

The opinion in support of the decision being entered today
is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte IAN D. DUNCAN

Appeal 2007-2254
Application 10/383,115
Technology Center 1600

Decided July 24, 2007

Before DONALD E. ADAMS, ERIC GRIMES, and NANCY J. LINCK,
Administrative Patent Judges.

Opinion by GRIMES, *Administrative Patent Judge*. Concurring opinion by
ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to methods that use particular tetracycline compounds for treating Alzheimer's disease. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

The Specification describes "a method of treating neurologic disorders such as Alzheimer's disease, . . . by administering an effective amount of a

tetracycline compound” (Specification 2). Examples of tetracycline compounds include doxycycline and minocycline (*id.* at 3).

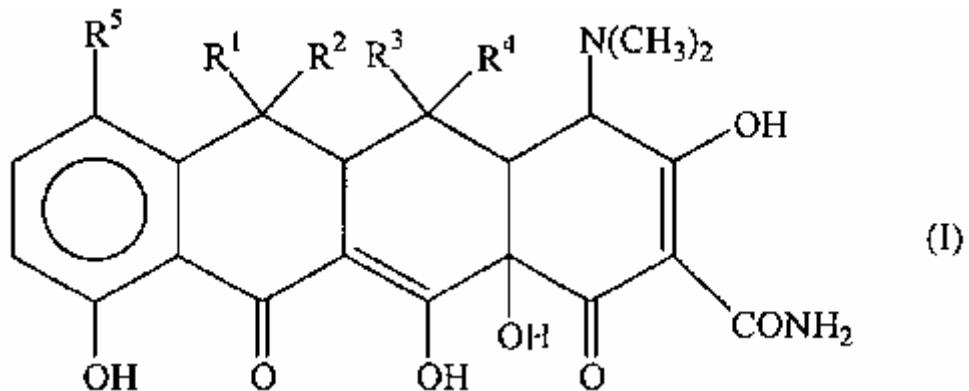
The Specification states that the “maximal dosage [of the tetracycline compound] for a subject is the highest dosage, which does not cause undesirable or intolerable side effects” (*id.* at 5). The Specification contemplates “doses from about 0.1 mg/kg/day to about 45 mg/kg/day, and suitably, from about 1 mg/kg/day to about 18 mg/kg/day” (*id.*).

DISCUSSION

1. CLAIMS

Claims 1-3, 7, 9, 14, 15, 17, 20, 21, 30, 31, 47, and 48 are pending and on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 1, which is representative and reads as follows:

1. A method of treating Alzheimers’ disease comprising administering to a mammal in need thereof a tetracycline compound formula (I)



wherein R¹ is H, CH₃ or OH and R² is H or OH, or R¹ and R² taken together are =CH₂, R³ and R⁴ are H or OH and R⁵ is H, Cl or N(CH₃)₂, in an amount effective to inhibit or reduce amyloid plaque formation

2. REFERENCES

The Examiner relies on the following references:

- | | | |
|---|----------------|--------------|
| Amin | U.S. 5,919,775 | Jul. 6, 1999 |
| Andréa C. LeBlanc et al., <i>Processing of Amyloid Precursor Protein in Human Primary Neuron and Astrocyte Cultures</i> , J. of Neurochemistry 1183-1190 (1997) (“LeBlanc”). | | |
| Juha Yrjänheikki et al., <i>Tetracyclines inhibit microglial activation and are neuroprotective in global brain ischemia</i> , 95 Proc. Natl. Acad. Sci. USA 15769-15774 (December 1998) (“Yrjänheikki”). | | |

3. OBVIOUSNESS

Claims 1-3, 7, 9, 14, 15, 17, 20, 21, 30, 31, 47, and 48 stand rejected under 35 U.S.C. § 103 as obvious over Amin and Yrjanheikki in view of LeBlanc.¹ The Examiner relies on Amin for teaching “the administration of tetracycline compounds to treat various inflammatory conditions characterized by nitric oxide production,” including Alzheimer’s disease (Answer 4). The Examiner argues that the “tetracycline compounds contemplated are disclosed in column 3 and . . . [include minocycline and doxycycline,]” and that “[o]ptimal dosages are disclosed in column 8, lines 59-66, which overlap with those recited in instant claims 14 and 15”

¹ The Examiner relies on Yrjänheikki and LeBlanc for teaching limitations of claims other than claim 1. However, because Appellant has not separately argued the claims, we need not discuss these references.

(*id.*). The Examiner also argues that the “determination of a preferred tetracycline, as well as optimal dosages, . . . are parameters well within the purview of those skilled in the art through no more than routine experimentation in view of the established utility of tetracyclines and the guidance provided by Amin” (*id.* at 5).

We conclude that the Examiner has set forth a *prima facie* case of obviousness. Amin describes “a method for inhibiting nitric oxide production or nitric oxide synthase expression or activity in a biological system by providing a tetracycline compound to the system in an amount which is effective to achieve the specified result” (Amin, col. 4, ll. 37-41). “Highly preferred tetracycline compounds include . . . doxycycline, or minocycline” (*id.* at col. 4, ll. 45-50). Amin also discloses that “NO [nitric oxide] appears to be involved in various medical conditions, including . . . neurodegenerative disorders such as Alzheimer’s disease” and that the “invention can be used to treat any of these diseases” (*id.* at col. 7, ll. 21-35).

In addition, Amin describes administering the tetracycline compounds in “the highest dosage which does not cause undesirable or intolerable side effects,” such as “in an amount of from about 0.1 mg/kg/day to about 30 mg/kg/day, and preferably from about 1 mg/kg/day to about 18 mg/kg/day” (*id.* at col. 8, ll. 59-64). Amin does not specifically describe administering the tetracycline compounds “in an amount effective to inhibit or reduce amyloid plaque formation,” as recited in claim 1. However, the amounts described in Amin overlap with the amounts described in the Specification at page 5 and in claims 14 and 15, which directly or indirectly depend from claim 1. Overlapping ranges support a *prima facie* case of

obviousness. *See In re Geisler*, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997). Therefore, we agree with the Examiner that the amounts suggested by Amin would inherently be “effective to inhibit or reduce amyloid plaque formation.”

Appellant argues that Amin “provides only the barest speculation that NO and/or overexpression of iNOS [inducible nitric oxide synthase] *may* be associated with Alzheimer’s pathology” and that “[s]uch speculative remarks . . . do not rise to the level of providing motivation to arrive at the presently claimed methods, nor do they rise to the level of providing any reasonable expectation of success” (Br. 7-8). Appellant argues that, “at best, [Amin] can only be considered an invitation to experiment” (*id.* at 8).

We are not persuaded by this argument. We conclude that Amin provides motivation to administer tetracycline compounds, such as the ones recited in claim 1, to treat Alzheimer’s disease. Amin states that “NO appears to be involved in various medical conditions, including . . . Alzheimer’s disease,” and that, “[s]ince many of these conditions are characterized by alterations in cytokine expression, it may well be that abnormally high expression or activity of inducible NOS is a key factor in the associated pathology” (*id.* at col. 7, ll. 21-34).

We do not agree that use of the terms “appears” and “it may well be” renders Amin sufficiently speculative such that one of ordinary skill in the art would not have had a reasonable expectation of success. In fact, Amin states that its invention “can be used to treat any of these diseases,” including Alzheimer’s disease (Amin, col. 7, ll. 34-35). We agree with the Examiner that these teachings in Amin would have provided one of ordinary

skill in the art with a reasonable expectation of success in treating Alzheimer's disease with tetracycline compounds, such as the ones recited in claim 1. "Obviousness does not require absolute predictability of success." *In re O'Farrell*, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

SUMMARY

We conclude that the Examiner has set forth a *prima facie* case that claim 1 would have been obvious over Amin and Yrjanheikki in view of LeBlanc, which Appellant has not rebutted. We therefore affirm the rejection of claim 1 under 35 U.S.C. § 103. Claims 2, 3, 7, 9, 14, 15, 17, 20, 21, 30, 31, 47, and 48 fall with claim 1.

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

ADAMS, *Administrative Patent Judge*, concurring.

I agree that claim 1 is the *prima facie* obvious under 35 U.S.C. § 103 the combination of Amin, Yrjanheikki and LeBlanc. I write separately, however, to clarify the basis for affirming the rejection of record.

Claim 1 is drawn to a method of treating Alzheimer's disease. The method requires that a tetracycline compound of formula (I) be administered to a mammal in an amount effect to inhibit or reduce amyloid plaque formation. As the majority and the Examiner recognize (*supra* 4 and Answer 4 respectively), Amin teaches the administration of tetracycline compounds within the scope of formula (I) to Alzheimer's patients (Amin, col. 7, ll. 21-25). Accordingly, the patient population in Amin is the same as that required in Appellant's claim 1. In addition, as the majority and the Examiner recognize (*supra* 4 and Answer 4 respectively), Amin teaches the administration of this tetracycline compound in an amount that overlaps the amount Appellant discloses to be effective (*cf.* Amin, col. 8, ll. 59-64 and Appellant's Specification 5: 12-16). More specifically, both Amin and Appellant's Specification disclose the same preferred range of from about 1 mg/kg/day to about 18 mg/kg/day (*id.*). Thus, Amin teaches the administration of the same effect amount of a tetracycline compound of formula I to the same patient population required in Appellant's claim 1.

While the majority is correct in their finding that “[o]verlapping ranges support a *prima facie* case of obviousness. *See In re Geisler*, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997),” the majority incorrectly bases their finding of obviousness on the rationale that “the

amounts suggested by Amin would *inherently* be ‘effective to inhibit or reduce amyloid plaque formation’” (*supra* 5, emphasis added). In this regard, I note that “[o]bviousness and inherency are different issues. ‘That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.’” *In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966).

As the majority recognizes “Amin does not specifically describe administering the tetracycline compounds ‘in an amount effective to inhibit or reduce amyloid plaque formation,’ as recited in claim 1” (*supra* 4). Instead, Amin teaches the use of tetracycline compounds within the scope of formula I to treat inflammatory and other diseases where NO production or iNOS expression or activity play a role (Amin, col. 7, ll. 5-20). As discussed above, Amin teach that Alzheimer’s disease is a disease in which NO appears to be involved. Thus, as the majority correctly points out “Amin provides motivation to administer tetracycline compounds, such as the ones recited in claim 1, to treat Alzheimer’s disease” (*supra* 5). Therefore, notwithstanding Amin’s lack of a specific teaching to inhibit or reduce amyloid plaque formation in Alzheimer’s patients by administering a tetracycline compound of formula I, “[i]t is a general rule that merely discovering and claiming a new benefit of an *old* process cannot render the process again patentable. *Verdegaal Bros., Inc. v. Union Oil Co. of Calif.*, 814 F.2d 628, 632-33, 2 USPQ2d 1051, 1054 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987); *Bird Provision Co. v. Owens Country Sausage, Inc.*, 568 F.2d 369, 375, 197 USPQ 134, 139 (5th Cir. 1978).” *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

On this record, Appellant's claim 1 is directed to the discovery of a new benefit of the old process taught by Amin. In my opinion, this newly discovered benefit of Amin's process does not render Appellant's process patentable.

Accordingly, I agree with the majority's decision to affirm the rejection of claim 1 under 35 U.S.C. § 103. Claims 2, 3, 7, 9, 14, 15, 17, 20, 21, 30, 31, 47, and 48 fall with claim 1.

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MICHAEL BEST & FRIEDRICH, LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON WI 53701