THE STATE OF SOUTH CAROLINA
In The Supreme Court

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

Opinion No 4592 (S C Ct App Filed July 15, 2009)

Monica Weston, Petitioner,

v

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

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BRIEF OF PETITIONER

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STATEMENT OF CASE

This is a federal preemption case It arises under the preemption provision in the Medical Device Amendments of 1976 (MDA) The plaintiff-petitioner (Customer) sued the defendants for injuries caused by contact lenses manufactured by CIBA Vision (CIBA) and sold by Kim's Dollar Store (Kim's) Contact lenses are a Class III Medical Device under the MDA The trial court granted summary judgment to CIBA based on federal preemption under the MDA Customer appealed The Court of Appeals affirmed the trial court and denied Customer's petition for rehearing This Court granted Customer's certiorari petition

BURDEN OF PROOF and STANDARD OF REVIEW

CIBA bore the burden of proving its affirmative defense of federal preemption *Eldridge v City of Greenwood*, 503 S E 2d 191, 197 (S C App 1999) Thus, in seeking summary judgment, CIBA bore the burden of showing there was no issue of fact as to whether it satisfied the MDA's requirements for federal peremption Rule 56, SCRCP In determining summary judgment, the evidence and inferences must be viewed in the light

most favorable to the non-moving party (Customer here) *Turner v Millıman*, 708 S E 2d 766, 769 (S C 2011) "All ambiguities, conclusions and inferences arising from the evidence must be construed most strongly against [the moving party – CIBA here] " *Tupper v Dorchester County*, 487 S E 2d 187, 191 (S C 1997) (emphasis added)

STATEMENT OF FACTS

Customer purchased colored, non-corrective contact lenses manufactured by CIBA These lenses do not correct visual acuity, *i e* , these lenses were not designed to, do not, and cannot correct any vision problems Their purpose is to cosmetically change the color of the eye, *i e* , non-corrective contact lenses are a Class III Medical Device that have no medical benefit

Contact lenses were developed to replace eyeglasses in correcting visual acuity With the advent of adding color to contact lenses, so as to change the color of the eye, non-corrective lenses became a viable product line despite not correcting visual acuity

CIBA aggressively marketed its colored, non-corrective lenses 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 (R 324-325, 339) This ad campaign was directed primarily at women between the ages of 18-34 (Id at 339-345), 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 (R 391)

Beginning in 2002, CIBA launched a $20 Million Dollar advertising campaign emphasizing FreshLook contact lenses as a cosmetic accessory like make-up (R 391) Beginning in 2003, CIBA also launched television advertising, the 2003 budget was $8 0

Million Dollars (Id at 326) In June 2003, CIBA updated its packaging to feature eye-catching graphics to appeal to consumers (Id at 390-391) [1]

All advertising campaigns were directed at persons with and without vision problems (Id at 330-335, 346-363) Approximately 20% of all FreshLook contact lens sales were non-corrective "plano" lenses that were for beauty enhancement, not vision correction (Id at 334, 337-338)

During these ad campaigns, CIBA 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 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)

A "black market" developed for colored, non-corrective contact lenses 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

[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 CIBA s knowledge that its lenses were in fact being sold by non professionals without a prescription directly to customers in a black market that CIBA intended the spruced up box to help generate sales directly to consumers

injuries to minor children (R 766, see also R 38-39, ¶¶ 10-11) In September 2002, and throughout the time of the above-summarized ad campaigns, CIBA knew there was an ever-growing problem with black market sales of its non-corrective lenses without a prescription and without the warning information that accompanied the packages (R 463-165, see also R 38-39, ¶¶ 10-11) 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, see also R 38-39, ¶¶ 10-11) 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 its non-corrective "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, see also R 38, ¶ 10) CIBA knew all of this conduct could cause and had caused serious injuries to consumers (R 469-470, see also R 38-39, ¶¶ 10-11)

By March 2004, CIBA knew that its non-corrective lenses accounted for 98% of black market sales (R 767) Despite all of this knowledge, CIBA failed to take reasonable steps to stop these sales to consumers like Customer (R 38-39 at ¶¶ 10-11)

In March 2004, Customer purchased CIBA's non-corrective ("plano") FreshLook Color lenses from 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)

FEDERAL PREEMPTION UNDER THE MDA

Federal preemption is an invasion of state sovereignty in derogation of the federalism principles that are the cornerstone of American government Thus, a statute imposing federal preemption is narrowly construed *Medtronic Inc v Lohr*, 116 S Ct 2240, 2250 (U S 1996)

There are three basic types of federal preemption (1) "express preemption," in which Congress defines the scope of preemption, (2) "field preemption," in which Congress so completely occupies a regulatory field that it has impliedly preempted state law, and (3) "conflict preemption," in which state laws are preempted to the extent they conflict with federal law, *i e*, when compliance with both state and federal law is impossible or state law frustrates the federal purpose and hinders fulfillment of federal objectives *State v 192 Coin-Operated Video Game Machines*, 525 S E 2d 872, 877 (S C 2000) The present case involves application of an express conflict preemption statute in the MDA, which provides in pertinent part that state laws concerning medical devices are preempted if (1) they are different from or in addition to the requirements imposed under the MDA, and (2) they relate to the safety or effectiveness of the device or to any other requirement imposed by the MDA 21 U S C § 360k(a)

The MDA preemption is rooted in the Food and Drug Act of 1906, which was Congress's first significant public health legislation and introduced a broad prohibition against the manufacture or sale of adulterated or misbranded foods and drugs *Medtronic Inc v Lohr*, 116 S Ct 2240, 2246 (U S 1996) Congress expanded this prohibition with

the Food, Drug, and Cosmetic Act of 1938 to include misbranded or adulterated medical devices and cosmetics, but medical devices otherwise remained largely unregulated *Id* In the 1960's and 1970's, there was a significant increase in the number and complexity of medical devices, and there were notable injury-producing failures (*e g* , the Dalkon Shield) *Id* , see also *Riegel v Medtronic Inc* , 128 S Ct 999, 1003 (U S 2008) Several states adopted regulations for medical devices in response to growing public concern *Id* Congress entered the fray with the adoption of Medical Device Amendments of 1976 (MDA), largely nullifying the state regulations in favor of detailed federal oversight and enacting the preemption statute at issue here *Id*

The federal oversight scheme was based upon classification of medical devices into one of three classes depending on the risks presented by the device Class I devices are largely benign and subject to the lowest level of regulations Class II devices present some dangers and are subject to somewhat higher standards Class III devices present the highest dangers and are subject to stringent standards *Riegel*, 128 S Ct at 1003 Contact lenses are Class III devices

Congress delegated the power to implement the MDA through regulations to the Secretary of Health and Human Services The Secretary in turn delegated this task to the Food and Drug Administration (FDA) *Lohr*, 116 S Ct at 2249 n 5 The FDA in turn developed a pre-market approval (PMA) process for Class III devices, which yields device-specific regulations and results in device-specific conflict preemption based on those regulations *Riegel*, 128 S Ct at 1004-1005, 107 In short, preemption does not arise directly from the statute enacted by Congress, rather, it arises from a device-specific, administrative review (PMA) conducted by specialists working for the FDA

Pre-market approval by the FDA is a rigorous process that has three basic steps First, the manufacturer submits an application for pre-market approval, which is typically a multi-volume document that details everything about the product, including the use of the product and proposed directions, warnings, and labeling *Riegel*, 128 S Ct at 1004 Second, the FDA reviews the application, possibly sending it to an expert panel for comment or requesting additional information from the applicant *Id* Third, if the FDA approves the application, it sends a "PMA letter" granting approval and noting any conditions imposed on the approval *Id* at 104-105

The issuance of a PMA letter subjects the device to federal regulation and triggers conflict preemption under the MDA Thus, any federal preemption for CIBA's non-corrective contact lenses arose if, and only if, CIBA received a PMA letter for its non-corrective lenses Concomitantly, a PMA letter approving CIBA's non-corrective lenses is the only evidence that is competent to prove federal preemption

ARGUMENT

I CIBA is entitled to preemption if and only if it received a pre-market approval (PMA) letter for its non-corrective lenses

As demonstrated above, CIBA has "preemption immunity" *if and only if*, CIBA applied for and received pre-market approval from the FDA for its non-corrective lenses It is undisputed that this pre-market approval, and the resulting "preemption immunity," is obtained *if and only if*, the FDA issued a pre-market approval letter (PMA) for the non-corrective lenses In other words, there is only one way for CIBA to prove preemption possession and presentation of a PMA letter for non-corrective lenses

It is undisputed that CIBA never sought and never received a PMA letter specifically for its non-corrective lenses as such It is undisputed that every PMA letter

approving contact lenses in a positive-to-negative diopter power range included language limiting the pre-market approval to lenses "indicated for the correction of visual acuity " It is undisputed that the non-corrective, zero power lenses at issue here do not and cannot correct visual acuity [2] It is thus indisputable that CIBA has failed to produce the only evidence that is competent to prove its entitlement to preemption immunity

II Viewing the evidence, inferences, and ambiguities in the light most favorable to Customer, and construing the same most strongly against CIBA, there is a question of fact as to whether CIBA applied for and/or received PMA approval for its non-corrective lenses

There are only two ways that CIBA could have obtained PMA approval for its non-corrective lenses First, it could have sought approval of its non-corrective lenses in a "stand alone" application for its its non-corrective lenses only CIBA's Head of Global Regulatory Affairs admitted, however, that CIBA never sought or obtained this "stand alone" approval of its non-corrective lenses (R 459)

Second, CIBA could have applied for pre-market approval of a diopter range of lenses, including non-corrective (zero power) lenses It appears CIBA asserts that it did so, but it did not submit any PMA application in support of its summary judgment motion that included non-corrective (zero power) lenses Rather, CIBA relies solely on PMA letters that approved lenses in a plus-to-minus diopter range and argues this necessarily included approval of its non-corrective lenses, because a plus-to-minus range includes zero Every "diopter range" letter, however, includes the limitation that the lenses being approved are "indicated for the correction of visual acuity " Non-corrective (zero power) lenses simply do not and cannot correct visual acuity At the very least, this limitation

[2] Diopter is a unit of measurement of the refractive power of lenses Glasses and contact lenses correct visual acuity by refracting and focusing light Non corrective (zero power) lenses do not refract or focus light

gives rise to an inference that the PMA letters relied upon by CIBA did not include approval of its non-corrective lenses Again, CIBA's Head of Global Regulatory Affairs admitted that all of CIBA's "diopter range" PMA letters included the limitation that the lenses being approved were "indicated for the correction of visual acuity " (R 461) The phrase "indicated for" is a term of art in pre-market approval process that limits the approval (and resulting preemption immunity) to the indicated use of the medical device

Preemption under the MDA for Class III medical devices arises only upon the issuance of a device-specific PMA letter that subjects the device to device-specific regulations and thereby gives rise to device-specific preemption Thus, preemption for any particular device can be proven only by a device-specific PMA letter Absent such proof, there simply is no preemption CIBA did not obtain a PMA letter for its non-corrective lenses and, therefore, it is not entitled to federal preemption for those lenses

III The Court of Appeals misapprehended how MDA preemption comes into existence and therefore misapprehended the requisite showing for summary judgment on the issue of preemption

The Court of Appeals misapprehended the touchstone for MDA preemption, to-wit a PMA letter from the FDA approving CIBA's non-corrective lenses as such, or a PMA letter approving a diopter range of lenses that included the non-corrective (zero power) lenses but did not limit the approval to lenses "indicated for the correction of visual acuity " This letter is simply the only way to prove MDA preemption The Court of Appeals, however, relied upon "affidavits, depositions, and documentation, *indicating* [CIBA's non-corrective lenses were] approved by the FDA pursuant to the PMA process " (Appx Tab A at 9) (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 non-corrective lenses as such through a PMA letter[3] This could be done by presentation of a PMA letter that approved the non-corrective lenses as such Absent this PMA letter, there simply cannot be any preemption, because it is the only means for obtaining FDA approval of non-corrective lenses as such, and this approval is the trigger for MDA preemption

Second, testimony from experts or others, by affidavit or deposition, simply cannot prove the touchstone requirement for preemption, *i e* , the requisite PMA letter This letter, not testimony reflecting at best a reading of some letter, is the only way to prove preemption Such testimony, at best, creates a question of fact but cannot demonstrate the absence of a question of fact as to whether CIBA requested and received a PMA letter actually approving non-corrective lenses as such

Third, the "documentation" relied upon by the Court of Appeals 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

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[3] Later in its opinion the Court of Appeals 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 (Appx Tab A at 11) (emphasis added) 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 non corrective 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 non corrective lenses as such It manifestly failed to do so under the undisputed facts in this case

protection (upon which the Court of Appeals relied heavily), the PMA merely and only approved adding UV protection to those lenses that had already been approved in a prior PMA(s) (Appx Tab A at 10) It did not approve non-corrective lenses as such Thus, any approval, if it exists, must be set forth in one of the prior PMAs, not the supplemental UV-PMA It is undisputed that there is no PMA letter that satisfies the touchstone requirement of approving non-corrective lenses as such or approving a diopter range of lenses without the limitation of being "indicated for the correction of visual acuity " The same is true of all other "documentation" relied upon by the Court of Appeals

Fourth, contrary to the Court of Appeal's apparent finding, there is no evidence that CIBA provided its non-corrective 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 (Appx Tab A at 11) Indeed, the record is devoid of any application for approval of non-corrective lenses as such or approval of a diopter range of lenses as such Though unclear, the Court of Appeals may have been 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 apparently included packages for non-corrective lenses (R 670) This is not conclusive evidence of FDA approval for the following reasons

1 The letter does not request approval of non-corrective lenses (R 667)

2 The 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) Again, it is this prior PMA (if it exists) that would trigger MDA preemption

3 Most importantly, the record is devoid of a PMA approving this letter and, even were there such a PMA, it would remain irrelevant to the question of summary judgment on preemption unless it approved non-corrective

> lenses as such or approved a diopter range of lenses 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 non-corrective lenses as such or a PMA letter approving a diopter range of lenses without the limitation of being "indicated for the correction of visual acuity " CIBA did not obtain a PMA letter for its non-corrective lenses and, therefore, it is not entitled to federal preemption for those lenses

IV The Court of Appeals misapprehended Customer's jurisdiction argument and appeared to usurp the exclusive jurisdiction of the FDA

Contrary to the Court of Appeals' opinion, Customer never argued the court does not have jurisdiction "over the subject matter of her suit " (Appx Tab A at 6) 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 A 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 non-corrective lenses as such

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

1 Non-corrective lenses, generally, are medical devices subject *to* regulation by the FDA

2 The FDA views non-corrective lenses as medical devices that are subject to regulation

3 CIBA views its non-corrective lenses as medical devices that are subject to regulation

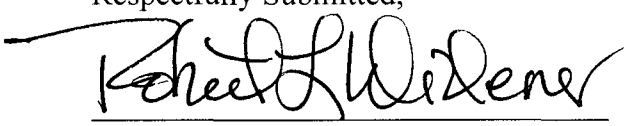
The Court of Appeals concluded "The question whether CIBA's FreshLook Colors contact lenses fit the statutory definition of medical devices, thus triggering the MDA's provision preempting state law, is properly a question of law for the circuit court" (Appx Tab A at 6) (emphasis added)

This simply is not the question Fitting the statutory definition of a medical device does not trigger preemption Actual regulation by the FDA through the issuance of a PMA is the only preemption trigger for a Class III medical device The controlling inquiry is ***not*** whether non-corrective lenses are medical devices, ***nor*** is it whether such lenses are "subject to" regulation Rather, the only inquiry is whether CIBA's non-corrective lenses have, in fact, been subjected to regulation by the FDA It matters not that CIBA's non-corrective lenses would be, could be, or should be subjected to regulation To assert federal preemption, CIBA must prove its non-corrective lenses as such have in fact been subjected to regulation by the FDA This actual regulation by the FDA is the "trigger" for federal preemption, and it can only be proven with a PMA letter specifically approving CIBA's non-corrective 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 obtain a PMA letter for its non-corrective lenses and, therefore, it is not entitled to federal preemption for those lenses

CONCLUSION

The protection of consumers from defective products is primarily the province of state law and state sovereignty Statutes creating federal preemption are an invasion of that state sovereignty and thus are narrowly construed Here, federal preemption arises not from a statute directly, but from an administrative review process that is commenced by an application from a manufacturer, *i e* , the manufacturer essentially asks the FDA to grant preemption that will insulate the manufacturer from state laws If an invasion of state sovereignty is to arise from decisions made in an administrative review process conducted by a federal agency at the request of a manufacturer, the manufacturer manifestly must show strict compliance with the regulatory process that triggers preemption Here, such compliance requires CIBA to possess and produce a PMA letter that approves its non-corrective lenses as such or approves a dioper range of its lenses that both includes its non-corrective (zero power) lenses and does not limit that approval to lenses "indicated for the correction of visual acuity " CIBA did not obtain a PMA letter for its non-corrective lenses and, therefore, it is not entitled to federal preemption for those lenses

Respectfully Submitted,



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CERTIFICATE OF SERVICE

I, Ann Shuler, an employee of the McNair Law Firm, certify that I have served a copy of the Brief of Petitioner by depositing a copy in the United States Mail, postage prepaid, on July 5, 2011 addressed to the attorneys of record, as follows

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