

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PATREA L. PABST

Appeal No. 95-0523
Application No. 07/885,490¹

HEARD: February 6, 1998

Before WINTERS, SOFOCLEOUS and WEIMAR, Administrative Patent Judges.

WEIMAR, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the examiner's decision finally rejecting claims 1-26.

Claims 1, 12 and 24-26 are illustrative of the subject matter and they read as follows:

¹ Application for patent filed May 19, 1992.

1. An improved non-human milk baby formula including protein, carbohydrate and lipid which is suitable for administration to an infant comprising an enzyme selected from the group consisting of protease enzymes and polysaccharide degrading enzymes, wherein the enzyme is in a form that will be enzymatically active in the digestive system of an infant to whom the baby formula is administered and is present in an amount effective to completely digest the enzyme substrate in the formula by the time the substrate reaches the end of the colon.

12. A method for improving the digestibility of a non-human milk baby formula which is suitable for administration to an infant comprising providing in the formula an enzyme selected from the group consisting of proteases and polysaccharide degrading enzymes, wherein the enzyme is in a form that will be enzymatically active in the digestive system of an infant to whom the baby formula is administered and is present in an amount effective to completely digest the enzyme substrate in the formula by the time the substrate reaches the end of the colon.

24. An additive to increase digestibility of non-human milk baby formula comprising a purified protease in combination with a purified polysaccharide degrading enzyme.

25. The additive of claim 24 further comprising a lipase.

26. The additive of claim 24 further comprising a simple carbohydrate degrading enzyme selected from the group consisting of lactase, sucrase, fructase, and extract of *Aspergillus niger*.

The references relied upon by the examiner are:

Gaull 1981	4,303,692	Dec. 1,
Puski et al. (Puski) 1989	4,830,861	May 16,
Schweikhardt et al. (Schweikhardt) 1990	4,925,680	May 15,

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Tang et al. (Tang) 1990	4,944,944	Jul. 31,
Jost et al. (Jost) 1991	5,039,532	Aug. 13,

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substrate contained in the formula. Claims 12-23 are directed
to methods

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of making the formula compositions of the above claims.
Claims 24-26 are directed to additive compositions containing specified enzymes.

As discussed on pages 1 and 2 of the specification, pediatricians recommend feeding infants with human breast milk. The claimed compositions are designed to mimic breast milk which contains proteases and polysaccharide-degrading enzymes in an active form.

DISCUSSION

The appealed rejection under 35 U.S.C. § 103

Claims 1-26 stand rejected under 35 U.S.C. § 103 over Gaull in view of Jost, Faigh, Schweikhardt, Puski and Tang. We first note that the Examiner's Answer (Paper #16) provides only a brief referral to the teachings of the references relied upon in the obviousness rejection and in our opinion mischaracterizes those teachings. The conclusion of obviousness is set forth in the Examiner's Answer, from the paragraph bridging pages 4 and 5 and the first full paragraph on page 5 as:

In the absence of unexpected results, it would have been obvious to a person of ordinary skill in the art, at the time the invention was

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made, to incorporate the enzymes as taught by
Jost et al., Miles (EP'986), Schweikhardt et al.,
Puski et al., and Tang et al. into that of Gaull

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because the use of enzymes in infant formulas in[sic] conventional in the art.

Applicant is merely using known components and process steps in order to obtain expected results, see In re Kerkhoven 205 USPQ 1069 and In re Gershon 152 USPQ 602.

With respect to claims 24-26 the rejection is silent as to the enzyme compositions that are set forth in these claims and how the prior art teachings relate to these compositions. We are constrained to reverse this rejection with respect to claims 24-26, in light of the failure of the examiner to explain which teachings are being relied upon to establish that these claims would have been obvious over the cited prior art.

Claims 1-23 require the addition of an enzyme to infant formulas, however more is required than the mere addition of enzymes to formula at any stage in production of the formula or in any form and amount. Claims 1-23 require the enzyme to be in a "form that will be enzymatically active in the digestive system of an infant to whom the baby formula is administered" and further that the enzyme "is present in an amount effective to completely digest the enzyme substrate in the formula by the time the substrate reaches the end of the

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colon." The examiner's statement of rejection does not mention these claim limitations. The statement would lead one to believe that "the enzymes as taught by Jost et al., Miles (EP'986), Schweikhardt et al., Puski et al., and Tang et al." are in a form and quantity such as is required by the claims. With the exception of Tang this is simply not the case. Moreover, the enzyme taught by Tang is neither a protease nor a polysaccharide-degrading enzyme, which all of the claims require, rather it is a lipase.

Appellant relies upon this aspect of the claims in arguing for the patentability of the claims at issue. See, for example, page 13 of the Appeal Brief, the third complete paragraph ("None of the prior art discloses addition of a protease or a carbohydrate degrading enzyme to baby formula which is not removed or inactivated prior to administration of the formula to the baby."). On page 14 of the Appeal Brief, in the second paragraph appellant argues that "the prior art teaches away from the need to add a protease or a carbohydrate degrading enzyme to a formula where the enzyme is available following ingestion" due to the fact that the prior art approach has been to use the enzymes to digest these

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substrates, to then inactivate or remove the enzymes, followed by administering the pre-hydrolyzed compositions. Both of these points bear directly on the determination of a *prima facie* case of obviousness with respect to claims 1-23.

The examiner has an initial burden of establishing that one of ordinary skill in the art would have found the claimed invention to have been obvious at the time that it was made. The evidence relied upon must support such a conclusion. As was set forth in In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991):

Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

Considering the rejection at issue, as is apparent from the Response to Argument section of the Examiner's Answer, on pages 5-10, such a proper analysis as is suggested in In re

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Vaeck has not been undertaken. On page 6, lines 2-13, of the Examiner's Answer the examiner's reasoning is stated thus:

The examiner agrees with appellant that the prior art teaches inactivating the enzyme after it is used to hydrolyse the protein of interest. The prior art and the claimed invention differs in the approach taken; but, the end result is the same. The claimed invention keeps the enzyme active so that it can be used to hydrolyze the protein in the formula after ingestion while the prior art teaches the protein is hydrolyze[sic] before ingestion. Both of these methods produce a baby formula that is more tolerable for babies with digestive problem[sic]. Thus, it would have been obvious for one skilled in the art to choose one method or the other with the same expectation of success. The way to keep the enzyme active would have been within the skill of one in the art.

The examiner's reliance on a proposition that "the way to keep the enzyme active would have been within the skill of one in the art" is misplaced. As explained by the Federal Circuit in

In re Vaeck, *supra*, the obviousness of a claimed composition must be based on the teachings of the applied prior art and not on whether an artisan of ordinary skill could produce the claimed compositions from materials known in the prior art. In this case the prior art contains no suggestion that one

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should make the claimed compositions, containing active proteases and/or polysaccharide degrading enzymes.

The examiner's reasoning focuses on the similarity of the end result for the infant that is fed the formula, but does not explain why one of ordinary skill in the art would have had a reasonable expectation of success in modifying the prior art. The fact that the prior art pre-digested the proteins and polysaccharides might well suggest that the skilled artisan would

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not have had a reasonable expectation that the same result would follow from inclusion of enzymes in formula which contains proteins and polysaccharides, where the enzyme is active in the digestive system. The contact time between enzyme and substrate, as well as the reaction conditions, are controllable in the production settings discussed by the prior art. The examiner's position does not explain why one of ordinary skill in the art would have had a reasonable expectation that the reaction parameters would be met by an infant's digestive system. Neither the statement of rejection nor the rebuttal explain the basis for any such reasonable expectation of success and the prior art does not teach a process wherein the protein and polysaccharide substrates are

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degraded in the digestive system. The examiner draws no comparison between the lipase degradation which Tang teaches as occurring in the digestive system after formula is ingested and any protease or polysaccharide degradation taking place in the digestive system.

It is well-established that hindsight shall not form the basis of a conclusion of obviousness under 35 U.S.C. § 103. "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure."

In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). As the Federal Circuit stated in Sensonic, Inc. v. Aerosonic Corp., 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996):

To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction - an illogical and inappropriate process by which to determine patentability. . . . The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made. [citations omitted]

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In our opinion, the examiner has engaged in impermissible hindsight in the formulation of the rejection at issue, particularly with respect to the expectation of success which must be contained or suggested in the prior art.

For the reasons stated above we fail to find a *prima facie* case of obviousness with respect to claims 1-26 based on the art before us.

New Grounds of Rejection Under 37 CFR § 1.196(b)

Claims 24-26 are rejected under 35 U.S.C. § 102 as anticipated by Mochizuki.

Mochizuki teaches a purified enzymatic composition which is extracted from the fermentate of *Aspergillus niger* and which comprises protease; polysaccharide degrading enzymes, such as dextranase, "-amylase and \$-amylase; lipase; lactase; and sucrase. See Mochizuki column 1, line 66 through column 2, line 75. While we recognize that Mochizuki does not teach "increasing digestibility of non-human milk baby formula" claims 24-26 are directed to compositions rather than methods of use and this claim language does not place a further limitation on the composition. Moreover, the facility to

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increase digestibility of any consumed material which contained the various substrates of the enzyme composition of Mochizuki, for example proteins, polysaccharides and fats, would be an inherent characteristic of the enzyme composition taught by the reference.

Claims 24-26 are rejected under 35 U.S.C. § 102 as anticipated by Sipos.

Sipos teaches enzyme compositions for ingestion by a mammal with an enzyme deficiency which results in a digestive disorder. See column 1, lines 13-20 of Sipos. The enzymes contained in the composition are selected from a list of enzymes that includes proteases; polysaccharide degrading enzymes, such as amylase; lipase; and lactase, i.e. β -galactosidase. See Sipos, column 4, line 67 through column 5, line 46. Sipos teaches that the enzyme compositions are intended to aid in the digestibility of food. See column 3, lines 8-15. In any case, the use of the composition to increase digestibility of a specific food, i.e. non-human milk baby formula, is not presented as a claim limitation in claims 24-26.

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Claims 24 and 25 are rejected under 35 U.S.C. § 102 as anticipated by Roy.

Roy teaches a composition which contains lipase, amylase and protease enzymes. See column 1, lines 29-34 of Roy. Roy teaches that the enzyme compositions are intended to aid in the digestibility of food. See column 1, lines 25-29. In any case, the use of the composition to increase digestibility of a specific food, i.e. non-human milk baby formula, is not presented as a claim limitation in claims 24 and 25.

CONCLUSION

The decision of the examiner refusing to allow claims 1-26 under 35 U.S.C. § 103 is reversed.

Claims 24-26 are newly rejected by the authority of 37 CFR § 1.196(b) and under 35 U.S.C. § 102 as anticipated by either Mochizuki or Sipos.

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Claims 24 and 25 are newly rejected by the authority of 37 CFR § 1.196(b) and under 35 U.S.C. § 102 as anticipated by Roy.

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

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

REVERSED; 37 CFR § 1.196(b)

SHERMAN D. WINTERS)	
Administrative Patent Judge)	
)	
)	
)	
)	BOARD OF PATENT
MICHAEL SOFOCLEOUS)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
)	
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Appeal No. 95-0523
Serial No. 07/885,940

Judge WEIMAR

Judge WINTERS

Judge SOFOCLEOUS

Typed: 16 Jul 98

DECISION: **REVERSED; 37 CFR §**

1.196(b)

Send Reference(s): Yes No
or Translation(s)

Panel Change: Yes No

3-Person Conf. Yes No

Heard: Yes No

Remanded: Yes No

Index Sheet-2901 Rejection(s):

Acts 2: _____

Palm: _____

Mailed:

Updated Monthly Disk: _____

Updated Monthly Report: _____