

The opinion in support of the decision being entered today was not written for publication in a law journal and is not binding precedent of the Board.

Paper No. 12

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DINESH GALA and
DONALD J. DIBENEDETTO

Appeal No. 2001-0987
Application 09/169,109

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ROBINSON Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 8, which are all of the claims pending in this application.

THE INVENTION

Applicants' invention relates to a crystalline "polymorph form 2 loratadine" having a specified x-ray powder diffraction pattern; a pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 2 loratadine and a pharmaceutically acceptable carrier; and a method of treating allergic reactions in a

mammal by administering to the mammal an anti-allergic effective amount of polymorph form 2 loratadine. Claim 1, which is illustrative of the subject matter on appeal, reads as follows:

1. Polymorph form 2 loratadine having the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensities("RI").

<u>d spacing</u> (± 0.05)	<u>RI</u>
8.95	Weak
6.37	Weak
5.64	Weak

THE REFERENCES

The prior art references relied on by the examiner are:

Villani	4,282,233	Aug. 4, 1981
Sims et al. (Sims) (PCT Application)	WO 95/01792	Jan.19, 1995

THE REJECTIONS

Claims 1 through 8 stand rejected under 35 U.S.C. §103(a) as unpatentable over the combined disclosures of Villani and Sims. Claims 1 through 8 further stand rejected under the judicially created doctrine of obviousness-type double patenting over claim 7 of Villani in view of Sims.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including Figures 1 and 2, and all of the claims on appeal; (2) the Appeal Brief (Paper No. 10); (3) the Examiner's Answer (Paper No. 11); and (4) the above-cited prior art references.

On consideration of the record, including the above-listed materials, we reverse the examiner's rejections.

DISCUSSION

The question here is whether the combined disclosures of Villani and Sims support a conclusion of obviousness of claims 1 through 8, which recite the crystalline polymorph form 2 of loratadine having a unique x-ray powder diffraction pattern and infrared spectrum. We answer that question in the negative.

Villani discloses polymorph form 1 of loratadine, but does not disclose or suggest that loratadine may assume distinct, crystalline polymorphic forms having different physical properties. Nor does Villani teach a person having ordinary skill in the art how to make polymorph form 2 of loratadine.

The Sims reference does not cure the deficiencies of Villani. Sims discloses a list of 16 non-sedating antihistamines, including loratadine, useful in combination therapy (Sims, page 8, lines 3 through 6). After listing those antihistamines, Sims refers to "a pharmaceutically acceptable salt, hydrate, or polymorph thereof" (id., lines 6 and 7). That reference to pharmaceutically acceptable salts, hydrates, or polymorphs, however, does not teach a person having ordinary skill in the art that loratadine may assume distinct, crystalline polymorphic forms having different physical properties. Rather, it appears that the above-quoted language constitutes boilerplate; and that Sims refers generally to pharmaceutically acceptable salts, hydrates, or polymorphs of any one of 16 non-sedating antihistamines without specifically suggesting that loratadine is capable of existing in the form of distinct crystalline polymorphs. On this point, we disagree with the examiner's finding that "Sims expressly teaches that loratadine may be in the form of polymorphs" (Examiner's Answer, page 3, lines 10 and 11). Nor does Sims teach a person having ordinary skill in the art how to make polymorph form 2 of loratadine.

On this record, applicants, and applicants alone, disclose that “loratadine can exist in the form of two distinct crystalline polymorphs, each having distinctly different physical properties” (Specification, page 2, first full paragraph). Applicants have discovered specific solvents and experimental conditions, producing a distinctly different polymorph form 2 of loratadine (Specification, page 3, last paragraph). Applicants discovered that crystallization of loratadine (prepared as described in U.S. Patent No. 4,282,233) from toluene, t-butylmethylether, heptane, or mixtures thereof, produce a polymorph form 2 loratadine. Applicants also discovered that using a t-butylmethylether-toluene mixture is preferred (Specification, page 4, second paragraph). This information stems from applicants’ specification, but not from the cited prior art. Further, neither Villani nor Sims discloses or renders obvious a method for making polymorph form 2 loratadine. As stated in In re Hoeksema, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968),

[I]f the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds. [footnote omitted]

The examiner relies heavily on this proposition of law set forth in Ex parte Hartop, 139 USPQ 525, 527 (Bd. Pat. App. 1962):

[M]erely changing the form, purity or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable.

According to the examiner, polymorph form 2 loratadine is merely another form of an old product (polymorph form 1 loratadine) and both forms possess the same utility.

Accordingly, the examiner concludes that applicants’ claims, reciting polymorph form

2 loratadine, are unpatentable. We disagree. Here, we invite attention to In re Cofer, 354 F.2d 664, 667, 148 USPQ 268, 271 (CCPA 1966), where the court substantially discredited PTO reliance on the above-quoted proposition of law in Hartop. Like the situation presented in Cofer, the examiner in this case has not adequately established that the prior art (1) suggests the polymorph form 2 of loratadine; or (2) discloses or renders obvious a method for making the polymorph form 2 of loratadine.

Accordingly, the examiner's rejection of claims 1 through 8 under 35 U.S.C. § 103(a) as unpatentable over Villani in view of Sims is reversed. For essentially the same reasons, the rejection of claims 1 through 8 under the judicially created doctrine of obviousness-type double patenting over claim 7 of Villani in view of Sims is also reversed.

The examiner's decision rejecting claims 1 through 8 is reversed.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
William F. Smith)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Douglas W. Robinson)	
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