

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 22

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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

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Ex parte WILLIAM J. TOUREK and  
SAMUEL DAISY JR.

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Appeal No. 2001-0941  
Application No. 08/890,705

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ON BRIEF

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Before WINTERS, SCHEINER, and GRIMES, Administrative Patent Judges.

GRIMES, 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 6-10 and 17-28, all of the claims remaining. Claim 6 is representative and reads as follows:

6. A method for manufacturing by dry granulation a tablet for the delivery of the active ingredient of St. John's Wort, said tablet comprising by weight of the tablet:  
  
40 to 75% by weight St. John's Wort extract,  
1.0-5.0% by weight binder,  
8-18% by weight dissolution regulator,  
up to 30% by weight filler,  
0.2 to 5.0% by weight glidant as a final proportion of glidant, and  
0.5 to 2.5% by weight lubricant as a final proportion of lubricant;

said method comprising the steps of:

- a) mixing components comprising:
  - 40 to 75% by weight St. John's Wort extract,
  - 1.0-5.0% by weight binder,
  - 8-18% by weight dissolution regulator,
  - up to 30% by weight filler,
  - and less than at least one of the final proportion of glidant and the final proportion of lubricant of 0.2 to 5.0% by weight glidant, and 0.5 to 2.5% by weight lubricant to form a slug,
- b) breaking the slug down into particulates which can be subsequently compressed into a tablet,
- c) adding sufficient glidant and/or lubricant to form a composition with final proportions of both glidant and lubricant of 0.2 to 5.0% by weight glidant, and 0.5 to 2.5% by weight lubricant, and
- d) compressing the composition to form a tablet.

The examiner relies on the following references:

Lavie et al. (Lavie)	4,898,891	Feb. 6, 1990
Evenstad et al. (Evenstad)	5,126,145	Jun. 30, 1992
Kikuta et al. (Kikuta)	5,288,485	Feb. 22, 1994
Erdelmeier et al. (Erdelmeier)	WO 97/13489	Apr. 17, 1997

Remington's Pharmaceutical Sciences (Remington's), 16<sup>th</sup> Ed., Chp. 89, "Tablets, Capsules, and Pills," pp.1553-1566 (1980)

Claims 6-10 and 17-28 stand rejected under 35 U.S.C. § 103 as obvious in view of Erdelmeier, Lavie, Remington's, Evenstad, and Kikuta.

We reverse.

#### Background

The specification discloses compositions comprising extracts of St. John's Wort (Hypericum perforatum), and methods of formulating these compositions into tablet form. The compositions comprise specific weight percent ranges of

Hypericum extract, dissolution regulator for sustained release, binder, filler, glidant, and lubricant (also referred to as “lubricant/glidant”). See, e.g., page 3, lines 1-6.

The specification discloses that “methods of forming the tablets of the invention generally excludes [sic] the typical wet granulation methods. . . . The nature of the supplement is such that conventional processing by wet compression or wet granulation did not work for reasons not previously known to the inventors. Initial efforts at wet granulation produced a tar-like product.” Page 8. Subsequent refinement of the wet granulation method, as well as tableting by “planetary mixing,” produced better results but only with manual control of the process. See id., pages 8-9.

The specification discloses that a “dry granulation” process was necessary “to enable the supplement materials to be tableted with consistency.” Page 9. In the disclosed method, all of the ingredients except for part of the glidant and/or lubricant are “blended into a first composition and compressed into a pre-tablet or slug. The slug is ground (and usually screened), the remaining glidant and/or lubricant from the final formulation is added to form a second composition, and then the second composition is compressed into a tablet.” Id.

The specification also states that such dry granulation processes had “previously been used where the components of the tablet are sensitive to moisture (as by degradation) or are unable to withstand the elevated temperatures of drying.” Id. However, “[t]he components of the present tablet are neither degraded by moisture nor sensitive to drying temperatures, so dry

granulation was not a natural method selected [sic] for the tableting of the St. John's Wort supplement." Id.

### Discussion

The claims are directed to the disclosed dry granulation method of making St. John's Wort supplements in tablet form. In claim 6, for example, St. John's Wort extract, binder, dissolution regulator, and filler, in specified weight percent ranges, along with something less than all of the glidant and/or lubricant that will be present in the final composition, are mixed together and formed into a slug. The slug is then broken down into particulates, the remaining glidant and/or lubricant is added, and the composition is compressed again to form a tablet.

The examiner rejected the claimed method as obvious in view of a combination of five prior art references. The examiner's explanation of the rejection is not entirely clear regarding which teachings are being combined, from which references, and based on what motivation. As we understand it, the rejection relied on Erdelmeier for its disclosure of St. John's Wort extract in tablet form, on Lavie, Remington's, and Evenstad for various aspects of tableting processes, and on Kikuta for digestible coatings. See the Examiner's Answer, pages 4-6. Since the broadest claim on appeal does not require a digestible coating, we will say no more about Kikuta.

The examiner characterized Erdelmeier as disclosing tableted compositions comprising 54% by weight St. John's Wort extract, 18% by weight cellulose, 16% by weight modified starch, 5.4% by weight sodium carboxymethyl-cellulose, 0.9% silica dioxide, 0.9% ascorbate, 0.9% magnesium stearate, and

3.6% hydroxypropylmethylcellulose. She concluded that “formulating compositions comprising active ingredients in extracts of St. John’s Wort, and inactive ingredients such as binders, dissolution regulators, fillers, glidants, and lubricants, in amounts encompassed by the claimed ranges, would have been obvious in view of the disclosure of Erdelmeier.” Examiner’s Answer, pages 4-5.

Appellants argue that Erdelmeier does not disclose compositions meeting the limitations of claim 6. See the Appeal Brief, pages 13-14. Appellants argue that the claims recite a composition comprising 1.0 to 5.0% binder, while Erdelmeier’s composition comprises 16% starch, “more than three times the maximum amount of binder limited by Applicants.” Id. Appellants also argue that the composition recited in the claims requires 8 to 18% of a dissolution regulator such as hydroxypropylmethylcellulose, while Erdelmeier’s composition has only 3.6% hydroxypropylmethylcellulose. Finally, Appellants argue that Erdelmeier discloses hydroxypropylmethylcellulose as a coating on the tablets, not as a dissolution regulator.

We note, first of all, that our review of Erdelmeier has been hampered by the examiner’s failure to obtain a translation of the reference, which is in German. However, since Appellants have not disputed the examiner’s characterization of Erdelmeier’s Example 8, we will accept it as accurate. Even so, we agree with Appellants that the reference does not disclose a composition within the scope of the instant claims. Claim 6 recites a composition comprising

- 40-75% by weight of St. John’s Wort extract,
- 1-5% by weight of a binder (e.g., starch; specification, page 5),

- 8-18% by weight of a dissolution regulator (e.g., hydroxypropylmethylcellulose; specification, page 4),
- 0-30% by weight of a filler (e.g., cellulose, specification, page 8),
- 0.2-5% by weight of a glidant (e.g. silicon dioxide, specification, pages 7-8), and
- 0.5-2.5% by weight of a lubricant (e.g., magnesium stearate, specification, pages 7-8).

According to the examiner, Erdelmeier's composition comprises 54% St. John's Wort extract, 18% cellulose, 16% modified starch, 5.4% sodium carboxymethylcellulose, 0.9% each of silica dioxide, ascorbate, and magnesium stearate, and 3.6% hydroxypropylmethylcellulose. The examiner did not match up the components of the prior art composition with the limitations of the claims, but the prior art composition appears to meet the claim requirements with respect to extract (54%), filler (cellulose, 18%), glidant (silicon dioxide, 0.9%) and lubricant (magnesium stearate, 0.9%).

However, the examiner provided no explanation of how the remaining components of the prior art composition meet the remaining claim limitations. That is, the claims require 1-5% by weight of a binder and 8-18% by weight of a dissolution regulator. With respect to these components, Erdelmeier's composition comprises 16% modified starch, 5.4% sodium carboxymethylcellulose, 0.9% ascorbate, and 3.6% hydroxypropylmethylcellulose. Starch is disclosed in the instant specification to be a binder (page 5) but 16% starch does not meet the claim limitation requiring 1-5% binder. Likewise, hydroxypropylmethylcellulose is disclosed in the specification to be a dissolution regulator, but

3.6% hydroxypropylmethylcellulose does not meet the claim limitation of 8-18% dissolution regulator.

The examiner asserted that “formulating compositions comprising [the recited ingredients] in amounts encompassed in the claimed ranges, would have been obvious in view of the disclosure of Erdelmeier.” Examiner’s Answer, pages 4-5. The examiner, however, cited no evidence and provided no scientific reasoning to support this assertion. We therefore agree with Appellants that the examiner has not shown that the cited references would have made obvious a method of making the composition recited in the instant claims.

A prima facie case of obviousness must account for all the limitations of the claims. See In re Angstadt, 537 F.2d 498, 501, 190 USPQ 214, 217 (CCPA 1976) (“[W]e must give effect to all claim limitations.” (emphasis in original)). The examiner has not adequately explained how the prior art would have rendered obvious the composition recited in the instant claims, and therefore has not shown that the claimed invention as a whole would have been prima facie obvious.

We also agree with Appellants that the examiner has not shown that the processing steps recited in the claims would have been obvious based on the cited references. The examiner cites Lavie, Remington’s, and Evenstad for their disclosures of individual elements of the claimed process. Lavie is cited for its disclosure of conventional processing of tablets containing a compound isolated from a different Hypericum species (Examiner’s Answer, page 5), Remington’s is cited for its disclosure of conventional dry granulation tableting (Examiner’s

Answer, pages 5-6), and Evenstad is cited for its disclosure of hydroxypropylmethylcellulose as a sustained release agent (Examiner's Answer, page 6).

The examiner cites these references, correctly, as teaching various limitations of the present claims, but provides no coherent rationale for why a person of ordinary skill in the art would have been led to combine those elements. For example, the examiner cites Remington's as disclosing conventional dry granulation tableting, and teaching that this method is "advantageous when the tablet ingredients are sensitive to moisture or are unable to withstand elevated temperatures during drying." Examiner's Answer, page 5. The instant specification, though, expressly notes that these conditions do not apply to the ingredients combined in the claimed process. See page 9.

In addition, Evenstad's disclosure of hydroxypropylmethylcellulose as a sustained-release agent is limited to tablets made by wet granulation. See column 1, line 63 to column 2, line 2 (emphasis added): "We have discovered a sustained release tablet comprising hydroxypropyl methylcellulose with sustaining properties . . . , sufficient water soluble pharmaceutical binder to permit wet granulation, an amount of internal hydrophobic component effective to permit wet granulation, and a water soluble medicament." The examiner has not explained how this disclosure would have led those skilled in the art to use hydroxypropylmethylcellulose in the claimed dry granulation process.

Thus, even if the cited references disclosed the elements of the instant claims, the examiner has not adequately explained why those of skill in the art would have been led to combine those elements. See In re Fritch, 972 F.2d

1260, 1266, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (“The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.”). See also In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000): “Most if not all inventions arise from a combination of old elements. Thus, every element of a claimed invention may often be found in the prior art. However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.”

Summary

The examiner has not shown that the cited references would have suggested the method defined by the instant claims to a person of ordinary skill in the art. We therefore reverse the rejection under 35 U.S.C. § 103.

REVERSED

Sherman D. Winters	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
Toni R. Scheiner	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
	)	
Eric Grimes	)	
Administrative Patent Judge	)	

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