

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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*Ex parte* MENOTTI CALVANI

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Appeal 2008-2538  
Application 10/478,372  
Technology Center 1600

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Decided: June 17, 2008

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Before ERIC GRIMES, LORA M. GREEN, and JEFFREY N. FREDMAN,  
*Administrative Patent Judges.*

GRIMES, *Administrative Patent Judge.*

**DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 involving claims to the treatment of diabetes. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

**BACKGROUND**

Type 2 diabetes “is currently treated with oral antidiabetes medicaments, which exert a positive action both on insulin resistance, i.e. the glitazones and on the altered insulin secretion, i.e. the sulfonylureas.

Despite being very useful, these compounds present some disadvantages due to their toxicity” (Spec. 2). The Specification discloses that “the use of the acetyl L-carnitine, or a pharmaceutically acceptable salt thereof, in association with the biotin exerts a remarkable synergic effect on the reduction in insulin resistance, which characterizes the Type 2 diabetes mellitus” (*id.* at 4).

## DISCUSSION

### 1. CLAIMS

Claims 6-10 are pending and on appeal. Claim 6 is representative and reads as follows:

Claim 6: A method for treating Type 2 insulin-resistant diabetes comprising administering to a subject in need thereof acetyl L-carnitine or a pharmaceutically acceptable salt thereof in association with biotin.

### 2. OBVIOUSNESS

Claims 6-10 stand rejected under 35 U.S.C. § 103 as obvious in view of McCarty<sup>1</sup> and Calvani.<sup>2</sup> The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner relies on McCarty as disclosing “a method of treating Type 2 diabetes by administering an oral composition comprising biotin, in a dosage between 25 µg to 200 mg daily” (Ans. 4). The Examiner finds that McCarty does not “disclose acetyl L-carnitine or a pharmaceutically acceptable salt thereof” (*id.*).

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<sup>1</sup> McCarty, US 5,929,066, July 27, 1999.

<sup>2</sup> Calvani et al., US 4,751,242, June 14, 1988.

The Examiner relies on Calvani as disclosing “a method of treating a patient with diabetic polyneuropathy … with acetyl L-carnitine or one of its pharmaceutically acceptable salts” (*id.*).

The Examiner concludes that “it would have been *prima facie* obvious to a person of ordinary skill in the art … to combine biotin as taught by McCarty et al. with acetyl L-carnitine as taught by Calvani et al. for the treatment of Type 2 insulin-resistant diabetes” (*id.* at 5). The Examiner reasons that a “person of ordinary skill in the art would have been motivated to make this combination because of the added benefit of treating diabetic polyneuropathy in a patient suffering from Type 2 diabetes” (*id.*).

We conclude that the Examiner has set forth a *prima facie* case that claim 6 would have been obvious to the ordinary artisan.

McCarty discloses a method for treating Type 2 diabetes by “administering to an affected individual a combination of chromic tripicolinate and biotin” (McCarty, abstract). McCarty also discloses that the combination “promote[s] significant reduction in blood glucose levels and stabilize[s] blood glucose levels” in individuals with Type 2 diabetes (*id.* at col. 2, ll. 57-62) .

Calvani discloses treatment of neuropathy by “[o]ral or parenteral administration of 1,000-2,000 mg/day of acetyl L-carnitine or an equivalent amount of a pharmacologically acceptable salt thereof” (Calvani, abstract). Calvani also discloses that peripheral neuropathies may be caused by a variety of underlying disorders, including “metabolic unbalances (diabetes, renal and liver insufficiency)” (*id.* at col. 1, ll. 47-55).

We agree with the Examiner that it would have been *prima facie* obvious to one of skill in the art to combine the teachings of McCarty and Calvani and thereby arrive at the invention of claim 6. One of skill in the art would have been motivated to treat both the underlying disease mechanism (i.e., diabetes) and a symptom associated with the disease (i.e., diabetic neuropathy) to achieve maximal therapeutic benefit to the patient.

Appellant argues there would have been no motivation for a person of ordinary skill in the art to combine the cited references and arrive at the claimed invention (Br. 9) because “no relationship with insulin-altered metabolism is postulated” in Calvani and because “Calvani discloses a different purpose for the use of acetyl L-carnitine” than the instantly claimed purpose (*id.* at 11). Appellant argues that Calvani discloses “the use of acetyl L-carnitine in peripheral neuropathies,” not to treat diabetes *per se* (*id.* at 9).

We are not persuaded by this argument. As we understand it, Appellant argues that the use of acetyl L-carnitine disclosed in Calvani is for the treatment of neuropathy generally and is not directed toward the treatment of the underlying metabolic deficiencies of diabetes. We are not persuaded that this argument shows any error in the rejection. Calvani discloses the use of acetyl L-carnitine for the treatment of a symptom of diabetes, neuropathy, and McCarty discloses the use of biotin to treat the metabolic disequilibrium (i.e., high blood glucose levels) that underlies the pathological effects of the disease. Thus, one of skill in the art would still be motivated to combine them to obtain maximum therapeutic effect in

mitigating both symptoms and an underlying cause of symptoms in a diabetic patient.

Appellant further argues that McCarty teaches away from the claimed invention because “McCarty teaches a method of treating type 2 diabetes by administering biotin together with chromic tripicolinate” (App. Br. 11). Appellant further argues that “[t]here is no reason to believe that a person having ordinary skill in the art would remove one component of a synergistic combination [i.e., chromic tripicolinate] and replace it with another component [i.e., acetyl L-carnitine]” and that it “would be far more logical to attempt to add further components in the McCarty combination in the hopes of creating an even more efficacious combination” (*id.* at 12).

We are not persuaded by this argument. Claim 6 uses the open claim language “comprising.” Therefore, it reads on treating a diabetic patient with acetyl-L-carnitine and biotin, *and anything else in addition*. Substitution of the acetyl L-carnitine of Calvani for the chromium picolinate of McCarty would not be required in order for the method suggested by the references to meet the limitations of claim 6.

#### SUMMARY

The Examiner’s rejection is supported by the preponderance of the evidence of record. We therefore affirm the rejection of claims 6-10 under 35 U.S.C. § 103.

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

AFFIRMED

Ssc:

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