

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board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. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID R. BORCHERDING, H. RANDALL MUNSON, AND
CARL K. EDWARDS III

Appeal No. 1998-2088
Application 08/372,712

ON BRIEF

Before WILLIAM F. SMITH, MILLS and GRIMES, Administrative Patent
Judges

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claim 18. Claims 3, 8 and 12 are canceled. Claims 1, 2, 4-7, 9-11, 13-16 and 22-26 are allowed.¹ Claims 17 and 19-21, the only other pending claims, were rejected by the Examiner in a new grounds of rejection in the

¹ Paper No. 15, mailed June 28, 1996.

Appeal No. 1998-2088
Application 08/372,712

Examiner's Answer (Id., page 7).^{2,3} Thus, claims 17-21 are before us for review in this appeal.

Claim 18 is representative and is reproduced below:

18. A method of inhibiting the TNF-a activity in a patient in need thereof comprising administering to said patient an effective antiinflammatory amount of a compound of claims 1 or 2.

The examiner has not relied upon any references.

This merits panel relies on the following references, already made of record in the PTO-892 attachment to Paper No.17, mailed 31 October 1995:

Fisher et al. (Fisher), "Influence of an anti-tumor necrosis factor monoclonal antibody on cytokine levels in patients with sepsis," Critical Care Medicine, Vol. 21, No. 3, pp. 318-327 (March 1993).

Wispé et al. (Wispé), "Tumor Necrosis Factor-Alpha inhibits Expression of Pulmonary Surfactant Protein," Journal of Clinical Investigation, Vol. 86, pp. 1954-1960 (December 1990.)

²During a telephone interview between the Examiner and Appellants' representative on July 21, 1997, it was decided that the Examiner would add a new grounds of rejection for claims 17 and 19-21 since they have the same language as claim 18 which was found to be indefinite by the Examiner. Appellants appear to have rejected the Examiner's offer of withdrawing the final rejection or canceling the claims by Examiner's amendment and allowing the application as alternative courses of action.

³There seems to be some confusion in Appellants' Reply Brief (paper 23) as to which claims are pending in the application. In section 3 of the Reply Brief, Appellants indicate that claim 18 is appealed and that claims 17-21 have been rejected for the same reasons as applied to claim 18. Appellants state that claims 1, 2, 4-7, 9-11 and 13-36 are pending. Id., page 3. In section 7, Appellants also state that "[n]ew claims 37-41 are not under appeal." Id., page 5. These claims are not under appeal because they are not pending in the application. It appears that Appellants' Reply Brief was accompanied by an amendment filed December 2, 1997, in which new claims 37-41 were presented. In a letter mailed February 2, 1998 (paper 24), Appellants were advised that the Reply Brief was entered and noted but that the amendment filed December 2, 1997, was not entered

Appeal No. 1998-2088
Application 08/372,712

Claims 17-21 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

We reverse.

DISCUSSION

Claim Construction

Considering the phrase “patient in need thereof” which was found to be indefinite by the Examiner, we are mindful that:

the definiteness of the language employed [in a claim] must be analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.

In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971) (footnote omitted).

The present specification provides guidance as to who is encompassed by the phrase “patient in need thereof”:

As used herein, the term “patient” refers to a warm-blooded animal such as a mammal which is suffering from, or is in danger of suffering from an acute or chronic inflammation, cellular injury or cell death associated with an immunological based disease. It is understood that humans, mice and rats are included within the scope of the term “patient.”

More specifically, administration of a compound of formulas (I), (II) or (III) to a patient results in inhibition of TNF-a activity in the patient which selectively inhibits TNF-a-mediated inflammatory events....

because it did not comply with 37 CFR § 1.116.

Appeal No. 1998-2088
Application 08/372,712

A patient is in need of treatment with an agent which inhibits TNF-a activity, such as a compound of formulas (I), (II) or (III), where the patient is suffering from certain autoimmune or other diseases for which elevated activity of TNF-a is implicated as a contributing factor in the progression of the disease.

Specification, page 57.

From this passage it is clear that the term “patient in need thereof” includes mammals in which TNF-a-mediated inflammatory events are implicated as a contributing factor in the progression of an acute or chronic disease or condition.

The rejection under 35 U.S.C. § 112, second paragraph

The Examiner’s position appears to be that the above passage does not satisfy the question “who is in need thereof.” Citing the first two paragraphs on page 57, the Examiner states:

this is a much broader concept than claim 18, and not particularly useful. It [the term] is not limited to TNF-a, as immunological based disease can be based on other cytokines such as the interleukin family, as well as other enzymes such as histamines, etc. Further the “in danger of suffering from...immunological based disease” would in its broadest sense cover everyone, since there is no such thing as immunity from such disease. At any rate, this paragraph is so broad that it would cover e.g. someone with Asthma....

[T]he claim language is broader than autoimmune diseases [which the Examiner does not find indefinite]. It also covers “other diseases for which elevated activity of TNF-alpha is implicated as a contributing factor in the progression of the disease.” This is openended [sic] and vague...

[o]ne cannot determine who is and who is not in need thereof just by measuring their TNF-alpha levels.

Appeal No. 1998-2088
Application 08/372,712

Examiner's Answer, pages 4-6.

The Examiner's concern with the apparent lack of specific levels for TNF-a to ascertain who is a "patient in need thereof" and the breadth of the claims form the basis of the holding of indefiniteness.

These concerns stem from the Examiner's consideration of the phrase "patient in need thereof" in isolation, not only without the benefit of the disclosure found in the specification, but also without the context of the claim as a whole. This is not appropriate. In In re Mattison, 509 F.2d 563, 565, 184 USPQ 484, 486 (CCPA 1975) the court, citing In re Moore, supra stated that a criticized phrase "does not stand in a vacuum" but must be considered in the context of the entire claim and that the claims must then be read in light of the specification. The present claims contain the limitations of "inhibiting TNF-a activity" and administering "an effective antiinflammatory amount of a compound." Upon reading the claims in their entirety and in light of the guidance found at page 57 (discussed supra) as well as relevant art of record, we conclude, contrary to the Examiner's assertions, that the metes and bounds of the claims can be readily determined by one of ordinary skill in the art.

Fisher and Wispé are illustrative of the art around the time the invention was made regarding TNF-a activity and the development of inflammatory responses associated with different diseases and conditions. Fisher teaches that the release

of the inflammatory monokine, tumor necrosis factor- α (TNF- α) mediates the biologic effects caused by bacterial endotoxins (see first column, page 319). Fisher further teaches that TNF- α has a central role as a mediator of sepsis by producing proinflammatory activities but this cytokine also induces other inflammatory mediators. Because of this major role, Fisher states TNF- α has become a primary target of immune-based therapies (Id., pages 324-325). Wispé also teaches that TNF- α is a potent mediator of immune function and inflammation (see page 1954) and that TNF- α activity affects ARDS (Adult respiratory distress syndrome) by inhibiting the production of pulmonary surfactant proteins (see page 1958). These references show that a nexus between TNF- α activity and inflammation was well known in the art. In addition, the references as well as Appellants' specification (see for example, page 57) teach that TNF- α activity induces other secondary cytokines which further mediate inflammation. Unlike the Examiner, we find no open endedness since the claim is drawn to inhibiting TNF- α activity which results in inflammation. That the inflammation caused by TNF- α activity may be implicated in several different diseases does not make the claim indefinite.

With regard to the Examiner's concern that there is an apparent lack of specific values for TNF- α levels which renders the claims indefinite, we again turn to the guidance provided by Mattison, 509 F.2d at 565, 184 USPQ at 486. In Mattison, the PTO was similarly concerned about a lack of absolute values which

Appeal No. 1998-2088
Application 08/372,712

would satisfy the limitation “substantially increase the efficiency of a compound as a copper extract.” In Mattison, the court in reversing the rejection under 35 U.S.C. § 112, second paragraph, held that because the specification disclosed general guidelines “for a proper choice of substituent” together with a representative number of examples, one skilled in the art would be able to determine the scope of the invention. As discussed supra, the present specification provides guidance as to the extent to which TNF-a activity must be reduced. According to Appellants’ disclosure, this reduction must effect a reduction in inflammation, further implying that the individual (patient) must also manifest inflammation. Therefore, the Examiner’s concern that the claims embrace individuals suffering from Alzheimer’s, Parkinson’s, Autism or migraine (Answer, page 6) is misplaced, at least to the extent such patients are not also suffering from inflammation and in need of an effective antiinflammatory amount of a compound.

Additionally, we believe that the Examiner’s concern of the breadth of the claims to be misplaced because the Examiner has improperly equated breadth with indefiniteness. It is well established that “breadth is not indefiniteness.”

In re Gardner, 427 F.2d 786, 788, 166 USPQ 138, 140 (CCPA 1970).

In reading the claim as a whole, considering the teachings found in the specification and being mindful that the second paragraph of section 112 simply requires the claims to “set forth and circumscribe a particular area with a

Appeal No. 1998-2088
Application 08/372,712

reasonable degree of precision and particularity," In re Moore, 439 F.2d at 1235, 169 USPQ at 238, we hold that the Examiner was in error in rejecting the claim as being indefinite. Accordingly, we reverse the rejection under 35 U.S.C. § 112, second paragraph.

REVERSED

William F. Smith)
Administrative Patent Judge)
)
)
) BOARD OF PATENT
Demetra J. Mills)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
Eric Grimes)
Administrative Patent Judge)

WS/DM

Appeal No. 1998-2088
Application 08/372,712

T. Helen Payne
Hoechst Marion Roussel, Inc.
Patent Department
Route #202-206/P.O. Box 6800
Bridgewater, NJ 08807-0800