

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN M. WOZNEY and THOMAS J. TUREK

Appeal No. 1999-1280
Application No. 08/379,813

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.
ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1-33, which are all the claims pending in the application.

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Claims 1 and 6 are representative of the claims on appeal and read as follows:

1. A method for treatment of a supraalveolar periodontal lesion or defect consisting essentially of administering to a site of said supraalveolar periodontal lesion or defect a pharmaceutically acceptable composition containing one or more purified or recombinant bone morphogenetic protein (BMPs) in an amount sufficient to cause regeneration of alveolar bone at the site of said lesion or defect in both a vertical and horizontal direction.
6. A method for treatment of a supraalveolar periodontal lesion or defect according to claim 1, wherein the composition comprises recombinant human BMP-12 and recombinant human BMP-2 in a suitable carrier.

The references relied on by the examiner are:

Antoniades et al. (Antoniades)	5,124,316	Jun. 23, 1992
Bentz et al. (Bentz)	5,393,739	Feb. 28, 1995

GROUND OF REJECTION

Claims 1-33 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to provide an enabling description of all Bone Morphogenetic Proteins (BMPs).¹

Claims 1, 2, 7-13, 18-24, and 29-33 stand rejected under 35 U.S.C. § 102 as being anticipated by Antoniades.

Claims 1-33 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bentz.

¹ We note the rejection of claims 1-33 is directly connected and relates to the objection to the specification. In re Hengehold, 440 F.2d 1395, 1403-1404, 169 USPQ 473, 479-480 (CCPA 1971).

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We affirm the rejection under 35 U.S.C. § 102, and reverse the rejections under 35 U.S.C. § 112, first paragraph and § 103.

DISCUSSION

In reaching our decision in this appeal, we considered appellants' specification and claims, in addition to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's Answer², and Supplemental Answer³ for the examiner's reasoning in support of the rejection. We further reference appellants' Brief⁴, Reply Brief⁵ and Supplemental Reply Brief⁶ for the appellants' arguments in favor of patentability. We note the examiner entered and considered appellants' Supplemental Reply Brief without comment.⁷

Background

The invention relates generally to the periodontia, the tissues immediately about the teeth. Periodontal disease results in a loss of connective tissue attachment to the tooth and loss of alveolar bone (specification, page 1). Periodontal lesions can affect the alveolar bone, the tissue apparatus which attaches tooth to bone, and/or furcation or interproximal tissue (specification, page 3). The lesions can affect the mandible or

² Paper No. 19, mailed October 8, 1997.

³ Paper No. 21, mailed November 25, 1997.

⁴ Paper No. 18, received August 12, 1997.

⁵ Paper No. 20, received November 10, 1997.

⁶ Paper No. 22, received December 22, 1997.

⁷ Paper No. 23, mailed February 2, 1998.

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maxilla. The invention involves treatment of periodontal lesions or defects with bone morphogenetic proteins (BMPs), preferably those with osteogenic activity and/or ligament-inducing activity (specification, page 4).

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

We recognize as did the examiner (Answer, page 9) that appellants' Brief failed to address the rejection under 35 U.S.C. § 112, first paragraph. In this regard, we note as set forth in 37 C.F.R. § 1.192(c)(8)(1997) "[t]he brief shall contain... [t]he contentions of appellant with respect to each of the issues presented for review...." However, in contrast to procedure followed by this examiner, the proper procedure for handling a deficiency in the Brief is set forth in 37 C.F.R. §1.192(d)(1997) "[i]f a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and provided with a period of one month within which to file an amended brief...."

On this record, the examiner failed to follow the procedure set forth in 37 C.F.R. §1.192(d) (1997). Nevertheless, appellants recognized the deficiency and presented arguments with a proposed amendment in their Reply Brief. We note that the examiner considered (Supplemental Answer, page 3) appellants' supplemental arguments presented in the Reply Brief. Thus, the examiner's procedural error is moot.

We note that the examiner did not enter appellants' amended claims presented in Reply Brief section entitled "PROPOSED AMENDED CLAIMS." See Supplemental Answer, page 2. Although the examiner's rationale for denying entry is unclear, we

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note that amendments after a final rejection are not a matter of right. See 37 CFR § 1.116 and § 1.195 and MPEP §§ 714.12-714.13, 1207 and 1208.03. In addition, we note the non-entry of an amendment is a petitionable, not an appealable, issue. See 37 C.F.R. § 1.181. Therefore, the “proposed amended claims” are not before this Merits Panel for review.

According to the examiner (Answer, pages 6-7):

The specification is not enabling for the invention as claimed because there is no teaching of other BMP's. Supraalveolar lesions include melanoma, amalgam tattoo to radiation osteonecrosis and these disorders are not enabled by the specification. Further, the long term augmentation of alveolar ridges which are under pressure from dentures is a notably difficult achievement and no evidence for the claimed method is shown for such a treatment.

Here, the examiner did not perform the fact-finding needed in order to reach a proper conclusion that the specification does not enable the claimed invention. The enablement requirement of 35 U.S.C. § 112, first paragraph, requires that the patent specification enable “those skilled in the art to make and use the full scope of the claimed invention without ‘undue experimentation.’” Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)).

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Whether making or using the invention would have required undue experimentation, and thus whether the disclosure is enabling, is a legal conclusion based on several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

We find no Wands analysis in this record. Instead, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. In the absence of a fact-based statement of a rejection based upon the relevant legal standards, the examiner has not sustained his initial burden⁸ of establishing a prima facie case of non-enablement.

Furthermore, to the extent that the examiner is concerned with the scope of the examples set forth in appellants' specification, we note that examples are not required to satisfy section 112, first paragraph. In re Strahilevitz, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982).

⁸ It is well settled that the examiner bears the initial burden of providing reasons why a supporting disclosure does not enable a claim. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

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In our opinion, as set forth above, the examiner failed to meet his burden of establishing a prima facie case of nonenablement. Accordingly, we reverse the rejection of claims 1-33 under 35 U.S.C. § 112, first paragraph.

THE REJECTION UNDER 35 U.S.C. § 102:

Appellants set forth (Brief, page 3) two claim groupings: Group I, claims 1-5, 7-16, 18-27, and 29-33, and Group II, claims 6, 17, and 28. Since the claims rejected under 35 U.S.C. § 102 (claims 1, 2, 7-13, 18-24, and 29-33) all fall within Group I, we limit our discussion to representative independent claim 1. Claims 2, 7-13, 18-24, and 29-33 will stand or fall together with claim 1. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

According to the examiner (Answer, page 4) Antoniades teaches:

BMP and osteogenin for treating periodontal defects which promotes growth of bone, periodontium or ligament. ... [T]he carrier may be natural and synthetic polymers such as collagen, bone substituting agents and inert gels or liquids such as methyl cellulose. ... [T]he composition prompts increased bone, connective tissue and cementum formation when applied to periodontal disease affected sites.

Regarding the claim limitations drawn to types of periodontal defects such as vertical, horizontal, furcation, and interproximal, Antoniades teaches periodontal disease defects in general and that teaching would include these well known defects.

All the features of the claims are shown by Antoniades for the same function as presently claimed.

In response, appellants argue (Brief, page 4) that “the examiner has effectively read out of the claims the recitation that the claimed method ‘consists essentially of’ administering to the site ... a composition comprising an effective amount of a bone

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morphogenic protein.” It is appellants’ position (id.) that the transitional phrase “consisting essentially of” precludes “the addition of an additional growth factor [that] would materially affect the present claim, and that BMPs are recited as the sole growth factor in the composition.”

According to appellants (id.):

The only method disclosed in Antoniadis is administering a polypeptide growth factor, such as platelet derived growth factor ... [wherein] BMP is taught only as an optional “differentiation factor” which may be used in addition to the “polypeptide growth factor”.... [Therefore] Antoniadis does not teach that use of a BMP without being accompanied by treatment with ... [a polypeptide growth factor] is effective for periodontal tissue regeneration.

It is appellants’ position (Reply Brief, page 2) “that the claim language excludes compositions in which PDGF or another growth factor is used as an active agent in addition to BMPs. This interpretation of the claims is consistent with the established meaning of the claim language ‘consisting essentially of’”.

We begin our review of this record with an analysis of the claims. Independent claim 1 is directed to “[a] method for treatment ... consisting essentially of administering to a site ... a pharmaceutically acceptable composition containing one or more purified or recombinant bone morphogenetic protein (BMPs)....” Similarly, independent claim 12 is directed to “[a] method for treatment ... said method consisting essentially of applying ... a pharmaceutically acceptable composition containing an effective amount of one or more purified or recombinant bone morphogenetic protein (BMPs)....” Independent claim 23 recites “[a] method for augmentation ... said method consisting

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essentially of applying ... a pharmaceutically acceptable composition containing an effective amount of one or more purified or recombinant bone morphogenetic protein (BMPs)....”

In each of the independent claims, the recitation “consisting essentially of” refers to an administering or applying step. The material administered or applied is a composition described using an open term, “containing”. See e.g. Loukomsky v. Gerlich, 264 F. 2d 907, 908, 121 USPQ 213, 214 (CCPA 1959) (“[a] solution ‘containing’ a specified ingredient does not cease to contain it merely because other ingredients are added.”). The open scope of the composition is emphasized in dependent claims 2-6, 13-17, 24-28, “the composition comprises ...” and claims 7-9, 18-20, 29-31, “the carrier comprises....”

Therefore, the appealed claims require treatment to “consist essentially of” administering a composition. The claims, however, do not limit the scope of ingredients in the composition. In this regard, we note that appellants affirmatively state (Brief, page 4) “that the claimed method ‘consists essentially of’ administering ... a composition comprising an effective amount of a bone morphogenetic protein.” Therefore we are not persuaded by appellants’ argument. The claimed method utilizes a composition comprising BMPs as a result the composition is open to include BMPs and other agents. We note Antoniades (column 2, lines 21-33) teach “In preferred embodiments, the step of applying includes applying a combination of a polypeptide growth factor and a differentiation factor ... most preferably the polypeptide growth

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factor is purified PDGF and the differentiation factor is partially purified or purified bone morphogenetic protein....”

On reflection, we agree with the examiner that Antoniadis anticipates the claimed method. Accordingly, we affirm the examiner’s rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Antoniadis. As discussed supra claims 2, 7-13, 18-24, and 29-33 fall together with claim 1.

THE REJECTION UNDER 35 U.S.C. § 103:

The examiner finds (Answer, page 6) that Bentz teaches “composition including BMP’s and TGF-B may be used to treat periodontal disease or alveolar ridge repairs ... [and that] various matrices may be used to administer BMPs including collagen and hydroxyapatite.” However, the examiner recognizes (id.) that “the claims differ from Bentz in that they specify types of periodontal defects, BMP-12 in the composition, and combining the BMP with autologous blood.” Nevertheless, the examiner concludes (Answer, pages 6-7) that these differences are obvious in view of the general teaching provided by Bentz.

In response, appellants argue (Brief, page 7) that “even if the cited references [sic] established [sic] a prima facie case of obviousness, which they [sic] do not, there is additional evidence of record in the application sufficient to rebut any such rejection.” Specifically, appellants argue (id.) that the specification discloses the following unexpected advantages of the claimed methods “(1) the regeneration of the entire periodontal attachment apparatus, including the cementum and ligamentous

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structure...; (2) the regeneration of bone in both the horizontal and vertical direction...; and (3) reduced occurrence of ankylosis and root resorption.

Although the examiner argues (Supplemental Answer, page 3) that “[r]egeneration of bone in horizontal and vertical directions is taught by Bentz,” the examiner failed to address appellants’ evidence of unexpected results regarding the regeneration of the cementum and ligamentous structure, and reduced occurrence of ankylosis and root resorption. We remind the examiner that “[w]hen prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over.” In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976). “If a prima facie case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.” In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986). In our opinion, the examiner has not carried his burden in response to rebuttal evidence.

In addition, appellants separately argue (Brief, page 8) that claims 6, 17, and 28 require “a combination of osteogenic proteins.” We note that these claims require the specific combination of recombinant human BMPs 2 and 12. The examiner, however, fails to identify any teaching or suggestion in Bentz that would lead one of ordinary skill to this particular combination. Therefore, in our opinion, for claims 6, 17, and 28, the

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examiner has not met his burden⁹ of presenting the evidence necessary to establish a prima facie case of obviousness. If the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Accordingly, we reverse the examiner's rejection of claims 1-33 under 35 U.S.C. § 103 over Bentz.

⁹ See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (the initial burden of establishing unpatentability rests on the examiner).

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

William F. Smith)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Donald E. Adams)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
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