

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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

Appeal No. 2006-1066
Application No. 09/810,109

ON BRIEF

Before SCHEINER, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a method of treating alcohol dependency. The examiner has rejected the claims as anticipated by and/or obvious over prior art. We have jurisdiction under 35 U.S.C. § 134. Because the cited references support a prima facie case of anticipation and/or obviousness, which Appellant has not rebutted, we affirm two of the four anticipation rejections and the obviousness rejection. We do not reach a decision regarding the remaining two anticipation rejections.

Background

The specification describes methods of treating alcohol dependency, as well as other conditions. Specification, page 3, lines 15-17. "Dependency" is defined as

any form of behavior that indicates an altered or reduced ability to make decisions resulting, at least in part, from the use of alcohol or opiates. . . . This term also includes the psychic craving for alcohol or an opiate that may or may not be accompanied by a physiological dependency. . . . Forms of “dependency” include habituation, that is, an emotional or psychological dependence on alcohol or an opiate to obtain relief from tension and emotional discomfort; tolerance, that is, the progressive need for increasing doses to achieve and sustain a desired effect; addiction, that is, physical or physiological dependence which is beyond voluntary control; and use of alcohol or an opiate to prevent withdrawal symptoms.

Page 4, line 19, to page 5, line 6.

To treat alcohol dependency, as well as the other conditions, the specification describes “administering a therapeutically-effective amount of a cytidine-containing, cytosine-containing, creatine-containing, uridine-containing, adenosine-containing, or adenosine-elevating compound to a mammal.” Page 3, lines 18-20. The specification defines “therapeutically-effective amount” as an amount of the compound “sufficient to produce a healing, curative, prophylactic, stabilizing, or ameliorative effect in the treatment of” the various conditions, including alcohol dependency. Page 8, lines 13-19.

Discussion

1. Claims

Claims 1 and 5-17 are pending and on appeal. Claim 1 is independent. Claims 5-17 each depend, directly or indirectly, from claim 1. Claims 5-7, 9-11, and 14-17 stand or fall together with claim 1. Appeal Brief, page 4. Claims 8, 12 and 13 were separately argued. Thus, we will focus on claims 1, 8, 12 and 13, which are representative and read as follows:

1. A method of treating alcohol dependency, comprising administering to a mammal a therapeutically-effective amount of a compound selected from the group consisting of a cytidine-containing compound, a cytosine-containing compound, a uridine-containing

compound, a creatine-containing compound, an adenosine-containing compound, and an adenosine-elevating compound.

8. The method of claim 1, wherein said cytidine-containing compound is CDP.
12. The method of claim 11, wherein said human is a child or adolescent.
13. The method of claim 11, wherein said human is over sixty years of age.

Claim 1 is directed to a method of treating alcohol dependency by administering to a mammal a therapeutically-effective amount of an adenosine-elevating compound or a compound containing cytidine, cytosine, uridine, creatine, or adenosine. Alcohol dependency is only referred to in the preamble of claim 1. However, in order to treat alcohol dependency, the mammal being treated must have alcohol dependency. Thus, the preamble of claim 1 is “necessary to give life, meaning, and vitality” to the claim. Pitney Bowes Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). As a result, we interpret the preamble of claim 1 to require the mammal that is treated to have alcohol dependency.

Claim 8 depends from claim 1 and limits the cytidine-containing compound to CDP. As drafted, claim 8 further limits only one member of the Markush group of claim 1; that is, the cytidine-containing compound. Claim 8 does not require administering CDP; it only requires that if a cytidine-containing compound is administered, that compound is CDP. Thus, claim 8 is directed to a method of treating alcohol dependency by administering any of the following compounds: CDP; a compound containing cytosine, uridine, creatine, or adenosine; or an adenosine-elevating compound.

Claims 12 and 13 each depends from claim 11, which depends from claim 1. Claim 11 recites that the mammal is a human. Claims 12 recites that the human is a child or adolescent. Claim 13 recites that the human is over sixty years of age.

2. Anticipation

The examiner rejected claims 1, 6, 7, 9, and 10 under 35 U.S.C. § 102(b) over Zappla.¹ As pointed out by the examiner, Zappla describes, at page 3, lines 6-19, administering cytidine-diphosphate-choline (“CDP-choline”) derivatives for therapy and prevention of fatty liver in alcoholics. Final Rejection, page 3, lines 9-10. The examiner reasoned that Zappla administers the same compound, in overlapping amounts, via the same route, to the same population, and therefore “Zappla et al. must inherently be treating the psychological aspects of alcoholism as well as the physical aspects.” *Id.*, page 3, lines 17-21.

Appellant argues that the term “alcoholic,” used in Zappla, is not synonymous with the term “alcohol dependency,” used in claim 1. In particular, Appellant argues that the term “alcoholic” can include an acute alcoholic that does not have an “alcohol dependency.” Thus, Appellant argues that treating an “alcoholic” does not necessarily treat a person having an “alcohol dependency.” Appeal Brief, page 8, lines 7-16.

The basic question raised by this argument is whether Zappla describes administering its compound to a mammal having alcohol dependency, as this term is defined in the specification. Cf. Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1379, 77 USPQ2d 1321, 1328 (Fed. Cir. 2005). We hold that it does.

¹ Zappla et al., EP 0 188 647, published July 30, 1986.

As noted above, Zappla describes administering CDP-choline derivatives to alcoholics for the treatment or prevention of fatty liver. Zappla, page 3, lines 6-19. As noted by the examiner, the term “alcoholic” refers to a person suffering from alcoholism and the term “alcoholism” refers to a disorder characterized by the excessive consumption of and dependence on alcoholic beverages, leading to physical and psychological harm and impaired social and vocational functioning. Examiner’s Answer, page 5, lines 8-13 (citing “www.dictionary.com”). We agree with the examiner that the terms “alcoholic” and “alcohol dependency” would be understood to mean basically the same thing.

For example, Stedman’s Medical Dictionary² defines an “alcoholic” as “[o]ne who suffers from alcoholism” or “[o]ne who abuses or is dependent upon alcohol.”

Stedman’s defines “alcoholism” as follows:

Chronic alcohol abuse, dependence, or addiction; chronic excessive drinking of alcoholic beverages resulting in impairment of health and/or social or occupational functioning, and increasing adaptation to the effects of alcohol requiring increased doses to achieve and sustain a desired effect; specific signs and symptoms of withdrawal usually are shown upon sudden cessation of such drinking.

These definitions reasonably appear to be the same as, or at least to substantially overlap, the instant specification’s definition of alcohol “dependency.”

Granted, Stedman’s includes separate entries for “acute” and “chronic” alcoholism and, of the two, only chronic alcoholism involves alcohol dependence.

However, Appellant has pointed to no evidence indicating that Zappla’s reference to

² Stedman’s Medical Dictionary, 27th edition, Lippincott Williams & Wilkins (2000). Copies of the cited definitions are attached.

“alcoholics” was intended to be limited to those suffering from acute, and not chronic, alcoholism. That it may be possible to use the term “alcoholic” to also encompass a person suffering from only acute alcoholism does not negate the description in Zappla of administering a CDP-choline derivative to an alcoholic, as the term is commonly used, that is, to a person suffering from “Chronic alcohol . . . dependence.” Thus, we find that Zappla describes administering a CDP-choline derivative to a mammal having alcohol dependency, as this term is defined in the specification.

Based on our determination that Zappla describes administering its compound to mammals having alcohol dependency, we conclude that the examiner has set forth a prima facie case that Zappla anticipates claim 1. In addition, Appellant has not provided any evidence that the compound and amounts thereof described in Zappla do not inherently treat alcohol dependency.

Appellant argues that Rapoport v. Dement, 254 F.3d 1053, 59 USPQ2d 1215 (Fed. Cir. 2001), supports his position. Appeal Brief, pages 12-13; Reply Brief, pages 10-11.

We disagree. In Rapoport, the court considered whether claims to a method of treating sleep apnea with buspirone was anticipated by a disclosure of treating anxiety secondary to sleep apnea with the same agent. The court interpreted the claims to be limited to treating the underlying disorder itself, based in part on the application’s statement that the drug should be administered “at the hour of sleep.” Id. at 1060, 59 USPQ2d at 1220. The allegedly anticipating reference did not specify that the drug should be administered at bedtime, see id. at 1062, 59 USPQ2d at 1221, and therefore

the evidence did not show that carrying out the prior art method would inherently result in treating sleep apnea.

Here, by contrast, Appellant has pointed to no difference that would result from administering a CDP-choline derivative to an alcoholic for the purpose of treating fatty liver, as in Zappla, or administering the same compound to the same person for the purpose of treating alcohol dependency. Since the claimed method reasonably appears to read on the method in the prior art, we agree with the examiner that claim 1 is anticipated.

For these reasons, we affirm the § 102 rejection of claim 1 over Zappla. Claims 6, 7, 9, and 10 fall with claim 1.

The examiner rejected claims 1 and 11 under 35 U.S.C. § 102(b) over Hata.³ As pointed out by the examiner, Hata states, at column 1, lines 37-39, that “alcoholism in human beings can be treated by the administration of a uridine diphosphate glucuronic acid.” In addition, Hata states, at column 2, lines 62-64, that the composition can be used for the treatment of chronic alcoholism. Examiner’s Answer, page 6, lines 8-11. The examiner reasoned that “Hata’s administration of uridine containing compounds to chronic alcoholics would have inherently performed the method as instantly claimed.” In particular, the examiner argued that Hata treats the same population with the same compound in the same amounts and in the same manner as Appellant. Final Rejection, page 4, lines 19-21.

³ Hata et al., U.S. Patent No. 4,027,017, issued May 31, 1977.

Appellant argues that the treatment regimes described in Hata do not inherently anticipate the claims because the alcohol-induced damage being treated in Hata may occur in subjects that are not alcohol dependent, e.g., in those suffering from acute alcoholism. Thus, Appellant argues that the methods of Hata do not necessarily treat the same population as the claims. Appeal Brief, page 10, line 11, to page 12, line 1.

As with Appellant's argument regarding Zappla, the basic question raised is whether Hata describes administering its compound to a mammal having alcohol dependency, as this term is defined in the specification. We hold that it does.

As pointed out by Appellant, Hata describes the treatment of acute alcoholism, as well as of chronic alcoholism. Hata, column 2, lines 16-18. However, the fact that Hata describes the treatment of acute alcoholism does not negate the description in Hata of administering uridine diphosphate glucuronic acid to treat chronic alcoholism. We agree with the examiner that the terms "chronic alcoholism" and "alcohol dependency" would be understood to mean basically the same thing. Thus, we hold that Hata does describe administering uridine diphosphate glucuronic acid to a mammal having alcohol dependency, as this term is defined in the specification.

Based on our determination that Hata describes administering its compound to mammals having alcohol dependency, we conclude that the examiner has set forth a prima facie case that Hata anticipates claim 1. In addition, Appellant has not provided any evidence that the compound and amounts thereof described in Hata do not inherently treat alcohol dependency. Thus, we affirm the § 102 rejection of claim 1 over Hata. Claim 11 falls with claim 1.

The examiner also rejected claim 1 under 35 U.S.C. § 102(b) over each of von Borstel⁴ and Hirota⁵. Having held that claim 1 is anticipated by both Zappla and Hata, we need not decide whether this claim is also anticipated by von Borstel or Hirota.

3. Obviousness

The examiner rejected claims 1 and 5-17 under 35 U.S.C. § 103 over the combination of Zappla and Hata in view of Watkins.⁶ (Although the Examiner's Answer does not list this rejection in its listing of the grounds of rejection, that omission appears to be a typographical error. Appellant listed this rejection as one of the issues being presented on appeal and the examiner indicated that Appellant's statement of the issues was correct. In addition, the examiner has addressed this rejection in his response to Appellant's argument. Therefore, we conclude that this rejection is properly before us on appeal.)

a) Claims 1, 5-7, 9-11, and 14-17

We have already found that each of Zappla and Hata describes the method of claim 1. Anticipation is the epitome of obviousness. In re McDaniel, 293 F.3d 1379, 1385-1386, 63 USPQ2d 1462, 1466 (Fed. Cir. 2002). Therefore, we affirm the § 103 rejection of claim 1. Claims 5-7, 9-11, and 14-17 fall with claim 1.

b) Claim 8

With regard to claim 8, the examiner argued that Watkins "bridges the gap between the obviousness of using CDP instead of CDP-choline, as Watkins teaches

⁴ von Borstel et al., U.S. Patent No. 5,691,320, issued November 25, 1997.

⁵ Hirota et al., JP 8-183737, published July 16, 1996.

⁶ Watkins et al., WO 00/06174, published February 10, 2000.

that CDP and CDP-choline act synergistically with uridine containing compounds and Hata teach[es] that uridine compounds are effective in treating alcoholics.” Examiner’s Answer, page 9, lines 18-21. Appellant argues that none of Zappla, Hata, or Watkins discloses the administration of CDP. Appeal Brief, page 16, lines 7-10. In particular, Appellant argues that “the Examiner has not provided a citation for the alleged teaching of Watkins, and Appellant finds no reference to the compound CDP in Watkins.” Reply Brief, page 13, lines 12-17.

Appellant’s argument raises valid questions about the examiner’s prima facie case with respect to claim 8. However, we agree with the examiner that the method of claim 8 is unpatentable because we hold that Hata describes the claimed method.

As discussed above, Hata describes the administration of a uridine-containing compound to a mammal having an alcohol dependency. As also discussed above, claim 8 only limits one member of the Markush group recited in claim 1 (i.e., it limits the cytidine-containing compound to CDP but does not require administering CDP). Therefore, claim 8 reads on administering a uridine-containing compound to a mammal having an alcohol dependency. Thus, Hata describes the method of claim 8 for the same reasons that it describes the method of claim 1. Anticipation is the epitome of obviousness. In re McDaniel, 293 F.3d at 1385-1386, 63 USPQ2d at 1466. Therefore, we affirm § 103 rejection of claim 8. However, because our reasoning differs from that of the examiner, we designate our affirmance as a new ground of rejection, with respect to claim 8, in order to give Appellant a fair opportunity to respond.

c) Claims 12 and 13

With regard to claims 12 and 13, the examiner argued that Hata and Zappla each “teach that their methods are effective to treat all humans in need thereof, and therefor[e] it would [have been] obvious to practice the method on any human of any age, as all patients in need thereof are treated by the art’s methods.” The examiner went on to argue that: “[i]t is well established that merely selecting proportions and ranges of a prior art method is not patentable absent a showing of criticality.” Examiner’s Answer, page 9, line 21, to page 10, line 6. Appellant argues that the age-based limitations of claims 12 and 13 are significant because these groups may be difficult to treat and therefore a prima facie case of obviousness has not been established. Appeal Brief, page 16, line 11, to page 17, line 5.

As discussed above, Zappla describes administering CDP-choline derivatives to alcoholics. In addition, Hata describes administering uridine diphosphate glucuronic acid to human beings with chronic alcoholism. Neither reference teaches that the disclosed methods are effective only for people in a specific age range. Thus, we agree with the examiner that one of ordinary skill in the art would have found it obvious to administer these compounds to a human being of any age in need of the treatment, including a human being in the age ranges recited in claims 12 and 13. Appellant has provided no evidence to show that those skilled in the art would have reason to doubt that the methods disclosed by Zappla and Hata would be successful when applied to patients in the age ranges recited in claims 12 and 13. Therefore, we affirm § 103 rejection of claims 12 and 13.

Summary

We affirm the rejection of claims 1, 6, 7, and 9 under 35 U.S.C. § 102 over Zapla, the rejection of claims 1 and 11 under 35 U.S.C. § 102 over Hata, and the rejection of claims 1 and 5-17 under 35 U.S.C. § 103. Because our reasoning with regard to claim 8 differs from that of the examiner, we designate our affirmance of the rejection of this claim as a new ground of rejection under 37 CFR § 41.50(b) in order to give Appellant a fair opportunity to respond.

Time Period for Response

Regarding the affirmed rejections, 37 CFR § 41.52(a)(1) provides "Appellant may file a single request for rehearing within two months from the date of the original decision of the Board."

In addition to affirming the examiner's rejections of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(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 the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should Appellant elect to prosecute further before the examiner pursuant to 37 CFR § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejections, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If Appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

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

AFFIRMED, 37 CFR § 41.50(b)

Toni R. Scheiner
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