6, line 16 of the specification of exemplary types of "non-interfering" substituents, we find the terminology "non-interfering substituent" as used in the claims would have been clearly understood by the hypothetical person of ordinary skill.

Likewise, the examiner has reached his conclusion about the meaning of the term "an acid linker having an acid linker length of 1 to 10" only by ignoring appellants' definition of the same in their specification. At page 7, line 7, appellants define the term as:

a divalent linking group symbolized as, -(La)-, which has the function of joining the indene nucleus to an acidic group ...

Thereafter, on page 8, line 6 through page 9, line 5, appellants further define what they intend by their claim terminology.

We cannot say that the terminology is conventional but it is defined. Admittedly, the claims are also of considerable scope; however, this, in and of itself, is not a basis for rejection. U.S. Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed. Cir. 1989). As the court suggested in In re Borkowski, 422 F.2d 904, 909, 164

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USPQ 642, 646 (CCPA 1970), the proper approach to take when claims are found to be of a scope such that they do not distinguish from the prior art is to reject such claims on prior art not reject them under the second paragraph of the statute.

It is also generally understood that an applicant for patent may be his own lexicographer so long as an applicant for patent clearly sets forth in applicant's specification the definition applicant intends for a particular claim term, even when that definition is different from the conventional, art-recognized definition. Beachcombers, Int. v. WildeWood Creative Products, Inc. 31 F.3d 1154, 1158, 31 USPQ2d 1653, 1656 (Fed. Cir. 1994); ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1579, 6 USPQ2d 1557, 1560 (Fed. Cir. 1988); Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759, 221 USPQ 473, 477 (Fed. Cir. 1984). As we have concluded above, appellants have certainly set forth the meaning they intend for their claim language.

For all the above reasons, the rejection under 35 U.S.C. § 112, second paragraph is **reversed**.

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THE REJECTIONS UNDER 35 U.S.C. § 103

We shall reverse each of the examiner's stated reasons for finding appellants' claimed invention to be unpatentable under 35 U.S.C. § 103. We find no reference relied on would have fairly suggested appellants' claimed group of indene-1-acetamides and we find no reference on which the examiner has relied would have suggested that appellants' compounds would have been expected to exhibit **sPLA₂** inhibition.

We presume the examiner's characterization of the "prior art" as disclosing "a generic group of benzylidene substituted indane compounds" is a reference to the "prior art" on which he relies and while we agree with the examiner's characterization of that "prior art" as disclosing "a generic group of benzylidene substituted indane compounds", we find no evidence in any of Girard, Shen '902 or Shen '852 of appellants' particularly substituted indene-1-acetamides. Specifically, and contrary to the examiner's conclusion, none of the cited prior art discloses at the positions bearing appellants' **R₆** or **R₇**, of the indene moiety an "acidic group" attached to the indene moiety by a linking group. Rather, each of the prior art references discloses a "carboxy"

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substituent directly attached to the indene moiety.

In Girard, the examiner directs our attention to the definition of R^4 as "carboxy" and, for the first time in his Answer at page 6, to the disclosure in column 2 wherein R^4 is defined as $O-R^8$, R^8 is R^9 and R^9 is lower alkyl substituted with $-COOH$ group. According to the examiner, the disclosure of R^4 as carboxy in general and the specific disclosure of the group $-O-(CH_2)_n-COOH$ "teach(es) and suggest(s) appellant's invention." However, when R^4 is "carboxy", the "carboxy" radical is attached directly to the indene moiety. With respect to the examiner's newly proposed interpretation of R^4 we simply observe that the examiner has mischaracterized the reference in reaching his conclusion. Specifically, while Girard does disclose that R^4 may be $-OR^8$ and R^8 may be R^9 , R^9 is defined as lower alkyl. Contrary to the examiner's representation, R^9 is not defined as lower alkyl substituted with $-COOH$. Rather, it is R^2 and R^3 which may be independently selected from the groups denominated as "c)" through "g)" in column 2 lines 29 through 39 of Girard. Suffice it to say we find no disclosure in Girard which would have suggested appellants' particularly substituted indene-1-acetamides.

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Accordingly, we **reverse** the examiner's rejection of the claims as it is founded on Girard.

We also disagree with the examiner's characterization of both the Shen '902 and Shen '852 disclosures that **R₃** and **R₄** may be "carb lower alkoxy which is $-\text{O}-(\text{CH}_2)_n-\text{COOH}$ ". Rather, we consider the described "carb lower alkoxy" groups to represent the chemical moiety $-\text{C}(\text{O})-(\text{lower alkoxy})$. Thus, each of the Shen references discloses moieties which attach directly to the indene moiety through the carboxy carbon terminus of the "carb lower alkoxy" substituent and not via a "linking" group as required by the claims. Accordingly, we **reverse** the examiner's rejection of the claims as it is founded on either Shen reference.

SUMMARY

The examiner's rejection of the claims under 35 U.S.C. § 112, second paragraph, is reversed.

The examiner's rejection of the claims as being unpatentable under 35 U.S.C. § 103 is reversed.

REVERSED.

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