

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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

Appeal No. 2006-0729
Application No. 10/322,566

ON BRIEF

Before SCHEINER, ADAMS, and GREEN Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 12-23. The only remaining claims on appeal (claims 24-27) were withdrawn from consideration as drawn to a non-elected invention. Brief, page 2.

Claims 12 and 18 are illustrative of the subject matter on appeal and are reproduced below:

12. Composition for topical use for treating and improving the aesthetic condition of the skin consisting essentially of, as active ingredient, a mixture of ethyl linoleate and triethyl citrate.
18. Composition of claim 12 wherein the composition further contains at least one additive selected from the group consisting of acetic acid, lactic acid, salicylic acid, tartaric acid, glycolic acid, clindamycin, minocycline, erythromycin, metronidazole, amoxycillin, triclosan, capryloyl glycine, azelaic acid, zinc hydroxide, zinc

chloride, vitamin A trans-retinoic acid, resorcinol, hyaluronic acid, gentamicin, mecloxycline, phenol, ascorbic acid, tocopherol, lipoic acid, phosphatidyl choline, phosphatidyl serine, chlorhexidine, irgasan, adapalene, and the dextrorotatory forms, levorotatory forms, racemic mixtures, cis forms, trans forms, salts, esters and amides thereof, in an excipient for external use.

The references relied upon by the examiner are:

Hong et al. (Hong)	6,028,067	Feb. 22, 2000
Chen et al. (Chen)	6,267,985	Jul. 31, 2001

GROUNDS OF REJECTION

Claims 18 and 22 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 12 and 18 stand rejected under 35 U.S.C. § 102(b) as anticipated by Hong.

Claims 12-23 stand rejected under 35 U.S.C. § 103 as being unpatentable over Chen.

We reverse.

BACKGROUND

According to appellant (specification, page 1, lines 23-29), sebum contains triglycerides which are hydrolysed into fatty acids and glycerol by the lytic enzymes released by bacteria present on human skin. The fatty acids released in this process result in chemical compounds that favor inflammation. Specification, bridging sentence, pages 1-2.

According to appellant (specification, page 4, lines 1-5), these lytic enzymes prefer ethylinoleate and triethylcitrate as their substrate over the triglycerides found in sebum. In accordance with appellant's claimed invention, the hydrolysis of ethylinoleate and triethylcitrate is preferred over the hydrolysis of triglycerides because

it results in a decrease in the sebum levels achieved by inhibiting the 5-alpha reductase enzyme, an enzyme which as stated above is the cause of the reduction of testosterone to dihydrotestosterone whose action is capable of increasing the production of sebum. Once ethylinoleate is hydrolysed into linoleic acid, it is able to inhibit the activity of 5-alpha reductase by a direct mechanism, whereas triethylcitrate, once hydrolysed into citric acid, acts in an indirect way creating an environment where the activity of the aforementioned enzyme is obstructed.

Specification, page 4, lines 11-19. Stated differently, the lytic enzymes produced by the bacteria "recognize the ethylinoleate and triethylcitrate mixture as the preferential substratum rather than the triglycerides of the sebum and so do not interfere with the structure of these triglycerides, thus reducing the inflammatory pathologies of seborrhea and acne." Specification, page 4, lines 20-23.

DISCUSSION

Definiteness:

Claims 18 and 22 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 12 on appeal is drawn, inter alia, to a composition that consists essentially of two active ingredients - ethylinoleate and triethylcitrate. Claim 18 on appeal depends from and further limits claim 12, inter alia, to a composition consisting essentially of ethylinoleate and triethylcitrate

which further comprises at least one additive selected from a Markush group of additives.¹

As we understand the examiner's reasoning (Answer, page 4), claims 18 and 22 are indefinite because they require that at least one additional additive is present in the composition which consists essentially of ethyllinoleate and triethylcitrate. It appears that the examiner's concern is that these additional additives may affect the basic and novel properties of a composition consisting essentially of ethyllinoleate and triethylcitrate. See Answer, pages 8-9.

Therefore, the issue before us is the interpretation of the transitional phrase "consisting essentially of." "Consisting essentially of" is a transition phrase commonly used to signal a partially open claim in a patent. . . . 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 Indus. Inc. v. Guardian Indus. Corp, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998).

What are, however, the basic and novel properties of appellant's claimed composition? At its core, the claimed invention is drawn to a composition that consists essentially of ethyllinoleate and triethylcitrate. See e.g., claim 12. Therefore, we must explore the basic and novel properties of ethyllinoleate and triethylcitrate. As discussed above, lytic enzymes produced by bacteria present on human skin prefer ethyllinoleate and triethylcitrate as a substrate over sebum

¹ The portion of the subject matter covered by claim 22 that is in controversy is essentially a combination of the subject matter set forth in claims 12 and 18.

triglycerides. Specification, page 4, lines 1-5. In addition, and in contrast to the hydrolysis of sebum triglycerides, the hydrolysis of ethylinoleate and triethylcitrate results in the reduction of inflammatory pathologies associated with seborrhea and acne. Specification, page 4, lines 20-23.

Therefore, as we understand it, an additive that would affect the basic and novel properties of the claimed composition would interfere with the hydrolysis, or the effect² of the hydrolysis, of ethylinoleate and triethylcitrate. Reading appellant's disclosure, one class of compounds that would affect the basic and novel properties of the claimed composition would be triglycerides, which are normally found in sebum and upon hydrolysis cause skin irritation and inflammation. See e.g., Specification, page 4, lines 1-5 and 20-23, and Brief, page 22. While the examiner has asserted that the "additives" set forth in claim 18 and 22 may affect the basic and novel properties of appellant's claimed composition, the examiner provides no evidence to support this assertion. In addition, we note that appellant has provided evidence (see Brief, pages 10-22, and Evidence Appendix) that the compounds listed in claims 18 and 22 are known to be used topically "for treating and improving the aesthetic condition of skin."

On reflection, we find the weight of the evidence falls with appellant. Accordingly, we reverse the rejection of claims 18 and 22 under 35 U.S.C. § 112, second paragraph.

² The reduction of inflammatory pathologies associated with seborrhea and acne.

Anticipation:

Claims 12 and 18 stand rejected under 35 U.S.C. § 102(b) as anticipated by Hong. According to the examiner (Answer, page 4), appellant's specification uses the term "active ingredients (agents)" and 'additive" interchangeably, therefore the examiner construes the term "active ingredient" as set forth in appellant's claimed invention to mean an "additive." With this construction of appellant's claimed invention, the examiner finds (*id.*), Hong "teach a composition comprising a mixture of ethyl linoleate and triethyl citrate with excipients as additives."

As we understand it, Hong discloses a "cyclosporin-containing microemulsion preconcentrate composition." Column 5, lines 22-23. According to Hong (column 5, lines 22-26), the composition comprises (1) cyclosporin as an active ingredient; (2) alkyl ester of polycarboxylic acid and/or carboxylic acid ester of polyols as a lipophilic solvent; (3) oil; and (4) surfactant." Hong lists triethyl citrate as an example of an alkyl ester of polycarboxylic acid. See Hong, column 6, lines 1-3. In addition, Hong lists ethyl linoleate as an example of an oil. See Hong, column 7, lines 59-62.

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). "Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In this regard, we note that the only disclosure in Hong,

which teaches a composition comprising ethyllinoleate and triethyl citrate is Example 4E, Table 4, column 13. Accord Brief, pages 30-32. We note, however, that in addition to ethyllinoleate and triethyl citrate, the composition set forth in Example 4E includes, inter alia, Miglyol 812. According to appellant (Brief, page 31), Miglyol 812 is a triglyceride. Accord Hong, column 7, lines 22-45. Therefore, as we understand it, the only disclosure in Hong of a composition comprising ethyllinoleate and triethylcitrate also contains triglycerides. While the examiner is correct (Answer, page 9), that Hong does not require triglycerides as an essential component of the disclosed composition, other than Example 4E, there is no other anticipatory disclosure in Hong that would teaches a composition comprising both ethyllinoleate and triethylcitrate. All other disclosures in Hong, either do not teach a composition comprising both ethyllinoleate and triethylcitrate, or require an extensive amount of picking and choosing from among a list of ingredients to arrive at appellant's claimed composition, neither of which are sufficient to support an anticipation rejection.

Therefore, since a triglyceride would affect the basic and novel properties of appellant's claimed invention, as discussed above, it is expressly excluded from appellant's claimed composition by use of the transitional phrase "consisting essentially of." Since, Hong's composition as set forth in Example 4E comprises triglycerides, we reverse the rejection of claims 12 and 18 under 35 U.S.C. § 102(b) as being unpatentable over Chen.

Obviousness:

Claims 12-23 stand rejected under 35 U.S.C. § 103 as being unpatentable over Chen. According to the examiner (Answer, page 6), Chen teach, inter alia, a composition for topical use comprising ethyl linoleate and triethyl citrate. However, as appellant points out (Brief, page 34), Chen's invention "relates to pharmaceutical compositions and methods for improved solubilization of triglycerides and improved delivery of therapeutic agents." Chen, abstract. In this regard, we note that Chen's compositions include "a triglyceride and a carrier," wherein the "carrier includes at least two surfactants, at least one of which is a hydrophilic surfactant." Chen, column 5, lines 10-13.

With regard to the components recited in appellant's claimed invention, Chen discloses ethyl linoleate as an example of a hydrophobic surfactant that may be included in the carrier. Chen, column 22, lines 22-40. In addition, Chen discloses triethylcitrate as an example of a solubilizer that may be optionally included in the composition to "enhance the solubility of the therapeutic agent^[3] or the triglyceride." Chen, column 33, line 62 – column 34, line 18. Therefore, as we understand it, Chen teaches a triglyceride composition that comprises, inter alia, ethyl linoleate and triethylcitrate.

As discussed a triglyceride would affect the basic and novel properties of appellant's claimed invention, and is therefore expressly excluded from appellant's claimed composition by use of the transitional phrase "consisting essentially of." Since, Chen's compositions comprise triglycerides, we reverse

³ According to Chen (abstract), a "therapeutic agent can be incorporated into the [triglyceride] compositions, or can be co-administered with the [triglyceride] composition."

the rejection of claims 12-23 under 35 U.S.C. § 103 as being unpatentable over Chen.

REVERSED

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Administrative Patent Judge)
)
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