NOTE: This disposition is nonprecedential.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*.

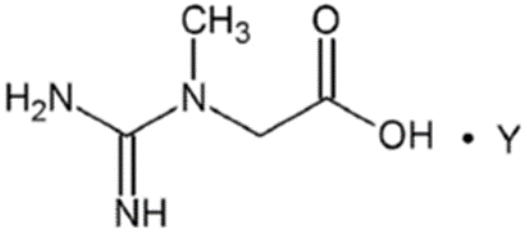
ThermoLife International LLC appeals a decision from the Patent Trial and Appeal Board ("Board") from two merged ex parte reexamination proceedings of U.S. Patent No. 7,777,074 ("the '074 patent"). The Board found that claim 6, which was added during reexamination, is anticipated under 35 U.S.C. § 102(b).[1] For the reasons below, we affirm.

I

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_3) and at least comprise one Nitrogen atom and three Oxygen atoms (NO_3)." '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.

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[1] 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).

B

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 "[c]ompounds of creatine," including "[t]he nitrate, $C_4H_9O_2N_3 \cdot HNO_3$," and

further describes creatine nitrate's properties.[2] 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,[3] which predates Barger, for its disclosure of a method for preparing creatine nitrate. The Board additionally cited another prior art publication Gmelin[4] for a similar disclosure.

Dessaignes teaches methods of preparing the "nitrate of creatine," identifying the salt with the chemical formula "$C^8H^{18}N^6O^4$, $N^2H^2O^6$." *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 $N^2H^2O^6$, and evaporating

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

[3] 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).

[4] 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.[5]

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

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[5] 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 experimentation. The Board also rejected ThermoLife's 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

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).

II

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.

A

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.[6]

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[6] 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. The 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

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 "$C^8H^{18}N^6O^4$, $N^2H^2O^6$," 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 '$N^2H^2O^6$' would mean two equivalents of nitric acid." *See* J.A. 3927, ¶ 23. Indeed, the

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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. Citing Dr. 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

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.

B

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

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

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 $N^2H^2O^6$, 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

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.

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.