

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte REYNOLD PANETTIERI and RICHARD MURRAY

Appeal No. 1997-2756
Application 08/242,728

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ROBINSON, Administrative Patent Judges.
ROBINSON, 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 3 and 6, all of the claims pending in the application.

Claims 3 and 6 read as follows:

3. A method of inhibiting proliferation of human airway smooth muscle cells comprising contacting human airway smooth muscle cells with an effective amount of an antithrombin agent so that proliferation of said cells is inhibited.

6. A method of treating asthma and related systems in an individual suffering from asthma comprising administering to said individual an effective amount of an antithrombin agent.

The references relied upon by the examiner are:

Murray et al. (Murray), "Receptor-Activated Ca Influx in Human Airway Smooth Muscle: Use of Ca Imaging and Perforated Patch-Clamp Techniques," The American Physiological Society, Vol. 264 (Cell Physiol. 33), pp. C485-C490 (1993).

Roth et al., "Inhibition of Receptor-Mediated Platelet Activation by Nedocromil Sodium," J. Allergy Clin. Immunol. Vol. 91, No. 6, pp. 1217-1225 (1993).

Grounds of Rejection

Claims 3 and 6 stand rejected under 35 U.S.C. § 102(b)¹. As evidence of anticipation, the examiner relies upon Murray.

Claims 3 and 6 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Roth.

We affirm the rejection of claim 6 under 35 U.S.C. § 103 as obvious over Roth and reverse the rejections of claims 3 and 6 under 35 U.S.C. § 102(b) and claim 3 under 35 U.S.C. § 103.

Background

The applicants' invention is described at pages 2-3 of the specification as being directed to a method of inhibiting cytosolic calcium release in human airway smooth

¹ In the Final Rejection of December 27, 1995 (Paper No. 7) the examiner rejected claims 1-3 and 6 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103 as obvious over Murray. The Examiner's Answer of November 6, 1996 (Paper No. 15) does not indicate that claims 3 and 6 are rejected under 35 U.S.C. § 103 as obvious over Murray. Thus, we have limited our consideration of this rejection to the question of whether claims 3 and 6 are properly rejected under 35 U.S.C. § 102(b) as anticipated by Murray.

muscle cells by treating the human airway smooth muscle cells with an effective amount of an antithrombin agent so that the release of cytosolic calcium is inhibited. This treatment is stated to result in the inhibition of the contraction and proliferation of human airway smooth muscle cells which occur in individuals suffering from asthma.

Discussion:

The rejection under 35 U.S.C. § 102

In rejecting claims 3 and 6, the examiner cites Murray as disclosing at page C-489, "the use of applicant' [sic, applicants'] pathway in the treatment of asthma." (Answer, page 3).

We have carefully considered the evidence and reasoning presented by the examiner in support of this rejection. However, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987). Here, the reference does not disclose inhibiting proliferation of human airway smooth muscle cells by contacting human airway smooth muscle cells with an effective amount of an antithrombin agent (claim 3) or treating asthma and related symptoms in an individual suffering from asthma by administered to the individual an effective amount of an antithrombin agent (Claim 6). The examiner acknowledges that the active agent

of Murray is histamine. (Answer, page 5). The examiner has not established, on this record, that histamine is an antithrombin agent. That the reference may suggest or describe the metabolic pathway associated with the condition being treated does not, standing alone, suggest the specific treatments presently claimed. Thus, Murray fails to anticipate the rejected claims. Therefore, the rejection of claims 3 and 6 under 35 U.S.C. § 102 is reversed.

The rejection under 35 U.S.C. § 103

In rejecting the claims under 35 U.S.C. § 103 the examiner notes that Roth, at page 1218, teaches the use of nedocromil sodium to treat asthma. (Answer, page 3). The examiner, additionally, notes that Roth teaches, at page 1222, column 1, first paragraph under DISCUSSION and page 1224, column 1, first full paragraph, that nedocromil sodium blocks or interferes with thrombin activity. (Answer to the Reply Brief, page 1). That nedocromil sodium interferes with thrombin activity is acknowledged at page 2, lines 5-9 of the Specification.

Claim 6:

As to claim 6, we would agree with the examiner's determination that the claim is unpatentable as being at least obvious over Roth. It would appear that the examiner has presented the rejection in terms of 35 U.S.C. § 103 in view of the focus on mechanism of action or the pharmacological pathway, described by appellants, on

which the currently claimed method is premised. However, claim 6 does not require a particular pharmacological effect, but is directed to a method of treating asthma by administering an antithrombin agent. As urged by the examiner, Roth teaches the treatment of asthma with a substance which is also described as having antithrombin activity.

Appellants urge that Roth does not teach the use of an antithrombin agent within the meaning of the present invention. (Principal Brief, pages 8-9). Appellants contend that (id.):

the normal activities of thrombin to which Appellants are referring, are " -thrombin-induced effects upon human ASM cells, specifically cytosolic calcium release and smooth muscle cell proliferation.

However, claim 6 does not reflect a limitation of this nature. Claim 6 is directed to a method of treating asthma and related symptoms comprising administering an effective amount of an antithrombin agent. At page 7 of the Specification, appellants state that "[b]y 'antithrombin agent' is meant to include any compound which deters the normal activities evoked by the presence of thrombin." (Emphasis added.) The declaration of Dr. Panettieri (Paragraph 4) urges that the pharmacological activity of nedocromil sodium is not antithrombin activity. Yet, this is inconsistent with appellants' own specification and it is with reference to the specification that one must interpret the claims. See In re Sneed, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983)("It is axiomatic that, in

proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification[] and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.") (citations omitted). Further, Roth explicitly describes the treatment of asthma with a substance which is characterized as inhibiting or blocking the activities evoked by the presence of thrombin. To the extent that appellants would urge that the phrase "an effective amount" as used in claim 6 should be read to require a specific pharmacological effect or result (Brief, page 7 and paragraph 4 of the Panettieri Declaration), we note that appellants have offered no evidence which would reasonably establish that nedocromil sodium does not inhibit " -thrombin.

Appellants, additionally, argue that Roth fails to teach the pharmacological effect on which the present invention is based (Reply Brief, page 2). However, claim 6 does not require a particular pharmacological effect, but defines the claimed subject matter in terms of the therapeutic effect of treating asthma. Further, as we have stated, Roth does state that nedocromil sodium inhibits or blocks the activity of thrombin. While not necessarily the pharmacological effect on which the described therapy is based, the method of treatment of asthma with a substance which has antithrombin activity is explicitly taught.

It is the initial burden of the patent examiner to establish that claims presented in an application for a patent are unpatentable. In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). We have carefully considered the evidence and discussion in support of the rejection presented by the examiner as well as the arguments and evidence presented by the appellants. On balance, a fair evaluation of the reference, applicants' specification and consideration of the claimed subject matter as a whole, dictates a conclusion that the examiner has established a prima facie case of unpatentability as to the subject matter of claim 6 which has not been overcome by appellants' arguments or evidence. Thus, on the record before us, we find no error in the examiner's determination that the subject matter of claim 6 is unpatentable over the disclosure of Roth. We, therefore, affirm the rejection of claim 6 under 35 U.S.C. § 103.

Claim 3:

Claim 3 differs from claim 6 in being directed to a method of inhibiting proliferation of human airway smooth muscle cells using an antithrombin agent. Roth does not describe such a method and the examiner has offered no evidence which would supply that which is missing from this reference. While Roth may describe the use of nedocromil sodium for the treatment of asthma, that is not what is claimed. A patentability determination must begin with the scope of the claims being ascertained. Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1567-68, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert denied, 481 U.S. 1052

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(1987). (“Analysis begins with a key legal question--what is the invention claimed?”). In similar fashion, the court stated in In re Wilder, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970), “[t]he first inquiry must be into exactly what the claims define.” The examiner's rejection of claim 3 is fatally defective since it does not properly account for and establish the obviousness of the subject matter claimed.

Where, as here, the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). We, therefore, reverse the rejection of claim 3 under 35 U.S.C.

§ 103.

SUMMARY

To summarize, the rejection of claims 3 and 6 under 35 U.S.C. § 102, over Murray, is reversed. The rejection of claim 3 under 35 U.S.C. § 103, over Roth, is reversed. The rejection of claim 6 under 35 U.S.C. § 103, over Roth, is affirmed.

No time period for taking any subsequent action in connection with this appeal may

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be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

SHERMAN D. WINTERS)
Administrative Patent Judge)
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) BOARD OF PATENT
WILLIAM F. SMITH)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
DOUGLAS W. ROBINSON)
Administrative Patent Judge)

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JANE MASSEY LICATA
WOODLAND FALLS CORPORATE PARK
210 LAKE DRIVE EAST
SUITE 201
CHERRY HILL, NJ 08002

DWR/jlb