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

FINAL BRIEF OF APPELLANT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

STATEMENT OF ISSUES

I The trial court erred in granting summary judgment, because CIBA failed to carry its initial burden of proof on the issue of PMA approval, and because there is a question of fact as to whether the FDA approved the FreshLook Colors plano lenses at issue here

II The trial court erred in granting summary judgment, because it did not have jurisdiction to consider whether a device is "to be regulated as a medical device," and because there is an issue of fact as to whether FreshLook Colors plano lenses were a medical device at the time of the sale to Customer

III The trial court erred in granting summary judgment, because there was no finding and no showing of any South Carolina law that conflicts with federal law on FreshLook Colors plano lenses

IV The trial court erred in refusing to amend or clarify its summary judgment order as to its dismissal of certain claims in the amended complaint and as to its "discovery" ruling

STATEMENT OF CASE

This is an appeal from an order granting partial summary judgment to Respondent (CIBA) upon the ground that certain claims by the Appellant (Customer) were pre-empted by federal law The case involves injuries caused by CIBA's "FreshLook Colors" contact lenses that do not correct visual problems but alter the color of the eyes, *i e* , "plano" lenses

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 Finding such approval, the trial court granted partial summary judgment to CIBA (R 1-18) The Customer made a timely "59(e)" motion, which the trial court denied (R 211-249, 19-20) The Customer timely appealed to this Court

STATEMENT OF FACTS

The FDA's pre-market approval (PMA) process begins with an application from the manufacturer (CIBA here) If the FDA approves the application, it issues a PMA order that takes the form of a letter and imposes conditions on the approval Thereafter, changes to the product must be submitted for approval by the FDA in a supplemental application yielding a supplemental PMA if approved The changed product cannot be marketed under the protection of federal preemption unless it is first approved by the FDA Absent a PMA letter on the product, there can be no federal preemption under 21 U S C § 360k(a) If the manufacturer violates the conditions imposed by the PMA letter, the approval is lost

In 2002 and prior thereto, all contact lenses were regulated as medical devices by the FDA In April 2003, the FDA issued Alert # 86-10 ("2003 Alert") stating that non-corrective lenses that changed the color of the eye without any claims of effecting physical or physiological change were "cosmetic devices " (R 752-760)

CIBA submitted only two PMA's in support of its summary judgment motion, both of which predate the 2003 Alert The first is a 2002 PMA approving a requested labeling change for the product line of "FreshLook COLORBLENDS " This PMA does not bear directly on any of the issues presented here The second PMA is a 2003 approval of a supplemental application for marketing "FreshLook Dimensions," both "Spherical and Toric with or without UV absorber " This supplemental PMA permitted marketing "with the following indication "

1 The Sperhical lenses "are indicated for the correction of visual acuity," both nearsighted and farsighted, in persons that may have astigmatism up to 2 0 diopters The lens also enhanced or altered the apparent color of the eye

2 The Toric lenses "are indicated for the correction of visual acuity,' both nearsighted and farsighted, in persons that may have astigmatism up to 6 0 diopters The lens also enhanced or altered the apparent color of the eye

The PMA letter immediately continued that "*The lenses* may be prescribed for extended wear " (emphasis added) By logic and grammar, this use of "The lenses" was a reference back to "Spherical" and "Toric" lenses that were "indicated for the correction of visual acuity " The PMA letter continued that "FreshLook" lenses with UV absorbing monomer helped protect against UV radiation (Id) Again, this is a reference back to the

"Spherical" and "Toric ' lenses that were "indicated for the correction of visual acuity " The PMA letter also required CIBA to include specific warnings about UV absorbing lenses and the dangers of UV radiation in "*all advertisements* and other descriptive material issued by the manufacturer, packer, or distributor " (emphasis added)

Importantly, neither of the PMA's submitted by CIBA concerned the precise product line at issue here "FreshLook Colors " Neither of these PMA's request approval for a lens line with a negative to positive power range that might arguably include a zero power lens, *i e* , the ' plano" type of lens at issue here CIBA did not submit a PMA for "FreshLook Colors" in support of its summary judgment motion Paul Oris, CIBA's "head of global regulatory affairs," admitted that the PMAs' from the FDA regarding FreshLook Colors lenses had an indication "for the correction of visual acuity " (R 451, 460-461) He admitted CIBA had never sought PMA approval specifically for non-corrective ("plano") color lenses (R 459) He further admitted that if a lens was "marketed for something other than the indicated use, then the approval [by the FDA in the PMA] is invalidated (Id at 41) Thus, if the FreshLook Color line was marketed for something other than the correction of visual acuity, then the approval of that lens would be invalidated (R 461-462) It is undisputed that the lens at issue here was for and was marketed as a non-corrective ("plano") lens that did not correct visual acuity Mr Oris admitted that the plano lens at issue here was intended to be introduced into the eye for "beautifying, promoting attractiveness, or altering the appearance" of the eye (R 476)

Beginning in 2001, CIBA launched a five-year, print advertising campaign for numerous FreshLook lens models directly to consumers at a cost of approximately $23 Million Dollars (Collins Dep at 20-21, 55) This ad campaign was directly primarily at

women between the ages of 18-34 (Id at 55-60 88), Customer here was 28 when she purchased the lenses An earlier ad campaign had been aimed at even younger teenage girls, using a teen icon (Christina Aguilera) and the leading internet site for marketing to teens (Collins Dep Exh 16) Beginning in 2002, CIBA launched a $20 Million Dollar advertising campaign emphasizing FreshLook Colors lenses as a cosmetic accessory like make-up (Collins Dep at 158) Beginning in 2003, CIBA also launched television advertising directly to the consumer, the 2003 budget was $8 0 Million Dollars (Id at 22) In June 2003, just after the alert-designation of "plano" lenses as cosmetic devices rather than medical devices, CIBA updated its packaging to feature eye-catching graphics to appeal to consumers (Id at 157-158) [1] All advertising campaigns were directed at persons with and without vision problems (Id at 28-29, 34-35, 38, 93-110) Approximately 20% of all FreshLook lens sales were "plano" lenses that were for beauty enhancement, not vision correction (Id at 37, 40-41)

During these ad campaigns, CIBA did not assert UV protection or extended wear capability, nor did it give any warning about these matters It also did not emphasize the need for a prescription to obtain the lenses, including the non-corrective ("plano") lenses, often stating only things like "see your participating eye care professional " These same ads were directed at persons without vision problems with phrases like 'Even if your vision is perfect " (See generally R 364-389, and 394-398, 399, 400-449) Many of the ads used phrases like "just for the moment" and "Just for tonight" (emphasis in original), while others invited the consumer to "Change the color of your eyes as often as you

[1] This was a very odd expenditure in light of CIBA s claim that lenses were never to be sold directly to consumers If as CIBA claims its intent was to always sell through an eye care professional there was no need to spruce up the box An inference thus arises from this fact particularly when combined with its proximity to the 2003 Alert and CIBA s knowledge that its lenses were in fact being sold by others directly to customers that CIBA intended the spruced up box to help generate sales directly to consumers

change your mind," all emphasizing a short-term beauty use of the lenses (R 394-398, 399, 418) Other ads emphasized coordination of lens color with makeup and other fashion accessories (*E g* , R 400, 428-445) Some ads referred to the FreshLook lenses as "*Cosmetic* Contact Lenses' (emphasis added) (*E g* , R 404-406, 418-420)

In August 2003, shortly after the issuance of the 2003 Alert that non-corrective lenses were cosmetic rather than medical devices, the FDA wrote CIBA to inquire about CIBA's failure to include all required warnings and information in its "direct-to-consumer" advertising CIBA responded with a November 2003 power-point presentation to the FDA on the "Advertising and Promotion of Contact Lenses ' (R 591-626) The agenda included "Fashion Category FreshLook Ads & Commercialization" and "Continuous Wear Category NIGHT & DAY Advertising " (Id) As to FreshLook Colors, CIBA emphasized this product line could make eyes "their most beautiful" and "enhance and change" eye color "with or without vision correction " (Id) In defending its FreshLook advertisements, CIBA emphasized that no UV claims were made in the ads and that a UV risk disclaimer was appropriate only if the ad made a UV claim, and combined this defense with a general position that if CIBA chose to "advertise for limited indication, [it was] not required to reveal complete risk information " (Id) In discussing the "Regulatory Framework," CIBA emphasized the "Recent Cosmetic Designation" of non-corrective lenses by the FDA in the 2003 Alert and that "not all contacts are restricted devices ' (Id)

In December 2003, CIBA sent the FDA a letter to follow up on the November 2003 power-point presentation (R 484-488) CIBA again asserted that absent a claim

of UV protection or extended wear capability in the advertising, there should be no requirement of related warnings and risk notices (R 484, 487-488, see also R 480-481)

By March 2002, CIBA knew its lenses were "being resold to unauthorized channels that passed them out like lollipops to teens" and knew of several resulting and significant injuries to minor children (R 766) In September 2002, and throughout the time of the above-summarized ad campaigns and discussions with the FDA about advertising, CIBA knew there was an ever-growing problem with unauthorized sales of its lenses without a prescription and without the warning information that accompanied the packages (R 463-165) CIBA knew that would-be users needed the usage instructions and medical advice to properly use and care for the lenses (R 465) CIBA knew its non-corrective ("plano") lenses were being sold at beauty product trade shows throughout the country, as well as beauty supply stores, nail salons, flea markets, video stores, and gas stations (R 465-466, 468, 474-475) It knew these sales were on the rise (R 468) CIBA knew that consumers often believed a prescription and professional fitting were not necessary for lenses that changed eye color without any vision correction *i e* , for "plano" lenses (R 468) It knew that these unauthorized sellers were "breaking down" the packages and selling individual blister packs with one-pair of lenses but without any warnings or instructions (R 467, 470-471) CIBA knew all of this conduct could cause and had caused serious injuries to consumers (R 469-470) By March 2004, CIBA knew that its color lenses accounted for 98% of all such sales (R 767) Despite all of this knowledge, CIBA failed to take reasonable steps to stop these sales to consumers like Customer (R 22 at ¶¶ 10-11)

Four months after CIBA's defense of its advertising practices to the FDA (March 2004), Customer purchased CIBA s non-corrective ("plano") FreshLook Color lenses from Respondent Kim's Dollar Store without proper usage instructions, without proper labeling, and without proper involvement by a qualified eye care professional (R 39 at ¶¶ 12-16) Two days later, the Customer experienced severe eye pain from an infection caused by the lenses (R 39-40 at ¶¶ 17-21) Her condition worsened despite treatment, and she eventually went blind in her left eye (R 40 at ¶ 21)

In 2005, Congress "overruled" the 2003 Alert and enacted 21 U S C § 360j(n)(1) to provide that all contact lenses were to be regulated as medical devices It must be remembered, however, that this legislation did not make federal preemption automatically applicable Preemption does not arise unless and until the manufacturer receives FDA approval in a PMA letter for the product at issue

ARGUMENTS

The Trial Court's Order The trial court relied on the affidavit of Paul Orris, CIBA's ' head of global regulatory affairs," as establishing the PMA process "undergone by the entire range of FreshLook Colors lenses (R 6, n 1) He further relied on an FDA acknowledgment that lens manufacturers often included non-corrective decorative lenses in PMA applications for a range of corrective powers in which zero power would fall within the range (Id) Based on these two matters, the trial court found the FreshLook Colors plano lens at issue here had been approved by the FDA in a PMA (R 7 at 7)

The court framed the "pivotal issue ' as whether "CIBA s non-corrective (plano) lenses, which were approved by the FDA along with a range of corrective lenses as FreshLook Colors through the PMA process," were medical devices when Customer

purchased them (R 7) The court further defined the issue by holding the Customer could not prevail, even if the lenses were cosmetic devices under the 2003 Alert, if they were nevertheless "to be regulated as medical devices" (R 12-13) [2] According to the court, this turned on whether the non-corrective lenses "have a medical, health or therapeutic use or have a physical or physiological effect" (R 14) [3] Relying on the UV protection and extended wear language in a July 2003 "package insert" for the general line of FreshLook lenses, the court ruled the lenses had such effects and were therefore not merely cosmetic (R 14-17) It is undisputed, however, that there were no "package inserts" for any of CIBA's FreshLook lenses Rather, this information was provided in a separate document that went only to the physicians and pharmacists The trial court also ruled the lenses were medical devices, even under the 2003 Alert, for these same reasons of UV protection and extended wear (R 17)

I THE TRIAL COURT ERRED IN GRANTING SUMMARY JUDGMENT, BECAUSE CIBA FAILED TO CARRY ITS INITIAL BURDEN OF PROOF ON THE ISSUE OF PMA APPROVAL, AND BECAUSE THERE IS A QUESTION OF FACT AS TO WHETHER THE FDA APPROVED THE FRESHLOOK COLORS PLANO LENSES AT ISSUE HERE

It is undisputed that federal preemption arises if, *and only if*, the FDA issued a PMA letter for the specific product before it was sold This document, and only this document, is the only basis for federal preemption Thus, the primary question is whether the FDA issued a PMA letter for FreshLook Colors plano lenses before the purchase by Customer As the party bearing the burden of proof on this issue at trial,

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[2] The court appeared to rely on a 1995 FDA ruling that non corrective lenses promoted as cosmetic only were nevertheless medical devices (R 13) This ruling however pre dated and was superseded by the 2003 Alert

[3] The court also stated Customer had acknowledged the lenses were medical devices by alleging the lenses had to be sold by prescription (R 14) This allegation was no such acknowledgment The lenses at issue here were sold during the 2003 Alert time period when the lenses were cosmetic devices but still had to be sold by prescription

CIBA bore the summary judgment burden of first demonstrating that it was entitled to federal preemption on this basis as a matter of law It failed to do so

The record in this case hints at the existence of a PMA addressed directly to the FreshLook Colors plano lens at issue here CIBA, however, did not submit any such PMA in support of its summary judgment motion Rather, it submitted two PMA's that pre-dated the 2003 Alert and involved FreshLook COLORBLENDS and FreshLook Dimensions rather than FreshLook Colors Neither of these PMA's sought approval of a power range that might have included a zero-power, plano lens The record is thus devoid of the only document that can trigger federal preemption Therefore, CIBA manifestly failed to carry its initial summary judgment burden on the question of federal preemption For this reason alone, the appealed order must be reversed Assuming federal preemption can be based on something other than a product-specific PMA, the trial court nevertheless erred in granting summary judgment, because there is conflicting evidence that precludes summary judgment

Relying on the affidavit of Paul Oris, the trial court accepted the 'hints of PMA's" as sufficient evidence to prove FDA approval in a PMA for FreshLook Colors plano lenses The Oris affidavit is one-page long with five numbered paragraphs (R 102-103) His affidavit summarily asserts that "all contact lenses" sold by CIBA as FreshLook Colors received pre-market approval by the FDA (Id) His affidavit, however, does not identify or quote any PMA, nor is any PMA attached to his affidavit as an exhibit His affidavit is thus nothing more than a hearsay recitation of what, at best, he may have read somewhere (but his affidavit does not even assert that he has seen or read any such PMA's) It is axiomatic that hearsay in an affidavit is not a valid basis for

summary judgment, because it is not admissible evidence In any event, there is also conflicting evidence on this point

Mr Oris gave deposition testimony that directly conflicts with the cursory assertions in his affidavit He admitted that

1 The plano lens at issue here was intended to be introduced into the eye for "beautifying, promoting attractiveness, or altering the appearance" of the eye (R 476)

2 CIBA has never sought PMA approval specifically for non-corrective ("plano") color lenses (R 459)

3 The PMAs' from the FDA regarding FreshLook Colors lenses had an indication "for the correction of visual acuity (R 451, 460-461) [It is undisputed that the lens at issue here was not for the correction of visual acuity]

4 If a lens was "marketed for something other than the indicated use, then the approval [by the FDA in the PMA] is invalidated (R 461)

5 Thus, if the FreshLook Colors line was marketed for something other than the correction of visual acuity, the approval of that lens would be invalidated (R 461-462)

This conflicting testimony from Mr Oris, standing alone, creates a question of fact that precludes summary judgment, particularly when the evidence and inferences are viewed as they must be in the light most favorable to Customer For this reason alone, the appealed order must be reversed [4]

[4] In addition the affidavits of Customer s expert also conflicted with Oris s affidavit thereby creating conflicting evidence that also standing alone precluded summary judgment (R 725 740 741-751)

II THE TRIAL COURT ERRED IN GRANTING SUMMARY JUDGMENT, BECAUSE IT DID NOT HAVE JURISDICTION TO CONSIDER WHETHER A DEVICE IS "TO BE REGULATED AS A MEDICAL DEVICE," AND BECAUSE THERE IS AN ISSUE OF FACT AS TO WHETHER FRESHLOOK COLORS PLANO LENSES WERE A MEDICAL DEVICE AT THE TIME OF THE SALE TO CUSTOMER

The trial court found the lenses purchased by Customer during the time of the 2003 Alert were "to be regulated as medical devices" based upon the UV protection and extended wear information in the "package insert" (which did not exist as an insert) This was error because the trial court did not have subject matter jurisdiction to make this decision, and because there is conflicting evidence and inferences on this matter

First, the question of whether or not something is "to be regulated as a medical device' is a matter with the sole province of the FDA No court has jurisdiction to decide this question Rather, the court's sole function is to determine whether something has in fact been regulated by the FDA as a medical device through the issuance of a PMA that triggers federal preemption As demonstrated in Argument I, above, CIBA failed its summary judgment burden on this issue

Second, if a trial court has jurisdiction to determine whether something is to be regulated as a medical device " there is conflicting evidence that precludes summary judgment The trial court relied solely on the statements made in the so-called "package insert " There is no competent evidence that these statements were submitted to or approved by the FDA with respect to FreshLook Colors plano lenses The only competent evidence would be the PMA for those lenses, and CIBA did not submit that PMA in support of its summary judgment motion Moreover, as demonstrated earlier, CIBA did not make any of these statements in its numerous, multi-million dollar

advertising campaigns Rather, it emphasized only the temporary beauty aspects of its color lenses, including its plano lenses

It is well established that the statements noted above (also known as indications of use) are the primary basis for medical device regulation From its inception in the 1935 Senate Report that gave rise to the medical device statutes, usage determines the categorization of a product as a food, drug, medical device, or cosmetic S Rep No 73-493, at 2-3 (1934) It is equally well-established that the manufacturer s representations in the sale of the product is compelling evidence of the indication of use *Id* , *Brown and Williamson Tobacco Corp v Food & Drug Admin* , 153 F 3d 155, 163 (4th Cir 1998), *aff d on other grounds*, 529 U S 120 (2000) The FDA has long accepted this principle, finding it "well settled that intended use is determined with reference to marketing claims" and that foreseeability by the manufacturer is insufficient because 'there must be 'objective intent' in the form of marketing claims " (R 769-775) Here, CIBA's marketing claims focused on the short-term, cosmetic use of its color lenses and did not claim UV protection or extended wear capability, nor did their marketing claims give any of the required warnings for such claims As shown earlier, CIBA defended this failure to warn *to the FDA* upon the basis of not making any such marketing claims and upon the 2003 Alert designation of plano lenses as cosmetics At the very least, therefore, there is conflicting evidence on the intended use of FreshLook Colors plano lenses for UV protection and extended wear that precludes summary judgment

Third, the record is devoid of a PMA that permits CIBA to market FreshLook Colors plano lenses with any claims of UV protection or extended wear capability This is the only permissible means for any product to be declared a medical device such that

federal preemption arises to preclude state law claims There being no evidence of such, there can be no such declaration by the trial court and, therefore, summary judgment was improper as a matter of law

Fourth, if CIBA believed as it now asserts that all of its plano color lenses were medical devices under past and present PMA's despite the 2003 Alert, then it had no reason to work so diligently on the ultimately successful legislative effort to subject plano lenses to medical device regulation It is undisputed, however, that CIBA undertook this work in May 2003 immediately after the April 2003 Alert, and that one reason was to protect itself from litigation by injured consumers (R 768) If there were no genuine question on this matter, CIBA had no need to do this work CIBA's own legislative efforts and the resulting inferences, therefore, demonstrate the existence of a genuine question of fact that precludes summary judgment

For each of the foregoing reasons, separately and together, the trial court erred in granting summary judgment and, therefore, the appealed order must be reversed

III THE TRIAL COURT ERRED IN GRANTING SUMMARY JUDGMENT, BECAUSE THERE WAS NO FINDING AND NO SHOWING OF ANY SOUTH CAROLINA LAW THAT CONFLICTS WITH FEDERAL LAW ON FRESHLOOK COLORS PLANO LENSES

The preemption statute provides only that a state cannot establish or continue in effect any requirement for a medical device that is "different from, or in addition to, any requirement" imposed by the FDA that relates to the safety or effectiveness of the device 21 U S C § 360k(a) Thus, the preemption statute operates to preclude only those state laws that conflict with existing federal laws and regulations on safety and effectiveness See *McMullen v Medtronic Inc* , 421 F 3d 482, 487 (7th Cir 2005)

The trial court did not find, and CIBA did not demonstrate, any South Carolina law that was "different from, or in addition to" any federal law or regulation For example, the FDA regulation codified at 21 C F R § 808 1(d) specifically states that "[the preemption statute] does not preempt state or local requirements of general applicability where the purpose of the requirement relates to other products in addition to [medical] devices ' The same regulation gives specific examples of requirements that would not be preempted including "general electrical codes, and the Uniform Commercial Codes (warranty of fitness), or unfair trade practices in which the requirements are not limited to devices " *Id* Accordingly, the FDA has stated that unfair trade practices acts are not preempted, and dismissal of Customer's South Carolina Unfair Trade Practices Act claim was improper Likewise, the common law duties, such as the duty to warn, relied upon by Customer are "generally applicable" to all products, not just medical devices Accordingly, the trial court improperly granted summary judgment as to Customer's failure to warn causes action

Moreover, CIBA failed to submit any PMA related to FreshLook Colors plano lenses Thus, it failed to show a conflict between state and federal law, because the PMA is the only possible source of "preempting" or "conflicting" federal law Without knowing the federal law as established by the applicable PMA, it is impossible to determine whether any state law conflicts with it and, absent such conflict, there is no preemption Thus, CIBA failed to demonstrate and the trial court failed to find any conflicting laws as to the plano lenses at issue here

In short, there was no showing of any conflict between state and federal law Thus, even if one assumes that FreshLook Colors plano lenses are subject to a PMA

issued by the FDA, the absence of any showing of any conflict with any state law pled in the amended complaint precludes preemption Accordingly, the appealed order should be reversed

IV THE TRIAL COURT ERRED IN REFUSING TO AMEND OR CLARIFY ITS SUMMARY JUDGMENT ORDER AS TO ITS DISMISSAL OF CERTAIN CLAIMS IN THE AMENDED COMPLAINT AND AS TO ITS "DISCOVERY" RULING

The trial court granted summary judgment ' to the extent [Customer s claims] rely on labeling, warning, packaging, instruction for use, design or similar alleged deficiencies " (R 4) Later in the order, the trial court described the scope of summary judgment

> Judgment is hereby entered against [Customer's] claims that are dependent on warning, labeling design, marketing, misbranding or similar claims Specifically, Count II, Count V and Count VI of the Complaint are hereby dismissed

(R 17) Customer is unclear as to what specific claims in her amended complaint are being dismissed Moreover, some of the specifically dismissed counts also contain and relate to other issues that were not the subject of CIBA's summary judgment motion nor addressed in the order, such as sales and distribution As another example, any FDA preemption on "marketing' would manifestly be limited to any restrictions imposed by a proper PMA (if one exists) but would not reach all potential claims based on CIBA's marketing tactics The trial court refused to clarify its order, and this was manifest error

In addition, the trial court ruled on discovery issues that were not before it The court precluded Customer from pursuing "any additional discovery on the issues of warnings, labels, packaging, use instructions, product design, marketing or illegal sales of contact lenses " (R 17-18) Since these discovery issues were not before the court, it erred in making this ruling Moreover, if any such ruling would otherwise be proper

upon the finding of preemption, it is unclear precisely what discovery is being precluded, just as it is unclear precisely which claims were being dismissed For example, the prohibition of discovery on "illegal sales" and "marketing" arguably goes to the heart of Customer's case and would preclude much discovery that would be relevant to the issues upon which the court did not grant summary judgment The trial court refused to remove its discovery ruling from the order and refused to clarify the scope of that ruling This was manifest error

CONCLUSION

The only permissible basis for federal preemption in this case is a PMA letter from the FDA that approves the distribution of FreshLook Colors plano lenses, provided CIBA complies with the conditions imposed by the PMA CIBA's failure to submit any such PMA precludes summary judgment as a matter of law Assuming preemption can be shown otherwise, there is conflicting evidence that precludes summary judgment

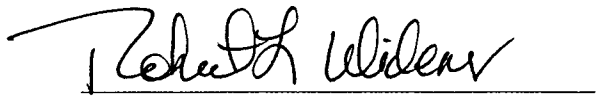
No court has jurisdiction to decide whether something is 'to be regulated as medical devices', that is the sole province of the FDA If the court had jurisdiction to do so, there is conflicting evidence that precludes summary judgment

CIBA failed to show that any South Carolina law conflicted with any federal requirement for FreshLook Colors plano lenses Thus, even if there is a PMA covering these lenses, there can be no federal preemption

The trial court erred in reaching any discovery issues and further erred in failing to clarify its discovery ruling The court also erred in refusing to clarify the scope of summary judgment Thus, if summary judgment is not reversed, this matter must be remanded for clarification (unless clarified by this Court on appeal)

For all of the foregoing reasons, as set forth more fully above, the appealed order should be reversed

Respectfully Submitted,



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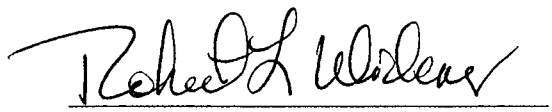
ERRATA NOTICE

The full paragraph beginning on page 3 and ending on page 4 of this brief does not contain citations to the Record because, at the time of drafting the brief, above-signed counsel relied upon exhibits to a summary judgment motion that, unbeknownst to him, had been withdrawn prior to the appealed order The first sentence of the full paragraph on page 6 of this brief has no citation to the Record because, at the time of drafting the brief, above-signed counsel relied upon a letter that, unbeknownst to him, had not been presented to the trial court

CERTIFICATE OF COUNSEL

With the exception of the matters noted in the errata notice on the preceding page of this brief, the undersigned certifies that this Final Brief complies with Rule 211(b) SCACR



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