

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MILTON G. MUTCHNICK

Appeal No. 1999-1236
Application 07/571,782¹

ON BRIEF

Before WILLIAM F. SMITH, LORIN and SPIEGEL, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1, 3 through 5 and 9 through 18, all the claims pending in the application.²

¹ Application for patent filed August 24, 1990.

² Notwithstanding entry authorization by the examiner annotated on the amendment filed January 8, 1997 (Paper No. 19), claim 8 has not been cancelled per appellant's request. This clerical oversight should be corrected upon return of the above identified application to the jurisdiction of the examiner.

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

1. A method for the treatment of a viral hepatitis patient having hepatic decompensation which comprises:

administering by injection subcutaneously an effective dosage of a thymosin selected from the group consisting of thymosin alpha₁ and a bovine calf extract containing thymosin alpha₁ in an effective amount so as to render said patient seronegative for the hepatitis viral DNA.

The references relied upon by the examiner are:

Eichberg et al. (Eichberg), "Effect of Thymosin Immunostimulation With and Without Corticosteroid Immunosuppression of Chimpanzee Hepatitis B Carriers," Journal of Medical Virology, Vol. 21, No. 1 (1987), pp. 25-37.

Mutchnick et al. (Mutchnick), "Thymosin Treatment of Chronic Active Hepatitis B (CAHB): A Preliminary Report on a Controlled Double Blind Study," Hepatology, Vol. 8, No. 5, (Sept/Oct 1988), p. 1270 (Abstract).

Additional references of record discussed by this merits panel are:

Waked et al. (Waked), "Experience With Interferon in Chronic Hepatitis B in Egypt," Journal of Chemotherapy, Vol. 2, No. 5, (1990), pp. 310-18.

Nevens et al. (Nevens), "Treatment of Decompensated Viral Hepatitis B-Induced Cirrhosis With Low Doses of Interferon Alpha," Liver, Vol. 13, (1993), pp. 15-19.

Dimopoulou et al. (Dimopoulou), "Interferon Alfa-2b for Decompensated Liver Disease Caused by Either Chronic Hepatitis B or C: Preliminary Results of a Pilot Study," Gut, Vol. 34 (Supplement), (1993), pp. S104-S105.

Claims 1, 3 through 5 and 9 through 18 stand rejected under 35 U.S.C. § 112, first paragraph (written description). Claims 1, 3 through 5 and 9 through 18 stand

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rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Mutchnick and Eichberg.

We vacate the examiner's rejections and institute a new ground of rejection.

DISCUSSION

"The name of the game is the claim." In re Hiniker Co., 150 F.3d 1367, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998). In deciding patentability issues under 35 U.S.C. § 103, the court observed in Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1567-68, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987), "Analysis begins with a key legal question--what is the invention claimed?" since "[c]laim interpretation...will normally control the remainder of the decisional process."

Here, both rejections revolve around the use of the phrase "hepatic decompensation" in the claims. The examiner believes that the phrase, added by amendment, does not enjoy written descriptive support in the original disclosure of this application. Appellant disagrees and urges that this phrase distinguishes the claimed invention from the prior art.

Our review of the record leads us to conclude that the real issue in this appeal is the scope and meaning of the phrase "hepatic decompensation," which in our view, cannot be readily ascertained. Until the scope of this phrase can be readily ascertained, it is

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premature to consider whether the phrase is described by the original disclosure and/or serves to distinguish the claims from the prior art. Accordingly, we vacate the examiner's rejections and institute a new ground of rejection under the provisions of 37 CFR § 1.196(b). In so doing, we take no position on the merits of these rejections. If claims in compliance with 35 U.S.C. § 112, second paragraph, are presented, both appellant and examiner should revisit these issues in light of the newly amended claims.

New Ground of Rejection under 37 CFR § 1.196(b)

Claims 1, 3 through 5 and 9 through 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

According to In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989), "An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process." In addition, "the definiteness of the language employed must be analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971).

In the instant claims, the phrase “hepatic decompensation” is indefinite since the scope of this phrase cannot be readily ascertained. It appears that liver disease can be broadly classified as being “compensated” or “decompensated.” The problem is on what basis an individual patient is placed in the compensated or decompensated category. From a review of the teachings in the prior art and appellant’s own specification, it appears that the criteria used to determine placement of a given patient into the category of having compensated or decompensated liver disease varies from one research study to the next. In other words, a patient which would be considered “compensated” by one group could be considered “decompensated” by another group.

For example, Nevens (made of record in Paper No. 15) describes a study involving the treatment of decompensated viral hepatitis B-induced cirrhosis with low doses of interferon alpha. All patients included in the study had decompensated liver cirrhosis. The criteria used to qualify the presence of hepatic decompensation in the patients is described in the first column on page 16 and in Table 1 on page 16 of Nevens as follows:

* Hypersplenism is defined as platelet count $< 100 \times 10^9$ per litre

	1	5	6	4	2	8	7
HBV-DNA (bd/ml)	30	103	1883	141	521	544	318
HBsAg	+	+	+	+	+	+	+
Albumin (> 3.8 g/dl)	5.82	3.80	3.31	3.3	5.82	5.82	3.85
BT (≤ 1 ml)	42	48	30	44	58	42	45
Bilirubin (< 1 mg/dl)	1.4	1.8	1.8	1.8	5.5	5.1	1.2
ALT (< 54 U/l)	31	128	131	521	23	25	80
Albumin/platelet ratio (≥ 1.5 in 50% of cases)	nd	nd	1.31	2.1	88.0	100	101
Encephalopathy					+		+
Spontaneous bacterial peritonitis	large	small	large	small	small	small	spontaneous
Hypersplenism, or splenomegaly	+	+	+	+			+
Spontaneous bacterial peritonitis	+						
Ascites	+	+	+	+		+	+
Age (years)	38	58	18	28	88	88	88
Sex	M	M	M	F	M	M	M
Patient no.	1	5	6	4	2	8	7

Table 1. Characteristic features of the patients before treatment

From Table 1 in Nevens, it can be seen that all patients 1 through 7 are classified as “decompensated.” However, not all of patients 1 through 7 have all of the symptoms or criteria used in that study to define “decompensated.” For example, patient number 5 lacks the presence of ascites, only patient number 1 has spontaneous bacterial peritonitis, patients 5 and 6 lack hypersplenism or splenomegaly, and patients 1-4 and 6 lack encephalopathy. From this information, it can be seen that all of the patients included in the research study were considered as having “decompensated” liver disease; however, not all of these patients were clinically the same in terms of the parameters used to define “decompensated.”

In another prior art research study by Dimopoulou (made of record in Paper No. 15), patients with decompensated liver disease were also treated with interferon alfa-2b.

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The parameters and values thereof used as a diagnosis of decompensated liver disease in the patients studied are described in the second column on page S104 of Dimopoulou as follows:

Patients were required to have decompensated liver disease proved by biopsy examination (the criteria used to define decompensated liver disease in this study included the presence of ascitis, serum albumin values below 3g/dl, and serum bilirubin values above 3 mg/dl)(positive for either hepatitis B surface antigen (HBsAg) or antibodies to hepatitis C virus (anti-HCV)), serum transaminases 2-5 times the upper limit of normal for more than six months, and absence of encephalopathy, active bleeding, renal failure, or detectable hepatocellular carcinoma.

Note that the parameters used by Dimopoulou to define “hepatic decompensation” differ in content and in the range of values from those parameters used by Nevens to define the same medical condition.

Another research study conducted by Waked (made of record in Paper No. 15) analyzes patients with compensated liver disease. However, in the first column on page 311 of Waked, criteria are defined which excludes certain patients from being included in the study. These excluded patients having values for certain parameters that fall outside of the range of “compensated” liver disease. The relevant portion of Waked is as follows:

Forty patients (31M, 9F) who were HBsAg and HBeAg positive for more than 6 months, with elevated aminotransferases, histologically active liver disease, normal blood counts, normal renal functions, and compensated liver

disease were included in this study. Exclusion criteria included normal aminotransferases (or elevated less than twice), biopsy features of chronic persistent hepatitis (CPH), inactive cirrhosis or normal histology; serum albumin < 3 gm/dl, serum bilirubin > 4 mg/dl, serum creatinine > 1.5 mg/dl; history of encephalopathy, ascites or bleeding esophageal varices; HDV infection, male homosexuality; pregnant females (or without adequate contraception); corticosteroid or antiviral therapy within the preceding 12 months; inadequate blood counts (hematocrit < 30%, leukocyte count < 3000/mm²; granulocytes < 1500/mm²; platelets < 75000/mm²); and symptomatic heart disease or ECG evidence of ischemic heart disease. Their pretreatment characteristics are shown in Table 1.

Again, the parameters used by Waked to define compensated/decompensated liver disease differ in content and in the range of values from those parameters used by either Nevens or Dimopoulou to define the same medical condition.

Finally, appellant's own specification is unclear concerning what criteria to use for defining a patient as having "decompensated" liver disease. In lines 20-34 on page 6 of the specification, the patients included within the study for the treatment of viral hepatitis by injection with an effective dosage of thymosin are described as follows:

Patients between the ages of 18 and 70 years with chronic type B hepatitis were included based on the following criteria: Presence of hepatitis B surface antigen (HBsAg) and elevated serum alanine aminotransferase (ALT) levels for at least 6 months; positive serum test for hepatitis B virus DNA

(HBV DNA); histologic confirmation of CAH (Knodell, R.G., et al., *Hepatology*, 1:431-435 (1981)) within the previous 3 months of randomization and evidence of compensated liver disease (prolongation of prothrombin time less than 4 seconds over control values, serum albumin ≥ 3 gm/dl, and serum total bilirubin ≤ 4 mg/dl). Additional requirements included a hemoglobin ≥ 10 gm, a platelet count $\geq 70,000/\text{mm}^3$, a white cell count (WBC) $\geq 3000^3$, a polymorphonuclear count (PMN) $\geq 1500/\text{mm}^3$ and serum creatinine ≤ 1.4 mg/dl.

All of the patients included in the study are stated to have compensated liver disease. Therefore, one of ordinary skill in the art would presume that those patients having decompensated liver disease would have values for the described parameters outside of the given ranges. However, it is not clear which of the several parameters listed are to be considered in making a diagnosis of "hepatic decompensation" since several additional requirements are described such as hemoglobin, platelet count, white cell count, serum creatinine, etc. It is not clear whether all of these parameters in addition to the prothrombin time, serum albumin levels and serum bilirubin levels must be considered in making a diagnosis of "hepatic decompensation," or whether only certain ones of the parameters listed are critical in distinguishing compensated versus decompensated liver disease.

From all of the ambiguities concerning how to define "decompensated liver disease" found in both the prior art and in appellant's own specification, no clear meaning

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can be assigned to the phrase “hepatic decompensation.” As a result, the scope of the claims cannot be reasonably ascertained. As set forth in In re Morris, 127 F.3d 1048, 1056, 44 USPQ2d 1023, 1029 (Fed. Cir. 1997), “[i]t is the applicants' burden to precisely define the invention, not the PTO's. See 35 U.S.C. § 112, ¶2.”

TIME PERIOD FOR RESPONSE

This opinion 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 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

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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...

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

VACATED-37 CFR § 1.196(b)

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Administrative Patent Judge)	
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