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Paper 13
Entered: August 4, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REVANCE THERAPEUTICS, INC.,
Petitioner,

v.

MEDY-TOX, INC.,
Patent Owner.

IPR2021-01204
Patent 9,480,731 B2

Before ZHENYU YANG, TIMOTHY G. MAJORS, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges.*

YANG, *Administrative Patent Judge.*

DECISION
Denying Petitioner's Request on Rehearing of
Decision Denying Institution
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Revance Therapeutics, Inc. ("Petitioner") filed a Petition (Paper 2 ("Pet.")), seeking an *inter partes* review of claims 3, 4, 11, and 12[1] of U.S. Patent No. 9,480,731 B2 (Ex. 1001, "the '731 patent"). Medy-Tox, Inc. ("Patent Owner") filed a Preliminary Response (Paper 7 ("Prelim. Resp.")). Petitioner filed a Reply (Paper 9), and Patent Owner filed a Sur-reply (Paper 10). We denied the Petition and did not institute *inter partes* review. Paper 11 ("Decision" or "Dec."). Petitioner filed a Request for Rehearing of the Decision. Paper 12 ("Req. Reh'g").

For the reasons explained below, we deny the Request for Rehearing.

II. STANDARD OF REVIEW

The party challenging a decision in a request for rehearing bears the burden of showing the decision should be modified. 37 C.F.R. § 42.71(d). 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." *Id.* When rehearing a decision on institution, the Board reviews the decision for an abuse of discretion. *Id.* at § 42.71(c). It is not an abuse of discretion to have made an analysis or conclusion with which a party disagrees. Instead, an abuse of discretion occurs if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004).

[1] Each of claims 3 and 4 indirectly depends from claim 1, and each of claims 11 and 12 indirectly depends from independent claim 9.

III. ANALYSIS

Petitioner contends that claims 3 and 11 would have been obvious over the combination of Ruegg,[2] BOTOX Label,[3] and Jung I,[4] and claims 4 and 12 would have been obvious over the combination of Ruegg, BOTOX Label, and Jung II.[5] Pet. 21–62. Specifically, relevant to our discussion here, Petitioner argued that "Ruegg teaches an animal-protein-free [botulinum toxin] composition having a duration of action 'longer' than an animal-protein-containing composition." *Id.* at 35. As support, Petitioner relied on Ruegg's comparison of the effects of "5.0 U/kg" of RT003 (an animal-protein-free composition) and BOTOX (an animal-protein-containing composition). *Id.* (citing Ex. 1004 ¶¶ 57–58, Figure 1; Ex. 1002 ¶ 93; Ex. 1019 ¶ 87).

In our Decision, we adopted Petitioner's proposed claim construction that "longer" lasting as recited in claim 1 means "the longer duration of efficacy of an animal-protein-free botulinum toxin composition when compared to an animal-protein-containing botulinum toxin composition that is dosed at the same or comparable amount and administered in the same manner (e.g., by injection) to the same or comparable location(s)."[6] Dec. 9.

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[2] US 2010/0168023 A1, published July 1, 2010 (Ex. 1004).
[3] BOTOX COSMETIC Product Information, Physicians' Desk Reference, 57th ed., pp. 547–52, Thomas PDR, New Jersey (2003) (Ex. 1007).
[4] U.S. 2010/0291136 A1, published November 18, 2010 (Ex. 1005).
[5] Korean Patent Pub. No. 10-2012-0112248 A, published October 11, 2012 (Ex. 1017).
[6] Instead of reciting the term "longer," claim 9 requires administering the animal-protein-free composition at an interval of time "greater" than that for an animal-protein-containing composition "*dosed at the same amount* and administered in the same manner and to the same location(s)." Ex. 1001, 32:38–48 (emphasis added). Thus, although we focus our discussion on

Under that claim construction, and in view of the undisputed knowledge in the field, as shown by Petitioner's own evidence, that "units are neither interchangeable nor convertible between different botulinum products" (Ex. 1006, 8), we determined that Petitioner did not show Ruegg compared the same or comparable amount of RT003 and BOTOX as would be required to demonstrate that the effect of RT003 met the claim recitation of "longer" with respect to BOTOX. Dec. 12–17. Thus, we concluded Petitioner did not demonstrate a reasonable likelihood of prevailing in its obviousness challenge. *Id.* at 17.

In its Request for Rehearing, Petitioner contends that we misapprehended the claim language, misapprehended the prior art, and overlooked its testimonial evidence. Reh'g Req. 4–13. We address each argument in turn.

A. Whether We Misapprehended or Overlooked the Claim Language

Petitioner contends that "[t]he Board misapprehended or overlooked that the challenged claims merely require dosing the 'same or comparable *amount*' (claims 3–4) or 'same *amount*' (claims 11–12) of the animal-protein-free and animal-protein-containing botulinum toxin compositions." Reh'g Req. 4. Petitioner contends that we "misconstrued this language to require dosing at the same or comparable *potencies*." *Id.* According to Petitioner, "[o]n its face," Ruegg's disclosure of 5.0 U/kg for two botulinum toxin compositions show they are the "same amount." *Id.* We are not persuaded.

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claim 1 (and its dependent claims 3 and 4), our analysis equally applies to claim 9 (and its dependent claims 11 and 12).

In our Decision, we adopted Petitioner's construction for "longer" lasting, emphasizing the language "*dosed at the same or comparable amount*." Dec. 13. That language, however, must be read from the point of "a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). As detailed in our Decision, an ordinarily skilled artisan, at the time relevant to our analysis, understood that units of biological activity are specific to each botulinum toxin A product and unit doses are not interchangeable. Dec. 14–16 (citing Ex. 1006, 8; Ex. 1007, 548; Ex. 1008, 3; Ex. 1009, 3; Ex. 1022, 227, 229). Specifically, we referred to BOTOX Label for warning that units of biological activity of BOTOX "cannot be compared" with units of any other botulinum toxin. *Id.* at 14 (quoting Ex. 1007, 548).

In view of this knowledge of the field, we were not, and remain not, persuaded that an ordinarily skilled artisan would have understood two different botulinum toxin compositions dosed with the same number of units to also be the "same or comparable" amounts, as Petitioner's proposed claim construction requires. Petitioner does not show we misapprehended and overlooked the claim language.

B. Whether We Misapprehended or Overlooked the Prior Art

Petitioner contends that "the Board misapprehended and overlooked the actual teachings of the art it relied upon." Req. Reh'g 7. We disagree.

Petitioner points out that, in the Decision, we discussed BOTOX Label (Ex. 1007), Carruthers 2013 (Ex. 1006), Brin (Ex. 1022), and XEOMIN Label (Ex. 1008).[7] *Id.* (citing Dec. 14–16). According to

[7] Although not mentioned in the Request for Rehearing, we also included DYSPORT Label in our Decision. *See* Dec. 16 (citing Ex. 1009).

Petitioner, because "none of those prior art references disclose RT003 or describe a comparison between RT003 and BOTOX," they "do not undermine the principle that 5.0 U/kg of RT003 is the same amount as 5.0 U/kg of BOTOX®." *Id.* We are not persuaded.

As explained above, we analyze patentability of a challenged claim, including the interpretation of claim language and the teachings of prior art, not in a vacuum but from the vantage point of a skilled artisan, with the knowledge of the relevant field. It is for this purpose that we discussed the teachings of those references.

Petitioner argues that "none of those prior art references disclose RT003 or describe a comparison between RT003 and BOTOX." Req. Reh'g 7. But the relevant field, as Petitioner acknowledged, is not so narrow. Indeed, according to Petitioner, the "formulation scientist aspect of the POSA" would have had experience "in developing formulations containing *botulinum* toxins" or "with purification, characterization, and clinical studies involving botulinum toxin formulations." Pet. 7. In addition, the "clinician aspect of the POSA" would have had "experience with administering *botulinum* toxin injections and evaluating results of such treatments." *Id.* Thus, to understand the knowledge of an ordinarily skilled artisan at the time of the invention, we look to not only Ruegg and BOTOX Label, which Petitioner specifically relied on, but also other prior art references discussing botulinum toxins, which Petitioner provided.

Relying on those other prior art references, Patent Owner argued "Petitioner has not demonstrated that a POSA would have understood simply using the same purported number of 'Units' of RT003 and BOTOX would be 'the same or comparable.'" Prelim. Resp. 46. We found this

argument supported and persuasive. *Id.* at 46–47 (pointing to prior art references for showing that unit doses of different botulinum toxins are not interchangeable (citing Exs. 1006, 1007, 1008, 1009, 1022)). Specifically, as we noted in the Decision, BOTOX Label warns that units of biological activity of BOTOX "cannot be compared" with units of any other botulinum toxin. Dec. 14 (quoting Ex. 1007, 548). In view of those prior art teachings, we determined that Petitioner did not sufficiently show that an ordinarily skilled artisan would have understood that 5.0 U/kg of RT003 and BOTOX are of the same or comparable amount. *Id.* at 16–17. Petitioner has not shown that we misapprehended or overlooked the actual teachings of the prior art relied upon in reaching this conclusion.

Petitioner also contends that we abused our discretion because we "heavily relied on Carruthers 2017." Req. Reh'g 9. Petitioner points out that "Carruthers 2017 was not a reference of record in this proceeding, although it had been used in the related IPR2021-01203 proceeding." *Id.* at 9–10. Petitioner is correct that, even though Patent Owner discussed Carruthers 2017 in the Preliminary Response as Exhibit 1054 (*see* Prelim. Resp. 48), that reference was not in the record in this proceeding.[8]

[8] Whether Carruthers 2017 had been expressly filed as an exhibit in this proceeding, Petitioner cannot reasonably claim any prejudice in the citation of Carruthers 2017 against its challenge here. Carruthers 2017 is Petitioner's own exhibit and was submitted in the concurrently filed companion case (IPR2021-01203) challenging the same patent as challenged here. As noted, Patent Owner raised essentially the same argument about Carruthers 2017 in this proceeding as in IPR2021-01203. *Compare* Prelim. Resp. 48, *with* IPR2021-01203, Paper 7, 48. Petitioner sought, and was permitted, to file additional pre-institution briefing (*see* Ex. 3001) yet raised no issue at that time with Patent Owner citing Carruthers 2017 against it in the Reply.

Our Decision, however, remains the same, with or without the reference to Carruthers 2017. Recognizing that Carruthers 2017 is not prior art, we discussed the knowledge in the field both before the '731 patent and "even in 2017, after the issuance of the challenged '731 patent as evinced by Carruthers 2017." Dec. 16. Indeed, as explained above, we relied on the teachings of BOTOX Label, Carruthers 2013, Brin, XEOMIN Label, and DYSPORT Label—all of which are undisputedly prior art of record—that units of botulinum toxins are not interchangeable. *Id.* at 14–16 (citing Ex. 1006, 8; Ex. 1007, 548; Ex. 1008, 3; Ex. 1009, 3; Ex. 1022, 227, 229). And we cited Carruthers 2017 merely to further confirm those teachings. *Id.* at 16 (quoting Carruthers 2017 for stating "units of daxibotulinumtoxinA [i.e., RT003 of Ruegg] should not be equated with the same number of units of onabotulinumtoxinA [i.e., BOTOX]"). Thus, our Decision would stand even without the reference to Carruthers 2017. Petitioner has not shown that we abused our discretion.

C. Whether We Misapprehended or Overlooked Testimonial Evidence

Petitioner argues that we misapprehended or overlooked the unrebutted testimony from its declarant, Dr. Andreas Rummel, that Ruegg discloses dosing the "same" or "same or comparable" amount of an animal-protein-free and an animal-protein-containing composition. Reh'g Req. 11 (citing Pet. 35, 55, 57–58 (citing Dr. Rummel's testimony at Ex. 1002 ¶¶ 93, 124, 133)). Again, we are not persuaded.

In paragraph 93, Dr. Rummel referred to Ruegg for "measur[ing] local muscle paralysis in mice using 'digit abduction score (DAS) assay' by injecting the animals . . . with 5.0 U/kg of either RT003 or BOTOX®." Ex. 1002 ¶ 93 (citing Ex. 1004 ¶¶ 57–58, Figure 1). Based on Ruegg's data,

Dr. Rummel testified that "Ruegg teaches the longer duration of action of an animal-protein-free composition, as required by claim 1." *Id.* Similarly, in paragraph 124, Dr. Rummel testified that, because, in Ruegg, "both RT003 and BOTOX® were dosed at '5.0 U/KG,'" "a POSA would have understood that Ruegg administered RT003 and BOTOX® . . . at the same doses," as required by claim 9. *Id.* ¶ 124 (citing Ex. 1004, Figure 1). And in paragraph 133, Dr. Rummel testified that "Ruegg provided sufficient information to a POSA to understand that, when comparing the animal-protein-free compositions and animal-protein-containing compositions, they should be dosed at the same amount." *Id.* ¶ 133 (citing Ex. 1004 ¶ 57, Figure 1).

"Opinion testimony rendered by experts must be given consideration, and while not controlling, generally is entitled to some weight." *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985). "Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination." *Id.*; *see also* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

It is true that we did not explicitly cite paragraphs 93, 124, and 133 of the Rummel Declaration in the Decision. That omission, however, does not mean we overlooked that testimony. *See Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1343 (Fed. Cir. 2003) ("The fact that the district court did not in its opinion recite every piece of evidence does not mean that the evidence was not considered."); *see also Medtronic, Inc. v. Daig Corp.*, 789 F.2d 903, 906 (Fed. Cir. 1986) ("We presume that a

fact finder reviews all the evidence presented unless he explicitly expresses otherwise."). Instead, we merely accorded proper weight to Dr. Rummel's testimony on the issue of whether Ruegg teaches the same or comparable doses of RT003 and BOTOX. Dr. Rummel considered BOTOX Label, Carruthers 2013, Brin, XEOMIN Label, and DYSPORT Label in formulating his opinions. *See* Ex. 1002 ¶ 23 (listing references and documents considered). Yet, he did not mention, let alone address, the prior art teachings that the units of BOTOX "cannot be compared" with units of any other botulinum toxin. *See, e.g.*, Ex. 1007, 548. In light of the lack of evidence supporting the comparison, we considered Dr. Rummel's testimony as providing evidence regarding the respective activities of 5.0 U/KG of RT003 and BOTOX, but not of their dosage equivalence. Petitioner has not shown our assessment is error.

As a result, based on the argument and record presented, the uncontroverted teachings from the multiple prior art references outweighs Dr. Rummel's testimony on this issue. Petitioner has not shown that we misapprehended and overlooked paragraphs 93, 124, and 133 of the Rummel Declaration.

IV. CONCLUSION

In sum, Petitioner has not shown that we misapprehended or overlooked the claim language, the teachings of the prior art, or Dr. Rummel's testimony. As a result, we deny Petitioner's Request for Rehearing.

V. ORDER

Accordingly, it is

ORDERED that Petitioner's Request for Rehearing is *denied*.

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