

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PEDIATRIC HAIR SOLUTIONS CORPORATION,  
Petitioner,

v.

UNIVERSITY OF UTAH RESEARCH FOUNDATION,  
Patent Owner.

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IPR2019-01230  
Patent 8,162,999 B2

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Before LINDA E. HORNER, JOHN G. NEW, and CARL M. DEFRANCO,  
*Administrative Patent Judges.*

DEFRANCO, *Administrative Patent Judge.*

PRELIMINARY GUIDANCE  
PATENT OWNER'S CONTINGENT MOTION TO AMEND

## I. INTRODUCTION

On January 14, 2020, we instituted *inter partes* review of claims 1–20 of U.S. Patent No. 8,162,999 B2 (“the ’999 patent”). Paper 13 (“Institution Decision” or “Inst. Dec.”). After institution, the exclusive licensee of the ’999 patent, Larada Sciences, Inc. (“Larada”),<sup>1</sup> filed a Motion to Amend. Paper 25 (“Motion” or “Mot.”). In its Motion, Larada proposes substitute claims 21–31, each of which corresponds to a respective one of challenged claims 1, 2, 7–11, 15–17, and 19. Motion 2. Larada also proposes to cancel claims 3–6, 12–14, 18, and 20. *Id.* Petitioner, Pediatric Hair Solutions Corporation (“PHS”), filed an Opposition to Larada’s Motion to Amend. Paper 33 (“Opposition” or “Opp.”).

Pursuant to the Board’s pilot program concerning motion to amend practice and procedures, Larada requests that we provide preliminary guidance concerning the proposed substitute claims. *See* Mot. 1; *see also* Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497 (Mar. 15, 2019) (“Notice”) (providing patent owners with the option to receive preliminary guidance from the Board on motions to amend).

We have considered Larada’s Motion and PHS’s Opposition. In this Preliminary Guidance, we provide information indicating our preliminary *non-binding* views on: (1) whether Larada has shown a reasonable likelihood that it has

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<sup>1</sup> As exclusive licensee with “all substantial rights” to the ’999 patent, Larada is the real party-in-interest. *See* Paper 7 at 1; Ex. 2001 ¶ 12. But, because a copy of Larada’s license is not in the record, we cannot confirm that Larada has been granted the right to amend the ’999 patent as part of its license rights. Thus, before we will further consider this motion to amend, Larada will need to make a showing that it has been granted the right to amend the patent or that it otherwise has a sufficient proprietary interest in the patent to permit amendment.

satisfied the statutory and regulatory requirements associated with filing a motion to amend in an *inter partes* review; and (2) whether PHS (or the record) establishes a reasonable likelihood that the proposed substitute claims are unpatentable. *See* 35 U.S.C. § 316(d); 37 C.F.R. § 42.121; *Lectrosonics, Inc. v Zaxcom, Inc.*, IPR2018-01129, 01130, Paper 15 at 4–8 (PTAB Feb. 25, 2019) (precedential); *see also* Notice, 84 Fed. Reg. at 9,497 (“The preliminary guidance . . . provides preliminary, non binding guidance from the Board to the parties about the [motion to amend].”).

In formulating our preliminary views on Larada’s Motion and PHS’s Opposition, we focus on the proposed substitute claims, and, more specifically, on the amendments to the challenged claims as proposed in the Motion. *See* Notice, 84 Fed. Reg. at 9,497. We do not address the patentability of the originally challenged claims. *Id.* Moreover, we have not considered the parties’ other substantive papers on the underlying merits of PHS’s challenges. We have considered, however, our Institution Decision in determining whether the amendments “respond to a ground of unpatentability involved in the trial.” *Lectrosonics*, Paper 15 at 5. We emphasize that the views expressed in this Preliminary Guidance are subject to change upon consideration of the complete record, including any revision to the Motion filed by Larada. Thus, this Preliminary Guidance is not binding on the Board when rendering a final written decision. *See* Notice, 84 Fed. Reg. at 9,500.

## II. PRELIMINARY GUIDANCE

### A. Statutory and Regulatory Requirements

For the reasons discussed below, at this stage of the proceeding, the current record reflects that Larada has not shown a reasonable likelihood that it has

satisfied the statutory and regulatory requirements associated with filing a motion to amend for at least some of the proposed substitute claims.

1. Reasonable Number of Substitute Claims

Does Larada propose a reasonable number of substitute claims for each challenged claim? (35 U.S.C. § 316(d)(1)(B); 37 C.F.R. § 42.121(a)(3)).

Yes, Larada proposes no more than one substitute claim for each challenged claim. Mot. 2. PHS does not argue otherwise. *See generally* Opp.

2. Respond to Ground of Unpatentability

Does the Motion respond to a ground of unpatentability involved in the trial? (37 C.F.R. § 42.121(a)(2)(i)).

Yes. Larada responds to the grounds of unpatentability on which we instituted trial. *See* Mot. 7–13. PHS does not argue otherwise. *See generally* Opp.

3. Scope of Amended Claims

Does the amendment seek to enlarge the scope of the challenged claims? (35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii)).

No. Proposed substitute independent claims 21, 27, and 29 retain or narrow all claim limitations of their corresponding challenged claims and include additional narrowing limitations. *See* Mot. 3, 26–28. Proposed substitute claims 22–26, 28, 30, and 31 merely change the dependency of their corresponding challenged claims. *Id.* PHS does not argue otherwise. *See generally* Opp.

4. New Matter

Does the amendment seek to add new subject matter? (35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii)).

Yes, as to proposed substitute claims 21–26 and 29–31 only. On this record, we find that Larada has not set forth sufficient written description

support under 35 U.S.C. § 112, paragraph one, in the originally filed disclosure of the '999 patent for proposed substitute claims 21–26 and 29–31.

Specifically, proposed substitute claim 21 adds the limitations of:

1) “maintaining [] heated air at the target area without constraint,” and  
2) “for a period of time and at a sufficient airflow to leave the scalp undamaged.” Mot. 26. Proposed substitute claims 22–26 depend from proposed substitute claim 21. *Id.* at 26–27. Proposed substitute claim 29 adds the limitations of: 1) “delivering the heated air without constraint,” and 2) “without damaging the scalp.” *Id.* at 28. Proposed substitute claims 30 and 31 depend from proposed substitute claim 29. *Id.* PHS contends that the Specification of the '999 patent does not support these limitations. Opp. 1–3. We address each limitation in turn.

*For the limitation “without constraint,”* Larada cites various sections of the Specification, as well as Figures 1–6, as providing adequate written description support. *See* Mot. 4, 6. But Larada’s purported support in the Specification pertains generally to applying heated air to a target area within specified ranges of temperature, airflow, and duration. *See id.* At this stage of the proceeding, we do not perceive that the Specification recites or otherwise specifies that the heated air is applied to the target area “without constraint.” *See generally* Spec.

Moreover, on the current record, we agree with PHS’s contention that “the plain meaning of ‘constraint’ is being limited or restricted.” Opp. 1 (citing Ex. 1021). Under that definition, the Specification’s description of applying heated air with restrictions on temperature, duration, and direction does not support Larada’s claiming any lack of constraint on the heated air. *Id.* Thus, at this stage of the proceeding, the current record reflects that “without constraint” is new matter not supported by the original Specification.

*For the limitations “to leave the scalp undamaged” and “without damaging the scalp,”* Larada cites various sections of the Specification, as well as Figures 1–6, as providing adequate written description support. *See* Mot. 4, 7. PHS responds that the written description does not include “any discussion of damage to the scalp, what would qualify as damage, or how to avoid it,” and, thus, provides no support for the term “without damaging the scalp.” Opp. 3 (citing Ex. 1001).

On the current record, we disagree with PHS. The Specification generally discusses various methods for safely treating head lice by applying heated air to a target area. *See* Ex. 1001, 1:52–54. The Specification further describes adjusting the method parameters, particularly temperature, to avoid pain and discomfort that naturally would precede damage to the scalp. *See id.* at 4:64–67; 7:17–19. Accordingly, the current record reflects that the original Specification reasonably conveys to one of ordinary skill in the art that the inventors possessed a method of treating head lice without damaging the scalp. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

### B. Patentability

For the reasons discussed below, at this stage of the proceeding, the current record reflects that PHS establishes a reasonable likelihood that proposed substitute claims 21–31 are unpatentable. In addressing patentability of the proposed substitute claims, we focus on Larada’s *amendments* to challenged claims 1, 2, 7–11, 15–17, and 19, as proposed in the substitute claims. We have previously addressed PHS’s showing of a reasonable likelihood of unpatentability of the challenged claims in our Institution Decision. *See* Inst. Dec. 8–13.

Does the record establish a reasonable likelihood that the proposed substitute claims are unpatentable on the following grounds?

#### 1. Eligibility

No. On this record, PHS has not shown a reasonable likelihood that the proposed substitute claims fail to claim patent eligible subject matter under 35 U.S.C. § 101.

PHS asserts that the substitute claims are “to one or more patent-ineligible laws of nature or natural phenomena—the natural relationship between air and ectoparasites.” Opp. 22. According to PHS, the substitute claims simply apply “a fact of nature—hot air kills ectoparasites.” *Id.* at 23. PHS further argues that the substitute claims “include no additional elements sufficient to transform the natural law or phenomenon of the claims into patent-eligible subject matter.” *Id.* at 24.

At this stage of the proceeding, we are not persuaded that PHS sufficiently explains why the substitute claims fail to recite patentable subject matter. From our review, proposed substitute claims 21–31 are directed to a method for eliminating an ectoparasite infestation by administering heated air *at a specific temperature, airflow, and duration of time*. Mot. 26–28. That the claims recite a specific relationship of temperature, rate, and time of airflow applied to the head persuades us that the substitute claims do not merely recite a natural relationship, as PHS argues. Rather, the substitute claims recite a patent eligible method of treating ectoparasite infestations. *See Vanda Pharm. Inc. v. West-Ward Pharm. Int’l Ltd.*, 887 F.3d 1117, 1136 (Fed. Cir. 2018).

## 2. Indefiniteness

Yes, in part. On this record, PHS (or the record) establishes a reasonable likelihood that proposed substitute claims 21–26 and 29–31 are unpatentable as being indefinite.

With respect to the limitation “*without constraint*,” PHS contends that “[n]either the written description, the claims, nor the plain meaning of the term informs a POSITA with reasonable certainty what aspect of the heated air is applied without constraint.” Opp. 3. Specifically, PHS contends that “without constraint”: 1) may refer to any metric of air temperature, airflow rate, direction, or treatment duration; and 2) conflicts with the expressly recited constraints (ranges) for these metrics. *Id.* at 3–4.

At this stage of the proceeding, we agree. As discussed above, the current record indicates the Specification lacks written description support for “without constraint.” *See supra* at 4–5. And Larada does not direct us to any portion of the prosecution history or expert declaration that explains the term’s meaning. Although Larada appears to interpret the term “without constraint” as allowing the heated air to blow freely over the scalp, the plain language of the claim does not support such a description. *See* Mot. 8–9. Rather, the plain meaning of the term conflicts with the various constraints explicitly recited by the claims, including that the heated air is applied at a specific direction, temperature, and rate for a specific time. Accordingly, the patent fails to inform, with reasonable certainty, those skilled in the art about the scope of the substitute claims. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

With respect to the limitations “*to leave the scalp undamaged*” and “*without damaging the scalp*,” PHS contends a person of ordinary skill in the art “cannot determine with reasonable certainty what qualifies as ‘damage’ in the claims.” Opp. 4–5. Specifically, PHS contends the term “damage” may include mere discomfort, and, therefore, is entirely subjective based on the individual patient. *Id.* At this stage of the proceeding, we disagree. As discussed above, the Specification generally describes methods for eliminating ectoparasite infestations that are safe and avoid pain or discomfort that would precede damage to the scalp. *See* Ex. 1001, 4:64–67, 7:17–19. Accordingly, the current record supports that a person of ordinary skill in the art would be able to ascertain the scope of “without damaging the scalp” with reasonable certainty. And, while the Specification states that “pain and discomfort thresholds are highly variable among individual humans, and thus the maximum useful temperature would be similarly variable” (*id.* at 4:65–67), we are of the view that a person of ordinary skill in the art would be able to discern a range of parameters that would avoid pain and discomfort to users with reasonable certainty.

### 3. Obviousness

Yes. On this record, PHS has shown a reasonable likelihood that the limitations added by proposed substitute claims 21–31 are unpatentable on the following grounds of obviousness:

- (1) Toshio (Ex. 1006) and Kobayashi (Ex. 1008);
- (2) Toshio, Kobayashi, and Anderson (Ex. 1011); and
- (3) Kobayashi and Anderson.

*See* Opp. 5–14. Also, as discussed below, Larada’s objective indicia of non-obviousness relates to the original claims, and does not appear to be co-extensive with the amendments proposed in the Motion. *See* Notice, 84 Fed. Reg. at 9,497. Accordingly, at this stage of the proceeding and based on the current record, we view the balance of the prior art and the objective indicia as favoring unpatentability of the substitute claims.

- (1) Toshio and Kobayashi (claims 21–24, 27, 29, 30)

Larada argues that Toshio’s cup-like box 28 fully encloses a target area of the scalp and thus prohibits heated air from passing into room air. Mot. 8. Because Toshio’s box 28 prohibits the heated air from blowing onto or away from the scalp, Larada argues, it is not “applying the heated air to the



target area without constraint” as claimed. *Id.* at 8–9. Finally, Larada argues that Toshio requires sucking the heated air out of the cup-like box 28 with pipes 29 to deliver the heated air “without damaging the scalp.” *Id.* at 9–10.

PHS argues that Toshio does not “state that all of the heated air is circulated through the suction pipes or that the box contains all heated air within such that none escapes.” Opp. 6. PHS further contends that Toshio’s box would be unlikely to provide an air-tight seal with a patient’s head because: (1) layers of hair create physical separation between the scalp and device; (2) patients’ heads naturally differ in head shape and size; and (3) Toshio’s device could be used for other body parts. *Id.* at 6–7. Finally, PHS contends that “Toshio has mechanisms to cut off the heater before reaching a dangerous temperature” and Kobayashi teaches air temperatures and airflow combinations within the claimed ranges that would not cause damage to the scalp. *Id.* at 8 (citing Ex. 1006, 2:46–50).

We view the current record as supporting PHS’s arguments that Toshio does not require that all the air be contained or constrained within Toshio’s cup-like enclosure such that no hot air escapes. *See* Opp. 6–7 (citing Ex. 1003 ¶ 109; Ex. 1006, 3:51–53). We also view the current record as showing that Toshio provides the heated air without damaging the scalp, particularly given (1) Toshio’s disclosure of “temperature warning sensors” that act “as a burn safety countermeasure” (*see* Ex. 1006, 2:45–50), and (2) Toshio’s, as well as Kobayashi’s, teaching of air temperatures and air flows within the claimed ranges (*see* Inst. Dec. 8, 11 (citing Ex. 1006, 2:33–38; Ex. 1008, 4–5)). Finally, the current record supports PHS’s argument that it would have been obvious to a person of ordinary skill in the art to apply the combined teachings of Toshio and Kobayashi to treat the scalp without causing damage. *See* Inst. Dec. 10–11 (discussing reason to combine the teachings of Toshio and Kobayashi).

(2) Toshio, Kobayashi, and Anderson (claims 25, 26, 28, 31)

Larada contends that a person of ordinary skill in the art would not have combined the prior art because Anderson’s comb cannot be physically combined with Toshio and the combination would change the principle of operation of Toshio and Kobayashi. Mot. 11–13. First, Larada argues that Toshio’s box 28 “does not provide any access” for a comb to separate and lift hair. *Id.* at 12. Second, Larada argues adding Anderson’s comb would preclude Toshio’s box 28 from being curved to follow the head shape. *Id.*

at 13. Third, Larada argues adding Anderson's comb would "redesign" Kobayashi, which teaches an apparatus to cover the whole head of infested children to overcome the escape behavior of lice. *Id.*

PHS responds that a person of ordinary skill in the art would have been led to combine Anderson's comb with Toshio's device to assist in dislodging nits and louse from the hair and scalp and prevent the lice from hiding under layers of hair. Opp. 10. PHS further argues that Kobayashi's teachings are not limited to covering the whole head of infested children, and that Anderson provides an alternative solution for escaping lice. *Id.* at 11–13.

In our view, the current record supports PHS's arguments that a person of ordinary skill would have been led to modify the combination of Toshio and Kobayashi with Anderson's comb. *See* Inst. Dec. 12 (citing Ex. 1003 ¶¶ 106–111, 115). Specifically, Anderson teaches a solution to the problem of escaping lice that is not incompatible with either of Toshio's or Kobayashi's heated air lice treatments. *See id.* (citing Ex. 1011 2:49–53, 3:30–37, 3:64–4:3, Fig. 1). Because obviousness does not require physically incorporating the structures of the references, the record does not support Larada's inoperability argument. *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983).

### (3) Kobayashi and Anderson (claims 21–31)

PHS argues that "Kobayashi expresses concern over lice escaping the heated air during application," and that Anderson solves the problem by dislodging nits and lice with a comb. Opp. 12–13. PHS further argues that Kobayashi's teachings are not limited to a hypothetical embodiment of covering the whole head, contrary to Larada's arguments. *Id.* (citing Mot. 13).

We view the current record as supporting PHS's arguments that a person of ordinary skill would have been motivated to combine Kobayashi and Anderson. *See* Inst. Dec. 12 (citing Ex. 1003 ¶¶ 106, 107, 109, 110). Kobayashi's teachings are not limited to a preferred embodiment of covering the whole head, but rather the reference as a whole teaches applying heated air for treating lice. *See In re Keller*, 642 F.2d 413, 424 (CCPA 1981). Moreover, Anderson provides an alternative solution to removing lice from the whole head, namely, using a comb as part of a combined treatment to dislodge the lice. *See* Inst. Dec. 12 (citing Ex.

1011, 2:49–53, 3:30–37, 3:64–4:3, Fig. 1). Accordingly, based on the current record, it appears that the resulting combination teaches a method of treating lice by applying heated air to the scalp without constraint and without damaging the scalp. *See* Opp. 12–14.

#### (4) Objective Indicia of Nonobviousness

Notwithstanding what the teachings of the prior art would have suggested to one skilled in the art, objective evidence of non-obviousness (so called “secondary considerations”) may lead to a conclusion that the challenged claims would not have been obvious. *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1339 (Fed. Cir. 2016).

Larada contends “[o]bjective indicia, especially commercial success, prove that the Subject Claims are not obviousness.” Mot. 13–24. Larada has submitted the same objective indicia to support patentability of the original claims. *See id.*; *see also* Paper 24 at 9–20.

PHS argues that the proposed substitute claims are not co-extensive with the commercial embodiment of the claims; therefore, there is no nexus between the proposed substitute claims and the alleged commercial success of the commercial embodiment. *See* Opp. 14–22.

We are guided by two principles in our analysis of Larada’s objective indicia. First, Larada must establish a nexus between the objective indicia and the merits of the claimed invention. *ClassCo, Inc., v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016). Second, our Preliminary Guidance relates to the amendments proposed in the Motion and does not address the patentability of the originally challenged claims. *See* Notice, 84 Fed. Reg. at 9,497. Accordingly, at this stage of the proceeding, we analyze the current record of objective indicia for a nexus to the substitute claims proposed in the Motion and not the originally challenged claims.

Larada submits a chart that “shows how claim 1 reads on Larada’s requirements for how the AirAllé device must be used” based on the device’s Operator Manual. Mot. 20–22. Larada contends that “[t]he Operator Manual shows that the heated air is applied to the client without constraint and escapes into the room air.” *Id.* at 21 (citing Ex. 2011, 20). However, Larada does not submit evidence that the alleged commercial success, FDA approval, or unsolicited praise relates specifically to the *amendments* of the original claims as opposed to the original claims themselves. *See* Mot. 18–24. Because Larada does not provide an

analysis demonstrating that any of its products are coextensive with the substitute claims, we determine that finding a presumption of nexus at this time is inappropriate at this time nor has Patent Owner provided sufficient evidence of nexus on the current record.

(5) Conclusion on Obviousness

Weighing PHS's evidence and arguments of obviousness of proposed substitute claims 21–31 against Larada's evidence and arguments of objective indicia of non-obviousness, we are persuaded that PHS demonstrates a reasonable likelihood of proving that the proposed substitute claims are unpatentable over the combined teachings of: (1) Toshio and Kobayashi; (2) Toshio, Kobayashi, and Anderson; and (3) Kobayashi and Anderson

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