

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 18

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte GEORGE PARADISSIS,  
R. SAUL LEVINSON,  
MITCHELL I. KIRSCHNER and  
MARC S. HERMELIN

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Appeal No. 2001-1909  
Application No. 09/016,786

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ON BRIEF

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Before WILLIAM F. SMITH, LORIN, and SCHEINER, Administrative Patent Judges.

LORIN, Administrative Patent Judge.

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 50-61, all the claims pending in the application.<sup>1</sup>

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<sup>1</sup> Pursuant to 35 U.S.C. § 6(b), we review the adverse decision of the examiner. In doing so, we have considered the record, including:

- Final Rejection (paper no. 6);
- Brief (paper no. 10);
- Examiner's Answer (paper no. 11); and,
- Reply Brief (paper no. 12).

Claims 50 and 59 are illustrative of the claims on appeal and read as

follows:

50. A method of optimizing the regeneration, maintenance or repair of nerve tissue that occurs naturally during sleep in a human, which comprises: administering to the human a therapeutically effective amount of a composition consisting essentially of at least one water-soluble B complex Vitamin independently selected from the group consisting of Vitamin B<sub>1</sub>, (Thiamine), Niacinamide, Folic Acid, Riboflavin (Vitamin B<sub>2</sub>), Pantothenic Acid (Vitamin B<sub>3</sub>), Vitamin B<sub>6</sub>, Pyridoxine, Vitamin B<sub>12</sub>,

wherein the water-soluble B complex Vitamin is administered at night to optimize the regeneration, maintenance or repair of nerve tissue that occurs naturally during sleep resulting from the presence of said B complex Vitamin.

59. A method of optimizing the regeneration, maintenance or repair of nerve tissue that occurs naturally during sleep in a human, which comprises: administering to the human,

(a) a first composition comprising at least one water-soluble B complex Vitamin independently selected from the group consisting of Thiamine, Niacinamide, Pyridoxine, Folic Acid, and Riboflavin, said first composition being released over an extended period of time from six hours up to twenty-four hours; and

(b) a second composition comprising at least one B complex Vitamin selected from the group consisting of Vitamin B<sub>12</sub> and Pantothenic Acid, said second composition being administered as an immediate release agent;

wherein the water-soluble B complex Vitamin is administered at night to optimize the regeneration, maintenance or repair of nerve tissue that occurs naturally during sleep resulting from the presence of said B complex Vitamin.

The references relied upon by the examiner are:

Zappia	U.S. 4,042,698	August 16, 1977
Briggs et al. (Briggs)	U.S. 4,752,479	June 21, 1988
Radebaugh et al (Radebaugh)	U.S. 4,806,359	February 21, 1989
Koltringer	U.S. 5,118,505	June 2, 1992
Edgren et al. (Edgren)	U.S. 5,204,116	April 20, 1993
Serfontein	U.S. 5,254,572	October 19, 1993

The rejections are:<sup>2</sup>

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<sup>2</sup> The examiner has withdrawn previously-applied rejections under 35 USC §§ 112 and 102. See Examiner's Answer, p. 2.

1. Claims 50-52 and 54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Koltringer.
2. Claims 50-61 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Koltringer by itself or in combination with Zappia or Serfontein.
3. Claims 56-61 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Koltringer by itself or in combination with Zappia or Serfontein, further in view of Briggs.
4. Claims 56-57 and 59-61 are rejected under 35 U.S.C. § 103(a) as being unpatentable over 1) Koltringer by itself or in combination with Zappia or Serfontein, or 2) Koltringer by itself or in combination with Zappia or Serfontein, further in view of Briggs as set forth above, further in view of either Edgren or Radebaugh.

### BACKGROUND

The specification (p. 1), describes the invention as related to methods for treating disease states, and particularly to a method for the prevention and treatment of certain disease states in humans by the continuous administration of vitamins and minerals.

The invention is based on (specification, p. 3)

[t]he discovery that the efficacy of vitamins and other nutritional agents in treating and preventing various disease states may be improved by administering therapeutically effective levels of these agents on a substantially continuous, i.e., over 24-hour period.

Three aspects to the invention are disclosed (see specification, pp. 3-4):

1. “a method of reducing the concentration of lipid peroxides formed by the autoxidation of lipids in a human, ... on a substantially continuous 24-hour basis, a therapeutically effective amount of a pharmaceutically-acceptable antioxidant agent”;
2. “a method of reducing the concentration of oxygen free radicals in a human, ... on a substantially continuous 24-hour basis, a therapeutically effective amount of a pharmaceutically-acceptable antioxidant agent”;
- and,
3. “a method of improving the regeneration of nerve tissue in a human ..., which comprises administering to the human, on a substantially

continuous 24-hour basis, a therapeutically effective amount of at least one pharmaceutically-acceptable B complex Vitamin.”

The third aspect of the invention relates to the subject matter of the claims on appeal.

The specification (page 10, lines 11-23<sup>3</sup>) states that the third aspect of the invention, by which at least one vitamin B complex is administered to a human on a substantially continuous 24-hour basis, “optimizes the natural nerve repair process which occurs during sleep.” The substantially continuous 24-hour administration may be achieved by either

- “multiple dosages during the daytime and at night,” (p. 7, lines 15-16); or,
- “administering ... a controlled release dosage” (p. 7, line 21) which
  - “may be administered about once every 24 hours” (p. 7, line 24), i.e., a 24-hour controlled release dosage form; or
  - “twice every 24 hours,” (p. 7, line 27), i.e., a 12-hour controlled release dosage form.

“Determination of the proper dosage for a particular situation is within the skill of the art. For convenience, the total daily dosage may be divided and administered in portions during the day if desired or at one time, morning, afternoon, night ... .”  
Specification, p. 14, lines 28-32.

The application was originally filed with 49 claims.<sup>4</sup> A preliminary amendment was filed canceling the original claims and adding claims 50-61.

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<sup>3</sup> The B complex Vitamins have been identified as major elements involved in the repair and maintenance of the nervous system. It has been noted that significant nerve tissue repair occurs during sleep, and in fact sleep physiologists have speculated that the major function of sleep is to allow the regeneration, maintenance, and repair of nerve tissue. The inventive process of continuous, 24-hour administration of vitamins therefore optimizes the natural nerve repair process which occurs during sleep. Conventional administration of vitamins during the daytime fails to account for the significant need for B complex Vitamins at night.

<sup>4</sup> Claims 1-15, 16-30 and 41-49, and 31-40 were directed to the first, second and third aspects of the invention, respectively. Claims 31-40, which like the present claims are directed to

Claims 50 and 59 of the preliminary amendment were further amended (see paper no. 5) to change, most notably, the administration of the composition from the original “substantially continuous 24-hour basis” to the current administration “at night.” The dependency of claim 56 was also changed from claim 52 to claim 50. Appellants (paper no. 5, p. 3) have stated that the basis for these changes can be found in the specification at page 10, lines 11-23, reproduced supra. Remaining claims 51-55, 57-58 and 60-61 remain unchanged.

Claim 50 is illustrative of the claims on appeal. It is directed to a process for “optimizing the regeneration, maintenance or repair of nerve tissue that occurs naturally during sleep in a human” involving administering a composition containing certain B-complex vitamins to a human. Claim 50 has two salient features:

1) the composition to be administered is one “consisting essentially of at least one water soluble B complex vitamin” independently selected from the group consisting of vitamins B (folic acid), B<sub>1</sub> (thiamine), B<sub>2</sub> (riboflavin), B<sub>3</sub> (niacinamide), B<sub>5</sub><sup>5</sup> (pantothenic acid), B<sub>6</sub> (pyridoxine), and B<sub>12</sub>; and,

2) the “administration” takes place “at night.”

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a method of improving the regeneration of nerve tissue, call for administering at least one pharmaceutically-acceptable B complex vitamin “on a substantially continuous 24-hour basis.” According to the dependent claims, the continuous 24-hour administration can be accomplished by a controlled release dosage (claim 33) that is administered once every 24 hours (claim 34) or the total dosage can be administered in portions over a 24-hour period (claim 35) by administering a controlled dosage twice every 24 hours (claim 36). The remaining claims are directed to the types of vitamins and agents (claims 32 and 40) and dosage forms (claims 37-39) that can be administered.

<sup>5</sup> There is a misspelling in claim 50. The claim as written specifies “Pantothenic Acid (Vitamin B<sub>3</sub>), In fact, pantothenic acid is another name for vitamin B<sub>5</sub>. This should be corrected.

DISCUSSION

After carefully reading the rejections, we are compelled to vacate the rejections and remand the application to the examiner. Our reasons are:

Reason #1

Claim 50 is in need of correction. It is our understanding that Pantothenic Acid is another name for Vitamin B<sub>5</sub>, not B<sub>3</sub>.

Reason #2

There is no antecedent basis in claim 52 for the phrase “the substantially continuous 24-hour administration” and there is no antecedent basis for the phrase “the dosage form” in claim 56. This raises a question of definiteness. Examiner should determine whether the scopes of claims 52 and 56 are reasonably ascertainable to those with skill in the art (see Ex parte Porter, 25 USPQ2d 1144, 1146(Bd. Pat. Apps. & Int. 1992)) and, if not, then consider rejecting these claims under the second paragraph of 35 U.S.C. § 112.

Reason #3

We are not entirely sure what the rejections are.

To understand the statements of the rejections, we have constructed the following table:

<i>§ 103 Rejection</i>	<i>Over Koltringer by itself</i>	<i>Or in combination with Zappia or Serfontein,</i>	<i>Or in combination with Zappia or Serfontein, further in view of Briggs,</i>	<i>Or in combination with Zappia or Serfontein, further in view of Briggs as set forth above, further in view of either Edgren or Radebaugh.</i>
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1	50-52, 54			
2	50-61	50-61		
3	56-61		56-61	
4	56-57 and 59-61	56-57 and 59-61		56-57 and 59-61

The table shows how confusingly the claims have been rejected over the prior art. Some of the claims (e.g., claim 50) are rejected multiple times over the same prior art combination. Other claims (e.g., claim 59) are rejected over seven possible different art combinations: Koltringer; Koltringer/Zappia; Koltringer/Serfontein; Koltringer/Zappia/Briggs; Koltringer/Serfontein/Briggs; Koltringer/Zappia/Briggs/Edgren; and, Koltringer/Serfontein/Briggs/Radebaugh. Still other claims (e.g., claim 56) get both treatments.

To add to the confusion, the discussion in the Examiner's Answer does not parallel the statements of the rejections. The discussion is more consistent with the claims being rejected as follows<sup>6</sup>:

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<sup>6</sup> We reach this conclusion because, given that examiner cites Koltringer to show "a method of administration of folic acid [vitamin B] for the regeneration of nerve cell and nerve fibers," Examiner's Answer, p. 4, wherein the folic acid is administered "as a continuous infusion," Examiner's Answer, p. 6, it is fairly evident that Koltringer is being applied as the primary reference. Examiner concedes, however, that Koltringer does not teach the claimed limitations of

- "administration of the composition at night [per se]," Examiner's Answer, p. 4, (see claims 50, 51 and 54);
- "the administration of [sic: the composition?] in a controlled release device," Examiner's Answer, p. 5, (see claims 52, 53, and 55);
- "a bilayer tablet containing a sustained release layer and an immediate release layer," Examiner's Answer, p. 8, (see claim 56); and,
- "the instant [bi-layer] tablet formulations," Examiner's Answer, p. 7, for example, a tablet which is enterically coated to reduce gastric irritation, (see claims 57 and 58, and 59-61).

To address these limitations, examiner relies on, respectively,

- Koltringer (for its disclosure of a "continuous infusion," Examiner's Answer, p. 6);
- Zappia ("teaches time release administration of B-complex vitamins," Examiner's Answer, p. 6) or Serfontein ("teaches time release formulations for the treatment of nerve cells," Examiner's Answer, p. 6.);
- Edgren or Radebaugh (both of which teach a "tablet formulation containing a sustained release layer and an immediate release layer," Examiner's Answer, p. 8); and,
- Briggs ("discloses controlled release formulations containing iron and B complex vitamins [which are] enterically coated and ... teaches two layers, both are for controlled release ... [and] indicates that the material in the outer layer is released in the upper gastrointestinal tract and the second layer is for controlled release," Examiner's Answer, pp. 7-8).

<i>§ 103 Rejection</i>	<i>Over Koltringer,</i>	<i>In view of Zappia or Serfontein,</i>	<i>And further in view of Briggs.</i>
1	50, 51, and 54		
2		52, 53 and 55	
3			58, 59-61
<i>§ 103 Rejection</i>		<i>In view of Edgren or Radebaugh,</i>	<i>And further in view of Briggs</i>
4		56	
5			57, 59-61

We need a clearer explanation of the rejections. This includes making sure that the statements of the rejections and the discussion of examiner's position agree with each other.

Reason #4

From our review of the Examiner's Answer, not all the limitations in the claims have been addressed. "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). The limitation in claim 55 of administering the composition twice every 24 hours does not appear to have been addressed. The claimed administering of a composition comprising two different components, different in terms of the vitamins and agents used and their releasability characteristics, set forth in claims 59-61, are not addressed.

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Accordingly, it follows that examiner intended to reject the claims under 35 USC § 103 as follows:

- Claims 50, 51, and 54 over Koltringer;
- Claims 52, 53, and 55 over Koltringer as applied to claims 50, 51, and 54, and further in view of Zappia or Serfontein;
- Claim 56 over Koltringer as applied to claims 50, 51, and 54, and further in view of Edgren or Radebaugh;
- Claim 57 over Koltringer in view of Edgren or Radebaugh as applied to claims 50, 51, 54 and 56, and further in view of Briggs;
- Claim 58 over Koltringer in view of Zappia or Serfontein as applied to claims 50-55, and further in view of Briggs.

Reason #5

Examiner has failed to recognize that the claims use language that is susceptible to different interpretations

“[D]uring patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.”

In re Zletz, 893 F.2d 319, 322, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

We specifically refer to the phrase “administered at night” as it is used in claims 50 and 59. The following passage from claim 50 is illustrative:

... wherein the water-soluble B complex Vitamin is **administered at night** to optimize the regeneration, maintenance or repair of nerve tissue that occurs naturally during sleep resulting from the presence of said B complex Vitamin.

There are two ways of interpreting “administered”: 1) the vitamin is introduced from outside the body to inside the body or (2) the vitamin is released inside the body.

The first interpretation would lead one to construe the phrase “administered at night” to mean introducing the vitamin to the body at night and would give the claim a scope that would cover, for example, swallowing or injecting the vitamin at night. Such a scope would not limit the duration of release of the vitamin within the body after the vitamin has been introduced into the body. As long as the introduction is at night, release of the vitamin could last for any period of time.

The second interpretation would lead one to construe the phrase “administered at night” to mean releasing the vitamin within the body at night and gives the claim a scope that would cover, for example, the presence of a time-release tablet within the body timed to release vitamin at night. Such a scope would not limit the period of time when the vitamin is introduced to the body prior to it being released within the body. As long as the vitamin is released within the body at night, the vitamin could be introduced at any time of the day.

Because of the effect a proper interpretation of the phrase has on the scope of the claims, it is important that examiner carefully analyze both possible interpretations. We also say this because, based on our review of the prosecution history, the former interpretation is the interpretation that examiner and appellants seem to have agreed upon and the one on which examiner has built the prima facie case of obviousness. The latter interpretation has not been addressed and yet the specification would appear to support it.

As we explained in the Background section supra, original claims 50-61 were drawn to improving nerve tissue repair by administering a vitamin B complex on a “substantially continuous 24-hour basis.” Claims 50 and 59 were subsequently amended (paper no. 5) to change the step of administration from a “substantially continuous 24-hour” administration to administration “at night.” In effect, this changed the thrust of the claimed invention from one focusing on the bioavailability of the vitamin in the body over a 24-hour period to one focusing on taking a vitamin exclusively at night. That is the interpretation examiner has relied upon in determining patentability.

At the time of the amendment, appellants stated that basis for the amendment could be found on page 10, lines 11-27 of the specification. However, that passage (see Background supra) does not disclose taking a vitamin at night. The passage indicates that significant nerve tissue repair occurs during sleep and that “[c]onventional administration of vitamins during the daytime fails to account for the significant need for B complex Vitamins at night.” However, this passage does not say when the vitamin should be taken. That is explained elsewhere in the specification.

In three places, the specification mentions “administering” the vitamin at “night”:

- “administering the agent in multiple dosages during the daytime and at night” (p. 4, lines 16-17);
- “administering the agent in multiple dosages during the daytime and at night” (p. 7, lines 15-16); and,
- “the total daily dosage may be divided and administered in portions during the day if desired or at one time, morning, afternoon, night” (p. 14, lines 30-32 ).

In none of these statements is “night” given any particular significance. “Night” is just one of a number of possible times for introducing the vitamin into the body, the purpose being to release the vitamin over a 24-hour period.

Reading the passage of p. 10, lines 11-27 in light of these disclosures, it becomes clear that appellants are seeking to overcome the short duration of present conventional dosages of vitamins; i.e., they do not last long enough to still be present in the human body during sleep (usually at night) when the vitamin B complex has the greatest impact on nerve tissue repair. Appellants appear to solve this problem, not by introducing a vitamin at night per se, but by

causing the vitamin to be released over a “substantially continuous 24-hour” period to include the night, thereby extending the bioavailability of the vitamin to coincide with the act of sleeping and concurrently optimizing nerve tissue repair.

For the foregoing reasons, examiner should first interpret the claims in light of the specification, being certain that the interpretation to be applied complies with the written description requirement of the first paragraph of 35 U.S.C. § 112. Based on that interpretation, examiner should then analyze the scope of the claims before making a patentability determination over the prior art.

Reason #6

One of the arguments that appellants make in their Brief (see p. 37), in rebuttal to the rejections of the claims under 35 U.S.C. § 103 over the primary reference Koltringer, is that Koltringer discloses two active ingredients (Gingko bilobae extract and a vitamin B complex) in contradistinction with the claimed process of administering a vitamin B complex alone. Examiner’s response (Examiner’s Answer, p. 4) is that “applicant has not shown that the other components in prior art teachings are detrimental in instant compositions.”

Notwithstanding that it is examiner’s burden, not appellants’, to establish a prima facie case of obviousness and therefore it is examiner who has the burden of showing that why one of ordinary skill would be led to modify the Koltringer method to solely administer a vitamin B complex, the use of a vitamin B as the sole active ingredient is well known. To that end, we cite U.S. Patent 4,945,083 (Jansen et al.) and U.S. Patent 4,432,975 (Libby). We also cite a publication

(Bernstein, "Vitamin B<sub>6</sub> in Clinical Neurology", Vitamin B<sub>6</sub>, Annals of The New Academy of Sciences, 1990, Part V., pp. 250-260) showing the use of a vitamin B as the sole active ingredient in treating nerve disorders.

Reason #7

Finally, appellants have filed a Declaration (paper no. 13). It has not been considered and should have been. If during subsequent prosecution, examiner again rejects the claims as prima facie obvious under 35 U.S.C. § 103 over prior art, the prima facie case must be reconsidered in light of this Declaration. See MPEP § 2141.

VACATE AND REMAND

In reviewing, on appeal, a PTO Board's findings and conclusions, the Federal Circuit has stated that "[f]or judicial review to be meaningfully achieved within these strictures<sup>7</sup>, the agency tribunal must present a full and reasoned explanation of its decision. The agency tribunal must set forth its findings and the grounds thereof, as supported by the agency record, and explain its application of the law to the found facts." In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1432-3 (Fed. Cir. 2002). "The agency tribunal must make findings of relevant facts, and present its reasoning in sufficient detail that the

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<sup>7</sup> "5 U.S.C. §706(2) The reviewing court shall—

(2) hold unlawful and set aside agency actions, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

\* \* \* \*

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute;"

In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1433-4 (Fed. Cir. 2002).

court may conduct meaningful review of the agency action.” Ibid. at 277 F.3d 1346, 61 USPQ2d 1435. “Remand for these purposes is required.” Ibid. at 277 F.3d 1346, 61 USPQ2d 1436.”

The Board also serves as a board of review. The Board is not a de novo examination tribunal (35 U.S.C. § 6(b)). Accordingly, in order for the Board to make a meaningful review of the rejections on appeal, examiner must present a full, clear and properly reasoned explanation in support of the final rejection. As we explained supra, that has not been done here. In vacating the rejections and remanding the application, we give the examiner a new opportunity to reassess the patentability of the claims and to present new grounds of rejection with the issues discussed above completely resolved.

We emphasize that we vacate examiner’s rejections. This means that the instant rejection no longer exists and the issues set forth herein cannot be satisfied by a Supplemental Examiner’s Answer. See Ex parte Zambrano, 58 USPQ2d 1312, 1313 (Bd. Pat. App. & Int. 2000).

VACATED AND REMANDED

WILLIAM F. SMITH )  
Administrative Patent Judge )  
)  
)  
) BOARD OF PATENT  
HUBERT C. LORIN )  
Administrative Patent Judge ) APPEALS AND  
)  
) INTERFERENCES

TONI R. SCHEINER )  
Administrative Patent Judge )

HL/dym

Nath & Associates  
1030 Fifteenth Street, N.W.  
Sixth Floor  
Washington, DC 20005-1503