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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte G. RASUL CHAUDHRY

Appeal 2012-001203
Application 11/435,204
Technology Center 1600

Before LORA M. GREEN, JEFFREY N. FREDMAN, and
ULRIKE W. JENKS, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims directed to a method of maintaining embryonic stem cells in culture by supplying a medium comprising a peptide having 80% sequence homology with SEQ ID NO: 1. The Examiner has rejected the claims for lack of written description. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The Specification is directed to "supporting the undifferentiated growth of human embryonic stem cells, and more particularly to factors which support undifferentiated growth of stem cells." (Spec. ¶ 0003.)

Claims 1, 2, 7, 8, 10, and 18-29 are on appeal, and can be found in the Claims Appendix of the Appeal Brief (App. Br. 19-20). Claims 1 and 25 are independent claims. Claim 1 is representative of the claims on appeal, and reads as follows:

> 1. A medium for culturing embryonic stem cells while maintaining the stem cells in an undifferentiated state, the medium comprising one or more isolated polypeptides sharing at least 80% homology to the amino acid sequence set forth in SEQ ID NO: 1.

The Examiner has rejected claims 1, 2, 7, 8, 10, and 18-29 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

As Appellant does not argue the claims separately, we focus our analysis on claim 1, and claims 2, 7, 8, 10, and 18-29 stand or fall with that claim. 37 C.F.R. § 41.37 (c)(1)(iv).

ISSUE

The Examiner takes the position that the "claims are not limited to media containing full-length ID (i.e., the protein with the sequence set forth in SEQ ID NO:1). They encompass media containing all variants of that

protein, so long as they are at least 80% identical to the protein." (Ans. 9.) "All that the specification demonstrates is that Fraction 5 contains a protein (or multiple proteins) that contains a 7-amino-acid sequence and an 8-amino-acid sequence that can also be found in full-length ID." (Ans. 9.)

Appellant contends that "Fraction III and Fraction 5 were analyzed by SDS-PAGE to estimate the size of isolated components in the fraction that support undifferentiated embryonic stem cell growth. *Id.*, ¶ 52. The SDS-PAGE analysis suggested a factor ranging from 20 kDa to 40 kDa involved in supporting undifferentiated hES cell growth." (App. Br. 11.) Appellant further contends that "the sequencing of every amino acid in a peptide sequence is not required to recite a particular sequence in a claim." (App. Br. 12.) The identification of SEQ ID NO:1 was based on "two particularly identified peptide residues: (i) a first peptide residue LRTNWIK and (ii) a second peptide residue DATVPDLK." (App. Br. 13.)

The issue on appeal is: Does the preponderance of the evidence of this record support the Examiner's conclusion that Appellant's specification fails to provide written descriptive support for the claimed invention?

FINDINGS OF FACT

FF1. The Specification provides "*[f]ractionation of the conditioned medium:* The conditioned medium (500 ml) was fractionated by salt precipitation using ammonium sulfate into three separate fractions (I, II and III)." (Spec. ¶ 0042.) Fraction III supported the growth of hES cells similar

to the MEF feeder layer (Spec. ¶ 0050). Fraction III was further analyzed by DEAE chromatography and SDS-Page analysis (Spec. ¶¶ 0044-0045, 0051.) "These [SDS-Page] bands suggest a factor ranging from 20,000-40,000 kD may be involved in supporting the hES cell growth." (Spec. ¶ 0052.)

FF2. The Specification identified peptides LRTNWIK and DATVPDLK using LC/MS/MS mass spectrometry analysis (Spec ¶ 0053, see also Fig. 6). "According to the NCBI data the mouse cDNA (1541 bases, SEQ ID NO:2) encoded a deduced nitroreductase family containing protein with 285 amino acids (SEQ ID NO: l) and a mass of approximately thirty-three (33) kDa." (Spec. ¶ 0053.)

PRINCIPLES OF LAW

When an Applicant claims a class, the Applicant "must describe that class in order to meet the description requirement of the statute." *In re Lukach*, 442 F.2d 967, 968 (CCPA 1971).

"[M]erely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species." *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010.) "[W]hile the description requirement does not demand any particular form of disclosure …, or that the specification recite the claimed invention in haec verba, a description that merely renders the

invention obvious does not satisfy the requirement." *Id.* at 1352 (citations omitted).

ANALYSIS

Claim 1 is directed to a medium comprising a protein that is 80% homologous to SEQ ID NO:1, which contains 285 amino acids (FF2). The Examiner finds that "[a] polypeptide sharing at least 80% homology to the sequence in SEQ ID NO:1 would have at least 228 amino acids in common with that sequence. There are literally thousands of such possible proteins, and Appellants [sic.] have not clearly demonstrated possession of even one" (Ans. 9.)

Appellant contends that "sequencing of every amino acid in a peptide sequence is not required to recite a particular sequence in a claim" and that there are two "pieces of evidence to support the reasonable conclusion that Fraction 5 according to the application examples includes an isolated polypeptide sharing at least 80% homology to the amino acid sequence set forth in SEQ ID NO: 1: (i) SDS-Page mass analysis and (ii) nanospray LC/MS/MS mass spectroscopy proteomic analysis." (App. Br. 12.)

We are not persuaded. We agree with the Examiner's finding that there are thousands of proteins that could meet the requirement of having at least 80% homology to SEQ ID NO:1 (Ans. 9). However, neither the Specification nor claims have set out what regions of SEQ ID NO:1 are critical in order to achieve the claimed activity of "maintaining the cells in an undifferentiated state." In other words, it is not known what

distinguishing attributes are shared by the members of the claimed genus that provide that function. There is no way other than trial and error to identify which member of this very large class of compounds retains the function of maintaining embryonic stem cells in an undifferentiated state.

It is well settled that

> the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. As the district court observed, "[t]he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment."

University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 926 (Fed. Cir. 2004).

The written description requirement can be met by disclosing "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964, (Fed. Cir. 2002).

Appellant has not provided any identification of a single region or multiple regions within SEQ ID NO: 1 which is involved in maintaining the embryonic stem cells in an undifferentiated state. In other words, Appellant

has not provided any identification of critical residues in the SEQ ID NO: 1 which is essential to this function.

As in *Rochester*, the present application discloses an assay for screening media for the ability to maintain the embryonic stem cells in an undifferentiated state but fails to provide which regions of SEQ ID NO: 1 other than the wild type found in faction III (FF1) possess the required function.

> As the district court pointed out: Tellingly, … what plaintiff's experts' [sic] do *not* say is that one of skill in the art would, from reading the patent, understand what compound or compounds-which, as the patent makes clear, are necessary to practice the claimed method-would be suitable, nor would one know how to find such a compound except through trial and error …. Plaintiff's experts opine that a person of ordinary skill in the art would understand from reading the ′850 patent what method is claimed, but it is clear from reading the patent that one critical aspect of the method-a compound that selectively inhibits PGHS-2 activity-was hypothetical, for it is clear that the inventors had neither possession nor knowledge of such a compound.

Rochester, 358 F.3d at 925-926.

Just as in *Rochester*, it is hypothetical which amino acid modifications of SEQ ID NO: 1 will share the claimed activity of "maintaining the stem cells in an undifferentiated state." In the Specification, there is no possession or knowledge of any protein other than the ammonium sulfate

precipitated fraction or the further purified DEAE fraction (FF1) that maintains the stem cells in an undifferentiated state.

The evidence of record supports the Examiner's conclusion that the disclosure of the Specification failed to provide descriptive support for claim 1.

SUMMARY

In summary, we affirm the rejection of claim 1 under 35 U.S.C. §112, first paragraph as failing to satisfy the written description requirement. Because Appellant does not argue the claims separately, we also affirm the rejection of claims 2, 7, 8, 10, and 18-29. 37 C.F.R. §41.37(c)(1)(iv).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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