

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHARLES P. TAYLOR JR.
and MARK L. WEBER

Appeal No. 95-2743
Application 08/023,016¹

ON BRIEF

Before WILLIAM F. SMITH, METZ and ELLIS, **Administrative Patent Judges**.

ELLIS, **Administrative Patent Judge**.

DECISION ON APPEAL

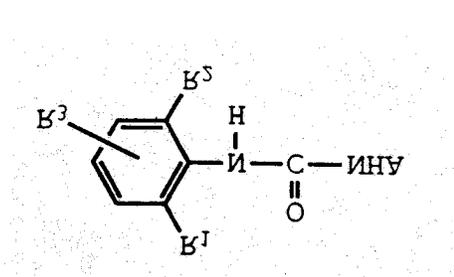
This is an appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 1, 2 and 4 through 19, all the claims remaining in the application.

¹ Application for patent filed February 25, 1993.

Claims 1, 2 and 4 are illustrative of the subject matter on appeal and read as follows:

1. A method for treating neurodegenerative diseases or disorders which comprises administering to a mammal in need a therapeutically effective amount of a compound selected from ralitoline, phenytoin, lamotrigine, carbamazepine, lidocaine or tetrodotoxin.

2. A method for treating neurodegenerative diseases or disorders to a mammal in need a amount of a compound



for treating neurodegenerative which comprises administering therapeutically effective of formula

wherein A is 4-pyridinyl; R₁ and R₂ are independently halogen, lower alkyl, lower alkoxy, or nitro, and R₃ is hydrogen, halogen, lower alkyl, lower alkoxy, or nitro, or a pharmaceutically acceptable acid addition salt thereof.

4. A method according to Claim 2 wherein the neurodegenerative disorder is acute brain injury.

The references relied on by the examiner are:

Lobbestael et al. (Lobbestael) 4,629,731 Dec. 16, 1986

Berkow, **The Merck Manual of Diagnosis and Therapy** (Merck Manual), Fourteenth Edition, Merck Sharp & Dohme Research Laboratories, Rahway, N.J., pp. 1304-13 (1982).

The references relied on by the appellants are:

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Scrip's Neurodegenerative Disorders Report, "Recent Trends in Research and Treatment of Neurodegenerative Disorders," PJB Publications, Ltd., pp. i-vi, 1-3, 165-170, & 205 (1992).

Bensimon et al. (Bensimon), "A Controlled Trial of Riluzone in Amyotrophic Lateral Sclerosis," **The New England Journal of Medicine**, Vol. 330, No. 9, pp. 585-591 (Mar. 3, 1994).

The claims stand rejected as follows:

I. Claims 1, 2 and 4 through 19 stand rejected under 35 U.S.C. § 101 as the claimed invention lacks patentable utility.

II. Claims 1, 2 and 4 through 19 stand rejected under 35 U.S.C. § 112, first paragraph, as "the disclosure is enabling only for claims limited in accord with the entire disclosure." Answer, p. 3.

III. Claims 1, 2 and 4 through 19 stand rejected under 35 U.S.C. § 103 as being unpatentable over Lobbestael and the Merck Manual.

We **reverse**.

Discussion

I.

The present invention is directed to a method of treating neurodegenerative diseases using known anticonvulsant compounds. Brief, p. 1.

The examiner argues that the claimed method lacks patentable utility as it encompasses the treatment of dementia conditions such as Alzheimer's disease. Answer, p. 3. According to the examiner, the "claims are incredible because there is

no treatment for dementia.” *Id.* The examiner cites the Merck Manual for support.

In addition, the examiner argues that (i) “there is no model recognized as reasonably predictive of success for treating Alzheimer’s disease,” and (ii) “Applicant fails to provide a general teaching that Applicant’s *in-vitro* assay is recognized by those skilled in the art as reasonably predictive for effective treatment of Alzheimer’s disease.” *Id.*

We find that the examiner’s position cannot be sustained.

It is well settled that “a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented *must* be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter *unless* there is reason for one skilled in the art to question the objective truth of the statement of utility or its scope.” *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 289, 297 (CCPA 1974). Here, we find that the examiner has not provided sufficient reasons as to why such persons would question the specification’s statements of utility. To the contrary, a complete reading of the only reference cited by the examiner, the Merck Manual, describes several types of dementia which are treatable and states that “dementia should not be regarded as a hopeless condition . . . Each case requires careful consideration, and the most appropriate investigations should be selected for each patient.” Merck Manual, p. 1309, col. 2, first complete para. In addition, the appellants have provided two references which describe potential treatments for neurodegenerative diseases including, *inter alia*, Alzheimer’s disease. Brief, p. 4, and attachments thereto. Conspicuous in its

absence, is any response by the examiner to the teachings of these references. Absent evidence to the contrary, we must presume that the appellants' references reflect the thinking of those skilled in the art with respect to useful treatments of neurodegenerative disorders; i.e., that these references demonstrate that one skilled in the art would not question the specification's statement of utility.

Accordingly, the rejection is reversed.

II.

Turning to the rejection under the first paragraph of § 112, we find the examiner argues that:

The following claims fail to identify a host with the treating [sic]: 4-19. Further, "a compound having anticonvulsant properties...etc." is broader than specific supporting embodiments.

Those claims are broader than warranted. As discussed supra, there is no effective dementia treatment, and Applicants failed to establish that Applicants' *in-vitro* assay reasonably predicts successful dementia therapy. Therefore, it would require undue experimentation by one skilled in the art to employ the method because she would have to determine whether it worked or not without guidance from Applicants [Answer, pp. 3-4].

We find these arguments unpersuasive.

First, it is not clear what the examiner intends by her statement that claims 4-19 fail to identify a host. These claims are dependent on claim 2 which identifies the host as a "mammal." The examiner has not raised any objection with respect to the

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mammalian host of claim 2 (or the mammalian host of claim 1), thus, it is not clear what § 112, first paragraph, issues the examiner intends.

As to the remainder of the rejection, it appears that the examiner is concerned that one skilled in the art could not make and use the claimed invention throughout its scope without undue experimentation. To that end we direct attention to **PPG Indus., Inc. v. Guardian Indus. Corp.**, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) wherein it was held that:

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., **In re Goodman**, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); **Amgen, Inc. v. Chugai Pharmaceutical Co.**, 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), **cert. denied**, 502 U.S. 856 (1991); **In re Vaeck**, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation “must not be unduly extensive.” **Atlas**

Powder Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.
Ex parte Jackson, 217 USPQ 804, 807 (1982).

As we discussed above, the examiner has not met her burden of establishing that there is no effective treatment for dementia. In fact, the evidence of record, demonstrates the contrary; i.e, numerous potential treatments for neurodegenerative diseases and disorders are under consideration. In the case before us, all we have is the examiner's assertion that one skilled in the art cannot make and use the claimed invention without undue experimentation. We do not find that the examiner has performed the fact finding necessary to support this assertion. Accordingly, we reverse the rejection.

III.

Turning to the rejection under 35 U.S.C. § 103, we find that the examiner has cited two references which allegedly render the claimed method unpatentable. Answer, p. 4. However, we do not find any statement of a rejection. Rather than explaining why the claimed invention would have been obvious in view of particular teachings in the cited

references, the examiner only responds to the arguments presented by the appellants in their main brief. The examiner has not (i) engaged in a proper, fact-based analysis of what subject matter is encompassed by the claims, or (ii) explained the relevance of the applied prior art. Simply put, the examiner has not met her burden of presenting a ***prima facie*** case of obviousness by showing that objective teachings in the applied prior art would have suggested the claimed invention to one of ordinary skill in the art. Accordingly, although we reverse the rejection, this does not mean that we find that the references cited by the examiner are not relevant. See the “Other Issues” section, ***infra***.

Other Issues

Upon return of this application to the examining corps, the examiner should consider whether she has adequately determined what subject matter is encompassed by the claims. In order to make a determination of obviousness, the examiner must first interpret and understand what is the claimed invention. ***Panduit Corp. v. Dennison Mfg. Co.***, 810 F.2d 1561, 1567, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987). We remind the examiner that it is well settled that “[d]uring patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.” ***In re Zletz***, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); ***In re Prater***, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969). Moreover, the “specification acts as a dictionary when it expressly defines terms used in the claims ...

claims must be read in view of the specification of which they are a part.” ***Vitronics Corp. v. Conceptronic Inc.***, 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1577 (Fed. Cir. 1996).

With this background in mind, we point out that the claims are not limited to the treatment of neurodegenerative diseases, as argued by the appellants in their brief, but that they include the treatment of neurodegenerative ***disorders***. In turning first to the specification to determine the meaning of the terms within the claims, we find that it discloses that neurodegenerative disorders include, ***inter alia***, head trauma.² Specification, p. 1, lines 21-24. The specification further discloses that “the instant invention would be useful in a range of incidents, for example, in ... status epilepticus.”³ ***Id.***, p. 2, lines 4-8. The specification still further discloses that “U.S. Patent 4,629,731 [Lobbestael] covers the phenyl pyridinyl urea compounds of the instant invention... and their use as an anticonvulsant.” Specification, p. 3, lines 32-35. The specification states that “[t]he term convulsions is intended to mean the characteristic body movements which are associated with the group of chronic central nervous system ***disorders*** termed epilepsies” [emphasis added]. ***Id.***, sentence bridging pp. 3-4. Thus, upon return of this application, the examiner should consider making a fact-based analysis and setting forth, on the

² The Merck Index relied on by the examiner teaches that epilepsy may be associated with a variety of cerebral disorders which include cerebral trauma.

³ Stedman’s Medical Dictionary, 24th Edition, defines status epilepticus as “a condition in which one major attack of epilepsy succeeds another with little or no intermission.” Stedman’s, p. 1334; copy attached to this decision.

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record, what conditions are encompassed by the phrase “neurological disorders.”

As to the claimed compounds, we point out that it is not clear from the examiner’s rejection which, if any, of the compounds set forth in claim 1 are taught by Lobbestael. We further point out that the specification discloses that the compounds described in claim 1 are known in the art. Specification, p. 8, lines 1-14. Thus, upon return of the application, the examiner should consider retrieving the prior art cited in the referenced section of the specification and evaluating them to determine whether they teach or suggest using the claimed compounds to treat neurological diseases or disorders. After making such analyses, the examiner will be in a better position to determine whether the claimed methods would have been obvious to one of ordinary skill in the art in view of the teachings of Lobbestael and the Merck Manual.

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The decision of the examiner is reversed.

REVERSED

WILLIAM F. SMITH)	
Administrative Patent Judge)	
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ANDREW H. METZ)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
)	
JOAN ELLIS)	
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