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Paper 13
Entered: March 9, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COHERUS BIOSCIENCES, INC.,
Petitioner,

v.

HOFFMAN-LaROCHE INC.,
Patent Owner.

Case IPR2017-01916
Patent 8,163,522 B1

Before SUSAN L. C. MITCHELL, TINA E. HULSE, and WESLEY B. DERRICK, *Administrative Patent Judges.*

MITCHELL, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Petitioner Coherus Biosciences, Inc. ("Petitioner") filed a petition (Paper 1, "Pet.") to institute an *inter partes* review of claims 1–10 (the "challenged claims") of U.S. Patent No. 8,163,522 B1 (Exhibit 1001, "the '522 patent"). *See* 35 U.S.C. §§ 311–319. Patent Owner Hoffman-LaRoche Inc. ("Patent Owner"), filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. *See* 35 U.S.C. § 314(b); 37 C.F.R. 42.4(a). To institute an *inter partes* review, we must determine that the information presented in the Petition shows "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). For the reasons set forth below, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of any challenged claim of the '522 patent. Therefore, we do not institute an *inter partes* review for any challenged claim of the '522 patent.

B. Related Proceedings

The parties identify two court proceedings involving the '522 patent, one of which has been terminated and one that is ongoing: *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274 (Fed. Cir. 2014) (terminated) and *Immunex Corp. v. Sandoz Inc.*, Case No. 2:16-cv-01118-CCC-JBC (D.N.J.) (pending). Pet. 7; Paper 8, 2.

The parties also identify a previously filed request for *inter partes* review of the '522 patent that was not instituted: *Coalition for Affordable*

Drugs V LLC v. Hoffman-LaRoche Inc., Case IPR2015-01792 (PTAB) ("the 1792 IPR"). Pet. 7, Paper 8, 2; Ex. 1010. Petitioner has also filed a request for *inter partes* review of related U.S. Patent No. 8,063,182 B1 ("the '182 patent"), Case IPR2017-02066. Paper 8, 2.

C. The '522 Patent (Ex. 1001)

The '522 patent is directed, in part, to polynucleotides encoding the extracellular region of an insoluble human TNF receptor (also, "TNF-R") described by an apparent molecular weight and as containing particular amino acid sequences in addition to all domains of the constant region of a human IgG_1 immunoglobulin heavy chain except the first domain of the heavy chain constant region. Ex. 1001, Abs., 2:26–49. The '522 patent also addresses methods for culturing a host cell comprising the polynucleotide and purifying the expression product of the polynucleotide from the cell. *Id.*

D. Illustrative Claims

Claims 1 and 4 are illustrative of the claimed subject matter. Claims 1 and 4 are reproduced below.

1. A method comprising the steps of:

(a) culturing a host cell comprising a polynucleotide, wherein the polynucleotide encodes a protein consisting of:

(i) the extracellular region of an insoluble human TNF receptor, wherein the insoluble human TNF receptor has an apparent molecular weight of about 75 kilodaltons as determined on a non-reducing SDS-polyacrylamide gel and comprises the amino acid sequence LPAQVAFXPYAPEPGSTC (SEQ ID NO: 10), and

(ii) all of the domains of the constant region of a human IgG immunoglobulin heavy chain other than the first domain of said constant region, and

(b) purifying an expression product of the polynucleotide from the cell mass or the culture medium.

Ex. 1001, 45:45–62.

4. A polynucleotide encoding a protein consisting of:

(a) the extracellular region of an insoluble human TNF receptor,

wherein the insoluble human TNF receptor (i) has an apparent molecular weight of about 75 kilodaltons as determined on a non-reducing SDS-polyacrylamide gel and (ii) comprises the amino acid sequence LPAQVAFXPYAPEPGSTC (SEQ ID NO: 10), and

(b) all of the domains of the constant region of a human IgG_1 immunoglobulin heavy chain other than the first domain of said constant region.

Id. at 46:44–55.

E. The Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims 1–10 are unpatentable under 35 U.S.C. § 103(a) based on the following grounds. Pet. 9.

References	Statutory Basis	Claims Challenged
Watson[1] and Smith[2]	§ 103	1–10
Smith, Watson, and Zettlmeissl[3]	§ 103	1–10

[1] Watson et al., *A Homing Receptor–IgG Chimera as a Probe for Adhesive Ligands of Lymph Node High Endothelial Venules*, 110 J. CELL BIOL. 2221–29 (June 1990) (Ex. 1003).
[2] Smith et al., U.S. Patent No. 5,395,760, issued March 7, 1995 (Ex. 1004).
[3] Zettlmeissl et al., *Expression and Characterization of Human CD4: Immunoglobulin Fusion Proteins*, 9 DNA & CELL BIOLOGY 347–53 (June 1990) (Ex. 1005).

Petitioner supports the Petition with the testimony of Dennis R. Burton, Ph.D. (Ex. 1002).

II. ANALYSIS

A. Application of 35 U.S.C. § 325(d) or 35 U.S.C. § 314(a)

Patent Owner asks that we use our discretion under 35 U.S.C. §§ 325(d) or 314(a) to deny *inter partes* review in this case. Prelim. Resp. 21–31. Specifically, Patent Owner asserts that we should exercise such discretion because Smith, used in both grounds in this case, was considered in the 1792 IPR and during examination of the '522 patent, Watson describes the same fusion protein as described in references used in the 1792 IPR challenge and by the Examiner during prosecution, and Zettlmeissl discloses the same fusion protein constructs described in a reference considered in the 1792 IPR. *Id*. at 27–28.

Petitioner asserts that its Petition differs from the petition in the 1792 IPR because "Watson and Zettlmeissl both provide a clear and compelling reason why a POSA would have specifically selected a fusion protein incorporating the hinge-CH2-CH3 region of an IgG." Pet. 17–18. Specifically, Petitioner argues that Zettlmeissl reports poor expression for fusion proteins with CH1 domains and excellent expression for a receptor protein that is joined to the hinge-CH2-CH3 region of human IgG1. *Id*. at 18. Likewise, Petitioner asserts that "Watson identifies *only one* location as optimal for fusion of a receptor protein to the immunoglobulin." *Id*.

Instead of analyzing whether there are differences between the art asserted in this Petition and that discussed during prosecution of the '522 patent or the previous Petition in the 1792 IPR, we find it more efficient to resolve our decision on institution on the merits presented in the Petition.

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