

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PHILIP S. PORTOGHESE and SANDRA L. OLMSTED

Appeal No. 1998-1489
Application 08/449,224

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ROBINSON, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

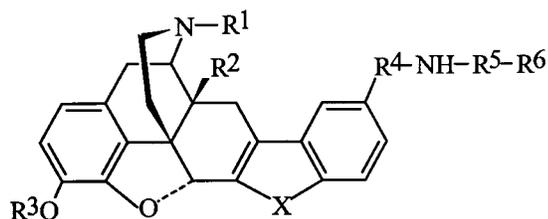
DECISION ON APPEAL

This appeal was taken from the examiner's decision finally rejecting claims 1 through 9 and 22, which are all of the claims remaining in the application.

REPRESENTATIVE CLAIMS

Claims 1 and 22, which are illustrative of the subject matter on appeal, read as follows:

1. A compound of the formula:



wherein R¹ is (C₁-C₅)alkyl, C₃-C₆(cycloalkyl)alkyl, C₅-C₇(cycloalkenyl)alkyl, (C₆-C₁₂)aryl (C₇-C₁₂)aralkyl, trans(C₄-C₅)alkenyl, allyl or furan-2-ylalkyl, R² is H, OH or O₂C(C₁-C₅)alkyl; R³ is H, (C₇-C₁₀)aralkyl, (C₁-C₅)-alkyl or (C₁-C₅)alkylCO; X is O, S or NY, wherein Y is H or (C₁-C₅)alkyl; R⁴ is CH₂ or C=O, R⁵ is CH₂, C=O or C=NH and R⁶ is (C₁-C₄)alkyl or NH(C₁-C₄)alkyl, optionally substituted by a non-terminal (C₁-C₂)alkyl group or by N(R⁷)(R⁸) wherein R⁷ and R⁸ are individually H or (C₁-C₃)alkyl, with the proviso that one of R⁴ or R⁵ is CH₂, and the pharmaceutically acceptable salts thereof.

22. A method for selectively blocking the binding of a kappa opioid-receptor agonist to kappa opioid receptors in mammalian tissue comprising said receptors, said method comprising contacting said tissue with an effective amount of a compound of claim 1 to block said receptors.

THE REFERENCES

In rejecting the appealed claims on non-prior art grounds, the examiner relies on these references.

Dappen et al. (Dappen '417)	5,225,417	Jul. 6, 1993
Dappen et al. (Dappen '249)	5,436,249	Jul. 25, 1995

GROUND OF REJECTION

Claims 1 through 9 and 22 stand rejected under 35 U.S.C. § 112, first and second paragraphs, as based on a non-enabling disclosure “and/or” failing to particularly point out and distinctly claim the subject matter which appellants regard as their invention (Final Rejection, Page 3)¹

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials:

- (1) the instant specification, including all of the claims on appeal;
- (2) applicants’ main Brief and Reply Brief;
- (3) the Examiner’s Answer and Supplemental Answer;
- (4) the above-cited prior art references; and
- (5) the decision and accompanying opinion in related Appeal No. 1997-2204 mailed February 28, 2001.

On consideration of the record, including the above-listed materials, we reverse the examiner’s rejections under 35 U.S.C. § 112.

DISCUSSION

I. Issues in common with Appeal No. 1997-2204

With the single exception noted infra, this appeal presents issues in common with those before the board in Appeal No. 1997-2204 (Application No. 08/440,989). In a

¹ In the Answer, Page 4, line 2, the examiner withdrew a previously entered rejection under 35 U.S.C. § 103

decision and accompanying opinion in the latter appeal, mailed February 28, 2001, the board reversed the examiner's rejections on non-prior art grounds. Having carefully considered the similar issues in this appeal, we find, again, that the examiner (1) does not provide sufficient analysis of the specification or how persons skilled in the art would read the instant claims in light of the specification; (2) does not provide adequate reasons to doubt the objective truth of statements made in appellants' specification; and (3) does not establish a prima facie case of indefiniteness of any appealed claim.

For reasons given in Appeal No. 1997-2204, we reverse the examiner's rejections under 35 U.S.C. § 112, first and second paragraphs, to the extent that they involve the same issues previously decided.

II. Remaining issue under 35 U.S.C. § 112, first paragraph

The remaining issue, which merits separate discussion, is whether the examiner erred in rejecting claims 1 through 9 and 22 under 35 U.S.C. § 112, first paragraph, based on the unavailability of requisite starting materials for preparing some of the compounds embraced by these claims (Examiner's Answer, pages 4 through 6).

Specifically, claims 1 through 9 and 22 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure because "competent sources of starting materials for R⁴ as carbonyl and X as O or NY are lacking and are required for enablement" (Examiner's Answer, Page 4, section (11)).

The examiner argues that

Dappen '417 patented the intermediate X as NY acids used for the claimed amides subsequently to instant parent filing date, raising a prima facie

presumption these acids were neither obvious nor known. The '417 and '249 patents [Dappen '417 and Dappen '249] evidence undue experimentation ... was required to obtain these materials. Dappen '249 generically claims the acid intermediate where X is O based partly on an application filed Feb. 24, 1993, also before appellants' parent filing date. The acid compounds where X is O are also prima facie novel and unobvious. (Examiner's Answer, paragraph bridging pages 4 and 5).

Based on the Dappen patents, the examiner concludes that "key intermediates, starting materials for instantly claimed products were not in fact available" (Examiner's Answer, Page 5, last paragraph). The examiner cites In re Howarth, 654 F.2d 103, 210 USPQ 689 (CCPA 1981), as "in point" without further comment or analysis (Examiner's Answer, paragraph bridging pages 5 and 6).

In Howarth, the issue centered on the availability of a starting material, clavulanic acid, essential to making the claimed derivatives of clavulanic acid. Howarth's specification provided no information enabling persons skilled in the art to prepare clavulanic acid, or directing them to reference materials containing such information. Nevertheless, Howarth relied on copies of patent specifications, which had been open for inspection in Rhodesia, Panama, and Luxemburg before his U.S. filing date, as describing the preparation of clavulanic acid. The solicitor replied that

Regardless of what the documents are called and regardless of the technical possibility of obtaining copies from the respective government offices, there is no evidence of actual dissemination to the public of the documents containing the specifications, nor is there any index, catalog or other customary research tool or even a descriptive title that would lead one of ordinary skill to the documents for information on the preparation of clavulanic acid. Therefore, the documents may not be relied on to supplement appellant's disclosure [In re Howarth, 654 F.2d at 105, 210 USPQ at 691].

The court agreed with that assessment. Observing that a conclusive presumption of knowledge of prior art is, in effect, a statutorily required fiction under 35 U.S.C. § 102 which “cannot be found in section 112,” the court stated that

When no guide at all has been given, as here, an applicant must show that anyone skilled in the art would have actually possessed the requisite knowledge or would reasonably be expected to check the source which the applicant relies upon to complete his disclosure and would be able to locate the information with no more than reasonable diligence (emphasis added, citation omitted) [654 F.2d at 107, 210 USPQ at 692-93].

On the facts presented, the court in Howarth affirmed the PTO rejection under 35 U.S.C. § 112, but those facts differ considerably from the facts presented here.

First, the examiner has not established that the intermediates of the Dappen references are the only starting materials that may be used to prepare the instantly claimed compounds. Second, appellants provide ample guidance how to make their compounds where R⁴ is carbonyl (specification, page 7, lines 9 through 16). In addition, appellants provide guidance how to make their compounds where X is O or NY, including incorporation by reference of U.S. Patent No. 4,816,586 (specification, page 7, lines 29 through 35). The examiner does not controvert the import of these disclosures.

This alone is sufficient to distinguish Howarth and to refute the examiner’s position. Further, in their specification, appellants cite a number of articles from recognized scientific journals reflecting the state of the prior art (see, for example, pages 6 through 9 of the specification). It is not disputed that these publications were available and accessible to the public at the time the invention was made. Appellants also refer to and rely on the Endo reference in their Appeal Brief, Page 7, line 27.² The only argument lodged by the examiner respecting any reference cited and relied on by

² Endo, Y. et al., Synthesis, 1980, 6, 461

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the appellants, either in the specification or in the Appeal Brief, is that the “instant specification contains no mention of the allegedly enabling Endo reference (which appellants don’t allege describes the necessary intermediate for the X is O R₄ carbonyl compound)” (Examiner’s Answer, page 5).

The Endo reference was published in 1980, before the effective filing date of this application. Again, this article was published in a recognized scientific journal and was available and accessible to the public at the time the invention was made. It cannot be gainsaid that it was not cited in the specification. However, it has long been settled that “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. 1986).

In light of the specification, considered in its entirety, and absent further evidence or explanation by the examiner, we reverse the rejection of claims 1 through 9 and 22 under 35 U.S.C. § 112, first paragraph, based on the unavailability of requisite starting materials.

CONCLUSION

The examiner’s decision, rejecting claims 1 through 9 and 22 under 35 U.S.C. § 112, first and second paragraphs, is reversed.

REVERSED

Sherman D. Winters
Administrative Patent Judge

William F. Smith
Administrative Patent Judge

Douglas W. Robinson
Administrative Patent Judge

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