

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LORRAINE ELISABETH PENA and MAW-SHENG WU

Appeal 2007-2919
Application 09/634,399
Technology Center 1600

Decided: March 25, 2008

Before TONI R. SCHEINER, DONALD E. ADAMS, and DEMETRA J. MILLS, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1, 5-8, 10, 13-22, 30, 35, 62, 66, 68, 70-76, 111, 112, 115, 116, and 123-134, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to a composition in the form of a single-phase gel (claims 1, 5-8, 10, 13-22, 30, 35, 62, 66, 68, 70-76, and 123-134) and a method of using the single phase gel (claim 111, 112, 115, and 116). Claims 1, 20, and 112 are illustrative:

1. A composition in the form of a single-phase gel comprising from about 5% to about 8% minoxidil, a crosslinked copolymer of acrylic acid as a thickening agent, and a pharmaceutically acceptable solvent, wherein said minoxidil is present at a concentration which is less than its solubility limit in said composition.

20. [A composition of claim 1, further comprising a neutralizing agent], wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.

112. A method [comprising topically administering a composition according to claim 1 to a region of hair loss on a patient], wherein said hair loss is selected from the group consisting of androgenic alopecia, frontal hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.

The Examiner relies on the following prior art references to show unpatentability:

Pena	US 5,225,189	Jul. 6, 1993
Samour	US 5,620,980	Apr. 15, 1997
Anton	US 5,798,426	Aug. 25, 1998
Preuilh	US 6,106,848	Aug. 22, 2000
Grollier	GB 2 194 887 A	Mar. 23, 1988
Ewers	DE 196 13 698 A1	Jan. 1, 1997

We note that the Examiner failed to list Anton, Grolier, and Samour in the Examiner's statement of the "Evidence Relied Upon" (Ans. 2-3

(emphasis removed)). We find these omissions to be an inadvertent typographical error.

The rejections as presented by the Examiner are as follows:

1. Claims 1, 5-8, 10, 13-19, 21, 22, 30, 35, 62, 66, 68, 70-75, 111, 115, 123-131, and 133 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Preuilh, Ewers, and Pena.
2. Claims 76, 112, 116, 132, and 134 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Preuilh, Ewers, Pena, and Samour.
3. Claims 20 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Preuilh, Ewers, Pena, Anton, and Grollier.

We reverse.

DISCUSSION

1. Claims 1, 5-8, 10, 13-19, 21, 22, 30, 35, 62, 66, 68, 70-75, 111, 115, 123-131, and 133 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Preuilh, Ewers, and Pena.

The claims are directed to a composition or method of topically administering a single-phase gel composition comprising, *inter alia*, a crosslinked copolymer of acrylic acid.

Pena teaches single-phase gel compositions comprising carbomers such as “Carbopol ® 934P” (Pena, col. 2, ll. 37-46). Appellants assert that “Carbopol® 910 and 934 are crosslinked *homopolymers* of acrylic acid” which are distinct from the claimed composition that requires “a crosslinked *copolymer* of acrylic acid” (App. Br. 6). The Examiner asserts, however, that a person of ordinary skill in the art would have recognized that Pemulen

TR1 as taught by Preuilh would have been useful as a thickener in the preparation of a single-phase gel,

because 1) emulsifying agents are known to modify the viscosity of the composition, and thus function as thickeners, (see instant specification [(Spec. 8: 5-7)] wherein, “thickening agent” is taught as an agent which may act as viscosity modifying agent, emulsifying agents, gelling agent, stabilizing agent), and 2) Preuilh teaches that Pemulen TR1 is compatible with minoxidil, and results in stable [oil-in-water emulsion] compositions.

(Ans. 11).

Appellants disagree. According to Appellants, Preuilh teaches that “such crosslinked copolymers of acrylic acid are useful as emulsifying agents. Preuilh does NOT teach or suggest the use of crosslinked copolymers of acrylic acid to thicken or gel the disclosed emulsions” (App. Br. 7). In this regard, Appellants direct attention to paragraph 10 of the Second Pena Declaration and assert that a person of ordinary skill in the art at the time the invention was made “would find no motivation in either . . . [Preuilh or Pena] to utilize a crosslinked copolymer of acrylic acid as a thickening or gelling agent, because there is no need for an emulsifying agent in a single-phase gel” (App. Br. 9; Second Pena Declaration ¶ 10).

Further, while Appellants’ Specification refers to thickening agents as including emulsifying agents, the Examiner fails to recognize that Appellants’ Specification is drawn to both gels, including single-phase gels, and emulsions (Spec. 4-5). In this regard, the Examiner has failed to identify a teaching in the prior art that would suggest the use of an emulsifying agent, such as Pemulen TR1, in a single-phase gel. The prior art of record teaches that Pemulen TR1 is an effective emulsifying agent for

use in emulsions (Preuilh, col. 2, ll. 4-63; App. Br. 6; First Pena Declaration ¶¶ 7-9; and Second Pena Declaration ¶¶ 8-10). The evidence of record does not teach the use of a crosslinked copolymer of acrylic acid in a single phase gel. The Examiner's recognition that Pemulen TR1 is compatible with minoxidil and results in stable oil-in-water emulsion compositions (Ans. 11) is not sufficient to bridge this evidentiary gap. Ewer fails to make up for this deficiency in the combination of Preuilh and Pena.

Accordingly, we reverse the rejection of claims 1, 5-8, 10, 13-19, 21, 22, 30, 35, 62, 66, 68, 70-75, 111, 115, 123-131, and 133 under 35 U.S.C. § 103(a) as unpatentable over the combination of Preuilh, Ewers, and Pena.

2. Claims 76, 112, 116, 132, and 134 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Preuilh, Ewers, Pena, and Samour.

The claims are directed to a composition or method of topically administering a single-phase gel composition comprising, *inter alia*, a crosslinked copolymer of acrylic acid. The Examiner relies on the combination of Preuilh, Ewers, and Pena as discussed above. The Examiner recognizes, however, that the combination of Preuilh, Ewers, and Pena does not teach the “preferred percent weights of polyols as about 53% as in claims 76, and 131, and modes of hair loss as recited in claims 112, 116, [and] 134” (Ans. 7). To make up for this deficiency the Examiner relies on Samour to teach “a method for treating hair loss, specifically androgenic alopecia” comprising the topical application of a composition comprising minoxidil and a composition comprising, *inter alia*, “0-90% lower alcohol [and] 0-98% lower glycol” (*id.*). Samour does not, however, make up for

the deficiencies in the combination of Preuilh, Ewers, and Pena discussed above.

Accordingly, we reverse the rejection of claims 76, 112, 116, 132, and 134 under 35 U.S.C. § 103(a) as unpatentable over the combination of Preuilh, Ewers, Pena, and Samour.

3. Claim 20 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Preuilh, Ewers, Pena, Anton, and Grollier.

Claim 20 depends from and further limits claim 1 to further comprise a neutralizing agent that is 2-amino-2-methyl-1-propanol.

The Examiner relies on the combination of Preuilh, Ewers, and Pena as discussed above. The Examiner recognizes, however, that the combination of Preuilh, Ewers, and Pena fails to teach a composition comprising a neutralizing agent that is 2-amino-2-methyl-1-propanol. To make up for this deficiency the Examiner relies on Grollier to teach “compositions suitable for inducing and stimulating hair growth or for decreasing loss of hair, which comprises minoxidil . . . and 2-amino-2-methyl-1-propanol” (Ans. 8). The Examiner relies on Anton to teach that amino methyl propanol is useful in neutralizing the acrylic polymer in acrylic polymer compounds and aqueous compositions thereof (Ans. 8). Neither Grollier nor Anton, however, make up for the deficiencies in the combination of Preuilh, Ewers, and Pena discussed above

Accordingly, we reverse the rejection of claim 20 under 35 U.S.C. § 103(a) as unpatentable over the combination of Preuilh, Ewers, Pena, Anton, and Grollier.

Appeal 2007-2919
Application 09/634,399

CONCLUSION

In summary, we reverse the rejections of record.

REVERSED

Ssc:

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891