

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 22

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MASAZUMI MISHIKAWA and SHOJI KIMURA

Appeal No. 1998-1245
Application No. 08/111,831

ON BRIEF

Before WINTERS, ROBINSON, and GRIMES, Administrative Patent Judges.
ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 8 - 14, which are all of the claims pending in this application.

The claims read as follows:

8. An antipsychotic comprising a lipoxygenase metabolite of docosahexaenoic acid or derivative thereof selected from the group consisting of 14-hydroxydocosahexaenoic acid, ethyl 14-hydroxydocosahexaenoate, 7-hydroxydocosahexaenoic acid or ethyl 7-hydroxydocosahexaenoate.
9. An antipsychotic comprising a P450 dehydrogenase metabolite of docosahexaenoic acid or derivative thereof selected from the group consisting of 7,8-epoxydocosapentaenoic acid or ethyl 7, 8-epoxydocosapentaenoate.

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10. A method for treating psychosis, comprising administering an effective dosage of at least one lipoxygenase metabolite of docosahexaenoic acid or derivative thereof.

11. The method according to Claim 10, wherein the lipoxygenase metabolite or derivative thereof is selected from the group consisting of 14-hydroxydocosahexaenoic acid, ethyl 14-hydroxydocosahexaenoate, 7-hydroxydocosahexaenoic acid or ethyl 7-hydroxydocosahexaenoate.

12. A method for treating psychosis, comprising administering an effective dosage of at least one P450 dehydrogenase metabolite of docosahexaenoic acid or derivative thereof.

13. The method according to Claim 12, wherein the P450 dehydrogenase metabolite or derivative thereof is selected from the group consisting of 7, 8-epoxydocosapentaenoic acid or ethyl 7, 8-epoxydocosapentaenoate.

14. A method for treating psychosis, comprising administering an effective dosage of a composition consisting essentially of a phospholipid or triglyceride of docosahexaenoic acid.

The references relied upon by the examiner are:

Kimura et al. (Kimura I), "Use of docosahexaenoic acid for improving brain function," Chemical Abstracts, Abstract No. 112:191978p (1990)

Horrobin et al (Horrobin), "Essential fatty acid composition for treating schizophrenia and inflammatory skin disorders," Chemical Abstracts, Abstract No. 113:158684n (1990)

Kimura et al. (Kimura II), "Pharmaceutical and food compositions containing docosahexaenoic acid derivatives for improvement of brain functions," Chemical Abstracts, Abstract No. 113:71343b (1990)

Goodman and Gilman's (Goodman and Gilman's), The Pharmacological Basis of Therapeutics, (6th Ed.), page 12 (1980)

VanRollins et al. (VanRollins I), "Oxidation of docosahexaenoic acid by rat liver microsomes," HCAPLUS, Abstract No. 1984:41994 (1984)

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VanRollins et al. (VanRollins II), "Synthesis of epoxide and vicinal diol regioisomers from docosahexaenoate methy esters," HCAPLUS, Abstract No. 1989:457336 (1989)

Grounds of Rejection

Claims 8 - 9 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Kimura I.

Claims 10 - 13 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Horrobin and Kimura I.

Claim 14 stands rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Horrobin and Kimura II.

We reverse for the reasons set forth herein.

Discussion

Background

The rejections of the claims on appeal, in their present form, were presented for the first time in the Examiner's Answer of March 25, 1996 (Paper No. 15) and were designated as new grounds of rejection. The examiner has relied on three abstracts published in Chemical Abstracts as evidence in support of these rejections. The examiner has, additionally, cited and apparently relies on, for the first time in the Supplemental Examiner's Answer of March 17, 1997 (Paper No. 19) two abstracts of separate articles by VanRollins et al. and a portion from Goodman and Gilman's. In the response filed September 25, 1995 (Paper No. 10) appellants urge that "Horrobin (U.S. Patent No. 5,120,760)-- describes in more detail the technology disclosed in Chemical Abstract '684." The U.S. Patent relies on the United Kingdom patent application 88/13766 for

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foreign priority and this foreign application is also referenced in the Horrobin abstract relied on by the examiner. Thus, there would appear to be a reasonable indication that the disclosure of the U.S. Patent corresponds to the abstract to Horrobin. It is not readily apparent why the examiner, having a full text document equivalent to the document abstracted by Chemical Abstracts, continued to rely on the abstract rather than the complete document. However, be that as it may, the rejection before us relies only on the abstracts and the subsequently cited Goodman and Gilman's. We note that the record does not indicate that either the examiner or appellants have attempted to make available for consideration the full text documents on which the abstracts to Kimura I and Kimura II are based.

Under these circumstances we could remand this application to the examining group for clarification as to the relevance of the U.S. Patent to Horrobin and for consideration of the full text articles on which the abstracts are based. A patentability determination under 35 U.S.C. § 103 is fact specific. Almost by definition the full text document which is abstracted is more fact rich than the abstract. It is the experience of the board that review of the full text document, when a rejection is premised upon an abstract, will most likely significantly strengthen or weaken the examiner's position. Rarely does consideration of the full text document leave one in the same position where one was after considering the abstract alone. However, in the interest of judicial economy and of reaching a disposition on the record presented, we elect to consider the issues raised by the rejections before us. In so doing, we note that we have limited our consideration of the

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issues raised by this appeal to the quantum of evidence provided by the specific abstracts relied on by the examiner.

The rejections under 35 U.S.C. § 103

Claims 8 - 9 stand rejected under 35 U.S.C. § 103 as being obvious over Kimura I. The examiner urges that this abstract "teaches that ethyl esters of docosahexaenoic acid (DHA) and DHA itself are known in compositions." (Answer, page 3). The examiner acknowledges that the claims are directed to "particular ethyl esters of DHA which are metabolites of DHA" (Id.) but urges that "one of ordinary skill would have been motivated to employ any particular ethyl ester in a composition since these compounds are known broadly in compositions, as is the parent compound, DHA, which results in formation of the instant metabolites on administration to a host." The examiner addresses claim 9 by stating that "[t]he pentanoic acid metabolites are also obvious from the prior art since they differ from the hexanoic acid patent, DHA, by only one double bond in the carbon chain." (Answer, sentence bridging pages 3-4).

In rejecting claims 10 - 13 under 35 U.S.C. § 103 as unpatentable over Horrobin and Kimura II the examiner states that Horrobin "teaches that DHA is known in compositions and methods for the treatment of psychosis" and differs from the claims "in that they are drawn to methods employing particular metabolites of DHA." (Answer, page 4). The examiner urges that Kimura II "teaches that DHA metabolites encompassed by the claims are known to have pharmacological activity." (Id.). The examiner concludes that

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"one or ordinary skill would have been motivated to employ any metabolite of DHA in a psychosis treatment with the expectation of similar activity, since the parent compound, DHA was known for the same purpose and its metabolites are expected to form in a host after its administration." (Id.). As in the previous rejection the examiner urges that "[t]he pentanoic acid metabolites are also obvious from the prior art since they differ from the hexanoic acid parent, DHA, by only one double bond in the carbon chain." (Id.).

In rejecting claim 14 under 35 U.S.C. § 103, the examiner, again, relies on Horrobin as teaching that "DHA is known in compositions and methods for the treatment of psychosis." (Answer, page 5). The examiner acknowledges that the "claim differs in that it is drawn to methods employing a phospholipid or triglyceride of DHA." (Id.). Kimura II is urged to teach that "DHA and its derivatives, including phospholipids and triglycerides, are known as a group, to have similar pharmacological activity." (Id.). Thus, "one or ordinary skill would have been motivated to employ a composition consisting essentially of a phospholipid or triglyceride of DHA in a method of treating psychosis since DHA was known for the same purpose and these derivatives would be expected to exhibit similar activity." (Id.).

As with any rejection under 35 U.S.C. § 103, the initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). On the record before us, we find that the examiner has failed to point to those facts or provide evidence which would reasonably support a prima facie case of obviousness within the meaning of 35 U.S.C. §

103 as to the claimed subject matter. The examiner's rejections before us would appear to be based on two propositions. The first is that, since DHA has been established to be useful in the treatment of schizophrenia (Horrobin), one of ordinary skill in this art would have expected the metabolites of DHA to have similar activity. The second is that, since Kimura I and Kimura II describe the use of certain derivatives of DHA in the form of compositions as useful for enhancing brain function, the compositions containing metabolite derivatives of DHA would have been obvious as would the use of the specific derivatives of DHA in the treatment of psychosis.

Considering first the question of whether one of ordinary skill in this art would expect the metabolites of DHA to have the same utility as DHA itself, we note that the examiner has cited Goodman and Gilman's as evidence that such activity would be expected. However, our reading of the portion of Goodman and Gilman's (page 12), relied on by the examiner, is less than definitive on this issue and in fact states that such metabolites "may exert effects that are similar to or different from those of the parent molecule." (Emphasis added.) Additionally, we agree with appellants' reasoning at pages 5-7 of the Supplemental Brief filed May 23, 1996 (Paper No. 18) in support of the conclusion that "it is impossible to predict the physiological activity of a metabolite from the known physiological activity of the substrate from which it is derived." Thus, while there is a possibility that the metabolites of DHA would have a pharmacological activity similar to that of the parent, this general statement from Goodman and Gilman's does not reasonably suggest a likelihood that these specific metabolites will be useful in this manner. More is

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required. This limited evidence does not establish that the prior art would have suggested to one of ordinary skill in the art that the metabolites of DHA would likely be useful in the treatment of psychosis and that one attempting to use these metabolites in the manner claimed would have a reasonable likelihood of success, viewed in light of the prior art.

See In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

As to the second proposition, we note that claims 8, 9, 11, and 13 are limited to specific compounds which are not described in the prior art initially relied on by the examiner. Similarly, claims 10 and 12 are directed to specific classes of metabolites which are not described in the prior art relied on by the examiner. The ethyl ester of DHA described by Kimura I does not correspond to any of the ethyl esters of claims 8, 9, 11, or 13. Further, there is no disclosure in any of these references which would establish that the designated P450 dehydrogenase metabolites of DHA were known or pharmaceutically active for any purpose. The general statements by the examiner relating to these metabolites do not raise to the level of evidence necessary to establish that these substances were known in this art at the time of the invention.

With regard to claim 14, the examiner has relied on Kimura II which discloses derivatives of DHA, including phospholipids and triglycerides, as useful in obtaining improvement in brain function. However, the examiner offers no evidence which would

suggest that improved brain function as described by Kimura II relates to the treatment of psychosis as claimed in claim 14.

The examiner has cited the two VanRollins abstracts, apparently, to establish that the metabolites of DHA utilized in claims 8 - 13 are known in the prior art. (Supp. Answer, pages 3 and 4). However, these abstracts provide no information as to the possible use of these derivatives to obtain a pharmacological effect or to suggest that any of the derivatives would be useful in treating psychosis as presently claimed. As we have stated above, merely because these compounds are metabolites of DHA does not, standing alone, suggest their use in the manner presently claimed. In fact, the only information to be found in this record which would suggest the use of the metabolites and or derivatives of DHA for the treatment of psychosis appears to be appellants' disclosure of the present invention. However, use of this information as a basis for establishing a prima facie case of obviousness, within the meaning of 35 U.S.C. § 103, would constitute impermissible hindsight.

Thus, we conclude, that on this record, the examiner has failed to provide facts or substantive evidence which would reasonably support a conclusion that the claimed subject matter would have been obvious within the meaning of 35 U.S.C. § 103. Where, as here, the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). Therefore, we reverse the rejections of claims 8 - 14 under 35 U.S.C. § 103.

Other Issues

Upon return of this application to the examining group we would urge the examiner to reconsider the patentability of claims 8 and 9 in light of the following remarks. We note that the examiner has apparently interpreted claims 8 and 9 as being directed to compositions which contain the specified metabolites of DHA. (Answer, page 3 and Supp.. Answer, page 3). While it is reasonable to interpret claims 8 and 9 as encompassing compositions, we would urge the examiner to consider whether the claims additionally encompass the individual compounds which are defined in the Markush group of each of these claims. We would read the phrase "An antipsychotic" as a statement of intended use or a characteristic of the substance being claimed. The term "comprising" is read as opening the claim to other possible unnamed ingredients, for example pharmaceutical carriers, but does not necessarily require that other ingredients be present. We find no limitation in either claim 8 or 9 which requires the presence of an additional ingredient. Thus, the claim would reasonably appear to read on the individual substances of the Markush groups of each claim. Should the examiner interpret the claim as reading on the individual compounds, the examiner should reevaluate the prior art, particularly the references to VanRollins to determine whether those compounds were known or obvious at the time of the invention by applicants. In so doing, we would urge the examiner to rely on the full text article rather than merely a limited abstract in the effort of considering the patentability of these claims. Should the examiner determine that there is reasonable basis for questioning the patentability of these claims, under either 35 U.S.C. § § 102 or

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103, the examiner should issue the appropriate office action explaining the basis of that determination and provide applicants with the appropriate opportunity to respond.

Summary

The rejections of claims 8 -14 under 35 U.S.C. § 103 are reversed.

REVERSED

SHERMAN D. WINTERS)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
DOUGLAS W. ROBINSON)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
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