

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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

Appeal No. 97-2833
Application 08/236,190¹

ON BRIEF

Before KIMLIN, WARREN and OWENS, *Administrative Patent Judges*.

OWENS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the examiner's final rejection of claims 34, 35, 37-39, 41-46, 48-50, 52-57, 59-61, 63-66, 82, 83, 85 and 87-91, which are all of the claims remaining in the application.

¹ Application for patent filed May 2, 1994. According to the appellant, the application is a division of Application 08/012,379, filed February 2, 1993.

THE INVENTION

Appellant's claimed invention is a method for managing body weight changes in a human by administering to the human a specified amount of one or more nicotine metabolites or pharmaceutically acceptable salts thereof. Claim 34 is illustrative and reads as follows:

34. A therapeutic method used to manage short-term human body weight changes through suppression of appetite or prevention of weight gain or induction of weight loss during the initial tobacco abstinence phase in nicotine-experienced or nicotine-naive individuals comprising of administering a nicotine metabolite or combination of nicotine metabolites or their pharmaceutically acceptable salts thereof to a human in need of such treatment, in an amount in the range of 1 to 100 milligrams per kilogram of body weight of the human per day calculated as the nicotine metabolite or combination of nicotine metabolites in the free base form that is effective to suppress appetite, prevent weight gain or induce weight loss in an individual in the need of such treatment.

THE REFERENCES

References relied upon by the examiner

Michaels	3,867,519	Feb. 18, 1975
Hutchinson et al. (Hutchinson)	3,870,794	Mar. 11, 1975
Abood (Abood '916)	4,966,916	Oct. 30, 1990

Joseph F. Borzelleca et al., "Studies on the Respiratory and Cardiovascular Effects of (-)-Cotinine", 137 *J. Pharm. Exper. Therapeutics*, 313-18 (1962) (Borzelleca).

The Health Consequences of Smoking - Nicotine Addiction, Report of the Surgeon General 197-208 (1988) (Surgeon General's report).

Reference relied upon by the board

Keenan	5,643,928	Jul. 1, 1997
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THE REJECTION

Claims 34, 35, 37-39, 41-46, 48-50, 52-57, 59-61, 63-66, 82, 83, 85 and 87-91 stand rejected under 35 U.S.C. § 103 as being unpatentable over the Surgeon General's report in view of appellant's admissions at pages 4-8 of the specification, Borzelleca, Michaels, Abood '916, and Hutchinson.

OPINION

We have carefully considered all of the arguments advanced by appellant and the examiner and agree with appellant that the aforementioned rejection is not well founded. Accordingly, this rejection will be reversed. We will introduce a new ground of rejection of claims 34, 35, 37-39, 41-46, 48-50, 52-57, 59-61, and 63-66 under the provisions of 37 CFR § 1.196(b).

The examiner argues that the Surgeon General's report teaches that nicotine suppresses appetite and reduces body weight and that appellant admits that the nicotine metabolites recited in appellant's claims were known in the art (answer, page 8). The examiner argues that because nicotine metabolites are produced after the administration of nicotine and because optimization of the amount of nicotine administered is within the skill of the artisan, appellant's claimed invention would have been *prima facie* obvious to one of ordinary skill in the art (answer, page 10).

The examiner argues that Borzelleca teaches that metabolites of nicotine were known to be pharmaceutically active compounds (answer, pages 8-9). This reference teaches that isolation of nicotine metabolites makes possible the investigation of the role of metabolites of nicotine in controlling or limiting the response to nicotine (page 313). Borzelleca discloses that in a reported preliminary study in anesthetized dogs, several nicotine metabolites produced depression, and high dosages produced death (page 314). Borzelleca reports that in his studies, (-)-cotinine produced depression in most mice and hyperexcitability in a few (page 316). We find in this reference no indication that nicotine metabolites are effective for suppressing appetite, preventing weight gain or inducing weight loss.

Michaels, Abood and Hutchinson are relied upon by the examiner for a disclosure of the methods of administration recited in appellant's dependent claims (answer, page 9).

The examiner has provided no evidence or convincing reasoning which shows that the prior art relied upon by the examiner would have fairly suggested, to one of ordinary skill in the art, administering to a human an amount of one or more nicotine metabolites or pharmaceutically acceptable salts thereof which is within the amount recited in appellant's claims and is sufficient to suppress appetite, prevent weight gain

or induce weight loss. The Benowitz article² cited in appellant's specification (page 8) teaches that cotinine is the major metabolite of nicotine and is present in the blood of tobacco smokers in much higher concentrations and remains longer than nicotine after cessation of smoking (page 604). Benowitz infused the fumarate salt of cotinine into subjects at a rate of 4 Fg base/kg/min for 60 min (page 605). This amount "was selected as one which would induce blood concentrations of cotinine in the range of that achieved by moderately heavy cigarette smokers" (page 605). Benowitz states that the cotinine infusion "was of a magnitude consistent with the expected reduction in preexperimental anxiety and tension that we usually see with similar subjects and paradigms that also include placebo infusions" (page 610). Benowitz concludes that "at levels to which smokers are generally exposed, cotinine exerts little, if any, pharmacologic effect" (page 610).

The amount of cotinine infused by Benowitz, i.e., 4 Fg/kg/min for 60 min, which, Benowitz states, is an amount which would induce blood concentrations of cotinine in the range of that of persons who smoke cigarettes moderately heavily (page 605), is 240 Fg/kg, which is less than one fourth the minimum amount of nicotine metabolite recited in appellant's claims, and Benowitz concludes that the infused amount has little if any pharmacologic effect (page 610). This reference, therefore, indicates that the

² Neal L. Benowitz et al., "Cotinine disposition and effects", 34 *Clin. Pharmacol. Ther.* 604-11 (1983).

amount of cotinine which is in the bloodstream of persons who smoke cigarettes moderately heavily would not have the pharmacologic effect of suppressing appetite, preventing weight gain or inducing weight loss. Furthermore, we find in the applied prior art no teaching that Benowitz's amount of cotinine of 240 Fg/kg corresponds to a total amount of nicotine metabolites within the range recited in appellant's claims. In addition, we do not find motivation from the applied prior art to administer, to a person in need of appetite suppression or weight gain prevention or loss, a larger amount of nicotine than that which would be ingested by smoking. We note that Hutchinson discloses administration of nicotine metabolites to treat emotional states characterized by anger, aggressivity, irritability, tensions, nervousness, fears and anxieties and to improve task performance (col. 1, line 53 - col. 2, line 20), but does not disclose administering the nicotine to patients in need of management of body weight changes.

For the above reasons, we conclude that the examiner has not carried her burden of establishing a *prima facie* case of obviousness of appellant's claimed invention.

Under the provisions of 37 CFR § 1.196(b), we enter the following new ground of rejection.

Claims 34, 35, 37-39, 41-46, 48-50, 52-57, 59-61, 63-66 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-11 of Keenan '928.³

Appellant's independent claim 34 differs from claim 1 of Keenan '928 in that 1) appellant's claim 34 recites administering one or more nicotine metabolites or their pharmaceutically acceptable salts whereas claim 1 of Keenan '928 recites administering cotinine or a pharmaceutical acceptable salt thereof, 2) in appellants' claim 34, administering 1-100 mg/kg of body weight of nicotine metabolites or their pharmaceutically acceptable salts in the free base form is recited, but the amount of cotinine or a pharmaceutical acceptable salt thereof is not recited in claim 1 of Keenan '928, and 3) appellant's claim 34 is directed toward managing short term human body weight changes whereas claim 1 of Keenan '928 is directed toward control of long term human body weight. Appellant's independent claims 45 and 56 differ from claim 1 of Keenan '928 only in the first and second respects noted above.

Because cotinine is a nicotine metabolite, the recitation in claim 1 of Keenan '928 of administering cotinine is a disclosure of administering a nicotine metabolite. Regarding the amount of cotinine administered in claim 1 of Keenan '928, it is proper to

³ No new ground of rejection is applied to claims 82, 83, 85 and 87-91.

use the specification of Keenan '928 as a dictionary to interpret the term "amount". See *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1577 (Fed. Cir. 1996) (A patent specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication."). The Keenan '928 specification states that the most preferred dosage range is 15-90 mg/kg/day of (-)-cotinine in the free base form (col. 6, lines 35-37), which falls within the range recited in appellant's claim 34. As for the duration of the treatment, one of ordinary skill in the art would have had a reasonable expectation that because cotinine or a pharmaceutically acceptable salt thereof is effective for long term weight control as recited in claim 1 of Keenan '928, it necessarily would be effective for weight control for a shorter length of time. The methods of administration recited in the claims which depend from appellant's claims 34, 45 and 56 would have been *prima facie* obvious to one of ordinary skill in the art in view of the recitation of such methods in the dependent claims of Keenan '928.

DECISION

The rejection of claims 34, 35, 37-39, 41-46, 48-50, 52-57, 59-61, 63-66, 82, 83, 85 and 87-91 under 35 U.S.C. § 103 as being unpatentable over the Surgeon General's report in view of appellant's admissions at pages 4-8 of the specification, Borzelleca, Michaels, Abood '916, and Hutchinson, is reversed. A new ground of rejection of claims 34, 35, 37-39, 41-46, 48-50, 52-57, 59-61, 63-66 has been entered

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under

37 CFR § 1.196(b).

This decision contains in 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 the appellant, WITHIN TWO MONTH FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection of avoid termination of proceedings (37 CFR § 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 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

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

REVERSED, 37 CFR § 1.196(b)

EDWARD C. KIMLIN)	
Administrative Patent Judge)	
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)	
)	BOARD OF PATENT
CHARLES F. WARREN)	
Administrative Patent Judge)	APPEALS AND
)	
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)	
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