

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte MICHAEL A. ZASLOFF and GLENN M. ANDERSON

Appeal No. 2007-0055
Application No. 10/053,299

ON BRIEF

Before ADAMS, MILLS, and LEOVITZ, Administrative Patent Judges.

LEOVITZ, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to methods of blocking microbial adherence to the surface of a eukaryotic cell. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 134. We affirm-in-part.

Background

“Infection by microbial organisms involves initial adherence to a [cell] surface. Failure of adherence is believed to prevent” microbes from invading epithelial cells. Specification, page 1, lines 21-23. Methods have been developed to block microbial infection by interfering with microbial adherence to cells. Id., page 1, lines 23-24.

The instant application provides a method for blocking adherence of microbes to eukaryotic cells “by applying isoleucine to the surface of the cells.” Id., page 1, line 29- page 2, line 1.

Discussion

Claim construction

The pending claims in the application are claims 1-16, 18, 25, 31, 32, 34, and 41-44. All pending claims are appealed. Br. 2. The claims stand rejected under two prior art rejections under § 103, each relying on a different prior art reference:

(1) Claims 1-6, 8-16, 18, 25, and 41-44 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Pederson¹; and

(2) Claims 1-13, 18, 25, 31, 32, 34, and 41-44 rejected under 35 U.S.C. § 103(a) as unpatentable over Zeng.² Br. 2, 24.

The claims do not stand or fall together because Appellants provided separate reasons for patentability for certain claims within each rejection.

The first step in an obviousness analysis is to determine the meaning and scope of the claims at issue. For this purpose, we focus on independent claims 1 and 11:

1. A method of blocking microbial adherence to a eukaryotic cell surface in a mammal by applying to said surface a pharmacologically acceptable composition consisting essentially of an amino acid component selected from the group consisting of at least one of the following: L(+/-) isoleucine, DL-isoleucine, D(-)-allo-isoleucine, L(+)-allo-isoleucine, and active analogs of isoleucine present in a microbial blocking quantity.

11. A pharma[c]ologically acceptable composition consisting essentially of:

¹ Pederson, U.S. Patent 6,607,711 B2, issued Aug. 19, 2003.

² Zeng, U.S. Patent 6,770,306 B1, issued Aug. 3, 2004.

A) from about 0.001 to about 99% by weight of an amino acid component selected from the group consisting of at least one of the following: L(+) isoleucine, DL-isoleucine, D(-)-allo-isoleucine, L(+)-allo-isoleucine, and active analogs of isoleucine;

B) at least one additional pharmacologically active substance selected from the group consisting of a fluoride, xylitol, an antibody, an anti-microbial agent, zinc ions, a decongestant, an anesthetic, an anti-oxidant, a vitamin, a microbial substance, a pre-biotic material, folic acid, echinacea, peppermint oil or extract, menthol, quassia, bistort, ginger, angelica, bayberry, chamomile, fish oil, or fractionated fish oil, a fatty acid, fiber, flaxseed, a plant extract, garlic or garlic extract, calcium, stannol esters, lutein, zeaxanthin, cryptoxanthin, isoflavone, an anti-inflammatory compound, an antifungal agent, and a food product; and optionally,

C) pharmacologically acceptable carrier materials and/or excipients.

Claim 1 requires that the “amino acid component” is “selected from the group consisting of” isoleucine stereoisomers and active analogs of isoleucine. “Transitional phrases, such as ‘comprising,’ ‘consisting of,’ and ‘consisting essentially of,’ are terms of art in patent law that ‘define the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.’ MPEP §2111.03; accord Vehicular Techs. Corp., 212 F.3d at 1382-83. The phrase ‘consisting of’ signifies restriction and exclusion of unrecited steps or components. MPEP §2111.03.” Conoco Inc. v. Energy & Environmental International LC, 460 F.3d 1349, 1360, 79 USPQ2d 1801, 1808-09 (Fed. Cir. 2006). Here, the phrase “consisting of” refers to the members of the group which define the amino acid component. Accordingly, we construe “consisting of” to limit the amino acid component to only those compounds specifically recited in the group (i.e., isoleucines), and to exclude the presence of other amino acid components. This construction applies to claims 11, 18, and 32 in which the phrase is also recited.

Claim 1 also uses another transitional phrase, “consisting essentially of,” stating that the claimed composition is “consisting essentially of an amino acid component” which is an isoleucine stereoisomer or active analog of it.

“Consisting essentially of” is a transition phrase commonly used to signal a partially open claim in a patent. Typically, “consisting essentially of” precedes a list of ingredients in a composition claim or a series of steps in a process claim. By using the term “consisting essentially of,” the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.

PPG Industries Inc. v. Guardian Industries Corp., 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998).

The specification defines the activity of the isoleucine compound as blocking the adherence of microbes to eukaryotic cells. Specification, page 4, line 6-17. This is also expressly required by the claim which recites that the isoleucine is “present in a microbial blocking quantity.” Accordingly, we understand this to be a “basic and novel” property of the claimed subject matter. In this context, we construe the phrase “consisting essentially of” to permit additional unlisted ingredients (with the exception of other amino acids) that do not affect the ability of the isoleucine compounds to block microbial adherence.

Claim 1 is a method of “blocking microbial adherence to a eukaryotic cell surface.” However, it does not require that the “blocking” actually treat or prevent a disease associated with infection, or that any specific amount of blocking must be achieved by the claimed method. Accordingly, we interpret the claim to cover any amount of blocking activity, including the blockade of one microbe from adhering to one cell.

Obviousness under 35 U.S.C. § 103

Pederson

Claims 1-6, 8-16, 18, 25, and 41-44 stand rejected under 35 U.S.C. § 103(a) as obvious over Pederson.

Pedersen teaches a mouth hygienic composition and methods of using it “for the treatment of halitosis [“bad breath”] [and] in the prevention of plaque formation, gingivitis, and calculus.” Pederson, column 1, lines 6-10. The composition comprises “a chelate comprising a metal ion moiety and an amino acid moiety.” Metals such as “Ag, Ca, Cu, Fe, Mg, Mn, Zn, Mo, Co, Se, Sn and V” are described as suitable. Id., column 6, lines 9-11. “Zn is a particularly useful metal . . . as the zinc ion, Zn²⁺.” Id., column 6, lines 11-13. “Any biologically acceptable amino acid can be used in the preparation of [the] metal amino acid chelates.” Id., column 6, lines 17-19. These include all the 20 naturally-occurring amino acids. Id., column 6, lines 20-25. Isoleucine is listed in this group. Id., column 6, line 22. Pederson states that the metal amino acid chelate reduces halitosis by facilitating the interaction of the metal ion with the odor-causing volatile sulfur compounds produced by bacteria in the oral cavity. Id., column 5, lines 53-57; column 6, lines 13-16. The chelate also reduces microbial growth and activity in the oral cavity. Id., column 8, lines 1-9.

Citing the disclosures indicated above, the Examiner asserts that Pederson teaches a chelate containing isoleucine in the treatment of oral diseases caused by microbial growth and activity, meeting the requirements of claim 1. Answer 4-5. He

especially relies on Pederson's disclosure of isoleucine (Answer 5: 20-21) and its use in the form of a chelate for reducing microbial growth in the oral cavity (Answer 4: 13-16).

Appellants argue that Pederson's composition requires a metal ion attached to amino acids by "coordinate covalent bonds," and therefore do not describe amino acids in its therapeutic composition. Br. 17 to 19: 9. "There is no disclosure in Pederson that a particular amino acid, isoleucine, not in the form a chelate with a metal ion, when applied to eukaryotic cells in a microbial blocking quantity can block microbes from attaching themselves to cell surfaces." Reply Br. 2: ¶ 5. They also argue that Pederson's metal chelates "functions by an entirely different mechanism" in which the metal ion reacts with a sulfur-containing amino acid in the oral cavity. Br. 19. In contrast, Appellants state that it is "the isoleucine compound that blocks microbial adherence" in the claimed subject matter. Id., 17.

To begin our analysis, we observe that Pederson does not disclose that its metal amino acid chelate blocks "microbial adherence to a eukaryotic cell surface in a mammal" as recited in claim 1. Rather, it describes the chelate as interacting with the odor producing volatile sulfur compounds that cause halitosis. Although the Examiner does not explicitly state so, it is apparent that he has inferred that microbial adherence would be blocked inherently when applying Pederson's metal amino acid chelate to the oral cavity. Inherency asks whether a subject matter is "necessarily" present in the prior art reference, "not merely probably or possibly present, in the prior art." Trintec Indus. v. Top-U.S.A., 295 F.3d 1292, 1295, 63 USPQ2d 1597, 1599 (Fed. Cir. 2002).

It is the Examiner's burden to provide "reason to believe . . . that the claimed subject matter may, in fact, be an inherent characteristic of the prior art." In re

Schreiber, 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997) (quoting from In re Swinehart, 439 F.2d 210, 213, 169 USPQ 226, 228 (CCPA 1971). See also In re Thrift, 298 F.3d 1357, 1365, 63 USPQ2d 2002, 2007 (Fed. Cir. 2002). Once the Examiner has satisfied this duty, the burden shifts to Appellant to provide evidence to the contrary. In this case, the question boils down to whether the Examiner provided sufficient reason to believe that Pederson's metal amino acid chelate solution necessarily would block microbial adherence when in contact with the mouth oral cavity.

To reach this question, we must first determine whether Pederson's metal amino acid chelate meets the limitation in claim 1 of a composition "consisting essentially of an amino acid component" which is an isoleucine stereoisomer or an active analog of it.

The Examiner asserts that Pederson's metal amino acid chelate meets the amino acid component requirement of the claim because "the amino acids are present in the metal chelates." Answer 7: 13-14. We do not concur with this conclusion because the isoleucine provided by Pederson is in the form of a chelate in which the amino acid is joined to the metal ion by "coordinate covalent bonds." Pederson, column 3, lines 65-67. It is not isoleucine, but isoleucine attached to a metal ion. "Special processing must be performed to create a stable (covalent) bond" of the type found in its chelate. Id., column 4, lines 24-25. Thus, we do not consider it to satisfy the claim limitation that the component be an isoleucine or a stereoisomer of it.

However, claim 1 permits the amino acid component to be an active analog of isoleucine. The specification does not provide a definition of isoleucine analogs, or give guidance on what is encompassed by the term. In examining the claims of an application, the PTO is permitted to adopt "the broadest reasonable meaning of the

words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.”

In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); In re Crish, 393 F.3d 1253, 1256, 73 USPQ2d 1364, 1367 (Fed. Cir. 2004). An “analog” is defined as a compound which has a similar, but not identical structure to another.³ Pederson’s chelate comprises the isoleucine structure which is attached to a metal ion. Pederson, column 3, lines 65-67. This structure is similar, but not the same as isoleucine, and therefore we consider it to be an isoleucine analog that falls within the scope of the claim.

Although Pederson’s chelate is an analog within the claim scope, there is no evidence of record that it would block microbial adherence as required by claim 1. Pederson shows that the amino (NH₂) and carboxyl (COOH) groups of the amino acid are coordinated to the metal ion (M). Pederson, column 6, lines 50-55. There is no evidence in the record for presuming that this structure would still possess the claimed microbial blocking activity. For this reason, we do not find that prima facie obviousness has been established for claim 1. Accordingly, we reverse the rejection as it applies to claims 1-6, 8-10, 18, and 41-44.

Claims 11-16, and 25

Claim 11 is a composition claim, and does not require that the isoleucine component block microbial adherence to a eukaryotic cell surface in a mammal. The composition comprises “A) from about 0.001 to about 99% by weight of an amino acid

³ Webster’s New Collegiate Dictionary 41 (1976)

component” which includes isoleucine stereoisomers and “active analogs of isoleucine”; “B) at least one additional pharmacologically active substance” selected from a list of materials; and optionally “C) . . . carrier materials and/or excipients.”

For claims 11-13, Appellants argue that Pederson does not disclose free isoleucine amino acids or the listed ingredients in combination with them. Reply Br. 6. We concur with Appellants that Pederson does not disclose isoleucine, per se. However, we have construed (above) the claimed isoleucine analog to encompass Pederson’s chelate.

Claim 11 recites that the isoleucine analog is “active,” but does not require that it be “active” in blocking microbial adherence. Any activity can satisfy the claim, including its activity in forming “chelates capable of releasing a metal ion under suitable conditions” as described by Pederson. Column 6, lines 41-44. Thus, we find that this element of the claim is met by Pederson.

For component “B)” of claim 11, the Examiner cites Pederson’s disclosure at column 7, lines 56-60 and column 8, lines 35-67 of fluoride compounds, antimicrobial agents, and xylitol, each which is a member of the list recited in claim 11, “B).” Answer 8. Appellants did not specifically challenge this finding and we find no fault in it.

According to Pederson, the metal ion amino acid chelate can be present in an amount up to 10%.” Id., column 5, line 36-38. As concluded by the Examiner, this amount at least overlaps with the “0.001 to about 99% by weight” recited in claim 11, and the narrower ranges in claims 12 (“0.002 to about 50%”) and 13 (0.1 to about 25%). Answer 5. It is well-established that even a slight overlap in ranges establishes prima facie obviousness. See e.g., In re Peterson, 315 F.3d 1325, 1329, 65 USPQ2d 1379,

1382 (Fed. Cir. 2003). Having established the existence of overlapping ranges, the burden shifted to Appellants to show that their invention would not have been obvious.

The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. These cases have consistently held that in such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.

In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990).

(Internal citations omitted.)

Appellants rely on evidence in the specification to establish “unexpected and surprising results.” Br. 22-24. “[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art.” In re Baxter Travenol Labs., 952 F.2d 388, 392, 21 USPQ2d 1281, 1285 (Fed. Cir. 1991). Here, the closest prior art is Pederson’s chelate. However, Appellants base their showing on using isoleucine alone, but do not compare it to Pederson’s chelate which is the closest prior art. Consequently, we conclude that Appellants have not provided adequate evidence to rebut the prima facie case. We affirm this rejection as it applies to claims 11-13. Claims 14-16 and 25 fall with claim 11 because separate reasons for patentability were not provided.

Because we have relied on arguments not raised previously by the Examiner, we designate this as a new ground of rejection to provide Appellants a fair opportunity to respond to it. See 37 C.F.R. § 41.50(b).

Zeng

Claims 1-13, 18, 25, 31, 32, 34, and 41-44 stand rejected under 35 U.S.C. § 103(a) as obvious over Zeng.

Zeng teaches a pharmaceutical composition comprising amino acids, oligopeptides and/or polypeptides which “can change the metabolic process of bacteria in the vagina and reduce vaginal acid production.” Zeng, column 3, lines 45-47. The compositions can be used to treat high acidity vaginitis and fungal vaginitis. Id., column 6, lines 35-40. In one example, Zeng applied a mixture of amino acids, including isoleucine, to a female patient diagnosed with “high-acidity in vagina accompanying fungal infection.” Id., column 13, “Experimental Example 4”; columns 8-9, “Example 8.” After application of the drug for three days, there was no evidence of fungal spores. Id.

The Examiner argues that Zeng teaches compositions which comprise isoleucine in amounts which overlap with the claimed ranges and amounts.

Zeng does not expressly teach Applicant's ranges of ‘microbial blocking quantities’ recited in instant claims 2-4. However, absent any showing of criticality accruable from the instant ranges, it would have been deemed obvious to one of ordinary skill in the art at the time the invention was made to determine suitable ranges or amounts of through the use of routine or manipulative experimentation to obtain the best possible results, as these are variable parameters within the art.

Answer 15-16.

Appellants contend that Zeng teaches compositions which comprise “formulations or combinations of many amino acids.” Br. 26 (quoting from Zeng, column 4, lines 11-21). They admit that isoleucine is included as one of the amino acids in Zeng’s mixture, but they argue none of the compositions employed by Zeng contain fewer than eight amino acids. Id., 26. Moreover, Zeng states that a “composition containing only one or two sodium salts of amino acids can also partly [partly] realize the object of the invention,” which Appellants argue “in effect directs one skilled in the art away from using only one or two amino salts.” Id., 26. Appellants also assert that the

amounts disclosed by Zeng do not overlap with the claimed amounts because “[w]hether or not any isoleucine [sic] remains in the vagina . . . is unknown and amounts to unfounded speculation.” Id., 27. Finally, they state that “[t]he discovery of optimum or workable ranges by routine experimentation for blocking cell surfaces using only isoleucine presupposes that Zeng knew about such a concept, which clearly he did not.” Id., 28.

As was the case for the rejection over the Pederson patent, it is apparent that the Examiner’s basis for the rejection of claim 1 over Zeng is also grounded in inherency, i.e., that the amino acid composition disclosed in Zeng would inherently block microbial adherence as required by claim 1. To determine the propriety of this rejection, we must determine whether there is reasonable basis to presume that Zeng’s composition achieves the goal stated in claim 1 of blocking microbial adherence. Schreiber, 128 F.3d at 1478, 44 USPQ2d at 1432.

As we have construed claim 1, the phrase that the amino acid component is “selected from a group consisting of” isoleucine stereoisomers or active analogs of it limits the amino acid component to these compounds, excluding other amino acids. This claim construction differs from the construction given to the claims by the Examiner (Answer 20: § 2) which we find to be improper. For this reason, we designate our rejection, which is described in more detail below, as a new ground of rejection. See 37 CFR § 47.50 (b).

At column 4, lines 47-49, of Zeng, it is stated that “[t]he composition containing only one or two sodium salts of amino acids can also part[ly] realize the object of the invention.” We find that this statement constitutes a description of a composition of

one amino acid that is able to partly achieve Zeng's goal of treating vaginitis. While such a composition might only be partially effective, as we have construed claim 1, blocking adherence of as few as one microbe would satisfy the claim limitation.

The Examiner points out (Answer 15) that Zeng teaches that the total content of amino acids in a composition is "preferably is 30-350 mmol/L." Zeng, column 5, lines 3-4. When isoleucine is the only amino acid in the composition, it would be present in an amount of 0.393%,⁴ which falls within the ranges described (e.g., specification, page 18, line 13) and claimed (e.g., claims 11-13) in the application as effective. Accordingly, because Zeng's concentration of isoleucine falls within the disclosed and claimed effective concentrations, we find it reasonable to have presumed that Zeng's composition would block microbial adherence as required by claim 1.

Appellants argue that Zeng's composition comprises amino acids to be used as neutralizing agents. Br. 27. We understand Appellants' characterization of Zeng's composition as a "neutralizing agent" to refer to the amino acid's activity in reducing acid production (which occurs by interfering with the metabolic processes of bacteria, not by actually "neutralizing" its activity as implied by Appellants). Zeng, column 3, lines 45-47. Appellants have not explained why the existence of this acid reducing activity would foreclose isoleucine from blocking microbial adherence to a eukaryotic cell surface. Accordingly, we do not find merit in their argument.

We have considered Appellants' evidence of "unexpected results," but do not consider it adequate to rebut the prima facie case for the reasons set forth by the

⁴ One mole of isoleucine is about 131 grams. The Merck Index 883 (1996). 30 mmol/1 liter is equivalent to 3.93 grams in 1000 ml or 0.393 grams in 100 ml which is about 0.393% by weight of isoleucine.

Examiner. Answer 21. Appellants have not provided persuasive arguments to the contrary.

The rejection of claim 1 under § 103(a) is affirmed, but subject to a new ground of rejection under 37 CFR § 41.50(b) based on a claim interpretation that is different from the Examiner's.

Claims 5-10, 41, 42, and 43 fall with claim 1 since they were not separately argued.

Claims 2, 3, and 4

Claims 2-4 recite ranges of isoleucine per cm² of eukaryotic cell surface. The Examiner states that the claim ranges overlap with the ranges described by Zeng. However, the Examiner argues that "it would have been deemed obvious to one of ordinary skill in the art at the time the invention was made to determine suitable ranges or amounts . . . through the use of routine or manipulative experimentation to obtain the best possible results, as these are variable parameters within the art." Answer, pages 15-16.

We agree with Appellants that the Examiner has not established a prima facie case of unpatentability for these claims. Although an overlap in ranges establishes prima facie obviousness, an exception has been recognized where a parameter had not been recognized as being a "result-effective variable." In re Antonie, 559 F.2d 618, 620, 195 USPQ 6, 8-9 (CCPA 1977). Concentration is identified by Zeng as a results-effective variable for reducing vaginal acidity, but the Examiner has not provided sufficient evidence that, in optimizing the ranges for this activity, the microbial blocking activity would also be realized. This problem is further compounded because we can

find no explanation in the record of how concentration (e.g., micrograms/ml) relates to quantity per square centimeter of cell surface area as recited in claims 2-4. There is no information in the record before us of how to convert solution concentration as described in Zeng to the surface area units which are recited claims 2-4. Consequently, we are unable to determine whether Zeng's concentration of isoleucine overlaps with the quantity of isoleucine recited in the instant claims. In sum, there is insufficient evidence of record to sustain this rejection. We reverse the rejection of claims 2, 3, and 4.

Claims 11-13 and 25

Claim 11 recites a composition comprising "from about 0.001 to about 99% by weight of an amino acid component" which is isoleucine or an active isoleucine analog, component B), and optionally component C).

In regard to the amounts present in claim 11, Appellants argue that "[w]hether or not any isoleucine remains in the vagina after such neutralization is unknown and amounts to unfounded speculation." Brief, page 27. We do not find this argument persuasive because the claim is to a composition, and does not require that isoleucine endure in the vagina for any length of time. As discussed *supra.*, p. 13 at fn.4, Zeng teaches a composition comprising 0.393% by weight of isoleucine. This amount falls within the scope of claims 11, 12, and 13. Accordingly, we affirm the rejection of these claims. Claim 25 falls with claims 11-13 because it was not separately argued.

Claim 18

Claim 18 is directed to a composition in the form of a toothpaste or gel. As pointed out by the Examiner (Answer 23), Zeng teaches that its composition may be a gel. Zeng, column 4, line 53; column 5, line 56; claim 5. Appellants did not identify an error in this finding. Br. 29. Consequently, we affirm the rejection of claim 18.

Claim 31, 32, 34

Claims 31 and 32 require the composition to be a wound ointment or cream. Claim 34 recites that it is “in the form of a skin ointment or cream.” We agree with the Examiner (Answer 23-24) that Zeng teaches that his composition can be in various forms, including a cream. Column 4, line 52. Appellants have not provided any evidence to distinguish the claimed ointment or cream from the composition described by Zeng. Consequently, we affirm the rejection of claims 31, 32, and 34.

Claim 44

Claim 44 is directed to a method of treating an infection which is caused by bacteria. Zeng teaches that vaginally administering a composition comprising amino acids can alter “metabolic processes of bacteria” and “bacterial flora” which are present in the vagina. Zeng, column 3, lines 45-47; column 6, line 65. By doing so, vaginal acidity is reduced, treating various vaginal disorders, including high acidity vaginitis and fungal vaginitis. *Id.*, column 1, line 65-column 2, line 5. Giving the claim its broadest reasonable interpretation, we construe it to include methods in which the infection results in high acidity vaginitis or fungal vaginitis. Thus, we concur with the Examiner that “Zeng’s formulation clearly provides for the effective treatment of bacterial conditions, as claim[ed] by Appellant[s].” Answer 24.

Appellants argue that “[c]hanging [the] metabolic process of bacteria to produce less acid is clearly not a statement that the bacterial can otherwise be killed or reduced in number.” Reply Br. 13-14. We do not find this argument persuasive because the claim does not require that the bacteria be “killed or reduced in number.” Locally administering Zeng’s composition treats bacterial infection associated with vaginitis, meeting the requirements of claim 44. The rejection of claim 44 is affirmed.

Other issues

Upon return of this application to the technology center, we encourage the Examiner and Appellants to consider an additional issue that was not addressed in the Brief or Answer. According to Pederson, the metal ion amino acid chelate oxidizes volatile sulfur compounds in the oral cavity. Pederson, column 8, lines 10-12. This apparently is based on the ability of the zinc ion to oxidize sulfhydryl groups. Id., column 1, lines 57-61. Pederson also states that “amino acids may contribute to the desirable formation of chelates capable of releasing a metal ion under suitable conditions.” Id., column 6, lines 40-45. These statements raise the question of whether the metal ion is released from the amino acid during its reaction with the volatile sulfur compounds, leaving free amino acid behind. If this were the case, free amino acid (e.g., isoleucine) would be available to block microbial adherence, raising an issue of inherent anticipation of at least claim 1. The Examiner should consider whether the facts in Pederson and other prior art make it reasonable to presume that free amino acid is released in Pederson’s method, and if so, an appropriate rejection should be entered.

Summary

The rejection of claims 1, 5-16, 18, 25, 31, 32, 34, and 41-44 is affirmed. The rejection of claims 2, 3, and 4 is reversed.

Regarding the affirmed rejection(s), 37 CFR § 41.52(a)(1) provides "[a]ppellant may file a single request for rehearing within two months from the date of the original decision of the Board."

In addition to affirming the examiner's rejection(s) of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(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 the appeal as to the rejected claims:

(1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should Appellants elect to prosecute further before the examiner pursuant to 37 CFR § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance

is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If Appellants elect prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

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; 41.50(b)

Donald E. Adams)	
Administrative Patent Judge)	
)	
)	
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Demetra J. Mills)	
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RML/lbg