

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte HARRY R. DAVIS

Appeal No. 2006-2368
Application No. 10/247,032

ON BRIEF

Before ADAMS, GREEN, and LEBOVITZ, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-3, 10, 12, 13, 17, 19, 20 and 30-35.¹ Claims 1 and 32 are representative of the claims on appeal, and read as follows:

1. A method for treating vascular inflammation in a subject comprising the step of administering (1) at least one sterol absorption inhibitor or at least one 5 α -stanol absorption inhibitor and (2) at least one cholesterol biosynthesis inhibitor to a subject having a blood level of c-reactive protein of greater than about 0.4 mg/dL.

¹ Claims 4-9, 14-16 and 21-29 are also pending, but stand withdrawn from consideration as being drawn to a non-elected invention. See Appeal Brief, page 1.

32. A method for reducing vascular c-reactive protein levels in a mammal comprising:

administering a therapeutically effective amount of (1) at least one sterol absorption inhibitor or 5 α -stanol absorption inhibitor and (2) at least one cholesterol biosynthesis inhibitor to a mammal having a blood level of c-reactive protein of greater than about 0.4 mg/dL.

The claims are subject to a restriction requirement, and appellants have elected the method as practiced with ezetimbre as the specific sterol adsorption inhibitor, and simvastatin as the cholesterol biosynthesis inhibitor. See Appeal Brief, pages 2-3.

The examiner relies upon the following references:

Rosenblum et al. (Rosenblum) 5,846,966 Dec. 08, 1998

Yuen et al. (Yuen) "C-reactive protein, oxidative stress, homocysteine, and troponin as inflammatory metabolic predictors of atherosclerosis in ESRD," Current Opinion in Nephrology and Hypertension, Vol. 9, No. 6, pp.621-30 (2000).

Erren et al. (Erren) "Systemic inflammatory parameters in patients with atherosclerosis of the coronary and peripheral arteries," Arterioscler Thromb Vasc Biol. Vol. 19, No. 10, pp. 2355-63 (1999).

Gruberg, "Inflammatory markers in acute coronary syndromes: C-reactive protein (CRP) and Chlamydia," American Heart Association Scientific Sessions (2000).

Claims 1-3, 10, 12, 13, 17, 19, 20 and 30-35 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Rosenblum as evidenced by Erren. In addition, the claims stand rejected under 35 U.S.C. §103(a) as being obvious over the combination of Rosenblum and Erren or Yuen, or as being obvious over the combination of Rosenblum, Erren or Yuen, and Gruberg. After careful review of the record and consideration of the issues before us, we affirm the rejection of

the claims under 35 U.S.C. §102(b). Because we affirm that rejection, we decline to reach the merits of the two rejections under 35 U.S.C.

§ 103(a)

DISCUSSION

Claims 1-3, 10, 12, 13, 17, 19, 20 and 30-35 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Rosenblum as evidenced by Erren.

We initially note that the claims stand or fall together. Appellants discuss the limitations of the different claims, see Appeal Brief, pages 5-6, but do not argue them separately. Merely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable. See 37 CFR § 41.37(c)(1)(vii). We thus focus our analysis on independent claims 1 and 32.

According to the Examiner's Answer:

Rosenblum [] teach[es] a method of treating or preventing atherosclerosis in [a, sic] mammal comprising administering to the mammal a combination of the compound[s] herein elected. See, particularly, claims 6-10. The method is particularly effective in human. See, particularly, column 20, lines 39-48. Note the recitation of the level of C-reactive protein is not see[n, sic] to further limit the claims because patient[s, sic] with vascular condition[s, sic], such as atherosclerosis, . . . inherently hav[e, sic] elevated c-reactive protein levels (See, e.g., Erren, the entire document, particularly, page 2355).

Examiner's Answer, page 4.

We recognize that in order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477,

44 USPQ2d 1429, 1432 (Fed. Cir. 1997). As set forth by the examiner, Rosenblum sets forth all of the limitations of claims 1 and 32, and the rejection of claims 1-3, 10, 12, 13, 17, 19, 20 and 30-35 under 35 U.S.C. § 102(b) is affirmed.

Appellant argues that Rosenblum does not “disclose the utility of such compounds for treating vascular inflammation and do[es] not disclose treating a subject having a blood level of c-reactive protein of greater than about 0.4 mg/dL,” and also “do[es] not disclose reducing vascular c-reactive protein (CRP) levels in a mammal, as presently claimed in Claim 32.” Appeal Brief, page 6.

Erren, according to appellant, while disclosing that “plasma concentrations of markers of inflammation are increased in patients with atherosclerosis,” does not teach “treatment for vascular inflammation or atherosclerosis,” and does not teach “substituted azetidinones and HMG-CoA reductase inhibitors (statins) for the treatment of vascular inflammation.” Id. at 6-7.

Relying on Rosco, Inc. v. Mirror Lite Co., 304 F.3d, 1373, 64 USPQ2d 1676 (Fed. Cir. 2002), for the proposition that “the inherent claim limitation must necessarily be present in the prior art reference, not merely probably or possibly present, to support a rejection under §102(b),” appellants contend that as demonstrated by Erren, “[a]ll patients with atherosclerosis do not have CRP levels above 0.4 mg/dL,” asserting that limitation is just possibly present, but not necessarily present. Id. at 7 (emphasis in original). Appellant also relies on

Choi² to support their assertion that “[l]evels of CRP above 0.4 mg/dL have simply not been demonstrated in all atherosclerosis patients.” Id. at 7-8.

Appellants arguments are not found to be convincing. As noted by the examiner, Rosenblum teaches a method of treating atherosclerosis through the administration of ezetimibe as the specific sterol adsorption inhibitor, and simvastatin as the HMG-CoA reductase inhibitor. Thus, the issue becomes whether treating a patient with atherosclerosis is treating a patient having a blood level of c-reactive protein of greater than about 0.4 mg/dL, and thus treating vascular inflammation (claim 1) or reducing vascular c-reactive protein levels (claim 32).

As noted by appellant, Erren teaches that only 50% of patients with coronary artery disease (CAD), but no peripheral artery disease (PAD), have c-reactive protein (CRP) levels of 0.4 mg/dL. See Erren, Table 3. But stated differently, 50% of atherosclerosis (CAD) patients had CRP levels greater than 0.4 mg/dL, and 25% had CRP levels greater than 14 mg/dL. Moreover, the use of “about” in the claims to describe the 0.4 mg/dL would actually include a higher percentage of patients that have CRP levels greater than about 0.4 mg/dL. Thus, in treating atherosclerosis patients with ezetimibe as the specific sterol adsorption inhibitor, and simvastatin as the HMG-CoA reductase inhibitor, as taught by Rosenblum, Erren demonstrates that out of 100 patients, more than 50 patients will have CRP levels greater than about 0.4 mg/dL. Thus, the required

² Choi et al. (Choi), “Association of High Sensitivity C-Reactive Protein with Coronary Heart Disease Prediction, but Not with Carotid Atherosclerosis, in Patients with Hypertension,” Circ. J.,

level of C-reactive protein is inherently present in 50 out of 100 atherosclerosis patients. And as the treatment of a single patient with ezetimibe as the specific sterol adsorption inhibitor, and simvastatin as the HMG-CoA reductase inhibitor, wherein the patient has a blood level of CRP greater than about 0.4 mg/dL would anticipate the methods of claims 1 and 32, Rosenblum is deemed to inherently anticipate the subject matter of those claims.

With respect to treating vascular inflammation (claim 1) or reducing vascular c-reactive protein levels (claim 32), those results would be inherent in the method of Rosenblum, as you are administering the same compounds, i.e., ezetimibe as the specific sterol adsorption inhibitor, and simvastatin as the HMG-CoA reductase inhibitor, to the same group of patients, atherosclerosis patients, more than half of which, as discussed above, have c-reactive protein levels greater than about 0.4 mg/dL. See Perricone v. Medicis Pharmaceutical Co., 432 F.3d 1368, 1377-78, 77 USPQ2d 1321, 1328 (Fed. Cir. 2005) (noting that the realization of a new benefit of an old process does not render that process patentable); see also Bristol-Myers Squibb Co. v. Ben Venue Laboratories, 246 F.3d 1368, 1376, 58 USPQ2d 1508, 1514 (Fed. Cir. 2001) (stating in the context of a claimed process that was drawn to the same use comprising the same steps of the prior art, “[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.”).

Our review of the Rosco case, cited by appellants, does not suggest a different result. That case involved “cross-view” mirrors, used on school buses,

allowing the bus deriver to view the front and passenger side of the bus. See id., 304 F.3d at 1376, 64 USPQ2d at 1679. In determining whether the curvature of the mirror was inherent in the prior art, the Court of Appeals for the Federal Circuit stated that “[i]nherent anticipation requires that the missing descriptive material is ‘necessarily present,’ not merely probably or possibly present, in the prior art.” Id., 304 F.3d at 1380, 64 USPQ2d at 1680. In the case before us, Erren demonstrates that the limitation of the patient having a CRP level greater than about 0.4 mg/dL is necessarily present in over half of atherosclerosis patients, the same patients being treated in the method taught by Rosenblum.

CONCLUSION

Because we find that the examiner has set forth a prima facie case of unpatenability of claims 1-3, 10, 12, 13, 17, 19, 20 and 30-35 as being anticipated by Rosenblum, that rejection is affirmed, and we decline to reach the merits of the remaining rejections.

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

AFFIRMED

Donald E. Adams)
Administrative Patent Judge)
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) BOARD OF PATENT
Lora M. Green)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
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Richard M. Lebovitz)
Administrative Patent Judge)

LG/dym

Schering-Plough Corporation
Patent Department (K-6-1, 1990)
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530