

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOEQ IP AG,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2016-01608
Patent 6,716,602 B2

Before TONI R. SCHEINER, ERICA A. FRANKLIN, and
MICHELLE N. ANKENBRAND, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

bioeq IP AG (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1, 3–4, 6–16, 18, 20, 22–25, 27–28, and 30–39 of U.S. Patent No. 6,716,602 B2 (Ex. 1001, “the ’602 patent”). Paper 3 (“Pet.”). Genentech, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 9 (“Prelim. Resp.”). Petitioner filed an authorized Reply to Patent Owner’s Preliminary Response, Paper 10 (“Reply”), to address corrections to the ’602 patent claims requested by Patent Owner in its Request for Certificate of Correction Under 35 U.S.C. § 254, Ex. 2009, submitted to the Director after the filing of the Petition.

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a).

Upon considering the Petition, Preliminary Response, and Reply, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims. Accordingly, we deny the Petition and decline to institute an *inter partes* review.

A. *Related Proceedings*

Petitioner and Patent Owner indicate that there are no related matters to this proceeding. Pet. 65; Paper 6, 2.

B. The '602 Patent

The '602 patent is directed to methods for increasing the yield of a heterologous recombinant protein produced by recombinant host cells. Ex. 1001, 3:12–14. The Specification explains that those methods involve “first increasing the protein production capacity of the cells in culture by culturing the cells at a high growth rate, and then decreasing metabolic rate of the cells (rate shift) to permit proper folding or assembly of the heterologous protein.” *Id.* at 3:14–18. Properly folded or assembled functional protein can be revealed by activity assays. *Id.* at 5:11–12.

C. Illustrative Claim

Claim 1 is representative of the challenged claims and is reproduced below:

1. A method for increasing the product yield of a properly folded polypeptide of interest produced by recombinant host cells, wherein expression of the polypeptide by the recombinant host cells is regulated by an inducible system, which method comprises

(a) culturing the recombinant host cells under conditions of high metabolic growth rate; and

(b) reducing the metabolic rate of the cultured recombinant host cells at the time of induction of polypeptide expression, wherein reducing the metabolic rate comprises reducing the feed rate of a carbon/energy source, or reducing the amount of available oxygen, or both, and wherein the reduction in metabolic rate result in increase yield of properly folded polypeptide.

Ex. 1001, 18:11–24.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 3–4, 6–16, 18, 20, 22–25, 27–28, and 30–39 of the '602 patent on the following grounds:

Reference(s)	Basis	Claim(s) challenged
Seeger ¹	§ 102(b)	1, 3–4, 6, 9, 15–16, 20–22, 24–25, 27–28, 30, 33, 39
Seeger	§ 103(a)	7–8, 31–32
Seeger and Makrides ²	§ 103(a)	10, 12, 23, 34, 36
Seeger and Cabilly ³	§ 103(a)	11, 13–14, 18, 35, 37–38

Petitioner also relies on the declaration of Dr. Morris Z. Rosenberg (Ex. 1002).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the

¹ Anke Seeger et al., *Comparison of temperature- and isopropyl-β-D-thiogalacto-pyranoside-induced synthesis of basic fibroblast growth factor in high-cell-density cultures of recombinant Escherichia coli*, 17 ENZYME & MICROBIAL TECH. 947–53 (1995) (Ex. 1010).

² Savvas C. Makrides, *Strategies for Achieving High-Level Expression of Genes in Escherichia coli*, 60 MICROBIOLOGICAL REVIEWS 512–38 (1996) (Ex. 1023).

³ Shmuel Cabilly, *Growth at sub-optimal temperatures allows the production of functional, antigen-binding Fab fragments in Escherichia coli*, 85 GENE 553–57 (1989) (Ex. 1032).

invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner proposes a construction for the claim phrase “reducing the metabolic rate,” that is recited in each of the challenged independent claims.⁴ Pet. 24. According to Petitioner, a person of ordinary skill in the art would have understood from the Specification that claim phrase means “altering the fermentation conditions to reduce or stop the growth/expansion of cells undergoing rapid growth and expansion, *or* for cells no longer undergoing rapid growth and expansion, reducing the oxygen uptake rate and/or the corresponding uptake of the corresponding carbon/energy source by the cells.” *Id.* at 25–26 (emphasis added).

Patent Owner asserts that Petitioner argues for “an overly complex ‘bifurcated definition’” that “attempts to import limitations from the specification.” Prelim. Resp. 18. According to Patent Owner, the phrase “reducing the metabolic rate” should be construed as defined by the Specification, i.e., “altering the host cell culture such that the host cells undergoing rapid growth and expansion reduce (or stop) growth and expansion.” *Id.* (quoting Ex. 1001, 4:12–15).

We agree with Patent Owner that the Specification provides an explicit definition for the claim phrase “reducing the metabolic rate.” The Specification states, “[a]s used herein, ‘reducing metabolic rate’ or ‘shifting down metabolic rate’ means altering the host cell culture such that the host

⁴ See Ex. 1001, 18:10–20:32; Ex. 2009, 7.

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