

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 Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Relevance Therapeutics, Inc. (“Petitioner”) filed a Petition (Paper 2 (“Pet.”)), seeking an *inter partes* review of claims 3, 4, 11, and 12 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.”)). With our authorization (Ex. 3001), Petitioner filed a Reply to the Preliminary Response (Paper 9, “Reply”), and Patent Owner filed a Sur-reply (Paper 10).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a).

For the reasons provided below, we determine Petitioner has not demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition. Accordingly, we deny institution of an *inter partes* review.

A. Related Matters

Petitioner also filed IPR2021-01204, challenging claims 1, 2, 5–10, 13, and 14 of the ’731 patent. Paper 4, 2; Reply 1–2.

The ’731 patent is the parent of U.S. Patent No. 10,143,728 (“the ’728 patent”). Ex. 1035, code (63). Previously, in a post-grant review, Patent Owner cancelled all original claims of the ’728 patent. *Galderma S.A. v. Medy-Tox, Inc.*, PGR2019-00062, Paper 66, 2 (PTAB July 16, 2021). In the final written decision of that case, the Board denied Patent Owner’s

non-contingent revised Motion to Amend with regard to proposed substitute claims 19–27. *Id.* at 34. An appeal of that decision by Patent Owner is currently pending before the Federal Circuit. PGR2019-00062, Paper 74.

B. The '731 Patent and Related Background

The '731 patent discloses “the use of an animal-protein-free botulinum toxin composition to treat a disease, disorder or condition in a patient in need thereof whereby the animal-protein-free botulinum toxin composition exhibits a longer lasting effect in the patient compared to an animal-protein-containing botulinum toxin composition.” Ex. 1001, 2:55–60.

Before the priority date of the '731 patent, botulinum toxin A (BoNT/A) had been used widely to temporarily treat facial wrinkles, such as glabellar lines. *Id.* at 1:13–37. Commercially available BoNT/A compositions at that time, including BOTOX (onabotulinumtoxinA), all contain animal proteins such as albumin. *Id.* at 1:38–39. Albumin, a serum product, however, was known to possibly be “contaminated with pathogens or microorganisms and thus acting as mediators of disease.” Ex. 1005¹ ¶ 5.

Animal-protein-free botulinum toxin compositions were known in the prior art. Ex. 1001, 2:63–66 (citing Ex. 1005), 3:9–12 (citing Ex. 1017²).

¹ U.S. 2010/0291136 A1, published November 18, 2010 (“Jung I,” Ex. 1005). Jung I is one of the asserted prior art references in this case.

² Korean Patent Pub. No. 10-2012-0112248 A, published October 11, 2012 (“Jung II,” Ex. 1017). Jung II is another asserted prior art reference in this case.

The animal-protein-free composition eliminates the potential risk of infecting the recipient with serum-derived pathogens or microorganisms, because it does not include an animal-derived protein, such as albumin, as a stabilizer for botulinum toxin. Ex. 1005 ¶ 23; Ex. 1017 ¶¶ 4, 5.

The '731 patent claims methods of “locally administering a therapeutically effective amount of an animal-protein-free botulinum toxin composition.” Ex. 1001, 31:67–32:2, 32:36–38. According to the '731 patent, “the animal-protein-free botulinum toxin composition [of its invention] exhibits a longer lasting effectiveness compared to an animal-protein-containing botulinum toxin composition.” *Id.* at 5:47–50.

C. Illustrative Claims

All claims challenged in the Petition are dependent claims. Claims 3 and 4 depend from claim 2, which in turn depends from claim 1. Claims 1–4 are reproduced below:

1. A method for treating a condition in a patient in need thereof, the method comprising the step of locally administering a therapeutically effective amount of an animal-protein-free botulinum toxin composition, whereby a symptom of the condition is thereby effectively alleviated for a period of time longer than that of an animal-protein-containing botulinum toxin composition, and wherein the condition is selected from the group consisting of glabellar lines, marionette lines, brow furrows, lateral canthal lines, and any combination thereof.
2. The method of claim 1, wherein the animal-protein-free botulinum toxin composition is in a form selected from the group consisting of a liquid composition and a lyophilized composition.
3. The method of claim 2, wherein the liquid composition comprises botulinum toxin, polysorbate 20, and methionine.

4. The method of claim 2, wherein the lyophilized composition comprises botulinum toxin, polysorbate, and methionine, and one or more components selected from the group consisting of a sugar, a sugar alcohol, and an ionic compound.

Ex. 1001, 31:66–32:19.

Claims 11 and 12 depend from claim 10, which in turn depends from independent claim 9. Claim 9 is similar to claim 1, except that instead of the “longer” lasting effect in claim 1, it recites:

the composition is administered at an interval of time between a first treatment and a second treatment effective to maintain alleviation of at least one symptom of the condition, that is greater than the interval of time for an animal-protein-containing botulinum toxin composition dosed at the same amount and administered in the same manner and to the same location(s) as that of the animal-protein-free composition.

Id. at 32:38–46.

The additional limitations recited in claims 10, 11, and 12 are identical, or substantially identical to those recited in claims 2, 3, and 4, respectively.

D. Asserted Challenge to Patentability

Petitioner asserts the following challenge to patentability:

Claims Challenged	35 U.S.C. § ³	References
3, 11	103	Ruegg, ⁴ BOTOX Label, ⁵ Jung I
4, 12	103	Ruegg, BOTOX Label, Jung II

In support of its arguments, Petitioner relies on the declarations of Andreas Rummel, Ph.D. (Ex. 1002) and Nowell Jay Solish, M.D., FRCP (Ex. 1019).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe a claim term “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.100(b) (2020). Under that standard, the words of a claim “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

³ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the ’731 patent has an effective filing date after March 16, 2013, the AIA version of § 103 applies.

⁴ US 2010/0168023 A1, published July 1, 2010 (Ex. 1004).

⁵ BOTOX COSMETIC Product Information, Physicians’ Desk Reference, 57th ed., pp. 547–52, Thomas PDR, New Jersey (2003) (Ex. 1007).

Relying on the Specification, Petitioner proposes the constructions of several terms, including “therapeutically effective amount,” “animal-protein,” “longer,” and “locally administering.” Pet. 19 (citing Ex. 1001, 4:12–18, 37–40, 48–59).

Claim terms need only be construed to the extent necessary to resolve the controversy. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011). On this record and for purposes of this Decision, only the term “longer” needs express construction.

We start by noting that the Board previously addressed a similar claim limitation in the related ’728 patent. PGR2019-00062, Paper 14 (Ex. 1050, “PGR Institution Decision”), 9–13. Claim 1 of the ’728 patent recites that the botulinum toxin composition that does not comprise an animal-derived product or recombinant human albumin “exhibits a longer lasting effect in the patient when compared to treatment of the same condition with a botulinum toxin composition that contains an animal-derived product or recombinant human albumin.” Ex. 1035, 32:8–17.

In the PGR Institution Decision, the Board stated:

Although the claims define “longer lasting effect” to require a comparison of compositions having the same toxin with and without animal protein for “treatment of the same condition . . . dosed at a comparable amount and administered in the same manner and to the same location(s),” the methodology for making such a comparison is not clear from either the claim language or the specification. As acknowledged by Patent Owner, at least some of the methods of comparison identified in the patent itself, showed either a “comparable” result or “lower responsiveness” for the animal-protein-free composition

(MT10109L or MT10109) as compared to the animal-protein-containing composition (BOTOX), whereas other methods of comparison showed that MT10109L or MT10109 “did better” than BOTOX.

Ex. 1050, 12.

Based on “the ’728 patent’s and Patent Owner’s own acknowledgement that some of the assessment techniques described in the specification caused the administration of MT10109 and MT10109L to fall within the claim scope, while other assessment techniques resulted in those same compositions falling outside the claim scope,” the Board concluded that the claims of the ’728 patent are indefinite. *Id.* at 13–14.

In the instant case, we do not decide whether the challenged claims are indefinite. *See* 35 U.S.C. § 311(b) (limiting an *inter partes* review to “only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications”); *see also* *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2141–42 (2016) (stating that the Patent Office would be acting “outside its statutory limits” by “canceling a patent claim for ‘indefiniteness under § 112’ in *inter partes* review”).

“Importantly, it is not always impossible to adjudicate a prior-art challenge, one way or the other, just because some aspect of a claim renders the claim indefinite.” *Intel Corp. v. Qualcomm Inc.*, Nos. 2020-1828, 2020-1867, 2021 WL 6122434, at *8 (Fed. Cir. Dec. 28, 2021); *see also* *Samsung Elecs. Am., Inc. v. Prisia Eng’g Corp.*, 948 F.3d 1342, 1355 (Fed. Cir. 2020) (noting that indefiniteness “does not necessarily preclude

the Board from addressing the patentability of the claims on section 102 and 103 grounds”). “For example, the indefiniteness of one limitation may not preclude the Board from rejecting a challenge by finding that another limitation is missing from the argued prior art and its argued combinations and modifications.” *Intel*, 2021 WL 6122434, at *8. As explained below, we decide Petitioner’s prior art challenge on this record without regard to whether the challenged claims are (or are not) indefinite for other reasons. *See* II.B.2.

In this case, Petitioner argues that “longer” lasting 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).” Pet. 20 (quoting Ex. 1001, 4:53–59). Patent Owner does not dispute this proposed construction. Prelim. Resp. 8.

For purposes of this Decision, we adopt Petitioner’s proposed construction because it is consistent with the express definition in the ’731 patent Specification. *See* Ex. 1001, 4:53–59.

B. Alleged Obviousness of Claims 3 and 11

Petitioner asserts that claims 3 and 11 of the ’731 patent would have been obvious over the combination of Ruegg, BOTOX Label, and Jung I. Pet. 21–58. Based on this record, and for at least the following reasons, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

1. Prior Art Disclosures

a. *BOTOX Label*

BOTOX Label states that each vial of BOTOX contains 100 U of BoNT/A, 0.5 milligrams of human albumin, and 0.9 milligrams of sodium chloride. Ex. 1007, 548. According to BOTOX Label, BOTOX is indicated for “the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients $\leq$ 65 years of age.” *Id.* at 549.

b. *Ruegg*

Ruegg explains that conventional botulinum toxin formulations, such as BOTOX, are stabilized with albumin during manufacturing. Ex. 1004 ¶ 13. According to Ruegg, there are several problems associated with this approach. *Id.* ¶ 14.

Ruegg provides injectable compositions comprising botulinum toxin non-covalently associated with a positively charged carrier molecule. Ex. 1004 ¶ 16. Ruegg’s compositions may exhibit various advantages over conventional botulinum toxin formulations, including “increased duration of clinical efficacy or enhanced potency relative to conventional botulinum toxin formulations, faster onset of clinical efficacy, and/or improved stability.” *Id.*; *see also id.* ¶ 24 (the same).

Ruegg states that its compositions may be administered to a subject for various therapeutic, aesthetic and/or cosmetic purposes. *Id.* ¶ 2. Specifically, the compositions may be injected into the skin or epithelium of patients with “cosmetic and subjective needs (e.g., altering or improving the

appearance of facial tissue).” *Id.* ¶ 44; *see also id.* ¶ 48 (“Desired effects include the relaxation of certain muscles with the aim of, for instance, decreasing the appearance of fine lines and/or wrinkles.”).

In Ruegg, “RT003 is an exemplary injectable formulation according to the invention that contains type A botulinum toxin (purified to remove all endogenous non-toxin proteins) and positively charged carrier with the sequence RKKRRQRRRG-(K)₁₅-GRKKRRQRRR.” *Id.* ¶ 56. Ruegg compared the duration of local muscle paralysis in mice injected with either RT003 or BOTOX, which contains exogenous albumin to stabilize BoNT/A. *Id.*

Ruegg measured the muscle paralysis using a digit abduction score (DAS) assay, which examines the ability of a mouse to extend its hind limbs and abduct its hind digits in a startle response. *Id.* ¶ 57. According to Ruegg,

These DAS assay data indicate that local muscle paralysis caused by the RT003 formulation lasts approximately twice as long as the local muscle paralysis caused by BOTOX®. This result has important implications for therapeutic uses of RT003 and other injectable botulinum toxin-containing compounds according to the invention. In particular, by using injectable compositions according to the invention, one can significantly reduce the frequency of follow-up injections required to maintain a particular cosmetic or therapeutic effect caused by the botulinum toxin. In turn, the reduced frequency of application can result in better long-term efficacy, as the subject is less prone to develop antibodies to the botulinum toxin.

Id. ¶ 59.

c. Jung I

Jung I teaches that “botulinum toxin received FDA approval for temporary improvement in the facial appearance of moderate-to-severe frown lines.” Ex. 1005 ¶ 2. It recognizes the need for a stabilizer in the formulation of botulinum toxin, and issues associated with using an animal-derived protein, such as albumin or gelatin, as a stabilizer. *Id.* ¶¶ 3–6.

Jung I discloses a liquid composition including botulinum toxin, polysorbate 20, and methionine. *Id.* ¶ 12. According to Jung I, “[e]mploying as botulinum toxin stabilizers, instead of the animal-derived protein albumin or gelatin, a combination of polysorbate and methionine . . . the liquid pharmaceutical composition according to the present invention eliminates the risk of contaminating the body with serum-derived pathogens or microorganisms and can be administered safely.” *Id.* ¶ 18.

Jung I states that the liquid pharmaceutical botulinum toxin composition according to its invention is useful in the cosmetic application for wrinkle reduction. *Id.* ¶ 59.

2. Analysis

Petitioner asserts that claims 3 and 11 of the ’731 patent would have been obvious over the combination of Ruegg, BOTOX Label, and Jung I. Pet. 21–58. Petitioner provides claim charts, mapping each limitation of claims 1–3 and 9–11 to the teachings of Ruegg, BOTOX Label, and Jung I. *Id.* at 23–30, 48–52. Petitioner further explains its arguments, including its contention that an ordinarily skilled artisan would have had a reason to combine the teachings of Ruegg and BOTOX Label, and Jung I would have

had a reasonable expectation of success when doing so. *Id.* at 30–48, 52–58. Despite its detailed presentation, Petitioner has not met its burden to show a reasonable likelihood that it would prevail in this challenge.

a. Claim 3

In analyzing Petitioner’s challenge of claim 3, we focus on the limitation “longer,” which is recited in claim 1 and required in challenged claim 3 through its indirect dependency from claim 1.

Petitioner relies on Ruegg for teaching “an animal-protein-free composition having a duration of action ‘longer’ than an animal-protein-containing composition.” Pet. 35. According to Petitioner, Ruegg injected mice “with 5.0 U/kg of either RT003 or BOTOX®.” *Id.* Based on the DAS score, Petitioner continues, Ruegg showed that “RT003’s effects last **“longer”** *in vivo* compared to an animal-protein-containing *botulinum* toxin composition (*i.e.*, BOTOX®).” *Id.*

As explained above, for purposes of this Decision, we adopt Petitioner’s proposed construction of the term “longer.” *See supra*, Section II.A (“[L]onger” lasting 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).” (emphasis added)). Although Petitioner is correct in pointing out that Ruegg compared the effect of “5.0 U/kg of either RT003 or BOTOX®” (Pet. 35; Ex. 1004, Figure 1),

Petitioner has not sufficiently shown that 5.0 U/kg of RT003 is the same or comparable amount as 5.0 U/kg of BOTOX.

Indeed, BOTOX Label explains that one unit (U) of BOTOX “corresponds to the calculated median intraperitoneal lethal dose (LD₅₀) in mice.” Ex. 1007, 548. BOTOX Label emphasizes that the method for performing the assay is specific to BOTOX. *Id.* “Due to specific details of this assay such as the vehicle, dilution scheme and laboratory protocols for the various mouse LD₅₀ assays,” it warns, units of biological activity of BOTOX “cannot be compared to nor converted into Units of any other botulinum toxin or any toxin assessed with any other specific assay method.” *Id.*

Petitioner’s other evidence, such as Carruthers 2013,⁶ shows “unit doses of one product cannot be used to generate doses of another.” Ex. 1006, 8. According to Carruthers 2013, it was known as early as in 1993, that the units of BOTOX (onabotulinumtoxinA) and DYSPORT (abobotulinumtoxinA) are different and that the dosing of these products are so different that “if one administers the same number of Dysport® units as when delivering Botox®, serious side effects may occur.” *Id.*

⁶ Carruthers, A. & Carruthers, J., Eds., Procedures in Cosmetic Dermatology: Botulinum Toxin, 3rd edition, Elsevier Saunders, Philadelphia (2013) (Ex. 1006). We cite to the original page number of this Exhibit, not the ones supplied by Petitioner.

Brin⁷ echoes Carruthers 2013’s teaching that BoNT/A products “are not interchangeable.” Ex. 1022, 227. Brin explains that no international standard exists for BoNT/A products. *Id.* at 229. “As a result, each manufacturer employs its own proprietary assay methods for testing potency units that includes a product-specific reference standard. For this reason, units of biological activity are specific to each BoNTA product and unit doses are not interchangeable.” *Id.*

Carruthers 2013 states that “[r]egulatory agencies worldwide have issued language stating that units are neither interchangeable nor convertible between different botulinum products.” Ex. 1006, 8. Petitioner’s other evidence supports this statement. *See, e.g.*, Ex. 1008,⁸ 3 (explaining that “[t]he potency Units of XEOMIN (incobotulinumtoxinA) for injection are specific to the preparation and assay method utilized,” and warning “[t]hey are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of XEOMIN cannot be compared to or converted into units of any other botulinum toxin products assessed

⁷ Brin et al., *Botulinum toxin type A products are not interchangeable: a review of the evidence*, 8 *Biologics: Targets and Therapy* 227–41 (2014) (Ex. 1022).

⁸ Xeomin® (incobotulinumtoxinA) prescribing information (July 2011) (Ex. 1008).

with any other specific assay method”); Ex. 1009,⁹ 3 (the same for DYSPORT).

Perhaps most fatal to Petitioner’s present challenge is Carruthers 2017,¹⁰ an article reporting a phase 2 clinical trial of Petitioner’s own product daxibotulinumtoxinA (RT002). Ex. 1054, 1322. Petitioner supported that clinical study, and its own researchers co-authored the article. *Id.* at 1321. According to Dr. Ruegg, the co-inventor of the Ruegg reference, RT002 in Carruthers 2017 and RT003 in Ruegg reference “have the same composition.” Ex. 1045 ¶ 7. According to Carruthers 2017,

The results of this study refer to the Revance injectable formulation of botulinum toxin Type A and cannot be generalized to any other formulations or serotypes of botulinum toxin Type A. The potency units of botulinum toxins are not interchangeable. As a result, units of daxibotulinumtoxinA [i.e., RT003 of Ruegg] should not be equated with the same number of units of onabotulinumtoxinA [i.e., BOTOX] as *the relative potencies of daxibotulinumtoxinA and onabotulinumtoxinA have not been established.*

Ex. 1054, 1330–31 (emphasis added).

Because the relative potencies of RT003 and BOTOX were not established (even in 2017, after the issuance of the challenged ’731 patent as evinced by Carruthers 2017), we are unpersuaded that an ordinarily skilled

⁹ DYSPORT® (abobotulinumtoxinA) prescribing information (July 2011) (Ex. 1009).

¹⁰ Carruthers et al., *Injectable DaxibotulinumtoxinA for the Treatment of Glabellar Lines: A Phase 2, Randomized, Dose-Ranging, Double-Blind, Multicenter Comparison with OnabotulinumtoxinA and Placebo*, 43 *Dermatol. Surg.* 1321–31 (2017) (Ex. 1054).

artisan would have understood that 5.0 U/kg of RT003 and BOTOX are of the same or comparable amount. Thus, Petitioner has not met its burden to show that, under its own proposed claim construction of “longer,” the effect of RT003 lasts “longer” than that of BOTOX.

In conclusion, Petitioner has not shown a reasonable likelihood that it would prevail on its asserted obviousness challenge of claim 3.

b. Claim 11

In analyzing Petitioner’s challenge of claim 11, we focus on the limitation “the same amount,” which is recited in claim 9 and required in challenged claim 11 through its indirect dependency from claim 9.

Claim 9 recites

the composition is administered at an interval of time between a first treatment and a second treatment effective to maintain alleviation of at least one symptom of the condition, that is greater than the interval of time for an animal-protein-containing botulinum toxin composition dosed at *the same amount* and administered in the same manner and to the same location(s) as that of the animal-protein-free composition.

Ex. 1001, 32:38–46 (emphasis added).

For the limitation “the same amount,” Petitioner again relies on Ruegg’s teaching that “both RT003 and BOTOX® were dosed at ‘5.0 U/KG.’” Pet. 50–51, 55 (citing Ex. 1004, Figure 1). For the same reason as explained above, we find Petitioner has not sufficiently shown that 5.0 U/kg of RT003 and BOTOX are of the same amount. *See supra*, Section II.B.2.a. Thus, Petitioner has not shown a reasonable likelihood that it would prevail on its asserted obviousness challenge of claim 11.

C. Alleged Obviousness of Claims 4 and 12

Petitioner asserts that claims 4 and 12 of the '731 patent would have been obvious over the combination of Ruegg, BOTOX Label, and Jung II. Pet. 58–62. Based on this record, and for at least the following reasons, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

1. Jung II

Similar to Jung I, Jung II recognizes the need for a stabilizer in the formulation of botulinum toxin, and issues associated with using an animal-derived protein, such as albumin or gelatin, as a stabilizer. Ex. 1017 ¶¶ 3–4. According to Jung II, “there is a need for a stabilizer which is both not derived from animals and which does not cause loss of botulinum toxin activity.” *Id.* ¶ 4.

Jung II discloses a lyophilized pharmaceutical composition comprising botulinum toxin, polysorbate, methionine and at least one substance selected from the group comprising sugar, sugar alcohol and ionic compound. *Id.* ¶ 8. According to Jung II, its lyophilized preparation of botulinum toxin “is not only able to maintain activity of botulinum toxin under high temperature conditions which may arise in the storage, transport and handling of botulinum toxin, but also has excellent stability in long-term storage.” *Id.*, Abstract.

2. Analysis

Similar to claim 3, claim 4 depends from claim 2, which in turn depends from claim 1. Similar to claim 11, claim 12 depends from claim 10, which in turn depends from claim 9.

Petitioner relies on Jung II for the additional limitation recited in claims 4 and 12. Pet. 58–62. For the other limitations, Petitioner relies on the same evidence and arguments as presented in its challenge of claims 3 and 11. *See id.* at 58 (“The analysis above and claim chart with respect to claim 3 apply in equal force to claim 4.”); 62 (“The analysis above and claim chart with respect to claims 4 and 11 apply in equal force to claim 12.”). In other words, Petitioner relies on Ruegg for teaching the “longer” lasting effect recited in claim 1, and “the same amount” recited in claim 9.

For the same reason explained above, Petitioner has not sufficiently shown that 5.0 U/kg of RT003 and BOTOX are of the same amount, or that, under its own proposed claim construction of “longer,” the effect of RT003 lasts “longer” than that of BOTOX. Thus, Petitioner has not shown a reasonable likelihood that it would prevail on its asserted obviousness challenge of claims 4 and 12.

III. CONCLUSION

For the reasons explained above, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable.

Patent Owner challenges the Petition for several other reasons. *See* Prelim. Resp. 12–46, 49–70. Because we deny the Petition for reasons explained above, we do not need to address those other arguments.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied, and we do not institute *inter partes* review of any claim of the '731 patent based on the ground asserted in the Petition.

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