

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

IOWA STATE UNIVERSITY RESEARCH	*	
FOUNDATION, INC., VANDERBILT	*	4:01-cv-90536
UNIVERSITY, and METABOLIC	*	
TECHNOLOGIES, INC.,	*	
	*	
Plaintiffs,	*	
	*	
v.	*	
	*	
WILEY ORGANICS, INC.,	*	
	*	
Defendant,	*	
	*	
v.	*	
	*	
CORNERSTONE NUTRITIONAL LABS,	*	
LLC, and GCI NUTRIENTS, INC.,	*	MEMORANDUM OPINION
	*	AND ORDER
Third-party Defendants.	*	
	*	

On May 22, 2002, Plaintiffs Iowa State University Research Foundation, Inc. (“ISURF”), Vanderbilt University (“Vanderbilt”), and Metabolic Technologies, Inc. (“MTI”) filed an amended complaint against Wiley Organics, Inc. (“Wiley”) alleging contributory infringement of and/or inducement to infringe some or all of a number of patents held by ISURF relating to the use of the substance β -hydroxy- β -methylbutyric acid (“HMB”) in humans and animals in violation of 35 U.S.C. § 271. On July 9, 2002, Defendant Wiley filed a Third Party Complaint against Cornerstone Nutritional Labs, LLC, Pharmline, Inc., and GCI Nutrients, Inc. asserting claims for indemnification in the event Plaintiffs sustain their claims for infringement against Wiley. On February 11, 2003, Defendant Wiley dismissed without prejudice its claims against Third-Party Defendant Pharmline, Inc. On April 25,

2003, Plaintiffs submitted two motions to this Court: 1) a Motion for Summary Judgment Against Defendant Wiley; and 2) a Motion for Claim Construction. In their summary judgment motion, Plaintiffs allege that there is no genuine issue of material fact relating to their claim of contributory infringement against Wiley. In their claim construction motion, Plaintiffs ask the Court to construe the terms “protein sparing,” “retention of nitrogen,” “subject,” and “patient” in claim 1 of U.S. Patent No. 5,348,979 (“the ‘979 patent”), entitled “Method of Promoting Nitrogen Retention in Humans.” On September 4, 2003, this Court heard oral argument from the parties on both motions. For the reasons detailed below, Plaintiffs’ Motion for Summary Judgment is **denied**. The Court’s construction of the disputed terms in the ‘979 patent is also set forth below.

I. FACTS

Plaintiff ISURF is the exclusive owner of U.S. Patent Nos. 4,992,470, 5,028,440, 5,087,472, 5,360,613, 6,031,000, 6,103,764, and 6,291,525. Plaintiff Vanderbilt co-owns the ‘979 patent with ISURF. Plaintiff MTI is currently the exclusive licensee of the aforementioned patents and has the exclusive right to grant sublicenses of rights in the patents. All of these patents relate to the use of HMB in humans and animals. HMB is a metabolite of the amino acid leucine. It occurs naturally in the body, but its normal level from dietary sources and natural processes is low.

Defendant Wiley is a custom chemical manufacturer that produces bulk quantities of pharmaceuticals, specialty gases, enzymes, resins, polymers, solvents, food additives, and other natural products. Wiley does not engage in retail sales of these chemicals; rather, it sells them to commercial customers. From approximately 1995 to 2000, Wiley manufactured and supplied HMB to Plaintiff MTI. Over a period of several years, Wiley also sold HMB to at least three other entities, Cornerstone

Nutritional Labs, LLC, Pharmline, Inc., and GCI Nutrients, Inc. Plaintiffs have alleged that Wiley's sales of HMB to entities other than Plaintiff MTI constitutes contributory infringement and that these end users of Wiley's HMB directly infringe claim 1 of the '979 patent.

At the root of both of Plaintiffs' motions is a fundamental disagreement between the parties relating to whether the '979 patent specifically covers the administration of HMB to normal, healthy human subjects as a means of building lean muscle mass. The '979 patent, issued in 1994, claims a method of administering HMB as a nutritional supplement to humans as a means of conserving protein in the body and reducing the amount of nitrogen excreted by the body.

II. CLAIM CONSTRUCTION

The Court's construction of claim 1 of the '979 patent impacts the questions of infringement that underlie the Court's analysis of summary judgment on the issue of contributory infringement. For this reason, the Court will address Plaintiffs' claim construction motion first.

A. The *Markman* Analysis

In affirming a decision of the Federal Circuit, the Supreme Court made clear in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-391 (1996), that courts must decide how to construe the claims of a patent as a matter of law. Plaintiffs in this case have requested that the court construe disputed language in claim 1 of the '979 patent. Claim 1 reads in its entirety:

The method of protein sparing, comprising orally or intravenously administering to a human subject an effective amount of β -hydroxy- β -methylbutyric acid (HMB) for increasing the retention of nitrogen, said HMB being in an edible or intravenously-administrable form selected from (I) its free acid form, (ii) its sodium, potassium, or calcium salt, (iii) its methyl or ethyl ester, or (iv) its lactone, and continuing the said administration of HMB until the amount of nitrogen in the patient's urine has substantially decreased.

Specifically, the Plaintiffs have asked the court to construe 1) “protein sparing” and “reduction of nitrogen” to mean building lean muscle mass; and 2) “subject” and “patient” to mean any person undergoing the claimed method. In response, Defendant Wiley argues that Plaintiffs’ proposed construction of these terms stretches beyond the “ordinary meanings” of the terms, and urges this Court to give these terms their ordinary meanings.

In construing claims, “[i]t is well-settled that . . . the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). In cases where the intrinsic evidence alone resolves any ambiguities in the claim language, a court should not rely on extrinsic evidence to alter or change the meaning of that language. *Id.* at 1583. The court can rely on expert testimony and other extrinsic evidence to help it understand the underlying technology, but extrinsic evidence about the proper construction of a claim term “may only be relied upon if the patent documents, taken as a whole, are insufficient to enable the court to construe disputed claim terms. Such instances will rarely, if ever, occur.” *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308-09 (Fed. Cir. 1999) (quoting *Vitronics*, 90 F.3d at 1585).

B. “Subject” and “Patient”

1. Claim Language

In any claim construction analysis, “[t]he appropriate starting point . . . is always with the language of the asserted claim itself.” *Phonometrics, Inc. v. Northern Telecom Inc.*, 133 F.3d 1459, 1464 (Fed. Cir. 1998) (citation omitted).

As the Supreme Court stated in *White v. Dunbar*, 199 U.S. 47, 52, 30 L.Ed. 303, 7 S.Ct. 72 (1886): ‘The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an invasion of the law to construe it in a manner different from the plain import of its terms.’

Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1458 (Fed. Cir. 1984). The words used in a patent claim are examined from the perspective of a person skilled in the art. *Tegal Corp. v. Tokyo Electron America, Inc.*, 257 F.3d 1331, 1342 (Fed. Cir. 2001).

Plaintiffs urge the Court to construe the words “patient” and “subject” in claim 1 to include anyone undergoing the protein sparing therapy described in claim 1. Defendant Wiley counters that the claim language does not cover normal, healthy individuals, such as body builders, who use HMB in combination with a resistance exercise program to increase lean muscle mass, but who do not monitor urinary nitrogen output nor cease using the supplement once nitrogen excretion decreases.

An examination of the dictionary definitions of the words “subject” and “patient” is insufficient to determine the proper construction of claim 1. The Oxford English Dictionary defines “patient” as, *inter alia*, 1) “[o]ne who suffers from bodily disease; a sick person;” 2) “[o]ne who is under medical treatment for the cure of some disease or wound; one of the sick persons whom a medical man attends; an inmate of an infirmary or hospital;” and 3) “[a] person or thing that undergoes some action, or to whom or which something is done; ‘that which receives impressions from external agents.’” The relevant definition of “subject” in the Oxford English Dictionary is “[t]hat which is or may be acted or operated upon; a person or thing towards which action or influence is directed, or that is the recipient of some treatment.” The Court does not believe these definitions conclusively determine which of the asserted claim constructions is the correct one. According to the dictionary definitions, both words are

susceptible of a construction that could support either Plaintiffs' position or Defendant's.

Looking beyond the words themselves to the context in which they are situated in the claim, however, the Court finds Defendant's proposed construction to be the more strongly supported. The critical phrase that informs the meaning of the words patient and subject is found at the end of claim 1. The claim specifies that the process of administering HMB is to be continued "until the amount of nitrogen in the patient's urine has substantially decreased." '979 patent, col. 6, lines 15-16. This phrase signals two things. First, the fact that a cessation of the process is contemplated after a "substantial decrease" in a patient's urinary nitrogen level indicates that the usage of HMB contemplated by claim 1 relates to normalizing urinary nitrogen levels in a patient or subject. If the phrase did not relate to restoring a normal nitrogen balance to the subject or patient, there would be nothing in the claim that would indicate to a person skilled in the art when a "substantial[] decrease[]" had occurred. Second, the phrase signals that the "subject" or "patient" is likely to be receiving the claimed treatment in a setting where there is a capacity to monitor urinary nitrogen levels. The Court is not aware of the full scope of ways in which urinary nitrogen levels can be assessed, but there has been no evidence presented by either party to indicate that such a measurement can be undertaken by an individual not actively under the care or treatment of a health care professional. Both of the conclusions that can be drawn from the final phrase of claim 1 support the Defendant's proposed construction of "subject" and "patient" as encompassing individuals other than normal, healthy individuals who are not experiencing nitrogen imbalance.

2. The Specification and Prosecution History

The patent specification, or written description, is examined "in particular to determine if the

patentee acted as his own lexicographer, as our law permits, and ascribed a certain meaning to [disputed] claim terms. If not, the ordinary meaning, to one skilled in the art, of the claim language controls.” *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998). Viewed as a whole, the ‘979 patent specification supports Defendant’s assertion that the words “subject” and “patient” in claim 1 do not refer to normal, healthy individuals who are not experiencing a negative nitrogen balance. Beginning with the abstract, which indicates that “[t]he method can be used with patients having a negative nitrogen balance due to disease conditions, and also with normal elderly persons who are subject to protein loss,”¹ and continuing throughout, the specification clearly paints a picture of the patented process as a therapeutic one, designed for use in elderly or infirm individuals.

First, the specification indicates that “[m]onitoring nitrogen content of urine is especially important where the patient has or is expected to have a persistent negative nitrogen balance.” ‘979 patent, col. 1, lines 34-37. Since the language of claim 1 clearly contemplates the monitoring of a subject or patient’s urine in conjunction with the administration of HMB, this assertion by the inventors in the specification supports a construction of “subject” or “patient” as an individual who “has or is expected to have a persistent negative nitrogen balance.”

Immediately following this passage, the patent specification details the situations in which

¹The patent specification discloses the link between protein and nitrogen in the body. Specifically, “accelerated protein breakdown . . . is manifested by increased nitrogen loss.” ‘979 patent, col. 1, lines 42-43. The Preliminary Expert Witness Statement of Dr. Donald C. Beitz, one of Plaintiffs’ experts, indicates that quantification of changes in bodily protein is possible through monitoring the change in the amount of “waste nitrogenous compounds” in a person’s urine. Plaintiffs’ Appendix in Support of Motion for Summary Judgment Against Defendant Wiley Organics, Inc. (“Plaintiffs’ App.”), Exhibit 16 at 804. Thus, a negative nitrogen balance, as manifested through testing of an individual’s urine, is indicative of excessive protein loss in the body.

promoting nitrogen retention, the subject of the patent, has “therapeutic importance”: where the patient has been subjected to trauma or stress *which could induce potential nitrogen loss*, where injury and sepsis result in *accelerated protein breakdown*, manifested by *increased nitrogen loss*, where a patient is experiencing a severe disease, like cancer or AIDS, or where an elderly patient is going through the normal aging process, which can involve a commensurate *loss of muscle protein*. ‘979 patent, col. 1, lines 38-48 (emphasis added).

The last paragraph of the “Summary of Invention” in the ‘979 patent summarizes the uses of the claimed invention: “In general, the method of this invention can be used to improve nitrogen balance for human subjects whenever it is medically desirable *to counter urinary nitrogen loss* which cannot be overcome nutritionally.” ‘979 patent, col. 3, lines 25-29 (emphasis added). The fact that the specification focuses specifically on nitrogen and protein *loss* supports the construction that the claimed invention is a process for using HMB therapeutically, where an individual - whether a “subject” or “patient” - has a nitrogen imbalance that manifests in increased urinary nitrogen levels.

Plaintiffs make three main arguments to counter this evidence and support their proposed construction of “subject” and “patient” as including any individual undergoing the claimed process: 1) particular passages in the specification support such a construction; 2) the experimental example disclosed in the specification was conducted on normal, healthy adult subjects; and 3) the doctrine of claim differentiation requires that claim 1 be read to include normal, healthy individuals. For the reasons discussed below, the Court finds these arguments unpersuasive.

First, Plaintiffs point to three passages in the specification that they believe support the position that claim 1 covers administration of HMB to normal, healthy individuals:

At dosages effective for promoting nitrogen retention, HMB is not known to be toxic or to have any undesirable side effects. It can be safely administered to persons afflicted with trauma, stress, or other catabolic condition, including people undergoing semistarvation. HMB can also be used in conjunction with weight reduction programs where it is desired to minimize loss of tissue protein. Moreover, it is believed that HMB can be regularly incorporated in food supplements for the elderly, thereby tend [sic] to offset the protein losses which may occur in persons of advanced age.

‘979 patent, col. 3, lines 15-25.

A substance that can increase nitrogen retention in humans who are not experiencing a negative nitrogen balance has manifest therapeutic potential.

‘979 patent, col. 3, lines 9-12.

HMB appears to be a potent agent for promoting nitrogen retention even in normal subjects.

‘979 patent, col. 6, lines 3-5.

As to the first passage, the Court does not find that it supports Plaintiffs’ position. The passage provides that HMB can be safely administered to a number of categories of people, but all of the categories of people are described as individuals whose nitrogen or protein levels are out of balance.² The Court finds that the specific enumeration in this passage of a number of categories of people who can undergo the therapy described in the patent, where each category is specifically denoted as susceptible to protein or nitrogen loss, more aptly supports the construction that claim 1 does not cover individuals whose protein and nitrogen levels are in balance or would be expected to be in balance.

As to the second passage, it also provides stronger support for Defendant’s proposed

²Although this particular passage does not give any indication of the nitrogen or protein levels of persons afflicted with trauma, stress, or other catabolic conditions, the specification notes elsewhere that trauma, stress, and injury can result in nitrogen loss. ‘979 patent, col. 1, lines 38-45.

construction than for Plaintiffs'. While the passage does contain a reference to "humans who are not experiencing a negative nitrogen balance," the sentence as a whole indicates that the use being claimed by the inventors is a therapeutic use. The healthy humans who can experience the benefits of nitrogen retention are not the focus of the inventors in this passage; rather, they are mentioned as a contrast to the population targeted by the process described in the claims of the '979 patent.

The last passage is equivocal, at best, for Plaintiffs. As with the previous passage, the words "even in" suggest that the inventors are drawing a contrast between the target population of the patented process, individuals with protein or nitrogen imbalances, and a separate and distinct population of "normal subjects" who are not the focus of the process claimed in the patent.

Plaintiffs additionally rely on the fact that the experimental study disclosed in the '979 patent was performed on "normal healthy adults." The study Plaintiffs point to was conducted on five, "well-nourished, healthy" male subjects who were "screened for normalcy." '979 patent, col. 5, lines 26-27, 64. The results of the study described by the inventors show a statistically significant decrease in the average amount of urine nitrogen during the period where the experimental subjects were fed HMB instead of a placebo. '979 patent, col. 5, lines 62-67. The Court does not find the study controlling as to the definition of "subject" and "patient" in claim 1. "The claim is the measure of [a patentee's] right to relief, and while the specification may be referred to to limit the claim, it can never be made available to expand it." *McClain v. Ortmyer*, 141 U.S. 419, 423 (1891); *see also Johnson & Johnston Associates Inc., v. R.E. Service Co., Inc.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) (en banc) ("[T]he claims, not the specification, provide the measure of the patentee's right to exclude."). In circumstances similar to those presented here, the Federal Circuit has declined to allow patent holders to narrowly

claim an invention “to avoid prosecution scrutiny by the [Patent and Trademark Office (“PTO”)]” and then use a more broadly worded specification to assert infringement. *See Johnson & Johnston Associates Inc.*, 285 F.3d at 1054-55. Sanctioning such a practice “would merely encourage a patent applicant to present a broad disclosure in the specification of the application and file narrow claims, avoiding examination of broader claims that the applicant could have filed consistent with the specification.” *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1107 (Fed. Cir. 1996). “By enforcing the *Maxwell* rule, the courts avoid the problem of extending the coverage of an exclusive right to encompass more than that properly examined by the PTO.” *Johnson & Johnston Associates Inc.*, 285 F.3d at 1055 (citing *Keystone Bridge Co. v. Phoenix Iron Co.*, 95 U.S. 274, 278 (1877)).

In the case at bar, the prosecution history provides compelling evidence that to construe the words “subject” and “patient” in claim 1 to include individuals who are not experiencing a negative nitrogen balance would in fact allow the very situation that the *Maxwell* rule seeks to avoid. In an Examiner’s Action dated June 16, 1993,³ addressing the application for what later became the ‘979 patent, the PTO examiner rejected the inventors’ proposed claims 1 through 14 on the basis of obviousness.⁴ In doing so, the examiner explained:

[T]o the skilled artisan motivated by a reasonable expectation of success, it would have

³Appendix in Support of Defendant’s Resistance to Plaintiffs’ Motion for Summary Judgment and Plaintiffs’ Motion for Claim Construction (“Defendant’s App.”), Exhibit A at 172-176.

⁴The proposed claim 1 addressed in the Examiner’s Action is identical to what later became claim 1 of the ‘979 patent, except that the proposed claim 1 addressed by the examiner included the parenthetical “(isovaleryl lactone)” after the word “lactone.” The examiner rejected the parenthetical as contrary to 35 U.S.C. § 112, requiring the potential patentee to particularly point out and distinctly claim the subject matter regarded as the invention. This amendment has no effect on the meaning of the words “subject” and “patient” in claim 1.

been obvious to employ HMB in patients *in a state of excess muscle protein degradation* because as highlighted by Nissen, HMB has been found to be more effective for improving growth metabolism of domestic mammals than KIC and the major effect of HMB is to increase markedly the development of lean tissue . . . The skilled artisan would have immediately appreciated that HMB *improves nitrogen balance* because muscle development in mammals, i.e., anabolism, necessarily requires a positive nitrogen balance.

(emphasis added).

The statements of the examiner shed light on the fact that review of the '979 patent application was based upon the PTO's understanding of the claims as covering the process described in claim 1 only for individuals with a negative protein or nitrogen balance. Consequently, to allow a broader meaning for the terms "subject" and "patient" to be imported from the specification would contravene the decision of the Federal Circuit in *Johnson & Johnston Associates Inc.*, 285 F.3d at 1054-55 (Fed. Cir. 2002) and would mean that the inventors were able to draft claims narrowly to avoid prosecution scrutiny, but then were later able, for infringement purposes, to take advantage of a broader meaning that had not been examined by the PTO.

The examiner's statement is significant in two additional respects. First, a PTO examiner assigned to examine a particular patent is skilled in the art of the patent which he or she is evaluating. *See In re Berg*, 320 F.3d 1310, 1315 (Fed. Cir. 2003) (patent examiners are "persons of scientific competence in the fields in which they work"). This examiner, a person skilled in the art at the time the patent was evaluated and issued, interpreted the claims of the '979 patent, including claim 1, as covering the administration of HMB to only those individuals "in a state of excess muscle protein degradation." The examiner's statement that HMB "improves nitrogen balance" provides further support that the examiner understood the proposed claims to cover a method of normalizing nitrogen

levels in the body, which can only have relevance where an initial imbalance exists.

Second, in making the above-cited statement in the Examiner's Action, the examiner put the inventors on notice of his understanding of the language of the claims, including claim 1. In responding to the Examiner's Action and proposing amendments to the claims, the inventors made no attempt to clarify the examiner's understanding of the scope of the claimed process to inform him or her, as Plaintiffs now argue, that the words "subject" and "patient" in claim 1 referred not only to individuals "in a state of excess muscle protein degradation," but also to normal, healthy individuals. This failure is incredibly strong evidence that such a construction was never intended by the language of claim 1. The Court finds it extremely difficult to believe that if the inventors had intended for the language of claim 1 to cover all individuals receiving the therapy therein described, the inventors would not have clarified this after a clear statement by the patent examiner evidenced a completely different understanding of the intended scope of the claim. Although the subjective intent of an inventor is irrelevant to a claim construction analysis in the abstract, to the extent such information is disclosed in the prosecution history of the patent it is highly relevant. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 987 (Fed. Cir. 1995) ("The subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim (except as documented in the prosecution history)"), *aff'd* 517 U.S. 370 (1996) ; *Springs Window Fashions LP v. Novo Industries, L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003) ("The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent."). Here, a person skilled in the art would have been put on notice by the examiner's statement that the '979 patent claimed a particular process as applied to a group of individuals "in a state of excess muscle protein

degradation.” Nothing in the inventors’ written response to the examiner’s statement,⁵ also contained in the prosecution history, would have indicated to a person skilled in the art that this was not in fact the proper scope of the claim. Thus, to allow such a construction to be imposed by Plaintiffs in this action over nine years after the patent issued would severely undermine the notice function served by the prosecution history.

The bulk of the specification supports the reading that is dictated by the language of the claim; that is, that the words “subject” and “patient” in claim 1 refer to individuals in a state of negative nitrogen balance. The Court finds no evidence that the inventors intended to act as their own lexicographers and give the words “patient” and “subject” a meaning different from that suggested by the claim language itself. Additionally, the Court finds that the prosecution history constitutes extremely compelling evidence that the terms “subject” and “patient” refer only to those individuals in a state of negative nitrogen balance.

Given the conclusiveness of the intrinsic evidence in determining the meaning of the words “subject” and “patient” in claim 1, the Court finds it unnecessary and improper to engage in an analysis of any extrinsic evidence, including expert testimony. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d at 1308-09; *Vitronics Corp. v. Conceptronics, Inc.*, 90 F3d at 1583.

Finally, Plaintiffs argue that their proposed construction of “subject” and “patient” as indicating any person undergoing the process described in claim 1 is supported by the doctrine of claim

⁵Defendant’s App., Exhibit A at 178-82.

differentiation. Plaintiffs argue that this doctrine dictates that claims should be presumed to cover different inventions and that claim constructions that result in separate claims covering the same invention should be avoided. Specifically, Plaintiffs point to the fact that the other independent claims of the '979 patent, claims 6, 11, and 14, each contain some limitation on the type of persons covered by the claim. Claim 6 covers a method of treating a person having a negative nitrogen balance, claim 11 covers a method of improving the protein nutrition of elderly human subjects, and claim 14 covers a method of treating patients who are receiving intravenous therapy and have an excessive loss of nitrogen. Plaintiffs argue against construing claim 1 to include any limitation that would render any of the individuals comprising the target populations of the processes described in claims 6, 11, or 14 a member of the claim 1 target population as well. That is, they argue against any construction of claim 1 that would find the process described therein to apply to individuals with a negative nitrogen balance, elderly individuals, or individuals receiving intravenous treatment who are experiencing an excessive loss of nitrogen. Such a construction, they argue, would render claim 1 redundant, and would violate the doctrine of claim differentiation.

First, the Court notes that claim 1 is the broadest of the independent claims of the '979 patent and can be differentiated in this way from each of the other independent claims. Claim 6 and claim 11 each claim a specific dosage of HMB, while claim 1 merely claims the method of administering "an effective amount" of HMB. Thus, claim 1 would not be redundant with respect to claim 6 or claim 11 if a person with a negative nitrogen balance, in the case of claim 6, or an elderly human subject, in the case of claim 11, received a dosage different from the ones described in claim 6 or claim 11, respectively. The Court finds no indication in the specification or prosecution history that the dosages

listed in claim 6 and claim 11 are the only appropriate dosages for elderly individuals or individuals with a negative nitrogen balance.

Claim 1 can be differentiated from claim 14 by examining the breadth of the claims as well. Claim 1 claims the use of HMB in any of four forms: 1) its free acid form, 2) its sodium, potassium, or calcium salt form; 3) its methyl or ethyl ester form; or 4) its lactone form. In contrast, claim 14 only claims the intravenous use of HMB in its calcium salt (Ca-HMB) form or its sodium salt (Na-HMB) form. Thus, claim 1 would not be redundant with respect to claim 14 where HMB was administered to a patient undergoing intravenous therapy either 1) other than intravenously (i.e. orally); or 2) in a form other than its calcium salt or sodium salt form. Since patentees can assert their claims in both broad and narrow aspects, claims are deemed differentiated if they differ in breadth from one another.

Friction Div. Products, Inc. V. E.I. Du Pont de Nemours & Co., Inc., 693 F.Supp. 114, 123-24 (D. Del. 1988), *aff'd*, 883 F.2d 1027 (Fed. Cir. 1989). As such, the Court finds no claim differentiation problem with construing the terms “subject” and “patient” in claim 1 to mean individuals with a negative nitrogen balance.

Even if such a problem were found to exist, however, “[a]lthough the doctrine of claim differentiation may at times be controlling, construction of claims is not based solely upon the language of other claims; the doctrine cannot alter a definition that is otherwise clear from the claim language, description, and prosecution history.” *O.I. Corp. v. Tekmar Co., Inc.*, 115 F.3d 1576, 1582 (Fed. Cir. 1997) (citing *Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1567, n.15 (Fed. Cir. 1990)); *see also Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998) (“[T]he doctrine of claim differentiation can not broaden claims beyond their correct

scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence. . . [Claims] that are written in different words may ultimately cover substantially the same subject matter.”). In this case, it is sufficiently clear from the context of the claim language, the patent specification, and the prosecution history that claim 1 refers to individuals in a state of negative nitrogen balance. The Court finds no evidence that the inventors intended to act as their own lexicographers and give the words “patient” and “subject” a meaning different from that suggested by the claim language itself. Additionally, the Court finds that the prosecution history constitutes extremely compelling evidence that the terms “subject” and “patient” refer only to those individuals in a state of negative nitrogen balance. Even if such a construction of claim 1 rendered one of the other independent claims of the ‘979 patent redundant, such a construction would nonetheless be proper and compelled based on the intrinsic evidence.

Given the conclusiveness of the intrinsic evidence in determining the meaning of the words “subject” and “patient” in claim 1, the Court finds it unnecessary and improper to engage in an analysis of any extrinsic evidence, including expert testimony. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d at 1308-09; *Vitronics Corp. v. Conceptiontronics, Inc.*, 90 F3d at 1583.

C. “Retention of Nitrogen”

Read in the context of claim 1, the phrase “retention of nitrogen” does not appear to pose a great interpretive challenge to the Court. Although Plaintiffs argue that “retention of nitrogen,” along with “protein sparing,” should be construed to mean building lean muscle mass, the Court does not believe that such an interpretation is warranted based on the language of the claim considered in

conjunction with the specification. The respective meanings of the terms “retention of nitrogen” and “protein sparing” are clear upon examination of the claim language and specification. The Court finds that a construction of these terms that reaches further to include a description of the secondary effects in the body when “retention of nitrogen” or “protein sparing” takes place is not warranted. The Federal Circuit has cautioned that a district court should not

under the rubric of claim construction . . . give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product. Rather, after a court has defined the claim with whatever specificity is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.”

PPG Industries v. Guardian Industries Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998).

The language of claim 1 indicates that retention of nitrogen refers to retaining nitrogen in the body. The claim describes a method that is undertaken by administering an effective amount of HMB for increasing the “retention of nitrogen.” The last clause of the claim indicates that the administration of HMB should be continued “until the amount of nitrogen in the patient’s urine has substantially decreased.” This indicates that determining whether retention of nitrogen has occurred is accomplished by measuring the amount of nitrogen excreted in the patient’s urine.

The specification as well offers a very clear picture of what nitrogen retention means in the context of the claims. In summarizing their invention, the inventors noted that in experiments leading to the invention, “nitrogen retention was increased [due to HMB supplementation] by an average of 18%.” ‘979 patent, col. 2, line 66. Later in the patent document, the inventors detail the results of the experiment to which they referred in citing an increase in nitrogen retention. In that experiment, the

authors reported an 18% decrease in the average amount of urine nitrogen in the subjects. ‘979 patent, col. 5, lines 62-64. Thus, retention of nitrogen refers to a decrease in the excretion of nitrogen from the body, as measured by the amount of nitrogen in a subject or patient’s urine.

D. “Protein Sparing”

The Court is of the opinion that the phrase “protein sparing” in claim 1 is capable of a similarly straightforward construction. As previously discussed, the patent specification discloses a direct link between protein and nitrogen loss in the body; namely, accelerated protein breakdown is manifested by increased nitrogen loss. ‘979 patent, col. 1, lines 42-43. “Protein wasting,” which is defined as “excessive breakdown of tissue proteins,” is equated with “excessive loss of body nitrogen.” ‘979 patent, col. 1, lines 16-20; *see also* ‘979 patent, col. 1, lines 51-52. “Protein sparing” is described as an antidote to protein wasting, or the breakdown of tissue proteins, with the specification indicating that “protein sparing therapy may be indicated” for elderly patients who are experiencing loss of muscle protein due to aging. ‘979 patent, col. 1, lines 45-48.

The structure of claim 1 demonstrates that “protein sparing” is the result that is achieved by the process described therein. ‘979 patent, col. 6, lines 7 (“The method of protein sparing, comprising . . .”). The process comprises administering HMB in one of a variety of forms “until the amount of nitrogen in the patient’s urine has substantially decreased.” Thus, an inference is created by the claim language that protein sparing is achieved when nitrogen retention occurs. The only method that is disclosed in the patent for measuring the fluctuation of protein in the body is the measurement of the nitrogen excreted in an individual’s urine. *See* ‘979 patent, col. 1, lines 16-20; ‘979 patent, col. 5, lines 64-68, col. 6, lines 1-3.

Viewing the intrinsic evidence as a whole, protein sparing in claim 1 means the retention of protein in the body sufficient to trigger a decrease in the level of nitrogen excreted by the body, as measured by urinary nitrogen levels.

III. SUMMARY JUDGMENT

A. The Legal Standard

In addition to requesting that this Court construe disputed terms of claim 1 of the '979 patent, the Plaintiffs in this action have also asked the Court to grant summary judgment on the issue of contributory infringement. Summary judgment is "as appropriate in a patent case as it is in any other case." *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670, 672 (Fed. Cir. 1990) (internal cites omitted). Fed. R. Civ. P. 56(c) provides that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." An issue is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material if the dispute over it might affect the outcome of the suit under the governing law. *Id.*

The moving party has the burden of demonstrating the absence of a genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *Anderson*, 477 U.S. at 248. In meeting its burden, the moving party may support his or her motion with affidavits, depositions, answers to interrogatories, and admissions. *See Celotex*, 477 U.S. at 323. Where the moving party bears the burden of proof on an issue, "he cannot prevail 'unless the evidence that he provides on that issue is

conclusive.” *E.E.O.C. v. Union Independiente de la Autoridad de Acueductos y Alcantarillados de Puerto Rico* (1st Cir. 2002) (quoting *Torres Vargas v. Santiago Cummings*, 149 F.3d 29, 35 (1st Cir. 1998)); *see also Calderone v. United States*, 799 F.2d 254, 258 (6th Cir. 1986) (where the moving party has the burden of proof on an issue, “his showing must be sufficient for the court to hold that no reasonable trier of fact could find other than for the moving party”) (emphasis and citation omitted).

Once the moving party has carried its burden, the nonmoving party must go beyond the pleadings and, by affidavits or by the depositions, answers to interrogatories, and admissions on file, designate the specific facts showing that there is a genuine issue for trial. *See* Fed. R. Civ. P. 56(c), (e); *Celotex Corp.*, 477 U.S. at 322-323; *Anderson*, 477 U.S. at 257. The role of summary judgment is to “pierce the boilerplate of the pleadings and assay the parties’ proof in order to determine whether trial is actually required.” *Wynne v. Tufts University School of Medicine*, 976 F.2d 791, 794 (1st Cir. 1992) (citations omitted). In order to survive a motion for summary judgment, the nonmoving party must present enough evidence for a reasonable jury to return a verdict in his or her favor. *Anderson*, 477 U.S. at 257.

On a motion for summary judgment, the Court is required to review the evidence in “a light most favorable to the non-movant, and all reasonable inferences must be drawn in the non-movant’s favor.” *J & M Corp. v. Harley-Davidson, Inc.*, 269 F.3d 1360, 1365 (Fed. Cir. 2001) (citing *Anderson*, 477 U.S. at 255). The Court does not weigh the evidence or make credibility determinations. *See Anderson*, 477 U.S. at 252. The Court only determines whether there are any disputed issues and, if so, whether those issues are both genuine and material. *Id.*

B. Discussion

In order to establish contributory infringement, Plaintiffs must prove four elements: 1) the defendant sold a component or material for use in practicing the patented process; 2) the component or material constitutes a material part of the invention; 3) the defendant knew that the item it sold was especially made or adapted for use in infringing the patented process; and 4) the item sold is not a staple article or commodity of commerce suitable for substantial noninfringing use. 35 U.S.C. § 271(c) (2003). Additionally, a finding of contributory infringement always depends on direct infringement of the patented process by the end users of the component or material. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 483 (1964); *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670, 673 (Fed. Cir. 1990). Because the Plaintiffs have failed to show the absence of a genuine factual dispute regarding two critical elements of Plaintiffs' contributory infringement claim, direct infringement by Wiley's end users and the lack of any substantial noninfringing uses of HMB, the Court denies Plaintiffs' motion for summary judgment.

At the heart of the dispute between these parties, as evidenced in the extensive briefing by the parties on the issue of claim construction, is whether the '979 patent is infringed when the process described in claim 1 of that patent is administered to body builders for the purpose of building lean muscle mass. That determination affects both the issues of whether HMB is a nonstaple article of commerce and whether the end users of the HMB sold by Defendant directly infringed the '979 patent, both essential elements of Plaintiffs' contributory infringement claim. As indicated in the Court's discussion of claim construction, a patent infringement analysis involves two steps. First, the claims must be construed in order to determine their proper scope and meaning. Determining the proper

construction of claims is done by courts as a matter of law. Second, the claims must be compared to the accused device or method. Whether a claim is infringed by the accused product is a question of fact. *J & M Corp. v. Harley-Davidson, Inc.*, 269 F.3d 1360, 1366 (Fed. Cir. 2001). This Court has, in this opinion, undertaken the first part of the infringement analysis, construing the disputed terms of the ‘979 patent. What remains to be determined as a matter of fact is whether the use of HMB in the body building and consumer fitness market infringes claim 1 of the ‘979 patent, viewing the claim in the light of the construction set forth by this Court.

The significance of the Court’s construction of claim 1 is that it highlights the relevance of the fact of the nitrogen balance of body builders and other fitness enthusiasts who take an HMB supplement to increase lean muscle mass. The Court notes that the parties have not tackled the issue of the nitrogen balance of body builders taking HMB supplements head-on. At the time the parties briefed the summary judgment motion, the Court had not yet decided claim construction, so the parties may not have viewed the nitrogen balance of body builders taking HMB as critical to the issue of infringement on summary judgment. However, the Court does have before it some evidence describing or demonstrating the body building use of HMB.⁶ Nowhere in this evidence is there any indication that a negative nitrogen balance is a prerequisite for body builders who desire to take HMB as a supplement to increase lean muscle mass.⁷ Consequently, viewing the evidence in the record in the light

⁶See Plaintiffs’ App., Exhibit 8; Defendant’s App., Exhibit C, Exhibit D.

⁷Although clearly not dispositive on this issue, Plaintiffs noted in their Brief of Authorities in Reply to Defendant’s Resistance to Motion for Claim Construction that body builders are “members of the general population of healthy adults” and would fall into the category of “normal well-nourished healthy adults that are not experiencing any medical problems or wasting conditions.”

most favorable to the non-moving party, the Defendant, the Court finds that a reasonable jury could find that the '979 patent is not infringed by the body building use of HMB.

The issue of whether the body building use of HMB infringes claim 1 of the '979 patent is relevant in determining 1) whether the end users of the HMB sold by Defendant Wiley directly infringed any patent held by Plaintiffs; and 2) whether HMB has any substantial noninfringing uses.

1. Direct Infringement

On the issue of direct infringement by Wiley's end users, an essential element of Plaintiffs' claim for contributory infringement, the only evidence before the Court that addresses what the end users of the HMB sold by Defendant Wiley actually did with the HMB they purchased is contained in an affidavit from Dr. Steven Nissen, the CEO of Plaintiff MTI. Dr. Nissen asserts that he has "carefully monitored the markets for HMB or HMB-containing products since the first substantial commercial sales of HMB in 1996" and is "aware of no substantial commercial use of HMB or HMB-containing products other than to increase muscle mass (primarily by fitness enthusiasts)" or to prevent muscle wasting.⁸ The only evidence Defendant has submitted to rebut the conclusion that its end users are engaged in retail sales of HMB or HMB-containing products for the purpose of increasing muscle mass is a sales summary of Wiley's HMB sales indicating that Defendant made some sales of small quantities of HMB,⁹ which Defendant argues permits the inference that the end use of HMB from these sales was for research purposes.

⁸Plaintiffs' Supplemental Appendix in Support of Motion for Summary Judgment against Defendant Wiley Organics, Inc., Exhibit 17 at 863.

⁹See Defendant's App., Exhibit E.

If there were conclusive evidence in the record that the body building use of HMB to increase lean muscle mass did in fact infringe claim 1 of the '979 patent, the record might be sufficient to sustain a finding of direct infringement on summary judgment by at least some of Wiley's end users. However, as discussed above, there is a genuine dispute over this issue. Since Plaintiffs have presented circumstantial evidence that it is this use that is practiced by Wiley's end users, there is a genuine dispute as to whether their use of the HMB provided to them by Defendant Wiley constitutes direct infringement.

2. Substantial noninfringing use

In order to make out the fourth prong of their contributory infringement claim, Plaintiffs must prove that there are no substantial noninfringing uses of HMB. The Court has already concluded that there is a genuine factual dispute as to whether the '979 patent is infringed by the body building use of HMB, opening the door to a finding that there is at least some use of HMB that does not infringe the '979 patent. After addressing the issue of infringement, there remains the question of whether any potentially noninfringing use of HMB can be deemed "substantial." The parties do not dispute that the market for HMB as a nutritional supplement is widespread and well-documented. The Plaintiffs introduced into evidence a book entitled "Building Muscle Mass, Performance and Health with HMB," co-authored by John Fuller, part of the research team at the University of Iowa that developed many of the patented HMB processes and currently Director of Animal Research for Plaintiff MTI.¹⁰ In it, the authors opine that "[i]n little over a year, HMB has become one of the most popular dietary supplements in sports nutrition." Plaintiffs' App. At 185. Plaintiff MTI's sales records show that between 1996 and 2001, MTI sold approximately 279,716 kilograms of HMB. Plaintiffs submitted

¹⁰Plaintiffs' App., Exhibit 8.

sublicense agreements that indicate that at least 11 of Plaintiff MTI's sublicensees offer HMB in the consumer nutrition/body building and fitness market.¹¹ Defendant Wiley's sales records also indicate that the use of HMB in the consumer fitness market is, under almost any definition, substantial. From 1995 to the present, Wiley has sold over \$13 million worth of CaHMB to its end users.¹² Exhibit E to Appendix in Support of Defendant's Resistance to Plaintiffs' Motion for Summary Judgment and Plaintiffs' Motion for Claim Construction. Such evidence, viewed in the light most favorable to Defendant, indicates that a reasonable jury could find the body building use of HMB to be "substantial."

Examining all the evidence in the record, the Court finds that there is a genuine and material dispute between the parties in this case sufficient to preclude a grant of summary judgment to Plaintiffs on the issue of contributory infringement. Plaintiffs bear the burden of proof on establishing the elements of contributory infringement, and this Court is mindful that "[s]ummary judgments in favor of parties who have the burden of proof are rare, and rightly so." *Turner v. Ferguson*, 149 F.3d 821, 824 (8th Cir. 1998). It is simply not undisputed that HMB had no substantial noninfringing uses, nor is it undisputed that Wiley's end users utilized the HMB in such a way as to infringe any patent Plaintiffs hold.

The Court need not address in the context of summary judgment the remaining elements of

¹¹These sublicense agreements demonstrate that MTI's sublicensees can formulate, sell, and otherwise commercially exploit HMB only in "Licensed Markets." Licensed markets are defined by the sublicense agreement as "those markets in which Licensed Products [HMB] are sold to body builders, athletes, or fitness enthusiasts for body shaping or to enhance body mass, strength and endurance, weight control and fat loss." The agreements specifically prohibit the sublicensees from selling products in "any medical food market" and from selling supplements targeted to "AIDS or cancer patients" or to customers "seeking dietary or nutritional benefit due to an existing disease." Plaintiffs' App., Exhibit 12 at 603, 614, 626, 638, 683, 700, 748. Sublicense agreements with substantially similar language can also be found at Plaintiffs' App., Exhibit 12 at 659, 679, 695, 720, 737.

¹²Defendant's App., Exhibit E.

Plaintiffs' contributory infringement claim or any affirmative defenses advanced by Defendant since the failure of Plaintiff to demonstrate that there is no genuine issue of material fact as to *any* element of its claim for relief is fatal to Plaintiffs' summary judgment motion. *See Gasser Chair Co., Inc. v. Infanti Chair Mfg. Corp.*, 60 F.3d 770, 773 (Fed. Cir. 1995).

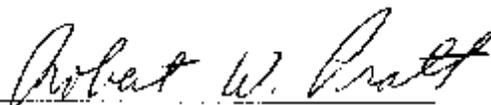
IV. ORDER

The Court construes the disputed claims of claim 1 of the '979 patent as follows. First, "subject" and "patient" refer to individuals in a state of negative nitrogen balance. "Nitrogen retention" refers to a decrease in the excretion of nitrogen from the body, as measured by the amount of nitrogen in a subject or patient's urine. "Protein sparing" refers to the retention of protein in the body sufficient to trigger a decrease in the level of nitrogen excreted by the body, as measured by urinary nitrogen levels.

Plaintiffs' Motion for Summary Judgment on the claim of contributory infringement under 35 U.S.C. § 271(c) is denied.

IT IS SO ORDERED.

Dated this ___3rd___ day of November, 2003.



ROBERT W. PRATT
U.S. DISTRICT JUDGE