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Paper No. 16
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COHERUS BIOSCIENCES, INC.,
Petitioner

v.

HOFFMANN-LAROCHE INC.,
Patent Owner

Case IPR2017-01916 (Patent 8,163,522 B1)
Case IPR2017-02066 (Patent 8,063,182 B1)

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

DERRICK, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Requests for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

In IPR2017-02066, Coherus Biosciences, Inc. ("Petitioner") filed a Petition (Paper 1 ("Pet.")) to institute an *inter partes* review of claims 1–36 of U.S. Patent No. 8,063,182 B1 (Ex. 1001 ("the '182 patent")). Hoffmann-LaRoche Inc. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). In IPR2017-01916, Petitioner filed a Petition (Paper 1) to institute an *inter partes* review of claims 1–10 of U.S. Patent No. 8,163,522 B1. Hoffman-LaRoche Inc. filed a Preliminary Response. Paper 9. Having considered the Petitions, the Preliminary Responses, and the evidence in each record, and applying the standard set forth in 35 U.S.C. § 314(a), which requires that Petitioner demonstrate a reasonable likelihood that it would prevail with respect to at least one challenged claim in a Petition, we *denied* Petitioner's requests and did not institute *inter partes* review. IPR2017-02066, Paper 11, 20 ("Decision" or "Dec."); IPR2017-01916, Paper 13, 24.

Petitioner filed virtually identical Requests for Rehearing in each case (IPR2017-02066, Paper 13 ("Reh'g Req."); IPR2017-01916, Paper 15), requesting reconsideration of the Decisions denying institution of *inter partes* review. Similar papers and exhibits were filed in both cases. For purposes of this decision, because the Requests for Rehearing set forth the same arguments and reasoning, we will treat both Requests in this single decision, discussing IPR2017-02066 as representative. Also, we will refer to the papers and exhibits in IPR2017-02066 in this decision. Similar papers and exhibits were filed in IPR2017-01916.

Petitioner's Requests are grounded on the claims encompassing both fusion proteins with a functional hinge, including two cysteine residues, and

fusion proteins with all of the amino acid sequence that is encoded by the corresponding hinge exon, including three cysteine residues. *See, e.g.*, Reh'g Req. 1, n.1, 14–15. Petitioner contends that we construed the phrase "all of the domains of the constant region . . ." so as to exclude a "functional hinge." *Id.* at 1. Petitioner argues: (1) that we overlooked Patent Owner's statements characterizing the hinge as a functional hinge, including admissions that the claims encompass a functional hinge; (2) that we improperly relied on a single prosecution history statement as a prosecution disclaimer; and (3) that nothing in the '182 patent specification supports a construction excluding a functional hinge. *Id.* at 2–14.

Petitioner further maintains that its "use of the term 'hinge' to refer to prior art fusion proteins comprising either a functional or genetic hinge was neither 'unclear' nor 'inconsistent.'" *Id.* at 14 (citing Dec. 10–11). Noting that "[n]either the '182 patent nor its prosecution history defines the boundaries of the hinge to include every amino acid in the genetically-encoded hinge," Petitioner contends that "the Board abused its discretion by requiring Petitioner to show this level of specificity in the prior art." *Id.* at 14–15.

We have considered Petitioner's Requests for Rehearing, and, for the reasons set forth below, Petitioner's Requests are *denied*.

II. STANDARD OF REVIEW

37 C.F.R. § 42.71(d) provides that:

> A party dissatisfied with a decision . . . may file a request for rehearing, without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each

> matter was previously addressed in a motion, opposition, or a reply.

See also Office Trial Practice Guide, 77 Fed. Reg. 48756, 48768 (Aug. 14, 2012). Under 37 C.F.R. § 42.71(c), "[w]hen rehearing a decision on petition, a panel will review the decision for an abuse of discretion." An abuse of discretion occurs when a "decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment." *PPG Indus. Inc. v. Celanese Polymer Specialties Co. Inc.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988) (citations omitted).

III. DISCUSSION

Petitioner's general argument that we misapprehended or overlooked matters in construing the claims does not address our reasoning set forth in the decision. Contrary to Petitioner's contentions, we did not construe the claims to be limited to fusion proteins comprising a hinge having the full amino acid sequence encoded by the corresponding hinge exon, including three cysteine residues. Although we did construe the claims to exclude "any protein with less than all of the amino acid sequence of the hinge domain of human IgG (or IgG_1) immunoglobulin heavy chain, even if functional," *see* Dec. 7, we could not discern from Petitioner's discussion of the claims and the art any consistent demarcation in the amino acid sequence of human IgG (or IgG_1) concerning where the first domain ends and the hinge domain begins. As we explained, the phrase "all of the domains of the constant region . . . other than the first domain of said constant region" leaves unsettled "where in the constant region the divide lies between the first domain of the constant region and the hinge domain." Dec. 7–8. What is settled, however, is that the ordinary and customary meaning of the terms

in the phrase requires that all constant region amino acid sequence that is not part of the first domain must be included in the fusion protein. *Id.* at 7.

As made explicit in the Decision, Petitioner failed to define in a consistent manner where the divide lies between the first domain of the constant region and the hinge domain. It was in light of this deficiency that we determined that Petitioner had not met the requisite burden for instituting *inter partes* review. *Id.* at 8. As we further explained:

> [W]ith respect to Zettlmeissl, Petitioner appears to assert that "all of the hinge domain" requires the hinge segment encoded by the hinge exon, including three cysteine residues. But with respect to Watson, Petitioner appears to assert that "all of the hinge domain" simply requires a portion of sequence that includes the two cysteine residues involved in joining the heavy chains.

Id. at 14. Notwithstanding the apparent differences in amino acid sequence, unacknowledged in the Petition, "Petitioner relies on Zettlmeissl and Watson as teaching the use of the same, identical portion of the IgG heavy chain, and relies on that portion for use in the fusion protein." *Id.* at 10 (citing Pet. 5); *see also id.* at 6, 12–14, Pet. 5 (stating "both [Watson and Zettlmeissl] reported optimal results by employing the ***identical*** portion of the IgG heavy chain as claimed in the '182 patent").

Petitioner's position set forth in the Request for Rehearing, nonetheless, is that the claims encompass both fusion proteins with a functional hinge, including two cysteine residues, and fusion proteins with all of the amino acid sequence that is encoded by the corresponding hinge exon, including three cysteine residues. Reh'g Req. 1, n.1, 3–4, 14–15. These two meanings of hinge not only differ as to how much sequence is included, they also lead to inconsistency as to the claims requiring "all of the

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