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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/002,001	05/31/2012	8067381	028284.0105X7US	2667

127044 7590 07/17/2015

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ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
07/17/2015	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOODBOLT DISTRIBUTION, LLC.
Requester and Respondent

v.

NATURAL ALTERNATIVES INTERNATIONAL, INC.
Patent Owner and Appellant

Appeal 2015–000225
Reexamination Control 95/002,001
Patent 8,067,381 B1
Technology Center 3900

Before, RICHARD M. LEBOVITZ, JEFFREY B. ROBERTSON, and RAE LYNN P. GUEST, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on the appeal by the Patent Owner from the Patent Examiner's decision to reject claims 1–14 and 32-34 in the above-identified *inter partes* reexamination of United States Patent 8,067,381 B1. The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315 (pre–AIA). We affirm.

BACKGROUND

The patent in dispute is this appeal is United States Patent 8,067,381 B1 ("the '381 patent") which issued Nov. 29, 2011, based on Application No. 13/215,073 filed Aug. 22, 2011. There are two named inventors, Roger Harris and Mark Dunnett. The patent is subject to a terminal disclaimer. The real party in interest and owner of the '381 patent is Natural Alternatives International, Inc. ("Patent Owner"). Owner Appeal Brief 1, dated May 14, 2014 ("Owner Appeal Br.").

A request for *inter partes* reexamination of the '381 patent was filed May 31, 2012 by Woodbolt Distributors, LLC ("Requester") under 35 U.S.C. §§ 311–318 and 37 C.F.R. §§ 1.902–1.997. Woodbolt is also the Respondent in this proceeding. An oral hearing was held April 15, 2015. A transcript of the hearing has been entered into the record ("Hearing Tr.").

According to Patent Owner, there is a related *inter partes* reexamination (95/002,048) and district court litigation. Owner Appeal Br. 1.

The '381 patent teaches that anaerobic stress "can cause the onset of fatigue and discomfort that can be experienced with intense exercise . . ., where oxygen availability may be limited . . . and with aging." '381 patent, col. 1, ll. 53-58. The claimed subject matter of the '381 patent is directed to a human dietary supplement that comprises beta-alanine or a derivative of it. *Id.*, col. 3, ll. 4–9. Beta-alanine is an amino acid. *Id.* According to the '381 patent, administering beta-alanine and glycine increases the anaerobic working capacity in a tissue. *Id.*, col. 2, ll. 48–65.

The claims stand rejected by the Examiner as follows:

1. Claim 1–14 and 32–34 under 35 U.S.C. § 102(b) as anticipated by Harris[1] (Ground Nos. 1 and 15; RAN p. 24).

2. Claim 1 under 35 U.S.C. § 102(b) as anticipated by each of Asatoor[2] and Gardner[3] (Grounds Nos. 2, 4, 16 and 18; RAN pp. 24–25).

3. Claims 1–4 and 32–34 under 35 U.S.C. § 102(b) as anticipated by are anticipated by EP '593[4] (Grounds Nos. 3 and 17; RAN pp. 25–26).

4. Claim 1 under 35 U.S.C. § 102(b) as anticipated by DeLacharriere '068[5] and '559[6] (Ground No.5; RAN p. 26-27).

5. Claim 1 under 35 U.S.C. § 102(b) as anticipated by Wu[7] (Ground No.6; RAN pp. 26–27).

6. Claims 1–5, 7, 8, 10–14 and 32–34 under 35 U.S.C. § 103(a) as obvious in view of Setra[8] and Asatoor (Grounds Nos. 7 and 19; RAN pp. 27-28).

7. Claims 1–5, 7, 8, 10–14 and 32-34 under 35 U.S.C. § 103(a) as obvious in view of Setra and Gardner (Grounds Nos. 8 and 20; RAN pp. 28).

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[1] Roger Harris, et al., US 5,965,596 (Oct. 12, 1999).
[2] A.M. Asatoor et al., Intestinal Absorption of Carnosine and its Constituent Amino Acids in Man, 11 Gut, 250 (1970).
[3] Michael L. G. Gardner et al., Intestinal Absorption of the Intact Peptide Carnosine in Man, and Comparison with Intestinal Permeability to Lactulose, 439 J. Physiology 411 (1991).
[4] Andre Rougereau, EP 0 280 593 B1 (pub. June 12, 1991).
[5] Olivier De Lacharriere et al., US 5,869,068 (Feb. 9, 1999).
[6] Olivier De Lacharriere et al., US 5,976,559 (Nov. 2, 1999).
[7] Hui-Chun Wu et al., Proximate Composition, Free Amino Acids and Peptides Contents in Commercial Chicken and Other Meat Essences, 10(3) J. Food and Drug Analysis 170 (2002).
[8] Glan Paolo Negrisoli, EP 0 449 787 A2 (pub. October 2, 1991).

8. Claim 6 under 35 U.S.C. § 103(a) as obvious in view of Setra, Asatoor, and Biola;[9] or Setra, Gardner, and Biola (Grounds Nos. 9, 10, 21 and 22; RAN pp. 29–30).

9. Claim 9 under 35 U.S.C. § 103(a) as obvious in view of Setra, Asatoor, and Casey;[10] or Setra, Gardner, and Casey (Grounds Nos. 11, 12, 23 and 24; RAN p. 30).

10. Claims 32-34 under 35 U.S.C. § 112, first and second paragraph (Grounds 13 and 14).

Claim 1 is the only representative claim on appeal and reads as follows:

> A human dietary supplement comprising at least one of:
> an amino acid wherein said amino acid is beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide;
> an ester of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; or
> an amide of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide.

Additional evidence

The following additional evidence is cited:

1. Declaration under 37 C.F.R. § 1.132 of Roger C. Harris, Ph.D. (dated Oct. 29, 2012) (hereinafter, "Harris Decl."). Dr. Harris is co-inventor of the '381 patent.

2. Declaration of Roger C. Harris, Ph.D. (dated March 8, 2013) which was prepared for the related litigation in District Court) (hereinafter, "Court Harris

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[9] Gianni Biolo et al., Insulin Action on Protein Metabolism, 7(4) Bailliere's Clinical Endocrinology and Metabolism (Oct. 1993).

[10] A. Casey et al., Creatine Ingestion Favorably Affects Performance and Muscle Metabolism During Maximal Exercise in Humans, 271 Am. J. Physiology E31 (1996).

Decl.")

3. Declaration under 37 C.F.R. § 1.132 of Craig Sale, Ph.D. (dated Oct. 10, 2012) (hereinafter, "Sale Decl."). Dr. Sale testified that he has a Ph.D. in exercise physiology and over 11 years of experience in this field when the declaration was executed. Sale Decl. ¶ 2.

4. Declaration under 37 C.F.R. § 1.132 of Stephen G. Kunin (dated Aug. 21, 2013) (hereinafter, "Kunin Decl."). Mr. Kunin is an expert in patent law and procedure with considerable experience in the field. Kunin Decl. ¶¶ 4–16.

5. Tallon, Ph.D., Mark, "A New Science in Muscular Performance," Product Number 17805, iSatori Technologies (undated).

6. Balcombe, B.S.E., "Athletic Edge Nutrition Presents The Beta-Alanine Revolution Featuring-IntraXCell®," 2010.

PRIORITY

All the claims in the '381 patent were found by the Examiner to be anticipated by Harris. Patent Owner contends that Harris is not prior art to the '381 patent, but rather the '381 patent is entitled to the benefit of the application from which the Harris patent arose. Accordingly, we need to address the priority claim of the '381 patent.

The application which led to the '381 patent was filed on August 22, 2011 as part of a family of continuation and continuation in-part applications ("application chain") as listed in the table below.[11] The bracketed numbers are for reference: [6] means the "sixth application," [5] means the "fifth application," and so on. It is not disputed each application was co-pending with the earlier-filed application at

[11] "CON" is a continuation application; "PROV" is a provisional application: "CIP" is a continuation-in-part application; "DIV" is a divisional application; "UK" is a United Kingdom application.

the time the priority claim was made at the PTO, as required under 35 U.S.C. § 120.

Type	Application No.	Filing Date	Patent	Issue Date
	13/215,073	Aug. 22, 2011	8,067,381 B1	Nov. 29, 2011
CON	12/806,356 [7]	08/10/2010		
	10/717,217 [5]	09/2/2008	Amendment filed claiming priority of only provisional application and deleting benefit of application chain	
CON	12/231,240 [6]	08/29/2008	7,825,084	11/2/2010
	10/717,217 [5]	11/18/2003	Preliminary amendment filed claiming priority of application chain	
CIP	10/717,217 [5]	11/18/2003	7,504,376	03/17/2009
PROV	60/462,238	04/10/2003		
CON	10/209,169 [4]	07/30/2002	6,680,294	1/20/2004
CON	09/757,782 [3]	01/09/2001	6,426,361	7/30/2002
DIV	09/318,530 [2]	05/25/1999	6,172,098	1/9/2001
	08/909,513 [1]	08/12/1997	5,965,596 [Harris]	10/12/1999
UK	9621914.2	10/21/1996		
UK	9616910.7	08/12/1996		

The Application Data Sheet, filed August 22, 2011, and Bibliographic Data Sheet, mailed October 17, 2011, of the '381 patent list Application 10/717,217 (the "fifth application") as a continuation-in-part of Provisional application 60/462,238 and Application 10/209,169 (the "fourth application"), and so on, all the way back

to the United Kingdom (UK) applications. However, when the '381 patent was filed on August 22, 2011, the fifth application no longer claimed priority to the fourth application nor the parent applications of the fourth application. Rather, as summarized in the table above, the priority claim of the fifth application was amended on September 2, 2008 to assert benefit of the provisional application, and to delete the priority claim to the first, second, third, and fourth US applications, and the two UK applications.

Although the '381 patent claims priority all the way back to the UK applications, the Examiner denied the priority claim on the basis that the fifth application, in the amendment dated September 2, 2008, deleted the claim to benefit of the fourth, third, second, and first US applications, and the two UK applications. Because priority to the earlier filed and predecessor applications had been disclaimed in the fifth application on September 2, 2008, the Examiner concluded that continuity had been broken, and the '381 patent was only entitled to claim benefit back to the filing date of the provisional application filed April 10, 2003 and the intervening applications. RAN 5–6.

Patent Owner argues that the amendment to the fifth application (10/17,217 [5]) took place on September 2, 2008 after the sixth application (12/231,240 [6]) had been filed on August 29, 2008, and that the sixth application's priority was established to the earlier filed applications (fourth application, third application, and so on) on the date when it was filed. Owner Appeal Br. 3–4. Patent Owner contends that sixth application, when it was filed August 29, 2008, had unbroken continuity to the UK applications which could not be divested of it by a subsequent change in priority to the fifth application. *Id.*

The issue is whether deleting the benefit claim in the fifth application, after the sixth application had been filed but during its pendency, broke continuity with the earlier filed applications (fourth application and earlier filed applications), and whether such break in continuity deprives the '381 patent of the benefit of the applications filed prior to the filing date of the provisional application.

Discussion

Patent Owner asserts "Because a priority claim is determined on the date of filing, the September 2, 2008 amendment cannot retroactively alter the properly claimed priority of the earlier filed '240 application [the sixth application]." Owner Appeal Br. 6. In support of this position, Patent Owner cited *In re Hogan*, 559 F.2d 595 (CCPA 1977) for its holding that compliance with 35 U.S.C. § 112 is determined as of the application filing date, indicating that priority is established as of this date, as well. Patent Owner also argued:

> Britannica clearly held that "[l]ater applications cannot amend [an earlier] application and restore its entitlement to priority." *Encyclopaedia Britannica, Inc. v. Alpine Elc. of Am., Inc.*, 609 F.3d 1345, 1350-51 (Fed. Cir. 2010). Similarly, a later application cannot remove an earlier application's entitlement to priority. The Examiner's conclusory determination to the contrary conflicts with the well-settled case law.

Id.

Initially, when the sixth application was filed, it was correctly stated that the sixth application is a continuation of the fifth application, and that the fifth application is a continuation-in-part application of Application 10/209,169 (the "fourth application"), and so on. However, during the pendency of the sixth application, on September 2, 2008, the fifth application was intentionally amended by Patent Owner to delete benefit to the earlier filed fourth application and its

parent applications. Consequently, the subsequent amendment to the sixth application dated April 19, 2010 making a priority claim to the earlier filed fourth application was incorrect because the priority claim to the fourth application had been deleted in the fifth application.

Patent Owner contends that the Examiner is attempting to retroactively divest the sixth application of its priority, but Patent Owner ignores the fact that Patent Owner intentionally deleted the priority benefit and broke the chain of priority while the sixth application was still pending. It was Patent Owner's intentional action which broke priority, not an action by the Examiner or the PTO. See MPEP § 211.02(a)III ("A cancellation of a benefit claim to a prior application may be considered as a showing that the applicant is intentionally waiving the benefit claim to the prior application in the instant application.")

Patent Owner contends that once the priority of the sixth application had been established, it cannot be changed or divested by a subsequent deletion of a benefit claim by an intermediate application in the chain of priority. Patent Owner relied on *Britannica* to support this position. In *Britannica*, a priority claim was found to be defective because an intermediate application had failed to contain specific reference to the earlier filed applications. *Britannica*, 609 F.3d at 1347–48. Britannica had argued that subsequently filed patents claimed priority to the intermediate and earlier filed applications and thus the public notice function would have been served and no harm was done. *Id.* at 1351. The court rejected this rationale, stating:

> Later applications cannot amend the '955 application and restore its entitlement to priority. The '955 application failed to claim priority to the '917 application. The applicants allowed the '955 application to go abandoned even after being informed by the PTO of its infirmities. It makes no sense to allow the applicant to rewrite history and

> resurrect the '955 application's priority claim. The '955 application did not contain a specific reference to the '917 application. Therefore, it failed to satisfy the requirements of § 120 and is not awarded the benefit of the earlier filing date in the United States.

Id.

The decision in *Britannica* was based on the interpretation of 35 U.S.C. § 120, which specifies the conditions for obtaining benefit of an earlier filing date in the United States. Section 120 (Nov. 29, 1999) reads as follows (emphasis added):

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

Britannica found that the application "similarly entitled to the benefit of the filing date of the application" must also contain a reference to any earlier filed applications to which priority is sought – a condition found to be defective in the intermediate application in *Britannica* which led to the break in priority. Britannica, 609 F.3d at 1350. In other words, in this specific case, for the fifth intermediate application to be accorded benefit of the filing dates of the earlier filed applications, it needed a specific reference to them. However, such reference was deleted by amendment. Patent Owner contends that such deletion cannot divest the sixth application of its priority under *Britannica*, but Patent Owner skips

over the fact that *Britannica* required all applications in the priority chain to contain specific references to earlier filed applications.

Mr. Kunin, in his declaration, argues that a correction in inventorship does not result in a loss of priority under § 120. Kunin Decl. ¶ 28. The circumstances, however, provided by Mr. Kunin are different from here because they involve a restriction requirement by the PTO under 37 C.F.R. § 1.142, not a deliberate action by Patent Owner as is the case here.

Contrary to Patent Owner's arguments, priority does not "vest" on the filing date of an application merely because an assertion is made that the application is entitled to priority of one or more earlier filed applications. See Kunin Decl. ¶¶ 35–36. In order to be accorded priority under § 120 to an earlier filed application, the "invention" must be "disclosed in the manner provided by the first paragraph of section 112." 35 U.S.C. § 120. The PTO is tasked with determining whether a claimed invention complies with § 112. See MPEP § 201.07 (8th Edition; August 2001); §§ 2163 and 2164. Thus, at any time during the prosecution of an application, the PTO may determine that a claim in an application is not entitled to the claimed benefit of an earlier filed application because it was not described or enabled in the application.

When the '381 patent was filed, it claimed the benefit of the fourth application as a parent of the fifth, sixth, and seventh applications. See Specification, filed Aug. 22, 2011 in Application 13/215,073. This assertion was not factually correct because the fifth application had deleted the benefit claim to the earlier filed fourth application and its parents. Under *Britannica*, 609 F.3d at 1351, a priority claim cannot simply be resurrected by making an assertion of priority to an earlier filed application, when such assertion is not compliant with

§ 120 because the specific reference to the earlier filed application had been deleted.

The theory Patent Owner has put forth to restore priority is that the sixth application should not be deprived of claiming priority to the fourth application by a change in a benefit claim in the fifth application. As we have already discussed, Patent Owner intentionally deleted the benefit claim in the fifth application, while the sixth application was pending. Section 120 specifically provides for an amendment to be made to an application's benefit claim ("and if it contains or is amended to contain a specific reference to the earlier filed application"). Once this amendment was made to the fifth application, the fifth application was entitled only to the benefit of the provisional application to which it had been "amended to contain a specific reference to." Patent Owner cannot have it both ways, cutting off the priority of the fifth application, while preserving the priority of its descendent sixth, seventh, and eighth (the '381 patent) applications. In sum, the fifth application failed to comply with § 120, which requires a specific reference to earlier filed applications entitled to the benefit of § 120. The fifth application is not entitled to the benefit of the fourth application since the specific reference to the fourth application was deleted in the fifth application.

Support for fifth application claims

In the Request for Reexamination, Requester argued that the fifth application, when filed, had claims to beta-alanine and glycine, and beta-alanine in specific numerical dosages, which had no § 112 support in the earlier-filed first, second, third, and fourth applications. Request 7. For this reason, Requester

contended that the fifth application was not entitled to claim priority under § 120 to any earlier filed application. *Id.* *See also* RAN 20.

Whether the fifth application was "entitled" to claim benefit to an earlier application is not at issue in this appeal. As already stated, Patent Owner voluntary amended the fifth application to disclaim benefit to the earlier filed application. It is therefore moot whether Patent Owner was required to make such an amendment, and certainly is not an appealable issue in this case.

Nonetheless, we observe that The Manual of Patent Examination and Procedure ("MPEP") § 2163.II.3(b) specifically instructs an examiner to determine whether a claim asserting entitlement to an earlier filed application is described in the earlier filed application or applications. An examiner is not instructed by the MPEP to review every earlier filed application to determine if the claims of the earlier filed application would be entitled to the asserted priority benefit. Section 120 does not expressly require such a determination either since it grants priority to "an application similarly entitled to the benefit of the filing date of the first application," referencing the "application" rather than the invention of the application. Rather, the focus is on continuity of disclosure, and whether every application in the chain of priority applications to which benefit is sought describes the later-filed claims. Consequently, Patent Owner's argument is not consistent with PTO procedure.

The case law is consistent with the MPEP.[12] In *Hollmer v. Harari*, 681 F.3d 1351, 1355 (Fed. Cir. 2012), the Federal Circuit held:

[12] Under Requester's theory, no continuation-in-part application with only claims to the new subject matter could ever serve as intermediate application in a priority benefit claim.

> "[T]o gain the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112." *Zenon Envtl., Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1378 (Fed. Cir. 2007) (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997)); see also *In re Hogan*, 559 F.2d 595, 609 (CCPA 1977) ("[T]here has to be a continuous chain of copending applications each of which satisfies the requirements of § 112 with respect to the subject matter presently claimed." (quoting *In re Schneider*, 481 F.2d 1350, 1356 (CCPA 1973))) (alteration in original). Thus, if any application in the priority chain fails to make the requisite disclosure of subject matter, the later filed application is not entitled to the benefit of the filing date of applications preceding the break in the priority chain. See *Lockwood*, 107 F.3d at 1571–72; *Hogan*, 559 F.2d at 609 . . . Whether the intervening patents in a chain of priority maintain the requisite continuity of disclosure is a question of law we review de novo. *Zenon*, 506 F.3d at 1379.

In *Kangaroos U.S.C., Inc.*, 778 F.2d 1571, 1574 (Fed. Cir. 1985), the court also referred the continuity of disclosure:

> The role of the parent application with respect to the divisional was solely to provide the continuity of disclosure required by § 120, thereby connecting the divisional through a chain of co-pendency back to the design application. It is not material whether the parent could have relied on a § 120 priority claim, because no intervening reference was cited against the claims of the parent.

In sum, Patent Owner's argument about entitlement to priority is not consistent with either PTO procedure or the pertinent case law. In any event, the Patent Owner intentionally cut off priority to the fifth application and the Patent Owner's conduct in doing so is not at issue in this appeal.

Summary

In view of the foregoing discussion, we conclude that the Examiner correctly denied priority past the fifth application. Accordingly, the earliest filing date of the claims at issue in this appeal is April 10, 2003, the filing date of the provisional application.

CLAIM INTERPRETATION

Claim 1 is directed to a "human dietary supplement" which comprises beta-alanine, an ester of beta-alanine, or an amide of beta-alanine. The interpretation of "human dietary supplement" is in dispute in this appeal. Patent Owner argues "human dietary supplement," when properly interpreted, has the following meaning:

> an addition to the human diet, ingested as a pill, capsule, tablet, powder or liquid, which is not a natural or conventional food, meat or food flavoring or extract, or pharmaceutical product and that increases the function of tissues when consumed over a period of time.

Owner Appeal Br. 6.

The Examiner considered the disputed phrase not to limit the claimed composition because "it states the purpose or intended use of the composition." RAN 7. The Examiner concluded that "any prior art composition containing beta-alanine, even if not disclosed for use as a 'human dietary supplement,' is anticipating prior art to the claims of the '381 Patent, because 'human dietary supplement' is only in the claim preamble." *Id.* Requester contends that the Examiner's interpretation is the correct one. Req. Resp't Br. 8.

Discussion

During reexamination of an unexpired patent, claims are given their broadest reasonable interpretation consistent with the patent specification. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1259 (Fed. Cir. 2010*); In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1148 (Fed. Cir. 2012). The "PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

The '381 patent describes "natural food supplements" as being "typically designed to compensate for reduced levels of nutrients in the modern human and animal diet." '381 patent, col. 1, ll. 40–42. Furthermore, the '381 patent teaches "useful supplements increase the function of tissues when consumed." *Id.* at col. 1, ll. 42–43. The '381 patent also teaches that it is "important to supplement the diets of particular classes of animals whose normal diet may be deficient in nutrients available only from meat and animal products." *Id.* at col. 1, ll. 44–46. The '381 identifies natural food supplements which are said to improve athletic performance. *Id.* at col. 1, ll. 48–52.

The invention of the '381 patent is described, in one aspect, as administering beta-alanine and other named compounds to increase the anaerobic working capacity in a tissue. '381 patent, col. 2, ll. 52–56, 60–63. The '381 patent describes a composition comprising beta-alanine or derivatives of it. *Id.* at col. 3, ll. 6–8. The '381 patent teaches that the composition can be a pharmaceutical composition, a dietary supplement, or sports drink which is formulated for humans.

Id. at col. 3, ll. 21–25. Furthermore, the '381 patent teaches that the composition "can be a dietary supplement that can be ingested, injected, or absorbed through the skin." *Id.* at col. 9, ll. 28–29. The '381 patent provides examples in which beta-alanine was administered to humans as a supplement. *Id.* at col. 14, ll. 17–20; col. 15, ll. 47–51; col. 18, ll. 20–23. In Example 4, for instance, "three doses of 40 milligrams per kilogram body weight of beta-alanine per day (i.e., administered in the morning, noon, and at night) for 2 weeks." *Id.* at col. 16, ll. 29–31. The '381 patent states that the effect of this supplementation on "carnosine content of muscle and isometric endurance at 66% of maximal voluntary contraction force was investigated." *Id.* at col. 16, ll. 32–34.

It is stated in the '381 patent:

> Supplementation with beta-alanine or compounds delivering beta-alanine on ingestion may have a positive effect on exercise capacity in sports and those general daily activities leading to lactate accumulation.

Id. at col. 20, l. 39–43

Based on this description in the '381 patent, we interpret a "human dietary supplement" comprising beta-alanine, or a derivative of it, is a composition that is formulated for humans, and that when administered to the human, can have a positive effect on a tissue function over time. While it is true that "[p]reamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim" (*Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 951 (Fed. Cir. 2006)), in this case it is clear from reading the '381 patent and the plain language of the claim that the "dietary supplement" must be in a form that is administrable to a human.

The Examiner takes the position that the dietary supplement is not a limitation because it is only recited in the preamble. "In considering whether a

preamble limits a claim, the preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to the general field of the claim." *On Demand Mach. Corp. v. Ingram Indus.*, 442 F.3d 1331, 1343 (Fed. Cir. 2006). As held in *On Demand*, the "preamble serves to focus the reader on the invention that is being claimed." The court concluded "the preamble in this case necessarily limits the claims, in that it states the framework of the invention." *Id.*

Here, the phrase "human dietary supplement" defines the invention and states its "framework" because the only purpose of the claimed supplement comprising beta-alanine disclosed in the '381 patent is as a supplement to a "normal diet" to "increase the function of tissues when consumed," specifically a tissue's anaerobic and exercise capacity. '381 patent, col. 1, ll. 40–43, 48–52; col. 2, ll. 52–56, 60–63. See discussion above.

However, we observe that the claim does not recite a specific amount of beta-alanine. In Example 4 discussed above, the supplement was administered for weeks. Consequently, we do not interpret the claim to require a specific amount, nor a specific effect after a single administration, only that over time it would increase tissue function.

Patent Owner argued that the statements in the preliminary amendment filed August 22, 2011, in the application which led to the '381 patent made it clear the phrase "human dietary supplement" limits the claim. Owner Appeal Br. 13. The statements made in the preliminary amendment are largely consistent with the interpretation that we afforded the phrase. However, Patent Owner wrote:

> By human dietary supplements the applicants mean an addition to the human diet in a pill, capsule, tablet, powder, or liquid form, which is not a natural or conventional food, and which effectively increases the

> function of tissues when consumed. This is supported by the specification at Col. 1, ll.18–25; Col. 3, ll. 54–59 and Examples 1–4 of U.S. Patent No. 6,426,361, for example. To be clear, the term "human dietary supplement", as claimed, does not encompass, and does not mean, a natural or conventional food, such as chicken or chicken broth, for example.

Preliminary Amendment in Application 13/215,073, p. 5, dated Aug. 11, 2001.

With respect to claim construction, the Federal Circuit held:

> this court gives primacy to the language of the claims, followed by the specification. Additionally, the prosecution history, while not literally within the patent document, serves as intrinsic evidence for purposes of claim construction. This remains true in construing patent claims before the PTO. See *In re Morris*, 127 F.3d 1048, 1056 (Fed. Cir. 1997).

Tempo Lighting, Inc. v. Tivoli, LLC, 742 F.3d 973, 977 (Fed. Cir. 2014)

> This court also observes that the PTO is under no obligation to accept a claim construction proffered as a prosecution history disclaimer, which generally only binds the patent owner.

Id. at 978.

We are thus not bound to Patent Owner's statements concerning the construction of "human dietary supplement." Specifically, Patent Owner stated that "the term 'human dietary supplement', as claimed, does not encompass, and does not mean, a natural or conventional food, such as chicken or chicken broth, for example." However, Example 2 in the '381 patent described the "effect of supplementation of a normal diet with single and multiple daily doses of beta-alanine." '381 patent, col. 14, ll. 17–18. The supplement administered was chicken broth. *Id.* at col. 14, ll. 20–37. *See also* col. 15, Table 15 listing "Broth" as a source of beta-alanine supplementation. In view of this explicit disclosure in the '381 of a chicken broth used as a supplement for beta-alanine, we find that Patent

Owner's attempt to exclude it from the claim is ineffective.

ANTICIPATION BY ASATOOR

Findings of Fact

A1. Asatoor is a scientific publication which describes the intestinal absorption of carnosine and its constituents in humans. Asatoor 250.

A2. Carnosine is a dipeptide of beta-alanine covalently bonded to histidine. *Id.*

A3. Asatoor describes the serum levels of beta-alanine and histidine after ingestion of carnosine. *Id.* at 250–51.

A4. Asatoor teaches:

> Histidine and β-alanine were taken together in an amount which would be produced after hydrolysis of the above dose of carnosine. Both the dipeptide and the amino acid mixture were taken dissolved in 500 ml water.

Id. at 251, col. 1, ll. 4–8.

A5. Asatoor teaches:

> It can be concluded that absorption of both β-alanine and of histidine is significantly more rapid after ingestion of the free amino acids than after ingestion of the equivalent amount of carnosine.

Id. at 252.

Figures 1 and 2 depict the concentration of histidine and beta-alanine in blood serum, showing that in each case the concentrations of the amino acids were higher when the amino acids were administered as compared to carnosine.

A6. Asatoor describes the results in dogs of intestinal absorption and says these results "may not be necessarily applicable to man." Asatoor 254. Asatoor next states: "Probably the main importance of this paper is to draw attention to the

uncertainties which face any interpretation of tolerance tests as indices of intestinal absorption in man." Asatoor addresses the results of intestinal absorption of the dipeptide and of free amino acids, discussing the fact there may be different interpretations on whether the intact peptide (carnosine) is hydrolyzed prior to absorption by the intestine or is absorbed by the intestine and then hydrolyzed intracellularly. *Id.* Asatoor concludes: "Such results in isolation are, therefore, speculative and any theoretical interpretation is completely speculative." *Id.*

Discussion

Claim 1, as discussed already, is directed to a human dietary supplement. We have interpreted the latter phrase to require that the supplement be administrable to humans. Asatoor describes administering the beta-alanine to humans, satisfying this aspect of the claim. A1. Because the administered compositions increases the beta alanine serum levels (A5) and appears to be identical to the claimed composition, there is reasonable basis to believe that it would serve as a dietary supplement, e.g., by increasing tissue function, such as anaerobic or exercise capacity.[13]

Patent Owner contends the composition is not anticipatory to the claim because Asatoor does "no more than teach that giving a single dose of beta-alanine can increase the beta-alanine concentration in the blood and that this is rapidly followed by excretion of beta-alanine by the kidneys." Owner Appeal Br. 16.

[13] Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977).

Patent Owner also refers to the declarations by Dr. Harris and Mr. Sales, and publications by Dr. Tallon and Mr. Balcombe. We have considered these declarations, but find them unpersuasive for the following reasons.

Dr. Harris testified that a single dose of beta-alanine "would be unlikely to have any measurable effect on fatigue. It is not clear that a single dose would even be directed to the muscles and not some internal storage location in the body, such as the liver where beta-alanine is made and regulated." Harris Decl. ¶ 13. *See also* ¶ 22.

Dr. Harris has misconstrued the claim. The claim does not require an effect on anaerobic or exercise capacity in a single dosage, or at all. The claim is not a method claim, but is directed to a human dietary supplement product capable of having such an effect when administered over time. Indeed, the examples in the '381 patent involve administration of beta-alanine for a week or more. '381 patent, col. 15, ll. 47–51; col. 16, ll. 29–34; col.18, ll. 20–23. The '381 patent teaches the "composition can be given over a period of at least about 3 days to about two, three, four or more weeks." *Id.* at col. 4, ll. 1–3. Consequently, Dr. Harris's discussion about the deficiencies of a single dose of beta-alanine are inconsistent with the scope of the claimed invention and the teachings in the '381 patent.

The question is whether the beta-alanine composition in Asatoor, when administered over a period of time, would be capable of affecting tissue function, such as anaerobic and exercise capacity. This requirement is consistent with the claim interpretation put forth by Patent Owner ("Here, the intended use affects the amount that needs to be ingested as well as the fact that it must be used over a period of time to be effective." Owner Appeal Br. 14–15) and the teachings in the '381 patent. Yet, Dr. Harris appears to focus his attention on the single dosage in

Asatoor, describing the deficiencies of the single dosage when the same could have been said for a single dosage in his own patent. *Id.* at 20–21.

The Sale declaration incorporates the statements in Dr. Harris's declaration, and discusses the failure of Asatoor to provide the "single amino acid beta-alanine in doses over many days as taught by the patent." Sale Decl. ¶ 8. This argument is not persuasive since the claim is not a method claim, but is rather directed to a human dietary supplement product that reads on the same product administered by Asatoor.

We have also considered the publications by Dr. Tallon and Mr. Balcombe, Exhibits 10 and 11, respectively. These publications appear to be sales brochures for beta-alanine which describe its effect on muscle. Patent Owner contends that these publications, as well as the declarations of Drs. Harris and Sale, establish that large amounts of beta-alanine are necessary to achieve the effects on muscle fatigue. Owner Appeal Br. 16–17. However, we have not been pointed to persuasive evidence in the Harris declarations that the amount of beta-alanine in Asatoor's dosage would be insufficient to achieve an effect on tissue function when administered over a period of days or weeks.

In a case such as this where patentability rests upon a property of the claimed material not disclosed within the art, i.e., the effect on muscle fatigue over time, the PTO has no reasonable method of determining whether there is, in fact, a patentable difference between the prior art materials and the claimed material. Therefore, when a claimed product appears to be substantially identical to a product disclosed by the prior art, the burden is on the patent owner to prove that the product of the prior art does not necessarily or inherently possess characteristics or properties attributed to the claimed product. *In re Spada,* 911

F.2d 705, 708 (Fed. Cir. 1990); *In re Fitzgerald,* 619 F.2d 67, 70 (CCPA 1980); *In re Best,* 562 F.2d 1252, 1254-55 (CCPA 1977). Patent Owner has not met this burden on the record before us.

In sum a preponderance of the evidence supports the determination that Asatoor is anticipatory to the claimed subject matter.

ANTICIPATION BY EP '593

Findings of Fact[14]

EP1. "[0001] The present invention relates to novel composition for use in therapy, particularly a combination of amino acid based on the one hand, and vitamins, on the other hand, can be used in therapeutic oncology."

EP2. "[00011] It has now been found that a composition containing [beta]-alanine in combination with various vitamins, has properties allowing its application in therapy for the treatment of cancer, whereas no comparable activity is observed when is used in isolation each of these compounds."

EP3. "[0012] The present invention thus provides a new composition based on [beta]-alanine and vitamins, used to treat cancer."

EP4. "[0015] [beta]-alanine can be used individually or, where appropriate, in combination with one or more other amino acids, for example 5-alanine and glycine, or [beta]-alanine, and taurine, can be combined."

EP5. "[0018] . . . the amount of amino acid administered per day is between 50g and 200g for an etching treatment and between 10 and 50g for maintenance therapy in adult men."

[14] Facts EP1-EP6 are from the English translation of EP '593; EP7 is from the French document. The brackets appear in the English translation only.

EP6. "[0022] The experimental results showed that the composition of the invention does not destroy cancer cells, but inhibits cell division."

Discussion

EP '593 describes a composition comprising beta-alanine which is administrable to a human (EP1-EP4) and which contains an amount of beta-alanine that is within the effective range described in the '381 patent. EP5; '381 patent, col. 3, l. 64-66 ("7.0 or more grams").

Patent Owner contends that "dietary supplements" do not encompass the pharmaceutical compositions disclosed in EP '593. Owner Appeal Br. 17–18. Patent Owner also argues that the cell division inhibiting activity described in EP '593 (EP6) is not the same activity described in the '381 patent. *Id.* at 17 ("Inhibiting tumor cell division is not the same as increasing the function of tissues when consumed.") Furthermore, Patent Owner argues that the preliminary amendment removed pharmaceuticals from the claims. *Id.* at 18.

Patent Owner's arguments are not persuasive. The beta-alanine composition described in EP '593 contains all the characteristics of the claimed human dietary supplement, anticipating it. Patent Owner did not explain how a "pharmaceutical composition" would be any different in its components than a dietary supplement. Dr. Harris's declaration does not provide evidence that the composition in EP '593 is different from a dietary supplement, but merely states that EP '593 does not disclose the same activity described in the '381 patent. Harris Decl. ¶¶ 25–30. However, such disclosure in EP '593 is not necessary since the compositions are the same, and the claims do not require the composition to have a specific activity. *See Spada,* 911 F.2d at 708; *Best,* 562 F.2d at 1254-55.

ANTICIPATION BY HARRIS

Patent Owner contends only that Harris (US 5,965,596) is a priority application to the '381 patent and cannot be prior art that anticipates the claims. Owner Appeal Br. 16. Because we have determined that the '381 patent's earliest filing date is Apr. 10, 2003, US 5,965,596, which issued Oct. 12, 1999, Harris is prior art under 35 U.S.C. § 102(b). Thus, we affirm the Examiner's decision that Harris anticipates the claimed subject matter, claims 1–14, and 32–34 for the reason given by the Examiner and as set forth in the Request.

ANTICIPATION BY GARDNER, DELACHARRIERE, WU

The anticipation rejection of claim 1 has been affirmed on other grounds. Consequently, we do not reach the issue of whether each of Gardner, DeLacharriere, and Wu anticipate claim 1.

OBVIOUSNESS IN VIEW OF SETRA AND ASATOOR

Findings of Fact

Setra

S1. Setra teaches that after increased muscular or cerebral activity, "uncontrolled proton release" occurs which "would cause an intracellular pH drop" and "muscle fatigue." Setra 2: 8–13.

S2. Setra teaches that dipeptides containing histidine, such as carnosine, can act as buffering agents and improve muscular functional capacity. *Id.* at 14–26

S3.

> All dipeptides with pKa near physiological pH can act as intracellular buffering agents; in addition to carnosine, other dipeptides containing histidine imidazole ring can be used such as:

> homocarnosine: α-aminobutyryl-L-histidine
> anserine: β-alanyl-L-1-methyl-histidine
> homoanserine: α-aminobutyryl-L-1-methyl-histidine
> ophidine: β-alanyl-L-3-methyl-histidine.

Id. at 16–21.

S4. Setra teaches administration of histidine. *Id.* at 2: 54.

Discussion

The Examiner found that Setra describes compositions comprising carnosine to prevent a drop in cellular pH and prevent muscle fatigue and weakness. RAN 14. The Examiner acknowledged that Setra does not teach a composition comprising beta-alanine. *Id.* However, the Examiner found that

> Asatoor in the same field of endeavor discloses a dietary composition (a mixture) comprising beta-alanine and L-histidine (free amino acids) . . . Asatoor discloses that the absorption of the free amino acids (beta-alanine or L-histidine) is significantly more rapid than the di-peptide (carnosine) (see pages 250 and 252).

Id.

Based on this teaching the Examiner determined it would have been obvious to a person of ordinary skill in the art at the time of the invention "to include beta-alanine, a known non-essential amino acid and a precursor of carnosine, alone or together with L-histidine in the compositions of Setra because Asatoor teaches the rapid intake of free amino acid beta-alanine." *Id.*

Patent Owner contends that the Examiner erred in rejecting the claims as obvious in view of Setra and Asatoor. Patent Owner argues: "[o]ne of ordinary skill in the art could not glean from Asatoor that the amino acid beta-alanine could get into the muscle and increase the function of the muscle tissue." Owner Appeal Br. 20.

In response to Patent Owner's arguments that the Examiner did not provide evidence that ingesting beta-alanine would lead to an increase in carnosine in muscles, the Examiner stated:

> It was well known in the art at the time of the invention that by providing increasing levels of histidine and beta-alanine in the diet would increase the concentration of carnosine in the skeletal muscle cells (for example see Dunnett Thesis (1996), and the references cited in the "Introduction" (pages 193–194)). Further, Hama was cited to show that beta-alanine administration results in increased concentrations of carnosine in rats.

RAN 28.

Hama[15] was provided by Requester on November 28, 2012 in response to the Harris declaration. Requester stated in the comments accompanying the publication:

> Harris fails to mention and his remarks completely ignore all of the references mentioned in the Dunnett Thesis discussed above, the work of Hama, which established that ingested beta-alanine passed through the gut into the blood stream and thence into muscle cells where it formed carnosine.

Requestor's Comments 24.

Hama has the following pertinent disclosure:

> The β-alanine solution was given daily for a week in a dose of 5 g per kg of body weight as shown in Fig, 2, β-alanine accumulated in both liver and gastrocnemius muscle. Anserine and carnosine were not detected in the liver, while the concentration of these dipeptides increased in the muscle after β-alanine administration.

Hama 150–151. Fig. 2 shows the accumulation in muscle of carnosine after rats were force fed with β-alanine. *Id.*

[15] Hama, T., et al., J. Nutr. Sci. Viraminol., 22, 147-157, 1976.

Patent Owner contends that the amount of beta-alanine administered to the rats is equivalent to 400 g in an 80 kg person, which is not "psychologically safe." Remarks made in Amendment dated Aug. 23, 2013, p. 34. Patent Owner also argues that the amount of beta-alanine administered to the rats is "known to kill 50% of the animals (LD50), on average. (Ex. 21)." *Id.* Exhibit 21 contains the following information: "Toxicity to Animals: Acute oral toxicity (LD50): 1000 mg/kg [Rat]," i.e., 1 g per kg. Thus, Patent Owner's argument about the LD50 is supported by the evidence because Hama teaches administration of 5 g per kg which is more than the LD50 of 1 g per kg. Hama 150. Dr. Harris also testified that such doses were lethal to rats. Harris Court Decl. ¶ 16. Patent Owner concludes that "[g]iving such lethal doses does not provide any relevant information on normal physiological functions in the human body." Remarks made in Amendment dated Aug. 23, 2013, p. 34. Patent Owner's remarks are supported by the evidence of record. Accordingly, we agree that Hama does not provide a reasonable expectation of success that administering beta-alanine to humans would increase its levels in muscle because the amounts administered to rats were lethal doses.

There is additional evidence that supports Patent Owner's position regarding lack of a reasonable expectation of success. An excerpt from the Ph.D. thesis of Mark Dunnett was made of record in this proceeding. Dr. Dunnett is co-inventor of the '381 patent. In the thesis, Dr. Dunnett wrote that Margolis (1985) showed that "very large doses of β-alanine . . . produced a ten-fold increase in skeletal muscle carnosine." Dunnett Thesis 194. A declaration was provided in the related litigation by Frank. L. Margolis, a co-author of Margolis (1985). Dr. Margolis testified that the "doses in my 1985 research were at such high amounts, the

rodents would not be expected to have responded in the same way they would respond to a lower physiologically safe dose. Administering comparably high levels in humans would be unacceptable, if not potentially lethal." Margolis Decl. ¶ 9. Dr. Margolis testified:

> researchers in the field of exercise physiology believe that it is necessary for humans to consume physiologically safe and sufficient amounts of beta-alanine for at least 2-4 weeks to see any measurable effect on muscle tissue performance. My study injected rodents with beta-alanine for 2-5 days at toxicologically high levels. This is not a good model for extrapolation to humans because of the evolutionary metabolic and dietary differences.

Id. at ¶ 11.

After considering Setra, the excerpts provided from the Dunnett thesis, and Hama, we agree with Patent Owner that the preponderance of the evidence does not support the Examiner's rejection. Setra alone provides no expectation that beta-alanine would increase carnosine. Setra teaches that it is the histidine portion of the dipeptide which acts as a buffer to reduce muscle fatigue, and even administers free histidine. S2–S4. Consequently, there is no apparent reason to have administered beta-alanine to reduce muscle fatigue. Hama describes beta-alanine administration to rats and an increase in carnosine in muscle, but these doses were above the LD50 and lethal. The evidence supports Patent Owner's position that the results from administering lethal doses of beta-alanine to rat are not necessarily predictive of administering physiologically safe dosages to humans.

Summary

For the foregoing reasons, we reverse the rejection of dependent claims 2–5, 7, 8, 10–14 and 32–34 as obvious in view of Setra and Asatoor. We also reverse the rejections of claims 6 and 9 because the additionally cited publications, Biola

and Casey, were not said by the Examiner to make up for the deficiencies in Setra and Asatoor.

We do not reverse the rejection of claim 1 because we found it be anticipated by Asatoor, alone. We thus affirm the rejection of claim 1 as obvious in view of Setra and Asatoor.

OBVIOUSNESS IN VIEW OF SETRA AND GARDNER

Obviousness rejections Grounds 7, 9, and 20 rely on Gardner, rather than Asatoor. RAN 14. Gardner does not make up for the deficiencies cited in either Setra or Asatoor. Consequently, we reverse these rejections, as well.

§ 112 REJECTIONS

Ground 13. The Examiner rejected new claims 15–36 as lacking written description. The Examiner only addressed claims 15 and 35. Claims 15 and 35 are not appealed. Appealed claims 32–34 do not depend from either of these claims. Consequently, since the Examiner has not provided a basis to reject claims 32–34 under 35 U.S.C. § 112, first paragraph, we reverse the written description rejection of these claims.

Ground 14. The Examiner rejected claims 32–34 as indefinite under § 112, second paragraph (pre-AIA). The Examiner stated:

> Claims 32–34 . . . are dependent on composition of 1 and recite the functional properties of the composition and states the form of the composition supplied. The claims are indefinite, since it is not clear whether the claims are drawn to a composition, or the function of the composition or the physical form of the composition.

RAN 10.

We reverse the rejection. The claims are directed to compositions so it is clear that they are composition claims. The new limitations recited in claims 32–34 recite properties and forms of the composition. The Examiner has not sufficiently explained why such properties and forms make the claims indefinite.

DECISION

The Examiner's decision adverse to the patentability of claims 1–14 and 32-34 is affirmed.

Requests for extensions of time in this proceeding are governed by 37 C.F.R. §§ 1.956 and 41.79(e).

AFFIRMED

ack

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