IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

LATEX ALLERGEN REDUCTION, LLC,	)	
	)	
Plaintiff/Counter-Defendant,	)	
	)	
v.	)	
	)	No. 10 C 129
DYNAREX CORPORATION,	)	
	)	
Defendant/Counter-Plaintiff.	)	
	)	
	)	
	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Latex Allergen Reduction, LLC ("LAR") has brought this suit against defendant Dynarex Corporation ("Dynarex") for patent infringement of LAR's U.S. Patent 5,777,004 (the "'004 Patent"). The '004 Patent is directed to a method of neutralizing protein allergens found in natural rubber latex. '004 Patent, Col. 2, lines 24-25. The proteins in natural rubber latex that cause allergic reactions are made of chemical chains called "peptides," which are themselves chemical chains of amino acids. The patented invention relies on a protease enzyme and a peptidase enzyme to break down or degrade the protein allergens in the natural rubber latex so that the remaining particles are "too small to elicit an allergic reaction in humans." *Id*. at Col. 4, lines 1-3. The preferred method of the '004 Patent involves a two-step process for treating natural rubber latex. *Id*. at Col. 5, line 29 - Col. 6, line 46. In the first treatment step, a protease enzyme solution

is applied to the latex. In a second step, a peptidase enzyme solution is introduced to continue the process of breaking down the proteins. *Id*. at Col. 6, lines 12-13. The patent explains that "[w]hen the protease treatment and the peptidase treatment yield the preferred [degree of chemical break down] the allergenicity of the latex is reduced below detectable levels." *Id*. at Col. 6, lines 41-46. The '004 Patent also states that the solutions of protease and peptidase enzymes can be simultaneously added in a single step. *Id*. at Col. 6, lines 49-54.

Because the parties disagree as to the meaning of certain terms and phrases used in the '004 Patent, this opinion construes those terms and phrases pursuant to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995).

I.

"[T]he interpretation and construction of patent claims, which define the scope of the patentee's rights under the patent, is a matter of law exclusively for the court." *Markman*, 52 F.3d at 970-71. Claim terms "are generally given their ordinary and customary meaning," *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996), which is to say the meaning those words would have to a person of ordinary skill in the art at the time of the patent's effective filing date. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). The so-called "intrinsic evidence," i.e., the claim language itself, the patent's specification, and

its prosecution history, is of paramount significance in construing disputed terms. While "extrinsic evidence," i.e., everything else, may be helpful to understand the meaning of technical or scientific terms, such evidence is considerably less reliable than intrinsic evidence for determining "the legally operative meaning of claim language," *id*. at 1317.

Analysis of the intrinsic evidence always begins with the language of the claims. *Vitronics*, 90 F.3d at 1582. Next comes the patent specification, which "'is always highly relevant to the claim construction analysis.'" *Phillips*, 415 F.3d at 1314 (quoting *Vitronics*, 90 F.3d at 1582). Nevertheless, "limitations from the specification are not to be read into the claims." *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1331 (Fed. Cir. 2004) (citations omitted). While a patentee is free to be his or her own lexicographer and ascribe a special definition to a given term, "any special definition given to a word must be clearly defined in the specification." *Markman*, 52 F.3d at 980. Like the specification, the prosecution history is considered reliable evidence of the meaning of claim terms, but it too "cannot 'enlarge, diminish, or vary'" the limitations in the claims. *Id.* (quoting *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 227 (1880)).

With these general principles in mind, I turn to the claim terms in dispute.

II.

A. "non-allergenic to humans"

1. All Protein Allergens vs. Two or More Protein Allergens

Claim 1 states:

> A method of neutralizing protein allergens in natural rubber latex comprising treating the natural rubber latex with a protease enzyme and a peptidase enzyme such that the protein allergens contained within the natural rubber latex are degraded to polypeptide fragments and amino acids which are **non-allergenic to humans**.

'004 Patent, Col. 11, lines 40-45 (emphasis added). LAR begins by proposing that "non-allergenic to humans" means that only the protein allergens *that are actually degraded* are incapable of producing an allergic reaction in most humans. To get to this articulation, LAR first argues that I should look to the preamble[1] of Claim 1 to understand the antecedent basis for the phrase "the protein allergens." According to LAR, the use of the phrase "protein allergens" in the preamble[2] to Claim 1 means that the invention requires only that two or more protein molecules be "degraded," and that the latex itself need not be made non or less allergenic so long as two or more protein molecules are

[1] Both parties have agreed that the phrases used in the preamble have no patentable weight.

[2] The pertinent section in the preamble states: "Disclosed is a method of treating natural rubber latex with protease and peptidase enzymes, whereby protein allergens contained within the latex are degraded so as to be rendered non-allergenic to humans. The protein allergen-free natural rubber latex produced by the method and articles fabricated from the protein allergen-free product are also disclosed." '004 Patent Preamble.

neutralized. LAR then uses this proposed understanding of "protein allergens" in the preamble to argue that "the protein allergens contained within the natural rubber latex" in Claim 1 is limited to two or more protein molecules. LAR goes on to explain that the clause "which are non-allergenic to humans" is plural and must modify "polypeptide fragments and amino acids" and not the singular noun, "latex." LAR suggests that "the prepositional phrase 'within the natural rubber latex' simply mirrors the language of the preamble and states where the protein allergens that are degraded are located." LAR Resp. at 15. LAR goes on to state that "the clear meaning of claim 1 is that *those protein allergens that are degraded* are degraded to polypeptide fragments and amino acids which are non-allergenic to humans." *Id*. (emphasis in original).

According to Dynarex, the claim language clearly "identifies which proteins need to be degraded: the protein allergens *contained within the natural rubber latex*." Dynarex Mem. at 10. The claim does not say "some protein allergens" or contain any other qualifier. Further, LAR's proposed construction should be rejected because it would deprive the invention of utility and render the claim invalid. According to Dynarex, "[d]egrading a small or limited quantity of the proteins contained with[in] the latex would clearly have no substantive effect on the allergenicity of the latex, and, thus, provide no utility." *Id.*

A preliminary issue I must address is whether Claim 1 requires that all the protein allergens contained within the natural rubber latex be degraded to a certain level (as advanced by Dynarex) or whether only two or more protein molecules must be degraded (as advanced by LAR). I conclude that the plain language of Claim 1 indicates that all the protein allergens contained within the latex must be degraded. The language of claim 1 expressly describes which protein allergens ("the" protein allergens contained within the natural rubber latex) must be degraded. Because I do not see any ambiguity in this language, I reject LAR's suggestion that I look to the preamble as an antecedent basis for the phrase "the protein allergens." *See* The United States Patent and Trademark Office Manual of Patent Examining Procedure 2173.05(e)(explaining that an antecedent basis is required in drafting a claim when the term is so vague or general that it would otherwise be invalid for indefiniteness); *see also Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) ("If the body of a claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction[.]").

The teachings of the specification support this conclusion. *Z4 Technologies, Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1348 (Fed. Cir. 2007) (fundamental rule of claim construction is that a claim should be construed consistent with the teachings of the specification). The specification makes clear that "[t]he invention is a method for neutralizing protein allergens in natural rubber latex, thereby rendering the latex and articles formed from the latex non-allergenic to humans." '004 Patent Col. 1, lines 6-8. The invention achieves its utility by applying enzyme treatments to the natural rubber latex "such that the protein allergens contained therein are degraded." *Id*. at Col. 2, lines 32-35. The patent also references "non-protein allergenic natural rubber latex" and the "non-protein allergenicity of the latex." *Id*. at Col. 8, lines 1-15. All of these references, in addition to the plain language of the claim, support my conclusion. Dynarex maintains that LAR's construction would make no sense in light of the purpose of the invention, as under LAR's construction the claimed method need only degrade some undefined quantity of allergenic proteins contained in the natural rubber latex to a non-allergenic level, even if the latex continues to contain substantial quantities of non-degraded proteins that remain allergenic to humans. I agree.

2. "Non-Allergenic to Humans"

In its response, LAR's proposed construction of "non-allergenic to humans" presupposes that I have agreed with its suggestion to limit Claim 1 to only those protein allergens that are actually degraded. Because I have rejected that argument, it is difficult to figure out exactly what LAR intends to argue with respect to the phrase "non-allergenic to humans." It is clear, however, that LAR argues that "non-allergenic" cannot mean that the invention completely eliminates the allergenicity of latex for all humans. According to LAR, that would be impossible. Instead, LAR proposes that it means some level of reduced allergenicity, and, in support, it points to portions of the specifications explaining that the protein allergens were "greatly reduced" or became "far less allergenic." LAR Resp. at 11-12. However, LAR never expressly asks the court to construe "non-allergenic" as "greatly reduced" allergenicity. In addition, LAR argues that the phrase "to humans" should be defined to mean "most humans." LAR asserts a person of ordinary skill in the art would understand the phrase "to humans" to mean "to most humans."

Dynarex stresses the "heavy presumption" courts must apply in favor of the ordinary meaning of a claim term, "unless the patentee unequivocally imparted a novel meaning" to the term. *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). Dynarex proposes that the claim term "non-allergenic to humans" be

given its plain and ordinary meaning that "the protein allergens contained within the natural rubber latex are degraded such that the natural rubber latex is incapable of producing an allergic reaction in any human." Dynarex Br. at 8. In its reply, it suggests that the following might be added to the end of that suggested phrasing: "as demonstrated by having non-detectable levels of protein allergens." Dynarex Rep. at 12. Dynarex points out that the specification makes clear that the invention is directed towards the problem of protein allergens in natural rubber latex causing an allergic reaction in humans. The specification further states that the method of the invention treats the latex with protease and peptidase enzymes in order "to degrade proteins found within the rubber latex to a molecular weight which renders the protein too small to elicit an allergic reaction in humans." '004 Patent, Col. 4, lines 1-3. Dynarex counters LAR's claim that total elimination of all protein allergens is impossible by asserting:

> Dynarex never argues that every last molecule of protein allergen needs to be eliminated. Dynarex simply contends that the protein allergens contained within the latex have to be degraded sufficiently such that the latex does not cause an allergic reaction in humans – just what the claim language says.

Dynarex Rep. at 8. Finally, Dynarex argues that construing "non-allergenic" to mean "greatly reduced" allergenicity and construing "to humans" to mean "to most humans" would be too indefinite, and would not "particularly point out and distinctly claim the subject

matter the patent applicant considers to be the invention." Dynarex Rep. at 9.

I start with the plain language of the phrase, "non-allergenic to humans." The phrase, as stated, clearly means that the treated latex does not produce an allergic reaction in any humans. It does not mean, however, that the treated latex is completely devoid of protein allergens, just that those allergens remaining are "too small to elicit an allergic reaction in humans." '004 Patent, Col. 4, lines 1-3. In an attempt to deviate from this plain meaning, LAR points to sections of the specification which describe the protein allergens as "greatly reduced" or "far less allergenic" than those found in untreated latex. Dynarex argues that these types of terms are far too vague and indefinite to provide an adequate construction of the term "non-allergenic."

I conclude that the term "non-allergenic to humans" means that "the protein allergens contained within the natural rubber latex are degraded such that the natural rubber latex is incapable of producing an allergic reaction in any human as demonstrated by having non-detectable levels of protein allergens." Even LAR points to examples in the specification which support this conclusion. *See* '004 Patent, Col. 6, lines 40-45 ("When the protease treatment and the peptidase treatment yield the preferred [degree of chemical break down] *the allergenicity of the latex is reduced below detectable levels*")(emphasis added); Col. 9, lines

44-46 (noting that the allergen content of the "Treated" sample was below the detection limit of the test). This conclusion is further supported by other parts of the specification, wherein the treated latex is described as "effectively protein non-allergenic" and "extremely protein allergen-free." '004 Patent, Col. 7, lines 65-66; Col. 2, lines 57-60. With respect to the phrase "to humans," LAR has failed to point to language in the claim, the specification, or the prosecution history which would convince me that the phrase should be given something other than its plain meaning.

Nor am I convinced that LAR's position is supported by the two cases cited by LAR. In *Microthin.com, Inc. v. Siliconezone USA, LLC*, 377 Fed. Appx. 8 (Fed. Cir. 2010), the court gave "non-slip" its ordinary meaning of "reduces or prevents smooth sliding action" and held that the patent at issue in that case did not distinguish between sticky and non-sticky characteristics. The real issue before the court was whether the product had "to reduce or prevent smooth sliding motion *without being sticky to the touch*." *Microthin.com*, 377 Fed. Appx. at 11 (emphasis added). Therefore, the parties were not fighting over, and the court did not address, whether "non-slip" means the reduction *or* prevention of smooth sliding action (which would be more akin to the issue in this case), but rather whether or not the claim could be read to address whether the absence of stickiness was also required. In light of

this, I do not find this case to be helpful in deciding the issue currently before me.

LAR's second case, *Koninklijke Philips Electronics N.V. v. Cinram Int'l, Inc., et al.*, 709 F. Supp. 2d 259 (S.D.N.Y. 2010), supports my construction of "non-allergenic to humans." In *Koninklijke*, the patent in suit involved a "non-transmissive" optical structure. 709 F. Supp. 2d at 262. The defendants urged the court to conclude that "non-transmissive" meant that the optical structure "does not transmit radiation such as light," while the plaintiff argued that the term should be understood as characterizing the method by which a disk is read. The district court reviewed both intrinsic and extrinsic evidence, to ultimately side with defendants. The court credited defendants' expert who averred that,

> [O]ne of ordinary skill in the art in 1972 would have read the '846 Patent and the prosecution history to unequivocally state that the optical structure does not transmit light. Schlesinger Decl. ¶ 6. More specifically, Dr. Schlesinger testified that the hypothetical person skilled in the art in 1972 would have understood that the optical structure should be made "as non-transmissive as possible and practical and that while theoretically and even actually some photons may pass this is irrelevant as they are not seen or detected on the other side of the structure.

Id. at 267. Based on all the evidence, the court construed the term "non-transmissive" to mean "an optical structure that reduces the transmission of radiant light to the greatest degree practicable consistent with the intended purpose." *Id*. at 268.

The construction I have reached with respect to "non-allergic to humans" is consistent with *Koninklijke*, in that I have construed "non-allergenic" in light of the intended purpose of the invention to conclude that "the protein allergens contained within the natural rubber latex are degraded such that the natural rubber latex is incapable of producing an allergic reaction in any human as demonstrated by having non-detectable levels of protein allergens." The optical structure in *Koninklijke* was deemed "non-transmissive" even if a non-detectable level of photons actually passed through it. Likewise here, I have concluded that "non-allergic to humans" allows for some of the protein allergens to remain, so long as they are below detectable levels.

B. "A Protease Enzyme and a Peptidase Enzyme"

Claim 1 claims a method of "treating the natural rubber latex with a protease enzyme and a peptidase enzyme." Dynarex argues that this plainly refers to treating natural rubber latex with *two* distinct enzymes: a "protease" enzyme and a "peptidase enzyme." Specifically, Dynarex asks me to construe this phrase as "both separate and distinct enzymes, wherein one enzyme is a protease enzyme and the other enzyme is a peptidase enzyme, and that the two enzymes are not the same."

In contrast, LAR asserts that Dynarex seeks to impose limitations on this phrase that do not appear in the claim. LAR proposes that the phrase "a protease enzyme and a peptidase enzyme"

be construed to mean "both two separate and distinct enzymes, wherein one enzyme is a protease enzyme and the other enzyme is a peptidase enzyme, as well as a single enzyme having both protease activity and peptidase activity." LAR Resp. at 19. According to LAR, "a protease enzyme and a peptidase enzyme" does not exclude the possibility that the protease and peptidase enzyme are the same, single enzyme having both protease and peptidase activity.

Both parties agree that the patent includes numerous references to treating the natural rubber latex with proteases and peptidases. *See, e.g.,* '004 Patent Abstract ("Disclosed is a method of treating natural rubber latex with protease and peptidase enzymes."); *id.* at Col. 2, lines 25-29 ("The method includes the step of treating natural rubber latex with at least one enzyme having protease activity and at least one enzyme having peptidase activity."); *id*. at Col. 2, lines 40-45 ("Then, in a first treatment step, treating the natural rubber latex with a protease enzyme in a vapor-tight vessel . . . . Then, in a second treatment step, treating the natural rubber latex with a peptidase enzyme in a vapor-tight vessel."); *id*. at Col. 4, lines 53-56 ("In short, any combination of one or more enzymes having protease activity and one or more enzymes having peptidase activity which, in combination or in sequence, will successfully cleave the proteins. . . ."); *id*. at Col. 6, lines 48-50 ("The present invention also includes a one

step hydrolysis wherein solutions of proteases and peptidases are simultaneously added[.]").

LAR argues, however, that the patent's description of a single step where a protease enzyme and a peptidase enzyme are added simultaneously encompasses a single enzyme with both protease and peptidase properties. LAR points to two sections of the specification to support its argument that "a protease and a peptidase enzyme" could also include one enzyme with both protease and peptidase properties. The portion of the specification LAR relies on provides,

> The method functions successfully using any now known or henceforth discovered **enzyme having protease and/or peptidase activity**. Such proteases and peptidases include, but are not limited to, enzymes isolated from animal, microbial, and plant sources. From a present cost perspective, enzymes derived from microbial sources are most economical due to their wide commercial availability. However, the preferred enzymes for use in the invention are **enzymes having protease and/or peptidase activity** which are isolated from mammalian sources or which are manufactured via recombinant genetics (or wholly synthetic methods) using mammalian gene-coding sequences.

'004 Patent, Col. 4, lines 4-15 (emphasis added). LAR points to the use of "and/or" in the above passage to argue that the specification contemplates one enzyme with both protease and peptidase activities.

The intrinsic evidence tends to support Dynarex's construction. As detailed in part above, the specification contains over 20 mentions of protease enzymes and peptidase

enzymes, and discusses them as separate enzymes. Moreover, the specification, in discussing the single-step option (wherein the protease and the peptidase enzymes are added to the latex simultaneously), states that the "protease and peptidase treatments may be combined into a single step if suitable *enzymes* are selected.[3] '004 Patent, Col. 4, lines 66-67 - Col. 5, line 1 (emphasis added). The use of the plural "enzymes" supports a construction that the protease and the peptidase enzymes are separate and distinct enzymes. Likewise, the following statement in the specification also supports Dynarex's position that even in the one-step treatment two distinct enzymes are required: "The present invention also includes a one step hydrolysis wherein *solutions of proteases and peptidases* are simultaneously added to the natural rubber latex." *Id*., at Col. 6, lines 49-51 (emphasis added). Finally, the specification states that, "[i]n short, any *combination* of one or more enzymes having protease activity and one or more enzymes having peptidase activity . . . may be utilized in the present method." *Id*. at Col. 4, lines 53-55 (emphasis added). As Dynarex points out, "[i]f the limitation 'a protease enzyme and a peptidase enzyme' were interpreted to encompass a method

[3] I reject LAR's contention that Dynarex's construction excludes a preferred embodiment. Dynarex does not dispute that the '004 Patent, in addition to a two-step treatment, contemplates a one-step treatment during which the protease and peptidase enzymes are simultaneously added. The question is whether or not that one-step treatment can be achieved with a single enzyme.

involving only one enzyme, there would be no 'combination' of anything." Dynarex Mem. at 13.

Because this issue of two enzymes versus one enzyme is not as clear cut as the "non-allergenic to humans" construction, I will also consider the expert testimony I heard at the evidentiary hearing in this matter. *See, e.g., Phillips*, 415 F.3d at 1317-19 (stating that a district court may, in its discretion, consider expert testimony to determine how one of ordinary skill in the art would understand the patent). Each side presented expert opinion in an attempt to support their proposed constructions. As detailed below, I credit the testimony of Dynarex's expert over that of LAR's, and conclude that the extrinsic evidence support Dynarex's construction.

Dynarex's expert, Dr. Louis DeFilippi[4], testified that a person of ordinary skill in the art would understand the '004 Patent to require the use of two separate enzymes: a protease enzyme and a peptidase enzyme. He testified that an enzyme is "a

[4] Dr. DeFilippi received a B.A. in chemistry with honors from Queens College in the City University of New York and received his Ph.D. in biological chemistry from the University of Michigan in Ann Arbor, Michigan. He did post doctorate work at the University of Michigan and Cornell University in Ithaca, New York. All of his academic study and research involved enzymes. His professional experience, which included working at UOP Research Center, Allied Signal Research and his own consulting practice, also involved enzymes. He testified that 50 to 75 percent of his 40+ years of experience has been dedicated to research and application of enzymes in industry. Dr. DeFilippi testified that he, as a person who had a degree in biochemistry and has studied enzymology, is a person of ordinary skill in the art. 4/11/11 Tr. at 17-18.

biological molecule that's a catalyst. It speeds up a reaction. Enzymes are very, very precisely defined and have very, very precise activities." 4/11/11 Tr. at 12. He further explained that the enzymes used in the '004 Patent are those which break down proteins. *Id*. at 13.

By way of background, Dr. DeFilippi described in detail the differences between protease enzymes and peptidase enzymes. He stated that every protein is made up of amino acids, and those amino acids are always found in the exact same sequence for a particular protein. These individual amino acids are held together by bonds called amide linkages. Turning first to protease enzymes, Dr. DeFilippi explained that a protease enzyme has "endo activity," which means that it cleaves the bond between two very specific amino acids, and does not cleave the bond between any of the other amino acids. This process of cleaving bonds results in smaller chains of amino acids, called peptides. In contrast, a peptidase enzyme, with "exo activity," starts at one end or the other of a peptide, and cleaves off one amino acid at a time from the end of the peptide. A peptidase will continue to cleave off one amino acid, from the end of the peptide, until only mono and dipeptides are remaining (or until it hits a particular kind of amino acid which can act as a blocker).

Dr. DeFilippi explained that, due to the distinct functions of each type of enzyme, a protease enzyme cannot do what a peptidase

enzyme does. A protease enzyme looks for a very specific amino acid (or a few amino acids) within in the protein chain.[5] According to Dr. DeFilippi, enzymes, which are "highly specific," "will perform certain catalytic actions and no other." 4/11/11 Tr. at 27. In light of this, Dr. DeFilippi testified that a person of ordinary skill in the art would understand the '004 Patent to "need two distinct and different enzymes, one is the protease and the second is the peptidase, where the protease is the one that has the endo activity and creates a family of peptides, and then the peptidase by its name you can tell already is the enzyme that attacks the peptides and breaks them down to smaller units, amino acids and then some smaller peptides." *Id*. at 28.[6]

[5] Dr. DeFilippi explained that you might fortuitously have one of the target amino acids at the end of the chain, and the protease might therefore cleave off an amino acid at the end of the chain, "but that's the exception, not the rule." 4/11/11 Tr. at 23.

[6] On cross examination, Dr. DeFilippi acknowledged that one could purchase a bottle of enzymes, either a "preparation" or an impure batch of enzymes, which could have both protease and peptidase activities. However, in both the case of a preparation and the case of an impure batch of enzymes, any potential combination of protease and peptidase activities would be the result of a mixture of different enzymes, and not the result of one enzyme.

Conversely, LAR's expert, Dr. Katrina Cornish[7], testified that one enzyme could have both protease and peptidase properties. Dr. Cornish explained that the term, "enzyme," can either be a very precise term or it can be used "much more imprecisely." 4/1/11 Tr. at 53. As an example, Dr. Cornish explained that it is very difficult to purify an enzyme, such that only one homogeneous enzyme is present. She went on to state that if she were to purchase a bottle of a commercially-available enzyme, that bottle could contain both protease and peptidase activities. Because the source for the product comes from a biological system, "you would tend to get some of the other things that are in that biological system as well, and unless you purify it extremely rigorously, you

[7] Dr. Cornish received a first class honors in biological sciences with a minor in biochemistry from the University of Birmingham, England. She received her Ph.D. from the same institution in plant biology, and has several post doctorate awards working for the United States Department of Agriculture ("USDA"). Since completing her academic studies, she has been employed by Yulex Corporation, the USDA, and Arizona State University. She is currently employed by the Ohio State University, as an Ohio Research Scholar and Endowed Chair in bioemergent materials specializing in biowaste materials with bio-based fillers and fibers, and also bio-based versions of synthetic polymers. Her work has focused on the guayule, which is a source of hypoallergenic latex which comes from a desert shrub. She has won numerous awards, published articles on latex, and holds at least four patents related to latex in the United States, and about 53 patents related to latex issued in other countries. Since 1987, Dr. Cornish's work has involved latex. Since 1990-1991, her work has also included studying the allergenicity of latex. According to Dr. Cornish, a person of ordinary skill in the art would be a scientist, an immunochemist, a biochemist, a product development person or an immunologist. Dr. Cornish testified that she is such a person.

know, really ad infinitum, you will get some contamination from the original system." *Id*. at 55. Again, by way of example, Dr. Cornish testified that if she were to purchase a bottle labeled as a "protease," assuming it was relatively inexpensive, "I would expect it to primarily be the one that the name said and that there would be a bunch of other things in it that probably aren't even listed." *Id*.

Taking a somewhat different tack, Dr. Cornish also testified that one's characterization of a particular enzyme is "really a matter of definition." 4/11/11 Tr. at 57. She stated that there are exopeptidases and endopeptidases. An exopeptidase can cleave the first or second bond in a peptide. An endopeptidase can cleave in the middle of the peptide. She explained that the difference between a protease (which cleaves in the middle of a peptide) and an endopeptidase (which also cleaves in the middle of a peptide) "is a matter of degree, semantics." *Id*. An enzyme could be called a protease when it first starts to chop a large protein into large peptides, and it might be considered an endopeptidase as the peptides chains get smaller. She testified that she, as a person of ordinary skill in the art, would practice the invention of the '004 Patent by "buy[ing] one bottle of one broad specificity protease, as broad specificity as I could find, and see if that one would do all of that without having to pay for another one." *Id*. at 69, 70 ("Q. So your testimony is reading this patent and the

claim language that says it's a treatment involving a protease and a peptidase, that what you would do is you would just go out and buy a protease? A. Exactly that is what I would do."). She explained that if one were to use a broad specificity protease, which cleaves bonds in multiple locations, "you may well end up in effect with exactly where you would be if you added one that was a specific peptidase to get down to those tiny, tiny fragments. But if I had this broad peptidase and found a lot of stuff, say 10,000 molecular weight protein – peptidase as well, I'd go throw peptidase in there and chop those peptides into much smaller ones again." *Id*. at 73-74.

I reject Dr. Cornish's testimony, and rely instead on Dr. DeFilippi's conclusion that the '004 Patent refers to two distinct enzymes, for a number of reasons. First, Dr. Cornish's theory that the patent contemplates that a person attempting to practice the patent would use an inexpensive, impure bottle of protease enzymes which might (or might not) contain separate peptidase enzymes has no support in the patent. As both experts testified, an inexpensive, impure bottle of protease enzymes would contain proteases (i.e., what the labels says it contains), but would also contain any number of other enzymes. Therefore, in this scenario, such a bottle may or may not contain peptidases. There is nothing in the patent or specifications which contemplates testing a bottle of impure proteases to determine if that bottle has sufficient

peptidases to perform the necessary peptidase activity. Ultimately, this theory is unsupported by the '004 Patent.

I likewise reject Dr. Cornish's second theory, which is that one skilled in the art would simply buy a broad specificity protease, add it to the natural rubber latex and hope that it, acting alone, would sufficiently break down the protein allergens small enough to fall below detectable levels (and would only add in a specific peptidase enzyme if the degradation was insufficient). This is clearly not what the '004 Patent contemplates. *See Phillips*, 415 F.3d at 1318 ("[A] court should discount any expert testimony that is clearly at odds with the claim construction mandated by . . . the written record of the patent."). The patent says nothing about using a broad specificity protease, checking the peptides to determine whether the peptides have been sufficiently broken down, and then, if not, adding in a peptidase enzyme to finish off the process. Therefore, Dr. Cornish's theory that a protease enzyme could do the job itself is incompatible with the '004 Patent.

In light of the language of the '004 Patent, the specifications and the compelling testimony of Dr. DeFilippi, I conclude that "a protease enzyme and a peptidase enzyme" means "both separate and distinct enzymes, wherein one enzyme is a protease enzyme and the other enzyme is a peptidase enzyme, and that the two enzymes are not the same."

ENTER ORDER:

Elaine E. Bucklo
United States District Judge

Dated: April 21, 2011