

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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

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

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Ex parte STEFANO BADER, ENRIQUE HAUSERMANN,  
and TIZIANA MONTI

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Appeal No. 2006-0182  
Application No. 10/254,862

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Heard: April 25, 2006

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Before SCHEINER, ADAMS and MILLS, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

**DECISION ON APPEAL**

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-3 and 5-11, which are all of the claims on appeal in this application.

Claim 1 is representative and reads as follows:

1. Nimesulide topical formulations in the form of gel systems comprising carboxyvinylpolymer neutralized with aqueous solutions of weak bases or a polyacrylamideisoparaffin and 5-40% by weight of a solvent selected from the group consisting of ethanol, isopropanol, diethylene glycol monoethyl ether, said formulations comprising nimesulide dispersed in said solvent, and said formulations having a water content from 40-95% by weight.

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The prior art references cited by the examiner are:

Jain et al. (Jain)	5,716,609	Feb. 10, 1998
Miyata et al. (Miyata)	5,837,735	Nov. 17, 1998

### Grounds of Rejection

1. Claims 1-3 and 5-11 stand rejected under 35 U.S.C. §103(a) as obvious over Miyata in view of Jain.
2. Claims 5 stands rejected under 35 U.S.C. §112, second paragraph, for indefiniteness.

We reverse these rejections.

## DISCUSSION

### Background

Nimesulide is a known anti-inflammatory agent whose therapeutic efficacy has been proven for some time, but which has the drawback of unfavorable chemical-physical characteristics. The main obstacle to the use of nimesulide is in fact its insolubility in water, and on the other hand, its poor solubility in solvents/raw materials usually employed in such formulations. Specification, page 1.

### 35 U.S.C. § 103(a)

Claims 1-3 and 5-11 stand rejected under 35 U.S.C. §103(a) as obvious over Miyata in view of Jain.

According to the Examiner, Miyata teaches a topical nimesulide gel formulation “wherein nimesulide (0.1-5%) is dispersed in a base component that comprises 2-20%

of an oily substance[,] . . . a basic substance . . . water (50-90% at col. 3, line 10), a hydrophilic polymer (e.g. carboxyvinyl polymer at column 3, lines 20-32)..." Answer, page 4.

The examiner argues that appellants' claims differ from Miyata in that they require a specific solvent such as ethanol, isopropanol, or diethylene glycol monoethyl ether.

The examiner concludes that (Answer, pages 4-5)

it would have been obvious to one of ordinary skill in the art to substitute the oily substances (taught in [Miyata]...) with ethanol, isopropanol or diethylene glycol monoethyl ether (required by instant claims) at the time the invention was made . . . because [Jain] US'609 teaches that the solvents (required by instant claims) such as lower alcohols (e.g, ethanol or isopropanol) or diethylene glycol monoethyl ether (transcutol®) and the vehicles (taught in US '735) such as propylene glycol, glycerol (=1,2,3-propanetriol), are functionally equivalent to each other wherein they are acting as a solubilizing agent for nimesulide. . . . It is readily apparent to one of ordinary skill in the art that the substitution would not alter the solubilizing activity significantly. One would have been motivated to make such substitution with reasonable expectation of success, because such substitution (well known solvents) is conventional knowledge and commonly practiced in the cosmetic/pharmaceutical field. One would have been motivated to do so, with reasonable expectation of success because such substitution could result in cost-effective manufacturing process because lower alcohols are easy to obtain. . . . The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by these cited reference.

We do not find that the examiner has provided sufficient evidence to support a prima facie case of obviousness. Appellants argue that the combination of Miyata with Jain is without motivation. We agree. In particular, appellants argue (Brief, page 9)

Propylene glycol and glycerol are described in MIYATA et al. . . . as examples of optional wetting agents for possible use in the dispersion (see column 4, lines 47-50 of MIYATA et al.). Therefore, the fact that two of the wetting agents mentioned in MIYATA et al. also appear in a list of solvents in JAIN et al. that includes the claimed solvents, in no way suggests replacing the distinct oily substance of MIYATA et al. with any of the solvents of JAIN et al. Indeed, even if one were to compare apples to apples, there is no motivation to replace any of the listed optional wetting agents of MIYATA et al. with any of the claimed solvents, notwithstanding that those solvents appear at column 5, lines 4-15 of JAIN et al. together with certain of the MIYATA et al. wetting agents. . . . [A] wetting agent serves to reduce the surface tension of a liquid, so as more readily to incorporate a suspended solid. One skilled in the art would thus not look to JAIN, relating as it does to solutions and not dispersions, for guidance in selecting alternative wetting agents.

In our view, the examiner has not provided sufficient evidence to show why one of ordinary skill in the art would have substituted the particular solvents of Jain for the wetting agents of Miyata. “In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. [The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.” In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). An adequate showing of motivation to combine requires “evidence that a 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.” Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76 (Fed. Cir. 2000) (quoting In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998)). We agree

with Appellants that the examiner has not met his burden of showing prima facie obviousness. We also remind the examiner that “it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” In re Wesslau, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965); see also In re Mercier, 515 F.2d 1161, 1165-66, 185 USPQ 774, 778 (CCPA 1975).

Thus we do not find that the examiner has established a prima facie case of obviousness, and the rejection of the claims for obviousness is reversed.

35 U.S.C. §112, second paragraph

Claim 5 stands rejected under 35 U.S.C. §112, second paragraph, for indefiniteness.

The examiner asserts that the phrase, “said concentration” in claim 1 renders the claim indefinite because it is not clear which component’s concentration is referenced as claim 1 does not recite the term “a concentration.” Answer, pages 3 and 7.

Appellants respond, arguing that they agree that the recitation “a concentration lacks antecedent basis” in claim 1, however, they argue one of ordinary skill in the art would readily understand that claim 5 refers to the concentration of the solvent because claim 5 limits the 5-40% weight range of claim 1 to 1 to 15%. Brief, page 4.

Appellants argue that such an interpretation of claim 5 is clear from a reading of dependent claims 2 and 3 which also use the term “concentration” in reference to the

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weight percent range of the solvent, thereby establishing this lexicon with respect to the solvent content.” Id.

While we agree with the examiner that claim 5 could have been more artfully drafted, in our view, one of ordinary skill in the art would understand that the concentration recited in claim 5 references the concentration of the solvent in terms of weight percent. “The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. The degree of precision necessary for adequate claims is a function of the nature of the subject matter.” Miles Lab., Inc. v. Shandon, Inc., 997 F.2d 870, 875, 27 USPQ 2d 1123, 1126 (Fed. Cir. 1993). Claim 5 is not so “insolubly ambiguous” to find indefiniteness. See, Exxon Research and Engineering Co. v. United States, 265 F.3d 1371, 1375, 60 USPQ2d 1272, 1276 (Fed. Cir. 2001).

The rejection of claim 5 for indefiniteness is reversed.

CONCLUSION

Therefore, the rejection of claims 1-3 and 5-11 under 35 U.S.C. §103(a) as obvious over Miyata in view of Jain is reversed. The rejection of claim 5 for indefiniteness under 35 U.S.C. §112, second paragraph is reversed.

REVERSED

TONI R. SCHEINER  
Administrative Patent Judge

DONALD E. ADAMS  
Administrative Patent Judge

DEMETRA J. MILLS  
Administrative Patent Judge

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DJM/lbg

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Young and Thompson  
745 South 23rd Street  
2<sup>nd</sup> Floor  
Arlington, VA 22202