UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WYLIE W. JR. VALE, KATHY A. LEWIS,
MARILYN H. PERRIN, KOICHI S. KUNITAKE,
JEAN E. RIVIER, and JOZSEF GULYAS

Appeal 2007-4128
Application 11/214,371
Technology Center 1600

Decided: April 14, 2008

Before DEMETRA J. MILLS, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal[1] under 35 U.S.C. § 134 from the Examiner's final rejection of claims 98 and 99.[2] We have jurisdiction under 35 U.S.C. § 6(b). The appealed claims read as follows:

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[1] This Appeal was heard on March 11, 2008.

98. A method of reducing glucagon production in an individual comprising administering to the individual an effective amount of corticotropin releasing factor receptor 2 ("CRF R2") antagonist.

99. The method of claim 98, wherein the CRF-R2 antagonist is a Urocortin III analog, the analog comprising a Urocortin III protein with an N-terminal deletion selected from the group consisting of the first five amino acids, the first six amino acids, the first seven amino acids and the first eight amino acids.

We reverse, but enter a new ground of rejection.

DISCUSSION

Claim 98 stands rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

According to the Examiner, "the genus of 'CRF R2 antagonist' has not been adequately described, since only one species, Urocortin III analog is disclosed." (Ans. 4.) The Examiner, while noting that Rühmann[3] discloses other CRF-R2 antagonists, argues that Rühmann teaches that there are structural and functional similarities between CRF R2 and CRF R1, and that as nonpeptidic antagonists of CRF R1 are known, there could be other, nonpeptidic antagonists to CRF R2 (*id.* at 5-6.)

The Examiner concludes:

> Thus, as the CRF R1 and CRF R2 are similar in structure, it can reasonably be concluded that there are other peptidic and

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[2] Claims 102, 103, 106, and 107 are also pending and stand objected to as depending from a rejected base claim but are otherwise free of rejection.
[3] Rühmann et al., "Structural requirements for peptidic antagonists of the corticotropin-releasing factor receptor (CRFR): Development of CRFR2β-selective antisauvagine-30," *Proc. Nat'l Acad. Sci., USA*, Vol. 95, pp. 15264-269 (1998).

> nonpeptidic antagonist[s] CRF R2 and the small subset of these antagonist family of urocortin III cannot be considered to be representative of the entire genus of CRF R2 antagonists, and therefore cannot be considered to be representative of the entire genus of CRF R2 antagonists, and therefore cannot be evidence of the possession of the entire genus of CRF R2 antagonists.
>
> Therefore, written description is not satisfied because one skilled in the art cannot predict other potential CRF R2 antagonists.

(*Id.* at 6.)

Appellants argue that the Specification "discloses . . ., in effect, *thousands* of CRF-R2 antagonists, including a wide assortment of peptides as well as antibodies." (App. Br. 4.) Appellants argue further, citing Rühmann, that "CRG-R2 antagonists are an 'art recognized' class of agents." (*Id.* at 5.)

"The burden of showing that the claimed invention is not described in the application rests on the PTO in the first instance." *In re Edwards,*, 568 F.2d 1349, 1354 (CCPA 1978). A written description of an invention involving a chemical genus, like a description of a chemical genus, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). While "examples explicitly covering the full scope of the claim language" is not typically required, a sufficient number of representative species must be included "to demonstrate that the [applicant] possessed the full scope of the invention." *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). This requirement applies not only to compositions of

matter, but to methods as well. *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004). However,

> the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.

Capon v. Eshhar, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

In the case before us, contrary to the finding of the Examiner, CRF-R2 antagonists, other than urocortin III analogs, are described by the Specification, and also known in the prior art, as evidenced by Rühmann. First, as noted by Appellants, the Specification teaches a large number of urocortin III analogs that can act as CRF-R2 antagonists (Spec. 7-8; *see also* claims 106 and 107). In addition, the Specification also teaches the use of urocortin III antibodies as the CRF-R2 antagonist (Spec. 9; *see also* claim 108).

Moreover, Rühmann teaches the development of CRF-R2 antagonists, wherein truncated and conformationally constrained analogs of CRF based on the amino acid sequences of h/rCRF, ovine CRF, rat urocortin, and sauvagine (Rühmann, p. 15264, second column). The reference also teaches the production of a specific antagonist to CRF-R2 (*id.* at 15267, second column).

Thus, given the disclosure of the CRF-R2 antagonists in the Specification, as well as the recognition of CRF-R2 antagonists as a class of compounds in the prior art, as evidenced by Rühmann, we find that the preponderance of the evidence supports a finding that claim 98 is supported

by an adequate written description. Thus, the rejection of the Examiner is reversed.

Claims 98 and 99 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable as being unpatentable over claim 1 of Vale Jr..[4] According to the Examiner:

> Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 98 and 99 refer to a method of reducing glucagons production in a patient by administering CRF R2 antagonist (claim 98) and where the antagonist is urocortin protein (claim 99), where the claim 1 of U.S. Patent No. 6,953,838 refers to a method of treating a pathophysiological state by administering of urocortin III protein.

(Ans. 6)

Appellants argue that "the claim[s] at issue in the application claims a species of the genus from the patent," asserting "a genus neither anticipates a species, nor does it render a species *prima facie* obvious on its own." (App. Br. 10.) Thus, Appellants assert that the Examiner has not met the burden of establishing a prima facie case of obviousness. As we agree, we are compelled to reverse the rejection.

We make the following new grounds of rejection using our authority under 37 C.F.R. § 41.50(b).

Claims 98 and 99 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5 of Vale Jr.

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[4] Vale Jr., US Patent No. 6,953,838 B2, issued October 11, 2005.

Claim 1 of Vale Jr. is drawn to:

> A method of treating a pathophysiological state, comprising the step of administering a pharmaceutical composition comprising a urocortin III protein and a pharmaceutically acceptable carrier to an individual in need of such treatment, the urocortin III protein having the amino acid sequence of SEQ ID NO:5 with an N-terminal deletion selected from the group consisting of the first five amino acids, the first six amino acids, the first seven amino acids and the first 8 amino acids.

Claim 5 of Vale Jr. adds the limitation that the pathophysiological state may be diabetes mellitus. In addition, the Specification teaches that glucagon "is a major hyperglycemic factor known to exacerbate diabetic glucose control." (Spec. 56, ll. 13-16.)

Instant claim 98 is drawn to a method of reducing glucagon production by administering a CRF-R2 antagonist, and instant claim 99 defines the CRF-R2 antagonist as Urocortin III protein with an N-terminal deletion selected from the group consisting of the first five amino acids, the first six amino acids, the first seven amino acids and the first eight amino acids.

Therefore, the agent required by claims 1 and 5 of Vale Jr. is encompassed by the CRF-R2 antagonist as required by instant claim 99. In addition, claim 5 of Vale Jr. is drawn to use of the agent to treat diabetes mellitus. As taught by the Specification, glucagon is a major hyperglycemic factor known to exacerbate diabetic glucose control. (Spec. 56, ll. 13-16.) Thus, claims 1 and 5 of Vale Jr. administer an agent that is a CRF-R2 antagonist as required by instant claims 98 and 99 to the same patient population—that is—patients with diabetes mellitus. The ability of the CRF R2 antagonist to reduce glucagon production would be an inherent property

of the compound, and is the mechanism by which the antagonist treats the pathophysiological state of diabetes mellitus. Thus, instant claims 98 and 99 are not patentably distinct from claims 1 and 5 of Vale Jr.

CONCLUSION

In summary, we reverse the rejections on Appeal, but institute a new ground of rejection.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(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 the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner . . . .

(2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record . . . .

REVERSED; 37 C.F.R. § 41.50(b)

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FULBRIGHT & JAWORSKI, L.L.P.
600 CONGRESS AVENUE
SUITE 2400
AUSTIN TX 78701