

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 27

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte JEAN A. SETTERSTROM, THOMAS R. TICE,  
ELLIOT JACOB, JOHN VAN HAMONT, EDGAR C. BOEDEKER,  
RAMASUBBU JEYANTHI, PHIL FRIDEN, F. DONALD ROBERTS, CHARLES E.  
MCQUEN, APURBA BHATTACHARJEF, ALAN CROSS, JERALD SADOFF  
and WENDELL ZOLLINGER

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Appeal No. 2001-1733  
Application No. 09/055,505

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ON BRIEF

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Before WINTERS, ADAMS and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

**REMAND TO THE EXAMINER**

After considering the record, we have concluded that this case is not in condition for a decision on appeal. For the reasons that follow we vacate the examiner's rejection under 35 U.S.C. § 103 and remand the application to the examiner for further action consistent with the views expressed herein.<sup>1</sup>

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<sup>1</sup> Lest there be any confusion, when the board vacates an examiner's rejection, the rejection ceases to exist. See Ex parte Zambrano, 58 USPQ2d 1312 (Bd. Pat. App. & Int. 2001).

### REPRESENTATIVE CLAIM

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A composition for the burst-free, sustained, programmable release of active material(s) over a period from 1-100 days, which comprises: (1) an active material and (2) a carrier which may contain pharmaceutically-acceptable adjuvant, comprised of a blend of uncapped and end-capped biodegradable-biocompatible copolymer.

### PRIOR ART

The examiner relies on the following prior art:

|                            |           |               |
|----------------------------|-----------|---------------|
| Ramstack et al. (Ramstack) | 5,650,173 | Jul. 22, 1997 |
|----------------------------|-----------|---------------|

### GROUND OF REJECTION

Claims 1-49, 51-132 and 134-177 stand rejected under 35 U.S.C. § 103 as being unpatentable over Ramstack.

Claims 50 and 133 have been cancelled. See Brief (Paper No. 19), page 1.

For the following reasons we vacate the pending rejection and remand the application to the examiner for further consideration.

### PROCEDURAL ERROR

As appellants make clear (Supplemental Reply Brief, Paper No. 23, page 1), “[a]ccording to MPEP [§] 1208.03[ ]and 37 CFR [§] 1.193(b)(1) [2000], after a reply brief is filed,

‘The primary examiner must either acknowledge receipt and entry of the reply brief or withdraw the final rejection and reopen prosecution to respond to the reply brief. A supplemental examiner’s answer is not permitted....’”

The rule, therefore, provides for two alternatives, (1) acknowledge receipt and entry of the reply brief without further comment on the merits of the claimed invention, or (2) reopen prosecution to address the merits of the claimed invention. The rule clearly sets

forth that a supplemental examiner's answer is not permitted unless the examiner is directed to enter a supplemental examiner's answer upon remand by the Board.

On this record, appellants filed a Reply Brief in response to the Examiner's Answer. See Paper No. 21. However, instead of following the procedure expressly set forth in 37 CFR § 1.193(b)(1) 2000, the examiner responded to the Reply Brief with a Supplemental Examiner's Answer. See Paper No. 22. This Supplemental Examiner's Answer was not permitted according to the rule and therefore amounts to a procedural error.

We note that appellants' Supplemental Reply Brief (page 1) requested clarification as to whether the examiner reopened prosecution. In response, the examiner states (Paper No. 24) that the Supplemental Examiner's Answer was not intended to reopen prosecution. Regardless of the examiner's intent, the Supplemental Examiner's Answer effectively reopened prosecution on the merits in this application. Accordingly, this application is not properly before this Panel for review.

As set forth in Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1033 (Fed. Cir. 1997), "[f]or an appellate court to fulfill its role of judicial review, it must have a clear understanding of the grounds for the decision being reviewed," this requires that "[n]ecessary findings ... be expressed with sufficient particularity to enable [the] court, without resort to speculation, to understand the reasoning of the Board, and to determine whether it applied the law correctly and whether the evidence supported the underlying and ultimate fact-findings." Like the Court of Appeals in Gechter, this board requires a clear understanding of the grounds for the decision being reviewed. Therefore, to clarify the issues on this record, and to provide the examiner an

opportunity to clearly set forth his position, we vacate the pending rejection and remand the application to the examiner for further consideration.

We encourage the examiner to take this opportunity to step back and review the record, together with the relevant prior art. If after this review, the examiner remains of the opinion that the claims on appeal are unpatentable, he should issue an appropriate Office action clearly setting forth the facts and reasons used in support of such a rejection. If the examiner maintains a rejection under 35 U.S.C. § 103, we suggest the examiner review MPEP § 706.02(j) for a model of how to explain a rejection under this section of the statute. Adherence to this model will of necessity require that the examiner consider the patentability of the claims in an individual manner, and set forth the facts and reasons in support of why individual claims are unpatentable.

#### OTHER ISSUES

While we take no position on the merits of the claimed invention, we offer the following comments to assist the examiner in his reevaluation of the claimed invention.

We note the Examiner's Answer (page 3) directs our attention to Paper No. 16 for the statement of the rejection. At page 3 of Paper No. 16, the examiner states "Ramstack et al. disclose a column 1, line 23 to column 3, line 22 various encapsulated micro particles containing various active agents." This is the examiner's only statement as to how Ramstack may relate to appellants' claimed invention. Clearly absent from this statement is any discussion of the second component of appellants' claimed composition, specifically "a carrier which may contain pharmaceutically-acceptable adjuvant, comprised of a blend of uncapped and end-capped biodegradable-biocompatible copolymer." We remind the examiner that "[a]ll words in a claim must be

considered in judging the patentability of that claim against the prior art.” In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

However, we note the examiner’s statement (Supplemental Examiner’s Answer, page 2), “[t]he particles formed by the Ramstack et al[.] reference could have a capped and uncapped end since butyl alcohol would supply the butyl group as previously urged by the applicant” [emphasis added]. In this regard, we note that Ramstack may just as well not have an end-capped and uncapped end. The examiner bears the initial burden of presenting a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Stated differently, the examiner has the initial duty of supplying the factual basis for his rejection. He may not, because he may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967). Accordingly, in the event of further prosecution, we encourage the examiner to ensure that his position is clearly supported by the prior art relied upon.

Also absent in the Examiner’s Answer is any discussion of how he construed the claimed invention. For example, as set forth in claim 1, the composition “may contain” a pharmaceutically-acceptable adjuvant. Does this mean that a pharmaceutically-acceptable adjuvant is not a required component of the composition? If so, then it seems reasonable that the composition comprises only an active material and a carrier. We remind the examiner, as set forth in In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989):

[D]uring patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and

clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.

In this regard we note that it is unclear whether the phrase “comprised of a blend of uncapped and end-capped biodegradable-biocompatible copolymer,” is intended to modify “a carrier” or “a pharmaceutically acceptable adjuvant.”

In the event of further prosecution we encourage the examiner to clearly set forth how he interprets the limitations set forth in the claimed invention.

FUTURE PROCEEDINGS

We state that we are not authorizing a Supplemental Examiner’s Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner which contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

VACATED; REMANDED

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|-----------------------------|---|-----------------|
| Sherman D. Winters          | ) |                 |
| Administrative Patent Judge | ) |                 |
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|                             | ) | BOARD OF PATENT |
| Donald E. Adams             | ) |                 |
| Administrative Patent Judge | ) | APPEALS AND     |
|                             | ) |                 |
|                             | ) | INTERFERENCES   |
|                             | ) |                 |
| Demetra J. Mills            | ) |                 |
| Administrative Patent Judge | ) |                 |

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