UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte FRANCIS X. SMITH and JOHN RANDALL TRACEY

Appeal 2008-5902
Application 10/842,162
U.S. Patent Publication 2005/0042198 A1
Technology Center 1700

Decided: November 24, 2008

Before: FRED E. McKELVEY, *Senior Administrative Patent Judge*, and RICHARD TORCZON and SALLY GARDNER LANE, *Administrative Patent Judges*.

McKELVEY, *Senior Administrative Patent Judge*.

DECISION ON APPEAL

A. Statement of the case

FXS Ventures, L.L.C. ("**FXS**"), the real party in interest, seeks review under 35 U.S.C. § 134(a) of a final rejection of claims 8-22, 22-25, and 37-39 as being unpatentable under (1) 35 U.S.C. § 112 for lack of a written description and (2) under 35 U.S.C. § 103 over the prior art.

We have jurisdiction under 35 U.S.C. § 134(a).

We affirm the lack of written description rejection and do not reach the obviousness rejection.

B. Findings of fact

The following findings of fact are believed to be supported by a preponderance of the evidence. Since the specification, as filed, does not have line numbers, references to the specification are to paragraph numbers of U.S. Patent Publication 2005/0042198 A1. To the extent that a finding of fact is a conclusion of law, it may be treated as such. Additional findings as necessary may appear in the Discussion portion of the opinion.

<u>The invention</u>

As filed, the invention related to an ophthalmic contact lens solution (claims 1-7) and a method for rendering a contact lens wettable comprising contacting the surface of a lens with the solution (claim 8-39).

The Examiner required restriction and FXS elected the method claims.

Method claim 8, *as filed*, read:

> 8. Method for rendering a contact lens wettable by contacting the surface of said lens with an aqueous solution comprising from 0.001 to about 10 prercent [sic-percent] by weight of an ethoxylated glyceride.

In a first-Office action (mailed 20 May 2005), the Examiner entered a number of § 112 rejections.

The Examiner also finally rejected claim 8 as being anticipated under 35 U.S.C. § 102(e) over Matsumoto, U.S. Patent 6,126,706. The remaining elected claims were also rejected over the prior art.

FXS responded by amending claim 8 to read as follows [strikeout and bracketed matter deleted; underlined added]:

> 8. A [[M]]method for rendering a contact lens wettable by contacting the surface of said lens with an aqueous solution comprising from 0.001 to about 10 ~~precent~~ percent by weight of an ethoxylated glyceride, 0.001 to 2.0 percent by weight of a physiologically acceptable buffer, a non-oxidizing preservative, and the balance water.

Amendment of 21 November 2005, page 6.

In the REMARKS section of the amendment, FXS states "[n]o new matter has been added by any of these minor changes." *Id.*, page 11.

Additionally, FXS maintained that "Matsumoto does not teach a non-oxidizing preservative. Claim 8, as amended, requires a non-oxidizing preservative. Accordingly, FXS told the Examiner that Matsumoto cannot anticipate amended claim 8. *Id.*, pages 13-14.

The Examiner's final rejection was mailed on 21 December 2005.

The Examiner rejected claim 8 and all claims which depend from claim 8 (all claims on appeal):

> under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the [now] claimed invention.

> Claim 8 recites the limitation "a non-oxidizing preservative," but the limitation 'non oxidizing' is not supported by the original disclosure or claims. This is a new matter rejection.

Final Rejection, mailed 21 December 2005.

The Examiner also rejected claim 8 and the other claims over the prior art.

For example claim 8 was rejected under 35 U.S.C. § 103 over Matsumoto and Su (U.S. Patent 4,748,189).

FXS did not file an amendment under Rule 116.

Instead, FXS proceeded directly to appeal.

In due course, FXS filed SUPPLEMENTAL APPEAL BRIEF on 29 May 2007 (hereinafter Appeal Brief).

FXS submits that the Examiner erred in making the lack of written description rejection. Appeal Brief, page 7.

FXS concedes that it added the phrase "non-oxidizing preservative" to overcome the Examiner's prior art rejection based on Matsumoto. *Id*. page 8.

According to FXS, "[t]he specification and claims as originally filed recite the term 'a preservative' throughout the disclosure. *Id*.

Relying on *In re Rasmussen*, 650 F.2d 1212 (CCPA 1981), FXS argues that the rejection is procedurally defective. According to FXS, the examiner should not have engaged in a "new matter" discussion.

On the "merits," FXS had the following to say [citations to cases omitted; bold in original, strikeout and bracketed matter added] (Appeal Brief, pages 8-9):

> Substantively, the Examiner's rejection is without basis. The Examiner had the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the [amended] claims. The examiner failed to provide any reasons, evidence, or rationale why one of ordinary skill in the art of ophthalmic and contact lens solutions would not recognized in Applicant's disclosure support for the limitation of "non-oxidizing preservative."
>
> By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory of has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage with introducing prohibited new matter.
>
> It is ~~inherently~~ known by those skilled in the art a contact lens wetting solution [inherently] will come in direct contact with the human eye. In the context of the contact lens wetting solution at issue, the term "preservative" instructs on skilled in the art to apply a preservative that would not cause irritation or discomfort when in contact with the human eye. In the

> Examiner's Non-Final Office Action [of 20 May 2005], the Examiner cited references involving oxidizing preservatives and iodine in solutions that are used to clean and disinfect contact lenses. However, these solutions **should not be directly applied to the human eye due to the risk of irritation and discomfort**. In response to the Examiner's rejection, Applicant amended Claim 8 to specifically disclaim solutions containing oxidizing preservatives. One skilled in the art would have ~~inherently~~ understood the term "preservative" in this context to encompass those preservatives that [inherently] do not cause irritation to the eye. Thus, Applicant's amendment of "non-oxidizing preservative" is supported by the disclosure and the claims as originally filed. Additionally, numerous examples of non-oxidizing preservatives are found within the specification. Section 112 does not require the recitation of claim language *ipsis verbis* within the specification to be considered adequately supported.

The Examiner was not convinced, and maintained the lack of written description requirement in the Examiner's Answer mailed 8 August 2007, page 4.

In the Examiner's Answer, the Examiner calls attention to a paragraph in the FXS application as filed [¶ 0008]:

> The additional preservatives employed in the present invention are known, such as polyhexamethylene biguanide, N-alkyl-2-pyrrolidone, chlorhexidine, polyhexamethylene-

> biguanide, alexidine, polyquatemium-1, hexetidine, bronopol and a very low concentration of hydrogen peroxide, e.g., 30 to 200 ppm.

The Examiner found that hydrogen peroxide is an oxidizing type disinfectant. Examiner's Answer, page 15.

FXS did not respond with a Reply Brief, so we have no basis for questioning the accuracy of the Examiner's finding concerning hydrogen peroxide.

FXS has not established factually in context whether the remaining compounds listed in ¶ 0008 are oxidizing or non-oxidizing.

Likewise, FXS has not established on this record how "non-oxidizing" is to be defined by one skilled in the art.

C. Discussion

<u>The lack of written description rejection</u>

Whether a specification, as filed, contains a written description of subject matter of a later added claim is a question of fact. *In re Alton*, 76 F.3d 1168, 1171 (Fed. Cir. 1996).

A question of fact is resolved on the basis of the evidence.

When a written description cannot be found in the specification, as filed, the only thing the PTO can reasonably be expected to do is to point out its non-existence. *Hyatt v. Dudas*, 492 F.3d 1365, 1377 (Fed. Cir. 2007).

In this case, the Examiner did exactly what *Hyatt v. Dudas* determined was reasonable; the Examiner notified FXS that "non-oxidizing" is not supported by the original disclosure. Final Rejection, page 3.

We therefore disagree with FXS that the Examiner "failed to provide any reasons" in support of the lack of written description rejection. *Cf.* Appeal Brief, page 8.

FXS did not respond to the Final Rejection with a Rule 116 amendment accompanied by evidence that might have established what non-oxidizing means to one skilled in the art in the context of the invention.

Rather, FXS proceeded directly to appeal where all it presents is attorney argument.

But, an argument of counsel cannot take the place of evidence in the record. *In re Cole*, 326 F.2d 769, 773 (CCPA 1964).

We have no idea what "non-oxidizing" means in the context of this invention.

We will observe that we were unable to find the phrase "non-oxidizing preservative" anywhere in the FXS specification or the large amount of prior art cited by the Examiner.

While the Examiner suggests that one of the compounds (hydrogen peroxide) listed in ¶ 0008 of the FXS specification is "oxidizing" rather than "non-oxidizing," apart from argument of counsel, there is no reliable evidence in the record which allows us to make a finding supported by substantial evidence that the other ¶ 0008 compounds are or are not oxidizing preservatives.

FXS has failed to establish that the Examiner erred in finding that "non-oxidizing preservative" was not described in the specification, as filed.

We have considered FXS's remaining arguments with respect to the § 112 rejection and find none that warrant reversal of the rejection. *Cf. Hartman v. Nicholson*, 483 F.3d 1311, 1315 (Fed. Cir. 2007).

The obviousness rejection

We do not reach the obviousness rejections because an affirmance of the lack of written description rejection disposes of all claims on appeal. We do not believe it necessary to address the obviousness of claims which contain a limitation not described by the specification, as filed. *Cf. In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970); *In re Steele*, 305 F.2d 859, 863 (CCPA 1962).

D. Decision

FXG has not sustained its burden on appeal of showing that the Examiner erred in rejecting the claims on appeal as being unpatentable based on a lack of written description.

Upon consideration of the appeal, and for the reasons given herein, it is

ORDERED that the decision of the Examiner rejecting all the claims on appeal for lack of a written description is *affirmed*.

FURTHER ORDERED that a decision of the Examiner's § 103 rejection is not necessary.

FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2008).

AFFIRMED

ack

cc (via First Class mail)

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