Trials@uspto.gov
571-272-7822

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC.,
Petitioner,

v.

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

Case IPR2016-00710
Patent 6,331,415 B1

Before TONI R. SCHEINER, LORA M. GREEN, and SUSAN L. MITCHELL, *Administrative Patent Judges.*

GREEN, *Administrative Patent Judge.*

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

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition (Paper 2, "Pet."), requesting institution of an *inter partes* review of claims 1–4, 11, 12, 14, 18–20, and 33 of U.S. Patent No. 6,331,415 B1 (Ex. 1001, "the '415 patent"). Petitioner also filed a Motion for Joinder, seeking joinder with IPR2015-01624. Paper 3, 1. Genentech, Inc. and City of Hope (collectively, "Patent Owner") did not file a Preliminary Response, but did file an Opposition to the Motion for Joinder. Paper 8. In addition, Petitioners in IPR2015-01624, Sanofi Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc., filed an opposition to the Motion for Joinder in that proceeding (Paper 25). Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that 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); *see* 37 C.F.R. § 42.108.

Upon consideration of the Petition, as well as the papers related to joinder, for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that they would prevail with respect to at least one of the challenged claims. We, thus, institute an *inter partes* review of claims 1–4, 11, 12, 14, 18–20, and 33 of the '415 patent.

A. Related Proceedings

Petitioner identifies IPR2015-01624, IPR2016-00383, and IPR2016-00460 as all challenging claims of the '415 patent. Pet. 44. Note that IPR2015-01624, to which IPR2016-00460 was joined, has been terminated (Paper 43). The Board declined to institute trial in IPR2016-00383 (Paper 16).

Patent Owner identifies U.S. patent applications, as well as issued patents, that relate to the '415 patent. Paper 7, 2–3. In addition, Patent Owner identifies other proceedings before the Office, such as interferences and reexaminations, that may relate to the '415 patent. *Id.* at 3. Patent Owner also identifies several district court proceedings that may relate to the '415 patent. *Id.* at 3–6.

B. Motion for Joinder (Paper 25)

Petitioner seeks joinder to IPR2015-01624, asserting that its Petition "raises the same grounds of unpatentability over the same prior art as those instituted by the Board in [IPR2015-01624]." Paper 3, 1. We note, however, that at the request of the involved parties, we terminated IPR2015-01624 on September 2, 2016 (Paper 43). Thus, Petitioner's Motion for Joinder is moot. We do, however, for the reasons set forth below, as well as in the Decision on Institution in IPR2015-01624 (Paper 15), institute on the same grounds we instituted in IPR2015-01624.

C. The '415 Patent (Ex. 1001)

The '415 patent issued on December 18, 2001, and claims priority to an application filed on April 8, 1983. *See* Ex. 1001, Title Page. It names Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel, as the 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. 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 12:58–62.

D. Illustrative Claims

Petitioner challenges claims 1–4, 11, 12, 14, 18–20, and 33 of the '415 patent. Independent claims 1 and 18, the only independent claims challenged, are illustrative, and 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.

Ex. 1001, 28:35–49; 29:31–36.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of the challenged claims of the '415 patent on the following grounds (Pet. 3):

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