

The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ZAKAUDDIN T. CHOWHAN and PATRICK H. VO

Appeal 97-1939
Application 08/375,049¹

Before: McKELVEY, Senior Administrative Patent Judge, and
SCHAFER and LEE, Administrative Patent Judges.

McKELVEY, Senior Administrative Patent Judge.

Decision on appeal under 35 U.S.C. § 134

Upon consideration of applicants' Appeal Brief (Paper 21)
and the Examiner's Answer (Paper 22), it is

ORDERED that the examiner's rejection of claims 37-
38, 42-43 and 45-46 as being unpatentable under 35 U.S.C.

¹ Application for patent filed 18 January 1995. The application on appeal is said to be a continuation of application 08/038,597, filed 16 March 1993. The real party in interest is Syntex (U.S.A.) Inc.

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§ 103 over Pagay, U.S. Patent 5,330,759 (1994)² in view of
Porter, U.S. Patent 4,556,552 (1985) is reversed.

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According to applicants, the claims stand or fall
together with claim 42.

Claim 42

Claim 42 reads [indentation and paragraph numbering
added]:

- An aqueous enteric coating dispersion
- [1] free of organic solvents, detackifiers,
glidants, and optional excipients and
 - [2] suitable for use in the preparation of an
enteric coated pharmaceutical dosage form,
 - [3] the dispersion prepared by combining in
 - [a] water
 - [b] one or more anionic polymers being
synthesized from methacrylic acid and an
acrylic acid ester,
 - [c] one or more plasticizers selected from
triethyl citrate and dibutyl phthalate, and
 - [d] ammonium hydroxide.

² Pagay is based on an application filed 26 August 1992 and therefore is prior art
vis-a-vis applicants under 35 U.S.C. § 102(e).

Pagay

Pagay describes an aqueous enteric coating dispersion containing items [a], [b] and [c] of applicants' claim 42.

Pagay differs from the subject matter of claim 42 in that claim 42 requires the presence of ammonium hydroxide whereas Pagay does not describe the use of ammonium hydroxide. The Pagay enteric coating dispersion is used to coat capsules "using air at a temperature in the range from 30EC to 60EC" (col. 3, lines 5-6).

There is no indication in Pagay that spray nozzles will clog at temperatures in the range of 30EC to 60EC. In an EXAMPLE (col. 5), coating using air temperatures of 40E-44EC is described (col. 6, line 43).

Porter

Porter also describes aqueous enteric coating dispersions made from film forming polymers, a plasticizer, an auxiliary film-forming polymer, pigment particles and optionally an anti-caking agent (col. 2, lines 42-46). The polymers and plasticizers are different from those described by Pagay. Porter describes the use of an anti-coalescing or stabilizing

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agent which may be ammonium hydroxide (col. 4, lines 5-6).

According to Porter (col. 4, lines 9-21):

The ammonia is not part of the coating powder; it is added after suspending the coating powder in water for about ½ hour, and before the spraying step. The coating suspension may be sprayed without adding the anti-coalescing agent, but there may be clogging problems if the spray equipment becomes too hot. If the anti-coalescing agent is added to the coating suspension, the coating suspension will not begin to coalesce and clog the spray apparatus until the temperature reaches about 60EC., whereas without the anticoalescing agent the coating suspension may start to coalesce and clog the spray apparatus when the temperature reaches about 27E-30EC.

Examiner's rationale

The examiner reasons that it would have been obvious to include ammonium hydroxide in the enteric coatings of Pagay.

According to the examiner (Examiner's Answer, pages 3-4):

While Pagay *** do[es] not mention any clogging problem, it would have been obvious to one of ordinary skill in the art to add an anti-coalescing agent such as ammonium hydroxide as disclosed by Porter *** since the spray temperature [of Pagay] is

above the value which Porter *** teach[es] that clogging at the nozzle may occur.

Discussion

It is true that applicants in their specification do not tell us clearly why ammonium hydroxide is present or desirable in their aqueous enteric coating dispersion. But, the fact is that ammonium hydroxide is present and claim 42 requires the presence of ammonium hydroxide. Thus, if there would have been any reason to add ammonium hydroxide to the Pagay enteric aqueous coating dispersion, we might agree with the examiner's rejection.

On this particular record, our difficulty with the examiner's rationale is that Pagay does not suggest that any clogging problem exists when spraying the Pagay enteric compositions at temperatures at which Porter says an anti-coalescing agent may be needed. Thus, on this record, any spray clogging problem described by Porter may be a function of the polymer and plasticizers used by Porter and not the spray temperature per se. Given that clogging was a known problem as early as the issue date (1985) of Porter, had Pagay encountered a clogging problem surely something would have

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been said about the problem in the Pagay specification. Pagay mentions no clogging problem. Accordingly, on this record, there is no reason or motivation to add ammonium hydroxide to the Pagay aqueous enteric coating dispersion. Compare Smiths Industries Medical Systems, Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356, 51 USPQ2d 1415, 1420-21 (Fed. Cir. 1999) (There is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time of the invention. The relevant inquiry is whether there is a reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the teachings of the references, and that would also suggest a reasonable likelihood of success. Such a suggestion or motivation may come from the references themselves, from knowledge by those skilled in the art that certain references are of special interest in a field, or even from the nature of the problem to be solved).

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For the benefit of the examiner and applicants, we make the following observation. Claim 42 contains the limitation "free of organic solvents, detackifiers, glidants, and

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optional excipients" (emphasis added). On the other hand, the specification describes a coating "free of organic solvents, detackifiers, glidants, and antifoam agents" (emphasis added; page 3, lines 15-16). In fact, the specification seems to state that excipients "may or may not be present" (page 4, line 17). Accordingly, there is a question of whether the invention, as presently claimed, is described in the specification as required by the first paragraph of 35 U.S.C. § 112. The examiner and applicants may wish to look into the matter when prosecution resumes before the examiner.

REVERSED.

	_____)	
	FRED E. MCKELVEY, Senior)	
	Administrative Patent Judge)	
)	
)	
	_____)	
	RICHARD E. SCHAFER)	BOARD OF
PATENT	Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
)	
	_____)	
	JAMESON LEE)	
	Administrative Patent Judge)	

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cc (via First Class mail);

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