

The opinion in support of the decision being entered today was not written for publication in a law journal and is not binding precedent of the Board.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 JILL A. PANETTA,
MICHAEL L. PHILLIPS, JON K. REEL,
JOHN K. SHADLE, SANDRA K. SIGMUND,
RICHARD L. SIMON and CELIA A. WHITESITT

Appeal No. 1997-2741
Application 08/213,873

ON BRIEF

Before WINTERS, ROBINSON, 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 1-8. Claim 9, the other pending claim in the application,¹ is not subject to any outstanding rejection.

¹ Originally, the application contained claims 1-24, all of which were rejected by the examiner. An amendment after the final rejection, canceling claims 10-24, was received on September 4, 1996, and approved for entry by the examiner. The amendment, however, was never entered. Upon return of this case, the examiner should see to it that this amendment is properly entered.

The claims are drawn to a method of treating conditions associated with β -amyloid peptide, including Alzheimer's disease and Down's syndrome, by administering one of a class of benzylidene rhodanine compounds. The examiner has rejected the claims under 35 U.S.C. § 112, first paragraph, on the basis that the specification does not enable practice of the full scope of the claimed invention without undue experimentation.

We reverse.

Background

As stated in Appellants' specification, aberrant production of β -amyloid peptide is associated with various disorders, including Alzheimer's disease, Down's syndrome, and advanced aging of the brain. See pages 1-2 and 99. The specification also states that the protease cathepsin D appears to be involved in the processing of β -amyloid peptide and the formation of associated plaques, and that inhibition of cathepsin D reduces β -amyloid plaques. Pages 3-4. Accordingly, Appellants claim a method of treating a disease associated with β -amyloid peptide by administering to a patient a benzylidene rhodanine compound which is disclosed to inhibit cathepsin D.

Discussion

As understood, the examiner rejected the claims because the specification provides insufficient guidance to enable a person of ordinary skill in the art to

practice the full scope of the claimed invention without undue experimentation.²

The examiner has conceded that the specification enables inhibition of β -amyloid peptide production in the brain (Examiner's Answer, page 3). However, he notes that the specification contains "no discussion or guidelines at all of any other organ system which is associated with β -amyloid. Nor is there any evidence that aspartyl protease (cathepsin D) is present in any system other than the brain."

Id. The examiner argues that the specification is not enabling for the full scope of the claims because its guidance "is limited to the brain system." Examiner's Answer, page 4.

Appellants state that "there are conditions in organs other than the brain which are associated with β -amyloid peptide," although they fail to identify any such disorders. Appellants argue that the full scope of the claims is enabled by the specification. In particular, Appellants point out that the level of ordinary skill in the art (of clinical medicine, presumably) is very high and that skilled artisans would be familiar with dosing schedules and regimens for the disclosed compounds. Appellants also argue that assays to test the cathepsin D-inhibiting activity of the subject compounds are disclosed, and that the scope of the claims

² The basis of the examiner's rejection is not as clear as it could be because of a pronounced change in emphasis between the final rejection and the Examiner's Answer. In the final rejection, the Examiner rejected the claims "under 35 U.S.C. § 112, first and second paragraphs." The explanation given was that "[t]he specification teaches the use of the compounds in the brain. However, there are other conditions 'associated with β -amyloid peptide' in other organ systems A [sic] which specification does not teach." The final rejection did not state with any clarity that it was on the basis of non-enablement. The Examiner's Answer explains, for the first time, that the rejection is based on non-enablement.

is “relatively modest.” Based on these factors, Appellants argue that the claims are enabled by the specification.

It is well-settled that enablement under 35 U.S.C. § 112, first paragraph, requires that a person of skill in the art be able to practice the full scope of the claimed invention without undue experimentation. Before considering the enablement issue, however, the claims must be construed to determine their proper scope. See, e.g., In re Cortright, 165 F.3d 1353, 1357, 49 USPQ2d 1464, 1466-67 (Fed. Cir. 1999). “[A]s an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant’s specification.” In re Morris, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

Here, the claims are drawn to a method of treating “a condition associated with β -amyloid peptide.” As the examiner notes, the specification contains no discussion of conditions associated with β -amyloid peptide in organ systems other than the brain. Notably, the title of the application at issue is “Treatment of Alzheimer’s Disease Employing Inhibitors of Cathepsin D.” In fact, the specification’s discussion of β -amyloid-associated disorders is almost entirely limited to Alzheimer’s disease. See, e.g., page 1, lines 13-15 (“it was proposed early on that β -amyloid peptide is involved in . . . Alzheimer’s disease”); page 3,

lines 29-30 (“elevated activity of cathepsin D has been observed in the brains of Alzheimer’s patients”); and page 4, lines 8-9 (“This invention provides methods for the treatment of Alzheimer’s disease in mammals.”).

In the only place the specification refers to any β -amyloid-associated disorders other than Alzheimer’s disease, it merely mentions two other brain disorders as subject to treatment with the disclosed compounds. See page 99, lines 9-13 (“The compounds of the present invention can be administered for prophylactic and/or therapeutic treatment of diseases related to the deposition of β -amyloid peptide, such as Alzheimer’s disease, Down’s syndrome, and advanced aging of the brain.”).

Thus, the specification and the prior art cited therein are focused entirely on disorders of the brain, and almost entirely on Alzheimer’s disease. The specification does not identify a single disorder associated with β -amyloid peptide that occurs in an organ other than the brain. The only indication in the record that β -amyloid peptide is associated with any disorders outside of the brain is in the Appeal Brief, where Appellants state that “there are conditions in organs other than the brain which are associated with β -amyloid protein.” Page 5. Appellants characterize such conditions as “well known to those of ordinary skill in the art,” but do not cite any evidence in the record that either supports this assertion or identifies such a condition.

While attorney argument can in some circumstances limit the scope of patent claims by means of prosecution history estoppel, see Haynes Int’l, Inc. v.

Jessop Steel Co., 8 F.3d 1573, 1579, 28 USPQ2d 1652, 1657 (Fed. Cir. 1993), we are aware of no authority saying that claims can be broadened beyond the scope defined by the specification merely through attorney argument. We therefore decline to accept Appellants' unsupported assertion that a person of ordinary skill in the art would know that β -amyloid peptide is associated with conditions in organs other than the brain.

Thus, when we read the claims in light of the specification, we conclude that the scope of the properly construed claims is limited to a method of treating a condition of the brain that is associated with β -amyloid peptide. This is the broadest reasonable meaning of the words in the claim, as they would be understood by one of ordinary skill in the art, taking into account the enlightenment that is afforded by Appellants' specification. See In re Morris, 127 F.3d at 1054, 44 USPQ2d at 1027.

Having construed the claims, we can now turn to the issue of enablement. When we do so, we conclude that proper interpretation of the claims has effectively disposed of the enablement issue. The examiner has conceded that the specification is enabling for inhibiting β -amyloid peptide production in the brain, and we have concluded that the scope of the claims is limited to treatment of disorders of the brain. Therefore, the examiner's position would appear to be that the claims as we have construed them are enabled throughout their scope.

Other Issues

We note that the application file contains an Information Disclosure Statement that was submitted on August 5, 1994, before the first Office action. The IDS was never initialed by the examiner to show that he considered the cited references. We also note that only the first two of the cited references are currently in the application file. (Whether the other references cited were also present at one time, we cannot tell.) Upon return of the case, the examiner should treat the IDS as appropriate under 37 CFR §§ 1.97 and 1.98.

Summary

We reverse the rejection for lack of enablement because the claims, properly construed, are limited to treatment of brain disorders and the examiner has conceded that the specification enables such treatments.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Douglas W. Robinson)	
Administrative Patent Judge)	APPEALS AND
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