THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte FRANK JAO, PATRICK S. L. WONG,
HOA T. HUYNH, KATHY McCHESNEY
and PAMELA K. WAT

Appeal No. 95-2244
Application 08/036,648[1]

ON BRIEF

Before METZ, GARRIS and WALTZ, Administrative Patent Judges.

METZ, Administrative Patent Judge.

DECISION ON APPEAL

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[1] Application for patent filed March 24, 1993. Said Application a continuation of U.S. Application Serial Numbers 07/971,011, filed on November 2, 1992, now U.S. Patent Number 5,252,338, issued on October 12, 1993; said application a continuation of U.S. Serial Number 07/799,451, filed on November 26, 1991, now U.S. Patent Number 5,190,765, issued on March 2, 1993; which is a continuation-in-part of U.S. Application Serial Number 07/722,622, filed on June 27, 1991, now U.S. Patent Number 5,160,744, issued November 3, 1992.

This is an appeal under 35 U.S.C. § 134 from the examiner's refusal to allow claims 19 through 26, all the claims remaining in this application.

THE INVENTION

The appealed subject matter is directed to a "dosage form" for administering drugs which is specially configured for delayed delivery of a drug. The "dosage form" includes (1) a drug composition comprising a dose of a particular type of drug and a polymer having particular viscosity properties which polymer permits or prevents the delayed release of the drug and (2) a drug-delayed delivery composition comprising a polymer of a particular molecular weight which forms part of the wall material of the "dosage form" and aids in delaying the rate of passage of fluid through the wall material. The appealed subject matter also includes a method of delayed delivery of a drug to a patient by giving the patient the above-described "dosage form".

Claim 19 is adequately representative of the appealed subject matter and is reproduced below for a more facile understanding of the appealed subject matter.

Claim 19. A dosage form for the delayed-delivery of

a drug to a fluid environment of use, wherein the dosage form comprises:

(a) a drug composition comprising a dose of 0.05 ng to 1.5 g of a calcium channel blocker drug, and a polymer comprising a molecular weight up to 1,000,000 and a rate of hydration in the presence of fluid that contacts the dosage form to change from a non-dispensable phase to a dispensable phase; and,

> (b) a drug-delayed delivery composition in the dosage form comprising a polymer possessing a 8,500 to 4,000,000 molecular weight that delays the delivery of the drug from the dosage form up to seven hours.

The examiner has not relied on any prior art in rejecting the appealed claims but instead has rejected the claims solely on formal grounds. Specifically, claims 19 through 26 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the claims are not "enabled" by appellants' disclosure. We reverse.

OPINION

It appears to be the examiner's position that appellants may not claim a "dosage form" without reciting that the dosage form includes a body member comprising a wall surrounding an internal structure and having an exit port. The examiner reasons that the claims before us claim only part of the internal structure of what appellants have defined as a "dosage form" in their disclosure. Thus, the examiner urges that the claims are not supported by appellants' disclosure because appellants' disclosure does not disclose that components "(a)" and "(b)", alone, constitute a "dosage form".

The examiner concludes that the claims before us are directed to drug compositions not "dosage forms".

We find that the examiner's position is founded on an unreasonable interpretation of the claims before us. The actual claim language recites that appellants claim "[a] dosage form" which "comprises" components "(a)" and "(b)". Under fundamental rules of claim interpretation, the term "comprises" does not exclude any other features, either disclosed features or features not disclosed or even contemplated. Accordingly, we interpret the claims on appeal to embrace the internal structure of appellants' "dosage form" and, implicitly embrace, the other unrecited features which are necessary to constitute appellants' "dosage form". We remind the examiner that it is the function of the specification, not that of the claims, to set forth the practical limits of operation of an invention. In re Johnson, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977).

It is also incumbent upon the examiner in making a rejection under the first paragraph of 35 U.S.C. § 112, to make out a prima facie case of lack of enablement. In re Strahilevitz, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982); In re Armbruster, 512 F.2d 676, 677, 678, 185 USPQ 152, 153 (CCPA 1975); In re Marzocchi, 439 F.2d 220, 224, 169 USPQ

367, 370 (CCPA 1971). Moreover, in determining whether or not a disclosure is enabling, it has been consistently held that the enablement requirement of

the first paragraph of 35 U.S.C. § 112 requires nothing more than objective enablement. In re Marzocchi, 439 F.2d at 223, 169 USPQ at 369. How such a teaching is set forth, whether by the use of illustrative examples or by broad descriptive terminology, is of no importance since a specification which teaches how to make and use the invention in terms which correspond in scope to the claims must be taken as complying with the first paragraph of 35 U.S.C. § 112 unless there is reason to doubt the objective truth of the statements relied upon therein for enabling support. *Id*.

In the instant case, mere resort to appellants' disclosure cited by the examiner in her Answer establishes that appellants' disclosure satisfies the enablement requirement of 35 U.S.C.
§ 112, first paragraph. Specifically, appellants' disclosure provides: a narrative description of useful materials; amounts of materials to be used; an exhaustive listing of exemplary materials; specific examples of the invention; comparative examples and more. Nothing in this record provides any evidence for why there is any reason to doubt the objective truth of appellants' statements.

Finally, we observe the examiner's comment on page 4 of her Answer wherein she states that she:

> does not doubt that the composition comprises drug and polymer, but remains of the opinion that the dosage form is encompassed by drug and polymer, as defined in independent claims, and said drug and polymer being contained within a wall, compartment etc as disclosed throughout the specification.

We consider this statement to constitute an expression by the examiner of a failure by appellants to claim that which they believe to be their invention under the second paragraph of 35 U.S.C. § 112 rather than an enablement question arising under the first paragraph. Suffice it to say that, absent evidence to the contrary, the subject matter set forth in the claims must be presumed to be "that which the applicant regards as his invention." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). The examiner has not rejected the claims under the second paragraph of 35 U.S.C. § 112 and, in any event, neither has the examiner provided the necessary "evidence to the contrary."

SUMMARY

Accordingly, for all the reasons stated above, the decision of the examiner rejecting claims 16 through 29 as unpatentable under 35 U.S.C. § 112, first paragraph, is REVERSED.

REVERSED

ANDREW H. METZ Administrative Patent Judge	)	
BRADLEY R. GARRIS Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
THOMAS A. WALTZ Administrative Patent Judge	)	

AHM/dal

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