

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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

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

Ex parte MARSARU NAKATANI,
SHIGEO FURUYOSHI, and
SATOSHI TAKATA

Appeal No. 2001-1264
Application No. 08/819,630

HEARD: April 23, 2002

Before WILLIAM F. SMITH, ADAMS, and GREEN, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 7 through 10 and 13, all the claims pending in the application.

Claim 7 is representative of the subject matter on appeal and reads as follows:

7. A method for removing a chemokine except interleukin-8, which comprises bringing an adsorbent which comprises a solid material having an anionic functional group into contact with body fluid containing the chemokine.

The references relied upon by the examiner are:

Yokohari et al. (Yokohari)	5,258,503	Nov. 2, 1993
Boos et al. (Boos)	5,403,917	Apr. 4, 1995
Okarma et al. (Okarma)	5,437,861	Aug. 1, 1995
Pliura et al. (Pliura)	5,545,328	Aug. 13, 1996
Charo et al. (Charo)	5,707,815	Jan. 13, 1998

The reference discussed by the merits panel is:

Hirai et al. (Hirai)	5,216,127	Jun. 1, 1993
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There are two rejections pending against claims 7 through 10 and 13 under 35 U.S.C. § 103(a). The first is premised upon Boos, Pliura, and “prior art statement on pages 1-5 of the specification.” The second is based upon Yokohari, Charo, and Okarma.

We vacate the examiner’s rejections, make a new ground of rejection under 37 CFR § 1.196(b), and raise other issues for the examiner and appellants to consider if prosecution is resumed.

Discussion

The claimed invention is directed to removing a chemokine except for interleukin-8 by contacting a body fluid containing the chemokine with an adsorbent which comprises a solid material having an anionic functional group. As explained by appellants, chemokines are a subset of cytokines and are typically produced in humans in response to an inflammatory event. Specification, page 1, lines 7-25.

As seen, one aspect of the claimed invention is that interleukin-8 is not removed in performing the claimed process. We believe the genesis for this negative limitation is found in the specification at page 6, lines 14-25 as follows:

The present applicant has previously filed the patent applications concerning the adsorbent for removing interleukins, which comprises a solid material having an anionic functional group (Japanese Patent Application No. 226906/1994 (National Republication of PCT Application No. PCT/JP95/01859 (WO 96/09115)) and Japanese Patent Application No. 229298/1995 (Japanese Unexamined patent publication No. 281101/1996)). Therefore, among interleukins, interleukin-8 having chemotaxis, which is a chemokine classified into CXC subfamily and has 8.6 of the isoelectric point, is excepted from the chemokine of the present invention.

Note also page 8, lines 28-29 of the specification which state “[h]owever, interleukin-8 is excepted from the chemokine in the present invention.”

Discussion

The statutory duty of the Board in ex parte appeals is to “review adverse decisions of examiners upon applications for patents.” 35 U.S.C. § 6(b). The two rejections set forth in the Examiner’s Answer are difficult to review for a number of reasons.

One reason is that neither the examiner nor appellants have discussed that aspect of the claimed invention which excludes interleukin-8 from being adsorbed in formulating their respective positions. As more fully developed in the new ground of rejection set forth below, until the metes and bounds of this aspect of the claimed invention are clarified, it is difficult to determine the patentability of the claims on appeal over the relevant prior art.

Another reason is that the examiner’s statements of the rejections do not reflect that the examiner considered the patentability of the claims on appeal using the correct legal standards. As a consequence, the examiner has not performed the

requisite fact finding needed in order to properly reach a conclusion of obviousness under this section of the statute.

For example, the statement of the first rejection which appears in the paragraph bridging pages 3-4 of the Answer, reads as follows:

Boos et al teach passing body fluid over solid absorption [sic, adsorption] material which is composed of a porous supporting material to which functional groups made of natural polyanion chains are covalently bound. The polyanions are polymers or copolymers of styrene type, such as styrene sulfonic acid. See column 2, lines 27-37 and 61. General classes of supports for ion exchange include divinyl-crosslinked polystyrenes. The fractogel supports can contain anionic functional groups. See Pliura et al, columns 7, 8 and 9. the specification teaches chemokine in body fluids. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat body fluid containing chemokine with anionic absorbent [sic].

As seen, the examiner has only concluded that it would have been obvious to “treat body fluid containing chemokine with anionic absorbent [sic].” The examiner has not explained why one of ordinary skill in the art would have had any reason, suggestion, motivation, or incentive to combine the prior art facts relied upon in order to arrive at the claimed subject matter.

The second rejection based upon Yokohari, Charo, and Okarma suffers from the same deficiency in that the examiner again failed to provide a reason, suggestion, motivation, or inventive as to why it would have been obvious to combine the relied upon teachings of the references in order to arrive at the claimed subject matter.

A further reason why the examiner’s position is difficult to review is that the examiner has made a glaring mistake of fact in stating her position. At page 5 of the answer the examiner states that “cytokines are generically called chemokines,” citing page 1, lines 19-20 of the specification. That portion of the specification actually sets

forth that the subset of cytokines which possess chemotaxis are generically named chemokines.

Where as here the metes and bounds of the claims cannot be readily determined, significant misstatements of fact are made and the rejections are based upon incorrect legal standards it is appropriate to vacate the rejections.

New Ground of Rejection Under 37 CFR § 1.196(b)

Claims 7 through 10 and 13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Each of the claims is directed to a method for removing a chemokine except interleukin-8. In reviewing this claim language in light of the supporting specification, we find the claims to be ambiguous as to their scope and meaning.

We believe the reason the exception for interleukin-8 appears in the claims on appeal is the patent activity described by applicants at page 6 of the specification. In an exchange held at oral argument, counsel stated his understanding that the language of the claim excepting interleukin-8 from the claimed method is intended to serve as a disclaimer of the subject matter in a patent rights enforcement sense. However, counsel's argument only adds to the confusion as to the scope and meaning of the claims on appeal.

The claim language excepting interleukin-8 from the claimed method renders the claims ambiguous and unclear. It is unclear from reading the claims in light of the specification whether interleukin-8 is not removed by the claimed adsorbent because the adsorbent is selected so that it adsorbs all chemokines except interleukin-8 or whether the process is to be operated with an adsorbent which is capable of adsorbing

interleukin-8 under certain conditions but the method is operated in such a manner that the required selective adsorption of chemokines but for interleukin-8 occurs.

Alternatively, it may be that the process must be operated such that the body fluid is pretreated to remove interleukin-8 prior to contact with the adsorbent. Another possibility is that the patient is selected such that the condition they are suffering from results in the presence of chemokines but for interleukin-8 so that treatment of body fluids from that patient would meet the stated exception. Another way in which the claims may be interpreted is that the claims are intended to encompass removal of chemokines from a body fluid of a patient using an adsorbent so long as the adsorbent does not remove interleukin-8 exclusively. In other words, the claimed method may encompass treatment of patients whose body fluids contain a number of chemokines including interleukin-8 so long as the adsorbent removes all chemokines including interleukin-8 while the claim would not include the treatment of such a patient if the adsorbent selectively removes interleukin-8 while not adsorbing any other chemokine.

When a claim is subject to so many alternative interpretations as to its metes and bounds and where the specification provides no guidance as to how the claims should be interpreted, the claims are fraught with ambiguity. 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 claim 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.

Apart from the possible alternative interpretations of the scope of the claims on appeal set forth, the argument posited by counsel at oral argument that the language "except interleukin-8" in the claims on appeal serves only as a legal disclaimer of certain undescribed subject matter adds only to the confusion.

Other Issues

1. Interleukin-8.

In considering the issues raised above in our new ground of rejection regarding this aspect of the claimed invention, appellants should review the patent activity referenced at page 6 of the specification and determine whether that activity resulted in documents which are available as prior art under United States patent laws. If the patent activity described in this portion of the specification did not result in legally available prior art under the patent laws of this country, it may be that the questioned language in the claims is surplusage and may be removed without engendering a prior art rejection.

2. Hirai, Yokohari.

If prosecution is resumed on the claims on appeal, the examiner and appellants should take a step back and reconsider the description of Yokohari as well as consider for the first instance on this record the disclosure of Hirai. From our review of the record, it is not clear that the examiner and appellants have considered Yokohari, and now Hirai, using the correct legal standards.

Yokohari describes the treatment of body fluid from a patient suffering from rheumatoid arthritis (RA) using an adsorbent which comprises a solid material having an anionic functional group. See column 3, lines 65 - column 4, line 9. That RA

patients are to be treated according to that to the process of Yokohari is seen in that the adsorbent having an anionic functional group of that reference is stated to adsorb rheumatoid factor (RF) which is associated with rheumatoid arthritis. See, e.g., column 1, lines 41-50.

It cannot be gainsaid that body fluids of patients suffering from RA contain chemokines. Appellants admit as much at page 4, lines 24-32 of the present specification. Thus, it appears reasonable to conclude that body fluids from RA patients containing RF to be treated in Yokohari will also contain chemokines. In other words, there is no evidence of record that RA patients whose condition has progressed to the point that they are presenting RF would not also of necessity be presenting chemokines. Thus, bringing an adsorbent which comprises a solid material having an anionic functional group into contact with body fluid of a patient suffering from RA for the purpose of removing RF as described in Yokohari will also of necessity remove the chemokines which appear to be present in such body fluid as now required by claim 7 on appeal. This is seen in that claim 7 only requires the broad manipulative step of bringing the body fluid in contact with an adsorbent which comprises a solid material having an anionic functional group. That is the same step described by Yokohari and since it appears that the same patient is to be treated by both Yokohari and the present invention, i.e., RA patients, it is reasonable to expect that the same result will be achieved, removal of chemokines as well as RF.

As set forth in In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1934)(citations omitted), “[i]t is the general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable.”

A similar analysis applies to Hirai. This reference describes the removal of serum amyloid protein from body fluids by use of an adsorbent which has an anionic functional group. See, e.g., the abstract. As explained in column 1, lines 15-32 of Hirai, amyloidosis is associated with various conditions including those of the kidney. As explained in the paragraph bridging pages 3-4 of the present specification, the condition identified as dialysis amyloidosis is associated with dialysis therapy as well as the overproduction of chemokines.

Thus, it appears that the treatment of body fluids from a patient suffering from dialysis amyloidosis per the teachings of Hirai using an adsorbent which comprises a solid material having an anionic functional group will necessarily remove chemokines.

Time Period for Response

This opinion contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

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

VACATED; 37 CFR § 1.196(b)

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