THE STATE OF SOUTH CAROLINA
In the Court of Appeals

APPEAL FROM RICHLAND COUNTY
In The Court of Common Pleas
G Thomas Cooper, Jr , Circuit Court Judge

Case No 05-CP-40-0655

Monica Weston, Appellant,

v

Kim's Dollar Store and CIBA Vision, a division of Novartis Company, Respondents

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FINAL BRIEF OF RESPONDENT CIBA VISION

Keith D Munson (SC Bar No 13400)
Sandi R Wilson (SC Bar No 16896)
Womble Carlyle Sandridge & Rice, PLLC
P O Box 10208
Greenville, SC 29603
Phone (864) 255-5400
Fax (864) 255-5480

Curtis L Ott
Turner, Padget, Graham & Laney, P A
P O Box 1473
Columbia, SC 29202
Phone (803) 254-2200
Fax (803) 799-3957

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STATEMENT OF THE CASE

Appellant Monica Weston ("Weston") alleges causes of action for personal injury against Respondent CIBA Vision, a Novartis Company ("CIBA"), stemming from her alleged illegal purchase and use of contact lenses without a prescription from Respondent Kim's Dollar Store ("Kim's") (Am Compl paras 8, 12, 15, 19, 24) (R pp 38-40) On February 23, 2005, Weston commenced her lawsuit in the Court of Common Pleas for Richland County asserting causes of action for negligence per se, negligence, breach of implied warranty, strict products liability, sale of a defective product, and unfair trade practices CIBA's answer generally denied Weston's allegations and asserted additional defenses including federal preemption

On June 8, 2006, CIBA filed a motion for summary judgment on the basis that the majority of Weston's claims and legal theories is subject to federal preemption pursuant to the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (21 U S C § 301, *et seq*) The Honorable G Thomas Cooper, Jr, held an extended hearing on CIBA's motion for summary judgment on August 28, 2006 On November 28, 2006, Judge Cooper issued an 18-page order granting summary judgment in favor of CIBA on the issue of federal preemption ("Order"), thereby terminating most of Weston's claims and theories Following the denial of Weston's motion for reconsideration, Weston filed this appeal on January 19, 2007, of Judge Cooper's Order

STATEMENT OF FACTS

Weston frames the issue underlying this appeal in her "Statement of Case" by asserting that "Federal preemption arises only if 'FreshLook Colors' plano lenses were approved by the FDA as 'medical devices' under its pre-market approval (PMA) process prior to sale of those devices to Customer " This is exactly what was established at the summary judgment hearing and set forth in detail in Judge Cooper's Order Weston spends almost half of her brief cherry-picking inflammatory and distorted passages from the record that are unrelated to this central and established fact (*See* Weston's Statement of Facts) For example, Weston goes on for pages discussing a meeting with the FDA, one of CIBA's advertising campaigns, and the fact that, as with many prescription drugs, there are examples of people reselling them inappropriately The meeting shows that the FDA was actively regulating these medical devices through its PMA approval authority With regard to the advertising campaign, Weston conveniently failed to point out the number of times these advertisements included "Contact lenses, even if worn for cosmetic reasons, are medical devices that should be worn under the prescription, direction and supervision of an eye care professional " (Julie Collins Dep Exhibit 29, p 2, Exhibit 32, p 2, Exhibit 37, p 2, and Exhibit 39, pp 4 and 8) (R pp 402, 411, 425, 431, and 435) Finally, if third-party instances of medical substance/device abuse nullified federal regulatory authority, there would be few, if any, prescription drugs or devices available in the United States

It is Weston's contention that she suffered temporary loss of vision in one eye as a result of wearing non-corrective color contact lenses manufactured by CIBA under the trade name, FreshLook Colors (Am Compl paras 3, 18-24, Transcript of Hearing

("Transcript") pp 4, 7) (R pp 37, 39-40, 264, 267) The contact lenses came in a range of powers from (-)20 00 Diopters to (+)20 00 Diopters, and are capable of correcting nearsightedness, farsightedness, and astigmatism At the zero-power point in the range, the lenses are "non-corrective" or "plano" lenses, although they still have medical and physiological effects For example, plano contact lenses can be used not only to change the color of the user's eye, but to address medical issues, such as monovision and ocular defects (Parisian Dep p 144) (R p 654)[1]

Weston suggests in her brief that the fact that CIBA had an advertising campaign that emphasized color change and ignored medical or physiological effects makes the lenses merely cosmetics under the Federal Food, Drug, and Cosmetic Act, rather than medical devices that have alternative cosmetic uses That a device manufacturer advertises one use at one time through a particular medium has no effect on the device's regulatory status For example, human-based collagen injection products are PMA-approved by the FDA for improvements of soft tissue appearance "such as wrinkles and acne scars "[2] That the manufacturer chooses to educate the "wrinkle" audience with TV commercials, while educating the "acne scar" audience with product information at the dermatologist's office, does not make collagen injections mere cosmetics Similarly, emphasizing the beauty quality of color contact lenses in beauty magazines does not convert color contact lenses, which have identified medical and physiological effects, into mere cosmetics

[1] Dr Suzanne Parisian is Weston s own expert on the application of federal preemption

[2] http //www fda gov/cdrh/pdf3/p800022s050a pdf

Weston alleges she purchased the contact lenses at issue without a prescription from Kim's on or about February or March 2004 (Am Compl para 12) (R p 39) Kim's was not affiliated with CIBA and was not licensed to sell the contact lenses (Am Compl paras 8-11, Transcript p 4) (R pp 38-39, p 264) The individual contact lenses Weston allegedly purchased from Kim's were marked prescription only and labeled not to be sold individually (Oris Dep pp 59-60, Exhibit 4) (R pp 470-471, p 588) Kim's, an unauthorized and unlicensed seller of contact lenses, obtained the lenses from a third party (30(b)(6) Dep of Kim's Dollar Store pp 37-38, Pl's Exhibit 1) (R pp 316-317, p 322) CIBA, the alleged manufacturer of the contact lenses Weston purchased from Kim's, did not have a business relationship with Kim's and did not distribute the lenses to Kim's (30(b)(6) Dep of Kim's Dollar Store pp 77-80) (R pp 318-321) At some point after wearing the lenses she bought at Kim's, Weston was diagnosed with an eye infection and ultimately suffered a temporary loss of vision in her left eye (Am Compl para 21) (R p 40) Weston raised several claims against CIBA premised largely on her contention that the labeling on the contact lenses marked for prescription use only "was misleading and lacked adequate information about the safe and effective uses" of the lenses she purchased and failed to provide adequate warnings of possible complications to the eye from wearing such lenses (Am Compl paras 28-29) (R p 41)

LEGAL FRAMEWORK

The question of federal preemption under the Medical Devices Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA") is a question of law for the court to decide *Cox v Shalala*, 112 F 3d 151 (4th Cir 1997) In evaluating whether

Weston raises a material fact in her appeal, it should be noted that factual findings supporting matters to be determined by the Court are made by the Court and not a jury *Gardner v Kirven*, 184 S C 37, 191 S E 814, 825 (1937) ("Where an appeal is taken from the findings of fact by a circuit judge, it is incumbent on the appellant to show that the decree of the circuit judge is against the weight of the evidence ") (citation omitted)) [3] The central issue in this appeal is whether the trial court committed reversible error in determining that certain claims raised by Weston against CIBA are subject to federal preemption on the basis that CIBA's FreshLook Colors contact lenses constitute a Class III medical device under the MDA The parties do not dispute that if the lenses at issue were approved as a Class III medical device pursuant to the FDA's pre-market approval ("PMA") process, then preemption applies (Weston Initial Brief p 5)[4]

A Class III medical device may only be marketed pursuant to the FDA's PMA process (subject to certain limited exceptions not relevant here) *See* FDCA § 515, 21 U S C § 360e Therefore, all Class III medical devices, such as contact lenses, marketed under FDA regulation in the United States have been approved by the FDA through its rigorous PMA process As the Seventh Circuit explained in a case similarly finding federal preemption of product liability claims

> Before a Class III device may be introduced to the market, the manufacturer must provide the [FDA] with a reasonable assurance that the device is safe and effective under the MDA To provide that assurance, a manufacturer must

[3] Judge Cooper heard oral argument on August 28, 2006 and issued his comprehensive 18 page Order on November 28, 2006, after three full months to study the application of federal preemption in this case

[4] Federal preemption arises only if the FreshLook Colors plano lenses were approved by the FDA as medical devices under its pre-market approval (PMA) process prior to the sale of those devices to Customer (Weston Initial Brief p 5)

> obtain premarket approval ("PMA") from the FDA This procedure is a "rigorous" process, in which the manufacturer must submit detailed information to the FDA regarding the safety and effectiveness of the device Manufacturers must provide the FDA with samples of the device, an outline of the device's components and properties, a description of the manufacturing process, copies of the proposed labels, various other data and information, and any other information the FDA requests The FDA spends an average of 1,200 hours per PMA application reviewing these materials

Mitchell v Collagen Corp , 126 F 3d 902, 905 (7th Cir 1997), *cert denied*, 523 U S 1020 (1998) In addition, FDA regulations permit manufacturers to seek approval for device modifications by submitting supplements to a prior PMA "All procedures and actions that apply to [a PMA] application also apply to PMA supplements " 21 C F R § 814 39 The PMA supplement process obviates the need to submit redundant information to the FDA regarding design features, manufacturing processes, or labeling that has already been approved by the FDA At the same time, the entirety of the PMA, including all supplements, are "'before' the agency at the time the supplement is reviewed " 51 Fed Reg 26342, 26354 (1986) The "FDA considers revisions proposed in a PMA supplement using the same type of rigorous scientific process utilized for review of original PMAs " *See* FDA Letter Brief filed as *amicus curiae*, *Horn v Thoratec*, 376 F 3d 163 (3d Cir 2004), available at 2004 WL 1143720, at *10 (May 14, 2004) (hereafter "*Horn* Amicus Brief") Consequently, every approval of a PMA supplement application is a renewal of the original PMA approval and the prior related PMA supplements [5]

[5] There were approximately 40 PMA supplement applications/approvals for FreshLook related contact lenses before Weston purchased the lenses at issue in this case (Parisian Dep Exhibit 7) (R pp 671 673)

The evidence that FreshLook Colors contact lenses were and are regulated by the FDA as Class III medical devices is overwhelming and uncontradicted Specifically, FreshLook Colors contact lenses were approved through the PMA Supplement process described above In cataloguing the approval to the trial court, CIBA submitted two PMA Supplement approval letters from the FDA related to the FreshLook Colors family of contact lenses, along with the testimony of CIBA's Director of Global Regulatory Affairs, the testimony of Weston's own expert (Parisian), and the testimony of Philip Phillips, former FDA Deputy Director of Science and Regulatory Policy for the Office of Device Evaluation

Weston now argues that a redundant and cumulative document that was not filed with the court is the only competent evidence of FDA pre-market approval and federal preemption ("CIBA did not submit a PMA for FreshLook Colors," Appellant Brief p 7) This is both incorrect and misleading [6] First, as acknowledged by Weston's expert, the PMA was issued in 1983 by the FDA with regard to an ancestor lens to the FreshLook Colors contact lens (Parisian Dep pp 88-89) (R pp 642-643) 21 C F R § 814 39 By 1994, approximately 30 PMA Supplements had been submitted to the FDA, with the FreshLook Colors lenses appearing in PMA Supplement 33 and thereafter (Parisian Dep Exhibit 6) (R pp 667-670) This included submission to the FDA of packaging approval for FreshLook Colors non-corrective (spherical power of 0 00) contact lenses

[6] In addition Plaintiff states in her brief (page 6) that CIBA submitted only a 2002 approval and a 2003 approval in support of its motion for summary judgment (referencing an Exhibit B) Apparently, Weston s counsel is operating from the wrong motion These approval letters were attached to a prior withdrawn motion for summary judgment in 2005 filed before the discovery leading to the current motion for summary judgment The submissions with the current motion included the PMA approval letter from the FDA for the exact contact lenses at issue in this case (FreshLook Colors UV) (R pp 674 678) Because this error is the foundation for Weston s entire brief most of her arguments are simply irrelevant to the Order granting summary judgment and can be summarily disregarded

(a/k/a "plano" lenses) (Parisian Dep p 137 and Exhibit 6)[7] (R pp 650, pp 667-670) In January 1996, CIBA obtained approval for a PMA Supplement (No 39) to its FreshLook Colors contact lenses for incorporating an ultra-violet absorber into the referenced lenses (*See* FDA FreshLook Colors UV Approval Letter, Parisian Dep Exhibit 8)[8] (R pp 674-678) It is uncontradicted that Weston's claim relates to FreshLook Colors contact lenses with UV absorbers as approved in PMA Supplement No 39 (Parisian Dep p 28 and Exhibit 4 (Exhibit 4 "represents what was on her package ")) (R p 630, p 655) (Oris Dep pp 65-66 (Q During the relevant period "all FreshLook Colors lenses that were manufactured, to be sold in North America were UV?" A "Yes ")) (R pp 472-473) Since Weston's lenses were UV lenses, it is the FDA approval letter for PMA Supplement No 39 (January 25, 1996) that is the most relevant to this case, and since each related supplement opens the entire preceding applications to FDA review, the FDA approval letter for PMA Supplement 39 also establishes renewal of the prior FDA approvals[9] Furthermore, because Judge Cooper relied on the UV protective properties of FreshLook Colors contact lenses in finding preemption, this confirms that Weston's formalistic demand to narrow consideration to

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[7] The FDA has also acknowledged that approval of a range of corrective powers includes approval of the zero power or plano lens *Import Alert 86 10 n 1 (R p 754, n 1)

[8] The FDA approval letter read, in part [the FDA] has completed its evaluation of your pre market approval application (PMA) supplement which requested approval for incorporating an ultra-violet absorber into the above referenced lenses [FreshLook Colors UV] Based upon the information submitted, the PMA Supplement is approved

[9] The record before Judge Cooper also included an August 22 2003 update to PMA Supplement No 39, which establishes that FreshLook Colors UV contact lenses were approved and regulated as medical devices in 2003 (Oris Dep Exhibit 11) (R pp 627-628)

only an approval letter for a predecessor version without UV protection is without merit [10]

Before any of CIBA's color contact lenses were sold commercially in the United States, they underwent a pre-market approval process (Parisian Dep pp 87-89, 94, 112, Exhibits 6, 7, 8, 12, Oris 2/28/06 Aff, Oris Dep pp 38, 123, 152, Phillips Aff paras 5-7) (R pp 641-645, 667-670, 671-673, 674-678, 681-682, pp 701-704, pp 458, 482-483, pp 706-707) In the PMA and PMA Supplement processes, CIBA was required to provide the FDA with assurances that the lenses are both safe and effective (*Id*) The submissions for CIBA's color contact lenses, which include the FreshLook Colors line, are voluminous The FDA employs experts to analyze the submissions and evaluate the safety and efficacy of these Class III devices *See Buckman Co v Plaintiffs Legal Comm*, 531 U S 341 (2001) This analysis includes consideration of the application, clinical data, manufacturing processes, and proposed labeling 21 U S C § 360e(c)

Furthermore, changes affecting the safety and effectiveness of the device require detailed documentation and reporting *See* 21 C F R § 814 39 Accordingly, once a PMA medical device is on the market, it remains subject to extensive and continuing regulation by the FDA *See Brooks v Howmedica Inc*, 273 F 3d 785, 789, 799 (8th Cir 2001) (en banc), *cert denied*, 535 U S 1056 (2002), *McMullen v Medtronic Inc*, 2005 WL 2043827, at *4 (7th Cir 2005) (discussing post-approval regulation), *see also* 21 C F R §§ 814 80-814 84 In regulating PMA-approved medical devices, the FDA has

[10] Even that predecessor version is before this Court as an attachment to Weston s unsuccessful Motion for Limited Remand and Abeyance

a wide range of available regulatory measures [11] In fact, Weston's reference to meetings with the FDA show the FDA was actively engaged in meaningful regulatory oversight

Alternatively, Weston argues that a 2003 Import Alert (Import Alert 86-10) temporarily reclassified all non-corrective lenses as mere cosmetics However, Import Alert 86-10 (R pp 752-760), simply provided an alternative classification for solely decorative lenses as opposed to non-corrective (plano) lenses with medical or physiological properties, such as FreshLook Colors For example, in 1995, the Food & Drug Administration issued a notice, including a "comprehensive legal analysis regarding the agency's jurisdiction" over such products 60 Fed Reg 41453 (Aug 11, 1995) ("FDA Public Notice") At page 16 of the FDA Public Notice, the FDA expressly stated that

> For example, FDA regulates as devices noncorrected tinted contact lenses that are expressly promoted only for their cosmetic effect of enhances eye color because they have physiological effects on the eye See Appendix to Legal Analysis

In the Appendix to Legal Analysis at p 49 of the FDA Public Notice, the FDA further stated

> 9 Noncorrective Tinted Contact Lenses The agency has taken the position that tinted contact lenses that do not correct or improve vision and are promoted to enhance eye color are medical devices This position is based on the fact that all contact lenses, including neutral lenses, have a physiological effect on the eye In 1986, the government obtained a consent decree of permanent injunction against the sale of a system used to make noncorrective tinted

[11] *See e g* 21 U S C § 360h(a) (requiring notice to health care professionals), 21 U S C § 360h(b) (requiring a manufacturer to offer repair, replacement or refund), 21 C F R § 810 1-810 18 (recall authority) 21 U S C § 332 (injunctions) 21 U S C § 333 (penalties) 21 C F R §§ 17 1-17 54 (penalties), 21 U S C § 334 (seizure), 21 U S C § 360e(e) (PMA revocation or suspension) 21 C F R § 814 46 (same)

> contact lenses on the ground that the system causes adulteration of a medical device, the lenses (emphasis added) (citing to *United States v Int l Hydron Corp*, No 87-2129 (E D N Y))

(R pp 152-155)

Moreover, in conjunction with Import Alert 86-10, the FDA also issued import alert guidance to FDA staff That guidance is expressly limited to the sampling and detention of "decorative contact lenses " (R pp 761-765) In the Guidance Document related to decorative contact lenses, the FDA suggests that the initial step should be to determine if the contact lenses fall within a PMA or 510(k) approval (i e , a medical device) Only if they do not have a PMA or 510(k) approval, are the products subject to being sampled or detained Clearly, even at the time that the FDA was issuing Import Alert 86-10, which excluded some noncorrective color lenses from the definition of medical device, the FDA was treating PMA-processed non-corrective color contact lenses (such as zero-power FreshLook Colors) as medical devices, and providing guidance to that effect to its staff This is further confirmed by the updated approval letter for FreshLook Colors UV dated August 22, 2003, more than three months after the issuance of Import Alert 86-10 [12]

Moreover, Import Alert 86-10 expressly states that any noncorrective contact lens that has a physiological effect or medical use is not "solely" for decorative purposes and therefore a medical device [13] Dr Parisian acknowledged in her deposition that a contact

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[12] Oris Dep Exhibit 11 (R pp 627 628)

[13] It may also be a cosmetic in the sense that it is prescribed to enhance the color of the eye However a particular product that is both a cosmetic and a device is regulated by the FDA as a device and thus subject to federal preemption

lens with a medical use would elevate the lens from a cosmetic to a medical device during all relevant times This is also true of FreshLook Colors As of July 2003, the FDA-approved package insert for FreshLook Colors contact lenses included the following indications for use "FreshLook soft contact lenses with UV-absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye" (Oris Dep Exhibit 6) (R pp 589-590) The package insert goes on to state that

> Long term exposure to UV radiation is one of the risk factors associated with cataracts UV-absorbing contact lenses help provide protection against harmful UV radiation

Clearly, under Import Alert 86-10, the FreshLook Colors lens (allegedly worn by Plaintiff) is a medical device beyond a sole decorative cosmetic product For example, in discussing what uses or effects might elevate a cosmetic product to a drug or medical device, the FDA expressly noted in Import Alert 86-10 that sunscreen claims make a cosmetic product a drug Moreover, Import Alert 86-10 expressly states that decorative contact lenses with additional medical uses (such as UV protection) are not subject to the Import Alert and are "properly regulated as medical devices" Consequently, there is no factual dispute that CIBA Vision FreshLook Colors contact lenses of the type allegedly obtained by Plaintiff provided UV absorbing protection, thereby taking them out of the category of solely decorative lenses Consequently, as a matter of law, the contact lens involved in this case must be considered a "medical device" (regardless of whether it is also a cosmetic) [14]

[14] The medical device conclusion is also compelled by the fact that the FreshLook Colors contact lens obtained by the Plaintiff was also approved for extended wear As noted in the July 2003 package insert certain physiological changes (which would take these lenses outside the definition of a cosmetic product) are also associated with extended wear lenses These include a weakening of the cornea s resistance to

In sum, all FreshLook Colors lenses manufactured by CIBA have undergone and received approval from the FDA under the PMA process (Parisian Dep pp 87-89, 94, 112, Exhibits 6, 7, 8, 12, Oris 2/28/06 Aff, Oris Dep pp 38, 123, 152, Phillips Aff paras 5-7, Order pp 6-10) (R pp 641-645, 667-670, 671-673, 674-678, 681-682, pp 701-704, pp 458, 482-483, pp 706-707, pp 6-10) FreshLook Colors contact lenses constitute a Class III medical device and are subject to regulation by the FDA and subject to federal preemption

Having set forth a summary of the overwhelming evidence of preemption, it is also worth noting that at the summary judgment hearing, CIBA sought to eliminate even immaterial and non-genuine questions of FDA approval by drafting a letter for the Court to send to the FDA (pursuant to the Code of Federal Regulations) specifically asking whether CIBA's plano (non-corrective) contact lenses were within the FDA's pre-market approval (Transcript p 44, lines 5-25) (R p 304) A copy of the proposed letter to the FDA was filed with the trial court (R pp 167-169) When asked by Judge Cooper of their position on seeking absolute confirmation from the FDA, Weston's counsel called it a "delaying tactic" to which "[w]e've actually filed a frivolous motion letter" (Transcript p 45, lines 1-5) (R p 305) Now on appeal, Weston takes the opposite position and claims the fact of FDA pre-market approval is critically uncertain as opposed to a frivolous concern Having succeeded in stopping the Court from obtaining absolute confirmation directly from the FDA itself, Weston's counsel now argues that only absolute confirmation directly from the FDA could be considered by the Court in granting

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infection a higher incident and degree of epithelial microcysts and infiltrates and endothelial polymegathism

summary judgment (thereby disregarding all the other evidence of pre-market approval and the fact that no evidence to the contrary was submitted by Weston) The central role of appellate courts is to correct errors in the court below, not to provide an alternative audience for litigants to take contrary positions *Hayne Federal Credit Union v Bailey*, 327 S C 242, 251, 489 S E 2d 472, 477 (1997) ("Judicial estoppel precludes a party from adopting a position in conflict with one earlier taken in the same or related litigation *"[W]here a party assumes a certain position in a legal proceeding and succeeds in maintaining that position he may not thereafter simply because his interests have changed assume a contrary position*) (internal citations omitted)

ARGUMENTS

I The trial court did not commit reversible error in determining that federal preemption (a matter of law to be determined by the Court) applied to certain of several causes of action raised by Weston

In her first argument on appeal, Weston contends that the trial court improperly determined that certain claims she filed are subject to federal preemption on two bases First, she contends that the affidavits, depositions, and voluminous documentation presented by CIBA in support of its motion for summary judgment were hearsay and therefore insufficient to establish that contact lenses manufactured by CIBA under the trade name FreshLook Colors received pre-market approval Second, she contends that plano (non-corrective) contact lenses such as those that allegedly caused Weston's injuries were not Class III medical devices because the product information and marketing material included the non-medical effect of enhancing or changing the color of the eyes As addressed below, both of Weston's contentions are without merit

A Weston failed to properly preserve for appeal the issue of whether CIBA presented non-hearsay evidence to the trial court regarding the fact that the contacts lenses manufactured by CIBA under the trade name FreshLook Colors underwent and received approval from the FDA pursuant to the PMA process

It is well-settled that an issue cannot be raised by a party for the first time on appeal, but must have been raised to and ruled upon by the trial court to be preserved *See e g Pye v Estate of Fox*, 369 S C 555, 633 S E 2d 505 (2006) (stating that an issue must generally be raised to and ruled upon by the circuit court to be preserved) In this instance, Weston's evidentiary argument that CIBA failed to present non-hearsay evidence in support of its position was articulated—for the first time—in a Rule 59(e) motion to reconsider In fact, the word "hearsay" was not even used by Weston in either the Memorandum in Opposition to CIBA's Motion for Summary Judgment her counsel filed prior to the summary judgment hearing or at any point during the hearing on CIBA's motion for summary judgment It is a fundamental precept of all litigation that hearsay objections cannot be raised for the first time on appeal *State v Caldwell*, 283 S C 350, 322 S E 2d 662 (1984), *Wimberly v Sovereign Camp, W O W*, 190 S C 158, 2 S E 2d 532, 558 (1939), *Stevens v U S*, 256 F 2d 619, 623 (9th Cir 1958) (regarding hearsay document "we hold that defendant waived error, if any, by failure to object, to except, or to request any limitation ")

The purpose of a Rule 59(e) motion is to preserve issues raised to but not ruled on by the trial court *Walsh v Woods* 371 S C 319, 325, 638 S E 2d 85, 88 (Ct App 2006) Accordingly, South Carolina courts have made it clear that "[a] party cannot use a motion to reconsider, alter or amend a judgment to present an issue that could have been raised prior to the judgment but was not " *Tallent v South Carolina Dep t of Transp* 363 S C

160, 165, 609 S E 2d 544, 546 (Ct App 2005) (citing *Kiawah Prop Owners Group v Public Serv Comm'n* 359 S C 105, 113, 597 S E 2d 145, 149 (2004)), *see also MailSource LLC v M A Bailey & Assoc* 356 S C 370, 374, 588 S E 2d 639, 641 (Ct App 2003) (holding that a party cannot raise an issue for first time in a Rule 59(e) motion which could have been raised at trial) In this instance, despite raising no hearsay objection in its written response to CIBA's motion for summary judgment or at the extended hearing on CIBA's motion, Weston is now asking the Court to reverse the decision of the trial court and ignore the voluminous evidence of pre-market approval (including the approval directly related to FreshLook Colors, PMA Supplement No 39) presented to the trial court by CIBA because an FDA certified and authenticated copy of every pre-market approval letter was not submitted to the trial court Weston's argument that every approval letter is required to show FDA regulatory oversight is akin to arguing that proof of the state renewing one's driver's license multiple times is not competent evidence of authority from the state to drive, without a copy of every driver license and driving test from age 16 forward Accordingly, Weston's argument is not only untimely, it is without merit

B CIBA presented competent evidence to the trial court in support of its motion for summary judgment

Assuming for purposes of argument that Weston properly preserved the issue of CIBA's alleged presentation of non-hearsay evidence to the trial court, the record nevertheless demonstrates that CIBA did present uncontradicted competent evidence that its FreshLook Colors contact lenses were subject to and approved by the FDA pursuant to the PMA process First, Weston's own expert concedes that CIBA received FDA

approval to market the FreshLook Colors lenses under a supplement to the PMA, which was first granted by the FDA to predicate contact lenses in 1983 (Parisian Dep p 87, lines 11-20 (stating that CIBA's "draft labeling" for the lenses "was one component in terms of the PMA product that [the FDA] approved")) (R p 641) When asked specifically about the FDA's approval of "this FreshLook Colors lens, which was apparently manufactured in 2003, from her review of the FDA documents related to FreshLook Colors and predecessor products," Dr Parisian confirmed that the FreshLook Colors lenses at issue in this case were approved by the FDA under supplements to a PMA granted "original approval" in 1983 and that "FDA has allowed companies just to piggyback in terms of the information" (Parisian Dep p 88) (R p 642) In fact, Dr Parisian specifically agreed that "the genealogy [i e, the PMA approval history] for the FreshLook Colors product begins with the 1983 PMA" (Parisian Dep p 89, lines 14-17) (R p 643) Further, Exhibits 7 and 8 to Dr Parisian's deposition are PMA supplemental approvals from the FDA allowing the marketing of FreshLook Colors lenses, pursuant to prior PMA approval (Parisian Dep pp 133-139) (R pp 646-652) These exhibits reflect the 39th (1996) and 42nd (1999) Supplements to the original 1983 PMA approval (R pp 671-673, 674-678) They clearly establish in the evidence before the Court that the FDA re-evaluated and renewed the original medical device approval of this family of contact lenses more than forty times This is significant because the "FDA considers revisions proposed in a PMA supplement using the same type of rigorous scientific process utilized for review of original PMA's" FDA's *Horn* Amicus Brief, *supra* Thus, it is not only procedurally improper but also completely baseless for Weston now to argue that there is no evidence that the FreshLook Colors lenses were approved by

the FDA, when Weston's own expert has expressly conceded this fact, and when the Court had before it PMA supplement approvals for the FreshLook Colors lenses, including the FDA approval for FreshLook Colors UV (PMA Supplement No 39, R pp 674-678) and the August 2003 updated FDA approval letter for FreshLook Colors UV (R pp 627-628)

Further, Paul Oris, Head of Global Regulatory Affairs for CIBA, the department responsible for the maintenance of all documents relating to the FDA's approval of contact lenses manufactured by CIBA, testified in pertinent part that CIBA submitted an application for the pre-market approval of its FreshLook Colors lenses and that the FDA evaluated the materials submitted by CIBA (Oris 2/28/06 Aff para 3) (R p 702) He further affirmed that CIBA's FreshLook Colors lenses received approval from the FDA under the PMA process (*Id*) Consistent with the testimony of both Suzanne Parisian and Paul Oris on this point, Philip Phillips (former Deputy Director, Science and Regulatory Policy, Office of Device Evaluation, Center for Devices and Radiological Health for the FDA) likewise testified that "FreshLook Colors plano (zero power) contact lenses are approved in the Premarket Approval (PMA) P830037 and the relevant supplements thereto" and are, in fact, Class III medical devices (Phillips Aff paras 2, 5) (R pp 705-706)

Regardless, even assuming that some evidence referred to in the summary judgment process was hearsay, that does not mean that there was no competent evidence of PMA approval before the trial court In addition to the non-hearsay evidence referenced above (including the approval letter for FreshLook Colors UV (R pp 674-678)), the experts' opinions that PMA approval existed is relevant evidence and can be

based on hearsay For example, it is "well-settled that an exception to the rule prohibiting hearsay exists when it is used by an expert An expert may base his opinion on hearsay evidence so long as it is of a type reasonably relied upon by other experts in the field" *State v Hutto*, 325 S C 221, 481 S E 2d 432, 433 (S C 1997) (citations omitted) Certainly, Weston cannot rebuke her own expert, Dr Parisian, and her sworn testimony outlined above that confirms the existence of PMA approval In addition, Weston never contested the expert credentials of Philip Phillips and even elicited in his deposition that he had been qualified as an expert in court when he was with the FDA in a medical device case (Phillips Dep pp 19-21) (R pp 690-692) Mr Phillips spent 24 years with the FDA, including service in the Division of Ophthalmic Devices (Phillips Dep pp 28, 34) (R pp 693-694) He testified at his deposition that the information he relied on, including information submitted with the PMA approval process, was information generally relied on by experts in his field and that his opinions were held to a reasonable degree of certainty for experts in his field (Phillips Dep pp 147, 148, 151) (R pp 695-697) Consequently, even hearsay information in this case could support competent testimony and evidence in support of summary judgment based on federal preemption as granted by Judge Cooper

In sum, even if Weston had timely raised the issue of CIBA's alleged presentation of hearsay evidence before the trial court, the evidence in the record clearly demonstrates that Weston's argument is baseless Accordingly, Weston's argument should be rejected

C CIBA's non-corrective FreshLook Colors contact lenses are subject to federal preemption

As set forth above, the FreshLook Colors contact lenses at issue underwent the rigorous PMA process and have been approved and are regulated by the FDA as Class III medical devices Thus, the pertinent question before the trial court was whether, in light of this fact, certain claims raised by Weston were properly subject to federal preemption This determination was not only within the jurisdiction of the trial court but an issue of law on which it was wholly appropriate for the trial court to rule *See Jameson v Ford Motor Co*, 373 S C 248, 261, 644 S E 2d 755, 762 (Ct App 2007), *Mattingly v Medtronic Inc*, 486 F Supp 2d 964 (E D Miss 2007) Weston's attempt to reframe the trial court's decision as an improper exercise of jurisdiction is therefore a red herring

1 All FreshLook Colors lenses were approved under the PMA process and are classified by the FDA as Class III medical devices

Before being brought to market, the FreshLook Colors lenses at issue in this action and their predecessor products underwent the arduous PMA process, the highest level of review by the FDA, under the Medical Device Amendments of 1976 ("MDA"), Pub L No 94-295, to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U S C § 321, *et seq* *See* FDCA § 515, 21 U S C § 360e The FDA concluded the devices were safe and effective for their intended uses and approved the design, manufacturing process, and labeling of the FreshLook Colors lens as described in CIBA's applications, pursuant to the PMA supplement procedure [15] Although the non-corrective lenses in this case may be argued to meet the definition of "cosmetic" under 21 U S C § 321(i)(1) as products

[15] Weston does not dispute that CIBA's FreshLook Colors lens were manufactured and labeled in conformance with the PMA process

introduced into the body (the eye) for beautifying or altering appearance, they are still Class III medical devices In defining a "cosmetic product," 21 C F R § 700 3 expressly states that a cosmetic can also be a medical device ("any cosmetic product which is also a drug or device ") (emphasis added) Thus, whether or not a product meets the definition of a cosmetic under the FDCA is not the end of the inquiry, the more significant question is whether it is regulated as a Class III medical device by the FDA

Weston's own expert, Suzanne Parisian, agrees In discussing whether these lenses are regulated as medical devices, Suzanne Parisian stated

> Just because [Congress] put it under the device regulations doesn't change that it's still a cosmetic It's a cosmetic, but it's being regulated under medical device regulations

(Parisian Dep pp 60-61) (R pp 639-640) This is in complete accord with CIBA's expert, Philip Phillips, who confirmed that it "is possible for a device to be both a 'cosmetic' and a 'device', and in such case, FDA's medical device regulations would apply " (Phillips Aff para 4) (R p 706) The FDA removed all doubt on this issue as it pertains to the exact product at issue in this case when it published a notice in the Federal Register noting that "FDA regulates as devices non-corrective tinted contact lenses that are expressly promoted only for their cosmetic effect of enhancing eye color " 60 Fed Reg 41453 p 16 (Aug 11, 1995) (see the detailed discussion of this FDA Public Notice, *supra*, at p 11) (R p 152) [16]

[16] Other examples of cosmetic products which are regulated as medical devices or drugs include lotion with sunscreen, toothpaste with fluoride, and novelty condoms 60 Fed Reg 41453 pp 48-49 (Aug 11, 1995) (R pp 154-155)

2 CIBA's non-corrective cosmetic FreshLook Colors contact lenses are medical devices and are subject to the medical device regulations

Weston cannot plausibly dispute that if CIBA's non-corrective FreshLook Colors contact lenses have a medical, health, or therapeutic use or have a physical or physiological effect, then the lenses are regulated as medical devices, even though they can also be categorized as cosmetic products *See* 21 C F R § 700 3 (such products are "also subject to the requirements of Chapter V of the Act," which includes the Medical Device Amendments of 1976) The FDA generally requires that products such as contact lenses have associated package inserts, which are provided directly to the learned intermediary prescribing the lenses The July 2003 FreshLook Colors lenses package insert was applicable to the Freshlook Colors non-corrective contact lenses at issue in this case (Oris Dep p 86, lines 19-25, Exhibit 6) (R p 477, pp 589-590) The July 2003 package insert was in accord with FDA requirements and obtained FDA approval (Oris Dep p 89, line 19 - p 90, line 2) (R pp 478-479) The FDA-approved package insert for FreshLook Colors contact lenses (Parisian Dep Exhibit 9, middle column) (R p 679) included the following "Indications (Uses)"

- " with UV-absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye " (medical/therapeutic use),[17]
- " Daily or Extended Wear " (emphasis added) (effecting physiological change),

The package insert goes on to state that

[17] UV protection has also been described as having a physiological effect In the FDA Public Notice at 60 Fed Reg 41453 p 49 (Aug 11 1995) (R p 155) the FDA noted that sunscreen impacted the structure of the body by altering the normal physiological response to solar radiation

> Long term exposure to UV radiation is one of the risk factors associated with cataracts UV-absorbing contact lenses help provide protection against harmful UV radiation

(*Id* , middle column, Actions)

A product's intended use is a significant consideration in determining whether it is a device under the FDCA It is an "objective" test and includes consideration of "labeling claims" and "written statements" about the product 21 C F R § 801 4, *see also In re Orthopedic Bone Screw Prods Liab Litig* , 1999 WL 33740509, at *10 (E D Pa 1999) (stating that the term intended use is "broadly defined and encompasses the manner in which a company characterizes its product in the marketplace ") This broad analysis includes how the product "affects the structure and function of the body, regardless of how the product is labeled or advertised " 60 Fed Reg 41453 p 15 (Aug 11, 1995) (R p 151) For example, in the FDA Public Notice, the FDA points out that if an active ingredient is present in therapeutic concentrations, it will be a drug even if the manufacturer does not claim the effect based on an implied intended use Similarly (as discussed, *supra*, at page 11), different marketing approaches to different user groups does not affect the FDA's classification of Class III medical devices

The package insert, especially the information listed under "Indications (Uses)," as well as PMA/PMA Supplement submissions to FDA over the years, makes perfectly clear that the non-corrective Freshlook Colors contact lenses involved in this case were intended for more than mere cosmetic color change Weston's own expert, Suzanne Parisian, acknowledged that the "UV" symbol on the blister pack and the PMA supplement information establish that these lenses contain an "ultraviolet ray protection

ingredient" to block UV radiation which "can be harmful to the human eye " (Parisian Dep pp 137-140) (R pp 650-653) This is sufficient to establish that lenses are "devices" under the FDCA as intended for use in the "prevention of disease " 21 C F R § 321(h)(2)

FreshLook Colors non-corrective contact lenses also meet the definition of "device" by affecting "the structure or any function of the body " 21 C F R § 321(h)(3) As noted in the July 2003 package insert and PMA documents, these lenses are approved for "extended wear" for up to seven (7) days Weston's expert, Suzanne Parisian, acknowledged that the anatomic and medical statements associated with "extended wear" claims would make these lenses medical devices (Parisian Dep pp 52-61) (R pp 631-640)

The package insert makes claims about oxygen permeability, oxygen transmissibility, and certain physiological changes associated with extended wear, including a weakening of the corneas' resistance to infection, a higher incident and degree of epithelial microcysts and infiltrates and endothelial polymegathism Accordingly, based both on the medical uses and the physiological effects of FreshLook Colors non-corrective contact lenses, they are properly categorized as medical devices as a matter of law

II The trial court did not commit reversible error in granting CIBA summary judgment on the basis that South Carolina law conflicts with and is preempted by federal requirements specific to the FreshLook Colors lenses at issue in this case

PMA approval of a medical device by the FDA results in device-specific federal requirements that preempt inconsistent state requirements, including those sought to be

imposed through tort liability *Horn v Thoratec Corp*, 376 F 3d 163 (3d Cir 2004), *Martin v Medtronic Inc* 254 F 3d 573 (5th Cir 2001), *Kemp v Medtronic Inc* 231 F 3d 216 (6th Cir 2000), *cert denied*, 534 U S 818 (2001) Specifically, the MDA expressly preempts any state law requirement "(1) which is different from, or in addition to, any requirement applicable under this [Act] to the device, and (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this [Act]" 21 U S C § 360k(a) Unlike certain other regulatory regimes relating to product safety, the MDA does not contain a savings clause that exempts state common law claims from the regulation's preemptive provision Accordingly, "virtually every court which has addressed this issue has concluded that preemption under the MDA extends to state court tort claims" *Scott v CIBA Vision Corp*, 38 Cal App 4th 307, 316 (Cal Ct App 1995), *see also Riegel v Medtronic Inc*, 451 F 3d 104, 106 (2d Cir 2006) (noting that the majority of circuits have concluded that "common law tort actions as to PMA-approved devices are preempted by the FDA"), *Mattingly v Medtronic Inc* 486 F Supp 2d 964 (E D Mo 1997) (applying federal preemption to state product liability claims on the basis that such claims are inconsistent with requirements imposed by the FDA), *Hunsaker v Surgidev Corp*, 818 F Supp 744, 751 (D Pa 1992) (finding that section 360k(a) preempts not only legislatively enacted requirements but also "jury-set standards," which "constitute new requirements which defendants must heed"), *Brooks v Howmedica Inc*, 273 F 3d 785, 796 (8th Cir 2001) ("A jury finding on negligent failure to warn would be premised on the fact that the label was not written in a particular way or did not contain certain information This would be equivalent to a state regulation imposing specific label requirements")

Contrary to Weston's assertion, the question is not whether the state common law and statutory causes of action asserted by Weston were developed specifically with respect to FreshLook Colors lenses, but whether the resolution of Weston's claims could impose a state requirement that is in addition to or different from those imposed by the FDA pursuant to the PMA and the PMA supplement processes In this case, the trial court correctly applied the doctrine of federal preemption because the disputed claims would, if accepted by the jury, impose requirements different from or in addition to the federal requirements applicable to the lenses Weston's allegations are necessarily an attack on the FDA's requirements for the lenses, because they attack the design and labeling of the lenses approved by the FDA through the PMA process "once the FDA approves a specific design, that design becomes in effect the FDA requirement" *Easterling v Cardiac Pacemakers Inc*, 986 F Supp 366, 374 (E D La 1997)

Courts routinely acknowledge that "any cause of action based on testing, labeling or marketing is preempted by the FDA standards for premarket approval" of a Class III device *Tarallo v Searle Pharmaceutical Inc*, 704 F Supp 653, 656 (D S C 1988) Further, according to the South Carolina District Court, the MDA "expressly precludes the individual states from establishing requirements different from or in addition to those promulgated by the FDA, [and] reveals on its face the congressional objective to prohibit, by the doctrine of express preemption, the proliferation of multiple, diverse, state by state device requirements" *Stewart v Int l Playtex Inc*, 672 F Supp 907, 909 (D S C 1987) As Judge Anderson explained in granting summary judgment to a manufacturer of tampons, a Class II device

> Plaintiff's common law tort claim alleging "inadequate warnings" seeks, by definition, to establish a tort labeling requirement which could be different from or in addition to the existing and applicable FDA requirement Therefore, because the following prerequisites are met, the preemption language in § 360k applies The plaintiff here argues South Carolina tort law, which plaintiff hopes will impose a more stringent labeling standard on defendant, is not a "requirement" as used in the regulation Therefore plaintiff maintains the express preemption declaration in § 360k is not applicable in these circumstances Despite plaintiff's assertions to the contrary, the term "requirement" as used in § 360k has been expressly defined by the FDA as *any* standard "having the force and effect of law (whether established by statute, ordinance, regulation *or court decision*)" 21 C F R § 808 1(b) (emphasis added) On its face, this definition encompasses the actions of a court of law entering judgment against the defendant for compensatory and punitive damages based upon "inadequate warnings " The FDA has therefore determined that a state's common law – to the extent it attempts to regulate matters already addressed by the FDA – shall be considered a § 360k "requirement " South Carolina tort law is, therefore not exempt from § 360k [P]laintiff sets forth several grounds for his argument that the federal regulations impose only a minimum standard of conduct Plaintiff maintains because a state can apply for an exemption to the preemption mandate, this proves the regulations set forth minimum levels of compliance This is not the case

Id at 909-10 As set forth above, numerous other courts have also held that a failure-to-warn claim is preempted by PMA approval of the medical device *See e g Brooks*, 273 F 3d at 796 Such decisions are consistent with the Supreme Court's affirmation that in areas where the federal government has regulated and preempted the field, "State[s] shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act " *Bates v Dow AgroSciences*

LLC, 125 S Ct 1788, 1798 (2005) (applying the Federal Insecticide, Fungicide, and Rodenticide Act)

In short, any state requirements imposed by a jury verdict in favor of the causes of action at issue would be in addition to or in contradiction of federal requirements Accordingly, under well-established principles of preemption enumerated by statute and adopted by numerous state and federal courts, many of which involve causes of actions virtually identical to those alleged here, Weston's causes of action under South Carolina law are preempted and were properly dismissed by the trial court

III The trial court did not commit reversible error in exercising its discretion over the discovery process by limiting discovery in a manner consistent with the remaining causes of action

Weston alleged the following bases for liability against CIBA Count I (negligence per se), Count II (negligence), Count III (breach of implied warranty), Count IV (strict product liability), Count V (sale of a defective product), and Count VI (unfair trade practices) In granting CIBA's motion for summary judgment on the basis of preemption, the Court specifically dismissed Counts II, V, and VI The trial court also granted CIBA summary judgment on the remaining counts set forth in Weston's Amended Complaint to the extent such counts "are dependent on warning, labeling, design, marketing, misbranding, or similar claims " *See* Order p 17 (R p 17) Thus, to the extent Weston's claims for negligence per se, breach of implied warranty, and strict liability are premised on CIBA's alleged failure to properly warn, label, design, market or brand its product, these claims are likewise not viable because they are preempted Accordingly, the trial court properly determined that further discovery on such issues is unnecessary

In regard to Weston's contention that the trial court's Order is allegedly "unclear as to what specific claims in her amended complaint are being dismissed," CIBA respectfully submits that it does not have any difficulty in ascertaining what claims have been dismissed As set forth above, the Order expressly dismisses Counts II, V, and VI and preserves Counts I, III, and IV only to the extent such claims are not premised on issues necessarily subject to preemption Thus, for example, and as set forth in her amended complaint, Weston may proceed on her product liability claim if she is able to present competent evidence of a manufacturing defect The difficulty with the trial court's Order lies not in its alleged lack of clarity, but in Weston's inability to present competent evidence in support of her remaining claims

Weston's primary concern appears to be in regard to the trial court's limitation of further discovery on issues no longer relevant pursuant to its decision to grant CIBA summary judgment on the basis of preemption Weston's concern purports to arise from the lack of clarity this prohibition provides to her and the fact that the court's limitations on discovery were not issued pursuant to a motion filed for the purpose of limiting discovery

Weston's first concern is unfounded The trial court's Order clearly states that it does not prevent discovery on issues not subject to preemption (for example, the existence of an alleged manufacturing defect) Moreover, to the extent that Weston does seek discovery on an issue that is subject to preemption but might nevertheless lead to the discovery of admissible evidence, the Order expressly directs Weston to file a motion and seek an order from the court allowing her to pursue such discovery Accordingly, if Weston has a justifiable basis for pursuing discovery on an issue subject to preemption on

the basis that it is likely to yield admissible evidence in support of one or more of her remaining claims, the trial court has provided her with the means to do so

Weston's remaining basis for opposing the trial court's limitation on discovery is similarly without merit It is well-settled that trial courts have wide latitude in controlling discovery and may do so either at the request of a party or on their own initiative *See e g Creighton v Coligny Plaza Ltd P ship* 334 S C 96, 109, 512 S E 2d 510, 517 (Ct App 1999) (trial court raised and ruled on issue of bifurcating trial sua sponte), *ML-Lee Acquisition Fund L P v Deloitte & Touche* 320 S C 143, 463 S E 2d 618 (Ct App 1996), *rev'd on other grounds*, 327 S C 238, 489 S E 2d 470 (1997) (upholding decision of trial court to limit discovery to documents directly at issue) As such, the rulings of a trial judge in matters involving discovery should not be disturbed on appeal absent a clear showing of an abuse of discretion *Bayle v South Carolina Dep t of Transp* , 344 S C 115, 542 S E 2d 736 (Ct App 2001) An abuse of discretion occurs only when the trial court's ruling is based on an error of law or, when based on factual conclusions, is without evidentiary support *Id* In this instance, no evidence exists of an abuse of discretion As set forth herein, the trial court did not err in granting CIBA summary judgment on the basis of preemption Accordingly, it is within the province of the trial court to limit further discovery to the issues remaining before it for a multitude of purposes including the management of its docket and to protect the parties from unnecessary oppression, annoyance, or undue burden and expense *See generally* Rule 26, SCRCP

CONCLUSION

Wherefore, for the reasons set forth above, CIBA respectfully requests that this Court affirm the Order of the trial court

Respectfully submitted,

June 18, 2008

Keith D Munson (SC Bar No 13400)
Sandi R Wilson (SC Bar No 16896)
Womble Carlyle Sandridge & Rice, PLLC
P O Box 10208
Greenville, SC 29603
Phone (864) 255-5400
Fax (864) 255-5480

Curtis L Ott
Turner, Padget, Graham & Laney, P A
Post Office Box 1473
Columbia, SC 29202
Phone (803) 254-2200
Fax (803) 799-3957
ATTORNEYS FOR RESPONDENT CIBA VISION

THE STATE OF SOUTH CAROLINA
In the Court of Appeals

APPEAL FROM RICHLAND COUNTY
In The Court of Common Pleas
G Thomas Cooper, Jr , Circuit Court Judge

Case No 05-CP-40-0655

Monica Weston, Appellant,

v

Kim's Dollar Store and CIBA Vision, a division of Novartis Company, Respondents

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CERTIFICATE OF COUNSEL

The undersigned certifies that this Final Brief of Respondent CIBA Vision complies with Rule 211(b) of the South Carolina Rules of Appellate Procedure

Keith D Munson (SC Bar No 13400)
Sandi R Wilson (SC Bar No 16896)
Womble Carlyle Sandridge & Rice, PLLC
P O Box 10208
Greenville, SC 29603
Phone (864) 255-5400
Fax (864) 255-5480

Curtis L Ott
Turner, Padget, Graham & Laney, P A
P O Box 1473
Columbia, SC 29202
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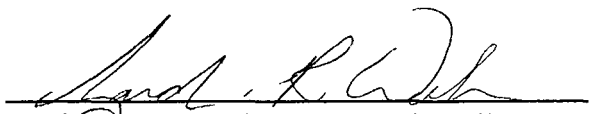
PROOF OF SERVICE

I certify that I have served the **FINAL BRIEF OF RESPONDENT CIBA VISION** by depositing copies of the same in the United States mail, postage prepaid, on June 18, 2008, addressed to all attorneys of record

Daniel T Sullivan
Young & Sullivan, L L P
907 Calhoun St
Columbia, SC 29201

A Victor Rawl, Jr
Andrew G Melling
Celeste T Jones
Robert Widener
McNair Law firm, P A
P O Box 11390
Columbia, SC 29211



Keith D Munson (SC Bar No 13400)
Sandi R Wilson (SC Bar No 16896)
Womble Carlyle Sandridge & Rice, PLLC
550 S Main Street, Suite 400
P O Box 10208
Greenville, SC 29603
(864) 255-5400

Curtis L Ott
Turner, Padget, Graham & Laney, P A
P O Box 1473
Columbia, SC 29202
(803) 254-2200

Attorneys for Respondent CIBA Vision