

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

XPaper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte LAURENCE A. ROTH
and STEPHEN JACK HERMAN

Appeal No. 2003-1167
Application No. 09/195,340

ON BRIEF

Before SCHEINER, ADAMS, and GREEN, 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 6, 14, 15, 18, 19, 21-24, 26 and 27, which are all the claims pending in the application.

Claim 14 is illustrative of the subject matter on appeal and is reproduced below:

14. A method for locally delivering a biologically active molecule to a site in the vascular system where treatment is needed to promote vascularization or revascularization of a tissue, the method comprising
 - a) selecting a biodegradable covalently polymerizable material,

- b) mixing a biologically active molecule with the material, wherein the biologically active molecule is effective to promote vascularization or revascularization of the tissue,
- c) applying the material to the site where treatment is needed, and
- d) covalently polymerizing the material to permit controlled release of a therapeutically effective amount of the biologically active molecule.

The references relied upon by the examiner are:

Hunziker	5,206,023	Apr. 27, 1993
Sierra et al. (Sierra)	5,290,552	Mar. 1, 1994
Marx	5,607,694	Mar. 4, 1997
Hubbell et al. (Hubbell)	5,626,863	May 6, 1997

GROUND OF REJECTION

Claims 6, 14, 18, 19 and 24 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Hubbell.

Claims 6, 14, 15, 18, 19, 21-24, 26 and 27 stand rejected under 35 U.S.C. § 103 as being unpatentable over Hubbell alone, or in combination with Sierra, Hunziker and Marx individually, or in combination.

We reverse.

DISCUSSION

THE REJECTION UNDER 35 U.S.C. § 102:

The examiner finds (Answer, bridging paragraph, pages 3-4), "Hubbell discloses a method of applying a composition containing monomers at the needed site and photo polymerizing the monomers to form a [sic] covalently linked polymers. The composition contains a biologically active material such as proteins, enzymes and nucleotides. The composition also contains microspheres carrying the active agent...." While the examiner appreciates (Answer,

page 6) that Hubbell does not teach vascularization, or the active agents of the claimed invention, the examiner asserts (Answer, page 4), “Hubbell teaches the administration of the composition after surgery. This means there is an incision and therefore, that area requires vascularization and Hubbell teaches the delivery of various active agents at this site.” In our opinion, the lack of specificity in the examiner’s argument serves only to emphasize his failure to establish a prima facie case of anticipation.

Hubbell discloses (abstract), the “[p]referred applications for the hydrogels include prevention of adhesion formation after surgical procedures, ... temporary protection or separation of tissue surfaces, adhering of [sic] sealing tissues together, and preventing the attachment of cells to tissue surfaces.” As the examiner recognizes, Hubbell makes no mention of vascularization, or for that matter, revascularization. In addition, the examiner makes no attempt to demonstrate a nexus between any “active agent” taught by Hubbell and appellants’ claimed biologically active molecule, which is required to be effective to promote vascularization or revascularization of tissue. To the contrary, the examiner admits that Hubbell does not teach the active ingredients of the claimed invention.

We remind the examiner that anticipation under 35 U.S.C. § 102 requires that a single prior art reference disclose each and every limitation of the claimed invention. Electro Med. Sys. S.A. v. Cooper Life Sci., 34 F.3d 1048, 1052, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994). For the foregoing reasons, it is our

opinion that the examiner failed to demonstrate that Hubbell discloses each and every limitation of the claimed invention.

Accordingly, we reverse the rejection of claims 6, 14, 18, 19 and 24 under 35 U.S.C. § 102(e) as being anticipated by Hubbell.

THE REJECTION UNDER 35 U.S.C. § 103:

As discussed above, the examiner recognizes (Answer, page 6) that Hubbell does not teach vascularization, or the active agents of the claimed invention. Accordingly, Hubbell alone is not sufficient to establish a prima facie case of obviousness. However, the examiner asserts (id.), “[o]ne skilled in the art would be motivated further to include [the] instant active agent since the references of Sierra, Hunziker and Marx teach the deliver[y] of these agents at the site based on the same principle, that is ‘polymerization at the site’....”

With emphasis on Hunziker, the examiner asserts (Answer, page 7),

Hunziker clearly states that the growth factor, Fibroblast growth factor is involved in the growth of vascular endothelial cells. Applicant’s [sic] arguments that Hunziker is not directed to vascularization are not found to be persuasive since Hunziker teaches the application of the composition after surgery and naturally the tissue healing involves vascularization.

However, Hunziker is directed to repairing defects in cartilage, and appellants point out (Brief, page 11) that “cartilage is avascular ([Hunziker], column 1, lines 37-38).” Therefore, appellants’ argue (id.), “Hunziker clearly fails to disclose a treatment which promotes vascularization or revascularization.” Appellants find the same flaw in the examiner’s reliance on Sierra and Marx, which according to appellants “are directed to repairing avascular cartilage.” Brief, page 12.

While we do not find the disclosures in Sierra and Marx to be as limited as appellants assert, we agree with appellants (id.) that Sierra, Marx and Hunziker, fail to disclose, individually, or in combination, the use of a biologically active molecule effective to promote vascularization or revascularization of a tissue as is required by appellants' claimed invention. Accordingly, Sierra, Marx and Hunziker fail to make up for the deficiency in Hubbell. In this regard, we remind the examiner that prima facie obviousness based on a combination of references requires that the prior art provide "a reason, suggestion, or motivation to lead an inventor to combine those references." Pro-Mold and Tool Co. v. Great Lakes Plastics Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996).

[E]vidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. . . . The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular.

In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (citations omitted). The suggestion to combine prior art references must come from the cited references, not from the application's disclosure. See In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

On this record, the examiner has failed to identify any evidence that would have led a person of ordinary skill in the art at the time the invention was made to combine the prior art references in a manner that would result in appellants' claimed invention. Therefore, it is our opinion that the examiner failed to provide the evidence necessary to support a prima facie case of obviousness.

Accordingly, we reverse the rejection of claims 6, 14, 15 18, 19, 21-24, 26 and 27 under 35 U.S.C. § 103 as being unpatentable over Hubbell alone, or in combination with Sierra, Hunziker and Marx individually, or in combination.

SUMMARY

The rejection of claims 6, 14, 18, 19 and 24 under 35 U.S.C. § 102(e) as being anticipated by Hubbell is reversed.

The rejection of claims 6, 14, 15 18, 19, 21-24, 26 and 27 35 U.S.C. § 103 as being unpatentable over Hubbell alone, or in combination with Sierra, Hunziker and Marx individually, or in combination is reversed.

REVERSED

Toni R. Scheiner)
Administrative Patent Judge)
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) BOARD OF PATENT
Donald E. Adams)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
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Lora M. Green)
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