

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 53

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ANTON BECK, EDWARD BERNSTINE,
NANCY HSIUNG and VERMUNI B. REDDY

Appeal No. 1996-3580
Application 07/970,227

HEARD: May 16, 2000

Before WILLIAM F. SMITH, SPIEGEL and SCHEINER, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 7, 13, 15 through 22, 24, 28, 36, 81, 82,

89, 90, 92 and 93, all the claims remaining in the application. Claims 7 and 81 are representative:

7. A mammalian cell consisting essentially of a cell transfected by a first expression vector, said transfected cell being capable of producing a biologically active heterodimeric protein having first and second subunits, said selected protein being selected from the group consisting of luteinizing hormone (LH), follicle stimulating hormone (FSH), chorionic gonadotropin (CG) and thyroid stimulating hormone (TSH), each of said subunits of said protein being encoded by said first expression vector under the control of a separate promoter, or progeny of said transfected cell containing the promoters and DNA sequences for said subunits imparted by said vector.

81. A mammalian cell consisting essentially of a cell transfected by a first expression vector and a distinct second expression vector, said transfected cell being capable of producing a biologically active heterodimeric protein having first and second subunits, said protein being selected from the group consisting of luteinizing hormone (LH), follicle stimulating hormone (FSH), chorionic gonadotropin (CG) and thyroid stimulating hormone (TSH), the first subunit of said protein being encoded by said first expression vector and the second subunit of said protein being encoded by said second expression vector, or progeny of said transfected cell containing the promoters and DNA sequences for said subunits imparted by said vectors.

The prior art discussed by appellants includes:

Shome et al. (Shome), "The Primary Structure of Bovine Thyrotropin," 246 The Journal of Biological Chemistry, No. 4, pp. 833-849 (1971).

Maghuin-Rogister et al. (Maghuin-Rogister), "Porcine Thyrotropin. The Amino-Acid Sequence of the α and β Subunits," 61 Eur. J. Biochem., pp. 157-163 (1976).

Sairam et al. (Sairam), "Human Pituitary Thyrotropin. The Primary Structure of the α and β Subunits," 55 Can. J. Biochem., pp. 755-760 (1977).

Gurr et al. (Gurr), "Cloning of cDNA Encoding the pre-\$Subunit of Mouse Thyrotropin," 80 Proc. Natl. Acad. Sci. USA, pp. 2122-2126 (April, 1983).

Vamvakopoulos et al. (Vamvakopoulos), "Synthesis, Cloning, and Identification of DNA Sequences Complementary to mRNAs for " and α Subunits of Thyrotropin," 77 Proc. Natl. Acad. Sci. USA, No. 6, pp. 3149-3153 (1980).

Pierce et al. (Pierce), "Glycoprotein Hormones: Structure and Function," 50 *Ann. Rev. Biochem.*, pp. 465-495 (1981).

The examiner has not relied on prior art in rejecting the claims on appeal. Rather, the claims stand rejected under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure. We reverse. In addition, we raise an issue for the examiner and appellants to consider upon return of the application.

DISCUSSION

Background

Luteinizing hormone (LH), follicle stimulating hormone (FSH), chorionic gonadotropin (CG), and thyroid stimulating hormone (TSH) are heterodimeric proteins with identical alpha subunits and similar, but distinct, beta subunits. Claims 7, 13, 15 through 19, 28, 36, 81, 82 and 93 are drawn to

mammalian cells transformed by one or two expression vectors encoding both subunits, and capable of producing biologically active heterodimeric LH, FSH, CG or TSH; claims 20 through 22 and 89 are drawn to expression vectors; and claims 24, 90 and 92 are drawn to methods of producing heterodimeric proteins.

Enablement

It is well settled that the examiner bears the initial burden of providing reasons why a supporting disclosure does not enable a claim. As stated in In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971):

[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

Having carefully reviewed the specification, including the working examples, in light of the examiner's commentary on pages 3 through 5 of the Examiner's Answer, and the arguments on pages 13 through 37 of appellants' main Brief, we hold that the examiner has not set forth a

reasonable basis for questioning the enablement of the claims on appeal.

The specification contains several working examples demonstrating production of active, heterodimeric human, bovine, porcine, and equine LH, FSH and CG, and various methods were used to obtain cDNA encoding the required "- and \$-subunits (specification, pages 9 through 57). For example, cDNA encoding the \$-subunit of porcine FSH was identified by screening a cDNA library with synthetic probes corresponding to portions of the mature protein sequence (specification, page 31). In addition, clones encoding the \$-subunits of equine LH and FSH were found by screening with bovine LH\$ cDNA and bovine FSH\$ cDNA, respectively (specification, pages 34 and 38). The specification indicates that the same strategies can be used to produce biologically active TSH (specification, pages 2 and 59).

According to the examiner, the specification is not enabling for production of biologically active TSH, primarily because "[t]he specification discloses reproducible methods for obtaining DNA sequences encoding both subunits of LH, FSH and CG, and the "-subunit of TSH" but "does not disclose a reproducible source for the TSH\$ DNA sequences" (Examiner's

Answer, page 4). However, "a patent need not teach, and preferably omits, what is well known in the art." Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987). In our view, the flaw in the examiner's reasoning is the failure to acknowledge the level of skill in the art at the time of appellants' invention.

The record establishes that "the amino acid and/or DNA sequences of [the] TSH $\$$ -subunit were well known to those of ordinary skill in the art" at the time of the invention (main Brief, page 28). In particular, the sequence of cDNA encoding the $\$$ -subunit of murine TSH was known, as were the amino acid sequences of the $\$$ -subunits of human, bovine, porcine and murine TSH. See Shome, Maghuin-Rogister, Gurr, Vamvakopoulos, Pierce (1981) and Sairam. The examiner has not explained why appellants' disclosure, together with what was known in the art at the time of the invention, does not satisfy the enablement requirement.

In addition, we note the examiner's concern that "an undue amount of experimentation" would be required to practice the claimed invention because "[t]he specification has not

taught the ratios of vectors containing DNA sequences encoding TSH" and \$ subunits which would result in the production of biologically active TSH" (Examiner's Answer, pages 4 and 5).

As explained in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988):

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman, [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. (footnote omitted).

Here, the fact finding needed to support the examiners assertion of undue experimentation has not been done.

Accordingly, the rejection of claims 7, 13, 15 through 22, 24, 28, 36, 81, 82, 89, 90, 92 and 93 under 35 U.S.C. § 112, first paragraph is reversed.

OTHER ISSUES

We note the issuance of U.S. Patent 5,639,639 to appellants. Patented claim 10 appears to be so similar to the present claims as to raise the issue of obviousness-type

double patenting. It is suggested that the examiner and appellants review the patent upon return of the application to

the examining group and take whatever action may be appropriate.

REVERSED

William F. Smith
Administrative Patent Judge)
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)
) BOARD OF PATENT

Carol A. Spiegel)
Administrative Patent Judge) APPEALS
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) INTERFERENCES

Toni R. Scheiner)
Administrative Patent Judge)

AND

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