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Paper 12
Entered: February 2, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COHERUS BIOSCIENCES INC.,
Petitioner,

v.

ABBVIE BIOTECHNOLOGY LTD.,
Patent Owner.

Case IPR2016-01018
Patent 9,114,166 B2

Before RAMA G. ELLURU, TINA E. HULSE, and ELIZABETH A. LAVIER, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

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

I. INTRODUCTION

Coherus Biosciences Inc. ("Petitioner") filed a Request for Rehearing (Paper 11, "Reh'g Req.") of our Decision Denying Institution of *Inter Partes* Review (Paper 10, "Dec.") holding that Petitioner had failed to establish a reasonable likelihood that it would prevail in showing that claims 1–4, 6–10, 13–16, 23–26, and 28 of U.S. Patent No. 9,114,166 B2 (Ex. 1001, "the '166 patent") are unpatentable.

Petitioner requests a rehearing of our decision, arguing that we misapprehended and overlooked (1) the state of the art, (2) the testimony of Petitioner's declarant, Dr. Mark C. Manning, and (3) that Relton[1] is presumed enabling. Reh'q Req. 4–15.

For the reasons stated below, Petitioner's request is *denied*.

II. STANDARD OF REVIEW

The party requesting rehearing has the burden to show that the decision should be modified. Under 37 C.F.R. § 42.71(d), the request for rehearing must identify, specifically, 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. When rehearing a decision on a petition, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may arise if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if an unreasonable judgment is made in weighing relevant factors. *In re Gartside*, 203 F.3d 1305, 1315-16 (Fed. Cir. 2000).

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[1] Relton, US 6,252,055 B1, issued June 26, 2001 (Ex. 1006).

III. ANALYSIS

A. The State of the Art

Petitioner argues that the Board misapprehended the state of the art by relying on statements regarding the formulation of proteins generally over several key points distinguishing IgG_1 antibodies specifically. Reh'g Req. 5. Petitioner first argues that IgG_1 antibodies are a particular antibody subclass that share a high degree of structural similarity and are approximately 95% identical to one another. *Id.* (citing Wang 2007,[2] 5–6). But, as Patent Owner noted in its Preliminary Response (Prelim. Resp. 24–25), the same review article that Petitioner relies on to support its argument, Wang 2007, also states that "[d]evelopment of commercially viable antibody pharmaceuticals has, however, not been straight forward. This is because the behavior of antibodies seems to vary, *even though they have similar structures*." Exhibit 2007, 5 (emphasis added).

Despite acknowledging the similarity in structures, Wang 2007 repeatedly states that the differences among antibody sequences affect the stability of antibody pharmaceuticals. *Id.* at 14 ("It should be stressed that one formulation excipient stabilizing a specific antibody may not be suitable for another because of the differences in their sequence."); *see also id.* at 21 ("Antibodies have similar tertiary structures. . . . Nevertheless, antibodies do experience a variety of instability similar to most proteins. . . . Due to the significant difference in the primary sequence among different antibodies, the relative severity of these degradation pathways can be significantly

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[2] Wang et al., *Antibody Structure, Instability, and Formulation*, 96 J. Pharm. Sciences 1–26 (2007) (Ex. 2007) ("Wang 2007").

different."). Finally, Wang 2007 concludes that one of the "major issues in antibody formulation [that is] apparently challenging and need[s] significant attention in the coming years [includes] development of stable high-concentration formulations." *Id.* Taken together, we are not persuaded that structural similarity of 95% amongst IgG_1 antibodies necessarily means a person of ordinary skill in the art would have expected all IgG_1 antibodies to behave similarly. Nor, for similar reasons, are we persuaded that Petitioner has shown sufficiently that a person of ordinary skill in the art would have had a reasonable expectation of success in formulating a stable, liquid, high-concentration D2E7 formulation, as required by the claims.

Petitioner further asserts that we erred by relying on statements in Dr. Manning's textbook (Ex. 1025[3]) and a review article by Wang (Ex. 1030[4]) regarding pharmaceutical proteins in general, rather than on Dr. Manning's testimony regarding IgG_1 antibodies, specifically. Reh'g Req. 6–10. We are not persuaded that we erred in relying on those statements, particularly given Wang 2007—which appears to be the same author as Ex. 1030 (Wang)—discusses antibody pharmaceutical formulations specifically, including IgG_1 antibodies, and reaches the same conclusion that developing antibody

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[3] *Rational Design of Stable Protein Formulations*, 13 PHARMACEUTICAL BIOTECHNOLOGY (John F. Carpenter & Mark C. Manning eds., 2002) (Ex. 1025).

[4] Wei Wang, *Instability, Stabilization, and Formulation of Liquid Protein Pharmaceuticals*, 185 INTL. J. PHARMACEUTICS 129–88 (1999) (Ex. 1030).

pharmaceuticals has not been straightforward even though they have similar structures. Ex. 2007, 3.

B. Dr. Manning's Testimony

Petitioner argues that the Board erred in relying on Patent Owner's alleged attorney argument over Dr. Manning's sworn testimony. Reh'g Req. 10–12. Patent Owner's argument, however, was supported by documentary evidence and is, therefore, not unsupported attorney argument. That Patent Owner did not submit a declaration to explain the cited prior art is not fatal to Patent Owner's case. As the Federal Circuit has explained, "Board members, because of expertise, may more often find it easier to understand and soundly explain the teachings and suggestions of prior art without expert assistance." *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1079 (Fed. Cir. 2015). Here, the background teachings of Manning and Wang (and Wang 2007) were sufficiently straightforward for us to understand without the need for expert testimony.

Moreover, Petitioner's remaining arguments are premised on its assumption that the statements we relied on in our Decision regarding proteins in general are contrary to the state of the art with respect to IgG_1 antibodies, specifically. As explained above, however, we are not persuaded by this argument, particularly given the consistent statements by Wang 2007 regarding antibodies, including IgG_1 antibodies.

Petitioner also argues that, at best, a factual dispute exists regarding the reasonable expectation of success, and that trial should be instituted to resolve the dispute. Reh'g Req. 13–14. Whether a factual dispute exists is not the standard to institute an *inter partes* review. The standard of review is whether Petitioner has demonstrated that there is a reasonable likelihood it

would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314(a). It was Petitioner's burden to make that showing, and, after reviewing the arguments and evidence of both sides, we determined that Petitioner had not done so.

C. Relton

Finally, Petitioner argues that the Board overlooked its argument that there is a presumption that Relton is enabled for both "claimed and unclaimed" disclosures. Reh'g Req. 14. We did not overlook Petitioner's argument; we simply did not find it persuasive. "Under § 103, . . . a reference need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein." *Amgen Inc. v Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003). We considered Relton for all that it teaches and, as stated in our Decision, in light of the prior art as a whole, we were not persuaded that Petitioner has shown sufficiently that Relton's generic disclosure of IgG_1 antibody formulations translates to a reasonable expectation of success in formulating a stable, liquid, high-concentration D2E7 formulation. Dec. 13.

IV. CONCLUSION

For the foregoing reasons, Petitioner has not demonstrated that we abused our discretion by misapprehending or overlooking any evidence or argument in its Petition.

V. ORDER

Accordingly, it is

ORDERED that Petitioner's Rehearing Request is denied.

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