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 No. 8,163,522

COHERUS BIOSCIENCES, INC.'S REQUEST FOR REHEARING
Under 37 C.F.R. §§ 42.71(c)-(d)

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Patent Trial and Appeal Board
United States Patent and Trademark Office
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Submitted Electronically via the PTAB E2E

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Pursuant to 37 C.F.R. §§ 42.71(c)-(d), Coherus Biosciences, Inc. ("Petitioner") hereby requests rehearing of the Board's Decision denying institution of *Inter Partes* Review of U.S. Patent No. 8,163,522 ("the '522 patent") entered March 9, 2018 (Paper No. 13) ("Decision" or "Dec.").

I. INTRODUCTION

The Board's Decision is premised on a narrow construction of the term "hinge" that deviates from the ordinary meaning of the term and improperly omits subject matter that Patent Owner characterized as within the claim scope both during prosecution and in an earlier IPR on the same patent. The Board concluded "that the broadest reasonable interpretation of the phrase '*all* of the domains of the constant region . . . other than the first domain of said constant region' means '*all* of the hinge, CH2, and CH3 domains.'" Dec. at 9. The Board's construction goes further and defines "hinge" to exclude a functional hinge.[1] *Id.* at 9-10. In reaching that conclusion, the Board overlooked or misapprehended that Patent Owner

[1] Although both the two- and three-cysteine forms of the hinge domain may be functional, as used herein, the term "functional hinge" refers to a hinge having the *two* cysteine residues involved in intramolecular bonding between the two heavy chains in IgG_1, as distinguished from the term "genetic hinge," which refers to a hinge having a complete, exon-encoded amino acid sequence with *three* cysteines.

characterized the invention as encompassing a functional hinge and that nothing in the ’522 patent specification supports a contrary conclusion.

First, the Board overlooked that, during prosecution, *Patent Owner* did not ascribe the importance to the boundaries of the hinge region that the Board has now found to be critical. Indeed, Patent Owner was the source of several statements—which the Board erroneously attributed to Petitioner—that characterize the hinge as encompassing a functional hinge. The Board heavily relied on a figure and accompanying description from Petitioner’s expert to conclude that Petitioner’s use of the term “hinge” referred to a functional hinge. Decision at 14-15, 17, 18, 20. However, the Board overlooked or misapprehended that this figure and description were a near verbatim reproduction of a figure and accompanying description ***submitted by Patent Owner*** during prosecution. *Compare* Ex. 1002 ¶39 *with* Ex. 1006 at 12. Patent Owner’s figure, like Petitioner’s, clearly depicts the hinge with two disulfide bonds (and thus, two cysteine residues) with the third disulfide bond (and third cysteine residue) linking the CH1 domain to the light chain. *See id.*

Second, the Board overlooked statements where Patent Owner characterized “***the invention***” as containing a hinge with two disulfide bonds—and thus requiring only two cysteine residues. Ex. 1006 at 13 (emphasis added); Ex. 1002 ¶40; Pet’n at 2.

Third, the Board overlooked or misapprehended that, in response to the prior CFAD IPR, Patent Owner agreed that the term "all of the domains of the constant region…" simply required "a hinge," (Ex. 1010 at 7), and did not dispute CFAD's explicit statement that the term includes a functional hinge, (*id.* at 10-12).

Claim terms are to be given their ordinary meaning unless the patentee, acting as its own lexicographer, has ascribed a special meaning, or the patentee has unmistakably and unambiguously disavowed claim scope in the specification or during prosecution. Here, the Board acknowledged that the ordinary meaning of "hinge" in the art encompasses both a functional hinge having two cysteine residues in each heavy chain *and* a genetic, exon-encoded hinge containing three cysteine residues in each heavy chain. Dec. at 19. Likewise, there can be no dispute that the ordinary meaning of the claim term "domain" includes both a functional hinge and an exon-encoded genetic hinge. Neither the Patent Owner nor the Board has pointed to any special or different definition of "hinge" in the specification, much less one that is at variance with the acknowledged ordinary meaning of the term.

Thus, the Board based its critical *narrowed* definition on a purported prosecution disclaimer. But that was error. Not only did the patent owner *not* unmistakably and unambiguously disavow a functional hinge, it in fact indicated during prosecution and in prior proceedings before this Board that the claim

encompassed functional hinges. The Board overlooked or misapprehended these critical points and thus improperly dismissed invalidating prior art. Therefore, the Board should grant Petitioner's Request for Rehearing, modify its claim construction, and institute the present IPR.

II. APPLICABLE LEGAL STANDARD

A. Request for Rehearing Standard

A request for rehearing "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, an opposition, or a reply." 37 C.F.R. § 42.71(d). "When rehearing a decision on petition, a panel will review the decision for an abuse of discretion." 37 C.F.R. § 42.71(c).

B. Claim Construction Standard

A claim in an unexpired patent subject to *inter partes* review is to be given its "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b); *see also Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016). Further, unless the patentee acts as its own lexicographer and ascribes a special meaning to a claim term or unmistakably and unambiguously disclaims claim scope, claim terms are given their ordinary and customary meaning. *See, e.g., In re Bigio*, 381 F.3d 1320, 1324-25 (Fed. Cir. 2004); *Idle Free Sys., Inc. v. Bergstrom, Inc.*, IPR2012-00027, 2013 WL 8149392,

at *3 (PTAB Jan. 31, 2013). "While the prosecution history can inform whether the inventor limited the claim scope in the course of prosecution, it often produces ambiguities created by ongoing negotiations between the inventor and the PTO. Therefore, the doctrine of prosecution disclaimer ***only applies to unambiguous disavowals***." *Grober v. Mako Prods., Inc.*, 686 F.3d 1335, 1341 (Fed. Cir. 2012) (emphasis added). "Even if an isolated statement appears to disclaim subject matter, the prosecution history as a whole may demonstrate that the patentee committed no clear and unmistakable disclaimer." *M.I.T. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1120 (Fed. Cir. 2016) (*quoting Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1342 (Fed. Cir. 2009)).

III. BASIS FOR RELIEF REQUESTED

A. The Board Erred in its Construction of "All of the Domains of the Constant Region…" When it Overlooked Patent Owner's Statements Characterizing the Hinge as a Functional Hinge

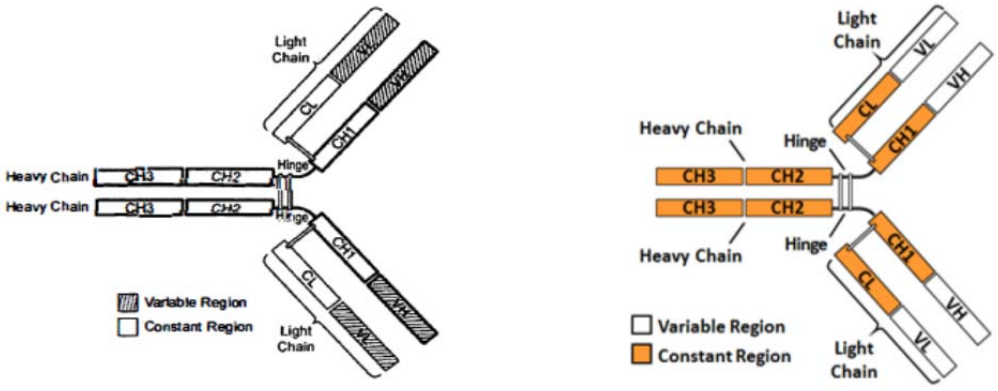
In construing "all of the domains of the constant region," the Board overlooked or misapprehended statements in the prosecution history where Patent Owner characterized the hinge as including a functional hinge.

1. The Board Overlooked That *Patent Owner*—Not Dr. Burton—Was the Source of the Schematic of IgG Comprising a Functional Hinge

The Board's Decision is based on a conclusion that Petitioner's description of the hinge is inconsistent to the extent it encompasses a functional hinge as well as a complete, exon-encoded genetic hinge. Dec. at 14-15, 18. The Board's basis

for concluding that Petitioner described a functional hinge is: (1) a schematic diagram appearing in Dr. Burton's declaration; and (2) Dr. Burton's accompanying description of that schematic. Dec. at 14; *see also id.* at 15, 17, 18. The Board overlooked or misapprehended that ***Patent Owner is the source of that schematic and description***. In other words, during prosecution, Patent Owner adopted the same interpretation of "hinge" as depicted in Dr. Burton's declaration.

First, the Board overlooked or misapprehended that Dr. Burton's representative IgG schematic was a near identical reproduction of a representative IgG schematic that Patent Owner submitted during prosecution of related U.S. Appln. No. 08/444,790, which issued as U.S. Patent No. 8,063,182 (the "'182 patent"). The Board stated in its Decision that Dr. Burton's schematic was "adapted from Ex. 1006," which is an excerpt from the prosecution history. Dec. at 14. The Board, however, did not acknowledge or address that Dr. Burton's schematic (right) is a near identical reproduction of a schematic submitted by Patent Owner during prosecution (left).

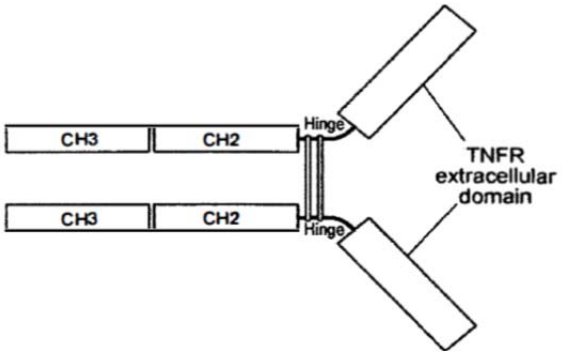


Compare Ex. 1006 at 12 (left) *with* Ex. 1002 ¶36 (right). Dr. Burton relied on Patent Owner's IgG schematic and specifically pointed out that this figure was from the prosecution history. *See* Ex. 1002 ¶36.

Second, the Board overlooked that Dr. Burton's description of the representative IgG schematic and location of the cysteine residues within the hinge and CH1 domains closely tracked *Patent Owner's* description of the location of the cysteine residues. *Compare* Ex. 1006 at 12 *with* Ex. 1002 ¶36. Specifically, Dr. Burton's statement that "in the human IgG1 molecule there is a third disulfide bond (shown above) ***that links the CH1 domain to the constant region of the light chain***" is equivalent to Patent Owner's statement during prosecution that "the two heavy chains are covalently linked to each other by ***disulfide bonds within the CH1*** and hinge." *Id.* (emphasis added). Thus, Dr. Burton's explanation of the location of the third disulfide bond (and third cysteine residue), which is fundamental to the Board's conclusion that Petitioner describes a functional hinge (*see* Dec. at 14-15, 17-18, 20), is the same as Patent Owner's. Ex. 1006 at 12. The Board 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. Indeed, under the Board's reasoning, based on Patent Owner's statements during prosecution, the claimed hinge must *include* a functional hinge.

2. The Board Overlooked Patent Owner's Statements During Prosecution Characterizing "The Invention" as Including a Functional Hinge

The Board also 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. During prosecution of the related '182 patent, Patent Owner submitted an appeal brief in which it argued that "***[t]he invention*** is depicted schematically below."



Ex. 1006 at 13 (emphasis added). Patent Owner's schematic clearly depicts a fusion protein with only two disulfide bonds (and thus two cysteine residues in each heavy chain) linking the heavy chains, representing that a functional hinge is encompassed by the claims and the third cysteine is not required. *Id.* Petitioner and Petitioner's expert ***relied on this figure in their description of the invention and the claim scope of the '522 patent***. Ex. 1002 ¶40 (*citing* Ex. 1006 at 13); Pet'n at 2. In his first paragraph describing the "Scope and Content of the '522 Patent," Dr. Burton reproduced the above figure in his description of the claims of the '522 patent. Ex. 1002 ¶40 (*citing* Ex. 1006 at 13). The Board clearly

overlooked these statements by Patent Owner, because it otherwise could not have reached the conclusion that "hinge" *excludes* a functional hinge. To the contrary, Patent Owner's statements compel the conclusion that the claimed hinge must *include* a functional hinge.

3. The Board Overlooked or Misapprehended Patent Owner Admissions and Its Own Construction from the CFAD IPR that the Claims Encompassed a Functional Hinge

In the CFAD IPR, Patent Owner acknowledged that a functional hinge was within the scope of the '522 patent claims. CFAD argued that prior art "defining hinge functionally" was within the scope of the claims. *See* Ex. 1010 at 12 ("Petitioner states that…Seed and Capon each discloses receptors linked to IgG1 upstream from the hinge region, ***with Capon defining the hinge region functionally***.") (emphasis added). Patent Owner did not dispute this and agreed that the claim term "all of the domains of the constant region…" meant simply a fusion protein broadly comprising, *inter alia,* "a hinge" without further limitation. Ex. 1008 at 26-27; Ex. 1010 at 6-7. Patent Owner cited Capon's teaching of "fusions retain[ing] ***at least functionally active hinge***," (Ex. 1008 at 31 *citing* Ex. 1019 at 10:10-12), when it admitted that Capon's fusions "***retain the hinge, C_H2, and C_H3 domains of the constant region*** of an immunoglobulin heavy chain" as required by the '522 patent claims, Ex. 1010 at 14 (emphasis added). Likewise, the Board in the CFAD IPR held that the claims require only "a hinge region," (*id.*

at 7), despite recognizing that CFAD relied on prior art "defining the hinge region functionally," (*id.* at 12).

B. The Board Overlooked Prosecution History Statements Characterizing the Hinge as a Functional Hinge, Instead Relying on a Single Prosecution History Statement to Support Its Position

The Board does not rely on the ordinary and customary meaning of "hinge" to arrive at its claim construction. Indeed, contrary to its claim construction, the Board recognized that the ordinary and customary meaning of "hinge," as understood in the art, encompasses both a functional hinge and a genetic hinge. *See* Dec. at 19 (noting that Byrn uses "hinge" to refer to a functional hinge); Dec. at 15 (noting that Ellison and Capon use "hinge" to refer to a genetic hinge). The ordinary meaning of the claim term "domain" likewise encompasses both a functional and a genetic hinge.[2] Despite this broad ordinary meaning, the Board's

[2] Patent Owner does not appear to dispute that a functional hinge is a "domain;" doing so would be inconsistent with the statement by Patent Owner's expert in a related litigation that "as a variety of references, including the ['182 and '522] patent[s], reflect, those working in the field understood that any ***functionally***, structurally, or genetically distinct units in immunoglobulins/ antibodies could be called 'domains.'" Decl. of Dr. Wall, *Immunex v. Sandoz Inc.*, No. 16-01118, Dkt. No. 133-3 (D.N.J. Dec. 1, 2016) (emphasis added) at ¶18; *see id.* ¶98.

claim construction *narrows* the claim scope to exclude functional hinge regions that lack even a single amino acid of the exon-encoded hinge. *See* Dec. at 9-10. The Board states that its "construction is consistent with statements the applicant made during prosecution that a fusion protein that includes only a portion of the hinge domain 'are missing the first several amino acids of this domain, and thus do not comprise 'all of the domains of the constant region of a human immunoglobulin IgG heavy chain other than the first domain.'" Dec. at 10 (*citing* Ex. 2110 at 35); *see also id.* at 9 (citing Ex. 1008 at 40).

That isolated statement from the prosecution history is in contrast to the other statements of record relied on by Petitioner demonstrating that Patent Owner considered "***the invention***" to include a functional hinge. Pet'n at 2; Ex. 1002 ¶40 (*citing* Ex. 1006 at 13); *see M.I.T.*, 839 F.3d at 1120 ("Even if an isolated statement appears to disclaim subject matter, the prosecution history as a whole may demonstrate that the patentee committed no clear and unmistakable disclaimer."). As evidenced above, Patent Owner characterized the invention as encompassing a functional hinge during prosecution. This is the *antithesis* of a clear and unmistakable disclaimer.

Moreover, the context of the statement relied upon by the Board further supports that there was no clear disavowal of claim scope. The statement was made with respect to two Comparative Examples (*i.e.*, Delta 57 and Protein 3.5D)

that were the subject of a Rule 132 declaration allegedly showing unexpected results. Ex. 2110 at 35. As Patent Owner stated during prosecution, these Examples were distinguished from the claimed invention for several reasons, including that they contained ***all*** of the following: (1) only fragments of the p75 TNFR extracellular region; (2) a linker of 27 amino acids; and (3) only a portion of the hinge domain. *See id.* The Comparative Examples were therefore outside the scope of the claims regardless of the nature of the hinge in the fusion protein.

This single prosecution history statement thus does not rise to the level of a clear and unambiguous disavowal of claim scope because (aside from being inconsistent with other statements by Patent Owner) it does not exclude all fusion proteins consisting of a functional hinge. *Grober*, 686 F.3d at 1341. Thus, the prosecution history, including the statements overlooked or misapprehended by the Board, compels a construction of "all of the domains of the constant region…," that encompasses a functional hinge.

C. The Board Overlooked or Misapprehended That Nothing in the '522 Patent Specification Supports its Claim Construction

The Board's claim construction also purports to rely on the '522 patent specification. Dec. at 10. Specifically, the Board's Decision states that "there is evidence in the record that the Specification of the '522 patent is consistent with this interpretation on the basis that the described fusion proteins include all of the amino acid sequence of the heavy chain constant region except the first domain."

Id. Notably, 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.* The Board, and Patent Owner, misconstrue the '522 patent specification.

First, nothing in the '522 patent specification describes that the fusion protein must comprise a complete, exon-encoded genetic hinge. *See* Ex. 1001. The '522 patent specification lacks both a definition of the hinge and any specificity as to where in the hinge region the receptor is attached to the IgG molecule. *See id.* The specification refers to vectors published in an unrelated Hoffmann-LaRoche patent application, European Patent Application No. 90107393.2 ("EP '393"), which is not incorporated by reference.[3] *See id.* at 9:14-32 and 21:12-16. The '522 patent does not describe these vectors; much less explain what hinge region they incorporate. Patent Owner instead relies on extrinsic publications cited in EP '393 to support its claim construction. *See* Ex. 2001 ¶¶40-45; Ex. 1002 ¶44.

Second, Example 11, on which the Board relies to support its construction (and which cites EP '393), is not relevant to the claimed subject matter. Example 11 is outside the scope of every claim of the '522 patent, as it does not include the

[3] EP '393 was not even available to a person of skill in the art as of the priority date of the '522 patent, as it did not publish until October 31, 1990. Ex. 1011.

extracellular region of the 75 kD TNF receptor. *See* Ex. 1002 ¶¶45-46, 50; Pet'n at 10. Additionally, Example 11 includes the constant region of an IgG_3—not IgG_1—as required by claims 3-6, 8, and 10 of the '522 patent. *See* Ex. 1002, ¶¶44-46, 50. Moreover, even if Example 11 was relevant to the claims and the specification did disclose that it included the complete, exon-encoded hinge (which it does not), it would be improper to import such a limitation into the claims of the '522 patent. *Williamson v. Citrix Online, LLC,* 792 F.3d 1339, 1346-47 (Fed. Cir. 2015) ("This court has repeatedly cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification."). Therefore, for multiple reasons, the specification fails to provide support for a construction of "all of the domains of the constant region…" that limits the claims to a complete, exon-encoded hinge.

In view of the above, the claims of the '522 patent clearly encompass a fusion protein with a functional hinge. Thus, Petitioner's use of the term "hinge" to refer to prior art fusion proteins comprising either a functional or genetic hinge was neither "unclear" nor "inconsistent." Dec. at 14. Rather, Petitioner's use of "hinge" is the ordinary meaning of that term, and is entirely consistent with the Patent Owner's use of that term during prosecution and in the previous CFAD IPR. *See* Ex. 1006 at 12-13; Ex. 1010 at 12-15. Neither the '522 patent nor its prosecution history defines the boundaries of the hinge to include every amino acid

in the genetically-encoded hinge, and the Board abused its discretion by requiring Petitioner to show this level of specificity in the prior art. Under the correct construction of "all of the domains of the constant region…," which includes a functional hinge-CH2-CH3 region, the Board's purported distinctions of Watson and Zettlmeissl, and the bases for denying institution, would be eliminated.[4]

IV. CONCLUSION

For all the reasons above, Petitioner respectfully requests that the Board modify its claim construction and institute *Inter Partes* Review of the '522 patent as set forth in the Petition.

Respectfully submitted,

Date: April 9, 2018 By: */ Joseph A. Hynds /*

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[4] The Board also misapprehended Petitioner's position regarding Watson. Petitioner contends that Watson teaches fusion proteins with a complete genetic, exon-encoded hinge. *See* Pet'n at 30. To the extent that the Board concluded otherwise, this factual finding was an improper weighing of the evidence that should have been reserved for trial. *See* 37 C.F.R. § 42.108(c).

CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of April, 2018, a true and correct copy of the foregoing **COHERUS BIOSCIENCES, INC.'S REQUEST FOR REHEARING UNDER 37 C.F.R. §§ 42.71(c)-(d)** was served, via electronic mail, upon the following counsel of record for Patent Owner Hoffmann-La Roche Inc.:

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