THE STATE OF SOUTH CAROLINA
In The Supreme Court

APPEAL FROM RICHLAND COUNTY
Court of Common Pleas

G Thomas Cooper, Jr , Circuit Court Judge

Opinion No 4592
Heard June 9, 2009 – Filed July 15 2009

Monica Weston — Petitioner

v

Kim s Dollar Store and CIBA Vision
a Division of Novartis Company — Respondents

AMENDED
APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

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INDEX

THE STATE OF SOUTH CAROLINA
In The Court of Appeals

Monica Weston, Appellant,

v

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

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Appeal From Richland County
G Thomas Cooper, Jr , Circuit Court Judge

Opinion No 4592
Heard June 9, 2009 – Filed July 15, 2009

AFFIRMED

Robert L Widener, Celeste T Jones, A Victor Rawl, Jr , and Andrew G Melling, all of Columbia, for Appellant

Curtis L Ott and Daniel T Sullivan, both of Columbia and Keith D Munson and Sandi R Wilson, both of Greenville, for Respondents

CURETON, A J Monica Weston appeals the circuit court's grant of summary judgment and dismissal of Counts II, V, and VI of her tort action against CIBA Vision (CIBA) On appeal, she argues the circuit court erred in granting summary judgment because (1) the circuit court lacked jurisdiction to determine whether the contact lenses at issue were federally regulated medical devices, (2) a genuine issue of material fact existed, and (3) there was neither a showing nor a finding that any South Carolina law conflicted with federal law In addition, Weston argues the circuit court erred in refusing to amend or clarify certain provisions of its summary judgment order We affirm

FACTS

CIBA sells contact lenses under the trade name FreshLook Colors FreshLook Colors contact lenses can be worn to change the color or appearance of the eye These contact lenses, however, are also capable of correcting nearsightedness, farsightedness, and astigmatism FreshLook Colors contact lenses come in a range of powers from (-)20 00 diopters to (+)20 00 diopters At the zero-power point in the range, the lenses are "non-corrective" or "plano" lenses, but the lenses can still have medical and physiological effects

In March 2004, Weston purchased two pairs of FreshLook Colors contact lenses at the zero-power point from Kim's Dollar Store (Kim's) [1] Along with changing the eye color, the contact lenses Weston purchased had UV protection and were marked with a "prescription only" symbol Kim's was not authorized to sell or distribute the contact lenses and had no affiliation with CIBA Additionally, Weston did not have a prescription for the contact lenses Weston was given no instructions concerning the care, cleaning, or usage of the lenses with her purchase, nor was she informed of the necessity of a medical prescription and oversight for usage of the contact lenses

[1] While Weston did not keep the actual pair of contacts she purchased or any of the packaging, both parties have stipulated the contacts involved were FreshLook Colors with ultraviolet (UV) protection, to be sold by prescription only, and approved for extended wear

After wearing a pair of the FreshLook Colors contact lenses, Weston developed an eye infection, which led to the temporary loss of vision in her left eye Weston then brought this action against Kim's and CIBA alleging six causes of action (1) negligence per se for selling misbranded contact lenses, (2) negligence in the manufacture, sale and/or distribution of contact lenses, and in failing to provide adequate warnings and instructions, (3) breach of implied warranty of merchantability and fitness because the lenses were not safely labeled, (4) strict liability for placing defectively labeled products into the stream of commerce, (5) sale of a defective product due to inadequate warnings, and (6) violation of the South Carolina Unfair Trade Practices Act by committing an unfair or deceptive act or practice, including inadequate labeling and warnings, in the conduct of trade or commerce CIBA's answer generally denied Weston's allegations and asserted additional defenses CIBA also made a motion for summary judgment on the basis that the majority of Weston's claims and legal theories were subject to federal preemption pursuant to the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act, 21 U S C A §§ 301-399a (West 1999 & Supp 2008) (FDCA)

Following a hearing on the matter, the circuit court granted CIBA's motion The circuit court found CIBA was entitled to summary judgment on the basis of federal preemption on all actions dependent on warning, labeling, design, marketing, misbranding, or other similar claims The circuit court also stated CIBA could file additional motions to test the viability of the remaining causes of action Finally, the circuit court restricted Weston from pursuing any additional discovery, without further court order, on the issues of warnings, labeling, packaging, use instructions, product design, marketing, or illegal sales of contact lenses This appeal follows

STANDARD OF REVIEW

When reviewing the grant of a summary judgment motion, this court applies the same standard that governs the circuit court under Rule 56(c), SCRCP Englert, Inc v Netherlands Ins Co , 315 S C 300, 302, 433 S E 2d 871, 873 (Ct App 1993) This standard requires all facts and reasonable inferences to be drawn therefrom to be viewed in the light most favorable to

the appellant Id However, "[a]n appellate court may decide questions of law with no particular deference to the trial court " In re Campbell, 379 S C 593, 599, 666 S E 2d 908, 911 (2008)

LAW/ANALYSIS

Weston argues the circuit court erred in granting summary judgment because (1) the circuit court lacked jurisdiction to determine whether the contact lenses at issue were federally regulated medical devices, (2) a genuine issue of material fact existed, and (3) there was neither a showing nor a finding that any South Carolina law conflicted with federal law We disagree

I Preemption

> The Supremacy Clause of the United States Constitution provides that federal law "shall be the supreme Law of the Land any Thing in the Constitution or Laws of any State to the Contrary notwithstanding " U S Const art VI Thus, as has been clear since the Supreme Court's decision in M'Culloch v Maryland, 17 U S (4 Wheat), 316, 4 L Ed 579 (1819), any state law that conflicts with federal law is "without effect " Cipollone v Liggett Group, Inc , 505 U S 504, 516, 112 S Ct 2608, 120 L Ed 2d 407 (1992) (citing Maryland v Louisiana, 451 U S 725, 746, 101 S Ct 2114, 68 L Ed 2d 576 (1981))
>
> In applying the Supremacy Clause, courts "start with the assumption that the historic police powers of the States [are] not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress " Medtronic v Lohr, 518 U S 470, 485, 116 S Ct 2240, 135 L Ed 2d 700 (1996) (citing Rice v Santa Fe Elevator Corp , 331 U S 218, 230, 67 S Ct 1146, 91 L Ed 1447 (1947)) Therefore, " '[t]he

> purpose of Congress is the ultimate touchstone' in every pre-emption case " Id (citing Cipollone, 505 U S at 516, 112 S Ct 2608, 120 L Ed 2d 407)

Jamison v Ford Motor Co , 373 S C 248, 261-62, 644 S E 2d 755, 762 (Ct App 2007) (quoting King v Ford Motor Co , 209 F 3d 886, 891 (6th Cir 2000))

"The interpretation of a statute is a question of law for the [c]ourt " In re Campbell, 379 S C 593, 599, 666 S E 2d 908, 910-11 (2008), accord Anderson v Sara Lee Corp , 508 F 3d 181, 191 (4th Cir 2007) (holding whether federal statute preempts state law is a question of law) The MDA generally preempts state law that affects medical devices covered by the MDA unless an exemption is granted

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter

21 U S C A § 360k(a) (West 1999) Under the FDCA, a "device" is

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other

> animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes

21 U S C A § 321(h) (West 1999) A "cosmetic" is an article, or a component thereof, "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance " 21 U S C A § 321(i) (West 1999) Federal law contemplates that a regulated device may simultaneously be classified as a cosmetic 21 C F R § 700 3 (1981) ("Any cosmetic product which is also a drug or device or component thereof is also subject to the requirements of Chapter V [of the FDCA] ")

Weston casts her argument as an attack on jurisdiction, presumably over the subject matter of her suit Subject matter jurisdiction is "the power of a court to hear and determine cases of the general class to which the proceedings in question belong " McCullar v Estate of Campbell, 381 S C 205, 206, 672 S E 2d 784, 784 (2009) Tort claims are within the jurisdiction of the circuit court Id When federal law seats exclusive jurisdiction over a particular type of claim in the federal courts, South Carolina courts must examine the federal law to determine whether it preempts state law Griggs v S C Elec & Gas Co , 320 S C 127, 129, 463 S E 2d 608, 609 (1995) Weston appears to argue the circuit court was somehow deprived of the authority to determine whether federal law preempted state law while presumably retaining the authority to award Weston damages for her loss This argument is meritless Interpreting federal statutes is an essential step in determining whether federal law preempts state law The question whether CIBA's FreshLook Colors contact lenses fit the statutory definition of medical devices, thus triggering the MDA's provision preempting state law, is properly a question of law for the circuit court Consequently, the circuit court did not err in construing federal law to determine it preempted South Carolina law in this matter

II Background Federal Regulation of Contact Lenses

For regulation purposes, the Food and Drug Administration (FDA) classifies medical devices into three categories Class I, Class II, and Class III 21 U S C A § 360c (West 1999) The FDA applies different levels of scrutiny and regulation to each category in order to establish the safety and effectiveness of a medical device Id Class III medical devices receive the highest level of scrutiny and may only be marketed pursuant to the FDA's premarket approval (PMA) process 21 U S C A § 360e (West 1999 & Supp 2008) The PMA process is rigorous, and it begins with the manufacturer of the medical device submitting detailed information to the FDA regarding the safety and efficacy of the device Riegel v Medtronic, 128 S Ct 999, 1004 (2008) The FDA spends an average of one thousand, two hundred hours reviewing all of the submitted information and "grants [PMA] only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness '" Id

After a product receives PMA, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness " Id at 1005 If such changes are to be made, the manufacturer may submit a supplemental PMA application to the FDA, which is evaluated in a similar fashion as the initial application Id This supplemental PMA process obviates the need to submit redundant information to the FDA regarding design features, manufacturing processes, or labeling that have already been approved by the FDA, because the entirety of the PMA, including all supplements, are before the FDA at the time the supplement is reviewed 51 Fed Reg 26,342, 26,354 (1986) Following PMA, the FDA continues to subject the medical devices to reporting requirements Riegel, 128 S Ct at 1005

According to the affidavit of CIBA's expert witness Philip Phillips, former Deputy Director for Science and Regulatory Policy in the Office of Device Evaluation for the FDA, all soft contact lenses automatically became Class III medical devices when the MDA was implemented in 1976 In 1994, the FDA drew a distinction between daily wear and extended wear soft contact lenses Daily wear lenses were reclassified as Class II medical

devices while extended wear lenses remained Class III medical devices These classifications applied to both plano lenses and corrective lenses

In 2003, the FDA issued Import Alert 86-10, which allowed for the possibility of obtaining cosmetic classification, under certain circumstances, for plano contact lenses intended solely for the decorative purpose of changing the eye color With a cosmetic classification, the lenses could be sold without having to undergo the rigorous PMA process If contact lenses were marketed with any claims of effecting physical or physiological changes, then even plano contact lenses that change the color of the eye would continue to be regulated as medical devices by the FDA The Import Alert provided a claim of sunscreen protection as an example of a claim that would disqualify a product as a cosmetic In 2005, Congress eliminated the carve-out set forth in Import Alert 86-10 by making all contact lenses, even solely decorative contact lenses, subject to regulation as medical devices by the FDA 21 U S C A § 360j(n)(1) (West Supp 2008)

III Summary Judgment

Rule 56(c), SCRCP, provides

> [Summary judgment] shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law

A Genuine Issue of Material Fact

"In determining whether any triable issue of fact exists, the evidence and all factual inferences drawn from it must be viewed in a light most favorable to the nonmoving party " Donahue v Multimedia, Inc , 362 S C 331, 337, 608 S E 2d 162, 165 (Ct App 2005) This court, however, is not "required to single out some one morsel of evidence to create an issue of fact that is not genuine " Englert, 315 S C at 302, 433 S E 2d at 873 (quotations and citations omitted) Generally, only "a mere scintilla of

evidence" is required to defeat a motion for summary judgment when the burden of proof is by a preponderance of the evidence Hancock v Mid-South Mgmt Co , 381 S C 326, 330, 673 S E 2d 801, 803 (2009) However, "in cases applying federal law, the non-moving party must submit more than a mere scintilla of evidence to withstand a motion for summary judgment " Id at 330-31, 673 S E 2d 803

Weston asserts a genuine issue of material fact exists as to whether FreshLook Colors contact lenses were subject to regulation by the FDA as a Class III medical device Specifically, Weston argues while PMA exists for all FreshLook Colors contact lenses with a diopter of greater or less than zero, the FreshLook Colors PMA excluded plano lenses because they have no effect on visual acuity In support, Weston points to language in letters from the Department of Health and Human Services (DHHS) addressing a PMA supplement stating FreshLook Colors contact lenses were "indicated for the correction of visual acuity " This indication, Weston reasons, excludes the lenses she purchased because, by definition, plano lenses do not correct vision Furthermore, according to Weston, CIBA's marketing of the plano FreshLook Colors lenses for beautification rather than for correction of visual acuity invalidates any PMA that might have applied We find this argument unpersuasive

Initially, we find FreshLook Colors contact lenses fit the FDCA's definition of a device, in that each lens is an "instrument or other similar or related article intended for use in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man " 21 U S C A § 321(h) As CIBA points out, these lenses contain UV protection for the prevention of disease, and as extended-wear lenses, they affect the structure of the eye Furthermore, we find CIBA presented uncontradicted competent evidence in the form of affidavits, depositions, and documentation, indicating FreshLook Colors contact lenses were Class III medical devices, subject to and approved by the FDA pursuant to the PMA process

Weston's expert witness, Dr Suzanne Parisian, acknowledged the PMA history for FreshLook Colors contact lenses began with the original 1983 PMA She further acknowledged through PMA Supplement 39 the FDA

allowed FreshLook Colors UV to include the UV symbol on its labeling CIBA then presented additional extensive evidence that through the supplemental PMA process the FreshLook Colors contact lenses in question received FDA approval through Supplement 39

Two letters from the DHHS discussed Supplement 39 The first letter, dated January 25, 1996, referenced "P830037/S39 FreshLook Colors UV and FreshLook LiteTint UV " This letter read

> The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for incorporating an ultra-violet absorber into the above referenced lenses Based upon the information submitted, the PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed) You may begin commercial distribution of the devices as modified by your PMA supplement upon receipt of this letter

The second DHHS letter, dated August 22, 2003, referenced two PMA supplements, one being "P830037/S39 FreshLook Colors UV and FreshLook LiteTint UV (phemfilcon A) UV Soft (hydrophilic) Contact Lenses "[2] This letter stated

> The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its evaluation of your premarket approval application (PMA) supplement[] referenced above and issued [an] approval order[] on January 25, 1996[,] for Supplement 39 We inadvertently made an error by not including the appropriate restricted

[2] The other PMA supplement referenced was "P830037/S46 FreshLook COLORBLENDS (phemfilcon A) UV Soft Contact Lenses "

device conditions of approval that apply to all UV absorbing contact lenses

The letter went on to provide the restrictions and warnings that applied to the referenced contact lenses However, despite the thoroughness with which the regulatory agencies reviewed CIBA's submissions, we find no indication in the record the DHHS or the FDA excluded any specific diopter or diopter range from the applicable PMA or its supplements By contrast, both the regulatory agencies and CIBA treated the plano lenses no differently than their corrective counterparts Plano lenses were included in the approved diopter range, were provided to the regulatory agencies as exemplars of the FreshLook Colors product, and were accompanied by all the same warnings, labels, and information as corrective FreshLook Colors lenses

In addition to this documentation, CIBA presented expert witnesses who confirmed the FreshLook Colors contact lenses in question were approved and regulated by the FDA Paul Oris, Head of Global Regulatory Affairs for CIBA, testified at his deposition that CIBA always treated FreshLook lenses as medical devices and that they were always approved through the PMA process[3] He stated, "All [FreshLook Colors] contact lenses, including plano, were approved by the FDA in the PMA process " Oris also explained the "Rx only" symbol on the package of the contact lenses at issue indicated the contacts were medical devices that should only

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[3] In her brief, Weston argues Oris's testimony is hearsay We find no evidence of this argument being made to the circuit court, and therefore, we decline to address it See Wilder Corp v Wilke, 330 S C 71, 76, 497 S E 2d 731, 733 (1998) ("It is axiomatic that an issue cannot be raised for the first time on appeal, but must have been raised to and ruled upon by the [circuit court] to be preserved for appellate review ") We note CIBA's brief argues this issue was not properly preserved because it was raised to the circuit court for the first time in a Rule 59(e) motion, and hearsay objections cannot be raised for the first time on appeal However, after reviewing the record we are unable to find the Rule 59(e) motion to which CIBA refers, so without a complete record for review, we need not reach CIBA's argument See Rule 210(h), SCACR ("[T]he appellate court will not consider any fact which does not appear in the Record on Appeal ")

be sold by prescription Oris further stated the package insert that was meant to accompany all FreshLook Colors contact lenses was drafted by CIBA pursuant to a PMA supplement

CIBA's expert witness Phillips confirmed in his deposition that the package insert that was to be included with all FreshLook Colors contact lenses was reviewed and approved by the FDA Phillips stated the package insert that was submitted and approved by the FDA as part of the FDA's PMA oversight function was "probably what [the] FDA looked at closer than any other aspect of labeling " He further stated this FDA-approved insert applied to the specific contact lenses at issue

Phillips provided further support that FreshLook Colors contact lenses were approved and regulated by the FDA and were unaffected by Import Alert 86-10 in his affidavit, which asserted

> FreshLook Colors Lenses of the type [at issue] are Class III medical devices This would include plano (zero power) FreshLook Colors lenses in 2004 FreshLook Colors plano (zero power) contact lenses are approved in the Premarket Approval (PMA) P830037 and the relevant supplements thereto CIBA['s] PMA approval was in accord with all applicable FDA requirements and resulted in legitimate approval of CIBA Vision FreshLook Colors contact lenses as Class III medical devices In PMA Supplement 33, [CIBA] obtained approval from the FDA to incorporate the UV absorber ingredient into FreshLook Colors lenses As of at least July 2003, the FDA approved [CIBA] package insert for FreshLook Colors lenses included significant information about UV absorbing properties and UV protection UV protection[] would constitute a "medical use" under Import Alert 86-10 and therefore further make FreshLook Colors plano lenses ineligible for regulation as a "cosmetic "
>
> [CIBA's] packaging, product information,

> warnings and labeling for FreshLook Colors contact lenses[] were in accordance with the FDA's PMA and PMA Supplement approvals and the agency's labeling regulation Throughout 2004, [CIBA] compliance with the Conditions of Approval, good manufacturing practices, medical device reporting requirements and other requirements reviewed by FDA were sufficient to maintain the PMA approval status for FreshLook Colors contact lenses

Furthermore, the record contains ample discussion and evidence on the distinction between a cosmetic and a medical device When discussing whether plano color contact lenses used to enhance the color of the eye are currently considered cosmetics, as the exception in Import Alert 86-10 had provided, Dr Parisian explained, "Just because [the FDA] put [the lenses] under the device regulations doesn't change that [the lenses are] still a cosmetic [The lenses are] a cosmetic, but [they are] being regulated under medical device regulation " When asked whether the FDA would consider plano color contact lenses intended to enhance the color of the eye for extended wear to be medical devices, Dr Parisian stated, "[The FDA] could, depending on the [manufacturer's] claims "

This notion of plano color contact lenses being both a cosmetic and a medical device was in complete accord with the evidence presented by CIBA and with federal law Phillips explained in both his deposition and his affidavit that classification as a cosmetic and a medical device was not mutually exclusive Further, CIBA presented the circuit court with a notice published in the Federal Register noting, "[The] FDA regulates as devices noncorrective tinted contact lenses that are expressly promoted only for their cosmetic effect of enhancing eye color because they have physiological effects on the eye " 60 Fed Reg 41,453 (1995)

Moreover, while Weston presented much discussion regarding the cosmetic purposes of FreshLook Colors contact lenses, the record was also replete with evidence of their medical, health, or therapeutic use and their physical or physiological effects, which requires the lenses to be regulated as medical devices See 21 C F R § 700 3(b) ("Any cosmetic product which is

also a drug or device or component thereof is also subject to the requirements of Chapter V of the [FDCA] ") Although Kim's did not provide Weston with the package insert intended to accompany the FreshLook Colors contact lenses she purchased, the lenses did have an applicable package insert that was in accord with FDA requirements and obtained FDA approval This insert included the following "Indications (Uses)" for the lenses "FreshLook soft contact lenses with UV-absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye," and "The lenses may be prescribed for Daily Wear or Extended Wear " The insert goes on to note, "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 "

This FDA approved language in the package insert clearly conveys the FreshLook Colors contact lenses in question had medical or therapeutic purposes and physiological effects on the eye, thus making the lenses medical devices See 21 U S C A § 321(h) ("The term 'device' means an instrument, apparatus, implement, or other similar or related article, which is intended for use in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body ") Weston's own expert witness did not contradict this conclusion Dr Parisian noted the UV symbol on the contact lenses' package and the PMA supplement information established the lenses in question contained a product to help block UV rays from the sun that can be harmful to the human eye Dr Parisian also acknowledged that when contact lenses are marketed "for extended wear, then it's a Class III [medical device] "

While these stated uses and warnings contained on both the packaging and package insert of FreshLook Colors contact lenses classify the lenses as medical devices subject to the MDA, they also indicate Import Alert 86-10's inapplicability to the contact lenses Import Alert 86-10 stated it applied to color contact lenses "[p]rovided they are not marketed with claims that they effect physical or physiological change [Import Alert 86-10] does not cover contact lenses that are intended for medical or therapeutic use and that are, therefore, properly regulated as medical devices under the [FDCA] " The evidence demonstrates the FreshLook Colors contact lenses in question

effect physiological changes and have medical or therapeutic uses, resulting in no change of classification following Import Alert 86-10

After reviewing the documents, depositions, affidavits, and all other evidence in the record, we find CIBA carried its burden of demonstrating no genuine issue of material fact existed as to whether FreshLook Colors contact lenses of all diopters underwent the rigorous PMA process and were, therefore, subject to regulation by the FDA See Englert, 315 S C at 302, 433 S E 2d at 873 (stating this court views all facts and reasonable inferences in light most favorable to appellant but is not "required to single out some one morsel of evidence to create an issue of fact that is not genuine"), see generally Weinberger v Bentex Pharms , Inc , 412 U S 645, 653 (1973) (explaining the FDA has jurisdiction to decide the status or class of a medical product)

B Judgment as a Matter of Law

Having reached this conclusion, we must address the issue of whether Weston's claims are subject to federal preemption, thereby entitling CIBA to judgment as a matter of law See 21 U S C A § 360k(a) (explaining the MDA expressly preempts certain state law requirements governing medical devices), Quigley v Rider, 357 S C 477, 483, 593 S E 2d 476, 479 (Ct App 2003) (explaining when state law and federal law conflict, the former must give way) Whether a federal statute preempts state law is a question of law for the court to decide See Campbell, 379 S C at 599, 666 S E 2d at 910-11, accord Anderson, 508 F 3d at 191 PMA approval of a medical device by the FDA results in device-specific requirements that preempt inconsistent state requirements, including those sought to be imposed through tort liability Riegel, 128 S Ct at 1007-08, Horn v Thoratec Corp , 376 F 3d 163, 169 (3rd Cir 2004), Martin v Medtronic, Inc , 254 F 3d 573, 584 (5th Cir 2001) Specifically, the MDA prohibits States from imposing on devices intended for human use "any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter " 21 U S C A § 360k(a) This preemption clause has been read to extend to state tort claims Riegel, 128 S Ct at 1008

The United States Supreme Court recently held "common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device " Id at 1007 The Supreme Court stated, "Absent other indication, reference to a State's 'requirements' includes its common-law duties " Id at 1008 The Supreme Court reasoned

> [C]ommon-law liability is "premised on the existence of a legal duty," and a tort judgment therefore establishes that the defendant has violated a state-law obligation And while the common-law remedy is limited to damages, a liability award "can be, indeed is designed to be, a potent method of governing conduct and controlling policy "

Id (internal quotations and citations omitted) Further, the Supreme Court agreed that "it is implausible that the MDA was meant to 'grant greater power (to set state standards different from, or in addition to federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes '"[4] Id (internal quotations and citations omitted)

In the present case, the circuit court correctly applied the doctrine of federal preemption because a jury's acceptance of the disputed claims could result in different or additional requirements from the federal requirements A jury could potentially find additional or different labeling is appropriate for the FreshLook Colors contact lenses, which would affect the model the FDA has already approved This is not permissible See id ("State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect ") Additionally, the United States

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[4] By contrast, in March 2009, the United States Supreme Court held federal law does not preempt state tort claims for injuries resulting from inadequate warning labels on prescription medications Wyeth v Levine, 129 S Ct 1187, 1201 (2009)

District Court for the District of South Carolina has stated that "any cause of action based on testing, labeling or marketing is preempted by the FDA standards for premarket approval " Tarallo v Searle Pharm , Inc , 704 F Supp 653, 656 (D S C 1988) Further, that court has found the MDA, "which expressly precludes the individual states from establishing requirements different from or in addition to those promulgated by the FDA, 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) (emphasis in original)

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, and therefore, Weston's causes of action under South Carolina law are preempted and were properly dismissed by the circuit court After carrying its burden of proving FreshLook Colors contact lenses were regulated by the FDA as Class III medical devices, CIBA then demonstrated it was entitled to judgment as a matter of law based on the doctrine of federal preemption Consequently, the circuit court correctly granted summary judgment on all actions dependent on warning, labeling, design, marketing, misbranding, or other similar claims See Donahue, 362 S C at 337, 608 S E 2d at 165 ("Summary judgment is proper only when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law ")

IV Remaining Issue

Finally, Weston argues the circuit court erred in refusing to amend or clarify certain provisions of its order granting partial summary judgment We do not reach this argument because we are unable to discern whether Weston raised to the circuit court the issues she now appeals An appellate court's review is limited to facts appearing in the record Rule 210(h), SCACR Weston's February 2007 motion seeking amendment or clarification of the circuit court's order granting partial summary judgment does not appear in the record Consequently, we are unable to review the circuit court's denial of that motion

CONCLUSION

As to whether the circuit court erred in granting summary judgment because it lacked jurisdiction to determine whether the contact lenses at issue were federally regulated medical devices, we find the circuit court properly interpreted federal statutes to determine whether the MDA preempted South Carolina law in this matter Accordingly, we affirm the decision of the circuit court on this issue

Regarding whether the circuit court erred in granting summary judgment because a genuine issue of material fact existed, we find the circuit court correctly concluded no genuine issue existed as to whether CIBA's FreshLook Colors contact lenses were federally regulated as medical devices Therefore, we affirm the decision of the circuit court on this issue

As to whether the circuit court erred in granting summary judgment because there was neither a showing nor a finding that any South Carolina law conflicted with federal law, we find any jury verdict imposing different requirements than the federal law would constitute an impermissible conflicting state law Consequently, we affirm the decision of the circuit court on this issue

We do not reach the issue of whether the circuit court erred in refusing to amend or clarify certain provisions of its summary judgment order because the motion underlying this issue does not appear in the record

Accordingly, the order of the circuit court is

AFFIRMED

HUFF and KONDUROS, JJ , concur

THE STATE OF SOUTH CAROLINA
In The Court of Appeals

APPEAL FROM RICHLAND COUNTY
In The Court of Common Pleas
James R Barber, III, Circuit Court Judge
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 Norvartis Company Respondents

PETITION FOR REHEARING

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ATTORNEYS FOR APPELLANT

Pursuant to Rules 221 and 224, SCACR, Appellant respectfully submits this Petition for Rehearing For the reasons set forth below, Appellant submits this Court should grant rehearing and issue an amended opinion that reverses the trial court and remands for trial

REHEARING ARGUMENTS

I This Court misapprehended the touchstone requirement for federal preemption in this case

Appellant (Customer) respectfully submits this Court has misapprehended the touchstone requirement for federal pre-emption in this case It is *undisputed* that federal pre-emption lies *if and only if* the FDA has issued a Pre-Market Approval (PMA) letter authorizing the sale of the zero-power lenses at issue here It is *undisputed* that Respondent (CIBA) has never requested PMA approval specifically for these zero-power lenses, as admitted by Paul Orris (CIBA s head of regulatory affairs) (R 459) It is *undisputed* that CIBA relies solely upon PMAs that approved lenses in a plus-to-minus diopter range contending that zero power is included in that range It is also *undisputed*, however, that every PMA letter approving this range of lenses also expressly stated that the approval was for lenses which were ' indicated for the correction of visual acuity (Orris, R 461) It is *undisputed* that indicated is a term of art in the PMA process and means "reason for use,' and it is *undisputed* that every application for PMA approval must identify the indication (use) being submitted for approval (Orris, R 460-461) Finally it is *undisputed* that zero power lenses are not and cannot be ' indicated for the correction of visual acuity,' because they cannot and do not correct visual acuity The foregoing *undisputed* facts, at the very least create a question of fact as to whether CIBA obtained PMA approval for its zero power lenses Thus, as matter of law it was error for the trial court to grant summary judgment under federal preemption

Rather than focus on the foregoing touchstone requirement, this Court relied upon "affidavits, depositions, and documentation *indicating* [CIBA's zero-power lenses were] approved by the FDA pursuant to the PMA process' (Op at Adv Sh p 107) (emphasis added) This was error for several reasons

First, CIBA bore the ultimate burden of proof on the defense of preemption, and in seeking summary judgment, it bore the burden of *demonstrating* not 'indicating actual FDA approval of its zero power lenses as such through a PMA letter [1] This could be done in only one of two ways (1) a PMA letter specifically approving zero-power lenses as such, or (2) a PMA letter approving a diopter range of lenses as such but without the limitation of the lenses being "indicated for the correction of visual acuity" There simply is no such letter in the record, nor has CIBA ever produced any such letter in the voluminous discovery in this case Absent this PMA letter, there simply cannot be any preemption, because it is the only means for obtaining FDA approval of zero-power lenses as such, which is an absolute prerequisite to federal preemption

Second testimony from experts or others by affidavit or deposition simply cannot prove the touchstone requirement for preemption *i e*, a PMA letter approving zero-power lenses as such or approving a diopter range of lenses as such but without the limitation of the lenses being indicated for the correction of visual acuity" The PMA letter, not testimony reflecting at best a reading of some letter, is the only way to prove preemption so as to entitle CIBA to summary judgment Such testimony, at best, creates a question of fact but cannot demonstrate the absence

[1] Later in its opinion this Court observed we find no *indication* in the record the DHHS or the FDA excluded any specific diopter or diopter range from the applicable PMA or its supplements (Op at Adv Sh p 108) (emphasis) This observation is factually incorrect and legally irrelevant Factually it is *undisputed* that every PMA letter approving a diopter range of lenses as such included the limitation of the lenses being indicated for the correction of visual acuity and it is *undisputed* that zero power lenses cannot and do not correct visual acuity Legally Customer bore no burden of proving exclusion or anything else Rather CIBA bore the burden of proving beyond question that the FDA has issued a PMA approval letter that actually included zero power lenses as such It manifestly failed to do so under the undisputed facts in this case

of a question of fact as to whether CIBA requested and received a PMA letter actually approving zero power lenses as such

Third, the "documentation" relied upon by this Court does not and cannot support summary judgment This documentation primarily consists of *supplemental* PMAs, which do not and cannot satisfy the touchstone requirement It is *undisputed* that the supplemental PMA process is an 'add-on" system, *i e*, it does not involve going back to ground zero and reconsidering or reapproving the prior PMAs or applications For example, with respect to the supplemental PMA regarding UV protection (upon which this Court relied heavily), the PMA merely and only approved adding UV protection to those lenses that had already been approved in a prior PMA(s) It is one of these prior PMAs, not the UV-PMA, that must satisfy the touchstone requirement of approving zero-power lenses as such or approving a diopter range of lenses as such but without the limitation of the lenses being "indicated for the correction of visual acuity' There is no such PMA in record before this Court, nor did CIBA submit any such PMA to the trial court nor has CIBA produced any such PMA in the voluminous discovery in this case The same is true of all the other documentation relied upon by this Court

Fourth, contrary to this Court s apparent finding, there is no evidence that CIBA provided its zero power lenses as exemplars" in support of an application for approval of zero-power lenses as such or approval a diopter range of lenses as such (See Op at Adv Sh p 108) Indeed, the record is devoid of any application for approval of zero-power lenses as such or approval a diopter range of lenses as such Though unclear, this Court may be referring to the 1994 submission letter appearing at R 667-670 That submission letter requested approval of language and information used in labeling and package inserts (R 667) The 'exemplars" for

this request included packages for zero-power lenses (R 670) This is not conclusive evidence of FDA approval of CIBA's zero power lenses as such for the following reasons

1 The submission letter does not request such approval (R 667)

2 The submission letter simply requests amendatory approval of labeling and package inserts for lenses that had been approved in a prior PMA(s), *i e* , it is part of the add-on" process noted above (R 667)

3 Most importantly, the record is devoid of any PMA approving this submission letter and, even were there such a PMA, it would remain irrelevant to the question of summary judgment on preemption unless it approved zero-power lenses as such or approved a diopter range of lenses as such but without the limitation of the lenses being ' indicated for the correction of visual acuity "

In short, no documentation" in the record satisfies the touchstone requirement for federal preemption Any such documentation can only be, and preemption can only be proven by, a PMA letter specifically approving CIBA's zero-power lenses as such or a PMA letter approving a diopter range of CIBA's lenses as such but without the limitation of the lenses being indicated for the correction of visual acuity " CIBA has never produced or submitted any such letter in discovery or to any court and, if it exists, Customer challenges CIBA to produce it in response to this Petition for Rehearing

II This Court misapprehended Appellant's jurisdiction argument

Customer respectfully submits this Court has misapprehended her jurisdiction argument Contrary to this Court's opinion, her argument is not and never has been that the court does not have jurisdiction over the subject matter of her suit (Op at Adv Sh p 103) Rather, her argument is that, in the absence of PMA approval from the FDA, no court has jurisdiction to rule

that a device is to be regulated as a medical device, thereby giving rise to federal preemption It is *undisputed* that such jurisdiction lies solely with the FDA The court's only permissible inquiry is whether the FDA has, in fact, granted PMA approval for the device This PMA approval by the FDA is the only possible basis for federal preemption and, at the very least, the undisputed facts of this case create a question of fact as to whether the FDA has, in fact, issued a PMA letter that approved CIBA's zero-power lenses as such

It appears this Court, like the trial court, has mistakenly usurped the exclusive jurisdiction of the FDA to approve medical devices, thereby giving rise to federal preemption In reading this Court's opinion, it appears this Court came to the following conclusions

1 Zero power lenses, generally, are medical devices *subject to* regulation by the FDA (Emphsis added)

2 The FDA and DHHS view zero power lenses as medical devices that are subject to regulation

3 CIBA views its zero powers lenses as medical devices that are subject to regulation

The controlling inquiry, however, is *not* whether zero power lenses are medical devices, *nor* is it whether such lenses are subject to ' regulation Rather, the only inquiry is whether CIBA's zero power lenses have, in fact, been subjected to regulation by the FDA It matters not that CIBA s zero power lenses would be, could be or should be subjected to regulation For CIBA to assert federal preemption, it must prove its zero power lenses as such have in fact been subjected to regulation This actual regulation, and the attending preemption, can only be proven with a PMA letter specifically approving CIBA's zero-power lenses as such or a PMA letter approving a diopter range of CIBA s lenses as such but without the limitation of the lenses being indicated

for the correction of visual acuity" CIBA did not present any such PMA letter to the trial court, nor is there any such PMA letter in the Record on Appeal before this Court, and CIBA has never produced such a PMA letter in discovery If such a letter exists, Customer challenges CIBA to produce it in response to this Petition for Rehearing

III This Court should grant Appellant's motion to supplement the record and review Appellant's arguments on the trial court's failure to clarify and amend the appealed order

This Court refused to consider Customer's arguments on the trial court's failure to clarify and amend its order (Op at Adv Sh p 115) This refusal was based on the absence of the correct 59(e) motion from the Record on Appeal, which was missing from the Record due to a clerical error in compiling the Record Appellant has filed herewith a Motion to Supplement the Record Upon granting the motion, Appellant respectfully submits this Court should address the issues raised on appeal

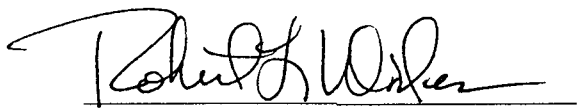
CONCLUSION

Federal preemption of state law claims is a drastic intrusion upon the fundamental principles of federalism that lie at the heart of the American governmental structure For this reason, as noted by this Court, there is a presumption against preemption, and the party asserting preemption must prove its right to do If CIBA desires to deny South Carolina its right to protect its citizens, CIBA must prove strict compliance with the statutory and regulatory requirements for preemption The only permissible basis for preemption in this case is the touchstone requirement of a PMA letter specifically approving CIBA s zero-power lenses as such or a PMA letter approving a diopter range of CIBA s lenses as such but without the limitation of the lenses being indicated for the correction of visual acuity CIBA did not present any such PMA letter to the trial court, nor is there any such PMA letter in the Record on Appeal before this Court, and

CIBA has never produced such a PMA letter in discovery If such a letter exists, Customer challenges CIBA to produce it in response to this Petition for Rehearing

For the reasons set forth above, and for the reasons presented in the Brief of Appellant and at oral argument, Appellant respectfully requests this Court to grant rehearing and issue an amended opinion that reverses the trial court and remands this case for a trial on the merits

Respectfully Submitted,



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ATTORNEYS FOR APPELLANT

August 30 2009
Columbia South Carolina

THE STATE OF SOUTH CAROLINA
In the Court of Appeals

APPEAL FROM RICHLAND COUNTY
In The Court of Common Pleas

James R Barber, III, Circuit Court Judge
G Thomas Copper, Jr , Circuit Court Judge

Case No 05-CP-40-0655

Monica Weston, Appellant,

v

Kims Dollar Store and
CIBA Vision, a division of Novartis Company Respondents

RESPONDENT CIBA VISION'S RETURN IN OPPOSITION TO PETITION FOR RECONSIDERATION

Appellant, Monica Weston, filed a Petition for Rehearing under Rules 221 and 224, SCACR, requesting that this Court issue an amended opinion and remand this case to trial In support of this Petition, Appellant submits that this Court's opinion misapprehends the law of federal preemption As set forth herein, Appellant's Petition should be denied as untimely Alternatively, the Petition should be denied on the basis that this Court did not misapprehend the law, rather, it is Appellant who misapprehends both the law of federal preemption and the

evidence that must be presented to establish the existence of federal preemption See Arnold v Carolina Power & Light Co , 168 SC 163, 167 SE 234 (1933) [1]

A APPELLANT'S PETITION FOR REHEARING IS UNTIMELY

The Court's opinion affirming entry of summary judgment in favor of Respondent was filed on July 15, 2009 (Opinion No 4592 – hereinafter, "Opinion Affirming Summary Judgment") [2] Pursuant to SCACR 221(a) "Petitions for rehearing must be actually received by the appellate court no later than fifteen (15) days after the filing of the opinion, order judgment or decree of the court " Instead of filing the Petition within the fifteen day deadline, on July 30, 2009, Appellate sent a letter to the Clerk of Court, acknowledge that July 30, 2009 was the deadline, but requested an extension until August 14, 2009 On August 3, 2009 (after the

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[1] What the South Carolina Supreme Court said over 75 year ago is equally applicable to this case

> *We regard this as an opportune time to say some things regarding petitions for rehearings which perhaps, we should have said a long time ago The purpose of a petition for rehearing seems not to be fully understood by some members of the bar Petitions of that character are allowed by the terms of rule 17 of this court The purpose of such a petition is to aid the court in deciding correctly a case heard by it The petition must show according to the rule the points supposed to have been overlooked or misapprehended by the Court The purpose of a petition for rehearing is not to have presented points which lawyers for the losing parties have overlooked or misapprehended and the purpose of a petition for rehearing is not just to have the case tried in this court a second time*
>
> *Petitions for rehearing are filed in at least three-fourths of the cases decided by this court Many of them we fear some time are filed just for delay It is a rare thing when the court grants such a petition Usually they are dismissed with a simple order to that effect for the reason that they contain nothing but a "rehash of what the losing party has said before matters which the court has already considered well and disposed of*

Arnold, 167 S E at 238

[2] The Appellate Opinion is currently available on Westlaw as 2009 WL 2136707 (S C App 2009)

deadline), the Court accepted the request and stated that "Please be advised that the Petition for Rehearing is due on August 14, 2009 It must be received by this office by 5 00 p m on the due date" Instead of filing the Petition by the August 14, 2009 deadline, on August 14, 2009, Appellate filed a motion, acknowledged that August 14, 2009 was the deadline, but requested a fifteen (15) day extension until August 31, 2009[3] On August 17, 2009 (after the August 14 deadline), the Court granted Appellant's motion[4] Appellant served its Petition on August 31, 2009

SCACR 221(a) requires that a petition for rehearing "must actually be received" by the appellate court within fifteen (15) days SCACR 221(a) requires that the party seeking a rehearing comply with SCACR 240 (formerly SCACR 224) SCACR 240(b) expressly states that the "time limits imposed by these Rules shall not be stayed by the filing a motion" Appellate twice failed to seek an extension, and failed to obtain relief, in time to avoid the expiration of the deadline for filing the petition for rehearing It appears from the letter dated July 30, 2009 (See Ex A), that Appellant was aware of the desire for an extension before the deadline Having waited until the deadline to seek the extension, it was incumbent upon the Appellant to actually obtain the extension before the expiration of the deadline as required by SCACR 240(b) Having done neither, the deadline for filing a petition for rehearing lapsed The Court's August 3, 2009 endorsement on the letter request for extension can not revive a lapsed deadline Camp v Camp, 378 S C 237, 241, 662 S E 2d 458, 460 (Ct App 2008) (holing that Appellant was too late in filing notice of appeal and citing Allender v Raytheon Aircraft Co, 439 F 3d 1236, 1238 (10th Cir 2006) for proposition that even court's improper extension of

[3] Actually a 15 day extension from August 14, would have elapsed on August 29

[4] The referenced filings related to the extension requests are attached hereto as composite Exhibit A

time could not revive the lapsed deadline), Kraus v Consolidate Rail Corp , 899 F 2d 1360, 1361-63 (1990) (time for filing Rule 59(e) motion lapsed after 10 days and Court's 10 day extension, did not excuse late filing, even though the extension was granted within the first 10 days and was relied on by the Appellant) Here Appellant could not have relied on the Court's extension because she allowed the time period to expire before the extension was granted Moreover, reliance on an office policy to routinely approve an initial request for extension would not supersede the dictate of SCACR 240(b) that the "time limits imposed by these Rules shall not be stayed by the filing a motion " That it might have been easily obtained does not eliminate the need for it to have been timely obtained

Appellant then repeated the same ineffective exercise on August 14, which similarly failed to revive the expired deadline Accordingly, Appellant's Petition for Rehearing must be dismissed as untimely As set forth below, Appellant's untimely Petition is harmless as the petition provides no justification to modify the Opinion Affirming Summary Judgment

B APPELLANT'S PETITION FOR REHEARING IS WITHOUT MERIT

Appellant's Petition for Rehearing should be denied as having no meritorious basis Appellant's argument is premised on the same logical fallacy submitted to and rejected by this Court in her brief on appeal Namely, that federal preemption can only arise under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (21 U S C § 301, *et seq*) if the FDA and the Respondent phrased the Premarket Approval (PMA) in the exact terms selected by Appellant Building on this unstable premise, Appellant simply scours the overwhelming evidence establishing Premarket Approval by the FDA and selects terms not used by the FDA in granting Premarket Approval Appellant proclaims that since her self-selected magical words were not recited by the FDA in granting Premarket Approval, there must be a genuine issue of

material fact [5] This tired argument is the same failed argument that Appellant made to the Trial Court and to this Court in her brief That is not the purpose of a petition for rehearing Kennedy v South Carolina Retirement System, 349 S C 531, 532, 564 S E 2d 322, 322 (S C 2001) ("The purpose of a petition for rehearing is not to have the case tried in the appellate court a second time "), see also, Jean H Toal, Shahin Vafai & Robert Muckenfuss, Appellate Practice in South Carolina 309 (1999) Further highlighting that Appellant is merely rehashing her prior arguments is the fact that she cites no legal authorities in her entire seven (7) page Petition

The most disturbing aspect about Appellant's Petition for Rehearing, is that she takes a position that is 180 degrees from her position before Judge Cooper below At the summary judgment hearing, CIBA sought to eliminate even non-genuine questions about FDA approval by drafting a letter for the Court to send to the FDA (pursuant to an approved procedure in the Code of Federal Regulations) specifically asking for further confirmation that Appellant's specific 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, Appellant'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) Having succeeded in stopping the Court from obtaining absolute confirmation directly from the FDA itself, Appellant now argues that only absolute confirmation directly from the FDA could be considered by the Court in

[5] The "magic words" Appellant argues for are essentially "Although the PMA application and the this PMA approval cover a range of powers (from (-) 20 diopters through (+) 20 diopters) of contact lenses, and, although, zero power lenses fall at the center of that range, as the FDA has repeatedly advised, nevertheless, the FDA, affirmatively states, in order that there can be no misunderstanding, that zero power lenses fall within the range covered by this PMA approval " Of course, had the FDA gone into this much detail in issuing it's approval, the approval "letter" would be a "book", and Appellant would have simply invented other magic words

granting summary judgment (thereby disregarding all the other evidence of pre-market approval and the fact that no evidence to the contrary was ever submitted by Appellant) [6] The Court did not accept the Appellant's strategic "about-face" when considering the initial appeal and it should not allow Appellant to recycle that tactic in this Petition 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) It is worth noting that Appellant choose not to file a Reply brief or otherwise try to explain her reversal of positions

This Court specifically acknowledged, addressed, and found "unpersuasive" Appellant's argument that CIBA Vision was required to submit a PMA approval letter specifically addressed to plano lenses (as opposed to a PMA approval letter that includes approval for a full diopter range of lenses that would necessarily include the plano or zero power lenses at issue in this case) see Opinion Affirming Summary Judgment, Page 5 [7] In so finding, this Court considered a wealth of uncontradicted evidence in the record concerning the PMA approval process and the regulatory requirements that pertain to the lenses at issue On the basis of this evidence, (and the absence of any contrary evidence submitted by Appellant), this Court concluded that the lenses at issue are Class III medical devices subject to and approved by the FDA pursuant to the PMA process As a necessary corollary, and in conformance with the Supreme Court's recent decision in Riegel v Medtronic, 128 S Ct 999 (2008), this Court concluded that Appellant's causes of

[6] See Final Brief of Appellant, page 9 (Heading I), wherein Appellant unsuccessfully argued " there is a question of fact as to whether the FDA approved the lenses at issue here "

[7] Weston v Kim's Dollar Store, 2009 WL 2136707 *5 (S C App 2009)

action are therefore properly preempted under the Federal FD & CA's Medical Device Amendments and affirmed the decision of the trial court See 21 U S C A §360(k)(a)

In the face of the great weight of the evidence in the record in support of Respondent's position and lacking any admissible evidence in contravention of the same, Appellant contends that PMA approval can purportedly be established in only the precise form she prescribes Appellant's argument is without legal support Rule 56, SCRCP, states that a motion for summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact " Here, the evidence in the record was uncontradicted According to Appellant, it simply was not the right evidence Appellant's argument is akin to claiming that the only means of establishing ownership of an item is by submitting the receipt for purchase Of course, ownership can be shown in any number of ways For example, possession, long time use, a stamped purchase order, a bill of lading, a store cashier's testimony, a store's surveillance camera, tax assessments/payments, or ownership of the raw materials are all ways to establish ownership of an item Indeed, South Carolina courts have long recognized both direct and circumstantial evidence and make no distinction between the weight or value allotted to each It is important to note that Appellant does not claim a factual issue exists because she has submitted a receipt showing that she owns the item, rather, she says that despite all the indicia of ownership listed above, a factual issue exists until the receipt is produced This is not the law and Appellant cannot avoid summary judgment by vague references to "phantom evidence" or artificial issues of fact Buekner v Sam's Club, Inc , 75 F 3d 290, 292 (7th Cir 1996)

The pertinent question is whether, once Respondent met its burden, Appellant came forward with any evidence demonstrating the existence of a genuine issue of material fact

Appellant did not do so Hence, the evidence in the record supports but one reasonable conclusion, namely, that the lenses at issue are Class III medical devices that are regulated by the FDA under a regulatory scheme that preempts the claims for which Judge Cooper entered, and this Court affirmed, summary judgment Riegel v Medtronic, 128 S Ct 999 (2008)

C THE EVIDENTIARY RECORD IS UNCONTESTED

Appellant argues that the Court should allow her a rehearing to address an evidentiary matter that she failed to raise at the summary judgment hearing and failed to preserve on appeal Appellant is not entitled to supplement the record, nor would supplementation serve any purpose whatsoever See Respondent's Response in Opposition to Appellant's Motion to Supplement the Record on Appeal Without granting the belated attempt to inject unpreserved matters into the Record on Appeal, Appellant's request for rehearing is baseless

Even if the supplementation is allowed, Appellant's request for rehearing based on the uncontested evidentiary record before the trial court is without merit [8] Although a review of summary judgment may be *de novo*, "the admission or exclusion of evidence in general is within the sound discretion of the trial court In both instances, the trial court's decision will not be disturbed on appeal absent an abuse of discretion" Fields v Regional Medical Center Orangeburg, 363 S C 19, 25-26, 609 S E 2d 506, 509 (2005), see also, Pike v South Carolina Dept of Transp , 343 S C 224, 234, 540 S E 2d 87, 92 - 93 (2000) Moreover, to "warrant reversal based on the admission or exclusion of evidence, the appellant must prove both the error of the ruling and the resulting prejudice "(emphasis added) Fields, 363 S C at 26, 609 S E 2d at 509 The abuse of discretion standard for evidentiary rulings applies at the summary judgment

[8] If the Court examines Appellant's unfiled Rule 59(e) motion/memorandum in connection with this Petition, Respondent requests that the Court also review pages 7-13 and 16-17 of the Final Brief of Respondent CIBA Vision, which set forth the futile nature of Appellant's substantive argument

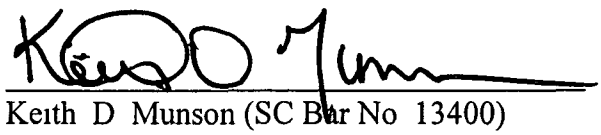
stage as well Bessinger v Bi-Lo, Inc , 329 S C 617, 620, 496 S E 2d 33, 35 (Ct App 1998) (summary judgment affirmed under abuse of discretion standard applied to evidentiary ruling of trial court), see also S E C v Phan, 500 F 3d 895, 912-913 (9th Cir 2007) (refusal to exclude evidence at summary judgment state is "reviewed for and abuse of discretion and warrants reversal only when the 'evidence ruling was manifestly erroneous *and* prejudicial '" (emphasis in original)(internal citation omitted)), LaSalle Bank Nat Ass'n v Nomura Asset Capital Corp , 424 F 3d 195, 211 (2nd Cir 2005) ("we review the trial court's evidentiary rulings, which define the summary judgment record, and give these rulings their due deference " (quoting, Christophersen v Allied-Signal Corp , 939 F 2d 1106, 1009 (5th Cir 1991)(en banc)), Brackens v Best Cabs, Inc , 146 Fed Appx 242, 245 (10th Cir 2005), E E O C v Green, 76 F 3d 19, 24 (1st Cir 1996) ("Ordinarily, the district court has broad authority to prescribe the evidentiary materials it will consider in deciding a motion for summary judgment "), Marks v Newcourt Credit Group, Inc , 324 F 3d 444, 457 (6th Cir 2003) (at summary judgment stage, all evidentiary rulings are reviewed for abuse of discretion, including whether supporting evidence is hearsay)

In light of the abuse of discretion/resulting prejudice standard of review applicable to the trial court's evidentiary determinations, Appellant cannot show that this Court overlooked or misapprehended any material issue justifying rehearing the appeal It is the Appellant who overlooked raising any objection to the trial court before or at the summary judgment hearing and failed to preserve the issue on appeal Regardless, as a substantive matter, the totality of the evidence submitted to the trial court overwhelmingly established federal preemption requiring

entry of summary judgment, and therefore, Appellant's failure to address and/or preserve this evidentiary issue was harmless [9]

In light of the above, Respondent respectfully requests that Appellant's Petition for Rehearing be denied

Respectfully submitted,



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ATTORNEYS FOR RESPONDENT CIBA VISION

Dated October 1, 2009

[9] In fact, it may have been strategic or fortuitous in allowing Appellant to concentrate on what she perceived to be her better arguments against summary judgment (although, ultimately also unsuccessful)

EXHIBIT A

July 30 2009

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Via Courier

Honorable Jeanette F Barber
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Re Weston, Monica v Kim s Dollar Store (2)
Opinion No 4592
Heard June 9, 2009 - filed July 15 2009

Dear Ms Barber

Appellant s Petition for Rehearing is currently due July 30 2009 Due to conflicts in the schedule of counsel Appellant respectfully requests a fifteen (15) day extension to file and serve the Petition for Rehearing This extension would make the Petition due on August 14, 2009 We have enclosed our firm's check in the amount of $25 00 We are notifying counsel of record of this request via facsimile and U S Mail

Respectfully yours

Robert L Widener

RLW/as
Enclosures

cc (via facsimile and U S Mail)
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The South Carolina Court of Appeals

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Re Weston, Monica v Kim's Dollar Store (2)

Dear Counsel

The following Order has been endorsed on your request for extension of time to file the Petition for Rehearing in the above entitled case on appeal

Motion Granted

s/ Jasper M Cureton, A J

August 03, 2009 "

Please be advised that the Petition for Rehearing is due on August 14, 2009 It must be received by this office by 5 00 p m on the due date

Sincerely,

Renee S Johnson
Administrative Specialist

WCA/rj

cc Curtis L Ott, Esquire
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039

August 14 2009

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Honorable Jeanette F Barber
Clerk of Court
S C Court of Appeals
Post Office Box 11629
Columbia, South Carolina 29211

Re Weston, Monica v Kim s Dollar Store

Dear Ms Barber

Enclosed for filing, please find the original and seven copies of Appellant s Motion for Extension to File and Serve Petition for Rehearing Also enclosed are the original Certificate of Service and our check in the amount of $25 00 By copy of this letter, we are serving all counsel of record with a copy of the motion via facsimile and by U S Mail

Respectfully yours,

McNAIR LAW FIRM P A

Robert L Widener

RLW/as
Enclosures

cc Curtis L Ott
Daniel T Sullivan
Keith D Munson

McNair Law Firm, P A
The Tower at 1301 Gervais
1301 Gervais Street 18th Floor
Columbia SC 29201

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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 Norvartis Company, — Respondents

MOTION FOR EXTENSION TO FILE
AND SERVE PETITION FOR REHEARING

The Petition for Rehearing in this case is due to be filed by August 14, 2009 Due to conflicts in the schedule of counsel Appellant Monica Weston respectfully requests a fifteen (15) day extension to file and serve the Petition This extension would make the Petition due on August 31, 2009

Respectfully submitted,

Robert L Widener
A Victor Rawl, Jr
McNair Law Firm, P A
Post Office Box 11390
Columbia, South Carolina 29211
(803) 799-9800

Columbia, SC
August 14, 2009

ATTORNEYS FOR APPELLANT

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 Norvartis Company Respondents

CERTIFICATE OF SERVICE

I Ann Shuler, an employee of the McNair Law Firm, certify that I have served a copy of the Appellant's Motion for Extension by facsimile and by depositing a copy in the United States Mail postage prepaid, on August 14, 2009 addressed to the attorneys of record, as follows

Keith D Munson, Esquire
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Attorneys for the Respondent CIBA Vision

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Attorney for the Respondent Kim's Dollar Store

Ann Shuler

The South Carolina Court of Appeals

JEANETTE F BARBER
CLERK

V CLAIRE ALLEN
DEPUTY CLERK

POST OFFICE BOX 11629
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August 17, 2009

Robert L Widener, Esquire
Celeste T Jones, Esquire
A Victor Rawl, Jr Esquire
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McNair Law Firm, PA
P O Box 11390
Columbia, SC 29211

Re Weston Monica v Kim's Dollar Store (2)

Dear Counsel

The following Order has been endorsed on your Motion for Extension of Time to File and Serve Petition for Rehearing in the above entitled case on appeal

"Motion Granted

s/ Jasper M Cureton, A J
For the Court

August 17, 2009 "

Please be advised that the Petition for Rehearing is due on August 31, 2009 It must be received by this office by 5 00 p m on the due date **THERE WILL BE NO FURTHER EXTENSIONS GRANTED**

Sincerely,

Renee S Johnson
Administrative Specialist

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JFB/rj

cc Curtis L Ott, Esquire
Daniel Thomas Sullivan, Esquire
Keith D Munson, Esquire
Sandi R Wilson, Esquire

THE STATE OF SOUTH CAROLINA
In The Court of Appeals

APPEAL FROM RICHLAND COUNTY
In The Court of Common Pleas
James R Barber, III, Circuit Court Judge
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 Norvartis Company Respondents

REPLY TO RETURN TO PETITION FOR REHEARING

Robert L Widener
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ATTORNEYS FOR APPELLANT

REPLY ARGUMENTS

I The Petition for Rehearing is timely

The Petition for Rehearing is timely under longstanding practice and procedure in both appellate courts since the adoption of the SCACR CIBA's argument to the contrary is based on a misunderstanding of appellate practice in South Carolina and is manifestly without merit

II Rehearing should be granted

States, not the federal government, have the primary authority and responsibility for protecting consumers from defective products The primacy of the states' authority is the cornerstone of the American system of government Federal preemption in this or any other field is possible, but it is the exception and is to be strictly construed in favor of states' rights When Congress sets forth requirements for triggering preemption, the law manifestly demands strict compliance with those requirements If CIBA wished to oust South Carolina's jurisdiction over the traditional state-law field of torts, it was incumbent upon CIBA to strictly comply with the requirements for preemption It failed to do so

Contrary to CIBA's arguments Appellant (Customer) has not "selected' the terms for preemption Those terms are undisputed and imposed by law (1) preemption arises only if the product has been submitted for approval by and actually approved by the FDA in its pre-market approval (PMA) process, and (2) such approval arises only if given in a PMA letter Here, it is undisputed that (1) CIBA never sought and never received a PMA letter approving its zero-power lenses as such, (2) all PMA letters referencing a diopter range that ostensibly included zero-power lenses as such limited the approval to lenses for the 'correction of visual acuity", and (3) zero-power lenses cannot and do not correct visual acuity These facts, standing alone, show

there is no preemption in this case and, at the very least, create an issue of fact that precludes the summary judgment granted by the trial court

Contrary to CIBA's arguments, Customer does not rely on the absence of 'magic words' in the PMAs To the contrary, Customer relies on the language used by the FDA in the PMA letters, to-wit the limitation of the approval to lenses for the 'correction of visual acuity," something that zero-power lenses cannot do

CONCLUSION

For the reasons set forth above and in the Petition for Rehearing, and for the reasons presented in the Brief of Appellant and at oral argument, Appellant respectfully requests this Court to grant rehearing and issue an amended opinion that reverses the trial court and remands this case for a trial on the merits

Respectfully Submitted,

Robert L Widener
Celeste T Jones
A Victor Rawl, Jr
Andrew G Melling
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ATTORNEYS FOR APPELLANT

October 15, 2009
Columbia, South Carolina

The South Carolina Court of Appeals

Monica Weston, Appellant

v

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

The Honorable G Thomas Cooper, Jr
Richland County
Trial Court Case No 2005-CP-40-00655

ORDER DENYING PETITION FOR REHEARING

PER CURIAM After a careful consideration of the Petition for Rehearing, the Court is unable to discover that any material fact or principle of law has been either overlooked or disregarded and hence, there is no basis for granting a rehearing It is, therefore, ordered that the Petition for Rehearing be denied

Thomas E. Huff J

J

Joseph M. Anderson A J

Columbia, South Carolina

November 19, 2009

cc Robert L Widener, Esquire
Celeste T Jones, Esquire
A Victor Rawl, Jr Esquire
Andrew G Melling, Esquire
Curtis L Ott, Esquire
Daniel Thomas Sullivan, Esquire
Keith D Munson, Esquire
Sandi R Wilson, Esquire

THE STATE OF SOUTH CAROLINA
In the Supreme Court

APPEAL FROM RICHLAND COUNTY
In The Court of Common Pleas

G Thomas Cooper, Jr , Circuit Court Judge

Case No 05-CP-40-0655

Opinion No 4592
Heard June 9, 2009 – Filed July 15, 2009

Monica Weston, Petitioner,

v

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

CERTIFICATE OF SERVICE

I, Ann Shuler, an employee of the McNair Law Firm, certify that I have served a copy of the Petitioner's Amended Appendix to Petition for a Writ of Certiorari by depositing a copy in the United States Mail, postage prepaid, on February 22, 2010 addressed to the attorneys of record, as follows

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Attorney for the Respondent Kim's Dollar Store

Ann Shuler