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

In re Application of:	)	
	)	
David RUBIN	)	Art Unit: 125
	)	
Serial No.: 583,798	)	Examiner: J. Goldberg
	)	
Filed: March 1, 1984	)	
	)	
For: TUMOR TREATMENT COMPOSITION	)	February 6, 1994
	)	

BRIEF ON APPEAL

The present appeal is taken from the action of the Examiner in finally rejecting claims 2 ~~and 4-22~~. The full text of the claims appears in appendix A attached hereto.

STATUS OF CLAIMS

Claims 2 ~~and 4-22~~ presently appears in this case. Claims 1 ~~and 3~~ have been cancelled. ~~All~~ of Claims 2 ~~and 4-22~~ presently appearing in this case ~~are~~ is subject to the present appeal.

STATUS OF AMENDMENTS

Subsequent to the final rejection of ~~May 19, 1988~~ Aug. 26, 1997, applicant filed an amendment dated ~~September 26, 1988~~ Nov. 24, 1997. By advisory action of ~~September 26, 1988~~ Dec. 28, 1997, the examiner indicated that upon

filing of an appeal, the proposed amendment would be entered.

SUMMARY OF THE INVENTION

The present invention relates to the discovery that a certain component of normal blood serum is selectively toxic to certain tumor cells and is not present in the sera of patients afflicted with such tumors.

In order to test the hypothesis that there might be a component in a normal individual's blood serum which prevents the invasion of cancer cells in a healthy individual, tests were ... type of neoplasm. If lysis results, then it would be expected that the compounds of the present invention would indeed be effective against these tumors in vivo.

THE PRIOR ART

The only references cited and applied against the claims in the final rejection of May 19, 1988, are:

> Adams, K.R. et al "Long Chain αx-dicarboxylic acids from Spores of Equisetum Spp.", J. Chem. Soc., 1969 (5) 456-7.
>
> Dyer, AW. "Index of Tumor Chemotherapy," March 1949, pp 10, 11 and 73, NIH.

Adams relates to a study of the spores of various species of Equisetum. Extracting these spores left two significant components, one being dimethyl triacontanedioate and the other being dimethyl octacosanedioate. In the sentence bridging the two pages of the article, it is stated:

> Long chain αx-dicarboxylic acids have been reported infrequently as natural products, and neither octacosanedioic acid nor triacontanedioic acid appears to have been so encountered previously.

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was tested. No test was conducted showing any effectiveness of suberic acid alone.

THE REJECTIONS

In the final rejection of May 19, 1988, claims 2 and 4-22 were rejected under 35 USC 103 as being unpatentable over the Dyer reference of record, the examiner stating:

...

Claims 2, 4, 11, 12 and 13 have been rejected under 35 USC 103 as being unpatentable over the Adams et al reference for the reasons fully set forth in paper no. 26, pages 2 and 3. In paper no. 26, the examiner merely referred to the reasons set forth in paper no. 19, page 2; in paper no. 19, page 2, the examiner referred to the reasons set forth in paper no. 17, pages 2 and 3. In Paper No. 17, the Examiner stated:

...

In paper no. 19 the Examiner added:

...

In paper no. 26, the examiner added:

...

> 9), the claims are indefinite in failing to recite a host. Cells cannot grow alone.

ISSUES

The following issues are presented in this appeal:

I. Does the teaching with respect to C_8-dicarboxylic acid in Dyer render the use of C_{12}-dicarboxylic acid in claims 5, 6, 9 and 14-19 prima facie obvious?

II. Does the teaching with respect to C_8-dicarboxylic acid in Dyer render the C_{16}-dicarboxylic acid in claims 2 and 11 prima facie obvious?

III. Does the teaching with respect to C_8-dicarboxylic acid in Dyer render the C_{28}-dicarboxylic acid in claims 4, 7, 10, 12, 13 and 20-22 prima facie obvious?

IV. Does the data in the present specification rebut any case of prima facie obviousness over Dyer which may have been established?

V. Does the prior art disclosure of octacosanedioic acid, without disclosure of any utility, render prima facie obvious the disodium salt thereof?

VI. Does the prior art disclosure of a compound not in a pharmaceutically acceptable carrier and without the teaching of any utility render obvious a composition of such compound in a pharmaceutical carrier?

VII. Is a general statement with respect to formulation

with pharmaceutically acceptable carriers in the specification sufficient to support the recitation thereof in a claim?

VIII. Is treatment of cancer cells in vitro sufficient utility to comply with 35 USC 101?

IX. Is the term "contacted" indefinite in a claim for a method of treating cancer cells which fails to recite a host?

GROUPING OF CLAIMS

As to the 35 USC 103 rejection over Dyer, applicant contends that all of the rejected claims do not stand or fall together. Insofar as issue I is concerned, claims 5, 6, 9 and 14-19 stand together. Insofar as issue II is concerned, claims 2 and 11 are patentable in their own right. Insofar as issue III is concerned, claims 4, 7, 10, 12, 13 and 20-22, as a group, are patentable in their own right and stand or fall together. The three groups of claims discussed above will also be argued separately with respect to issue IV.

With respect to the rejection of claims 2, 4, 11, 12 and 13 over Adams, claims 13, 11 and 12 as a group are patentable in their own right for the issues which will be discussed with respect to issue V, and claims 2, 4, 11 and 12 as a group are patentable in their own right and stand together insofar as the arguments presented in issue VI are concerned. Thus, claims 11 and 12 are free of this rejection if either of the arguments of

issues V or VI are successful.

Insofar as the objection to the specification and the rejection of claims 2, 4, 11 and 12 under 35 USC 112, first paragraph, claims 2, 4, 11 and 12 stand or fall together.

Insofar as the rejection of claims 14-22 under 35 USC 101 and 35 USC 112, second paragraph, all of claims 14-22 stand or fall together.

A R G U M E N T

The Teaching with Respect to C_8-Dicarboxylic Acid in Dyer does not Render the use of C_{12}-Dicarboxylic Acid in Claims 5, 6, 9, 11 and 14-19 Prima Facie Obvious

All of claims 5, 6, 9, 11 and 14-19 are drawn to methods of treatment of certain neoplasms using a saturated straight chain aliphatic dicarboxylic acid, or a pharmaceutically acceptable salt

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tion, insofar as claims 5, 6, 9, 11 and 14-19 are concerned, are therefore respectfully urged.

The Dyer Teaching with Respect to C_8-Dicarboxylic Acid Certainly Does Not Render the C_{16}-Dicarboxylic Acid of Claims 2 and 11 Prima Facie Obvious

Claims 2 and 11 do not read on compositions including C_{12}-dicarboxylic acid. The smallest dicarboxylic acid of claims 2

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Reversal of the examiner and withdrawal of this rejection with respect to all of the claims are therefore respectfully

urged.

The Prior Art Disclosure of Octacosanedioic Acid, without Disclosure of Any Utility, Does Not Render Prima Facie Obvious the Disodium Salt Thereof

Claim 13 is a compound claim drawn to the disodium salt of octacosanedioic acid in substantially pure form. The disodium

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Accordingly, reversal of the Examiner and withdrawal of the 35 USC 103 rejection of claims 11, 12 and 13 over Adams are respectfully urged.

The Prior Art Disclosure of a Compound, without Disclosure of Any Utility, Does Not Automatically Render Obvious a Composition of Such a Compound with a Pharmaceutically Acceptable Carrier

The Examiner has taken the position that if a compound is known, regardless of whether any utility for the compound is

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also comply with 35 USC 112. Reversal of the examiner withdrawal of this rejection are therefore also respectfully urged.

CONCLUSION

The claims as submitted are believed to truly set forth the inventive concept of the present invention and to patentably define over the prior art. The prior art rejections are not applicable for the reasons discussed hereinabove. All of the claims are based on an enabling disclosure, and fully comply with 35 USC 112. Furthermore, the proof of utility of record in this

case is sufficient to comply with 35 USC 101.

WHEREFORE, reversal of the Examiner and allowance of claims 2 and 4-22 is earnestly solicited.

Respectfully submitted

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