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for publication and is not binding precedent of the Board.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. 57

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte NICHOLAS S. BODOR

Appeal No. 2000-2156
Application No. 08/431,727

HEARD: March 7, 2002

Before WINTERS, SCHEINER, and MILLS, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 110 through 115, 123, and 124, which are all of the claims remaining in the application.

Representative Claim

Claim 123, which is illustrative of the subject matter on appeal, reads as follows:

123. A method for the design of a soft drug entity, the in vivo metabolic disposition of which proceeds in predictable manner into an inactive metabolite moiety and nontoxic moieties thereof after eliciting its desired therapeutic response, comprising (a) identifying a nontoxic, therapeutically inactive candidate metabolite of a given drug entity known to elicit a particular therapeutic response, and (b) structurally converting such therapeutically inactive metabolite into an activated, structurally-related drug

species that also elicits such particular therapeutic response, but which activated drug species will in vivo metabolically cleave into said identified inactive metabolite moiety and other nontoxic moieties thereof.

The Prior Art Reference

In the statement of rejection under 35 U.S. C. § 103, the examiner includes the following prior art reference:

Bodor	3,884,905	May 20, 1975

We also note the examiner's reference to Design of Prodrugs (Bundgaard, H., Ed.), Elsevier Sci. Pub. B.V. (Biomedical Division), Chapter 11, "Prodrugs versus soft drugs," pp. 333-54 (1985), authored by the inventor, Nicholas Bodor. According to the examiner, the rejection under 35 U.S. C. § 103 is "bolstered" by that publication (Final Rejection, Paper No. 43, page 5, last paragraph). Further, in responding to applicant's arguments with respect to rejections under 35 U.S. C. § 112, the examiner repeatedly refers to U.S. Patent No. 5,760,216 issued June 2, 1998, to Chorghade et al. (Examiner's Answer, Paper No. 50, section (11) entitled "Response to Argument"). According to the examiner, "[t]he Chorghade et al. patent is cited as an ancillary reference, to establish a fact" (Paper No. 50, page 5, lines 13 and 14). The examiner has not established, however, that either Chapter 11, "Prodrugs versus soft drugs," or U.S. Patent No. 5,760,216, constitutes legally available prior art in this case;

or that either reference may be relied on to establish facts known to a person having ordinary skill in the art at the time the invention was made. In any event, neither of

those references was included in the statement of any rejection on appeal. As stated in In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970),

> Where a reference is relied on to support a rejection, whether or not in a "minor capacity," there would appear to be no excuse for not positively including the reference in the statement of the rejection.

Here, Chapter 11, “Prodrugs versus soft drugs,” and U.S. Patent No. 5,760,216 are not included in the statement of any rejection before us, and we shall not consider those references further.

The Rejections

Claims 123, 124, and 110 through 115 stand rejected under 35 U.S. C. § 112, first paragraph, as based on a non-enabling disclosure; and under 35 U.S. C. § 112, second paragraph, as not particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. Claims 123, 124, and 110 through 115 further stand rejected under 35 U.S. C. § 103 as unpatentable over U.S. Patent No. 3,884,905.

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (I) the instant specification, including all of the claims on appeal;

(II) applicant’s Appeal Brief (Paper No. 49), including the publications by Nicholas S. Bodor referenced therein, and the Reply Brief (Paper No. 51); (III) the Final Rejection (Paper No. 43) and the Examiner’s Answer (Paper No. 50); (IV) U.S. Patent

No. 3,884,905 issued May 20, 1975 to Bodor; (V) the declaration of Patrick P. Deluca, executed July 30, 1999; the declaration of Anwar A. Hussain, executed July 30, 1999; and the declaration of Nicholas S. Bodor, executed February 1, 1993.

On consideration of the record, including the above-listed materials, we reverse the examiner's prior art and non-prior art rejections.

Discussion

Initially, we emphasize that this tribunal serves to review cases on appeal; the board does not engage in de novo examination of patent applications ("The Board of Patent Appeals and Interferences shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents ."). 35 U.S.C. § 6(b). Here, the rejections presented for review do not rise to the level of superficial plausibility and we shall not belabor the record with extensive comments. We reverse the examiner's prior art and non-prior art rejections for reasons succinctly set forth in applicant's principal brief, and we add the following the following comments for emphasis only.

It is well settled that a patent applicant may, within reason, be his own lexicographer. Lear Siegler, Inc. v. Aeroquip Corp., 733 F.2d 881, 888, 221 USPQ

1025, 1031 (Fed. Cir. 1984); Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983). Furthermore, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification, and claim language should be read in light of the

specification as it would be interpreted by one of ordinary skill in the art. In re Sneed, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983). Keeping those principles in mind, we note the definition of “soft drug” in the specification, page 2, lines 16 through 24, and applicant’s discussion of the “inactive metabolite” approach for designing “soft drugs” in the specification, page 2, line 25 through page 3, line 7. This record does not reflect that the examiner considered applicant’s definition of “soft drugs” in the specification, or that the examiner read applicant’s claim language in light of the specification as it would be interpreted by one of ordinary skill in the art. Had the examiner done so, we believe that the rejections entered under 35 U.S.C. § 112, first paragraph; 35 U.S.C. § 112, second paragraph; and 35 U.S.C. § 103(a) would have been resolved before forwarding the case to us for a disposition.

In Paper No. 50, section (10) entitled “Grounds of Rejection,” the examiner made clear that all of the appealed claims were rejected under 35 U.S.C. § 112, first paragraph; 35 U.S.C. § 112, second paragraph; and 35 U.S.C. § 103(a). According to the examiner, “[t]hese rejections are set forth in prior Office action, Paper No. 43 dated 02/04/99" (Paper No. 50, page 3, penultimate paragraph). But the examiner went on to restate each rejection, providing reasons different from those set forth in the prior Office action (Paper No. 50, page 3, last paragraph; and page 4, first two paragraphs). This caused a substantial amount of confusion because it is unclear, on the record, whether the reasons set forth in the Examiner’s Answer (Paper No. 50) supplant those set forth in the prior Office action or add to those set forth in the prior Office action. In any event, we reviewed all of the reasons proposed by the examiner and find that they all

lack merit.

We note the examiner's statement that applicant's claim language "does not set fixed metes and bounds" to any person skilled in the art (Paper No. 50, page 3, last paragraph). According to the examiner, when claims do not adequately fix the metes and bounds of the invention, they should be rejected under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure. That is not our understanding of the law. If the claims failed to delineate the metes and bounds of applicant's invention, and we hold that they do not, such failure would give rise to a rejection under 35 U.S.C. § 112, second paragraph. Again, the Examiner's Answer is confusing and unhelpful in framing the issues on appeal.

Finally, we express our dismay at the examiner's statement that

> Claim 123 is drawn to a research strategy for designing soft drugs . . . no limits are placed on what sort of drug this is practiced with, <u>making classification and therefore, examination impossible</u>. [Paper No. 43, page 2, last paragraph; emphasis added]

Again, it is not the duty of the board to examine patent applications <u>de novo</u>. That is the duty of the patent examiner. On return of this case to the examining corps, we trust that the application will be adequately classified, searched, and examined.

<u>Conclusion</u>

In conclusion, we find little merit in the rejections presented for review under 35 U.S.C. § 112, first paragraph; 35 U.S.C. § 112, second paragraph; or 35 U.S.C. § 103(a). Each of those rejections is <u>reversed</u> for reasons succinctly set forth in applicant's principal brief.

The examiner's decision is reversed.

REVERSED

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Sherman D. Winters	)
Administrative Patent Judge	)
	)
	)
	) BOARD OF PATENT
Toni R. Scheiner	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
Demetra J. Mills	)
Administrative Patent Judge	)

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