

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte YECHEZKEL BARENHOLZ
and ELISHALOM YECHIEL

Appeal No. 1997-1913
Application 08/238,149¹

ON BRIEF

¹ According to appellants, this application is a continuation of 07/986,664, filed January 22, 1993, now abandoned; which is a continuation of 07/714,069, filed July 10, 1991, now abandoned; which is a continuation of 07/323,516, filed March 14, 1989, now abandoned; which is a continuation of 06/832,929, filed February 24, 1986, now U.S. Patent 4,812,314.

Before WINTERS, WILLIAM F. SMITH, and SCHEINER, Administrative Patent Judges.
SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. ? 134 from the final rejection of claims 23 through 25, all of the claims remaining in the application. Appellants state at page 3 of the Brief of February 22, 1996, that the claims are divided into two groups, the first consisting of claims 23 and 25, and the second consisting of claim 24, and provide arguments as to separate patentability. Claims 23 and 24 are representative of the two groups, and read as follows:

23. A method of reversing age-related changes in heart muscle cells in a subject, comprising
intravenously administering to the subject, in a therapeutically effective amount, liposomes having a lipid component comprising phosphatidylcholine having an acyl chain composition which is characteristic, at least with respect to transition temperature, of the acyl chain components of phosphatidylcholines in the heart cells of the subject at a younger age, said liposomes being substantially free of sphingomyelin, and
repeating said administering over a period of at least several days until a significant drop in the subject's serum creatinine phosphokinase is observed.

24. The method of claim 23, wherein the phosphatidylcholine is egg phosphatidylcholine.

The references relied on by the examiner are:

Williams et al. (Williams), ?Intravenously Administered Lecithin Liposomes: A Synthetic Antiatherogenic Lipid Particle,? Perspectives in Biology and Medicine, Vol. 27, No. 3, pp. 417-31 (1984)

UK Pat. App. (Taylor)

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Jan. 30, 1982

In reaching our decision on this appeal we have given careful consideration to appellants' specification and claims, and to the respective positions articulated by appellants and by the examiner. We refer to the Examiner's Answer (Paper No. 23, mailed April 24, 1996) for the examiner's reasoning in support of the rejection. For appellants' arguments, we refer to the Brief (Paper No. 21, filed February 22, 1996) and the Reply Brief (Paper No. 24, filed June 27, 1996). We note that in Paper No. 25, mailed July 17, 1996, the examiner acknowledged the Reply Brief and indicated that it had been entered.

Claims 23-25 stand rejected under 35 U.S.C. ? 103(a). As evidence of obviousness, the examiner relies upon Williams in combination with Taylor. We reverse.

BACKGROUND

Claim 23, the sole independent claim on appeal, is drawn to a method of reversing age-related changes in heart muscle cells in a subject. According to page 8, lines 17-19, of the specification, these changes include a decrease in phosphatidylcholine (PC) levels and a concomitant increase in sphingomyelin (SM) and cholesterol levels. The method is carried out by intravenous administration of a therapeutically effective amount of a liposome which comprises PC, and which is substantially free of sphingomyelin. Appellants state at page 8, lines 19-22, that the liposomes "are designed to promote exchange of PC from liposomes to heart cell membrane, and exchange of SM from the heart muscle to the liposomes." The PC employed has "an acyl chain composition which is characteristic, at least with respect to transition temperature, of the acyl chain

components of PC in the heart cells of the subject at a younger age." The specification states at page 9, lines 13-17, that the acyl chain length and the degree of acyl chain saturation increase with age. The administration is repeated "over a period of at least several days" until there is a significant drop in the serum creatinine phosphokinase level of the subject. Guidance as to the dosage and timing of the administration is provided in the specification at pages 13-14 and 19-20.

DISCUSSION

Claims 23-25 stand rejected under 35 U.S.C. ? 103(a) over Williams in combination with Taylor. The examiner bears the initial burden of establishing a prima facie case of obviousness under 35 U.S.C. ? 103. In re Warner, 154 USPQ 173, 177 (CCPA 1967). In so doing, he or she must consider every limitation of the claimed invention. See In re Royka, 490 F.2d 981, 180 USPQ 580, 582-83 (CCPA 1974); In re Wilson, 165 USPQ 494, 496 (CCPA 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art").

Claim 23 requires that the PC employed have "an acyl chain composition which is characteristic, at least with respect to transition temperature, of the acyl chain components of PC in the heart cells of the subject at a younger age." According to the specification (see page 9, lines 13-17), both the acyl chain length and the degree of acyl chain saturation increase with age. Thus, we agree with appellants that the requirements of claim 23 are

not satisfied by intravenous administration of any arbitrary PC.² Rather, for any given subject, claim 23 requires intravenous administration of a PC having an objectively determined transition temperature (a function of the acyl chain composition). The specification indicates that one such PC can be egg PC.

Williams teaches that intravenous administration of PC (lecithin) results in regression of atherosclerosis, and attributes this to the ability of intravenously injected lecithin to form circulating liposomes which "take up cholesterol from many sources, including the arterial wall." Page 417, second paragraph. Intravenous administration of preformed lecithin liposomes has a similar effect. Page 422. According to Williams, "lecithin liposomes appear ideally suited as injectable, antiatherogenic lipid particles." Page 426. The examiner acknowledges that Williams "may not specify the lecithin or PC used is pure or purified egg (yolk) lecithin." Examiner's Answer, page 3. Appellants agree

² Natural PC, or lecithin, "comprises a mixture of the diglycerides of fatty acids (e.g., stearic, palmitic, myristic, linoleic, and oleic acids) linked to the choline ester of phosphoric acid and is found in all living plants and animals." Taylor at page 2.

and emphasize that Williams' disclosure of PC (lecithin) liposomes is generic, and not all lecithin liposomes would meet the requirements of claim 23. Reply Brief, page 2.

The examiner relies on Taylor to address this deficiency in Williams. Taylor discloses colloidal suspensions of liposomes formed from egg yolk lecithin (page 2, lines 30-31, and page 4, lines 39-40). According to the examiner, "it would have been obvious to one skilled in the art to use pure or purified egg (yolk) lecithin as the lecithin in the method of [Williams] because Taylor [] discloses it as commercially available and also suitable for administration to human or lower animals." Examiner's Answer, page 4.

Appellants point out, however, that Taylor's egg yolk lecithin is distearoyl lecithin, a synthetic molecule manufactured commercially by hydrogenating egg yolk lecithin (see page 2, lines 30-31), but the egg PC of the invention "is predominantly 1-palmitoyl, 2-oleyl PC and 1-palmitoyl, 2-linoleyl PC" (Reply Brief, page 2; and page 9, lines 21-24, of the specification). According to the specification at page 9, lines 13-17, hydrogenation (saturation) is a characteristic of PC in aging subjects. The examiner acknowledged and entered the Reply Brief, but did not respond to this or any other point raised therein. Thus, it appears that the examiner failed to fully appreciate or address all the requirements of claim 23. In our view, and in the absence of a fact-based analysis to the contrary, administration of hydrogenated egg PC does not satisfy those requirements.

35 U.S.C. § 103 requires that obviousness be determined based on the claimed subject matter as a whole. Where, as here, the determination of obviousness is based on

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less than the entire claimed subject matter, the examiner's conclusion is legally unsound and cannot stand. On this record, we reverse the examiner's rejection of the claims under 35 U.S.C. ? 103.³

The decision of the examiner is reversed.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
William F. Smith)	
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
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Toni R. Scheiner)	
Administrative Patent Judge)	

³ Because we conclude that the examiner failed to make out a prima facie case of obviousness as to claim 23, the sole independent claim, we need not specifically address the remaining arguments raised in appellants' Brief and Reply Brief as to separate patentability of claim 24.

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