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") sued Dynarex Corporation ("Dynarex") alleging that Dynarex sells or offers for sale latex gloves which infringe Patent No. 5,777,004 (the "'004 Patent"). The '004 Patent is directed to one or more methods of using enzymes to eliminate allergy-causing proteins contained in natural rubber latex in order to make the latex non-allergenic to humans. LAR alleges that Dynarex sells latex gloves manufactured using the claimed method.

On April 21, 2011, I construed a number of contested claim terms. Now before me is Dynarex's motion for summary judgment on Claims 1 and 11. Because plaintiff has made clear that it cannot withstand summary judgment on Claim 11, I grant Dynarex's motion with respect to Claim 11. In addition, for all the reasons given below, I also grant Dynarex's motion for summary judgment on Claim 1 of the '004 Patent.

II.

Summary judgment is appropriate if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Once the moving party shows that there is no genuine issue of material fact, the burden of proof shifts to the nonmoving party to designate specific facts showing that there is a genuine issue for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986).

An infringement analysis involves two steps. *See J&M Corp. v. Harley Davidson, Inc.*, 269 F.3d 1360, 1366 (Fed. Cir. 2001). First, a court must determine as a matter of law the scope and meaning of the claims through claim construction. *Id*. Second, the construed claims must be compared to the allegedly-infringing device or method. *Id*.

Having already construed the claims at issue, I turn now to the second step. "To prove infringement, the patentee must show that the accused [method] meets each claim limitation either literally or under the doctrine of equivalents." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 812 (Fed Cir. 2002). LAR argues that Dynarex's method literally infringes the '004 Patent. "Summary judgment of no literal infringement is proper when, construing the facts in a manner most favorable to the nonmovant, no reasonable jury could find that the accused [method]

meets every limitation recited in the properly construed claim." *Id*.

Dynarex argues that it is entitled to summary judgment because two limitations of the '004 Patent are not present in the method utilized in making its gloves. First, it argues that its gloves are not "non-allergenic to humans" because its gloves have detectable levels of protein allergens.[1] Second, Dynarex maintains that LAR cannot prove that the method used by Dynarex to make gloves uses two separate and distinct enzymes, wherein one enzyme is a protease enzyme and the other enzyme is a peptidase enzyme, and the two enzymes are not the same. Because I conclude that LAR has failed to put forward evidence which shows that the method utilized by Dynarex results in gloves which are "non-allergenic to humans," I need not address the issue of the two separate enzymes.

Turning, then, to the phrase "non-allergenic to humans," I construed that phrase to mean "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." 4/21/11 Opin. at 10. Dynarex argues that LAR has no testing or other evidence to prove that Dynarex sold or offered for

[1] Dynarex makes clear that its motion for summary judgment, with respect to the "non-allergenic to humans" limitation, is directed to all gloves sold or offered for sale by Dynarex using either Savinase or K-Zyme. Dynarex maintains that it, since 2003, has used either Savinase or K-Zyme in its glove-making process.

sale any latex gloves having "non-detectable" levels of protein allergens.[2]

A bit of background is required to understand LAR's response. Dynarex sells enzyme-treated latex gloves under the trade name Allotex. Dynarex acquired the rights to make and sell Allotex gloves in 2003 from Tillotson Healthcare, which was then in Chapter 11 reorganization and has since been liquidated. Dynarex has never manufactured latex or latex gloves itself, but instead contracts with suppliers to manufacture the gloves using the Allotex process.

According to Dynarex, gloves that are manufactured for sale by Dynarex are periodically tested for protein allergens before being shipped to Dynarex. The Dynarex production gloves are tested using either the LEAP test or the ASTM D6499 ELISA Inhibition Test. The LEAP test and ASTM D6499 ELISA Inhibition test are recognized in the field as being appropriate tests for determining whether latex gloves have detectable levels of antigens. Dynarex markets its gloves only as having "reduced allergenicity."

In support of its claim of infringement, LAR points to testing done in 1999 by Tillotson Healthcare, performed four years before Dynarex acquired the Allotex process.[3] According to LAR, there

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[2] LAR failed to respond to Dynarex's Second Set of Requests To Admit and has moved to withdraw those admissions. Because I did not rely on any potential admissions in ruling for Dynarex in this motion, that motion is denied [84] as moot.

[3] LAR also attempts to rely on a number of other documents to support its position. Having reviewed them, none are availing.

were two batches of Tillotson Healthcare gloves which, when tested for the presence of allergens, recorded a "nd," or "non-detect" result for protein allergens. Without addressing the fact that the tests were done by Tillotson Healthcare, and not Dynarex, LAR relies on these two batches from 1999 to argue that Dynarex has sold gloves which are "non-allergenic to humans."

In reply, Dynarex maintains that LAR has failed to put forward evidence that *Dynarex*, as opposed to Tillotson Healthcare, sold or offered for sale any gloves made with non-allergenic latex. Importantly, Dynarex has put forward evidence that all the tests done on Dynarex gloves have uniformly shown that the gloves have detectible levels of protein allergens. While LAR attempts to refute this by pointing to the Tillotson Healthcare tests, LAR has not identified any test on Dynarex gloves which show nondetectable levels of protein allergens.

LAR points to two pages in a power point presentation. LAR provides no context for the document and the author and audience are unknown. Neither page supports LAR's position, as it is impossible to discern what values the chart and graph assigned to the enzyme-treated proteins. Finally, in a single sentence, LAR points to Exhibits 8,9 and 10 as support. LAR provides no argument, explanation or context for these documents. It is not appropriate for a party to merely cite to three highly technical exhibits and expect the court to do its work for it. As a result, I find LAR has waived any argument that Exhibits 8, 9, and 10 support its position that Dynarex is selling gloves which are non-allergenic to humans. *See United States v. Lanzotti*, 205 F.3d 951, 957 (7th Cir. 2011) (perfunctory and undeveloped arguments are waived).

In addition, Dynarex argues that these tests are irrelevant because the Tillotson Healthcare gloves were different from the Dynarex gloves for two reasons. First, the Tillotson Healthcare tests were performed on gloves which involved latex that had been enzyme-treated for far longer periods of time and at significantly higher temperatures than the production process utilized by Dynarex (which treats the latex with enzymes for 16 hours at room temperature).[4] Dynarex L.R. 56 Statement of Fact #55. Second, the gloves manufactured by Tillotson Healthcare underwent a leaching process – after the enzyme treatment – to remove additional protein allergens from the gloves. The tests relied on by LAR were performed on manufactured gloves, not on the latex just after the enzyme treatment. Thus, even if I were to consider the Tillotson Healthcare tests, Dynarex argues that those tests do not show that the reduction of the protein allergens was achieved by the claimed enzyme-treatment method. According to Dynarex, "These tests cannot

[4] LAR attempts to dispute the notion that the "nd" results were the result of this experimental testing phase by stating, "There is evidence of record showing the results of experiments in which natural rubber latex was treated with [an enzyme] for less than 72 hours and which had "nd" LEAP assay results." LAR Resp. to Dynarex L.R. 56.1 fact # 56. Once again, LAR completely fails to direct the court to the specific test results it feels support its position. In any case, I do not see any test results in exhibits 8, 9 or 10 which reference a "nd" result and involved an enzyme treatment for 16 hours at room temperature. The second sentence in LAR's response to Dynarex fact #56 is likewise irrelevant as it says nothing about any "nd" results connected to latex which was treated with an enzyme for 16 hours at room temperature. Therefore, Dynarex's fact #56 is undisputed.

show that the enzyme-treated latex used to make the gloves had non-detectable levels of protein allergens because the gloves were subject to further non-enzyme treatment to remove protein allergens during manufacturing." Dynarex Reply at 4.

Even assuming I could consider the tests performed by Tillotson Healthcare, such tests would only be relevant here if the Tillotson Healthcare gloves were treated and manufactured in the same way that Dynarex treats and manufactures its gloves.[5] However, the critical problem with LAR's reliance on the Tillotson Healthcare test results is that the gloves which tested "nd" were different in two critical respects, detailed above, from Dynarex gloves. In light of these differences, I am not convinced that the Tillotson Healthcare glove tests are relevant to the question of whether Dynarex has sold gloves which are "non-allergenic to humans."

The language of Claim 1 also supports Dynarex's position that the relevant testing must be done on "natural rubber latex" (as opposed to manufactured gloves) and further that the crucial point for testing is post-enzyme treatment (but prior to any additional steps to reduce the allergenicity). Claim 1 describes "a method of neutralizing protein allergens in natural rubber latex

[5] Rather frustratingly, LAR does not even acknowledge that the tests it relies upon were not performed by Dynarex. Nor does LAR address the differences between the Tillotson Healthcare latex and gloves and the Dynarex latex and gloves.

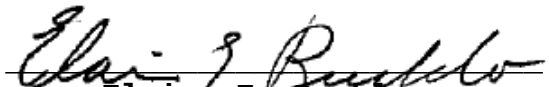
comprising treating the natural rubber latex with a protease enzyme and a peptidase enzyme *such that* the protein allergens . . . are degraded to . . . fragments and amino acids with are non-allergenic to humans." '004 Patent, Claim 1 (emphasis added). I read this language, focusing on the phrase "such that," as providing support for Dynarex's position that the critical time for testing, and determining whether the latex is non-allergenic to humans, is just after the enzymes described in Claim 1 have done their work. Further, the method is directed not to manufactured gloves, but to "natural rubber latex." Thus, it is clear that it is the natural rubber latex which must be tested for the presence of any protein allergens. To even be arguably relevant here, LAR would need to show that the Tillotson Healthcare gloves were non-allergenic to humans after the latex was treated with enzymes. LAR has pointed to no such tests. In fact, Dynarex has put forward evidence from Thomas Tillotson, a former principal of Tillotson Healthcare, that the tests performed on the Tillotson Healthcare latex, just after the latex was treated with enzymes but *prior to* any additional steps, "uniformly indicated that the protein allergens in the latex had been reduced, but that the level of protein allergens remained above-detectable levels." Tillotson Aff. at ¶ 4. In other words, Tillotson averred that the Tillotson Healthcare latex retained detectable levels of protein allergens at the critical stage – just after the conclusion of the enzyme treatment.

Literal infringement requires that every element of the invention as claimed is present in the accused method. LAR has failed to put forward any evidence that the method utilized by Dynarex results in gloves which are "non-allergenic to humans." Therefore, Dynarex has not literally infringed '004 Patent.

III.

As explained more fully herein, defendant's motion for summary judgment on independent Claims 1 and 11 [80] is granted. Because LAR cannot prove infringement of independent Claims 1 and 11, Dynarex is entitled to summary judgment as to all dependent claims of the '004 Patent as well. Thus, summary judgment is entered as to all counts of LAR's complaint. LAR's motion to withdraw admissions pursuant to FRCP 36(b) [84] is denied as moot.

ENTER ORDER:



Elaine E. Bucklo
United States District Judge

Dated: December 15, 2011