

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ABDUL GAFFAR, JOHN J. AFFILITTO, THOMAS G. POLEFKA,
NURAN NABI and MARILOU T. JOZIAK

Appeal No. 1995-4903
Application No. 07/926,016¹

ON BRIEF

Before JOHN D. SMITH, PAK and LIEBERMAN, Administrative Patent Judges.

LIEBERMAN, Administrative Patent Judge.

DECISION ON APPEAL

¹ Application for patent filed August 7, 1992. According to appellants, this application is a continuation-in-part of Application No. 07/794,783 filed November 25, 1991, now U.S. Patent No. 5,208,009 issued May 4, 1993; which is a continuation-in-part of Application No. 07/631,232 filed December 20, 1990, now U.S. Patent No. 5,096,699 issued March 17, 1992; which is a continuation-in-part of Application No. 07/594,598 filed October 9, 1990, now U.S. Patent No. 5,158,763 issued October 27, 1992.

Appeal No. 1995-4903
Application No. 07/926,016

This is an appeal under 35 U.S.C. § 134 from the examiner's refusal to allow claims 1 through 16 which are all of the claims in the application.

THE INVENTION

Appellants' invention is directed to an oral care composition containing effective amounts of azacycloalkane-2,-diphosphonate which is an anticalculus agent and an effective amount of a bis(halo phenyl) antimicrobial agent. The composition also contains a toxicologically acceptable oral carrier.

THE CLAIMS

Claims 1 and 15 are illustrative of appellants' invention and are reproduced below.

1. An oral care composition comprising
 - (a) an effective amount of a source of an azacycloalkane-2,-diphosphonate anion as an anticalculus agent;
 - (b) an effective amount of a bis(halo phenyl) antimicrobial agent; and
 - (c) a toxicologically acceptable oral carrier.

Appeal No. 1995-4903
Application No. 07/926,016

15. An oral care composition according to claim 1 wherein the antimicrobial agent is triclosan and said composition additionally contains a synthetic anionic polymeric polycarboxylate of a molecular weight in the range of about 5,000 to 2,000,000 in an amount effective to increase anticalculus action of the azacycloalkane phosphonate anion.

Appeal No. 1995-4903
Application No. 07/926,016

THE REFERENCES OF RECORD

As evidence of obviousness, the examiner relies upon the following references.

McCune et al. (McCune) 1970	3,488,419	Jan. 6,
Irani et al. (Irani) 1972	3,671,644	Jun. 20,
Widder et al. (Widder) 1972	3,687,154	Jul. 18,
Haefele (Haefele '002) 1976	3,934,002	Jan. 20,
Haefele (Haefele '807) 1976	3,937,807	Feb. 10,
Ploger et al. (Ploger '772) 1976	3,941,772	Mar. 2,
Agricola et al. (Agricola) 1976	3,959,458	May 25,
Ploger et al. (Ploger '443) 1976	3,988,443	Oct. 26,
Vinson et al. (Vinson) 1977	4,022,880	May 10,
Haefele (Haefele '616) 1977	4,025,616	May 24,
de Vries 1986	4,569,838	Feb. 11,
Hayes (Hayes '456) 1986	4,575,456	Mar. 11,
Hayes (Hayes '504) 1987	4,659,504	Apr. 21,
Klueppel et al. (Klueppel) 1989	4,820,507	Apr. 11,
Degenhardt et al. 1989	4,877,603	Oct. 31,
(Degenhardt '603)		
Parran, Jr. et al. (Parran) 1991	5,015,466	May 14,

(filed Jun. 26, 1990)

Appeal No. 1995-4903
Application No. 07/926,016

Gaffar et al. (Gaffar) 1992	5,158,763	Oct. 27, (filed Oct. 9, 1990)
European patent application 1989 (Degenhardt '233)	321 233	Jun. 21,
German patent (Henkel '177) 1971	1 938 177	Feb. 11,
German patent (Henkel '178) 1971	1 938 178	Feb. 11,
French patent (Henkel '580) 1971	2,055,580	Apr. 13,
French patent (Henkel '579) 1971	2,055,579	May 7,
Japanese patent (Kanebo) 4, 1985	60-58500	Apr.

THE REJECTIONS

Claims 1, 2, 4, 5, 7, 8, 10, 11, 13 and 16 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 through 16 of U.S. Patent No. 5,158,763.

Claims 1, 2, 4, 5, 7, 8, 10, 11, 13 and 16 stand rejected under 35 U.S.C. § 103 as unpatentable over Haefele (I-II-III) combined with Ploger (I-II).²

² The rejection as stated in both the Answer and the Final Rejection mailed May 25, 1994 fails to state the statutory grounds of the rejection.

(continued...)

Appeal No. 1995-4903
Application No. 07/926,016

Claims 1, 3, 4, 6, 7, 9, 10, 12, 14 and 15 stand rejected under 35 U.S.C. § 103 as unpatentable over Vinson and Ploger (I-II), combined in view of Irani³, Parran, Gaffar and further in view of Henkel⁴ and Kanebo.

Claims 1, 2, 4, 5, 7, 8, 10, 11, 13 and 16 stand rejected under 35 U.S.C. § 102 as anticipated by or in the alternative under 35 U.S.C. § 103 as obvious over de Vries and Hayes, (I-II).⁵

OPINION

²(...continued)

However, in view of the rejection being over Haefele combined with Ploger and appellants' concurrence in the Brief, page 5, the rejection is necessarily under 35 U.S.C. § 103.

³ The Answer, page 10, refers to Irani('633). No such Irani patent exists. We refer to Irani ('644) as listed in the prior art of record. See Answer, page 6.

⁴ There are four Henkel patents listed in the prior art of record, Answer, pages 6 and 7. We have considered each Henkel reference.

⁵ The rejection as stated in both the Answer and the Final Rejection mailed May 25, 1994 improperly states the statutory grounds of the rejection using § 103 instead of § 102. However as the rejections are stated in the alternative, as anticipated by or obvious over, we conclude that the rejection is made both under §§ 102 and 103. Appellants' concurrence, Brief, page 4 is noted.

Appeal No. 1995-4903
Application No. 07/926,016

As an initial matter, appellants submit that the claims do not stand or fall together. Appellants' argument on behalf of separate consideration of three Groups of claims appears in the Brief, page 3. Group I is directed to rejections relating to the antibacterial agent chlorhexidine. Group II is directed to rejections related to the antibacterial agent triclosan. Group III is directed to claim 15 and adds an additional component, i.e. a polymeric polycarboxylate. Since each of the Groups I and II are encompassed by claim 1, and claim 15 is dependent on claim 1, we will limit our consideration to claims 1 and 15 as we have determined that it is dispositive of each of the issues before us.

We have carefully considered all of the arguments advanced by appellants and the examiner. We agree with appellants that the aforementioned rejections over Vinson and Ploger (I-II), combined in view of Irani, Parran, Gaffar and further in view of Henkel and Kanebo and the rejection over de Vries and Hayes, (I-II) on the grounds of anticipation is not well founded. Accordingly, we will not sustain those rejections.

Appeal No. 1995-4903
Application No. 07/926,016

We agree with the conclusions reached by the examiner that the rejections over de Vries and Hayes, (I-II) under 35 U.S.C.

§ 103 and the rejections over Haefele (I-II-III) combined with Ploger (I-II) are well founded. Accordingly, we will sustain those rejections.

We will also sustain the rejection on the ground of judicially created doctrine of obviousness-type double patenting.

The Rejections Over de Vries And Hayes⁶

As to the rejection of the appealed claims under 35 U.S.C.

§ 102, appellants emphatically disagree that either de Vries or Hayes anticipates the invention as claimed. See Brief, page 4. We agree. The examiner in the Answer relies on Hayes, at column 3, lines 50-51, column 7, lines 25-30, 37-39, column 5, line 55, column 6, line 6. He further relies on de Vries,

⁶ Hayes('504) is a division of Hayes('456). We refer in our decision to Hayes('504).

Appeal No. 1995-4903
Application No. 07/926,016

at column 4, lines 19-19, column 9, lines 15-20, column 8, lines 1-14 and claim 6. See Answer, pages 16 and 17.

The portions of Hayes relied upon by the examiner focus on those parts of the Hayes patent, which disclose components falling within the scope of appellants' claimed subject matter. However, contrary to the examiner's analysis of Hayes, patentee is replete with teachings of the presence of phosphonic groups which may provide anticalculus or antiplaque effect. See column 3, lines 9-51. The optional presence of numerous antibacterial agents is disclosed at column 5, line 55 through column 6, line 6.

Similarly, the examiner relied upon those portions of de Vries, which disclose components falling within the scope of appellants' invention. De Vries is likewise replete with teachings of the presence of phosphonic groups which may provide anticalculus or antiplaque effect. See column 3, line 43 to column 4, line 22. Similarly the optional presence of numerous antibacterial agents is disclosed at column 7, line 63 through column 8, line 14.

In both the Hayes and de Vries patent the respective disclosures include components which are azacycloalkane-

Appeal No. 1995-4903
Application No. 07/926,016

2,diphosphonate anions utilized as anticalculus agents. Each reference discloses bis(halophenyl) antimicrobial agents. However, based upon the above teachings we cannot agree with the examiner that the claimed invention is anticipated by either Hayes('504) or de Vries. In order to arrive at the claimed subject matter a person having ordinary skill in the art would have to carefully pick and choose and combine various disclosures among the teachings of both Hayes('504) and de Vries to obtain an oral care composition comprising the two required components of the claimed subject matter in effective amounts. While some picking and choosing may be entirely proper in making an obviousness rejection under 35 U.S.C. § 103, it has no place in making a rejection under 35 U.S.C. § 102(b) for anticipation. See In re Arkley, 455 F.2d 586, 587, 172 USPQ 524, 526 (CCPA 1972). We find that each reference does not provide a disclosure with sufficient specificity to constitute a description of the claimed composition within the purview of 35 U.S.C. § 102(b). See In re Schaumann, 572 F.2d 312, 317, 197 USPQ 5, 10 (CCPA 1978). Accordingly, we shall not sustain either rejection of the

Appeal No. 1995-4903
Application No. 07/926,016

claims on appeal under 35 U.S.C. § 102 as anticipated by Hayes('504) or de Vries.

Notwithstanding our finding supra regarding anticipation, it should be noted that rejections under 35 U.S.C. § 103 may be appropriate and proper where the subject matter claimed is not identically disclosed or described. Accordingly, we shall next consider the rejection of the claims over Hayes('504) or de Vries under 35 U.S.C. § 103.

Hayes('504) discloses a gel dentifrice which is an oral care composition. We find that the composition may contain antinucleating agent which provide anticalculus or antiplaque effect as required by component (a) of the claimed subject matter. See Hayes('504) column 3, lines 9-11. The specific azacycloalkane-2,2- diphosphonic acid compound required by the claimed subject matter is disclosed in column 3, lines 38-39, and 43-46 and is incorporated by reference to Ploger at line 20. Component (b) required by the claimed subject matter is disclosed at column 5, line 68. We find that 1,6-di-p-chlorophenylbiguanidohexane is appellants' claimed chlorhexidine. Our finding is supported by appellants' specification at column 3, lines 2-3.

Appeal No. 1995-4903
Application No. 07/926,016

We now turn to the rejection over De Vries. We find that de Vries discloses an oral care composition in the form of a dentifrice. See column 1, lines 7-16. We find that the composition may contain antinucleating agent which provides anticalculus or antiplaque effect as required by component (a) of the claimed subject matter. See de Vries column 3, lines 44-47. The specific compound azacycloalkane-2,2-diphosphonic acid required by the claimed subject matter is disclosed in column 4, lines 6-7, and 11-14. Additional azacycloalkane-2,2-diphosphonic acid compounds within the scope of the claimed subject matter are also incorporated by reference to U. S. Patent No. 3,988,443 (Ploger) at column 3, line 55. Component (b) required by the claimed subject matter is disclosed at column 8, line 7. As noted supra, we find that 1,6-di-p-chlorophenylbiguanidohexane is appellants' claimed chlorhexidine. Our finding is again supported by appellants' specification at column 3, lines 2-3.

The dispositive issue under § 103 for each of Hayes('504) and de Vries is whether a person having ordinary skill in the art would have found a suggestion in each of the teachings of Hayes('504) and de Vries to prepare an oral care

Appeal No. 1995-4903
Application No. 07/926,016

composition containing effective amounts of an azacycloalkane-2,-diphosphonate ion and effective amounts of a bis(halophenyl) antimicrobial agent in accordance with appellants' claimed subject matter and whether Hayes('504) and de Vries would have revealed that such a person would have had a reasonable expectation of success. See In re Vaeck, 947 F.2d at 493, 20 USPQ2d at 1442.

Based upon our findings supra, we answer both questions in the affirmative for each of Hayes('504) and de Vries. It is our position that it would have been obvious to one having ordinary skill in the art to prepare an oral care composition as required by appellants' claimed invention, from the disclosure of either Hayes('504) or de Vries.

The Rejection of Haefele(I-II-III) Combined with Ploger (I-II)⁷

Appellants argue that there is nothing found within the prior art that can be considered to motivate the combination

⁷ Ploger('443) is a division of Ploger('772). We refer in our decision to Ploger('772). The three Haefele patents contain similar disclosures, and we refer to Haefele('002) in our decision.

Appeal No. 1995-4903
Application No. 07/926,016

of the specific materials. See Brief, page 5. We disagree. Haefele('002) discloses an oral composition for plaque containing both a bisguanamide and an anticalculus agent. See column 1, lines 39-43. We find that the bisguanamides are exemplified by chlorhexidine or salts thereof. We further find that chlorhexidine and its salts are the bisguanamides of choice. See Examples V through XXIII.

Numerous phosphonic acids including many patents drawn to phosphonic acid containing anticalculus agents are disclosed by Haefele('002) beginning at column 4, line 28 through column 7, line 4. Based upon this extensive disclosure, we conclude that any phosphonic acid anticalculus agent may be used with Haefele's('002) preferred chlorhexidine. However, the specific azacycloalkane-2,-diphosphonate of the claimed subject matter is not taught.

Ploger('772) discloses the diphosphonic acids of the claimed subject matter, and teaches that the compounds are useful in toothpastes and mouthwashes where they prevent formation of tartar and plaque. Hence, we conclude that they are by definition anticalculus agents. See Abstract and column 3, lines 38-43. Based upon the above considerations,

Appeal No. 1995-4903
Application No. 07/926,016

we conclude that it would have been obvious to the person having ordinary skill in the art to incorporate any pharmaceutically acceptable phosphonic acid known to be an anticalculus agent in the oral composition of Haefele('002). Accordingly, we sustain the rejection of the examiner.

The Rejection Of Vinson And Ploger (I-II), With Irani, Gaffar, Parran, Henkel and Kanebo

"[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability." See In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The examiner relies upon a combination of up to eleven references to reject the claimed subject matter and establish a prima facie case of obviousness. The basic premise of the rejection is that the primary reference to Vinson discloses an oral care composition containing an anticalculus mixture having present triclosan (component (b)) as one of the antibacterial agents taught therein. The Ploger references disclose the azacycloalkane diphosphonic acid which constitute component (a), and the balance of the references provide motivation for

Appeal No. 1995-4903
Application No. 07/926,016

combining the respective components of Vinson and Ploger. We disagree.

The examiner relies upon Irani for its teaching that phenolic bactericides can be improved in bactericidal activity in the presence of a polyphosphonic acid. See column 1, lines 40-45. However, the examiner has not shown that Irani discloses either of the claimed components. Nor is this hypothesis a sufficient teaching that one of ordinary skill in the art would use it to select either of the required components of the claimed subject matter.

Parran discloses an oral care composition containing triclosan in combination with tartrate-succinate as an anticalculus composition. Parran discloses that adjunct materials may be added to the composition including a diphosphonate. See column 12, lines 36-40. However, the function of the phosphonate is never disclosed and no correlation with anticalculus activity is presented by Parran. Indeed, Parran relies upon other specific components to provide anticalculus activity. We interpret Parrans' silence on the function of the phosphonates as indicative of a lack of anticalculus activity. Accordingly, we conclude that there is

Appeal No. 1995-4903
Application No. 07/926,016

no reason based on this record to substitute the azacycloalkane diphosphonate compounds of Ploger for the diphosphonates of Parran.

The balance of the Henkel references and the Kanebo reference are directed to antibacterial soaps, which would be neither safe nor effective for utilization in an oral cavity. Although the examiner states that Henkel and Kanebo describe the stabilization of triclosan with a diphosphonate in a bactericidal soap, Answer, page 15, we conclude that bactericidal soaps cannot be considered as exemplary of an antibacterial oral composition as required by the claimed subject matter.

Furthermore, the examiner must show reasons that the skilled artisan confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. We determine that there is no reason, suggestion, or motivation to combine the references in the manner proposed by the examiner. Accordingly, the examiner has not established a prima facie case of

Appeal No. 1995-4903
Application No. 07/926,016

obviousness. See In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1458 (Fed. Cir. 1998).

The Obviousness-Type Double Patenting Rejection

We note that appellants have indicated that they, "will file a terminal disclaimer when and if the remaining rejections are resolved, therefore, it does not appear pertinent to address this issue at this time." See Brief, page 2, footnote 1. We regard appellants' statement as acquiescing in the examiner's rejection. Hence, we summarily sustain it.

DECISION

The rejection of claims 1, 2, 4, 5, 7, 8, 10, 11, 13 and 16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U. S. Patent No. 5,158,763 is affirmed.

The rejection of claims 1, 2, 4, 5, 7, 8, 10, 11, 13 and 16 under 35 U.S.C. § 103 as unpatentable over Haefele (I-II-III) combined with Ploger (I-II) is affirmed.

Appeal No. 1995-4903
Application No. 07/926,016

The rejection of claims 1, 3, 4, 6, 7, 9, 10, 12, 14 and 15 under 35 U.S.C. § 103 as unpatentable over Vinson and Ploger (I-II), combined in view of Irani, Parran, Gaffar and further in view of Henkel and Kanebo is reversed.

The rejection of claims 1, 2, 4, 5, 7, 8, 10, 11, 13 and 16 stand rejected under 35 U.S.C. § 103 as obvious over de Vries and Hayes, (I-II) is affirmed.

The rejection of claims 1, 2, 4, 5, 7, 8, 10, 11, 13 and 16 stand rejected under 35 U.S.C. § 102 as anticipated de Vries and Hayes, (I-II) is reversed.

However, because our rationale for affirming each of the grounds of rejection under § 103 materially differs from that of the examiner as we have set forth above, we have designated our affirmance as involving a new ground of rejection pursuant to 37 CFR 1.196(b).

The decision of the examiner is affirmed-in-part.

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

Appeal No. 1995-4903
Application No. 07/926,016

§ 1.196(b) provides, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellants, 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 (37 CFR § 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. . . .

Appeal No. 1995-4903
Application No. 07/926,016

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, 1.196(b)

JOHN D. SMITH)	
Administrative Patent Judge)	
)	
)	
)	
)	BOARD OF PATENT
CHUNG K. PAK)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
)	
)	
)	
PAUL LIEBERMAN)	
Administrative Patent Judge)	

bae

Appeal No. 1995-4903
Application No. 07/926,016

Connolly & Hutz
O.P.O. Box 2207
Wilmington, DE 19899-2207