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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

domains of the constant region . . . other than the first domain [CH1] of said constant region," as explained in the Decision. If the hinge includes sequence encompassing all three cysteine residues encoded by the hinge exon, then the fusion protein including sequence having only two of the cysteine residues would not include all constant region amino acid sequence that is not part of the first domain. Dec. 13–14. Conversely, if the hinge does not require the third cysteine residue, but is nonetheless a "hinge" such that omitted sequence is only from the first domain of the constant region, then the fusion protein including sequence encompassing all three cysteine residues encoded by the hinge exon would not, as contended by Petitioner, have the included "receptor . . . attached directly to the hinge-CH2-CH3 region" (emphasis added). *Id.* at 6. As emphasized in the Decision, "Petitioner cannot have it both ways, particularly without an explanation why" (*id.* at 14), and we are directed to nothing indicating that we overlooked or misapprehended any such explanation provided in the Petition (*see generally* Reh'g Req.).

Turning to the specific matters Petitioner contends that we misapprehended or overlooked, we find none persuasive.

Petitioner contends that we overlooked Patent Owner's statements characterizing the hinge as a functional hinge. *Id.* at 5–10. In particular, Petitioner contends that we overlooked or misapprehended that Patent Owner was the source of the schematic and accompanying description included in Dr. Burton's declaration. *Id.* at 5–7. Petitioner maintains that while we stated "that Dr. Burton's schematic was 'adapted from Ex. 1006,' which is an excerpt from the prosecution history, . . . we did not

acknowledge that [the] schematic . . . is a near identical reproduction of a schematic submitted by Patent Owner during prosecution." *Id.* at 6.

We did not, however, overlook or misapprehend the ultimate source of the schematic set forth in Dr. Burton's declaration. Citing Dr. Burton's declaration, we acknowledged that Dr. Burton "identified [the schematic] as '[a] schematic depiction of an IgG immunoglobulin' (Ex. 1006, 12)" and quoted Dr. Burton's characterization of the schematic as "[a]dapted from Ex. 1006, 12."[1] Dec. 11–12 (citing Ex. 1002 ¶ 36). Indeed, we cited the very same paragraph from Dr. Burton's declaration that Petitioner cites as "specifically point[ing] out that this figure was from the prosecution history." *See* Reh'g Req. 7 (citing Ex. 1002 ¶ 36).

As to Dr. Burton's description of the schematic, Petitioner maintains that we "clearly overlooked that Dr. Burton's description of the hinge region is the same as Patent Owner's description, because otherwise the Board could not have reached the conclusion that the claims *exclude* a functional hinge." *Id.* at 7. Petitioner contends that Dr. Burton's description "closely tracked *Patent Owner's* description of the location of the cysteine residues." *Id.* (citing Ex. 1002 ¶ 39, Ex. 1006, 12). Petitioner also contends that we overlooked "statements made during prosecution in which the Patent Owner explicitly characterized 'the invention' as including a hinge with only two disulfide bonds, and thus, requiring only two cysteine residues." *Id.* at 8 (emphasis omitted).

[1] Exhibit 1006 is not an excerpt of the prosecution history of the '182 patent; it is an appeal brief from the prosecution history of patent application 08/444,790, a divisional of the application from which the '182 patent issued.

As explained above, the Decision is not grounded on the claims excluding a functional hinge; it is grounded on Petitioner's inconsistent position on what constitutes the hinge. Thus, even if Dr. Burton's description were identical to a description of an IgG immunoglobulin set forth at some point by Patent Owner, that fact would not overcome the underlying deficiency.

As to the argument that we overlooked or misapprehended what happened in the CFAD IPR,[2] Petitioner again relies on the misapprehension that the Decision is grounded on the conclusion that "hinge" excludes a functional hinge. *Id.* at 9–10. Petitioner's argument, however, that the Board's construction in the CFAD IPR necessarily encompassed a functional hinge is not persuasive. Petitioner, referring to the decision denying institution in the CFAD IPR (Ex. 1010), argues that CFAD contended "that prior art 'defining hinge functionally' was within the scope of the '522 patent claims" (Reh'g Req. 9 (quoting Ex. 1010, 12)) and that Patent Owner admitted as much in "cit[ing] Capon's teaching of 'fusion proteins retain[ing] at least functionally active hinge" (emphasis omitted) (*id.* (citing Ex. 1008, 31 (citing Ex. 1019, 10:10–12))). The offered construction, not contested by Patent Owner, however, was merely "that the claim phrase 'all of the domains . . . other than the first domain of said constant region' should be interpreted as '-hinge-CH2-CH3' region of . . . immunoglobulin heavy chain.'" Ex. 1010, 5–6. The Board did not need to reach, nor did the Board reach, whether the "hinge" was a functional hinge including sequence

[2] *Coalition for Affordable Drugs V LLC v. Hoffman-LaRoche Inc.*, Case IPR2015-01792 (PTAB) ("CFAD IPR").

having only two of the cysteine residues or an exon-encoded hinge including sequence having all three cysteine residues. *See generally id.*

Petitioner contends that we, overlooking other prosecution history statements, improperly relied on a single statement as a prosecution disclaimer. Reh'g Req. 10–12. Petitioner argues that despite a broad ordinary meaning for the term hinge (and domain), that our "claim construction *narrows* the claim scope to exclude functional hinge regions that lack even a single amino acid of the exon-encoded hinge." *Id.* at 10–11 (citing Dec. 7–8). As discussed above, however, we determined that "all of the constant region forming domains, i.e., CH1, hinge, CH2, and CH3 domains, is included except that forming the first domain" (Dec. 7), and that Petitioner failed to define in a consistent manner where "the divide lies between the first domain of the constant region and the hinge domain" (*id.* at 8). Not having construed the claims to require the full exon-encoded hinge, it follows that we also did not rely on the statements made by Patent Owner as a disclaimer that narrowed the claims.

Petitioner also notes that "Patent Owner does not appear to dispute that a functional hinge is a 'domain;' [because] doing so would be inconsistent with the statement by Patent Owner's expert [in] a related litigation." Reh'g Req. 10, n.2 (citing Decl. of Dr. Wall, *Immunex v. Sandoz Inc.*, No. 16-01118, Dkt. No. 133-3 (D.N.J. Dec. 1, 2016)). The issue, however, is not that there is an inconsistency with a position taken by Patent Owner in a related litigation, but rather the failure of Petitioner to define the divide between the first domain and the hinge domain in light of the apparent inconsistency between the two proffered grounds, which inconsistency is neither acknowledged, nor addressed in the Petition. *See*

generally Dec. We further note that Dr. Wall's declaration cited by Petitioner is not evidence of record in this proceeding. *See* Reh'g Req. 10, n.2.

Despite arguing we erred in limiting the claims to exclude a functional hinge, which is only at issue with regard to the ground based on Watson in view of Smith (*see generally* Dec.), Petitioner also contends that we "misapprehended [its] position regarding Watson" and states its position as "contend[ing] that Watson teaches fusion proteins with a complete genetic, exon-encoded hinge." Reh'g Req. 15 n.4 (citing Pet. 29–30). Petitioner further maintains that any conclusion to the contrary constituted "an improper weighing of the evidence that should have been reserved for trial." *Id.* (citing 37 C.F.R. § 42.108(c)); *see also* Paper 10 (Transcript of January 3, 2018, Conference Call), 19:6–8, 28:6–9, 29:2–5.

As an initial matter, we are not persuaded that we misapprehended Petitioner's position as to Watson's teaching as it was set forth in the Petition. Petitioner fails to explain how the cited pages constitute an argument that Watson teaches fusion proteins with a "complete genetic, exon-encoded hinge." *See* Reh'g Req. 15 n.4 (citing Pet. 29–30). We cannot have misapprehended an argument that was never made. Regardless, it would not avail Petitioner's position even if Watson did teach a complete genetic, exon-encoded hinge. The salient issue is not that the prior art does not disclose such a hinge, but rather that Petitioner failed to set forth a consistent, tenable position as to claim construction. As explained in the Decision, the use of the complete genetic, exon-encoded hinge is inconsistent with Dr. Burton's definition of a hinge and would also not provide a fusion protein having, as contended by Petitioner, the included

"receptor . . . attached directly to the hinge-CH2-CH3 region" in accord with that definition. Dec. 6, 11–12. These deficiencies remain even if Watson did teach a complete genetic, exon-encoded hinge, such that the hinges taught by Watson and Zettlmeissl were identical.

Petitioner contends that we overlooked or misapprehended that nothing in the '182 patent specification supports our claim construction. Reh'g Req. 12–13. Petitioner contends that "[t]he Board's claim construction also purports to rely on the '182 patent specification" and highlights that "the Board's opinion does not cite to the specification, but instead cites to Patent Owner's *interpretation* of examples from the patent specification." *Id.* (citing Dec. 7–8). Petitioner then contends that "nothing in the '182 patent specification describes that the fusion protein must comprise a complete, exon-encoded genetic hinge" and that "Example 11, . . . is not relevant to the claimed subject matter . . . [because it] does not include the extracellular region of the 75 kD TNF receptor . . . [and] includes the constant region of an IgG_3—not IgG_1—as required by claims 4-6, 13-17, 20-21 and 26-29 of the '182 patent." *Id.* at 13–14 (citing Ex. 1001, Ex. 1002 ¶¶ 44–46, 50).

Petitioner again misapprehends that the Decision is grounded on the conclusion that "hinge" excludes a functional hinge. As explained above, however, the Decision rests on the unacknowledged inconsistency between the two proffered grounds and the lack of any clarifying explanation in the Petition.[3] As to Petitioner's further argument, the cited declaration

[3] Further, if Watson did teach the use of a complete, exon-encoded hinge as Petitioner now contends, there would be an unacknowledged inconsistency between Dr. Burton's definition of hinge and both grounds, without any clarifying explanation.

testimony—discounted by Petitioner as "Patent Owner's interpretation" (*id.* at 12–13)—is, as we stated, "*evidence* in the record that the Specification of the '182 patent is *consistent with* [Patent Owner's] interpretation" (emphasis added) (Dec. 8). Petitioner's various arguments, contending that the '182 patent specification is not limited to the use of a complete, exon-encoded hinge, are inapposite to whether it is open to such.

Petitioner contends that the Board abused its discretion by requiring a greater level of specificity as to the hinge than the ordinary meaning, which includes both a functional and a genetic hinge. *Id.* at 14–15. Petitioner, however, did not simply rely on the ordinary meaning of the term hinge in its Petition. *See generally* Pet. Rather, as explained above, Petitioner set forth a definition by way of Dr. Burton's declaration, and also by contending that Watson and Zettlmeissl teach the use of the identical portion of the IgG heavy chain, without acknowledging the apparent differences in the portions used (or explaining how they are nonetheless "identical"). Petitioner's argument, thus, falls short because it is contrary to the challenge as defined by its Petition, even if the incompatible, inconsistent definitions effectively proffered by its challenge might fall within the scope of the ordinary meaning of the term hinge raised now in the Request for Rehearing.

On this record, Petitioner neither persuades us that we overlooked or misapprehended any matter, nor sufficiently shows that denying *inter partes* review of claims 1–36 of the '182 patent or claims 1–10 of the '522 patent represents an abuse of discretion.

IV. ORDER

Accordingly, it is hereby:

ORDERED that Petitioner's Requests for Rehearing in IPR2017-01916 and IPR2017-02066 are *denied*.

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

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