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for publication and is not binding precedent of the Board.

Paper No. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN C.S. BREITNER and KATHLEEN A. WELSH-BOHMER

Appeal No. 2003-0865
Application No. 09/300,789

ON BRIEF

Before WILLIAM F. SMITH, SCHEINER, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-23 and 26, all of the claims remaining. Claims 1, 11, and 23 are representative and read as follows:

1. A method of preventing or delaying the onset of the clinical symptoms of Alzheimer's disease or related neurodegenerative disorder comprising:

i) identifying an individual at risk of developing said disease or disorder;

ii) administering to said individual an amount of a nonsteroidal anti-inflammatory agent sufficient to effect said prevention or delay; and

iii) monitoring said individual for the development of clinical symptoms of said disease or disorder.

11. A method of preventing or delaying the onset of Alzheimer's disease or related neurodegenerative disorder. The method comprises:

i) identifying an individual at risk of developing the disease or disorder;

ii) administering to the individual an amount of a histamine H2 receptor blocking agent sufficient to effect the prevention or delay; and

iii) monitoring the individual for the development of clinical symptoms of the disease or disorder.

23. A method of preventing or delaying the onset of Alzheimer's disease or related neurodegenerative disorder comprising:

i) identifying an individual at risk of developing the disease or disorder;

ii) administering to the individual an amount of an agent that inhibits excitotoxic neuronal cell death sufficient to effect the prevention or delay; and

iii) monitoring the individual for the development of clinical symptoms of said disease or disorder.

The examiner does not rely on any references.

Claims 1-23 and 26 stand rejected under 35 U.S.C. § 101 as lacking utility, and claim 23 stands rejected under 35 U.S.C. § 112, first paragraph, as nonenabled.

We reverse both rejections.

Background

The specification discloses "a method of preventing or delaying the onset and progression of Alzheimer's disease and related neurodegenerative disorders. The method involves the administration to individuals at risk of developing the disease a non-steroidal anti-inflammatory agent and/or a histamine H2 receptor blocking agent." Page 1. Exemplary nonsteroidal anti-inflammatory agents include acetylsalicylic acid (aspirin) and ibuprofen. See pages 9-10. Exemplary histamine H2 receptor blocking agents include ranitidine (Zantac®). Page 10.

The specification theorizes that

> both nonsteroidal anti-inflammatory agents and histamine H2 receptor blocking agents may inhibit the pathogenesitic process of Alzheimer's disease . . . via processes mediated by COX [cyclooxygenase], including excitatory events in the n-methyl-d-aspartate (NMDA) pathway. . . . Under aberrant conditions (eg [sic], excessive stimulation), the NMDA pathway can induce excitotoxic cell death. . . . The fact that both nonsteroidal anti-inflammatory agents and H2 blockers prevent or delay the onset of Alzheimer's disease may result from the involvement of COX and the NMDA pathway in development of the disease.

Pages 12-13. Based on this observation, the specification speculates that "inhibition of Alzheimer's disease pathogenesis can be expected to be effected using compounds, other than those described above, that similarly impact on the NMDA pathway and thereby protect against neuronal cell death that may underlie the neurodegeneration of Alzheimer's disease and related disorders." Pages 13-14.

Discussion

The claims are directed to a "method of preventing or delaying the onset" of Alzheimer's disease or another neurodegenerative disease, by identifying an individual at risk of the disease, administering a nonsteroidal anti-inflammatory agent and/or a histamine H2 receptor blocking agent, and monitoring the individual for onset of the disease. The examiner rejected all of the claims as lacking utility, and rejected claim 23 as nonenabled.

1. Utility

The examiner rejected the claims as inoperative, and therefore as lacking the utility required by 35 U.S.C. § 101. The examiner reasoned that

> [t]he claims are drawn to preventing the onset of the clinical symptoms of Alzheimer's disease and preventing the onset of the clinical symptoms of related neurodegenerative disorders. As of the filing of the instant application no successful model or trial has been demonstrated by the applicants or by any other practitioner for the preventing [of] the onset of the clinical symptoms of Alzheimer's disease. . . .

Paper No. 9, page 2 (emphases in original).

Notwithstanding the evidence provided on pages 15-34 of the specification, the examiner also asserted that "Applicants have not provided any evidence for preventing the onset of the clinical symptoms of Alzheimer's disease." Id., page 3. The examiner apparently reasoned that no amount of evidence would suffice to show "prevention" of Alzheimer's symptoms. See id.:

> Regarding any putative evidence of prevention [of] the onset of Alzheimer's disease, such cannot be forthcoming because there is no time limit for the onset of the disease. That is, the disease can arise at any time after any experimentally designated time limit.

Id., page 3.

We reverse the examiner's rejection. First, we disagree with the examiner's position that, since "the disease can arise at any time after any experimentally designated time limit," preventing the symptoms of Alzheimer's disease cannot be proven by experimental evidence. We agree instead with Appellants that "a sufficient delay constitutes prevention." Appeal Brief, page 6. That is, if the symptoms of Alzheimer's disease are delayed sufficiently that the individual dies before the symptoms manifest themselves, the symptoms of Alzheimer's disease have been effectively prevented.

In addition, even if the examiner's interpretation was correct, the rejection is improper for another reason: the claims are not directed to a method of "preventing" the symptoms of Alzheimer's disease; they are directed to a method of preventing or delaying the onset of those symptoms. Thus, the claimed method is operative if it functions to either prevent or delay the onset of symptoms. The examiner has not asserted that the claimed method does not function to delay the onset of Alzheimer's disease symptoms. Therefore, the method is not inoperative. The rejection under 35 U.S.C. § 101 is reversed.

2. Enablement

The examiner rejected claim 23 as nonenabled. Claim 23, unlike the other claims on appeal, is not limited to administration of a nonsteroidal anti-inflammatory agent and/or a histamine H2 receptor blocking agent. Claim 23 encompasses administration of any "agent that inhibits excitotoxic neuronal cell death." The examiner's rejection reads as follows:

> Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for non-steroidal anti-inflammatory agents and histamine H2 receptor blocking agents, does not reasonably provide enablement for any agents that can inhibit excitotoxic neuronal cell death. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims [sic]. On page 4, line 26 bridging page 5, line 3, applicants disclose nonsteroidal anti-inflammatory agents and histamine H2 receptor blocking agents. No other agents are disclosed.

Paper No. 9, page 4.

Appellants argue that "the Examiner has provided no evidence or reasoning inconsistent with the disclosure to support her view." Appeal Brief, page 7.

Again, we agree with Appellants. The examiner bears the burden of showing that practicing the full scope of the claimed invention would have required undue experimentation. See In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions

of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

Here, the examiner has provided no evidence or scientific reasoning to show that undue experimentation would have been required in order to practice the claimed method using agents other than nonsteroidal anti-inflammatory agents and histamine H2 receptor blocking agents. The examiner cannot satisfy her burden of showing nonenablement simply by pointing out that no other specific agents are disclosed in the specification.

The guidance provided in the specification is only the starting point for the enablement analysis. "[A] patent need not teach, and preferably omits, what is well known in the art." Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1987). Thus, a proper analysis of enablement in this case must take into account other agents known in the art that inhibit excitotoxic neuronal cell death. Other potentially relevant considerations are set out in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The examiner has provided no evidence that agents, other than nonsteroidal anti-inflammatory agents and histamine H2 blockers, having the recited property could not have been identified through routine experimentation.

Therefore, she has not carried the initial burden of showing nonenablement. The rejection under 35 U.S.C. § 112, first paragraph, is reversed.

Summary

The examiner has not shown that the claimed method was inoperative, or that the method of claim 23 would have required undue experimentation to practice. We therefore reverse the rejections under 35 U.S.C. §§ 101 and 112, first paragraph.

REVERSED

WILLIAM F. SMITH Administrative Patent Judge	))))
TONI R. SCHEINER Administrative Patent Judge	) BOARD OF PATENT)) APPEALS AND)) INTERFERENCES)
ERIC GRIMES Administrative Patent Judge	))

EG/vsh

NIXON & VANDERHYE
1100 NORTH GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714