02-14953-GG

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ALLEGIANCE HEALTHCARE CORPORATION

Plaintiff-Appellant/Cross-Appellee,

v.

LONDON INT'L GROUP, LTD., SSL AMERICAS, INC.
AND LRC NORTH AMERICA, INC.

Defendants-Appellees/Cross-Appellants.

On Appeal From The United States District Court
For The Northern District Of Georgia, Atlanta Division

BRIEF OF APPELLEES/CROSS-APPELLANTS
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AND LRC NORTH AMERICA, INC.

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1.1, Appellees London International Group, Ltd., SSL Americas, Inc., and LRC North America, Inc. certify that the following persons or entities have an interest in the outcome of this appeal, number 02-14953-GG:

Carol A. Ahern

Allegiance Corporation

Allegiance Healthcare Corporation

American Threshold Industries, Inc.

AXA Financial, Inc.

Bondurant, Mixson & Elmore, LLP

Cardinal Health, Inc.

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Honorable Charles A. Pannell, Jr.

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STATEMENT REGARDING ORAL ARGUMENT

Appellees, London International Group, Ltd., SSL America's, Inc., and LRC North America, Inc. request oral argument. Although the legal issues are clear, the record is substantial, resulting from a four-week trial in this Lanham Act case concerning advertising for surgical gloves. On cross-appeal, Appellees request their attorneys' fees pursuant to the jury's finding that Allegiance brought its Lanham Act claims maliciously and in bad faith. Oral argument might assist the court in understanding the facts and reviewing the parties' claims.

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STATEMENT OF JURISDICTION

This is an appeal from a final judgment in a Lanham Act false advertising case in which the jury found that Appellees, London International Group, Ltd., SSL America's, Inc., and LRC North America, Inc. (collectively "Regent") did not violate the Lanham Act, but that Appellant, Allegiance Healthcare Corporation ("Allegiance"), did violate the Lanham Act, and did so willfully, deliberately, maliciously, and in bad faith. Following post-trial motions and the court's ruling on issues withheld from the jury pursuant to Rule 52, the court entered an injunction in favor of Regent and denied Allegiance any relief.

The district court had federal question jurisdiction pursuant to 28 U.S.C. § 1331, diversity jurisdiction pursuant to 28 U.S.C. § 1332(a), and supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367. This Court has jurisdiction over the case pursuant to 28 U.S.C. § 1291. Allegiance timely appealed, and Regent timely cross-appealed.

STATEMENT OF THE ISSUES

1. Whether substantial evidence supporting the jury's verdict justified the district court in (i) exercising its discretion to deny Allegiance's motion for a new trial on its Lanham Act claims; and (ii) deciding, as a matter of law, not to overturn the jury's verdict in favor of Regent on (a) Allegiance's Lanham Act claims and (b) Regent's Lanham Act counterclaim?

2. Whether the court properly exercised its discretion in (i) denying injunctive relief and restitution to Allegiance for its claims under state law because there was no risk of future harm; and (ii) granting an injunction to Regent where there was no evidence that Allegiance would stop its false advertising?

3. Whether the district court correctly exercised its discretion in admitting evidence of information known to and relied upon by customers, and relied upon by Regent, with explicit limiting instructions, when the evidence was not admitted for the truth of the matter asserted?

4. On cross-appeal, whether the court misapplied controlling law, and thereby erred as a matter of law in failing to enter judgment for Regent on Allegiance's claims under the Georgia Unfair Deceptive Trade Practices Act?

5. On cross-appeal, whether the court misapplied the relevant law, and thereby abused its discretion in denying attorneys' fees to Regent under the Lanham Act, where the jury found that Allegiance's conduct in bringing this case was malicious and in bad faith, and where Allegiance's conduct precisely fit the statutory definition of an "exceptional case" warranting attorneys' fees?

STATEMENT OF THE CASE

I. COURSE OF PROCEEDINGS AND DISPOSITION BELOW.

Allegiance brought this case alleging various claims of false advertising by Regent regarding its powder-free BIOGEL surgical gloves. Faced with declining sales of its own powdered surgical gloves, Allegiance unsuccessfully attempted to gain access to Regent's BIOGEL technology or develop its own. Allegiance then filed this case, alleging violations of the Lanham Act as well as the California and Georgia deceptive trade practices acts, seeking hundreds of millions of dollars in monetary relief. Not only did Allegiance fail to prove that Regent made any false advertising claims about its natural rubber latex surgical gloves, but the jury also found, based on substantial evidence, that: (i) Allegiance was actually the one that violated the Lanham Act; (ii) Allegiance's violation of the Lanham Act was malicious, fraudulent, deliberate, willful or were acts in which there was evidence of fraud or bad faith; and, (iii) Allegiance's very bringing of this lawsuit against Regent was malicious, fraudulent, deliberate, willful, or in bad faith (RE9).

Prior to filing suit, Allegiance did not investigate Regent's claims about its gloves, and it had no evidence that Regent had misrepresented its product. Throughout the four years of complex litigation, Allegiance repeatedly abused the judicial process and was sanctioned a number of times. It was even held in contempt by the court. Allegiance's suit against Regent was based on malicious

anticompetitive motives, and the jury's findings of bad faith, malice and fraud were amply supported by the record. Based on the jury's verdict and the evidence, the court awarded Regent injunctive relief and denied Allegiance both the monetary and injunctive relief it was seeking (RE9, 12, 13).

II. STATEMENT OF THE FACTS.

A. Surgical Gloves And The Powder Problem.

This is a suit about natural rubber latex ("NRL") surgical gloves. Doctors and operating room nurses wear surgical gloves to protect themselves and their patients from pathogens and contaminants encountered during surgery. NRL gloves have excellent barrier properties, but they are sticky and difficult to put on, especially on wet hands (R443, Tr:1470-71).

For many years, glove manufacturers have used cornstarch powder as a lubricant to help hands slip into the gloves (R445, Tr:1953). It has long been recognized, however, that cornstarch powder can contaminate surgical wounds and cause potentially dangerous granulomas and adhesions (R438, Tr:713-714; R439, Tr:741, 1473, 1623; R444, Tr:1810; R445, Tr:1910; *see*, *e.g.*, DX-686, DX-657B, DX-733). As early as 1984, a third-party competitor advertised and sold a powder-free glove designed to eliminate "powder related peritonitis, granuloma, adhesion, and tissue trauma" (DX -1268). However, this early powder-free glove was difficult to don with wet hands (Tr:1966).

B. Regent Introduced The Superior BIOGEL Surgical Glove.

Regent introduced the BIOGEL glove in the United States in 1989 (Tr:1971). Its unique feature is a hydrogel coating, much like soft contact lens material inside the glove (Tr:1491-1492). This coating makes it easy to don the gloves with wet hands, even though they are powder-free (Tr:1492, 1971). Initially, Regent promoted the glove as an answer to the problems of adhesions and granulomas (Tr:1473). The BIOGEL glove also had the added advantage of being usable without prewashing (Tr:742-743; PX-550). Since 1991, the FDA has required a "caution statement" on packaging for powdered surgical gloves advising that the gloves be washed before use to eliminate surface powder (Tr:737-738), but this caution statement does not appear on the BIOGEL package because the gloves are powder-free (Tr:742-743).

C. The Surgical Glove Market Changed.

In the early 1990's, latex allergy became a public health issue when it was learned that proteins naturally found in NRL gloves may cause allergic reactions in susceptible individuals (Tr:1960-62). In March 1991, an FDA Alert sent to the healthcare industry advised "healthcare professionals to identify their latex sensitive patients and be prepared to treat allergic reactions promptly" (DX-1282).

At the same time, articles in medical journals began reporting research, unconnected to Regent, that latex proteins bind to cornstarch powder on powdered

gloves, and that the protein-laden powder carries allergens to persons not wearing the gloves (Tr:1499-1500).[1] Allegiance's predecessor, Baxter,[2] knew this as well. In 1991, its Director of Regulatory and Consumer Affairs wrote that cornstarch "acts as a vehicle to which latex protein may attach," and that wheezing and breathing difficulty was "most probably caused by inhalation of the allergen" (DX-1092).

The Executive Summary in Baxter's own Rood Report,[3] which surveyed the opinions of leading specialists selected by Baxter, also concluded that "powder acts as a vehicle for transmission of the proteins" (DX-606, p.3). Dr. John Yunginger of the Mayo Clinic responded to the Rood survey by stating that powder "is the vehicle for the latex proteins being taken up into the air and respired. This can cause sensitization" (*Id.*, p.27).

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[1] *See*, *e.g.*, Tomazic et al., "Cornstarch Powder on Latex Products is an Allergen Carrier" (DX-1023) (admitted under limiting instruction); Baur et al., "Airborne Antigens from latex gloves" (DX-664) (admitted under limiting instruction).

[2] Allegiance was spun off from Baxter Healthcare on October 1, 1996. Allegiance carried on Baxter's medical glove business in all respects and without interruption (Tr:701-704).

[3] Allegiance withheld this document from Regent during discovery despite Regent's two motions to compel (R220, R262). The district court overruled a spurious claim of attorney-client privilege on this document and ordered production (R301), but it was not until a few weeks before trial — after denial of Allegiance's motion for reconsideration (R345) — that Regent finally saw the document.

Concern about latex allergy made the protein content of surgical gloves a "hot topic" (Tr:1495). In early 1994, the *Journal of Allergy and Clinical Immunology* published an article by Dr. Yunginger and others at the Mayo Clinic that compared protein and allergen levels of many brands of NRL medical gloves (DX-357). This study was independent; Regent was not involved (Tr:1496). The study revealed that Regent's BIOGEL glove was very low in allergens and proteins. The BIOGEL glove was reported to contain less than 5 AU/ml of allergen and less than 15 µg/ml of protein. By comparison, Baxter's standard powdered TRIFLEX glove was reported to contain 5810 AU/ml of allergen and 246 µg/ml of protein (*Id.*, pp. 3-4). This article received wide publicity and independently buttressed Regent's marketing and sales of its BIOGEL glove (Tr:1496). Indeed, Baxter characterized the study as "a risk to our sizable base of business" and anticipated that "fallout at the customer level . . . probably will occur" (DX-441).

Regent's BIOGEL glove, which was originally developed to address the problems of damp donning and surgical complications, was therefore uniquely positioned to benefit from the growing concern about glove powder, protein and latex allergy. While Allegiance contends that Regent created this "climate of fear" (Tr:753), the overwhelming evidence, including Allegiance's own documents

(DX-441), demonstrates that the concerns evolved from outside sources and Regent was merely the beneficiary of a market shift.

During the 1990's, major medical institutions, such as the Mayo Clinic, Brigham and Women's Hospital in Boston and the Harvard Medical School, decided to stop buying powdered gloves and to go "powder-free" (Tr:1539-40). Meanwhile, influential governmental agencies and professional associations publicly endorsed powder-free gloves:

- **American College of Allergy, Asthma and Immunology (ACAAI), and American Academy of Allergy Asthma Immunology (AAAI):** "Only powder-free latex gloves should be purchased and used. This will reduce latex rubber aeroallergen levels and exposure" (Joint Statement, July 1997) (DX-580) (with limiting instruction);
- **American Academy of Dermatology**: "All medical and dental facilities are encouraged to exclusively use powder-free gloves with low NRL antigen levels" (Position Paper, July 1998) (DX-582) (with limiting instruction);
- **American Nurses Association**: "[A]ll healthcare institutions should . . . implement the use of low allergen powder-free gloves in all settings" (Position Paper, September 1997) (DX-588) (with limiting instruction);
- **National Institute of Occupational Safety and Health (NIOSH)**: "If you choose latex gloves, use powder-free gloves with reduced protein content" ("NIOSH Facts" page on website, dated June 1997) (DX-784) (with limiting instruction).

In May 1998, the FDA held a three-hour teleconference on latex allergy that was broadcast to over 5,000 locations, including hospitals nationwide (Tr:871-872). Panels of allergists, researchers, physicians and government officials made presentations (*Id.*). In a memorandum summarizing the conference, William Saxelby, the head of Allegiance's glove business, said that "the argument that powder-free products are safer went largely unchallenged" (DX-186).

As these facts became well known, other companies developed powder-free gloves (Tr:707-708), and advertised them using many of the same advertising claims challenged by Allegiance so as not to include Allegiance's ads. A 1996 brochure for Safeskin's powder-free glove stated that it was "hypoallergenic" and "eliminates the aerosolization of glove powder" (DX-947A). Ansell-Perry advertised that its "hypoallergenic" powder-free glove solved the problem of "aeroallergen transmission" (DX-947J, p. 6).

At trial, Mr. Saxelby testified that development of a powder-free glove had been his "number one R&D initiative" from the time he joined Baxter in 1991 (Tr:727, 800). However, Baxter and Allegiance failed in their attempts to bring out a competitive powder-free glove (Tr:591-593; 792-800; 1004-1005; DX-393). Meanwhile, by 1999, Regent's BIOGEL glove had gained a 22% market share by dollar volume (Tr:679).

Recognizing the superiority of the BIOGEL glove, Baxter initiated discussions on a joint venture which would give Baxter access to the BIOGEL technology (Tr:955). Baxter's interest in the joint venture continued until 1996 (DX-553), but no argument was ever consummated. Baxter's motive for seeking the deal was summarized by one of its own due diligence documents, which assumed that the market would "continue to convert to powder-free driven by latex allergies, occupational asthma, starch granuloma and user-preference concerns" (DX-558, BHM-184762). At no time during these negotiations did Baxter ever object to Regent's claims about its powder-free gloves (Tr:1015). Indeed, Baxter expressed agreement with them. In March, 1996, Mr. Saxelby wrote to Regent's Chief Executive and admitted that "powder-free glove benefits are valuable and growing (airborne particles, allergies, litigation risk, procedure to procedure cost benefits, and more)." (DX-553, BHM 184706). From this the jury could rightly infer that Mr. Saxelby, the head of the Allegiance glove business and the man who authorized this lawsuit (R440, Tr:1126), recognized that the market was shifting and that his company was not prepared to compete in this transformed market.

D. The BIOGEL Glove Succeeded Because It Was The Right Product For A Transformed Market.

Testimony from an experienced operating room nurse, Ric Cuming, vividly illustrated the superiority of Regent's BIOGEL glove. As soon as Cuming used the BIOGEL glove, he knew that it was what he wanted to wear because of its

"comfort, fit, [and] dependability" (R448, Tr:2553). He said the glove "wouldn't rip as easily" and "felt better on [his] hands" (Tr:2554). Cuming was convinced enough to "hide a box in [his] locker"— a decision he made without ever having seen any advertisements for BIOGEL gloves (Tr:2555). Cuming also testified that one nurse colleague had to leave work for a year due to latex allergy, but was able to return once his hospital converted to a powder-free environment (Tr:2556).

By the end of the trial, it was obvious that Regent had not "moved the market" through false advertising, as Allegiance alleged. Rather, the market had moved due to external forces, and Regent legitimately capitalized on this with its superior, powder-free BIOGEL product. Meanwhile, when Allegiance failed to create a competitive product, saw its own market share diminishing, and failed in its attempt to gain access to Regent's technology, Allegiance filed suit. Allegiance's suit had no basis in the Lanham Act, but rather, as the jury found, was driven by malicious anticompetitive motives.[4]

[4] Throughout four, hard-fought years of litigation, Allegiance employed numerous tactics to harm Regent as a competitor. Allegiance filed an unfounded lawsuit in Oregon against a researcher, Dr. Beezhold, and Margaret Fay (Tr:720, 729), which was dismissed. Allegiance was ordered to pay Dr. Beezhold's attorney's fees and costs (Tr:732, 743). Even these dismissals did not prompt Allegiance to drop identical, unfounded allegations in this lawsuit; Regent was forced to move for partial summary adjudication on the Beezhold allegations (R136), which the district court granted (R243).

Allegiance also committed numerous discovery and procedural abuses. It was held in contempt once (R181, p.5), was sanctioned two other times (R181,

(continued...)

SUMMARY OF THE ARGUMENT

The jury's verdict finding that Regent committed no Lanham Act violations but that Allegiance violated the Act willfully, deliberately, maliciously and in bad faith should be affirmed. Substantial record evidence exists to support the jury's conclusions that, while the product claims in Regent's advertisements were neither false nor misleading, one of Allegiance's advertisements contained claims that were deliberately false.

The court correctly enjoined Allegiance from continuing to violate the law by perpetuating its false advertisement. The court also properly determined that an injunction against Regent under Allegiance's state law claims was not necessary because Regent had long ago stopped disseminating any incorrect credentials about Margaret Fay, and there was no prospect that Regent would do so in the future.

Regarding governmental and other documents that Allegiance claims should not have been admitted, Allegiance "opened the door" to their introduction by raising issues about Regent's good faith and Allegiance's damages. Allegiance "invited" these alleged errors, and may not complain about them on appeal. The documents, moreover, were not hearsay evidence because they were not admitted

(...continued)

pp.8-9; R213, p.10), and was found to have failed to comply with a court order yet another time (R351). Regent successfully moved to compel discovery no less than five times (R181, pp.1-2; R181, pp.8-9; R243, p.2; R243, pp.2-3; R301), and filed another motion to compel (R90), which was withdrawn only after Allegiance finally agreed to comply with Regent's demand (R91).

for the truth of their contents. The court restricted their introduction by admitting them pursuant to explicit limiting instructions.

Regent raises two issues on cross-appeal. First, the district court erred as a matter of law in holding that Regent violated the Georgia Unfair Deceptive Trade Practices Act. The Georgia act parallels the Lanham Act, and Regent's success on the Lanham Act claim mandated judgment in its favor on the Georgia claim.

Finally, the jury found this to be an "exceptional" case warranting attorneys' fees because Allegiance brought this Lanham Act case deliberately, maliciously and in bad faith, while simultaneously engaging in its own false advertising. However, the court incorrectly denied Regent's request for fees because it erroneously failed to restrict its analysis to federal law and allowed irrelevant state law determinations to influence its decision. The jury was entitled to consider the facts in the context of the Lanham Act claims alone, and the court was required to assess attorneys' fees only in relation to the Lanham Act claims and in light of Regent's position as the prevailing party. This Court should affirm the jury's verdict in favor of Regent in all respects, but should reverse judgment against Regent on the Georgia claims and remand this case to the district court for an assessment of attorneys' fees under proper application of Lanham Act law.

ARGUMENTS AND AUTHORITIES IN REPLY

I. STANDARDS OF REVIEW.

A. The Evidence Must Be Viewed In The Light Most Favorable To Regent In Reviewing The District Court's Denial Of Allegiance's Motion For Judgment As A Matter Of Law.

In reviewing the denial of a motion for judgment as a matter of law, this Court reviews *de novo* whether the evidence points so strongly and overwhelmingly in favor of Allegiance that a reasonable jury could not arrive at a contrary verdict. *Slicker v. Jackson*, 215 F.3d 1225, 1229 (11th Cir. 2000) (*citing Bogle v. Orange Cty. Bd. of County Comm'rs*, 162 F.3d 653, 656 (11th Cir. 1998)). This Court will neither "sift facts nor draw inferences from such facts," *Grey v. First Nat'l Bank*, 393 F.2d 371, 381 (5th Cir. 1968), weigh the evidence, or determine the credibility of witnesses. *See Lipphardt v. Durango Steakhouse*, 267 F.3d 1183, 1186 (11th Cir. 2001); *see also Shannon v. BellSouth Telecomms., Inc.*, 292 F.3d 712, 715 (11th Cir. 2002) (Court will not "second-guess" jury or substitute its own judgment). Rather, the Court reviews the evidence "in a light most favorable to the non-moving party, with all reasonable inferences drawn in [its] favor." *McCormick v. Aderholt*, 293 F.3d 1254, 1258 (11th Cir. 2002). The Court "disregard[s] all evidence favorable to the moving party that the jury is not required to believe." *Reeves v. Sanderson Plumbing Prods., Inc.,* 530 U.S. 133, 151 (2000).

Where, as here, the moving party had the burden of proof, the movant's task is even more difficult. This Circuit has held that it is an "extreme step [to direct] a verdict in favor of the party having the burden of proof." *EEOC v. Massey Yardley Chrysler Plymouth, Inc.,* 117 F.3d 1244, 1250 (11th Cir. 1997). The jury generally is free to reject any or all of the movant's evidence and conclude that the movant did not meet its burden, regardless of whether it credits any of the non-movant's testimony. *Id.* Courts have even held that a directed judgment in favor of a party carrying the burden at trial is appropriate only when it would be "impossible" for the jury to find for the non-movant or that there was "insufficient evidence from which the jury could rationally have made any other finding." *Allen v. Zurich Ins. Co.*, 667 F.2d 1162, 1164-65 (4th Cir. 1982) (quoting *Mihalchak v. American Dredging Co.*, 266 F.2d 875, 877 (3d Cir. 1959)).

To win a motion for judgment as a matter of law, Allegiance had to demonstrate at trial that it proved each and every element of its case by testimony that could not have been disbelieved or disregarded by the jury. The cases on which Allegiance relies are irrelevant. In each, the motion for judgment as a matter of law had been brought by the party who did not have the burden at trial. Allegiance did not meet its burden at trial, and ample evidence supports the jury's verdict.

B. This Court Defers To The Trial Court's Observations During Trial And Its Discretion In Denying A Motion For New Trial.

This Court will reverse the denial of a motion for new trial only for abuse of discretion. *Lambert v. Fulton Cty., Ga.*, 253 F.3d 588, 595 (11th Cir. 2001). Deference is "due the trial court's first-hand experience of the witnesses, their demeanor, and a context of the trial. This deference is particularly appropriate where a new trial is denied and the jury's verdict is left undisturbed." *Wood v. Mobark Indus., Inc.*, 70 F.3d 1201, 1206 n.2 (11th Cir. 1995) (quoting *Rosenfeld v. Wellington Leisure Prods., Inc.*, 827 F.2d 1493, 1498 (11th Cir. 1987).

The abuse of discretion standard is "more rigorous when the basis for the motion was the weight of the evidence." *Williams v. City of Valdosta*, 689 F.2d 964, 974 (11th Cir. 1982) (reversing district court's decision to grant new trial). The district court's discretion to grant a new trial based on the "weight of the evidence" is "very narrow," and its denial on that ground is rarely disturbed. *Hewitt v. B.F. Goodrich Co.*, 732 F.2d 1554, 1559 (11th Cir. 1984) (trial court abused discretion by granting new trial). It is "critical that a judge does not merely substitute his judgment for that of the jury." *Lipphardt,* 267 F.3d at 1186 (restoring jury verdict); *Redd v. City of Phenix City, Ala.*, 934 F.2d 1211, 1214 (11th Cir. 1991) (court is not free to substitute its own credibility choices and inferences for the reasonable credibility choices and inferences of the jury). Allegiance failed to cite any case in which this Court overturned a district court's

denial of a plaintiff's motion for new trial based on the "great weight of the evidence." Regent's research has found no such case. The court's denial of Allegiance's motion for a new trial should be affirmed.

C. A New Trial Based On Admission Of Evidence Requires A Showing Of "Substantial Prejudice."

This Court reviews evidentiary rulings for abuse of discretion and reverses for a new trial only where there is "substantial prejudice." *Brochu v. Riviera Beach*, 304 F.3d 1144, 1155 (11th Cir. 2002). Here, the court properly admitted the challenged evidence and issued appropriate limiting instructions to the jury.

D. The Standard Of Review For The Grant Or Denial Of Injunctive Relief Is Highly Deferential.

The district court has broad discretion to grant or deny an injunction based upon established principles of equity. *See Hecht Co. v. Bowles*, 321 U.S. 321, 329, 64 S. Ct. 587, 591, 88 L. Ed. 754, 760 (1944); *Pacific & S. Co. v. Duncan*, 792 F.2d 1013, 1014-15 (11th Cir. 1986). Rulings on injunction requests will be reviewed only for "clear abuse of discretion." *United States v. Gilbert*, 244 F.3d 888, 908 (11th Cir. 2001). However, reversal is warranted if this Court determines that the district court made a "clear error of judgment . . . or has or applied an incorrect legal standard." *SunAmerica Corp. v. Sun Life Assurance Co. of Can.*, 77 F.3d 1325, 1333 (11th Cir. 1996) (internal citations omitted).

II. SUBSTANTIAL EVIDENCE SUPPORTS THE JURY'S VERDICT ON THE LANHAM ACT CLAIMS (Responsive To Argument II Of Allegiance's Br., pp. 39-42).

A. Allegiance Failed To Carry Its Burden Of Proof Under The Lanham Act.

Section 43(a) of the Lanham Act governs false advertising:

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce . . .any false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities or geographic origin of his or her or another person's goods, services or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

1. Allegiance Misdirects Its Argument To Acts Not Covered By The Lanham Act.

To fall within the statute's boundaries, a representation must (1) be false or misleading; and (2) be made in commercial advertising or promotion; and (3) misrepresent the nature, characteristics or qualities of the goods, i.e., the NRL gloves sold by these parties.

Much of Allegiance's argument focuses on acts of Regent that, even if proven, could not, as a matter of law, have created a basis for liability, either because they did not concern the "nature, characteristics or qualities of the goods," or because they did not meet the four-part test to determine whether a

misrepresentation was made in "commercial advertising or promotion." That test requires that the communication:

> (1) constitute commercial speech;
>
> (2) be made by a defendant in direct competition with plaintiff;
>
> (3) for the purposes of influencing the purchase of its goods and services; and
>
> (4) "while the representations need not be made in a 'classic advertising campaign,' but may consist of more informational types of 'promotion,' the representations . . . must be disseminated sufficiently to the relevant purchasing public to constitute 'advertising' or 'promotion' within that industry."

Moulton v. VC3, 2000 U.S. Dist. LEXIS 19916, at *13-14 (N.D. Ga. Nov. 6, 2000) (citations omitted) (Addenda A-1, *infra*).

Under this standard, the following acts, even if Regent had committed them, could not have formed a basis for liability under Section 43(a) as a matter of law:

- requesting that a researcher not publish the results of a study funded by Regent;
- opting not to support or provide funding for a piece of research;
- "ghost-writing" scientific manuscripts; or
- not announcing, publicly, that it asked Peggy Fay to resign because she lacked credentials she told Regent she had.

None of these acts even met the first requirement of constituting commercial speech. Further, they were not "misrepresentations . . . in commercial advertising

or promotion" and they did not concern the "nature, characteristics or qualities" of Regent's goods. *See Moulton*, 2000 U.S. Dist. LEXIS 19916, at *12.

2. Allegiance Failed To Prove That Any Of Regent's Actions Violated Section 43(a) Of The Lanham Act.

Regarding representations that fall within the purview of Section 43(a), Allegiance had the burden of proving that:

> (1) "the defendant made false or misleading statements about its product in an advertisement;
>
> (2) the advertisement actually deceived, or had the tendency to deceive, the targeted audience;
>
> (3) the deception is material;
>
> (4) the defendant's advertised product traveled in interstate commerce; and
>
> (5) the plaintiff has been or is likely to be injured as a result of the false or misleading advertisements."

Hyman v. Nationwide Mut. Fire Ins. Co., 304 F.3d 1179, 1195-96 n.13 (11th Cir. 2002).[5]

The burden of proving falsity was on Allegiance. Regent was not required to prove that a claim was true. Where a claim explicitly stated that it was supported by research or test results (a "tests prove" claim), Allegiance was required to prove that the research or tests were not sufficiently reliable to support

[5] *Hyman* was decided after the trial, during which Allegiance was obligated to meet the essentially identical burdens set forth in *Energy Four, Inc. v. Dornier Med. Sys., Inc.*, 765 F. Supp. 724, 730 (N.D. Ga. 1991).

the proposition for which they were cited, something that Allegiance could not do. *See BASF Corp. v. Old World Trading Co.*, 41 F.3d 1081, 1089-90 (7th Cir. 1994); *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62-63 (2d Cir. 1992).

Regarding claims that were ambiguous or literally true, but alleged to be misleading, Allegiance had to "*prove* actual deception by a preponderance of the evidence, showing how customers actually do react, not merely how they might react," to recover money damages. *Energy Four*, 765 F. Supp at 732 n.3. Allegiance had to present evidence showing consumers were actually misled. *Id*. at 732. In *BellSouth Adver. & Publ'g Corp. v. Lambert Publ'g*, 45 F. Supp. 2d 1316, 1321 (S.D. Ala. 1999), *aff'd*, 207 F.3d 663 (11th Cir. 2000), the Court held:

> [A]bsent a showing of absolute falsity, it is absolutely essential for the Plaintiff to show actual deception by using reliable consumer or market research (citations omitted). It is not for the Court to determine, based solely on some intuitive or visceral reaction, whether an advertisement is deceptive (citations omitted). Plaintiff cannot obtain relief simply by arguing how consumers *could* react; rather, it must show how consumers *actually* react.

(emphasis original); *accord American Council v. American Bd. of Podiatry Surgery*, 185 F.3d 606, 616 (5th Cir. 1999); *Johnson & Johnson Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir. 1992). At trial, Allegiance presented *no* evidence showing how *any* medical professional perceived Regent's claims, let alone that anyone was misled.

The district court instructed the jury that, where a claim was either literally true or ambiguous, but was alleged to have created a misleading impression, consumer deception could also be proved by showing that the claim was made willfully or in bad faith.[6] Because there was *no* evidence of consumer perception, the *only* way remaining for Allegiance to prevail was to prove that Regent had acted in bad faith. This, Allegiance could not do, and the jury found that Regent did not act in bad faith.

Allegiance attempts to demonstrate Regent's alleged bad faith by taking Regent's documents and deposition testimony out of context. In an effort to convince this Court—as Allegiance failed to do with the jury—that the rise of powder-free gloves was a marketing scheme concocted by Regent, Allegiance ignores substantial evidence from articles published in peer-reviewed journals and the positions taken by government agencies and professional societies upon which Regent relied in making its claims. This evidence was admitted under limiting instructions, and was not introduced or relied upon for the truth of the matters asserted. However, where the issue is Regent's alleged "bad faith," this evidence helped establish that Regent had reasonable, sound, and good faith bases for making each of its advertising claims.

[6] (R451, Tr:2846:23-2847:3). Regent objected to this instruction (Tr:2864:7-15) on the ground that it was contrary to the controlling *Energy Four* and *BellSouth* decisions, which require proof of consumer misperception.

B. Regent's Advertising Claims Were Not False.

1. Regent's Claim That Its Glove Was "Hypoallergenic" Was Valid.

The government's definition of "hypoallergenic" (i.e., manufactured so as to reduce risk of chemical sensitivity) differed from the dictionary definition of "hypoallergenic" (i.e., lower in allergens) (PX-539; R434, Tr:154; R443, Tr:1506-07; R445, Tr:1915). Regent had a "510(k)" approval from the United States Food and Drug Administration authorizing Regent to label its gloves as hypoallergenic (DX-522, 528A), and the BIOGEL glove met the FDA standard during the entire time that it was marketed as hypoallergenic (Tr:1507).

Plainly, the "hypoallergenic" claim was not literally false. Allegiance's argument that the claim was "misleading" was premised upon memoranda and testimony of Regent employees who speculated that the hypoallergenic claim *might* cause healthcare professionals to believe that BIOGEL gloves are safe for persons with latex allergy. But Allegiance never adduced the testimony of a single nurse, doctor, technician or other healthcare worker as to how he or she perceived the claim; nor did Allegiance offer any survey evidence showing that anyone was misled. On the contrary, Regent's Technical Services Director testified that he had "never talked to a nurse, doctor, [or] health care worker who was confused by a hypoallergenic glove"(Tr:2078).

Thus, the only way remaining for Allegiance to prevail on this claim was to show that Regent made its hypoallergenic claim in "bad faith." The jury knew, however, that (1) the FDA had approved Regent's use of "hypoallergenic;" (2) many other companies sold their low-chemical-additive gloves as "hypoallergenic;"[7] (3) Regent's glove always met the FDA "hypoallergenic" standard;[8] (4) a 1993 OSHA regulation *required* healthcare providers to make "hypoallergenic" gloves "readily accessible to employees who are allergic to gloves normally provided;"[9] (5) Regent did not make the hypoallergenic claim after the effective date of the FDA prohibition;[10] and (6) Regent consistently advised customers and healthcare workers that its gloves were *not* safe for persons with latex allergy.[11] This was more than enough evidence from which a reasonable jury could conclude that Regent was making the "hypoallergenic" claim in good faith.

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[7] (R437, Tr:355); *see* list of "hypoallergenic" gloves in (DX-357; Tr:1013) ("Q.: And your hypoallergenic glove was ULTRADERM, correct? A. Yes, Sir"); (DX-808; R447, Tr:2444).

[8] (Tr:1507).

[9] (DX-630).

[10] (Tr:1915; Tr:150, 175, 197).

[11] *See* (PX-1013; Tr:2072-73).

2. Allegiance Failed To Prove A Violation In The Alleged "Barrier" Claim.

There was *no* evidence that Regent ever claimed its hydrogel coating acted as a "barrier to latex proteins," as Allegiance asserts. At most, the advertisements cited by Allegiance say that the hydrogel coating inside the BIOGEL glove "buffers the wearer from direct contact with the latex." [12]

This claim is literally true. The undisputed testimony was that the hydrogel coating on the inside of the glove separates the wearer's hand from the latex, although it is not a complete barrier (Tr:162). Allegiance introduced no scientific evidence to refute this.

Allegiance apparently contends that those viewing the ads might interpret "buffers the wearer from the latex" to mean "creates a barrier to latex proteins." However, Allegiance introduced no evidence that anyone ever interpreted the "buffer" claim as a "barrier" claim, or that any latex-allergic person thought he or she could use a BIOGEL glove because of the protection provided by the hydrogel coating.

In asserting that Regent made the buffer claim in bad faith, Allegiance seizes upon internal Regent memoranda that either caution against a *barrier* claim (which Regent never made) or simply question the basis for a buffer claim. Allegiance

[12] Of the advertisements cited on page 14 of Allegiance's brief, three of them (PX-64, 65 and 441) make no buffer or barrier claim at all.

produced no scientific evidence contrary to the "buffer" analogy, and none is known. More importantly, Allegiance ignores two articles in peer-reviewed medical journals that Regent relied upon for the buffer claim: a 1991 article reporting that "the inside coating [of the BIOGEL glove] is an effective barrier against latex" (DX-703; Tr:1641-43); and a 1992 article reporting that the hydrogel coating "protects the hands from direct contact with the latex" (DX-667; Tr:1590-91). Both articles were admitted under a limiting instruction, but they provided a sufficient basis for a reasonable jury to conclude that Regent had a good faith belief in its statement—especially when Allegiance failed to adduce any scientific evidence that the claim was false or that anyone was deceived by it.

3. Allegiance Failed To Prove Its Alleged "Contributed To Or Caused Latex Allergies" Claim.

Allegiance did not show the jury a single advertisement in which Regent said that the "powder on NRL gloves contributed to or caused latex allergies." The exhibits cited by Allegiance made much more specific, undisputedly accurate claims: (i) that absence of glove powder "eliminates a carrier for airborne allergens" (PX-42, 575), or "eliminates a carrier for airborne latex proteins" (PX-574); (ii) that BIOGEL powder-free gloves "reduce the risk of wound contamination" (PX-620 at L615634), (iii) that glove powder "can bind latex proteins" and "airborne, can do double duty as an allergen" (PX-579); (iv) that starch powder has been shown to cause "serious post-op complications and . . .

ha[s] been implicated as [an] airborne carrier[] of microbes, allergic chemicals and latex proteins (PX-571); and (v) that "post-op problems caused by glove powder . . . have been virtually eliminated" (PX-69 at L603055).[13]

Rather than focus on a claim that Regent *did* make, Allegiance attacks a claim that Regent did *not* make: that inhalation of airborne allergens bound to glove powder, in itself, causes sensitization. Regent scientists and witnesses agreed that such a claim would be unsupported, due to the impossibility of doing an experiment which would pinpoint a single cause for any person being allergic to anything.[14]

The evidentiary excerpts cited by Allegiance show Regent's scientists cautioned the company not to make any claim that airborne latex particles *per se*

[13] Some of the exhibits that Allegiance cites on page 19 of its Brief do not make any claims about glove powder and appear to have been included there only because they used the word "risk." E.g., "risk of using lower quality gloves . . . include post-op complications and exposure to allergens and blood borne pathogens" (PX-65, 441), or "Surgical gloves are an essential risk-reduction tool" (PX-575).

[14] As former Regent executive Gareth Clarke explained, it would be impossible to find people (other than newborn babies) who had never been exposed to latex previously and just get them to ingest latex powder (Tr:171; *see also* Tr:2382) (double-blind study would be impossible and unethical, because "you're basically trying to make healthy people sick"). Further, as Regent's Technical Services Director Milt Hinsch explained, "there is no pure science that will say that aerosolized latex allergens on corn starch sensitizes people, but it seems to be common sense that when you get down to allergens, we're talking about things like rag weed, we're talking about things like pollen, and, you know, people are sensitized that way all of the time" (Tr:2443).

cause sensitization, and Regent took their advice. Allegiance's attempt to misuse these cautionary statements, its failure to prove its case, and the evidence against Allegiance all support the jury's verdict.

4. Allegiance Failed To Prove Any Falsehood In The "In-Use Failure Rate" Claim.

Allegiance introduced no test results or scientific evidence to support its assertion that Regent's "in-use failure rate" claim was false. Nor did Allegiance invalidate the methodology of the Fay-Dooher study, which Regent used to support its claim of lower in-use failure. As it attempted at trial, Allegiance asks this Court to infer that the Fay-Dooher study was unreliable and false merely because Ms. Fay conducted it. The jury heard the witnesses, evaluated their credibility, and rejected this unsupported inference.

The article reporting the Fay-Dooher study (PX-674) was subjected to independent peer-review (Tr:1618-19, 1646-47), published in a reputable medical journal, and described as "excellent" by the journal's Senior Associate Editor (PX-57). Allegiance did not refute that the study was accurate and correct as of the time it was published in 1992. Moreover, the Fay-Dooher study was buttressed four years later. As reported in a regular Regent monthly report (PX-642):

> Comparative study between Dextran Clear and Biogel was completed by Denton International at UCLA Medical Center. The Biogel glove failed in-use 2.5-4.3% while the Dextran Clear glove failed an average 12%-14%.

The claim was further supported by the testimony of Ric Cuming, who actually wore BIOGEL gloves while working as an operating room nurse and found that "they were dependable in that they wouldn't rip as easily" (Tr:2554).

Allegiance relies heavily on a 1998 memorandum (PX-529) reporting a study by Dr. Newsom that showed a BIOGEL failure rate of 10%. Allegiance concludes that the Newsom study must be correct, and consequently proves that the Fay-Dooher study was wrong. This issue, however, rested within the province of the jury, which was free to decide that the Newsom study (which, in its published form, DX-1283, was admitted only under a limiting instruction) was incorrect, and that the three other pieces of evidence—the Fay-Dooher study, the Denton study, and Mr. Cuming's actual experience—were correct. Further, the jury heard uncontradicted testimony that the Newsom study could not be compared to other studies because of the differences in methodology, and that the study demonstrated that Regent's gloves did in fact have a lower failure rate than other surgeons' gloves (Tr:1992-93). The jury's determination was amply supported on this record, and the trial court correctly exercised its discretion in denying Allegiance's motion for new trial. [15]

[15] As to the other advertising claims decided by the jury (RE9), Allegiance's failure to specify any error waives any further argument. *See Artisan Contractors Ass'n of Am., Inc. v. Frontier Ins. Co.*, 275 F.3d 1038, 1039 n.1 (11th Cir. 2001).

III. THE DISTRICT COURT CORRECTLY DENIED ALLEGIANCE'S MOTION FOR JUDGMENT AS A MATTER OF LAW ON REGENT'S COUNTERCLAIM (Responsive To Argument III(A) Of Allegiance's Br., pp. 42-43).

Allegiance does not challenge the sufficiency of the evidence supporting the jury's verdict for Regent on its counterclaim against Allegiance for violation of the Lanham Act. Instead, Allegiance contends that its advertising claim is not a statement of fact capable of being literally false. However, the claim is both a statement of fact and a "description of fact" capable of being literally false, and the jury found it to be literally and willfully false.

Allegiance's advertisements asserted: 1) "it is unknown whether it [the latex cornstarch combination] is respirable;" 2) "the combination may be too heavy to be airborne, and therefore, sink rapidly to the floor;" and 3) "the particles may be too large to be respirable." (Tr:541-43; Tr:1067; R449, Tr:2575, DX-16, DX-19) (emphasis added). These are statements of fact because whether something is "unknown" is itself a fact, separate from what is asserted to be unknown. Such a statement is false if the fact was known when Allegiance asserted that it was *not*. Similarly, stating that the combination "may be" too heavy to be airborne or "may be" too large to be respirable is false if the combination is *not* too heavy to be airborne or the particles are *not* too large to be respirable.

The Lanham Act also prohibits "any false or misleading *description* of fact." 15 U.S.C. § 1125(a) (emphasis added). Allegiance's advertising constituted a

description of fact because it described the nature or quality of the referenced subject. For example, it described the respirability of the latex cornstarch combination as being "unknown," as opposed to known. This description is capable of being false, and it is false because the respirability was not "unknown" as advertised by Allegiance. Because Allegiance's advertising was capable of being false, a question of fact was properly presented to the jury for consideration. The evidence supported the jury's verdict, and the district court correctly denied Allegiance's motion for judgment as a matter of law.

IV. THE DISTRICT COURT PROPERLY EXERCISED ITS DISCRETION IN GRANTING AN INJUNCTION TO REGENT AND DENYING AN INJUNCTION TO ALLEGIANCE.

A. The District Court Acted Within Its Broad Discretion In Granting Regent Injunctive Relief To Prevent Allegiance's Future Violations Of The Law (Responsive To Argument III(B) Of Allegiance's Br., pp. 43-44).

Allegiance contends that it should not have been enjoined because Regent did not prove that Allegiance was continuing to cause harm. Allegiance fails to acknowledge the district court's broad discretion to consider all the facts and circumstances when granting an injunction. *See Hecht Co.*, 321 U.S. at 329; *Pacific & S. Co.*, 792 F.2d at 1014-15.

A literally false advertising claim is presumed to cause irreparable injury. *See Syntex, Inc. v. Interpharm, Inc.*, 1993 U.S. Dist. LEXIS 10761, at *25-26 (N.D. Ga. Mar. 18, 1993) (Addenda A-2, *infra*); *Energy Four,* 765 F. Supp. at 733 (N.D.

Ga. 1991). Here, that presumption is buttressed by the jury's finding of willfulness because Allegiance *intended* to deceive the public and admits it still wants to do so (RE9, p.10).

Allegiance employee Deborah Davis testified during discovery that the advertising claims were distributed to Allegiance sales representatives for use with customers (R509, p. 20, Exh. A). Other Allegiance employees confirmed this at trial (Tr:541-43, 564-66). Prior to entry of the injunction, Allegiance did not present any evidence that it had stopped disseminating the advertising, that Allegiance salespersons were not using it in their presentations to customers, or that it intended to stop doing so.

Even after the jury found Allegiance's statements to be willfully false and the district court entered the injunction, Allegiance's own in-house counsel confirmed that Allegiance continues to make the statements in "ongoing scientific debate" (R493/497, Trull Aff.).[16] Although the injunction is properly limited to commercial speech, Allegiance continues to disregard the proven falsity of its statements (Tr:1516-1517).

The nature of the harm from Allegiance's claims is also highly pertinent. Both patients and healthcare workers rely on surgical gloves to protect their careers

[16] Mr. Trull's affidavit was submitted after the injunction was granted, in support of Allegiance's post-judgment motion to stay the injunction.

and their lives (Tr:623-624). Allegiance's false claims relate *directly* to the safety of those products, and thus the harm goes beyond mere monetary damage to Regent or even consumers. The entry of an injunction to protect the public health and safety, to prevent misinformation, and to protect latex-sensitive individuals from potentially life-threatening allergic reactions, is not an abuse of discretion. In view of all of the evidence, the court correctly exercised its discretion in imposing the injunction prohibiting Allegiance's false and self-serving advertisements.

B. Similarly, The District Court Appropriately Exercised Its Discretion In Denying Allegiance Injunctive Relief When None Was Needed (Responsive To Issue IV Of Allegiance's Br., pp. 44-50).

The district court also correctly exercised its discretion in denying injunctive relief to Allegiance under its California and Georgia state law claims because no injunctive relief was needed. The jury found that none of Regent's advertisements or claims regarding its powder-free BIOGEL gloves was false or misleading. Even Margaret Fay's articles and research were correct and valid; it was only her credentials that were inaccurate.

Regarding the issue of Margaret Fay's lack of credentials, the evidence showed that upon learning of this problem, Regent took immediate remedial action and asked for Ms. Fay's resignation (Tr:1517). Ms. Fay has not worked for Regent since July 1997. Regent cured its own innocent mistake by removing Ms. Fay's articles from its sales presentation book (DX-657, Tr:2098-99), and it is undisputed

that Regent has not circulated any promotional materials containing her false credentials since at least March, 1999 (RE12:13). As the district court correctly held, injunctive relief is not an appropriate remedy for past wrongs that pose no threat of harm in the future. *Logan v. Burgers Ozark Country Cured Hams, Inc.,* 263 F.3d 447, 465 (5th Cir. 2001); *see also* O.C.G.A. § 10-1-373 (authorizing injunctions only when persons are "likely to be damaged").

The court also correctly concluded that "there is no present likelihood of injury to Allegiance" (RE12:8). As for Regent's articles and papers that are already in circulation, the court noted that the jury found that none of them had caused any damage to Allegiance in the past (RE12:8), and therefore they could not, and would not, cause any damage to Allegiance in the future. In short, Regent took remedial action promptly upon notice of the situation, and the jury found that no damage ever flowed from it (RE9).

Regardless, Allegiance cannot obtain an injunction under the Georgia Act because as discussed in Section VI, *infra*, Regent did not violate Georgia law and judgment on that count should be reversed.[17]

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[17] Because there was no violation of Georgia law, there was also no predicate violation of the California law as found by the Court (RE12:23). Also, the California law is unconstitutional as being vague, ambiguous, and overly broad in scope to the extent it seeks to regulate activity occurring wholly outside of California. *See Pennoyer v. Neff*, 95 U.S. 714, 720-22 (1878); *Lesnick v. Hollingsworth & Vose Co.*, 35 F.3d 939, 941 (4th Cir. 1994). The district court (continued...)

Nor did the district court improperly create a *de minimis* exception to the California Health and Safety Code, as Allegiance argues. Allegiance presented no evidence that Regent disseminated the disputed advertisements to anyone other than those in the medical professions. Contrary to Allegiance's assertion, the court did not acknowledge any proof otherwise. Rather, the court properly interpreted the statute to reject Allegiance's contention that the mere (but unproven) possibility that a member of the general public could come across Regent's material was not within the statute's bounds (RE12:22-23). Allegiance cites no authority that would require or even justify that the statute be applied or interpreted any differently.

In addition, there was no need for the district court to consider injunctive relief against Regent because Allegiance concedes, as it must, that Regent has not distributed the accused advertisements since 1999 (Tr:2765). S*ee Logan*, 263 F.3d at 465 (*citing Seven-Up v. Coca-Cola Co.*, 86 F.3d 1379, 1390 (5th Cir. 1996)). The district court properly exercised its discretion in denying injunctive relief to Allegiance for its claims under California and Georgia state law because no injunctive relief was permissible or needed.

(...continued)

opined that the law was unconstitutional (R450, Tr:2668-2669), but did not rule on this issue in its opinion accompanying the judgment.

V. THE DISTRICT COURT PROPERLY EXERCISED ITS DISCRETION IN ADMITTING DOCUMENTS AUTHORED BY GOVERNMENT AGENCIES AND OTHERS UNDER EXPLICIT AND REPEATED LIMITING INSTRUCTIONS (Responsive To Argument I Of Allegiance's Br., pp. 30-39).

Allegiance's principal argument is that the district court abused its discretion by admitting documents "authored by governmental agencies or third-party healthcare or industry associations" that contained "position statements or articles about NRL gloves or NRL allergy."[18] Because these documents were probative of central issues, and because each was admitted under an instruction limiting its use to these issues, the district court correctly exercised its discretion. Allegiance was not substantially prejudiced by their introduction into evidence.

A. Allegiance "Opened The Door" By Raising Issues That Required The Introduction Of These Documents.

Allegiance raised the issues of Regent's good faith and causation of "lost profits." It accused Regent not only of engaging in false advertising (RE2, Count I), but also of doing so willfully (*Id.*, Count II). Indeed, because Allegiance had no evidence of how consumers perceived Regent's allegedly misleading advertising

[18] Allegiance does not specify the exhibits about which it complains. However, by Regent's count, no more than ten such documents were admitted, each with a limiting instruction: DX-580 (R444, Tr:1761); DX-585 (R445, Tr:1938); DX-584 (R445, Tr:1913); DX-585 (R443, Tr:1595); DX-588 (R445, Tr:1934-35); DX-620 (R445, Tr:1925); DX-656B (R443, Tr:1589); DX-784 (R444, Tr:1784-85); DX-956 (R445, Tr:1941); DX-1282 (R445, Tr:1957). A total of 395 documents were admitted in this four-week trial.

claims, Allegiance could not prevail unless it could demonstrate that Regent's ads were made with a willful intent to deceive. Despite the evidence and the jury's verdict, Allegiance continues to assert on appeal Regent's supposed "willful and reckless manipulation of the medical glove marketplace." (Allegiance Br., 2).

Allegiance attributes *all* of its lost sales to Regent's allegedly false advertising — and no other factor (R442, Tr:1392-93). Allegiance sought over $140,000,000 in damages (Tr:1563), but to collect damages for lost profits, Allegiance had to prove that they were substantially caused by Regent's "false" advertising (Tr:2854). Allegiance's claims opened the door to the evidence Allegiance sought to have excluded. "It is a cardinal rule of appellate review that a party may not challenge as error a ruling or other trial proceeding invited by that party." *See United States v. Ross*, 131 F.3d 970, 988 (11th Cir. 1997); *see also Ford ex. rel. Estate of Ford v. Garcia*, 289 F.3d 1283, 1293 (11th Cir. 2002) (invited error precludes finding of plain error or reversal). Allegiance made Regent's intent and good faith in making its ad claims, and its own lost sales and decline in market share, central issues in this case. To assess Allegiance's claims, the jury was entitled to know on what scientific evidence and information Regent relied. The jury also was entitled to know that the marketplace was relying on the recommendations of significant professional organizations and government

agencies that endorsed powder-free gloves. This evidence was relevant to the key issues of intent, causation, and damages.[19]

The district court carefully admitted this evidence pursuant to limiting instructions, reminding the jury repeatedly that this evidence was to be considered only with respect to the issues of Regent's good faith and the marketplace conditions that affected demand for powder-free gloves (*see, e.g.*, Tr:1589, 1595, 1963, 2014, 2494). In its charge, the court again explicitly instructed the jury that any scientific article whose author was not called to testify could only be used to consider Allegiance's damages or Regent's good faith and not "as evidence of the truth of the statements" (RE8, 425, Tr:2842-43).[20] Allegiance did not object to this instruction (*Id.*, Tr:2865-2867), and thereby waived any objection it may have to it

[19] By contrast, Allegiance sought to admit FDA guidelines on latex gloves for a completely improper and prejudicial purpose: to convince the jury that Regent's "violation" of these guidelines was somehow a violation of law or proof of the falsity of Regent's claims (RE2:9-10). The district court correctly ruled that these guidelines are non-binding, and thus their use of language like "must" and "shall" would confuse the jury and create a prejudicial effect outweighing any probative value (RE6:10-12). There was no inconsistency and no unfairness to Allegiance in these rulings.

[20] Allegiance complains specifically only about documents "authored by governmental agencies or third party healthcare or industry associations" (Alleg. Br. 30), but the same analysis here applies to articles from peer-reviewed medical journals. Upon Allegiance's objection, any such articles were admitted with a limiting instruction, for the purpose of showing reliance by Regent and/or impact on the marketplace, and not for the truth of the matters asserted. *See*, *e.g.*, Tr:1500, 1503-04, 1629, 1773-74.

now, on appeal. *See* FED. R. CIV. P. 51; *Landsman Packing Co. v. Continental Can Co.*, 864 F.2d 721, 726 (11th Cir. 1989).

B. The Documents Were Not Hearsay Because They Were Not Admitted For Their Truth, And Were Subject To Specific And Explicit Limiting Instructions.

The district court appropriately exercised its discretion under Fed. R. Evid. 105 in admitting these documents. "Under Rule 105, evidence should generally be admitted if it is relevant to one issue [or] one theory, even if it is inadmissible as to others, in the same case." 1 WEINSTEIN'S FEDERAL EVIDENCE §105.04[1][a] (*citing Lumbermens Mut. Cas. Co. v. Renuart-Bailey-Cheely Lumber and Supply Co.*, 387 F.2d 423, 425 (5th Cir. 1968)). Limiting instructions are routinely used when admitting documents which otherwise would be deemed hearsay, not for the truth of the matter asserted, but for some other purpose.

In *Worsham v. A.H. Robins Co.,* 734 F.2d 676 (11th Cir. 1984), a products-liability case involving the Dalkon Shield intrauterine device, the district court admitted reports by doctors and company representatives about adverse reactions to the shield, not for the truth of the content of the reports, but to show that the defendant had notice about such problems. *Id*. at 686. The defendant argued that these reports exposed the jury "to the opinion of 'experts' who could not be cross-examined," but this Court affirmed, holding that "[t]he documents were properly

submitted and admitted into evidence as proof of Robins' state of mind and therefore did not constitute hearsay." *Id*. at 686-87.

Similarly, in *Wyatt v. Otis Elevator Co.*, 921 F.2d 1224 (11th Cir. 1991), a case involving an allegedly defective elevator door, the district court admitted evidence of other incidents involving elevator door failure solely for the purpose of showing defendant's knowledge of the problem. This Court affirmed, holding that "considering the oft-repeated limiting and cautionary instructions to the jury, we cannot say that there was reversible error." *Id*. at 1228.

The Fifth Circuit reached the same conclusion on a similar issue in *Mauldin v. Upjohn Co.*, 697 F.2d 644 (5th Cir. 1983), a products liability case concerning an antibiotic drug which allegedly caused colitis as a side effect. Plaintiff sought to admit "adverse reaction" reports from doctors to show the defendant's awareness of the problem. *Id*. at 648. The defendant objected on two grounds — hearsay and undue prejudice—because the report also discussed reactions other than colitis. *Id*. The district court admitted the reports under a limiting instruction to consider them only on the issue of notice. *Id*. at n.7. The Fifth Circuit affirmed, noting that hearsay was not implicated because the reports were not offered to prove the truth of their contents. *Id*. at n.6. As to prejudice, the Court held that even though the plaintiff's counsel dwelled on the reports, the limiting instruction prevented any jury confusion. *Id.* The strong presumption is that a jury will follow a court's

limiting instructions. *Parter v. Randolph*, 442 U.S. 62, 74-75, 99 S. Ct. 2132, 60 L. Ed. 2d 713 (1979), *United States v. Acevedo*, 141 F.3d 1421, 1426 (11th Cir. 1998).

Allegiance complains primarily of the admission of unspecified "governmental documents," which it asserts should not have been admitted under Fed. R. Evid. 803(8).[21] However, these documents were *not* admitted under the hearsay exception set forth in Rule 803(8). Rather, they were admitted as non-hearsay—not for the truth of the matters asserted, but for their bearing on Regent's state of mind, good faith, and their impact on the market (Tr:1784-85, 1925, 1957). Allegiance's Rule 803(8) argument is irrelevant.

Allegiance misplaces heavy reliance on *Toole v. McClintock*, 999 F.2d 1430 (11th Cir. 1993) (Alleg. Br., 33). In *Toole,* the plaintiffs sought to admit an FDA report to "corroborate testimony by their expert witness." *Id*. at 1434. Essentially, the plaintiffs in *Toole* wanted to rely on the truth of the report to prove liability. The sole issue was admissibility under the hearsay exception in Rule 803(8). That rule is not implicated here because the Court did *not* admit the documents under Rule 803(8), but rather as non-hearsay.

[21] Of the 395 exhibits admitted at trial, only three "governmental documents" are at issue: a page from the NIOSH Web site (DX-784), a 1997 "Medical Glove Powder Report" from the Center for Devices and Radiological Health (DX-620), and an FDA Alert on latex allergy from 1992 (DX-1282).

Indeed, in *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307 (11th Cir. 2000), which confirmed and explained *Toole v. McClintock,* this Court recognized the difference between inadmissible hearsay and non-hearsay documents admitted for the purpose of showing a party's state of mind. *Id*. at 1313 (explaining *McClintock*, 999 F.2d at 1422 n.7). There, this Court rejected Baxter's challenge to the admission of hundreds of complaints about breast implants, holding that they were admissible "for the purpose of showing that Baxter had notice of the fragility of its product." *Baxter,* 235 F.3d at 1313. The same distinction applies here.

Allegiance also complains that the court's "error" was compounded by the jury charge, which instructed the jury that it could consider third party/scientific documents not for the truth of the matter asserted, but to "determine the situation in the marketplace" (Allegiance Br. 37-38; R425; RE8, 2843). The court's reinforcement of its limiting instructions was entirely proper. *See Wyatt*, 921 F.2d at 1228.

Moreover, Allegiance waived this argument. It raised no objection either at the charge conference or after the limiting instruction was given (R450, Tr:2628-36, 2865-2867). Indeed, Allegiance's counsel helped compose its precise wording (Tr:2679-2681). Allegiance's assistance in crafting the charge, and its failure to object, forecloses its attack on the charge on appeal. *See* Fed. R. Civ. P. 51; *Landsman Packing Co.,* 864 F.2d at 726.

Finally, even if this argument was not waived, it is wrong. There is no legal doctrine, in this Circuit or any other, that bars use of third-party documents for the relevant, non-hearsay purpose of assisting in a determination of causation or good faith. The significance of these documents rested in the fact that these issues and concerns were being discussed widely and that Regent and others relied on them — not the truth of their content.[22]

Allegiance's reliance on the cases it cites is misplaced. In *Canyon View Ranch v. Basin Elec. Power Corp.*, 628 P.2d 530 (Wyo. 1981), for example, the state appellate court simply affirmed the trial court's exclusion of evidence under the abuse of discretion standard, under the particular circumstances of that case. *Id*. at 537. There was no discussion of any jury instruction because the evidence was excluded. Here, Allegiance ascribed the entire shift in preference toward powder-free gloves to one cause: Regent's alleged false advertising. Trial testimony repeatedly confirmed that the positions taken by professional and government entities were relied upon by customers in making purchase decisions and by Regent in formulating its advertising claims (*E.g.*, Tr:1956-57, 1940-41,

[22] As Judge Pannell put it:

> "If George Bush got on television and said, don't buy powdered latex gloves, there is a national emergency, quit buying them, it's a health hazard, we interrupt this program, they could bring that government statement in to show why people quit buying powdered latex gloves" (Tr:1783).

1757-58). Those documents showed that powder-free gloves and issues related to powder were "hot topics" in the medical community, wholly independent from anything Regent did.

Under these circumstances, total exclusion of this evidence would have deprived the jury of critical information needed to understand the marketplace and put the allegations into context. The admission of this evidence under the limiting instructions struck the right balance, and was well within the trial court's discretion.

ARGUMENTS AND AUTHORITIES ON CROSS-APPEAL

VI. THE COURT ERRED AS A MATTER OF LAW IN NOT ENTERING JUDGMENT FOR REGENT ON ALLEGIANCE'S CLAIMS UNDER THE GEORGIA UNFAIR DECEPTIVE TRADE PRACTICES ACT (Count V Of The Amended Complaint).

A. Standard Of Review.

The jury found that Regent committed no violations of the Lanham Act, and the court entered judgment in favor of Regent on Allegiance's Lanham Act claims (RE9; RE11; RE13). As a matter of law, this Court and the Georgia district courts have uniformly recognized that disposition of a party's Lanham Act claims is dispositive of its claims under the Georgia Unfair Deceptive Trade Practices Act ("GUDTPA"). *Jellibeans, Inc. v. Skating Clubs*, 716 F.2d 833, 839 (11th Cir. 1983) (*citing Amstar Corp. v. Domino's Pizza, Inc.*, 615 F.2d 252 (5th Cir. 1980)); *Energy Four*, 765 F. Supp. at 731; *Original Appalachian Artworks, Inc. v.*

Schlaifer Nance & Co., 679 F. Supp. 1564, 1578 (N.D. Ga. 1987). In *Original Appalachian Artworks*, the court explicitly ruled that "[s]ince the court has found that [the defendants] did not violate the Lanham Act, it necessarily follows that they did not violate the Georgia statute." 679 F. Supp. at 1578. However, despite the court's and the parties' acknowledgement that Allegiance's GUDTPA claims would be determined by the outcome of its Lanham Act claims, the court held that Regent had violated Georgia law (R450, Tr:2668-69; RE12:7).

This Court reviews the legal standard applied by the court below *de novo*, and will reverse if the district court applied an incorrect legal standard. *See Kosow v. Commissioner*, 45 F.3d 1524, 1528 (11th Cir. 1995); *Mini Maid Servs. Co. v. Maid Brigade Sys., Inc.*, 967 F.2d 1516, 1517 (11th Cir. 1992). This Court may also apply the correct legal standard and render judgment for Regent. *See Walker v. Mortham*, 158 F.3d 1177, 1179-80 (11th Cir. 1998).

B. The Court Erred As A Matter of Law In Holding That Regent Violated The GUDTPA.

Controlling authority instructs that the disposition of Allegiance's Lanham Act claims also decides its GUDTPA claims. *See Jellibeans*, 716 F.2d at 839; *Energy Four*, 765 F. Supp. at 731; *Original Appalachian Artworks*, 679 F. Supp. at 1578. The district court failed to apply longstanding precedent in deciding this issue. Therefore, the judgment must be reversed, and this Court should either render judgment for Regent or remand with instructions for the

district court to enter judgment on Count V of the amended complaint in favor of Regent. *See Kosow*, 45 F.3d at 1528; *Walker*, 158 F.3d at 1179-80.

VII. THE DISTRICT COURT INCORRECTLY ANALYZED THE ISSUE OF ATTORNEYS' FEES UNDER THE LANHAM ACT AS A MATTER OF LAW, AND THUS ABUSED ITS DISCRETION IN DENYING REGENT'S REQUEST FOR ATTORNEYS' FEES.

A. Standard Of Review.

The jury found and the district court agreed that Regent did not commit any of the Lanham Act violations alleged by Allegiance (RE9:8-9; RE12:20). The jury further found that Allegiance acted maliciously, fraudulently, deliberately, willfully, and in bad faith toward Regent in bringing and pursuing this four-year-long lawsuit (RE9:9). Finally, the jury found in favor of Regent on its counterclaim, deciding that it was Allegiance who had committed Lanham Act violations, and that Allegiance had done so maliciously, fraudulently, deliberately, willfully, and in bad faith (RE9:10).

Despite these findings, and its own recognition that Regent prevailed on all of the Lanham Act claims—both as defendant and as plaintiff—the court erroneously denied Regent's request for attorneys' fees based on legally irrelevant state law determinations and by disregarding the jury's findings of malice that

make this the "exceptional" case warranting an award of fees (Regent RE1)[23]. The court discounted the jury's verdict, overlooked Regent's successful counterclaim, and improperly focused on extraneous issues. As a matter of law, the proper focus should have been on the Lanham Act claims alone.

This Court reviews attorneys' fee decisions generally for abuse of discretion. However, it reviews a district court's legal analysis assessing fees under the *de novo* standard of review. *See Loggerhead Turtle v. County Council,* 307 F.3d 1318, 1322 (11th Cir. 2002); *Lipscher v. LRP Publ'ns, Inc.*, 266 F.3d 1305, 1319-20; *see also Montgomery v. Noga*, 168 F.3d 1282, 1303 (11th Cir. 1999) (only where district court weighed the relevant factors is the fee determination reviewed for abuse of discretion).

Failure to apply the correct legal standard when assessing fees constitutes an abuse of discretion as a matter of law. *See Johnson v. Breeden*, 280 F.3d 1308, 1326-27 (11th Cir. 2002) (abuse of discretion occurs in award of fees if judge fails to apply proper legal standard or to follow proper procedures in making fee determination); *Goodheart Clothing Co., Inc. v. Laura Goodman Enter., Inc.*, 962

[23] Regent properly detailed and substantiated its attorneys' fee claim in the court below pursuant to Fed. R. Civ. P. 54(d); s*ee Gordon v. Heimann*, 715 F.2d 531, 534 (11th Cir. 1983). Regent hereby preserves its claim to approximately $9 million in attorneys' fees, as detailed in its substantiating memoranda and other filings (R462, R465, R487, R501).

F.2d 268, 272 (2d Cir. 1992) (court that fails to consider fees when bad faith Lanham Act conduct exists has abused its discretion).

B. The District Court Improperly Looked Beyond The Lanham Act Claims And Relied On Irrelevant State Law Claims In Denying Regent's Well-Founded Request For Attorneys' Fees.

The Lanham Act provides that the court may award attorneys' fees to the prevailing party in exceptional cases. 15 U.S.C. § 1117(a). In denying fees, the district court incorrectly allowed state law determinations — some of which are based on lesser standards and all of which are irrelevant to the Lanham Act — to influence its decision.[24] The proper and only focus should have been on the Lanham Act claims and Allegiance's conduct. *See Lonestar Steakhouse & Saloon, Inc. v. Longhorn Steaks, Inc.*, 106 F.3d 355, 364 (11th Cir. 1997) (remanding for determination of fees under Lanham Act even though party did not prevail on Georgia state law claims); *Montgomery*, 168 F.3d at 1304-05 (analyzing copyright and Lanham Act claims separately); *Neva, Inc. v. Christian Duplications Int'l, Inc.*, 743 F. Supp. 1533, 1543 (M.D. Fla. 1990); Annotation, Robin C. Larner, *Award of Attorneys' Fees Under § 35(a) of Lanham Act (15 USCS § 1117(a)) Authorizing*

[24] Although the state claims are legally irrelevant to a proper analysis of an attorneys' fee award under the Lanham Act, the court legally erred in deciding Allegiance's GUDTPA claims against Regent (see § IV, *supra*). Reversal of the court's decision on the GUDTPA claim would also warrant a remand for reconsideration of the fees. *See Frehling Enters., Inc. v. International Select Group, Inc.*, 192 F.3d 1330, 1342 (11th Cir. 1999) (remanding because the basis underlying the district court's decision was overturned on appeal).

Award in "Exceptional Cases," 82 A.L.R. Fed. 143, 198 (1987). Indeed, Regent prevailed both as defendant on Allegiance's Lanham Act claims and as plaintiff on its own Lanham Act counterclaim.

To receive fees under the Lanham Act, a party need not have prevailed in the litigation taken as a whole. *See Lonestar Steakhouse*, 106 F.3d at 364, *Neva*, 743 F. Supp. at 1543. Courts routinely grant partial fee awards to parties who prevail on Lanham Act claims, but not on other claims. *See, e.g., Gracie v. Gracie*, 217 F.3d 1060, 1069-70 (9th Cir. 2000); *Neva*, 743 F. Supp. at 1543 (plaintiff prevailed on some but not all claims); *see also Hensley v. Eckerhart,* 461 U.S. 424, 435-37 (1983) (apportionment of fees); *Norman v. Housing Auth.*, 836 F.2d. 1292, 1302-03 (11th Cir. 1988).

The jury found, and the court agreed, that Regent was the prevailing party on all Lanham Act claims and that Allegiance brought its Lanham Act claims maliciously, fraudulently, and in bad faith.[25] The jury also found that in violating the Lanham Act, Allegiance acted maliciously, fraudulently, and in bad faith. Regent is entitled to recover fees and expenses on two independent grounds — as

[25] Allegiance was granted no relief, whereas Regent was granted an injunction (RE13). Regent also prevailed on those claims that were dismissed on summary judgment pursuant to the court's March 26, 2001 order (R243). *See Tire Kingdom, Inc. v. Morgan Tire & Auto, Inc.,* 253 F.3d 1332, 1334 (11th Cir. 2001) (awarding fees to party who prevailed on summary judgment).

the prevailing defendant on Allegiance's Lanham Act claims and as the prevailing plaintiff on its Lanham Act counterclaim.

In deciding whether to award fees, the court collapsed the analysis and improperly focused on the state claims and the outcome of the entire suit when it speculated that the jury might have found otherwise if it had known of the state law violations (Regent RE1, 4). First, it was entirely proper for the jury to focus exclusively on the facts in the context of the Lanham Act claims. *See Neva,* 743 F. Supp. at 1543. The district court should not have speculated about what the jury might have found, but should have focused on what the jury did find.

Second, all parties, including Allegiance, agreed to withhold the state law claims from the jury and to let the court decide them (R442, Tr:1459). Even assuming the jury could properly consider the state law claims—a position that is neither legally supportable nor true—it was incumbent on Allegiance to ensure that the jury received this information, by proposing either a jury instruction or an interrogatory that would have required the jury to consider it. Because Allegiance did not even argue below that *if* the jury would have considered the state claims, *then* its verdict would have been different, any such argument on appeal would be

both speculative and waived.[26] *See Ford*, 289 F.3d at 1293-94 (where party agrees to court's proposed handling of an issue, this constitutes invited error and waiver of the right to object on appeal); *see also Stewart & Stevenson Servs., Inc. v. Pickard*, 749 F.2d 635, 641 (11th Cir. 1984) (to preserve error, party must either propose or be denied special interrogatory).

Third, the court overlooked the fact that Regent prevailed on its counterclaim and the jury found Allegiance's violation to be willful, fraudulent and in bad faith. This alone warranted an award of attorneys' fees. *See Allergy Asthma Tech., Ltd. v. I Can Breathe, Inc.*, 195 F. Supp. 2d 1059, 1072, 1074 (N.D. Ill. 2002) (awarding fees for Lanham Act false advertising counterclaim). The Court's failure to explain or even mention its denial of attorneys' fees on the counterclaim warrants a remand. *See Frankenmuth Mut. Ins. Co. v. Escambia Cty., Fla.*, 289 F.3d 723, 733-34 (11th Cir. 2002) (vacating and remanding because court could not discern basis for denial of fees); *Keefe v. Bahama Cruise Line*, 867 F.2d 1318, 1323 (11th Cir. 1989).

Finally, once the proper legal standard is applied, this is a highly exceptional case. An exceptional case is one in which a party "acts in a 'malicious,' 'fraudulent,' 'deliberate,' or 'willful' manner." *Tire Kingdom*, 253 F.3d at 1334;

[26] After it entered judgment, the district court invited supplemental briefs on the issue of attorneys' fees (R489). Allegiance raised no such argument in its brief (R500).

Burger King Corp. v. Pilgrim's Pride Corp., 15 F.3d 166, 168 (11th Cir. 1994). That is exactly what the jury found here.

As a matter of fact, the jury determined that Allegiance (i) brought its Lanham Act case maliciously, fraudulently, deliberately, or in bad faith, *and* (ii) violated the Lanham Act maliciously, fraudulently, deliberately, willfully or by act in which there was evidence of fraud or bad faith (RE9:8-10; RE12:20). These are fact-findings by the jury that cannot be reversed unless they are clearly erroneous, *Seatrax, Inc. v Sonbeck Int'l, Inc.*, 200 F.3d 358, 372-73 (5th Cir. 2000),[27] and the jury's finding of exceptionality is highly relevant to any fee determination. *See Montgomery,* 168 F.3d at 1303 (court granted fees in light of jury's "willful" and "exceptional" findings). The court committed legal error by improperly allowing irrelevant state claims and facts other than Allegiance's conduct to influence its attorneys' fee decision in reference to Lanham Act claims (Regent RE1, 5). The Court also erred when it disregarded the jury's findings that Allegiance violated the Act and prosecuted its case with malice and bad faith.

[27] "We review a district court's award of attorneys' fees for abuse of discretion, and its findings as to whether a case is exceptional for clear error." *Id.*

C. This Is A Highly Exceptional Case Because Of Allegiance's Relentless, Offensive And Egregious Conduct.

1. Allegiance's Conduct In This Case Rivals The Worst Ever Seen In Similar Lanham Act Cases.

Allegiance brought this suit against Regent purely for anticompetitive reasons, attempting to financially harm Regent, reduce its market share, and damage its business. When Allegiance's contractual efforts to obtain Regent's unique powder-free glove technology and a joint sales venture failed, Allegiance used litigation to try to damage Regent (Tr:799-800; DX-553; DX-52). Allegiance's Lanham Act claims against Regent were baseless and Allegiance knew this, even before filing suit.

The record shows that Allegiance filed suit without a shred of evidence supporting its Lanham Act claims against Regent (Tr:1424-1425, 1126-1427). During seventeen days of trial and despite having the burden of proof, Allegiance proffered no scientific tests of its own, no studies and no expert testimony on any liability issue. It offered no evidence from any buyer or user of Regent's gloves to show how Regent's advertising was perceived. There was no evidence that Allegiance had ever studied any Regent glove. With the exception of Margaret Fay's inflated credentials, which Regent did not contest Tr:126-128), the only evidence supporting Allegiance's allegations was obtained in discovery, taken out

of context from Regent's documents and depositions, *after* Allegiance filed its complaint.

Compounding its bad faith, Allegiance adopted a strategy of delay and harassment during the case. On five separate occasions, Allegiance was ordered to produce documents or witnesses after Regent moved to compel (R181, pp.1-2; R181, pp.8-9; R243, p.2; R243, pp.2-3; R301). It was held in contempt once (R181, p.5), was sanctioned two other times (R181, pp.8-9; R213, p.10) and was found to have failed to comply with a court order yet another time (R351). It unjustifiably withheld production of the Rood Report (DX-606) until a few weeks before trial, nearly evading disclosure of a document that was critical to Regent's defense (*see* footnote 3, *supra*).

Allegiance also filed a related but separate suit designed to intimidate Regent and scientists who agreed with Regent. It filed suit in Oregon against Dr. Beezhold, a researcher for the Guthrie Institute in Pennsylvania (Tr:1766), claiming he had made false statements on behalf of Regent (Tr:744). Although that suit was dismissed and Dr. Beezhold was awarded attorneys' fees and costs (Tr:743, 821), Allegiance refused to withdraw parallel allegations in the instant suit based on the same activities (RE2:9-10). Instead, it forced Regent to defend against those claims, which had already been rejected by one court, and which, like

the Lanham Act claims, Allegiance knew to be meritless. The district court in this case dismissed the Beezhold claims (R243).

Allegiance strong-armed Dr. Gordon Sussman, a Canadian citizen who was not a party to this suit or agent of any party. Allegiance waited to catch Dr. Sussman when he was in the United States attending a conference, slapped him with a subpoena, and then tried several times to have him held in contempt. *Allegiance Healthcare Corp. v. London Int'l Group PLC*, 2000 U.S. App. LEXIS 33564, at *2 (11th Cir., Aug. 28, 2000) (Addenda A-3, *infra*). The district court refused and this Court affirmed. *Id*. at 48. All this was done despite Dr. Sussman's offer to submit to deposition if Allegiance agreed not to sue him too, but Allegiance refused. *Id*.

Allegiance also needlessly increased Regent's litigation costs and wasted the time of the court and jury. Regent never contested the allegations concerning Fay's inflated credentials (RE3:10-11; Tr:126-128), but Allegiance spent considerable trial time on the issue. Allegiance even named Fay a co-defendant in the lawsuit against Dr. Beezhold. Allegiance offered to drop its suit if Fay would admit that her research was flawed (Tr:1654). Fay refused to do so because her research was substantiated and valid (Tr:1654), as the jury found. In early 1997, Allegiance's in-house counsel threatened Fay and told her "I'm going to bury you.

I'm going to destroy you. I'm going to destroy your credibility. You will never practice again" (Tr:1653-54).

2. Under This Circuit's And Other Circuit's Precedent, Regent Should Be Awarded The Attorneys' Fees It Incurred As A Result Of Allegiance's Bad Faith And Malicious Conduct.

The facts set forth above are far more egregious than those found in other cases in which attorney's fees were awarded. In *Tire Kingdom*, this Court affirmed an attorney's fee award to the defendant in a Lanham Act case where the plaintiff alleged deceptive trade practices through the use of false advertising. 253 F.3d at 1336. After dismissing the plaintiff's claims, the court found it an exceptional case because (1) the plaintiff's claims were meritless, and (2) the plaintiff acted in bad faith and with improper motives. *Id*. There, as here, the plaintiff had in its possession, but failed to disclose until one month before trial, research and survey information that refuted its Lanham Act claims against the defendant. *Id*., s*ee also Am. United Life Ins. Co. v. American United Life Ins. Co.*, 731 F. Supp. 480 (S.D. Fla. 1990) (awarding fees where "entire controversy and . . . harm . . . suffered could easily have been avoided" because party failed even to inquire into validity of Lanham Act claim before filing suit).

In *S Indus., Inc. v. Centra 2000, Inc.*, 249 F.3d 625, 627-28 (7th Cir. 2001), the Court affirmed a fee award to the defendant based on the plaintiff's pattern of abuse and improper litigation. The plaintiff filed unfounded Lanham Act claims

and engaged in litigation gamesmanship that multiplied the defendant's cost of litigation. *Id*. Over the four-year legal proceeding, the plaintiff failed to produce evidence, failed to respond to discovery requests, failed to follow court rules, increased the cost of litigation, and generally refused to cooperate, instead delaying and harassing the defendant. *Id*. The Court also noted that S Industries filed other lawsuits designed to harass, and had a pattern of using litigation as a tactic. *Id*. at n.1. The Court affirmed the district court's award of fees, noting that "[t]his was not a murky case." *Id*. at 627.

Similarly, in *SecuraComm Consulting, Inc. v. Securacom, Inc.*, 224 F.3d 273 (3d Cir. 2000), the Third Circuit affirmed fees where the defendant filed meritless counterclaims, tried to strong-arm the plaintiff, filed separate suits to harass, and even threatened to "bury" the plaintiff financially. *Id*. at 275. The Court believed that after unsuccessfully trying to obtain intellectual property rights contractually, the defendant then sought to destroy its adversary financially through oppressive litigation tactics. *Id*. at 283. The Court specifically noted that the fee provision of the Lanham Act was designed to punish culpable conduct, which includes bad faith, fraud and malice in infringement *or* improper lawsuits and litigation abuse. *Id*. at 281-83. It is a remedy for unfounded Lanham Act suits. There, as here, the party sanctioned with fees embarked on a deliberate effort to bury its competitor by filing multiple suits and litigating unfairly. *Id*. at 282. Fees were awarded because

the case involved "a sweeping attempt to beat a financially weaker opponent through the use of vexatious litigation." *Id*. at 283. These are the same tactics and strategy Allegiance attempted in this case after it was unable to obtain Regent's technology, develop its own, or increase its own market share legitimately.

This case presents the hallmarks of an exceptional case warranting attorneys' fees. The district court failed to award fees for reasons unrelated to the standards governing under the Lanham Act. It erred as a matter of law, and therefore abused its discretion in denying fees in this exceptional and egregious case. *See Johnson*, 280 F.3d at 1262, *Lipscher*, 266 F.3d at 1320, *Goodheart*, 962 F.2d at 272. Moreover, while considering extraneous and irrelevant state law, the court failed to consider that Regent prevailed on its Lanham Act counterclaim, and that the jury also found malice, fraud, and bad faith on the part of Allegiance in its violation of the Lanham Act. Based on the jury's findings and the applicable Lanham Act law, Regent should be awarded its attorneys' fees. *See Montgomery,* 168 F.3d at 1303 (court awarded fees on basis of jury finding).

CONCLUSION

For these reasons, the judgment should be affirmed in all respects, except that the district court's decision not to award attorneys' fees to Regent should be reversed and remanded to the district court for determination of the amount of attorneys' fees to be awarded to Regent pursuant to the Lanham Act, both in the court below and on appeal.

December 9, 2002 Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B). This brief contains 12,464 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it was prepared in Microsoft Word, version 2002. The print is Times New Roman in 14 point, proportional space.

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the Brief of Appellees/Cross-Appellants is being served upon counsel to the parties as indicated:

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This 9th day of December, 2002.

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