

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LIFEWAVE, INC.,  
Petitioner,

v.

EDWARD BLENDERMANN,  
Patent Owner.

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Case IPR2016-00571  
Patent 8,617,590 B2

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Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and  
TINA E. HULSE, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION  
Denying Institution of *Inter Partes* Review  
37 C.F.R. § 42.108

## I. INTRODUCTION

LifeWave, Inc. (“Petitioner”) filed a Petition (Paper 2; “Pet.”) to institute an *inter partes* review of claims 1, 2, 9, 12, 14, 16, and 18 of U.S. Patent No. 8,617,590 B2 (Ex. 1001; “the ’590 patent”). Patent Owner Edward Blendermann (“Patent Owner”) filed a Patent Owner Preliminary Response. Paper 6 (“Prelim. Resp.”). We apply the threshold for review under 35 U.S.C. § 314.

For the reasons provided below, we determine Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim of the ’590 patent. *See* 35 U.S.C. § 314(a). We, therefore, deny the Petition for an *inter partes* review.

### A. *Related Proceedings*

The parties identify the following co-pending case involving the ’590 patent: *Edward L. Blendermann v. LifeWave, Inc.*, Case No. 2:15-cv-14265 (S.D. Fla. 2015). Pet. 5; Paper 4.

### B. *The ’590 Patent (Ex. 1001)*

The ’590 patent discloses methods for increasing muscle strength by wearing a nutrient holding device (e.g., a necklace or locket) during the performance of physical activity. Ex. 1001, Abstract, 1:9–13. The nutrient may include substances such as vitamins, minerals, amino acids, phytomorphagens, herbs, enzymes, and hormones. *Id.* at 2:63–3:1.

*C. Challenged Claims*

Challenged claims 1, 2, 9, 12, 14, 16, and 18 of the '590 patent are reproduced below:

1. A method of improving muscle strength and endurance during physical activity (exercise) by wearing a nutrient holding device, said device incorporating a waterproof enclosure containing at least one nutrient, whereby said waterproof enclosure does not contain a magnet, polarizer, sulfur powders or crystals.

2. A method of improving muscle strength and endurance during physical activity by wearing a nutrient holding device containing at least one nutrient whereby the nutrient material is only separated from the body by the covering of said holding device; the thickness of said holding device may be up to 3 mm.

9. A method according to claim 1 where said nutrient is in the form of a solid, powder, gel or liquid.

12. A method according to claim 1 where said nutrients are selected from vitamins, minerals, blue-green algae, essential fatty acid, phytomorphagens, glandulars, amino acids, herbs and hormones.

14. A method according to claim 1 where stimulation occurs at mechanoreceptor sites which are located throughout the surface of the body, thus allowing for multiple placement points for this device.

16. A method according to claim 1 where said waterproof housing acts to preserve the integrity of the enclosed nutrients and also acts as a barrier separating this nutrient material and the skin thereby avoiding any dermatological consequences or any pharmaceutical event.

18. A method of improving muscle strength according to claim 1 by wearing a nutrient holding device in the form of a non transdermal patch that adheres to the body.

Ex. 1001, 10:56–12:26.

*D. Asserted Grounds of Unpatentability*

Petitioner challenges claims 1, 2, 9, 12, 14, 16, and 18 of the '590 patent on the following grounds. Pet. 6.

| Ground | References                                                             | Basis    | Claim[s] challenged     |
|--------|------------------------------------------------------------------------|----------|-------------------------|
| 1      | Pinter <sup>1</sup>                                                    | § 102    | 1, 2, 9, 12, 14, 16, 18 |
| 2      | Cron <sup>2</sup>                                                      | § 103(a) | 1, 2, 9, 12, 14, 16     |
| 3      | Cron and Driskill <sup>3</sup>                                         | § 103(a) | 1, 2, 9, 12, 14, 16     |
| 4      | Francis, <sup>4</sup> Spitler, <sup>5</sup> and Miyashita <sup>6</sup> | § 103(a) | 1, 2, 9, 12, 14, 16, 18 |

Petitioner relies also on the Declaration of C. Norman Shealy in support of the proposed grounds of unpatentability. Ex. 1015 (“Shealy Decl.”).

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<sup>1</sup> Pinter, U.S. Patent No. 6,277,142 B1, issued Aug. 21, 2001. Ex. 1019 (“Pinter”).

<sup>2</sup> Cron et al., U.S. Patent No. 6,148,822, issued Nov. 21, 2000. Ex. 1011 (“Cron”).

<sup>3</sup> Driskill et al., U.S. Patent No. 5,289,644 issued Mar. 1, 1994. Ex. 1014 (“Driskill”).

<sup>4</sup> Francis, Jr., U.S. Patent No. 4,856,651, issued Aug. 15, 1989. Ex. 1018 (“Francis”).

<sup>5</sup> Spitler, U.S. Patent No. 5,005,374, issued Apr. 9, 1991. Ex. 1016 (“Spitler”).

<sup>6</sup> Miyashita, U.S. Patent No. 5,233,981, issued Aug. 10, 1993. Ex. 1017 (“Miyashita”).

## II. ANALYSIS

### A. Claim Interpretation

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016) (upholding the use of the broadest reasonable interpretation standard). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Only terms that are in controversy need to be construed, however, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

We interpret the following terms of the challenged claims as part of our analysis. The Petition does not require explicit construction of any other claim term at this time.

1. “*method of improving muscle strength and endurance during physical activity*”

The preambles of independent claims 1 and 2 recite a “method of improving muscle strength and endurance during physical activity by wearing a nutrient holding device.” We recognize that, in general, “[a]n intended use or purpose usually will not limit the scope of the claim because such statements usually do no more than define a context in which the invention operates.” *Boehringer Ingelheim Vetmedica, Inc. v.*

*Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003). “But, . . . preamble language will limit the claim if it recites not merely a context in which the invention may be used, but the essence of the invention without which performance of the recited steps is nothing but an academic exercise.” *Id.* (citing *Griffin v. Bertina*, 285 F.3d 1029, 1033 (Fed. Cir. 2002)).

In *Boehringer*, for example, the Federal Circuit found the “growing and isolating . . . virus” language of a preamble was limiting because “‘growing’ and ‘isolating’ are not merely circumstances in which the method may be useful, but instead are the *raison d’être* of the claimed method itself.” *Boehringer*, 320 F.3d at 1344–45. Without the preamble, the court found that “the claimed method [was] reduce[d] to nothing more than a process for producing cytopathic effects in sheets of cultured MA–104 cells—a process whose absence of fathomable utility rather suggests the academic exercise.” *Id.* at 1345. The court thus recognized that one of ordinary skill in the art would not understand the utility of the process without the “growing” and “isolating” language of the preamble.

We conclude that, as in *Boehringer*, one of ordinary skill in the art would not understand the utility of the process of the challenged claims, viewed in light of the Specification, without the preamble language of the claims. The body of each of independent claims 1 and 2 is absent any clear language indicating that the utility of the invention is improving muscle strength and endurance during physical activity. As such, we find the preamble of the claim recites the essence of the invention and states an essential limitation to the claims.

2. “*the thickness of said holding device may be up to 3 mm*”

Petitioner contends that the phrase “thickness of said holding device may be up to 3 mm” recited in claim 2 is reasonably construed to mean “the material of the holding device separating the nutrients from the user’s skin must be 3 mm or less.” Pet. 18–19. We disagree. The claims recite both a holding device and a covering for said holding device, such that “the nutrient material is only separated from the body by the covering of said holding device.” The thickness element of claim 2 expressly limits the holding device, not the covering that separates the body and the nutrients.

*B. Petitioner’s Asserted Anticipation and Obviousness Grounds*

3. *Ground 1: Anticipation of Claims 1, 2, 9, 12, 14, 16, 18 by Pinter*

Petitioner contends that claims 1, 2, 9, 12, 14, 16, and 18 are anticipated by Pinter (Ex. 1019). Pet. 19–29. For at least the reasons discussed below, we are not persuaded that Petitioner has presented sufficient evidence to establish that Pinter discloses all limitations of claims 1, 2, 9, 12, 14, 16 and 18.

A claim is unpatentable under 35 U.S.C. § 102 if a prior art reference discloses every limitation of the claimed invention, either explicitly or inherently. *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 (Fed. Cir. 1995); *see MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (holding that “[t]o anticipate, a single reference must teach every limitation of the claimed invention,” and any limitation not taught explicitly must be taught inherently and would be so understood by a person experienced in the field); *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991) (the dispositive question is “whether one skilled in the art

would reasonably understand or infer” that a reference teaches or discloses all of the elements of the claimed invention). “[A]n inherent property must necessarily be present in the invention described by the count, and it must be so recognized by persons of ordinary skill in the art.” *Hitzeman v. Rutter*, 243 F.3d 1345, 1355 (Fed. Cir. 2001).

Pinter does not expressly disclose a method of improving muscle strength and endurance during physical activity. Petitioner nonetheless contends that Pinter discloses such a method and characterizes the teachings of Pinter as follows:

Pinter discloses a device that promotes energy flow within an organism. [Ex. 2019, Abstract]. The device in Pinter is a nutrient holding device at least because it holds nutrients. Ex. 1019, 7:64-8:7, and claim 16. Pinter discloses the device is to be worn by a user, and that wearing the device results in promotion of healthy energy flow throughout the user by reducing imbalances. Ex. 1019, 13:58-14:1. Balancing energy flows within the user improves muscle strength and endurance during physical activity. Ex. 1015, ¶¶ 49-50.

Pet. 22–23. Petitioner attempts to support its position that Pinter inherently discloses the recited method with the Declaration of Dr. Shealy, who testifies that “an imbalance in energy flow decreases muscle strength and endurance,” and further that “[r]educing or eliminating an imbalance in energy flow brings muscle strength and endurance back to the higher levels present before an imbalance occurs.” Ex. 2015 ¶¶ 49–50.

We are not persuaded. Dr. Shealy’s opinion is not supported by objective evidence. 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.”). The record otherwise lacks sufficient evidence to

support Dr. Shealy's conclusion that wearing Pinter's device for promoting energy flow would inherently result in a method of improving muscle strength and endurance during physical activity. *See Motorola, Inc. v. Interdigital Technology Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) ("An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself."); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983) (reversing trial court's judgment of invalidity because expert's testimony of inherent anticipation, unsupported by the evidentiary record, cannot serve as a basis for a finding of anticipation).

In view of the above, we find that Petitioner has failed to establish that Pinter discloses a "method of improving muscle strength and endurance during physical activity" as required by claims 1, 2, 9, 12, 14, 16, and 18.

Furthermore, with regard to claim 2, Petitioner argues that Pinter discloses the element of claim 2 requiring that "the thickness of said holding device may be up to 3 mm" based on its analysis of Fig. 1B of Pinter providing a cross-sectional view of an embodiment of the disclosed bioenergy channelizer unit.

We are not persuaded by Petitioner's arguments that Pinter discloses the requirement of a "thickness of said holding device may be up to 3 mm." Arguments based on measurements obtained from patent drawings are regarded as having little value where the patent does not disclose that the drawings are to scale and absent any disclosure related to quantitative values. *Hockerson-Halberstadt, Inc. v. Avia Group International, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000) ("[P]atent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes

if the specification is completely silent on the issue.”); *see also, In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977) (“Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value.”).

In view of the above, we find that Petitioner has failed to establish that Pinter discloses each element of claim 2.

*4. Grounds 2 and 3: Obviousness of Claims 1, 2, 9, 12, 14, and 16 over Cron and over the Combination of Cron and Driskill*

Petitioner contends that claims 1, 2, 9, 12, 14, and 16 are unpatentable under 35 U.S.C. § 103 over Cron. Pet. 29–40. Petitioner further contends that claims 1, 2, 9, 12, 14, and 16 are unpatentable under 35 U.S.C. § 103 over the combination of Cron and Driskill. Pet. 40–49.

For at least the reasons discussed below, we are not persuaded that Petitioner has presented sufficient evidence to establish that Cron, alone or in combination with Driskill, would have rendered obvious any one of claims 1, 2, 9, 12, 14, and 16.

*a. Claims 1, 9, 12, 14, and 16*

According to Petitioner, Cron describes a pedal device that is integrated into the sole of a shoe. Pet. 32 (citing Ex. 1011, 5:60–6:16). Petitioner further contends that Cron describes placing phosphates (asserted to be nutrients) within an enclosure formed between two layers of the sole of a shoe. *Id.* at 32, 35 (citing Ex. 1011, 2:54–60, 4:10–40, Figures 3–6; Ex. 1015 ¶¶ 41–44). Petitioner reasons that, because “Cron states the two layers may be formed from the semi-rigid fabric used to manufacture the sole of a shoe,” and that “[t]he use of waterproof materials, such as rubber, as the

layers of the soles of shoes was so well-known and ubiquitous by the priority date of the '590 Patent as to not even require further documentation,” “it would have been obvious to form the sole described in Cron with a waterproof material as the two semi-rigid layers, thereby creating a waterproof enclosure.” *Id.* at 35.

We are not persuaded. Petitioner bears the burden of proof. We have not been given sufficient evidence to support a finding that the pocket, described in Cron, formed by the two layers of fabric forming the sole of the shoe would necessarily form a waterproof enclosure. Petitioner has otherwise failed to adequately articulate a reason why a person of ordinary skill in the art would have modified the teachings of Cron to ensure that the pocket formed by the two layers of fabric forming the sole of the shoe is waterproof. Petitioner provides a list of patents disclosing the use of waterproof materials in the soles of shoes, but has not persuasively articulated how such teachings may be combined with Cron to arrive at a waterproof enclosure containing a nutrient. Accordingly, based on the current record, we find that Petitioner has not met its burden in showing that Cron discloses the required waterproof enclosure.

Petitioner’s reliance on Driskill does not cure these deficiencies. Petitioner combines Cron and Driskill as follows:

Cron does not provide a material for use as the layers of the insole. Driskill, on the other hand, teaches that the use of waterproof materials to form an insole was known in the art. Ex. 1014, 4:48–51. In particular, Driskill expressly states that layers of materials such as “waterproof leather, waterproof artificial leather, waterproof leather board, waterproof cellulosic board, waterproof polymeric board, waterproof fabric, or combinations thereof” can be used to form an insole. *Id.* The function of the

waterproof enclosure is to protect the integrity of the contents/nutrient. Ex. 1001, 5:24–25. Driskill’s use of waterproof materials provides the same function. The combination of Cron’s nutrient-holding enclosure formed between two layers of the insole of a shoe and Driskill’s layers of waterproof materials used to form an insole teaches the claimed limitation.

Pet. 42–43.

We are not persuaded. Driskill discloses waterproof footwear. Ex. 1014, 2:53–55. The footwear is made waterproof by binding the body of the shoe, or upper, to the bottom surface of the insole, which may be made of waterproof material. *Id.* at 2:25–31, 7:7–11. However, we have not been given sufficient evidence to support a finding that Driskill suggests waterproofing the layers of fabric or other material that form the insole itself. Thus, we are not persuaded that the combination of the disclosures in Cron and Driskill would achieve the recited element of a waterproof enclosure containing at least one nutrient. Petitioner has otherwise failed to adequately articulate a reason why a person of ordinary skill in the art would have modified the teachings of Cron to ensure that the pocket formed by the two layers of fabric forming the sole of the shoe is waterproof.

For the reasons given, we decline to institute an *inter partes* review trial on either Ground 2 or Ground 3 with respect to claims 1, 9, 12, 14, and 16.

*b. Claim 2*

Petitioner contends that the thickness of the upper layer of the sole in contact with the user’s skin meets the requirement of claim 2 that “the thickness of said holding device may be up to 3 mm.” This argument is

based on its proposed claim construction that the phrase limits the material of the holding device separating the nutrients from the user's skin. Pet. 37–38. As set forth above, we decline to adopt this claim construction. Petitioner has failed otherwise to establish that the device disclosed in Cron comprises a holding device with a thickness of up to 3 mm. Petitioner's reliance on Driskill does not cure this deficiency.

For the reasons given, we decline to institute an *inter partes* review trial on either Ground 2 or Ground 3 with respect to claim 2.

*5. Ground 4: Obviousness of Claims 1, 2, 9, 12, 14, 16, and 18 over the Combination of Francis, Spitler, and Miyashita*

Petitioner contends that claims 1, 2, 9, 12, 14, 16, and 18 are unpatentable under 35 U.S.C. § 103 over the combination of Francis, Spitler, and Miyashita. Pet. 49–60. For at least the reasons discussed below, we are not persuaded that Petitioner has presented sufficient evidence to establish that the combination of Francis, Spitler, and Miyashita teaches or suggests all limitations of claims 1, 2, 9, 12, 14, 16 and 18.

*a. Claims 1, 9, 12, 14, 16, and 18*

According to Petitioner, Francis describes a chemical thermal pack that can be used to produce or absorb heat to warm or cool parts of the body for a variety of reasons. Pet. 52 (citing Ex. 1018, Abstract, 1:7–17, 2:34–36). Spitler discloses thermal wraps for cooling an individual or a product. Ex. 1016, 25–28. Miyashita discloses a hot compress structure, which, by the generation of heat, accelerates local blood circulation to improve a local metabolism. Ex. 1017, Abstract.

Petitioner combines Francis, Spitler, and Miyashita as follows:

Francis does not specifically state that one of these uses would involve use during exercise, however, Spitler specifically states that the use of thermal wraps to heat or cool body parts during exercise was known. Ex. 1016, 1:13–16. Reduction of pain enhances endurance and muscle strength, as physical resources are not consumed in the tolerance of pain. Ex. 1015, ¶¶ 25, 33. Moreover, Miyashita describes that the hot compress structure promotes “local blood circulation by the generation of heat to improve local metabolism.” Ex. 1017, 1:17–18. Improved metabolism will improve muscle strength and endurance. Ex. 1015, ¶ 26. As such, it would have been obvious to use the thermal pack described in Francis during exercise, as is taught by Spitler because this would be nothing more than employing a known device for a known use. [*See KSR Int’l Co. v. Teleflex Inc.* 550 U.S. 398 (2007).]. This use would have resulted in the known effect of enhancing muscle strength and endurance during such exercise by virtue of the gains to strength and endurance provided through the alleviation of pain, and/or through improved metabolic function provided by the thermal pack. Ex. 1015, ¶¶ 25, 26, 33, and Ex. 1017, 1:17–18.

Pet. 52.

Dr. Shealy testifies that “[t]he presence of pain impedes muscle strength and endurance” and that “using a device to reduce pain would increase muscle strength and endurance during exercise.” Ex. 1015 ¶ 25.

Patent Owner argues that Petitioner’s attempted inherency argument must fail because the information offered fails to show that reducing pain or improving metabolism necessarily leads to improving muscle strength and endurance during physical activity. Prelim. Resp. 46–48. We agree. Petitioner relies on the testimony of Dr. Shealy, unsupported by the objective evidence, as the basis for establishing a link between reducing pain or improving metabolism and improving muscle strength and endurance during physical activity. While such a link may be established in certain

circumstances, the evidence of record is insufficient to show that the limitation at issue is necessarily present, or the natural result of the combination of elements explicitly disclosed by the prior art. *See PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1194–96 (Fed. Cir. 2014) (“A party must . . . meet a high standard in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis—the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art.”).

For the reasons given, we decline to institute an *inter partes* review trial on Ground 4 with respect to claims 1, 9, 12, 14, 16, and 18.

*b. Claim 2*

Petitioner argues that Francis in view of Spitler and Miyashita suggests the element of claim 2 requiring that “the thickness of said holding device may be up to 3 mm” based on its proposed claim construction that the phrase limits the material of the holding device separating the nutrients from the user’s skin. Pet. 57. As set forth above, we decline to adopt this claim construction. Petitioner has failed otherwise to establish that the proposed combination of references teach or suggest a holding device with a thickness of up to 3 mm.

For the reasons given, we decline to institute an *inter partes* review trial on Ground 4 with respect to claim 2.

### III. CONCLUSION

Petitioner has failed to establish a reasonable likelihood that it would prevail in showing that any of claims 1, 2, 9, 12, 14, 16, and 18 of the ’590 patent are unpatentable in view of the asserted references.

IV. ORDER

Accordingly, it is

ORDERED that the Petition is *denied* as to all challenged claims of the '590 patent.

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