

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

Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte  
THOMAS BOCK,  
PAUL SAEGMUELLER,  
PETER SIEGER  
and DIETRICH TUERCK,

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Appeal No. 2003-0913  
Application No. 09/277,049

**ON BRIEF**

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Before LIEBERMAN, MILLS and GRIMES, Administrative Patent Judges.

LIEBERMAN, Administrative Patent Judge.

**DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 from the decision of the examiner refusing to allow claims 4 through 19 and claims 1 through 3 and 21 through 25 as amended subsequent to the final rejection, which are all the claims pending in this application.

**THE INVENTION**

The invention is directed to a solid pharmaceutical composition comprising a salt of

meloxicam and a conventional powdered carrier or excipient. In a specific embodiment the meloxicam salt is a meloxicam meglumin salt monohydrate or dihydrate. A separate embodiment is also directed to a method for the preparation of the meloxicam meglumin monohydrate and dihydrate salts. Additional limitations are described in the following illustrative claims.

### THE CLAIMS

Claims 1, 6 and 14 are illustrative of appellants' invention and are reproduced below.

1. A solid pharmaceutical composition suitable for oral administration comprising:
  - (a) a salt of meloxicam selected from the group consisting of the sodium salt, the potassium salt, the ammonium salt, the salt formed with meglumin, the salt formed with Tris-(hydroxymethyl)aminomethane, and the salts formed with basic amino acids; and
  - (b) a conventional powdered carrier or excipient.
6. Crystalline meloxicam meglumin salt monohydrate or crystalline meloxicam meglumin salt dihydrate.
14. A process for preparing an orally administrable solid pharmaceutical preparation containing meloxicam in the form of the crystalline meloxicam-meglumin salt monohydrate, the process comprising:
  - (a) heating meloxicam and meglumin in a solvent mixture of a water-miscible organic solvent and water;
  - (b) adding meloxicam-meglumin salt monohydrate seed crystals to the solvent mixture containing meloxicam and meglumin to obtain crystalline meloxicam-meglumin salt monohydrate;
  - (c) separating crystalline meloxicam-meglumin salt monohydrate from the solvent mixture;



Claims 1 through 5 and 21 through 25 stand rejected under 35 U.S.C. §102(b) as being anticipated by Luger or Trummlitz.<sup>1</sup>

Claims 1 through 5 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Trummlitz in view of Luger.

### OPINION

We have carefully considered all of the arguments advanced by the appellants and the examiner and agree with the examiner that the rejection of the claims under §§ 102(b) and 103(a) are well founded. Accordingly, we affirm the rejections for the reasons discussed herein. We agree with the appellants that the rejections under 35 U.S.C. § 112, first and second paragraphs are not well founded. Accordingly, we reverse these rejections.

As an initial matter, it is the appellants' position that, "claims 1 to 5 and 21 to 25 stand or fall together and claims 6 to 19 stand or fall together." See Brief, page 3. Accordingly, we select claims 1 and 6 as representative of the claimed subject matter and limit our consideration thereto. See 37 CFR §1.192(c)(7) (2001).

#### *The Rejections under § 112*

Any analysis of the claims for compliance with 35 U.S.C. § 112 should start with the second paragraph, then proceed with the first paragraph. In re Angstadt, 537 F.2d 498, 501, 190 USPQ 214, 217 (CCPA 1976). "The legal standard for definiteness [under the second paragraph of 35 U.S.C. § 112] is whether a claim reasonably apprises those of

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<sup>1</sup>Although the statement of the rejection utilized the conjunctive "and", the rejection in fact considers the references in the alternative.

ordinary skill in the art of its scope.” In re Warmerdam, 33 F.3d 1354, 1361, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). The inquiry is to determine whether the claim sets out and circumscribes a particular area with a reasonable degree of precision and particularity. The definiteness of the language employed in a claim must be analyzed not in a vacuum, but in light of the teachings of the particular application. In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). Those of ordinary skill in the art would clearly understand the term, “conventional” in claim 1 are those excipients or carriers that are usually or customarily added to pharmaceutical agents utilized in oral administration. Our position is supported by the examples of excipients or carriers found in the specification on page 9, lines 5 and 6 and Examples 4 through 7.

Based upon the above findings and analysis, the rejection of the examiner under § 112, second paragraph is not sustainable.

We turn next to the examiner’s rejection under the first paragraph of 35 U.S.C. § 112, on the grounds of lack of enablement. When rejecting a claim under the enablement requirement of section 112, the PTO bears the initial burden of setting forth a reasonable explanation as to why it believes the scope of protection provided by the claimed subject matter is not adequately enabled by the description of the invention provided in the specification of the application. This includes providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If this burden is met, the burden then shifts to the appellants to provide suitable proofs that the specification is enabling. In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367,

369-70 (CCPA 1971).

The examiner's position is that the claimed subject matter is not enabled in the specification, because claims 6 through 19 describe a process of making crystalline meloxicam meglumin salt monohydrate and dihydrate by seeding the salt with the seed crystal of the identical substance, in the absence of showing how the seed crystal is prepared. As the examiner has stated, it is requisite that the specification provides, "guidance on how the first crystalline salt monohydrate (or dihydrate) is made." See Answer, page 9.

We are persuaded however, that the specification and the art of record provide adequate guidance and assurance that the seed crystals required by the claimed process can be easily obtained. In this respect, the appellants have stated in the specification that, "this condition can be met with a meloxicam-meglumin salt if, during crystallization of the salt from a mixture of a water-miscible organic solvent and water, seed crystals consisting of crystalline meloxicam-meglumin salt monohydrate, preferably seed crystals of a meloxicam-meglumin salt monohydrate form previously crystallised from acetone/water, are added to the mixture. A product is then obtained, reproducibly and uniformly, which corresponds to the crystalline form of the seed crystals used." See specification page 9, lines 23-28. Accordingly, a method for the preparation of a seed crystal is provided by the specification. Furthermore, the prior art of record to Luger relied upon by the examiner in the art of record indicates that meloxicam salts are customarily crystallised in the presence of solvents. In this respect, Luger states that, "[I]ight yellow crystals of  $\text{NH}_4^+(\text{C}_{14}\text{H}_{12}\text{O}_4\text{N}_3\text{S}_2)^-$  were prepared from the

acidic form by addition of ethanolic ammonia and subsequent crystallization from water-isopropanol.” Based upon the above findings and analysis, we conclude that salts of meloxicam are readily obtained from solution. Therefore, the examiner’s position is not supported by the record before us. Accordingly, the rejection of the examiner under § 112, first paragraph is not sustainable.

#### The Rejection under § 102(b)

In order for a claimed invention to be anticipated under 35 U.S.C. § 102(b), all of the elements of the claim must be found in one reference. Scripps Clinic & Research Found. v. Genentech Inc., 927 F.2d 1565, 1576, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). The examiner relies upon references to either Trummlitz or Luger to reject the claimed subject matter and establish a prima facie case of anticipation. It is the appellants’ position that, “neither Luger *et al.* nor Trummlitz *et al.* disclose, suggest, or otherwise hint at solid pharmaceutical preparations suitable for oral administration that contain meloxicam salts and a conventional powdered carrier or excipient.” See Brief, page 8.

Meloxicam identified as (4-hydroxy-2-methyl-N-(5-methyl-2-thiazoyl)-2H-1, 2-benzothiazine-3-carboxamide-1,1-dioxide, specification, page 2 is disclosed by Trummlitz in Example 1. The sodium salt is disclosed in Example 2 and the N-Methyl-glucamine salt, i.e., the meglumin salt is disclosed in Example 3. We find that Trummlitz discloses that the compounds of the invention are utilized in the form of non-toxic pharmacologically accepted salts which exhibit anti-inflammatory and anti-thrombotic activity. See column 12, lines 48-57. Meloxicam among other compounds is

administered perorally to rats and other warm blooded animals. See column 13, lines 31-47 and column 15, lines 49-57. The meloxicam is administered in dosage unit form consisting essentially of an inert pharmaceutical carrier and one effective dosage unit of the active ingredient in the form of tablets or powders. *Id.* We further find that Examples 20 through 22 disclose a tablet containing meloxicam in combination with corn starch, polyvinylpyrrolidone, magnesium stearate, and colloidal silicic acid among other components. We further find that these components fall within the scope of carriers and excipients identified in the specification. See specification, page 9, lines 5-6 which discloses examples of carriers and excipients including magnesium stearate, crosslinked polyvinyl pyrrolidone and various starches and the examples which disclose soluble polyvinyl pyrrolidone. Based upon the above findings and analysis, we conclude that the teachings and disclosure of Trummlitz establish a prima facie case of anticipation with respect to the claimed subject matter.

A discussion of Luger is not needed in reaching our decision.

The Rejection under § 103(a)

We shall also affirm the rejection of the claims as unpatentable over Trummlitz. It is well settled that the ultimate obviousness is lack of novelty. The claims cannot have been anticipated and not have been obvious. In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982).

### **DECISION**

The rejection of claims 1, 4 and 14 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellants' regard as the invention is reversed.

The rejection of claims 6 through 19 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make/or use the invention is reversed.

The rejection of claims 1 through 5 and 21 through 25 under 35 U.S.C. §102(b) as being anticipated by Luger or Trummlitz is affirmed.

The rejection of claims 1 through 5 under 35 U.S.C. §103(a) as being unpatentable over Trummlitz in view of Luger is affirmed.

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

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**

PAUL LIEBERMAN	)	
Administrative Patent Judge	)	
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DEMETRA J. MILLS	)	BOARD OF PATENT
Administrative Patent Judge	)	APPEALS
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ERIC GRIMES	)	
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