No. 18-

IN THE

Supreme Court of the United States

NATURAL ALTERNATIVES INTERNATIONAL, INC.,

Petitioner,

v.

ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Did the Court of Appeals for the Federal Circuit err in analyzing rulings by the Patent Trial and Appeals Board when it failed to base its decision on the Board's stated reasoning that was the only reasoning briefed by the Patent Office, failed to explain its reasons for departing from the agency guidance, and removed patent law from the ambit of normal property law to create a non-statutory exception to property law?

When is priority established for a patent application under the Trade-Related Aspects of Intellectual Property Rights (TRIPs) so that a Patent Owner can change priority in one application without affecting the priority of applications that have already established priority?

TABLE OF CONTENTS

Table of Contents

Table of Contents

TABLE OF APPENDICES

TABLE OF CITED AUTHORITIES

Page

Cases:

Cited Authorities

Statutes:

Cited Authorities

INTRODUCTION

This case arises from *inter partes* reexamination proceedings at the Patent and Trademark Office, resulting in the erasure of an issued patent's priority claim. The Office's Manual of Patent Examination Procedure ("MPEP") provides guidance on priority statement requirements, including § 201.11 that describes the Office's application of Section 120 of the Patent Act—the statute that lists the requirements necessary for an applicant to establish an entitlement to a claim of "priority" in a patent application family. Priority, in the context of patent applications, allows a patent applicant to file "Continuation" applications containing the same pertinent subject matter. Continuation applications allow an applicant to submit several patent claim sets covering different inventions while retaining the filing date of the earliest filed application, so long as the statutory requirements are satisfied. Such priority claims allow a patent applicant to obtain multiple patents covering varying scope and subject matter, while avoiding rejections based on prior art references that arose after the earliest filing date. In some instances, a patent applicant may wish to waive a priority claim, thus removing this relationship to the earliest filed application. MPEP § 201.11 informed the public that such a disclaimer of priority would only affect the "instant" patent application where the disclaimer occurred.

The Office and the Federal Circuit did not give any deference to the plain language of the guidance and ignored the issues of first impression. Although the plain reading of "instant" application in the Office's own guidance should only involve the individual application with a disclaimed priority, the Office and the Federal

Circuit determined any disclaimer affects not only the "instant" application, but any later-filed application. The Federal Circuit's holding means this disclaimer occurs even when the later-filed application was filed before the priority claim was disclaimed. This departure from the normal tenets of property law is illogical. Despite the plain and logical interpretation of the controlling statute, legislative commentary and the Office's guidance supporting Petitioner's position, the Federal Circuit's ruling could sever the priority claims of many issued patents, rendering them invalid and valueless long after innovators have built businesses and transactions on their patent foundation.

This Petition involves two issued patents that were filed from applications that fully complied with all requirements of the Patent Act. This challenge to the Office's improper treatment of patent priority claims is not a matter of mere semantics, but is a challenge of the agency's strained and illogical application of the statute and its willingness to issue decisions contradicted by its own guidance. Because of the adverse consequences to patent owner's property rights, this is an important case that this Court should address.

PETITION FOR A WRIT OF CERTIORARI

Petitioner Natural Alternatives International, Inc. ("Petitioner") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The Patent Trial and Appeal Board's Reexamination Decisions (Pet. App. 19a-103a) and that Board's denial of a Request for Rehearing (Pet. App. 104a-106a) are unreported. The Federal Circuit's opinion (Pet. App. 1a-18a) is reported at 904 F.3d 1375 (Fed. Cir. 2018).

JURISDICTION

The judgment of the court of appeals was entered on October 1, 2018. On December 21, 2018, the Chief Justice extended the time to file a petition for a writ of certiorari to and including February 28, 2019. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

35 U.S.C. § 120

Benefit of earlier filing date in the United States

An application for patent for an invention disclosed in the manner provided by section 112(a) (other than the requirement to disclose the best mode) in an application previously filed in the United States, or as provided by section 363 or 385, which names an inventor or joint inventor 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. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the requirement for payment of the fee specified in section 41(a)(7), to accept an unintentionally delayed submission of an amendment under this section.

STATEMENT OF THE CASE

For over 100 years, the term of a U.S. Patent was 17 years, measured from the date the patent issued. To bring U.S. patent law into conformity with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs") as negotiated in the Uruguay Round, the patent term was changed to 20 years from the earliest claimed priority in 1995. Appx6976. As recognized by the US Patent and Trademark Office ("USPTO") after the TRIPs changes, an applicant could gain an extension of the patent term for an individual patent by disclaiming an earlier priority that was given to the patent application. *Id.*

Priority is established by satisfying the requirements of 35 U.S.C. § 120. The USPTO provided guidance on the changes to U.S. patent law due to the TRIPs Agreement. That guidance was incorporated in the Manual of Patent Examination Procedure ("MPEP") to assist Examiners and the public in understanding how the USPTO would

treat applications filed after June 8, 1995. The MPEP informed the public that a disclaimer of priority would affect only the "instant" patent application. The "instant" application is that individual application with a disclaimed priority. In this case, the USPTO and the Federal Circuit determined any disclaimer will affect not only the "instant" application, but other applications that had already been filed before the priority was disclaimed and had thus established priority.

The two patents at issue are: U.S. Patent Nos. 8,067,381 ("the '381 patent") (Appx0330-0362)[1], and 8,129,422 ("the '422 patent") (Appx7709-7742) (collectively "the patents-at-issue"). The '381 and '422 patents were denied their claimed priority and the Patent Trial and Appeal Board ("PTAB") used an earlier priority patent, U.S. Patent No. 5,965,596 ("the '596 patent"), as prior art to reject the '381 and '422 patents for anticipation. If the priority claims of the patents at issue remain intact, they are not anticipated.

The gravamen of this case involves priority under § 120. A Continuation-In-Part application ("CIP") is an application that operates like a Continuation, except that it includes new subject matter. *See* 37 C.F.R. 1.53(b); MPEP § 201.08. A CIP can disclaim a priority claim if an applicant wishes to pursues the new subject matter, which can extend the patent's term but can expose the application to rejections under later-arising prior art references. *Id.*

1. References to "Appx." are for the Federal Circuit Appendix; reference citations to "Pet. App." are for the Appendix to this Petition.

During prosecution of this patent family, a CIP was filed in 2003 claiming priority all the way back to the earliest filing date (as well as foreign priority). This CIP issued as U.S. Patent No. 7,504,376 ("the '376 patent"). A Continuation—which issued as U.S. Patent No. 7,825,084 ("the '084 patent")—of this CIP was filed in 2008 while the CIP was pending. When the '084 Continuation of the '376 CIP was filed, the '084 Continuation's priority had already been established and claimed priority back to the original filing date (as well as the foreign priority date) as set forth in the '084 Continuation's "Cross Reference of Related Applications," the Patent Owner described as required under § 120 and which is found in the prosecution history as well as in the issued patent. In other words, the '084 Continuation was filed during the pendency of the '376 CIP, while the '376 CIP claimed priority all the way back to the original filing date. Several days **after** the '084 Continuation was filed, the '376 CIP—but not the '084 Continuation—was amended to thereafter disclaim priority to the originally filed application. The '376 CIP's Cross Reference of Related Applications was amended to reflect that amendment to the '376 CIP's priority claim.

Nothing in that amendment indicated intent to cease the priority claim of the '084 Continuation that had already been filed before the amendment and already established its priority back to the original filing date. The Cross Reference of Related Applications data supplied for the '084 Continuation to the USPTO continued to list that Continuation as claiming priority all the way back to the originally filed application and its foreign priority. In contrast to the '084 Continuation, when the '376 CIP was amended, its Cross Reference of Related Applications was also amended to reflect the fact that the Related

Application status no longer went back to the priority of the original filing.

This case arrived at the Federal Circuit after the '084 Continuation and the '376 CIP issued as patents, which were asserted against Woodbolt Distribution, LLC ("Woodbolt") in a patent infringement case filed in U.S. District Court. Woodbolt later initiated *inter partes* reexaminations ("Reexamination(s)") of those patents, seeking to invalidate them in view of references that became applicable as a result of the alleged priority break. The Reexamination Examiner agreed with Woodbolt and found those patents invalid. Petitioner appealed the Examiner's decision to the Patent Trials and Appeal Board, which upheld the Examiner's decision. In the interim, Petitioner and Woodbolt resolved their dispute, so Woodbolt did not participate in Petitioner's appeal to the Federal Circuit. The USPTO, however, intervened.

On October 1, 2018, the Federal Circuit affirmed the USPTO's decision. It concluded that the amendment to the '376 CIP's priority statement severed the priority claim of the '084 Continuation. It held: (1) the already-established priority claim in the '084 Continuation was void and did not vest once § 120 was satisfied; (2) despite MPEP § 211.01 limiting waiver to the "instant application", that language actually means "instant application and other applications" (though the full reach of that is not specified); (3) priority claims are only established as a single growing chain; and (4) the statutory allowance to alter CIP patent term can also result in unintended severance of such a priority chain.

This Court should decide if the change of priority to the '376 CIP that occurred after the Continuation was

filed acted, *nunc pro tunc,* to divest the '084 Continuation of its already established, continuously claimed, priority and served to nullify the clear statement by the inventors in the Cross Reference of Related Applications regarding what priority was claimed.[2]

STATEMENT OF THE FACTS

In August and October of 1996, two patent applications were filed in the United Kingdom, establishing the earliest possible priority date.[3] On August 12, 1997 the first of several U.S. applications was filed claiming priority to these U.K. filings under § 119(a). The first U.S. filing (Original Application) issued as U.S. Patent No. 5,965,596 on October 12, 1999. On May 25, 1999, a Second Application had been filed, claiming priority to the Original Application under § 120 as well as under § 119(a) for the U.K. filings: it issued as U.S. Patent 6,172,098 on January 9, 2001. A Third Application was filed on the day of issuance, claiming priority under § 120 and becoming U.S. Patent No. 6,426,361 on July 30, 2002. A Fourth Application was filed July 30, 2002, claiming priority under § 120, and issuing as U.S. Patent No. 6,680,294 on January 20, 2004. A Provisional Application was filed on April 10, 2003. A Fifth Application (that issued as the '376

2. Due to the different pace of progress by the patents under reexamination, the '381 patent arrived on appeal before the '422 patent. The '422 patent is a Continuation of the '084 Continuation. The '381 patent is a Continuation of that '422 Continuation.

3. The invention was based on the ability to increase what was believed to be a homeostatic level of carnosine in animal muscles by giving beta alanine to the animal at an unnaturally high level for a long period of time. *See* Appx0828-0829; Appx1155-1157.

CIP) was filed on November 18, 2003 claiming priority to the Fourth Application under § 120 and claiming priority to the Provisional Application under 35 U.S.C. § 119(e). A Sixth Application (that issued as the '084 Continuation) was filed on August 29, 2008 claiming priority under § 120 to the Fifth Application all the way back to the Original Application and the U.K. applications.

As required, a Cross Reference of Related Applications was filed in the Sixth Application. For the August 29, 2008 Sixth Application, this Cross Reference put the USPTO and the public on notice that the Sixth Application claimed priority to the original filing. Appx0007-0010; *conf.* Appx0163 and Appx1258-1259. Thus, the prosecution history of the Sixth Application demonstrated the priority claimed by the Patent Owner, which established the priority claim on the date that the provisions of § 120 were satisfied, which was August 29, 2008. In each of the First through the Sixth Applications there was co-pendency, common inventorship, and a claim for priority with the Cross Reference of Related Application showing the relationship at the time of each filing, and each of the applications contained all of the disclosure set forth in the Original Application.

On September 2, 2008, several days after the Sixth Application was filed and its priority was established, a filing in the Fifth Application—now separate from the Sixth Application—provided an amended Cross Reference of Related Applications for the Fifth Application removing its priority claim to the earliest application. *See* Appx0422; Appx1210.

While this amended priority to the earliest application, there was no change to the Cross Reference of Related

Applications of the Sixth Application, and the Patent Owner's understanding was that the Sixth Application continued to claim priority all the way back to the Original Application, as indicated in its Cross Reference of Related Applications. The same patent Examiner handled both the Fifth and Sixth Applications and did not find fault with canceling some of the priority of the Fifth Application, even though a loss of priority of the Sixth Application would have meant that the patent to the Original Application would have been prior art, if the Sixth Application could not claim priority to the Original Application.

The Fifth Application issued as the '376 CIP on March 17, 2009 and the Sixth Application issued as the '084 Continuation on November 2, 2010. Prior to issuance of the '084 Continuation, a Seventh Application was filed on August 10, 2010, claiming priority to the Sixth Application and thereby through the family of applications through to the Original Application and the U.K. filings. This application issued as the '422 patent on March 6, 2012. An Eighth Application was filed August 22, 2011, claiming priority under § 120 to all of the earlier applications and also to the U.K. applications. That patent issued on November 29, 2011 as the '381 patent. Though filed after the Seventh Application, the Eighth Application issued before the Seventh Application.

As shown in the following table, the '381 patent was filed as one application in a family including Continuation, Divisional, and Continuation-in-Part applications.

Application No.	Numerical Filing Order	Application Type	Filed	Issued	Patent No.
13/215,073	Eighth	Continuation	Aug. 22, 2011	Nov. 29, 2011	8,067,381 (‘381)
12/806,356	Seventh	Continuation	Aug. 10, 2010	Mar. 6, 2012	8,129,422 (‘422)
12/231,240	Sixth	Continuation	Aug. 29, 2008	Nov. 2, 2010	7,825,084 (‘084)
10/717,217	Fifth	CIP	Nov. 18, 2003	Mar. 17, 2009	7,504,376 (‘376)
60/462,238	Provisional		Apr. 10, 2003		
10/209,169	Fourth	Continuation	July 30, 2002	Jan. 20, 2004	6,680,294 (‘294)
09/757,782	Third	Continuation	Jan. 9, 2001	July 30, 2002	6,426,361 (‘361)
09/318,530	Second	Divisional	May 25, 1999	Jan. 9, 2001	6,172,098 (‘098)
08/909,513	First	Original	Aug. 12, 1997	Oct. 12, 1999	5,965,596 (‘596)
UK 9621914.2			Oct. 21, 1996		
UK 9616910.7			Aug. 12, 1996		

Each application in the family tree met the requirements for priority under § 120 at the time of filing: *i.e.*, each application (1) shared the same inventors; (2) contained adequate disclosure under 35 U.S.C. § 112, first paragraph; (3) was copending with its preceding application at the time of filing; and (4) disclosed the relationship of all prior applications by specific reference to application number, filing date and type of application.

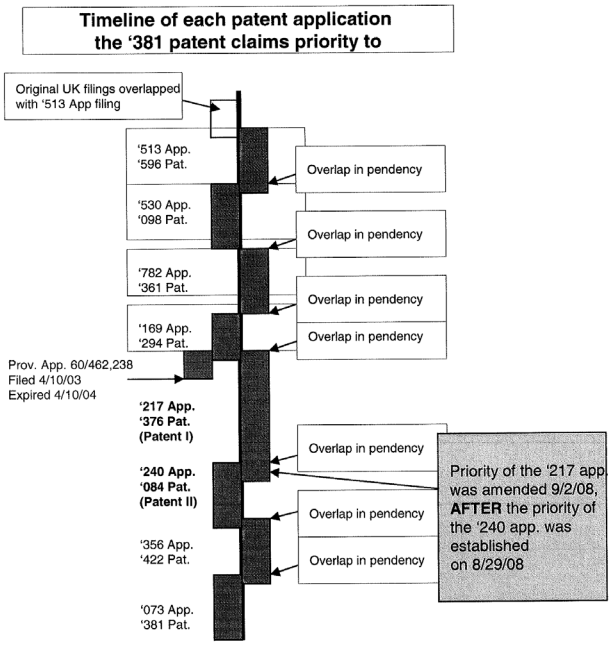
While the Fifth Application—according to the above table listing—was pending and possessing priority back to the U.K. applications, the Sixth Application was filed as a Continuation of the CIP Fifth Application and also claimed priority back to the U.K. applications. **After** that Sixth Application was filed on August 29, 2008—meeting all requirements for priority under § 120 and having established priority to the earliest applications—the Fifth Application's Cross Reference of Related Applications was amended, affecting the priority of the Fifth Application. At that moment-in-time for the different applications, the Sixth Application's priority was already established as it contained a Cross Reference of Related Applications that claimed priority to the earliest filings, and its priority was unaffected by a later act in the Fifth Application.

1. THE ALLEGED PRIORITY BREAK AROSE DUE TO A CHANGE IN THE FIFTH APPLICATION'S PRIORITY CLAIM OCCURRING AFTER THE SIXTH APPLICATION ESTABLISHED ITS PRIORITY

On May 31, 2012, a request for reexamination of the '381 patent (issued from the Eighth Application) was filed. The Reexamination Examiner rejected the Eighth Application on a number of grounds raised by the Third

Party Requestor, asserting a priority break when the Petitioner had waived the Fifth Application's claim to the earliest Original Application. Neither the Reexamination Examiner nor the Third Party Requestor explained how the priority of the Sixth Application—which was filed before the cancelling of the Fifth Application priority and that had maintained its specific Cross Reference of Related Applications—had also lost its priority.

The Patent Owner traversed the rejections, providing an illustration of the "Timeline of each patent application the '381 patent claims priority to", reprinted below. Appx0564-0565. That timeline showed the overlap for the patents, demonstrating "that the '240 application was filed on August 29, 2008, **before** the amendment to priority of the '217 application filed on September 2, 2008." Appx1260 (emphasis in original).



The Petitioner argued a rejection based on the '596 patent was improper because the '381 and '422 patents claimed priority from the '596 patent. The Petitioner's position was that the priority claim in the '381 patent was established on the day it was filed because on that date it fully satisfied all of the requirements of § 120 as set forth in case law and the MPEP and that the priority of the Sixth Application had never been disclaimed. At that time and all times after, the Cross Reference of Related Applications in the Sixth Application continued to indicate priority was claimed all the way back to the Original Application.

Patent Owner also showed that the case law cited by the Third Party Requestor only addressed a priority break in a dramatically different, distinguishable factual scenario. The case law cited evaluated a break in the priority chain where each related application was sequentially filed and received priority while one or more applications in the chain *never* claimed or established priority, unlike the facts in the instant case. Here, a related application was filed and did claim priority, while the change in priority occurred in a **different** application **after** the priority was established. *See* Appx0970-0971; Appx0974-0975; Appx1584-1590; and Appx1257-1260 (citing *Loughlin v. Ling*, 684 F.3d 1289, 1293 (Fed. Cir. 2012)).

The Petitioner argued that the Third Party Requestor and Examiner's position ignored case law holding that the priority is determined and vests on the date of filing when the requirements of § 120 are satisfied. The Petitioner also argued that the USPTO position amounted to legally disfavored *nunc pro tunc* action where the September 2, 2008 change in the Fifth Application reached back in time to destroy the established priority of an application

filed earlier on August 29, 2008. The Petitioner further argued that USPTO's position meant that no patents could be presumed valid if there was an earlier filed application still under prosecution within the patent family, because the Patent Owner could disclaim priority in the application under prosecution and destroy the validity of later filed and already issued patents by changing the priority dates of already issued patents *sub silentio*.

2. THE MPEP RECITES THAT A CHANGE IN PRIORITY ONLY AFFECTS THE PRIORITY OF THE APPLICATION IN WHICH IT WAS FILED.

The Petitioner further argued that the USPTO's position contradicted the guidance to Examiners and the public in the MPEP. *See generally* Appx1584-1588; Appx0970-0978; Appx1238; and Appx1258-1259. The MPEP and its guidance are established by the USPTO. *See* U.S. Patent Office Website, https://www.uspto.gov/web/offices/pac/mpep/mpep-0015-foreword.html (last visited Fed. 28, 2019). The MPEP, addressing the change that patent term measurements were based on the earliest priority date and not the issue date, stated:

> It is expected, in certain circumstances, that applicants may cancel their claim to priority by amending the specification or submitting a new application data sheet…to delete any references to prior applications…. 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.

MPEP § 201.11(III)G (emphasis added).[4] Thus, the MPEP contemplated that applicants would cancel priority under certain circumstances to increase term but that such a cancellation of priority would only apply to the instant application that was amended, not to other patent applications with already established priority claims. Appx7286; Appx1259-1260. That language was included prior to the filing of the Fifth Application. The USPTO has not yet explained the full effect of changes to the "instant application." To date, the USPTO has only argued that Petitioner's interpretation relying on the plain meaning of that term construes it "too narrowly." Pet. App. 14a.

3. THE *NUNC PRO TUNC* EFFECT TO § 120 ASSERTED BY THE PTAB PANEL HAS BEEN REJECTED FOR OTHER ELEMENTS OF § 120.

In response to the USPTO's initial rejection in the Reexamination proceeding, the Petitioner provided a declaration from Mr. Steve Kunin refuting the Examiner's position that there was a priority break.[5] Appx1248-1249; Appx1253-1260. Among other issues, Mr. Kunin indicated

4. This appears to have become part of the MPEP in the 8th ed. Rev. 1, February 2003, long before the priority change of the Fifth Application.

5. Mr. Kunin was Deputy Commissioner for Patent Examination Policy in the Office of the Commissioner for Patents in the USPTO from 1994 through October 2004 where he helped establish patent policy for the USPTO as well as patent office practice and changes in the MPEP. Appx1251. During this period, he oversaw the transition to measuring patent term from the priority date as well as practice procedure changes and MPEP changes resulting from the Uruguay Round Agreements of the General Agreement on Tariffs and Trade (GATT) which went into effect in June of 1995. *Id.*

that based on his 34 years with the USPTO and 42 years practicing and teaching Patent Office Practice and Procedure, he believed that:

> The '381 patent is compliant with 35 U.S.C. § 120, 37 C.F.R. § 1.78 and MPEP 201.11 and is entitled to the right of priority to the filing date of U.S. Patent No. 5,965,596 and the priority dates of the two U.K. applications (1996).

Appx1248-1249. He went on to explain that the Reexamination Examiner "overlooked relevant USPTO policy, practice, and procedure as well as important facts and committed reversible error," and that "[t]he claim for the right to priority of the '381 patent as set forth in Column 1, lines 8-27 [of the '381 patent] is correct." Appx1248-1249; Appx1253. Mr. Kunin's Declaration went on to explain in detail the requirements of § 120 and show how the application satisfied those requirements, as well as the requirements of 35 U.S.C. § 119, 37 C.F.R. § 1.78, and MPEP § 201.11. Appx1253-1256.

Mr. Kunin explained that the Examiner's improper analysis required the priority amendment to the Fifth Application on September 2, 2002 relate back in time *nunc pro tunc* to affect the already established priority of the Sixth Application that was filed August 29, 2008. Appx1256-1257. Mr. Kunin also explained that "35 U.S.C. § 120 does not provide for such a *nunc pro tunc* effect" and the § 120 inventorship requirement does not have a *nunc pro tunc* effect, as set forth in MPEP § 201.03. *Id.* As explained by Mr. Kunin and MPEP § 201.03, § 120 requires that there be an inventorship overlap between the originally filed patent application or a second application

claiming priority to that patent or application. Appx1256-1257.

Mr. Kunin exemplified this principle by describing how in the situation where inventor A contributes only to invention 1 and inventor B contributes only to invention 2 there is no *nunc pro tunc* time effect. In such a case, a restriction requirement could be made where invention 1 is elected. Prior to the correction of inventorship in the parent application, a divisional application, claiming benefit under § 120 to the parent application, could be filed claiming only invention 2 and naming only inventor B. When the inventorship of the original application is then changed to only list inventor A, it would not defeat the priority claim for inventor B and invention 2 because such a change—even though it affects a fundamental part of § 120 (*i.e.*, the required overlap of inventors)—does not go back in time to affect the vested priority of the Divisional application.

As explained by Mr. Kunin:

> The USPTO considers that the inventorship overlap required by 35 U.S.C. § 120 is met in this instance because at the time of filing of the divisional application, the inventorship overlap was maintained….[A]s recognized by the USPTO in MPEP § 201.03, [the] correction of inventorship in the parent application does not cause a loss of the § 120 priority right in the divisional application.

Appx1257 (citations omitted). There is no reason to expect certain parts of § 120 acted retroactively while others

did not. Thus, at the time of filing, the overlap exists and priority is established. A later amendment does not divest the § 120 benefit.

Mr. Kunin explained how the Sixth Application met all of the requirements of § 120, 37 C.F.R. § 1.78, and MPEP §201.11 at the time of its filing date and on August 29, 2008 and that "pursuant to the first sentence of § 120, is treated as **having been effectively filed on the earlier date**." Appx1258-1259 (citing *Loughlin*, 684 F.3d at 1294). Mr. Kunin further explained that each application in the connected continuing applications filed after the Sixth Application—which includes the applications that matured into the '381 patent—similarly met the statutory requirements. Appx1259-1260.

As a demonstrative, the Petitioner provided the following illustration of the priority on August 29, 2008:

6th ---------- U.K. filing

5th ---------- U.K. filing

4th ---------- U.K. filing

On September 2, 2008 this became:

6th ---------- U.K. filing

5th ---------- 2003 filing

4th ---------- U.K. filing

The Petitioner argued that the USPTO position meant that even issued patents could get a new priority

and extended term when a daughter application issued as a patent before the parent application issued. This was because the parent application could have a change in priority that would go back in time and affect the priority and term on its already vested and issued daughter applications.

The Petitioner also argued the USPTO's position ran afoul of well-established case law addressing changes in priority to issued patents. Petitioner explained that the D.C. Circuit and the CCPA had long ago established that only a reissue application could be used to change the priority of an issued patent. *Brenner v. State of Israel*, 400 F.2d 789 (D.C. Cir. 1968) (Appx7897-7898); *Fontign v. Okamato*, 518 F.2d 610, 622 (CCPA 1975) (cannot change priority of issued patent except through reissue). Appx7897-7898. In the case of the Patent Owner, or any other applicant with a daughter application issuing before the parent, a change in the parent application priority—even years after the daughter application issued as a patent—would affect the issued patents term and priority. This could affect the alienability of issued patents.

ARGUMENT

The USPTO and Federal Circuit committed error in not granting priority to the Sixth Application. Both the Seventh and Eighth Application satisfied all of the requirements of § 120 at the time of filing. The holding is at odds with the MPEP, statements by the deputy commissioner for patent examination policy in the office of the commissioner for patents during the relevant time period, and case law

A. THE DECISION DEPARTS FROM CASE LAW AND RAISES NEW UNANSWERED ISSUES.

These applications contained a Cross Reference of Related Applications that informed the public that the applications intended to claim back to the U.K. filings in 1996. The case law is clear regarding what is necessary to obtain the benefit of priority. The decision to depart from this case law and create new, unstated requirements leads to unintended and unaddressed consequences, such as whether this determination only affects applications, issued patents or also applies to reissue proceedings: there is no reasoned legal jurisprudence set forth by the PTAB or the Federal Circuit regarding why it should not apply to all three, but the record is unclear and is a trap for patent applicants if not clarified. The error in not granting priority to the Sixth Application means it, as well as the Seventh and Eighth Applications, should be granted priority to the U.K. applications. When that correct priority is granted, the asserted prior art rejection is removed.

1. THE GRANDPARENT APPLICATION OF THE '381 PATENT FULLY SATISFIED THE REQUIREMENTS OF § 120 ON AUGUST 29, 2008 WHEN IT WAS FILED

The patents-at-issue that were subject to reexamination are Continuations of the Sixth Application resulting in their invalidation. The PTAB panel faulted the priority of the Sixth Application. Accordingly, if the PTAB's analysis of the Sixth Application is incorrect, and the Sixth Application is granted the priority set forth in its Cross Reference of Related Applications, then the Seventh

Application as well as the Eighth Application (*i.e.*, the applications that became the patents-at-issue) should be granted the priority of the Sixth Application back to the U.K. filings.

The '381 patent met all requirements under § 120 at filing and properly claimed priority to August 12, 1996 (the date of the initial U.K. Application). This is demonstrated through a proper analysis under MPEP § 201.11 and 35 U.S.C. §§ 120, 119(e), and 37 C.F.R. § 1.78. *See* Appx1254. "The first sentence of § 120 permits an application to claim the benefit of an earlier filing date, such that the application is treated as having been effectively filed on the earlier date." *Loughlin*, 684 F.3d at 1294.

As relevant to the case before this Court, there are three prongs of § 120 that must be satisfied to claim benefit of an earlier filing date: the priority-claiming application must (1) satisfy the requirements of § 112, first paragraph (*i.e.*, **adequate disclosure**), (2) be **co-pending** (*i.e.*, overlapping in pendency) with the application from which priority is immediately being claimed, and (3) contain or be amended to contain a **specific reference** to the application from which priority is being claimed.[6] *See* Appx0970-0971;

6. Commentary by one of the authors of 35 U.S.C. § 120, Examiner-in-Chief P.J. Federico, also supports Petitioner's analysis. According to Federico, only three conditions were necessary to obtain the priority date of a prior application: (1) the invention must be disclosed sufficiently under the 1st ¶ of § 112; (2) the second application must be at least transiently co-pending with the first application; and (3) the second application must contain specific reference to the first application. P.J. Federico, COMMENTARY ON THE NEW ACT, 1954 Edition of the U.S. Code Ann., reprinted in 75 J. Pat. & Trademark Off. Soc'y 161

Appx1584-1587; Appx1243-1260; and Appx7685-7686. There is no dispute that the three prongs were satisfied at the time of the Sixth Application's filing, before the Fifth Application had its priority limited. Accordingly, there is no dispute the priority tree was intact prior to the amendment to the Sixth Application

"The first sentence of § 120 permits an application to claim the benefit of an earlier filing date, such that the application is treated **as having been effectively filed on the earlier date**." *Loughlin*, 684 F.3d at 1294 (emphasis added); *see also* Appx1259-1260; and Appx1255-1256 with footnote. "Provided the criteria in § 120 are met, applications ***'shall,'* without exception,** receive the benefit of the earlier filing date." *Loughlin*, 684 F.3d at 1293 (emphasis added). Once the priority requirements of § 120 were met at the time of filing the Sixth Application, it was treated as having "the same effect…as though filed on the date of the prior application." 35 U.S.C. § 120. Thus, on August 29, 2008, the Sixth Application was filed and had the same effect as if filed on August 12, 1997 (the Original Application's filing date). The subsequent priority amendment of the Fifth Application—an entirely different application—four days later on September 2, 2008 had no effect on the Sixth Application's already established priority claim to the earlier patents and applications.

(1993) ("Commentary"). "When these three conditions obtain[,] the second application is entitled to have the same effect as though filed on the same date that the first application was filed, with respect to an invention disclosed in both applications." *Id*. at 192-93. "Co-pendency" refers to the requirement that the second application must be "filed before the patenting or abandonment of or termination of proceedings on the first application." *Id*. at 193; *see also* Appx0972.

Appx1256-1257; Appx1260; *see also* Appx1257 for inventorship analogy.

As set forth in the Kunin Declaration, the issue of *nunc pro tunc* changes under § 120 has already been decided by the USPTO. That decision indicates that for the inventorship overlap required by § 120, the decision at the time of filing—not days later—controls. Appx1257. Thus, changes do not affect other applications *nunc pro tunc*. *Id*. The PTAB simply dismissed the inventorship issue by arguing that the present situation is different from the MPEP and Kunin's inventorship scenario because the inventorship scenario is "not a deliberate action by Patent Owner as is the case here." Appx0012. The PTAB is wrong for two reasons.

First, the Patent Owner did not intend to divest the Sixth Application of its priority, as set forth in the specification of the Sixth Application in the Cross Reference to Related Applications. Second, the inventorship scenario and the instant issue are similar in that both are issues under § 120 and both require a "deliberate action" by the applicant. In the inventorship scenario, the applicant specifically amended the inventorship at the time filing the divisional application. In the instant case, Petitioner amended the priority claim of the earlier-filed Fifth Application only after the later-filed Sixth Application had met all requirements at the time of filing. The PTAB erred in disregarding the inventorship scenario as it informs how other aspects of § 120 should be treated, *i.e.*, by not giving *nunc pro tunc* effect to an action in an entirely different application.

The Federal Circuit upheld the PTAB position that "priority does not 'vest' merely because an assertion is

made that the application is entitled to priority of one or more earlier filed application." Appx0012. Such reasoning ignores the Federal Circuit's position that when "the criteria in § 120 are met, applications 'shall,' without exception, receive the benefit of the earlier filing date." *Loughlin*, 684 F.3d at 1293. Moreover, there is no law or regulation contrary to Petitioner's position on priority vesting at the time of filing.

The Federal Circuit erred in its treatment of "vesting" and added requirements to § 120 not contained in the statute. It said that Petitioner's "vesting" argument "conflates properly claiming priority and demonstrating entitlement to priority." Pet. App. 10a. In support, the Federal Circuit quoted *In re NTP, Inc.*, saying patent "claims 'are not entitled to an earlier priority date merely because the patentee claims priority.'" *Id.* (654 F.3d 1268, 1276 (Fed. Cir. 2011)). Its reliance on that case shows that the Federal Circuit did not adequately consider the issue and upheld an arbitrary and capricious USPTO decision because the priority issue in that case concerned the written description requirement under 35 U.S.C. § 112, thus § 120 was never satisfied and the entitlement was never earned. *In re NTP*, 654 F.3d at 1272. That case is consistent with Petitioner's position. Here, the USPTO does not dispute all of the requirements of § 120 were satisfied at the time of filing, unlike the patent application in *In re NTP* which did not. The Federal Circuit's cited cases, like those cited by the USPTO below, similarly fail to apply to this situation because those cases never satisfied § 120's requirements or related to a different legal issue. *See, e.g.*, Pet. App. 10a (citing *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309, 1315-16 (Fed. Cir. 2018), *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d

1299, 1305-06 (Fed. Cir. 2008)); Pet. App. 12a (citing *In re Janssen Biotech, Inc.*, 880 F.3d 1315 (Fed. Cir. 2018) (holding that an applicant couldn't amend an issued patent's priority claim to overcome a double patenting rejection in a reexamination proceeding)).

If the requirements for priority under § 120 are met at the time of filing, then the new application's priority under § 120 "is treated **as having been effectively filed on the earlier date.**" *Loughlin*, 684 F.3d at 1293-4 (emphasis added); *see also* Appx1259-1260; Appx1255-1256.

The Federal Circuit's rationale ignored Petitioner's argument that none of the cases cited to support the USPTO's rationale ever satisfied § 120's requirements and never received the entitlement to priority. This argument does not conflate vesting with entitlement. *See* Pet. App. 10a-11a. Petitioner's argument is simple. Because each and every application met the requirements of § 120 at the time of filing, the priority chain of each application was established at that time. Therefore, it is irrelevant whether the USPTO reviews the priority on the day of filing, or a year, or a decade later. Priority was properly established by virtue of meeting all the requirements of § 120, as stated in that section and *Loughlin*, 684 F.3d at 1293.

Therefore, each newly filed application has its own priority chain back to the earliest application to which it is able to satisfy those requirements. That is unaffected by a later amended priority of a different, earlier filed application, as long as the newly filed application has already established its chain under § 120. Specifically, the Fifth Application established its priority chain at filing.

B. THE FEDERAL CIRCUIT SUPPLIED ITS OWN INTERPRETATION OF "INSTANT APPLICATION", IMPROPERLY DEVIATING FROM ITS PLAIN MEANING.

The Federal Circuit attempted to distinguish the language of MPEP § 201.11 with another provision in the MPEP. Pet. App. 14a-15a. Although the argument was not made by the USPTO, it concluded that the MPEP makes it clear when actions in an application solely affect that application. *Id.* (citing MPEP § 1490(VI)(B) (9th ed., Rev. 8) (2017) ("A terminal disclaimer filed to obviate a nonstatutory double patenting rejection is effective only with respect to the application or patent identified in the disclaimer unless by its terms it extends to continuing applications . . . ."). The Federal Circuit's references to that language is notable because it does not use the word "instant" nor does it include additional words that modify "instant" in any way. *See id.* That section uses different language altogether and provides no context for the disputed term here. Such a comparison of different terms, used for a different purpose, in a different context is not justified by any statutory interpretation canon. Indeed, Petitioner's interpretation relying on the plain meaning of the guidance produces a result consistent with the statutory intent (*see* supra, n. 6) and should be the most favored interpretation. *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997) ("The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole.").

C. IT IS IMPROPER TO CONSIDER PRIORITY CLAIMS IN A PATENT FAMILY AS A SINGLE CHAIN.

Rather than treating additional continuation filings as merely adding an additional link in a single growing chain, § 120 and the case law must be interpreted as providing for a new priority chain being created at each new filing. Viewing priority in this manner gives the proper effect established through § 120. The First through Sixth Applications, therefore, would have six different chains based on meeting the requirements of § 120 at the time of filing. The Sixth Application met the requirements at filing and therefore had links back to the earliest filings. Subsequent to the Sixth Application's chain formation, the applicant amended the Fifth Application's priority claim to remove the benefit of the First through Fourth Applications' priority days after it was filed. This should affect the Fifth Application's chain only.

Because applications are afforded their priority when § 120 requirements are met, the application is treated as having been effectively filed on the earlier date. Therefore, the First through Sixth Applications are treated as if all six applications were filed the same day. There should be no impact on the Sixth Application (treated as filed the same day as the First Application), when there is a priority amendment in the Fifth Application. There is no justification for rejecting the priority claim of the Sixth, Seventh or Eighth Application when there was an amendment to the priority of another application **after** the priority of the Sixth Application was vested at filing.

The PTAB ignored the case law and MPEP's effect on the September 2, 2008 priority amendment in the Fifth

Application. The MPEP guides practitioners and instructs the USPTO by stating:

> It is expected, in certain circumstances, that applicants may cancel their claim to priority by amending the specification or submitting a new application data sheet…to delete any references to prior applications … 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.

MPEP § 201.11(III)(G) (emphasis added). Applying this to the Fifth Application, the amendment was filed after the Sixth Application was filed and the Sixth Application's priority back to the earliest applications was established. *See* Appx0564-0565.

The September 2, 2008 amendment changed the priority of **only** the Fifth Application, *i.e.*, the **instant** application, and not the established priority of any other application, as the PTAB panel and Examiner erroneously assert. Instead, to support its position, the PTAB cited MPEP § 211.02(a) III, quoting "a cancellation of a benefit claim to a prior application may be considered as showing that the applicant is intentionally waiving the benefit claim to the prior application *in the same application*." *See* MPEP § 211.02(a) III (emphasis added). Thus, the MPEP is very concerned that an applicant must make an affirmative indication of waiver of priority and that waiver is only construed "**in the same application**." Here the applicant was very clear that it was **not** waiving the priority in the Sixth Application, which had already

stepped into the shoes of earlier applications carrying it back to the earliest filings. That there was no change to the Cross Reference of Related Applications in the Sixth Application further evidences this position. At worst, to the extent the lack of a change to the Sixth Application's Cross Reference of Related Applications causes any confusion, it's effect is merely a scrivener's error. On April 19, 2010 the Patent Owner did amend the Cross Reference of Related Applications to update the Cross Reference with patent numbers for issued applications, but nevertheless indicated the priority claim that was made at the time of filing on August 28, 2008 still continued. See Pet.App. 107a.

When considering priority claims, the PTAB stated that "*Britannica* required all applications in the priority chain to contain specific references to earlier filed applications." Pet. App. 76a (citing *Encyclopedia Britannica v. Alpine Electronics of America*, 609 F.3d 1345 (Fed. Cir. 2010)). When the Sixth Application was filed, all applications contained specific reference to earlier filed Applications. As discussed above, each and every application contained specific references to earlier filed applications at the time of filing and each application referenced each earlier application by type and relation at the time priority vested through meeting all requirements under § 120. Thus, the PTAB erred in denying the '381 patent its established priority claim.

The PTAB concluded that the "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." Pet. App. 77a.

First, the PTAB is incorrect in stating that Petitioner was attempting **to resurrect** a priority claim, because the priority claim vested at the time of filing the '381 patent—requiring no resurrection. *Id.* Second, the PTAB acted arbitrarily and capriciously by taking an overly limited view of priority claims.

The USPTO is simply viewing priority as a single growing chain. Such a view contradicts the MPEP and case law, and limits an applicant's ability to seek protection. For example, if while an application A is pending, an applicant files a CIP claiming priority to application A, and after prosecution of the CIP, that CIP no longer possessed claims fully supported in application A, then the applicant should consider amending the priority claim to gain term. Before such an amendment, however, applicant can file a Continuation of the CIP, which claims priority back to the application A. That Continuation can contain claims to subject matter of both the CIP and the application A without experiencing self-collision with its priority document. Under the PTAB's basis, the amendment in the later issued CIP would have the *nunc pro tunc* effect of removing the Continuation application's priority to application A. This is illogical and can only result from an overly simplistic view of priority.

The PTAB's position is contrary to *Loughlin*, wherein if the requirements for priority under § 120 are met at the time of filing, then the new application priority under § 120 "is treated **as having been effectively filed on the earlier date**" and the "application ***'shall,'* without exception,** receive the benefit of the earlier filing date." *Loughlin*, 684 F.3d at 1293-4 (emphasis added); *see also* Appx1259-1260; Appx1255-1256.

The priority for applications 1 through 6 on August 29, 2008 was:

6th ---------- U.K. filing

5th ---------- U.K. filing

4th ---------- U.K. filing

3rd ---------- U.K. filing

2nd ---------- U.K. filing

1st ---------- U.K. filing

At the time of filing, each of the First through Sixth Application filings claimed priority back to the earliest filings, so when filed, each application had "the same effect, as to such invention, as though filed on the date of the prior application", *i.e.*, back to the earliest filings. *See* 35 U.S.C. § 120. This illustration means that once the requirements of § 120 are satisfied, the priority chain is fully formed unless an applicant specifically changes that priority.

On September 2, 2008, the priority of each member of the family was:

6th ---------- U.K. filing

5th ---------- 2003 filing

4th ---------- U.K. filing

3rd ---------- U.K. filing

2^{nd} ---------- U.K. filing

1^{st} ---------- U.K. filing

Thus, amending the priority of the Fifth Application several days after filing the Sixth Application affected only the Fifth Application, *i.e.*, "the instant application" according to MPEP § 201.11(III)G.

In contrast, the USPTO position is that priority is not assessed on a stand-alone basis once § 120 is satisfied. In other words, the agency's treatment writes out of § 120 the concept that, when filed, the application has "the same effect…as though filed on the date of the prior application." Instead, the USPTO took the position that all patent applications claiming priority in the family are inextricably linked as a single chain where any change—at any time—affects all applications and patents in the family. If the USPTO wanted that, they should have set forth this non-statutory position in the MPEP, not set forth the exact opposite of this position by saying the priority affects only the "instant" application. In other words—in spite of their guidance in the MPEP—the USPTO posits that on August 29, 2008, priority was not as shown above, but as:

6^{th} ---- 5^{th} ---- 4^{th} ---- 3^{rd} ---- 2^{nd} ---- 1^{st} ---- U.K. filings.

The USPTO's view is that the established priority of the Sixth Application was divested several days later, when the Fifth Application was amended, and the priority became:

6^{th} --------- 5^{th} --------- 2003.

This is because the USPTO believes that patents are only linearly linked together, in spite of what the applicant states during prosecution.

The PTAB failed to explain how § 120, the MPEP, or the case law are satisfied by their interpretation. While the PTAB suggested their decision was somehow required by *Britannica*, it failed to comprehend the important difference between that case and the instant case. In *Britannica*, there was an original filing in 1989 and a Continuation in 1993. 609 F.3d at 1345-51. The Continuation **never** claimed priority to the 1989 filing there, even though the USPTO clearly indicated the 1993 application "made no claim of priority to any earlier filed application." *Britannica*, 609 F.3d at 1347.

The pictorial representation of *Britannica* was thus:

3rd ---------- 1993

2nd ---------- ~~1993~~

1st ---------- 1989

Or using the PTAB's panel's viewpoint:

[3rd] ---------- [2nd] ---------- 1993.

Britannica would not have secured a priority date of 1989 under either Petitioner's vesting-at-filing position, nor by the USPTO's viewpoint affirmed by the Federal Circuit.

D. THE STATUTE ALLOWS FOR AMENDMENT OF PATENT TERM WHEN FILING CIP APPLICATIONS.

The PTAB never explained why amending the Fifth Application's priority claim was more damaging to the Sixth Application than completely abandoning the Fifth Application. This is not a case of patent applicants having it "both ways" as asserted by the Federal Circuit. Pet. App. 17a. Instead, Petitioner's argument is squarely aligned with the statutory benefits of CIP's afforded to it: a CIP may contain new matter, which can allow an applicant to alter priority claims to extend patent term when the invention is focused on the new matter. On the other hand, an applicant filing an intervening CIP focused on that new matter shouldn't forgo the ability to file additional Continuation applications focused on the original subject matter. This is not "having it both ways." *See id.* This is a straightforward interpretation based on the intents of those two types of applications.

E. NUNC PRO TUNC ACTION IS DISFAVORED IN U.S. LAW.

The USPTO's position that events occurring after the filing of the Sixth Application in an entirely different application retroactively strip the Sixth Application of its priority is disfavored under U.S. law. The "presumption against retroactive legal action is deeply rooted in our jurisprudence, and embodies a legal doctrine centuries older than our Republic." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994); *see also* Appx0977-0978. The Federal Circuit previously held the same view disfavoring retroactivity and acts that take away or impair vested rights acquired under existing laws, or create a new

obligation, or attach a new disability, in respect to transactions or considerations already past. *Princess Cruises, Inc. v. U.S.*, 397 F.3d 1358, 1362 (Fed. Cir. 2005); *see also* Appx0977-0978. When the Sixth Application was filed, a filing date going all of the way back to the foreign filing vested. Nothing that occurred **after** the filing of that application in any different application can divest the Sixth Application of that properly claimed priority date. Appx0977-0978.

F. THE FEDERAL CIRCUIT'S AFFIRMANCE IS CONTRARY TO THIS COURT'S PRECEDENT FROM *CHENERY*.

The Federal Circuit affirmed the USPTO's decision despite noting several instances where the Board's interpretation fell short of the reasoning required by the Administrative Procedures Act ("APA") (Pet. App. 14a, 16a), which violates this Court's precedent. *Sec. & Exch. Comm'n v. Chenery Corp.*, 318 U.S. 80, 95 (1943) ("an administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained."). In other words, an agency's decision must turn on its own rationale. While an appellate court can affirm on other legal grounds than those supplied by a lower tribunal, it should not supplant the agency's duty to provide a fulsome rationale. *See In re Aoyama*, 656 F.3d 1293, 1299 (Fed. Cir. 2011). The Federal Circuit should not gap-fill in favor of an agency's determination.

The Federal Circuit's *Chenery* violation is evident when it considered Petitioner's arguments to the USPTO under MPEP § 201.11, which dictates that changes to

an application's priority statement apply only to the "instant application." Pet. App. 14a. That court noted that "[a]lthough the Board did not explicitly address this argument, the [US]PTO responds that [Petitioner] reads MPEP § 201.11 'too narrowly.'" *Id.*

The Federal Circuit acknowledges the USPTO's decision was insufficient and inserted its own rationale to justify the expansive reading of "instant application" based on the USPTO's arguments in front of it. This is improper for at least two reasons. First, *Chenery* and the APA do not allow for a court to mop up the slop created by an insufficient agency determination by supplementing rationale that should have been provided below. A patent applicant should not have to obtain an appellate decision to get an explanation of the legal basis for being deprived of its patent rights. Such action violates the Due Process Clause of the U.S. Constitution. *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 642 (1999). Second, neither the Federal Circuit nor the USPTO explain what definition should be applied to "instant application." It merely agrees with the USPTO's appellate argument that Petitioner's definition relying on the plain meaning of the term "instant" (meaning the particular application at issue) is too narrow of a definition. Rather than using that plain definition that clearly delineates the scope of that waiver, the USPTO's assessment creates an unbounded scope, creating tremendous legal uncertainty and is improper. It acts to deprive patent owners of their valuable property rights to issued patents. This Court has never considered the important issues presented. It should do so now.

CONCLUSION

For the foregoing reasons, the Court should grant this Petition and review the Federal Circuit's affirmance of the PTAB's determination that the '381 and '422 patents lacked a priority claim under § 120, and clarify the proper interpretation of § 120.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, DATED OCTOBER 1, 2018

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2017-1963

NATURAL ALTERNATIVES
INTERNATIONAL, INC.,

Appellant,

v.

ANDREI IANCU, UNDER SECRETARY OF
COMMERCE FOR INTELLECTUAL PROPERTY
AND DIRECTOR OF THE UNITED STATES
PATENT AND TRADEMARK OFFICE,

Intervenor.

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 95/002,048.

October 1, 2018, Decided

Before PROST, *Chief Judge,* MOORE and REYNA, *Circuit Judges.*

PROST, *Chief Judge.*

Appendix A

Woodbolt Distributors, LLC ("Woodbolt") requested that the United States Patent and Trademark Office ("PTO") reexamine U.S. Patent No. 8,129,422 ("the '422 patent") owned by Natural Alternatives International, Inc. ("NAI"). The PTO ordered *inter partes* reexamination, and the examiner rejected the challenged claims as anticipated by or obvious over cited prior art, including a parent of the reexamined patent. NAI appeals the Patent Trial and Appeal Board's ("Board") final determination affirming the examiner's rejections and its subsequent denial of NAI's request for rehearing.

The '422 patent issued from the seventh U.S. application in a chain of eight U.S. applications generally directed to increasing athletes' endurance. This opinion addresses NAI's priority challenge as to the '422 patent. Our companion opinion, *Natural Alternatives International, Inc. v. Matal*, No. 17-1962, addressed NAI's priority challenge as to the patent issuing from the eighth application—U.S. Patent No. 8,067,381 ("the '381 patent").

Because the facts and procedural history in the two cases are substantially identical, we do not repeat our discussion of those topics here. Regarding the merits of this appeal, we affirm the Board's final determination and its denial of NAI's request for rehearing for the reasons stated in our companion opinion.

AFFIRMED

APPENDIX B — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, DATED OCTOBER 1, 2018

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2017-1962

NATURAL ALTERNATIVES
INTERNATIONAL, INC.,

Appellant ,

v.

ANDREI IANCU, UNDER SECRETARY OF
COMMERCE FOR INTELLECTUAL PROPERTY
AND DIRECTOR OF THE UNITED STATES
PATENT AND TRADEMARK OFFICE,

Intervenor.

October 1, 2018, Decided

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 95/002,001.

Before PROST, *Chief Judge*, MOORE and REYNA, *Circuit Judges.*

Appendix B

PROST, *Chief Judge*.

Woodbolt Distributors, LLC ("Woodbolt") requested that the United States Patent and Trademark Office ("PTO") reexamine U.S. Patent No. 8,067,381 ("the '381 patent") owned by Natural Alternatives International, Inc. ("NAI"). The PTO ordered *inter partes* reexamination, and the examiner rejected the challenged claims as anticipated by or obvious over cited prior art, including a parent of the reexamined patent. NAI appeals the Patent Trial and Appeal Board's ("Board") final determination affirming the examiner's rejections and its subsequent denial of NAI's request for rehearing. Woodbolt is not a party to this appeal. The Director of the PTO has intervened to defend the Board's decision. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A). We affirm.

BACKGROUND

Between 1997 and 2011, NAI filed a chain of eight U.S. patent applications generally directed to increasing athletes' endurance. The eighth application matured into the '381 patent, the subject of this appeal. NAI filed the first application in the chain on August 12, 1997, and within five years, it had filed three more. In each such continuing application, NAI included a priority benefit statement under 35 U.S.C. § 120 claiming priority back to the filing date of the first U.S. application, which eventually issued on October 12, 1999, as U.S. Patent No. 5,965,596 ("the '596 patent").[1] NAI also filed a provisional application ("the

1. Each U.S. application in the chain also included a priority benefit statement under 35 U.S.C. § 119(a), claiming priority back to

2003 provisional application") on April 10, 2003, while the fourth application was still pending before the PTO. Before the fourth application issued on January 20, 2004, NAI filed the fifth application, a continuation-in-part, on November 18, 2003. The fifth application claimed priority to the fourth through first applications and to the 2003 provisional application. Intervenor's Br. 4-5. NAI filed its sixth application on August 29, 2008, during the fifth application's pendency. At that time, the sixth application correctly claimed priority to the fifth application, and the fifth application correctly claimed priority to the fourth application, and so on.

I

On September 2, 2008, just four days after filing its sixth application, NAI amended the "Cross Reference of Related Applications" section of the fifth application to delete the benefit claim to the fourth through the first applications and to claim priority under 35 U.S.C. § 119(e) to only the 2003 provisional application. J.A. 8035; *see* 35 U.S.C. § 119(e) (governing claiming priority to an earlier-filed provisional application). Thus, when the fifth application issued as U.S. Patent No. 7,504,376 ("the '376 patent") on March 17, 2009, it claimed the benefit of only the 2003 provisional application's filing date. The sixth through the eighth applications subsequently issued as patents, but with a statement seeking the benefit of the fifth through the first applications, in addition to the 2003

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the filing date of a British patent application that NAI filed in 1996 ("the 1996 British application"). The validity of that priority claim is not before us today, so we do not discuss it.

provisional application. The '381 patent on appeal here issued from the eighth application on November 29, 2011.

II

District court litigation involving the '381 patent commenced between NAI and Woodbolt in December 2011.[2] In May 2012, during that proceeding, Woodbolt sought *inter partes* reexamination of the asserted patent claims.[3] The request alleged that "the asserted claim to priority of the '381 Patent is defective" because the "applicants deliberately and expressly terminated their claim to the priority of the first four applications[,]" which thus "broke[] the chain of priority between the Fourth and Fifth Applications." J.A. 45-46. During reexamination, NAI did not dispute that it had waived priority to the fourth through the first applications in its fifth application. J.A. 971. But it insisted that the sixth application maintained priority back to the first application because NAI did not amend the "Cross Reference of Related Applications" in the sixth application. According to NAI, it was irrelevant what happened to the fifth application once the sixth application became entitled to the first application's filing date. J.A. 975. Unpersuaded, the examiner finally rejected the reexamined claims in view of prior art including the

2. Woodbolt and NAI have since settled their lawsuit concerning the '381 patent. *See* Appellant's Br. 1.

3. Under the Leahy-Smith America Invents Act, *inter partes* review replaced *inter partes* reexamination as the avenue for third-party patentability challenges in the PTO. *See* Pub. L. No. 112-29, § 6(a), 125 Stat. 284, 299-304 (2011).

'596 patent (i.e., the patent that issued from the first application), and then closed prosecution.[4] J.A. 1210, 1226.

NAI appealed the examiner's decision to the Board. The Board determined that when NAI filed the eighth application, "[t]he fifth application [was] not entitled to the benefit of the fourth application since the specific reference to the fourth application was deleted in the fifth." J.A. 13. Because the eighth application claimed priority to the first application via the fifth application, the Board determined that the eighth application (and thus the '381 patent) was also not entitled to the benefit of the fourth through the first applications. *See* J.A. 16. The Board issued a final written determination affirming the examiner's rejections and denied NAI's request for rehearing.

Discussion

NAI challenges the Board's priority determination.[5] According to NAI, the Board erred by denying the '381 patent priority back to the first U.S. application in the priority chain under § 120. Appellant's Br. 2-3.

I

Entitlement to priority under § 120 is a legal determination based on underlying fact findings. *See In*

4. The eighth application is a "Continuation of a Continuation of the Sixth Application/Patent[.]" *See* Appellant's Br. 26-27; Intervenor's Br. 3-5.

5. NAI's challenge to the Board's finding of anticipation relies entirely on the priority date issue. *See* Appellant's Br. 3 n.2, 46-47.

re Owens, 710 F.3d 1362, 1366 (Fed. Cir. 2013). When the underlying facts are undisputed, priority date determination is purely a legal question. *Medtronic CoreValve v. Edwards Lifesciences Corp.*, 741 F.3d 1359, 1363 (Fed. Cir. 2014). Because this appeal presents no disputed factual issues relevant to the Board's priority determination, we review the Board's legal conclusions *de novo*. *See Stevens v. Tamai*, 366 F.3d 1325, 1330 (Fed. Cir. 2004).

II

NAI argues that the Board erred by denying the '381 patent priority back to the first U.S. application in the priority chain. *See* Appellant's Br. 46-47. Its argument proceeds in four parts. First, NAI contends that priority to the first application "vested" with the sixth application once the sixth application met all the criteria of § 120. *See id.* at 31-34. Second, NAI claims that this is so—even though an intervening application waived priority to the first application—because a waiver of priority is limited to the instant application and does not extend to subsequent applications. *Id.* at 35-36. Third, in NAI's view, the Board reached a contrary determination because the Board erroneously viewed priority as a single growing chain rather than multiple fixed chains. Appellant's Br. 34, 38. Fourth, such a view, according to NAI, "limits an applicant's ability to seek protection" when "amending [a] priority claim to gain [patent] term." *Id.* at 38. We address each part of NAI's argument in turn.

Appendix B

A

NAI first argues that the Board erred in its determination that "priority does not 'vest.'" *Id.* at 33. According to NAI, "[p]riority properly vested by virtue of meeting all the requirements of § 120." *Id.* at 34. NAI asserts that *Loughlin v. Ling* dictates this conclusion because it states that "[p]rovided the criteria in § 120 are met, applications 'shall,' without exception, receive the benefit of the earlier filing date." 684 F.3d 1289, 1293 (Fed. Cir. 2012); *see* Appellant's Br. 31. The Board considered this argument and found it unpersuasive. *See* J.A. 12.

Section 120 of title 35 sets forth requirements for a U.S. patent application to claim priority based on an earlier-filed nonprovisional application. *See Medtronic CoreValve*, 741 F.3d at 1363. When NAI filed the application that became the '381 patent, § 120 provided the following:

> An application for patent for an invention [1] disclosed in the manner provided by section 112(a) . . . [2] 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, [3] 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 [4] if it contains or is amended to contain a specific reference to the earlier filed application. No application

> shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section.

35 U.S.C. § 120 (2000) (emphases and numbering added). "Specific reference," in the context of § 120, means that the application seeking the benefit must state (or be amended to state) that it claims the benefit of the earlier-filed application's filing date, identifying each earlier-filed application by number and explaining how the applications are related to one another. *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309, 1315-16 (Fed. Cir. 2018).

NAI's "vesting" argument conflates properly claiming priority and demonstrating entitlement to priority. Patent claims "are not entitled to an earlier priority date merely because the patentee claims priority." *In re NTP, Inc.*, 654 F.3d 1268, 1276 (Fed. Cir. 2011). Rather, "for a patent's claims to be entitled to an earlier priority date, the patentee must *demonstrate* that the claims meet the requirements of 35 U.S.C. § 120." *Id.* (emphasis added). Accordingly, claims in a patent or patent application are not entitled to priority under § 120 at least until the patent owner *proves* entitlement to the PTO, the Board, or a federal court. *See PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305-06 (Fed. Cir. 2008) (explaining

that "when neither the PTO nor the Board has previously considered priority, there is simply no reason to presume that claims in a [continuation-in-part] application are entitled to the effective filing date of an earlier filed application," so the district court may place the burden on the patent owner to "come forward with evidence to prove entitlement to claim priority to an earlier filing date"); *see also In re NTP, Inc.*, 654 F.3d at 1277 ("[W]hen a patentee argues that its claims are entitled to the priority date of an earlier filed application, the examiner must undertake a priority analysis to determine if the patentee meets the requirements of § 120."); Manual of Patent Examining Procedure ("MPEP") § 201.08 (providing that "[t]he [PTO] does not need to make a determination as to whether the [35 U.S.C. § 112(a)] requirement of 35 U.S.C. [§] 120" is met "unless the filing date of the earlier nonprovisional application is relied upon in a proceeding before the [PTO]").

Furthermore, examiners and adjudicators cannot be expected to scrutinize the prosecution history of an application and each parent application to determine whether the application would have met § 120's requirements at any point during its pendency. *See, e.g., Droplets*, 887 F.3d at 1317 (explaining that "it would be improper to place the burden on the public to unearth and decipher a priority claim when the 'patentee is the person best suited to understand the genealogy and relationship of her applications,' and a 'requirement for her to clearly disclose this information should present no hardship'"); *see also Medtronic CoreValve*, 741 F.3d at 1366 ("Congress may well have thought that Section 120 was necessary

to eliminate the burden on the public to engage in long and expensive search of previous applications in order to determine the filing date of a later patent." (quoting *Sticker Indus. Supply Corp. v. Blaw-Knox Co.*, 405 F.2d 90, 93 (7th Cir. 1968))).

In re Janssen Biotech, Inc. is instructive here. 880 F.3d 1315 (Fed. Cir. 2018). In *In re Janssen Biotech*, the patentee attempted during reexamination to amend its patent to delete a benefit claim to a parent application, among other proposed amendments. *Id.* at 1320. We noted that even though the patentee "had never received issued claims . . . on the subject matter originating from the [parent] application, more than thirty-two issued patents 'reached through the [reexamined] patent for benefit of a prior filing date' and 'the patentability of those claims . . . cannot be determined without reopening examination of those patents in view of the deletion of the subject matter in the [reexamined] patent." *Id.; see id.* at 1323; *see also G.D. Searle LLC v. Lupin Pharms., Inc.*, 790 F.3d 1349, 1355 (Fed. Cir. 2015) (observing that if a patent owner had obtained foreign patent protection based on a Patent Cooperation Treaty ("PCT") application, altering the scope of the PCT application could call into question the proper scope of those foreign patents). In short, we have previously acknowledged that amending an earlier-filed parent application may affect the priority of its child applications.

And we do so again here. The Board determined that when filed, the eighth application did not meet the "specific reference" requirement of § 120 as to the filing date of the

first application. J.A. 11-12. That was so, according to the Board, because the eighth application claimed the benefit of the first application's filing date by way of the fifth application, and NAI had amended the fifth application to claim priority to only the 2003 provisional application. *See id.* In other words, because the fifth application lacked priority to the first application, the eighth application's priority claim to the first application (via the fifth application) did not satisfy all of § 120's requirements. The Board, therefore, did not err in determining that the '381 patent was not entitled to claim the benefit of the filing date of the first application under § 120, as the priority claim in the '381 patent was defective from the start.

B

Next, NAI avers that although "a claimed benefit to an earlier filing date may later be altered in the instant application according to MPEP § 201.11, . . . that alteration applies only to the instant application—not other, . . . applications."[6] Appellant's Reply Br. 15. According to the MPEP, which is "commonly relied upon as a guide to patent attorneys and patent examiners on procedural matters," *Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1439 (Fed. Cir. 1984), "[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*," MPEP § 201.11(III)(G) (8th ed., Rev. 1) (2003) (emphasis added); MPEP § 211.02(a)(III) (9th ed., Rev. 7) (2015) (same).

6. Although outdated, we refer to MPEP § 201.11 to remain consistent with Appellant's briefs. *See, e.g.*, Appellant's Reply Br. 7. The subject matter of § 201.11, however, now exists in MPEP § 211.

Although the Board did not explicitly address this argument, the PTO responds that NAI reads MPEP § 201.11 "too narrowly." Intervenor's Br. 34-35. Specifically, the PTO notes that "the [MPEP] passage does not state that cancellation of a benefit claim may be considered a waiver in *only* the instant application." *Id.* at 35. The PTO, applying this broader interpretation, asserts that "the intentional cancellation of a benefit claim pursuant to MPEP § 201.11 can similarly affect another application's entitlement to a benefit claim." *Id.* We agree with the PTO.

As an initial matter, we note that the MPEP "does not have the force of law[,]" *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995), and does not bind us, *Litton Sys.*, 728 F.2d at 1439. Nonetheless, we have reviewed MPEP § 201.11 and find that nothing in its text limits the scope of waiver to *only* the instant application. Indeed, § 201.11 does not contemplate all possible consequences of waiving a benefit claim in a particular application. Moreover, at least in the context of terminal disclaimers, the MPEP has *explicitly* indicated when a disclaimer applies only to the instant application and not to downstream applications. *See, e.g., Hagenbuch v. Sonrai Sys.*, 2015 U.S. Dist. LEXIS 39083, *10-13 (N.D. Ill. Mar. 27, 2015) (explaining that "[t]he MPEP in effect in 1993 described the effect of a disclaimer that, by its terms, applied only to the 'instant application'"); *see also* MPEP § 1490(VI)(B) (9th ed., Rev. 8) (2017) ("A terminal disclaimer filed to obviate a nonstatutory double patenting rejection is effective only with respect to the application or patent identified in the disclaimer unless by its terms it extends to continuing applications . . . .").

C

Further, NAI summarily concludes that "[r]ather than the dogmatic view of seeing additional continuation filings merely adding an additional link in a single growing chain, § 120, and the case law, must be interpreted as providing for a new priority chain being created at each new filing." Appellant's Br. 34.

NAI, however, neither explains why § 120 compels this interpretation of priority claims nor provides any case law to support its conclusion. Nor does NAI provide any argument to undermine the long-standing interpretation of priority as a single chain, growing with each additional continuation. The Supreme Court has previously explained that under § 120, parent and continuing applications "are to be considered as parts of the same transaction, and both as constituting one continuous application, within the meaning of the law." *Godfrey v. Eames*, 68 U.S. 317, 326, 17 L. Ed. 684 (1863); *see also Sticker Indus.*, 405 F.2d at 93 (stating that "each application in a long chain grows out of the one immediately preceding it"). We therefore decline to adopt NAI's interpretation of chain of priority.

D

Finally, NAI argues that the Board's determination impermissibly "limits an applicant's ability to seek protection" when "amending the priority claim to gain [patent] term." *See* Appellant's Br. 38. NAI's argument suggests that NAI need not trade the benefit of an earlier filing date in order to gain patent term. *See id.*

at 36 (arguing that by waiving priority in the parent application, it was not waiving priority in the child application). Although the Board did not explicitly address this argument, the PTO asserts that because NAI "chose to delete the benefit claim in its fifth U.S. application and thereby obtained a longer term for the patent issuing therefrom[,]" a "consequence of this voluntary action is that [NAI's] sixth through eighth U.S. applications would no longer be entitled to the benefit of the filing date of its fourth through first U.S. applications." Intervenor's Br. 14. Again, we agree with the PTO.

Continuation-in-part ("CIP") applications, like the fifth application in this case, uniquely highlight the trade-off between priority and patent term.[7] In CIP applications, priority is assessed on a claim-by-claim basis. *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 557 n.6 (Fed. Cir. 1994). An applicant can obtain an earlier effective filing date for claims in a CIP application only if those claims find support in an earlier-filed nonprovisional application. *Id.* Claims reciting new matter, however, are entitled to only the filing date of the CIP application and not to the filing date of the earlier-filed application. *Id.* Because the standard patent term is twenty years after an application's *earliest-claimed* priority date, *see* 35

7. "A continuation-in-part is an application filed during the lifetime of an earlier nonprovisional application . . ., repeating some substantial portion or all of the earlier nonprovisional application and *adding matter not disclosed* in the said earlier nonprovisional application." *Univ. of W. Va. v. Van Voorhies*, 278 F.3d 1288, 1297 (Fed. Cir. 2002).

U.S.C. § 154(a)(2) (emphasis added),[8] the claims reciting new matter are not entitled to the parent application's earlier filing date, and they therefore have a truncated patent term (i.e., less than twenty years). *See* 5 Donald S. Chisum, Chisum on Patents § 16.04[6][b] (2016).

An uncommon but permissible way for patent applicants to avoid losing term on claims that recite new matter is to disclaim the benefit of earlier filing dates. *See* MPEP §§ 211.02(a)(III). Thus, by deleting the benefit claim in a CIP application, the twenty-year patent term of the patent issuing from that CIP application would extend from the CIP application's filing date instead of the parent application's earlier filing date. *See id.* Of course, once the CIP application adopts the later filing date, the CIP application and its children become vulnerable to rejections based on a larger pool of prior art—including former parent applications in some cases. *See, e.g., Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1352 (Fed. Cir. 2012) (finding that "[d]ue to breaks in the chain of priority," the "[parent] patent [was] prior art for some of the asserted claims").

Under NAI's theory of priority, however, NAI could gain patent term on its fifth application while simultaneously shielding its child applications (including the eighth application) from their former parents. For the reasons discussed herein, NAI cannot have it both ways.

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8. As of June 8, 1995, *see* Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994), U.S. applications that claim priority to an earlier-filed U.S. application will have a patent term of twenty years from the filing date of the earliest U.S. application to which it claims a priority benefit. 35 U.S.C. § 154(a)(2).

Appendix B

III

We have considered NAI's remaining arguments and find them unpersuasive. For the foregoing reasons, the Board's final decision invalidating the challenged claims is affirmed.

AFFIRMED

APPENDIX C — DECISIONS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT TRIAL AND APPEAL BOARD

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 2016-000745
Reexamination Control 95/002,048
Patent 8,129,422 B2
Technology Center 3900

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

LEBOVITZ, *Administrative Patent Judge.*

Appendix C

DECISION ON APPEAL

This is a decision on the appeal by the Patent Owner from the Patent Examiner's decision to reject claims 12-19,[1] 22-34, 36-39, and 42-44 in the above-identified *inter partes* reexamination of United States Patent 8, 129,422. The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315 (pre-AIA). We affirm, but designate the affirmances new grounds of rejection.

BACKGROUND

The patent in dispute is this appeal is U.S. Patent 8,129,422 B2 ("the '422 patent") which issued March 6, 2012, based on Application No. 12/806,356, filed Aug. 10, 2010. There are two named inventors, Roger Harris and Mark Dunnett. The patent is subject to a terminal disclaimer to the term of U.S. 7,825,084. The real party in interest and owner of the '422 patent is Natural Alternatives International, Inc. ("Patent Owner"). Reel/Frame 24935/0010.

A request for *inter partes* reexamination of the '422 patent was filed July 19, 2012 on behalf of Woodbolt Distributors, LLC ("Requester") under 35 U.S.C. §§ 311-18 and 37 C.F.R. §§ 1.902-1.997. Woodbolt is also the Respondent in this proceeding. An oral hearing was held March 16, 2016. A transcript of the hearing will be entered into the record in due course ("Hearing Tr.").

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1. In the Appeal Brief, Patent Owner canceled claim 18 by amendment pursuant 37 CFR 41.33(b)(1) and 1.116(b)(1). Appeal Br. 1. However, we could not find a paper in the records where the Examiner entered the amendment.

Appendix C

This *inter partes* reexamination is related to the *inter partes* examination of U.S. Patent No. 8,067,381 B1, Reexamination Control 95/002,001 ("'001 Reexamination"). The final rejection by the Examiner in the latter reexamination was appealed to the Patent Trial and Appeal Board ("PTAB") and assigned appeal number 2015-000225. A decision ("'001 Decision") was mailed in this related reexamination on July 17, 2015 in which the Examiner was affirmed. '001 Decision. The claims in the '001 Reexamination are directed to a dietary supplement comprising beta-alanine, the same dietary supplement which is claimed in this present reexamination.

The '422 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." '422 patent, col. 1, ll. 50-56. The claimed subject matter of the '422 patent is directed to compositions that comprise beta-alanine or a derivative of it. *Id.* at col. 8, ll. 27-34. Beta-alanine is an amino acid. According to the '422 patent, administering beta-alanine increases beta-alanylhistidine dipeptide in muscle tissue which favorably affects muscle performance. *Id.* at col. 8, l. 34 to col. 9, l. 4. The dipeptide increases the buffering capacity of muscles and decreases muscle fatigue. *Id.* at col. 1 ll. 38-40; col. 14, ll. 25-28.

Claims 12-19, 22-34, 36-39, and 42-44 stand rejected by the Examiner as unpatentable under 35 U.S.C. §§ 102 and 103. Claim 12 is representative of the rejected claims and is reproduced below:

Appendix C

12. A method to avoid or delay the onset of muscular fatigue in a subject, comprising:

a) providing to the subject an amount of an amino acid to blood or blood plasma effective to increase beta-alanylhistidine dipeptide synthesis in muscle tissue, wherein said amino acid is at least one of:

i) beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide;

ii) an ester of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; or

iii) an amide of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; and

b) exposing the muscle tissue to the blood or blood plasma, whereby the concentration of beta-alanylhistidine is increased in the muscle tissue, thereby avoiding or delaying the onset of muscular fatigue,

wherein the amino acid is provided as a dietary supplement, and

wherein the subject is not a horse.

Appendix C

PRIORITY

One of the threshold issues in the present *inter partes* reexamination is whether the claims are entitled to the priority of U.S. Application 08/909,513, filed August 12, 1997 ("the '513 application") claiming priority to UK applications filed in 1996. Appeal Br. 3. This issue was decided against Patent Owner in the related '001 Reexamination and the claims were denied benefit of the '513 priority application. '001 Decision 15. The earliest filing date of the claims was determined to be April 10, 2003. *Id.* As a result of this determination, the patent based on the '513 application — U.S. Patent 5,965,596 ("Harris '596") — was determined to be prior art and anticipatory to all claims in the '001 Reexamination. *Id.* at 26.

The priority issue in this present reexamination is the same as in the '001 Reexamination. Both sets of claims involve dietary supplements comprising beta-alanine. The application from which the '422 patent arose claims benefit of the same chain of priority applications as does the patent in the '001 Reexamination. The Patent Owner is the same in both reexaminations and has made the same priority arguments in this case as in the '001 Reexamination. For consistency and efficiency, we incorporate the priority discussion and determination in the '001 Decision into this decision. We deny the '422 patent benefit of the '513 priority application for the same reasons as in the '001 Decision. The '001 Reexamination Decision is attached. The earliest filing date of the '422 patent is April 10, 2003. Consequently, Harris '596 is prior art to the '422 patent.

Appendix C

REJECTIONS

The claims stand rejected by the Examiner as follows:

l. Claims 12-19, 22-34, and 38-44 under 35 U.S.C. § 102(b) as anticipated by Harris '596.[2]

2. Claims 12, 17, 19, 25-27, 31, 38, and 39 under 35 U.S.C. § 102(b) as anticipated by Gardner.[3]

3. Claims 12, 13, 17, 19, 25-27, 31, 38, 39, and 44 under 35 U.S.C. § 102(b) as anticipated by Asatoor.[4]

4. Claims 12, 17, 19, and 22 under 35 U.S.C. § 102(b) as anticipated by EP593.[5]

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2. Roger Harris, *et al.*, US 5,965,596 (iss. Oct. 12, 1999) ("Harris '596").

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 411-22 (1991) ("Gardner").

4. A.M. Asatoor *et al.*, *Intestinal Absorption of Carnosine and its Constituent Amino Acids in Man*, 11 Gut, 250-54 (1970) ("Asatoor").

5. Andre Rougereau, EP 0 280 593 B1 (pub. June 12, 1991) (French language) ("EP593") (all references to EP593 are to the English translation of it.

5. Claims 12, 17, and 19 stand rejected under 35 U.S.C. § 102(b) as anticipated by Wu[6] as evidenced by Li.[7]

6. Claims 12-19 under 35 U.S.C. § 103(a) as obvious in view of Setra[8] and Bakardjiev[9] or Bauer.[10]

7. Claims 12-19, 22-39, and 42-44 under 35 U.S.C. § 103(a) as obvious in view of Setra and Asatoor.

8. Claims 12-19, 22-39, and 42-44 under 35 U.S.C. § 103(a) as obvious in view of Setra and Gardner.

9. Claims 23, 24, and 28 under 35 U.S.C. § 112, first paragraph, as lacking a written description in the '422 patent for the claims added during reexamination.

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6. Hui-Chun Wu & Chyuan-Yuan Shiau, *Proximate Composition, Free Amino Acids and Peptides Contents in Commercial Chicken and Other Meat Essences*, 10 J. Food and Drug Analysis 170-77 (2002) ("Wu").

7. Y.F. Li *et al. Bioactivities of Chicken Essence*, 77 J. of Food Science, R 105-10 (201 2) ("Li").

8. Gian Paolo Negrisoli, EP 0 449 787 A2 (pub. Oct. 2, 1991) ("Setra").

9. Anastasia Bakardjiev & Karl Bauer, *Transport of β-alanine and biosynthesis of carnosine by skeletal muscle cells in primary culture*, 225 Eur. J. Biochem., 617-23 (1994) ("Bakardjiev").

10. Karl Bauer & Michael Schulz, *Biosynthesis of carnosine and related peptides by skeletal muscle cells in primary culture* 219 Eur. J. Biochem., 43-47 (1994) ("Bauer").

Appendix C

CLAIM INTERPRETATION

We begin with claim interpretation because before a claim can be compared to the prior art, it must by properly interpreted. During reexamination of an unexpired patent, the PTO must give claims their broadest reasonable construction consistent with the specification. *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004); *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1259 (Fed. Cir. 2010); *In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1146 (Fed. Cir. 2012).

"avoiding or delaying the onset of muscular fatigue"

Claim 12 is directed to a "method to avoid or delay the onset of muscular fatigue in a subject." The method comprises "providing to the subject an amount of an amino acid to blood or blood plasma effective to increase beta-alanylhistidine dipeptide synthesis in muscle tissue." The amino acid is beta-alanine or an ester derivative of it. The muscle is exposed to the blood or blood plasma comprising the beta-alanine "thereby avoiding or delaying the onset of muscular fatigue."

The Examiner did not give the functional limitation "avoiding or delaying the onset of muscular fatigue" patentable weight and interpreted the claim to read on administration of "any amount of beta-alanine." Right of Appeal Notice (mailed Aug. 8, 2014) (hereinafter "RAN") 7. The Examiner's rationale for this interpretation is that Example 4 of the patent showed no change in muscle carnosine (a "beta-alanylhistidine dipeptide") after

two weeks of administration of three daily doses of 40 mg/kg beta-alanine. *Id.* at 6. The Examiner found this to be a "contradiction" because the claims require both an increase in carnosine concentration in the muscle and a delay in muscle fatigue onset. *Id.* The Examiner also found that the dosages in the patent are lower than those described as effective in Patent Owner's evidence of relevant dosages, namely that provided in Tallon and Balcombe (3.2 grams per day), providing an additional contradiction to the teachings in the patent. *Id.* at 6-7.

Upon consideration of this issue, we conclude that the Examiner improperly ignored the functional limitation recited both in the preamble and body of the claim. The '422 patent describes using beta-alanine and its derivatives to increases the anaerobic capacity of muscle and delay muscle fatigue. '422 patent, col. 8, ll. 27-39. The patent explains that the beta-alanine increases the synthesis of beta-alanylhistidine dipeptides, such as carnosine, which buffer hydronium ions in the muscle and improves muscle performance. *Id.* at col. 8, ll. 36-67. The purpose of administering the beta-alanine is therefore to enhance muscle function, such as avoiding or delaying muscle fatigue. *Id.* at col. 7, ll. 3-7; col. 8, ll. 66-67. In this context, it is improper to ignore the explicit statements both in the preambles and the bodies of claims 12, 25, and 44 that the method is for "avoiding or delaying the onset of muscular fatigue" and that the "beta-alanylhistidine dipeptide" produced from beta-alanine administration accomplishes the stated purpose of the claim and the invention described in the '422 patent.

Appendix C

Example 4 investigated the effect of administration of 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 on the carnosine content of muscle and isometric endurance at 66% of maximal voluntary contraction force (MVC). '422 patent, col. 17, ll. 19-24. The results showed an increase in endurance time for 5 of the 6 subjects tested, and in one subject taking a higher dose of beta-alanine. *Id.* at col. 18, n. 33-40. The Examiner criticized this study because the inventors reported that there was no apparent change in the muscle carnosine content in the muscle of the six subjects biopsied. *Id.* at col. 18, ll. 29-30.

In our opinion, the fact that Example 4 did not show an increase in muscle can1osine is not a basis to ignore the functional limitations of claim 12 . Claim 12 requires administration of beta-alanine or a derivative of it to accomplish the purpose of the claim to avoid or delay muscle fatigue. This method is described in the '422 patent and performed in Example 4. Example 4 did not validate the mechanism by which the beta-alanine improved the muscle performance (i.e., by increasing carnosine content in the muscle). However, a rise in blood levels of beta-alanine was reported with three smaller doses per day of 10 mg/kg of body weight each (*id.* at col. 16-17 (Example 3)) and the stated purpose of the method for treating muscle fatigue (*id.* at col. 18, ll. 33-40) was demonstrated. Co-inventor Roger C. Harris, Ph.D., provided a declaration (dated October 28, 2013) in which he attached the results of experiments, including the results of the experiments in Example 4 of the '422 patent, which "show that the muscle

carnosine content increased for three of the six subjects, but the muscle content for all six subjects tested averaged out to no increase. (Exhibit 1 at page 11)." 2013 Harris Decl. ¶ 4. Dr. Harris explained that the differences could be due to variation in responses observed in populations and inaccurate test methods. *Id.* at ¶¶ 3, 6. In view of this evidence, and the fact that the Example 4 shows that administration of beta-alanine achieved the purpose of the claimed method, we conclude that the Examiner's reason to ignore the functional limitations based on a "contradiction" in Example 4 is not supported by the weight of evidence.

The Examiner also found that the wide dosage range, including low dosages and single-administrations to be inconsistent with teachings in the '422 patent that sustained treatment with beta-alanine is necessary to delay onset of muscle fatigue. RAN 6-7. We do not agree. As argued by Patent Owner, the claims are not limited to humans or large animals, but cover small animals where lower dosages would be appropriate. Consequently, the disclosure of various dosages is not inconsistent and does not defy logic as asserted by the Examiner. Moreover, as discussed below, the claims cover administration of multiple daily doses, where individual doses could be more or less depending upon the time period over which they are administered.

Appendix C

Single dosage

Patent Owner contends that the claim requires more than one "single dose" of beta-alanine. Appeal Br. 10. Patent Owner argues that

> neither Examiner nor Requester has produced any scientific data or facts to demonstrate that the delay of muscular fatigue achieved by the claimed method, as evidenced in Example 4, was not from the "amount. . . effective" required in the method of Claim 12 or that short term exposure of a single dose has an effect.

Id. Patent Owner asserts that as "evidenced by declarations from those of skill in the art (Ex. 7 ¶¶ 13, 20-22; Ex. 8 ¶8) and the scientific publications (Ex. 9 at 5; Ex. 10 at 18), it is known that an effective amount is not a single dose and certainly not *de minimis* amounts." Appeal Br. 11.

First, we look to the '422 patent written description because claims must be interpreted in light of it. The '422 patent describes administering a composition comprising beta-alanine in multiple doses over periods of two or three days or more (col. 4, ll. 10-26; col. 3, ll. 65-67; col. 10, ll. 24-28). However, while administration might be preferably administered more than two or three days, we have not been guided to adequate disclosure in the '422 patent or to language in the claims which would exclude administration of one dosage only from being effective to achieve the claimed result of delaying muscle fatigue. Figure 9 of the '422 patent shows an increase in plasma beta-alanine

after a single administration (col. 17, ll. 1-15) and such an increase in plasma levels of beta-alanine is described in the '422 patent as leading to the increase in the beta-alanylhistidine dipeptide. *Id.* at col. 9, ll. 5-13. Thus, it is not inconsistent with the patent that a single dose of beta-alanine could have a transient increase in the beta-alanylhistidine dipeptide and produce a corresponding short-lived delay in muscle fatigue.

Patent Owner directs us to disclosure in the '422 patent that long term administration of beta-alanine led to increase in beta-alanylhistidine dipeptide (Appeal Br. 9), but such result does not provide evidence that shorter term administration would not result in a detectable amount so of delay in onset of muscle fatigue. Dr. Harris, in the context of discussing the anticipation rejections, stated that a "single dose of beta-alanine would be unlikely to have any measurable effect on fatigue," stating that it could be stored at another "location in the body, such as the liver" (2012 Harris Decl. ¶ 13), but Dr. Harris did not provide objective evidence to support this statement. For example, Dr. Harris did not explain why a single-dose might be directed to the liver, but, other regimens covered by the claim, such as one-dose daily for three days, would not be directed to the liver.

We decline to import limitations from the '422 patent into the claims. "For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Claims 12 and 25

recite "providing to the subject an amount of an ami110 acid to blood or blood plasma effective to increase beta-alanylhistidine dipeptide synthesis in muscle tissue." The claim does not specify a time period over which the "amount . . . effective" to increase the dipeptide is provided. The discussion at column 8 under the "Detailed Description" teaches that increasing the amount of beta-alanylhistidine dipeptides within muscle favorably affects muscle performance. '422 patent, col. 8, ll. 66-67. The dipeptide is synthesized within the body from beta-alanine and L-histidine. *Id.* at col. 8, ll. 49-50. We have not been directed to a teaching in the patent that a single-dose would not increase levels of the beta-alanine in the blood and result in an increase in synthesis of the dipeptide.

In addition to this reasoning, we also note that dependent claims specifically require that the supplement "is provided on consecutive days" (claim 22) and "provided for at least 14 days" (claims 23, 24, 28 (although differently worded).

Under the doctrine of claim differentiation:

> ["D]ifferent words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed. Cir. 1999). Although the doctrine is at its strongest "where the limitation sought to be 'read into' an independent claim already appears in a dependent claim," *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898,

> 910 (Fed. Cir. 2004), there is still a presumption that two independent claims have different scope when different words or phrases are used in those claims, *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1365-69 (Fed. Cir. 2000)[.]

Seachange Int'l, Inc. v. C-COR, Inc., 413 F.3d 1361, 1368-69 (Fed. Cir. 2005).

Claim 12 recites that an amount of beta-alanine is provided to the subject. Dependent claims specifically require that the supplement "is provided on consecutive days" (claim 22) and "provided for at least 14 days" (claims 23, 24, 28). Independent claim 44 recites "the use of the dietary supplement for administration over a continuous period of time." Each of these claims are presumptively narrower than claim 12 in requiring consecutive or continuous administration of the beta-alanine supplement. Thus, reading these limitations into claim 12, and requiring claim 12 to read on repeated administration of beta-alanine would be improper based on the doctrine of claim differentiation.

In reaching this conclusion, we have not ignored the report by Mark Tallon, Ph.D., that "research . . . on β-alanine in humans demonstrated that by consuming 800 mg four times a day for five weeks, a significant load or increase in muscle carnosine levels was achieved[]" and that "3.2 grams of β-alanine supplementation daily, can likely impart the desired benefits." Ex. 3, pp. 5, 6. However, Patent Owner has not identified language in

the claim that requires a specific degree of increase in can1osine in the muscle nor a specific degree of delay in muscle fatigue. For this reason, we conclude that the claims cover any detectable amount of improvement in muscle fatigue even if such amount is not long-term or optimal.

"amount . . . effective"

The claims comprise providing an amount of an amino acid to blood or blood plasma effective to increase beta-alanylhistidine dipeptide synthesis in muscle tissue, which avoids or delays the onset of muscular fatigue. We interpret the *effective amount* to encompass 1) a single dosage (*see* above) or 2) multiple dosages administered over one or more days, where the total amount of the dosages is effective to increase the dipeptide and delay muscle fatigue.

The interpretation that "amount . . . effective" also covers the quantity of beta-alanine over a time period when 2) multiple dosages are administered is the interpretation espoused by Patent Owner (Appeal Br. 14) and consistent with the '422 patent. For example, the '422 patent describes administering small amounts of beta-alanine, e.g., 80 mg, to large amounts, e.g., 16 gm, in a per day amount, with little guidance on which amounts at a single-dosage increase the dipeptide synthesis and delay muscle fatigue.

Appendix C

"dietary supplement"

The claim requires the beta-alanine to be administered as a "dietary supplement." Patent Owner contends that "dietary supplement" is a structural limitation to the claim. Appeal Br. 13. Patent Owner argues that an Amendment filed October 11, 2011, during the prosecution of the application which led to the '422 patent, disavowed pharmaceuticals and foods as dietary supplements (*id.* at 16, 22). Patent Owner also asserts that the '422 patent clearly delineates dietary supplements from pharmaceuticals and foods (*id.* at 16).

The '422 patent teaches that "the composition is a pharmaceutical composition, a dietary supplement or a sports drink." '422 patent, col. 3, ll. 18-19. The patent also teaches that compositions of the invention can be used for the "preparation of a dietary supplement (including, e.g., drinks, gels, foods) or pharmaceutical composition for humans or animals." *Id.* at col. 5, ll. 11-14.

Patent Owner asserts that dietary supplement is a structural limitation, but did not provide evidence of its structure, other than to assert it is different from a food or pharmaceutical. Appeal Br. 17. We take note of the fact that pharmaceuticals may require approval by the FDA to be marketed for treatment of a disease while supplements are subject to a different standard of review. However, Patent Owner did not elucidate a *structural* difference between dietary supplements and pharmaceutical agents. In the Remarks filed October 11, 2011 in the application that led to the '422 patent ("Remarks"), it was stated

that "By dietary supplements the Applicant means an addition to the 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." Remarks 6. Pharmaceuticals are typically administered as pills and capsules. Patent Owner contends they disavowed "pharmaceuticals" in the Remarks, but we have not been directed to a clear statement where such disavowal was made.

While we agree that that the '422 patent uses the terms "dietary supplements" and "pharmaceuticals," it appears that "pharmaceuticals" are being used in its normal conventional way to mean a regulated drug. For example, the '422 patent describes administering insulin and insulin-action modifiers, such as sulphonylurea, a thiazolidinedione or a biguanide, which are traditional drugs to treat diabetes ('422 patent, col. 2, ll. 48-60; col. 3, ll. 16-17), and therefore would be recognized by one of ordinary skill in the art as "pharmaceuticals." Thus, the evidence indicates that the term "pharmaceuticals" is used in the '422 patent to mean regulated drugs, but not for beta-alanine and the other disclosed amino acids and dipeptides. Nonetheless, Patent Owner has not provided a definition that would exclude the pharmaceuticals disclosed in the '422 patent from being considered dietary supplements, and thus being a narrower class within a broader class. Accordingly, we decline to give "dietary supplements" the narrow reading advocated by Patent Owner.

Patent Owner also states that foods were disavowed during the prosecution of the '422 patent. Appeal Br. 22. Patent Owner cites the Remarks which, we agree contain the following statement: "To be clear, the term 'dietary supplement', as claimed, does not encompass, and does not mean, a natural or conventional food, such as chicken or chicken broth, for example." Remarks 6. Based on this statement and in the content of the '422 patent which is supplementing foods and diets with beta-alanine (e.g., at col. 1, ll. 38-45; col. 2, ll. 45-60), we will not construe "dietary supplement" to read on a conventional food, absent processing, derivation, or, e.g., the addition of beta-alanine to it.

1. ANTICIPATION BY HARRIS '596

Patent Owner contends that Harris '596 is a direct parent to the '422 patent and is not anticipatory prior art. Appeal Br. 19. Because we have determined that the '422 patent's earliest filing date is April 10, 2003, Harris '596, which issued October 12, 1999, is prior art under 35 U.S.C. § 102(b) (pre-AJA). Thus, we affirm the Examiner's decision that Harris '596 anticipates claims 12-19, 22-34, and 38-44 for the reason given by the Examiner and as set forth in the Request.

2. ANTICIPATION BASED ON GARDNER

Gardner describes experiments on the intestinal absorption of carnosine. Gardner 411 ("Summary"). As part of the experiments, Gardner described ingestion of "an approximately isotonic test meal containing

2g β-alanine plus 2 g histidine" by one subject. *Id.* at 413: 10-11. The Examiner found that Garner's description of ingesting 2 g of beta-alanine meets the claimed dietary supplement. RAN 23.

Patent Owner contends that Gardner does not anticipate the claimed method because the claims do not cover a single-dosage, but rather "administering the dietary supplement of free amino acid beta-alanine given over a period of at least multiple days." Appeal Br. 20.

As discussed above, we will not import limitations from the '422 patent into the claims. Even if multiple doses are preferred and most effective, the claim language does not exclude a single dose from achieving the claimed result. The 2 gm amount of beta-alanine disclosed by Gardner falls within the range described in the '422 patent. '422 patent, col. 9, ll. 35-38 ("In one aspect, the total amount of beta-alanine (or other composition of the invention) administered can be at least 200mg, from 200 mg to 5 g, or from 5 g or more per day for a human"). In example 5 of the '422 patent, beta-alanine was administered at 1.6 gm a day. *Id.* at col. 19, ll. 29-33). Based on this evidence, there is reasonable basis to believe that all the functional limitations of the claims are met.[11]

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11. 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 contends that Gardner does not describe the dosage between 0.4 g and 16 g recited in claim 25. Appeal Br. 21. This argument is not correct, because Gardner expressly describes administering 2g beta-alanine as discussed above.

For the foregoing reasons, we affirm the rejection of claims 12, 17, 19, 25-27, 31, 38, and 39 as anticipated by Gardner.

3. ANTICIPATION BY ASATOOR

Asatoor describes a single administration of beta-alanine and L-histidine to human subjects. Asatoor 250 ("**Methods**"). Asatoor teaches that histidine and beta-alanine "were taken together in an amount which would be produced after hydrolysis of the above dose of carnosine." *Id.* at 251. The Examiner found the amounts were equivalent to 1.8 g of beta-alanine. RAN 18. The Examiner found that Asatoor's description of ingesting 1.8 g of beta-alanine meets the claimed dietary supplement. RAN 18. The tests "were carried out at intervals of at least two weeks." Asatoor 250-251.

Patent Owner's arguments with respect to Asatoor are substantially identical to those discussed above for Gardner as being unpersuasive. PO App. Br. 19-22.

We affirm the rejection of claims 12, 13, 17, 19, 25-27, 31, 38, and 39 as anticipated by Asatoor for the same reasons as for Gardner.

Appendix C

We reverse the rejection of claim 44 because the Examiner did not establish that Asatoor's disclosure of "intervals of at least two weeks" constitutes a description of "administration [of beta-alanine] over a continuous period of time."

4. ANTICIPATION BY EP593

EP593[12] describes a composition containing beta-alanine in combination with various vitamins for the treatment of cancer. EP593 ¶ 11. EP593 teaches that "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." *Id.* if 18. The Examiner found that such amounts fall within the range of dosages cited in the '422 patent and thus would have been reasonably expected to delay onset of muscle fatigue as required by the claims. RAN 21. Patent Owner contends that EP593 describes pharmaceuticals for treatment of cancer, which was disavowed during the prosecution of the '422 patent. Appeal Br. 22-23. Patent Owner states (citing *In re Halleck*, 422 F.2d 911 (CCPA 1970)), "a therapeutic use does not inherently anticipate or render obvious a use in another non- therapeutic method." *Id.* at 23. Patent Owner also argues that the dosages administered in EP593 are lethal. *Id.* at 24.

Patent Owner contends that EP593's beta-alanine composition is a "pharmaceutical" which is excluded

12. References to EP593 are to the English translation. However, the referenced amounts only appear in the original.

from the claim, but Patent Owner has not identified a characteristic of it that makes it different from the beta-alanine composition of the claim. EP593 is administering beta-alanine, not a regulated drug. *See* "CLAIM INTERPRETATION." Patent Owner has not explained why their own beta-alanine is not a pharmaceutical, while the beta-alanine of EP593 is a pharmaceutical.

Patent Owner cited *Halleck* for holding that a composition for therapeutic use could not inherently anticipate a non-therapeutic use. There is no such *per se* rule. In *Halleck*, the claims were drawn to compositions comprising a substance for stimulating animal growth. *Halleck*, 422 F.2d at 912. The PTO had cited Merck's description of a pharmaceutical comprising the same substance used to stimulate animal growth, but for a therapeutic indication. *Halleck*, 422 F.2d at 913. The court found that it was not "clear that therapeutic administration of the materials according to the teaching of Merck would inherently result in a feed composition containing an amount of substance effective for growth stimulation or that the animal would be administered such an amount." *Id.* This case is distinguishable from *Halleck* because the Examiner found that EP593 describes amounts of beta-alanine which would reasonably be expected to delay muscle fatigue, thus providing factual basis to assert the claim limitations would inherently be met by EP593.

Patent Owner also asserts the dosages described in EP593 would be lethal. Appeal Br. 24. This argument is based on Material Safety Data Sheet for Beta-Alanine (Ex. 16). The data sheet has the following information under "Toxicological Information":

> Routes of Entry: Ingestion.
> Toxicity to Animals: Acute oral toxicity (LO5O): 1000 mg/kg [Rat].
> Chronic Effects on Humans: Not available.
> Other Toxic Effects on Humans:
> Very hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant).
> Special Remarks on Toxicity to Animals: Not available.
> Special Remarks on Chronic Effects on Humans: Not available.
> Special Remarks on other Toxic Effects on Humans: Not available.

The evidence of lethality is for a rat. We understand that such information could not be obtained for a human, but Patent Owner did not provide arguments as to why this value is pertinent to a human.

Nonetheless, based on the Examiner's findings, Patent Owner contends that EP593 describes "initial set of dosages of 360g and later maintenance doses of 120g and 80g providing the individual is still alive (initial ingestion of 3.6g/kg of body weight for a 100kg human). Given the LD50 dose for a 100kg subject is 100g, this is nearly four times the amount expected to kill." Appeal Br. 24.

The Examiner erred in finding that EP593 discloses "a total consumption of 360 g, 120 g, and 80 g." RAN 21.

Example 1 of EP593 is a composition comprising 90 gm beta-alanine. Paragraph 27 states that the dose is

"administered 24 hours to an etching treatment" and the "administration is made orally in four equal parts, every six hours."

Example 2 of EP593 is a composition containing 30 gm beta-alanine. Paragraph 29 teaches that the composition is administered for maintenance therapy in four parts over 24 hours.

Example 3 is a composition containing 20 gm beta-alanine. Paragraph 32 also indicates that the composition is administered over a 24 hour period.

Thus, the Examiner incorrectly found that 90 gm of beta-alanine is administered four times a day. Rather, the translation teaches that the dose of 90 gm is administered over a 24 hour period in four equal parts of 22.5 g each. The LD50 for a rat is 1000 mg/kg or 1 gm/kg. Patent Owner identified a body weight of 100 kg for a human, which would be 100 gm for the LD50 based on the rat. Appeal Br. 24. Thus, at the highest daily dosage of Example 1, the amount of beta-alanine is 90 gm, administer in 4 doses of 22.5 g each, which is less than then LD50 of a rat, and the other dosages disclosed in EP593 are even less. Consequently, the evidence does not support a finding that EP593 describes administering lethal amounts of beta-alanine.

For the foregoing reasons, we affirm the rejection of claims 12, 17, 19, and 22 as anticipated by EP593.

Appendix C

5. ANTICIPATION BASED ON WU

Wu teaches that "essences" of chicken, beef, clam, and eel have been available in Taiwan markets as nutritional supplements. Wu 170 (col. 2). Wu teaches the free amino acid and peptide content of these essences. *Id.* Table 2 shows the free amino acid content of six essences of chicken, where the highest level of beta-alanine content is 9.5 mg/100 g (D). Table 3 shows the free amino acid content of beef, hard clam, freshwater clam, and eel essences, where the highest level of beta-alanine content is 13.4 mg/100 g in eel essence. The Examiner found that Wu's description of a meat essence with free beta-alanine meets the claimed dietary supplement. RAN 25.

Patent Owner contends that the Amendment filed in the application which led to the '422 patent specifically disavowed "natural or conventional food" such as that of "beef, pork, chicken, meat extract supplements and predigested meat/protein supplements" and does not encompass "naturally occurring compositions." Appeal Br. 25; Ex. 2 at 6, 7.

Patent Owner also argues:

> Wu teaches an average of 7.6 mg (a de minimis amount) of free beta-alanine per 100 g of beef essence (not beef). This would require a total daily intake of 165.69 kg of beef essence (or 365.28 pounds) for a 105kg person.

Response to ACP (Aug. 23, 2013) 31. Patent Owner states: "Requiring a person to eat almost twice their weight daily

in beef essence is not possible because it contains high amounts of MSG and NaCl." Appeal Br. 25; 2012 Harris Decl. ¶ 34.

The calculation made by Patent Owner is based on Example 4's supplementation with 40 mg beta-alanine per kilogram. 2012 Harris Decl. ¶ 34. The claims, however, do not require this amount of beta-alanine. The '422 patent teaches that daily dosages as low as 80 mg of beta-alanine can be administered. ("In an 80 kilogram person, suitable dosages per day can be between 0.08 grams to 16.0 grams of beta-alanine." Col. 9, ll. 50-52.)

Such amount would require less two pounds of the chicken essence (9.5 mg beta-alanine /100 g essence) or eel essence (13.4 mg beta-alanine /100 g essence), a much lower amount than the amounts proposed by Patent Owner. Nonetheless, there is insufficient evidence in the record to determine how much of the essence is generally ingested by a human per day. Thus, the Examiner did not meet the burden of showing that Wu describes a method of providing an amount of beta-alanine effective to "to increase beta-alanylhistidine dipeptide synthesis in muscle tissue" and "avoid or delay the onset of muscular fatigue in a subject." In addition, there is insufficient evidence to determine whether the "essence" is natural food, or a derivative of a food that would constitute a "food supplement." The rejection of claims 12, 17, and 19 as anticipated by Wu is reversed.

Appendix C

6. OBVIOUSNESS BASED ON SETRA AND BAUER OR BAKRDJIEV

Setra describes the use of carnosine "for the treatment of muscular fatigue and improving athletic performances in persons subjected to prolonged physical efforts." Setra 2:3-5. Setra explains that carnosine, and other dipeptides comprising the histidine imidazole ring, serve as intracellular buffering agents which treated the uncontrolled release of protons during increased muscle activity which is one of the main causes of muscle fatigue. *Id.* at 2:9-25. Setra does not describe utilizing beta-alanine to increase the carnosine levels. However, the Examiner cited Bakardjiev or Bauer for teaching that uptake of beta-alanine by embryonic chick pectoral muscle cell cultures results in the biosynthesis of carnosine. RAN 38 (citing Bakardjiev, Abstract and Bauer, Abstract). The rate of uptake and biosynthesis increased under differentiation conditions. *See* Bakardjiev 620 (emphasis in original) ("**Uptake of β-alanine as a function of muscle cell differentiation**.") The Examiner determined it would have been obvious to the person of ordinary skill in the art to modify the carnosine treatment of Setra by administering free beta-alanine and using the biosynthesis reaction described in Bakardjiev (and Bauer) in order provide a method for delaying the onset of muscular fatigue in a subject. RAN 38. The Examiner stated:

> [T]here is a reasonable likelihood that upon the ingestion of beta-alanine, this amino acid level is increased in muscle tissue and then incorporated into beta-alanylhistidine

> (carnosine), at least in chickens, and likely humans as well. Consequently, the motivation to combine Setra with Bauer and Barkardjiev [sic, Bakardjiev] is that the administration of beta-alanine is expected to increase the concentration in muscle tissue and thereafter to be incorporated into beta-alanylhistidine.

RAN 63.

Patent Owner argues that "Bauer and Bakardjiev use isolated systems of immature myoblasts from embryonic chick pectoral muscle. These primitive immature muscle cell systems are not representative of processes of *in vivo systems*." Appeal Br. 28 (footnote omitted). Dr. Harris testified that ''Neither reference demonstrates an ability to increase carnosine levels in mature muscle cells in vivo beyond the normal levels and processes, nor that these immature cells would increase carnosine above steady state levels." *Id.* (citing 2012 Harris Decl. ¶ 48). Dr. Harris also distinguished immature muscle cell culture systems from processes that occur in the body, including describing the different possible fates of beta-alanine in the body, such as being directed to tissues other than muscle, and undergoing metabolism, oxidation, excretion, and uptake by tissues in the body other than muscle. *Id.* ¶¶ 50-52. Based on these differences, Dr. Harris concluded that one of ordinary skill in the art would "not be able to see any link between this isolated system and that of an in vivo system that works to destroy greater than 90% of consumed beta-alanine." *Id.* ¶ 52.

Patent Owner's argument is persuasive. The Examiner did not provide evidence that the chick muscle cell culture system described Bakardjiev would reasonably predict the fate of beta-alanine in the body of a subject. As pointed out by Dr. Harris, there are significant differences between an isolated cell culture system and a body with multiple organs, tissues, and numerous pathways which are absent from an isolated cell. Obviousness requires a reasonable likelihood of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (Fed. Cir. 1986). In this case, while Bakardjiev may have demonstrated that carnosine is synthesized from beta-alanine in differentiating chick muscle cells in cell culture, a preponderance of the evidence does not support the Examiner's conclusion that it would be reasonably likely that administration of beta-alanine and L-histidine to a subject would result in the production carnosine in such amounts to delay or avoid the onset of muscle fatigue. The same argument holds true for Bauer which contains the same teachings as in Bakardjiev. The Examiner also did not provide sufficient reason to have replaced carnosine with the precursor beta-alanine; the Examiner stated it was likely to work, but did not provide an adequate reason to have made the substitution. Accordingly, the obviousness rejection of claim 12-19 as obvious in view of Setra and Bakardjiev or Bauer is reversed.

7, 8. OBVIOUSNESS BASED ON SETRA AND ASATOOR OR GARDNER

The teachings in Setra, Asatoor, and Gardner have been explained above. The Examiner found it would

have been obvious to have administered beta-alanine in Setra's method for treating muscle fatigue, as taught by Asatoor and Gardner, "for the purpose of reducing muscle fatigue by reducing the hydronium ion concentration in the muscles as taught by Setra." RAN 27, 32.

The preponderance of the evidence does not support the Examiner's rejection. The Examiner has not provided evidence, or a rationale, as to why providing beta-alanine to a subject would be reasonably expected to reduce muscle fatigue. Setra teaches that carnosine, and other dipeptides comprising the histidine imidazole ring, serve as intracellular buffering agents which treated the uncontrolled release of protons during increased muscle activity which is one of the main causes of muscle fatigue. Setra 2:9-25. The Examiner states:

> [I]t 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 composition of Setra because Asatoor teaches the rapid uptake of free amino acid beta-alanine and Gardner also teaches the uptake of beta-alanine from the intestine into the blood while carnosine is degraded quickly in the bloodstream. The purpose for combining Setra with either Asatoor and/or Gardner is to support the amount of carnosine in the muscle tissue by including beta-alanine that

> can combine with histidine to from carnosine in the muscle tissue.

RAN 61.

However, the Examiner did not establish that administering histidine and beta-alanine would have resulted in increased levels of carnosine in the muscle. Asatoor and Gardner provided beta-alanine and L-histidine, but the Examiner did not direct our attention to disclosure in these publications that carnosine levels were increased. Consequently, there is inadequate evidence that ingesting both amino acids would have resulted in carnosine levels in such amounts that would delay or avoid the onset of muscle fatigue as taught by Setra. Accordingly, the obviousness rejection of claims 12-19, 22-39, and 42-44 as obvious in view of Setra and Asatoor or Gardner is reversed.

9. WRITTEN DESCRIPTION REJECTION

The written description rejection of claims 23, 24, and 28 (RAN 9) reciting providing the dietary supplement for at least 14 days is reversed because the '422 patent clearly describes a fourteen day period ("two weeks") or more. '422 patent, Fig. 17, col. 4, ll. 22-26, col. 10, ll. 24-28; Examples 4-5.

CONCLUSION

All the claims are anticipated by Harris '596 (rejection 1).

We affirm anticipation rejections 2-4. Since our claim interpretation is different from the Examiner's and our rationale for affirming the rejections is different from the Examiner's, we designate the affirmances 2-4 as new grounds of rejections.

Rejections 5-7 are reversed.

TIME PERIOD

This decision contains a new ground of rejection under 37 C.F.R. § 41.77(b). Section 41.77(b) provides that "[a] new ground of rejection . . . shall not be considered final for judicial review." That section also provides that Patent Owner, WITHIN ONE MONTH FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal proceeding as to the rejected claims:

> (1) *Reopen prosecution.* The owner may file a response requesting reopening of prosecution before the examiner. Such a response must be either an amendment of the claims so rejected or new evidence relating to the claims so rejected, or both.
>
> (2) *Request rehearing.* The owner may request that the proceeding be reheard under § 41.79 by the Board upon the same record. The request for rehearing must address any new ground of rejection and state with particularity the

> points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

In accordance with 37 C.F.R. § 41.79(a)(1), the "[p]arties to the appeal may file a request for rehearing of the decision within one month of the date of: . . . [t]he original decision of the Board under § 41.77(a)." A equest for rehearing must be in compliance with 37 C.F.R. § 41. 79(b). Comments in opposition to the request and additional requests for rehearing must be in accordance with 37 C.F.R. § 41.79(c)-(d), respectively. Under 37 C.F.R. § 41.79(e), the times for requesting rehearing under paragraph (a) of this section, for requesting further rehearing under paragraph (c) of this section, and for submitting comments under paragraph (b) of this section may not be extended.

An appeal to the United States Court of Appeals for the Federal Circuit under 35 U.S.C. §§ 141-144 and 315 and 37 C.F.R. § 1.983 for an *inter partes* reexamination proceeding "commenced" on or after November 2, 2002 may not be taken "until all parties' rights to request rehearing have been exhausted, at which time the decision of the Board is final and appealable by any party to the appeal to the Board." 37 C.F.R. § 41.81. *See also* MPEP § 2682 (8th ed., Rev. 8, July 2010).

Requests for extensions of time in this *inter partes* reexamination proceeding are governed by 37 C.F.R. § 1.956. *See* 37 C.F.R. § 41.79.

Appendix C

In the event neither party files a request for rehearing within the time provided in 37 C.F.R. § 41.79, and this decision becomes final and appealable under 37 C.F.R. § 41.81, a party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. *See* 37 C.F.R. §§ 90.1 and 1.983.

AFFIRMED; 37 C.F.R. § 41.77(B)

Appendix C

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.

Appea1 2016-000745
Reexamination Control 95/002,048
Patent 8,129,422 B2
Technology Center 3900

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

LEBOVITZ, *Administrative Patent Judge.*

DECISION ON REQUEST FOR REHEARING

This is a decision on the Request for Rehearing by Patent Owner ("Req. Reh'g" dated June 13, 2016) of the Decision on Appeal of May 13, 2016 ("DOA").

Appendix C

Patent Owner filed a Request for Rehearing on June 13, 2016. A Request for Rehearing "must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection." 37 C.F.R. § 41.77(b)(2). In this case, new grounds of rejection were set forth because the Decision determined that "the Examiner improperly ignored the functional limitation recited both in the preamble and body of the claim" of "avoiding or delaying the onset of muscular fatigue." DOA 7, 28. However, in the Request for Rehearing, Patent Owner did not address this limitation as it related to the affirmance of Rejections 1-4 (DOA 5). Rather, Patent Owner simply repeated arguments already made during the Reexamination proceeding, and particularly failed, in the 25-page Request for Rehearing, to direct our attention to specific errors or misapprehensions in the Decision.

Specifically, Patent Owner: (1) repeated its arguments that the Application was improperly denied the benefit of its priority applications (Req. Reh'g 2-3); (2) argued that the Board had misconstrued the dosage requirements of the claims (*id.*, 4-16) while admitting that such arguments had been made "repeatedly . . . throughout this reexamination" (*id.*, 6); and (3) argued that the Board has improperly given "dietary supplement" its narrow meaning advocated by Patent Owner, while admitting that such arguments have been "repeated" by Patent Owner throughout the reexamination. *Id.*, 17 ("Appellant has repeatedly explained that the Amendment disavowed 'pharmaceuticals' of beta-alanine, such as in BP '593 cited by the Panel in Rejection 4. The October

11, 2011 Amendment clearly and unambiguously stated the invention required a 'dietary supplement' – not a pharmaceutical.").

Priority

Patent Owner contends "there is no reasoned legal analysis by the Panel regarding why the asserted break in priority--occurring after filing--should treat an application any differently than an issued patent." Req. Reh'g 3.

In the Decision, we referred to the discussion of priority in the related '001 Reexamination (DOA 2). In the Decision in the '001 Reexamination, this panel stated:

> *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.

'001 Reexamination Decision 10.

The panel also stated:

> Contrary to Patent Owner's 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.

Id., 11.

Thus, while it is evident that Patent Owner disagrees with the priority determination made in this Reexamination proceeding, it is not true that "[t]here is no reasoned legal analysis by the Panel." Req. Reh'g 3. The above-reproduced passages illustrate the Panel's reasoned analysis.

In the Request for Rehearing, Patent Owner further stated:

> This complication is unnecessary if the Panel instead follows the determination of Judge Lourie and the Federal Circuit that the priority is determined on the day of filing and amendments to different families do not, *nunc pro tunc*, affect the filing date of already filed applications. *Loughlin v. Ling*, 684 F.3d 1289, 1293-94 (Fed. Cir. 2012).

Req. Reh'g 3.

In *Loughlin*, the issue was whether the Board correctly interpreted § 135(b)(2) in view of the plain language of the statute and the benefit provision of § 120. *Loughlin*, 684 F.3d. at 1293. The court stated: "The first sentence of § 120 permits an application to claim the benefit of an earlier filing date, such that the application is treated as having been effectively filed on the earlier date." *Id.* The court determined that the Board correctly construed "an application filed" in § 135(b)(2) as including an application filed earlier and benefiting from the provisions of § 120. *Id.* Patent Owner did not direct our attention to where in the decision "amendments to different families" were at issue in *Loughlin*, and we have found no mention of amendments. Req. Reh'g 3. Consequently, Patent Owner's reliance on this case to support their argument is unavailing.

Dosage

Claim 12 is drawn to a "method to avoid or delay the onset o fmuscular fatigue in a subject, comprising: a) providing to the subject an amount of" beta-alanine or an

ester or amide of it. We interpreted the claim to include a single one-time dosage of beta-alanine. DOA 10. We found that the Examiner had reasonable basis to believe that the single dosages administered in Gardner and Asatoor met the claim requirement of "avoiding or delaying the onset of muscular fatigue" because the administered amounts fell within the amounts disclosed in the '422 patent to be effective for this purpose. DOA 17–18, 19.

We discern no points misapprehended or overlooked in our determination that the claims are reasonably interpreted to include a single one-time dosage of beta-alanine which is effective to avoid or delay the onset of muscular fatigue. The '422 patent describe specific examples in which multiple dosages over two or more days are administered. '422 patent, col. 4, ll. 24-26. However, the '422 patent also generally refers to dosages over a 24-hour period without requiring multiple dosages during that period or without requiring periods of more than a day. *Id.*, col. 3, ll. 57-61 ("In one aspect, the total dosage of the beta-alanine for a 24-hour period is at least about 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.1, 6.2, 6.3, 6.4, 6.5 or more grams."). The claims do not contain express language of "multiple" dosages or "multiple" days over which dosages must be administered. Absent such express language that easily could have been introduced into the claim, Patent Owner contends that the requirement of increasing "alanylhistidine dipeptide synthesis in muscle tissue," "thereby avoiding or delaying the onset of muscular fatigue," and dietary supplementation dictates such multi-dose/multi-day dosage regimen. However,

Patent Owner has not directed us to disclosure in the '422 patent that requires such a claim interpretation. Instead, the patent describes a broad range of dosages for beta-alanine (e.g., from 100 mg to 6.5 grams (*id.*, col. 3, ll. 23-30)) without a clear explication that certain dosages must be administered over a period of days to achieve the claimed functional requirements.

Patent Owner cites to speculation by Dr. Harris about the fate of a single-dosage of beta-alanine, but we found such opinion testimony to be unpersuasive because it lacked objective scientific evidence to support it and because it did not distinguish a similar fate occurring with dosages of beta-alanine administered multiple times. DOA 11. Also, we do not find sufficient evidence that "dietary supplementation" means administration "over time" as alleged by Patent Owner. Req. Reh'g 22. For example, we have reviewed paragraphs 13-17 of the Harris Declaration dated December 13, 2012 cited by Patent Owner and do not find well-reasoned support for this interpretation.

In addition, Patent Owner cited publications by Mr. Bacombe and Dr. Tallon as supporting "Appellant's position that a 'one-time' single dose is not contemplated by the claims." Req. Reh'g 8. We addressed these reports in the Decision. *See, e.g.*, DOA 13. During reexamination of an unexpired patent, the PTO must give claims their broadest reasonable construction consistent with the specification as they would be understood by one of ordinary skill in the art. *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004); *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). Patent Owner did not explain how the Bacombe and Tallon reports bear upon the interpretation of the '422 patent claims. For example, while preferred embodiments may require beta-alanine to be administered over days or weeks as described by Mr. Bacombe and Dr. Tallon, such preferences does not negate the broader disclosure in the '422 patent covering a single effective dosage of beta-alanine.

We also have not been pointed to discernible points misapprehended or overlooked in our conclusion that Patent Owner did not meet the burden of demonstrating that the Examiner's determination was incorrect that the single-dosage of beta-alanine administered in Gardener and Asatoor avoided or delayed the onset of muscular fatigue. The dosages described in the publications fall within the range disclosed in the '422 patent. DOA 17. We simply have not been provided with evidence that the 2 and 1.8 gram dosages administered in Gardner and Asatoor, respectively, would not have avoided or delayed the onset of muscular fatigue in such a susceptible subject. *See Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1379 (Fed. Cir. 2005). Absent such evidence, and because the dosages are the same as those described in the '422 patent, we conclude that the Examiner did not err in determining that the publications were anticipatory to the claimed subject matter.

Patent Owner also states that the panel ignored the limitation of "dietary supplementation." Req. Reh'g 17. This is not correct. The Decision contained a section titled "dietary supplement" in which we concluded that

"Patent Owner did not elucidate a *structural* difference between dietary supplements and pharmaceutical agents." DOA 15. Patent Owner takes the position that the administration of beta-alanine in EP '593 is administration of a pharmaceutical drug, while administration of beta-alanine in their own patent is of a dietary supplement not anticipated by EP '593, despite it being the same compound in the same quantity and in a form that Patent Owner has not distinguished other than by name. Req. Reh'g 23. Patent Owner asserts that the amounts in EP '593 are to treat cancer, but admits that such amounts are overlapping: "the Panel trudges forth and alleges anticipation based only on the fact that there is a potential overlap in dosing ranges." *Id.*, 24. To the contrary, facts were established by the Examiner and in the Decision that the amount of beta-alanine administered in EP '593 falls within the range described in '422 patent. DOA 19; RAN 21. Because the amounts are the same, there is reasonable basis to believe that muscle fatigue would be avoided or delayed as claimed.

In view of the foregoing reasons, the rehearing is denied.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

DENIED

APPENDIX D — DECISIONS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT TRIAL AND APPEAL BOARD

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.*

Appendix D

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.

Appendix D

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).

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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).

4. Claim l 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 l -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).

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).

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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).

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

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.

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

Appendix D

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 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.

Appendix D

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

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.

Appendix D

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]	11/18/2008	7,504,376	03/17/2009
PROV	60/462,238	4/10/2003		
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		

Appendix D

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)111 ("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 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.

Appendix D

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. ln 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.

Appendix D

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") § 2163.11.3(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 NlPEP.[12] In *Hollmer v. Harari*, 681 F.3d 1351, 1355 (Fed. Cir. 2012), the Federal Circuit held:

> "[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. US. 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

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.

> 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.

Appendix D

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 modem 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.

Appendix D

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 1nuscle 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, n. 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.*

Appendix D

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 (AS) 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. 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.

---

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).

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

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.

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."

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-atninobutyryl-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.

Appendix D

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.*

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

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

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. if 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.

Appendix D

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

AFFIRMED

Appendix D

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 REQUEST FOR REHEARING

Patent Owner requests rehearing of the Decision on Appeal entered July 17, 2015 ("DOA") in the above-

identified reexamination of U.S. Pat. No. 8,067,381 B1 ("the '381 patent"). The '381 patent claims benefit of earlier filed applications, identified in the previous decision as the seventh, sixth, fifth, fourth, and so on, applications. DOA 6. In the Decision, the '381 patent was denied benefit to Application No. 10/209,169 ("the fourth application") and its ancestors because priority to it has been deleted by amendment during the pendency of the continuation application, Application No. 10/717,271 ("the fifth application"), from which the '381 patent arose. *Id.*, 8-15. As a consequence, the '381 patent was given the earliest filing date of Apr. 10, 2003, the date when a provisional application was filed, which is the only application to which the fifth application, as amended, claimed benefit. *Id.*, 6, 15.

In the Request for Rehearing, Patent Owner repeats its argument that priority vested at the time the sixth application was filed and that "[a]ny subsequent amendment of priority would only affect that individual application, i.e., the fifth application." Req. Reh'g 4. Patent Owner further contends that the sixth application, to which the '381 patent claims benefit (from the chain starting with the seventh application), "retained its priority to the entire patent family because it was filed with a complete priority chain prior to the amendment of the priority chain of the fifth application." *Id.*

Because this argument was already addressed in the Decision, we see no need of additional analysis. However, we further note a peculiarity that arises if Patent Owner's argument for priority is accepted. The fifth application matured into U.S. Pat. No. 7,504,376. DOA 6. U.S. Pat. No.

7,504,376 claims the benefit of only provisional application 60/462,238, filed Apr. 10, 2003. *See* U.S. Pat. No. 7,504,376 under "Related U.S. Application Data." However, on the other hand, Patent Owner in this proceeding asserts the 10/717,217 application "(the fifth application") is a CIP of the 10/209,169 application ("the fourth application"). DOA 6. 10/717,217, therefore, for one purpose is a CIP and, for another purpose, 10/717,217 is not a CIP and only claims benefit to a provisional application. We are not aware of a statutory provision which would allow an application to invoke two different claims to priority under 35 U.S.C. §§ 119 and 120 depending upon in which chain of applications it appears.

DENIED

APPENDIX E — EXCERPT OF THE SIXTH APPLICATION'S CROSS REFERENCE OF RELATED APPLICATIONS

Please amend the specification at page 1, under "Related Application," lines 4-16 as follows:

This application is a continuation of ~~allowed~~ U.S. patent application Ser. No. 10/717,217, filed November 18, 2003, now U.S. Patent No. 7,504,376, which claims the benefit of priority under 35 U.S.C. Section 119(e) of U.S. Provisional Application No. 60/462,238 filed April 10, 2003 and that is a continuation-in-part (CIP) of U.S. application serial no. 10/209,169, filed July 30, 2002, now U.S. Patent No. 6,680,294, which is a continuation of U.S. application serial no. 09/757,782, filed January 9, 2001, now U.S. Patent No. 6,426,361, which is a continuation of U.S. application serial no. 09/318,530, filed May 25, 1999, now U.S. Patent No. 6,172,098, which is a divisional of U.S. application serial no. 08/909,513, filed August 12, 1997, now U.S. Patent No. 5,965,596, which claims the benefit of foreign priority under 35 USC 119 to United Kingdom application nos. 9621914.2, filed October 21, 1996, now terminated and 9616910.7, filed August 12, 1996, now terminated. The aforementioned applications are incorporated by reference in their entirety.