

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte MICHAEL S. DEY, FREDERICK J. BEX
and ALAN CORBIN

Appeal No. 2005-0317
Application No. 09/962,352

ON BRIEF

Before SCHEINER, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, 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 claims 13-30, all of the claims remaining. Claim 13 is representative and reads as follows:

13. A method of treating an estrogen receptor positive carcinoma selected from the group consisting of estrogen receptor positive carcinoma of the breast, uterus, ovary, fallopian tube, cervix, vagina, liver, pituitary, central nervous system, hypothalamus, bone, skin, kidney, urethra, and prostate in a mammal in need thereof which comprises administering to said mammal an effective antineoplastic amount of 17 α -dihydroequillin or a sulfate or glucuronide conjugate thereof orally, parenterally, transdermally, topically, rectally, intravaginally, intranasally, or intrabronchially; wherein said 17 α -dihydroequillin or a sulfate or glucuronide conjugate thereof is in substantially purified form.

The examiner relies on the following reference:

Physicians Desk Reference (PDR), 43rd ed., pp. 2355-2358 (1989)

Claims 13-30 stand rejected under 35 U.S.C. § 103 as obvious in view of the PDR. We reverse.

Background

“Estrogens have been shown to play an important role in the modulation of estrogen receptor positive breast carcinoma. Binding of endogenous estrogens, in particular 17 β -estradiol (E₂), to the estrogen receptor has been linked to proliferation of the carcinoma cells.” Specification, paragraph [001]. “Current trends in the treatment of estrogen receptor positive breast carcinoma are focused on the use of anti-estrogenic agents that prevent the binding of E₂ to the estrogen receptor.” Paragraph [002]. One such anti-estrogen is tamoxifen. Id.

The specification discloses a method of treating estrogen receptor-positive carcinoma by administration of 17 α -dihydroequilin. See, e.g., paragraph [006]. The specification discloses that 17 α -dihydroequilin blocked the proliferative effect of 17 β -estradiol in an in vitro assay, similar to tamoxifen. See paragraphs [010] to [013]. The specification also discloses that treatment with 17 α -dihydroequilin in vivo caused a reduction in the size of tumors induced in rats. See paragraphs [014] to [015].

Discussion

The claims are directed to a “method of treating an estrogen receptor positive carcinoma . . . which comprises administering . . . an effective antineoplastic amount of 17 α -dihydroequilin . . . in substantially purified form.”

The examiner rejected the claims as obvious in view of the Premarin[®] entry in the Physician's Desk Reference (PDR). See the Examiner's Answer, pages 3-4:

The PDR discloses that Premarin[®] . . . contains a mixture of conjugated estrogens, including the recited 17 α -dihydroequilin and its sulfate ester. It further discloses . . . that it can be used for palliation to treat prostate cancer and breast cancer.

Instant independent claim 13 differs over the PDR in reciting only 17 α -dihydroequilin or a sulfate or glucuronide conjugate in substantially purified form. However, the instant phrase "substantially purified" and "comprising" language would allow for the presence of other estrogens.

Appellants argue that the examiner has misinterpreted the claim language. See the Reply Brief, page 2: "[S]ubstantially purified form' as applied to the 17 α -dihydroequilin or a sulfate or glucuronide conjugate thereof means substantially free of other estrogens." "[W]hile the PDR teaches the administration of Premarin[®], which contains 17 α -dihydroequilin and 17 α -dihydroequilin sulfate salts, the PDR does not teach that 17 α -dihydroequilin or its salts are in substantially purified form, i.e., substantially free of other estrogenic components." Appeal Brief, page 10. "Thus, while the claim is open to additional steps, the step recited in the claim requires administering 17 α -dihydroequilin or a sulfate or glucuronide conjugate thereof in substantially purified form, not as the PDR teaches, the administration of a mixture of conjugated estrogens." Reply Brief, pages 3-4.

We agree with Appellants' interpretation of the claim language. "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." In re Sneed, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983). However, claims must not be read so broadly as to vitiate an express limitation. See In re Wilder, 429 F.2d 447, 450,

166 USPQ 545, 548 (CCPA 1970) (“[E]very limitation positively recited in a claim must be given effect in order to determine what subject matter that claim defines.”); In re Angstadt, 537 F.2d 498, 501, 190 USPQ 214, 217 (CCPA 1976) (“[W]e must give effect to all claim limitations.”).

Here, the claims are directed to a “method . . . comprising administering . . . an effective antineoplastic amount of 17 α -dihydroequilin . . . in substantially purified form.” The examiner’s claim interpretation effectively reads out the final limitation from the claim. That is, under the examiner’s interpretation, the claim is open to administration of 17 α -dihydroequilin in combination with other estrogens. Under this interpretation, the claim would have the same scope as one that read a “method . . . comprising administering . . . an effective antineoplastic amount of 17 α -dihydroequilin.”

As Appellants have pointed out, their interpretation of the claim language is supported by the working examples in the specification, which involve administration of 17 α -dihydroequilin without any other estrogens. It is also supported by the prosecution history, during which Appellants have consistently interpreted the claim to require administering 17 α -dihydroequilin in “substantially purified form, i.e., substantially free of other estrogenic components.” See, e.g., the response filed September 17, 2002, page 7. Both the specification and the prosecution history are relevant to construing claim language. See Renishaw plc v. Marposs Societa per Azioni, 158 F.3d 1243, 1248, 48 USPQ2d 1117, 1120 (Fed. Cir. 1998) (“[A] claim must be read in view of the specification of which it is a part.”); id. at 1249 n.3, 48 USPQ2d at 1121 n.3 (“Likewise, any interpretation that is provided or disavowed in the prosecution history also shapes the claim scope.”).

We interpret the claim language requiring “administering . . . 17 α -dihydroequilin . . . in substantially purified form” to mean administering 17 α -dihydroequilin in a form that is substantially free of other estrogenic components. Since Premarin[®] contains 17 α -dihydroequilin in a mixture with other estrogenic components, the PDR’s disclosure does not meet all of the limitations of the claimed method, and the examiner has not adequately explained how it would have suggested the claimed method to those of skill in the art. The examiner’s rejection is reversed.

REVERSED

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Administrative Patent Judge)	
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