

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the board.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. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

MAILED

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

JUL 26 1995

Ex parte WAYNE K. ANDERSON
and
DENNIS C. DEAN

PAT.&T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Appeal No. 94-2812
Application 07/729,986¹

ON BRIEF

Before GOLDSTEIN, JOHN SMITH and TURNER, Administrative Patent Judges.

TURNER, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the Examiner's decision finally rejecting claims 6-15, 19-21, 28-31, 36-43, 46 and 47, which are all of the claims remaining under rejection. Claims 22, 23, 34,

¹ Application for patent filed July 15, 1991. According to appellants, the application is a continuation-in-part of Application 07/371,504, filed June 26, 1989.

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and 35 stand objected to. Illustrative claims 6, 28 and 36 are appended to this decision.

The references of record cited by the Examiner but not relied upon for purposes of any prior art rejection are:

Devita, et al. (Devita) "Cancer Principles and Practice of Oncology," Lippincott., pp. 144-145 (1985)

Moossa et al. (Moossa) "Comprehensive Textbook of Oncology, Williams and Wilkins, pp. 199-200 (1986)

Claims 6 and 7 stand rejected under 35 U.S.C. § 112, second paragraph since certain terms are ambiguous and render the claims unclear. Claims 6-15, 19-21, 28-31, 36-43, 46 and 47 stand rejected under 35 U.S.C. § 101 because the scope of the compounds embraced by the claims and all of the tumors embraced thereby are not commensurate with the understood predictability of the art. Finally, claims 6-15, 19-21, 28-31, 36-43, 46 and 47 stand rejected under 35 U.S.C. § 112, first paragraph as the specification lacks enablement as to how to use all of the compounds embraced by the claims. We shall not affirm the rejection under 35 U.S.C. § 112, second paragraph. We shall not affirm the rejection of claims 6-15, 19-21, 28-31, 36-43, 46 and 47 under 35 U.S.C. § 101. We shall not affirm the rejection of claims 6-15, 19-21, 28-31, 46 and 47 under 35 U.S.C. § 112, first paragraph. We shall affirm the rejection of claims 36-43 under 35 U.S.C. § 112, first paragraph.

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The Examiner indicates that the claims stand or fall together since the Brief does not include a statement that they do not stand or fall together.

OPINION

We have carefully reviewed the record before us, including each of the arguments and comments advanced by Appellants and the Examiner in support of their respective positions. This review leads us to conclude that the Examiner's position is well founded with respect to the rejection of claims 36-43 under 35 U.S.C. § 112, first paragraph. We do not agree with the position of the Examiner with respect to the remaining rejections under § 112, first and second paragraphs and § 101 and reverse. Our reasons follow.

REJECTION OF CLAIMS 6 AND 7 UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner indicates in the Answer that the terms "substituted alkyl", "aryl" and "amine group up to about 20 carbon atoms" are indefinite. We agree with the position of Appellants. These terms are not, in our view, indefinite. Definiteness of language employed in claims must be analyzed, not in a vacuum, but always in light of teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing an ordinary level of skill in the pertinent art. In re Moore, 439 F.2d 1232, 169 USPQ 236 (CCPA

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1971). Viewing the terms in light of the specification at pages 4 and 8, we cannot conclude that one of ordinary skill in the relevant art, having the disclosure and claims before him or her, would not be possessed of a reasonable degree of certainty as to the subject matter encompassed within the claims. Accordingly, we reverse the rejection.

REJECTION OF CLAIMS 6-15, 19-21, 28-31, 36-43, 46 AND 47 UNDER 35 U.S.C. § 101

We note at the outset that the claims are directed to compounds (claims 6-15, 19-21), pharmaceutical compositions (claims 28-31, 46, and 47) comprising the compounds, and methods of using the compounds to inhibit the growth of tumors (claims 36-43).

Appellants in the claims here on appeal have identified in the specification several specific utilities for the compounds including use as bactericides, fungicides and as agents for the inhibition of the growth of tumors (specification, pages 1 and 2). Having disclosed a credible utility for the compounds (e.g., as bactericides and fungicides), we conclude that there is no reasonable basis to challenge the utility for the compounds embraced by the claims here on appeal. See In re Gottlieb, 328 F.2d 1016, 140 USPQ 665, 668 (CCPA 1964). Insofar as the claimed utility of inhibiting the growth of tumors, the disclosure at pages 32-35 reflect at least some degree of activity and

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usefulness for certain of the compounds in the treatment of tumors in mice. The Examiner argues that the credible utilities disclosed in the specification are all encompassing and include all bacteria and even some viruses. We find ourselves in agreement with Appellants and the comments at page 10 of the main Brief as the Examiner has offered no evidence to challenge the truth of the asserted utility as fungicides and bactericides. We are not aware of any controlling case law which holds that utility is lacking merely because a claim or claims might embrace an organism against which certain of the compounds would be ineffective. The Examiner also states that the scope of the claims is not commensurate with the understood predictability of the art. The Examiner further states that the claims recite (or embrace) myriads of heterocyclic compounds and all cancer tumors. Presumably, the Examiner is of the view that certain of the compounds/compositions are useless or ineffective for the claimed use. Nonetheless, the Examiner has not explained why this view gives rise to a challenge to utility nor has the Examiner offered any evidence to support the challenge to utility. On this record, the Examiner has not established a prima facie showing that the claimed invention has no utility and has presented no specific evidence to support a lack of a credible utility. Accordingly, the rejection is reversed.

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REJECTION OF CLAIMS 6-15, 19-21, 28-31, 36-43, 46 AND 47 UNDER 35
U.S.C. § 112, FIRST PARAGRAPH

We shall affirm this rejection as it applies to claims 36-43 but not as it applies to claims 6-15, 19-21, 28-31, 46 and 47.

CLAIMS 36-43

Appellants have taken the position that the disclosure in the specification is sufficiently enabled under § 112, first paragraph (Brief, page 8). The first paragraph of § 112 requires, inter alia, that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without "undue experimentation". In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 at 1444 (Fed. Cir. 1991). It is also clear from the first paragraph of § 112 that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification. In re Fisher, 427 F.2d 833, 166 USPQ 18 at 24 (CCPA 1970). In situations involving unpredictable factors such as chemical reactions and physiological activity, the scope of enablement varies with the degree of unpredictability of the factors involved. *Id.* at 24. In the present case, the cancer tumors against which the compounds would be effective represent a factor having a high

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degree of unpredictability based upon conventional knowledge in the art. Similarly, the compounds which might be useful therefor represent another factor having a degree of unpredictability. Thus, the disclosure must be sufficient to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. Where, as here, a claim 36 represents a diverse group of apparently unknown compounds being employed to treat a condition known to be very difficult to effectively treat in view of contemporary knowledge in the art, the level of disclosure required will be greater than the level of disclosure required for an invention involving a predictable factor or factors. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 at 1445 (Fed. Cir. 1991). Appellants argue that the specification is enabling and that the PTO has the burden of providing specific reasons why the specification is not enabling. Those reasons are indicated above in discussing the unpredictability factors and they are supported by the data which, at pages 34 and 35 of the specification, reveals that only 4 of the 9 compounds tested (about 44%), were found to be useful for further testing or screening. None of the pyrroliziny carbamate compounds were shown to be effective in the tests. The relevant claims embrace a wide variety of compound types which are said to be useful in inhibiting the growth of tumors but the specification presents, in the data, a very clear basis for the position taken by the

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Examiner that the specification is not enabling for the scope of the subject matter sought to be patented without the use of undue experimentation. Accordingly, we affirm the rejection as it applies to claims 36-43.

CLAIMS 6-15, 19-21, 28-31, 46 AND 47

We shall not affirm this rejection. It is apparent that the specification describes credible utilities for the compounds embraced by the claims including use as bactericides and fungicides. The Examiner has provided no evidence to suggest that controlling bacteria and fungi is particularly difficult, dangerous, or that a remedy for controlling same does not presently exist. As pointed out by Appellants at page 11 of the Brief, many compounds are known to possess such utility. We do not view the disclosure at pages 11 and 12 as an invitation to experiment. Rather, we view the disclosure as providing ample guidance to one of ordinary skill in the art. For example, the compounds are disclosed as having a credible utility as bactericides or fungicides and they are taught at pages 11 and 12 as being useful as antimicrobial agents in soaps and deodorants. We have little doubt that such a disclosure is sufficient for the skilled worker to practice the invention having the specification before him or her. We are not aware that the utility is unpredictable such that the skilled worker would have difficulty in practicing the invention and the Examiner has provided no

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evidence to the contrary. We are thus of the opinion that the position of the Examiner is not well founded. Accordingly, we reverse the rejection under § 112, first paragraph.

For the reasons set forth above, we affirm the rejection of claims 36-43 under 35 U.S.C. § 112, first paragraph and reverse the remaining rejections under 35 U.S.C. § 112, first and second paragraphs and § 101.

The decision of the Examiner is affirmed-in-part.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR 1.136(a).

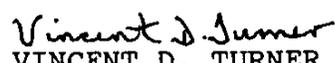
AFFIRMED-IN-PART



MELVIN GOLDSTEIN)
Administrative Patent Judge)



JOHN D. SMITH)
Administrative Patent Judge)



VINCENT D. TURNER)
Administrative Patent Judge)

) BOARD OF PATENT
) APPEALS
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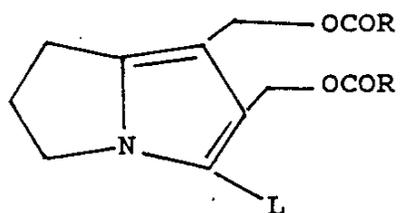
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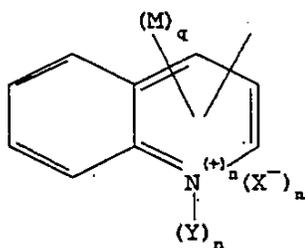
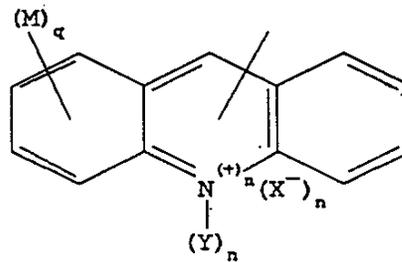
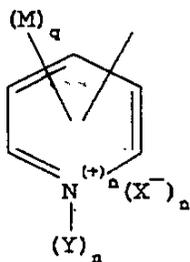
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APPENDIX

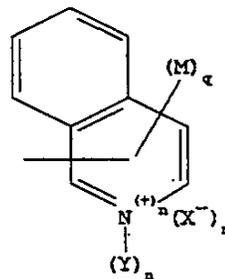
6. A bis-acyloxymethyl compound having the structure:



Wherein L is selected from:



; and



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Appendix Cont'd

wherein Y is selected from hydrogen or $\begin{matrix} & O \\ & || \\ Z' & -C-O-C-Z \\ & | \\ & Z' \end{matrix}$; each R and Z

is independently selected from hydrogen or substituted and unsubstituted alkyl, cycloalkyl, aryl, alkenyl, cycloalkenyl, alkynyl, and amine group of up to about 20 carbon atoms; each Z' is independently selected from hydrogen and substituted or unsubstituted alkyl of up to about 20 carbon atoms; M is Z or is selected from halogen, nitro, hydroxyl, nitrile and substituted [sic, substituted] or unsubstituted carboxylic acid group, carboxylic acid ester group, carboxylic acid amide group, sulfonic acid group, sulfonic acid amide group, ether group, thioether group, acylated hydroxyl, sulfonamide, sulfonurea, sulfoxide group and sulfone group containing up to about 20 carbon atoms; each n is the same and is 0 or 1; q is from 0-4; and, X is the anion of an acid.

28. A pharmaceutical comprising a pharmaceutical diluent and a compound of claim 6.

36. A method for inhibiting the growth, in a warm blooded animal, of a cancer tumor comprising administering to said warm blooded animal, an effective cancer tumor inhibiting amount of a compound selected from the group consisting of 2,3-dihydro-5-(4-pyridinyl)-6,7-bis(hydroxymethyl)-1H-pyrrolizine Bis; 2,3-dihydro-5-6,7-bis(hydroxymethyl)-1H-pyrrolizine Bis; 2,3-dihydro-5-6,7-bis(hydroxymethyl)-1H-pyrrolizine Bis; 2,3-dihydro-5-6,7-bis(hydroxymethyl)-1H-pyrrolizine Bis; 2,3-dihydro-5-(3-pyridinyl)-6,7-bis(hydroxy-methyl)-1H-pyrrolizine Bis; 2,3-dihydro-5-6,7-bis(hydroxymethyl)-1H-pyrrolizine Bis; 2,3-dihydro-5-6,7-bis(hydroxymethyl)-1H-pyrrolizine Bis; 2,3-dihydro-5-6,7-bis(hydroxymethyl)-1H-pyrrolizine Bis; 1-4-{5} Pyridinium iodide; 1-4-{5}pyridinium iodide; 1-3-{5} pyridinium iodide; 1-3-{5}pyridinium iodide; and 1-methyl-4-{5}pyridinium iodide.