

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MASSIMO CALANCHI, MARCO ZEMA, GABRIELE BRUNETTI and
ENZO GIORGETTI

Appeal No. 95-4962
Application No. 07/972,660¹

ON BRIEF

Before RONALD H. SMITH, JOHN D. SMITH and PAK, Administrative Patent Judges.

PAK, Administrative Patent Judge.

DECISION ON APPEAL

Calanchi et al. (appellants) appeal from the examiner's final rejection of claims 1 through 3 and 7 through 11, which are all of the claims pending in the application.

¹ Application for patent filed November 6, 1992. According to the appellants, the application is a continuation of Application No. 07/644,062, filed January 22, 1991, now abandoned.

Claim 1 is representative of the subject matter on appeal and reads as follows:

1. A targeted drug release formulation for delivery of drugs to the intestinal tract of the ileum and colon of a mammal consisting essentially of a plurality of multidose minitabulet units each said unit having a particle size of less than about

5 mm and consisting essentially of a minitabulet core containing a drug selected from the group consisting of penicillin G, calcitonin, heparin, ferritin, sucralfate, mebeverine hydrochlorate, acarbase dimethycone, simethicone and immunoglobulin surrounded by two membranes consisting essentially of a pH dependent polymer which is soluble at a pH greater than about 5.5 and the second of said membranes consisting essentially of one or more polymers such that said second membrane is substantially insoluble in but permeable to gastric fluids, and wherein

- a) said formulation is characterized with a dissolution rate in a simulated gastric environment such that over a period of 8 hours substantially all of the drug is released, and the release is further characterized by the release of no more than about 10% drug after 3 hours and no more than about 75% drug after 6 hours;
- b) said pH dependent polymer is selected from the group consisting of anionic copolymers based on methacrylic acid and methacrylic acid methyl ester, cellulose acetate phthalate, hydroxypropylmethylcellulose phthalate, polyvinyl acetate phthalate, shellac, hydroxypropylmethylcellulose acetate succinate, carboxymethylcellulose, cellulose acetate trimellitate, copolymers of maleic acid and derivatives of phthalic acid; and
- c) said substantially insoluble membrane is selected from the group consisting of copolymers

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formed from acrylic and methacrylic acid esters with a low content of quaternary ammonium groups, neutral copolymers based on ethyl acrylate and methyl methacrylate and having an average molecular weight of 800,000, ethylcellulose, polyethylene, polysiloxanes and mixtures thereof.

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The references relied on by the examiner are:

Ikegami et al. (Ikegami) 06, 1985	4,533,562	Aug.
Mehta 1989	4,800,087	Jan. 24,

Remington's Pharmaceutical Sciences, Mack Publishing, (1990)
pp. 1306-1307 (hereinafter referred to as "Remington").

The references relied on by appellants are:

Zeitoun et al. (Zeitoun) 21, 1984	4,432,966	Feb.
Edgreen et al. (Edgreen) 05, 1985	4,503,030	Mar.

The reference of record relied on by the Board is:

Eichel et al. (Eichel) (Published European Patent Application)	0239,361	Sep. 30, 1987
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The appealed claims stand rejected as follows:

(1) Claims 1 through 3 and 7 through 10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention;

(2) Claims 1 through 3 and 7 through 10 under 35 U.S.C. § 103 as unpatentable over Mehta in view of Remington; and

(3) Claims 1 through 3 and 7 through 10 under 35 U.S.C. § 103 as unpatentable over Ikegami in view of Remington.

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OPINION

We have carefully reviewed the entire record before us, including all of the arguments advanced by the examiner and appellants in support of their respective positions. This review leads us to conclude that the examiner's rejections are not well-founded. Accordingly, we will not sustain any of the foregoing rejections. Our reasons for this determination follow.

35 U.S.C. § 112, SECOND PARAGRAPH

The examiner has rejected appealed claims 1 through 3 and 7 through 10 under 35 U.S.C. § 112, second paragraph. In this regard, the examiner alleges that "[t]he term 'derivatives' appearing in 'derivatives of phthalic acid'. . . leads to speculation what particular compounds are being claimed." Although the term in question appears to be broad, we note that the broadness of claim language should not be equated with indefiniteness within the meaning of § 112. See In re Johnson, 558 F.2d 1008, 1016 n.17, 194 USPQ 187, 194 n.17 (CCPA 1977);

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In re Miller, 441 F.2d 689, 693, 169 USPQ 597, 600 (CCPA 1971); In re Gardner, 427 F.2d 786, 788, 166 USPQ 138, 140 (CCPA 1970); Ex parte Scherberich, 201 USPQ 397, 398 (Bd. App. 1977). Also, we find that the examiner's allegation is conclusory and is not sufficient to establish a prima facie case of unpatentability under § 112, second paragraph. Moreover, the examiner has not rebutted appellants' position set forth at pages 6 through 8 of the Brief, which refers to prior patents to establish that the term "derivatives" is well accepted in the art. Accordingly, we reverse the examiner's decision rejecting claims 1 through 3 and 7 through 10 under 35 U.S.C. § 112, second paragraph.

35 U.S.C. § 103

The examiner has also rejected appealed claims 1 through 3 and 7 through 11 under 35 U.S.C. 103 in view of either Mehta or Ikegami taken together with Remington. We cannot sustain these rejections for essentially those reasons set forth at pages 8 through 14 of the Brief. We only add that the prior art references relied on by the examiner also do not teach,

nor would have suggested, the claimed two membranes capable of releasing a drug in the claimed rate.

NEW REJECTION UNDER § 1.196(b)

Under the provisions of 37 CFR § 1.196(b), the following new ground of rejection is entered against claims 1, 3, 7 and 9 through 11.

Claims 1, 3, 7 and 9 through 11 are rejected under 35 U.S.C. § 103 as unpatentable over the disclosure of the Eichel reference.

The Eichel reference describes a "sustained-release pharmaceutical preparation comprising an admixture of uncoated and/or single walled water soluble drug, such as aspirin, and **dual walled coated drug** (emphasis supplied)." See abstract. The dual wall structure has an inner wall microencapsular control coating and an outer wall enteric coating. Id.; see also page 3, lines 15-18. "The inner wall microencapsular control coating is preferably selected from the group consisting of ethyl cellulose, hydroxy propyl cellulose and carboxy methyl cellulose." See page 3, lines 27-28. The preferred outer wall enteric coating is cellulose acetate phthalate which dissolves at pH 7.5 as found in the intestine. See page 3, lines 31-34. "Other enteric coatings may be used as long as they do not readily dissolve or disperse in the

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gastric juices of the stomach but do dissolve or disperse in the intestinal fluid of the intestines." See Page 3, lines 34-36. The other enteric coatings include hydroxy propyl cellulose phthalate, polyvinyl acetate phthalate, hydroxyethyl ethyl cellulose phthalate, cellulose acetate tetrahydrophthalate, shellac "or other film-forming materials which dissolve or disperse in the intestine but remain intact in the stomach are possible alternatives. See page 3, lines 36-39 and page 4, lines 48-51. "The dual walled coated drug has a delayed, gradual, long-term release which takes place in the intestines. . . ." See abstract. The core drug employed includes vitamins, minerals, antibiotics and other analgesics. See page 3, lines 42-43. Any drug can be used so long as it is reasonably water soluble. See page 3, line 40. It can be inferred from the teaching of a microcapsule having a core drug that the particle size of the core drug is less than about 5 mm as required by the claims. See, e.g., page 6, line 64. Although the Eichel reference does not specifically mention the claimed property which is defined in terms of dissolution rates, we find that the Eichel reference provides the dissolution studies of a dual coated aspirin set forth in

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Tables I and II at pages 5 and 6. These studies indicate that the dissolution rate is dependent on the amount of polymers employed. See also the paragraph bridging pages 4 and 5. Moreover, the desired sustained-release rate of a drug is dependent on the desired concentration of a drug in a blood stream, thus avoiding the risk of toxicity associated with a higher concentration of the drug therein. See page 3, lines 60-65 and page 4, lines 1-9. Accordingly, we conclude that optimizing the amount of the polymers employed to obtain desired dissolution rates presumably as claimed would have been obvious to one of ordinary skill in the art. See In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990); In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) (optimizing a known result-effective variable is well within the ambit of one of ordinary skill in the art). One of ordinary skill in the art would have had a reasonable expectation of avoiding the risk of toxicity associated with a high concentration of a drug in the blood stream via controlling the rate of its dissolution.

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This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63,122 (Oct. 21, 1997)). 37 CFR § 1.196(b)) provides that "[a] new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the applicant will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED; 37 CFR § 1.196(b)

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RONALD H. SMITH)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
JOHN D. SMITH)	APPEALS AND
Administrative Patent Judge)	INTERFERENCES
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CHUNG K. PAK)	
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JENINE GILLIS

Appeal No. 95-4962
Serial No.

07/972,660

Judge PAK

Judge RON H. SMITH

Judge JOHN D. SMITH

Typed: 31 Jul 98
Revised: 12 Aug 98

DECISION: REVERSED; 37 CFR §

1.196b

Send Reference(s): Yes No
or Translation(s)

Panel Change: Yes No

3-Person Conf. Yes No

Heard: Yes No

Remanded: Yes No

Index Sheet-2901 Rejection(s): _____

Acts 2: _____

Palm: _____

Mailed: Updated Monthly Disk: _____

Updated Monthly Report: _____