

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 46

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HANS-PETER GAULER and SATISH BHATIA

Appeal No. 1997-2744
Application No. 08/243,520

ON BRIEF

Before WINTERS, ADAMS and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-12, which are all the claims pending in the application.

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

1. A method for the treatment of osteoporosis in a mammal having reduced cortical bone mineral density or preventing the same in a mammal prone thereto comprising administering to said mammal an effective amount for said treatment or prevention of a compound selected from IGF-1, an active fragment thereof, an active analog thereof, or an active fragment of either IGF-1 or its analog.

The references relied upon by the examiner are:

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Isgaard et al. (Isgaard), "Effects of local administration of GH and IGF-1 on longitudinal bone growth in rats," Am. J. Physiol., Vol. 250, pp. E367-E372 (1986)

Mueller et al. (Mueller), "Insulin-like growth factor-I increases trabecular bone mass in the ovariectomized rat," J. Bone Mineral Research, Vol. 6, Supp. 1, pp. S221, Abstract 549 (1991)

GROUND OF REJECTION

Claim 1-12 stand rejected under 35 U.S.C. § 103 as being unpatentable over Isgaard in view of Mueller.

We reverse.

DISCUSSION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's Answer¹, and the examiner's Supplemental Answer² for the examiner's reasoning in support of the rejections. We further reference appellants' Brief³, and appellants' Reply Brief⁴ for the appellants' arguments in favor of patentability.

¹ Paper No. 39, mailed September 12, 1996.

² Paper No. 42, mailed December 27, 1996.

³ Paper No. 37, received July 5, 1996.

⁴ Paper No. 40, received November 19, 1996.

THE REJECTION UNDER 35 U.S.C. § 103:

Initially, we note the examiner's statement of the rejection (Answer, ¶ 11) "[c]laims 15-23 are rejected under 35 USC 103. This rejection is set forth in the prior Office action of September 20, 1994 paper number 18." This statement appears to be in error. Paper number 18 refers to a rejection of claims 1-12, not claims 15-23. In fact this record never contained 23 claims. Furthermore, while both the examiner's Answer (¶ 13) and appellants' Brief refer to the combination of Isgard and Mueller, Paper No. 18 sets forth a single rejection under 35 U.S.C. § 103 over Isgard. Therefore, since the most recent Final Rejection⁵ of the claims is more consistent with the arguments of the examiner and appellants we believe the examiner intended to refer to this paper for the basis of the rejection. With this clarification, we proceed to address the merits of the examiner's rejection.

The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In satisfying this initial burden, "[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." In re Wesslau, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965); see also In re Mercier, 515 F.2d 1161, 1165-66, 185 USPQ 774, 778 (CCPA 1975).

The examiner finds (Answer, bridging paragraph, pages 3-4) that "Mueller teaches that appellants' active [sic] used to treat experimental rats [sic] used to

determine the effect of a compound on osteoporosis, i.e.; an ovariectomized [sic] rat. Isgaard teaches that the claimed known active agent would have activity to increase long bone growth.” The examiner finds (Answer, page 4) that “[r]egardless [of appellants arguments and the Guler Declaration] the suggestion in the Mueller reference that the claimed known active agents can be used to treat osteoporosis is deemed sufficient suggestion to use applicants claimed active agents to treat the medical disorder osteoporosis.”

Appellants emphasize the conclusion in Mueller that “[c]ortical bone mass was only weakly affected by OVX [ovariectomy] and by treatment with either [IGF-1 or parathyroid] hormone,” arguing (Brief, page 6) that “the ovariectomized rat model they used was inadequate to study the effect of IGF-1 on cortical bone since OVX did not appear to significantly affect such bone.” Appellants then argue (Brief, page 9) with reference to the Guler Declaration that the “103 rejection is based on an improper ‘obvious to try’ standard.”

According to appellants, the Guler Declaration establishes (Brief, page 10) that:

- (1) “it could not be predicted from Isgaard that IGF-1 would be effective in the treatment of osteoporosis of cortical bone” ...;
- (2) “Mueller pertains to trabecular bone, not cortical bone” ...; and
- (3) “any results obtained with respect to trabecular bone cannot be extrapolated to cortical bone since the two bone types are structurally and metabolically different.”

⁵ Paper No. 31, mailed January 5, 1995.

The examiner dismisses the Guler Declaration (Answer, page 4) as “opinion only since it does not set forth how the trabecular bone and cortical bone differ structurally and metabolically.” The examiner erred in dismissing the Guler Declaration without consideration. As set forth in In re Lindell, 385 F.2d 453, 456, 155 USPQ 521, 524 (CCPA 1967) “some weight ought to be given to a persuasively supported statement of one skilled in the art on what was not obvious to him” [citation omitted].

Furthermore, as explained by appellants (Reply Brief, pages 2-4):

Dr. Guler stated the following with respect to the distinctions between cortical bone and trabecular bone:
In this regard, the skeleton is made up of both cortical, or compact bone, and trabecular or cancellous bone. ... Trabecular bone has a higher turnover rate than cortical bone (about eight times as high). Based on the foregoing, it is my opinion that any results obtained with respect to trabecular bone cannot be extrapolated to cortical bone since the two bone types are structurally and metabolically different.

...

Dr. Guler distinguished the structure and metabolism of immature bone found in young mammals as studied in Mueller from that of mature bone which is the locus of cortical bone osteoporosis ...

Cortical bone osteoporosis, which can be caused by post-menopausal estrogen deficiency, is a disease of mature bone and mature bone differs both structurally and metabolically from immature bone. ... [T]he composition of mature bone differs from immature bone. For example, bone is made up of a matrix component and several salts. Newly formed bone generally has a considerably higher percentage of matrix in relation to salts as compared with mature, compact bone. Thus, any results from studies concerning immature bone cannot be extrapolated to mature bone.

Therefore, in contrast to the examiner's position, the Guler Declaration did set forth how the trabecular and cortical bone differ structurally and metabolically.

Appellants' argue (Brief, page 7) that "[e]ven the title of Mueller's article, '*Insulin-like Growth Factor-I Increases Trabecular Bone Mass in the Ovariectomized Rat* ... reflects the extent of the conclusions that the authors themselves were able to draw from this study." Furthermore, appellants' argue (Brief, page 8) that there is no motivation to combine the references since Isgaard does not teach the use of the claimed active agent to treat osteoporosis in a mammal having reduced cortical bone mineral density and Mueller conclude that cortical bone mass was only weakly affected by OVX and by treatment with either IGF-1 or parathyroid hormone.

We agree. As set forth in In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991):

Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under [35 U.S.C.] § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.... Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.

In view of all the evidence presented in this record, we agree with appellants (Brief, page 10) that "[a]t best, Isgaard and Mueller might 'render it 'obvious to try' to use IGF-1 to treat or prevent osteoporosis in mammals having reduced cortical bone mineral density ... [h]owever, neither of these references provides any

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guidance as to the expectation of success of such a use for IGF-1.” Absent a reasonable expectation of success, the examiner’s rejection cannot be sustained.

Accordingly, we reverse the examiner’s rejection of claim 1-12 under 35 U.S.C. § 103 as obvious over Isgaard in view of Mueller.

REVERSED

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

Michael W. Glynn
Novaris Corporation
564 Morris Avenue
Summit, NJ 07901