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Paper No. 16
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENZYME CORPORATION,
Petitioner,

v.

GENENTECH, INC. AND CITY OF HOPE,
Patent Owner.

Case IPR2016-00383
Patent 6,331,415 B1

Before LORA M. GREEN, ERICA A. FRANKLIN, and SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Genzyme Corporation ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–4, 9, 11, 12, 14–20, and 33 of U.S. Patent No. 6,331,415 B1 (Ex. 1001, "the '415 patent"). Paper 2 ("Pet."). Genentech, Inc. and City of Hope (collectively "Patent Owner") filed a Preliminary Response. Paper 10. In addition, after authorization from the Board (Paper 11), Petitioner filed a Reply to the Preliminary Response. Paper 12.

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." Upon considering the Petition and the Preliminary Response, we determine that Petitioner has failed to demonstrate a reasonable likelihood that it would prevail in showing the unpatentability of any of the challenged claims. Accordingly, we decline to institute an *inter partes* review.

A. Related Proceedings

Petitioner identifies IPR2015-01624, which was filed by Sanofi-Aventis U.S. LLC ("Sanofi") and Regeneron Pharmaceuticals, as challenging claims in the '415 patent. Pet. 58. Trial was instituted in IPR2015-01624 on February 5, 2016. IPR2015-01624, Paper 15.

Patent Owner identifies also several district court and PTO proceedings related to the '415 patent. Paper 6.

B. The '415 Patent (Ex. 1001)

The '415 patent issued on December 18, 2001, and claims priority to an application filed on April 8, 1983, now U.S. Patent No. 4,816,567. *See*

Ex. 1001, Title Page. Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel are the listed co-inventors. *Id.*

The '415 patent relates generally to processes for producing immunoglobulin molecules in a host cell transformed with a first DNA sequence encoding the variable domain of the heavy chain and a second DNA sequence encoding the variable domain of the light chain, as well as vectors and transformed host cells used in such processes. *Id.*, Abstract. More specifically, the first and second DNA sequences are present in either different vectors or in a single vector, and independently expressed so that the immunoglobulin heavy and light chains are produced as separate molecules in the transformed single host cell. *See id.*, cols. 1, 15, 18, 21, and 33.

According to the Specification of the '415 patent, there were two major sources of vertebrate antibodies that could be generated *in situ* by the mammalian B lymphocytes or in cell culture by B-cell hybrids (hybridomas). *Id.* at 1:42–45. The Specification notes, however, that monoclonal antibodies produced by these two sources suffer from disadvantages, including contamination with other cellular materials, instability, production of an undesired glycosylated form, high cost, and an inability to manipulate the genome. *Id.* at 2:40–66. The Specification recognizes that "the use of recombinant DNA technology can express entirely heterologous polypeptides—so-called direct expression—or alternatively may express a heterologous polypeptide fused to a portion of the amino acid sequence of a homologous polypeptide." *Id.* at 4:33–37.

The Specification states that "[t]he invention relates to antibodies and to non-specific immunoglobulins (NSIs) formed by recombinant techniques using suitable host cell cultures," which can "be manipulated at the genomic level to produce chimeras of variants which draw their homology from species which differ from each other." *Id.* at 4:53–59. The Specification further indicates that "[t]he ability of the method of the invention to produce heavy and light chains or portions thereof, in isolation from each other offers the opportunity to obtain unique and unprecedented assemblies of immunoglobulins, Fab regions, and univalent antibodies." *Id.* at 12:52–62.

C. Illustrative Claims

Petitioner challenges claims 1–4, 9, 11, 12, 14–20, and 33 of the '415 patent. Claims 1, 15, 18, and 33 are independent. Independent claims 1 and 18 are illustrative, and are reproduced below:

> 1. A process for producing an immunoglobulin molecule or an immunologically functional immunoglobulin fragment comprising at least the variable domains of the immunoglobulin heavy and light chains, in a single host cell, comprising the steps of:
>
> (i) transforming said single host cell with a first DNA sequence encoding at least the variable domain of the immunoglobulin heavy chain and a second DNA sequence encoding at least the variable domain of the immunoglobulin light chain, and
>
> (ii) independently expressing said first DNA sequence and said second DNA sequence so that said immunoglobulin heavy and light chains are produced as separate molecules in said transformed single host cell.
>
> 18. A transformed host cell comprising at least two vectors, at least one of said vectors comprising a DNA sequence encoding at least a variable domain of an immunoglobulin heavy chain and at least another one of said vectors comprising a DNA sequence encoding at least the variable domain of an immunoglobulin light chain.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–4, 9, 11, 12, 14–20, and 33 of the '415 patent on the following grounds (Pet. 3):

References	Basis	Claims Challenged
Salser[1]	§ 102(e)	1–4, 9, 11, 12, 15–20, and 33
Salser and Ochi[2]	§ 103(a)	1–4, 9, 11, 12, 14–20, and 33
Salser and Southern[3]	§ 103(a)	2, 18, and 20

Petitioner relies also on the Declaration of Margaret H. Baron, M.D., Ph.D. Ex. 1058.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable constructions in light of the Specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, No. 15–446, 2016 WL 3369425, at *12 (U.S. June 20, 2016) (upholding the use of the broadest reasonable interpretation standard). Under the broadest reasonable

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[1] Salser et al., U.S. Patent No. 4,396,601, issued Aug. 2, 1983 (Ex. 1002) ("Salser").

[2] Ochi et al., *Transfer of a Cloned Immunoglobulin Light-Chain Gene to Mutant Hybridoma Cells Restores Specific Antibody Production*, 302 NATURE 340–42 (1983) (Ex. 1003) ("Ochi").

[3] P.J. Southern and P. Berg, *Transformation of Mammalian Cells to Antibiotic Resistance with a Bacterial Gene Under Control of the SV40 Early Region Promoter*, 1 J. MOLECULAR AND APPLIED GENETICS 327–341 (1982) (Ex. 1004) ("Southern").

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