

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(2) is not binding precedent of the Board.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 ROBERT E. KLOSE

Appeal No. 95-2441
Application 07/987,211¹

ON BRIEF

Before WINTERS, Administrative Patent Judge; McKELVEY, Senior Administrative Patent Judge; and GRON, Administrative Patent Judge.

GRON, Administrative Patent Judge.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

¹ Application for patent filed December 8, 1992. According to applicant, this application is a continuation of Application 07/706,859, filed May 29, 1991, now U.S. Patent 5,190,775, patented March 2, 1993.

Appeal No. 95-2441
Application 07/987,211

This is an appeal under 35 U.S.C. § 134 from an examiner's rejections of Claims 1-13 and 26-29, all claims pending in this application.

Introduction

Claims 1, 6-13 and 27-29 stand rejected under 35 U.S.C. § 102 as anticipated by, or under 35 U.S.C. § 103 as unpatentable in view of, the teaching of Ghebre-Sellassie, U.S. Patent 4,971,804, patented November 20, 1990. Claims 1-13 and 26-29 stand rejected under 35 U.S.C. § 103 as being unpatentable in view of the combined teachings of Sibbald et al. (Sibbald), U.S. Patent 3,541,204, patented November 17, 1970; Iijima et al. (Iijima), U.S. Patent 4,948,589, patented August 14, 1990; UK Patent Specification 765,885, published January 16, 1957; and Hawley, The Condensed Chemical Dictionary, Tenth Edition, Van Nostrand Reinhold Co., New York, NY, pp. 246, 450, 546, 929, 930, 961, 968, 986, and 1095 (1981). Claims 1 and 26 are representative of the claimed inventions and read:

1. A composition of matter comprising particles suitable for introduction of a bioactive substance to the post-rumen portion of the digestive system of a ruminant substantially without introducing said substance to the rumen portion of the digestive system, said particles having

Appeal No. 95-2441
Application 07/987,211

a specific gravity between about 0.3 and 2.0 and comprising:

- (a) a core comprising bioactive substance;
- (b) a hydrophobic coating encapsulating said core in a quantity sufficient to essentially preclude introduction of bioactive substance into the rumen; and
- (c) a surfactant applied to the surface of the hydrophobic coating in a quantity sufficient to ensure that said particles do not float on the rumen.

26. A composition of matter comprising particles suitable for introduction of choline chloride to the post-rumen portion of the digestive system of a ruminant substantially without introducing choline chloride to the rumen portion of the digestive system, said particles having a specific gravity between about 0.3 and 2.0 and comprising:

- (a) a core comprising approximately 70 percent by weight choline chloride on a cereal carrier; and
- (b) a hydrophobic coating encapsulating said core in a quantity sufficient to essentially preclude introduction of choline chloride into the rumen

Discussion

1. Rejections over Ghebre-Sellassie

Ghebre-Sellassie (G-S) describes (G-S, col. 1, l. 59-68):

. . . a water-dispersible formulation of gemfibrozil
. . . in which finely divided particles of pure
gemfibrozil
are uniformly coated with a mixture of a wax and at least

Appeal No. 95-2441
Application 07/987,211

one hydrophilic material and the coated particles in turn are overcoated with a minor amount of a surfactant, optionally together with flavoring agents.

At first glance, the compositions appellant claims and G-S describes reasonably appear to be the same. Appellant and G-S both overcoat a bioactive core substance encapsulated by a hydrophobic material with a surfactant. The examiner supports his finding that G-S anticipates the subject matter appellant claims by concluding that the functional language, "suitable for introduction of the bioactive substance to the post-rumen portion of the digestive system of a ruminant substantially without introducing said substance to the rumen portion of the digestive system," in appellant's claims, does not limit the bioactive substance of the claimed composition to one which is useful exclusively in ruminants (Ans., p. 6). According to the examiner, G-S describes the composition of encapsulated bioactive substance that appellant claims regardless of its intended use for treating humans and appellant's intended use for treating ruminants (Examiner's Answer (ANS.), p. 6). The evidence of record does not enable us to find, as the examiner apparently did, that persons having ordinary skill in the art would

Appeal No. 95-2441
Application 07/987,211

have considered gemfibrozil, a material widely used as an antihyperlipoproteinemic agent in treating humans (G-S, col. 1, l. 9-11), useful for treating the same or a similar malady in ruminants. Moreover, we conclude that the bioactive substances employed in appellant's "particles suitable for introduction of a bioactive substance to the post-rumen portion of the digestive system of a ruminant" (Claim 1) are limited to bioactive substances having recognized utility for use in ruminants.

"Whether a preamble of intended purpose constitutes a limitation to the claims is . . . determined on the facts in each case in view of the claimed invention as a whole." In re Stencel, 828 F.2d 751, 754-55, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987). Here, the "language is essential to particularly point out the invention defined by the claims." Compare In re Bulloch, 604 F.2d 1362, 1365, 203 USPQ 171, 174 (CCPA 1979).

Accordingly, we are obliged to reverse the examiner's finding that the subject matter appellant claims is anticipated by the water dispersible gemfibrozil compositions described by G-S. Furthermore, we reverse the examiner's holding that G-S's teaching of water dispersible gemfibrozil compositions for use

Appeal No. 95-2441
Application 07/987,211

in treating hyperlipoproteinemia in humans reasonably would have suggested the use of the same type of delivery system for treating or feeding ruminants gemfibrozil or bioactive substances recognized in the art for use in treating or feeding ruminants to persons having ordinary skill in the art. We find that G-S encapsulates gemfibrozil with a hydrophobic coating in order to avoid the particularly unpleasant after-taste humans associate with gemfibrozil (G-S, col. 2, l. 17-21). The examiner has not explained why persons having ordinary skill in the art would have been led by G-S's teaching to employ the same or a similar means to deliver bioactive feed supplements or any other treating agent to ruminants. The examiner's rejection appears to be based on impermissible hindsight.

2. Rejection in view of Sibbald, Iijima, UK, and Hawley

We find, as did the examiner (Ans., p. 4, first full para.), that Sibbald describes compositions comprising bioactive material totally encapsulated with a hydrophobic coating. The compositions are expressly designed to transport the bioactive material through the rumen of a ruminant. The

Appeal No. 95-2441
Application 07/987,211

examiner finds that Iijima similarly describes encapsulating choline chloride with a hydrophobic binder to transport the bioactive substance through the rumen (Ans., p. 4, second full para.). The examiner points (Id.) to Sibbald's express teaching that (Sibbald, col. 3, l. 55, to col. 4, l. 7):

[t]he density of the capsules must be sufficient to ensure that they do not remain floating on the surface of the rumen contents for an undue period of time and, at the same time the density must not be so great that the capsules fall to the floor of the rumen and remain there indefinitely. The capsules generally have a density of about 0.8-2.0 and preferably about 1.0-1.4. The capsule can be conveniently regulated by varying the ingredients forming the core of the capsule, e.g., by the addition of a high density weighting agent such as kaolin, chromium sesquioxide or barium sulfate.

On the basis of the combined teachings of Sibbald and Iijima, the examiner found that persons having ordinary skill in the art would have been led to employ conventional techniques to better disperse choline chloride encapsulated particles in the contents of the rumen for more efficient passage therethrough. Thus, the examiner reasoned that persons having ordinary skill in the art would have been led by the combined teachings of Sibbald and Iijima, further combined with UK's teaching to apply surfactants to pulverant substances to improve their dispersion in water and Hawley's teaching that use of surface-

Appeal No. 95-2441
Application 07/987,211

active agents to reduce the surface tension of water is well-known, to apply surfactants to the particles described in Sibbald and Iijima to improve their dispersion in the contents of the rumen and passage through the rumen. Here also, the examiner has rejected the claimed subject matter based on the impermissible hindsight of appellant's own disclosure.

On this record, the only teaching or reasonable suggestion that encapsulated bioactive substance, which is maintained at Sibbald's instruction at a density of 0.8 to 2.0, still floats on the surface of the contents in the rumen, is not adequately dispersed in the contents of the rumen, and is not efficiently transported through the rumen "substantially without introducing said substance to the rumen portion of the digestive system" (Claim 1), appears in appellant's specification. While we agree with the examiner that persons having ordinary skill in the art, recognizing that Sibbald's controlled density capsules still float in the rumen, reasonably would have been led to better disperse the capsules in the contents of the rumen using art-recognized surface-active agents, we find in this record no prior art recognition

Appeal No. 95-2441
Application 07/987,211

of a continuing dispersion problem. As said in Diversitech Corp. v. Century Steps Inc., 850 F.2d 675, 679,

7 USPQ2d 1315, 1318 (Fed. Cir. 1988):

The problem confronted by the inventor must be considered in determining whether it would have been obvious to combine references in order to solve that problem.

While the incentive to apply a surfactant to Sibbald's and/or Iijima's particles need not be the same as appellant's incentive to do so, the prior art must provide some reason for persons having ordinary skill in the art to do what appellant has done. Where, as here, the prior art teaches that the particle floating and/or settling problems associated with encapsulated bioactive substances presented to the rumen are substantially eliminated by controlling particle density, we see no reason why that teaching would have led persons having ordinary skill in the art to further improve dispersibility. A person having ordinary skill in the art "is not one who undertakes to innovate, whether by . . . systematic research or by extraordinary insights . . ." Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 454, 227 USPQ 293, 298 (Fed. Cir. 1985).

Appeal No. 95-2441
Application 07/987,211

The examiner has the initial burden to establish a *prima facie* case of unpatentability under 35 U.S.C. § 103. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). The case for unpatentability of the invention of Claim 26 under section 103 has not been adequately explained by the examiner. Faced with his initial burden, the examiner merely states

(Ans., pp. 7-8):

The applicant then argues that none of the cited documents disclose the use of 70% choline chloride on a cereal carrier as specified in Claim 26. While Iijima et al. does not incorporate cereals into their composition they acknowledge the fact that cholines are adsorbed on powdered carriers such as corn cob meal but are not used in ruminants since they would "decompose in the rumen" (col. 1, lines 25 to 33.) It would have been obvious to one of ordinary skill in the art to coat a choline chloride/ cereal composition with a hydrophobic coating since the subject of the patent is coating compositions to protect them from decomposing in the rumen.

The above statement is the totality of the examiner's effort to support the rejection. We are at a loss to understand why the prior art reasonably would have suggested the invention of Claim 26 in view of Iijima's teaching. Iijima teaches that liquid choline or liquid choline absorbed on 50% corn cob meal eliminates problems associated with deliquescent crystalline

Appeal No. 95-2441
Application 07/987,211

choline for use as a feed additive. However, those products were not useful in the feed of ruminants, because they decomposed in the rumen. To solve the aforementioned problems and use choline as a feed additive, Iijima teaches persons skilled in the art to coat choline or one of its derivatives with a hydrophobic binder to prevent solubilization or decomposition by the rumen solution (Iijima, col. 5, l. 50-53). The amount of choline in the granular choline composition prior to being coated with the hydrophobic binder preferably is 40 to 70% by weight, more preferably 40 to 55% by weight (Iijima, col. 2, l. 47-50). Even assuming persons having ordinary skill in the art would have been led by Iijima's teaching to coat choline chloride on a cereal carrier with a hydrophobic binder, an assumption inconsistent with Sibbald's recommendation of a density of 0.8 to 2.0, persons having ordinary skill in the art would have had to stretch Iijima's teaching to find a reasonable suggestion to prepare a "core comprising approximately 70% by weight of choline chloride on a cereal" (Claim 26). Moreover, to stretch Iijima's teaching to include about 70% choline chloride on a cereal carrier appears to be inconsistent with Iijima's preferences and would appear to serve no purpose whatsoever.

Appeal No. 95-2441
Application 07/987,211

We again find that the examiner's rejection is based in the hindsight of appellant's disclosure. No *prima facie* case of unpatentability of Claims 1-13 and 26-29 under 35 U.S.C. § 103 in view of the combined prior art teachings having been established in this case, we reverse the examiner's rejections.

3. New Ground of Rejection Under 37 CFR § 1.196(b)

We attach hereto a copy of Klose, U.S. Patent 5,190,775, patented March 2, 1993, which issued from parent Application 07/706,859, filed May 29, 1991. Claims 1-12 of the patent are drawn to methods of using the compositions of presently appealed Claims 1-13 and 26-29. Both the patented methods for administering the presently claimed compositions and the presently claimed compositions themselves are explicitly stated in the claims for use in administering or introducing "a bioactive substance to the post-rumen portion of the digestive system of a ruminant substantially without introducing the substance to the rumen portion of the digestive system" (Klose, patented Claim 1; Claim 1 of this appeal). Were we to allow the presently claimed compositions to issue without requiring a terminal disclaimer of applicant's patent rights thereto which would extend beyond

Appeal No. 95-2441
Application 07/987,211

the term of his patent, applicant would be entitled to exclude others from using the claimed compositions in the manner indicated in Klose's patented method claims far beyond the term of the earlier patent.

Of course, all we have said presumes that the compositions and the methods of using the compositions are patentably indistinct inventions and that the examiner has not required restriction between the compositions and methods of using the compositions. We hold that the applicant's presently appealed composition claims and the patented claims drawn to methods of using the same composition are patentably indistinct. In support thereof, we note that claims drawn both to methods of using the compositions here claimed and the compositions themselves were initially presented together for examination in the patented application. See In re Berg, 140 F.3d 1428, 1431-1437, 46 USPQ2d 1226, 1228-1233 (Fed. Cir. 1998).

We have searched the patented file for evidence that the examiner required restriction between the presently appealed composition claims and the patented claims drawn to methods of using the compositions here claimed. We found none. Accordingly, under 37 CFR § 1.196(b), we hereby newly reject

Appeal No. 95-2441
Application 07/987,211

Claims 1-13 and 26-29 for obviousness-type double patenting of
Claims 1-12 of Klose, U.S. 5,190,775, patented March 2, 1993.

Conclusion

We reverse the examiner's rejections of Claims 1, 6-13
and 27-29 under 35 U.S.C. § 102 as anticipated by, or under 35
U.S.C. § 103 as unpatentable in view of, the teaching of
Ghebre-Sellassie.

We reverse the examiner's rejection of Claims 1-13 and
26-29 under 35 U.S.C. § 103 as being unpatentable in view of
the combined teachings of Sibbald, Iijima, UK Patent
Specification 765,885, and Hawley.

Under 37 CFR § 1.196(b), we hereby newly reject Claims 1-
13 and 26-29 for obviousness-type double patenting of Claims
1-12 of Klose, U.S. 5,190,775, patented March 2, 1993.

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."

Appeal No. 95-2441
Application 07/987,211

37 CFR § 1.196(b) also provides that the appellant,
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
(§ 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 application 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. . . .

Appeal No. 95-2441
Application 07/987,211

REVERSED; 37 CFR § 1.196(b)

SHERMAN D. WINTERS)
Administrative Patent Judge)

FRED E. MCKELVEY)
Senior Administrative Patent Judge)

AND

TEDDY S. GRON)
Administrative Patent Judge)

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Appeal No. 95-2441
Application 07/987,211

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