THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 45

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED
MAR 29 1995
PAT.&T.M. OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DOMINIC MAN-KIT LAM and PETER J. KELLEHER

Appeal No. 94-1204
Application 07/517,364[1]

ON BRIEF

Before WINTERS, DOWNEY, and GRON, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

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[1] Application for patent filed May 1, 1990. According to appellants, the application is a continuation-in-part of Application 07/204,168, filed June 8, 1988, now U. S. Patent No. 4,871,350; which is a continuation-in-part of Application 06/927,318, filed November 4, 1986, now abandoned.

DECISION ON APPEAL

This appeal was taken from the examiner's decision refusing to allow claims 21 through 26, 28, 30, 31, and 36 through 38, which are all of the claims remaining in the application.

Claims 21 and 36 are representative:

21. A method for inhibiting posterior lens capsule opacification after extracapsular cataract extraction from a host eye, said method comprising the step of:

introducing, in conjunction with said extracapsular cataract extraction, into at least one area of said eye selected from the group consisting of: the anterior chamber; the posterior chamber and the residual lens capsule in an amount sufficient to inhibit proliferation of lens epithelial cells, a cytotoxic agent comprising a targeting moiety capable of binding to said lens epithelial cells conjugated to a cytotoxic moiety, wherein said cytotoxic agent is capable of killing said lens epithelial cells without additional agents.

36. A method for preventing secondary cataract formation in vivo following extracapsular cataract and lens extraction from a host eye comprising the steps of:

introducing through the limbus into the anterior chamber of said eye, prior to said extracapsular extraction, a monoclonal antibody or fragment thereof capable of binding specifically to epithelial cells present in said anterior chamber in an amount and for a time sufficient to bind to said epithelial cells;

removing any unbound monoclonal antibody or fragment thereof;

extracting said extracapsular cataract and lens from said eye;

injecting into the capsular area or a substantially intact residual lens capsule of said eye, in an amount sufficient to inhibit proliferation of any remnant lens epithelial cells, an immunotoxin comprising a targeting moiety capable of binding specifically to lens epithelial cells and a cytotoxic moiety, whereby at least said cytotoxic moiety is internalized by said

remnant lens epithelial cells whereby said remnant lens epithelial cells are killed and secondary cataract formation is prevented.

The references relied on by the examiner are:

Emery et al. (Emery)	4,432,751	Feb. 21, 1984
Voisin et al. (Voisin)	4,340,535	Jul. 20, 1982
Lam et al. (the '350 patent)	4,871,350	Oct. 3, 1989

THE ISSUES

The issues presented for review are:

(1) whether the examiner correctly rejected claims 21, 22, 25, and 26 under 35 U.S.C. § 102 as anticipated by Emery;

(2) whether the examiner correctly rejected claim 28 under 35 U.S.C. § 103 as unpatentable over Emery;

(3) whether the examiner correctly rejected claims 23, 24, and 38 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Emery and Voisin;

(4) whether the examiner correctly rejected claims 30, 31, and 36 through 38 under the judicially created doctrine of "obviousness-type" double patenting over claims 1 through 4 of U. S. Patent No. 4,871,350; and

(5) whether the examiner correctly rejected claims 21 through 26, 28, 30, 31, and 36 through 38 under 35 U.S.C. § 112, second paragraph, as indefinite.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials:

(1) the instant specification and all of the claims on appeal;

(2) appellants' Brief before the Board;

(3) the Examiner's Answer; and

(4) the prior art references cited and relied on by the examiner.

Having carefully considered those materials, we find that the examiner's rejections are untenable. Accordingly, for the reasons set forth infra, we do not sustain any of the examiner's prior art or non-prior art rejections. We enter new grounds of rejection under the provisions of 37 CFR § 1.196(b).

THE EXAMINER'S REJECTIONS

Considering first the rejection of claims 21, 22, 25, and 26 under 35 U.S.C. § 102 as anticipated by Emery, we believe that the examiner's stated position leaves much to be desired. See the terse statement of rejection set forth in the Answer, page 4. Nevertheless, it appears that this § 102 rejection is predicated on a finding that Emery's complement fully meets the limitation of "a cytotoxic agent" in claim 21. We disagree.

As specifically recited in claim 21, the cytotoxic agent "is capable of killing said lens epithelial cells without additional agents." Emery's complement, however, is not capable of killing lens epithelial cells without additional agents, but only kills lens epithelial cells in conjunction with the monoclonal antibodies disclosed by the reference.

Nor does Emery disclose a cytotoxic agent comprising a monoclonal antibody or fragment thereof conjugated to a cytotoxic moiety. See appellants' Brief before the Board, page 7.

For these reasons, the examiner has failed to establish that Emery clearly and unequivocally discloses the subject matter sought to be patented in claims 21, 22, 25, and 26. The examiner's rejection of those claims under 35 U.S.C. § 102 is reversed.

Turning to the rejection of claim 28 under 35 U.S.C. § 103 as unpatentable over Emery, we observe that claim 28 depends from claim 25. The latter claim recites the step of introducing into the eye "a non-cytotoxic agent capable of binding to said other epithelial cells [other than lens epithelial cells] to which said cytotoxic agent is capable of binding." Emery does not disclose or suggest such a step. Rather, the monoclonal antibodies disclosed by Emery are specific to lens epithelial

cells. See appellants' Brief before the Board, paragraph bridging pages 8 and 9. Accordingly, we disagree that Emery suggests the subject matter sought to be patented in claim 28 and we reverse the rejection of that claim under 35 U.S.C. § 103 based on teachings found in Emery.

Further according to the examiner, a person having ordinary skill in the art would have arrived at the subject matter sought to be patented in claims 23, 24, and 38 in view of the combined disclosures of Emery and Voisin. See the Answer, page 5, second complete paragraph. We disagree. Voisin discloses the preparation of "conjugates" in which the A chain of ricin is coupled to an antibody capable of selectively recognizing a given antigen at the surface of cancerous cells. Voisin further discloses the use of those "conjugates" for the treatment of cancer. That patent is not within the field of appellants' endeavor, namely, using monoclonal antibodies against lens epithelial cells and inhibiting the proliferation of remnant lens epithelial cells after extracapsular extraction. Nor is Voisin within the field of Emery's endeavor. Nor is Voisin reasonably pertinent to the particular problem with which appellants were involved at the time the invention was made. As outlined in the "Background" section of the instant specification, that problem relates to developing substantially specific methods for

preventing secondary cataract formation or posterior lens capsule opacification thereby avoiding potential side effects due to the use of cytotoxic agents. On these facts, we conclude that Voisin is from a non-analogous art. Accordingly, the rule precluding rejections based on a combination of teachings of references from non-analogous arts is here applicable and, for this reason, the examiner's § 103 rejection must fall. See In re Wood, 599 F.2d 1032, 202 USPQ 171 (CCPA 1979).

Even assuming arguendo that the Voisin patent were considered "analogous," nevertheless, we would not sustain this rejection because the combination of references does not reasonably suggest the claimed invention. The examiner myopically focuses on features which he believes the references have in common, but overlooks substantial differences in the references, i.e., features which they do not have in common. First, Emery relates to the treatment of secondary cataracts by using monoclonal antibodies against lens epithelial cells and preventing proliferation of remnant lens epithelial cells after extracapsular extraction. In contrast, Voisin relates to the preparation of "conjugates" in which the A chain of ricin is coupled with an antibody capable of selectively recognizing a given antigen at the surface of cancerous cells. Voisin discloses using those "conjugates" for the treatment of cancer.

Second, Emery and Voisin disclose substantially different types of toxins. Emery discloses a standard complement referenced at column 3, lines 33 through 36, whereas Voisin discloses the A chain of ricin. Third, the disclosures of Emery and Voisin are conceptually quite different. Emery does not disclose using an antibody conjugated or coupled to a cytotoxic agent. On the contrary, Voisin teaches just such a construction.

For these reasons, the examiner's rejection of claims 23, 24, and 38 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Emery and Voisin is reversed.

With respect to the rejection of claims 30, 31, and 36 through 38 under the judicially created doctrine of "obviousness-type" double patenting over claims 1 through 4 of U. S. Patent No. 4,871,350, this rejection also lacks merit. The examiner's position to the contrary, notwithstanding, the claims of the '350 patent do not teach or suggest a pre-treatment step using a monoclonal antibody or fragment thereof capable of binding to epithelial cells generally. Those claims are restricted to inhibiting the proliferation of lens epithelial cells. See appellants' Brief before the Board, page 11. Accordingly, the examiner's double patenting rejection is reversed.

The rejection of claims 21 through 26, 28, 30, 31, and 36 through 38 under 35 U.S.C. § 112, second paragraph, as indefinite

is manifestly untenable for the reasons set forth by appellants in their Brief before the Board. Accordingly, this rejection is reversed.

NEW GROUNDS OF REJECTION

Under the provisions of 37 CFR § 1.196(b), we enter the following new grounds of rejection.

Claims 21 through 24 are rejected under the judicially created doctrine of "obviousness-type" double patenting over claims 1 through 4 of U. S. Patent No. 4,871,350. Both sets of claims define a substantially similar method for inhibiting posterior lens capsule opacification after extracapsular cataract extraction, although the application claims are somewhat broader in scope. Independent claim 21 of this application recites introducing the cytotoxic agent into "at least one area of said eye selected from the group consisting of: the anterior chamber; the posterior chamber and the residual lens capsule," whereas claim 1 of the '350 patent recites introducing the cytotoxic agent "into the anterior chamber of the eye." By the same token, independent claim 21 recites a cytotoxic agent comprising "a targeting moiety" which is somewhat broader in scope compared with the monoclonal antibody or fragment thereof recited in patent claim 1. Nevertheless, based on our

review of the respective sets of claims, we find it clear that claims 21 through 24 of this application define merely an obvious variation of the invention disclosed and claimed in claims 1 through 4 of the '350 patent. See In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

In setting forth this new ground of rejection of claims 21 through 24 for "obviousness-type" double patenting, we are mindful of the terminal disclaimer proffered by appellants in Paper No. 18, filed August 8, 1991. By way of memorandum dated August 22, 1991, the Office of Publications, Certificates of Correction Branch notified the examiner that the disclaimer is not acceptable because "[t]here is no record of assignment ... recorded in PTO for this application." See Paper No. 19 in the record. In Paper No. 21 mailed August 29, 1991, page 3, the examiner advised appellants that the disclaimer is not acceptable. In their response filed December 9, 1991, appellants acknowledge that the terminal disclaimer is "defective" and state that "at this time a new Terminal Disclosure [sic] is not being submitted." See Paper No. 24, page 7. On appeal, appellants do not present any argument or arguments predicated on the filing of a proper terminal disclaimer.

Claims 21 through 26, 28, 30, 31, and 36 through 38 are rejected under 35 U.S.C. § 112, first paragraph, as based

on a specification which does not contain an adequate, written description of the invention now claimed. The recitation of "a targeting moiety" in these claims is broader than a monoclonal antibody, or fragment thereof, or equivalent thereof, or any other description in the original specification. The term "a targeting moiety" is not supported expressly or implicitly in the specification as filed.

This rejection would be overcome and the problem would be resolved with an amendment along the lines already proposed in the record. See appellants' Brief before the Board, page 10, last paragraph. We suggest to both appellants and the examiner that such an amendment be resubmitted and entered.

CONCLUSION

We do not sustain the examiner's prior art or non-prior art rejections. Under the provisions of 37 CFR § 1.196(b), we enter new grounds of rejection under the judicially created doctrine of "obviousness-type" double patenting and under 35 U.S.C. § 112, first paragraph. The examiner's decision refusing to allow claims 21 through 26, 28, 30, 31, and 36 through 38 is reversed.

Any request for reconsideration or modification of this decision by the Board of Patent Appeals and Interferences based upon the same record must be filed within one month from the date

of the decision (37 CFR § 1.197). Should appellants elect to have further prosecution before the examiner in response to the new rejections under 37 CFR § 1.196(b) by way of amendment or showing of facts, or both, not previously of record, a shortened statutory period for making such response is hereby set to expire two months from the date of this decision.

Effective August 20, 1989, 37 CFR § 1.196(b) has been amended to provide that a new ground of rejection pursuant to the rule is not considered final for the purpose of judicial review under 35 U.S.C. § 141 or § 145.

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

REVERSED - 37 CFR § 1.196(b)

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Administrative Patent Judge)
)
MARY F. DOWNEY)
Administrative Patent Judge) BOARD OF PATENT
) APPEALS AND
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Appeal No. 94-1204
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