No. 2018-2189

# United States Court of Appeals for the Federal Circuit

IN RE: THERMOLIFE INTERNATIONAL LLC, *Appellant*.

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in Merged *Ex Parte* Reexamination Nos. 90/011,394 & 90/011,869.

#### COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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February 10, 2020

#### UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 2018-2189

IN RE: THERMOLIFE INTERNATIONAL LLC

#### **CERTIFICATE OF INTEREST**

Counsel for Appellant certifies the following:

1. Full Name of Party represented by me:

ThermoLife International LLC

2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:

ThermoLife International LLC

3. Parent corporations and publicly held companies that own 10 percent or more of stock in the party:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

Baker Hostetler LLP: William Smith.

Booth Udall Fuller, PLC: Pacer K. Udall.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. See Fed. Cir. R. 47.4(a)(5) and 47.5(b).

The following case in the United States District Court for the District of Arizona was stayed pending conclusion of *ex parte* reexamination Nos. 90/011,869 and 90/011,394 but was dismissed without prejudice with leave to

reinstate: *ThermoLife International, LLC v. Pure Assay Ingredients, Inc.*, No. 2:12-cv-00144.

Dated: February 10, 2020 Respectfully submitted,

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe that this appeal requires

answers to the following precedent-setting questions of exceptional importance:

(1) Whether the Court may substitute its own factual conclusions for the

PTO's to affirm a revocation of a patentee's patent rights.

(2) Whether the Court may affirm agency action based on new grounds raised

for the first time by agency counsel on appeal.

(3) Whether the Court may use a patentee's inventive disclosure to enable the

prior art.

The panel decision conflicts with at least the following controlling decisions

of this Court or the Supreme Court: Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v.

State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983); SEC v. Chenery Corp., 332 U.S.

194 (1947); SEC v. Chenery Corp., 318 U.S. 80 (1943); Ariosa Diagnostics v.

Verinata Health, Inc., 805 F.3d 1359 (Fed. Cir. 2015); In re Morsa, 803 F.3d 1374

(Fed. Cir. 2015); In re Sang-Su Lee, 277 F.3d 1338 (Fed. Cir. 2002).

/s/ Robert J. Gajarsa

ATTORNEY OF RECORD

FOR APPELLANT

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#### INTRODUCTION

The panel opinion contains three errors that should be corrected on rehearing by the panel or the full Court.

- (1) Under the *Chenery* doctrine, appellate courts cannot subrogate agencies' decision making authority to weigh evidence and make factual findings. But that is exactly what happened here. The panel opinion erroneously affirms the revocation of ThermoLife's long-held patent rights to the blockbuster nutritional compound "creatine nitrate" by finding evidence of crucial facts "unpersuasive," even though the Board never addressed those facts. Op. 16. That was error. At minimum, remand is warranted for the PTO to consider the overlooked facts and provide a reasoned explanation.
- (2) The panel opinion also runs afoul of *Chenery* by affirming the Board's anticipation decision based on argument and facts that PTO counsel first raised on appeal. Below, the Board assumed that the key prior art reference ("Dessaignes") disclosed the correct formula for creatine nitrate because the number of atoms in the reported formula could be simply divided by two to arrive at the correct formula. Appx16. There was no record support for that theory, and the Board cited none. On appeal, the PTO newly suggested that ThermoLife's expert affirmatively did the same thing. The panel opinion adopts that factual suggestion as a basis for affirmance. But attorney argument and new purported facts raised in the first

instance on appeal cannot support affirmance (particularly when erroneously taken out of context). The Court "must judge the propriety of [agency] action solely by the grounds invoked by the agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947).

(3) Finally, the panel opinion legally errs by relying on the inventive method for making creatine nitrate disclosed in ThermoLife's patent as proof that a different method supposedly disclosed in the prior art for making the compound was enabled. That is contrary to this Court's established precedent that a patentee's specification may not be used "for filling in gaps in the prior art." Morsa, 803 F.3d at 1378. The Board's theory that the panel affirmed was simple, yet flawed: a 160-year-old prior art method disclosed in Dessaignes for purportedly making a nitrate of creatine (which no one ever replicated since) was enabled despite lacking critical details (such as correct reactant amounts) or actually not functioning because ThermoLife's disclosed method worked and was supposedly "substantially identical." Op. 9-10, 13. But ThermoLife's method requires hydrating a mixture of creatine nitrate and nitric acid and then crystallizing, not mixing and then evaporating, as the prior art directed. The Board—and the panel opinion—assumes such changes would be accounted for by background skill and experimentation of a POSITA because ThermoLife's method includes those inventive alterations. There is no evidence or explanation to support that assumption, however, other than ThermoLife's disclosure. That is not a proper use of a patentee's inventive disclosure—it is

hindsight (that, if anywhere, belongs in an obviousness analysis, not an anticipation rejection).

The panel should rehear this appeal to fix these legal errors, or the full Court should intervene. *See Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1039 (Fed. Cir. 2016) (en banc) (vacating panel opinion that improperly resolved factual issues on appeal, contrary to the "appellate function").

#### **BACKGROUND**

This appeal concerns an *ex parte* reexamination of ThermoLife's Patent No. 7,777,074. Blue Brief ("BB") 13. That patent issued in 2010 after three years of prosecution and recited a claim (claim 1) to a group of inventive amino acid salts, including creatine nitrate. BB13. During reexamination, claim 1 was rewritten as several narrower independent claims, each listing compounds from that group. BB14. Creatine nitrate appeared in proposed claim 6, which is the subject of this appeal. BB14.<sup>1</sup> *All* of ThermoLife's claims (including claim 6) were allowed over "Barger," a reference from the early 1900s that (according to the PTO) identified a chemical formula for creatine nitrate. BB15.

Contrary to the conclusion in the panel opinion (at 3), ThermoLife disclosed the formula and structure for creatine nitrate in its patent. *See*, *e.g.*, Appx35, Appx38 (4:5-10, 9:4-18); Appx34 (1:6-10) (incorporating provisional application entirely); Provisional Patent Application No. 60/973,229 (¶¶ 24-28).

However, the PTO subsequently retracted its allowance of claim 6 without warning. BB15-16.<sup>2</sup> The PTO reasoned that Barger rendered creatine nitrate obvious when combined with modern art that purportedly taught how a POSITA would make an organic salt (e.g., creatine nitrate) by mixing a base (e.g., creatine) with an acid (e.g., nitric acid). BB16. ThermoLife disproved that theory with several declarations by renown experts. BB16-17. The PTO withdrew its obviousness rejection. BB17.

The reexamination certificate should then have issued. But it did not. The Examiner decided that, while Barger may not have rendered creatine nitrate *obvious* in light of modern teachings, it *alone anticipated* the compound. BB17-18. ThermoLife appealed to the Board. Rather than address the Examiner's clear error,<sup>3</sup> the Board crafted new grounds to reject claim 6 as anticipated based on two 160-year-old references ("Dessaignes" and "Gmelin") that an APJ saw on Google while surfing the Internet during oral argument. BB18. According to the Board, claim 6 was anticipated either directly by those new references or by Barger read in light of them. BB18-19.

<sup>&</sup>lt;sup>2</sup> ThermoLife's other claims to amino acid salts were maintained and allowed.

<sup>&</sup>lt;sup>3</sup> The knowledge and ability of a POSITA does not change based on whether § 102 or § 103 is applied.

The first reference, "Dessaignes," was a letter by a French scientist who stated that he made the "same" "nitrate of creatine" compound by either (i) bubbling nitrous gas through a solution of creatine to cause crystallization, or (ii) mixing creatine and nitric acid and then evaporating. Appx4150; *see* BB19-20. Dessaignes was *already* disclosed by ThermoLife during reexamination and addressed at length in declarations by Dr. Chamberlin, which the Board ignored. BB19 n.3; Appx3920-3934.

The second reference, "Gmelin," was a compendium of chemical literature of the time (the 1850s) and recounted Dessaignes's reported results and methods. BB20; Appx4157-4158. Gmelin also recited the teaching of Liebig—the discoverer of creatine—who unequivocally stated that mixing creatine with nitric acid would produce nothing or, if the acid were strong enough, creat*inine* nitrate (which is not the claimed creat*ine* nitrate compound). BB20; Appx4157.

Because of the new grounds for rejection, prosecution was reopened. BB21. ThermoLife provided several new expert declarations explaining (and re-explaining, for Dessaignes) how the new prior art failed to disclose, *inter alia*, an operable method for making creatine nitrate. BB21; *e.g.*, Appx4170-4226. Those declarations and the established record included the following critical facts:

(1) Based on irrefutable chemical process equations now known to modern chemists for the bubbling method, the "same compound" made by Dessaignes's two methods could not even *theoretically* be creatine nitrate. Appx4150; Appx4212-4213; BB23-24; Reply Brief ("GB") 9-11, 17.

- (2) Based on established atomic elemental weights now known to modern chemists, Dessaignes's reported results irrefutably proved that his mix-and-evaporate method did not work. As Dr. Chamberlin explained, even (generously) assuming for the sake of argument that there were equimolar amounts of reactants after dividing Dessaignes's formulas by two, the 1.057 grams of creatine that Dessaignes used would have required 0.508 grams of nitric acid, together totaling 1.565 grams, nowhere near the theoretical or actual final amount Dessaignes reported. Appx3927; GB15 n.5; BB24-25, 45.
- (3) Dessaignes described only the properties of the compound produced by his bubbling method. Appx4150; GB9-10.
- (4) It was uncontested that creatine *dehydrates* in acid to form creatinine. Appx3695; Appx4157-4158; BB9, 20, 44 n.15, 47; GB2, 19. Indeed, as Gmelin taught 160 years ago (based on a disclosure by Liebig, who discovered creatine), adding creatine to strong acid forms creatinine nitrate and adding creatine to weak nitric acid causes no reaction whatsoever. Appx4157-4158; BB46-47; GB22-23.
- (5) ThermoLife's disclosed inventive method for making creatine nitrate in the '074 patent differed from Dessaignes's mix-and-evaporate method in critical ways—ThermoLife's disclosed method required *hydrating* a mixture of creatine and nitric acid (through an independent step of adding water) and then crystallizing (not evaporating) to form creatine nitrate. GB19-20; BB47-48; Appx34 (1:47-55); Red Brief ("RB") 13, 39-40; Appx4158; Appx4466-4467; Appx4683-4684.<sup>4</sup>

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<sup>&</sup>lt;sup>4</sup> The record included dozens of other critical facts that proved the prior art references were, at minimum, ambiguous. *See, e.g.*, BB2-6, 30-52; GB1-3, 8-30.

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Those crucial facts plainly constitute preponderant evidence of nonenablement, yet the Board substantively ignored all of them.<sup>5</sup> The Board even insisted that it was not relying on Dessaignes's bubbling method, yet it looked to the properties of the compound produced by that bubbling method to conclude that Dessaignes actually made creatine nitrate. GB9-10. And, despite (i) the clear differences between ThermoLife's inventive method and the prior art, (ii) the undisputed fact that creatine dehydrates to form creatinine, and (iii) the express teaching in the prior art that simply mixing creatine with nitric acid would never produce creatine nitrate, the Board declared that the step of adding water was not "critical" and that ThermoLife's method was "substantially identical" to Dessaignes's mix-and-evaporate method so any enabling details missing from the prior art would be added based on background skill and common sense of a POSITA, just as ThermoLife supposedly did. See, e.g., Appx26-27, Appx30; BB26-27, 60-61; see also Appx22 ("We find the amount of guidance provided in the prior art to

The Board tentatively recognized Gmelin's express teaching that creatine nitrate could not be made by mixing, but did not substantively respond. *See*, *e.g.*, Appx15, Appx26. Indeed, the Board inexplicably reasoned that Gmelin's teaching that mixing creatine and nitric acid will never produce creatine nitrate somehow "does not address specifically or disparage Dessaignes's particular process of making creatine nitrate by combining creatine and nitric acid." Appx15. Of course it does—it teaches that mixing creatine with nitric acid will never work to produce creatine nitrate. Overcoming that was key to ThermoLife's invention.

be substantial, particularly as the process described appears to be substantially identical to the method taught by the '074 patent ....").

ThermoLife appealed to this Court, repeatedly raising each of those overlooked facts. The panel affirmed. Like the Board, however, the panel opinion does not address any of those facts.

#### **ARGUMENT**

#### I. THE PANEL OPINION ERRS BY DECIDING FACTS ON APPEAL

This Court cannot affirm agency action based upon a new "determination of fact" that the "agency alone is authorized to make and which it has not made." SEC v. Chenery Corp., 318 U.S. 80, 88 (1943). Applying that principle, this Court has consistently held that, although it may decide "purely legal" questions in the first instance, it cannot "make factual and discretionary determinations that are for the [Board] to make." Ariosa, 805 F.3d at 1365-66; see In re Van Os, 844 F.3d 1359, 1362 (Fed. Cir. 2017). Accordingly, when the Board fails to address critical facts in the record or sufficiently explain its conclusions, this Court must "vacat[e] and remand for further explanation from the Board" to "avoid usurping its fact-finding authority." Rovalma, S.A. v. Bohler-Edelstahl GmbH & Co. KG, 856 F.3d 1019, 1026 (Fed. Cir. 2017).

That precedent mandates remand here. There is no material dispute that the Board failed to address the critical scientific evidence discussed (*supra* at 7) in any

substantive way. The overlooked evidence goes to the heart of Board's anticipation ruling. Indeed, it would have been dispositive. As ThermoLife's expert (Dr. Chamberlin) explained, in light of atomic elemental weights known to modern chemists, Dessaignes's ancient mix-and-evaporate method did not work. *Supra* at 7. Atomic weights of elements are irrefutable scientific facts; such evidence, once properly addressed by the Board, would preclude finding Dessaignes's mix-and-evaporate method enabled. Without addressing those points directly, the panel opinion appears to improperly decide in the first instance that the evidence is "unpersuasive." Op. 16. Only the Board can exercise that "fact-finding authority," backed by reasoned explanation. *Rovalma*, 856 F.3d at 1026; *see Chenery*, 318 U.S. at 88; *Van Os*, 844 F.3d 1362; *Ariosa*, 805 F.3d at 1365; *Lee*, 277 F.3d at 1344–45.

The fact that Dessaignes's mixing method did not actually work is not surprising. The prior art—including the very scientist who discovered creatine (Liebig)—taught that mixing creatine and nitric acid could at best produce only creatinine nitrate (again, a different, unclaimed compound). See supra at 7. And the difference between creatine and creatinine in the presence of acid? Water. Id. There was no dispute that creatine dehydrates in acid to form creatinine. Id. That is why Dessaignes's method did not work—it mixed creatine with acid and then further dehydrated it through evaporation, producing creatinine nitrate (not creatine nitrate), exactly as the prior art (Gmelin, through Liebig) taught. Any chemist would

understand that; it is why no scientist has ever successfully repeated Dessaignes's mixing method. *See* BB9, 20, 44 n.15, 47; GB2, 19-20. Indeed, as Dr. Chamberlin explained, "[o]ne would certainly think that in the more than 150 years of chemistry research worldwide since 1854, someone would have needed to make or use such a simple salt, especially if making it were as trivial as the [PTO] purports." Appx4224.

That is also why ThermoLife's method is different than—and not anticipated by—Dessaignes's mix-and-evaporate method. ThermoLife's disclosed method taught that a mixture of creatine and nitric acid should be *hydrated* and then *crystallized*, not *dehydrated* through evaporation. *Supra* at 7. Accordingly, ThermoLife's method produces creat<u>ine</u> nitrate—not creat<u>inine</u> nitrate. ThermoLife's method is supported by irrefutable science and, most importantly, actually works, which is why the industry has copied it rather than Dessaignes's nonfunctional method (another objective fact that the Board ignored). *See* BB59; GB29-30.

It is also insufficient under the Administrative Procedure Act for the Board to summarily conclude—and for the panel to affirm based on the assumption (*see* Op. 13, 15)—that Dessaignes's inoperable mix-and-evaporate method would eventually be transformed into a functional one resembling ThermoLife's based on common knowledge and skill of a POSITA. *E.g.*, Appx22-23, Appx26-27. In addition to improperly shifting the rejection from § 102 to § 103 (*see* BB53-54, 57-59; GB27-

30), the Board cited *nothing* to support that conclusion except its own say-so and the fact that ThermoLife developed an operable method. *See*, *e.g.*, Appx27 (concluding that "varying concentrations" when making organic salts is "high school chemistry" and "routine for an ordinary artisan" without any citations or further explanation). Such "[c]onclusory statements" premised on a POSITA's "basic knowledge" and "common sense" are incompatible with "the Administrative Procedure Act." *Lee*, 277 F.3d at 1344–45 (citations omitted).

The Board's reasoning must be fully explained in light of the *whole* record, including the overlooked facts (*supra* at 7). As this Court has held, "the Board's findings must extend to *all* material facts and must be documented on the record, lest the 'haze of so-called expertise' acquire insulation from accountability." *Id.* (emphasis added). That is what happened here—the Board buried crucial dispositive facts in the "haze" of its bare prognostications on a POSITA's skill and purported trial-and-error revisions to the prior art method. The panel opinion condones, rather than corrects, that error. Remand should be ordered for the Board to provide a proper explanation on all material facts in the record.

<sup>&</sup>lt;sup>6</sup> And relying on ThermoLife's inventive method was legal error too. *See infra* III.

# II. THE PANEL OPINION ERRS BY AFFIRMING BASED ON ATTORNEY ARGUMENT

There is a second *Chenery* problem. Agency decisions must be affirmed "solely by the grounds invoked by the agency" below, not new arguments and factual grounds presented by an agency's attorney on appeal. *Chenery*, 332 U.S. at 196; *see State Farm*, 463 U.S. at 43, 50-52. If the agency's rationale is "inadequate or improper, [this Court] is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis." *Chenery*, 332 U.S. at 196; *see State Farm*, 463 U.S. at 43, 50-52. But that is what the panel opinion does here.

A critical question to the anticipation inquiry was whether Dessaignes disclosed a correct formula for creatine nitrate (it did not). *See* BB33, 50-51; GB14; Op. 11. The Board assumed without any substantive explanation that the formula was correct even though it was off by two-fold for each element. Appx16. ThermoLife's expert proved that hypothesis made no sense; formulas cannot be simply divided in half, and the weights reported by Dessaignes appears at times to match incorrect percentages based on the incorrect formula. *See* Appx3927; Appx4198-4199; Appx4208-4215; BB22-25, 33, 50-51; GB18-19; *see also* Appx4214-4215 (Dessaignes's disclosure was just "not science").

In briefing on appeal, the PTO suggested for the first time that the Board's theory was justified because ThermoLife's expert performed the same divide-in-half operation to Dessaignes's reported amount of nitric acid to criticize Dessaignes's

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results.<sup>7</sup> RB30. ThermoLife objected to that impermissible attorney argument on appeal. GB14. But the panel opinion erroneously relies on it anyway to affirm the Board's conclusion that Dessaignes correctly disclosed creatine nitrate. Op. 9-10. And the panel opinion goes further to craft its own factual finding that even the PTO did not suggest—that Dessaignes's formula is somehow supported by molar ratios purportedly disclosed sixty years *later* in Barger. Op. 10 (citing Appx4045, discussing Barger); RB20 (citing Appx4045 only when discussing Barger). That is clear error under *Chenery* and *State Farm*.

That error was not harmless. Disclosure of a correct formula in Dessaignes was critical to the Board's opinion. BB33, 50-51; GB14; Op. 11. Indeed, Dessaignes was the only anticipatory reference that supposedly disclosed a method for making creatine nitrate and that could have properly shifted the burden to ThermoLife to disprove enablement. *See* Appx16; BB52-54. But without the PTO's new (yet still-flawed) theory in support, there was nothing in the record to justify the Board's conclusion that Dessaignes disclosed a correct formula for creatine nitrate. *See* Appx3927; Appx4198-4199; Appx4208-4215; BB22-25, 33, 50-51; GB18-19.

The Board and the panel opinion cite to the same paragraph in Dr. Chamberlin's declaration with this assumption that also includes his conclusion based on it (i.e., that Dessaignes's mix-and evaporate method did not work, *see supra* at 7 (point two)). Op. 9 (citing Appx3927); RB30 (same). If the veracity of Dr. Chamberlin's *underlying assumptions* are considered, his *conclusions* must be, too, as a matter of logic, fairness, and due process.

The panel's opinion should be corrected to eliminate this clear error, and the Board should explain the basis (if any) for its conclusion on remand.

# III. THE PANEL OPINION ERRS BY USING THERMOLIFE'S INVENTIVE METHOD TO ENABLE THE PRIOR ART

A patentee's specification may be used to "determine the knowledge of a [POSITA]" but not "for filling in gaps in the prior art." *Morsa*, 803 F.3d at 1378. The latter, however, is precisely what the Board did—a legal error the panel endorses. *See* Op. 13, 15; BB60-61.

The path followed by the Board and the panel opinion uses ThermoLife's inventive method to fill gaps in Dessaignes's 160-year-old mix-and-evaporate method. According to the Board, that method was fully enabled because ThermoLife's disclosed mixing method was "substantially identical." Op. 13; see Op. 15; Appx22, Appx26-27, Appx30. But ThermoLife's method is only enabled because it is different. Supra at 7, 11. Contrary to Dessaignes's mix-and-evaporate method, ThermoLife's method requires hydrating a mixture of creatine nitrate and nitric acid (through an independent step of adding water) and then crystallizing, not evaporating, the resulting solution. *Id.* The Board and the panel opinion seemingly chalk those inventive differences up to background skill without a basis for doing so other than ThermoLife's inventive disclosure of them. See Op. 13, 15; Appx22, That is merely "filling in gaps in the prior art" with Appx26-27, Appx30. ThermoLife's inventive disclosure, which is foreclosed. *Morsa*, 803 F.3d at 1378.

For example, the Board and the panel opinion appear to assume that ThermoLife's independent step of adding water to hydrate a mixture of creatine nitrate and nitric acid was merely a way based on common sense or background skill to change the "concentration of nitric acid" used in the process. Op. 15; see Op. 13-14. That assumption is wrong as a matter of logic and science. ThermoLife's step of hydrating a creatine/nitric acid mixture is an important independent step that has nothing to do with acid concentration. ThermoLife's addition of water to a reactive mixture that has already been combined constitutes hydrating the product of a reaction (creatine mixed with nitric acid, which produces creatinine), not changing the input to that reaction, i.e., the concentration of acid. See, e.g., GB2, 19-20. That is common sense to a chemist—just like it is common sense to a mathematician that the parentheses in the equation "(5+10) x 5" change the result from 55 to 75. See id. Just as any chemist now knows that hydrating a creatine/nitric acid solution and crystallizing (as ThermoLife instructs) and *not* dehydrating it (i.e., evaporating it, as

The fact that ThermoLife *added* a new independent step (hydrating the mixture) also did not matter to the Board because, at the end of ThermoLife's patent (Appx41 (15:49-59)), there was a general boilerplate reservation that the "*order* of steps" recited could be changed. Appx22-23 (emphasis added); Op. 14 (citing same reservation). But altering the "*order*" of steps in a method does not mean *eliminating* or substantively *changing* them. Moreover, ThermoLife's disclosure expressly states that the inventions "comprise ... Amino Acid, Nitric ... Acid and water *mixed in a specific order*." Appx39-40 (12:65-13:6) (emphasis added); *see* BB13, 47-48. Neither the agency decision nor the panel opinion addresses that express restriction. *See* GB20.

the prior art instructs) is critical because the difference between creatine and

creatinine is water. Supra at 7, 11.

ThermoLife taught the world how to make creatine nitrate. Dessaignes did

not. Altering Dessaignes's method to become ThermoLife's method was the product

of invention, not common sense and common skill. Even if that conclusion

somehow could be disputed, however, the question cannot be resolved based on

ThermoLife's inventive disclosure (and is a question of obviousness, at best, not

anticipation). Remand should be ordered for the Board to fix that error and develop

a properly substantiated conclusion and record for review.

**CONCLUSION** 

The Court should grant panel or en banc rehearing.

Dated: February 10, 2020

Respectfully submitted,

/s/ Robert J. Gajarsa

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**CERTIFICATE OF SERVICE** 

I hereby certify that on February 10, 2020, I electronically filed the foregoing

Combined Petition for Panel Rehearing and Rehearing En Banc with the United

States Court of Appeals for the Federal Circuit through the Court's CM/ECF system.

All parties are represented by registered CM/ECF users and will be served by the

CM/ECF system.

/s/ Robert J. Gajarsa

Robert J. Gajarsa

Counsel for Appellant

### CERTIFICATE OF COMPLIANCE

I hereby certify that this petition complies with the type-volume limitations of Fed. R. App. P. 35(b)(2)(A) because it contains 3,827 words, excluding the parts of the foregoing exempted by Fed. Cir. R. 35(c)(2).

<u>s/ Robert J. Gajarsa</u> Robert J. Gajarsa

Counsel for Appellant

# ADDENDUM PURSUANT TO FEDERAL CIRCUIT RULE 35(e)(3)(I)

NOTE: This disposition is nonprecedential.

## United States Court of Appeals for the Federal Circuit

IN RE: THERMOLIFE INTERNATIONAL LLC, *Appellant* 2018-2189

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. 90/011,394, 90/011,869.

Decided: January 10, 2020

ROBERT J. GAJARSA, Latham & Watkins LLP, Washington, DC, argued for appellant. Also represented by GABRIEL BELL.

FRANCES LYNCH, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for appellee Andrei Iancu. Also represented by THOMAS W. KRAUSE, JOSEPH MATAL, MAUREEN DONOVAN QUELER.

Before PROST, Chief Judge, TARANTO and STOLL, Circuit Judges.

PROST, Chief Judge.

Casse: 1188-22118899

IN RE: THERMOLIFE INTERNATIONAL LLC

ThermoLife International LLC appeals a decision from the Patent Trial and Appeal Board ("Board") from two merged ex parte reexamination proceedings of U.S. Patent No. 7,777,074 ("the '074 patent"). The Board found that claim 6, which was added during reexamination, is anticipated under 35 U.S.C. § 102(b). For the reasons below, we affirm.

Ι

The '074 patent claims priority to an application filed in 2007 and is directed to various amino acid compounds. As relevant to this appeal, the '074 patent discloses nitrates of amino acid compounds. The specification teaches that "Nitrates are a class of compounds that are salts of Nitric Acid (HNO<sub>3</sub>) and at least comprise one Nitrogen atom and three Oxygen atoms (NO<sub>3</sub>)." '074 patent col. 6 ll. 45-47.

Claim 6, which was added during ex parte reexamination of the '074 patent and is the only claim on appeal, is directed in part to nitrates of creatine. Claim 6 recites:

#### 6. A Compound having the structure of:

wherein Y is selected from the group consisting of a Nitrate and a Nitrite.

Because the claim at issue in this case have effective filing dates prior to March 16, 2013, we apply pre-AIA § 102(b).

J.A. 44.

Creatine is a nonessential amino acid or amino acid derivative that is naturally occurring in the human body and is commonly used in nutritional supplements. '074 patent col. 4 ll. 11–19. At the time of filing, it was known that creatine is capable of forming a number of salts by reaction with a number of acids. Claim 6 recites one such salt, creatine nitrate. See '074 patent col. 6 ll. 45-47.

The '074 patent teaches that creatine nitrate may be prepared by "combining nitric acid and Creatine, mixing with water, and leaving to crystallize." '074 patent col. 9 ll. 19–21. The specification does not state the chemical formula or the structural formula for creatine nitrate. The specification does, however, identify the structural formula of creatine, which reveals that the chemical formula of creatine is  $C_4H_9N_3O_2$ . See '074 patent col. 4 ll. 1–9; see also id. at J.A. 44 (claim 6).

В

The '074 patent issued in 2010 with two claims. Two separate requests for ex parte reexamination were subsequently filed. These requests were merged into a single ex parte reexamination proceeding, during which the original claims of the '074 patent were cancelled and other claims, including claim 6, were added. Though all other newly added claims were allowed, claim 6 was finally rejected as anticipated under 35 U.S.C. § 102(b) over a prior art publication Barger.

Barger is a compendium of bases, and in relevant part, describes creatine and its structure. See J.A. 3809–815, 5063. Barger specifically teaches "[clompounds of creatine," including "[t]he nitrate, C<sub>4</sub>H<sub>9</sub>O<sub>2</sub>N<sub>3</sub> · HNO<sub>3</sub>," and further describes creatine nitrate's properties.<sup>2</sup> J.A. 3812. Barger does not describe the structure of creatine nitrate or a method of making it.

ThermoLife appealed the examiner's rejection of claim 6 to the Board. See In re ThermoLife Int'l LLC, No. 2015-006203, 2016 WL 406381 (P.T.A.B. Feb. 1, 2016) ("Board Decision I"). ThermoLife argued that Barger is ambiguous and also that Barger is not enabling because it does not teach a method of preparing creatine nitrate. The Board disagreed, but nonetheless identified additional evidence to demonstrate that Barger is enabling. Specifically, the Board cited the prior art publication Dessaignes, which predates Barger, for its disclosure of a method for preparing creatine nitrate. The Board additionally cited another prior art publication Gmelin<sup>4</sup> for a similar disclosure.

Dessaignes teaches methods of preparing the "nitrate of creatine," identifying the salt with the chemical formula "C<sup>8</sup>H<sup>18</sup>N<sup>6</sup>O<sup>4</sup>, N<sup>2</sup>H<sup>2</sup>O<sup>6</sup>." *See* J.A. 4150. In one of these methods, Dessaignes states that creatine nitrate may be produced by "dissolving 1.057 gr. of crystallized creatine in nitric acid containing 0.447 gr. of N<sup>2</sup>H<sup>2</sup>O<sup>6</sup>, and evaporating

<sup>2</sup> Barger, G., THE SIMPLER NATURAL BASES, R.H.A. Plimmer & F.G. Hopkins (eds.), "Monographs on Biochemistry," Longmans, Green & Co., London (1914).

<sup>&</sup>lt;sup>3</sup> M. Dessaignes, "Scientific and Medicinal Chemistry: Examination of some Products of the Transformation of Creatine," 12 (279), THE CHEMICAL GAZETTE OR JOURNAL OF PRACTICAL CHEMISTRY, 201–04 (June 1, 1854).

<sup>&</sup>lt;sup>4</sup> Leopold Gmelin, "Creatine," HANDBOOK OF CHEMISTRY, Vol. 10: Organic Compounds Containing Eight and Ten Atoms of Carbon, pp. 249–55, Henry Watts, trs., printed for the Cavendish Society, London (1856).

at 86° F." J.A. 4150. Dessaignes does not teach the structural formula of creatine nitrate.

The Board determined that "the salt described in Barger was conventionally made by dissolving crystallized creatine in the requisite quantity of nitric acid and allowing to crystallize by evaporation of the water, as evidenced by Dessaignes and Gmelin, identically to that described in the '074 patent." Board Decision I, at \*6. The Board therefore concluded that Barger's teaching of creatine nitrate did not require a citation to, or a description of, how to make the salt. Id. (citing Motorola, Inc. v. Interdigital Tech. Corp., 121 F.3d 1461, 1472 (Fed. Cir. 1997)). Because the Board had relied on new evidence to support its affirmance, it entered new grounds of rejection for claim 6: claim 6 is rejected under 35 U.S.C. § 102(b) as anticipated by: (a) Barger, as evidenced by Dessaignes and Gmelin, and (b) Dessaignes or Gmelin.<sup>5</sup>

ThermoLife elected to reopen prosecution as to the new grounds and submitted additional declarations and argument purporting to show that all three references, Barger, Dessiagnes, and Gmelin, are ambiguous and not enabling. The examiner, however, disagreed and finally rejected claim 6 on all grounds. ThermoLife again appealed to the Board.

In its second decision on appeal, the Board stated that the issue was whether "based on a preponderance of the evidence, has [ThermoLife] shown that the Examiner erred in maintaining the new grounds of rejection in light of

In Board Decision I, the Board expressly adopted all findings of the examiner in the final rejection and the examiner's answer in that appeal. Board Decision I, at 4. The Board's decision has not been vacated or otherwise reversed. The analysis and conclusions therein remain part of the prosecution history.

further arguments and evidence of record . . . ?" See In re ThermoLife Int'l LLC, No. 2018-001029, 2018 WL 2335128, \*3 (P.T.A.B. May 21, 2018) ("Board Decision II"). The Board answered in the negative, again rejecting ThermoLife's arguments that the references are ambiguous and not enabling. First, as to ambiguity, the Board found that each of the references, including Barger and Dessaignes, unambiguously identify creatine nitrate and disclose its chemical formula and other physical properties. The Board expressly refuted ThermoLife's argument that Dessaignes teaches the incorrect chemical formula for creatine nitrate by doubling the number of atoms of each element in the formula. The Board stated that Dessaignes's formula "converts" to the correct formula. Id. at \*8. The Board also stated that "[w]ithout sufficient evidence to support a finding of clear error, we are unwilling to find the express teaching of a nitrate of creatine in four separate references to be ambiguous." *Id*.

The Board also expressly rejected ThermoLife's argument that Dessaignes is ambiguous due to potential inaccuracies in its disclosure or because of differences between the method of preparing creating nitrate taught in Dessaignes and the method taught by the '074 patent. The Board found that the method in Dessaignes is "substantially identical to that described in the '074 patent." Id. at \*10.

Next, the Board found that ThermoLife had not met its burden to show that the asserted prior art is not enabling. See id. at \*10–17 (citing In re Antor Media Corp., 689 F.3d 1282, 1288 (Fed. Cir. 2012)). Specifically, the Board found that the record demonstrated that a skilled artisan as of the '074 patent's application in 2007 could have made creatine nitrate from Dessaignes's teaching without undue ex-The Board also rejected ThermoLife's perimentation. argument that Dessaignes did not, in fact, make creatine nitrate, because as an initial matter, actual manufacture is not required to satisfy enablement. The Board further

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rejected ThermoLife's argument based on its finding that ThermoLife has not "conclusively shown" that Dessaignes's mixing process does not produce creatine nitrate, or that the findings of Dessaignes are "necessarily inaccurate." *Id.* at \*16, \*17.

ThermoLife appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

П

Anticipation is a question of fact that considers whether a single reference describes the claimed invention "with sufficient precision and detail to establish that the subject matter existed in the prior art." Wasica Finance GmbH v. Continental Automotive Sys., Inc., 853 F.3d 1272, 1284 (Fed. Cir. 2017) (quoting Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1120 (Fed. Cir. 2002)); see also In re Hyatt, 211 F.3d 1367, 1371 (Fed. Cir. 2000). As a matter of law, an ambiguous reference cannot anticipate a claim. Wasica Finance, 853 F.3d at 1284.

Once an examiner has shown a prima facie case of anticipation, because "a prior art printed publication cited by an examiner is presumptively enabling," the burden of proving that the prior art is not enabling shifts to the patent owner. Antor Media, 689 F.3d at 1288. Whether a prior art reference is enabled is a question of law based on underlying factual findings. In re Morsa, 803 F.3d 1374, 1376 (Fed. Cir. 2015). We review the Board's legal conclusions de novo and the Board's factual findings for substantial evidence. Morsa, 803 F.3d at 1376.

On appeal, ThermoLife argues that the cited prior art does not anticipate claim 6 of the '074 patent because the prior art does not expressly and unambiguously disclose the claimed invention. ThermoLife also argues that the cited prior art does not enable the claimed invention. We address each argument in turn.

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#### A

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ThermoLife argues that the prior art does not anticipate claim 6 of the '074 patent because each reference fails to expressly and unambiguously disclose the claimed invention. According to ThermoLife, the references do not teach anything relevant to the claimed creatine nitrate compound because they are designed to produce compounds with different formulas. We disagree. Substantial evidence supports the Board's determination that claim 6 is anticipated by at least Barger as evidenced by Dessaignes and by Dessaignes alone. Because we affirm with respect to these grounds, we do not reach ThermoLife's remaining arguments related to Gmelin.

Barger teaches the "nitrate" of creatine recited by claim 6. Barger further correctly reports the chemical formula of creatine nitrate  $(C_4H_9N_3O_2 \cdot HNO_3)$ , which consistent with claim 6, identifies the chemical formula for creatine nitrate as creatine with nitric acid. Compare J.A. 3812 (Barger) with '074 patent col. 4 ll. 1–10, col. 6 ll. 45–47 and J.A. 44 (claim 6). Further still, Barger describes the properties of creatine nitrate, and Barger discloses the correct chemical formula and structural formula for creatine, one of creatine nitrate's starting materials.

To the extent that ThermoLife argues that the Board's anticipation decision should be reversed because the Board copied the incorrect chemical structure of creatine from Barger into the body of the decision, we are not persuaded that this constitutes reversible error. Board's statement that "Barger provides a chemical structure for creatine" is correct. Board Decision II, at \*5; see also J.A. 5063. Additionally, throughout reexamination, the correct creatine structure from Barger was repeatedly cited by the examiner and those citations were adopted by the Board. See e.g., Board Decision I, at \*2. Moreover, as

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Though ThermoLife acknowledges that Barger's express disclosure of creatine nitrate "appears like it could match the claimed compound," ThermoLife nonetheless argues that the disclosed chemical formula "could just as easily refer to creatinine nitrate monohydrate or any other number of compounds." See Appellant's Br. 34; see also id. at 3. As the Board found, ThermoLife's argument is undermined by the clear description in Barger, which specifically identifies the disclosed chemical formula as being that of creatine nitrate and not another compound. Board Decision II, at \*7. Substantial evidence supports the Board's finding that Barger unambiguously discloses creatine nitrate as recited by claim 6.

Like Barger, Dessaignes expressly teaches the "nitrate of creatine," which is the combination of creatine and nitric acid. J.A. 4150. Dessaignes identifies creatine nitrate with the chemical formula "C<sup>8</sup>H<sup>18</sup>N<sup>6</sup>O<sup>4</sup>, N<sup>2</sup>H<sup>2</sup>O<sup>6</sup>," and Dessaignes specifically teaches a method for preparing creatine nitrate by mixing creatine and nitric acid. *Id*.

ThermoLife, however, argues that the Board erred in finding that Dessaignes's reported chemical formula, which doubles the number of each of the atoms, "converts" to the correct chemical formula. *Board Decision II*, at \*8. According to ThermoLife, such conversion has "no place in chemistry." Appellant's Br. 50–51. But ThermoLife's argument lacks evidentiary support. *See id.* In contrast, the Board's conclusion is supported by testimony offered by ThermoLife's own expert, Dr. Richard Chamberlin, with respect to another statement in Dessaignes. He stated that "[o]ne would assume that the 'N²H²O6' would mean two equivalents of nitric acid." *See* J.A. 3927, ¶ 23. Indeed, the

Barger has otherwise clearly identified creatine nitrate, it is not required to disclose its structure or the structure of its starting material in order to anticipate. *See In re Baranauckas*, 228 F.2d 413, 415 (C.C.P.A. 1955).

chemical formula for creatine nitrate in Dessaignes is consistent with the correct ratio of one mole of creatine to one mole of nitric acid. *See* J.A. 4045. Substantial evidence supports the Board's finding that Dessaignes unambiguously discloses the correct chemical formula for creatine nitrate.

ThermoLife's remaining arguments that the Board erred in finding the prior art unambiguous are similarly unpersuasive. ThermoLife, for example, argues that while the prior art may disclose creatine nitrate, there "is no way to know whether the 'creatine' that the references refer to creatine as it is known today." Appellant's Br. 37. ThermoLife supports this argument with expert testimony by Dr. Trevor H. Levere, a chemistry historian, which the Board discounted because Dr. Levere is not capable of determining whether a chemist in 2007 would have been able to perform Dessaignes's mixing method without undue experimentation. Board Decision II, at \*17. Chamberlin, the Board also found that as of the time of the '074 patent's alleged invention in 2007, the art of salt formation was well-known, and that mixing crystallized creatine and nitric acid as described in Dessaignes would have required no more than routine experimentation. Id. We credit the Board's fact finding and determine that it is supported by substantial evidence.

ThermoLife also briefly argues that the Board legally erred in determining that the prior art is not ambiguous because in its view, the Board required ThermoLife to prove that the prior art was ambiguous by clear error, rather than by preponderant evidence. ThermoLife's only evidence that the Board applied an incorrect standard is the Board's lone statement that "[w]ithout sufficient evidence to support a finding of *clear error*, we are unwilling to find the express teaching of a nitrate of creatine in four separate references to be ambiguous." *Id.* at \*8 (emphasis added). Contrary to ThermoLife's suggestion, this statement does not apply to the Board's ultimate finding

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regarding whether the cited prior art unambiguously anticipates the prior art. Instead, the Board's statement is made in response to ThermoLife's specific argument that the prior art is ambiguous because it discloses incorrect chemical formulas, or otherwise contains errors, rendering the prior art ambiguous—the same argument considered above. See id.

The Board's decision shows that it correctly considered the ultimate question of whether the prior art unambiguously teaches the claimed invention. The Board framed the issues on appeal by asking whether the examiner's anticipation rejections should be maintained "based on a preponderance of the evidence." *Id.* at \*3. Then the Board correctly applied the law. The Board explained that it was "unwilling to find the express teaching of a nitrate of creatine in four separate references to be ambiguous," because ThermoLife attempted to "undermine an express teaching [of the prior art] with no more than conjecture." *Id.* at \*8. We agree.

The evidence demonstrates that the Board correctly found that both Barger and Dessaignes expressly disclose creatine nitrate as recited in claim 6, and also that neither Barger nor Dessaignes teaches incorrect formulas for creatine nitrate. These are factual findings that we review for substantial evidence. See Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347, 1355 (Fed. Cir. 2005) ("What a prior art reference discloses in an anticipation analysis is a factual determination . . . ."). Because Barger and Dessaignes do not include the errors alleged by ThermoLife, ThermoLife has not shown that the prior art is ambiguous by preponderant evidence.

On the facts of this case, therefore, we do not think that the Board's errant statement constitutes reversible error. We determine that to the extent that the Board incorrectly stated the preponderant evidence standard in a single statement, such error was harmless. *In re Watts*, 354 F.3d 1362, 1369 (Fed. Cir. 2004) ("We have previously made clear that the harmless error rule applies to appeals from the Board just as it does in cases originating from district courts.").

Accordingly, we affirm the Board's decision that the prior art discloses a prima facie case of anticipation.

R

Because we determine that the Board correctly found a prima facie case of anticipation, we now turn to ThermoLife's argument that the prior art is not enabling. More particularly, ThermoLife argues that the prior art lacks enablement because in its view, the prior art does not disclose a method of preparing creatine nitrate. *See Antor Media*, 689 F.3d at 1288.

With respect to Barger, in its first appeal to the Board during reexamination, ThermoLife argued that the reference was not enabling for failure to describe a method of making creatine nitrate. In response, the Board disagreed that Barger lacked enablement but also cited Dessaignes, among other references, as evidence that "Barger's teaching of creatine nitrate is the recitation of a material that was so conventional to organic chemists at the time of the invention that there was not need either for citation or for a description of how to make the salt." *Board Decision I*, at \*6 (citing *Motorola*, 121 F.3d at 1472).

On appeal before this court, ThermoLife argues that Dessaignes does not cure the deficiency of Barger because it also is not enabling. According to ThermoLife, the preparation of a salt like creatine nitrate is complex and the method taught by Dessaignes would not teach a person of ordinary skill in 2007 to make creatine nitrate. ThermoLife also argues that Dessaignes does not teach the same method as the '074 patent, but instead discloses a different step for adding water. ThermoLife further argues that the method in Dessaignes may not make creatine

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nitrate at all, and that it is not possible to determine whether creatine nitrate was actually made based on the disclosures in Dessaignes.

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ThermoLife made each of these arguments in its second appeal to the Board during reexamination. The Board correctly rejected each. See Board Decision II, at \*10-17. For example, the Board found that preparing creatine nitrate from Dessaignes would not have been beyond the skill of the ordinary artisan in 2007 because the specific disclosures including the amounts of creatine and nitric acid, as well as evaporation temperature, would have provided sufficient information to such an artisan to prepare creatine nitrate. See id., at \*13. Indeed, as the Board found, the directions in the prior art for preparing creatine nitrate are "substantially identical" to the method taught by the '074 patent. See id. at \*12; compare '074 patent col. 9 ll. 19–21 (preparing creatine nitrate by "combining nitric acid and Creatine, mixing with water, and leaving to crystallize") with J.A. 4150 (Dessaignes) (preparing creatine nitrate by "dissolving 1.057 gr. of crystallized creatine in nitric acid containing 0.447 gr. of N<sup>2</sup>H<sup>2</sup>O<sup>6</sup>, and evaporating at 86° F"). The amount of direction included in the '074 patent's specification is evidence of the knowledge in the art, and therefore, is also evidence of what amount of disclosure is required from the prior art to be enabling. See Morsa, 803 F.3d at 1378 ("There is a crucial difference between using the patent's specification for filling in gaps in the prior art, and using it to determine the knowledge of a person of ordinary skill in the art."); see also Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 781 (1985) (noting that appellee's "own patent application does not undertake to tell anyone how to make the alloy it describes and seeks to patent. It assumes that those skilled in the art would know how").

To the extent that the method for preparing creatine nitrate in the '074 patent may not be completely identical to the prior art, i.e., mixing with water as compared to dissolving, the Board found that there was no evidence in the record to suggest that the difference would be "critical." See Board Decision II, at \*12. Instead, the Board found that the '074 patent itself taught that the difference in the methods would not be critical to preparing creatine nitrate. Id. (citing '074 patent col. 15 ll. 49–59 ("[I]t will be understood that such manufacture is not limited to the specific order of steps or forms as disclosed . . . since many possible manufacturing processes and sequences of steps may be used to manufacture Amino Acid Compound implementations in a wide variety of forms."). We conclude that the Board's findings are supported by substantial evidence.

ThermoLife also argues that the Board's decision should be reversed or vacated because the Board improperly required it to demonstrate lack of enablement by clear error rather than by preponderant evidence. ThermoLife cites three sentences from the Board's decision as evidence that the Board applied the wrong standard in determining whether the prior art lacked enablement. First, ThermoLife cites the Board's statement that "[w]ithout sufficient evidence to support a finding of clear error, we are unwilling to find the express teaching of a nitrate of creatine in four separate references to be ambiguous." *Id.* at \*8. This is the same statement discussed above. As is clear from that discussion, the Board's statement is not related to whether the prior art is enabling, but instead relates to whether the prior art was ambiguous. We are not persuaded that the Board's statement in the context of ambiguity is relevant to the standard it applied during its separate discussion of whether the prior art is enabling.

ThermoLife additionally cites two other sentences from the Board's opinion that relate to enablement, but which nonetheless fail to prove that the Board committed reversible error. In these statements, the Board explained that ThermoLife has not "conclusively shown Dessaignes' mixing process does not produce creatine nitrate," *id.* at \*16, and that the Board was not persuaded "that the findings of

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Dessaignes are *necessarily* inaccurate," *id.* at \*17 (emphasis in original). These statements, however, do not expressly demonstrate that the Board applied an incorrect standard, particularly where the Board had already correctly framed ThermoLife's burden for proving a lack of enablement in the immediately preceding paragraph. *Id.* at \*16 ("If Patent Owner can establish, *by preponderance of the evidence* of record, that the skilled artisan cannot make what is alleged in the prior art using the steps taught in the prior art, only then is a presumed reliable prior art reference deemed to be unreliable and ineligible as an anticipatory reference as a matter of law.") (emphasis added); *see also id.* at \*3.

But even were we to assume that by using the words "conclusively" and "necessarily" the Board required more than preponderant evidence, we nonetheless do not find reversible error. Because enablement is a question of law, which we review de novo, on appeal we apply the Board's findings of fact to determine whether its ultimate legal conclusion is supported by preponderant evidence. *See Morsa*, 803 F.3d at 1376. Based on the record of this case, we conclude that it is.

The Board's fact finding establishes that the method taught by Dessaignes would enable a person of ordinary skill in the art to prepare creatine nitrate. See Board Decision II, at \*10–17. The Board further found that based on the knowledge of the ordinarily skilled artisan in 2007, to the extent experimentation would be required to prepare creatine nitrate from Dessaignes's method (e.g., to determine the concentration of nitric acid to use), such experimentation would have been no more than routine. See id. at \*15, \*17; see also Morsa, 803 F.3d at 1377; In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). And to the extent it would have been unclear whether creatine nitrate was in fact made, the Board found that the skilled artisan in 2007 would have had many methods for confirming the product. Board Decision II, at \*15.

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When the Board's findings of fact are taken together, ThermoLife's argument that Dessaignes's method would not have enabled an ordinarily skilled artisan in 2007 to prepare creatine nitrate is supported only by mere speculation. Such speculation or conjecture fails to show that, by a preponderance of the evidence, the prior art is not enabling. Accordingly, to the extent the Board applied the incorrect standard, on this record, such error is harmless and does not warrant reversal. See In re Watts, 354 F.3d at 1369.

We have considered ThermoLife's additional arguments and find them unpersuasive. For the above described reasons, we affirm the Board's decision that claim 6 is anticipated.

#### **AFFIRMED**

Costs

The parties shall bear their own costs.