165741

THE STATE OF SOUTH CAROLINA
In the Court of Appeals

APPEAL FROM RICHLAND COUNTY
In The Court of Common Pleas

C Thomas Cooper, Jr , Circuit Court Judge

SEALED

Case No 05-CP-40-0655

Monica Weston, Appellant,

v

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

AMENDED RECORD ON APPEAL
VOLUME I

KEITH D MUNSON
SANDI R WILSON
WOMBLE CARYLE SANDRIDGE & RICE
POST OFFICE BOX 10208
GREENVILLE, S C 29603
(864) 255-5400

CURTIS L OTT
TURNER, PADGET, GRAHAM & LANEY
POST OFFICE BOX 1473
COLUMBIA, S C 29202
(803) 254-2200

DANIEL T SULLIVAN
YOUNG and SULLIVAN
907 CALHOUN STREET
COLUMBIA, S C 29201
(803) 252-3663

ATTORNEYS FOR RESPONDENT

ROBERT L WIDENER
CELESTE T JONES
A VICTOR RAWL JR
ANDREW G MELLING
McNAIR LAW FIRM
POST OFFICE BOX 11390
COLUMBIA, S C 29211
(803) 799-9800

STEVENS B ELLIOTT
POST OFFICE BOX 6922
COLUMBIA, S C 29260
(803) 254-7980

ATTORNEYS FOR APPELLANT

INDEX

VOLUME I

Order Granting Partial Summary Judgment	1
Order Denying Plaintiff's 59(e) Motion	19
Complaint	21
Amended Complaint	37
CIBA Vision's Answer to Amended Complaint	53
CIBA Vision s Motion for Summary Judgment, with Exhibits A through E	69
CIBA Vision s Supplemental Memorandum of Law in Support of CIBA Vision's Motion for Summary Judgment, with Exhibits A through E	128
CIBA Vision's Second Supplemental Memorandum of Law in Support of CIBA Vision's Motion for Summary Judgment, with Exhibits 1 through 3	170
Plaintiff's 59(e) Motion	211
CIBA Vision's Opposition in Response to Plaintiff's Rule 59(e) Motion	250
Transcript of 8/28/06 hearing	261
Deposition Transcript 30(b)(6) of Kim's Dollar Store (Seo Ha)	
Direct by Ms Wilson, pp 37-38, 77-80	315
Exhibit 1	322
Deposition Transcript, Julie Collins, Direct by Mr Rawl, pp 20-22, 24-26, 28-29, 34-35, 37-41, 55-60, 88, 93-110, 131-158	323
Exhibit 16	392
Exhibit 19	394
Exhibit 20	395
Exhibit 21	396
Exhibit 22	397
Exhibit 23	398
Exhibit 26	399
Exhibit 28	400
Exhibit 29	401
Exhibit 30	404
Exhibit 31	407
Exhibit 32	410
Exhibit 33	412
Exhibit 34	415
Exhibit 35	418
Exhibit 36	421
Exhibit 37	424
Exhibit 38	426
Exhibit 39	428
Exhibit 40	446
Exhibit 41	448

VOLUME II

Deposition Transcript, Paul Oris,
Direct by Mr Rawl, pp 7-10, 21, 35-36, 38-42, 48-51,
54, 57-60, 65-66, 80-81, 84, 86, 89, 90, 98-99, 123, 152 450
Exhibit 2 484
Exhibit 4 588
Exhibit 6 589
Exhibit 10 591
Exhibit 11 627
Deposition Transcript, Suzanne Parisian, M D ,
Direct by Mr Munson, pp 28, 52-61,
87-89, 94, 112, 133-140, 144 629
Exhibit 4 655
Exhibit 5 656
Exhibit 6 667
Exhibit 7 671
Exhibit 8 674
Exhibit 9 679
Exhibit 12 681
Deposition Transcript, Philip James Phillips,
Direct by Mr Rawl, pp 7-10, 19-21, 28, 34, 147-148 685
Re-Direct by Mr Rawl, p 151 697
Exhibit 4 698
Exhibit 9 699
Affidavit of Paul Oris 701
Affidavit of Phil Phillips 705
Exhibit A 709
Exhibit B 724
Affidavit of Suzanne Parisian, filed 8/24/06 725
Affidavit of Suzanne Parisian, filed 2/27/06 741
Alert #86-10 752
FDA Guidance document 761
CIBA Supp 1122 766
CIBA PMA Supp 0036 767
CIBA PMA Supp 0079 768
10/17/02 Letter by FDA Chief Counsel Troy to Gibbs 769
Certificate of Counsel 776

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	
COUNTY OF RICHLAND	)	Civil Action No 05-CP-40-0655
	)	
Monica Weston,	)	
	)	
Plaintiff,	)	
	)	**ORDER GRANTING DEFENDANT CIBA VISION'S MOTION FOR SUMMARY JUDGMENT BASED ON FEDERAL PREEMPTION**
vs	)	
	)	
Kims Dollar Store and CIBA Vision, a division of Novartis Company,	)	
	)	
Defendants	)	
	)	

For the reasons set forth herein, the Court hereby grants CIBA Vision's Motion for Summary Judgment as follows

I INTRODUCTION

In this civil action, Plaintiff suffered temporary loss of vision in one eye allegedly as a result of wearing non-corrective contact lenses manufactured by CIBA Vision ("CIBA") and purchased by Plaintiff at Kims Dollar Store ("Kims"), in or about March 2004 Kims is not affiliated with CIBA in any way In addition, Kims was not licensed to sell contact lenses

The predominant theory underlying Plaintiff's claims against CIBA is that CIBA's labeling, packaging, warnings and marketing were inadequate to protect Plaintiff CIBA seeks summary judgment because such claims are preempted by the Medical Devices Amendments of 1976 to the Food, Drug and Cosmetics Act and the regulatory scheme of the Food and Drug Administration (21 U S C §360k and 21 CFR 808 1) The Court is in the unique position of being asked to render or deny Summary Judgment to CIBA as the fact finder with reference to the applicability or non-applicability of the aforesaid Act Plaintiff argues that the lenses at issue

fall within a short-lived narrow exception to medical device status for solely decorative lenses, which was first announced by the Food & Drug Administration (FDA) in 2003 and subsequently eliminated by Congress in 2005

Plaintiff alleges the following bases for liability against CIBA and Kims (1) negligence per se based on violation of S C Code Ann § 39-25-20 et seq 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, pursuant to S C Code § 15-73-10, (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 This summary judgment order does not address whether Plaintiff might have viable theories for manufacturing defects

II STATEMENT OF FACTS[1]

CIBA sells non-corrective contact lenses under the trade name FreshLook Colors[2] (Am Compl ¶ 3) FreshLook Colors contact lenses can be worn to change the eye's color or appearance (Am Compl ¶ 7) On or about March 12, 2004, Plaintiff purchased two pairs of FreshLook lenses from Kims (Am Compl ¶ 12) Kims was not an authorized distributor of the contact lenses and did not ask Plaintiff for a prescription or provide Plaintiff with any

[1]To avoid any dispute, these are the facts as alleged in the Amended Complaint

[2] Referred to in the Complaint as "FreshLook Lenses" FreshLook Color Lenses come in a range of power to correct nearsightedness, farsightedness, and astigmatisms At the "Zero Power" point on the range, they are non-corrective or "plano" lenses Therefore, many models of contact lenses have corrective and non-corrective versions, depending on the power level

instructions regarding the use or care of the lenses (Am Compl ¶¶ 13, 14, Def Kims' Dep[3] at 58) At some point after wearing a pair of FreshLook Lenses she bought at Kims, Plaintiff was diagnosed with an eye infection, and ultimately suffered loss of vision in her left eye (Am Compl ¶ 21) Plaintiff alleges that the labeling on the FreshLook Lenses "was misleading and lacked adequate information about the safe and effective uses of the FreshLook Lenses" and failed to provide adequate warnings of possible complications to the eye from wearing FreshLook Lenses (Am Compl ¶¶ 28-29)

III SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate "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" Rule 56(c), SCRCP, Baushman v Am Telephone & Telegraph Co, 306 S C 101, 410 S E 2d 537, 545 (1991) In determining the appropriateness of granting summary judgment, the Court is not "'required to single out some one morsel of evidence to create an issue of fact that is not genuine'" Englert, Inc v Netherlands Ins Co, 315 S C 300, 302, 433 S E 2d 871, 873 (Ct App 1993) (quoting Main v Corley, 281 S C 525, 527, 316 S E 2d 406, 407 (1984)) Where a defendant establishes an entitlement to judgment as a matter of law, the court must grant summary judgment Humana Hospital-Bayside v Lightle, 305 S C 214, 216, 407 S E 2d 637, 638 (1991), Dyer v Moss, 284 S C 208, 211 325 S E 2d 69, 70 (Ct App 1985)

---

[3] Seo Ha was the Rule 30(b)(6) deponent for Defendant Kims Dollar Store References to his deposition will be cited hereinafter as "Def Kims' Dep"

IV CONCLUSIONS OF LAW

As set forth more fully herein, each of Plaintiff's causes of action are subject to summary judgment to the extent they rely on labeling, warning, packaging instruction for use, design or similar alleged deficiencies Plaintiff's claims and legal theories are preempted under federal law pursuant to the Federal Food, Drug, and Cosmetic Act, the Medical Device Amendments of 1976, and/or the regulatory scheme of the FDA

A The FDA Review Process for Medical Devices

As part of the Medical Devices Amendments of 1976 ("MDA"), Pub L No 94-295, to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U S C § 321 et seq., as amended by the Safe Medical Devices Act of 1990, Pub L No 101-629, the FDA classifies medical devices into three categories See FDCA § 513(a)(1), 21 U S C § 360c(a)(1) Class I devices tend to be simple and common articles, such as bedpans and wheelchairs Class II devices are more complex but usually similar to existing devices Both classes of devices may be marketed with only general controls

In contrast, Class III devices may only be marketed pursuant to FDA's premarket approval ("PMA") process (subject to certain limited exceptions not relevant here) See FDCA § 515, 21 U S C § 360e The PMA process is rigorous Manufacturers submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews and approves As the Seventh Circuit explained in a case finding federal preemption of product liability claims based on products approved by the FDA through the rigorous PMA process

> Before a Class III device may be introduced to the market, the manufacturer must provide the [FDA] with a reasonable assurance that the device is safe and effective under the MDA To provide that assurance, a manufacturer must obtain premarket approval ("PMA") from the FDA This procedure is a "rigorous" process, in which the manufacturer must submit detailed information to the

> FDA regarding the safety and effectiveness of the device Manufacturers must provide the FDA with samples of the device, an outline of the device's components and properties, a description of the manufacturing process, copies of the proposed labels, various other data and information, and any other information the FDA requests The FDA spends an average of 1,200 hours per PMA application reviewing these materials

Mitchell v Collagen Corp , 126 F 3d 902, 905 (7th Cir 1997), cert denied, 523 U S 1020 (1998)

Once approved, the manufacturer is required to comply with the design, manufacturing processes, and labels specified in the PMA See 21 C F R §§ 814 39, 814 80 Changes affecting the safety and effectiveness of the device require detailed documentation, reporting and FDA approval See 21 C F R § 814 39 Further, once a PMA medical device is on the market, it remains subject to extensive and continuing regulation by the FDA See Brooks v Howmedica, Inc , 273 F 3d 785, 789, 799 (8th Cir 2001) (en banc), cert denied, 535 U S 1056 (2002), McMullen v Medtronic, Inc , 2005 WL 2043827, at *4 (7th Cir 2005) (discussing post-approval requirements), see also 21 C F R §§ 814 80-814 84 Moreover, the FDA has a wide range of available remedies, including revoking device approval, if the manufacturer fails to comply with requirements imposed by the PMA process [4]

FDA regulations also permit manufacturers to seek approval for device modifications by submitting supplements to a prior PMA *"All procedures and actions that apply to [a PMA] application also apply to PMA supplements"* 21 C F R § 814 39 (emphasis added) The

---

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

PMA supplement 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 At the same time, the entirety of the PMA, including all supplements, are "'before' the agency at the time the supplement is reviewed" 51 Fed Reg 26342, 26354 (1986) "FDA considers revisions proposed in a PMA supplement using the same type of rigorous scientific process utilized for review of original PMAs" See FDA Letter Brief filed as *amicus curiae*, Horn v Thoratec, 376 F 3d 163 (3d Cir 2004), available at 2004 WL 1143720, at *10 (May 14, 2004) ("hereafter Horn amicus brief")

B PMA Approval Establishes Device-Specific Requirements

"[F]ederal requirements specific to individual products are imposed through the PMA process" McMullen, 2005 WL 2043827 at *4 As a Class III medical device approved by the PMA supplement process, FreshLook Colors contact lenses were subject to stringent requirements and FDA scrutiny under the MDA See 21 U S C § 360c(a)(1)(C) [5] Before a Class III medical device can be sold commercially in the United States, the manufacturer must provide the FDA with reasonable assurance that the device is both safe and effective under the FDA's rigorous PMA process See 21 U S C § 360e(d)(2) As explained above, PMA submissions are voluminous, and the FDA employs experts to evaluate safety and efficacy because of the complexity and risk that Class III devices entail See Buckman Co v Plaintiffs' Legal Comm , 531 U S 341 (2001), Horn amicus brief at *6-9 PMA review of Class III devices

[5] The PMA process undergone by the entire range of Freshlook Colors lenses is outlined in the Affidavit of Paul Oris dated December 22, 2005, and is generally not contradicted by Plaintiff FDA acknowledges that contact lens manufacturers include non-corrective decorative lenses in approval applications for a range of corrective powers in which zero power would fall within the range See Import Alert #86-10, 68 F R No 65, p 16520, 1621 n 1 (April 4, 2003)

involves the submission of a detailed application, including clinical data, manufacturing processes and proposed labeling 21 U S C § 360e(c)

As the Eighth Circuit has explained

> Through its approval of the PMA application and its continuing series of directives, the [FDA] impose[s] specific federal requirements on [the manufacturer]

Brooks, 273 F 3d at 798 Similarly, the Seventh Circuit has observed that

> During the PMA process, the federal government, it can truly be said, has ' weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers "

Mitchell v Collagen Corp , 126 F 3d at 902, 911 (7th Cir 1997), cert denied, 523 U S 1020 (1998) (citations omitted), see also McMullen, 2005 WL 2043827 at *4 [6]

C The MDA Preempts State Law Claims

The question of federal preemption under the MDA is a question of law for the court to decide See, e g , Cox v Shalala, 112 F 3d 151 (4th Cir 1997) This includes the pivotal issue in this case of 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 Class III medical devices in March 2004 when Plaintiff allegedly purchased non-corrective lenses from Kims See Weinberger v Bentx Pharmaceuticals, Inc , 412 U S 645, 653 (1973) (whether a product is a device is a matter within the jurisdiction of the FDA) At the hearing, Plaintiff would not consent to seeking guidance from the FDA as authorized under 21 C F R 808 5 and

[6] Courts in the Third, Fifth, and Sixth Circuits agree See, e g , Horn v Thoratec Corp , 376 F 3d 163 (3d Cir 2004), Martin v Medtronic, Inc , 254 F 3d 573, 583-84 (5th Cir 2001), cert denied, 534 U S 1078 (2002), Kemp v Medtronic, Inc , 231 F 3d 216 (6th Cir 2000), cert denied, 534 U S 818 (2001)

instead argued that the contract lenses fall within a purely cosmetic exception that existed between 2003 and 2005

Pursuant to the MDA, 21 U S C § 360c, et seq., the FDA regulates the marketing and sale of prescription medical devices in the United States Congress enacted the MDA in 1976 to expand the authority of the FDA to regulate medical devices The MDA *expressly* preempts certain state law requirements governing medical devices as follows

> [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 [Act] 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 [Act]

21 U S C § 360k(a) In its implementing regulation, the FDA has included "court decisions' within the scope of federal preemption (21 C F R 808 1(b)) [7]

By enacting the MDA, Congress established a scheme for the comprehensive regulation of medical devices As the FDA has noted

> Congress enacted the MDA and vested in FDA the authority to implement its provisions, including making a determination whether Class III devices meet the PMA approval standard of a "reasonable assurance of safety and effectiveness" It is within FDA's discretion to determine the quantity and quality of data necessary to meet this standard and it is a scientific task for which FDA is uniquely qualified

(See Statement of Interest of the United States of America at 9, Murphree v Pacesetter, Inc, Civil No CT-005429-00-3 (Tenn Cir Ct Dec 12, 2003) (citations omitted) (hereafter

[7] At oral argument, Plaintiff's counsel suggested that federal FDA standards could be viewed as merely minimal standards However, that argument has been previously rejected in South Carolina Stewart v International Playtex, Inc, 672 F Supp 907, 910 (D S C 1987) (federal standard is the "only standard" not a minimum standard) Moreover, considering the federal mandatory standard as a minimum standard would be contrary to the statute, the implementing regulations and the relevant case law

"Murphree Statement of Interest"))[8] One of the explicit goals of the MDA is "national uniformity in product regulation" Brooks 273 F 3d at 797 In this regard, the FDA has warned that the "prospect of hundreds of individual juries determining the propriety of particular device approvals, or the appropriate standards to apply to those approvals, is the antithesis of the orderly scheme Congress put in place and charged FDA with implementing" (Murphree, Statement of Interest at 8) FDA's position is in complete accord with South Carolina law which holds that a jury verdict can be subject to federal preemption Whaley v CSX Transportation, Inc., 362 S C 456, 481, 609 S E 2d 286, 299 (2005) ("To uphold the jury's verdict would conflict with the uniformity and consistency that the [Locomotive Inspection Act] is designed to provide Therefore, we hold that [plaintiff's] claim under the [Act] is preempted"), Stewart v International Playtex, Inc., 672 F Supp 907, 909 (D S C 1987) ("[c]ommon law tort claim

---

[8] According to the FDA

> State common law tort actions threaten the statutory framework for the regulation of medical devices, particularly with regard to FDA's review and approval of product labeling State actions are not characterized by centralized expert evaluation of device regulatory issues Instead, they encourage, and in fact require, lay judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population – the central role of FDA – sometimes on behalf of a single individual or group of individuals That individualized redetermination of the benefits and risks of a product can result in relief – including the threat of significant damage awards or penalties – that creates pressure on manufacturers to add warnings that FDA has neither approved, nor found to be scientifically required, or withdrawal of FDA-approved products from the market in conflict with the agency's expert determination that such products are safe and effective This situation can harm the public health by retarding research and development and by encouraging "defensive labeling" by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments

See FDA Letter Brief filed as *amicus curiae*, Horn v Thoratec, 376 F 3d 163 (3d Cir 2004), available at 2004 WL 1143720, at *25-26 (May 14, 2004) The United States Supreme Court deems FDA's views on preemption as substantial in informing a court's consideration of the MDA's preemption provision See Lohr, 518 U S at 495-96

alleging inadequate warning seeks, by definition, to establish a tort labeling requirement different from or in addition to the existing applicable FDA requirement") [9]

D CIBA's Non-corrective FreshLook Colors Contact Lenses were Subject to Federal Preemption in 2004

Before being brought to market, the FreshLook lenses at issue in this action and their predecessor products underwent the arduous PMA process, the highest level of review by the FDA, under the Medical Device Amendments of 1976 ("MDA"), Pub L No 94-295, to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U S C § 321 et seq See FDCA § 515, 21 U S C § 360e As part of its PMA applications, CIBA submitted extensive materials regarding the design, manufacture, and labeling of the device The FDA concluded the devices were safe and effective for their intended uses and approved the design, manufacturing process and labeling of the FreshLook lens as described in CIBA's applications, pursuant to the PMA supplement procedure After reviewing CIBA's application, the FDA approved the FreshLook lens for commercial release Plaintiff does not dispute that CIBA's FreshLook lens were manufactured and labeled in conformance with the PMA process

---

[9] Preemption of civil tort actions is also in accord with other jurisdictions wherein, "virtually every court which has addressed this issue has concluded that preemption under the MDA extends it to state court tort claims " Scott v CIBA Vision Corp , 38 Cal App 4th 307, 316 (Cal Ct App 1995) (citing six federal appellate court decisions and one Supreme Court decision) Logically, an intention to preempt state laws different from, or in addition to, any requirement relating to the safety or effectiveness of a medical device under the MDA must include tort claims triable by a jury, since "jury-set standards in reality constitute new requirements which defendants must heed " Hunsaker v Surgidev Corp , 818 F Supp 744, 751 (D Pa 1992) A damages award is a form of regulation no less effective than a statute San Diego Bldg Trades Council v Garmon, 359 U S 236, 245 (1959) See, e g , Brooks, 273 F 3d at 796 ("A jury finding on negligent failure to warn would be premised on the fact that the label for [the device] was not written in a particular way or did not contain certain information This would be equivalent to a state regulation imposing specific label requirements ")

As noted above, it is clear that state common-law actions constitute state requirements for purposes of preemption under the MDA See, e g , Brooks, 273 F 3d at 796 ("A jury finding on negligent failure to warn would be premised on the fact that the label for [the device] was not written in a particular way or did not contain certain information This would be equivalent to a state regulation imposing specific label requirements")

Thus, the question is not whether state tort law causes of action were developed specifically with respect to FreshLook lenses, but whether a judgment on the causes of action pleaded by Plaintiff would impose a state requirement that is in addition to or different from those imposed by the PMA federal requirements As the Eighth Circuit makes plain in Brooks, a judgment on Plaintiff's causes of action would do just that "The state requirement in this case would come from a common law duty as applied by an individual jury " Id at 797 The South Carolina Supreme Court agreed with regard to federal preemption under a similar statutory provision in the Locomotive Inspection Act, noting that a jury verdict would impose additional requirements to which a manufacturer would be forced to comply Whaley, 362 S C at 481 Therefore, Plaintiff's state law claims herein are preempted because they would, if accepted by the jury, impose state requirements which are different from or in addition to the federal requirements applicable to the device

For example, in Martin v Medtronic, Inc , 254 F 3d 573 (5th Cir 2001), which involved a Class III PMA pacemaker, plaintiffs' product liability claims included, as they do here, negligence, strict liability, and breach of warranty The complaint also alleged gross negligence and breach of Texas Deceptive Trade Practices Act See id In affirming the district court's dismissal, the Fifth Circuit explained that the product liability claims were preempted because they sought to impose requirements different from or addition to those imposed by the FDA

when it approved the "the design of lead, the labeling on the lead, and the manner of manufacturing of the lead Martin, 254 F 3d at 584-85, accord Brooks, 273 F 3d at 796 (warning claims), Mitchell 126 F 3d at 913, Horn, 376 F 3d at 176-77, Kemp, 231 F 3d at 236-37, McMullen, 2005 WL 2043827, at *5 This is so because CIBA's PMA applications to the FDA included detailed information specifying the exact design, manufacturing methods and controls for the related contact lenses Thus, "once the FDA approves a specific design, that design becomes in effect the FDA requirement" Easterling v Cardiac Pacemakers, Inc, 986 F Supp 366, 374 (E D La 1997)

E Products Meeting the Definition of "Cosmetics" can also be "Devices" under the Food, Drug and Cosmetic Act and Amendments

On April 4, 2003 the FDA published Import Alert #86-10, which carved out an exception to medical device regulation for non-corrective decorative lenses intended solely to change the color of the eye and without any claims of health uses or physical/physiological change See 68 F R No 65, p 16520 (April 4, 2003) Lenses falling within this narrow definition were deemed mere "cosmetics" as opposed to "devices" and outside the PMA requirements discussed above, which form the basis for the preemption in this case [10]

It is undisputed that the non-corrective lenses in this case meet the definition of "cosmetic" under 21 U S C § 321(i)(1) as products introduced into the body (the eye) for beautifying or altering appearance Nevertheless, the FDA, in Import Alert #86-10, stated that non-corrective decorative contact lenses that have a "medical or therapeutic use" are "properly regulated as medical devices" Id at 16521 As noted above, whether or not a product meets the

[10] 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 the medical device statutes and regulations 21 U S C § 360j(n)(1)

definition of a cosmetic under the Act is not the end of the inquiry, the more significant question is whether it should be regulated as a medical device Consequently, Plaintiff cannot prevail by showing the lenses meet the definition of a cosmetic if, in addition, they are to be regulated as medical devices In defining a "cosmetic product," 21 C F R § 700 3 expressly states that a cosmetic can also be a medical device ("any cosmetic product which is also a drug or device ') (emphasis added)

Plaintiff's own expert, Suzanne Parisian, agrees In discussing whether these lenses are now medical devices, Suzanne Parisian stated

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

(Dep of Suzanne Parisian, pp 60-61) (emphasis added) This is in complete accord with CIBA's expert, Phillip J Phillips,[11] who confirmed that it "is possible for a device to be both a *cosmetic* and a *device*, and in such case, FDA's medical device regulations would apply " (Affidavit of Phillip J Phillips, ¶ 4) Finally, the FDA removed all doubt on this issue as it pertains to the exact product at issue in this case when it published a notice in the Federal Register noting that "FDA regulates as *devices* non-corrective tinted contact lenses that are expressly promoted only for their *cosmetic* effect of enhancing eye color " (60 F R 41453, p 16, August 11, 1995) [12]

---

[11] Mr Phillips was Deputy Director, Science and Regulatory Policy, Office of Device Evaluation of the FDA during the relevant period

[12] Other examples of cosmetic products which are regulated as medical devices or drugs include lotion with sunscreen, toothpaste with floride, and novelty condoms 60 F R 41453, pp 48-49 (August 11, 1995)

F CIBA's Non-Corrective Cosmetic Freshlook Colors Contact Lenses were also Medical Devices and Subject to the Medical Device Regulations

If CIBA's cosmetic non-corrective FreshLook Colors contact lenses have a medical, health or therapeutic use or have a physical or physiological effect, then the lenses will also be medical devices and will be regulated as medical devices, despite being cosmetic products See 21 CFR 700 3 (such products are "also subject to the requirements of Chapter V of the Act" which includes the Medical Device Amendments of 1976) In fact, Plaintiff acknowledges the medical device status of these contact lenses in her Amended Complaint, wherein she avers that "Federal and South Carolina law require that these lenses be sold by or on the order of a eye care professional" (Am Compl ¶ 9)

FDA generally requires that products such as contact lenses have associated package inserts The July 2003 FreshLook lenses package insert was applicable to the Freshlook Colors non-corrective contact lenses at issue in this case (Oris Dep , p 86, lines 19-25 & Ex 6) The July 2003 package insert was in accord with FDA requirements and obtained FDA approval (Oris Dep , p 89, line 19 – p 90, line 2) The FDA-approved package insert for FreshLook Color contact lenses included the following "Indications (Uses)"

- " to enhance or alter the apparent color of the eye " (decorative use),[13]
- " with UV-absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye " (medical/therapeutic use),[14]

[13] Plaintiff's expert acknowledged that this language created a decorative purpose for these lenses in addition to correcting visual acuity (Parisian Dep , p 134, lines 7- p 135, line 2) (Q And the enhance or alter the apparent color of the eye, that's a decorative purpose? A Correct ")

[14] UV protection has also been described as having a physiological effect In FDA's analysis in its public notice at 60 F R 41453, Page 49 (August 11, 1995), the FDA noted that sunscreen impacted the structure of the body by altering the normal physiological response to solar radiation

- " Daily or Extended Wear " (emphasis added) (effecting physiological change),[15]

The package insert goes on to state that

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

A product's intended use is a significant consideration in determining whether it is a device under the Act This is an "objective" test and includes consideration of "labeling claims" and "written statements" about the product 21 C F R §801 4, see also In re Orthopedic Bone Screw Products Liability Litigation, 1999 WL 33740509, *10 (E D Pa 1999) (stating that the term *intended use* is "broadly defined and encompasses the manner in which a company characterizes its product in the marketplace ") This broad analysis would include how the product "affects the structure and function of the body, regardless of how the product is labeled or advertised " 60 F R 41453, Page 15 (August 11, 1995) (FDA Public Notice) [16]

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

---

[15] Although it is a cumulative point and not necessary for entry of summary judgment, the FreshLook contact lens obtained by the Plaintiff was also approved for "extended wear " As noted in the July 2003 package insert, certain physiological changes are also associated with extended wear These include a weakening of the corneas resistance to infection, a higher incident and degree of ephithelial microcysts and infiltrates and endothelial polymegathism

[16] In this Notice, the FDA points out that if an active ingredient is present in therapeutic concentrations, it will be a drug even if the manufacture does not claim the effect based on an implied intended use

the human eye " (Parisian Dep , pp 137-140) This is sufficient to establish that lenses are "devices" under the Act as intended for use in the "prevention of disease " (21 C F R 321(h)(2))

FreshLook Colors non-corrective contact lenses also meet the definition of "device" by affecting "the structure or any function of the body " (21 C F R 321 (h)(3)) As noted in the July 2003 package insert and PMA documents, these lenses are approved for "extended wear" for up to seven (7) days Plaintiff's expert, Suzanne Parisian, acknowledged that the anatomic and medical statements associated with "extended wear" claims would make these lenses medical devices [17] The package insert makes claims about oxygen permeability, oxygen transmissibility, and certain physiological changes associated with extended wear, including a weakening of the corneas' resistance to infection, a higher incident and degree of ephithelial microcysts and infiltrates and endothelial polymegathism Accordingly, based both on the medical uses and physiological effects of FreshLook Colors non-corrective contact lenses, they are properly

---

[17] In her deposition, Suzanne Parisian stated

Q In your opinion, in 1995 did the FDA consider zero-powered plano color lenses capable of extended wear to be Class III medical devices?

A The minute you throw in extended wear, you've changed it to something different This is just a purely cosmetic device that its only purpose is to change the color of the eye We're not talking extended wear

Q [I]f it's authorized for extended wear, does that make it a medical device?

A And you're making claims that -- in terms of oxygen, you know, that you're -- once you start making medical claims about that you can wear it safely, you're not going to have oxygen depravation, then you start going into medical device because you're actually making claims about what it can do in terms of your anatomy and your eye and so forth So you've walked over The minute you start getting into extended wear and all these other things, you're starting to walk into making medical claims

Q Okay So let me ask you this If the FDA approved a plano color contact lens intended to enhance the color of the eye for extended wear, would FDA consider that to be a medical device?

A They could, depending on the claims

(Parisian Dep , pp 52-61)

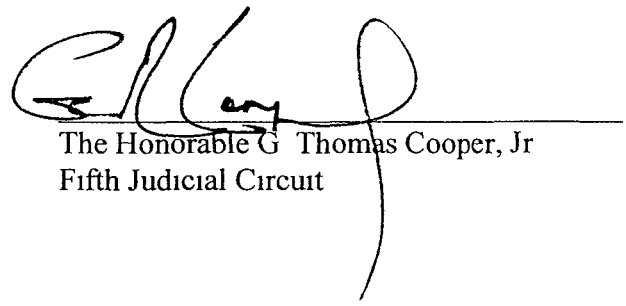
categorized as a matter of law as medical devices at the time they were obtained by Plaintiff in 2004

Even under Import Alert #86-10, which Plaintiff relies on to suggest mere cosmetic status, these FreshLook Colors lenses are medical devices For example, in discussing what uses or effects might elevate a cosmetic product to a drug or medical device, the FDA expressly noted in Import #86-10 that sunscreen claims make a cosmetic product a drug Moreover, Import Alert #86-10 expressly states that decorative contact lenses with additional medical uses (such as UV protection) are not subject to the Import Alert and are "properly regulated as medical devices" Consequently, there is no factual dispute that CIBA Vision FreshLook Color lenses of the type allegedly obtained by Plaintiff provided UV absorbing protection, thereby taking them out of the category of solely decorative lenses In addition, they were authorized for extended wear, which causes physiological changes to the eye and again mandates medical device status Consequently, as a matter of law, the contact lens involved in this case must be considered a "medical device" (regardless of whether it is also a cosmetic)

WHEREFORE for all the foregoing reasons, CIBA is entitled to summary judgment on the basis of federal preemption Judgment is hereby entered against Plaintiff'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 To the extent Plaintiff's other claims are no longer viable (for example, Plaintiff raises a strict liability claim for manufacturing defect but may not be able to proceed on that theory without an expert or the actual product), CIBA is entitled to bring additional motions to test these causes of action Finally, Plaintiff is restricted from pursuing, without further court order, any additional discovery

on the issues of warnings, labeling, packaging, use instructions, product design, marketing or illegal sales of contact lenses

AND IT IS SO ORDERED



The Honorable G Thomas Cooper, Jr
Fifth Judicial Circuit

November 28, 2006
Columbia, South Carolina

RECEIVED
NOV 30 2006
McNair Law Firm PA

STATE OF SOUTH CAROLINA

COUNTY OF RICHLAND

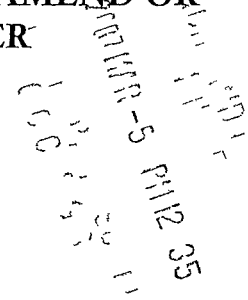
THE COURT OF COMMON PLEAS
FIFTH JUDICIAL CIRCUIT
2005-CP-40-0655

MONICA WATSON
Plaintiff,

v

KIM'S DOLLAR STORE and CIBA VISION, a Division of NOVARTIS COMPANY,
Defendant,

ORDER DENYING MOTION TO ALTER/AMEND OR RECONSIDER



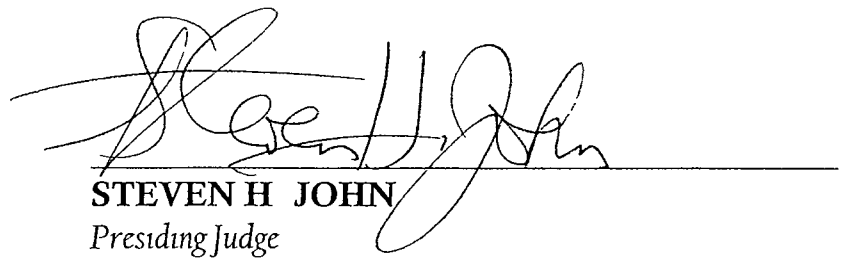
Following the Court's January 31, 2007 Order compelling the Defendants CIBA to answer the discovery request at issue, the Plaintiffs made a Motion to Alter/Amend or, in the Alternative, to Reconsider on February 15, 2007 The Court has reviewed the Plaintiffs' Motion and finds that the request in the Plaintiffs' motion deals with specific non-compliance with the Court's Order to Compel, as opposed to a point of contention with the Order itself

Additionally, as the Court has stated to both parties previously, jurisdiction in this matter lies with the Fifth Judicial Circuit, as it was not retained by this Court in its capacity as a visiting presiding Judge for the Fifth Judicial Circuit

Thereupon, the Court finds that an additional hearing would be redundant and unnecessary Therefore, it is

RECEIVED
2007
McNair Law Firm PA

ORDERED that the Plaintiffs' Motion to Alter/Amend or, in the Alternative, to Reconsider is denied, and the prior ruling granting summary judgment reaffirmed



STEVEN H JOHN
Presiding Judge
Fifth Judicial Circuit

February 26, 2007
Conway, South Carolina

STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND	)	
Monica Weston,	)	Civil Action No _____
	)	
Plaintiff	)	
	)	
vs	)	
	)	**COMPLAINT**
Kim s Beauty Supply Inc and CIBA Vision a division of Norvatis Company	)	(Jury Trial Requested)
	)	
Defendant	)	
	)	

2005 FEB 10 PM 4 14
CLERK OF COURT
RICHLAND COUNTY, S.C.
FILED

The Plaintiff herein complaining of the Defendants would respectfully show unto the Court as follows

1 The Plaintiff Monica Weston is a resident and citizen of Richland County South Carolina

2 The Defendant Kim s Beauty Supply Inc (hereinafter Kim s) is a South Carolina corporation with several store locations in Richland County South Carolina

3 The Defendant CIBA Vision a division of Norvatis Company (hereinafter CIBA Vision) is a Delaware corporation with its principal place of business in Atlanta Georgia CIBA Vision conducts business and sells non-corrective decorative colored contact lenses under the trade name FreshLook Colors (hereinafter FreshLook Lenses) throughout the United States including Richland County South Carolina

4 Venue is proper in the Court of Commons Pleas for Richland County

5 This Court has personal jurisdiction over the parties and subject matter jurisdiction over this action

6 At all times relevant, CIBA Vision themselves, or by use of others did manufacture create design label package distribute supply market sell warn and otherwise distribute in interstate commerce FreshLook Lenses Ciba Vision placed FreshLook Lenses into the stream of commerce throughout the United States, including Richland County, South Carolina, where they ultimately reached the Plaintiff who used them

7 FreshLook Lenses are non-corrective decorative contact lenses worn to change the color or appearance of the eye

8 At all times relevant Kim s sold decorative contact lenses including FreshLook Lenses to consumers including Plaintiff

9 Federal and South Carolina law require that these lenses be sold by or on the order of a licensed eye care professional

10 The defendant Ciba Vision has for years known that these decorative contact lenses were being marketed and distributed directly to consumers without a prescription, through unlicensed sources such as flea markets convenient stores and beauty supply stores They have additionally received reports of various eye injuries including among others corneal ulcers associated with the wearing of decorative contact lenses which can progress rapidly and if left untreated could lead to infection of the eye This uncontrolled infection can lead to corneal scaring and vision impairment and in the most severe cases the condition can result in blindness and eye loss

11 CIBA Vision has for several years been aware of the reports of decorative contact lenses being sold by unlicensed distributors to consumers without prescriptions, yet failed to take reasonable or adequate steps to protect against such behavior or to

provide adequate warnings and/or instructions to consumers receiving lenses from such unlicensed distributors

12 On or about March 12 2004 Plaintiff entered defendant Kim s Beauty Supply store located on Beltline Boulevard Columbia South Carolina The Kim s sales clerk withdrew a case of assorted contact lenses from underneath the counter and showed them to Plaintiff Plaintiff selected two pair of FreshLook Lenses for which she paid $21 a pair

13 Plaintiff was provided with no instructions concerning the care cleaning or usage of the FreshLook Lenses nor was Plaintiff informed of the necessity of a medical prescription and oversight for usage of this product

14 Plaintiff was provided with no warnings of the risks associated with the use of the FreshLook Lenses from either defendant

15 Plaintiff was never asked for a prescription for the lenses and was sold the FreshLook Lenses without a prescription

16 The individual packages of FreshLook Lenses sold to Plaintiff contained no instructions on the care cleaning or usage of the lenses and provided no warnings of the risks associated with their use

17 On or about March 12 2004 Plaintiff wore one of the pairs of contact lenses for approximately five hours Plaintiff never wore that pair of contact lenses again

18 On or about March 13, 2004 Plaintiff wore the other pair of contact lenses for approximately five hours which caused her eyes to become irritated

19 On the morning of March 14 2004 Plaintiff awoke with eye pain and irritation

20 Plaintiff's eye pain and irritation continued to get worse over the next few days and on March 18 2004 Plaintiff went to the emergency room at Palmetto Richland Memorial Hospital and was evaluated The initial diagnoses was an eye infection for which Plaintiff was prescribed eye drops

21 Plaintiff was subsequently seen by her physician at the Palmetto Richland Eye Clinic and was diagnosed as having a continuing eye infection requiring further medications and treatment Plaintiff was seen several times a week at both the emergency room and the eye clinic over a several month period for the treatment of her worsening eye condition Plaintiff's eye condition continued to worsen to the point that Plaintiff has now been rendered permanently blind in her left eye

COUNT I - NEGLIGENCE PER SE

22 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

23 At all times herein mentioned, defendants had a duty to comply with the South Carolina State statutes regarding the sale of decorative contact lenses

24 Defendants violated S C Code Ann § 40-37-10 and § 40-37-260 by selling decorative contact lenses, in that defendants were practicing optometry dispensing and causing to be dispensed prescription lenses outside the care of a licensed optometrist

25 Defendants additionally violated S C Code Ann § 39-25-20 *et seq* in that they sold decorative contact lenses that were misbranded

26 Defendants acts constitute a misbranding as defined by S C Code Ann § 39-25-20 (k) and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom under the theory of negligence per se

27 Defendants had a duty to manufacture, label and sell the Freshlook Lenses with truthful and adequate warnings to the ultimate user

28 The labeling on the decorative contact lenses was misleading and lacked adequate information on the safe and effective use of the FreshLook Lenses

29 The labeling on the decorative contact lenses was misleading and failed to provide adequate warnings of severe and disabling medical conditions including eye infection corneal ulcers corneal vascularization abrasions epithelial staining bacterial conjunctivitis ulcerative keratitis and other related eye injuries

30 Plaintiff as a purchaser and user of decorative contact lenses is within the class of persons the statutes described above are designed to protect and Plaintiff's injuries are the type of harm these statutes are designed to prevent

31 Defendants failed to meet the standard of care set by the above statutes and regulations which were intended for the benefit of individuals such as Plaintiff making Defendants negligent per se

32 As a direct and proximate result of Defendants careless, reckless negligent willful and wanton violations of the above statutes Plaintiff was severely injured and rendered blind in her left eye suffered pain therefrom incurred medical and related expenses in the treatment of her injuries suffered physical handicap, suffered psychological and emotional injuries sustained permanent injuries, lost earning capacity, loss of consortium and suffered loss of enjoyment of life

33 Since the injuries suffered by Plaintiff are continuing in nature she will continue to suffer pain psychological and emotional injuries, pecuniary loss and lost earning capacity physical handicap and permanent injury in the future will be further compelled to expend great sums of money for medical care and related treatment for said injury and will continue to suffer loss impairment and loss of enjoyment of life

34 Plaintiff has also sustained economic loss, including loss of earnings and diminution or loss of earning capacity

35 That as a result of the foregoing the Plaintiff demands compensatory damages for her injuries and conscious pain and suffering and economic losses and in addition thereto demands punitive damages for the careless reckless willful and wanton disregard for the above statutes resulting in Plaintiff's injuries and conscious pain and suffering for her costs herein incurred, and for such other and further relief as this Court deems just and proper

COUNT II - NEGLIGENCE

36 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

37 Defendants are sellers of decorative contact lenses including FreshLook Lenses

38 Defendants had a duty to exercise reasonable care in the sale and distribution of the FreshLook Lenses

39 Defendants owe a duty to the expected consumers and purchasers of FreshLook Lenses including Plaintiff, to exercise reasonable care in the manufacture sale, promotion and/or distribution of decorative contact lenses including a duty to take

reasonable steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects

40 Defendants owe additional and further duties

a) To provide adequate and complete instructions for the use of FreshLook Lenses

b) To provide adequate and complete warnings of the risks associated with FreshLook Lenses, the warning signs associated with those risks and the measures necessary to avoid and/or mitigate those risks and

c) To promptly amend and supplement such instructions and warnings upon the discovery of information indicating that such amendment and supplementation was necessary

41 That in breach of those duties Defendants violated the applicable standards of care and failed to exercise due care and knew or reasonably should have known, that the FreshLook Lenses created a high risk of unreasonably dangerous and untoward side effects and failed to exercise due care so at to avoid risks to individuals to whom they sold the FreshLook Lenses

42 The FreshLook Lenses sold by Defendants are not accompanied by appropriate instructions on the use of the lenses, or warnings of the risks incidents symptoms and scope of severity of the possible injuries from the use of the lenses

43 Defendants were negligent reckless careless, willful and wanton in the sale and distribution of the FreshLook Lenses in that they

a) sold the decorative contact lenses to Plaintiff without requiring a prescription,

b) failed to inform Plaintiff that she needed to obtain a prescription before purchasing decorative contact lenses

c) failed to provide proper instructions on the use of the decorative contact lenses to Plaintiff at the time of their sale

d) failed to provide proper adequate and complete warnings regarding all possible adverse side effects and risks associated with the use of decorative contact lenses

e) Failed to use reasonable care in designing/manufacturing/distributing and/or labeling FreshLook Lenses so as to reduce or eliminate the aforementioned risks

f) Failed to provide proper warnings regarding all possible adverse side effects associated with the use of FreshLook Lenses and the comparative severity and duration of such adverse effects

g) By placing an unsafe product into the stream of commerce

h) Failed to timely supplement and/or amend their package labeling to warn of the risks of the use of FreshLook Lenses, upon the discovery of information indicating that such action was necessary and was otherwise careless or negligent

i) recklessly and knowingly omitted and concealed material facts regarding the safety use and risks of decorative contact lenses and

j) were otherwise careless negligent grossly negligent reckless and acted with willful and wanton disregard for the rights of Plaintiff

44 It was foreseeable that a breach of the aforementioned duties would cause injury and/or related damages to the ultimate consumers of FreshLook Lenses including Plaintiff

45 Defendants knew or should have known that its customers including the Plaintiff would suffer injuries as a result of defendants failure to exercise reasonable and ordinary care as described above

46 Defendants negligence was the proximate cause of the injuries suffered by Plaintiff

47 As a direct and proximate result of defendants careless reckless negligent willful and wanton acts Plaintiff was severely injured and rendered blind in her left eye suffered pain therefrom incurred medical and related expenses in the treatment of her injuries suffered physical handicap suffered psychological and emotional injuries, sustained permanent injuries and suffered permanent impairment lost earning capacity loss of consortium and suffered loss of enjoyment of life

48 Since the injuries suffered by Plaintiff are continuing in nature she will continue to suffer pain psychological and emotional injuries pecuniary losses and lost earning capacity physical handicap and permanent injury in the future will be further compelled to expend great sums of money for medical care and related treatment for said injuries, and will continue to suffer loss impairment and loss of enjoyment of life

49 Plaintiff has also sustained economic loss, including loss of earnings and diminution or loss of earning capacity

50 That as a result of the foregoing the Plaintiff demands compensatory damages for her injuries and conscious pain and suffering and economic losses, and in

addition thereto demands punitive damages for the careless, reckless, willful and wanton acts of negligence resulting in Plaintiff's injuries and conscious pain and suffering, for her costs herein incurred and for such other and further relief as this Court deems just and proper

COUNT III – BREACH OF IMPLIED WARRANTY

51 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

52 At the time Defendants sold and distributed the decorative contact lenses, for use by Plaintiff Defendants knew of the use for which the lenses were intended and impliedly warranted that they were of merchantable quality and reasonably fit and suitable for the ordinary purpose for which such goods are used

53 Defendants breached the implied warranty of merchantability because the decorative contact lenses were not of merchantable quality and were not safe or fit for their intended use and unfit for the ordinary purposes for which they were intended

54 As a direct and proximate result of Defendants breach of the implied warranty of merchantability Plaintiff was severely injured and rendered blind in her left eye suffered pain therefrom incurred medical and related expenses in the treatment of her injuries suffered physical handicap suffered psychological and emotional injuries sustained permanent injuries lost earning capacity loss of consortium and suffered loss of enjoyment of life

55 Since the injuries suffered by Plaintiff are continuing in nature she will continue to suffer pain, psychological and emotional injuries, pecuniary loss and lost earning capacity physical handicap and permanent injury in the future, will be further

compelled to expend great sums of money for medical care and related treatment for said injuries and will continue to suffer loss impairment and loss of enjoyment of life

56 Plaintiff has also sustained economic loss including loss of earnings and diminution or loss of earning capacity

57 That as a result of the foregoing the Plaintiff demands compensatory damages for her injuries and conscious pain and suffering and economic losses, and in addition thereto demands punitive damages for the careless reckless willful and wanton breach of the implied warranty resulting in Plaintiff's injuries and conscious pain and suffering for her costs herein incurred and for such other and further relief as this Court deems just and proper

COUNT IV – STRICT PRODUCTS LIABILITY

58 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

59 Defendants are vendors distributors manufacturers and/or suppliers of FreshLook Lenses

60 Defendants did in fact manufacture and sell the FreshLook Lenses sold to Plaintiff

61 That at the time of Plaintiff's injury Plaintiff was using FreshLook Lenses for the purpose for which they were intended and in a reasonable manner foreseeable by Defendants

62 The FreshLook Lenses as sold by Defendants were in a defective and unreasonably dangerous condition at the time they were placed into the stream of

commerce in ways which include, but are not limited to one or more of the following particulars

a) The FreshLook Lenses were unreasonably dangerous and were not reasonably safe as intended to be used subjecting Plaintiff to risks which exceeded the benefit of the lenses

b) The FreshLook Lenses were defective in that the risk of their use was more dangerous than the ordinary consumer would expect

c) The FreshLook Lenses contained insufficient and/or inadequate warnings to alert consumers and users of the risks of adverse effects

d) The FreshLook Lenses were not distributed with adequate warnings of the risks of adverse events and/or the appropriate usage and cleaning of the lenses

63 Plaintiff used the decorative contact lenses for their intended purpose

64 As a direct and proximate result of the defective and unreasonably dangerous condition of the FreshLook Lenses Plaintiff was severely injured and rendered blind in her left eye suffered pain therefrom, incurred medical and related expenses in the treatment of her injuries suffered physical handicap suffered psychological and emotional injuries sustained permanent injuries lost earning capacity loss of consortium and suffered loss of enjoyment of life

65 Since the injuries suffered by Plaintiff are continuing in nature she will continue to suffer pain, psychological and emotional injuries pecuniary losses and lost earning capacity physical handicaps and permanent injuries in the future will be further

compelled to expend great sums of money for medical care and related treatment for said injuries and will continue to suffer loss impairment and loss of enjoyment of life

66 Plaintiff has also sustained economic loss including loss of earnings and diminution or loss of earning capacity

67 That as a result of the foregoing the Plaintiff demands compensatory damages for her injuries and conscious pain and suffering and economic losses, and in addition thereto demands punitive damages for the careless reckless willful and wanton acts of negligence resulting in Plaintiff's injuries and conscious pain and suffering for her costs herein incurred and for such other and further relief as this Court deems just and proper

COUNT V – SALE OF A DEFECTIVE PRODUCT

68 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

69 Defendants are sellers engaged in the business of selling decorative contact lenses

70 The decorative contact lenses sold to Plaintiff by Defendants reached Plaintiff without substantial change in the condition in which they were sold

71 The decorative contact lenses sold to Plaintiff by Defendants were a defective product due to inadequate warnings of the risks associated with their use and inadequate instructions for the use of the decorative contact lenses

72 As a direct and proximate result of the defective and unreasonably dangerous condition of the decorative contact lenses Plaintiff was severely injured and rendered blind in her left eye suffered pain therefrom, incurred medical and related

expenses in the treatment of her injuries suffered physical handicap suffered psychological and emotional injuries sustained permanent injuries lost earning capacity loss of consortium and suffered loss of enjoyment of life Defendants are liable for the physical harm caused to the Plaintiff as provided for in S C Code Ann § 15-73-10

73 Since the injuries suffered by Plaintiff are continuing in nature she will continue to suffer pain, psychological and emotional injuries pecuniary losses and lost earning capacity, physical handicaps and permanent injuries in the future will be further compelled to expend great sums of money for medical care and related treatment for said injuries and will continue to suffer loss impairment and loss of enjoyment of life

74 Plaintiff has also sustained economic loss including loss of earnings and diminution or loss of earning capacity

75 That as a result of the foregoing the Plaintiff demands compensatory damages for her injuries and conscious pain and suffering and economic losses and in addition thereto demands punitive damages for the careless reckless willful and wanton acts of negligence resulting in Plaintiff's injuries and conscious pain and suffering for her costs herein incurred and for such other and further relief as this Court deems just and proper

COUNT VI – S C UNFAIR TRADE PRACTICES ACT

76 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

77 Under the South Carolina Unfair Trade Practices Act (SCUTPA) South Carolina Code Ann § 39-5-10 *et seq* , unfair methods of competition and unfair

deceptive acts or practices in the conduct of any trade or commerce are declared unlawful and the action may be brought under SCUTPA for treble damages (SC Code Ann § 39-5-140) and attorneys fees may be awarded along with the costs of suit

78 The aforementioned enumerated actions by Defendants in willfully and knowingly selling decorative contact lenses to the Plaintiff in violation of federal and state statutes, amounted to an unfair or deceptive act or practice in the conduct of a trade or commerce as prohibited under SCUTPA As a result of these actions by Defendants Plaintiff suffered actual ascertainable damages Additionally as Defendants sold decorative contact lenses to the general public in violation of federal and state statutes, there is a clear adverse impact on the public interest

79 In accordance with the SCUTPA Plaintiff is entitled to treble damages and attorneys fees for bringing suit

PRAYER FOR RELIEF

WHEREFORE Plaintiff prays for a jury trial and judgment against the defendants for both actual and punitive damages in an appropriate amount to be determined at trial treble damages and attorneys fees as provided by S C Code Ann § 39-5-140 together with the costs and disbursements of this action and for such other and further relief as this Court may deem just and proper

Respectfully submitted

McNAIR LAW FIRM P A
Post Office Box 11390
Columbia South Carolina 29211
Andrew G Melling
Celeste T Jones
A Victor Rawl, Jr
(803) 799-9800
(803) 376-2278 (facsimile)

By _____
Andrew G Melling SC Bar # 009521
Attorneys for the Plaintiff Monica Weston

February 10 2005
Columbia South Carolina

STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND	)	
Monica Weston	)	Civil Action No 05-CP-40-0655
	)	
Plaintiff	)	
	)	
vs	)	**AMENDED COMPLAINT**
	)	
Kims Dollar Store and CIBA Vision a division of Novartis Company	)	(Jury Trial Requested)
	)	
Defendant	)	
	)	

2005 FEB 23 A 11:55

The Plaintiff herein complaining of the Defendants would respectfully show unto the Court as follows

1 The Plaintiff Monica Weston is a resident and citizen of Richland County South Carolina

2 The Defendant Kims Dollar Store (hereinafter Kims) is a South Carolina corporation with several store locations in Richland County South Carolina

3 The Defendant CIBA Vision a division of Novartis Company (hereinafter CIBA Vision) is a Delaware corporation with its principal place of business in Atlanta Georgia CIBA Vision conducts business and sells non-corrective decorative colored contact lenses under the trade name FreshLook Colors (hereinafter FreshLook Lenses) throughout the United States including Richland County, South Carolina

4 Venue is proper in the Court of Commons Pleas for Richland County

5 This Court has personal jurisdiction over the parties and subject matter jurisdiction over this action

6 At all times relevant CIBA Vision themselves or by use of others did manufacture create design label package distribute supply market sell warn and otherwise distribute in interstate commerce FreshLook Lenses Ciba Vision placed FreshLook Lenses into the stream of commerce throughout the United States including Richland County South Carolina where they ultimately reached the Plaintiff who used them

7 FreshLook Lenses are non-corrective decorative contact lenses worn to change the color or appearance of the eye

8 At all times relevant Kims sold decorative contact lenses including FreshLook Lenses, to consumers including Plaintiff

9 Federal and South Carolina law require that these lenses be sold by or on the order of a licensed eye care professional

10 The defendant Ciba Vision has for years known that these decorative contact lenses were being marketed and distributed directly to consumers without a prescription through unlicensed sources such as flea markets convenient stores and beauty supply stores They have additionally received reports of various eye injuries including among others corneal ulcers associated with the wearing of decorative contact lenses which can progress rapidly and if left untreated could lead to infection of the eye This uncontrolled infection can lead to corneal scaring and vision impairment and in the most severe cases the condition can result in blindness and eye loss

11 CIBA Vision has for several years been aware of the reports of decorative contact lenses being sold by unlicensed distributors to consumers without prescriptions yet failed to take reasonable or adequate steps to protect against such behavior or to

provide adequate warnings and/or instructions to consumers receiving lenses from such unlicensed distributors

12 On or about March 12 2004 Plaintiff entered defendant Kims Dollar Store located on Beltline Boulevard Columbia South Carolina The Kims sales clerk withdrew a case of assorted contact lenses from underneath the counter and showed them to Plaintiff Plaintiff selected two pair of FreshLook Lenses for which she paid $21 a pair

13 Plaintiff was provided with no instructions concerning the care cleaning or usage of the FreshLook Lenses nor was Plaintiff informed of the necessity of a medical prescription and oversight for usage of this product

14 Plaintiff was provided with no warnings of the risks associated with the use of the FreshLook Lenses from either defendant

15 Plaintiff was never asked for a prescription for the lenses, and was sold the FreshLook Lenses without a prescription

16 The individual packages of FreshLook Lenses sold to Plaintiff contained no instructions on the care cleaning, or usage of the lenses and provided no warnings of the risks associated with their use

17 On or about March 12 2004, Plaintiff wore one of the pairs of contact lenses for approximately five hours Plaintiff never wore that pair of contact lenses again

18 On or about March 13, 2004, Plaintiff wore the other pair of contact lenses for approximately five hours, which caused her eyes to become irritated

19 On the morning of March 14 2004 Plaintiff awoke with eye pain and irritation

20 Plaintiff's eye pain and irritation continued to worsen over the next few days and on March 18 2004 Plaintiff went to the emergency room at Palmetto Richland Memorial Hospital and was evaluated The initial diagnoses were an eye infection for which Plaintiff was prescribed eye drops

21 Plaintiff was subsequently seen by her physician at the Palmetto Richland Eye Clinic and was diagnosed as having a continuing eye infection requiring further medications and treatment Plaintiff was seen several times a week at both the emergency room and the eye clinic over a several month period for the treatment of her worsening eye condition Plaintiff's eye condition continued to worsen to the point that Plaintiff has now been rendered permanently blind in her left eye

COUNT I - NEGLIGENCE PER SE

22 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

23 At all times herein mentioned defendants had a duty to comply with the Federal and South Carolina State statutes regarding the manufacture, promotion and sale of decorative contact lenses Defendants violated those Federal and State statutes

24 Defendants violated S C Code Ann § 40-37-10 and § 40-37-260 by selling decorative contact lenses, in that defendants were practicing optometry dispensing and causing to be dispensed prescription lenses outside the care of a licensed optometrist

25 Defendants additionally violated S C Code Ann § 39-25-20 *et seq* in that they sold decorative contact lenses that were misbranded

26 Defendants acts constitute a misbranding as defined by S C Code Ann § 39-25-20 (k) and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom under the theory of negligence per se

27 Defendants had a duty to manufacture label and sell the Freshlook Lenses with truthful and adequate warnings to the ultimate user

28 The labeling on the decorative contact lenses was misleading and lacked adequate information on the safe and effective use of the FreshLook Lenses

29 The labeling on the decorative contact lenses was misleading and failed to provide adequate warnings of severe and disabling medical conditions including eye infection corneal ulcers corneal vascularization abrasions epithelial staining bacterial conjunctivitis ulcerative keratitis and other related eye injuries

30 Plaintiff as a purchaser and user of decorative contact lenses is within the class of persons the statutes described above are designed to protect and Plaintiff's injuries are the type of harm these statutes are designed to prevent

31 Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individuals such as Plaintiff making Defendants negligent per se

32 As a direct and proximate result of Defendants careless reckless negligent willful and wanton violations of the above statutes Plaintiff was severely injured and rendered blind in her left eye, suffered pain therefrom, incurred medical and related expenses in the treatment of her injuries suffered physical handicap suffered

psychological and emotional injuries, sustained permanent injuries lost earning capacity loss of consortium and suffered loss of enjoyment of life

33 Since the injuries suffered by Plaintiff are continuing in nature, she will continue to suffer pain psychological and emotional injuries pecuniary loss and lost earning capacity physical handicap and permanent injury in the future will be further compelled to expend great sums of money for medical care and related treatment for said injury and will continue to suffer loss, impairment, and loss of enjoyment of life

34 Plaintiff has also sustained economic loss including loss of earnings and diminution or loss of earning capacity

35 That as a result of the foregoing the Plaintiff demands compensatory damages for her injuries and conscious pain and suffering and economic losses and in addition thereto demands punitive damages for the careless reckless willful and wanton disregard for the above statutes resulting in Plaintiff s injuries and conscious pain and suffering for her costs herein incurred and for such other and further relief as this Court deems just and proper

COUNT II - NEGLIGENCE

36 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

37 Defendants are sellers of decorative contact lenses including FreshLook Lenses

38 Defendants had a duty to exercise reasonable care in the sale and distribution of the FreshLook Lenses

39 Defendants owe a duty to the expected consumers and purchasers of FreshLook Lenses including Plaintiff to exercise reasonable care in the manufacture sale promotion and/or distribution of decorative contact lenses including a duty to take reasonable steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects

40 Defendants owe additional and further duties

a) To provide adequate and complete instructions for the use of FreshLook Lenses

b) To provide adequate and complete warnings of the risks associated with FreshLook Lenses the warning signs associated with those risks and the measures necessary to avoid and/or mitigate those risks and

c) To promptly amend and supplement such instructions and warnings upon the discovery of information indicating that such amendment and supplementation was necessary

41 That in breach of those duties Defendants violated the applicable standards of care and failed to exercise due care and knew or reasonably should have known, that the FreshLook Lenses created a high risk of unreasonably dangerous and untoward side effects and failed to exercise due care so at to avoid risks to individuals to whom they sold the FreshLook Lenses

42 The FreshLook Lenses sold by Defendants are not accompanied by appropriate instructions on the use of the lenses, or warnings of the risks incidents, symptoms and scope of severity of the possible injuries from the use of the lenses

43 Defendants were negligent reckless, careless willful and wanton in the sale and distribution of the FreshLook Lenses in that they

a) sold the decorative contact lenses to Plaintiff without requiring a prescription

b) failed to inform Plaintiff that she needed to obtain a prescription before purchasing decorative contact lenses

c) failed to provide proper instructions on the use of the decorative contact lenses to Plaintiff at the time of their sale

d) failed to provide proper adequate and complete warnings regarding all possible adverse side effects and risks associated with the use of decorative contact lenses

e) Failed to use reasonable care in designing/manufacturing/distributing and/or labeling FreshLook Lenses so as to reduce or eliminate the aforementioned risks

f) Failed to provide proper warnings regarding all possible adverse side effects associated with the use of FreshLook Lenses and the comparative severity and duration of such adverse effects,

g) By placing an unsafe product into the stream of commerce

h) Failed to timely supplement and/or amend their package labeling to warn of the risks of the use of FreshLook Lenses upon the discovery of information indicating that such action was necessary and was otherwise careless or negligent

i) recklessly and knowingly omitted and concealed material facts regarding the safety use and risks of decorative contact lenses and

j) were otherwise careless negligent grossly negligent reckless and acted with willful and wanton disregard for the rights of Plaintiff

44 It was foreseeable that a breach of the aforementioned duties would cause injury and/or related damages to the ultimate consumers of FreshLook Lenses including Plaintiff

45 Defendants knew or should have known that its customers including the Plaintiff would suffer injuries as a result of defendants failure to exercise reasonable and ordinary care as described above

46 Defendants negligence was the proximate cause of the injuries suffered by Plaintiff

47 As a direct and proximate result of defendants careless reckless negligent willful and wanton acts Plaintiff was severely injured and rendered blind in her left eye suffered pain therefrom incurred medical and related expenses in the treatment of her injuries suffered physical handicap suffered psychological and emotional injuries sustained permanent injuries and suffered permanent impairment lost earning capacity loss of consortium and suffered loss of enjoyment of life

48 Since the injuries suffered by Plaintiff are continuing in nature she will continue to suffer pain psychological and emotional injuries pecuniary losses and lost earning capacity physical handicap and permanent injury in the future will be further compelled to expend great sums of money for medical care and related treatment for said injuries and will continue to suffer loss impairment and loss of enjoyment of life

49 Plaintiff has also sustained economic loss including loss of earnings and diminution or loss of earning capacity

50 That as a result of the foregoing the Plaintiff demands compensatory damages for her injuries and conscious pain and suffering and economic losses and in addition thereto demands punitive damages for the careless reckless willful and wanton acts of negligence resulting in Plaintiff's injuries and conscious pain and suffering for her costs herein incurred and for such other and further relief as this Court deems just and proper

COUNT III – BREACH OF IMPLIED WARRANTY

51 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

52 At the time Defendants sold and distributed the decorative contact lenses for use by Plaintiff Defendants knew of the use for which the lenses were intended and impliedly warranted that they were of merchantable quality and reasonably fit and suitable for the ordinary purpose for which such goods are used

53 Defendants breached the implied warranty of merchantability because the decorative contact lenses were not of merchantable quality and were not safe or fit for their intended use and unfit for the ordinary purposes for which they were intended

54 As a direct and proximate result of Defendants breach of the implied warranty of merchantability, Plaintiff was severely injured and rendered blind in her left eye, suffered pain therefrom incurred medical and related expenses in the treatment of her injuries, suffered physical handicap, suffered psychological and emotional injuries

sustained permanent injuries lost earning capacity, loss of consortium and suffered loss of enjoyment of life

55 Since the injuries suffered by Plaintiff are continuing in nature she will continue to suffer pain psychological and emotional injuries pecuniary loss and lost earning capacity physical handicap and permanent injury in the future will be further compelled to expend great sums of money for medical care and related treatment for said injuries and will continue to suffer loss, impairment and loss of enjoyment of life

56 Plaintiff has also sustained economic loss including loss of earnings and diminution or loss of earning capacity

57 That as a result of the foregoing the Plaintiff demands compensatory damages for her injuries and conscious pain and suffering and economic losses and in addition thereto demands punitive damages for the careless reckless willful and wanton breach of the implied warranty resulting in Plaintiff's injuries and conscious pain and suffering for her costs herein incurred and for such other and further relief as this Court deems just and proper

COUNT IV – STRICT PRODUCTS LIABILITY

58 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

59 Defendants are vendors distributors manufacturers and/or suppliers of FreshLook Lenses

60 Defendants did in fact manufacture and sell the FreshLook Lenses sold to Plaintiff

61 That at the time of Plaintiff's injury Plaintiff was using FreshLook Lenses for the purpose for which they were intended and in a reasonable manner foreseeable by Defendants

62 The FreshLook Lenses as sold by Defendants were in a defective and unreasonably dangerous condition at the time they were placed into the stream of commerce in ways which include but are not limited to one or more of the following particulars

a) The FreshLook Lenses were unreasonably dangerous and were not reasonably safe as intended to be used subjecting Plaintiff to risks which exceeded the benefit of the lenses

b) The FreshLook Lenses were defective in that the risk of their use was more dangerous than the ordinary consumer would expect

c) The FreshLook Lenses contained insufficient and/or inadequate warnings to alert consumers and users of the risks of adverse effects

d) The FreshLook Lenses were not distributed with adequate warnings of the risks of adverse events and/or the appropriate usage and cleaning of the lenses

63 Plaintiff used the decorative contact lenses for their intended purpose

64 As a direct and proximate result of the defective and unreasonably dangerous condition of the FreshLook Lenses Plaintiff was severely injured and rendered blind in her left eye, suffered pain therefrom incurred medical and related expenses in the treatment of her injuries suffered physical handicap suffered

psychological and emotional injuries sustained permanent injuries lost earning capacity loss of consortium and suffered loss of enjoyment of life

65 Since the injuries suffered by Plaintiff are continuing in nature she will continue to suffer pain psychological and emotional injuries pecuniary losses and lost earning capacity physical handicaps and permanent injuries in the future will be further compelled to expend great sums of money for medical care and related treatment for said injuries and will continue to suffer loss impairment and loss of enjoyment of life

66 Plaintiff has also sustained economic loss, including loss of earnings and diminution or loss of earning capacity

67 That as a result of the foregoing the Plaintiff demands compensatory damages for her injuries and conscious pain and suffering and economic losses and in addition thereto demands punitive damages for the careless reckless willful and wanton acts of negligence resulting in Plaintiff's injuries and conscious pain and suffering for her costs herein incurred and for such other and further relief as this Court deems just and proper

COUNT V – SALE OF A DEFECTIVE PRODUCT

68 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

69 Defendants are sellers engaged in the business of selling decorative contact lenses

70 The decorative contact lenses sold to Plaintiff by Defendants reached Plaintiff without substantial change in the condition in which they were sold

71 The decorative contact lenses sold to Plaintiff by Defendants were a defective product due to inadequate warnings of the risks associated with their use and inadequate instructions for the use of the decorative contact lenses

72 As a direct and proximate result of the defective and unreasonably dangerous condition of the decorative contact lenses Plaintiff was severely injured and rendered blind in her left eye suffered pain therefrom incurred medical and related expenses in the treatment of her injuries suffered physical handicap suffered psychological and emotional injuries sustained permanent injuries lost earning capacity loss of consortium and suffered loss of enjoyment of life Defendants are liable for the physical harm caused to the Plaintiff as provided for in S C Code Ann § 15-73-10

73 Since the injuries suffered by Plaintiff are continuing in nature she will continue to suffer pain psychological and emotional injuries pecuniary losses and lost earning capacity physical handicaps and permanent injuries in the future will be further compelled to expend great sums of money for medical care and related treatment for said injuries and will continue to suffer loss, impairment and loss of enjoyment of life

74 Plaintiff has also sustained economic loss including loss of earnings and diminution or loss of earning capacity

75 That as a result of the foregoing, the Plaintiff demands compensatory damages for her injuries and conscious pain and suffering and economic losses, and in addition thereto demands punitive damages for the careless reckless willful and wanton acts of negligence resulting in Plaintiff's injuries and conscious pain and

suffering for her costs herein incurred and for such other and further relief as this Court deems just and proper

COUNT VI – S C UNFAIR TRADE PRACTICES ACT

76 Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows

77 Under the South Carolina Unfair Trade Practices Act (SCUTPA), South Carolina Code Ann § 39-5-10 *et seq* unfair methods of competition and unfair deceptive acts or practices in the conduct of any trade or commerce are declared unlawful and the action may be brought under SCUTPA for treble damages (SC Code Ann § 39-5-140) and attorneys fees may be awarded along with the costs of suit

78 The aforementioned enumerated actions by Defendants in willfully and knowingly selling decorative contact lenses to the Plaintiff in violation of federal and state statutes amounted to an unfair or deceptive act or practice in the conduct of a trade or commerce as prohibited under SCUTPA As a result of these actions by Defendants, Plaintiff suffered actual ascertainable damages Additionally as Defendants sold decorative contact lenses to the general public in violation of federal and state statutes there is a clear adverse impact on the public interest

79 In accordance with the SCUTPA Plaintiff is entitled to treble damages and attorneys fees for bringing suit

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for a jury trial and judgment against the defendants for both actual and punitive damages in an appropriate amount to be determined at trial treble damages and attorneys fees as provided by S C Code Ann § 39-5-140 together

with the costs and disbursements of this action, and for such other and further relief as this Court may deem just and proper

Respectfully submitted

McNAIR LAW FIRM P A
Post Office Box 11390
Columbia South Carolina 29211
Andrew G Melling
Celeste T Jones
A Victor Rawl Jr
(803) 799-9800
(803) 376-2278 (facsimile)

By _____
Andrew G Melling, SC Bar # 009521
Attorneys for the Plaintiff Monica Weston

February 23 2005
Columbia South Carolina

STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND	)	
Monica Weston	)	Civil Action No 05-CP-40-0655
	)	
Plaintiff,	)	
	)	
v	)	**ANSWER TO AMENDED COMPLAINT**
	)	**AND CROSSCLAIM AGAINST KIMS**
Kims Dollar Store and CIBA Vision a division of Novartis Company,	)	**DOLLAR STORE**
	)	
Defendants	)	
	)	

The Defendant Novartis Pharmaceuticals Corporation, d/b/a CIBA Vision Corporation, ("CIBA Vision') answering the Amended Complaint of the Plaintiff, would respectfully show unto the Court as follows

FOR A FIRST DEFENSE

1 CIBA Vision denies all allegations of the Amended Complaint not specifically admitted to, explained or denied

2 CIBA Vision does not have sufficient information or knowledge to form a belief as to the allegations of paragraph 1 of the Amended Complaint and therefore they are denied

3 In response to paragraph 2 of the Amended Complaint, CIBA Vision states that it is a corporation organized and existing under the laws of the State of Delaware and that it conducts business in Atlanta, Georgia CIBA Vision further states that its business includes wholeselling colored contact lenses under the trade name FreshLook and that these contact lenses are subsequently sold, upon information and belief, in Richland County, South Carolina

4 Paragraphs 4 and 5 of the Amended Complaint state legal conclusions to which no response is necessary

5 In response to paragraph 6 of the Amended Complaint, CIBA Vision admits that it designed, manufactured packaged, labeled, marketed distributed, and sold FreshLook contact lenses in the United States and, upon information and belief CIBA Vision admits that FreshLook contact lenses were resold in Richland County, South Carolina CIBA Vision specifically denies that it sold FreshLook contact lenses to Defendant Kims Dollar Store CIBA Vision does not have sufficient information or knowledge to form a belief as to the remaining allegations of paragraph 6 of the Amended Complaint and therefore, they are denied

6 CIBA Vision admits that FreshLook contact lenses have the capacity to change the color or appearance of the eye CIBA Vision denies the remaining allegations in paragraph 7 of the Amended Complaint

7 CIBA Vision specifically denies that it sold FreshLook contact lenses to Kims Dollar Store Otherwise, CIBA Vision is without sufficient information or knowledge to form a belief as to the allegations of paragraph 8 of the Amended Complaint and therefore they are denied

8 Paragraph 9 of the Amended Complaint states a legal conclusion to which no response is necessary

9 CIBA Vision is generally aware of reports that unlicensed retailers unrelated to CIBA Vision have engaged in the distribution of decorative contact lenses directly to consumers CIBA Vision sells its contact lenses to licensed eye care professionals, businesses licensed to dispense contact lenses, and to authorized distributors who are permitted to resell lenses only to licensed eye care professionals CIBA Vision admits that it has knowledge of various eye

injuries associated with the wearing of contact lenses CIBA Vision further admits upon information and belief, that if eye injuries are not treated appropriately infections vision impairment, and/or blindness can result CIBA Vision denies the remaining allegations in paragraph 10 of the Amended Complaint

10 CIBA Vision denies the allegations in paragraph 11 of the Amended Complaint

11 CIBA Vision is without sufficient information or knowledge to form a belief as to the allegations of paragraphs 12 through 21 of the Amended Complaint and therefore they are denied

ANSWERING FIRST CAUSE OF ACTION

(Negligence Per Se)

12 As to paragraph 22 of the Amended Complaint CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

13 In response to paragraph 23 of the Amended Complaint, CIBA Vision admits that it has a duty to comply with certain federal and state statutes concerning contact lenses but denies that it acted in violation of any federal and state statutes applicable to the manufacture promotion and sale of the contact lenses at issue and otherwise denies the remaining allegations of this paragraph

14 CIBA Vision denies the allegations of paragraphs 24 through 26 of the Amended Complaint

15 Paragraph 27 of the Amended Complaint states a legal conclusion to which no response is necessary To the extent this paragraph misstates the applicable standard, it is denied

16 CIBA Vision denies the allegations of paragraphs 28 through 29 of the Amended Complaint

17 CIBA Vision is without sufficient information or knowledge to form a belief as to the allegations of paragraph 30 of the Amended Complaint and therefore, they are denied

18 CIBA Vision denies the allegations of paragraphs 31 through 35 of the Amended Complaint

ANSWERING SECOND CAUSE OF ACTION

(Negligence)

19 As to paragraph 36 of the Amended Complaint CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

20 CIBA Vision admits that it sells FreshLook contact lenses but denies that it sold or authorized the sale of FreshLook lenses to Defendant Kims Dollar Store The remaining allegations in paragraph 37 of the Amended Complaint are denied

21 Paragraphs 38 through 40 of the Amended Complaint state a legal conclusion to which no response is necessary To the extent Plaintiff misstates any applicable legal standard or fails to account for all possible defenses, excuses, or justifications, these allegations are denied

22 CIBA Vision denies the allegations of paragraphs 41 through 43 of the Amended Complaint

23 CIBA Vision is without sufficient information or knowledge to form a belief as to the allegations of paragraph 44 of the Amended Complaint, and therefore, they are denied

24 CIBA Vision denies the allegations of paragraphs 45 through 50 of the Amended Complaint

ANSWERING THIRD CAUSE OF ACTION

(Breach of Implied Warranty)

25 As to paragraph 51 of the Amended Complaint, CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

26 CIBA Vision acknowledges that under certain circumstances implied warranties can arise as a matter of law, however, CIBA Vision denies that it made any intended or implied warranties as alleged in paragraph 52 of the Amended Complaint CIBA Vision denies the remaining allegations of paragraphs 52 through 57 of the Amended Complaint

27 CIBA Vision denies the allegations of paragraphs 53 through 57 of the Amended Complaint

ANSWERING FOURTH CAUSE OF ACTION

(Strict Product Liability)

28 As to paragraph 58 of the Amended Complaint CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

29 CIBA Vision admits that it is a vendor distributor manufacturer, and/or supplier of FreshLook contact lenses The remaining allegations in paragraph 59 of the Amended Complaint are denied

30 CIBA Vision denies the allegations in paragraphs 60 through 67 of the Amended Complaint

ANSWERING FIFTH CAUSE OF ACTION

(Sale of a Defective Product)

31 As to paragraph 68 of the Amended Complaint, CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

32 CIBA Vision admits that its business includes manufacturing and distributing FreshLook contact lenses but otherwise denies the allegations in paragraph 69 of the Amended Complaint

33 CIBA Vision is without sufficient information or knowledge to form a belief as to the allegations of paragraph 70 of the Amended Complaint, and therefore, they are denied

34 CIBA Vision denies the allegations in paragraphs 71 through 75 of the Amended Complaint

ANSWERING SIXTH CAUSE OF ACTION

(Unfair Trade Practices)

35 As to paragraph 76 of the Amended Complaint, CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

36 Paragraph 77 of the Amended Complaint states a legal conclusion to which no response is necessary To the extent Plaintiff misstates the applicable legal standard or fails to account for applicable legal defenses excuses, or justifications, it is denied

37 CIBA Vision denies the allegations of paragraphs 78 and 79 of the Amended Complaint

38 CIBA Vision denies that Plaintiff is entitled to the relief requested by her in the Amended Complaint

FOR A SECOND DEFENSE

39 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

40 The Amended Complaint fails to state claims upon which relief can be granted against CIBA Vision

FOR A THIRD DEFENSE

41 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

42 CIBA Vision alleges that any alleged injuries and damages of the Plaintiff were due to the intervening and superseding acts of others for which CIBA Vision is not responsible

FOR A FOURTH DEFENSE

43 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

44 Any claim against CIBA Vision is or may be barred by the applicable statute of limitations, repose, or other limiting statutes, codes or laws

FOR A FIFTH DEFENSE

45 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

46 While CIBA Vision does not admit that the Plaintiff was injured by any product sold distributed or manufactured by it CIBA Vision states that any product which it sold distributed or manufactured was free of defects at the time it left the possession of and control of CIBA Vision

FOR A SIXTH DEFENSE

47 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

48 The accident and the resulting damages were an act of God and therefore CIBA Vision is not liable for any damages the Plaintiff may have sustained

FOR A SEVENTH DEFENSE

49 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

50 The manufacture sale, warnings, packaging, and labeling of CIBA Vision's product conform to what was technologically known and feasible at the time

FOR A EIGHTH DEFENSE

51 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

52 CIBA Vision alleges that the negligent grossly negligent reckless willful and wanton conduct on the part of the Plaintiff acted as the sole proximate cause of the Plaintiff's alleges injuries and damages Accordingly the Plaintiff's Amended Complaint and all causes of action against CIBA Vision are barred

FOR A NINTH DEFENSE

53 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

54 CIBA Vision alleges that the injuries and damages of the Plaintiff if any were the direct and proximate result of the Plaintiff's own negligence, gross negligence, recklessness, willfulness and wantonness which combined and concurred with any negligence on the part of CIBA Vision, which is specifically denied and admitted solely for the purpose of this defense only and the accident and alleged damages of the Plaintiff would not have occurred if the Plaintiff had not been guilty of such negligence, recklessness, willfulness, and wantonness The Plaintiff's claim is barred to the extent its negligence is more than 50 percent of the negligence of this action To the extent that the Plaintiff is contributorily negligent but such negligence is less

than 50 percent of the negligence in this case, the Plaintiff's recovery should be reduced by the percentage of such contributory negligence

FOR A TENTH DEFENSE

55 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

56 Plaintiff's causes of action for negligence, strict product liability, sale of defective product and unfair trade practices are barred by the Economic Loss Rule Doctrine

FOR A ELEVENTH DEFENSE

57 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

58 Plaintiff's claims are barred by the Doctrine of Preemption under the Medical Devices Act of the Food Drug & Cosmetics Act, 21 U S C § 360, *et seq* and related Code of Federal Regulation provisions

FOR A TWELFTH DEFENSE

59 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

60 Plaintiff's causes of action based on the marketing, distribution, and sale of the FreshLook Color contact lenses are barred because the marketing, distribution and sale of such lenses were in accordance with any and all applicable state and federal laws and regulations

FOR A THIRTEENTH DEFENSE

61 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

62 Plaintiff's causes of action are barred or otherwise limited by any applicable expressed written limited warranties and disclaimers accompanying the product, which the Plaintiff accepted at the time she acquired the product at issue in this litigation

FOR A FOURTEENTH DEFENSE

63 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

64 To the extent there were any modification, alterations, or misuse of the product after the time it left the possession of CIBA Vision, Plaintiff's causes of action are barred to the extent the modification alteration, or misuse is the proximate cause of Plaintiff's alleged injuries

FOR A FIFTEENTH DEFENSE

65 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

66 To the extent Plaintiff failed to take reasonable steps or seek appropriate medical care upon her discovery of any problem with the product, she has failed to mitigate her damages and therefore her causes of action are barred in whole or part

FOR A SIXTEENTH DEFENSE

67 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

68 Plaintiff's causes of action are barred by the terms of her informed consent

FOR A SEVENTEENTH DEFENSE

69 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

70 Plaintiff's claims for punitive damages should be stricken because any award of punitive damages in favor of Plaintiff would violate the United States Constitution with respect to privileges and immunities, due process and equal protection CIBA Vision alleges that Plaintiff's claims for punitive damages violate the V, VI, VII, VIII, and XIV Amendments to the Constitution of the United States, in the following particulars

(a) Plaintiff's claims for punitive damages violates the V Amendment (double jeopardy) because multiple awards of punitive damages can be imposed upon CIBA Vision for the same act or omission

(b) Plaintiff's claims for punitive damages violates the VI and XIV Amendments because such damages may be imposed based upon the burden of proof applicable in civil cases whereas punitive damages are a fine or penalty and are quasi-criminal in nature,

(c) Plaintiff's claims for punitive damages violate CIBA Vision's right to access to the Courts guaranteed by the VII and XIV Amendments because the threat of an award of unlimited punitive damages prevents CIBA Vision's full exercise of that right,

(d) Plaintiff's claims for punitive damages violates the VIII Amendment guaranty that excessive fines shall not be imposed,

(e) Plaintiff's claims for punitive damages violate due process and equal protection clauses of the XIV Amendment for the following reasons

(1) The standard or test determining the requisite mental state of CIBA Vision for imposition of punitive damages is void for vagueness,

(2) There is a lack of objective guidelines on which a finder of fact might base its award and further, the guidelines which do exist are arbitrary and void for vagueness,

(3) Insofar as punitive damages are not measured against actual injury to the Plaintiff and are left wholly to the discretion of the jury, there is no objective standard that limits the amount of such damages that may be awarded, and the amount of punitive damages that may be awarded is indeterminant at the time of CIBA Vision's alleged egregious conduct

(4) The tests or standards for the imposition of punitive damages differ from state to state such that a specific act or omission of a given defendant may or may not result in the imposition of punitive damages or may result in differing amounts of punitive damages depending upon the state in which suit is filed such that the defendant is denied equal protection of the law and

(5) Punitive damages may be imposed without a requisite showing of ill will or wrongful motive

Furthermore, any award of punitive damages is further limited by the United States Supreme Court s decision in *State Farm v Campbell*, 123 S Ct 1513 (2003)

FOR A EIGHTEENTH DEFENSE

71 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

72 Plaintiff's claims for punitive damages should be stricken because any award of punitive damages in favor of Plaintiff would violate the South Carolina Constitution with respect to privileges and immunities due process and equal protection Furthermore, any award of punitive damages is further limited by the United States Supreme Court s decision in *State Farm v Campbell* 123 S Ct 1513 (2003)

FOR A NINETEENTH DEFENSE

73 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

74 Plaintiff's claim for a jury trial as to the amount of punitive damages fails because Plaintiff has no right to have a jury determine the appropriate amount of punitive damages

FOR A TWENTIETH DEFENSE

75 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

76 Plaintiff's claims may be barred by the Doctrine of Spoliation of Evidence

FOR A TWENTY-FIRST DEFENSE

77 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

78 To the extent Plaintiff has received compensation from other sources as a result of the claims alleged in the Amended Complaint, CIBA Vision is entitled to a set-off

FOR A TWENTY-SECOND DEFENSE

79 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

80 The Amended Complaint should be dismissed to the extent that any injuries or expenses incurred by the Plaintiff were caused in whole or in part by any third party or other person or entity for whose conduct CIBA Vision was not responsible or with whom CIBA Vision had no legal connection

FOR A TWENTY-THIRD DEFENSE

81 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

82 The Amended Complaint should be dismissed to the extent that Plaintiff's claims are barred by virtue of the intervention of a learned intermediary or intermediaries to whom CIBA Vision discharged any duty

FOR A TWENTY-FOURTH DEFENSE

83 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

84 The Amended Complaint should be dismissed to the extent that any injuries or expenses incurred by the Plaintiff were caused by any pre-existing and/or unrelated medical conditions injuries, or illnesses

FOR A TWENTY-FIFTH DEFENSE

85 CIBA Vision realleges and incorporates each of the proceeding paragraphs as if fully set forth herein

86 Plaintiff's Cause of Action for strict liability fails because the FreshLook Color contact lens is a prescriptive medical device pursuant to the South Carolina Defective Products Act and Restatement of Torts (Second) § 402A (e g , comment k)

CROSSCLAIM AGAINST KIMS DOLLAR STORE

(Indemnification/Contribution)

87 CIBA Vision realleges and incorporates each of the preceding paragraphs as if fully incorporated herein

88 In the event Plaintiff establishes liability against CIBA Vision for damages based upon the allegations contained in the Complaint against CIBA Vision with respect to alleged negligence defects acts, or omissions regarding its product, CIBA Vision asserts that such liability is based upon the acts and/or omissions of Kims Dollar Store and will establish that the acts and/or omissions of Kims Dollar Store were the sole and/or proximate cause of Plaintiff's damages

89 In the event Plaintiff establishes liability for negligence, defects acts, or omissions regarding CIBA Vision's product, CIBA Vision alleges that it is without fault with respect to the sale and distribution of its products and with respect to any modifications to its products or product packaging and is therefore entitled to judgment against Kims Dollar Store for full and complete contractual and/or equitable indemnity against such liability plus costs, expenses and attorneys fees

90 In the alternative to its claim of indemnification in the event Plaintiff establishes liability for negligence, defects, acts, or omissions regarding CIBA Vision's product, CIBA Vision alleges that the negligence of Kims Dollar Store joined and concurred with its negligence if any and therefore, CIBA Vision is entitled to judgment against Kims Dollar Stores for contribution pursuant to S C Code § 15-38-20

WHEREFORE, Defendant Novartis Pharmaceuticals Corporation d/b/a CIBA Vision Corporation, having fully answered the Amended Complaint prays that it be dismissed with costs and for other and further relief as the Court may deem just and proper

Keith D Munson (S C Bar #13400)
Sandi R Wilson (S C Bar #16896)
WOMBLE CARLYLE SANDRIDGE & RICE
a Professional Limited Liability Company
104 S Main Street Suite 700
P O Box 10208
Greenville, SC 29603
(864) 255-5400

Attorneys for CIBA Vision

March 28, 2005
Greenville, South Carolina

RECEIVED
MAR 28 2005
McNair Law Firm, PA

STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND	)	
Monica Weston,	)	Civil Action No 05-CP-40-0655
	)	
Plaintiff,	)	
	)	**DEFENDANT CIBA VISION'S**
v	)	**MOTION FOR SUMMARY JUDGMENT**
	)	
Kims Dollar Store and CIBA Vision, a division of Novartis Company,	)	
	)	
Defendants	)	
	)	

PLEASE TAKE NOTICE that Defendant CIBA Vision, through counsel, will move before the presiding judge of the Richland County Court of Common Pleas at such time and place as the Court may determine prior to the trial of this case, but no sooner than ten (10) days after service hereof, for an order pursuant to Rule 56 of the South Carolina Rules of Civil Procedure granting CIBA Vision summary judgment in its favor on the basis that each of Plaintiff's claims are preempted by federal law pursuant to the Medical Device Amendments of 1976 to the Federal Food, Drug & Cosmetic Act

I INTRODUCTION

Plaintiff alleges that she suffered permanent injury in one eye as a result of wearing non-corrective contact lenses manufactured by CIBA Vision and purchased by Plaintiff at Kims Dollar Store ("Kims"), an unauthorized seller, in or about March 2004 [1] Kims is not affiliated with CIBA Vision in any way Plaintiff alleges that federal and state law require non-corrective

[1] Although Plaintiff alleged permanent blindness (Am. Compl ¶ 21) she underwent successful surgery to restore her vision last fall, as evidenced by medical records recently produced by Plaintiff (See Pl Supp Resp to Def Req to Prod Nos 1 3,5 &6)

contact lenses to be sold "on the order of a licensed eye care professional," and that CIBA Vision knew "that these decorative contact lenses were being marketed and distributed directly to consumers without a prescription, through unlicensed sources such as flea markets, convenient stores, and beauty supply stores " (Am Compl ¶¶ 9-11)

Plaintiff alleges the following basis for liability against CIBA Vision and Kims (1) negligence per se based on violation of S C Code §§ 40-37-10 and 40-37-260 by "practicing optometry dispensing and causing to be dispensed prescription lenses outside the care of a licensed optometrist" and violation of S C Code Ann § 39-25-20 et seq by 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, (4) strict liability for placing a defective product into the stream of commerce, pursuant to S C Code § 15-73-10, (5) sale of a defective product, and (6) violation of the SCUTPA by committing an unfair or deceptive act or practice in the conduct of trade or commerce Because the Medical Device Amendments of 1976 to the Federal Food, Drug & Cosmetic Act preempts all of Plaintiff's claims, CIBA Vision moves for summary judgment

II PLAINTIFF'S ALLEGATIONS

Plaintiff alleges that CIBA Vision manufactures non-corrective contact lenses under the trade name FreshLook Colors [2] (Am Compl ¶ 3) FreshLook Colors lenses are worn to change the eye's color or appearance [3] (Am Compl ¶ 7) In addition, Plaintiff acknowledges that

[2] CIBA Vision manufactures FreshLook Color contact lenses in a broad range of corrective powers, both negative powers (for nearsightedness) and positive powers (for farsightedness) This range includes a zero power, which is non-corrective

[3] Although a significant majority of FreshLook Color lenses are worn primarily to correct vision

"Federal and South Carolina law require that these lenses be sold by or on the order of a licensed eye care professional" (Am Compl ¶ 9)

Plaintiff alleges that on or about March 12, 2004, she purchased two pairs of FreshLook Colors lenses from Kims (Am Compl ¶ 12) Kims was not an authorized distributor of the contact lenses and did not ask Plaintiff for a prescription or provide Plaintiff with any instructions regarding the use or care of the lenses (Am Compl ¶¶ 13, 14, Def Kims' Dep [4] at 58) Plaintiff further alleges that after wearing the lenses she bought at Kims on two occasions, Plaintiff developed an eye infection, which led to temporary blindness in her left eye [5] (Am Compl ¶18-21)

Plaintiff alleges in Count I that the labeling on the FreshLook Colors lenses "was misleading and lacked adequate information about the safe and effective uses of the FreshLook Lenses" and failed to provide adequate warnings of possible complications to the eye from wearing FreshLook Lenses [6] (Am Compl ¶¶ 28-29) Plaintiff alleges in Count II that CIBA Vision's failure to warn and improper labeling were violations of S C Code §§ 40-37-10 and 40-37-260 (Am Compl ¶ 38-43) In Count III, Plaintiff alleges that Defendants are liable for breach of implied warranty of merchantability Count IV of the Amended Complaint alleges that Defendants are strictly liable to Plaintiff because the FreshLook Colors lenses were "in a defective and unreasonably dangerous condition at the time they were placed into the stream of

[4] Seo Ha was the Rule 30(b)(6) deponent for Defendant Kims Dollar Store References to his deposition will be cited hereinafter as Def Kims' Dep ' and excerpts are attached as **Exhibit A.**

[5] Review of Plaintiff's medical records reveals that her non compliance with medical treatment is likely what led to her blindness

[6] Plaintiff purchased individual contact lenses blister packs, which were marked as not to be sold individually and as requiring a medical prescription Each blister pack is about the size of individually portioned half & half coffee creamer containers

commerce," and because the lenses "contained insufficient and/or inadequate warnings" (Am Compl ¶ 62) In Count V, Plaintiff alleges that Defendants are liable under S C Code Ann § 15-73-10, because FreshLook Colors lenses "were a defective product due to inadequate warnings and inadequate instructions" (Am Compl ¶¶ 71-72) Finally, Plaintiff alleges that the Defendants' acts constitute "unfair methods of competition and unfair deceptive [sic] acts or practices in the conduct of any trade or commerce," in violation of the SCUTPA

For the reasons set forth below, Plaintiff's claims are completely preempted by federal law, specifically by the Medical Devices Amendments to the Food, Drug, & Cosmetic Act

III SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate "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" Rule 56(c), SCRCP, Baushman v Am Telephone & Telegraph Co, 306 S C 101, 410 S E 2d 537, 545 (1991) Summary judgment is designed to save valuable trial time and thus assist in securing speedy and inexpensive justice Royster Co v Eastern Distribution, Inc, 301 S C 18, 389 S E 2d 863, 864 (1990) In determining whether any triable issues of fact exists, the Court is not "'required to single out some one morsel of evidence to create an issue of fact that is not genuine'" Englert, Inc v Netherlands Ins Co, 315 S C 300, 302, 433 S E 2d 871, 873 (Ct App 1993) (quoting Main v Corley, 281 S C 525, 527, 316 S E 2d 406, 407 (1984))

A party's response to a motion for summary judgment "must set forth specific facts, admissible in evidence, showing there is a genuine issue for trial If he does not so respond, summary judgment should be entered against him" Moody v McLellan, 295 S C 157, 163, 367

S E 2d 449, 453 (1988) (citations omitted) Moreover, if the plaintiff fails to establish a genuine issue of fact as to just one essential element necessary to the cause of action, the existence of factual issues relating to other elements becomes immaterial and therefore subject to summary judgment Hooven-Lewis v Caldera, 249 F 3d 259, 265 (4th Cir 2000), Geiserman v MacDonald, 893 F 2d 787, 793 (5th Cir 1990) (citing Celotex Corp v Catrett, 477 U S 317, 323 (1986)), Fender & Latham, Inc v First Union Nat'l Bank, 316 S C 48, 446 S E 2d 448, 449 (1995) As Judge Winter aptly concluded in Bland v Norfolk and Southern Railroad Co., the function of a motion for summary judgment is to smoke out if there is any case, and, if there is no case, to conserve judicial time and energy by avoiding an unnecessary trial by providing a speedy and efficient summary disposition " 406 F 2d 863, 866 (4th Cir 1969)

IV LEGAL ARGUMENTS AND AUTHORITIES

In conjunction with discussing why Plaintiff's causes of action are completely preempted by the Medical Device Amendments of 1976 to the Federal Food, Drug, & Cosmetic Act, it is necessary briefly to describe the method by which the FDA approves medical devices and the device-specific conditions and requirements imposed by the FDA for approval, including the approval of the FreshLook Colors lenses at issue in this case

A The FDA Review Process for Medical Devices

As part of the Medical Devices Amendments of 1976 ("MDA"), Pub L No 94-295, to the Food, Drug, & Cosmetic Act ("FDCA"), 21 U S C § 321 et seq., as amended by the Safe Medical Devices Act of 1990, Pub L No 101-629, the FDA classifies medical devices into three categories See FDCA § 513(a)(1), 21 U S C § 360c(a)(1) Class I devices tend to be simple and common articles, such as bedpans and wheelchairs Class II devices are more

complex but are usually similar to existing devices Both classes of devices may be marketed with only general controls

In contrast, Class III devices may only be marketed pursuant to FDA premarket approval ("PMA") See FDCA § 515, 21 U S C § 360e This process is rigorous To obtain PMA for a Class III device, manufacturers must submit detailed information to the FDA regarding the safety and efficacy of their devices As the Seventh Circuit explained in a case finding federal preemption of product liability claims similar to those alleged by Plaintiff and based on products approved by the FDA through the PMA process

> Before a Class III device may be introduced to the market, the manufacturer must provide the [FDA] with a reasonable assurance that the device is safe and effective under the MDA To provide that assurance, a manufacturer must obtain premarket approval ("PMA") from the FDA This procedure is a "rigorous" process, in which the manufacturer must submit detailed information to the FDA regarding the safety and effectiveness of the device Manufacturers must provide the FDA with samples of the device, an outline of the device's components and properties, a description of the manufacturing process, copies of the proposed labels, various other data and information, and any other information the FDA requests The FDA spends an average of 1,200 hours per PMA application reviewing these materials

Mitchell v Collagen Corp , 126 F 3d 902, 905 (7th Cir 1997), cert denied, 523 U S 1020 (1998)

PMA approval culminates in Conditions of Approval issued by the FDA that incorporate the design and labeling approved by the FDA for the device Once approved, the manufacturer is required to comply with the design, manufacturing processes, and labels specified in the PMA See 21 C F R §§ 814 39, 814 80 Among other things, "[t]he FDA retains rigid control over the entirety of the labeling and packaging of Class III products " King v Collagen Corp , 983 F 2d 1130, 1135 (1st Cir 1993) The FDA's control extends to the size and location of a warning on a

label, as well as the warning's content See 21 U S C § 360e(c)(1) & 21 C F R §§ 801 4, 801 5, 801 15, & 814 20(b)(10) (1995) A medical device maker must submit a proposed label to the FDA for analysis and review prior to obtaining PMA for the product 21 U S C § 360e(d)(2)(A), (B), & (D)

Changes affecting the safety and effectiveness of the device require detailed documentation, reporting, and FDA approval See 21 C F R § 814 39 Further, once a PMA medical device is on the market, it remains subject to extensive and continuing regulation by the FDA See Brooks v Howmedica, Inc , 273 F 3d 785, 789, 799 (8th Cir 2001) (en banc), cert denied, 535 U S 1056 (2002), McMullen v Medtronic, Inc , 2005 WL 2043827, at *4 (7th Cir 2005) (discussing post-approval requirements), see also 21 C F R. §§ 814 80-814 84 Moreover, the FDA has a wide range of available remedies, including revoking device approval, if the manufacturer fails to comply with requirements imposed by the PMA process [7]

FDA regulations also permit manufacturers to seek approval for device modifications by submitting supplements to a prior PMA *"All procedures and actions that apply to [a PMA] application also apply to PMA supplements"* 21 C F R § 814 39 (emphasis added) The PMA supplement 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 At the same time, *the entirety of the PMA*, including all supplements, are "'before' the agency at the time the supplement is reviewed" 51 Fed Reg 26342, 26354 (1986) *"FDA considers revisions proposed in a PMA supplement using the same type of rigorous scientific*

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

process utilized for review of original PMAs " See FDA Letter Brief filed as *amicus curiae*, Horn v Thoratec, 376 F 3d 163 (3d Cir 2004), available at 2004 WL 1143720, at *10 (May 14, 2004) (emphasis added) [8]

B PMA Approval Establishes Device-Specific Requirements

"[F]ederal requirements specific to individual products are imposed through the PMA process " McMullen, 2005 WL 2043827 at *4 The FreshLook Colors lenses are a Class III medical device approved by the FDA pursuant to the PMA supplement process (Affidavit of Paul Oris ¶¶ 3-4)[9] See Tarallo v Searle Pharmaceutical, Inc , 704 F Supp 653, 656 (D S C 1988) ("Included in this [Class III] category are soft contact lenses and associated agents and solutions ") Therefore, the FreshLook Colors lenses at issue in this case were subject to stringent FDA requirements and scrutiny (Oris Aff ¶¶ 3-4) Before FreshLook Colors lenses could be sold commercially in the United States, CIBA Vision was required in the PMA and PMA supplement processes to provide the FDA with assurances that the lenses are both safe and effective (Id ¶ 5) The submissions for CIBA's contact lenses, including FreshLook Colors lenses, are voluminous The FDA employs experts to analyze the submissions and evaluate the safety and efficacy of these Class III devices See Buckman Co v Plaintiffs' Legal Comm , 531 U S 341 (2001), Horn amicus brief at *6-9 This analysis includes consideration of the application, clinical data, manufacturing processes, and proposed labeling 21 U S C § 360e(c)

[8] Hereinafter Horn amicus brief attached hereto as **Exhibit B**

[9] Paul Oris is the Head of Global Regulatory Affairs at CIBA Vision References to his affidavit will be cited hereinafter as Oris Aff ¶ __ ' which is attached as **Exhibit C**

As the Eighth Circuit has explained, "Through its approval of the PMA application and its continuing series of directives, the [FDA] impose[s] specific federal requirements on [the manufacturer] Brooks, 273 F 3d at 798 Similarly, the Seventh Circuit has observed that

> [T]he PMA process can constitute the sort of specific federal regulation of a product that can have preemptive effect During the PMA process, the federal government, it can truly be said, has "weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers "

Mitchell, 126 F 3d at 911 (citations omitted), see also McMullen, 2005 WL 2043827 at *4 Courts in the Third, Fifth, and Sixth Circuits agree See, e g , Horn v Thoratec Corp , 376 F 3d 163 (3rd Cir 2004), Martin v Medtronic, Inc , 254 F 3d 573, 583-84 (5th Cir 2001), cert denied, 534 U S 1078 (2002), Kemp v Medtronic, Inc , 231 F 3d 216 (6th Cir 2000), cert denied, 534 U S 818 (2001)

C **The MDA Preempts Plaintiff's State Law Claims**

State law that conflicts with federal law is preempted under the Supremacy Clause of the United States Constitution U S Const , Art VI, cl 2 Preemption may occur when (1) Congress expressly preempts state regulation, (2) Congress intends federal law to "occupy the field," or (3) state law conflicts with federal law Crosby v Nat'l Foreign Trade Council, 530 U S 363, 372 (2000) A state law may be either expressly or impliedly preempted by federal law The question of federal preemption under the MDA is a question of law for the court to decide See Cox v Shalala, 112 F 3d 151 (4th Cir 1997)

Pursuant to the MDA, the FDA regulates the marketing and sale of prescription medical devices in the United States Congress enacted the MDA in 1976 to expand the FDA's authority to regulate medical devices, while also protecting innovations in device technology from being

stifled by unnecessary restrictions H R Rep No 94-853 at 12-13 (1976), reprinted in 1976 U S C C A N 1070, Slater v Optical Radiation Corp , 961 F 2d 1330, 1331 (7th Cir 1992) The MDA *expressly* preempts certain state law requirements governing medical devices

> [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 [Act] 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 [Act]*

21 U S C § 360k(a) (emphasis added) In applying § 360k, "virtually every court which has addressed this issue has concluded that preemption under the MDA extends to state court tort claims " Scott v CIBA Vision Corp , 38 Cal App 4th 307, 316 (Cal Ct App 1995) (citing six federal appellate court decisions and one Supreme Court decision) [10] Logically, an intention to preempt state laws different from, or in addition to, any requirement relating to the safety or effectiveness of a medical device under the MDA must include tort claims triable by a jury, since "jury-set standards in reality constitute new requirements which defendants must heed " Hunsaker v Surgidev Corp , 818 F Supp 744, 751 (D Pa 1992) A damages award is a form of regulation no less effective than a statute San Diego Bldg Trades Council v Garmon, 359 U S 236, 245 (1959) See, e g , Brooks, 273 F 3d at 796 ("A jury finding on negligent failure to warn would be premised on the fact that the label for [the device] was not written in a particular way or did not contain certain information This would be equivalent to a state regulation imposing specific label requirements")

In fact, the FDA itself "has made clear that the 'State requirement' referred to in section 360k includes any requirement having the force and effect of law 'whether established by statute, ordinance, regulation, *or court decision* '" Scott, 38 Cal App 4th at 317 (quoting 21

[10] A copy of this decision is attached as **Exhibit D**

C F R § 808 1(b) (1995)) The FDA's views on preemption should substantially inform a court's consideration of the MDA's preemption provision See Medtronic, Inc v Lohr, 518 U S 470, 495-96 (1996) According to the FDA

> State common law tort actions threaten the statutory framework for the regulation of medical devices, particularly with regard to FDA's review and approval of product labeling State actions are not characterized by centralized expert evaluation of device regulatory issues Instead, they encourage, and in fact require, lay judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population – the central role of FDA – sometimes on behalf of a single individual or group of individuals That individualized redetermination of the benefits and risks of a product can result in relief – including the threat of significant damage awards or penalties – that creates pressure on manufacturers to add warnings that FDA has neither approved, nor found to be scientifically required, or withdrawal of FDA-approved products from the market in conflict with the agency's expert determination that such products are safe and effective This situation can harm the public health by retarding research and development and by encouraging "defensive labeling" by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments

Horn amicus brief

As the FDA has further noted, in a statement of interest critical of the putative expert report of Suzanne Parisian in another matter (ironically the same expert retained by Plaintiff in this case) "Congress enacted the MDA and vested in FDA the authority to implement its provisions, including making a determination whether Class III devices meet the PMA approval standard of a 'reasonable assurance of safety and effectiveness ' It is within FDA's discretion to determine the quantity and quality of data necessary to meet this standard and it is a scientific task for which FDA is *uniquely qualified* " Statement of Interest of the United States of America at 9, Murphree v Pacesetter, Inc , Civil No CT-005429-00-3 (Tenn Cir Ct Dec 12, 2003)

(citations omitted) (emphasis added) [11] One of the explicit goals of the MDA is "national uniformity in product regulation" Brooks v Howmedica, Inc, 273 F 3d 785, 797 (8th Cir 2001) (en banc) cert denied, 535 U S 1056 (2002) [12]

Further, legislative history indicates this was the reason the preemption provision was included within the MDA "[I]f a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened" H R Rep No 94-853 at 45 As the Federal Government has noted in emphasizing the policy concerns that underlie preemption, the "*prospect of hundreds of individual juries determining the propriety of particular device approvals or the appropriate standards to apply to those approvals is the antithesis of the orderly scheme Congress put in place and charged FDA with implementing*" Murphree Statement of Interest (emphasis added)

In construing the preemptive effect of the MDA, five Circuit Courts of Appeal – the Third, Fifth, Sixth, Seventh, and Eighth – have held that PMA approval of a medical device by the FDA results in device-specific federal requirements that preempt inconsistent state requirements, including those sought to be imposed through tort liability See Horn v Thoratec Corp, 376 F 3d 163 (3rd Cir 2004), Martin v Medtronic, Inc, 254 F 3d 573 (5th Cir 2001), Kemp v Medtronic, Inc, 231 F 3d 216 (6th Cir 2000), cert denied, 534 U S 818 (2001), McMullen v Medtronic, Inc, 2005 WL 2043827, at *4 (7th Cir 2005), Brooks v Howmedica, Inc, 273 F 3d 785 (8th Cir 2001) (en banc) The Fourth Circuit has similarly held that the MDA preempts tort claims involving medical devices approved under the 510(k) exemption for Class II

[11] References to this Statement of Interest will be cited hereinafter as 'Murphree Statement of Interest, and excerpts are attached as **Exhibit E**

[12] In fact the FDA itself recently stated that it intends to preempt the field of state laws with regard to labeling of prescription drugs See 21 C F R. parts 201, 314 601 71 Fed Reg 3 922, 3 934, 3,969 and 3 935-36 (January 24 2006) This clearly evinces a belief that FDA regulation pursuant to the FDCA preempts additional or contrary state law requirements

devices. See Murphy v. Playtex Family Prods., 69 Fed Appx. 140, 2003 WL 21470312 (4th Cir 2003) (holding that the specific requirements for tampon labeling preempts state law failure-to-warn claims)

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

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

Id at 909-910

In Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), a majority of the Supreme Court agreed that state law actions, including state law duties of general applicability, are preempted to the extent they impose conditions on a device manufacturer that are different from or in addition to the kind of federal requirements that trigger the MDA's express preemption provision See Lohr, 518 U S at 503-05 (O'Connor, J , Rehnquist, C J , Scalia, J , and Thomas, J , concurring and dissenting), 509-11 (Breyer, J , concurring in part) [13] Consistent with the concurrences in Lohr, federal appellate courts have overwhelmingly concluded that common-law tort actions are subject to preemption under the MDA See Horn, 376 F 3d at 175-76, Martin, 254 F 3d at 579-80, Kemp, 231 F 3d at 223-24, Mitchell, 126 F 3d at 911-13

Thus, the question is not whether the state common law and statutory causes of action asserted by Plaintiff were developed specifically with respect to FreshLook Colors lenses, but whether the resolution of Plaintiff's claims could impose a state requirement that is in addition to or different from those imposed by the FDA pursuant to the PMA and PMA supplement processes As the Eighth Circuit made plain in Brooks, a judgment on Plaintiff's causes of action would do just that "The state requirement in this case would come from a common law duty as applied by an individual jury" Id at 797 In this case, Plaintiff's state law product liability claims of negligence per se, negligence, breach of implied warranty, strict liability and sale of a defective product, as well as violation of the SCUTPA, are preempted because they would, if accepted by the jury, impose state requirements which are different from or in addition to the federal requirements applicable to the device

Such allegations are necessarily an attack on the design and labeling of a device approved by the FDA and, "once the FDA approves a specific design, that design becomes in effect the

[13] Moreover, construing another preemption statute the Supreme Court recently reiterated that 'the term 'requirements reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties" Bates v Dow AgroSciences LLC, 125 S Ct 1788, 1798 (2005) see also Geier v Am. Honda Motor Co , 529 U S 861 897 (2000) (Stevens, J , dissenting) (noting that a majority of the Supreme Court in Lohr agreed that common-law tort actions may be preempted under the MDA's preemption clause), accord McMullen, 2005 WL 2043827 at *4 (citing Bates and Geier for this proposition)

FDA requirement" Easterling v Cardiac Pacemakers, Inc , 986 F Supp 366, 374 (E.D. La. 1997) Therefore, any state requirements imposed by a jury verdict in favor of Plaintiff's causes of action in this case would be in addition to or in contradiction of federal requirements Accordingly, under well-established principles of preemption enumerated by statute and adopted by numerous state and federal courts, many of which involve causes of actions virtually identical to those alleged here, Plaintiff's causes of action under South Carolina law should be preempted

V CONCLUSION

For all the foregoing reasons, CIBA Vision is entitled to summary judgment with respect to each of Plaintiff's claims

Keith D Munson (S C Bar #13400)
Sandi R Wilson (S C Bar #16896)
James J Pascoe (S C Bar # 71104)
WOMBLE CARLYLE SANDRIDGE & RICE
a Professional Limited Liability Company
104 S Main Street, Suite 700
P O Box 10208
Greenville, SC 29603
(864) 255-5400
Attorneys for Defendant CIBA Vision

June 7, 2006
Greenville, South Carolina

COPY OF TRANSC ᵖT

IN THE COURT OF COMMON PLEAS
STATE OF SOUTH CAROLINA
COUNTY OF RICHLAND

MONICA WESTON,

Plaintiff,

vs

CASE NO 05-CP-40-0655

KIMS DOLLAR STORE and CIBA VISION, a division of Novartis Company,

Defendants

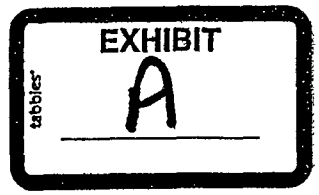
30(b)(6) DEPOSITION OF

SEO HA

August 9, 2005
10 05 a m

Young & Sullivan
907 Calhoun Street
Columbia, South Carolina

Ashley James, Court Reporter



Alexander Gallo & Associates, Inc.
COURT REPORTING & VIDEO SERVICES
TRIAL PRESENTATIONS
ATLANTA'S TECHNOLOGICAL LEADERS IN LITIGATION SUPPORT & MULTIMEDIA PRESENTATIONS

ATLANTA GEORGIA WASHINGTON DC CHICAGO ILLINOIS NEW YORK NEW YORK

Telephone (404) 495-0777
Facsimile (404) 495 0766
Toll Free (877) 495-0777

Complimentary Conference Rooms
Throughout Georgia And
Major Cities Nationwide

500 The Candler Building
127 Peachtree Street
Atlanta Georgia 30303

Plus or the resale of contact lenses by those stores?

[Question translated]

MR FORKER He say he hasn't -- he didn't never saw that it was purchasing or selling of the contact lens He never seen it and mostly he did it himself, so he -- the Paul Ha doesn't have any transaction

Q From what companies did Kims Dollar Plus purchase contact lenses?

[Question translated]

A SK

MR FORKER SK

[Discussion between translator and deponent]

MR FORKER He does not remember exact company name, it's SK something

Q Was it SK Enterprises Group?

[Question translated]

A Yeah

MR FORKER Yes

Q Did Kims Dollar Plus purchase contact lenses from any other vendors?

[Question translated]

A No

deponent]

MR. FORKER There was no pictures except writing

Q At any point in time, did you employee any licensed eye care professionals at Kims Beauty or Kims Dollar Plus?

[Question translated]

A No

MR FORKER No

Q Did you ever obtain a license to sell contact lenses at either Kims Dollar Plus or Kims Beauty?

[Question translated]

A No

MR FORKER No

Q Tell me about your procedure with regard to the sale of contact lenses to customers?

[Question translated]

MR FORKER When the customer came into the store, look for the contact lens, and he ask what color the contact lens they wanted and then they sell

Q Did you provide the customer with any instructions regarding the use or care of

2004 WL 1143720 (3rd Cir)

For opinion see 376 F 3d 163

Briefs and Other Related Documents

United States Court of Appeals
Third Circuit
HORN
v
THORATEC
No 02-4597
May 14 2004

Amicus Brief

Marcia Waldron Clerk United States Court of Appeals for the Third Circuit 21400 United States Courthouse 601 Market Street Philadelphia 19106- 1790

***1** Dear Ms Waldron

This letter-brief is being filed on behalf of the United States as *amicus curiae* in response to this Court s letter of February 27 2004 After briefing and oral argument by the parties the Court requested the views of the United States Food and Drug Administration (FDA) on the following issue

With respect to the Thoratec Heartmate which was reviewed by FDA are state common law claims of design defect labeling strict liability negligence and failure to warn preempted by § 360(a) of the Medical Device Amendments to the Food Drug and Cosmetic Act?

As explained in this letter the United States believes that Section 521 (a) of the Federal Food Drug and Cosmetic Act (FDCA) 21 U S C § 360k(a) does preempt these state common law claims because they would impose a requirement different ***2** from or in addition to the requirements imposed by FDA in granting pre-market approval to the Thoratec HeartMate [FN1] The Government believes that this view is compelled in order to achieve Congress s important public health protection purposes carried out through FDA s implementation of the FDCA

FN1 Although the Court s letter refers to the pre-emption provision as codified at Section 360(a) it actually appears at 21 U S C § 360k(a)

I Interests of the United States

The United States has a strong interest in the pre-emption question before the Court and appreciates the fact that the Court has sought our views

In this case the Court must determine whether federal law preempts claims brought under Pennsylvania common law alleging defects in the design manufacture

© 2006 Thomson/West No Claim to Orig U S Govt Works



2004 WL 1143720 (3rd Cir)

labeling and warnings pertaining to a Class III medical device that was approved by FDA in 1994 after undergoing the agency s pre-market approval process Because FDA is responsible for regulating the safety and effectiveness of medical devices and the conditions for their design manufacture performance labeling and use the United States has a substantial stake in ensuring that state common law tort judgments do not interfere with implementation of this important federal scheme As we explain below we believe that in the FDCA Congress provided that FDA pre-market approval for a new medical device preempts state law tort judgments that do *3 not merely effectuate the regulation of that device imposed by the agency A contrary rule would undermine overall public health protection

We acknowledge that as the briefs filed by the private parties reveal this position represents a change for the United States In an *amicus* brief filed in the Supreme Court in 1997 at the Court s invitation in *Smiths Industries Medical Systems Inc v Kernats cert denied* 522 U S 1044 (1998) (No 96- 1405) the Government stated that 21 U S C § 360k(a) does not preempt a state tort law claim concerning an FDA-approved device We explain in this letter-brief that based on further analysis of the relevant legal and policy issues by FDA the agency charged with administering the MDA and implementing its preemption provisions - - as well as the recent rulings by several courts of appeals and state courts- - the Government has instead determined that state tort claims such as those raised here are indeed preempted with respect to FDA-approved devices This change in views has not been taken lightly and we assure the Court that the filing of this letter taking this position has been authorized by the Solicitor General

II Nature of The Case

This letter-brief is predicated on the following understanding of this case drawn from the parties briefs

*4 Plaintiff the executrix of the estate of her late husband Daniel Ray Horn brought this suit against Thoratec Corporation formerly known as Thermo Cardiosystems Inc (TCI) for negligence strict liability and breach of warranty TCI made a device called the HeartMate Implantable Left Ventricular System (HeartMate) which was implanted inside Mr Horn who was awaiting a heart transplant As explained below the HeartMate is a Class III medical device that received pre-market approval from FDA in 1994 following the agency s extensive investigation into the device s safety and effectiveness

Mr Horn experienced difficulties with the device and died shortly after undergoing exploratory surgery to determine the cause of his medical problems

Plaintiff s allegations in her complaint focus upon one aspect of the design and manufacture of the HeartMate a screw ring that attached the elbow of the device to the body of the heart pump and that was secured to the device by a suture Plaintiff presented state tort claims sounding in strict liability negligence and breach of warranty and fitness for intended use These claims rested on allegations of defective design defective manufacture and failure to warn More specifically plaintiff makes two main claims first that TCI should have employed a design to prevent the screw rings used to hold the device in place

© 2006 Thomson/West No Claim to Orig U S Govt Works

inside the patient s chest from becoming disconnected (plaintiff asserted that TCI overlooked better alternatives to the design *5 it chose) second that TCI should have issued warnings to doctors through either revisions in the product labeling or correspondence to health care professionals (commonly called Dear Doctor letters) against using the device if the suture as placed in the device packaging would face the patient s sternum

TCI moved for summary judgment on the ground that FDA s approval of the device for marketing under the 1976 Medical Device Amendments to the FDCA (the MDA) which are codified at 21 U S C §§ 360c-360k expressly preempted plaintiff s state law claims which sought to impose requirements different from or in addition to requirements imposed through the agency s pre-market approval process Plaintiff has appealed the district court s grant of summary judgment

III Statutory and Regulatory Background

The contours of the underlying statutory scheme governing FDA regulation of medical devices and the practice under that scheme are crucial in understanding the preemption issue here In enacting the MDA Congress established a comprehensive plan for regulation by the Department of Health and Human Services (HHS) of medical devices HHS has delegated this task to FDA

A The MDA creates three classes of medical devices which receive different levels of regulation Class III medical devices are those (1) for which there is insufficient information to determine that general controls and special controls are *6 adequate to provide reasonable assurance of safety and effectiveness and (2) that are purported or represented to be for a use in supporting or sustaining human life or for use of substantial importance in preventing impairment of human health or that present a potential unreasonable risk of illness or injury 21 U S C § 360c(a)(1)(C) Class III devices are subject to the most stringent regulatory controls of all device classes

B Under the MDA the manufacturer of a Class III medical device must obtain FDA s approval of a premarket approval application (a PMA) before marketing the device in interstate commerce (unless the device is not subject to the PMA requirement) 21 U S C § 360e

A manufacturer seeking the necessary FDA approval must submit an application containing full reports of clinical investigations whether adverse or supportive known to or that should reasonably be known to the applicant and that concern the safety or effectiveness of the device 21 U S C § 360e(c)(1)(A) 21 C F R § 814 20(b)(8)(i) The manufacturer s application must contain a full statement of the components ingredients properties and principles of operation of the device 21 U S C § 360e(c)(1)(B) It must include a full description of the methods used in and the facilities and controls used for the manufacture processing and when relevant packing and installation of the device 21 U S C § 360e(d) The *7 PMA must identify discuss and analyze any other data information or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any source foreign or domestic including information derived from investigations

© 2006 Thomson/West No Claim to Orig U S Govt Works

other than those proposed in the application and from commercial marketing experience 21 C F R § 814 20(b)(8)(ii) Even unpublished information must be included in the PMA if it is possessed or reasonably obtainable by the applicant if requested 21 C F R § 814 20(b)(8)(iii)

The PMA must also include specimens of the labeling proposed to be used for the device 21 U S C § 360e(c)(1)(F) The proposed labeling must provide adequate directions for use 21 U S C § 352(f) FDA by regulation has defined this to mean directions under which the layman can use a device safely for its intended use 21 C F R § 801 5 Because a prescription device by definition cannot be used safely by a layperson without professional supervision FDA regulations afford an exemption from the statutory requirement of adequate directions for use for a prescription device whose labeling includes any relevant hazards contraindications side effects and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended * * * 21 C F R § 801 109(c)

*8 In reviewing a PMA FDA scientists carefully evaluate all of the data and information submitted by the manufacturer which must be periodically updated during the review process to assure the continuing completeness of the application 21 C F R § 814 37 FDA may request additional information as necessary to provide a complete and accurate picture of the product and may supplement the expertise of its in-house scientific personnel with advice from scientific advisory committees of outside experts 21 C F R §§ 14 171 814 20(b)(13) FDA regulations also specifically authorize FDA to evaluate the device s safety and effectiveness using information other than that submitted by the applicant 21 C F R § 814 45(c)

C The agency s approval of a PMA reflects its conclusion that there is a reasonable assurance of safety and effectiveness of the device under the conditions set forth in the labeling for the product 21 U S C § 360e(d) In addition PMA approval means that FDA has determined that the proposed labeling for the device complies with the detailed labeling requirements set forth in 21 C F R parts 801 and (if applicable) 809 and is neither false nor misleading 21 U S C § 360e(d) 21 C F R § 814 45 Preparation of a PMA and FDA s process of reviewing a PMA constitute a massive undertaking The agency s review process for a PMA is thorough and scientifically rigorous generally taking an average of 1 200 hours of review time by the agency See *Medtronic Inc v Lohr* 518 U S 470 477 (1996)

*9 Class III devices are also subject to an additional set of conditions of approval imposed by FDA pursuant to the restricted device provisions of the FDCA FDA can declare a device restricted if because of its potential for harmful effect or the collateral measures necessary to its use restrictions are necessary for there to be reasonable assurance of safety and effectiveness Restrictions on sale distribution or use may be imposed by notice-and-comment rulemaking 21 U S C § 360j(e) Restrictions on sale or distribution may also be imposed as conditions of PMA approval 21 U S C § 360e(d)(1)(B) 21 C F R § 814 82 Designation of a device as restricted triggers other provisions of the Act - most notably provisions governing the content of advertising 21 U S C §

© 2006 Thomson/West No Claim to Orig U S Govt Works

352(q) (r) The vast majority of devices covered by approved PMAs are also restricted devices

The bases for FDA s PMA approval for a device include the circumstances specified in the proposed labeling under which the device meets the statutory safety and effectiveness standard the design characteristics of the device as submitted to FDA any conditions of approval for the device identified by FDA through the PMA process and the conditions determined by FDA to be necessary if the device is a restricted device Conditions of approval are conveyed to the applicant by the agency *10 in an approval order which takes the form of a letter 21 C F R § 814 44 As the approval order states violation of any of these conditions automatically invalidates the approval See 21 C F R § 814 82(c)

Once FDA approves a Class III medical device the holder of the approval may not change the design of the device in a manner affecting its safety or effectiveness without FDA approval 21 U S C § 360e(d)(6)

In other words and of considerable significance here after FDA approves a PMA for a medical device the applicant generally may not make changes affecting the device s safety or effectiveness without the FDA s approval of the change through a PMA supplement 21 C F R § 814 39 If a manufacturer changes a device in a manner that affects its safety or effectiveness without FDA approval its distribution of the altered product is unlawful 21 C F R § 814 80

FDA considers revisions proposed in a PMA supplement using the same type of rigorous scientific process utilized for review of original PMAs 21 U S C § 360e(d)(6)(A) 21 C F R § 814 39 Changes to the design of a device that affect safety or effectiveness are approved only if nonclinical data demonstrate that the modification creates the intended additional capacity function or performance of the device and if clinical data provide a reasonable assurance of safety and effectiveness for the changed device under the conditions in the labeling *1121 U S C § 360e(d)(6)(B) FDA is authorized to require when necessary additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness *Ibid*

Certain labeling changes that enhance safety without a corresponding effectiveness impact are eligible for implementation without prior FDA approval And some manufacturing changes are also accorded special treatment 21 U S C § 360e(D)(6) 21 C F R § 814 39 Even under these circumstances the agency may disapprove a change after it has been implemented Because all other changes that could affect safety and effectiveness require FDA approval manufacturers have substantial incentives to obtain FDA agreement before a change is implemented

D Most medical devices do not undergo the FDA pre-market approval process that covered the HeartMate Class I and II devices are not subject to the PMA requirement Also in general a Class III medical device is not subject to the PMA requirement if it was marketed prior to the MDA s enactment (21 U S C § 360e(b)(1)(A)) and a regulation requiring submission of PMAs has not been issued for the device or if it is substantially equivalent to a predicate device A predicate device may be either one marketed prior to the MDA s enactment or one

© 2006 Thomson/West No Claim to Orig U S Govt Works

substantially equivalent to a device marketed prior to the statute s enactment 21 U S C § 360j(1)

*12 A manufacturer can obtain an FDA finding of substantial equivalence by submitting a pre-market notification to the agency in accordance with Section 510(k) of the FDCA 21 U S C § 360(k) A device found to be substantially equivalent to a predicate device is said to be cleared by FDA (as opposed to approved by the agency under a PMA) A pre-market notification submitted under Section 510(k) is thus entirely different from a PMA which must include data sufficient to demonstrate to FDA that the device is safe and effective See *Lohr* 518 U S at 478-79 (The § 510(k) notification process is by no means comparable to the PMA process)

The number of medical devices that receive PMA review each year is dwarfed by the number of those that are marketed pursuant to cleared section 510(k)s In fiscal year 2003 for example original PMAs represented only 54 of the 9 872 major submissions received The previous fiscal year original PMAs accounted for 49 of 10 323 total submissions [FN2]

FN2 Office of Device Evaluation Center for Devices and Radiological Health ODEFY03 Annual Report 17 (http // www fda gov/cdrh/annual/fy2003/ode/2003 pdf)

E The HeartMate is a Class III medical device A PMA was submitted for the device in March 1992 and after an extensive analysis FDA approved it in September 1994 and subsequently published a notice of the approval [FN3] See *13 61 Fed Reg 51712 (October 3 1996) FDA subsequently approved multiple PMA supplements for the HeartMate covering a variety of changes to the conditions of approval relating to labeling manufacturing and design

FN3 At the time FDA approved the HeartMate in 1994 the agency published approvals in the Federal Register Such notices advised interested persons of the right to request a formal hearing or a review of the application See 21 U S C § 360e(g) Currently FDA provides initial notice of a PMA approval on the internest and publishes a quarterly list of devices receiving PMA approval in the Federal Register 21 C F R § 818 44

IV Plaintiffs Causes of Action Are Preempted by Federal Law

The preemption issue here turns on the express preemption clause in the MDA which reads

[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 § 360k(a) Under interpretive regulations issued by FDA state or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a

© 2006 Thomson/West No Claim to Orig U S Govt Works

particular device 21 C F R §808 1(d)

As we demonstrate FDA imposed such requirements through the PMA process The manufacturer generally cannot make changes in the design labeling or *14 manufacturing processes specified in the PMA that affect safety and effectiveness without FDA approval

A The Supreme Court s ruling in *Medtronic Inc v Lohr* 518 U S 470 (1996) provides the starting point today because the Court there considered whether state tort law claims with respect to a medical device marketed under the Section 510(k) clearance process were preempted Thus the Court examined the bounds of Section 360k(a) although in a different context than in the case at bar Justice Stevens opinion in *Lohr* reflected the views of four Justices and Parts I II III V and VII of the opinion in which Justice Breyer joined constitute the opinion of the Court See 518 U S at 508 (Breyer J concurring)

In ruling against preemption in that setting the *Lohr* Court explained that federal requirements reflect[ing] important but entirely generic concerns about device regulation generally [are] not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements 518 U S at 501

In his separate opinion concurring in the Lohr judgment Justice Breyer further reasoned that given FDA s regulation implementing Section 360k(a) state requirements are preempted under the MDA where FDA has established specific counterpart regulations or other specific federal requirements applicable to a *15 particular device and a state requirement is different from or in addition to the specific FDA requirements 518 U S at 507 (Breyer J concurring) [FN4]

FN4 Most federal courts of appeals applying *Lohr* have found this to be the analysis endorsed by the Court See *Kemp v Medtronic Inc* 231 F 3d 216 (6th Cir 2000) *cert denied* 534 U S 818 (2001) *Brooks v Howmedica Inc* 273 F 3d 785 (8th Cir 2001) *cert denied* 535 U S 1056 (2002) *Mitchell v Collagen Corp* 126 F 3d 902 (7th Cir 1997) *In re Orthopedic Bone Screw Products Liability Litigation* 159 F 3d 817 822 (3d Cir 1998)

B Under this analytical framework the MDA preempts plaintiff s claims here Although FDA has issued no specific counterpart regulation for the HeartMate the agency s approval of this device through the PMA process does impose specific requirements for the product including requirements for its design manufacturing performance labeling and use In approving the PMA for the HeartMate FDA considered a variety of factors such as the risk-benefit profile of the product the nature of the medical conditions the product is intended to treat and the availability of alternative therapies See 21 U S C 360e(d) In the words of *Lohr* 518 U S at 501 this is a case "in which the Federal Government has weighed the competing interests relevant to the particular requirement in question reached an unambiguous conclusion about how those competing considerations should be resolved in a particular set of case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers

© 2006 Thomson/West No Claim to Orig U S Govt Works

*16 As explained earlier in reviewing a PMA FDA considers in great depth and detail the performance and design specifications methods of manufacture labeling and indications for use of a proposed medical device 21 C F R § 814 20 When FDA approves a PMA it does so following a thorough review of a substantial scientific record The approval perforce embodies the agency s conclusion that there is a reasonable assurance of safety and effectiveness of the device 21 U S C § 360e(d)

FDA s approval of the specific device as covered by the PMA governs that device with respect to labeling manufacturing design distribution sale and use In addition as the agency s approval orders state and consistent with 21 C F R § 814 80, a device that does not comply with conditions of approval established through the PMA process is adulterated or misbranded and subject to seizure or other FDA enforcement action See App A-216

Hence although FDA does not itself design any medical devices through the PMA approval process it certainly establishes specific requirements applicable to a particular device because the specifications for that device s design performance manufacture labeling and use are approved by the agency based on what the applicant submits See *Kemp v Medtronic Inc* 231 F 3d at 216 And those attributes are fixed in place as they can be materially changed only with FDA *17 approval As noted above if a manufacturer materially changes the design or labeling of a device without FDA approval distribution of the altered product is unlawful 21 C F R § 814 80

This resolution of the PMA process and its future impact fit well within the common definition of require which is 2 To call for as fitting demand 3 To impose an obligation on compel 4 To command order *The American Heritage Dictionary* (2d Coll Ed 1982) As a condition of marketing the HeartMate FDA plainly imposed obligations on its manufacturer

C The second part of the proper analysis under Section 360k(a) requires determining whether the state law tort claim involves a requirement different from or in addition to the specific federal requirements established through the PMA process Here plaintiff seeks to impose liability based on asserted flaws in the design labeling and manufacture of the HeartMate as approved by FDA despite the fact that it complied with FDA requirements Thus plaintiff does attempt to impose a requirement different from FDA This conclusion is shown by part of Justice O Connor s opinion in *Lohr* concurring in part and dissenting in part on behalf of four Justices and joined by Justice Breyer as a fifth Justice for this portion See 518 U S at 503-04

*18 The four Justices agreeing with Justice O Connor made a majority for the conclusion that state tort law judgments do impose a requirement for purposes of preemption under the MDA when a common law action would impose a requirement different from or in addition to that applicable under the FDCA - just as it would pre-empt a state statute or regulation that had that effect 507 U S at 511 As Justice O Connor also observed Justice Breyer reached the same conclusion * * * I believe that ordinarily insofar as the MDA preempts a state requirement embodied in a state statute rule regulation or other administrative

© 2006 Thomson/West No Claim to Orig U S Govt Works

action it would also preempt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action 507 U S at 504-05 (emphasis added)

There is no allegation that the HeartMate s design labeling or methods of manufacture deviated from those set forth in the PMA approved by FDA Accordingly any finding of liability based upon TCI s failure to satisfy a standard different from those approved by FDA in the PMA process would necessarily rest upon an implicit requirement that this device be designed manufactured or marketed in a way that differs from the way approved by FDA In light of the conclusion of five Justices in *Lohr* such a holding would constitute a common law requirement different from or in addition to the specific FDA requirements *See Kemp v Medtronic* 231 F 3d at 232 *Brooks v Howmedica Inc* 273 F 3d at 796 ***19***Mitchell v Collagen Corp* 126 F 3d at 913 *Michael v Siley Inc* 46 F 3d 1316 (3d Cir 1995)

Moreover the conclusion by five Justices in *Lohr* that the legal standard embedded in a state tort law judgment would constitute a requirement for purposes of Section 360k(a) is significant for an additional reason Such a requirement would stem from the application by a court of a general common law duty to a specific device such as the HeartMate If such state law judgments constitute device-specific requirements for the purposes of Section 360k(a) then clearly so also does FDA s application to a specific device of the general obligation to ensure that a Class III medical device meets the federal standards of safety and efficacy

Thus because five Justices have concluded that a state common law tort judgment is a requirement under Section 360k(a) surely an FDA decision approving a PMA and the design manufacture and labeling attributes of the HeartMate similarly establishes a requirement under that provision as well

D While the decision in *Lohr* thus establishes the framework for applying Section 360k(a) the ruling by the majority there that Section 510(k) clearance by FDA does not preempt state common law tort judgments does not provide the answer in this case because as the Supreme Court itself observed the Section 510(k) procedure is quite unlike the PMA process That Court emphasized that the PMA ***20** approval process is by no means comparable to the Section 510(k) clearance process 518 U S at 478

As previously noted under the Section 510(k) process FDA clears" a new medical device as substantially equivalent to a predicate device As the Supreme Court observed this process focuses upon equivalence not safety 518 U S at 493 And under FDA s regulations Section 510(k) clearance does not denote official approval of the device 21 C F R § 807 97

In contrast to the Section 510(k) review process which typically requires an average of only twenty hours to complete (*Lohr* 518 U S at 479) PMA approval is far more rigorous requiring an average of 1 200 hours *Id* at 518 U S at 477 Unlike a Section 510(k) clearance which only determines whether two products are substantially equivalent PMA approval consummates an exhaustive inquiry into the

© 2006 Thomson/West No Claim to Orig U S Govt Works

risks and efficacy of a device *Buckman Co v Plaintiffs Legal Comm* 531 U S 341 348 (2001)

In *Lohr* not surprisingly the Court premised its holding against preemption on the fact that the device had been cleared only through the Section 510(k) process a limited form of review *Lohr* 518 U S at 478 A manufacturer may change the design and labeling of a Section 510(k)-cleared device as long as it continues to be substantially equivalent to its predicate 21 C F R § 807 81 In direct contrast to the *21 PMA regime FDA does not approve changes to a Section 510(k)-cleared device Rather the manufacturer simply has to demonstrate that its device is still substantially equivalent to its predicate Moreover the range of changes that a manufacturer can make to a cleared device with getting prior authority from FDA is broader than for an approved device A manufacturer of a cleared device must submit a Section 510(k) notice to FDA only for changes that could significantly affect safety or effectiveness of the device or that represent a major change in the intended use of the device 21 C F R § 807 81

Thus agency actions and responsibilities in the Section 510(k) and PMA processes are quite different For the latter in stark contrast to the former after a very lengthy process involving thousands of pages of documentation and many hours of expert analysis and often including substantial give-and-take between the agency and the manufacturer FDA approves a new device including detailed specifications for its design manufacture performance labeling and use Any of these specifications may be changed in way that affects safety and effectiveness only with FDA s authorization

E After issuing its decision *in Lohr* the Court granted vacated and remanded to the Sixth and Seventh Circuits to consider whether the PMA process was sufficiently different from the Section 510(k) process to warrant a different outcome *22 See *Mitchell v Collagen Corp* 518 U S 1030 (1996) (granting certiorari vacating judgment and remanding for consideration in light of *Lohr) Martin v Teletronics Pacing Sys Inc* 518 U S 470 (1996) (same)

After reconsidering the issue of the preemptive effect of the PMA process in light of the Supreme Court s analysis in *Lohr* both of those Circuits adhered to their prior position finding that the FDA s approval of a PMA for a device indeed preempted different state requirements *Mitchell v Collagen Corp* 126 F 3d 902 (7th Cir 1997) *Martin v Teletronics Pacing Sys Inc* 105 F 3d 1090 (1996) (same)

Every court of appeals to address this precise issue since *Lohr* - including the only Circuit to support plaintiff s no-preemption position - has treated the matter as undecided by *Lohr* See *Goodlin v Medtronic* 167 F 3d 1367 1371 (11th Cir 1999) *Mitchell v Collagen Corp* 126 F 3d at 907 (finding it important to stress that the factual situation before the Court in *[Lohr]* was substantially different from the one before us today *Lohr* dealt with the scope of the preemption provision of the MDA in the context of the expedited substantially equivalent process not the full PMA process) *Kemp v Medtronic* 231 F 3d at 221 227 *Martin v Medtronic* 254 F 3d at 580

© 2006 Thomson/West No Claim to Orig U S Govt Works

F The view that plaintiff s claims here are preempted is consistent with the language and purpose of Section 360k(a)

***23** We note first that plaintiff s contrary position would largely nullify this section Congress well knew when it adopted the MDA that FDA does not design medical devices Rather Congress charged FDA with reviewing devices developed by manufacturers to ensure that they are safe and effective If the agency had to specify the design of a device for there to be express preemption no cause of action involving any Class III device approved pursuant to the PMA process would ever be preempted because the FDA merely approves or disapproves the device in question * * * *Kemp v Medtronic* 231 F 3d 216 227 (6th Cir 2000) However motivating Justice Breyer s refusal to join Part VI of Justice Stevens opinion in *Lohr* * * * was his lack of conviction that future incidents of MDA pre-emption of common-law claims will be few or rare *Ibid* If MDA preemption depended upon FDA itself imposing the design of a device in a regulation preemption would be exceedingly rare effectively reading the preemption provision out of the statute To give effect to the words of the statute FDA must be able to impose requirements without the agency developing devices in the first instance

We second emphasize that the requirements imposed by FDA approval of a PMA are no less effective because the design has been proposed by the manufacturer FDA can impose requirements by rule or order regardless of whether or not the requirements were initially suggested to the agency by an outside party FDA does ***24** not and has never used notice-and-comment regulations to approve individual products or to establish product-specific requirements for manufacture performance labeling and use Rather a PMA order is better conceptualized as an individual adjudication that imposes specific requirements on the device Although the PMA approval order does not itself expressly reiterate all of the specific features the device s design labeling and manufacturing processes must have it specifically approves as a matter of federal law those features as set forth in the application and binds the manufacturer to produce and market the product in compliance with the specifications as approved by FDA

We also certainly recognize that Section 518 of the FDCA (21 U S C § 360h) authorizes FDA to order a manufacturer to issue a warning to health care professionals or device users to repair or replace a device to refund the cost of a device or to recall a device Subsection (d) of this section states that compliance with any such order shall not relieve any person from liability under Federal or State law In awarding damages for economic loss in an action brought for the enforcement of any such liability the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account 21 U S C § 360h(d)

Although this provision recognizes that manufacturers may be found liable in state tort actions we believe by virtue of the preemption provision that the liability ***25** contemplated is for actions alleging that a manufacturer failed to follow the requirements of an approved PMA As the Supreme Court unanimously found in *Lohr* [w]here a state cause of action seeks to enforce an FDCA requirement that claim does not impose a requirement that is different from or in addition

© 2006 Thomson/West No Claim to Orig U S Govt Works

to requirements under federal law * * * Section 360k does not preclude States from imposing different or additional remedies but only different or additional requirements *Lohr* 518 U S at 513 (O Connor J concurring in part and dissenting in part)

G There are very strong public policy considerations that support the Government s view that PMA approval by FDA preempts a state common law tort suit that would if successful impose liability when a manufacturer is doing only what FDA approved

State common law tort actions threaten the statutory framework for the regulation of medical devices particularly with regard to FDA s review and approval of product labeling State actions are not characterized by centralized expert evaluation of device regulatory issues Instead they encourage and in fact require lay judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population - the central role of FDA - sometimes on behalf of a single individual or group of individuals That individualized ***26** redetermination of the benefits and risks of a product can result in relief- including the threat of significant damage awards or penalties - that creates pressure on manufacturers to add warnings that FDA has neither approved nor found to be scientifically required or withdrawal of FDA-approved products from the market in conflict with the agency s expert determination that such products are safe and effective This situation can harm the public health by retarding research and development and by encouraging defensive labeling by manufacturers to avoid state liability resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments [FN5]

> FN5 We also note that the FDCA device regulation scheme offers far more immediate protection for consumers from design flaws than does the tort system Manufacturers must report injuries associated with a device to FDA Where an adverse event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health manufacturers must report the event to FDA within five days 21 CFR § 803 53(a) FDA can then evaluate the nature of the adverse event and determine whether it was caused by a flaw in the device If FDA were to find that a device flaw is causing injury and presents an unreasonable risk of substantial harm to the public health the agency may order the manufacturer to notify health care professionals patients or others about the flaw or to repair replace or recall the device This system allows FDA to take immediate action to protect the public health In stark contrast the tort system normally takes years to reach resolution and the resolutions it reaches are often not consistent with the broader risk-benefit calculus the agency makes

The Government s assessment of the potential impact of common law suits of this kind on the FDA s ability to perform its role is plainly entitled to deference In ***27** assessing the preemptive effect of a statute or administrative action the views of the agency charged with administering that statute are entitled to great weight See *Geier v American Honda Motor Co* 529 U S 861 (2000) In addition Congress has given the FDA a unique role in determining the scope of § 360k s preemptive effect *Medtronic Inc v Lohr* 518 U S at 495-96 The fact that an

© 2006 Thomson/West No Claim to Orig U S Govt Works

agency has changed its views does not affect the primacy of its role or the fact that its views merit deference

Further when a manufacturer fails to report injuries associated with its device or the safety issue is otherwise attributable to the manufacturer s misconduct FDA has ample authority to take action as recognized in *Buckman Co v Plaintiffs Legal Committee* 531 U S 341 347-48 (2001) For example last year Endovascular Technologies (EVT) pled guilty to charges relating to a failure to report widespread serious adverse events associated with one of its devices and knowingly and intentionally misleading FDA about device malfunctions EVT agreed to pay a total of $92 4 million to settle civil and criminal charges As this example illustrates FDA has the tools necessary to protect the public health with due consideration for the need to encourage appropriate use of medical devices [FN6]

FN6 Plea Agreement United States v Endovascular Technologies Inc No CR 02-0179SI(N D Cal June12 2003(availableathttp // www usdoj gov/usao/can/press/assets/applets/2003_06_12_Endovascular_ plea pdf)

***28** H Plaintiffs opening brief asserts that the Government has previously taken the position that state law is not preempted under facts like those presented here Plaintiff relies chiefly upon statements that appeared in an *amicus curiae* brief opposing certiorari filed in December 1997 That brief was filed in *Smiths Industries Medical Systems Inc v Kernats cert denied* 522 U S 1044 (1998) (No 96-1405) There the Government stated that PMA approval does not impose specific federal requirements for purposes of preemption under the MDA Plaintiff also cites statements in an *amicus* brief filed by the United States in *Lohr* which includes an explanation why Section 360k(a) approval does not impose a federal requirement that can form the basis for preemption

Further the position presented in the United States *amicus* filing in *Kernats* does not reflect FDA s current views The Government s earlier position that PMA approval does not impose a specific federal requirement reflected two underlying points First it rested upon the proposition that a PMA reflects a design production method and labeling proposed by the manufacturer and that FDA s approval of a privately devised design therefore does not convert the features of that design into federal requirements even though it carries legal consequences for the manufacturer This proposition does not adequately account for the highly detailed and prescriptive nature of the PMA process and the approval order that results from it

***29** The Government s brief in *Kernats* also suggested that because the PMA process represents FDA s endorsement of a minimum standard PMA approval should not displace state common law that may provide additional protection to consumers This suggestion does not take sufficient account of the state-of-the-art risk management principles that FDA currently follows In recent years FDA has recognized that more risk minimization does not necessarily yield greater public health benefits Risk minimization measures such as labeling warnings and market withdrawal may actually present substantial disadvantages More warnings can

© 2006 Thomson/West No Claim to Orig U S Govt Works

discourage appropriate product use Market withdrawal can deprive patients of a useful therapeutic product Therefore FDA review of a PMA focuses not only on identifying the risk minimization appropriate for the device but also on ensuring that the measures selected do not present their own public health disadvantages By imposing additional risk minimization measures state co-regulation may disrupt the careful balancing performed by FDA in the PMA process Moreover as we have pointed out a manufacturer generally may not deviate from the specifications in the PMA concerning device design fabrication and labeling Given this important restriction the PMA approval does not simply establish minimums that manufacturers of Class III medical devices may choose to exceed In fact, a PMA approval sets a ceiling as well as a floor

***30** Although the views stated here differ from the views that the Government advanced in 1997 those new views reflect a reasoned analysis And as the Supreme Court has made clear because an agency s initial view is not carved in stone a revised agency statutory interpretation is entitled to deference even if it represents a break with prior interpretations *Rust v Sullivan* 500 U S 173 186 (1991) *Motor Vehicle Manufacturers Association v State Farm Mutual Automobile Insurance Co* 463 U S 29 41-42 (1983)

The change in governmental policy here also reflects in part the decisions applying *Lohr* issued by the federal courts in the seven years since that case was decided Since 1997 three circuits have held that approval through a PMA constitutes a federal requirement that may have a preemptive effect under the MDA *See Martin v Medtronic Inc* 254 F 3d 573 *Kemp v Medtronic Inc* 231 F 3d 216 *Mitchell v Collagen Corp* 126 F 3d 902 The Government now believes that the position stated in this letter-brief is a better implementation of the statutory scheme

V Conclusion

For these reasons the United States believes that this Court should affirm the district court s dismissal of this action The district court concluded that FDA had established specific federal requirements for the HeartMate through the PMA process because the agency s approval reflected a determination that the device was safe and ***31** effective That approval required TCI to sell the product only in the form approved by FDA and to obtain further regulatory approval from the agency if it wished to make any material change to the device The district court also concluded that plaintiffs state common law tort action would impose requirements on the product that differed from or were additional to those imposed through the PMA process which had culminated in the agency s determination that the device was safe as designed These rulings are correct and this Court should make clear that the types of claims here are preempted under federal law

11 NO 8 Andrews Med Devices Litig Rep 8

11 NO 8 Andrews Med Devices Litig Rep 8

HORN v THORATEC

© 2006 Thomson/West No Claim to Orig U S Govt Works

2004 WL 1143720

Briefs and Other Related Documents (Back to top)

2003 WL 24131418 (Appellate Brief) Reply Brief of Appellant Barbara Horn (Jun 20 2003)Original Image of this Document (PDF)

2003 WL 24131419 (Appellate Brief) Brief of Amicus Curiae Product Liability Advisory Council on Behalf of Defendant-Appellee (Jun 11 2003)Original Image of this Document (PDF)

2003 WL 24131417 (Appellate Brief) Brief of Amicus Curiae Chamber of Commerce of the United States of America Supporting Appellee Thoratec Corporation and Urging Affirmance of the Judgment (Jun 09 2003)Original Image of this Document (PDF)

2003 WL 24131421 (Appellate Brief) Brief for Appellee Thoratec Corporation (Jun 04 2003)Original Image of this Document (PDF)

2003 WL 24131422 (Appellate Brief) Brief for Appellee Thoratec Corporation (Jun 04 2003)Original Image of this Document (PDF)

2003 WL 24131423 (Appellate Brief) Brief For Appellee Thoratec Corporation (Jun 04 2003)Original Image of this Document (PDF)

2003 WL 24131420 (Appellate Brief) Brief of Appellant Barbara Horn (May 01 2003)Original Image of this Document (PDF)

02-4597 (Docket) (Dec 27 2002)

END OF DOCUMENT

© 2006 Thomson/West No Claim to Orig U S Govt Works

106

STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND	)	
Monica Weston,	)	Civil Action No 05-CP-40-0655
Plaintiff,	)	AFFIDAVIT OF PAUL G ORIS
v	)	
Kims Dollar Store and CIBA Vision, a division of Novartis Company,	)	
Defendants	)	

FILED
2006 FEB 28 AM 9:10
BARBARA A SCOTT
C C & G S

I, Paul G Oris hereby depose and state as follows

1 I am employed by CIBA Vision Corporation in the position of Head Global Regulatory Affairs

2 As Head Global Regulatory Affairs I am knowledgeable with regard to the regulatory requirements applicable to the contact lenses manufactured and sold by CIBA Vision Corporation under the trade name FreshLook Colors

3 All contact lenses manufactured and sold by CIBA Vision Corporation under the trade name FreshLook Colors are approved as Class III medical devices As a Class III medical device FreshLook Colors contact lenses had to receive and did receive pre-market approval from the Food and Drug Administration ("FDA") prior to being distributed for commercial sale

4 Extensive materials relating to the design, manufacture and sale of FreshLook Colors contact lenses were submitted to the FDA in a pre-market approval application ("PMA) The FDA evaluated the PMA and approved the manufacture and sale of FreshLook Colors contact lenses subject to certain conditions relating to design, manufacturing process, and

EXHIBIT
tabbies
C

product labeling Failure to comply with the conditions of approval is a violation of the Federal Food, Drug, and Cosmetic Act

5 Prior to commercial distribution of FreshLook Colors contact lenses, the FDA reviewed and approved all product labeling Any proposed changes with regard to the labeling of FreshLook Colors contact lenses must first be approved by the FDA This includes but is not limited to any change that purports to affect the safety of the device

AFFIANT FURTHER SAYETH NAUGHT

Paul G Ons

Sworn to before me this
22 day of December, 2005

Notary Public
My Commission Expires _____

Notary Public, [redacted] County, Georgia
My Commission Expires May 31, 2008

LESLIE SCOTT, Plaintiff and Appellant

v.

CIBA VISION CORPORATION, Defendant and Respondent

No. H012313

Court of Appeal, Sixth District, California

Sep 15, 1995

SUMMARY

Plaintiff, who was injured when she put a contact lens in her eye that she had mistakenly rinsed in a lens cleaning solution rather than a similarly packaged saline solution, brought a products liability action against the lens cleaning solution manufacturer. The trial court granted summary judgment for defendant, concluding that the action was preempted by the Medical Device Amendments (21 U.S.C. § 360k) of the federal Food, Drug and Cosmetic Act (21 U.S.C. § 360c et seq.), which forbid all state requirements that are different from or in addition to specific federal requirements regarding the same device. At the same time, the court denied plaintiff's motion for a continuance to allow her to complete discovery and obtain extensive documents relating to the preemption issue. (Superior Court of Santa Clara County, No. 723376, Read Ambler, Judge.)

The Court of Appeal affirmed. It held that the preemption language of 21 U.S.C. § 360k applies to state tort claims even though it provides only that a state may not establish or continue in effect any requirement that is different from or in addition to any requirement under the act or that relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act, the state requirement referred to includes any requirement having the force and effect of law whether established by statute, ordinance, regulation or court decision. The court further held that the federal scheme contains specific counterpart requirements applicable to contact lens cleaning solutions and that defendant submitted sufficient proof to establish that at the time of plaintiff's injury defendant had complied with federal requirements and was approved by the Food and Drug Administration and subject to its regulation. Finally, the court held that it was not an abuse of discretion to deny the motion for a continuance since in opposing the summary judgment motion plaintiff failed to comply with the affidavit requirement of Code Civ. Proc., § 437c, subd. (h). (Opinion by Bamattre-Manoukian, J., with Cottle, P. J., and Wunderlich, J., concurring.) *308

HEADNOTES

Classified to California Digest of Official Reports

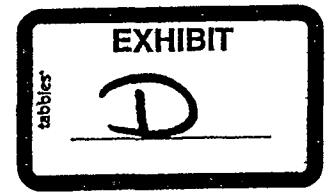
(1) Appellate Review § 144 -Scope of Review--Questions of Law and Fact--Statutory Interpretation.
Statutory interpretation is a judicial function involving only questions of law, and the appellate court independently reviews the trial court's determination.

(2) Continuance § 4 -Review--Denial of Continuance Where No Affidavit Supporting Need for Discovery Submitted.
Where a continuance is not mandatory in that the conditions of Code Civ. Proc., § 437c, subd. (h) (submission of affidavits in opposition to summary judgment motion supporting need for further discovery) have not been met, the trial court's denial of a continuance is reviewed under the abuse of discretion standard.

(3) Constitutional Law § 34 Distribution of Governmental Powers Between Federal and State Governments Conflicts Between Federal and State Powers - Express Preemption.
When Congress has considered the issue of preemption and has included in the enacted legislation a provision expressly addressing that issue, there is no need to engage in an analysis of implied preemption principles. Instead, a court looks only to the express preemption provision and considers the scope of its application from the language employed by Congress.

(4a, 4b) Products Liability § 40--Strict Liability in Tort -Defenses--Federal Preemption--Medical Devices--Applicability to State Tort Claims.
The preemption language of the Medical Device Amendments (21 U.S.C. § 360k) of the federal Food, Drug and Cosmetic Act (21 U.S.C. § 360c et seq.) applies to state tort

Copr. © Bancroft-Whitney and West Group 1998



claims even though it provides only that a state may not es tablish or continue in effect any requirement that is dif ferent from or in addition to any requirement under the act or that relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act State regulation can be as effect ively exerted through an award of damages as through some other form of preventive relief Indeed the Food and Drug Administration itself through its regulations has made clear that the state requirement referred to in 21 U S C § 360k includes any requirement having the force and effect of law whether established by statute ordinance regulation or court decision

[See 6 Witkin, Summary of Cal Law (9th ed 1988) Torts §§ 1310 1311] *309

(5) Constitutional Law § 34 Distribution of Governmental Powers Between Federal and State Governments- Express Preemption -Statutory Construction
The language of express preemption provisions must be in terpreted narrowly resolving any ambiguity in favor of pre serving state power

(6) Products Liability § 40 Strict Liability in Tort DefensesFederal Preemption Medical Devices--Contact Lens Cleaning Product Existence of Federal Counterpart Requirements
In a products liability action against a contact lens cleaning product manufacturer the trial court did not err in determin ing that plaintiff's claims were preempted by the Medical Device Amendments (21 U S C § 360k) of the federal Food Drug and Cosmetic Act (21 U S C § 360c et seq) which forbid all state requirements that are different from or in addition to specific federal requirements regarding the same device notwithstanding plaintiff's claim that there were no specific counterpart requirements in the federal scheme applicable to contact lens cleaning solutions A product specific warning issued by the Food and Drug Ad ministration is not necessary for preemption The product at issue by virtue of its class III status was expressly made subject to the specific counterpart regulations contained in the amendments including Food and Drug Administration approval of the proposed label Plaintiff's complaint alleged the product was unsafe and dangerous because the warnings were inadequate If she were to prevail a judgment in her favor would constitute a requirement different from or in addition to the federal label requirements

[Federal pre-emption of state common-law products liability claims pertaining to drugs medical devices and other health related items note 98 A L R Fed 124]

(7) Products Liability § 48--Strict Liability in Tort Evidence Sufficiency--Compliance With Federal Re quirements Preempting State Tort Claim
In a products liability action against a contact lens cleaning product manufacturer the trial court did not err in determin ing that plaintiff's claims were preempted by the Medical Device Amendments (21 U S C § 360k) of the federal Food Drug and Cosmetic Act (21 U S C § 360c et seq) which forbid all state requirements that are different from, or in addition to specific federal requirements regarding the same device notwithstanding plaintiff's claim that defend ant did not submit sufficient proof to establish that at the time of her injury defendant had complied with federal re quirements and was approved by the Food and Drug Ad ministration (FDA) and subject to its regulation The FDA had determined the product was safe and postapproval *310 reports had been submitted The fact that plaintiff purchased the product in its unmodified form after the FDA approved a change in its packaging was irrelevant since the record demonstrated that at the time of injury the product was sub ject to regulation and had been approved for marketing both in its original and its improved packaging

(8) Appellate Review § 111--Briefs- Form and Requisites Reply Brief
An appellate court does not entertain issues raised for the first time in a reply brief in the absence of a showing of good cause why such issues were not raised in the opening brief

(9) Products Liability § 28--Breach of Warranty -Defenses Federal Preemption -Medical Devices -Inadequate Warnings
Implied warranty claims premised on inadequate warnings are preempted by the Medical Device Amendments (21 U S C § 360k) of the federal Food Drug and Cosmetic Act (21 U S C § 360c et seq) which forbid all state require

Copr © Bancroft Whitney and West Group 1998

ments that are different from or in addition to specific federal requirements regarding the same device for the reason that the Food and Drug Administration (FDA) premarket approval process regulates the content and appearance of class III medical device labels If a fact finder applying state breach of warranty law could find that a label complying with FDA requirements was deficient such a finding would establish a standard for an adequate warning that would be in addition to the requirements under and thus violative of the act

(10) Products Liability § 12 Negligence- Negligence Per Se Medical Devices Federal Preemption
Negligence per se claims are preempted by the Medical Device Amendments (21 U S C § 360k) of the federal Food Drug and Cosmetic Act (21 U S C § 360c et seq) which forbid all state requirements that are different from, or in addition to specific federal requirements regarding the same device There is no basis for allowing a negligence claim to proceed based on the per se presumption codified in Evid Code, § 669 while finding that negligence itself is a preempted cause of action Absent preemption California plaintiffs would have an advantage over plaintiffs in other jurisdictions all of which prohibit state claims based on asserted violations of federal regulations

(11) Continuance § 2 Grounds To Obtain Discovery to Resist Summary Judgment Failure to Comply With Affidavit Requirement
In a products liability action against a contact lens cleaning product manufacturer the trial court, in granting summary judgment for defendant on the ground of federal preemption did not abuse its discretion in *311 denying plaintiff's request for a continuance so that she could complete discovery and obtain over 15 000 pages of documents she claimed were relevant to the preemption issue Although plaintiff had obtained discovery orders from another judge these did not amount to compliance with the affidavit requirement of Code Civ Proc , § 437c subd (h) the purpose of which is to inform the court of outstanding discovery that is necessary to resist the summary judgment motion The only issue at summary judgment was whether the action was preempted and defendant s moving papers established all preemption issues in its favor It was incumbent on plaintiff to show by affidavit that the extensive discovery request could reasonably lead to evidence necessary to refute the essential facts of preemption but she submitted no such affidavit

(12) Constitutional Law § 34- Distribution of Governmental Powers Between Federal and State Governments Conflicts Between Federal and State Powers - Express Preemption Absence of Federal Remedy- Medical Devices
The absence of a federal remedy will not defeat federal preemption where Congress has indicated an express intent to preempt state common law damages actions as it has by passage of the Medical Device Amendments (21 U S C § 360k) of the federal Food Drug and Cosmetic Act (21 U S C § 360c et seq) which forbid all state requirements that are different from or in addition to specific federal requirements regarding the same device

(13) Products Liability § 35- Strict Liability in Tort -Duty to Warn Medical Devices -Federal Preemption
Federal Food and Drug Administration regulations implementing the Medical Device Amendments (21 U S C § 360k) of the federal Food Drug and Cosmetic Act (21 U S C § 360c et seq) do not form a floor of protection leaving states free to construct a regulatory ceiling Rather the regulations which specifically provide for approval and review of the labeling of class III devices were intended to establish and do establish the maximum consumer protection regarding the adequacy of warnings

COUNSEL

Jonathan D Gordon for Plaintiff and Appellant

Brobeck Phleger & Harrison Diane S Rice Norma I Loza and Thomas M Peterson for Defendant and Respondent *312

BAMATTRE MANOUKIAN, J

Plaintiff Leslie Scott (Scott) appeals from a summary judgment entered in favor of CIBA Vision Corporation (CIBA) CIBA manufactures and distributes a contact lens cleaning product called AOSEPT The trial court determined that Scott s products liability claims against CIBA based on inadequate warnings on the AOSEPT bottle were preempted by the Medical Device Amendments to the federal Food

Copr © Bancroft Whitney and West Group 1998

Drug and Cosmetic Act (the Act) (21 U S C § 360c et seq) We agree and consequently we affirm the judgment

Statement of Facts

CIBA manufactures and markets a contact lens cleaning and disinfecting system for use with soft contact lenses The product includes a cleaning solution called AOSEPT which contains hydrogen peroxide a lens cup and holder and a neutralizing agent The lenses are cleaned and disinfected by placing them in the lens holder for a number of hours with the AOSEPT and the neutralizing agent The label on the AOSEPT bottle warns the user Do Not Put AOSEPT® Solution That Has Not Been Neutralized in Your Eye The instructions for use of the product contain similar warnings

CIBA also manufactures and markets a sterile saline solu tion product which is used as a neutralizing rinse and is compatible with eye contact The AOSEPT and the saline solution were sold in similar plastic bottles with white tops

On August 1 1991 plaintiff Scott mistakenly rinsed her contact lens with the AOSEPT solution believing it to be the saline solution She placed the lens directly into her eye causing eye injuries

Statement of the Case

On July 29 1992 Scott filed a products liability complaint against CIBA alleging that she had used the product in a manner which was reasonably foreseeable as involving a substantial danger and that adequate warnings of the danger were not given Her complaint included causes of action for strict liability negligence and breach of implied warranty She claimed CIBA was aware that consumers of its product would have difficulty distinguishing between the AOSEPT bottle and the saline solution bottle when their contact lenses were removed She alleged further that around the time of her injury CIBA had begun to market the AOSEPT solution with a red top on the ***313** bottle to distinguish it at a glance from the saline solution however CIBA also con tinued to market the solution in the old bottle knowing that its failure to properly warn consumers or to put distinctive markings on the bottles was causing injuries These facts she alleged showed CIBA was guilty of malice fraud and oppression entitling her to punitive damages

On July 9 1993 CIBA filed a motion for summary judg ment on the ground that AOSEPT was a class III medical device regulated exclusively by the Food and Drug Admin istration CIBA contended that under the preemption provi sion of the 1976 Medical Device Amendments (the MDA) 21 United States Code section § 360k (hereafter section 360k) state claims relating to the safety of the device were preempted by the federal regulatory scheme

The motion was fully briefed by both sides and following oral argument on August 10 1993 the court issued a minute order dated August 13 1993 granting the motion By letter to the court counsel for Scott objected that he had not been allowed to respond at oral argument to matters raised for the first time in CIBA s reply brief In response to the letter the court vacated its order and scheduled further oral argument, which was held October 28 1993

On December 20 1993 the court issued a second minute or der granting summary judgment to CIBA on the ground that Scott s state law tort claims were preempted by the MDA The court also denied Scott s request to continue the matter until further discovery was completed Judgment was entered January 10 1994

Standard of Review

The question whether Scott s claims are preempted turns on the interpretation and application of the preemption clause of the MDA (§ 360k) (1) Statutory interpretation is a judi cial function involving only questions of law (*Sutco Con struction Co v Modesto High School Dist* (1989) 208 Cal App 3d 1220, 1228 [256 Cal Rptr 671]) On appeal we independently review the trial court s determination (*Melamed v City of Long Beach* (1993) 15 Cal App 4th 70, 76 [18 Cal Rptr 2d 729]) If the preemption provision ap plies to Scott s product liability claims CIBA has estab lished a complete defense and summary judgment was ap propriate (Code Civ. Proc , § 437c)

(2) In regard to Scott s claim that the trial court erred in denying her a continuance we find that a continuance was not mandatory because the conditions of Code of Civil Pro cedure section 437c subdivision (h) were not ***314** met We therefore review the court s denial of a continuance under the abuse of discretion standard (*Mahoney v Southland*

Copr © Bancroft Whitney and West Group 1998

Mental Health Associates Medical Group (1990) 223 Cal App 3d 167, 171 172 [272 Cal Rptr 602])

General Principles Regarding Preemption

Many of Scott s arguments are grounded on the strong pre sumption against federal preemption of state police powers which stems from the respect due to federal state relations (*Cipollone v Liggett Group, Inc* (1992) 505 U S 504, 518 519 [120 L Ed 2d 407, 423 424, 112 S Ct 2608, 2618]) Particularly in the area of public health and safety regulations she argues state and local regulations must be allowed to co-exist with federal regulations (*Hillsborough County v Automated Medical Labs* (1985) 471 U S 707, 716 717 [85 L Ed 2d 714 723 724, 105 S Ct 2371]) A congressional intent to preempt all state law she continues may be implied only where the scheme of federal regulation is sufficiently comprehensive to infer that Congress left no room for supplementary state regulation (*Ibid. Fidelity Federal Sav & Loan Assn v de la Cuesta* (1982) 458 U S 141, 152 153 [73 L Ed 2d 664, 674 675, 102 S Ct 3014, 3022]), or where state law actually conflicts with federal law making compliance with both a physical impossibility (*Florida Avocado Growers v Paul* (1963) 373 U S 132, 142 143 [10 L Ed 2d 248, 256 257, 83 S Ct 1210] *Pacific Gas & Elec v St Energy Resources Comm n* (1983) 461 U S 190, 203 [75 L Ed 2d 752, 765, 103 S Ct 1713, 1722])

Scott s reliance on these principles of implied preemption is misplaced however since this is a case where Congress s intent to preempt has been explicitly stated in the statute s language (*Cipollone v Liggett Group, Inc , supra*, 505 U S 504, 516 [120 L Ed 2d 407, 422, 112 S Ct 2608, 2617]) (3) When Congress has considered the issue of preemption and has included in the enacted legislation a provi sion expressly addressing that issue there is no need to en gage in an analysis of implied preemption principles (*Id* at pp 518 519 [120 L Ed 2d at pp 423 424, 112 S Ct at p 2618] *Greenwood Trust Co* v *Com of Mass* (1st Cir 1992) 971 F 2d 818, 823) Cases cited by Scott (*Hillsborough County v Automated Medical Labs , supra*, 471 U S 707 *Florida Avocado Growers v Paul, supra*, 373 U S at pp 142 143 [10 L Ed 2d at pp 256 257] *Michigan Canners & Freezers v Agricultural Bd* (1984) 467 U S 461, 469 [81 L Ed 2d 399, 406, 104 S Ct 2518] *Silkwood v Kerr McGee Corp* (1984) 464 U S 238 [78 L Ed 2d 443, 104 S Ct 615]) which deal with implied preemption are thus in apposite here Instead we look only to the express preemp tion provision and consider the scope of its application from the language employed by Congress (*Greenwood Trust Co* v *Com. of Mass , supra*, 971 F 2d at p 823 *King v Collagen *315 Corp* (1st Cir 1993) 983 F 2d 1130, 1134 *Stamps v Collagen Corp* (5th Cir 1993) 984 F 2d 1416, 1425, fn 9)

The Preemption Provision of the MDA

Congress enacted the MDA to give the Food and Drug Ad ministration (FDA) comprehensive regulatory authority over medical devices (*Slater v Optical Radiation Corp* (7th Cir 1992) 961 F 2d 1330, 1331, H R Rep No 853 94th Cong 2d Sess pp 1 6 13 (1976)) Pursuant to the MDA medical devices are grouped into three classes based on the degree of regulation necessary to assure safety and effectiveness (*Mendes v Medtronic Inc* (1st Cir 1994) 18 F 3d 13, 14 21 U S C § 360c)

All classes of devices are subject to general controls in cluding labeling requirements and good manufacturing prac tices (See e g 21 U S C §§ 360i 360j) Class III devices pose the greatest risks and thus are the most highly regu lated (21 U S C § 360c(a)(1)(C) *Stamps v Collagen Corp , supra*, 984 F 2d at p 1419) Class III devices require premarket approval (PMA) an extensive evaluation process which permits the FDA to determine whether a proposed product provides reasonable assurance of its safety and ef fectiveness (*Ibid* 21 U S C §§ 360c(a)(1)(C) 360e)

Contact lens cleaning products such as AOSEPT are class III devices under the MDA and thus must comply with the PMA process (21 C F R § 886 5928 (1995))

The PMA process requires a manufacturer to submit a de tailed application to the FDA including information pertain ing to product specifications intended use manufacturing methods and proposed labeling (21 U S C § 360e(c)) The FDA refers each application to a panel of qualified experts who prepare a report and recommendation accepting or re jecting the application (21 U S C § 360e(d) *Stamps v Col lagen Corp , supra*, 984 F 2d at p 1419) Once the product

Copr © Bancroft-Whitney and West Group 1998

receives PMA the sponsor of the product may begin to mar ket the product Any subsequent changes in the product re quire submission of a PMA supplement application (21 C F R § 814 39 (1995)) Furthermore to ensure continued validity of the PMA the product sponsor is required to sub mit postapproval reports at one-year intervals identifying any changes in the device or any reports from clinical in vestigation or scientific literature concerning the device (21 U S C § 360i 21 C F R § 814 84 (1995))

The MDA contains an express preemption provision at sec tion 360k which provides in subdivision (a) as follows *316

[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 require ment applicable under [the Act] 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 [the Act]

Scott argues that state tort claims are not mentioned in sec tion 360k and thus were not intended by Congress to be preempted She argues further that there are no specific re quirements applicable to AOSEPT under the Act And she claims that because CIBA was able to make changes to the packaging of AOSEPT subsequent to premarket approval this illustrates the FDA s lack of post PMA regulation and control of the product She claims preemption should not operate because CIBA did not establish that it had complied with FDA requirements And finally she cites recent Cali fornia authority for the proposition that certain state causes of action survive federal preemption under the MDA

Establish or Continue in Effect Any Requirement

(4a) Scott maintains that these words in the MDA s preemp tion provision refer only to requirements established by laws or regulations enacted by the states and do not encompass common law tort actions Since state tort claims are not ex pressly included in the language of the preemption clause she argues such claims should not be preempted (5) We must interpret the language of express preemption provi sions narrowly resolving any ambiguity in favor of pre serving state power (*Cipollone v Liggett Group, Inc , supra*, 505 U S at pp 509, 544-548 120 L Ed 2d at pp 441-442, 443 444, 112 S Ct at pp 2632, 2634] (separate conc and dis opn of Scalia J))

(4b) Although the language of section 360k does not ex pressly include tort claims virtually every court which has addressed this issue has concluded that preemption under the MDA extends to state court tort claims (*King v Colla gen Corp , supra*, 983 F 2d at p 1134 *Stamps v Collagen Corp , supra*, 984 F 2d at p 1421 *Mendes v Medtronic, Inc , supra*, 18 F 3d at p 18 *Moore v Kimberly Clark Corp* (5th Cir 1989) 867 F 2d 243 *Slater v Optical Radi ation Corp , supra*, 961 F 2d 1330 *Gile v Optical Radi ation Corp* (3d Cir 1994) 22 F 3d 540, 542 543, see also *Cipollone v Liggett Group, Inc , supra*, 505 U S at p 521 [120 L Ed 2d at pp 425-426, 112 S Ct at p 2620] [interpreting similar language in the Public Health *317 Ci garette Smoking Act] *Evraets v Intermedics Intraocular, Inc* (1994) 29 Cal App 4th 779 [34 Cal Rptr 2d 852], *Powers v Optical Radiation Corp* [FN*] (Cal App))

FN* Reporter s Note Opinion (B081789) deleted upon direction of Supreme Court by order dated November 2 1995

As the cited cases observe state regulation can be as effect ively exerted through an award of damages as through some other form of preventative relief (See e g *San Diego Building Trades Council v Garmon* (1959) 359 U S 236, 245 [3 L Ed 2d 775, 783 784, 79 S Ct 773, 780]) Thus jury set standards in reality constitute new require ments which defendants must heed (*Hunsaker v Surgidev Corp* (D Pa 1992) 818 F Supp 744, 751) Indeed the FDA itself has made clear that the State requirement referred to in section 360k includes any requirement having the force and effect of law whether established by statute ordinance regulation *or court decision* (21 C F R § 808 1(b) (1995) italics added) Recent California precedent is in accord (*Ev raets v Intermedics Intraocular, Inc , supra*, 29 Cal App 4th at p 786)

Scott cites *Callan v G D Searle & Co* (D Md 1989) 709

Copr © Bancroft Whitney and West Group 1998

F.Supp. 662, to support a contrary position. We find *Callan* to be unpersuasive. *Callan* involved an intrauterine device which the court found was not classifiable as a medical device and was therefore not regulated by the MDA. Nonetheless, the court went on to discuss whether plaintiff's state tort claims would be preempted under section 360k if the intrauterine device were in fact regulated by the MDA. The court's comments can thus be discounted as dicta and indeed run against the great weight of authority in federal and state case law.

Specific Counterpart Regulations

Not all state laws regulating a particular device are preempted under section 360k. Only state requirements which are "different from or in addition to" specific federal requirements regarding the same device are affected. (§ 360k(a)(1).) As the federal regulations provide, state and local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the [A]ct. (21 C.F.R. § 808.1(d) (1995).)

(6) Scott argues that in this case there were no specific counterpart regulations or requirements in the federal scheme applicable to contact lens cleaning solutions. Therefore her state tort claims should not be preempted.

We disagree. All class III medical devices are subject to the requirements of the MDA including the extensive review and evaluation involved in the *318 PMA process. Among other things, "[t]he FDA retains rigid control over the entirety of the labeling and packaging of class III products." (*King v. Collagen Corp., supra*, 983 F.2d at p. 1135.) The control extends to the size and location of a warning on a label as well as its content. (See e.g. 21 U.S.C. § 360e(c)(1) and 21 C.F.R. §§ 801.4, 801.5, 801.15, 814.20(b)(10), (e) (1995).) In fact the product's sponsor must submit a proposed label to the FDA for analysis and review prior to gaining PMA for the product. (21 U.S.C. § 360e(c)(1)(F).) A PMA application will be denied if there is an insufficient showing that the product is safe and effective under the conditions of use prescribed, recommended or suggested in the proposed labeling thereof or if the proposed labeling is misleading in any particular. (21 U.S.C. § 360e(d)(2)(A), (B), (D).)

The MDA also imposes extensive postapproval regulations to keep the FDA apprised of any new information or safety findings relating to class III devices. (21 U.S.C. §§ 360e(e), 360i; see also 21 C.F.R. § 803 (1995).) Furthermore, under the product problem reporting program, health professionals and consumers can notify the FDA when they have had an adverse experience involving an approved medical device. The FDA may withdraw approval of the device permanently or suspend its approval temporarily at any time if it determines that the device has become unsafe or its labeling inadequate. (21 U.S.C. § 360e(e).)

Ophthalmic devices are covered under 21 Code of Federal Regulations section 886 et seq. (1995). The soft contact lens cleaning solution is specifically identified in section 886.5928 as a device intended to clean, disinfect, wet, or store a soft contact lens and is classified as a class III device subject to the PMA process. (21 C.F.R. § 886.5928(a), (b) (1995).)

Scott argues that the FDA has not promulgated a specific warning with regard to contact lens cleaners as it has with other products, for example, cigarettes or tampons. We do not believe a product specific warning issued by the FDA is necessary for preemption. Here the AOSEPT product, by virtue of its class III status, was expressly made subject to the specific counterpart regulations contained in the MDA including FDA approval of the proposed label. Scott's state tort action is based on allegations that the product was unsafe and dangerous because the warnings on the label were inadequate. If she were to prevail, a judgment in her favor would constitute a requirement different from or in addition to the labeling requirements which were specifically imposed by the MDA in the process of approving this particular product for marketing. (21 C.F.R. § 808.1(d) (1995).)

Recent cases support this view and illustrate the complete preemptive effect of the PMA process on state law tort claims involving inadequate *319 labeling or failure to warn. In *Stamps v. Collagen Corp., supra*, 984 F.2d 1416, for example, the court concluded that the class III PMA process itself constitutes a specific requirement applicable to a

Copr. © Bancroft-Whitney and West Group 1998

particular device within the meaning of both section 360k of the MDA and section 808 1(d) of the Code of Federal Regulations (984 F 2d at pp 1421-1422, fn 3) [Plaintiff] s inadequate labeling and failure to warn al legations are preempted by the MDA The Class III regulat ory structure involves the FDA in considerable oversight regarding proposed package labeling of a device (*Id* at pp 1421 1422) *Martello v CIBA Vision* (8th Cir 1994) 42 F 3d 1167, which involved the same product as in our case reached the same result (In accord *King v Collagen Corp*, *supra*, 983 F 2d 1130 *Slater v Optical Radiation Corp*, *supra*, 961 F 2d 1330 *Duncan v Iolab Corp* (11th Cir 1994) 12 F 3d 194 *Tarallo v Searle Pharmaceutical Inc* (D S C 1988) 704 F Supp 653, 656 [any cause of action based on testing labeling or marketing is preempted by the FDA standards for premarket approval])

We conclude in line with this authority that the FDA pre market approval of the AOSEPT product is a specific counterpart regulation to state tort law (21 C F R § 808 1(d) (1995))

Scott points out that the federal regulatory scheme allows a manufacturer to make post-PMA changes to a product, such as strengthening warnings without first obtaining approval from FDA She contends that this demonstrates a lack of federal regulation in this area Thus a state action resulting in a strengthened warning would not be contrary to any spe cific federal counterpart and would therefore not be preemp ted

Scott is inaccurate in her assertion that safety-enhancing changes made to a class III device are not regulated by the FDA The Code of Federal Regulations provides a specific process for obtaining a PMA Supplement from the FDA when unanticipated adverse effects or device failures neces sitate a labeling manufacturing or other device modifica tion (21 C F R § 814 39(a) (1995)) If a manufacturer makes a change which enhances the safety of the device or the safety in the use of the device such a change may be placed into effect prior to written FDA approval (21 C F R § 814 39(d)(2) (1995)) However the manufacturer must nonetheless submit a Special PMA Supplement applica tion which details the basis for the change and identifies the date that such changes are to be effected Furthermore the applicant must receive [] acknowledg[]ment from [the] FDA of receipt of the supplement prior to placing the pro posed changes in effect (21 C F R § 814 39(d), (e) (1995)) That is the procedure CIBA followed here as we explain more fully below Thus the post PMA changes to the AO SEPT product do not reflect action outside the federal regu latory scheme but rather compliance with it. *320

Compliance With the PMA Process

(7) Scott contends CIBA did not submit sufficient proof to establish that at the time of her injury AOSEPT had com plied with PMA requirements and was approved by FDA and subject to its regulation We believe the record estab lishes compliance

The record shows that the initial application for PMA was filed June 10 1982 and that the AOSEPT product first re ceived PMA under the name SEPTICON on March 17 1983 with an assigned PMA number of P820040 At that time the product was manufactured and sold by American Optical Corporation The published notice of approval dated April 8 1983 states that the PMA was based on the recommendation of the ophthalmic device section of the Ophthalmic Ear Nose and Throat and Dental Devices Pan el an FDA advisory committee After review and evalu ation the FDA determined the product had been shown to be safe and effective for use as recommended in the submit ted labeling

On March 21 1984 the American Optical Corporation ap plied for a supplemental PMA incorporating improvements in the currently approved SEPTICON system, and changing the name of the improved version to AOSEPT New la beling was submitted This application was evaluated and approved by FDA which issued a supplemental PMA au thorizing marketing of the product as modified October 3 1984

In 1985 CIBA purchased the American Optical Corpora tion s soft contact lens business thus acquiring the right to manufacture and distribute American Optical Corporation s line of soft contact lens products including AOSEPT On February 25 1986 CIBA notified FDA of the purchase and applied for a supplemental PMA for repackaging of the products This supplemental PMA was approved May 5

Copr © Bancroft Whitney and West Group 1998

1986

As with all class III devices subject to the PMA process continued approval was conditioned upon submission of an nual postapproval reports The conditions of approval of a product further provided that the manufacturer could effect changes enhancing the safety of a product specifically by strengthening the warning on the label or the instructions for use of the product by submitting a Special PMA Supple ment application detailing the proposed changes

This procedure was followed by CIBA in 1990 when it sent a special PMA supplement application notifying the FDA that it would be changing the white bottle tops to red bottle tops on AOSEPT and two other contact *321 lens cleaning and disinfecting products The application explained that this change was being instituted to increase consumer safety because lens care products in similar bottles were often con fused with the result that products not intended for ocular instillation namely lens cleaners and disinfectants were ac cidentally put directly into the eye The red bottle top was intended to alert the consumer to this danger CIBA also proposed to revise the labeling which would include a warning not to insert the product with the red bottle top dir ectly into the eye The special PMA supplement application included samples of the revised bottle labeling

CIBA received approval from the FDA for this special PMA supplement on February 8 1991 The approval letter identi fied AOSEPT by the original PMA number P820040 and indicated that CIBA was authorized to begin commercial distribution of the product as modified

Scott s injury occurred several months later on August 1 1991 When she mistakenly applied AOSEPT to her contact lens and then inserted the lens directly into her eye she was apparently using a bottle with the old white top

The fact that Scott purchased the product in its unmodified form is not relevant to the question of preemption The re cord adequately demonstrates that the AOSEPT product was subject to class III MDA regulation at the time of the injury and that the FDA had in fact approved the product for mar keting both in its original and in its new improved pack aging

Scott cites *Meyer v International Playtex Inc* (D N J 1988) 724 F Supp 288, 293 and *National Bank of Com merce v Kimberly Clark Corp* (8th Cir 1994) 38 F 3d 988, 993, for the proposition that her state tort claims are not preempted if it is shown that defendant s warnings were not in compliance with applicable federal standards

Meyer and *National Bank* are inapposite since those cases concerned class II devices namely tampons which are not subject to the same rigorous PMA process under the MDA as are class III devices The court in *National Bank* noted that if the tampon were subject to the class III requirements including approval of all labeling prior to marketing plaintiff's claims that defendant s warnings failed to comply would be preempted [A]ctual agency approval the court stated in a footnote eliminates any possible claims under state tort law for failure to comply with federal require ments (*National Bank of Commerce v Kimberly Clark Corp supra* 38 F 2d at p 994 fn 4)

Here the evidence as summarized above established that the AOSEPT labeling was in full compliance with FDA re quirements at the time of Scott s *322 accident in 1991 AO SEPT had FDA approval as it was originally packaged with the white bottle top and CIBA had obtained supplemental approval in February of 1991 to begin marketing the product with a red top instead of white Scott claims that CIBA did not include in evidence prior annual reports sup plemental applications and other proof that the conditions of approval continued to be satisfied However she has not shown how the reports and supplemental applications from prior years would affect the product s class III FDA ap proved status at the time of the injury

Scott raises several additional evidentiary claims in her reply brief [FN1] (8) We do not entertain issues raised for the first time in a reply brief in the absence of a showing of good cause why such issues were not raised in the opening brief (*American Drug Stores, Inc v Stroh* (1992) 10 Cal App 4th 1446 [13 Cal Rptr 2d 432] *Neighbours v Buzz Oates Enterprises* (1990) 217 Cal App 3d 325, 335, fn 8 [265 Cal Rptr 788]) No good cause appearing here we will disregard these issues

FN1 She contends that the declarations in support

Copr © Bancroft Whitney and West Group 1998

of CIBA s motion contained inadmissible hearsay and were made without personal knowledge of the attached documents She claims further that CIBA s proof included unsworn hearsay letters from its own employees and uncertified copies of documents from the FDA

Recent California Authority

Recently two California cases from the Second District have addressed the issue of federal preemption under the MDA (*Evraets v Intermedics Intraocular, Inc , supra,* 29 Cal App 4th 779 and *Powers v Optical Radiation Corp supra*) The device involved in both of those cases was an intraocular lens (IOL) which is implanted surgically into the eye (See also *Gile v Optical Radiation Corp , supra,* 22 F 3d 540 and *Slater v Optical Radiation Corp , supra,* 961 F 2d 1330, concerning a similar device)

While *Evraets* and *Powers* provide important state precedent in this area they differ from our case in one respect the IOL is an investigational device As such it is subject to the Investigational Device Exemption Regulations for intraocular lenses (21 C F R 813 et seq (1995)) but it is exempt from the PMA requirements Exemption from the PMA process in the case of an investigational device is intended to encourage the discovery and development of useful medical products (21 U S C § 360j(g)(1)) Unlike the manufacturer of a nonexempt class III device such as CIBA the manufacturer of an investigational device who has applied for and received the exemption is not required to establish the safety and effectiveness of the device before it can be sold *323(*Slater v Optical Radiation Corp , supra,* 961 F 2d at pp 1331 1332) In other respects both exempt and nonexempt devices are regulated by the FDA and both are subject to the MDA preemption provision

Evraets and *Powers* were both dismissed on demurrers in the trial court On appeal in *Evraets* the court held that causes of action for negligence and strict liability were preempted by the MDA but that other causes of action were not, including breach of express and implied warranty fraud and negligence per se *Powers* adopted *Evraets* for the most part concluding however that a cause of action alleging negligence per se was preeempted [FN2] In a dissent in *Powers* Justice Turner concluded that fraud based state tort claims were also preempted under the MDA

FN2 *Powers* also noted that appellant had properly concede[d] that a breach of implied warranty claim was preempted (*Powers v Optical Radiation Corp supra*)

We need not enter the debate regarding the preemptive effect of the MDA on state law fraud claims since Scott has not pleaded a cause of action for fraud Her complaint includes only products liability causes of action for strict liability negligence and implied warranty As to the first two causes of action our conclusion that these claims are preempted by the MDA is in accord with *Evraets* and *Powers* As to the breach of implied warranty claim, the *Evraets* court departed from established law by finding that such a state law cause of action could survive preemption (See e g *Duncan v Iolab Corporation, supra,* 12 F 3d 194 *Slater v Optical Radiation Corp , supra,* 961 F 2d at pp 1332-1334 *Mendes v Medtronic, Inc , supra,* 18 F 3d at p 19) The court went on to find however that in the case of the IOL which is sold to the surgeon who then implants it in the patient s eye the requisite privity was lacking

Scott asks that we find there is privity here and that we therefore adopt the *Evraets* court s analysis and conclude that her breach of implied warranty claim survives preemption under the MDA We decline to do so Scott s claim is based on allegations that the manufacturer of the device which was safe if used as directed failed to provide adequate directions and warnings (9) Established precedent holds that implied warranty claims premised on inadequate warnings are preempted by the MDA for the reason that the FDA premarket approval process regulates the content and appearance of class III medical device labels (*Mendes v Medtronic, Inc , supra,* 18 F 3d at p 18 *Moore v Kimberly Clark Corp , supra,* 867 F 2d at pp 246 247 *King v Collagen Corp , supra,* 983 F 2d at p 1139) If a fact finder applying state breach of warranty law could find that a label which complied with FDA requirements was deficient such a finding would establish a standard for *324 an adequate warning which would be in addition to the requirements applicable under the Act (*Mendes v Medtronic, Inc , supra,* at p 18) That result is prohibited under section 360k

Copr © Bancroft-Whitney and West Group 1998

(10) Next Scott urges us to adopt the holding in *Evraets* that a claim of negligence per se survives preemption In *Ev raets* the claims which were allowed were based on allega tions of lack of informed consent and product adulteration Those claims are specific to the investigational device ex emption requirements for IOL s and do not apply to our case In any event however we disagree with *Evraets* that negligence per se provides a theory of recovery which is not preempted

In *Evraets* the court reasoned that where federal laws and regulations establish a certain standard of conduct violation of those laws may provide the basis for a state law claim The court thus recognized the right of an injured person to sue a manufacturer of a medical device for failure to comply with federal laws governing that device *Powers* disagreed with this analysis finding it was tantamount to creating a private right of action to enforce FDA regulations concern ing medical devices where no such right exists (*Powers v Optical Radiation Corporation supra* 37 Cal App 4th at p 1452) The *Powers* majority continued [W]e hesitate to find such a right because doing so would place with non expert triers of fact the determination whether a medical device complies with applicable federal regulations a ne cessarily complicated technical question better left to the FDA s expertise (*Ibid*) The court concluded that there is no private right of action to enforce compliance with FDA regulations and that any assertion of failure to comply is preempted (*Id.* at p 1454 *Rodriguez v SK & F Co* (1st Cir 1987) 833 F 2d 8, 9 *Pacific Trading Co v Wilson & Co Inc* (7th Cir 1976) 547 F 2d 367, 370)

We agree with *Powers* on this issue As that court observed there is no basis for allowing a negligence claim to proceed, based upon the per se presumption codified in Evidence Code section 669 while finding that negligence itself is a preempted cause of action Moreover if this were so Cali fornia plaintiffs would have an advantage over plaintiffs in other jurisdictions all of which prohibit state claims based on asserted violations of federal regulations (*Reeves v Ac romed Corp* (5th Cir 1995) 44 F 3d 300 *Michael v Shiley Inc* (3d Cir 1995) 46 F 3d 1316 *National Bank of Com merce v Kimberly Clark Corp., supra*, 38 F 3d at p 994, fn 4 *Gile v Optical Radiation Corp , supra*, 22 F 3d at p 544)

Denial of Motion for a Continuance

(11) Scott contends that the trial court should have granted a continuance of the summary judgment motion so that she could complete discovery *325 and obtain over 15 000 pages of documents she claims are relevant to the preemp tion issue

At the time Scott filed her written response to CIBA s sum mary judgment motion July 26 1993 she argued that the motion was premature because she had not completed ne- cessary discovery The day after her responding papers were filed a different superior court judge ruled on her pending motions to compel production of documents and to compel further answers to interrogatories granting the motions with certain limitations An order was filed July 28 1993 detail ing documents to be produced and interrogatories to be answered by CIBA within 30 days In addition a special master was appointed to supervise further discovery matters

When the court initially granted CIBA s summary judgment motion by minute order dated August 13 1993 those dis covery orders were outstanding The court subsequently va cated its order granting summary judgment to allow further oral argument on matters raised for the first time in CIBA s reply brief on the summary judgment motion Scott filed a motion asking the court to take judicial notice of the pending discovery orders and argued again at the second oral argument on the summary judgment motion that CIBA s motion was premature because discovery was not complete

In its second order granting CIBA summary judgment, the court specifically denied counsel s request for a continuance The court stated as its reason that no affidavit had been filed in support of the request for a continuance pursuant to Code of Civil Procedure section 437c subdivision (h) That sec tion provides as follows If it appears from the affidavits submitted in opposition to a motion for summary judgment or summary adjudication or both that facts essential to justi fy opposition may exist but cannot for reasons stated then be presented the court shall deny the motion or order a continuance to permit affidavits to be obtained or discovery to be had or may make any other order as may be just

Copr © Bancroft Whitney and West Group 1998

Scott claims that the discovery orders which detailed documents ordered to be produced by CIBA amounted to affidavits within the meaning of Code of Civil Procedure section 437c subdivision (h) in that they identified the outstanding evidence necessary to oppose the summary judgment motion The court apparently rejected this claim although it took judicial notice of the discovery orders

The purpose of the affidavit required by Code of Civil Procedure section 437c subdivision (h) is to inform the court of outstanding discovery which is necessary to resist the summary judgment motion (*326*Wachs v Curry* (1993) 13 Cal App 4th 616, 622 624 [16 Cal Rptr 2d 496], *People ex rel Department of Transportation v Outdoor Media Group* (1993) 13 Cal App 4th 1067, 1077 [17 Cal Rptr 2d 19] *Korens v R W Zukin Corp* (1989) 212 Cal App 3d 1054, 1061 [261 Cal Rptr 137]) To be entitled to a continuance the party opposing the motion for summary judgment must show that its proposed discovery would have led to facts essential to justify opposition (13 Cal App 4th at p 1077)

Here the only issue at summary judgment was whether Scott s products liability action was preempted under section 360k As we have discussed above there are basically two aspects to the inquiry was the product which allegedly caused plaintiff's injury a medical device subject to the requirements of the MDA and did plaintiff's tort claims seek to impose requirements different from or in addition to those already imposed under the federal scheme relating to that product s safety? CIBA s moving papers established both of these issues in its favor It was incumbent upon plaintiff to show by affidavit that the extensive discovery requested could reasonably lead to evidence necessary to refute the essential facts of preemption Scott submitted no such affidavit Since the conditions of section 473c subdivision (h) were not met continuance was not mandatory (*Mahoney v Southland Mental Health Associates Medical Group, supra,* 223 Cal App 3d at pp 171 172 [272 Cal Rptr 602]) We find no abuse of discretion in the court s denial of a continuance under the circumstances here (*Ibid.*)

Protection of Consumers of Medical Devices

We turn last to public policy considerations raised by Scott She argues that the MDA were enacted to address the perceived inadequacy of existing law to protect consumers from increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used (Sen Rep No 33 94th Cong 2d Sess p 5 reprinted in 1976 U S Code Cong & Admin News pp 1070 1075 *Larsen v Pacesetter Systems Inc* (1992) 74 Hawaii 1 [837 P 2d 1273] *Elbert v Howmedica Inc* (D Hawaii 1993) 841 F Supp 327, 329) This purpose would be frustrated she argues by precluding state tort claims based on injuries resulting from those medical devices In her view the public can be protected only if we regard the FDA regulations as establishing the minimum safety standards If those standards have not adequately protected consumers from unsafe medical products consumers should be allowed to proceed in state court to supplement federal regulations and establish a ceiling on consumer protection (See e g *Ferebee v Chevron Chemical Co* (D C Cir 1984) 736 F 2d 1529, 1543 [237 App D C 164] *Hunsaker v Surgidev Corp , supra,* 818 F Supp at p 749) Otherwise injured parties will have no remedy whatsoever *327

(12) The absence of a federal remedy will not defeat preemption however where Congress has indicated an express intent to preempt state common law damages actions as it has by passage of the MDA (*Stamps v Collagen Corp , supra,* 984 F 2d at p 1425, see also fn 11) Moreover Scott s argument that the FDA regulations form the floor of protection while the states are free to construct a regulatory ceiling has been rejected in federal court in *Stamps v Collagen Corp , supra,* 984 F 2d at page 1424 (13) We conclude as did the court in *Stamps* that the federal regulations in this case which specifically provided for FDA approval and review of the labeling of this class III device were intended to establish and did establish the maximum consumer protection regarding the adequacy of warnings Thus preemption is unavoidable

Scott s argument that preemption under the MDA is tantamount to granting manufacturers of medical devices virtual immunity from liability for all manner of improper acts has similarly been rejected (*Gile v Optical Radiation Corp , supra,* 22 F 3d 540) The detailed evaluation review and regulation we have discussed herein are designed to expose shoddy clinical investigations and negligently designed and manufactured medical devices Moreover as the court

Copr © Bancroft Whitney and West Group 1998

pointed out in *Gile* a manufacturer who violates FDA regulations or the provisions of the Act is subject to punishment by significant fines civil penalties and imprisonment (*Id* at p 546)

While the broad purpose of the FDA scheme is to promote public health that purpose encompasses not only the protection of the individual user of the product but also the need to encourage research and development and permit new and improved devices to be marketed without delay Setting uniform standards for manufacturers and providing a shield from state law intrusion is consistent with this purpose (*King v Collagen Corp , supra*, 983 F 2d 1130, 1138 citing U S Code Cong & Admin News 94th Cong 2d Sess vol 3 p 1070 et seq *Tarallo v Searle Pharmaceutical, Inc , supra*, 704 F Supp at p 655 *Mendes v Medtronic, Inc , supra*, 18 F 3d at p 16) Thus Congress could reasonably have weighed possible loss in isolated cases against benefits to the public generally Perfection is impossible and a few individuals may be denied full protection at the cost of benefitting the rest (*King v Collagen Corp , supra*, 983 F 2d at p 1138 conc opn of Aldrich J)

Finally Scott contends that the FDA has been ineffective in the task of regulating medical devices The only way the FDA can ensure the safety of medical devices she argues is to rely upon the manufacturers themselves to voluntarily report incidents causing injuries a practice which clearly runs against their economic interests Thus the FDA is incapable of discharging *328 its obligation to protect consumers from unsafe medical products Scott stresses this point citing at length from a report entitled Less Than the Sum of its Parts Reforms Needed in the Organization Management and Resources of the Food and Drug Administration s Center for Devices and Radiological Health A Report by the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce of the United States House of Representatives May 1993 (103d Cong 1st Sess Comm Print No 103 N) We decline to address this issue which is well beyond the scope of our inquiry regarding preemption under section 360k

Disposition

The judgment is affirmed

Cottle P J and Wunderlich J concurred

Appellant s petition for review by the Supreme Court was denied December 21 1995 Mosk J and Kennard J were of the opinion that the petition should be granted *329

Cal App 6 Dist. 1995

Scott v CIBA Vision Corp

END OF DOCUMENT

Copr © Bancroft Whitney and West Group 1998

PETER D KEISLER
Assistant Attorney General

EUGENE M THIROLF
Director, Office of Consumer Litigation
DRAKE CUTINI
Attorney, Office of Consumer Litigation
U S Department of Justice
P O Box 386
Washington, DC 20044
(202) 307-0044

Attorneys for the United States

IN THE CIRCUIT COURT OF TENNESSEE FOR THE THIRTIETH JUDICIAL DISTRICT AT MEMPHIS, SHELBY COUNTY, TENNESSEE

GARY MURPHREE,

Plaintiff,

v CIVIL NO CT-005429 00-3

PACESETTER, INC ,
JAMES G PORTERFIELD, M D ,
AND JOHN DOES ONE THROUGH TEN,
ET AL.,

Defendants

STATEMENT OF INTEREST OF THE UNITED STATES OF AMERICA

I INTRODUCTION

The United States, on behalf of the United States Food and Drug Administration (FDA) of the U S Department of Health and Human Services, submits this statement of interest of its views regarding the device approval and regulatory process of the Federal Food, Drug, and



Cosmetic Act (FDCA), and how the device at issue in the instant case fits the statutory scheme The United States believes that Congress has charged FDA with determining the issue this Court has identified as a jury issue, that is whether a particular device has been approved by FDA and, in effect, whether it was reviewed by FDA using the appropriate regulatory pathway 21 U S C §§ 360c-360k. Relying on its scientific expertise, FDA determines the proper regulatory pathway for medical devices If juries were to make this determination in the first instance, rather than FDA, it would result in an unworkable, chaotic system that Congress sought to avoid by charging FDA with the responsibility for regulating medical devices

II. BACKGROUND

Given the Court's decision that a jury should determine how FDA has regulated the device in question, the Tendril DX Model 1388T Endocardial, Steroid Eluting, Screw-In Pacing Leads (Model 1388T), an understanding of the device regulation scheme is critical to this case In enacting the Medical Device Amendments (MDA) to the FDCA in 1976, 21 U S C §§ 360c-360k, Congress established a comprehensive scheme for the regulation of medical devices Congress charged the United States Secretary of Health and Human Services with regulating devices under this scheme The Secretary has delegated that authority, in turn, to FDA. 21 C F.R. § 5 10(a)(1)

The MDA established three classes of devices that receive varying degrees of regulation, Class I, Class II, and Class III Class III devices – the classification relevant to this case – are those subject to the most stringent regulation A Class III device is one that cannot be classified in Class I or Class II and either (1) is for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or (2) presents a

potential unreasonable risk of illness or injury 21 U S C § 360c(a)(1)(C)

Before marketing a Class III medical device, the FDCA requires that device manufacturers either obtain FDA approval of an application for premarket approval (PMA) or qualify for an exemption from the PMA requirement. Id. § 360e To receive PMA approval, a manufacturer must submit an application containing full reports of investigations that provide "reasonable assurance' of the device's safety and effectiveness Id § 360c(a)(1)(C) A Class III device qualifies for an exemption from the PMA requirement if (1) it was marketed prior to enactment of the MDA (pre-amendment device) and a regulation requiring submission of PMAs has not been issued for the device, id § 360e(b)(1)(A), or (2) if it is 'substantially equivalent" to a predicate device (a pre-amendment device or one of its "substantially equivalent" successors) and a regulation requiring submission of PMAs has not been issued for the device Id § 360e(b)(1)(B) A device is found "substantially equivalent" to a predicate device through what is known as the 510(k) notification process Id. § 360(k) A device that is found "substantially equivalent" to a predicate device is "cleared" by the FDA for marketing and does not have to be approved through the PMA process

Manufacturers frequently add new features to, or change the design of, a device When a Class III device has a PMA approval and the holder of the approval changes the design of the device in a manner that affects its safety or effectiveness, the manufacturer must submit a supplemental application (PMA supplement) Id. § 360e(d)(6)(A) FDA will approve the PMA supplement if clinical data demonstrates the safety and effectiveness of the changed device Id. § 360e(d)(6)(B)

If a 510(k)-cleared device is changed in a way that renders the device no longer

'substantially equivalent to the predicate device, then the device ceases to be exempt from the PMA requirement, and may not be marketed without PMA approval Id §§ 360c(f), 360c(a) The change to the device thus triggers a move from the 510(k) process to the PMA process

The device at issue in this case, Model 1388T, is a Class III device that received PMA approval from FDA on June 20, 1997 Its predecessor device, Tendril Model 1188T, had been marketed pursuant to a 510(k) clearance, which meant that it was "substantially equivalent" to a predicate device Endocardial pacing leads (also called permanent pacemaker electrodes) are Class III devices 21 C F R. § 870 3680(b) This type of device was marketed prior to the enactment of the MDA. Thus those leads that were on the market prior to the MDA were allowed to stay on the market pending FDA publication of a regulation requiring submission of PMAs for the pre-amendments devices and those devices that have been found substantially equivalent to them Subsequent entrants to the market gained FDA clearance through the 510(k) process by demonstrating "substantial equivalence" to a predicate device

When Pacesetter changed the Model 1188T by adding a new feature, the steroid-eluting tip, it changed the device sufficiently that it was no longer "substantially equivalent" to the predicate device The addition of the new feature triggered the requirement that the new device, Model 1388T, obtain PMA approval In other words, the change put the device on a different regulatory pathway Pacesetter submitted a PMA application for Model 1388T to FDA, FDA reviewed the application, and on June 20, 1997, FDA approved the PMA for the device

III ARGUMENT

In its July 13, 2002, informal letter ruling (formally entered in the Court's October 15, 2002 Order) this Court stated, first, that the Plaintiff's claims are preempted by the MDA if FDA

approved a PMA for Model 1388T and, second, that whether Model 1388T was approved by FDA "under the full PMA process or the 510(k) process" is an issue of fact for a jury's determination. The Court decided the first issue correctly Following the Court's correct determination of the first issue, and given that FDA has approved a PMA for Model 1388T, the Plaintiff's claims should be preempted by the MDA Nevertheless, in its July 13, 2002, letter ruling, the Court concluded that it is an open question of fact whether there is a full PMA approval for Model 1388T and, therefore, that this issue is one for a jury's determination It is the view of the United States that this issue is not a factual question, but a question of law

There is an approved PMA for Model 1388T FDA approved a PMA for Pacesetter s Tendril DX Model 1388T Endocardial, Steroid Eluting Screw-In Pacing Leads on June 20,1997 It published a notice of the approval in the Federal Register on December 30, 1998 (63 Fed Reg. 71930, 71931) (PMA number P960013) There is no issue of fact as to whether FDA approved this device.

Plaintiff, relying on the testimony of a former employee of FDA's Center for Devices and Radiological Health, Dr Suzanne Parisian, argues that the PMA approval for Model 1388T only covers the steroid eluting tip of the device, while the rest of the device is covered by the 510(k) clearance of its predecessor device, Model 1188T Affidavit of Suzanne Parisian at 5, ¶ 20 This argument is in error

Although the device regulation scheme as a whole may be complex, the law on whether PMA approval may apply to only part of a device is clear To approve a PMA, FDA must find that there is a "reasonable assurance of safety and effectiveness" of the device as it is described in

the application 21 U S C § 360c(a)(1)(C) Every PMA must meet this legal standard to be approved The law does not allow for any exceptions

Furthermore, it is the whole device as it is described in the application that must meet this legal standard. The MDA does not include a provision allowing FDA to approve a PMA for one feature of the device described in the application. FDA would violate the law were it to approve a PMA for a device if only part of the device met the "reasonable assurance of safety and effectiveness" standard, while part of it met a different standard, such as the "substantial equivalence ' standard Thus, FDA can and does approve a PMA only when the entire device that is the subject of the submission meets the correct PMA legal standard.

The PMA approval encompasses the entire device, which in this case includes both the pacing leads and the steroid eluting tips The scope of what constitutes the device is set forth in the approval letter, which is attached hereto, and the Federal Register notice of the approval FDA is very deliberate in identifying the precise scope of approval When FDA sends a letter to an applicant telling them that their PMA is approved, the whole device, as it is described in that letter, is PMA-approved In this case, FDA stated that it was approving Tendril DX Model 1388T/K Endocardial, Steroid Eluting Screw-In Pacing Leads 63 Fed. Reg. at 71931 Thus, FDA has determined that the device comprises, and the PMA approval covers, both the leads and the steroid eluting tips

Putting the technical and scientific language of Dr Parisian's affidavit aside, the issue is quite simple either the entire device as described in the approval letter meets the PMA approval standard, or it does not Once FDA sends a letter to an applicant telling it that its PMA is approved, the whole device, as it is described in that letter, is PMA-approved The issue of

whether the PMA approval of Model 1388T is a "full PMA" for the whole device or only a PMA for part of the device is thus a matter of law, not fact, because the law simply does not permit PMA approval for one part of a device as described in a PMA submission while the rest of the device receives 510(k) clearance

Furthermore, it is inappropriate for a jury to second-guess FDA's scientific judgment on such a matter that is within FDA's particular expertise FDA determines the scope of a device, including the components it comprises, and the appropriate regulatory pathway for the device In this case, the agency determined that the device requires PMA approval If a company is uncertain about what type of regulation a device requires, it will typically consult with FDA and the agency will tell the company if a PMA is required The company relies on FDA's decision, as it must. FDA subsequently determines whether the device meets the PMA approval standard. The agency makes a reasoned and deliberate decision as to the correct pathway of regulation and whether to approve the device Juries lack the scientific knowledge and technical expertise necessary to make such judgments They are not qualified to second-guess whether a device, in its entirety, was regulated through the correct pathway

The Court's uncertainty as to the status of Model 1388T may have arisen because Dr Parisian used the history of this device to mischaracterize its status It is correct that Model 1188T is a 510(k)-cleared device It is also correct that the addition of a steroid eluting tip to Model 1188T required the submission of a PMA application for the new device designated as the Model 1388T However, the steroid eluting tip was not the sole subject of the PMA. Rather, it was the trigger that prompted submission of a PMA application for the entire device

FDA has approved PMAs for other endocardial, steroid eluting pacing leads See 64 Fed. Reg 68694, 68695 (Dec 9, 1999), 61 Fed Reg 55153 (Oct 24, 1996) Furthermore, FDA approves other PMAs when the approval order describes one or more components that are included as part of the PMA approval. The entire PMA-approved device, including its components, as described in the approval letter and Federal Register notice of the approval, must meet the "reasonable assurance of safety and effectiveness" standard This is necessary because FDA has determined that the component must be subject to Class III controls to provide a reasonable assurance of safety and effectiveness of the device as a whole.

For state courts to determine that the scope of such PMA approvals is subject to second-guessing by a jury would severely disrupt the carefully constructed, comprehensive regulatory scheme Congress put in place for medical devices Indeed, the prospect of hundreds of individual juries determining the propriety of particular device approvals, or the appropriate standards to apply to those approvals, is the antithesis of the orderly scheme Congress put in place and charged FDA with implementing

Such uncertainty as to the status of medical devices would create chaos for both the regulated industry and FDA If the device industry were uncertain as to whether a particular device was 510(k)-cleared or PMA-approved, and could not rely on FDA's determination as definitive, companies would not know whether to submit a 510(k) notification or a PMA application before marketing a new device of the same type Similarly, such uncertainty would paralyze FDA's surveillance and compliance efforts because the agency would not know whether conditions of approval it established in a PMA approval apply to the entire device or only one feature of the device, or whether the labeling it approved in a PMA applies to the whole device or

one feature of the device It would further add to the confusion if different state courts came to different conclusions, with some courts determining that there is a "full" PMA approval for an entire device and others determining that there is a PMA approval for only one feature of the same device Such disarray is contrary to Congress' intent, as the legislative history of the MDA confirms See H R. Rep No 94-853, at 45 (1976) ("if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.")

To avoid such an outcome, Congress enacted the MDA and vested in FDA the authority to implement its provisions, including making a determination whether Class III devices meet the PMA approval standard of a "reasonable assurance of safety and effectiveness " 21 U S C 360e(d) See also Medtronic, Inc v. Lohr, 518 U S 470, 496 (1996), H R. Rep No 94-853, at 13 (1976) It is within FDA's discretion to determine the quantity and quality of data necessary to meet this standard, 21 C F R. § 860 7, and it is a scientific task for which FDA is uniquely qualified. See Lohr, 518 U S at 496 See also Schering Corp v FDA, 51 F 3d 390, 399 (3d Cir 1995) (safety and effectiveness determination under similar FDCA provisions applying to drugs falls "within the ambit of FDA's expertise ') Premo Pharm Lab , Inc v. U S., 629 F 2d 795, 803 (2d Cir 1980) (noting FDA's expertise ' of a complex scientific nature '), Berlex Labs , Inc v FDA, 942 F Supp 19, 25 (D D C 1996) (recognizing FDA's scientific expertise), Bristol Myers Squibb Co, v Shalala, 923 F Supp 212, 216 (D D C 1996) (acknowledging FDA's technical expertise)

Exercising its scientific judgment, FDA determines whether data in a PMA application provide a "reasonable assurance of safety and effectiveness" of the device Regardless of what

studies FDA relies upon, the same legal standard applies for every PMA, FDA must determine that the studies provide a "reasonable assurance of the safety and effectiveness" of the entire device Whether the PMA for Model 1388T constituted a "full PMA" for the device, as described in the approval letter and Federal Register notice of the approval, or a partial PMA approval/partial 510(k) clearance, is a question of law The law only allows for "full" PMA approval for a device as a whole Model 1388T in its entirety has received PMA approval

IV CONCLUSION

For the foregoing reasons, the United States urges the Court to grant Defendant's Petition for Certification for Interlocutory Appeal

Respectfully submitted,

PETER D KEISLER
Assistant Attorney General

EUGENE M THIROLF
Director
Office of Consumer Litigation

DRAKE CUTINI
Attorney
Office of Consumer Litigation
Civil Division
U S Department of Justice
P O Box 386
Washington, DC 20044
(202)307-0044

OF COUNSEL

ALEX M. AZAR II
General Counsel
Department of Health and Human Services

PAULA M STANNARD
Deputy General Counsel
Department of Health and Human Services

DANIEL E TROY
Chief Counsel
Food and Drug Division

ERIC M BLUMBERG
Deputy Chief Counsel
Food and Drug Division

LAURA R. EPSTEIN
Associate Chief Counsel
Food and Drug Division

STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND	)	
	)	
Monica Weston	)	Civil Action No 05-CP-40-0655
	)	
Plaintiff,	)	
	)	**SUPPLEMENTAL MEMORANDUM OF**
v	)	**LAW IN SUPPORT OF CIBA VISION'S**
	)	**MOTION FOR SUMMARY JUDGMENT**
Kims Dollar Store and CIBA Vision, a division of Novartis Company,	)	
	)	
Defendants	)	
	)	

On August 18 2006, counsel for CIBA Vision took the deposition of Suzanne Parisian Plaintiff's listed expert witness with regard to preemption issues [1] On August 24 (received August 25) 2006 Plaintiff served numerous documents in opposition to CIBA Visions' Motion for Summary Judgment on the issue of federal preemption This supplemental Memorandum of I aw is provided to give the Court further assistance in determining these legal issues In further support of the Motion for Summary Judgment CIBA Vision states as follows

I FDA CONSIDERED ALL NON-CORRECTIVE COLOR CONTACT LENSES TO BE MEDICAL DEVICES PRIOR TO ISSUING IMPORT ALERT 86-10 (APRIL 4, 2003) WHICH PROVIDED AN ALTERNATIVE CLASSIFICATION FOR SOLELY DECORATIVE LENSES

In her deposition, Suzanne Parisian took the position that the FDA never considered non-corrective contact lenses to be medical devices She maintained that position despite being confronted with FDA documentation to the contrary She further suggests that Import Alert 86 10 was in essence the FDA's first indication of a position regarding non corrective contact lenses

[1] After the hearing on July 12 2006 the August 18 2006 deposition date was the only date that Suzanne Parisian would make herself available

RECEIVED
AUG

McGarLa PA

This opinion is incorrect and should be disregarded by the Court For example, in 1995, the Food & Drug Administration issued a notice regarding its jurisdiction as a medical device over smokeless tobacco products [60 FR 41453, August 11, 1995) In its 'comprehensive legal analysis regarding the agency's jurisdiction over such products the FDA catalogued a number of other devices over which it maintained "medical device" authority At page 16 of the Notice, the FDA expressly states that

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

In the Appendix to Legal Analysis at p 49 of the FDA Notice the FDA states as follows

> 9 Noncorrective Tinted Contact Lenses The agency has taken the position that tinted contact lenses that do not correct or improve vision and are promoted to enhance eye color are medical devices This position is based on the fact that all contact lenses, including neutral lenses, have a physiological effect on the eye In 1986 the government obtained a consent decree of permanent injunction against the sale of a system used to make noncorrective tinted contact lenses on the ground that the system causes adulteration of a medical device the lenses (emphasis added) (citing to United States v International Hydron Corp , No 87-2129 (E D N Y))

The relevant pages of the FDA Notice is attached hereto as Exhibit A

Moreover in conjunction with Import Alert 86-10 the Food & Drug Administration also issued guidance to FDA staff That guidance is expressly limited to the sampling and detention of "decorative contact lenses " A copy of the FDA Guidance is attached hereto as Exhibit B In the Guidance related to decorative contact lenses, the FDA suggests that the initial step should be to determine if the contact lenses fall within a PMA or 510(k) approval (i e , a medical device) Only if they do not have a PMA or 510(k) approval are the products subject to being sampled or detained Clearly even at the time that the FDA was issuing Import Alert 86-10 which excluded

some noncorrective color lenses from the definition of medical device the FDA was treating nonexempt decorative contact lenses as medical devices and providing guidance to that effect to its staff Consequently Suzanne Parisian s opinion that the FDA had not previously taken the position that noncorrective decorative contact lenses were medical devices, is incorrect and casts doubt on her remaining opinions in this case To the contrary, based on the references cited above, the FDA's position that decorative contact lenses are medical devices began in at least 1986, continued through 1995 and survived, in part, beyond the Import Alert relied on by the Plaintiff

II THERE IS NO FACTUAL DISPUTE AS TO THE STATUS OF FRESHLOOK COLORS NONCORRECTIVE COLOR LENSES AS MEDICAL DEVICES AT ALL TIMES RELEVANT TO THIS LITIGATION

Import Alert 86-10 expressly states that any noncorrective contact lens that has a physiological effect or medical use is not solely for decorative purposes and therefore a medical device [2] Dr Parisian acknowledge in her deposition that a contact lens with a medical use would elevate the lens from a cosmetic to a medical device during all relevant times As of July 2003, the FDA approved package insert for FreshLook Color lenses included the following indications for use FreshLook soft contact lenses with UV-absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye (The July 2003 approved package insert is attached as Exhibit 6 to the deposition of Paul Oris and as Exhibit 9 to the deposition of Phil Phillips, which he relied on in forming his opinions that the lens in question is a medical device) (a copy of the July 2003 package insert is attached hereto as Exhibit C for the Court s convenience) The package insert goes on to state that

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

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

Clearly, under Import Alert 86-10 the FreshLook Color lens (allegedly worn by Plaintiff) is a medical device beyond a sole decorative cosmetic product For example, in discussing what uses or effects might elevate a cosmetic product to a drug or medical device, the FDA expressly noted in Import 86-10 that sunscreen claims make a cosmetic product a drug Moreover, Import Alert 86-10 expressly states that decorative contact lenses with additional medical uses (such as UV protection) are not subject to the Import Alert and are "properly regulated as medical devices ' Consequently, there is no factual dispute that CIBA Vision FreshLook Color lenses of the type allegedly obtained by Plaintiff provided UV absorbing protection thereby taking them out of the category of solely decorative lenses Consequently, as a matter of law, the contact lens involved in this case must be considered a ' medical device' (regardless of whether it is also a cosmetic) [3]

III DR PARISIAN'S AFFIDAVITS AND OPINIONS SHOULD BE DISREGARDED BY THIS COURT PURSUANT TO SOUTH CAROLINA RULE OF EVIDENCE 7 02

Specifically Suzanne Parisian does not have the specialized knowledge, skill experience or training to provide an admissible opinion or assist the Court in legal determinations of this summary judgment motion Suzanne Parisian is not an ophthalmologist or optometrist She has no formal medical training or courses in ophthalmology or ophthalmic devices She has never manufactured, designed, evaluated or reviewed a contact lens of any kind She acknowledged in

[3] Although it is a cumulative point and not necessary for entry of summary judgment, it is worth pointing out that the FreshLook contact lens obtained by the Plaintiff was also approved for ' extended wear As noted in the July 2003 package insert certain physiological changes (which would take these lenses outside the definition of a cosmetic product) are also associated with extended wear These include a weakening of the corneas resistance to infection a higher incident and degree of ephithelial microcysts and infiltrates and endothelial polymegathism

her deposition that while at the FDA for only four years, she had no involvement with eye devices or devices reviewed by the Division of Ophthalmic Devices Her resume suggests that she has some expertise based on writing a book about the FDA However, at her deposition she acknowledged that the book was merely a compilation of FDA-related statutes, regulations and public information She has been rebuffed by other courts and limited in providing opinions in other cases (all regarding devices for which she would have had more interaction than contact lenses when she was at the FDA) In Oakberg v Zimmer, Inc (USDC for Missouri 2004) she was prevented from offering opinions regarding the content of FDA regulations the application of FDA regulations to defendant s operations, the defendant s alleged violations of FDA regulations and the FDA regulatory clearance or reporting requirements (A copy of this and other limiting orders are attached to her deposition which is being filed contemporaneously herewith) In Oakberg and two other cases the court excluded her opinions on alleged failures to warn (which is the key issue involved in this preemption motion) In one case, Murphee v Pacesetter (also attached as an exhibit to her deposition) the FDA was actually compelled to intervene and file a Statement of Interest in opposition to Suzanne Parisian s opinions regarding the FDA In its Statement of Interest the FDA asserted that Suzanne Parisian was in error concerning a medical device s regulatory history and that she mischaracterized its status and that her opinion was clouding the status of the medical device and 'would create chaos for both the regulated industry and FDA ' Her opinions in this case are subject to similar if not more severe criticism For example, as set out above, Suzanne Parisian's opinion that the FDA did not take the position that decorative contact lenses were medical devices prior to 2005 is clearly contradicted by the FDA references *supra*

The bulk of Suzanne Parisian s Affidavit and opinions in this case (as in other cases) is to inappropriately substitute herself for the Court and/or the FDA For example opinions or purported

factual issues regarding whether CIBA Vision may have been in technical noncompliance with an FDA requirement is both irrelevant and beyond her purview to conclude What is factually undisputed is that the FDA never took any action to withdraw, revoke, suspend, terminate or invalidate CIBA Vision's PMA and PMA Supplement approval for FreshLook Colors lenses in a range including noncorrective powers which were approved by the FDA for the correction of visual acuity, the enhancement of eye color and the protection from UV radiation Consequently Suzanne Parisian s opinions regarding these matters do not prevent entry of summary judgment in favor of CIBA Vision on federal preemption

IV PHIL PHILLIPS' EXPERT OPINIONS ESTABLISH CIBA VISION'S ENTITLEMENT TO SUMMARY JUDGMENT ON THE ISSUE OF FEDERAL PREEMPTION

In contrast to Suzanne Parisian, CIBA Vision retained Philip J Phillips to review the issues in this case and provide his expert analysis regarding the issues underlying the application of federal preemption Mr Phillips was first employed by the FDA in 1981 and retired in February 2005 During his extensive career with the FDA he was deeply involved with the Division of Ophthalmic Devices, even serving as the Acting Deputy Director He retired as the Deputy Director for Science and Regulatory Policy of the Office of Device Evaluation As set forth in his affidavit previously filed with the Court there is no question that CIBA Vision s FreshLook Color lenses (including the contact lens subject to this litigation) were at all relevant times medical devices falling within the federal preemption authority of the Medical Devices Amendments of 1976 He has reviewed the relevant documents and other information and confirmed that the lens at issue in this case was PMA approved, the labeling was FDA approved and required the lens included medical uses and physiological characteristics exceeding the solely' decorative exemption of Import Alert 86-10, and that CIBA Vision s PMA approval as a Class III medical device for the contact lens in question

remained intact through all relevant time periods in this case including beyond the date Plaintiff acquired the lens in question All of Phil Phillips' opinions and analyses were confirmed and verified to a reasonable degree of expert certainty at his deposition Because of the delay in scheduling Suzanne Parisian's deposition (see discussion above), counsel for CIBA Vision did not have a copy of her deposition until Monday, August 21, 2006 Phil Phillips finalized and submitted his affidavit on Tuesday, August 22 2006[4] Thereafter his deposition was taken in Washington DC on August 24, 2006 (yesterday) Counsel for CIBA Vision has asked for an expedited transcript which he hopes to receive on Sunday afternoon, August 27, 2006, to be able to bring to the hearing on August 28 2006

V GUIDANCE FROM THE FDA

If the Court determines that it cannot enter summary judgment in favor of CIBA Vision because it is unable to resolve some of the regulatory issues created by the opinions of Suzanne Parisian or the submissions of Plaintiff, CIBA Vision would request that the Court seek guidance from the FDA 21 CFR 808 5 expressly allows any state or interested party to request an advisory opinion from the FDA with respect to matters concerning preemption of state or local device requirements Such a request should be in the format set forth in 21 CFR 10 85 Pursuant to Whaley v CSX Transportation Inc , 326 S C 456 609 S E 2d 286 (2005), there is no question that the South Carolina Supreme Court would consider a verdict in a civil action to constitute state action which can be preempted by the federal preemption provisions of the Medical Devices Act Therefore to the extent the Court has questions about the regulatory environment applicable to this contact lens and the preemption issues in this case, the FDA has a procedure in place to provide

[4] Counsel for CIBA Vision had outlined Phil Phillips opinion in a detailed multi-paged letter, dated July 2006

assistance through advisory opinions CIBA Vision has previously sought clarification from the Office of the Chief Counsel for the FDA regarding a number of these preemption issues We have had contact with the FDA but no definitive answer A formal request from the Court through the regulatory provision would add considerable momentum to efforts to gain FDA's insights on the regulatory issues in this case We have prepared a draft letter that might be appropriate for invoking the assistance of the FDA on these issues This proposed letter is attached hereto at Exhibit E [5] CIBA Vision would invite the Plaintiff's counsel to send a similar letter requesting clarification of any additional issues they might deem relevant However, in order to avoid any unnecessary delay, we would request that the Court send this letter promptly and that the Plaintiff's counsel submit their letter, if any, by September 1, 2006

For the foregoing reasons and based on the analysis and information in the original motion and the exhibits and other record information filed with regard to the Motion for Summary Judgment or otherwise filed with the Court CIBA Vision respectfully requests this Court enter summary judgment in favor of CIBA Vision as requested in its original motion

(Signature page to follow)

[5] We will be glad to provide the Court with an electronic version in its preferred format so it can make whatever modifications it finds desirable

August 25, 2006

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

Keith D Munson
Sandi R Wilson
Womble Carlyle Sandridge & Rice
A Professional Limited Liability Company
P O Box 10208
Greenville, SC 29603
Phone (864) 255-5400
Fax (864) 255-5480

ATTORNEYS FOR DEFENDANT CIBA VISION

Westlaw

60 FR 41453-01 1995 WL 473693 (F R)

(Cite as 60 FR 41453)

NOTICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No 95N-0253J]

Analysis Regarding The Food and Drug Administration s Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products

Friday August 11 1995

***41453** AGENCY Food and Drug Administration HHS

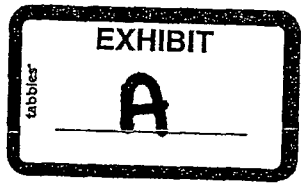
ACTION Notice analysis regarding agency jurisdiction

SUMMARY The Food and Drug Administration (FDA) is publishing a document entitled Nicotine In Cigarettes And Smokeless Tobacco Products Is A Drug And These Products Are Nicotine Delivery Devices Under the Federal Food Drug and Cosmetic Act and announcing the availability of appendices to this document FDA has conducted an extensive investigation and has engaged in comprehensive analysis regarding the agency s jurisdiction over nicotine-containing cigarettes and smokeless tobacco products The results of that inquiry and analysis support a finding at this time that nicotine in cigarettes and smokeless tobacco is a drug and that these products are drug delivery devices within the meaning of the Federal Food Drug and Cosmetic Act Nonetheless because the agency recognizes the unique importance of the jurisdictional issue as well as the factual justification for any proposed rule in this area the agency invites comment on these matters Comments submitted will receive full and serious consideration

DATES Written comments by November 9 1995

ADDRESSES Nicotine In Cigarettes And Smokeless Tobacco Products Is A Drug And These Products Are Nicotine Delivery Devices Under the Federal Food Drug and Cosmetic Act and its appendices may be purchased from Superintendent of Documents U S Government Printing Office (GPO) Washington DC 20402 202-783-3238 Nicotine In Cigarettes And Smokeless Tobacco Products Is A Drug And These Products Are Nicotine Delivery Devices Under the Federal Food Drug and Cosmetic Act and its appendices are available for public examination in the Dockets Management Branch (HFA-305) Food and Drug Administration rm 1-23 12420 Parklawn Dr Rockville MD 20857 between 9 a m and 4 p m Monday through Friday

© 2006 Thomson/West No Claim to Orig U S Govt Works



60 FR 41453-01 1995 WL 473693 (F R)

(Cite as 60 FR 41453)

FOR FURTHER INFORMATION CONTACT Philip L Chao Office of Policy (HF-23) Food and Drug Administration 5600 Fishers Lane Rockville MD 20857 301-827-3380

SUPPLEMENTARY INFORMATION The appendices referred to in the document entitled Nicotine In Cigarettes And Smokeless Tobacco Products Is A Drug And These Products Are Nicotine Delivery Devices Under the Federal Food Drug and Cosmetic Act are available from GPO (address above)

Elsewhere in this issue of the Federal Register the agency is publishing a proposed regulation of nicotine-containing cigarettes and smokeless tobacco products The agency recognizes the unique importance of the jurisdictional issue underlying this regulation as well as the factual justification for any proposed rule in this area The agency invites comments on these matters Comments submitted will receive full and serious consideration

The text of Nicotine In Cigarettes And Smokeless Tobacco Products Is A Drug And These Products Are Nicotine Delivery Devices Under the Federal Food Drug and Cosmetic Act follows

BILLING CODE 4160-01-F

Nicotine In Cigarettes And Smokeless Tobacco Products Is A Drug And These Products Are Nicotine Delivery Devices Under The Federal Food, Drug And Cosmetic Act

U S Food and Drug Administration

Department of Health and Human Services

August 1995

PREFACE

The Food and Drug Administration (FDA) has conducted an extensive investigation and has engaged in comprehensive legal analysis regarding the agency s jurisdiction over nicotine-containing cigarettes and smokeless tobacco products The results of that inquiry and analysis support a finding at this time that nicotine in cigarettes and smokeless tobacco products is a drug and that these products are drug delivery devices within the meaning of the Food Drug and Cosmetic Act Nonetheless because the agency recognizes the unique importance of the jurisdictional issue as well as the factual justification for any proposed rule in this area the agency invites comment on these matter Comments submitted will receive full and serious consideration

Elsewhere in the same issue of the Federal Register in which this document is published the agency is issuing a proposed regulation of nicotine-containing cigarettes and smokeless tobacco products under the restricted device provisions of the Act Comments should be sent to FDA s Dockets Management Branch and identified with the docket number 95N-0253J Comments should be submitted by the date identified in the Federal Register

© 2006 Thomson/West No Claim to Orig U S Govt Works

60 FR 41453-01 1995 WL 473693 (F R)

(Cite as 60 FR 41453)

Traditionally the FDA has initiated enforcement actions in cases where the agency determines that a product is a drug or a delivery device Because the agency has elected to embark on this initiative through rulemaking no enforcement action will be brought pending completion of that process

SUMMARY TABLE OF CONTENTS

INTRODUCTION

PART ONE LEGAL ANALYSIS OF JURISDICTION OVER TOBACCO PRODUCTS

I CIGARETTES AND SMOKELESS TOBACCO PRODUCTS AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY BECAUSE THEY HAVE PHARMACOLOGICAL EFFECTS AND LEAD TO ADDICTION

II TOBACCO MANUFACTURERS INTEND THAT THEIR PRODUCTS HAVE ADDICTIVE AND SIGNIFICANT PHARMACOLOGICAL EFFECTS

III NICOTINE-CONTAINING CIGARETTES AND SMOKELESS TOBACCO PRODUCTS ARE DRUG DELIVERY SYSTEMS THAT ARE APPROPRIATELY REGULATED AS DEVICES

PART TWO FINDINGS

EVIDENCE THAT CIGARETTES AND SMOKELESS TOBACCO ARE INTENDED TO AFFECT THE STRUCTURE AND FUNCTION OF THE BODY

I NICOTINE HAS DRUG EFFECTS ON THE BODY

II STATEMENTS RESEARCH AND ACTIONS BY TOBACCO COMPANIES

PART THREE REGULATORY OBJECTIVES

APPENDICES

DETAILED TABLE OF CONTENTS

INTRODUCTION vi
PART ONE LEGAL ANALYSIS OF JURISDICTION OVER TOBACCO PRODUCTS 1
INTRODUCTION AND SUMMARY 2
I CIGARETTES AND SMOKELESS TOBACCO PRODUCTS AFFECT THE

© 2006 Thomson/West No Claim to Orig U S Govt Works

STRUCTURE OR ANY FUNCTION OF THE BODY BECAUSE THEY HAVE PHARMACOLOGICAL EFFECTS AND LEAD TO ADDICTION 6

II TOBACCO MANUFACTURERS INTEND THAT THEIR PRODUCTS HAVE ADDICTIVE AND SIGNIFICANT PHARMACOLOGICAL EFFECTS 10
A OBJECTIVE INTENT IS THE APPROPRIATE STANDARD 11
B THE EVIDENCE DEMONSTRATES INTENT TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY 21
1 The addictive Psychoactive and Other Pharmacological Effects of Nicotine are Widely Known and Foreseeable by Any Reasonable Person in the Position of a Tobacco Manufacturer 22
2 Consumers Use Tobacco Products to Obtain the Pharmacological Effect of Nicotine and to Satisfy Their Addiction to Nicotine 29
3 Tobacco Manufacturers Know That Nicotine Has Pharmacological Effects and That Consumers Use Tobacco for Those Effects and Have Acted to Facilitate That Use 30

III NICOTINE-CONTAINING CIGARETTES AND SMOKELESS TOBACCO PRODUCTS ARE DRUG DELIVERY SYSTEMS THAT ARE APPROPRIATELY REGULATED AS DEVICES 60

CONCLUSION 65

APPENDIX TO LEGAL ANALYSIS 68

PART TWO FINDINGS 71

I NICOTINE HAS DRUG EFFECTS ON THE BODY 73
A NICOTINE HAS PHYSIOLOGICAL AND CENTRAL NERVOUS SYSTEM EFFECTS 74
B NICOTINE IS ADDICTIVE 78
1 Major Public Health Groups and Leading Experts concur 78
2 Epidemiological Data Establishes That Tobacco Users Display the Clinical Symptoms of Addiction 86
3 Laboratory Studies Establish That Nicotine Produces Pharmacological Effects Similar to Those of Other Addictive Substances 94
4 Nicotine s Sensory Effects Are Secondary to its Psychoactive Effects 102
5 Other Factors Associated with Tobacco Use are Secondary 106
C MARKETED TOBACCO PRODUCTS DELIVER PHARMACOLOGICALLY ACTIVE DOSES OF NICOTINE 108

© 2006 Thomson/West No Claim to Orig U S Govt Works

60 FR 41453-01 1995 WL 473693 (F R)

(Cite as 60 FR 41453)

1 Amount of Nicotine Necessary to Produce a Physiological Response in the Central Nervous System 108
2 Nicotine Delivery From Currently Marketed Tobacco Products 110
D CONSUMERS USE TOBACCO PRODUCTS FOR DRUG EFFECTS 115
1 To Satisfy Addiction 115
2 To Affect Mood and Control Weight 118

II STATEMENTS RESEARCH AND ACTIONS BY TOBACCO COMPANIES 121
A INDUSTRY STATEMENTS ON NICOTINE S DRUG EFFECTS 122
1 Statements That Nicotine s Drug Effects Are Essential to Tobacco Use 123
2 Statements Recognizing That Nicotine Is Addictive 143
3 Statements That Tobacco Products Are Nicotine Delivery Systems 156
B INDUSTRY RESEARCH ON THE DRUG EFFECTS OF NICOTINE 160
1 Industry Research on Nicotine s Effects on the Brain 164
2 Industry Research on Nicotine Delivery to the Blood and Brain 174
3 Industry Research Establishes That Nicotine Produces Pharmacological Effects Similar to Those of Other Addictive Drugs 179
C INDUSTRY RESEARCH ON THE CONSUMER S NEED FOR AN ADEQUATE DOSE OF NICOTINE 183
1 Industry research on Importance of Supplying Sufficient Nicotine to Provide Consumer Acceptance and Satisfaction 183
2 Industry Research to Determine the Minimum and Maximum Dose of Nicotine Required by Consumers of Tobacco 188
3 Industry Research on How Consumers Compensate to Achieve an Adequate Dose of NIcotine 198
4 Industry Research and Knowledge of Tobacco Users Inability to Quit 206
D INDUSTRY PRODUCT DEVELOPMENT RESEARCH TO ENSURE AN ADEQUATE DOSE OF NICOTINE 213
1 Industry Emphasis on Nicotine in Product Development Research 213
2 Industry Research on Maintaining Adequate Nicotine Delivery When Lowering Tar 222
E INDUSTRY MANIPULATION AND CONTROL OF NICOTINE DELIVERY IN MARKETED TOBACCO PRODUCTS 232
1 Industry manipulation and Control of Nicotine in Cigarettes 232
2 Industry Manipulation and Control of Nicotine in

© 2006 Thomson/West No Claim to Orig U S Govt Works

Smokeless Tobacco 273
F INDUSTRY ALTERNATIVE TOBACCO PRODUCTS 289
1 Industry Development of Nicotine Substitutes That Mimic Nicotine s Drug Effects 289
2 Industry Research on Acetaldehyde As a Reinforcer 298
3 Industry Development of Alternative Cigarettes That Deliver Nicotine 302
G INDUSTRY KNOWLEDGE THAT NICOTINE S SENSORY EFFECTS ARE SECONDARY TO ITS PHARMACOLOGICAL EFFECTS 311
H INDUSTRY FAILURE TO REMOVE NICOTINE FROM TOBACCO DESPITE AVAILABLE TECHNOLOGY 324

PART THREE REGULATORY OBJECTIVES 324

APPENDICES

1 Background on Nicotine Pharmacology

2 Corporate Relationship Between Brown and Williamson and British-American Tobacco Co

3 FDA Letters to Tobacco Manufacturers

4 Bibliography of Industry-Funded Research

5 Marketing of Cigarettes and Smokeless Tobacco in the U S

6 Citizen Petitions and Submitted Comments

7 Statement by David A Kessler M D Commissioner of Food and Drugs on Nicotine-Containing Cigarettes before the Subcommittee on Health and the Environment Committee on Energy and Commerce U S House of Representatives March 25 1994

8 Statement by David A Kessler M D Commissioner of Food and Drugs on the Control and Manipulation of Nicotine in Cigarettes before the Subcommittee on Health and the Environment Committee on Energy and Commerce U S House of Representatives June 21 1994

9 Remarks by David A Kessler M D Commissioner of Food and Drugs The Samuel Rubin Program the Columbia University School of Law March 8 1995

10 Additional Documents

© 2006 Thomson/West No Claim to Orig U S Govt Works

60 FR 41453-01 1995 WL 473693 (F R)

(Cite as 60 FR 41453)

INTRODUCTION

Part One of this document (Legal Analysis of Jurisdiction over Tobacco Products) consists of three main sections Section I demonstrates that nicotine s addictive and other pharmacological properties are effects on the structure or any function of the body within the meaning of the Act s definition of a drug Section II demonstrates that tobacco manufacturers intend their products to have these effects within the meaning of the Act because these effects are widely known and foreseeable to the industry most consumers use tobacco products to obtain these effects and tobacco manufacturers understand that consumers use tobacco products to obtain nicotine s pharmacological effects and design their products to be used for these effects Section III explains why regulation of cigarettes and smokeless tobacco products as devices is most appropriate at this time

Part Two of this document (Findings) consists fo two main sections Section I presents the scientific evidence of nicotine s addictive and other pharmacological effects This section also explains how marketed tobacco products deliver pharmacologically active doses of nicotine and how consumers use these products to obtain various drug effects Section II describes the statements extensive research and other actions by tobacco manufacturers regarding nicotine s pharmacological effects This section identifies the industry s numerous acknowledgements that nicotine in tobacco acts as a drug and is addictive and the industry s extensive research on nicotine s drug effects on the body Section II also describes the considerable industry research on supplying sufficient nicotine to provide satisfaction determining the minimum and maximum dose of nicotine required by consumers and assessing how consumers compensate to achieve an adequate dose of nicotine

Section II provides further evidence that manufacturers intend to market these products for their pharmacological effects including explanations of the industry s product development research to ensure that their products deliver doses of nicotine adequate to achieve pharmacological effects manipulation and control of nicotine in marketed products development of nicotine substitutes and alternative products that provide nicotine s drug effects knowledge that nicotine s sensory effects are secondary to its pharmacological effects and failure to remove nicotine from tobacco despite the available technology to do so

Part Three of this document (Regulatory Objectives) summarizes FDA s objectives in regulating cigarettes and smokeless tobacco products This section explains why despite the significant public health problem caused by cigarettes and smokeless tobacco products it would not be appropriate to remove them from the market because approximately 40 million Americans are addicted to these products The section summarizes the evidence that almost all tobacco use begins during childhood or adolescence and that the prevalence of tobacco use by children and adolescents is increasing Therefore the goal of FDA s regulatory action will be to reduce tobacco use by children and teenagers and prevent future generations from becoming addicted to nicotine-containing tobacco products

© 2006 Thomson/West No Claim to Orig U S Govt Works

60 FR 41453-01 1995 WL 473693 (F R)

(Cite as 60 FR 41453)

PART ONE LEGAL ANALYSIS OF JURISDICTION OVER TOBACCO PRODUCTS

INTRODUCTION AND SUMMARY 2

I CIGARETTES AND SMOKELESS TOBACCO PRODUCTS AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY BECAUSE THEY HAVE PHARMACOLOGICAL EFFECTS AND LEAD TO ADDICTION 6

II TOBACCO MANUFACTURERS INTEND THAT THEIR PRODUCTS HAVE ADDICTIVE AND SIGNIFICANT PHARMACOLOGICAL EFFECTS 10

A OBJECTIVE INTENT IS THE APPROPRIATE STANDARD 11

B THE EVIDENCE DEMONSTRATES INTENT TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY 21

1 The Addictive Psychoactive and Other Pharmacological Effects of Nicotine Are Widley Known and Foreseeable by Any Reasonable Person in the Position of a Tobacco manufacturer 22

2 Consumers Use Tobacco Products to Obtain the Pharmacological Effects of Nicotine and to Satisfy Their Addiction to Nicotine 29

3 Tobacco Manufacturers Know That Nicotine Has Pharmacological Effects and That Consumers Use Tobacco for Those Effects and Have to Facilitate That Use 30

a Tobacco Manufacturers Studies and Statements Demonstrate Knowledge That Nicotine in Tobacco Is Addictive and Has Psychoactive Effects 31

b Tobacco manufacturers Know That Consumers Use Tobacco Products for the Pharmacological Effects of Nicotine 38

c Tobacco Manufacturers Have Acted to Facilitate and Sustain the Consumer Use of Tobacco Products for Their Pharmacological Effects 43

d Smokeless Tobacco Manufacturers Manipulate Nicotine Delivery and Foster Graduation of Users From Low to High Nicotine Products 56

III NICOTINE-CONTAINING CIGARETTES AND SMOKELESS TOBACCO PRODUCTS ARE DRUG DELIVERY SYSTEMS THAT ARE APPROPRIATELY REGULATED AS DEVICES 60

CONCLUSION 65

APPENDIX TO LEGAL ANALYSIS 67

INTRODUCTION AND SUMMARY

© 2006 Thomson/West No Claim to Orig U S Govt Works

60 FR 41453-01 1995 WL 473693 (F R)

(Cite as 60 FR 41453)

FDA has jurisdiction over consumer products including foods drugs medical devices biologics and cosmetics under the Federal Food Drug and Cosmetic Act (FDCA or the Act) 21 U S C §§ 301-394 a statute enacted to safeguard the public health and to protect consumer welfare H R Rep No 2139 75th Cong 3d Sess 1-2 (1938)

The Act defines drug and device in a parallel manner The term drug is defined in relevant part as an article intended for use in the diagnosis cure mitigation treatment or prevention of disease or intended to affect the structure or any function of the body 21 U S C § 321(g)(B) (C) The term device is defined as an instrument or other similar article intended for use in the cure mitigation treatment or prevention of disease or intended to affect the structure or any function of the body 21 U S C § 321(h)(2) (3) These definitions are broad in scope and encompass a range of products wider than those ordinarily thought of as drugs or medical devices Indeed FDA has regulated such diverse non-therapeutic products as narcotics without medical claims and tanning booths pursuant to these definitions The question of whether a product is a drug or device is one that the FDA has jurisdiction to decide with administrative finality subject to the types of judicial review provided [in the FDCA] Weinberger v Bentex Pharmaceuticals Inc 412 U S 645 653 (1973) see id at 652-54 CIBA Corp v Weinberger 412 U S 640 643-44 (1973) see also Biotics Research Corp v Heckler 710 F 2d 1375 1377 (9th Cir 1983)

Under the Act FDA has jurisdiction over nicotine-containing cigarettes and smokeless tobacco products (hereafter cigarettes and smokeless tobacco products) if they are intended to treat a disease or to affect the structure or any function of the body As set forth in greater detail below the evidence now available to the agency demonstrates that cigarettes and smokeless tobacco products fall well within the definitions of drug and device [FN1] It is well established that nicotine in tobacco is highly addictive causes other psychoactive effects such as relaxation and stimulation and affects weight regulation These responses to nicotine are effects on the structure or function of the body within the meaning of the Act

FN1 The quality quantity and scope of the evidence available to FDA today is far greater than any other time when FDA has considered regulation of cigarettes and smokeless tobacco products *See* **LEGAL ANALYSIS** § I B 1 *infra* p 22

The evidence before the agency also demonstrates that manufacturers intend to market and distribute products that affect the structure or function of the body within the meaning of the Act Under the Act Agency regulations well-established case law and longstanding Agency practice discussed in detail below intended for use and intended to affect can be demonstrated by evidence that drug-like (pharmacological) effects in a large proportion of consumers are foreseeable by a reasonable manufacturer consumers use the product predominantly and even nearly exclusively for its significant pharmacological effects or manufacturers actually know that the product will be used for its significant pharmacological effects and have taken steps to encourage such use In

© 2006 Thomson/West No Claim to Orig U S Govt Works

60 FR 41453-01 1995 WL 473693 (F R)

(Cite as 60 FR 41453)

determining the intended use of a product all relevant evidence may be considered including the product s effect on consumers consumer behavior and statements regarding the product manufacturers conduct and statements results of scientific studies and the other circumstances surrounding the distribution of the product

In 1988 the U S Surgeon General issued a report formally recognizing that nicotine in cigarettes causes addiction He had similar finding for smokeless tobacco products in 1986 Today nearly every major public health organization in this country and many experts who consult for the tobacco companies consider tobacco products containing nicotine to be addictive In fact recent major studies show tnat 75% to 90% of frequent smokers of tobacco are addicted Thus manufacturers of these products can reasonably be expected to foresee that their products are likely to lead to addiction in a large proportion of consumers

This evidence also demonstrates that the vast majority of smokers and many smokeless tobacco consumers because they are addicted to nicotine use cigarettes and smokeless tobacco to satisfy nicotine dependence Many of these consumers also use these products to affect mood and to control weight Consumers use cigarettes predominantly and even nearly exclusively for their pharmacological effects

Finally internal tobacco industry documents demonstrate the industry s longstanding knowledge of and extensive research on the significant addictive and pharmacological effects of nicotine Moreover manufacturers of tobacco products have conducted product development research regarding the levels of nicotine necessary to produce pharmacological effects in tobacco users and also on methods of manipulating the amount of nicotine delivered by cigarettes FDA s investigation has revealed that tobacco manufacturers actively control the amount and rate at which nicotine from marketed cigarettes and smokeless tobacco is delivered to consumer Smokeless tobacco manufacturers both manipulate the amount of nicotine delivered by their products and promoter the graduation of smokeless tobacco consumers from the lowest to the highest nicotine products demonstrating an intention to facilitate nicotine dependence

In summary the evidence before the agency demonstrates that cigarettes and smokeless tobacco products are intended to affect the structure and function of the body Accordingly the record [FN1a] before the agency demonstrates that cigarettes and smokeless tobacco products are drug delivery systems whose purpose is to deliver nicotine a drug and hence are devices under the Act Given the current evidence the nature of the products and the nature of the regulatory framework cigarettes and smokeless tobacco products should be regulated as devices under the Federal Food Drug and Cosmetic Act

FN1a The phrase record as used throughout this document is not used as a term of art but is used instead to refer to the accumulation of evidence gathered during FDA s investigation

© 2006 Thomson/West No Claim to Orig U S Govt Works

60 FR 41453-01 1995 WL 473693 (F R)

(Cite as 60 FR 41453)

I CIGARETTES AND SMOKELESS TOBACCO PRODUCT AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY BECAUSE THEY HAVE PHARMACOLOGICAL EFFECTS AND LEAD TO ADDICTION

The definition of drug in the Food and Drugs Act of 1906 included only articles intended to be used for the cure mitigation or prevention of disease Pub L No 59-384 34 Stat 768 § 6 Congress added section 201(g)(1)(C) [FN2] when it enacted the Federal Food Drug and Cosmetic Act of 1938 in order to expand the reach of the drug definition to encompass products that escaped regulation under the 1906 act Section 201(g)(1)(C) and the parallel section 201(h)(3) governing devices reach products that do not have therapeutic uses but have or are promoted as having significant pharmacological or physiological effects As House Report 2139 explained

FN2 Section 201 of the Federal Food Drug and Cosmetic Act is now codified at 21 U S C § 321

[t]he definition of drug is expanded to include articles other than food intended to affect the structure or any function of the body of man or other animals These expansions are needed to give jurisdiction over a great number of drugs which are not amenable to control under the present law

H R Rep No 2139 at 3 reprinted in 6 Legislative History 300 302 (emphasis added) The principal example given in the legislative history of products intended to affect the structure or any function of the body is weight management products The structure or any function language was needed because obesity and extreme thinness were not considered diseases Congress was concerned with both the egregious nature of the claims for some of these products as well as the health risks associated with their use See 78 Cong Rec 8960 (73d Cong 2d Sess May 16 1934)(prepared statement of Senator Copeland) reprinted in 2 Legislative History at 831

While Congress primary focus in 1938 was on products intended for weight management it adopted language that included all products that affect the structure or function of the body This expansion of the drug definition was needed to protect the consumer against a multiplicity of abuses not subject to the [1906 act] S Rep No 646 74th Cong 1st Sess 1 reprinted in 4 Legislative History at 93 As one court explained

The legislative history of the 1938 Act discloses that the law which broadened the drug definition was enacted in part and perhaps in important part to control fraudulent remedies for obesity and leanness But it also discloses that the expansion of the drug definition was not aimed solely at these remedies They were merely illustrative of a comprehensive class of preparations which were intended to affect the structure or function of the body to which the legislation was directed

United States v Article Consisting of 36 Boxes Lineaway Temporary Wrinkle Smoother 284 F Supp 107 110 (D Del 1968) aff d 415 F 2d 369 (3d Cir 1969)

© 2006 Thomson/West No Claim to Orig U S Govt Works

(emphasis added)(citations omitted)

Consistent with the statutory language and Congress intent to insure that FDA has the authority to regulate products with non-therapeutic but pharmacological effects FDA has interpreted the provisions to encompass products that intrinsically have pharmacological or physiological effects even though they are not promoted for therapeutic purposes Examples of such products are topical hormones sunscreens and tanning booths See Appendix to Legal Analysis Judicial constructions of sections 201(g)(1)(C) and 201(h)(3) are consistent with this interpretation See e g E R Squibb & Sons Inc v Bowen 870 F 2d 678 683 (D C Cir 1989)(summarizing cases) United States v Undetermined Quantities of Cal-Ban 3000 776 F Supp 249 253 (E D N C 1991) ([T]he term drug should be interpreted broadly and not limited to only products which are commonly known as drugs)

Courts have been careful to distinguish between remote physical effects which arguably might fall within the literal language of section 201(g)(1)(C) or section 201(h)(3) and significant effects on structure or function which clearly fall within the provisions ambit [R]emote physical effect[s] on the body are not covered by the structure or function provision E R Squibb & Sons 870 F 2d at 682 On the other hand products intended to prevent pregnancy thus affecting the reproductive function of the human body fall within the definition Id at 682-83

For example a product intended to reduce the number of bacteria in an animal s digestive system and oral cavity is a drug within the meaning of section 201(g)(1)(C) because it was intended to alter a function of the animal s body United States v Undetermined Quantities Pet Smellfree 22 F 3d 235 240 (10th Cir 1994) Similarly liquid solutions intended to cause hair growth and prevent hair loss are drugs within the meaning of section 201(g)(1)(C) because the hair growth process is a function of the human body United States v Kasz Enterprises Inc 855 F Supp 534 540 (D R I 1994) judgment modified on other grounds 862F Supp 717 (D R I 1994) Likewise an apparatus containing oxygen that is intended to improve athletic performance by increasing a tired athlete s intake of oxygen falls within sections 201(g)(1)(C) and 201(h)(3) because enhanced oxygen absorption alters a bodily structure or function United States v Eighteen Units More or Less Of An Article of Drug SPORTS OXYGEN Civ No 89-2085 (D N J October 27 1992) reprinted in Food Drug and Cosmetic Act Judicial Record 1991-92 115 Cocaine and similar substances with parallel addictive and psychoactive effects also fall within the drug definition because they affect the structure or any function of the body [FN3]

FN3 In fact the Controlled Substances Act 21 U S C §§ 801-904 which prohibits the sale of drugs such as cocaine defines drug by reference to section 201(g)(1) of the FDCA 21 U S C § 802(12)

In each of these cases a significant pharmacological effect on the body can bring a substance within the drug definition even when the product has no

© 2006 Thomson/West No Claim to Orig U S Govt Works

60 FR 41453-01 1995 WL 473693 (F R)

(Cite as 60 FR 41453)

therapeutic effect On numerous other occasions the Agency has reached similar conclusions and has taken regulatory action See Appendix to Legal Analysis for examples As is discussed at p 22 et seq it is now widely accepted that nicotine has pharmacological effects on both the structure and function of the central nervous system particularly the brain Addiction is a direct result of nicotine s effects on the structure and function of the body Id Based on the record before the agency cigarettes and smokeless tobacco products affect the structure or any function of the body within the meaning of sections 201(g)(1)(C) and 201(h)(3)

II TOBACCO MANUFACTURERS INTEND THAT THEIR PRODUCTS HAVE ADDICTIVE AND SIGNIFICANT PHARMACOLOGICAL EFFECTS

The FDCA FDA s regulations and judicial decisions interpreting the Act and analogous provisions in other public welfare statutes all demonstrate that intended to and intended for as used in the Act denote objective intent as that term has become commonly understood by the courts Objective intent may be determined by what a reasonable person would understand in the circumstances presented or whether a reasonable person would believe that the defendant s conduct would lead to certain events See e g United States v Articles of Banned Hazardous Substances Baby Rattles 614 F Supp 226 231 (E D N Y 1985) ([t]he only rational interpretation of the word intended in the statue calls for an objective test of intent whether a reasonable person would believe that the object is a toy) W Page Keeton et al Prosser and Keeton on the Law of Torts § 8 at 36 (5th ed 1984) (relying on circumstantial evidence [one] may infer that the actor s state of mind was the same as a reasonable person s state of mind would have been)

The courts have also described objective intent in terms of foreseeability For example in United States v Focht the Third Circuit held that the intent requirement in the intended to produce [banned] fireworks language of the regulations implementing the Federal Hazardous Substance Act (FHSA) could be satisfied by a demonstration that it was foreseeable that the components sold by the defendant would be used to build banned products 882 F 2d 55 59- 60 (3d Cir 1989) see 15 U S C § 1261(q) Similarly in defining discriminatory intent in a voting rights case the Fifth Circuit held that [o]bjective intent presumes that a person intends the natural and foreseeable consequences of his voluntary actions Lee v Lee County Bd of Ed 639 F 2d 1243 1267 (5th Cir 1981) [FN4]

FN4 Subjective intent on the other hand considers the actual state of mind of the responsible actor *See e g* Ellington v Metropolitan Life Ins Co 696 F Supp 1237 1242 (S D Ind 1988) (a subjective intent test requires a determination that the defendant actually foresaw the result of his conduct and persisted nonetheless) This standard which focuses on the actor s actual desires and knowledge has been applies in certain areas of criminal law when the critical issue is the culpability of a particular actor *See e g* Morisette v United States 342 U S 246 250-52 (1952) It is not used as a standard of proof for intent in public health and welfare statutes such as the FDCA

© 2006 Thomson/West No Claim to Orig U S Govt Works

Subsection A infra demonstrates that an objective intent standard is the appropriate standard under the FDCA The evidence in subsection B infra demonstrates that tobacco manufacturers intend cigarettes and smokeless tobacco products to affect the structure or any function of the body within the meaning of the FDCA

A OBJECTIVE INTENT IS THE APPROPRIATE STANDARD

The FDCA is a consumer protection statute which has as its explicit purpose the prohibit[ion of] the movement in interstate commerce of adulterated and misbranded foods drugs devices and cosmetics Pub L No 75-717 75th Cong 3d Sess (1938) see also H R Rep No 2139 at 1-2 reprinted in 6 Legislative History at 300-01 (this act seeks to set up effective provisions against abuses of consumer welfare the old law contains serious loopholes [and] is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions the 1938 Act amplifies and strengthens the provisions [of the 1906 act] designed to safeguard the public health and prevent deception and it extends the scope of the old law to include certain drugs that now escape regulation)

Given the Act s focus on consumer welfare and public health protection interpreting the phrases intended for use and intended to affect to require a showing of subjective intent -- which would limit the relevant evidence to what is in the mind of the manufacturer or vendor as shown by express representation promotional claims or otherwise-- would frustrate those legislative policy goals As one court found in determining that an objective intent standard is appropriate in construing a consumer protection statute [t]he subjective interpretation of intent is urged by claimant could seriously diminish the effectiveness of FHSA [the Federal Hazardous Substances Act] because it would enable a manufacturer to introduce dangerous articles into commerce on the unreasonable but good faith belief that the articles would not be used by children Baby Rattles 614 F Supp at 232 The court further noted that the language of the FHSA nowhere speaks specifically of the manufacturer s subjective intent and that a subjective intent standard could not possibly comport with Congress intent in enacting the FHSA Id 231-32 The same reasoning extends to the Federal Food Drug and Cosmetic Act The language and purposes of the FDCA support an objective intent standard that allows consideration of information about the foreseeable uses of the product for pharmacological purposes as well as any statements or actions by the vendor that might show the vendor s actual purpose in marketing a product or refute the vendor s claims regarding the product s intended use

Although the FDCA is not primarily a criminal statute designed to punish law breakers it does include criminal penalties to enforce its provisions See e g 21 U S C § 333 It is relevant that the Act imposes a strict liability standard that is applicable to criminal prosecutions and assesses criminal liability even where there is no evidence of actual knowledge of the alleged conduct on the part of the corporate defendant 21 U S C § 331 see United

© 2006 Thomson/West No Claim to Orig U S Govt Works

States v Dotterweich 320 U S 277 280-81 (1943) United States v Park 421 U S 658 670-73 (1975) see also Smith v California 361 U S 147 152 (1959) (some penal statutes dispense with any element of knowledge on the part of the person charged food and drug legislation being a principal example The usual rationale for such statutes is that the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors-- in fact an absolute standard which will not hear the distributor s plea as to the amount of care he has used)

Moreover FDA s regulations interpreting sections 201(g)(1) and 201(h) which were adopted after notice and comment rulemaking and therefore have the force and effect of law explicitly adopt an objective intent standard Those regulations which were originally promulgated in 1952 describe the evidence relevant to determining intent to include

such [manufacturers or vendors] expressions or by the circumstances surrounding the distribution of the article This objective intent may for example be shown by labeling claims advertising matter or oral or written statements by such [manufacturers or vendors] or their representatives It may be shown by the circumstances that the article is with the knowledge of such [manufacturers or vendors] or their representative offered and used for a purpose for which it is neither labeled nor advertised

21 C F R § 201 128 (1994)(drugs)(emphasis added) see 21 C F R § 801 4 (1994) (parallel provision for devices) see also 17 Fed Reg 6818 (July 24 1952) Thus under these regulations evidence of objective intent is not limited to expressions in labeling or advertising but may be based on the totality of the relevant evidence showing the seller s awareness of how its product is actually used and affects the structure or function of the body regardless of how the product is labeled or advertised

The foregoing interpretation of the statutory language is also consistent with FDA s regulatory policy decisions and actions As demonstrated in the Appendix to Legal Analysis FDA has used both general knowledge and recognition of products nature and effects as well as their actual uses and effects to determine whether products fall within the statutory definitions of drug or device

FDA has used the known or inherent pharmacological effects of particular ingredients to determine that products are intended to affect the structure or any function of the body even where there are no public expressions by the seller that the product is to be used for those effects See Appendix to Legal Analysis For example in the context of a proposed rule on vaginal products for over-the-counter use the Agency stated

If an active ingredient is present in a therapeutic concentration the product is a drug even if that product does not claim to produce the effect which will result from the action of the therapeutically effective ingredient

© 2006 Thomson/West No Claim to Orig U S Govt Works

48 Fed Reg 46694 46701 (October 13 1983) In its tentative conclusion to comments on this issue the Agency reiterated

[t]he type and amount of ingredient(s) present in a product even if that product does not make explicit drug claims must be considered in determining its regulatory status For example the mere presence of a pharmacologically active ingredient could make a product a drug even in the absence of explicit drug claims In these cases the intended use would be implied because of the known or recognized drug effects of the ingredient (e g fluoride in a dentifrice)

59 Fed Reg 5226 5227 (February 3 1994)(emphasis added)

Thus products containing ingredients or components with known pharmacological effects including fluoride and hormones have-- on that basis alone and in the absence of express claims-- been determined to be intended to affect the structure or function of the body because they contained a pharmacologically active ingredient See Appendix to Legal Analysis FDA has also regulated as devices products that affect the structure or function of the body even when the vendor makes no claims regarding the products For example 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 See Appendix to Legal Analysis

The courts have consistently held that the statutory language imposes an objective intent standard United States v Undetermined Quantities Pet Smellfree 22 F3d 235 236 239(10th Cir 1994) (referring to objective intent in the context of considering whether a product is a drug) United States v Kasz Enterprises Inc 855 F Supp 534 542 (D R I 1994)(it is the objective intent of the vendor not the vendor s subjective explanations and disclaimers which determines the intended use of a product) (emphasis added) judgement modified on other grounds 862 F Supp 717 (D R I 1994) Clinical Reference Laboratory v Sullivan 791 F Supp 1499 1506 n 8 (D Kan 1992)(intended use depends upon the objective intent of hte persons responsible for its labeling) (emphasis added) aff d in relevant part rev d in part on other grounds sub nom United States v An Undetermined Number of Unlabeled Cases 21 F 3d 1026 (10th Cir 1994) United States v Two Plastic Drums 761 F Supp 70 72 (C D Cal 1991)(In determining intended use the inquiry should focus on the vendor s-objective intent)(emphasis added) United States v Articles of Drug Neptone No C-83-0864-EFL CCH Food and Drug Reporter ¶ 38 240 at 39 294 (N D Cal October 25 1983) (objective manifestations of intent are clearly sufficient)

The Environmental Protection Agency (EPA) and the Consumer Product Safety Commission (CPSC) have also adopted an objective intent standard in construing similar provisions in the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) and the Federal Hazardous Substances Act (FHSA) and courts have uniformly upheld those interpretations See e g N Jonas & Co Inc v EPA 666 F 2d 829 833 (3d Cir 1981) United States v Focht 882 F2d 55 58-60 (3d Cir 1989) Baby Rattles 614 F Supp at 231-32 Judicial constructions of those statutes

© 2006 Thomson/West No Claim to Orig U S Govt Works

60 FR 41453-01 1995 WL 473693 (F R)

(Cite as 60 FR 41453)

Nonetheless because the agency recognizes the unique importance of the jurisdictional issue as well as the factual justification for any proposed rule in this area the agency invites comment on these matters Comments will receive full and serious consideration

APPENDIX TO LEGAL ANALYSIS

Examples of FDA s Regulation of Products as Drugs or Devices Based on the Product s Inherent Nature, Actual Use or Its Effect on the Structure or Function of the Body

FDA has on a number of occasions asserted jurisdiction over a product even though the product s labeling and the vendor s advertising or other express representations did not establish that the product was a drug or a device within the meaning of the Act The agency has found intended use and intended effects based on the inherent nature of the product its actual use or effects or a combination of these factors Some examples follow

1 Stimulant Narcotic Chewed or Used as Tea Beginning in the early 1980 s FDA regulated as unapproved drugs imports of catha edulis or khat a shrub whose leaves act as a stimulant narcotic that affects the central nervous system when chewed or used as tea even though the agency did not have any information about or claims by vendors FDA Import Alert 66-23 (March 26 1982 revised April 2 1986 and February 9 1993) FDA issued an import alert for the product deeming it a drug in the absence of any labeling or other material that would establish intended use See FDA Import Alert 66-23 (March 26 1982) FDA initiated a seizure of khat in Buffalo in 1985 and the product was ultimately forfeited and destroyed FDA Import Alert 66-23 (April 2 1986 revision) Knowledge of khat s use came from United Nations reports and other general sources of information about customs and practices regarding the use of khat Id

2 Imitation Cocaine FDA took numerous enforcement actions in the 1980 s against caine products that were used to imitate cocaine Caine contained bulk anesthetic powders such as lidocaine or mannitol and was often sold as incense or novelty cocaine

Memorandum from Chief Prescription Drug Compliance Branch (August 4 1982) reprinted in RX Drug Study Bulletin #258 The agency used laboratory analyses of the products the manner in which the products were offered and sold such as through magazines not associated with the legitimate drug industry (e g the National Enquirer High Times Soldier of Fortune and Easy Rider) and at headshops with other drug paraphernalia and street information that the products provide a cheap high to determine the products intended use See id In 1984 the government seized a caine product from Golden Rod Music in Dayton OH FDC 64350 Case No C-3-84-686 (S D Ohio) The product consisted of more than 25 percent ephedrine as determined by laboratory analysis Id Also in 1984 FDA issued a regulatory letter to Mid-America Drug Co Evansville IN concerning marketing of caine products FDA Administrative File for Mid-America Drug Co regulatory letter 84-DT-12 The firm voluntarily discontinued sales of the products as did several other firms that received regulatory letters at about

© 2006 Thomson/West No Claim to Orig U S Govt Works

the same time Id response to regulatory letter 84-DT-12 see also FDA Administrative File for Sam s Imports Dearborn MI regulatory letter 85-DT-3 and response FDA Administrative File for NALPAC Ltd Oakpark MI regulatory letter 85-DT-5 and response FDA Administrative File for Tower Enterprises Ida MI regulatory letter 85-DT-2 and response In 1994 the government prosecuted Edwin and Thomas Dews in Michigan for selling a product called Milky Trails labeled as a room odorizer but in fact containing lidocaine Case No 94 CR 20040-BC (E D Mich)

3 Hormones in Topical Preparations The agency has formally taken the position that any statement in the labeling indicating that hormones are present in topical products will be considered to be an implied claim for therapeutic purposes or to affect the structure or function of the body and will make the product a drug even in the absence of more specific claims 58 Fed Reg 47611 47612 (September 9 1993) Drug Study Bulletin No 67 (March 28 1994) see also 54 Fed Reg 40618 40619 (October 2 1989) The agency has also taken the position that even in the absence of labeling indicating that hormones are present in the product the mere presence of hormones at levels that affect the structure or any function of the body or the inclusion of certain hormones that do not have any legitimate cosmetic uses would be sufficient for a determination that the product is a drug 58 Fed Reg at 47611

4 Fluoride in Dentifrice Products FDA considers dentifrice products containing fluoride to be drugs irrespective of whether any claims are made because fluoride is widely accepted as an anti-cavity agent by the dental products industry and consumers and because fluoride affects the structure of the tooth See 59 Fed Reg 6084 6088 (February 9 1994) see also 50 Fed Reg 39854 (September 30 1985)

5 Thyroid in Food Supplements In 1984 the government seized and destroyed a thyroid-containing product that had been marketed as a food supplement by an Arkansas firm FDC 64270 Case No B-C-84-61 (E D Ark) FDA had concluded that the product was a drug based on the recognized effects of thyroid products on the structure and function of the human body

6 Interferon In 1983 FDA established a due diligence requirement regarding manufacturers distribution of interferon a biologic product composed of proteins See 48 Fed Reg 52644 (November 21 1983) At the time interferon could be used only for investigational purposes in laboratory animals and tests in vitro However interferon received wide media coverage as a potential miracle cure in the treatment of cancer and viral infections in humans Because of its concern over diversion of interferon to unapproved uses the Agency issued the notice to prevent use of interferon in humans

7 Eye Ailment Device In the 1960 s FDA undertook an enforcement action against a metal tube containing a light bulb round metal discs and colored glass filters used by a medical practitioner in his office in the treatment of various eye malfunctions and conditions A district court upheld the Agency s conclusion

© 2006 Thomson/West No Claim to Orig U S Govt Works

that this use made the tube a device even though the practitioner made no claims for the product United States v An Article of Device Labeled in Part Cameron Spitler Amblo-Syntonizer 261 F Supp 243 245 (D Neb 1966)

8 Novelty Condoms In early 1994 FDA took the position that novelty condoms that are usable as condoms would be regulated as condoms even in the absence of express claims (e g for birth control or to prevent sexually transmitted diseases) Letter from Ronald Johnson Director Office of Compliance CDRH to Manufacturers Distributors and Importers of Condoms February 23 1994 The agency s position was based on the belief that because of the inherent nature and exclusive use of the article people would actually use the condoms for prophylactic purposes even though they were not so labeled The Agency stated that [l]abeling a functional condom as a novelty is not sufficient to escape the regulatory requirements applicable to condoms specifically and medical devices in general Instead a manufacturer would have to render the product completely unusable as a condom Id

9 Noncorrective Tinted Contact Lenses The agency has taken the position that tinted contact lenses that do not correct or improve vision and are promoted to enhance eye color are medical devices This position is based on the fact that all contact lenses including neutral lenses have a physiological effect on the eye In 1986 the government obtained a consent decree of permanent injunction against the sale of a system used to make noncorrective tinted contact lenses on the ground that the system causes adulteration of a medical device the lenses FDA INJ 1145 United States v International Hydron Corp No 87-2129 (E D N Y)

10 Sunscreens Between 1940 and the 1970 s FDA changed its position regarding the degree to which sunscreens were drugs under the Act See 58 Fed Reg 28194 (May 12 1993) FDA had stated in a 1940 advisory opinion that a product promoted for the prevention of damage from the sun was a drug while a product promoted for acquiring an even tan was a cosmetic Id at 28204 FDA changed its view of the latter category of products however because [s]ince 1940 there has been a significant body of information developed on the harmful effects of the sun on human health and a significant change has occurred in consumer perception of the purpose of suntanning products Id FDA explained that sunscreen products affect the structure and function of the body by altering the normal physiological response to solar radiation and that consumers expect protection from such products irrespective of the way in which such products are promoted Id

11 Tanning Booths FDA has taken the position that tanning booths are devices under the Act because by exposing the body to ultraviolet rays they are intended to affect the structure or function of the body Based on this position the Agency has initiated seizure actions in recent years against various tanning booths including among others those in the possession of Chic Wig Boutiques Clarksville Indiana FDC 66099 Case No NA 91-64-C (N D Ind) The Indiana firm signed a consent decree with regard to this device Id see also FDC 66224 (Chic Tanning Studio Tampa Florida) Case No 92- CV-70829-DT (M D Fl) FDC 65453 (Sunburst Sun Spa Anchorage Alaska) Case No A-87-625-CIV (D Alaska)

© 2006 Thomson/West No Claim to Orig U S Govt Works

Guidance for FDA Staff

SAMPLING AND DETENTION WITHOUT PHYSICAL EXAMINATION OF DECORATIVE CONTACT LENSES

Comments and suggestions regarding this document should be submitted by [date] to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm 10-61, Rockville, MD 20852

After [date], submit comments to Thaddeus J Poplawski Division of Import Operations and Policy (HFC-170), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857 Comments should be identified with the docket number [03D-0118]

For questions regarding this document contact Thaddeus J Poplawski at 301-443-6553

U S Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
April 2003

03D-0118

EXHIBIT B tabbies

GDL 1

IMPORT ALERT# 86-10 4/1/03 SAMPLING OR DETENTION WITHOUT PHYSICAL EXAMINATION OF DECORATIVE CONTACT LENSES

TYPE OF ALERT: Increased Coverage
Detention without Physical Examination (DWPE)

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public)

PRODUCT: Decorative contact lenses that are (1) intended to change the appearance of the eye in decorative fashion and (2) intended for distribution directly to the wearer, without the involvement of a qualified eye care professional. The alert does not cover contact lenses that are intended for vision correction, prosthetic or other medical use.

PRODUCT CODE:
86H[][]PX
86H[][]JK
86H[][]QD
86M[][]UW
86M[][]VN
86M[][]WL
86N[][]CZ
86N[][]IC
86L[][]PL
86L[][]PM

PROBLEM: FDA believes these products present substantial risks to ocular health including corneal scarring and blindness when dispensed without the involvement of a qualified eye care practitioner. In legal terms, they appear to be adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act.

PAC: HAZ - Hazardous Conditions
AAP - Approvals

PAC FOR COLLECTION: 82008

COUNTRY: All (ZZ)

MANUFACTURER/ SHIPPER FEI: See Attachment

CHARGE: The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a poisonous or deleterious substance which may render it injurious to users under the conditions prescribed in the labeling or under

such conditions of use as are customary or usual [Adulteration, Section 601(a)]

or

The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it is not a hair dye and appears to bear or contain a color additive which is unsafe within the meaning of Section 721(a) [Adulteration Section 601(e,]

or

The article is subject to refusal of admission pursuant to Section 801(a)(3) in that its labeling appears to be false or misleading within the meaning of Section 201(n) [MISBRANDING, Section 602(a)]

OASIS CHARGE CODE
POISONOUS
COSM COLOR
COSM MISB

RECOMMENDING OFFICE
Office of the Chief Counsel (GCF-1)

PEASON FOR ALERT
This alert was initiated in response to information indicating a risk of permanent eye damage including corneal infections resulting in scarring and (potentially) blindness resulting from product use and particularly wear beyond the recommended period lens sharing between individuals improper fit

GUIDANCE
Review all entries of contact lenses to determine their PMA/510(k) status If a PMA/510(k) is not on file and the product is not listed on the Attachment the product may be sampled and/or detained without physical examination as follows

* If the product is labeled solely to change the appearance of the eye in decorative fashion, districts may sample and/or detain the shipment using the charges cited in this alert For guidance contact James F Saviola, O D , F A A O CDRH Office of Device Evaluation (HFZ-460) (FAX 301-480-4201)

* If the product is labeled for vision correction or prosthetic use districts may detain the shipment using the appropriate charge as referenced in Import Alert# 89-08

Appropriate OASIS screening criteria has been set

PRIORITIZATION GUIDANCE
N/A

FOI
No purging required

KEYWORDS
Decorative Contact Lenses, Noncorrective Contact Lenses Cosmetic Contact Lenses Novelty Contact Lenses, Plano Contact Lenses

PREPARED
BY Ted Poplawski DIOP (301) 443-6553

DATE LOADED
INTO FIARS April 1 2003

ATTACHMENT FOR IMPORT ALERT# 89-10

Manufacturers/Shippers of Decorative Contact Lenses not recommended for DWPE

FIRM PRODUCT DESCRIPTION

At the time of publication in the Federal Register there were no firms identified

CIBA Vision

PACKAGE INSERT for FreshLook (phemfilcon A) Spherical and Toric Soft Contact Lenses, including FreshLook Tinting Tint, FreshLook Colors, FreshLook ColorBlends, FreshLook Color Enhancers, FreshLook Radiance, FreshLook Dimensions, Phemfilcon A Soft Contact Lenses

Non-prescribed for Frequent Replacement or Extended Wear

09972/D7408

Important: This package insert is effective as of July 2003 and supersedes all prior inserts for the products described below Please read carefully and keep this information for future use. This package insert is intended for the eye care professional, but should be made available to patients upon request. The eye care professional should provide the patient with appropriate instructions that pertain to the patient's prescribed lenses Copies of this package insert are available without charge from CIBA Vision Corporation by calling CIBA Vision Customer Service at 1 800-241 5999 or download from our web-site at www.cibavision.com CIBA Visio makes available a Patient Instruction Booklet that is recommended to be given to the patient.

℞ only

CAUTION FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED EYE CARE PROFESSIONAL.

DESCRIPTION

FreshLook Spherical (phemfilcon A) soft (hydrophilic) contact lenses are available in Handling Tint, Colors Color Enhancers ColorBlends Radiance and Dimensions. FreshLook Toric soft contact lenses are available in Handling Tint and ColorBlends. The FreshLook soft contact lens family contains several products that incorporate a UV absorber Each of these products is identified appropriately on the product package. The lens wearing schedule may be prescribed for either Disposable Wear or Frequent Replacement. In the Disposable Wear Program, the lens wearing time prescribed by the eye care professional is for either daily wear or extended wear from 1 to 7 days/6 nights. Patients should be instructed to dispose of the lenses at each removal and to use lens care products only on an emergency basis. In the Frequent Replacement Program, the lens wearing time prescribed by the eye care professional is for either daily wear or extended wear from 1 to 7 days/6 nights. Each time the lens needs to be removed before the replacement time period has elapsed, the lens must be both cleaned and disinfected prior to placing it back on the eye CIBA Vision recommends that the lens be discarded and replaced with a new lens every 2 weeks, or as recommended by the eye care professional. The eye care professional is encouraged to determine the wearing schedule based on response of the patient.

PRODUCT DESCRIPTION Lens Material

The lens material, phemfilcon A, is a hydrophilic copolymer of 2-hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate and methacrylic acid crosslinked with ethyleneglycol dimethacrylate. FreshLook UV contact lenses contain a proprietary UV-absorbing monomer which has been incorporated into the polymer matrix of the lens to absorb ultraviolet (UV) light.

FreshLook Colors, FreshLook ColorBlends FreshLook Color Enhancers and FreshLook Radiance soft contact lenses are made by modifying the clear FreshLook lens by affixing a colored pigment on that portion of the front surface of the lens which corresponds to the Iris. FreshLook Dimensions soft contact lenses are made by modifying the tinted FreshLook lens by affixing a colored pigment on that portion of the front surface of the lens which corresponds to the Iris Additionally a colored pigment is affixed to the front surface of the Toric lens to act as a unique orientation mark identified as (FreshMark). The colored pigments consist of the following color additives listed in the color additive provisions of 21 CFR: iron oxides, titanium dioxide, [phthalocyaninato (2-)] copper, chromium oxide carbazole violet mica coated with iron oxide and mica coated with titanium dioxide

FreshLook Spherical and Toric with Handling Tint soft contact lenses are tinted green with the color additive phthalocyanine green for easy visibility for handling FreshLook Dimensions lenses are also tinted green with the color additive phthalocyanine green for a better contrast in the printed portion of the lens These color additives are not removed by lens handling or cleaning/disinfecting procedures The lens coloring process does not alter the optical and performance characteristics

Lens Properties

The physical properties of the lens are

Specific Gravity	1 152
Refractive Index:	1 409
Light Transmittance	
Fr hLook with Handling Tint with or without UV	95% minimum
FreshLook Colors with or without UV	95% minimum
Surface Character	Hydrophilic
Water Content:	55%
Optical Zone (FreshLook Colors)	5mm
Optical Zon (FreshLook with Handling Tint)	5mm to 9mm (varies with power)
UV Transmittance†	0-10% in the ultraviolet portion of the spectrum (250-400nm) averaged across the spectrum
Oxygen Permeability (Dk)	16 1x10⁻ ml O₂cm /sec ml mmHg
Oxygen Transmissibility (Dk/L)	20x10⁻ml O cm/sec ml mmHg @ 35°C

(Dr Irving Fatt Method)

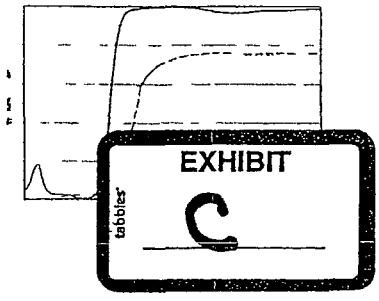
†The referenced data was determined from Methods for Determining Ultraviolet Transmission of UV blocking Contact Lenses by Dr H Faubl International Contact Lens Clinic Vol 25 no 5 1998

Representative of the thinnest lens design

Figure 1 (below) illustrates the transmittance of a typical FreshLook UV and/or FreshLook Progressive Bifocal with Handling Tint lens (thinnest lens to be marketed) a human cornea and a human lens

Curve 1 represents the transmittance of the thinnest (0.08mm nominal center thickness) lens to be marketed

FIGURE 1 TYPICAL TRANSMITTANCE PROFILE OF A FRESHLOOK UV WITH HANDLING TINT CONTACT LENS VS A HUMAN CORNEA AND A HUMAN LENS



A small transmittance peak appears in Curve 1 in the 250-290 range The transmittance across this waveband is 0.12% average with a maximum of 29% This peak is located in the wavelength of ultraviolet radiation (250-290nm) which is not transmitted to the earth's surface.

Curves 2 and 3 represent the transmittance characteristics of a human cornea from a 24-year-old person and a human lens from a 25-year-old person respectively

1. Human cornea from a 24 year old person as described in Lerman, S Radiant Energy and the Eye MacMillan, New York, 1980 p.56, figure 2 21
2. Human crystalline lens from a 25 year old person as described in Wexler M. Hitchins V.M., Optical Radiation and Visual Health, CRC Press Boca Raton Florida, 1986 p 19 figure 5

ACTIONS

When placed on the cornea a hydrated FreshLook Spherical soft contact lens acts as a refracting medium to focus light rays on the retina. The FreshLook Toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina. The thinnest FreshLook UV lenses (3.50 diopters and lower) block 98% UVA radiation and 94% UVB radiation averaged across the spectrum. The degree of UV radiation blockage of FreshLook UV lenses will increase for thicker lenses FreshLook Spherical and Toric soft contact lenses with Handling Tint provide ease of patient handling and easy visibility but do not affect iris color. The visibility tint allows the lens to become visible to wearers when not on the eye

Patients should be advised of the following

Warning UV absorbing contact lenses are NOT substitutes for protective UV absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed

NOTE. Long term exposure to UV radiation is one of the risk factors associated with cataracts Exposure is based on a number of factors such as environmental conditions (altitude geography cloud cover) and personal factors (extent and nature of outdoor activities) UV absorbing contact lenses help provide protection against harmful UV radiation. However clinical studies have not been done to demonstrate that wearing UV-absorbing contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care professional for more information.

Available Lens Parameters

FreshLook soft contact lenses are hemispherical shells of the following dimensions:

Spherical Lens Parameters		
Chord Diameter	12 0 t 15 0 mm	
Center Thickness	Extended Wear and 0 08 to 0 18mm (Varies with power)	Daily Wear 0.08 to 0.58mm (Varies with power)
Base Curves	7 80 to 9 00 mm	
Powers:	20.00 Diopters to +20.00 Diopters for Daily Wear 20.00 Diopters to +4.50 Diopters for Extended Wear	
Toric Lens Parameters		
Chord Diameter	12.0 to 15 0 mm	
Center Thickness	Extended Wear and 0 08 to 0 19mm (Varies with power)	Daily Wear 0.08 to 0.56mm (Varies with power)
Base Curve	7.80 to 9.00 mm	
Powers:	20.00 Diopters to +20 00 Diopters for Daily Wear -20.00 Diopters to +4.50 Diopters for Extended Wear	
Cylinder	-0 75 Diopters to -8 00 Diopters	
Prism Ballasted	0.25 Diopters	
Axis	0° to 180 in 1 steps	

INDICATIONS (USES)

Vision Correction

Spherical

FreshLook Spherical (phemfilcon A) soft (hydrophilic) contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 2.0 diopters that does not interfere with visual acuity The FreshLook Spherical Colors, Color Enhancers ColorBlends Radiance and Dimensions lenses act to enhance or alter the apparent color of the eye

Toric

FreshLook Toric (phemfilcon A) soft (hydrophilic) contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 6 0 diopters. The FreshLook Toric ColorBlends lenses act to enhance or alter the apparent color of the eye

The lenses may be prescribed for Daily Wear or Extended Wear in not-aphakic persons from 1 to 7 days between removal for cleaning and disinfection or disposal as recommended by the eye care professiona or for Daily Wear in aphakic persons. The eye care professional may prescribe the lens in either the single use disposable wear or for frequent replacement with cleaning disinfection and scheduled replacement. When prescribed for frequent replacement the lens may be disinfected using a chemical disinfection system FreshLook soft contact lenses with UV absorbing monomer help protect against transmission of harmful UV radiation to the cornea and into the eye

CONTRAINDICATIONS (REASONS NOT TO USE)

FreshLook soft contact lenses are contraindicated when any of the following conditions exist:

- Acute and subacute inflammation or infection of the anterior chamber of the eye.
- Active disease injury or abnormality affecting the cornea, conjunctiva or eyelids.
- Microbial infection
- Insufficiency of lacrimal secretion (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity if not aphakic)
- Use of medication that is contraindicated including eye medications
- Patient history of recurring eye or eyelid infections includ ng styes or of adverse effects associated with contact lens wear or of intolerance or abnormal ocular response to contact lens wear
- History of patient non-compliance with contact lens care and disinfection regimens wearing restrictions wearing schedule or follow-up visit schedule
- Patient's inability or unwillingness because of age infirmity o other mental or physical conditions or an adverse working or living environment to understand or comply with any lens care requirements warnings precautions restrictions or directions
- Allergy to any ingredient such as mercury or Thimerosal in a solution which must be used to care for the lens
- Patients who require only vision correction and who would not o could not, adhere to a recommended care system for lenses or who are unable to place and remove lenses should not be provided with them.
- Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
- If eyes become red or irritated
- Any active corneal infection (bacterial fungal or viral) Serious eye injury and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products Therefore after a thorough eye examination, including appropriate medical background patients must be fully apprised by the prescribing professional of all the risks associated with contact lens wear To minimize these risks the need for strict compliance with the care regimen including cleaning of the lens case if the patient is on the Frequent Replacement Program wearing restrictions wearing schedules, and follow-up visit schedule must be emphasized to the patient (see considerations listed in CONTRAINDICATIONS and PRECAUTIONS Sections)

Since eye injury can develop rapidly it is most important that patients be instructed in the possible signs or symptoms of problems and the need to remove the lenses and be examined by the prescribing eye care professional or a corneal specialist immediately if they experience any symptoms such as those listed below under the ADVERSE EFFECTS Section. (Professionals examining patients presenting such symptoms should refer to the Professional Fitting Guide and Patient Instruction Booklet)

Extended Wear The risk of ulcerative keratitis has been shown to be greater among users of extended wear contact lenses than among users of daily wear contact lenses The risk among extended wear lens users increases with the number of consecutive days that the lenses are worn between removals beginning with the f rst overnight use Some researchers believe that these complications are caused by one or more of the following a weakening of the cornea's resistance to infections particularly during a closed-eye condition as a result of hypoxia an eye environment which is somewhat more conducive to the growth of bacteria and other microorganisms particularly when a regular periodic lens removal and disinfection or disposal schedule has not been adhered to by the patient, contamination of lens and/or lens care products poor pe sonal hygiene by the patient; patient unsuitability to the particular lens or wearing schedule accumulation of lens deposits damage to the lens improper fitting; length of wearing time and the presence of ocular debris or environmental contaminants. Additionally smoking increases the risk of ulcerative keratitis in contact l ns users. While the great majority of patients successfully wear contact lenses extended wear of lenses also is reported to be associated with a higher incidence and degr e f pithelial microcysts and infiltrates and endothelial polymegathism which require consideration of discontinuation or restriction of extended wear The epithelial conditions are reversible upon discontinuation of lens wear The reversibility of endothelial effects of contact lens wear has not yet been established As a result, professionals views of extended wearing times vary some do not prescribe extended wear at all others prescribe flexible wearing times with occasional overnight wear and others prescribe extended wean g periods from 1 to 7 days/6 nights with specified intervals of no lens wear for certain patients with follow-up visits as in the case of the Frequent Replacement Program with a proper care regimen. Some professionals also recommend frequent replacement of lenses at intervals such as one to two weeks

WARNINGS

Advise patients of the following warnings pertaining to contact lens wear

- Serious eye injury scarring of the cornea and loss of vision may result from problems associated with wearing contact lenses and using contact lens care products. To reduce these risks emphasize to the patient the need for strict compliance with the lens care regiment including hand washing proper lens disinfection cleaning of the lens case wearing restrictions wearing schedules and follow-up visit schedules
- Eye problems including corneal ulcers can develop rapidly and if left untreated lead to loss of vision. Instruct patients at the dispensing visit and subsequent visits to immediately remove their lenses and promptly contact their eye care professional if they should experience eye discomfort foreign body sensation excessive tearing vision changes redness of the eye or other problems with their eyes
- Non-compliance with the manufacturer's labeled lens care instruction may put the patient at significant risk of developing a serious eye infection
- Tap water distilled water or homemade saline solution should NOT be used as a substitute for any component in the lens care process The use of tap and distilled water has been associated with Acanthamoeba keratitis, a corneal infection that is resistant to treatment and cure
- Smoking increases the risk of corneal ulcers for contact lens users especially when lenses are worn overnight or while sleeping

PRECAUTIONS

In prescribing contact lenses the Precautions should be ca efully observed It is also strongly recommended that the professional eview with the patient the appropriate Pati nt Instruction Bookl t (describ ng either the Frequent Replacement Program or the D spos bl Wear Program) available from CIBA Vis pri r t disp i g the le ses and ensure that th pat nt understands it contents

49

CIBA000109

Due to the small number of patients enrolled in clinical investigation of lenses not all refracti e powers desig configurations or lens parameters available in the len material are evaluat d in signifi cant numbers Consequently when selecting an appropriate lens design and parameters the eye care professional should consider all characteristics of the lens that can affect lens performance and ocular health, including oxygen permeability wettability central and peripheral thickness and optic zone diameter.

The potential impact of these factors on the patient s ocular health should be carefully weighed against the patient s need for refractive correction therefore the continuing ocular health of the patient and lens performance on the eye should be carefully monitored by the prescribing eye care professional.

In the Disposable Wear Program the FreshLook soft contact lenses are intended to be disposed of once they are removed from the patient's eye Therefore it is important that patients be instructed to always have available a pair of new sterile lenses In the event that a lens must be removed from the eye because of dust, a foreign body or other contaminant on the lens or the lens becomes dehydrated (dry) the lens should be removed and replaced with a new sterile replacement lens If replacement lenses are not available the patient should follow emergency lens care directions.

In the Frequent Replacement Program, in the even that a lens must be removed from the eye because of dust, a foreign body or other contaminant on the lens or the lens becomes dehydrated (dry) the lens should be removed cleaned and disinfected before reinsertion. If the lens becomes dehydrated the patient should follow the lens care directions for CARE FOR A DEHYDRATED LENS. In the Frequent Replacement Program, or in the event of Emergency Lens Care in the Disposable Wear Program chemical disinfection solution may not be used with heat unless specifically indicated in the labeling for heat and chemical disinfection In the Frequent Replacement Program or in the event of Emergency Le s Care, CIBA Vision recommends use of sterile solutions Sterile non-preserved solutions should be used if the patient is allergic to preservatives· such solutions must be discarded after the time specified in their label directions

Contact lens wear may not be suitable for certain occupations or in other instances may require eye protection equipment Therefore the patient should always inform his/her employer that contact lenses are being worn Environmental fumes smoke dust, vapors and windy conditions must be avoided in order to minimize the chances of lens contamination or physical trauma to the cornea.

Eye injury from irritation or infection and damage to lenses may result from lens contamination. The patient should be instructed to refrain from using saliva or anything other than the recommended solution for lubricating or wetting lenses The patient should also be informed to wash and rinse hands before handling contact lenses at all times.

Eye care professionals should instruct the patient to remove the lenses immediately if the eyes become red or irritated

The patient should be informed that contact lenses should not come into contact with any cosmetics lotions soaps c eams hairsprays or deodorants that it is best to put on lenses before putting on makeup and that water based cosmetics are less likely to damage lenses than oil-based products

The patient should be informed not to use aeros l or pump products such as hairspray while the lenses are worn since liquid and vapors may damage the lens

The patient should be instructed to handle the lenses car fully and avoid dropping or touching them with fingernails which can cause contamination or damage of the lens The patient should also be told that if the lens becomes nicked or torn it should not be worn

Tweezers or other tools should not be used by patients to remove a lens from the lens container. The lens should be poured into the hand Lenses should be cleaned in the palm of the hand rather then between thumb and finger.

Patients should be instructed on and be able to demonstrate prompt removal of the lenses

Fluorescein should not be used while the lenses are on the patient's eye The lenses absorb this dye and become discolored Fluorescein in the eye should be thoroughly flushed with a sterile saline solution recommended for in-eye use and a new lens should be reinserted only after at least one hour

A lens must move freely on the eye for a proper fit For further information refer to the appropriate FreshLook soft contact lens Professional Fitting Guide

Some patients will not be able to tolerate extended wear even if able to tolerate the same or another lens on a daily wear basis Patients should be carefully evaluated for extended wear prior to prescription and dispensing and professionals should conduct early and frequent follow up examinations to determine ocular response to extended wear. To prevent contamination and avoid serious eye injury the patient should be instructed to empty and rinse the lens case with fresh rinsing solution and allow the lens cas to air dry between each lens disinfection cycle as in the Frequent Replacement Program, or in the event of Emergency Lens Care.

The pat ent should be instructed to inform his or her physician that contact lenses are worn and to consult his or her eye care professional before using any medication in the eye

Exposure to water while wearing contact lenses in activities such as swimming water skiing and hot tubs may increase the risk of ocular infection including but not limited to Acanthamoeba keratitis.

Oral contraceptive users could develop visual changes or changes in lens tolerance when using contact lenses. Patients should be cautioned accordingly

Certain medications such as antihistamines decongestants diuretics muscle relaxants tranquilizers and those for motion sickness may cause dryness of the eye increased lens awareness or blurred vision. Should these conditions exist, proper remedial measures should be prescribed

Depending on the severity this could include the use of lubricating drops that are indicated for use with soft contact lenses or the temporary discontinuance of contact lens wear while such medication is being used

A patient who has been prescribed FreshLook contact lenses on a daily wear schedule should be cautioned to remove the lenses before sleeping

ADVERSE EFFECTS

Potentially serious complications are usually accompanied by one or more of the following signs and symptoms

- Foreign body sensation
- Excessive watering (tearing) of th eyes or other eye secretions including mucopurulent discharge
- Redness of the eyes
- Photoph bia (light sensitivity)
- Burning stinging itching or other pain associated with the eyes
- Comfort is less compared to when lens was first placed on eye
- Poor visual acuity
- Blurred vision, rainbows or halos a ound objects
- Feeling of dryness

If the patient notices any of the above signs or symptoms, he or she should be instructed to IMMEDIATELY REMOVE THE LENSES

- If the discomfort or problem stops look closely at the lens
  - If the lens is in any way damaged DO NOT put the lens back in the eye. Discard the lens
  - If the lens has dirt an eyelash or other foreign body on it, or the problem stops clean disinfect and reinsert the lens. If in the Frequent Replacement Program or discard the lens and replace it with a new sterile replacement lens If in the Disposable Wear Program

If the discomfort or problem continues after removal of the lens or upon reinsertion immediately remove lenses and promptly contact his or her eye care professional The eye care professional must determine the need for examination, treatment or referral without delay

Patients should be informed that a serious condition such as infection corneal ulcer corneal vascularization or iritis may be present and may progress rapidly Less serious reactions such as abrasions epithelial staining and bacterial conjunctivitis should be treated appropriately to avoid complications Additionally contact lens wear may be associated with ocular changes that require consideration of discontinuation or restriction of wear. These include but are not limited to local or generalized corneal edema, epithelial microcysts, epithelial staining infiltrations neovascularization endothelial polymegathism tarsal papillary changes conjunctival infection or iritis

ADVERSE EFFECT REPORTING

If a patient experiences any serious adverse effects associated with the use of FreshLook (phemfilcon A) contact lenses eye care professionals please notify CIBA Vision Corporation technical consultation at 1-800-241 7468.

FITTING GUIDES AND PATIENT INFORMATION BOOKLETS

The lens must move adequately on the eye for a proper fit and continued health of the eye When prescribing FreshLook lenses for extended wear, it is important to reevaluate the lens fit for adequate movement at various times after the patient sleeps while wearing lenses. This reevaluation should include a follow-up visit as soon as possible after the patient awakens, as well as at other times of the day If the fit is judged to be too tight or steep the patient must be refit into a lens that provides the criteria of a well-fitted lens

Conventional methods of fitting contact lenses apply to FreshLook soft contact lenses For a detailed description of the fitting technique refer to the appropriate CIBA Vision *Professional Fitting Guide.*

It is strongly recommended that the patient be provided appropriate *Patient Information Booklet* available from CIBA Vision and understands its contents prior to dispensing the lenses

Copies of Fitting Guides and Patient Information Booklets for FreshLook lenses are available without charge from. CIBA Vision Corporation, Duluth Georgia USA 30097 or by calling a CIBA Vision customer service representative at 1 800-241-5999

LENS REPLACEMENT SCHEDULES

In a planned replacement program the replacement schedule is determined by the eye care professional based upon the patient's physiological condition CIBA Vision recommends frequent replacement of FreshLook lenses at intervals of every two weeks. The eye care professional may determine a replacement schedule greater or less than these suggested intervals based upon clinical examination of the patient, professional judgment, and clinical experience with the lenses because individual responses to contact lenses vary. When FreshLook lenses are prescribed for disposable wear the contact lens is considered a single use medical device in which the lenses are worn from 1 to 7 days and discarded upon removal from the eye

WEARING SCHEDULES

The wearing schedule should be determined by the eye care professional CIBA Vision recommends that contact lens wearers see their eye care professional twice each year or if directed more frequently The maximum suggested wearing time each day should be determined by the eye care professional based upon the patient's physiological eye condition because individual responses to contact lenses vary The eye care professional may prescribe the lens for frequent replacement with cleaning disinfection and scheduled replacement. When prescribed for frequent replacement, the lens may be disinfected using a chemical (not heat) disinfection system.

DAILY WEAR: There may be a tendency for the daily wear patient to over-wear the lenses initially Therefore the importance of adhering to a proper initial daily wearing schedule should be stressed to these patients The wearing schedule should be determined by the eye care professional and provided to the patient. These lenses may be worn in the Frequent Replacement Program.

EXTENDED WEAR. (Greater than 24 hours or while asleep) The wearing schedule should be determined by the prescribing eye care professi nal for each individual patient, based upon a full examination and patient history as well as the professional's experience and professional judgment.

CIBA Vision recommends beginning extended wear patients with the recommended initial daily wear schedule followed by a period of daily wear and then the gradual introduction of extended wear one night at a time, unless individual considerations indicate otherwise. The eye care professional should examine the patient in the early stages of extended wear in order to determine corneal response. The lens must be removed, cleaned and disinfected or disposed of and replaced with a new lens as determined by the prescribing eye care professional (See the factors discussed in WARNING Section) Once removed a lens should remain out of the eye for a period of rest overnight or longer as determined by the prescribing eye care professional.

LENS CARE DIRECTIONS

Disposable Wear (Emergency Lens Care)

No lens care is indicated, as lenses are discarded upon removal from the eye. Lenses should only be cleaned, rinsed and disinfected on an emergency basis when replacement lenses are not available. (See BASIC INSTRUCTIONS FOR LENS CLEANING, RINSING AND DISINFECTION below.)

Planned Replacement.

Patients must adhere to a recommended care regimen. Lenses must be cleaned rinsed and disinfected after removal and prior to reinsertion on the eye according to the package inserts and patient instructions provided with the lens care products recommended by the eye care professional. Failure to follow the compl te regimen in accordance with the manufacturer's package inserts and patient instructions may contribute to problems (see ADVERSE EFFECTS) and/or result in the development of serious ocular complications as discussed in WARNINGS

Basic Instructions for Lens Cleaning and Disinfection

When lenses are dispensed the patient must be provided with appropriate and adequate instructions and warnings for lens care handling The eye care professional should recommend appropriate and adequate procedures and products for each individual patient in accordance with the particular lens wearing schedule and care system. The specif c instructions for such products and the particular characteristics of the patient should also be taken into consideration.

The basic general instructions for general lens care are as provided below·

- Always wash and rinse your hands before handling your contact lenses
- The lenses should be cleaned and disinfected before reinserti Into the eye Use a suggested chemical (not heat) lens care system recommended by the professional since heat may cause discoloration
- Use and follow the instructions of lens care products intended for use with soft (hydrophilic) contact lenses
- Always use lens care solutions before they reach the expiration date.
- Always keep the lenses completely immersed in the recommended storage solution when they are not being worn (stored)
- In the Frequent Replacement Program CIBA Vision recommends that sterile solutions be used in the soft lens care system Sterile non preserved solutions should be used only if the patient is allergic t preservatives When used sterile non-preserved solutions must be discarded after the time specified in their label directions

Refer to the PRECAUTION Section for further information on lens care and handling.

CARE FOR A DEHYDRATED LENS

Disposable Wear Program If a soft (hydrophilic) contact lens is exposed to air while off the eye It may become dry and brittle Dehydrated lenses should be disposed of Therefore it is important that the patient always have a pair of new sterile replacement lenses available

Frequent Wear Program If a soft (hydrophilic) contact lens is exposed to air while off the eye It may become dry and brittle and need to be rehydrated If the lens is adhering to a surface such as a counter top apply sterile saline solution before handling

Eye care professionals should review the following information on rehydrating the lens with the patient.

- Handle the lens carefully
- Place the lens in a storage case and soak the lens in a recommended rinsing and storing solution for at least an hour until it returns to a soft state
- Clean and disinfect the rehydrated lens using a recommended lens care system.
- If after soaking the lens does not become soft, the lens should not be used until examined by the eye care professional

CARE FOR A STICKING LENS

If the lens sticks (stops moving) or begins to dry on the eye the patient should be instructed to apply several drops of the recommended lubricating or rewetting solution directly to the eye and wait until the lens begins to move freely on the eye before removing it If non-movement of the lens continues after several minutes the patient should be instructed to immediately consult the eye care professional

IN OFFICE USE OF TRIAL LENSES

Eye care professionals should educate contact lens technicians concerning proper use of trial lens s

Each contact lens is shipped sterile in a sealed blister p ck containing borate buffered saline Hands should be thoroughly washed rinsed and dried with a lint free towel prior to handling a lens In order to insure sterility the blister pack should not be opened until immediately prior to use. For fitting and diagnostic purposes the lenses should be disposed of after a single use and not be re-used from patient to patient.

EMERGENCIES

The patient should be informed that if chemicals of any kind (household products gardening solutions laboratory chemicals etc.) are splashed into the eyes the patient should flush eyes immediately with tap water and call or visit the eye care professional or a hospital emergency room without delay

HOW SUPPLIED

Each sterile lens is packaged in a foil sealed plastic container containing a borate buffered saline solution with 0 005% poloxamer and is steam sterilized. The package is marked with the lens power diameter base curve cylinder and axis (if applicable) expiration date manufacturing lot number and if applicable UV absorber lens tint and opaque color

ADDITIONAL INFORMATION

For answers to your questions about FreshLook soft contact lenses or to report any adverse reactions contact our Professional Consultation Services at 1-800-241 7468 during regular business hours

For additional copies of the Eye Car Professional Package Insert Professional Fitting Guide and Patient Instruction Booklets contact our Customer Service Department at 1 800-241 5999

PATENT PROTECTED

U S Patents 4 976 533 5 062 701 5 020 898 5 936 705 4 668 240 4 720 188 4 704 017 4 582 402 4 668 240· 5 414 477 5 637 726

Patents Pending for FreshLook Progressive Bifocal

GB Patents 0346032 0498835 0158999· 0187137 0440107

FR Patents 0346032 0498835 0158999 0187137 0440107

AUS Patents 620886 636679 569649 634624

CN Patents 26003 4158 4136 3788 4157

PH Patents 26412 29984 23319

SG Patents 9790790-1 9790791-9 9090530 8 9290545 4

TW Patents NI-42746 NI 63667 NI 26506 NI 51612

BR Patents P18600017 9 P190078012 P18600017 9

HK Paten

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth Georgia USA 30097

Date/Part No July 2003
D7400B/096137

CIBA Vision
Novartis Company

CIBA000110

the statute which may be identical to a provision in the act

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to de vices

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services registration or regu latory programs

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U S C 2011 note) as amended the Ra diation Control for Health and Safety Act of 1968 (Pub L 90–602 (42 U S C 263b *et seq*)) and other Federal statutes until such time as the Food and Drug Administration issues specific re quirements under the Federal Food Drug and Cosmetic Act applicable to these types of devices

(10) Part 820 of this chapter (21 CFR part 820) (CGMP requirements) does not preempt remedies created by States or Territories of the United States the District of Columbia or the Commonwealth of Puerto Rico

(e) It is the responsibility of the Food and Drug Administration subject to review by Federal courts to determine whether a State or local requirement is equal to or substantially identical to requirements imposed by or under the act or is different from or in addition to such requirements in accordance with the procedures provided by this part However it is the responsibility of States and political subdivisions to determine initially whether to seek ex emptions from preemption Any State or political subdivision whose require ments relating to devices are pre empted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption in ac cordance with the procedures provided by this part

(f) The Federal requirement with re spect to a device applies whether or not a corresponding State or local require ment is preempted or exempted from preemption As a result if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal require ment the Federal requirement applies to all circumstances not covered by the State or local requirement

[43 FR 18665 May 2 1978 as amended at 45 FR 67336 Oct 10 1980 61 FR 52654 Oct 7 1996]

§ 808 3 Definitions

(a) *Act* means the Federal Food Drug and Cosmetic Act

(b) *Compelling local conditions* includes any factors considerations or cir cumstances prevailing in or char acteristic of the geographic area or population of the State or political subdivision that justify exemption from preemption

(c) *More stringent* refers to a require ment of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the act

(d) *Political subdivision* or *locality* means any lawfully established local governmental unit within a State which unit has the authority to estab lish or continue in effect any require ment having the force and effect of law with respect to a device intended for human use

(e) *State* means a State American Samoa the Canal Zone the Common wealth of Puerto Rico the District of Columbia Guam Johnston Island Kingman Reef Midway Island the Trust Territory of the Pacific Islands the Virgin Islands and Wake Island

(f) *Substantially identical to* refers to the fact that a State or local require ment does not significantly differ in ef fect from a Federal requirement

§ 808 5 Advisory opinions.

(a) Any State political subdivision or other interested person may request an advisory opinion from the Commis sioner with respect to any general mat ter concerning preemption of State or local device requirements or with re spect to whether the Food and Drug Administration regards particular State or local requirements or pro posed requirements as preempted

(1) Such an advisory opinion may be requested and may be granted in ac cordance with § 10 85 of this chapter

EXHIBIT
tabbies
D

(2) The Food and Drug Administration in its discretion and after consultation with the State or political subdivision may treat a request by a State or political subdivision for an advisory opinion as an application for exemption from preemption under § 808 20

(b) The Commissioner may issue an advisory opinion relating to a State or local requirement on his own initiative when he makes one of the following determinations

(1) A requirement with respect to a device for which an application for exemption from preemption has been submitted under § 808 20 is not preempted by section 521(a) of the act because it is (i) Equal to or substantially identical to a requirement under the act applicable to the device or (ii) is not a requirement within the meaning of section 521 of the act and therefore is not preempted

(2) A proposed State or local requirement with respect to a device is not eligible for exemption from preemption because the State or local requirement has not been issued in final form In such a case the advisory opinion may indicate whether the proposed requirement would be preempted and if it would be preempted whether the Food and Drug Administration would propose to grant an exemption from preemption

(3) Issuance of such an advisory opinion is in the public interest

Subpart B—Exemption Procedures

§ 808 20 Application.

(a) Any State or political subdivision may apply to the Food and Drug Administration for an exemption from preemption for any requirement that it has enacted and that is preempted An exemption may only be granted for a requirement that has been enacted promulgated or issued in final form by the authorized body or official of the State or political subdivision so as to have the force and effect of law However an application for exemption may be submitted before the effective date of the requirement

(b) An application for exemption shall be in the form of a letter to the Commissioner of Food and Drugs and shall be signed by an individual who is authorized to request the exemption on behalf of the State or political subdivision An original and two copies of the letter and any accompanying material as well as any subsequent reports or correspondence concerning an application shall be submitted to the Dockets Management Branch (HFA–305) Food and Drug Administration rm 1–23 12420 Parklawn Dr Rockville MD 20857 The outside wrapper of any application report or correspondence should indicate that it concerns an application for exemption from preemption of device requirements

(c) For each requirement for which an exemption is sought the application shall include the following information to the fullest extent possible or an explanation of why such information has not been included

(1) Identification and a current copy of any statute rule regulation or ordinance of the State or political subdivision considered by the State or political subdivision to be a requirement which is preempted with a reference to the date of enactment promulgation or issuance in final form The application shall also include where available copies of any legislative history or background materials pertinent to enactment promulgation or issuance of the requirement including hearing reports or studies concerning development or consideration of the requirement If the requirement has been subject to any judicial or administrative interpretations the State or political subdivision shall furnish copies of such judicial or administrative interpretations

(2) A comparison of the requirement of the State or political subdivision and any applicable Federal requirements to show similarities and differences

(3) Information on the nature of the problem addressed by the requirement of the State or political subdivision

(4) Identification of which (or both) of the following bases is relied upon for seeking an exemption from preemption

(i) The requirement is more stringent than a requirement applicable to a device under the act If the State or political subdivision relies upon this

and any draft of any proposed or final standard will be furnished to an interested person upon request and may be discussed in detail

(i) The provisions of § 10 65 apply to meetings and correspondence relating to draft notices and regulations

(j) The provisions of this section restricting discussion and disclosure of draft notices and regulations do not apply to situations covered by §§ 20 83 through 20 89

[44 FR 22323 Apr 13 1979 as amended at 54 FR 9035 Mar 3 1989 64 FR 398 Jan 5 1999]

§ 10 85 Advisory opinions

(a) An interested person may request an advisory opinion from the Commissioner on a matter of general applicability

(1) The request will be granted when ever feasible

(2) The request may be denied if

(i) The request contains incomplete information on which to base an informed advisory opinion

(ii) The Commissioner concludes that an advisory opinion cannot reasonably be given on the matter involved

(iii) The matter is adequately covered by a prior advisory opinion or a regulation

(iv) The request covers a particular product or ingredient or label and does not raise a policy issue of broad applicability or

(v) The Commissioner otherwise concludes that an advisory opinion would not be in the public interest

(b) A request for an advisory opinion is to be submitted in accordance with § 10 20 is subject to the provisions of § 10 30 (c) through (l) and must be in the following form

(Date) _____ _____

Division of Dockets Management Food and Drug Administration Department of Health and Human Services 5630 Fishers Lane Rm 1061 Rockville MD 20852

REQUEST FOR ADVISORY OPINION

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to _____ (the general nature of the matter involved)

A. *Issues involved*

(A concise statement of the issues and questions on which an opinion is requested)

B. *Statement of facts and law*

(A full statement of all facts and legal points relevant to the request)

The undersigned certifies that to the best of his/her knowledge and belief this request includes all data information and views relevant to the matter whether favorable or unfavorable to the position of the undersigned which is the subject of the request

(Signature) _____
(Person making request) _____
(Mailing address) _____
(Telephone number) _____ _____

(c) The Commissioner may respond to an oral or written request to the agency as a request for an advisory opinion in which case the request will be filed with the Division of Dockets Management and be subject to this section

(d) A statement of policy or interpretation made in the following documents unless subsequently repudiated by the agency or overruled by a court will constitute an advisory opinion

(1) Any portion of a FEDERAL REGISTER notice other than the text of a proposed or final regulation e g a notice to manufacturers or a preamble to a proposed or final regulation

(2) Trade Correspondence (T C Nos 1–431 and 14–8A) issued by FDA between 1938 and 1946

(3) Compliance policy guides issued by FDA beginning in 1968 and codified in the Compliance Policy Guides manual

(4) Other documents specifically identified as advisory opinions e g advisory opinions on the performance standard for diagnostic X ray systems issued before July 1 1975 and filed in a permanent public file for prior advisory opinions maintained by the Freedom of Information Staff (HFI-35)

(e) An advisory opinion represents the formal position of FDA on a matter and except as provided in paragraph (f) of this section obligates the agency to follow it until it is amended or revoked The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with an advisory opinion which has not been amended or revoked

(f) In unusual situations involving an immediate and significant danger to health the Commissioner may take appropriate civil enforcement action contrary to an advisory opinion before amending or revoking the opinion This

action may be taken only with the approval of the Commissioner who may not delegate this function Appropriate amendment or revocation of the advisory opinion involved will be expedited

(g) An advisory opinion may be amended or revoked at any time after it has been issued Notice of amendment or revocation will be given in the same manner as notice of the advisory opinion was originally given or in the FEDERAL REGISTER and will be placed on public display as part of the file on the matter in the office of the Division of Dockets Management The Division of Dockets Management shall maintain a separate chronological index of all advisory opinions filed The index will specify the date of the request for the advisory opinion the date of the opinion and identification of the appropriate file

(h) Action undertaken or completed in conformity with an advisory opinion which has subsequently been amended or revoked is acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance When ever possible an amended or revoked advisory opinion will state when action previously undertaken or completed does not remain acceptable and any transition period that may be applicable

(i) An interested person may submit written comments on an advisory opinion or modified advisory opinion Four copies of any comments are to be sent to the Division of Dockets Management for inclusion in the public file on the advisory opinion Individuals may submit only one copy Comments will be considered in determining whether further modification of an advisory opinion is warranted

(j) An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards but not as a legal requirement

(k) A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section A statement or advice given by an FDA employee orally or given in writing but not under this section or § 10 90 is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion does not necessarily represent the formal position of FDA and does not bind or otherwise obligate or commit the agency to the views expressed

[44 FR 22323 Apr 13 1979 as amended at 46 FR 8455 Jan 27 1981 59 FR 14364 Mar 28 1994 65 FR 56477 Sept 19 2000]

§ 10 90 Food and Drug Administration regulations recommendations and agreements

(a) *Regulations* FDA regulations are promulgated in the FEDERAL REGISTER under § 10 40 or § 10 50 and codified in the Code of Federal Regulations Regulations may contain provisions that will be enforced as legal requirements or which are intended only as guidelines and recommendations or both The dissemination of draft notices and regulations is subject to § 10 80

(b) [Reserved]

(c) *Recommendations* In addition to the guidelines subject to paragraph (b) of this section FDA often formulates and disseminates recommendations about matters which are authorized by but do not involve direct regulatory action under the laws administered by the Commissioner e g model State and local ordinances or personnel practice for reducing radiation exposure issued under 42 U S C 243 and 263d(b) These recommendations may in the discretion of the Commissioner be handled under the procedures established in paragraph (b) of this section except that the recommendations will be included in a separate public file of recommendations established by the Division of Dockets Management and will be separated from the guidelines in the notice of availability published in the FEDERAL REGISTER or be published in the FEDERAL REGISTER as regulations under paragraph (a) of this section

(d) *Agreements* Formal agreements memoranda of understanding or other similar written documents executed by FDA and another person will be included in the public file on agreements established by the Freedom of Information Staff (HFI–35) under § 20 108 A document not included in the public file is

August 28 2006

[DRAFT LETTER SEEKING FDA INPUT REGARDING PREEMPTION]

Via Certified Mail
Return Receipt Requested

Division of Dockets Management
Food & Drug Administration
Department of Health & Human Services
5630 Fishers Lane Room 1061
Rockville Maryland 20852

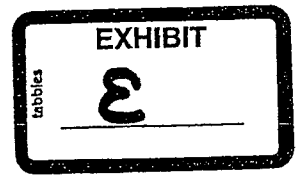
Re **Request for Advisory Opinion and FDA Guidance Pursuant to 21 CFR §808 5**
Monica Weston v Kim's Dollar Store and CIBA Vision, et al
Civil Action No 2005-CP-40-0655 (Richland County, SC)

On August 28 2006 this Court held a hearing and heard arguments on the application of federal preemption to various causes of action raised in the *Weston* civil action This Court has determined that guidance from the FDA on general issues of federal preemption related to non corrective color contact lenses could assist the Court in resolving legal issues in this case Therefore pursuant to 21 CFR 808 5 and in the format required by 21 CFR 10 85 this Court seeks the guidance of the FDA as follows

A Issues Involved On April 4 2003 the FDA issued Import Alert 86-10 related to the classification of non corrective color contact lenses [68 FR 16520] The matters surrounding Import Alert 86-10 raise several general issues relevant to the resolution of the legal issues currently before this Court, including

1 When the FDA approves a pre market approval application or a 510(k) approval for a range of contact lens powers including zero power (non corrective) is the FDA also approving the zero power (non-corrective) lens? [See Impact Alert 86 10 footnote 1]

2 Prior to Import Alert 86 10 did the FDA regulate non corrective extended wear color contact lenses as Class III medical devices? If not what was their classification prior to Import Alert 86-10? If so did Import Alert 86-10 change



the Class III medical device status of these PMA approved medical devices? (if so effective when and was change applicable to lenses already manufactured and distributed by manufacturers)?

3 If an indication of use or intended use of a non corrective color contact lenses includes UV protection and statements that UV radiation is harmful to the eye and can cause cataracts and that the contact lenses contain UV absorbing ingredients that act to protect against UV radiation would the FDA consider such lenses to be more than solely for decorative purposes under Import Alert 86 10 and therefore, 'properly regulated as medical devices? [See, 21 CFR 700 35 'sunscreen claims make a product a drug]

4 Pre market approval (PMA) orders and PMA supplement approval orders routinely contain a statement to the effect that failure to comply with the conditions of approval invalidates the approval order Is there a required FDA review process before an invalidation of a PMA approval can be effective? Assuming an individual civil litigant can establish a violation of the FDA s Conditions of Approval would that established fact invalidate a PMA approval without any action by the FDA?

5 Were CIBA Vision Freshlook Colors non corrective lenses (authorized for extended wear) PMA approved by the FDA as of February/Mach of 2004 as Class III medical devices?

B Statement of Facts and Law According to the Amended Complaint in this civil action (attached hereto) Monica Weston purchased CIBA Vision FreshLook Colors non corrective color lenses from a beauty supply store in Columbia South Carolina in February or March of 2004 She subsequently developed an eye infection which led to her undergoing a corneal transplant Ms Weston has sued CIBA Vision under numerous causes of action significantly alleging improper labeling and inadequate warnings Ms Weston seeks actual economic statutory and punitive damages against CIBA Vision

Section 521(a) [21 U S C 360(k)(A) states that "no State or political subdivision of the 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 Act 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 Act In the Code of Federal Regulations [21 CFR §808 1(b)] this federal preemption provision is explained as prescribing inconsistent state acts 'whether established by statute ordinance regulation or court decision To the extent Plaintiff's causes of action are preempted by federal preemption CIBA Vision would be entitled to summary judgment of the preempted claims Consequently CIBA Vision s motion for summary judgment based on federal preemption requires this Court to make a determination concerning the applicability and scope of federal preemption

Pursuant to 21 CFR §808 5(a) any state political subdivision or interested person may request an advisory opinion from the FDA Commissioner concerning whether the FDA would consider a specific state medical device requirement (or proposed requirement) to be preempted by federal law This Court as a subdivision of the State of South Carolina officially requests that the FDA issue an advisory opinion regarding the issues outlined under Section A *supra*, to assist this Court in determining whether and to what extent any of Plaintiff's causes of action in the Amended Complaint are considered preempted by federal preemption

This Court understands that CIBA Vision through counsel Allen G Minsk previously on June 20, 2006, submitted a letter and attachments to Sheldon T Bradshaw Esq , requesting that the FDA submit a statement of interest or an amicus brief on the federal preemption issues raised in the current motion for summary judgment Because 21 CFR §808 5(a) allows for any interested person to request clarification from the FDA on a federal preemption issue I have advised Plaintiff's counsel to submit any request for clarification they may have concerning these issues by September 1 2006 This Court would request that the FDA consider all the requests submitted with regard to the *Weston v CIBA Vision* matter and provide one response directly to this Court

Please do not hesitate to call my office with any questions In the meantime the Court would appreciate a preliminary response as to whether the FDA will take up consideration of this matter and its likely timetable for a response This would greatly assist the Court in managing its calendar

Very truly yours

The Honorable G Thomas Cooper

cc

Sheldon T Bradshaw J D Chief Counsel
Office of the Chief Counsel (GCF 1)
5600 Fishers Lane
Rockville Maryland 20887

Keith Munson Esq
Victor Rawl Esq
Danny Sullivan Esq

WCSR 341538lv1

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	
COUNTY OF RICHLAND	)	Civil Action No 05-CP-40-0655
Monica Weston,	)	
	)	
Plaintiff,	)	
	)	**SECOND SUPPLEMENTAL**
vs	)	**MEMORANDUM OF LAW IN**
	)	**SUPPORT OF CIBA VISION'S**
Kims Dollar Store and CIBA Vision, a division of Novartis Company,	)	**MOTION FOR SUMMARY JUDGMEN**
	)	
Defendants	)	
	)	

On October 25, 2006, Plaintiff's counsel filed what they characterized as supplemental authority regarding the pending summary judgment motion Although the cases attached were indeed supplemental ' they do not constitute authority' in this matter For the further guidance of the Court, Defendant CIBA Vision provides these additional references that are both supplemental and authoritative regarding the issues before the Court on CIBA Vision s motion for summary judgment

The glaring deficiencies in Plaintiff's referenced cases are that they deal with motions addressed to the pleadings (instead of motions addressed to the evidence, as with a summary judgment motion) and they do not involve Class III medical devices Initially, these cases can be disregarded because they were determined on the basis of the allegations of the pleadings, with no consideration of the evidence as is required at the summary judgment stage More importantly, however they deal with prescription drugs and not Class III medical devices Consequently, their discussion of implied preemption or presumptions against preemption is totally irrelevant to this case Class III medical devices are subject to Congressional **express** preemption under Section 21 U S C 360k of the Medical Devices Act of 1976 There is no express preemption provision related

RECEIVED
OCT 27 2006

to pharmaceutical drugs and therefore the entire analysis in the referenced cases is totally irrelevant This distinction was reiterated recently in the case of Hughes v Cook, ____ F Supp 2d ____ 2006 W L 2808087 (W D Tenn Sept 27, 2006) (Exhibit 1 hereto) The Hughes case involved product liability claims arising from a coronary stent (a Class III medical device) The court noted that the MDA expressly preempts certain state law requirements governing medical devices, citing 21 U S C § 360k The court went on to hold that when Congress "inserts an express preemption provision into a statute, 'a court may not look beyond it to consider implied preemption '" Id at *4 (citations omitted) The ultimate conclusion of the court in Hughes was that the plaintiff's claims were preempted under the express provision of the Medical Devices Act and that the defendant was entitled to judgment as a matter of law Id at *9 The court further noted that its conclusion was "heavily reinforced" by the FDA's amicus curiae brief submitted in Horn v Thoratec Corp (The Horn case has been previously provided to this Court under Tab 30 of Binder 2 of the authority supporting summary judgment)

Even if the Court looks to prescription drug cases in analyzing these issues it should be noted that the FDA expressly disagrees that strengthening warning statements without first obtaining permission from the FDA provides a loophole to mandatory preemption (as Plaintiff suggests) In Re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation, 2006 W L 2374742 (N D Cal Aug 16, 2006) (citing 71 Fed Reg 3935 (2006)) Rather the FDA s announced position is that the determination whether labeling revisions are necessary is in the end, squarely and solely FDA's under the Act Id The Court further noted that FDA interprets the Act to establish both a floor' and a ceiling Finally the Court acknowledged that the FDA's interpretation of the preemptive effect of its regulations is entitled to deference Id at *6 (citing, Geier v American Honda Motor Corp 529 U S 861 883 (2000))

In reviewing supplemental authority regarding medical devices, which is the subject of this case and the motion for summary judgment, CIBA Vision has identified additional authority squarely in line with the analysis provided in its motion and supporting memorandum of law On October 3, 2006, the U S District Court for the Northern District of Ohio issued an order in the case of In Re Sulzer Hip Prosthesis and Knee Prosthesis Liability Litigation ____ F Supp 2d ____, 2006 W L 2869547 (N D Ohio Oct 3, 2006) (Exhibit 2 hereto) This case involved product liability claims associated with hip and knee prostheses (Class III medical devices) After reviewing the state of the law on medical device express preemption, the court concluded that 'these cases reveal that Section 360k(a) preempts almost every type of state law claim that seeks to hold a defendant liable for a PMA approved medical device Id at *5 The court went on to observe that the 'cases are unanimous in concluding that a state law claim for failure to warn is preempted, in light of the fact that the PMA process includes FDA scrutiny of the warning labels that the manufacturer must supply with the medical device' Id The court also referenced a recent Second Circuit opinion holding that [w]e now join this growing consensus and hold that tort claims that allege liability as to a PMA approved medical device not withstanding the devices adherence to the standards upon which it obtained premarket approval from the FDA, are preempted by Section 360k(a) " Id at *4 (citing, Riegel v Medtronic, Inc , 451 F 3d 104, 106 (2nd Cir 2006), petition for cert filed 75 U S L W 3065 (Aug 3 2006))

Finally after the hearing on August 28, 2006, counsel for CIBA Vision obtained a copy of the book *FDA Inside & Out*, written by Plaintiff's consultant, Suzanne Parisian Contrary to the positions taken by Plaintiff in this case and the implications of Suzanne Parisian in her deposition, she acknowledges in the book that a 'cosmetic' can require premarket approval if it can be categorized as both a "cosmetic" and a "drug" (or medical device) In fact, contrary to Plaintiff's

argument that, if a product is categorized as a cosmetic, it cannot be anything other than a cosmetic Suzanne Parisian actually coined her own term for these combined products – cosmeceuticals' Consistent with CIBA Vision's argument for summary judgment, Suzanne Parisian s book notes that ' cosmetics making *therapeutic claims* that may affect the structure or function of the body are regulated as both and must be scientifically proven safe and effective for its therapeutic claims before it can be marketed She goes on in her book to note that the FDA's approach to contact lenses was that each contact lens marketing application was being subjected to the rigorous scientific scrutiny of a PMA [premarket approval] According to Suzanne Parisian, that rigorous scrutiny involves the following summary of safety and effectiveness data device description (pictures, drawings engineering representations principles of operation properties, draft labeling), manufacturing information (in accordance with the Quality System Regulation) certification of performance reference to and status of compliance with any performance standards non-clinical laboratory studies (product testing, biological testing, analytical testing, animal testing and other laboratory testing as appropriate), clinical studies device labeling (indications contraindications, warnings precautions adverse events device description, usage instructions troubleshooting patient information and references) operating and instructional manual The relevant pages of Suzanne Parisian's book are attached hereto as Exhibit 3 Clearly, Suzanne Parisian's objective analysis in her book of the issues involved in this litigation is significantly inconsistent with the Plaintiff's arguments and the consultant s retained testimony in her deposition

In conclusion this supplemental authority reiterates the undisputed position in CIBA Vision s summary judgment papers Even if Plaintiff's counsel can point to an Import Alert advising custom agents on procedures for detaining misbranded products to suggest that certain non-corrective contact lenses could be categorized as cosmetics there is no question that CIBA

Vision s Extended Wear FreshLook Colors contact lenses with UV radiation protection and eye structure effects, were also Class III medical devices Moreover these contact lenses underwent premarket approval by the FDA (as described above) and are **expressly** preempted from state law and regulation under 21 U S C § 360k Defense counsel previously provided the Court a copy of an article from the October 2006 edition of *The Florida Bar Journal* entitled The 10,000 Pound Gorilla – Federal Preemption in Class III Medical Device Cases This article provided additional, objective analysis of the application of the Medical Devices Act to preempt the range of state law tort claims brought by Plaintiff in this case Struggle as they may to convince the Court of their position with repeated submissions of supplemental authority Plaintiff's counsel cannot wiggle out from under this 10,000 pound gorilla Consequently, the Court should enter summary judgment in favor of CIBA Vision as set forth in the previously submitted proposed order

October 27 2006 By

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

Keith D Munson
Sandi R Wilson
Womble Carlyle Sandridge & Rice
A Professional Limited Liability Company
P O Box 10208
Greenville, SC 29603
Phone (864) 255-5400
Fax (864) 255-5480

ATTORNEYS FOR DEFENDANT CIBA VISION

Westlaw

2006 WL 2808087

F Supp 2d 2006 WL 2808087 (W D Tenn)

(Cite as 2006 WL 2808087 (W D Tenn))

Motions Pleadings and Filings

Only the Westlaw citation is currently available

United States District Court
W D Tennessee
Western Division
Patricia HUGHES (Surviving Spouse of James R Hughes Deceased) Plaintiff
v
Stephen L COOK, M D the Stern Cardiovascular Center P A Baptist Memorial Hospital Inc Baptist Memorial Hospital Baptist Memorial Hospital East and Medtronic Ave Inc Defendants
No 2 06CV02027 BBDTMP

Sept 27 2006

Background Patient s widow sued manufacturer of a coronary stent asserting claims of strict product liability negligence and breach of express and implied warranties arising out of the surgical implantation of the stent in the patient Following removal of the action from state court the manufacturer moved for summary judgment

Holding The District Court Donald J held that the state law claims were preempted by the Medical Device Amendments (MDA)
Motion granted

[1] Products Liability ⇦0

313Ak0 k
Tennessee tort claims of strict product liability negligence and breach of express and implied warranties brought against the manufacturer of a coronary stent the balloon of which allegedly failed to properly deflate after deployment were preempted by the Medical Device Amendments (MDA) the tort claims if successful would have imposed state specific requirements that were different or in addition to the specific Premarket Approval Process (PMA) Supplement safety and effectiveness requirements approved by the Food and Drug Administration (FDA) which did not specifically require that the balloon always function Federal Food Drug and Cosmetic Act § 521(a) 21 U S C A § 360k(a) 21 C F R § 808 1(d)

[2] States ⇦0
360k0 k
Preemption is based on the Supremacy Clause of the United States Constitution which provides that the laws of the United States shall be the supreme law of the land U S C A Const Art VI cl 2

[3] Statutes ⇦0
361k0 k
If Congress inserts an express preemption provision into a statute a court may not look beyond it to consider implied preemption but rather the court is bound by the express statutory language

[4] Federal Courts ⇦0
170Bk0 k
When no single rationale commands the agreement of five Justices of the Supreme Court the holding may be viewed as that position taken by those Members who concurred in the judgment on the narrowest grounds
Louis P Chiozza Jr Chiozza & Associates Memphis TN for Plaintiff

Bradley E Trammell Leo Maurice Bearman Jr Baker Donelson Bearman Caldwell & Berkowitz Memphis TN Ginger F Heyman Michael K Brown Mildred Segura Reed Smith LLP Los Angeles CA for Defendant

ORDER GRANTING DEFENDANT MEDTRONIC VASCULAR S MOTION FOR SUMMARY JUDGMENT

©2006 Thomson/West No Claim to Orig U S Govt Works

Exh. 1

DONALD District Court J

*1 Before the Court is the motion (D E # 2) by Defendant Medtronic Vascular Inc (formerly Medtronic AVE Inc) (Medtronic or Defendant) for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure On January 28 2005 Patricia Hughes (Plaintiff) representing her deceased husband John R Hughes filed the present action in the Circuit Court of Shelby County Tennessee claiming strict product liability negligence and breach of express and implied warranties arising out of the surgical implantation of a Medtronic coronary stent in her husband [FN1] Plaintiff's action was removed to the United States District Court for the Western District of Tennessee on January 13 2006 Defendant has moved for summary judgment on two grounds (1) Plaintiff's claims are preempted by federal law and alternatively (2) Plaintiff has failed to demonstrate that the Medtronic stent was defectively and negligently designed manufactured and labeled For the reasons stated herein this Court finds that the Defendant s motion is warranted and GRANTS Defendant s motion

I BACKGROUND

Defendant is a manufacturer and distributor of medical devices including the Medtronic S670 Discrete Technology Rapid Exchange Coronary Stent System (S670D) (Mem Supp Def s Mot Summ J 2 Pl s Resp Mem Opp n Mot Summ J 8) On December 5 2000 Mr Hughes was admitted to Baptist Memorial Hospital East in Memphis Tennessee for an angioplasty procedure (Comp ¶ 17 Mem Supp Def s Mot Summ J 1) This procedure required the surgical insertion of the S670D stent a three millimeter expandable mess tube made of medical grade stainless steel into Mr Hughes blocked artery (Aff Charles H Swanson ¶ 6) When implanted a balloon inside the S670D stent is inflated which expands the stent and creates a miniature scaffolding that opens the artery (*Id*) Following expansion of the stent the balloon inside the stent is deflated and removed (Mem Supp Def s Mot Summ J 2 Pl s Resp Mem Opp n Mot Summ J 8) The now expanded stent however is left in place to keep the artery open thus allowing the lining of the artery to eventually heal around it (Aff Charles H Swanson ¶ 6)

On December 5 2000 Dr Stephen L Cook one of Mr Hughes treating physicians performed the angioplasty procedure (Compl ¶ 18) Dr Cook having worked with the S670D at least a dozen times removed the S670D from its packaging and observed that it was not twisted or bent (Pl s Resp Memo Opp n Mot Summ J 8) Dr Cook inserted the S670D into a bifurcated lesion located at the junction of two of Mr Hughes arteries (Mem Supp Def s Mot Summ J 2) Although this junction created a near right angle making insertion more difficult Dr Cook found nothing unusual about Mr Hughes anatomy or medical history that warranted special precaution (*Id* at 10)

Following insertion of the S670D Dr Cook successfully inflated the balloon inside the stent (*Id* at 11) Once the stent had been expanded however Dr Cook was unable to deflate and remove the balloon resulting in significant restriction of blood flow to Mr Hughes heart (*Id*) Dr Cook first suspected that the difficult angle of the artery junction had created a kink in the balloon (*Id* at 9) After inspecting the balloon and discovering no kink Dr Cook then suspected that the indeflator a medical device used to inflate and deflate the stent balloon was malfunctioning (*Id* at 11) Dr Cook changed indeflators but was still unable to deflate the balloon (*Id*) After an unsuccessful attempt to deflate the balloon with empty syringes Dr Cook finally deflated and removed the balloon with a rotoblator (*Id* at 12 Mem Supp Def s Mot Summ J 5) Mr Hughes however suffered a heart attack and was placed on life support (Mem Supp Def s Mot Summ J 5) Following emergency coronary artery bypass surgery Mr Hughes died on December 6 2000 (*Id*)

*2 The Plaintiff has asserted Tennessee common law and statutory law claims of negligence strict liability and breach of express and implied warranties relating to the design manufacture

© 2006 Thomson/West No Claim to Orig U S Govt Works

labeling and sale of the S670D stent [FN2] (Comp ¶ 32) Specifically Plaintiff alleges that the Defendant (1) failed to properly manufacture a non defective product (2) failed to provide and follow warnings and/or safety precautions for the use and operation of the stent (3) failed to follow the laws regulating the manufacturing shipping maintenance and quality control of the stent (4) breached implied warranty of merchantability and fitness for a particular purpose (5) breached express warranties and (6) negligently manufactured designed distributed and marketed the S670D stent (*Id*)

II SUMMARY JUDGMENT

Summary judgment is proper 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 Fed R Civ P 56(C) Although hearsay evidence may not be considered on a motion for summary judgment *Jacklyn v Schering Plough Healthcare Prods Sales Corp* 176 F 3d 921 927 (6th Cir 1999) evidentiary materials presented to avoid summary judgment otherwise need not be in a form that would be admissible at trial *Celotex Corp v Catrett* 477 U S 317 324 106 S Ct 2548 91 L Ed 2d 265 (1986) *Thaddeus X v Blatter* 175 F 3d 378 400 (6th Cir 1999) The evidence and justifiable inferences based on facts must be viewed in a light most favorable to the nonmoving party *Matsushita Elec Indus Co v Zenith Radio Corp* 475 U S 574 587 106 S Ct 1348 89 L Ed 2d 538 (1986) *Wade v Knoxville Utilities Bd* 259 F 3d 452 460 (6th Cir 2001)

Summary judgment is proper against a party who fails to make a showing sufficient to establish the existence of an element essential to that party s case and on which that party will bear the burden of proof at trial *Celotex* 477 U S at 322 The moving party can prove the absence of a genuine issue of material fact by showing that there is a lack of evidence to support the nonmoving party s case *Id* at 325 This may be accomplished by submitting affirmative evidence negating an essential element of the nonmoving party s claim or by attacking the nonmoving party s evidence to show why it does not support a judgment for the nonmoving party 10a Charles A Wright et al *Federal Practice and Procedure* § 2727 at 35 (2d ed 1998)

Once a properly supported motion for summary judgment has been made the adverse party may not rest upon the mere allegations or denials of [its] pleading but must set forth specific facts showing that there is a genuine issue for trial Fed R Civ P 56(e) A genuine issue for trial exists if the evidence would permit a reasonable jury to return a verdict for the nonmoving party *Anderson v Liberty Lobby Inc* 477 U S 242 248 106 S Ct 2505 91 L Ed 2d 202 (1986) To avoid summary judgment the nonmoving party must do more than simply show that there is some metaphysical doubt as to the material facts *Matsushita Elec Indus Co v Zenith Radio Corp* 475 U S 574 586 106 S Ct 1348 89 L Ed 2d 538 (1986)

III DISCUSSION

*3 The Defendant contends that it is entitled to judgment as a matter of law on two grounds (1) the Plaintiff's Tennessee tort claims challenge the safety and effectiveness of the S670D stent a Class III medical device and thus are preempted by 21 U S C § 360k(a) (2000) and alternatively (2) the Plaintiff has failed to produce any evidence creating a genuine issue of material fact as to whether under Tennessee law the S670D was defectively or negligently designed manufactured labeled and sold

A Preemption of State Law Claims Under 21 U S C § 360k(a)

[1] In 1976 Congress enacted the Medical Device Amendments (MDA) Pub L No 94 295 90 Stat 539 (1976) (codified as amended in scattered sections of 15 U S C 21 U S C 42 U S C) to the Food Drug and Cosmetics Act Pub L No 75 717 52 Stat 1040 (1938) (codified as amended at 21 U S C § 301 397 (2000)) The amendments a response to mounting consumer and regulatory

© 2006 Thomson/West No Claim to Orig U S Govt Works

concern allowed the Food and Drug Administration (FDA) to regulate the design manufacture and labeling of medical devices and required the FDA to classify medical devices into three categories based on the risk that they pose to the public 21 U S C § 360c(a)(1) (2000) *Medtronic Inc v Lohr* 518 U S 470 476 77 116 S Ct 2240 135 L Ed 2d 700 (1996) Devices in Class I present no unreasonable risk of illness or injury and are subject only to minimal FDA regulation § 360c(a)(1)(A) Class II devices are potentially more harmful and although they can be marketed prior to FDA approval they must comply with stricter federal performance regulations § 360c(a)(1)(B)

Class III devices receive the strictest FDA regulation A Class III medical device is one that

> (I) (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls would provide reasonable assurance of its safety and effectiveness and
> (ii) (I) *is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health* or (II) *presents a potential unreasonable risk of illness or injury*

§ 360c(a)(1)(C) (emphasis added)

To market a Class III device the MDA requires the manufacturer to undergo a Premarket Approval Process (PMA) in order to provide [the FDA with] reasonable assurance of [the device's] safety and effectiveness [FN3] *Id* A manufacturer provides reasonable assurance by submitting an extremely detailed application which includes information relating to intended use [of the device] safety studies and test results principles of operation descriptions and specifications of [the device's] components a description of intended manufacturing methods facilities and controls packing proposed labeling and installation *Isbell v Medtronic Inc* 97 F Supp 2d 849 851 (W D Tenn 1998) (citing 21 U S C § 360e(c)(2) (2000) 21 C F R § 814 20 (2006)) Once the application is submitted the FDA spends an average of 1200 hours reviewing and scrutinizing the proposed device *Lohr* 518 U S at 477 If the FDA approves the medical device the manufacturer may then release the device commercially in accordance with the PMA approval order 21 C F R § 814 80 (2006)

[4] Any proposed changes to a PMA approved Class III medical device must be submitted to and approved by the FDA through the PMA Supplement process 21 C F R § 814 39 (2006) The PMA Supplement process employs the same procedures and level of extensive scrutiny that the original PMA process incorporates although the information required is limited to that necessary to support the proposed modifications *Isbell* 97 F Supp 2d at 851

[2][3] In addition to requiring medical device classification and approval the MDA also expressly preempts certain state law requirements governing medical devices

> [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 § 360k(a) (2000) (emphasis added) Preemption is based on the Supremacy Clause of the United States Constitution which provides that the Laws of the United States shall be the supreme Law of the Land U S Const art VI cl 2

Historically federalism concerns have prevented federal law from preempting the states police powers relating to public health and safety unless Congress intent to do so [was] clearly expressed *Kemp v Medtronic Inc* 231 F 3d 216 222 (6th Cir 2000) (citing *Hillsborough County Florida v Automated Medical Lab Inc* 471 U S 707 715

© 2006 Thomson/West No Claim to Orig U S Govt Works

105 S Ct 2371 85 L Ed 2d 714 (1985)) If Congress however inserts an express preemption provision into a statute "a court may not look beyond it to consider implied preemption *Id* Rather the court is bound by the express statutory language

Despite the express language of § 360k(a) the Supreme Court in *Medtronic Inc v Lohr* 518 U S 470 116 S Ct 2240 135 L Ed 2d 700 (1996) (plurality opinion) wrestled with the scope of the MDA s preemption clause Of specific concern to the Court was whether state common law tort claims involving Class III devices were preempted under § 360k(a) The medical device in *Lohr* a pacemaker was a Class III medical device that had received FDA approval under the less extensive substantially equivalent exception to the PMA process [FN4] *Id* at 480 Following implantation in the plaintiff the pacemaker failed allegedly resulting in a complete heart block that required emergency surgery *Lohr* 518 U S at 480 81 The plaintiff's physician claimed that the pacemaker was defective and the plaintiff brought suit claiming strict products liability and negligence for defective design manufacture assembly and sale *Id* at 481

In a plurality opinion authored by Justice Stevens the Court noting the absence of PMA approval held that none of the plaintiffs common law tort claims were preempted by § 360k(a) [FN5] *Id* at 501 02 The Court however acknowledging that it need not go beyond [the express] language to determine whether Congress intended the MDA to pre empt at least some state law disagreed over the domain expressly pre empted i e the scope of the preemption *Id* at 484 (quoting *Cipollone v Liggett Group Inc* 505 U S 504 517 112 S Ct 2608 120 L Ed 2d 407 (1992)) The plurality determined that the word requirement in § 360k(a) was ambiguous and that [t]he ambiguity in the statute and the congressional grant of authority to the [FDA] on the matter contained within it provide[d] a sound basis for giving substantial weight to the [FDA] s view of the statute *Id* at 496 (citation omitted)

*5 The FDA s regulations concerning § 360k(a) state

> State or local regulations are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act thereby making any existing *divergent State or local requirements applicable to the device different from or in addition to the specific Food and Drug Administration requirements* There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not requirements applicable to a device within the meaning of section 521(a) of the act

21 C F R § 808 1(d) (2006) (emphasis added) The Justices forming the plurality however disagreed on whether general state common law torts directed at a Class III medical device could ever amount to divergent State or local requirements *Id*

Justice Stevens writing for Justices Kennedy Souter and Ginsburg concluded that § 360k(a) only preempted device specific enactments of positive law by [state] legislative or administrative bodies not the application of general rules of common law by [state] judges and juries *Lohr* 518 U S at 487 88 Justice O Connor however writing for Justices Rehnquist Scalia and Thomas concluded that general common law torts always amounted to state requirements because successful common law causes of action operate to require manufacturers to comply with common law duties *Id* at 510 (O Connor J concurring in part and dissenting in part) Therefore Justice O Connor believed that § 360k(a) preempted state common law claims to the extent that their recognition would impose any requirement different from or in addition to [FDA approved] requirements [already] applicable to the device *Id* at 512

[4] Justice Breyer concurring in part and concurring in the judgment essentially agreed with Justice O Connor s interpretation of requirement in § 360k(a) [FN6] He concluded that [o]ne can reasonably read the word requirement [in § 360k(a)

© 2006 Thomson/West No Claim to Orig U S Govt Works

] as including the legal requirements that grow out of the application in particular circumstances of a State s tort law *Id* at 504 (Breyer J concurring in part and concurring in the judgment) To illustrate this point Justice Breyer set forth the following hypothetical

> Imagine that in respect to a particular hearing aid component a federal MDA regulation requires a 2 inch wire but a state agency regulation requires a 1 inch wire If the federal law embodied in the 2 inch MDA regulation pre empts the state 1 inch agency regulation why would it not similarly pre empt a state law tort action that premises liability upon the defendant manufacturer s failure to use a 1 inch wire (say an award by a jury persuaded by expert testimony that use of a more than 1 inch wire is negligent)? The effects of the state agency regulation and the state tort suit are identical To distinguish between them for pre emption purposes would grant great 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

*6 *Id* Therefore if the MDA pre empts a state requirement embodied in a state statute rule regulation or other administrative action it would also pre empt a similar requirement that takes the form of a standard of care or behavior imposed by a state law tort action *Id* at 504 05

The Sixth Circuit Court of Appeals in *Kemp Medtronic Inc* 231 F 3d 216 (6th Cir 2000) *cert denied* 534 U S 818 122 S Ct 48 151 L Ed 2d 19 (2001) adopted Justice Breyer s reasoning in *Lohr* The court held that general state common law tort claims involving Class III medical devices are preempted by § 360k(a) if the device has received FDA approval under the extensive PMA Supplement process *Id* at 237 In *Kemp* the plaintiff's pacemaker a Class III medical device with PMA Supplement approval failed to properly regulate the plaintiff's heartbeat *Id* at 218 19 Due to the malfunction the plaintiff fainted and fell on a concrete floor resulting in serious injury to her skull and temporary loss of sight speech and cognitive and motor ability *Id* The plaintiff alleged strict products liability and negligence specifically claiming negligence *per se* for failure to comply with FDA standards fraud on the FDA and failure to warn *Id* at 218 220

The Sixth Circuit focusing on § 360k(a) translated *Lohr* s emphasis on the FDA regulations into a three part MDA preemption test (1) [has] the FDA established *specific counterpart regulations* or other specific federal requirements that are (2) [*specific*] to a particular device and thus (3) make state regulations *different from or in addition to* the specific FDA requirements? *Id* at 224 (emphasis added) *see also Cupek v Medtronic Inc* 405 F 3d 421 424 (6th Cir 2005) (affirming Kemp s three part test for MDA preemption)

The court determined that the first and second parts of this preemption test were satisfied by the pacemakers s PMA Supplement approval Because the PMA and PMA Supplement process employed the same degree of extensive scrutiny the court concluded that PMA Supplement approval constitutes [FDA] approval of the product s design testing intended use manufacturing methods performance standards and labeling [that] is specific to the product *Id* at 226 27 (quoting *Mitchell v Collagen Corp* 126 F 3d 902 913 (7th Cir 1997)) Therefore the PMA Supplement process taken together with conditions of approval imposed on the device by the FDA creates device specific federal requirements that include the information submitted to and approved by the FDA in the PMA supplement *Id* at 227 28 (citing *Martin v Telectronics Pacing Systems Inc* 105 F 3d 1090 (6th Cir 1997)) *see also Enlow v St Jude Med Inc* 171 F Supp 2d 684 689 (W D Ky 2001) *Isbell v Medtronic Inc* 97 F Supp 2d 849 860 61 (W D Tenn 1998)

To determine if the third part of the preemption test was met the court analyzed each of the plaintiff's general tort claims separately The court concluded that the strict products liability and negligence claims if successful would force the defendant manufacturer to alter the PMA approved design manufacturing processes and labels thus imposing

© 2006 Thomson/West No Claim to Orig U S Govt Works

specific state requirements different from or in addition to the specific federal requirements contained in the PMA Supplement *Id* at 229 232 236 (A jury verdict in plaintiffs favor on plaintiffs negligence per se claims would amount to a state requirement different from or in addition to the federal requirements) Furthermore the court concluded that the plaintiff's fraud on the FDA claim was preempted stating that the adjudication of the claim would allow individual juries to undertake a counterfactual FDA review thus imposing different state requirements *Id* at 235 36

*7 The Sixth Circuit s decision in *Kemp* is heavily reenforced by the FDA a *amicus curiae* brief submitted in *Horn v Thoratec Corporation* 376 F 3d 163 (3d Cir 2004) In *Horn* the Third Circuit Court of Appeals applying the three part MDA preemption test confirmed that PMA Supplement approval amounts to device specific federal requirements and preempted the plaintiff's state common law claims (defective design manufacturing defect failure to warn etc) due to severe tension with § 360k(a) *Id* at 169 177 To arrive at this decision the court relied heavily on the FDA s *amicus curiae* brief which stated

> State common law tort actions threaten the statutory framework for the regulation of medical devices particularly with regard to FDA s review and approval of product labeling State actions are not characterized by centralized expert evaluation of device regulatory issues Instead they encourage and in fact require lay judges and juries to second guess the balancing of benefits and risks of a specific device to their intended patient population the central role of FDA sometimes on behalf of a single individual or group of individuals That individualized redetermination of the benefits and risks of a product can result in relief including the threat of significant damage awards or penalties that creates pressure on manufacturers to add warnings that FDA has neither approved nor found to be scientifically required or withdrawal of FDA approved products from the market in conflict with the agency s expert determination that such products are safe and effective This situation can harm the public health by retarding research and development and by encouraging defensive labeling by manufacturers to avoid state liability resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments

Brief for Food and Drug Administration as Amici Curiae Supporting Respondents *Horn v Thoratec Corp* 376 F 3d 163 (3d Cir 2004) (No 02 4597) 2004 WL 1143720 at *25 26 (3d Cir May 14 2004) (hereinafter FDA Brief')

In view of the standard established by the Sixth Circuit in *Kemp* this Court must affirmatively answer two questions for preemption to apply (1) Is the Medtronic S670D stent subject to device specific federal requirements under the MDA and (2) do Plaintiff's Tennessee tort claims impose different or additional specific state requirements?

(I) Device Specific Federal Requirements

The Medtronic S670D stent a Class III medical device was submitted to the FDA on April 23 1999 under the PMA Supplement process a process that employs the same extensive review applicable to an original PMA *See Isbell* 97 F Supp 2d at 851 (Aff Charles H Swanson ¶ 21) The affidavit of Dr Charles H Swanson establishes that the S670D s design testing manufacturing methods facilities controls materials and labeling were subject to FDA review (Aff Charles Swanson ¶¶ 21 23) To receive PMA Supplement approval the Defendant submitted a summary of the coronary stent s safety and effectiveness device design and manufacturing information performance standards technical data including testing a bibliography labeling and warning information clinical data supporting the safety and effectiveness of the S670D stent and any additional information the FDA required 21 C F R § 814 20 (2006) (Aff Charles Swanson ¶ 21) Following an extensive review of the Defendant s submitted materials the FDA with reasonable assurance of [the S670D s] safety and effectiveness approved the S670D for commercial sale on November 23 1999 § 360c(a)(1)(C) (Aff Charles Swanson ¶ 21)

© 2006 Thomson/West No Claim to Orig U S Govt Works

*8 The Plaintiff has failed to offer any evidence that refutes Dr Swanson s affidavit or challenges the Defendant s assertion that the S670D stent is a Class III medical device that has received PMA Supplement approval Therefore this Court concludes that the S670D s PMA Supplement approval constitutes [FDA] approval of the product s design testing intended use manufacturing methods performance standards and labeling and is specific to the product i e the FDA has imposed device specific federal requirements on the S670D stent *Kemp* 231 F 3d at 226 27 (quoting *Mitchell v Collagen Corp* 126 F 3d 902 913 (7th Cir 1997))

(ii) Different or Additional State Requirements

Because PMA Supplement approval constitutes federal device specific safety and effectiveness requirements § 360k(a) of the MDA must preempt any state common law tort claims that if successful would impose different or additional safety and effectiveness requirements *See Isbell* 97 F Supp 2d at 861 *see also* Kemp 231 F 3d at 228 (stating that the information submitted to and approved by the FDA in both the PMA and as modified by the PMA supplement comprise the specific federal requirements) Section 360k(a) however does not preempt a state tort claim alleging that a device defect was the result of the Defendant s failure to comply with the FDA approved design specifications manufacturing process or labeling requirements *Isbell* 97 F Supp 2d at 861 n 9 (citing *Martin v Telectronics Pacing Systems Inc* 105 F 3d 1090 (6th Cir 1997)

The Plaintiff argues that her Tennessee tort claims (strict product liability negligence breach of express and implied warranties) if successful would not impose device specific state requirements on the S670D that are different from or in addition to the specific federal requirements contained in the PMA Supplement approval Specifically the Plaintiff argues that her claims merely seek to enforce existing PMA Supplement safety and effectiveness requirements because [t]here can be no doubt that the FDA would require the [S670D s] balloon [to] deflate after deployment of the stent (Pl Resp Mem Opp n Mot Summ J 6) To support this assertion the Plaintiff offers the affidavits of two physicians who circumstantially conclude that the S670D was defective because on December 5 2000 all other operating room equipment appeared to be working properly (Pl Resp Mem Opp n Mot Summ J 8 11) The Plaintiff however offers no evidence to support her assertion that the FDA specifically conditioned PMA Supplement approval on the S670D balloon functioning properly i e deflating every time it was used

Congress and the FDA have both recognized that Class III medical devices present a potential unreasonable risk of illness or injury and are merely purported or represented to be for use in supporting or sustaining human life § 360c(a)(1)(C) (2000) The Plaintiff's argument however that the S670D balloon was required to always function i e always deflate fails to account for the potential unreasonable risk of illness or injury that accompanies this type of medical device and surgical procedure Furthermore the Plaintiff's argument fails to acknowledge that PMA Supplement approval only constitutes approval of the [S670D s] design testing intended use manufacturing methods performance standards and labeling not the device s success rate [FN7] *Id* at 226 27 (quoting *Mitchell v Collagen Corp* 126 F 3d 902 913 (7th Cir 1997))

*9 Because the FDA under PMA Supplement approval did not specifically require that the S670D balloon always function i e always deflate the Plaintiff's tort claims if successful would impose state specific requirements on the S670D that are different or in addition to the specific PMA Supplement safety and effectiveness requirements approved by the FDA *See* § 360c(a)(1)(C) *Kemp* 231 F 3d at 228 Therefore this Court concludes that under MDA § 360k(a) the Plaintiff's Tennessee tort claims are preempted and Defendant is entitled to judgment as a matter of law

B Genuine Issue of Material Fact

Alternatively Defendant has moved for summary

© 2006 Thomson/West No Claim to Orig U S Govt Works

judgment on Plaintiff's claims of strict products liability negligence and breach of express and implied warranties on the ground that Plaintiff has failed to present evidence creating a genuine issue of material fact under Tennessee statutory and common law The Court need not discuss the Plaintiff's evidence under Tennessee law in light of its determination that all of Plaintiff's Tennessee tort claims are preempted by 21 U S C § 360k(a) (2000)

IV ORDER

For the foregoing reasons the Court GRANTS Defendant s motion for summary judgment finding that the Plaintiff's common law tort claims are preempted by federal law thus leaving no genuine issues of material fact as to Plaintiff's claim Therefore Defendant is entitled to judgment as a matter of law The clerk is directed to enter judgment accordingly

FN1 Jurisdiction is based on diversity of citizenship *See* 28 U S C § 1332 (2000)

FN2 The Plaintiff has alleged statutory claims under the Tennessee Products Liability Act of 1978 Tenn Code Ann §§ 29 28 101 to 108 (2000) and Tenn Code Ann §§ 47 2 313 to 315 (2000) Claims asserted under Tenn Code Ann § 47 2A 212 (2000) have no apparent applicab lity in this case

FN3 Some Class III medical devices are exempt from the rigorous PMA approval process if they fall under one of two exceptions (1) the device is substantially equivalent to other devices that were in existence when the MDA classification system was enacted in 1976 or (2) the device is being used in human beings as part of an FDA approved experiment to collect data i e the investigational device exemption 21 U S C § 360e(b)(1)(B) (2000) 21 U S C § 360j(g) (2000) *see also* 21 C F R §§ 812 813 (2006) In the present case the S670D stent did not fall under either exception and received actual PMA Supplement approval Therefore this Court s discussion is limited to the rigorous PMA approval process only (Aff Charles H Swanson ¶ 20)

FN4 A medical device that is substantially equivalent to a Class III medical device in existence when the MDA was enacted in 1976 can avoid the rigorous PMA approval process 21 U S C § 360e(b)(1)(B) (2000) 21 U S C § 360j(g) (2000) *see also* 21 C F R §§ 812 813 (2006) *supra* note 3 Also known as the 510(k) process this process is by no means comparable to the PMA process *Lohr* 518 U S at 479 The 510(k) process is completed in an average of 20 hours does not require the manufacturer to submit much information and is rarely denied *Id*

FN5 Justice Stevens was joined by Justices Kennedy Souter and Ginsburg Justice Breyer concurred in part and concurred in the judgment Therefore the five sections joined by Justice Breyer i e sections I II III V and VII represent the opinion of the Court

FN6 When no single rationale commands the agreement of five Justices of the Supreme Court the holding may be viewed as that position taken by those Members who concurred in the judgment on the narrowest grounds *Marks v United States* 430 U S 188 193 97 S Ct 990 51 L Ed 2d 260 (1977) Justice Breyer s concurrence therefore takes on heightened significance in interpreting *Lohr* s holding

FN7 In fact every case in which a court has held that § 360k(a) of the MDA preempts state common law tort claims has involved a malfunctioning Class III device *See e g Kemp v Medtronic Inc* 231 F 3d 216 218 237 (6th Cir 2000) (holding

© 2006 Thomson/West No Claim to Orig U S Govt Works

> that plaintiff's state common law claims were preempted by the MDA despite the fact that the pacemaker lead [failed] to properly regulate [plaintiff's] heatbeat)

Motions Pleadings and Filings (Back to top)

2 06cv02027 (Docket) (Jan 13 2006)

END OF DOCUMENT

© 2006 Thomson/West No Claim to Orig U S Govt Works

313Ak46 1 Most Cited Cases
Patients state law claims against manufacturer of orthopedic knee implant for failure to warn were preempted by Medical Devices Amendment (MDA) to Food Drug and Cosmetic Act where manufacturer had obtained premarket approval (PMA) for device from Food and Drug Administration (FDA) and FDA had approved manufacturer's warnings and instructions for use of device by physicians and reviewed manufacturer s training requirements Federal Food Drug and Cosmetic Act § 521(a) 21 U S C A § ɔ60k(a)

[3] States ⇦18 65
360k18 65 Most Cited Cases
Patients state law claims against manufacturer of orthopedic knee implant for failure to warn were preempted by Medical Devices Amendment (MDA) to Food Drug and Cosmetic Act where manufacturer had obtained premarket approval (PMA) for device from Food and Drug Administration (FDA) and FDA had approved manufacturer s warnings and instructions for use of device by physicians and reviewed manufacturer s training requirements Federal Food Drug and Cosmetic Act § 521(a) 21 U S C A § ɔ60k(a)

[4] Sales ⇦427
343k427 Most Cited Cases
Patients state law claims against manufacturer of orthopedic knee implant for breach of implied and express warranty were preempted by Medical Devices Amendment (MDA) to Food Drug and Cosmetic Act where manufacturer had obtained premarket approval (PMA) for device from Food and Drug Administration (FDA) and FDA had approved manufacturer s warnings and instructions for use of device by physicians and reviewed manufacturer s training requirements Federal Food Drug and Cosmetic Act § 521(a) 21 U S C A § 360k(a)

[4] States ⇦18 15
360k18 15 Most Cited Cases
Patients state law claims against manufacturer of orthopedic knee implant for breach of implied and express warranty were preempted by Medical Devices Amendment (MDA) to Food Drug and Cosmetic Act where manufacturer had obtained premarket approval (PMA) for device from Food and Drug Administration (FDA) and FDA had approved manufacturer s warnings and instructions for use of device by physicians and reviewed manufacturer s training requirements Federal Food Drug and Cosmetic Act § 521(a) 21 U S C A § ɔ60k(a)

[5] **Products Liability** ⇦46 1
313Ak46 1 Most Cited Cases
Patients state law claims that manufacturer of orthopedic knee implant was negligent per se as result of its failure to meet approved Food and Drug Administration (FDA) requirements were not preempted by Medical Devices Amendment (MDA) to Food Drug and Cosmetic Act Federal Food Drug and Cosmetic Act § 521(a) 21 U S C A § 360k(a)

[5] States ⇦18 65
360k18 65 Most Cited Cases
Patients state law claims that manufacturer of orthopedic knee implant was negligent per se as result of its failure to meet approved Food and Drug Administration (FDA) requirements were not preempted by Medical Devices Amendment (MDA) to Food Drug and Cosmetic Act Federal Food Drug and Cosmetic Act § 521(a) 21 U S C A § 360k(a)

Andrew M Greenwell James R Harris Harris & Greenwell Corpus Christi TX Charles R Parker Hill & Parker Houston TX Daniel E Becnel Jr Reserve LA James R Dugan II Stephen B Murray Jr Murray Law Firm New Orleans LA Don Barrett Barrett Law Office Lexington MS John L Davidson Davidson Bowie Sims Flowood MS Michael E Cox Biloxi MS John R Climaco Climaco Lefkowitz Peca Wilcox & Garofoli R Eric Kennedy Weisman Kennedy & Berris Timothy A Spirko Buckingham Doolittle & Burroughs Debra J Horn Meyers Roman Friedberg & Lewis Mary B McKee Hickman & Lowder Peter J Brodhead Spangenberg Shibley & Liber Phillip A Ciano Ciano & Goldwasser Timothy J Gallagher Schwarzwald & McNair Cleveland OH Richard S Wayne Strauss & Troy Stanley M Chesley Waite Schneider Bayless &

© 2006 Thomson/West No Claim to Orig U S Govt Works

Westlaw

H

Motions Pleadings and Filings

Only the Westlaw citation is currently available

United States District Court
N D Ohio
Eastern Division
In re SULZER HIP PROSTHESIS AND KNEE PROSTHESIS LIABILITY LITIGATION
This Document Relates to
HOWARD
v
SULZER ORTHOPEDICS INC 1 03CV9006
BURGESS
v
SULZER ORTHOPEDICS INC 1 04CV9005
No 1 01 CV 9000

Oct 3 2006

Background Patients brought products liability actions in state and federal court against manufacturer of orthopedic knee implant After actions were removed to federal court and transferred by Judicial Panel on Multi District Litigation manufacturer moved for summary judgment

Holdings The District Court O'Malley J held that
(1) patients state law claims against manufacturer for failure to warn were preempted by Medical Devices Amendment (MDA) to Food Drug and Cosmetic Act
(2) patients breach of warranty claims were preempted but
(3) patients claims for negligence per se were not preempted
Motions granted in part

[1] **Courts** ⇨96(7)

106k96(7) Most Cited Cases
In determining whether products liability claim against manufacturer of orthopedic knee implant was preempted by Medical Devices Amendment (MDA) to Food Drug and Cosmetic Act multi district litigation (MDL) court was required to apply law of regional circuit in which it sat rather than law of regional circuit in which action was originally filed before it was transferred by Judicial Panel on Multi District Litigation where transferor court adhered to minority view on issue Federal Food Drug and Cosmetic Act § 521(a) 21 U S C A § 360k(a)

[2] **Products Liability** ⇨46 1
313Ak46 1 Most Cited Cases
To determine whether particular claim is preempted by Medical Devices Amendment (MDA) to Food Drug and Cosmetic Act district court must look through general duties imposed by state law causes of action and consider effect that successful lawsuit asserting those causes of action would have and determine whether they threaten federal premarket approval (PMA) process requirements Federal Food Drug and Cosmetic Act § 521(a) 21 U S C A § 360k(a)

[2] **States** ⇨18 65
360k18 65 Most Cited Cases
To determine whether particular claim is preempted by Medical Devices Amendment (MDA) to Food Drug and Cosmetic Act district court must look through general duties imposed by state law causes of action and consider effect that successful lawsuit asserting those causes of action would have and determine whether they threaten federal premarket approval (PMA) process requirements Federal Food Drug and Cosmetic Act § 521(a) 21 U S C A § 360k(a)

[3] **Products Liability** ⇨46 1

© 2006 Thomson/West No Claim to Orig U S Govt Works

Exh. 2

Chesley Janet G Abaray Burg Simpson Eldredge Hersh Jardine Cincinnati OH Paul L Jackson Roetzel & Andress Akron OH John T Murray Murray & Murray Sandusky OH David W Zoll Zoll & Kranz Toledo OH Sylvia Antalis Goldsmith Law Office Sylvia A Goldsmith Avon OH Steven E Clark Clark & Mitchell Oklahoma City OK Keith Johnson Ft Mitchell KY Keith M Fleischman Milberg Weiss Bershad Hynes & Lerach LLP Lee Squitieri Squitieri & Fearon New York NY Steven M Tindall Lieff Cabraser Heimann & Bernstein San Francisco CA Timothy E Eagle Varnum Riddering Schmidt & Howlett Grand Rapids MI Laura Citrano Neil Papiano Iverson Yoakum Papiano & Hatch Los Angeles CA Frank Hilton Green Tomlinson Pritchard Mccall & Jones K Dee Hutsler III Birmingham AL for Plaintiffs

J Patrick Herald Richard M Franklin James J Dries Baker & McKenzie Chicago IL David W Brooks Bradley D Honnold Harvey L Kaplan Matthew D Keenan Lori C McGroder Shook Hardy & Bacon Kansas City MO Jeffrey M Whitesell Irene C Keyse Walker Robert C Tucker Tucker Ellis & West Mary M Bittence Baker & Hostetler Cleveland OH Richard F Scruggs Scruggs Law Firm Pascagoula MS Sidney A Backstrom Scruggs Law Firm Oxford MS Steven J Boranian Reed Smith Crosby Heafey LLP San Francisco CA Werner L Polak Shearman & Sterling New York NY for Defendants

MEMORANDUM & ORDER

OMALLEY District J

*1 This opinion discusses three cases that have been transferred to this Court as related to Multi District Litigation (MDL) No 1401 known as *In re Sulzer Orthopedics Inc Hip Prosthesis and Knee Prosthesis Products Liability Litigation* [FN1] The three cases are (1) *Moore v Sulzer Orthopedics Inc* case no 02 CV 9116 (2) *Howard v Sulzer Orthopedics Inc* case no 03 CV 9006 and (3) *Burgess v Sulzer Orthopedics Inc* case no 04 CV 9005

The Court earlier issued an opinion granting summary judgment to the defendants in the *Moore* case *Moore v Sulzer Orthopedics Inc* 337 F Supp 2d 1002 (N D Ohio 2004) Sulzer now seeks dismissal of the *Howard* and *Burgess* cases as well For the reasons stated below Sulzer s request is GRANTED in part specifically all of the claims asserted in *Howard* and *Burgess* are DISMISSED except for their claims of negligence per se

I History

The *Moore Howard* and *Burgess* cases share the following factual and procedural similarities Each plaintiff alleges in his complaint that he underwent knee replacement surgery and received an orthopedic knee implant manufactured by Sulzer known as the Natural Knee II Tibial Baseplate (referred to below as the NK II) The NK II is one component of a system used for complete knee replacements Each plaintiff further alleges that (1) his implant was coated with a lubricant during the manufacturing process (2) Sulzer failed to remove this lubricant completely before the implant was placed in his body (3) the lubricant then caused the implant to bond improperly to his bones and (4) he ultimately had to have the implant removed and replaced Each plaintiff asserts various claims under their applicable state law such as strict liability for defective design and manufacture negligence for defective design and manufacture and failure to warn

Further the plaintiff in each case originally filed his lawsuit in a court other this one Specifically after Moore filed his case in Florida state court Sulzer removed the action to the United States District Court for the Middle District of Florida Howard filed his case in the United States District Court for the Northern District of Oklahoma And after Burgess filed his case in Arkansas state court Sulzer removed the action to the United States District Court for the Western District of Arkansas Each of the three cases was then transferred to this Court as related to MDL No 1401

Unlike *Howard* and *Burgess* however the *Moore*

© 2006 Thomson/West No Claim to Orig U S Govt Works

case has progressed to a resolution In *Moore* Sulzer moved for summary judgment on the ground that all of Moore s claims were preempted by federal law The essence of Sulzer s argument was as follows

(1) Sulzer applied successfully to the FDA for premarket approval (PMA) of its NK II pursuant to the Medical Devices Amendment (MDA) to the Food Drug and Cosmetic Act 21 U S C § 360c *et seq* The FDA s PMA process involves rigorous review of the design manufacturing methods quality control procedures clinical investigations and labeling and marketing of the medical device

*2 (2) the MDA contains an express preemption clause that precludes a State from establish[ing] or continu[ing] in effect with respect to [any medical device examined by the FDA in the PMA process] any requirement which is different from or in addition to any requirement applicable to the device under the MDA itself 21 U S C § 360k(a) and

(3) the state law causes of action stated by Moore would all work to impose requirements on the NK II that were different from or in addition to the FDA requirements and were thus preempted

Moore s response to Sulzer s syllogism began by observing that there is a split of authority amongst the federal appellate courts regarding the extent of MDA preemption [FN2] For example in *Goodlin v Medtronic Inc* 167 F 3d 1367 1371 (11th Cir 1999) the Eleventh Circuit Court of Appeals concluded that common law duties imposed by state tort law are *not* requirement [s] that are different from or in addition to any requirement applicable to the device under the MDA Accordingly the *Goodlin* court allowed a plaintiff to pursue claims that his FDA approved pacemaker was defective In contrast in *Kemp v Medtronic Inc* 231 F 3d 216 221 (6th Cir 2000) *cert denied* 534 U S 818 122 S Ct 48 151 L Ed 2d 19 (2001) the Sixth Circuit Court of Appeals rejected the *Goodlin* analysis concluding that the plaintiff's state law claims which related to the same FDA approved pacemaker discussed in *Goodlin* were preempted

Moore argued that this Court should apply the law from the Eleventh Circuit Court of Appeals (as set out in *Goodlin*) instead of the law from the Sixth Circuit Court of Appeals (as set out in *Kemp*) even though this Court is within the Sixth Circuit Noting that his case had been transferred to this MDL Court from the Eleventh Circuit, Moore argued that the transferee forum must apply the law of the transferor court *Moore* 337 F Supp 2d at 1009 This Court rejected Moore s argument however concluding this Court s preemption analysis addresses a question of *federal* law and this Court is required to apply the Sixth Circuit s interpretations of federal law to any case that is transferred to it *Id* at 1011 (footnote omitted emphasis in original) Accordingly the Court granted Sulzer s motion for summary judgment and dismissed Moore s case Moore did not appeal

In light of the Court s conclusion in *Moore* Sulzer moved the Court to issue an Order requiring all similarly situated plaintiffs including Howard and Burgess [FN3] to show cause why their cases should not also be dismissed The Court acquiesced to this request and the parties have submitted briefs regarding whether and the extent to which the Court s reasoning in *Moore* should apply to *Howard* and *Burgess*

II Medical Devices and Preemption

The Court picks up where it left off in its *Moore* opinion the entirety of which is incorporated herein by reference [FN4]

*3 Critically in *Moore* the plaintiff advanced only one argument in response to Sulzer s summary judgment motion that the law of the Sixth Circuit as set out in *Kemp* was not applicable and that instead the Court should apply the law of the Eleventh Circuit as set out in *Goodlin* Because this argument failed Sulzer s motion carried But this Court noted that other arguments not advanced by Moore might yield different results

Conceivably the Court s easy conclusion that it must apply the *Kemp* preemption analysis and not the *Goodlin* preemption analysis would not be dispositive of the pending motion As the *Kemp*

© 2006 Thomson/West No Claim to Orig U S Govt Works

court noted a claim premised on the violation of FDA requirements established for a Class III device through the PMA process is not automatically preempted *Kemp* 2>1 F 3d at 230 Moore could conceivably argue for example that Sulzer was negligent in its manufacture of the NK II he received because Sulzer completely failed to undertake a manufacturing step say a product rinse or a quality control inspection that is required by the FDA Alternatively Moore could contend that Sulzer *added* a manufacturing step or process that was in addition to and materially deviated from the manufacturing processes approved by the FDA But Moore does not offer any such argument or point to any such fact

Moore 337 F Supp 2d at 1011

Howard and Burgess offer two arguments why the reasoning in *Moore* should not control their case First Howard offers additional support for the argument that *Kemp* should not control and this Court should apply the law of the transferor court Second relying in part on the language quoted above from *Moore* Howard and Burgess both argue that even if *Kemp* does apply at least some of their claims survive the doctrine of federal preemption The Court examines these arguments below

A Applicable Law

Like the Eleventh Circuit Court of Appeals in *Goodlin* the Tenth Circuit has suggested tha certain common law duties imposed by state tort law are *not* requirement[s] that are different from or in addition to any requirement applicable to the device under the MDA *See Oja* v *Howmedica Inc* 111 F 3d 782 789 (10th Cir 1997) (the duties imposed by Oja s negligent failure to warn claim do not constitute positive enactments of state law sufficient to constitute a state requirement developed with respect to a medical device) [FN5] Because Howard filed his case in the Tenth Circuit he seeks application of the law as set out in *Oja* instead of the Sixth Circuit law set out in *Kemp* [FN6] Howard offers a number of cogent arguments that Moore did not raise to support the proposition that the law of the transferor court should apply [FN7]

[1] For the reasons stated in *Moore* however the Court remains unpersuaded First even if this Court were free to choose between the Tenth and Sixth Circuit s analyses of the law of MDA preemption the Court would choose the latter *See Moore* 337 F Supp 2d at 1011 n 7 (Not only does the Court find the *Kemp* analysis more consistent with the *Lohr* plurality than the *Goodlin* analysis but under *Goodlin* the preemption provision of the MDA becomes virtually meaningless a result Congress cannot have intended)

*4 Second the Sixth Circuit Court of Appeals has directed this Court to use the law of this Circuit in precisely these circumstances In *In re Cardizem CD Antitrust Litig* >32 F 3d 896 (6th Cir 2003) *cert denied* 543 U S 9>9 125 S Ct 307 160 L Ed 2d 248 (2004) the appellate court observed that when examining questions of federal law in a federal multidistrict litigation[ ] there is a preference for applying the law of the transferee district *Id* at 912 n 17 As this Court noted in *Moore* the Sixth Circuit added the caveat that this rule was less clear when the law of the transferee court is unique to [that] particular circuit and arguably divergent from the predominant interpretation of a federal law *Id Moore* 337 F Supp 2d at 1010 Howard seeks the shelter of this caveat but the requisite conditions are not present In *Moore* the undersigned wrote

> MDA p eemption analysis set out n *Kemp* is not unique to the Sixth Circuit nor is it divergent from the predominant interpretation *See Brooks* v *Howmedica Inc* 273 F 3d 785 795 (8th Cir 2001) ([m]ost courts of appeal have interpreted *Lohr* to mean that the MDA preempts common law claims to the extent that they interfere or conflict with specific federal requirements) (citing *Kemp* and other cases) Thus it is clear that this Court must apply the *Kemp* preemption analysis and not the *Goodlin* analysis

Id at 1010 Since then two additional Courts of appeal have joined the majority view stated in *Kemp* making it even more clear that *Oja* and *Goodlin* are the divergent case *See Riegel* v

© 2006 Thomson/West No Claim to Orig U S Govt Works

Medtronic Inc 451 F 3d 104 106 (2nd Cir 2006) *petition for cert filed* 75 U S L W 3065 (Aug 3 2006) ([w]e now join this growing consensus and hold that tort claims that allege liability as to a PMA approved medical device notwithstanding that device s adherence to the standards upon which it obtained premarket approval from the FDA are preempted by Section 360k(a)) *Horn v Thoratec Corp* 376 F 3d 163 (3rd Cir 2004) (we together with our sister Courts of Appeal who have read *Lohr* in the same fashion as we have and together with the FDA s current position hold that Horn s claims are preempted by § 360k(a)) (footnote omitted) *See also Gomez v St Jude Medical Diag Division Inc* 442 F 3d 919 (5th Cir 2006) (reaffirming the Fifth Circuit s adherence to the majority view first set out in *Martin v Medtronic Inc* 254 F 3d 573 (5th Cir 2001)) *Cupek v Medtronic Inc* 405 F 3d 421 (6th Cir 2005) (reaffirming *Kemp*) *McMullen v Medtronic Inc* 421 F 3d 482 (7th Cir 2005) (reaffirming the Seventh Circuit s adherence to the majority view first set out in *Mitchell v Collagen Corp* 126 F 3d 902 (7th Cir 1997))

Simply Howard seeks application of a minority view on the scope of MDA federal preemption and *Cardizem* holds that this MDL court must apply the majority view if it has been adopted by the Sixth Circuit Because *Kemp* shares the majority view this Court will apply the law of the Sixth Circuit to Howard s case not the law of the Tenth Circuit

B Preempted Claims

*5 Howard and Burgess assert a slew of claims against Sulzer including (1) strict liability for design defect (2) strict liability for manufacturing defect (3) strict liability for defective marketing and/or failure to warn (4) negligence (5) breach of implied warranty (6) breach of express warranty (7) deceit by concealment (8) negligence per se (9) medical monitoring (10) fraud and (11) loss of consortium This Court must determine whether each of these claims is preempted by § 360k(a) of the MDA Fortunately this obligation is made easier because seven different Courts of Appeals including the Sixth Circuit in *Kemp* and *Cupek* have undertaken the same task examining the preemptive effect of the MDA on a great variety of state law claims including virtually all of the sorts of claims advanced by Howard and Burgess Taken together these cases reveal that § 360k(a) preempts almost every type of state law claim that seeks to hold a defendant liable for a PMA approved medical device the only exception is a claim that the medical device failed to conform with the FDA requirements prescribed by the PMA [FN8] The Court reviews these cases briefly below

[2] As an initial matter to determine whether a particular claim is preempted all of the appellate courts require a district court to look through the general duties imposed by the state law causes of action and consider the effect a successful lawsuit asserting those causes of action would have and determine whether they threaten the federal PMA process requirements *Gomez* 442 F 3d at 929 30 Unsurprisingly the cases are unanimous in concluding that a state law claim of design defect is preempted As the *Gomez* court recognized [t]o permit a jury to second guess the [medical device s] design by applying the Louisiana statutory standard for unreasonably dangerous design would risk interference with the federally approved design standards and criteria *Id* at 930 *See also Horn* 376 F 3d at 176 (the design defect claims would require [the defendant] either to use an entirely different design or to use different materials or to place [a part] in a different position * * * [The defendant] is prohibited however by the FDA s PMA approval order from making any such changes)

[3] Similarly the cases are unanimous in concluding that a state law claim for failure to warn is preempted in light of the fact that the PMA process includes FDA scrutiny of the warning labels that the manufacturer must supply with the medical device [FN9] Quoting *Gomez* again

> The FDA approved [defendant] Kendall s warnings and instructions for physicians contained in the Instructions for Use (IFU) through the PMA process That process required the FDA to approve clinical studies and evaluate the results to specify the labeling requirements and and approve the label that issued The FDA

© 2006 Thomson/West No Claim to Orig U S Govt Works

also approved the Patient Guide used to provide information and warnings to patients again through the PMA process Kendall s training requirements were also subjected to and approved in the PMA process To permit a jury to decide Gomez s claims that the information warnings and training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA s exclusive role and expertise in this area and risk imposing inconsistent obligations on Kendall The district judge correctly found that Gomez s state law claims that Kendall s labeling warning information and training were inadequate or incomplete are preempted
*6 *Gome* 451 F 3d at 931

The Sixth Circuit agrees entirely with the reasoning of *Gome* Any claim under state law then that Defendant failed to warn patients beyond warnings required by the FDA or that Defendant failed to recall a product without first going through the PMA supplement process would constitute state requirements different from or in addition to the requirements of the federal PMA application and supplement process *Cupek* 405 F 3d at 424 *See also* Horn 376 F ɔd at 176 (holding that the plaintiff's failure to warn claims are preempted because they would require [the defendant] to provide different warnings and instructions from those approved by the FDA) *Martin* 254 F 3d at ɔ83 (the PMA process imposed specific federal equirements as to labeling manufacturing and design for the purposes of preemption) *Kemp* 231 F 3d at 2ɔ6 (to the extent that plaintiff's claim is premised on the adequacy of the warnings reviewed and approved by the FDA the claim is preempted) *Brooks* 273 F 3d at 796 (The effect of a jury finding of negligent failure to warn would be that state law would require [the defendant] to change the label and package insert for [the medical device] but [the defendant] may not unilaterally make such changes under federal law) *McMullen* 421 F 3d at 488 (A claim that a manufacturer failed to provide an adequate warning at the time of sale would be based on the assertion that the manufacturer should have provided a different warning than the one approved by the FDA Such a state law claim would impose a requirement that was different from or in addition to the applicable federal requirements and would be preempted) [FN10]

[4] The cases are also unanimous in decreeing a similar fate for claims for breach of implied warranty As explained by the *Mitchell* court an implied warranty claim is based on the accepted standards of design and manufacture of the products In the case of a product that has gone through the PMA process these criteria are set by the FDA *Mitchell* 126 F 3rd at 915 Allowing a plaintiff to pursue a breach of implied warranty claim would create an irreconcilable conflict a judgment for breach of implied warranty that rested on allegations about standards other than those permitted by the FDA would necessarily interfere with the PMA process and indeed supplant it *Id* Accordingly claims for breach of implied warranty are preempted *See also Riegel* 451 F 3d at 121 22 (plaintiffs claims for strict liability breach of implied warranty and negligent design testing inspection distribution labeling marketing and sale would if successful impose state requirements that differed from or added to the PMA approved standards for the [medical device]) *Horn* ɔ76 F ɔd at 168 (reaffirming MDA preemption of claims for breach of implied warranty of merchantability and fitness for a particular purpose)

*7 Indeed it is the rare state law claim that the above cited federal appellate courts conclude is *not* preempted by § 360k(a) of the MDA and those rare examples are instructive In *Martin* two plaintiffs brought a variety of state law claims against the manufacturer of their pacemaker Medtronic including negligence gross negligence strict liability breach of warranty and violation of the Texas Deceptive Trade Practices Act *Martin* 254 F 3d at 575 The district court found all of the plaintiffs claims were preempted except one the claim that Medtronic had deviated from FDA requirements *Id* The *Martin* court affirmed this conclusion reasoning that common law duties that incorporate the PMA process such as the general duty to take due care to comply with the PMA

© 2006 Thomson/West No Claim to Orig U S Govt Works

process in labeling or manufacturing will never contain specific requirements that are additional to or different from federal requirements Therefore claims based on those duties are not preempted *Id* at 582 n 8 (citing *Lohr* 518 U S at 495)

[5] Put more simply state tort suits that allege as the basis of their claim that the approved FDA requirements have not been met are not preempted *Id* at 583 Other state law claims are Thus the plaintiffs in *Martin* were permitted to pursue one claim that Medtronic had not complied with the FDA approved manufacturing process After discovery was complete however the district court granted Medtronic s motion for summary judgment finding that [the plaintiffs] failed to produce evidence of alleged deviations from FDA requirements and the appellate court affirmed *Id* at 575

The Sixth Circuit reached an identical conclusion in *Kemp* where the plaintiffs brought ten common law and statutory products liability claims under Ohio law against defendant Medtronic *Kemp* 231 F 3d at 219 The district court found that the MDA preempted plaintiffs strict products liability claims for defective design failure to warn and nonconformance to representations as well as their claims for negligent design negligent failure to warn breach of express and implied warranties and fraudulent misrepresentation *Id* But the district court did not find that the MDA totally preempted plaintiffs claims [ruling] that any claims alleging the [medical device] deviated from FDA specifications were not preempted *Id* at 419 20

As in *Martin* this conclusion provided cold comfort to the plaintiffs who then pursued their claim for negligence per se for failure to adhere to FDA requirements The plaintiffs were unable to adduce evidence sufficient to support this claim and suffered summary judgment On appeal the Sixth Circuit Court of Appeals agreed with the plaintiffs that a claim premised on the violation of FDA requirements established for a [medical] device through the PMA process is not automatically preempted *id* at 230 but also agreed that summary judgment on the plaintiffs negligence per se claim for lack of evidence was appropriate [FN11]

*8 *Gomez* presents a slight variation on this theme In *Gomez* the district court found that federal law preempted [the plaintiff's] state law claims for defective design failure to warn breach of express warranty negligence in training and consent forms and redhibition *Gomez* 442 F 3d at 927 The district court allowed the plaintiff to pursue however her claim that the defendant fail[ed] to manufacture the [medical] device in accordance with FDA specifications *Id* at 926 The parties proceeded to trial and after the close of evidence the district court granted a Rule 50 motion for judgment as a matter of law The appellate court affirmed the district court s conclusion that the defective manufacturing claim was not preempted The district judge properly limited Gomez s negligence claims to a claim that the [medical device] used in her surgery was defectively manufactured because it did not comply with the FDA approved specifications *Id* at 933 Unlike in *Martin* and *Kemp* however the *Gomez* court reversed the trial court s order granting the Rule 50 motion concluding that the plaintiff had introduced sufficient evidence of defect and causation to allow the jury to resolve her manufacturing defect claim *Id* at 938 Specifically the plaintiff had adduced evidence that the manufacturer did not comply with FDA standards requiring disposal of manufacturing lots with a nonconformance percentage in excess of 0 01% *Id* at 935 36

Martin Kemp and *Gomez* stand for the proposition that virtually all state law claims seeking to hold a defendant liable for injuries caused by an FDA approved medical device are preempted except for a claim that the medical device failed to conform with the PMA requirements prescribed by the FDA Kindred conclusions are also stated in the other cases on point *See Riegel* 451 F 3d at 106 (With regard to the plaintiffs remaining claim for negligent manufacturing which premised liability on the theory that the particular [medical device] deployed during plaintiff appellant Charles Riegel s angioplasty had not been manufactured in

© 2006 Thomson/West No Claim to Orig U S Govt Works

accordance with the PMA approved standards we agree with the district court that this claim was not preempted but that no genuine issue of material fact existed and thus affirm the district court s summary judgment dismissal of that claim as well) *Brooks* 273 F ɔd at 789 (Brooks is correct in her assertion that a claim of failure to comply with FDA regulations is not preempted by the MDA since such a state claim imposes no requirement different from or in addition to any federal requirement but her claim for negligence per se must be dismissed because she presented no evidence that Howmedica violated federal regulations or refused to add warnings drafted by the FDA changed FDA approved labels failed to meet regular reporting requirements failed to report a known hazard to the FDA or failed to comply with federal law in any other respect) Indeed in those cases where the courts concluded that all of the plaintiffs claims were preempted the courts were careful to note that the plaintiffs did *not* assert that the defendant had failed to comply with FDA requirements *See Horn* 376 F 3d at 179 (Horn has not asserted that [the defendant] has in any way failed to conform with the FDA requirements prescribed by its PMA nor that it deviated from or violated any of the FDA s federal statutes or regulations) *Papile* 107 F 3d at 743 ([the plaintiff] does not allege negligent manufacture)

*9 To be fair two courts have concluded that breach of express warranty claims are *not* automatically preempted In *Riegel* however there was no discussion of why this claim was not preempted and the claim was dismissed after discovery revealed that the instructions for the medical device clearly disclaimed any express warranty *Riegel* 451 F 3d at 108 In *Mitchell* the court did explain that a state law claim for breach of express warranty is not preempted because [express] warranties arise from the representations of the parties and are made as the basis of the bargain between them A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA and therefore we cannot say that such a cause of action is preempted *Mitchell* 126 F 3d at 915 The analysis went no further however because the plaintiffs never specified whether their claim was based on an express or an implied warranty and did not ever state[ ] the nature of any express warranty accordingly the claim was dismissed on summary judgment *Id* In any event neither *Mitchell* nor *Riegel* provides sufficient reason to ignore the Sixth Circuit s conclusion in *Kemp* that the MDA preempted [the] plaintiffs claims for breach of express and implied warranties *Kemp* 231 F 3d at 219 [FN12]

In sum the only claims stated by Howard and Burgess that are not preempted by § 360k(a) of the MDA are their claims of negligence per se where they assert that Sulzer failed to conform with the FDA requirements established for the NK II through the PMA process Their other claims for design defect manufacturing defect defective marketing failure to warn negligence breach of implied warranty breach of express warranty and deceit are all preempted [FN13]

III Remaining Evidentiary Issues

As noted above the *Gomez* court permitted a plaintiff to pursue a claim that the defendant failed to manufacture a medical device in accordance with FDA specifications and further concluded that the plaintiff had adduced enough evidence in support of this claim to survive a Rule 50 motion for judgment as a matter of law The latter conclusion is unusual to the point of being unique most plaintiffs who were allowed to pursue similar preempted claims such as the plaintiffs in *Martin Kemp Riegel* and *Brooks* find themselves unable to adduce sufficient evidence of the defendant s failure to adhere to PMA requirements to survive summary judgment

Sulzer insists the more common result will occur in this case and further argues that enough discovery has already occurred in the MDL to allow the Court to enter judgment *now* on Howard s and Burgess s claims for negligence per se That is Sulzer insists the state of the evidentiary record shows already that there is no issue of material fact and it is entitled to judgment as a matter of law on Burgess s and Howard s claims of negligence per se

© 2006 Thomson/West No Claim to Orig U S Govt Works

*10 There is substantial strength to Sulzer's argument For example one position Howard has taken to support his claim of negligence per se is that like those plaintiffs whom this Court certified as members of the MDL settlement class Howard's NK II underwent machining *after* porous coating thereby allowing machine oil to remain on the surface of the finished implant (which caused the implant not to bond properly to the bone) In response Sulzer notes that (1) extensive discovery by all parties leading up to the MDL Settlement Agreement identified all those implants where machining occurred *after* porous coating and Howard's implant was not among them and (2) specific manufacturing records reflect that Howard's implant was machined *before* porous coating Having reviewed all of this evidence carefully during the Final Fairness Hearing and having heard from MDL discovery counsel regarding their extensive efforts at identifying which implants were defective and why it is hard for the undersigned to imagine that additional discovery will provide Howard with evidence to support his theory that his implant was in fact machined after porous coating

Another position Howard takes to support his claim of negligence per se is to note that he had his implant tested by a chemical laboratory and the results show the implant had on it traces of chemicals normally associated with mineral [machine] oil Howard avers that it is axiomatic that such residues should not be remain [sic] on the implanted device and a manufacturing process that fails to remove such residue would materially deviate from any FDA requirements because such residue should never be present on such implants at the time of implantation. Howard affidavit at ¶¶ 7 9 [FN14] This analysis appears faulty in two respects First the Court heard evidence at the Final Fairness Hearing that it is impossible to remove *all* of the machine oil from an implant [FN15] Thus it is not axiomatic that because Howard's implant may test positive for machine oil residue Sulzer must have deviated from FDA manufacturing requirements Second Howard suggests that the FDA requirements applicable to the NK II must include cleaning processes and quality controls with mandated maximum levels of residue and he alleges these maximums were exceeded in his case It is at least as likely however that while the FDA requirements mandate certain cleaning processes and quality controls those requirements do not mandate specific maximum residue levels That is the cleaning procedures are mandated but not the precise results If so Howard's claim for negligence per se will fail so long as Sulzer followed the required cleaning processes and quality controls regardless of how residue free those manufacturing steps actually left his NK II And Sulzer has already adduced evidence that it followed all the required cleaning processes and quality control steps when it manufactured Howard's implant

*11 Ultimately however the Court concludes it would be premature to enter judgment on Howard's and Burgess's remaining claims at this juncture Howard and Burgess argue they should be allowed to pursue their own discovery to test the veracity of Sulzer's evidentiary submissions and also to see if they can uncover some other deviation from FDA requirements by Sulzer that caused their particular NK II implants not to work as intended The current state of the evidence suggests this may be an uphill battle but it is theirs to choose to fight If Sulzer is correct it may reassert its argument that it is entitled to judgment on Howard's and Burgess's negligence per se claims in the context of Rule 56 Howard and Burgess must each be allowed an opportunity to conduct discovery to uncover factual support for their single remaining claim

Under separate order the Court will schedule a telephonic status hearing with the parties to set new discovery and other deadlines

IT IS SO ORDERED

FN1 Sulzer Orthopedics Inc was later renamed Centerpulse Orthopedics Inc and then purchased by Zimmer Holdings Inc The Court refers to the defendant as Sulzer

FN2 This split derives from the fractured plurality opinion delivered by the Supreme Court when it confronted the scope of the

© 2006 Thomson/West No Claim to Orig U S Govt Works

MDA preemption provision in *Medtronic Inc v Lohr* 518 U S 470 116 S Ct 2240 135 L Ed 2d 700 (1996) *See Moore* 337 F Supp 2d at 1007 09 (discussing *Lohr* and the split in federal appellate authority)

FN3 The Court's Order also applied to three other similarly situated plaintiffs whose cases had been transferred to this MDL *McDonough v Sulzer Orthopedics Inc* case no 04 CV 9002 *Hulse v Sulzer Orthopedics Inc* case no 03 CV 9009 and *Boyd v Sulzer Orthopedics Inc* case no 03 CV 9003 These three cases have already been dismissed however either because the plaintiffs stipulated to dismissal or did not respond to the Court's show cause order

FN4 Rather than setting out again the history of this MDL and the Court's analysis of federal preemption in the context of the MDA the Court simply incorporates in full the reasoning and analysis set out in *Moore* 337 F Supp 2d 1002 Should any party later wish to appeal this Order the Court makes clear here that *Moore* must be included as an addendum to this Order and made a part of the appellate record

FN5 In fact it is not completely accurate to state that the *Oja* and *Goodlin* courts reached the same conclusion The Eleventh Circuit was alone among the Courts of Appeals when it ruled in *Goodlin* that § 360k(a) does not preempt common law claims involving PMA approved devices While the Tenth Circuit had earlier ruled in *Oja* that the MDA did not preempt common law tort claims against a medical device manufacturer the device at issue in *Oja* did not undergo the § 360e(c) PMA analysis rather it underwent the far less rigorous Investigative Device Exception (IDE) process Even assuming that *Oja* stands for the proposition that the Tenth Circuit would adopt fully the *Goodlin* preemption analysis however the Court concludes it is bound to follow *Kemp* and not *Oja*

FN6 Burgess does not make a similar argument because the law of the Eighth Circuit which would control if this Court were to adopt the rule that the law of the transferor court applies is consonant with the law of the Sixth Circuit *See Brooks v Howmedica Inc* 273 F 3d 785 796 (8th Cir 2001) *cert denied* 535 U S 1056 122 S Ct 1914 152 L Ed 2d 823 (2002) (The failure to warn claim asserted by Brooks would interfere or conflict with the specific federal requirements imposed during the regulation of Simplex A jury finding of negligent failure to warn would be premised on the fact that the label for Simplex was not written in a particular way or did not contain certain information This would be equivalent to a state regulation imposing specific label requirements)

FN7 The Court finds especially provocative but ultimately not persuasive the following two pronged argument which Moore did not raise but Howard did (1) the law of the transferor court applies when transfers are made pursuant to 28 U S C § 1404(a) because a defendant should not get a change of law as a bonus for a change of venue *Van Dusen v Barrack* 376 U S 612 635 84 S Ct 805 11 L Ed 2d 945 (1964) and the same anti forum shopping policy should adhere in cases where the transfer is made in an MDL pursuant to 28 U S C § 1407 and (2) if anything the reasoning behind the *Van Dusen* rule applies even more strongly in the MDL context given that the transferee court would often have no independent basis to exercise personal jurisdiction over the transferred MDL plaintiff

FN8 The cases that inform this Court's

© 2006 Thomson/West No Claim to Orig U S Govt Works

analysis listed in order of Circuit Court are (Second) *Riegel v Medtronic Inc* 451 F 3d 104 (2nd Cir 2006) (Third) *Horn v Thoratec Corp* 376 F 3d 163 (3rd Cir 2004) (Fifth) *Gomez v St Jude Medical Diag Division Inc* 442 F 3d 919 (5th Cir 2006) *Martin v Medtronic Inc* 254 F 3d 573 (5th Cir 2001) (Sixth) *Kemp v Medtronic Inc* 231 F 3d 216 (6th Cir 2000) *cert denied* 534 U S 818 122 S Ct 48 151 L Ed 2d 19 (2001) *Cupek v Medtronic Inc* 405 F 3d 421 (6th Cir 2005) (Seventh) *McMullen v Medtronic Inc* 421 F 3d 482 (7th Cir 2005) *Mitchell v Collagen Corp* 126 F 3d 902 (7th Cir 1997) (Eighth) *Brooks v Howmedica Inc* 273 F 3d 785 795 (8th Cir 2001) (Ninth) *Papike v Tambrands Inc* 107 F 3d 737 (9th Cir 1997) As noted above the Court does not rely upon the Tenth Circuit s opinion on *Oja* or the Eleventh Circuit s opinion in *Goodlin* because they do not adhere to the majority view

FN9 A PMA application shall contain * * * specimens of the labeling proposed to be used for [the medical] device 21 U S C § 360e(c)(1)(F) If the labeling is found to be false or misleading in any particular the application for approval must be denied *Id* § 360e(d)(2)(D)

FN10 Also preempted are claims premised on a *post sale* duty to warn where the plaintiff alleges the defendant was required to provide *additional* warnings in light of later received reports of injury to others caused by the same medical device *McMullen* 421 F 3d at 488 (emphasis in original) *See Cupek* 405 F 3d at 422 424 25 (concluding that the plaintiff's post sale failure to warn and post sale failure to recall claims were preempted) *Gomez* 442 F 3d at 931 (Gomez s state law claims related to [the defendant s] alleged failure to provide information obtained after the FDA approved the [medical device] risk the same interference with the federal regulatory scheme as her other claims and are preempted)

FN11 The trial court and the Sixth Circuit Court of Appeals reached essentially the same conclusions again in *Cupek*

FN12 It is also worth noting that Howard states his breach of express warranty claims are based upon the statements contained in the package inserts and other written materials associated with the [NK II] and not any independent representations between the parties Response brief at 27 (docket no 9) The written materials Howard points to of course are reviewed as part of the FDA s PMA process success on this claim would necessarily create conflict with the FDA s requirements Burgess does not provide any explanation for the basis of his claim of breach of express warranty

FN13 There are three other claims stated by Howard and Burgess Howard s claim for medical monitoring is actually a request for injunctive relief entitlement to which depends on the success of a substantive claim Thus this claim necessarily rises and falls with Howard s other claims Similarly Howard s and Burgess s spouses claims for loss of consortium are derivative so they are preempted to the extent the underlying substantive claims are preempted
Finally with his claim of fraud Burgess contends that when Sulzer identified certain lots of NK II implants it had manufactured improperly and provided settlement benefits to recipients of these implants pursuant to the MDL Settlement Agreement Sulzer knew there were *additional* NK II implants that were improperly manufactured (such as Burgess s) and Sulzer purposefully excluded recipients of these implants from

© 2006 Thomson/West No Claim to Orig U S Govt Works

the settlement This claim is clearly a collateral attack on this Court s Final Fairness Hearing at which time the Court heard extensive evidence regarding the efforts that both plaintiffs and defendants undertook to identify all persons who were proper members of the settlement class Indeed Burgess s fraud allegations fail not only for lack of specificity but also for lack of any basis in reality it is pure fiction (and insulting) for Burgess to allege that the members of [the settlement class] were selected wholly upon information supplied by defendants as to which manufacturing lots of the device contained the defective product Amended complaint at ¶ 24 Two days worth of testimony at the Final Fairness Hearing convinced this Court otherwise The time for appealing the Court s determinations regarding class membership is long past and Burgess may not collaterally attack this Court s conclusions in this regard in his current case

FN14 Howard is himself an orthopedic surgeon who frequently implanted in others Sulzer s NK II

FN15 *See* case no 01 CV 9000 master docket no 327 exhibit 18 ¶ 11 (affidavit of Dr Toby Hayes) (The use of machining and cooling oils in manufacturing operations results in some measurable residual oil on all orthopaedic implants even with the use of rigorous cleaning procedures * * * With monitoring these levels can be maintained below those known in the industry to be safe and effective) exhibit 25 ¶ 9 (affidavit of Dr William Maloney) (Although orthopedic implants commonly contain some amount of [oil] residue the level of residue in a number of these cases exceeded that which would be normally expected)

Motions Pleadings and Filings (Back to top)

2006 WL 3720357 (Trial Motion Memorandum and Affidavit) Response to Tommy Jacks and Sulzer's Opposition to Reopen the Time to File an Appeal Regarding the Rights of Class Plaintiff Susan F Kuhn (Feb 2 2006)

2006 WL 3720356 (Trial Motion Memorandum and Affidavit) Motion to Reopen the Time to File an Appeal Regarding the Rights of Class Plaintiff Susan F Kuhn (Jan 10 2006)

2005 WL 1555012 (Trial Pleading) Defendant s Reply to Plaintiff's Response to this Court s Show Cause Order (Feb 1 2005)

2005 WL 1555007 (Trial Pleading) Plaintiff David Abeyta S Response to Opinion and Order to Show Cause (Jan 28 2005)

2004 WL 3125043 (Trial Pleading) Amended Complaint (Sep 20 2004)

2004 WL 3147890 (Trial Motion Memorandum and Affidavit) Centerpulse Orthopedics Inc s Sur Reply Regarding the Court s Preemption Show cause Order (Sep 17 2004)

2004 WL 3147623 (Trial Motion Memorandum and Affidavit) Plaintiffs Objection to Defendants Motion to Stay Discovery (With Authorities) (Jul 27 2004)

2004 WL 3147609 (Trial Motion Memorandum and Affidavit) Plaintiffs Objection and Response to Defendants Combined Motion to Dismiss and Motion for Summary Judgment and Plaintiffs Motion to Strike (Jun 8 2004)

2004 WL 3684531 (Trial Motion Memorandum and Affidavit) Class Members Ronald E Barger and Ellen A Barger s Motion for Reconsideration of Order Declaring Class Members Have no Right to Appeal Benefits Determinations by Special Master and Petition for Order Allowing Their Participation in Fund Distributio n (Jan 22 2004)

© 2006 Thomson/West No Claim to Orig U S Govt Works

2004 WL 3684552 (Trial Motion Memorandum and Affidavit) Memorandum of Law in Support of Class Members Ronald E Barger and Ellen A Barger s Motion for Reconsideration of Order Declaring Class Members Have no Right to Appeal Benefits Determinations by Special Master and Petition for Order Allowing Partici pation in Fund Distribution (Jan 22 2004)

2004 WL 3684533 (Trial Motion Memorandum and Affidavit) Class Members Elisabeth Wiener and Stanley Wiener s Motion for Reconsideration of Order Declaring Class Members Have no Right to Appeal Benefits Determinations by Special Master and Petition for Order Allowing Their Participation in Fund Distribution (Jan 22 2004)

2004 WL 3684554 (Trial Motion Memorandum and Affidavit) Memorandum of Law in Support of Class Members Elisabeth Wiener and Stanley Wiener s Motion for Reconsideration of Order Declaring Class Members Have no Right to Appeal Benefits Determinations by Special Master and Petition for Order Allowing Particip ation In Fund Distribution (Jan 22 2004)

2004 WL 3684535 (Trial Motion Memorandum and Affidavit) Class Member Susan Fischer s Motion for Reconsideration of Order Declaring Class Member Has no Right to Appeal Benefits Determinations by Special Master and Petition for Order Allowing Her Participation in Fund Distribution (Jan 22 2004)

2004 WL 3684556 (Trial Motion Memorandum and Affidavit) Memorandum of Law in Support of Class Member Susan Fischer s Motion for Reconsideration of Order Declaring Class Members Have no Right to Appeal Benefits Determinations by Special Master and Petition for Order Allowing Participation in Fund Distribut ion (Jan 22 2004)

2004 WL 3684557 (Trial Motion Memorandum and Affidavit) Class Members Joseph p Lamia and Jennie Lamia s Motion for Reconsideration of Order Declaring Class Members Have no Right to Appeal Benefits Determinations by Special master and Petition for Order Allowing Their Participation In Fund Distribution (Jan 22 2004)

2004 WL 3684538 (Trial Motion Memorandum and Affidavit) Memorandum of Law in Support of Class Members Joseph P Lamia and Jennie Lamia s Motion for Reconsideration of Order Declaring Class Members Have No Right to Appeal Benefits Determinations by Special Master and Petition for Order Allowing Participati on In Fund Distribution (Jan 22 2004)

2004 WL 3125047 (Trial Pleading) Zimmer Austin Inc s Answer to Plaintiffs Amended Complaint (2004)

2004 WL 3147798 (Trial Pleading) Defendant Centerpulse Orthopedics Inc s Answer to Plaintiffs Complaint and Jury Claim (2004)

2003 WL 24000686 (Trial Pleading) Centerpulse Usa Inc s and Centerpulse USA Holding Co s Answer to the Plaintiffs Complaint (Sep 4 2003)

2003 WL 24253754 (Trial Pleading) Centerpulse Orthopedics Inc s Answer to the Plaintiffs Complaint (Sep 4 2003)

2003 WL 24253755 (Trial Pleading) Centerpulse Usa Inc s and Centerpulse Usa Holding Co s Answer to the Plaintiffs Complaint (Sep 4 2003)

2003 WL 24253710 (Trial Motion Memorandum and Affidavit) Memorandum of Points and Athorities in Support of Petitioner Linda Mediate s Motion to Enforce Settlement (Aug 8 2003)

2003 WL 22350993 (Trial Filing) Response to the Court s June 12 2003 Order Re Common Benefit Fees by Thomas A Schultz on Behalf of Lopez Hodes Restaino Milman & Skikos (Jun 19 2003)

2003 WL 24253709 (Trial Motion Memorandum and Affidavit) Memorandum of Law in Support of Class Members Ronald E Barger and Ellen A Barger s Petition Requesting Court to Find Claims were Timely as a Result of Excusable Neglect and Allowing Participation in Fund Distribution (Jun 19 2003)

© 2006 Thomson/West No Claim to Orig U S Govt Works

2003 WL 21996906 (Trial Motion Memorandum and Affidavit) Specially Appearing Defendant Lawrence D Dorr M D %7Ds Opposition to Louise and Navarro Stafford%7Ds Motion for Order Declaring That the Final Class Action Settlement Agreement Does not preclude Plaintiffs from Maintaining a State Action for Indepe ndent Negligence Against Dr Dorr Declaration of Henry Yekikian (Jan 8 200ɔ)

2003 WL 24000520 (Trial Pleading) Answer and Jury Demand of Defendant Centerpulse Orthopedics Inc (2003)

2002 WL 32151807 (Trial Motion Memorandum and Affidavit) Motion for Order Declaring that the Final Class Action Settlement Agreement Does Not Preclude Louise and Navarro Stafford From Maintaining a State Action for Independent Negligence Against Lawrence Dorr M D (Dec 18 2002)

2002 WL 32151743 (Trial Motion Memorandum and Affidavit) Claimant%7Ds Motion for Authority to Opt Out of Class Action Settlement With Brief in Support Attached (Oct 15 2002)

2002 WL 32151796 (Trial Motion Memorandum and Affidavit) Plaintiff%7Ds Memorandum in Support of Motion to Remand (Aug 9 2002)

2002 WL 32151797 (Trial Motion Memorandum and Affidavit) Pla ntiff%7Ds Memorandu n i Support of Motion to Remand (Aug 9 2002)

2002 WL 32970228 (Trial Motion Memorandum and Affidavit) PlaintiffS Memorandum in Support of Motion to Remand (Aug 9 2002)

2002 WL 32970229 (Trial Motion Memorandum and Affidavit) Plaintiff's Memorandum in Support of Motion to Remand (Aug 9 2002)

2002 WL 32156882 (Verdict Agreement and Settlement) Judgment & Order (May 31 2002)

2002 WL ɔ2970243 (Trial Pleading) First Amendment to Class Action Settlement Agreement (May 2002)

2002 WL ɔ215700ɔ (Trial Motion Memorandum and Affidavit) Brief In Support of Cigna Healthcare s Motion to Intervene (Apr 29 2002)

2002 WL 32970225 (Trial Motion Memorandum and Affidavit) Brief in Support of Cigna Healthcare s Motion to Intervene (Apr 29 2002)

2002 WL 32970227 (Trial Motion Memorandum and Affidavit) Aetna s and Cobalt s Memorandum of Law in Support of Their Motion to Intervene as to Final Approval of Proposed Settlement Under Rules 24(a)(2) and 24(b)(2) and for Consolidation Under Rule 42 (Apr 29 2002)

2002 WL ɔ2970241 (Trial Pleading) Complaint in Intervention of Class Member Walter Bosley in Pending Class Action Settlement (Apr 27 2002)

2002 WL 32970242 (Trial Pleading) Complaint in Intervention of Class Member Helga Hika in Pending Class Action Settlement (Apr 27 2002)

2002 WL 32970223 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 26 2002)

2002 WL 32970224 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 26 2002)

2002 WL 3297021ɔ (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 22 2002)

2002 WL ɔ2970214 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 22 2002)

2002 WL ɔ2970215 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 22 2002)

2002 WL 32970216 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 22 2002)

© 2006 Thomson/West No Claim to Orig U S Govt Works

2002 WL 32970217 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 22 2002)

2002 WL 32970218 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 22 2002)

2002 WL 32970219 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 22 2002)

2002 WL 32970220 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 22 2002)

2002 WL 32970221 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 22 2002)

2002 WL 32970222 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (Apr 22 2002)

2002 WL 32970240 (Trial Pleading) Master Answer of Defendants Sulzer Orthopedics Inc Sulzer Medica Usa Inc and Sulzer Medica Usa Holding Company to Plaintiffs Fifth Amended and Consolidated Class Action Complaint (Mar 19 2002)

2002 WL 32970239 (Trial Pleading) Complaint (Mar 15 2002)

2002 WL 32151787 (Trial Motion Memorandum and Affidavit) Defendant Sulzer Orthopedic Incorporated Emergency Motion to Vitiate State Court Order enforcing Judgment (Mar 11 2002)

2002 WL 32151786 (Trial Motion Memorandum and Affidavit) Notice Of Motion And Motion For Relief From Stay Memorandum Of Points And Authorities Declaration of Eileen R Ridley (Feb 19 2002)

2002 WL 32970237 (Trial Pleading) Plaintiffs Fourth Amended and Consolidated Class Action Complaint (Feb 12 2002)

2002 WL 31186940 (Verdict and Settlement Summary) (Feb 1 2002)

2002 WL 32151736 (Trial Motion Memorandum and Affidavit) Opposition of Richard and Sally Jozwiak to Sulzer Motion to Enforce Injunction by Vacating Attachment Orders and Quashing Writs of Garnishment (Jan 8 2002)

2002 WL 32155866 (Trial Motion Memorandum and Affidavit) Motion to Enforce Injunction by Vacating Attachment Orders and Quashing Writs of Garnishment (Jan 8 2002)

2002 WL 32970226 (Trial Motion Memorandum and Affidavit) Motion to Intervene to Preserve Objections and Appellate Rights (2002)

2001 WL 34872590 (Trial Pleading) Amended Complaint (Dec 3 2001)

2001 WL 34131467 (Trial Motion Memorandum and Affidavit) Defendant Sulzer Orthopedics Inc %7Ds Opposition to Plaintiffs%7D Motion for Remand (Nov 9 2001)

2001 WL 34131466 (Trial Motion Memorandum and Affidavit) Notice of Motion and Motion for Remand Memorandum of Points and Authorities Declaration of Sharon J Arkin (Nov 2 2001)

2001 WL 34131982 (Trial Motion Memorandum and Affidavit) Defendant Sulzer Orthopedics Inc %7Ds Motion for Order Enjoining Related Knee Replacement Litigation Pending Final Approval of Class Settlement (Oct 12 2001)

2001 WL 34131997 (Trial Pleading) Plaintiffs%7D Second Amended and Consolidated Class Action Complaint (Oct 12 2001)

END OF DOCUMENT

© 2006 Thomson/West No Claim to Orig U S Govt Works

FDA

INSIDE & OUT

S Parisian, M D
Former **Chief Medical Officer**
Office of Device Evaluation
Center for Devices & Radiological Health, FDA

Exh. 3

FAST HORSE PRESS
P O Box 246
Front Royal, VA 22630
email info@fasthorsepress com
540-636-6740

All rights are reserved No part of this book may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording or by any information storage and retrieval system without the written permission from the author except for the inclusion of brief quotations in a review

Copyright© 2001 by Suzanne Parisian, MD

First Printing

Printed in the United States of America

Library of Congress Number 2001116097

ISBN 0 9707109 1 7

Warning- Disclaimer

The purpose of **FDA, Inside & Out** has been to inform educate and entertain The author and publisher shall have neither liability nor responsibility to any person or entity with respect to any loss or damage caused, or alleged to be caused directly or indirectly by the information contained in this book

FDA, Inside & Out has been designed by Dr Parisian to provide the reader with information regarding the subject matter intended to have been covered in this book It is sold with the understanding that neither Dr Parisian nor the publisher are engaged in rendering legal services **The author is not a lawyer** and is providing her own interpretation of FDA regulations, history and previous requirements based solely upon her own experiences and interactions with FDA The author s statements and opinions are her own and should not be construed in any way to represent official opinions and statements of either the FDA, the U S Government or the publisher

Every effort has been made by the author to verify that the information contained within FDA, Inside & Out is as complete and accurate as possible The text relies upon publicly available documents that may be obtained and verified by the reader with applicable sources for obtaining the documents provided by the author There may be mistakes both typographical and in content and the pertinent laws and regulations may change Therefore the text should be used only as a general guide regarding the requirements of the FDA This text contains information regarding the FDA that is applicable up to the printing date

The specific examples of manufacturers, products and related FDA actions described within this text have been derived from public record Examples have been selected and provided by the author only for the purpose of elucidating the functioning and history of FDA Product and product issues were selected from the public record by the author with no intent, implied or otherwise regarding providing an expression of her personal opinions about the manufacturer, manufacturing practices and product performance No confidential information regarding manufacturers, products, FDA or U S Government actions have been provided in the text

CHAPTER 2

The spirit of policy and that of bureaucracy are diametrically opposed The essence of bureaucracy is its quest for safety its success is calculability Profound policy thrives on perpetual creation on a constant redefinition of goals Good administration thrives on routine the definition of relationships which can survive mediocrity Policy involves an adjustment of risks administration an avoidance of deviation

Henry A Kissinger (1923-) A World Restored Metternich, Castlereagh and the Problems of Peace 1812 1822, **17 3, 1957**

Food and Drug Administration (FDA)

I will now provide you with the following brief history about how things have come into being at the FDA Before I joined the FDA, I had absolutely no clue as to what type of organization was hiding behind the regulatory name FDA Physicians trained in the U S are rarely, if ever, exposed to issues involving the regulation of products by the FDA I thought, as I have found most people do, that there were essentially two centers, namely Foods and Drugs and somehow the FDA had something to do with the generation of the Physician s Desk Reference (PDR) which was a book that I used to look up drug information for treating my patients I quickly learned that there was much, much more to FDA than foods and drugs and that they did not publish the PDR

Overview of the FDA

FDA s actions virtually touch the lives of every American every day FDA's mandate from Congress is to ensure that the food we eat is safe, the cosmetics we use won t hurt us, the medicines and medical devices that we use are safe and effective, and that radiation-emitting products, such as microwaves, don t harm us Food and drugs for our pets and farm animals also come under the scrutiny of the FDA FDA is required by law to ensure that all FDA-regulated products are truthfully and accurately labeled The product label is required to provide the user with all the necessary information that will ensure that the product is used safely

claims also applies to the meaningless terms safe for sensitive skin and 'allergy tested

Under FDA s umbrella good manufacturing practice guidelines (GMP) even cosmetic products that are not regulated as drugs are required to have been thoroughly tested for safety and are subject to quality control requirements during manufacture The law does not require that the FDA review cosmetic testing results before the cosmetics are marketed Nevertheless, FDA does require the presence of specific safety warnings when problems have become apparent for specific categories of cosmetics or when product safety testing has not been performed by the manufacturer

FDA's Regulation of a "Drug" versus a "Cosmetic" Product

Cosmetic effects are generally considered by FDA and the FDCA to be temporary and superficial However, the Act makes no provisions for an article that would be considered a **"cosmeceutical"** (i e drug and cosmetic) that may exert a more prolonged effect An example of such a product is the regulation by FDA of Alpha-Hydroxy Acid (AHA)

Cosmetics, as we have already discussed are brought to the market without a premarket approval process by FDA On the other hand, new drugs are subjected to a rigorous premarket approval that requires a sponsor demonstrate that the product is not only safe but also effective for its marketed intended use (See chapter for Center for Drug Evaluation and Research (CDER)) Since obtaining approval of new drugs is usually considered an expensive and time consuming process particularly when premarket review is not required for cosmetics marketers of personal care products would obviously prefer to market their products as cosmetics rather than as drugs

Cosmetics Containing "Drug" Active Ingredients

Cosmetics making therapeutic claims that they may affect the structure or function of the body are regulated as both drugs and cosmetics and must meet the applicable labeling requirements for both For a combination drug and cosmetic product, the first entry of the ingredient list will include the term Active Ingredient The active ingredient is the ingredient that makes the product effective and it must be safe for its intended use However, active ingredients are not legally required to be identified by this term The law however, does require that the active ingredient(s) be listed first followed by a list of all inactive cosmetic ingredients

A product with a drug and cosmetic classification must be scientifically proven safe and effective for its therapeutic claims before it can be marketed If the product is not FDA considers it to be a misbranded drug and then can take a regulatory action against it under the FDCA

Therefore, how does FDA determine "drug versus cosmetic"?

The definitions for cosmetics and drugs in the FDCA refer to an article s intended use The intended use of a product is determined principally by the claims that are made on the product label However, the agency has even, on occasion, decided that the final drug versus cosmetic categorization of a product should be based on statements made on behalf of the product at the point of sale or training and guidance provided to sales persons who will be selling the product at the cosmetic counter

drug The agency again agreed that the intended use of a product is the primary determining factor as to whether a product is a drug, cosmetic, or both

The addition of fluoride to a dentifrice is provided as an example This reflects that agency's policy that a dentifrice formulated using therapeutic levels of fluoride as an active ingredient is considered a drug even if product labeling does not make drug claims A similar situation exists for shampoo products that include anti dandruff ingredients at therapeutic levels in the formulation but make no anti-dandruff claims

Clearly, avoiding overt claims that have in the past been interpreted by the agency to be drug claims will not guarantee that a product will be classified as a cosmetic, rather than a drug

The Alpha Hydroxy Acids (AHAs)- Drug versus Cosmetic

Baby boomers and others who once sought out the sun s rays with little thought of future skin damage may now be paying a price for their tans The price is billions of dollars that are now paid annually for cosmetics containing alpha hydroxy acids (AHAs) AHAs are derived from fruit and milk sugars and attract consumers with their supposed ability to reduce wrinkles, spots, and other signs of aging sun-damaged skin

In the April 6 1994 speech referenced above, by John E Bailey, Ph D Acting Director, Office of Cosmetics and Colors FDA **Skin Care- State of the Art, A regulatory Review- Alpha-Hydroxy Acid** he continued with his discussion of FDA s situation in terms of its regulation of AHAs

"With the AHA products, there are 2 basic issues that are of interest to FDA First there s the safety of these products Second is whether or not these products are drugs and should be regulated as such or are these cosmetics?

In considering these questions let s first discuss what we know (and don t know) about these products

(A) They are exceedingly popular products Virtually every major cosmetic manufacturer now offers an AHA product for sale indeed, many companies have more than one type of product in their line

They are marketed using a wide variety of individual ingredients, ingredient combination, concentrations and preparation These include products marketed directly to consumers and for salon use only AHA products, by some accounts are single handedly responsible for the estimated 10 percent growth in the cosmetics industry that occurred in 1993

They are heralded as leading the industry into the world of true cosmeceuticals Consumer awareness is described as exceptional with the closest competition being

Congress reportedly found that MDA s regulatory plan requiring FDA s evaluation and completion of PMA s and FDA s issuance of performance standards had not been followed by the agency (*Subcommittee on Oversight and Investigations May 1983 report **Medical Device Regulation The FDA's Neglected Child**) The subcommittee report reiterated its concern that the FDA had barely begun to fully implement" the requirements of the 1976 amendments

> the FDA was regulating many of the riskiest devices as if they were the least risky by failing to classify devices so that the staggered system of regulatory controls could take hold, the FDA was failing to require PMA's for the pre-nendment's dev ces, and the FDA failed to implement the reporting requirements for devices

The Congressional subcommittee report concluded that the FDA had established procedures that were regulating cardiac pacemakers as if they were no riskier to the public health than tongue depressors The agency s failure to implement a system of adverse event reporting (ADE) requirements for manufacturers of devices had resulted in the agency s lack of knowledge about the risks associated with certain devices While there was concern expressed about the agency's under regulating risky devices, the subcommittee also pointed to examples where the opposite had also been true Specifically, Congress expressed concerns that the FDA was over regulating noncritical devices An example provided by the subcommittee of the agency s wasting time with over regulation of non-risky devices was the agency's persistence of classifying contact lenses (* considered by Congress as a substantially equivalent or me too device) class III devices requiring the submission of PMAs Therefore each contact lens marketing application was being subjected to the rigorous scientific scrutiny of a PMA It appeared that the agency should have been placing agency review efforts into requesting PMAs for riskier devices such cardiac pacemakers

After conducting the 1984 hearings the Congressional subcommittee turned specifically to a review of FDA's handling of the regulation of Investigational Device Exemptions (IDEs)(i e clinical trials) IDEs are the device version of INDs for drugs and biologics (See Chapter 5 CDER and 6 CBER)

Obtaining approval of an IDE for a significant risk investigation from FDA permits interstate transport for restricted use, of a class III device within a controlled and monitored clinical trial settings The device that is subject of an IDE automatically is considered as class III device because the device as proposed to be used within the IDE has not yet cleared for marketing in the U S for that intended use Therefore, the safety and effectiveness of the IDE device, as required by the FDCA, for that intended use cannot be assured by FDA The purpose of the IDE is to allow the sponsor to legally collect human performance data for the IDE s device for an intended use The safety and effectiveness data gathered from the IDE or IDEs will be used for support of a future marketing application for FDA While conducting the IDE, manufacturers (sponsors) are required to strictly control and monitor the distribution of the IDE devices Devices intended for use in an IDE are to be labeled as "Investigational Devices per FDCA. There is to be the continued monitoring and oversight of the investigation and subject safety by an acceptable Institutional Review Board (IRB) and the IDE sponsor (See Chapter 12 IDE and Chapter 13, IRB) The FDA reviews a sponsor s submitted IDE protocol to determine that

Modules can contain various types of information ranging from pictorial representations of the device to clinical study data Since they may be submitted at various times throughout the development and review process each module is to contain an easily identifiable **executive summary** describing the content of the submission and conclusions drawn from the data These summaries will then serve the dual purpose of providing an overview summary of the submitted module, and when assembled at the time of the final PMA submission these module executive summaries should be able to form a working draft of the **Summary of Safety and Effectiveness Data** (SSED) for the device The module sponsor should keep in mind that the information provided in the modules should follow the content requirements as listed in 21 CFR 814 20 for a PMA

Deficiencies identified during review of a module will be communicated to the module sponsor s official correspondent FDA may work interactively with the module sponsor to resolve deficiencies Written correspondence regarding the status of the module will be in the form of a deficiency or acceptance letter This letter will generally be issued within 90 days of receipt of the module or of receipt of a response to a module deficiency letter When the review team finds that the issues in a module have been resolved, a memo regarding the acceptance of the module will be added to the file and a status letter to the module sponsor will be issued declaring the module closed These review memos can be compiled at a later date to serve as the complete review documentation and memorandum for the PMA A running list of open and closed modules will be maintained by the review team leader

Premarketing Approval Application (PMA) Elements

As of October 2000, there continues to still be **no fee** for a sponsor to submit a PMA to either CDRH or CBER This is in contrast to the fees that are required to submit either a NDA or a BLA, to CDER or CBER, which are covered under the Prescription Drug User Fee Act (PDUFA)

The elements of all PMAs, whether modular or nonmodular , can be grouped under the following 12 generic types of headings (Each section or heading could potentially consist of one or more modules, with the content of each module being device-specific)

1) General Information
2) Table of Contents
3) Summary of Safety and Effectiveness Data (SSED), -(Now recommended to also be included electronically for ODE as a compatible copy on disk)
4) Device Description- pictures, drawings, engineering representations, principle of operation, properties, draft labeling,
5) Manufacturing Information- in accordance with the Quality Systems Regulation (QSR) [21 CFR part 820] (*formerly called Good Manufacturing Practices- GMP),
6) Certification of conformance, reference to and status of compliance with any performance standards,

7) Non-clinical Laboratory Studies-

Product Testing Bench chemistry electrical safety, battery testing electromagnetic compatibility, engineering firmware hazards analysis, MRI compatibility predicted reliability and durability software stress wear

Biological Testing Biocompatibility immunology microbiology, toxicology

Useful Life Testing Reuse shelf life sterilization

Analytical Testing (for IVDs)

Animal Testing of the finished device,

Other laboratory or animal testing as appropriate

There must also be a written statement indicating if each laboratory study was conducted in compliance with 21 CFR Part 58 (Good Laboratory Practices (GLP)) or a statement of the reasons for non-compliance

8) Clinical studies

A description of the intended use (-if measured end point is not a clinically significant result or event to the non-medical public a statement of why it should be regarded as evidence of effectiveness)

Justification for a single investigator if applicable

Description and copy of the clinical protocols (*provide a reference to all IDE/IDE supplement identification numbers where these have been submitted to the Agency and approved)

Number of investigators and numbers of subjects for each

Subject inclusion/exclusion criteria

Description of study population and study period

Study endpoints

Safety and Effectiveness data

Description of the study protocol used

Indicate if any subjects were not part of the IDE (e g foreign or nonsignificant risk study)

Explanation of the applicability of foreign data to the US population

Subject demographics including a single table listing all subjects and important subject information as requested by the review division

A subjects accountability tabulation is suggested in format as requested by the review division

Clearly tabulate and characterize the reported adverse events

Statistical analysis (*suggest it be provided on disk e g Excel SAS) of safety

Statistical analysis (* ') of

Benefit/effectiveness/treatment success

Conclusions drawn from the study

9) Bibliography/References

10) Device labeling

Indications

Contraindications

Warnings

Precautions

Adverse events
Device description
Usage instructions
Troubleshooting
Patient information
References

11) Operating and Instruction Manual
12) Post-marketing Plan Commitments for Studies if applicable
13) Environmental assessment or claim of categorical exclusion

The PMA Procedure

A PMA shell, for a modular PMA, can be developed at any time before the PMA submission, including prior to or during the IDE process In cases where an IDE will not be submitted as during nonsignificant risk *in vitro* diagnostic device development it is still suggested that the PMA shell be developed prior to initiation of the clinical studies or any other studies intended to demonstrate safety and effectiveness

For a device beyond the initial stages of development a shell may be established at any time before submission of the final PMA However the earlier FDA and the applicant agree to the types of data necessary for a module review the more efficient will be the potential development and review process

The potential PMA sponsor should develop the shell for their product including the identification of the proposed modules and submit it to CDRH for review Applicants should contact the division staff for submission instructions Within 30 days of receipt of the proposed PMA shell FDA is to have completed its review of the proposed shell/modules and provide comments either in writing or in a meeting with the applicant (by video telephone, or face to face)

If the shell is discussed during the meeting, the division representative responsible for taking meeting minutes will summarize the agreements/deficiencies at the end of the meeting After the meeting FDA will send written confirmation of any agreements or deficiencies for the proposed shell within 30 days This communication may be as a cover letter with the meeting minutes attached (*I also recommended that a sponsor take their own minutes of agency meetings and discussions and offer to provide them to FDA to be placed in the administrative record) FDA and the applicant should work to reach an agreement on what information will be considered complete for stand-alone modules The sum of the modules will constitute the shell for approval of the product

When agreement has been reached on the shell and the modules the shell should be formally submitted to the Document Mail Center (DMC) at

Document Mail Center (HFZ 401)
Office of Device Evaluation
CDRH
9200 Corporate Boulevard

STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND	)	
Monica Weston	)	Civil Action No 05-CP-40-0655
	)	
Plaintiff	)	
	)	
vs	)	
	)	
Kim's Dollar Store and CIBA Vision, a division of Novartis Company,	)	
	)	
Defendant	)	
	)	

2006 OCT -6 PM 4 22

CARRARA A. SCOTT
CCC & GS

PLAINTIFF'S MOTION FOR RECONSIDERATION/CLARIFICATION OF SEPTEMBER 26, 2006 ORDER AND/OR PLAINTIFF'S MOTION TO ALTER OR AMEND JUDGMENT

TO KEITH MUNSON ESQ AND SANDI WILSON ESQ , Attorneys for CIBA Vision

YOU WILL PLEASE TAKE NOTICE that the plaintiff by and through undersigned counsel, hereby moves pursuant to Rule 59(e) of the South Carolina Rules of Civil Procedure for an Order altering or amending the Court s order dated and filed September 25 2006

On July 12, 2006 the Court heard argument on plaintiff's motions for sanctions with regard to defendant CIBA Vision's violation of two previous orders compelling discovery On September 25 2006, the Court issued a written order stating Ciba Vision acted in willful and knowing violation of Judge Johnson's Order dated September 26, 2005 and Judge Cooper's Order dated March 2 2006 and it is ordered to comply with these orders The Court then indicated that it was requiring CIBA Vision to pay plaintiff's reasonable attorneys fees associated with her motions for sanctions and associated with the re-taking of the depositions of Holly Guest, and the other corporate deposition designees, to which CIBA Vision had previously objected based on its motion to stay The Court ordered fees to the plaintiff in the amount of

$3,000, but indicated as follows "The Court had a difficult time in determining the amount of time and charges of plaintiff's counsel that are related to plaintiff's effort to have defendant comply with the court orders Thus the court set an amount it believes is appropriate It is plaintiff's position that $3 000 is not a reasonable award of expenses or fees to pay for the amount of time plaintiff's counsel devoted to have defendant comply with the court orders or the amount of time to go back to Atlanta to continue with the depositions as ordered by the Court Accordingly plaintiff respectfully requests that the Court clarify reconsider, and/or alter or amend its award of attorneys fees and costs to the plaintiff

I FACTUAL BACKGROUND

Plaintiff Monica Weston alleges that she purchased CIBA Vision's FreshLook Colors non-corrective plano color contact lenses from Kim's Dollar Store (a beauty supply) store in March of 2004 (Plano is another word for non-corrective) Plaintiff alleges that the color non-corrective contacts were sold over the counter, without a prescription without any instructions for care use or handling, and without any warning that use of the product could make her go blind Ms Weston alleges that she inserted the contacts in her eyes, and from only wearing them for a few hours the contacts caused her to develop an infection called keratitis, which caused her tremendous pain and eventually caused blindness Monica Weston was blind in one eye for approximately one and a half years at which point she received a corneal transplant which partially restored her vision

CIBA VISION HAS TESTIFIED THAT IT KNEW THAT THE COLOR CONTACTS AT ISSUE IN THIS CASE WERE DANGEROUS, KNEW THAT THE GENERAL PUBLIC DID NOT KNOW OF THESE DANGERS, AND KNEW THAT

MEMBERS OF THE PUBLIC WERE ACTUALLY BEING INJURED BY CIBA VISION'S PRODUCTS

CIBA Vision through its S C R Civ P 30(b)(6) designees testified as follows

Q Is it true that CIBA Vision was aware as of September of 2002 that many companies were participating in the activity of breaking down the individual boxes of color contact lenses and selling them to individuals without a prescription, and without package inserts?

MS WILSON Objection

THE WITNESS Yes

Q (By Mr Rawl) And is it true that CIBA Vision was aware that this conduct was going on in locations such as beauty supply stores, nail salons flea markets, video stores, and gas stations, and that the conduct was on the rise?

MS WILSON Objection

THE WITNESS Yes

Q isn't it true that as of 2002, CIBA Vision was aware that consumers often believed that they do not need a prescription or do not need to be fit by an eye doctor for these lenses because they use them merely to change eye color and not to correct vision?

MS WILSON Objection

THE WITNESS Yes

30(b)(6) Depo of CIBA Vision Witness Paul Oris p 55, l 24- p 56, l 24 (emphasis added)

Q And you would agree that the purchase and use of CIBA's contact lenses by persons who have not been examined by a doctor, and who have not received proper instructions and medical warnings, could cause serious injury including loss of vision

A Yes

30(b)(6) Depo of CIBA Vision Witness Paul Oris, p 46, ll 7-13

Q Would you agree that the process of selling the FreshLook Colors contact lenses without having first been fitted by an eye care professional, and without the warning inserts, transforms a safe and effective product into a dangerous product, with a potential to blind users?

A Yes

30(b)(6) Depo of CIBA Vision Witness Paul Orris, p 48, ll 5-12 (emphasis added)

Q And CIBA Vision was aware that, prior to 2004 consumers were actually being injured by wearing the CIBA Vision FreshLook Colors contact lenses, without being first -- being fitted by an eye care professional

MS WILSON Objection

THE WITNESS Yes

30(b)(6) Depo of CIBA Vision Witness Paul Orris, p 58, ll 1-8 (emphasis added)

Q So you would agree that CIBA Vision was aware that -- in September of 2002, that companies were engaged in the widespread unauthorized distribution and sale of CIBA's color contact lenses without prescription, on a national scale

MS WILSON Objection

THE WITNESS Yes

Q (By Mr Rawl) And you would agree that at that time, CIBA Vision knew that the instructions for use and the medical advisories that went along with the color contact lenses, were needed by consumers to properly use and care for the lenses

A Yes

30(b)(6) Depo of CIBA Vision Witness Paul Orris, p 49, ll 11-25 (emphasis added)

Q And that the sales of those contact lenses individually without the package insert is confusing and deceiving to the public

MS WILSON Objection

THE WITNESS Yes

30(b)(6) Depo of CIBA Vision Witness Paul Oris, p 53, ll 17-21 (emphasis added)

Q And do you know when CIBA Vision first got notice that their plano color contact lenses were being sold without a prescription, and without the warnings?

Q Do you know -- can you tell me the earliest year that you are aware that CIBA Vision was aware of it?

A That I was aware of it? 1999

Q Okay And to your knowledge, the practice is still going on today

A That's my understanding

30(b)(6) Depo of CIBA Vision Witness Paul Oris, p 80, ll 4-17

Plaintiff has alleged several causes of action, including that CIBA Vision should have placed warnings on the packages of its decorative plano color contact lenses regarding the danger of injury

II DOCUMENTS AND INFORMATION THAT CIBA VISION PRODUCED AFTER SANCTIONS HEARING

Prior to the July 12, 2006 hearing, CIBA had produced 2245 pages of documents After Judge Barber said that he would strike CIBA s answer if they did not comply with the two prior orders within 15 days, CIBA produced 7269 more pages of documents [1] Also, while CIBA

[1] Included in the 7269 pages of documents produced after the sanctions hearing were ___ pages hand-delivered to plaintiff's office an hour and a half after the hearing ended This box of documents was clearly ready to be produced even though CIBA Vision indicated to the court only an hour and a half prior to the document delivery that it was unaware of any additional documents that needed to be produced Specifically on page 69 of the hearing transcript, ll 7-18 CIBA Vision s counsel stated

Ms Wilson Your Honor I have a concern as a practical matter The fact that we believe that we re in compliance with the court order that we ve

Vision has not produced all of the remaining 30(b)(6) witnesses as ordered by the court, it has produced three more Through those witnesses and the documents produced pursuant to this Court s order, Defendant has disclosed the following information

1 CIBA Vision knew in June 2003 that it needed to put consumer warnings on its contacts CIBA Vision produced the notes of CIBA Vice President Rick Weisbarth (CIBA Supp 0572-0573) which admit that the labeling is not adequate (no warnings), and that CIBA needed to address safety issues for the contacts to the consumer However, CIBA Vision decided not to put any warnings on the contacts

2 CIBA Vision knew that it was selling millions of cosmetic contacts to unauthorized wholesalers who were distributing the lenses to hundreds of non-prescription retail stores around the country See CIBA Vision Supp 0453, 0454 0503 – 0513 (Please note on CIBA Vision Supp 0453 Arlene Mesnard of CIBA Vision states that ' I refer to some customers as wholesaler ' I use this term to indicate customers who purchase lenses for resale to optical businesses You can certainly call them by another name – unauthorized distributor, for example) The other documents listed indicate that in 2002 alone over $5 000,000 worth of plano color contact lenses were sold by CIBA to unaccountable sources

3 CIBA Vision produced emails acknowledging that the company would not be able to defend a decision to continue to sell to an account once CIBA Vision had knowledge that that account was reselling the color plano lenses to improper sources (See CIBA Vision Supp 1122)

---

	produced all of the documents that are responsive to the court order And my fear is because they re taking the position that we haven t I don t know what those documents are that they re claiming they haven t gotten And I don t want to be called up for sanction –
The Court	Well why don t you talk to them?
Ms Wilson	Okay Well I just wanted to voice that for the record I don t know what those documents are that they claim

4 CIBA has admitted that 98% of all of the color cosmetic contacts that are being sold without a prescription and without any warnings are CIBA contacts (See PMA Supp 0036-0038)

The above information is damaging information for CIBA Vision and is clearly the reason CIBA Vision willfully refused to comply with the two previous discovery orders

III LEGAL ARGUMENT

Rule 37(a)(4) of the South Carolina Rules of Civil Procedure states that if the motion is granted, the court shall, after opportunity for hearing require the party whose conduct necessitated the motion to pay the moving party the reasonable expenses incurred in obtaining the order, including attorney s fees

In the present situation, the severity of the misconduct of Defendant, CIBA Vision cannot be overstated The conduct of CIBA Vision is a direct affront to the authority of this Court and the integrity of the discovery process CIBA has openly defied two direct Orders of this Court and willfully refused to comply with this Court s rulings Such defiance warrants holding CIBA Vision in contempt and entering severe sanctions against it

South Carolina Rule of Civil Procedure 37(b)(2)(C) specifically grants the court the authority to enter a default upon a party s failure to obey a previous order to provide or permit discovery In addition to allowing the entry of default judgment Rule 37(b)(2) provides for five lesser sanctions once a violation is established These are

(1) deeming certain facts to be established,

(2) refusing to allow the disobedient party to support designated claims or defenses or prohibiting him from introducing designated matters in evidence,

(3) holding the disobedient party in contempt of court,

(4) requiring the payment of reasonable expenses, including attorney s fees[2], and

(5) making any other orders in regard to failure as are just

This Court has discretion to determine the proper sanctions for violations of the discovery rules and of orders of the Court A trial court s selection of a sanction will be reversed only for abuse of that discretion Griffin Grading and Clearing, Inc v Tire Service Equipment Manufacturing Company , 334 S C 193 511 S E 2d 716 (Ct App 1999) However, sanctions must be adequate "to protect the rights of discovery provided by the Rules Downey v Dixon, 294 S C 42, 45, 362 S E 2d 317, 318 (Ct App 1987) For instance, in Downey, the Court of Appeals reversed an order imposing a sanction that was too lenient to protect the opposing party s rights of discovery and too lenient to serve as a deterrent to others The Court explained that

> The rights of discovery provided by the Rules give the trial lawyer the means to be prepared for trial Where these rights are not accorded, prejudice must be presumed and unless the party who has failed to submit to discovery can show a lack of prejudice, reversal is required

Id at 46 362 S E 2d at 319 (Emphasis added) The Court further observed that [i]t is perfectly obvious that few, if any, litigants would willingly submit to the discovery provided by the Rules if the alternative were simply paying $50 ' Id at 45-46, 362 S E 2d at 318

Initially, plaintiff requests that the Court strike defendant CIBA Vision s answer as the appropriate sanction in this case [3] In the alternative, plaintiff requests that the Court increase the

---

[2] An award of attorney s fees is mandatory under this rule unless the court finds the failure to provide or permit discovery is substantially justified S C R C P 37(b)(2)

[3] The sanctions available for violation of an order compelling discovery include contempt and/or striking a defendant s answer Griffin Grading 334 S C at 198 511 S E 2d at 718 citing S C R C P 37(b)(2)(C) In Griffin Grading the Court of Appeals affirmed an order striking the defendant s answer where the trial court found no lesser sanction would be effective to address willful disobedience This ultimate sanction requires a showing of bad faith willful disobedience or gross indifference to the

award of attorneys fees and costs to include the actual amount of time and charges of plaintiff's counsel related (1) to have defendant comply with the court s discovery orders and (2) to plaintiff's efforts to re-depose CIBA Vision s witnesses Please see the Affidavit of A Victor Rawl, Jr , filed in support of this motion Mr Rawl clarifies and summarizes the tasks for which plaintiff is requesting attorney s fees and costs [4] At the time Ms Jones affidavit in support of an award of fees and costs was submitted, plaintiff understood the scope of what the court intended counsel to submit to be much broader than what was included in the court s order of September 25 2006 However, after reviewing the Court's written order, it is apparent that the Court's intended scope of the attorneys fee award to be narrower Accordingly, plaintiff has broken down the attorneys' time records attached to Ms Jones affidavit into specific tasks that plaintiff believes to be covered by the Court's written order awarding sanctions Please see Affidavit of A Victor Rawl, Jr attached hereto Based on Mr Rawl s affidavit, plaintiff requests that the Court award her attorneys fees of $73 751 00 to date and costs of $7,758 94 to date Plaintiff further requests that she be allowed to file a later request for additional attorneys fees and costs after her attorneys have completed the depositions as ordered by the Court (At this time, CIBA Vision has made available some but not all of the 30(b)(6) designees but CIBA Vision has not yet produced Mr Kehoe or Ms Guest [5] At this time Plaintiff is aware of at least

---

rights of the moving party Id at 199 511 S E 2d at 719 Factors to consider include the nature of the discovery the posture of the case willfulness and the degree of prejudice Id

[4] Attached to the Affidavit of Celeste Jones, submitted to the court in support of plaintiff's claim for attorneys fees, suit money and costs are the actual time records of plaintiff's counsel related to all efforts to make defendant comply with discovery, the time to review the responses and documents received from defendant the time to initially take the 30(b)(6) depositions of CIBA Vision the time to retake certain of the 30(b)(6) depositions of CIBA Vision pursuant to the Court s order and the time related to drafting researching preparing for and arguing the motions for sanctions

[5] At the hearing of July 12 2006 the Court asked counsel for CIBA Vision the following question

6 more depositions that would fall within the scope of this court s order Ms Guest, Mr Kehoe the three witnesses who offered affidavits as to the computer search, and the 30(b)(6) designee as to CIBA's financials)

Without increasing the amount of attorneys' fees awarded, it is plaintiff's position that the sanction would be too lenient to protect her rights of discovery and too lenient to serve as a deterrent to CIBA Vision and others CIBA Vision withheld over 7000 pages of documents for over a year in violation of two court orders The information was requested back in February of 2005 CIBA has forced plaintiff and her counsel to incur significant expense to force CIBA to comply with the courts orders Accordingly plaintiff respectfully requests that CIBA be required to pay for the actual time and costs incurred as a result of CIBA s actions

---

THE COURT You all will acknowledge that you did not produce witnesses pursuant to their request under 30(b)(6) in some of the areas or fields that they wanted witnesses?

MS WILSON That is correct Your Honor pursuant to our motion to stay and a protective order

Tr p 53

Further the Court stated as follows

THE COURT If they need to redepose your – anybody because (1) you failed to answer you failed to produce or they come up with information from the information you give them you re going to pay for it

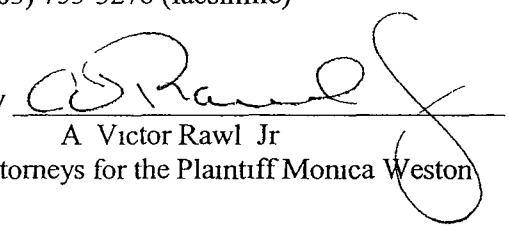
Tr p 55

IV CONCLUSION

For the reasons outlined above, plaintiff respectfully requests the court to grant her motion to alter or amend

Respectfully submitted,

McNAIR LAW FIRM, P A
Post Office Box 11390
Columbia, South Carolina 29211
Celeste T Jones
A Victor Rawl Jr
Andrew G Melling
(803) 799-9800
(803) 753-3278 (facsimile)

By 
A Victor Rawl Jr
Attorneys for the Plaintiff Monica Weston

October 6, 2006
Columbia, South Carolina

STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND	)	
Monica Weston	)	Civil Action No 05-CP-40-0655
	)	
Plaintiff	)	
	)	
vs	)	
	)	
Kim s Dollar Store and	)	
CIBA Vision, a division of Novartis	)	
Company,	)	
	)	
Defendant	)	
	)	

STATE OF SOUTH CAROLINA	)	
	)	AFFIDAVIT OF A VICTOR RAWL JR
COUNTY OF RICHLAND	)	

PERSONALLY APPEARED BEFORE ME, A Victor Rawl Jr who being duly sworn deposes and states that if he were called as a witness in the above-entitled action he would truthfully and accurately testify as follows

1 My name is A Victor Rawl Jr and I am an attorney for the plaintiff Monica Weston

2 I am a shareholder in the McNair Law Firm in Columbia South Carolina and I am licensed to practice law in South Carolina

3 Attached hereto as Exhibit 1 is the Affidavit of Celeste T Jones in Support of Plaintiff's Claim for Attorneys Fees Suit Money and Costs Attached to the affidavit of Ms Jones are the time records of plaintiff's counsel and staff related to all efforts to make defendant CIBA Vision comply with discovery the time to review the responses and documents received from defendant, the time to take the first round of 30(b)(6) depositions of CIBA Vision, the time to retake certain of the 30(b)(6) depositions of

CIBA Vision pursuant to the Court s order and the time related to drafting researching preparing for and arguing the motions for sanctions

4 After plaintiff's counsel received the Court s Order of September 25 2006 it was clear that the Court intended a more narrow scope of attorneys fees than was attached to the affidavit of Ms Jones Accordingly the undersigned based on the records attached to the affidavit of Ms Jones has summarized the time records and broken them down into the tasks the undersigned believes to be within the scope of the Court s order for sanctions Please see Exhibit 2 attached hereto

5 The undersigned believes that the fees reflected on Exhibit 2 and below are reasonable for the tasks outlined thereon

6 If CIBA Vision had not refused to comply with discovery in this case plaintiff's counsel would not have had to work over $70 000 worth of time to force CIBA to comply with the orders

7 Additionally based on the Court s statements at the hearing on July 12 2006 that CIBA Vision would pay for all of plaintiff's fees and costs to depose the CIBA 30(b)(6) designees that were improperly withheld from plaintiff on the first trip to Atlanta plaintiff s counsel traveled back to Atlanta to continue the depositions The time and fees incurred for that trip are outlined on Exhibit 2 The actual costs incurred for that trip from 8/13-16/2006 are as follows

MILEAGE	HOTELS and MEALS	COURT REPORTER	TOTAL COSTS
$463 70	$4 080 44	$3 214 80	$7 758 94

7 At this time CIBA Vision has made available some but not all of the 30(b)(6) designees but CIBA Vision has not yet produced Mr Kehoe or Ms Guest At this time Plaintiff is aware of at least 6 more depositions that would fall within the scope of this court s order Ms Guest Mr Kehoe the three witnesses who offered affidavits as to the computer search and the 30(b)(6) designee as to CIBA s financials Plaintiff requests that she be allowed to file a later request for the additional attorneys fees and costs incurred after her attorneys have completed the depositions as ordered by the Court

FURTHER AFFIANT SAYETH NOT

A Victor Rawl Jr

Sworn to and subscribed before me
this 10th day of October 2006

Notary Public for South Carolina

My commission expires 12/9/2013

STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND	)	
Monica Weston	)	Civil Action No 05-CP-40-0655
	)	
Plaintiff	)	
	)	
vs	)	**AFFIDAVIT OF CELESTE T JONES IN SUPPORT OF PLAINTIFF'S CLAIM FOR ATTORNEY FEES, SUIT MONEY AND COSTS**
	)	
Kim s Dollar Store and CIBA Vision a division of Novartis Company,	)	
	)	
Defendants	)	
	)	

PERSONALLY APPEARED BEFORE ME Celeste T Jones who, being duly sworn, swears and deposes that if she were called as a witness in the above-entitled action she would truthfully and accurately testify as follows

QUALIFICATIONS OF COUNSEL

1 My name is Celeste T Jones I am an attorney for the Plaintiff Monica Weston

2 I am a shareholder in the McNair Law Firm of Columbia, South Carolina

3 I graduated from the University of South Carolina School of Law in 1980 and was admitted to the South Carolina Bar in May of 1981 I am also admitted to practice before the Federal Courts of the District of South Carolina and the Fourth and Eleventh Circuit Courts of Appeals and the United States Supreme Court I have been in private practice since May of 1981

4 I am a member of various professional organizations These organizations include the South Carolina Bar, the American Board of Trial Advocates

(ABOTA), the American Health Lawyers Association (AHLA), and the Fourth Circuit Judicial Conference I was selected by my peers for inclusion in The Best Lawyers in America® 2006 and was previously selected in 2003-2004 I have also been selected for inclusion in Chambers USA and Americas Leading Lawyers for Business

5, My practice primarily involves healthcare, commercial and product litigation The majority of my current case load involves representing healthcare providers

LEGAL AUTHORITIES

6 I incorporate Rule 407 of the South Carolina Appellate Court Rules, Rule 1 5 of the Rules of Professional Conduct and further call the attention of the Court to the holdings in Downey v Dixon, 294 S C 42 362 S E 2d 317 (S C App 1987) and Sessions v Withers, 327 S C 409, 488 S E 2d 888 (S C App 1997) Nienow v Nienow, 268 S C 161, 232 S E 2d 504 (1997), Atkinson v Atkinson, 279 S C 454, 309 S E 2d 14 (S C App 1983), EDM v TAM, 307 S C 471 415 S E 2d 812 (1992), Sherman v Sherman 307 S C 280, 414 S E 2d 809 (S C App 1992) and Glasscock v Glasscock, 304 S C 158, 403 S E 2d 313 (1991), concerning the factors and criteria which should be considered in setting of attorney fees I rely upon the discretion of this Court in determination of the amount of fees based, among other things, upon the Court s file, the Court s knowledge of the litigation between these parties, which reflects nature, extent and difficulty of the services rendered, the time necessarily devoted to the case, the beneficial results accomplished the professional standing of counsel, and fees customarily charged in this area for similar legal services

7 The undersigned is informed and believes that this Court is authorized to order the payment of costs and fees as sanctions imposed by this court pursuant to Rule 37(a)(2) SCRCP Downey v Dixon, 294 S C 42 362 S E 2d 317 (S C App 1987) Griffin Grading & Clearing, Inc v Tire Service Equipment Mfg, 334 S C 193, 511 S E 2d 716 (S C App 1999)

TIME AND COSTS

8 The undersigned is informed and believes that during this case the time that has been spent, as set forth more fully hereafter, was necessary to the protection of my client s interests and in order to make as concise and clear a presentation to the Court as possible in connection with the issues now before the Court

9 That the undersigned, in accordance with the time and expense records of her office, which are maintained on a daily basis, states to the Court that the following time expenditures have necessarily been made in connection with plaintiff's time and expenses related to CIBA Vision s failure to answer discovery, failure to produce documents and the Motions for Contempt and Sanctions filed on June 8 2006 and June 15 2006

10 Our firm's normal and customary hourly rates range from $400 to $195 per hour for attorney time and from $115 per hour for paralegal time The undersigned believes that the per hour for attorney time and the per hour for paralegal time, reflected in Exhibit A hereto is appropriate to this case in light of the issues involved the complexity of proof, and the magnitude of the case

11 Thus far costs in connection with CIBA Vision's failure to comply with the prior orders of Judge Johnson and Judge Cooper, the two Motions for Sanctions and to take and retake the 30(b)(6) depositions of CIBA Vision are reflected in Exhibit A hereto, and incorporated herein

12 The plaintiff has not yet been provided with all 30(b)(6) deponents by CIBA Vision or taken the depositions of Guest and Kehoe Upon completion of these matters counsel will supplement this affidavit

REQUEST FOR AWARD AND CONCLUSION

13 The undersigned respectfully submits, based not only upon the time necessarily devoted to this case but also upon the other criteria which have been held to be relevant in the setting of attorney fees, costs and suit money, that this Court review the file herein, together with this Affidavit and grant judgment in favor of the undersigned's client against the defendant CIBA Vision for attorney fees suit money and costs and that the defendant CIBA Vision be required to pay the same within a reasonable time as may be determined by the Court

Respectfully submitted,

McNAIR LAW FIRM, P A
Post Office Box 11390
Columbia South Carolina 29211
Celeste T Jones
A Victor Rawl Jr
Andrew G Melling
(803) 799-9800

By _____
Celeste T Jones, SC Bar # 3173
Attorneys for the Plaintiff

August 31, 2006
Columbia, South Carolina

Sworn to and subscribed before me
this 31st day of August, 2006

Pamela K Jolley
Notary Public for South Carolina
My commission expires 12/9/2013

BILLING OFFICE.

BANK OF AMERICA TOWER
1301 GERVAIS STREET
SUITE 1600
COLUMBIA, SOUTH CAROLINA 29201
TELEPHONE 803/799-9600
FACSIMILE 803/799-9604

MCNAIR LAW FIRM, P A

ATTORNEYS AND COUNSELORS AT LAW

www.mcnair.net

REMITTANCE ADDRESS

ATTN ACCOUNTS RECEIVABLE
POST OFFICE BOX 11390
COLUMBIA, SOUTH CAROLINA 29211
TAX ID # 57-0703244

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 1

OUR MATTER # 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

PROFESSIONAL SERVICES RENDERED THROUGH 08/22/06

03/21/06	REVIEW DISCOVERY RESPONSES FROM CIBA (INFO MISSING)		
	A V RAWL	1 00 HRS	$295 00
03/21/06	RECEIPT AND REVIEW OF PLAINTIFF'S DOCUMENT PRODUCTION CONFERENCE WITH AVR RE NO ANSWER TO INTERROGATORIES AND REQUESTS TO PRODUCE		
	M A BUONFORTE	1 30 HRS	$149 50
03/22/06	RECEIPT AND REVIEW OF DISCOVERY FROM CIBA VISION		
	A G MELLING	1 30 HRS	$253 50
03/28/06	REVIEW CIBA'S DISCOVERY RESPONSES RE MISSING INFO REVIEW MAB'S SUMMARY OF INFORMATION MISSING		
	A V RAWL	2 00 HRS	$590 00
03/28/06	INDEX RECENT DOCUMENT PRODUCTION FROM CIBA, COMPARE DOCUMENTS PRODUCED WITH DISCOVERY RESPONSES PREPARE EMAIL RE MISSING DOCUMENTS/INFORMATION TO CTJ AVR AND AGM TELEPHONE CALL WITH AVR		
	M A BUONFORTE	5 70 HRS	$655 50
03/29/06	REVIEW AND ANALYSIS OF DOCUMENT PRODUCTION FROM CIBA		
	C T JONES	2.30 HRS	$920 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

MCNAIR LAW FIRM, P A
ATTORNEYS AND COUNSELORS AT LAW

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 2

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

04/10/06	REVIEW DISCOVERY		
	A G MELLING	0 60 HRS	$117 00
05/19/06	DRAFT LETTER TO SANDI WILSON RE MONICA'S DEPOSITION AND OVERDUE DISCOVERY TELEPHONE CONFERENCE WITH S WILSON CONFERENCE WITH CTJ		
	A G MELLING	1 30 HRS	$253 50
05/22/06	CONFERENCE WITH AVR AND MAB RE CIBA'S DISCOVERY RESPONSES REVIEW RESPONSES		
	A G MELLING	0 80 HRS	$156 00
05/22/06	MEET WITH AGM RE DISCOVERY ISSUES REVIEW DISCOVERY RESPONSES FROM DEFENDANT		
	A V RAWL	2.70 HRS	$796 50
05/24/06	DOCUMENT REVIEW		
	A G MELLING	0 70 HRS	$136 50
05/25/06	REVIEW LATEST DOCUMENT PRODUCTION FROM CIBA		
	A V RAWL	3 00 HRS	$885 00
05/25/06	CONFERENCE WITH AVR RE 30(B)(6) FOR CIBA, CANCEL COURT REPORTER FOR 30(B)(6) RETRIEVE CIBA'S DOCUMENT PRODUCTION FOR AVR REVIEW		
	M A BUONFORTE	1 50 HRS	$172.50
05/26/06	REVIEW ALL DOCUMENTS PRODUCED TO DATE FOR DISCOVERY/SANCTIONS LETTER		
	A V RAWL	6 50 HRS	$1 917 50
05/30/06	DRAFT 9-PAGE LETTER TO DEFENDANT RE DISCOVERY AND MOTION FOR SANCTIONS		
	A V RAWL	4 50 HRS	$1 327 50

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 3

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM S DOLLAR STORE - PRODUCT LIABILITY

05/31/06	CONFERENCE WITH MAB CONFERENCE WITH AVR RE DISCOVERY		
	A G MELLING	0 60 HRS	$117 00
05/31/06	FINALIZE LETTERS TO S WILSON RE DISCOVERY DEFICIENCIES		
	A V RAWL	3 40 HRS	$1 003 00
06/01/06	REVIEW AND ANALYSIS OF CORRESPONDENCE TO PLAINTIFF'S COUNSEL		
	C T JONES	0 30 HRS	$120 00
06/05/06	WORK ON STRATEGY RE COMPUTER SYSTEM SEARCH BECAUSE CIBA REFUSES TO PROVIDE COMPUTER DOCUMENTS PER ORDER, DRAFT EMAIL TO SANDI WILSON RE 2006 REVIEW COMPUTER 30(B)(6) AND OTHER 30(B)(6)		
	A V RAWL	1 50 HRS	$442 50
06/06/06	DRAFT MOTION FOR SANCTIONS DRAFT COMPUTER 30(B)(6) NOTICE		
	A V RAWL	6 00 HRS	$1 770 00
06/07/06	DRAFT MOTION FOR SANCTIONS EMAILS TO AND FROM PLAINTIFF RE REVIEW DOCUMENTS		
	A V RAWL	4 00 HRS	$1 180 00
06/08/06	DRAFT LETTER TO SANDI WILSON RE SUMMARY JUDGMENT AND STAY MOTIONS IN BAD FAITH AND IN CONTEMPT OF ORDER, DRAFT DEPOSITION NOTICES AND AMENDED 30(B)(6) NOTICE OF CIBA, REVIEW OF CIBA S MOTION FOR SUMMARY JUDGMENT AND MOTION TO STAY RESPOND TO FACTUAL INACCURACIES RE LETTER OF 6/7 FROM SANDI, FINALIZE AND FILE MOTION FOR SANCTIONS MEETING WITH CTJ AND AGM RE STRATEGY		
	A V RAWL	8 00 HRS	$2 360 00
06/08/06	REVIEW OF CORRESPONDENCE AND PLEADINGS FROM DEFENDANTS		
	C T JONES	2.00 HRS	$800 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges.
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 4

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

06/08/06	FINALIZED MOTION TO BE FILED COORDINATED WITH COURIERS TO HAVE IT FILED AT COURTHOUSE MADE COPIES FOR DISTRIBUTION MADE ENVELOPS AND SET UP DISTRIBUTION WORKED WITH AVR TO MAKE APPOPRIOATE CHANGES SCANNED AND EMAILED COPY TO AVR, ALL PER AVR		
	D B DAY	2.80 HRS	$98 00
06/12/06	CORRESPONDENCE FROM SANDI RE SUMMARY JUDGMENT MOTION DRAFT EMAILS TO SANDI, BEGIN PREPARATION FOR 30(B)(6) DEPOSITIONS		
	A V RAWL	6 00 HRS	$1 770 00
06/12/06	REVIEW EMAIL CORRESPONDENCE RE DOCUMENT PRODUCTION AND MOTION CONFERENCE WITH AVR RE DOCUMENT REVIEW		
	M A BUONFORTE	1 50 HRS	$172.50
06/14/06	CONFERENCE WITH AVR AND MAB RE RULE 56(F) MOTION AND SANCTIONS MOTION		
	A G MELLING	1 00 HRS	$195 00
06/14/06	DRAFT LETTER TO MUNSON RE CORRESPONDENCE TO JUDGE KINARD AND MOTION FOR SANCTIONS		
	A V RAWL	2.70 HRS	$796 50
06/14/06	REVIEW DEFENDANT'S PROPOSED ORDER AND RESPONSES WITH AVR		
	C T JONES	0 80 HRS	$320 00
06/15/06	RESEARCH AND DRAFT 3RD MOTION FOR SANCTIONS AND 56(F) MOTION		
	A V RAWL	4 00 HRS	$1 180 00
06/15/06	REVIEW CORRESPONDENCE FROM DEFENDANT RE DEPOSITIONS AND LIMITING DISCOVERY DRAFT CORRESPONDENCE TO DEFENDANT RE DISCOVERY REVIEW CORRESPONDENCE FROM COURT		
	A V RAWL	3 00 HRS	$885 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 5

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

06/15/06	DRAFT AND FINALIZE CORRESPONDENCE TO SANDI WILSON RE DIFFERENCES IN THEIR FIRST DOCUMENT PRODUCTION AND PREPARE FAX COVER, PREPARE DISCOVERY LIST PER AVR'S REQUEST ASSIST IN THE PREPARATION OF THIRD MOTION FOR CONTEMPT PREPARE MOTION SLIP AND CORRESPONDENCE TO CLERK OF COURT FOR FILING REVISE AND EDIT CORRESPONDENCE TO SANDI WILSON RE DEPOSITION SCHEDULING NUMEROUS CONFERENCES WITH AVR RE SAME REQUEST REVIEW AND SCAN CORRESPONDENCE FROM SANDI WILSON RE DEPOSITION OF HOLLY GUEST ANDPAUL REVIEW CORRESPONDENCE FROM SANDI WILSON TO JUDGE KINARD REQUEST FOR CONTINUANCE FROM SANDI WILSON CONFERENCE WITH BD RE EXHIBITS FOR MOTION		
	M A BUONFORTE	7 50 HRS	$862.50
06/16/06	DRAFT LETTER TO JUDGE KINARD RE MOTIONS AND SCHEDULING ORDER, REVIEW DISCOVERY REQUESTS AND DEVISE STRATEGY FOR ANSWERING PREPARATION FOR 30(B)(6) DEPOSITIONS		
	A V RAWL	6 00 HRS	$1 770 00
06/16/06	REVIEW NUMEROUS EMAIL CORRESPONDENCE FROM AVR, FINALIZE CORRESPONDENCE TO JUDGE KINARD PREPARE 30(B)(6) MOTION TO KIMS AND CORRESPONDENCE FORWARDING SAME REVIEW E-MAIL FROM AVR RE DOCUMENTS FORWARDED BY SANDI WILSON FOR LOT NUMBERS CONFERENCE WITH BD RE MATERIAL LOT NUMBERS GOING TO SAME ADDRESSES NUMEROUS E MAILS CORRESPONDENCE TO AVR RE STATUS OF VARIOUS MATTERS		
	M A BUONFORTE	5 00 HRS	$575 00
06/17/06	PREPARE FOR DEPOSITIONS IN ATLANTA		
	M A BUONFORTE	2 00 HRS	$230 00
06/20/06	REVIEW CIBA'S MOTION TO QUASH REVIEW AND REPLY TO CORRESPONDENCE WITH SANDI WILSON RE DEPOSITIONS AND DOCUMENT REVIEW		
	A V RAWL	3 00 HRS	$885 00
06/20/06	REVIEW CORRESPONDENCE AND EMAILS WITH AVR		
	C T JONES	0 50 HRS	$200 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date An additional invoice will be rendered for subsequent charges
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 6

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

06/20/06	PREPARE NOTEBOOK FOR AVR FOR UPCOMING DEPOSITIONS		
	M A BUONFORTE	3 70 HRS	$425 50
06/25/06	SELECT EXHIBITS FOR DEPOSITIONS PREPARATION FOR 30(B)(6) DEPOSITIONS		
	A V RAWL	8 00 HRS	$2,360 00
06/25/06	PREPARATION FOR DEPOSITIONS AND PACK FILE FOR TRIP TO ATLANTA		
	M A BUONFORTE	2.50 HRS	$287 50
06/26/06	PREPARATION FOR 30(B)(6) DEPOSITIONS SELECT AND ORGANIZE 40+ EXHIBITS FOR DEPOSITIONS CALL FROM JUDGE BARBER RE STATUS CONFERENCE SET-UP STATUS CONFERENCE CALL		
	A V RAWL	16 00 HRS	$4 720 00
06/26/06	TRAVEL TO ATLANTA, ASSIST AVR RE PREPARATION FOR 30(B)(6) DEPOSITION OF CIBA VISION ON 6/27/06		
	M A BUONFORTE	14 50 HRS	$1 667 50
06/27/06	PREPARATION FOR AND REPRESENTATION AT STATUS CONFERENCE CALL WITH JUDGE BARBER, DEPOSE CIBA 30(B)(6) DESIGNEE ORIS PREPARATION FOR DEPOSITION OF COLLINS		
	A V RAWL	12.00 HRS	$3 540 00
06/27/06	ATTEND CIBA'S 30(B)(6) DEPOSITION ASSIST AVR RE PREPARATION FOR ADDITIONAL 30(B)(6) WITNESS FOR DEPOSITION ON 6/28/06		
	M A BUONFORTE	10 00 HRS	$1 150 00
06/28/06	PREPARATION FOR AND DEPOSE 30(B)(6) DESIGNEE JULIE COLLINS REVIEW DOCUMENT PRODUCED TODAY VIA HAND DELIVERY PREPARATION FOR DEPOSITION OF HOLLY GUEST		
	A V RAWL	11 00 HRS	$3 245 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 7

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM S DOLLAR STORE - PRODUCT LIABILITY

06/28/06	ATTEND JULIA COLLINS 30(B)(6) DEPOSITION ASSIST AVR IN PREPARATION FOR HOLLY GUEST DEPOSITION		
	M A BUONFORTE	9 70 HRS	$1 115 50
06/29/06	PREPARATION FOR AND DEPOSE HOLLY GUEST RETURN TRAVEL TO COLUMBIA		
	A V RAWL	11 00 HRS	$3,245 00
06/29/06	ATTEND HOLLY GUEST DEPOSITION RETURN TRAVEL TO COLUMBIA		
	M A BUONFORTE	8 50 HRS	$977 50
07/03/06	REVIEW DOCUMENTS AND CORRESPONDENCE		
	A G MELLING	0 50 HRS	$97 50
07/05/06	WORK ON STRATEGY FOR MOTIONS HEARING ON DISCOVERY MOTIONS AND SANCTIONS		
	A V RAWL	3 50 HRS	$1 032 50
07/05/06	REVIEW EMAIL CORRESPONDENCE CONFERENCE WITH AVR RE UPCOMING MOTIONS HEARING ON 7/12/06 TELEPHONE CALLS TO AND FROM CLERK'S OFFICE RE MOTION HEARING SCHEDULED FOR 7/17/06		
	M A BUONFORTE	1 30 HRS	$149.50
07/06/06	REVIEW DOCUMENTS AND CORRESPONDENCE		
	A G MELLING	0 50 HRS	$97 50
07/06/06	DETERMINE WHAT DOCUMENTS NEEDED FOR SANCTIONS MOTIONS NOTEBOOKS AND WHAT CASES NEEDED REVIEW MOTION FOR SANCTIONS AND LETTER TO DETERMINE 10 SPECIFIC EXAMPLES OF HOW CIBA IGNORED DISCOVERY ORDERS OUTLINE ARGUMENTS FOR HEARING		
	A V RAWL	5 10 HRS	$1 504 50

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

MCNAIR LAW FIRM, P A
ATTORNEYS AND COUNSELORS AT LAW

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 8

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

07/06/06	CREATED A MOTIONS HEARING NOTEBOOK PER MAB		
	D B DAY	2.50 HRS	$87 50
07/06/06	REVIEW EMAIL CORRESPONDENCE REVIEW MOTION NOTEBOOK FOR HEARING ON 7/12/06 ATTEMPT TO CONTACT COURT REPORTER RE DEPOSITIONS IN ATLANTA, CONFERENCE WITH AVR		
	M A BUONFORTE	1.50 HRS	$172.50
07/07/06	UPDATED MOTIONS HEARING NOTEBOOK PER MAB		
	D B DAY	1 50 HRS	$52.50
07/07/06	ASSIST IN PREPARATION FOR MOTION HEARING ON 7/12/06 CONFERENCE WITH AVR, BEGIN PREPARING INDEX OF ALL DOCUMENTS PRODUCED BY CIBA		
	M A BUONFORTE	2 60 HRS	$299 00
07/09/06	CONFERENCE WITH AVR, CTJ AND MAB RE SANCTIONS HEARING RELATED WORK		
	A G MELLING	2 00 HRS	$390 00
07/09/06	REVIEW DEFENDANT CIBA VISION'S MOTION RE DISCOVERY AND REVIEW CASES CITED THEREIN IN PREPARATION FOR HEARING		
	A V RAWL	2.50 HRS	$737 50
07/09/06	PREPARATION FOR MOTION HEARING		
	C T JONES	1 50 HRS	$600 00
07/09/06	PREPARATION FOR HEARING		
	C T JONES	1 50 HRS	$600 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 9

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

07/09/06	PREPARATION FOR MOTION HEARING ON 7/12/06 MEETING WITH CTJ AVR AND AGM COMPLETE INDEX OF CIBA DOCUMENT PRODUCTION		
	M A BUONFORTE	4 60 HRS	$529 00
07/10/06	CONFERENCE WITH MAB PREPARE FOR SANCTIONS HEARING		
	A G MELLING	1 40 HRS	$273 00
07/10/06	DETERMINE DOCUMENTS NEEDED FOR POWER POINT PRESENTATION ON SANCTIONS DRAFT TIMELINE OF IMPROPER DISCOVERY ACTIVITIES OF DEFENDANT CIBA, PREPARATION FOR HEARING REVIEW 30(B)(6) DEPOSITION TRANSCRIPTS AND HOLLY GUEST DEPOSITION FOR SANCTIONS FOR CITING AND PARTS TO BE READ TO THE JUDGE		
	A V RAWL	7 00 HRS	$2,065 00
07/10/06	OFFICE CONFERENCE/MEETING FOR CLIENT WITH AVR/PREPARATION FOR HEARING		
	C T JONES	2.00 HRS	$800 00
07/10/06	RECEIPT AND DOWN LOAD DEPOSITION OF PAUL ORIS JULIE COLLINS AND HOLLY GUEST PRINT OUT COPIES FOR AVR, CONFERENCE WITH BD RE PREPARATION OF DOCUMENTS FOR BLOW UP AND POSTER BOARDS PREPARATION FOR HEARING ON 7/12/06		
	M A BUONFORTE	7 50 HRS	$862.50
07/11/06	PREPARATION FOR MOTIONS FOR SANCTIONS AND PREPARE POWER POINT PRESENTATION RE SAME		
	A V RAWL	7 00 HRS	$2 065 00
07/11/06	PREPARATION FOR HEARING OFFICE CONFERENCE/MEETING FOR CLIENT WITH AVR AND S B ELLIOTT		
	C T JONES	3 50 HRS	$1 400 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date An additional invoice will be rendered for subsequent charges
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 10

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

07/11/06	PREPARATION FOR MOTION HEARING ON 7/12/06		
	M A BUONFORTE	9 30 HRS	$1 069 50
07/11/06	CONFERENCE WITH AVR RE HEARING		
	R W DIBBLE	0 10 HRS	$45 00
07/12/06	PREPARE FOR AND ATTEND SANCTIONS HEARING- CONFERENCE WITH CTJ AVR, MAB AND CIBA VISION'S LAWYERS RE DISCOVERY		
	A G MELLING	7 80 HRS	$1 521 00
07/12/06	PREPARE FOR AND ARGUE MOTIONS (INCLUDING SANCTIONS) BEFORE JUDGE BARBER PREPARATION FOR AND MEET WITH OPPOSING COUNSEL PURSUANT TO JUDGE'S ORDER TO MEET AND DISCUSS OUTSTANDING DISCOVERY		
	A V RAWL	7 20 HRS	$2 124 00
07/12/06	PREPARATION FOR AND REPRESENTATION IN COURT- DRAFT ORDER		
	C T JONES	5 50 HRS	$2 200 00
07/12/06	MEET WITH OPPOSING COUNSEL		
	C T JONES	1 50 HRS	$600 00
07/12/06	PREPARATION FOR AND ATTEND MOTION HEARING- MEETING WITH CTJ AVR, AGM AND OPPOSING COUNSEL RE MISSING DOCUMENTS MEETING WITH CTJ AVR AND AGM RE DRAFTING OF ORDER		
	M A BUONFORTE	7 10 HRS	$816 50
07/12/06	CONFERENCE WITH CTJ RE STATUS OF HEARING ON MOTION TO COMPEL		
	R W DIBBLE	0 30 HRS	$135 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 11

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

07/13/06	REVIEW PREBILL TO DETERMINE FEES AND COSTS TO BE PAID BY CIBA VISION WORK ON DRAFTING JUDGE'S ORDER, CONFERENCE WITH CTJ AND MAB		
	A G MELLING	6 00 HRS	$1 170 00
07/13/06	REVIEW NOTES FROM HEARING AND MEET WITH CTJ AGM AND MAB REVIEW LEGAL FINDING NECESSARY FOR SANCTIONS FINDING REVISE/DRAFT PROPOSED ORDER PER JUDGE BARBER'S INSTRUCTIONS		
	A V RAWL	4.50 HRS	$1,327 50
07/13/06	PREPARATION OF ORDER, REVIEW NEWLY PRODUCED DOCUMENTS CONFERENCE WITH S B ELLIOTT RE DISCOVERY ORDER CONTENT		
	C T JONES	2 50 HRS	$1 000 00
07/13/06	DRAFT CORRESPONDENCE RE SUMMARY OF MEETING ON 7/12/06 NUMEROUS CONFERENCES WITH AVR, AGM AND HARRY RAGSDALE RE LANGUAGE FOR DRAFTING OF ORDER FOR JUDGE BARBER		
	M A BUONFORTE	3 10 HRS	$356 50
07/14/06	FINALIZE PROPOSED ORDER TO JUDGE BARBER, EMAIL SAME TO OPPOSING COUNSEL, EMAILS TO/FROM SANDI WILSON RE REQUESTING DELAY CALLS TO JUDGE BARBER'S CHAMBERS (NO ANSWER) CALL FROM CURTIS OTT RE DISCUSSIONS RE PROPOSED ORDER, MAKE CHANGES TO PROPOSED ORDER RE DISCUSSION WITH OTT AND MAKE TWO VERSIONS DRAFT LETTER TO JUDGE BARBER, DRAFT LETTER TO SANDI WILSON RE OUTSTANDING DISCOVERY NOT RECEIVED		
	A V RAWL	4 30 HRS	$1 268 50
07/14/06	CONFERENCE WITH AVR RE DISCOVERY ISSUES AND SUBMISSION OF ORDER TO COURT		
	C T JONES	1 00 HRS	$400 00
07/17/06	REVIEW CORRESPONDENCE FROM CIBA VISION		
	A G MELLING	0 50 HRS	$97 50

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

07/17/06	REVIEW LETTER TO JUDGE BARBER RE PLAINTIFF'S PROPOSED ORDER REVIEW NEW DOCUMENTS DELIVERED WEDNESDAY OF LAST WEEK PER JUDGES ORDER		
	A V RAWL	2.40 HRS	$708 00
07/17/06	REVIEW CORRESPONDENCE FROM CURTIS OTT RE PROPOSED ORDER		
	M A BUONFORTE	0 20 HRS	$23 00
07/19/06	REVIEW CORRESPONDENCE FROM OPPOSING COUNSEL RE DISCOVERY COMPLIANCE ISSUES		
	C T JONES	1 00 HRS	$400 00
07/21/06	REVIEW AND REVISE CTJ'S RESPONSE TO JUDGE BARBER RE CURTIS OTT'S PROPOSED ORDER, DRAFT LETTER TO KEITH MUNSON RE DEPOSITION SCHEDULE CALLS TO STEVE ELLIOTT RE PROPOSED ORDER		
	A V RAWL	5 00 HRS	$1 475 00
07/21/06	EDIT AND REVISE CORRESPONDENCE TO KEITH MUNSON EDIT AND REVISE CORRESPONDENCE TO JUDGE BARBER, CONFERENCE WITH AVR, RETRIEVE AND DUPLICATE FDA DOCUMENTS PREPARE FEDERAL EXPRESS SHIPPING FOR DR. PARISIAN'S DOCUMENTS REVIEW OF CORRESPONDENCE FROM KEITH MUNSON REVIEW EMAIL CORRESPONDENCE		
	M A BUONFORTE	4 70 HRS	$540 50
07/24/06	BEGIN REVIEW OF PORTIONS OF CIBA DOCUMENT PRODUCTION TELEPHONE CALL WITH MONICA, RECEIPT AND REVIEW OF NOTICE OF DEPOSITION FOR MONICA		
	M A BUONFORTE	4 30 HRS	$494 50
07/26/06	REVIEW CORRESPONDENCE FROM AND TO KEITH MUNSON CONFERENCE WITH MAB RE PREVIOUS LAWSUITS FILE REVIEW		
	A G MELLING	1 00 HRS	$195 00

07/26/06	COMPLETE REVIEW OF CIBA'S 7/12 DOCUMENT PRODUCTION CONFERENCE WITH AVR RE POSSIBILITY OF ADDITIONAL LAWSUITS AGAINST CIBA AND DRAFT EMAIL REVIEW CORRESPONDENCE FROM KEITH MUNSON CONFERENCE WITH AGM		
	M A BUONFORTE	4 50 HRS	$517 50
07/27/06	DOCUMENT REVIEW		
	A G MELLING	1 60 HRS	$312.00
07/27/06	MEET WITH CTJ AND AGM RE RESPONSE TO KEITH MUNSON'S LETTER, REVIEW NEW DISCOVERY RESPONSES FROM CIBA PER JUDGE BARBERS ORDER		
	A V RAWL	4 00 HRS	$1 180 00
07/30/06	BEGIN REVIEW OF DOCUMENT PRODUCTION RECEIVED ON 7/27/06		
	M A BUONFORTE	3 50 HRS	$402.50
07/31/06	CONTINUE REVIEW OF CIBA DOCUMENTS PRODUCED ON 7/27/06 NUMEROUS ATTEMPTS TO CONTACT MONICA, DRAFT AMENDED DEPOSITION NOTICES FOR CIBA 30(B)(6) IT 30(B)(6) HOLLY GUEST AND MIKE KEHOE REVIEW CORRESPONDENCE FROM CURTIS OTT RE PLAINTIFFS' SUBPOENAS TO CIBA'S EXPERTS CONFERENCE WITH AVR, CONFERENCE WITH AGM		
	M A BUONFORTE	6 50 HRS	$747 50
08/01/06	REVIEW AND ANALYSIS OF CORRESPONDENCE FROM DEFENDANT RE DISCOVERY –EXPERT PRODUCTION AND SCHEDULING OF 30(B)(6) DEPOSITIONS		
	C T JONES	1 00 HRS	$400 00
08/01/06	FINALIZE CORRESPONDENCE AND AMENDED DEPOSITION NOTICES, CONTINUE REVIEW OF DOCUMENTS CONFERENCE WITH AVR, ATTEMPTS TO CONTACT MONICA		
	M A BUONFORTE	3 20 HRS	$368.00

MCNAIR LAW FIRM, P A
ATTORNEYS AND COUNSELORS AT LAW

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 14

OUR MATTER NO 037580.00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

08/02/06	CONFERENCE WITH AVR, MAB RE DOCUMENTS AND INADEQUATE DISCOVERY RESPONSES		
	A G MELLING	1 20 HRS	$234 00
08/02/06	CONTINUE REVIEW OF DOCUMENTS		
	M A BUONFORTE	3 70 HRS	$425 50
08/03/06	WORK ON DISCOVERY TELEPHONE CONFERENCE WITH MONICA		
	A G MELLING	1 50 HRS	$292.50
08/03/06	CONTINUE REVIEW OF DOCUMENTS CONFERENCE CALL WITH MONICA AND AGM RE RESPONDING TO KEITH MUNSON CORRESPONDENCE		
	M A BUONFORTE	1 60 HRS	$184 00
08/04/06	CONFERENCE WITH MAB RE DOCUMENTS PRODUCED BY CIBA VISION		
	A G MELLING	0 60 HRS	$117 00
08/04/06	CONFERENCE WITH AGM RE RESPONSES TO KEITH MUNSON'S CORRESPONDENCE REVIEW NEW CORRESPONDENCE FROM KEITH MUNSON CONTINUE REVIEW OF DOCUMENT PRODUCTION		
	M A BUONFORTE	2.80 HRS	$322.00
08/06/06	CONTINUE REVIEW OF DOCUMENTS		
	M A BUONFORTE	0 50 HRS	$57 50
08/07/06	REVIEW CORRESPONDENCE FROM DEFENDANTS		
	C T JONES	1 00 HRS	$400 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 15

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

08/07/06	CONTINUE REVIEW OF CIBA DOCUMENTS		
	M A BUONFORTE	2 20 HRS	$253 00
08/08/06	WORK ON DISCOVERY ISSUES		
	A G MELLING	0 90 HRS	$175 50
08/09/06	OFFICE CONFERENCE/MEETING FOR CLIENT WITH AGM RE SUPPLICATION DISCOVERY RESPONSES		
	C T JONES	1 00 HRS	$400 00
08/09/06	CONTINUE REVIEW OF DOCUMENTS RECEIPT OF FAX CONFIRMING COURT REPORTERS FOR DEPOSITIONS NEXT WEEK IN ATLANTA		
	M A BUONFORTE	1.50 HRS	$172.50
08/10/06	CONFERENCE WITH MAB RE DISCOVERY ISSUES REVIEW CORRESPONDENCE		
	A G MELLING	0 50 HRS	$97 50
08/10/06	REVIEW NEWLY PRODUCED DOCUMENTS FOR 30(B)(6) USE PLAN STRATEGY FOR 30(B)(6) DEPOSITIONS CORRESPONDENCE WITH CIBA RE 30(B)(6) DEPOSITIONS		
	A V RAWL	10 10 HRS	$2 979 50
08/10/06	OFFICE CONFERENCE/MEETING FOR CLIENT WITH CTJ RE DISCOVERY AND STATUS CONFERENCE NEXT WEEK, REVIEW AND ANALYSIS OF CORRESPONDENCE FORM MUNSON		
	C T JONES	4 00 HRS	$1 600 00
08/10/06	COMPLETE REVIEW OF CIBA NEW DOCUMENT PRODUCTION		
	M A BUONFORTE	6 00 HRS	$690 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges.
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 16

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

08/11/06	CONFERENCE WITH MAB AVR, AND CTJ RE 30(B)(6) DEPOSITIONS PREPARE FOR DEPOSITIONS AND DOCUMENT REVIEW		
	A G MELLING	2.30 HRS	$448 50
08/11/06	PREPARATION FOR 30(B)(6) DEPOSITIONS CORRESPONDENCE WITH CIBA RE WITNESSES NOT AVAILABLE AND CIBA REFUSAL TO PRODUCE ALL 30(B)(6) DESIGNEES NEXT WEEK		
	A V RAWL	11 20 HRS	$3 304 00
08/11/06	COURT ORDERED DISCOVERY REVIEW AND EVALUATION		
	C T JONES	4 00 HRS	$1 600 00
08/11/06	REVIEW NUMEROUS EMAIL CORRESPONDENCE RE UPCOMING DEPOSITIONS WEEK OF 8/14/06 CONFERENCES WITH AVR RE SCHEDULE AND LOCATION CONFERENCE WITH CTJ RE DOCUMENT REVIEW FILE/DOCUMENT MANAGEMENT		
	M A BUONFORTE	2 50 HRS	$287 50
08/12/06	CONFERENCE WITH MAB CTJ AND AVR RE 30(B)(6) DEPOSITIONS PREPARE FOR DEPOSITIONS AND REVIEW DOCUMENTS		
	A G MELLING	3 50 HRS	$682.50
08/12/06	DRAFT LIST OF PRIMARY DEPOSITION THEORIES AND MAIN LINES OF QUESTIONING MEET WITH CTJ AGM MAB RE 30(B)(6) DEPOSITION STRATEGY AND DEPOSITIONS REVIEW CIBA LATEST DOCUMENT PRODUCTION FOR SELECTION OF EXHIBITS FOR 30(B)(6) DEPOSITIONS AND ORGANIZESAME		
	A V RAWL	14 50 HRS	$4 277 50
08/12/06	PREPARATION FOR HEARING AND DEPOSITIONS		
	C T JONES	3 50 HRS	$1 400 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date An additional invoice will be rendered for subsequent charges
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 17

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

08/12/06	PREPARATION FOR DEPOSITIONS IN ATLANTA		
	M A BUONFORTE	7 00 HRS	$805 00
08/13/06	PREPARE FOR UPCOMING DEPOSITIONS WITH AVR AND MAB TRAVEL TO ATLANTA		
	A G MELLING	10 50 HRS	$2,047 50
08/13/06	COMPLETE EXHIBIT SELECTION FOR 30(B)(6) DEPOSITIONS CONTINUE WORKING ON 30(B)(6) OUTLINE AND STRATEGY TRAVEL TO ATLANTA		
	A V RAWL	10 70 HRS	$3 156 50
08/13/06	PREPARATION FOR HEARING/REVIEW DISCOVERY ISSUES		
	C T JONES	2.00 HRS	$800 00
08/13/06	PREPARATION FOR DEPOSITIONS IN ATLANTA, PREPARE DOCUMENTS FOR EXHIBITS EMAIL JULIA COLLINS DEPOSITION TO SUZANNE PARISIAN PACK FILE AND TRAVEL TO ATLANTA		
	M A BUONFORTE	11 50 HRS	$1 322 50
08/14/06	CONFERENCE CALL WITH JUDGE BARBER AND ALL COUNSEL PREPARE FOR AND ATTEND DEPOSITION OF JENNIFER SHIELDS PREPARE FOR DEPOSITION OF SUSAN GELLING		
	A G MELLING	9 90 HRS	$1 930 50
08/14/06	PREPARATION FOR AND ATTEND HEARING ON STATUS OF SANCTIONS ORDER, PREPARATION FOR AND DEPOSE CIBA 30(B)(6) COMMUNICATIONS/ PRESS RELEASE WITNESS (JENNIFER SHIELDS) PREPARATION FOR C&D LETTER WITNESS AND REVIEW RELATED DOCUMENTS AND PREPARE EXHIBITSFOR DEPOSITION		
	A V RAWL	14 00 HRS	$4 130 00
08/14/06	PREPARATION FOR AND ATTEND STATUS CONFERENCE		
	C T JONES	3 50 HRS	$1 400 00

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING
PAGE 18

OUR MATTER NO 037580 00001 MONICA WESTON
RE KIM'S DOLLAR STORE - PRODUCT LIABILITY

08/14/06	PREPARATION OF CORRESPONDENCE TO DEFENDANT'S COUNSEL RE COURT'S ORDER ON DISCOVERY AND DEPOSITIONS		
	C T JONES	2 00 HRS	$800 00
08/14/06	PREPARATION FOR AND ATTEND DEPOSITION OF JENNIFER SHIELDS ASSIST AVR IN PREPARATION FOR DEPOSITION OF SUSAN GILLEY ON 8/15/06		
	M A BUONFORTE	10 00 HRS	$1 150 00
08/15/06	PREPARE FOR AND ATTEND DEPOSITION OF SUSAN GELLING PRPEARE FOR DEPOSITION OF DR. WEISBARTH		
	A G MELLING	9 80 HRS	$1 911 00
08/15/06	PREPARATION FOR AND DEPOSE CIBA 30(B)(6) WITNESS (SUSAN GELLING) ON C&D LETTERS PREPARATION FOR WEISBARTH DEPOSITION		
	A V RAWL	12.80 HRS	$3 776 00
08/15/06	PREPARATION FOR AND ATTEND DEPOSITION OF SUSAN GILLEY ASSIST AVR RE PREPARATION FOR RICHARD WEISBARTH DEPOSITION ON 8/16/06		
	M A BUONFORTE	10 00 HRS	$1 150 00
08/16/06	PREPARE FOR AND ATTEND DEPOSITION OF DR. WEISBARTH		
	A G MELLING	12.40 HRS	$2,418 00
08/16/06	PREPARATION FOR AND DEPOSE CIBA 30(B)(6) -- DR. WEISBARTH		
	A V RAWL	15 00 HRS	$4 425 00
08/16/06	PREPARATION FOR AND ATTEND DEPOSITION OF RICHARD WEISBARTH		
	M A BUONFORTE	14 50 HRS	$1 667 50

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

08/17/06 RETURN TRAVEL TO COLUMBIA

A G MELLING 3 60 HRS $702 00

08/17/06 PACK UP FILE RETURN TRAVEL TO COLUMBIA, SCAN AND EMAIL DOCUMENTS TO AVR AS REQUESTED

M A BUONFORTE 6 00 HRS $690 00

SUMMARY OF FEES

	HOURS	DOLLARS
A G MELLING	84 30	16 438 50
A V RAWL	266 10	78 499 50
C T JONES	47 90	19 160 00
D B DAY	6 80	238 00
M A BUONFORTE	217 10	24 966 50
R W DIBBLE	0 40	180 00

TOTAL FEES FOR PROFESSIONAL SERVICES $139 482 50

DISBURSEMENTS

COPIES	1 175 47
COST OF DEPOSITION	2,482.75
FILING FEES	25 00
LEGAL PROFESSIONAL SERVICES	377 15
MEALS	168 72
MOTION FEES	50 00
RESEARCH	26 16
TRAVEL	3 222.86

TOTAL DISBURSEMENTS $7,528.11

TOTAL CURRENT BILLING FOR THIS MATTER $147,010 61

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date An additional invoice will be rendered for subsequent charges
DB#798497

MCNAIR LAW FIRM, P A
ATTORNEYS AND COUNSELORS AT LAW

REMITTANCE ADDRESS
POST OFFICE BOX 11390
COLUMBIA, SOUTH CAROLINA 29211
TELEPHONE 803/799-9800
FACSIMILE 803/799-9804
TAX ID # 57-0703244

REMITTANCE COPY

Please return this portion with your payment to ensure proper credit to your account

MONICA WESTON

08/22/06
INVOICE # 584795

A G MELLING

OUR FILE NO 037580 00001 MONICA WESTON
RE KIM S DOLLAR STORE - PRODUCT LIABILITY

FOR PROFESSIONAL SERVICES THROUGH 08/22/06

PROFESSIONAL SERVICES	$139 482 50
DISBURSEMENTS	$7,528 11
TOTAL	$147,010 61

Please make check payable to McNair Law Firm, P A

$ _____
Amount Enclosed

PAYABLE UPON RECEIPT
This invoice includes all fees and costs posted as of the above date. An additional invoice will be rendered for subsequent charges
PB#798497

Task	Timekeepers								Total for Task	
	Celeste Jones		A Victor Rawl Jr		Andrew Melling		Mary Ann Buonforte			
	Rate $ 400 00		Rate $ 295 00		Rate $ 195 00		Rate $ 135 00			
	Hours	Fees	Hours	Fees	Hours	Fees	Hours	Fees	Hours	Fees
Fees Associated with Bringing Motions for Sanctions										
Draft 9 page letter to defendant outlining all discovery violations prior to filing motion for sanctions		$	7 9	$ 2 330 50		$		$	7 9	$ 2 330 50
Research preparation and drafting of the motions for sanctions	1	$ 400 00	18	$ 5 310 00	1	$ 195 00	3	$ 405 00	23	$ 6 310 00
Preparation for argument and preparation of Power Point presentation for sanctions hearing	8 5	$ 3 400 00	22 6	$ 6 667 00	1 4	$ 273 00	16 6	$ 2 241 00	49 1	$ 12 581 00
Time at courthouse for hearing on motion for sanctions	2	$ 800 00	2	$ 590 00	2	$ 390 00	2	$ 270 00	8	$ 2 050 00
Court ordered meeting with CIBA Counsel immediately following hearing re discovery missing	1 5	$ 600 00	1 5	$ 442 50	1 5	$ 292 50	1 5	$ 202 50	6	$ 1 537 50
Draft proposed order granting sanctions motion	1	$ 400 00	5 5	$ 1 622 50	0	$	0	$	6 5	$ 2 022 50
Review time records for attorneys fees affidavit	1 5	$ 600 00	1	$ 295 00	6	$ 1 170 00	0	$	8 5	$ 2 065 00
Status conference re sanctions motions (prep and attend)	5 5	$ 2 200 00	5	$ 1 475 00	2	$ 390 00	0	$	12 5	$ 4 065 00
Total	21	$ 8 400 00	63 5	$ 18 732 50	13 9	$ 2 710 50	23 1	$ 3 118 50	121 5	$ 32 961 50
Fees Associated with Re deposing 30(b)(6) witnesses										
Preparation of exhibits and for 30(b)(6) depositions prior to returning to Atlanta	3 5	$ 1 400 00	33 6	$ 9 912 00	8 4	$ 1,638 00	13 4	$ 1 809 00	58 9	$ 14 759 00
Travel to/from Atlanta (driving time)	0	$	7 2	$ 2 124 00	7 2	$ 1 404 00	7 2	$ 972 00	21 6	$ 4 500 00
Time in Atlanta preparing for and/or taking 30(b)(6) depositions (8/13/06 8/17/06)	0	$	37 3	$ 11 003 50	30 1	$ 5 869 50	34 5	$ 4 657 50	101 9	$ 21 530 50
Total	3 5	$ 1 400 00	78 1	$ 23 039 50	45 7	$ 8 911 50	55 1	$ 7 438 50	182 4	$ 40 789 50
Total Timekeeper	24 5	$ 9 800 00	141 6	$ 41 772 00	59 6	$ 11 622 00	78 2	$ 10 557 00	303 9	$ 73 751 00

Please note that CIBA Vision has still not produced all of the witnesses required by the court and accordingly plaintiff requests leave to submit the rest of counsel s time records at a later date

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	
COUNTY OF RICHLAND	)	Civil Action No 05 CP-40-0655
	)	
Monica Weston	)	
	)	
Plaintiff,	)	
	)	**CIBA VISION'S OPPOSITION IN**
vs	)	**RESPONSE TO PLAINTIFF'S RULE**
	)	**59 MOTION**
Kims Dollar Store and CIBA Vision, a division of Novartis Company	)	
	)	
Defendants	)	
	)	

CIBA Vision opposes Plaintiff's Motion for Reconsideration/Clarification and/or to Alter or Amend Judgment pursuant to SCRCP 59(e) The Court s Order was appropriately entered more than conforms to the summary judgment standard and is unmistakably clear in meaning and effect [1] The Court correctly determined – following lengthy oral argument on the issue of preemption and review and analysis of the extensive briefs exhibits affidavits and deposition transcripts submitted by the parties – that certain state law (both common law and statutory) claims were preempted by federal law (a matter exclusively for the Court s determination) No legitimate grounds for reconsideration of the Court s Order have been raised, and Plaintiff's Motion should be summarily denied without any further hearing or briefing

INTRODUCTION

Plaintiff's counsel spends most of their Motion trying to distract the Court with a fanciful emotional appeal almost wholly irrelevant to the summary judgment issues (For example

[1] It is worth noting that a proposed order which contained all the language of which Plaintiff now complains, was reviewed and commented upon at length by Plaintiff's counsel Nor is another hearing necessary, as the Court previously allotted the parties over an hour to argue these issues

DEC 19 2006

concocting the unsupported supposition that CIBA promotes and actively participates in the illegal sale of its contact lenses) In reality, it is Plaintiff who deserves little sympathy in this case She was a 28 year old certified nursing professional at the time of her eye infection A friend told her of a beauty supply store where she could get contact lenses without a prescription, and she illegally purchased individual lenses marked prescription only and labeled not to be sold individually The store had a disclaimer sheet signed by purchasers to relieve the store of liability for illegally purchasing lenses In addition, despite being a nursing professional Plaintiff did not purchase any eye care products (such as disinfecting solution) and slept in the contacts Through her handling of the contacts, she introduced bacteria into her eye and developed an eye infection After a couple of weeks, Plaintiff presented herself to a Richland County emergency room and obtained prescriptions for an antibacterial eye ointment and Tylox (a narcotic analgesic containing oxycodone) She did not fill the prescription for the antibacterial ointment and developed an additional infection Notwithstanding her certified nursing profession background her medical records are replete with references to non-compliant behavior culminating with the suggestion that she may need to be discharged from the eye clinic to avoid liability Subsequently, Plaintiff had corneal transplant surgery in the infected eye and now sees without the aid of glasses

LEGAL STANDARD UNDER RULE 59

Contrary to Plaintiff's argument that the Court improperly decided issues of fact that are the province of the jury, the question of federal preemption under the Medical Devices Amendments of 1976 (MDA) is a question of law for the court to decide *See e g Cox v Shalala* 112 F 3d 151 (4th Cir 1997) Therefore t was not only appropriate but necessary for the Court to determine whether preemption applies

Plaintiff was fully heard on these issues and Rule 59 does not afford Plaintiff a second bite at the apple[2] 'Reconsideration of a judgment after its entry is an extraordinary remedy which should be used sparingly A litigant may not use Rule 59 to re-litigate issues already decided by the court It is an improper use of the motion to reconsider to ask the Court to rethink what the Court already thought through – rightly or wrongly" *In re Cable & Wireless PLC* 332 F Supp 2d 896 899 900 (E D Va 2004) (emphasis added) (citing *Clapper v Chesapeake Conference of Seventh Day Adventists* 1998 WL 904528 *3 (4th Cir Dec 29 1998) ("The Rule 59(e) motion may not be used to re litigate old matters)), *see Thompson v Direct Impact Co* 63 F Supp 2d 721 724 (E D Va 1998) ([A] Rule 59(e) motion is not a vehicle for obtaining post judgment reargument on issues already decided") *aff'd* 188 F 3d 503 (4th Cir 1999), *see also Hanover Ins Co v Corrpro Cos* 221 F R D 458 460 (E D Va 2004) ('Rule 59(e) does not entitle [plaintiffs] to a second bite at the apple)[3] Because Plaintiff merely asks the Court to reconsider its analysis the Motion is improper and should be summarily denied without further briefing or hearing

Specifically the Court already considered and rejected Plaintiff's arguments that the FreshLook Colors contact lenses at issue in this case are exclusively cosmetics, and not also medical devices that CIBA Vision did not obtain PMA approval for the lenses as medical devices, and that federal law does not preempt Plaintiff's state common law and statutory

---

[2] And there is not much left of this apple as Plaintiff's counsel took multiple bites with their prior briefs, objections and supplemental filings

Because Federal Rule 59 is substantially similar to Rule 59 of the South Carolina Rules of Civil Procedure, the admonition of these cases is applicable Rule 59 S C R C P (This Rule is substantially the Federal Rule)

claims[4] Because Plaintiff merely rehashes those arguments in its instant Motion the Court having carefully weighed them before entering its Order, should decline to revisit them now In fact, when the wrapping paper is stripped away, it is clear that none of the arguments raised by Plaintiff constitute new evidence rather they are slight variations on arguments already made by Plaintiff and they are based on evidence and testimony already submitted to and considered by the Court Our courts have made it clear that "[a] party cannot use a motion to reconsider, alter or amend a judgment to present an issue that could have been raised prior to the judgment but was not" *Tallent v South Carolina Dept of Transp* 363 S C 160 165 609 S E 2d 544 546 (Ct App 2005) (citing *Kiawah Prop Owners Group v Public Serv Comm'n* 359 S C 105, 113 597 S E 2d 145 149 (2004)) *see also MailSource LLC v M A Bailey & Assoc* 356 S C 370 374 588 S E 2d 639 641 (Ct App 2003) (holding that a party cannot raise an issue for first time in a Rule 59(e) motion which could have been raised at trial) Consequently, Plaintiff's Motion should be denied as failing to comply with the standard for bringing a Rule 59(e) motion

PLAINTIFF'S ARGUMENTS ARE PROCEDURALLY IMPROPER AND, OTHERWISE SHOULD BE DISREGARDED ON THE MERITS

As set forth above Plaintiff's attempt to rehash its prior arguments is procedurally improper under Rule 59 Nevertheless CIBA Vision will briefly outline the fallacies in Plaintiff's substantive arguments

[4] Regarding this last point, the parties have extensively briefed whether federal law imposes device specific requirements on the FreshLook Colors lenses and whether a jury verdict on Plaintiff's state law claims – combined with the state statutes invoked by Plaintiff – would constitute an additional and/or conflicting requirement These issues were central not only to the initial briefs submitted by the parties and oral argument but also by several supplemental briefs and correspondence addressed to the Court The submissions by both sides directed the Court to dozens of state and federal decisions as well as allegedly relevant portions of testimony from CIBA Vision s 30(b)(6) witnesses and expert and from Plaintiff's expert – the same testimony regurgitated and again disingenuously taken out of context by Plaintiff now Therefore there is

I FreshLook Colors Extended Wear UV Protecting Contact Lenses are Medical Devices

Plaintiff's entire argument against federal preemption continues to hinge on a single implied reference that these contact lenses were cosmetics and the false assumption that the contact lenses cannot be both a cosmetic and a medical device The evidence presented to the Court clearly establishes that the lenses remained medical devices In fact the same document (Import Alert 86 10) relied on by Plaintiff to suggest some contact lenses could be considered cosmetics, clearly provides that these extended wear lenses, which provide UV-radiation protection and affect the physiology of the eye, would also be medical devices Plaintiff's own expert in her book about the FDA, coined the term cosmeceutical to describe dual status products such as these contact lenses Whether these lenses are cosmetic is irrelevant and therefore does not create an issue of fact What is uncontradicted, even by Plaintiff's own expert, is that these extended wear UV radiation protection contact lenses are medical devices and therefore subject to federal preemption under the express language of the Medical Devices Amendments of 1976

II FreshLook Colors Contact Lenses were Pre-Market Approved by the Federal Drug Administration

Plaintiff's desperation in bringing this Motion is exemplified by the post hearing attack on the business record custodial authentication of some of the pre-market approval (PMA) documentation of CIBA Vision Freshlook Colors contact lenses (the contacts that Plaintiff alleges are at issue in this case) Despite raising no objection at the hearing or in the briefs Plaintiff's counsel now wants the Court to reverse itself and ignore all the evidence of pre

---

no basis for reconsideration of the central issue of preemption and it would be improper to revisit this issue under Rule 59

market approval because an FDA certified and authenticated copy of the pre market approval satisfactory to Plaintiff's counsel was not submitted as part of the extensive proof of pre market approval This would be the equivalent of asking the Court to ignore a confession because the prosecutor did not also submit the accused s fingerprints Not only should these arguments be rejected because of Plaintiff's failure to raise them in a timely manner as required by our Rules but also because they are without merit

First Plaintiff's own expert conceded that CIBA Vision received FDA approval to market the FreshLook Colors lenses under a supplement to the PMA, which was first granted by the FDA to predicate contact lenses in 1983 [5] (Parisian Dep p 87 ll 11 20 (stating that CIBA Vision s draft labeling for the lenses was one component in terms of the PMA product that [FDA] approved')) When asked specifically about FDA's approval of this FreshLook Colors lens which was apparently manufactured in 2003 from your review of the FDA documents related to FreshLook Colors and predecessor products, Dr Parisian confirmed that the FreshLook Colors lenses at issue in this case were approved by FDA under supplements to a PMA granted 'original approval in 1985 and that 'FDA has allowed companies just to piggyback in terms of the information (Parisian Dep p 88) In fact Dr Parisian specifically

[5] As explained at length in CIBA Vision s briefs in support of summary judgment All procedures and actions that apply to [a PMA] application also apply to PMA supplements 21 C F R § 814 39 (emphasis added) The PMA supplement 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 At the same time the entirety of the PMA including all supplements are before the agency at the time the supplement is reviewed 51 Fed Reg 26342 26354 (1986) 'FDA considers revisions proposed in a PMA supplement using the same type of rigorous scientific process utilized for review of original

agreed that the genealogy [i e the PMA approval history] for that FreshLook Color product begins with the 1983 PMA' (Parisian Dep p 89 ll 14 17) Further Exhibits 7 and 8 to Dr Parisian's deposition are PMA supplement approvals from the FDA allowing the marketing of FreshLook Colors lenses, pursuant to prior PMA approval [6] Thus, it is not only procedurally improper but also completely baseless for Plaintiff now to argue that there is no evidence that the FreshLook Colors lenses were approved by the FDA when her own expert has expressly conceded this, and when the Court had before it at least two of the FDA s PMA supplement approvals for the FreshLook Colors lenses

III CIBA Vision's Pre-Market Approval for FreshLook Colors Contact Lenses has Not Been Suspended or Revoked

The PMA status of the FreshLook Colors contact lenses has remained valid for these lenses and their predecessors since 1983 The FDA is the only regulatory authority empowered to invalidate the PMA approval of these lenses Despite all the innuendo suggested by Plaintiff's counsel the FDA has continued to maintain the PMA status of these contact lenses (and it is uncontroverted that the FDA is well aware of the existence of illegal contact lenses purchases such as Plaintiff's) [7] It is disingenuous for Plaintiff's counsel to suggest that summary judgment should be denied because CIBA Vision did not also prove the negative that the FDA does not consider CIBA Vision in violation of the PMA approval First every time a PMA Supplement is submitted the entire PMA is re opened to the FDA s rigorous analysis In addition CIBA

PMAs See FDA Letter Brief filed as *amicus curiae Horn v Thoratec* 376 F 3d 163 (3d Cir 2004) available at 2004 WL 1143720 at *10 (May 14 2004) (hereafter *Horn* amicus brief)

[6] The entirety of the deposition of Dr Parisian (Plaintiff's own expert) was before the Court as part of the summary judgment evidence

[7] Of course anytime a product is regulated there will be illicit channels for illegal distribution much like oxycodone and other narcotic based prescriptions

Vision would remind the Court that at the hearing in August, it suggested that to the extent there were any questions about the applicability of preemption in this case the Court should contact the FDA to seek guidance in the form of an agency opinion, as authorized under 21 C F R 808 5 The fact that Plaintiff's counsel objected to the Court seeking input from the FDA is as telling as any argument by the parties

IV The Requirements Suggested by Plaintiff's Numerous Theories of Liability in the Amended Complaint would Impose Different Requirements from those Imposed by the FDA

Plaintiff's final salvo is to suggest that a jury finding in her favor would not impose requirements different than the FDA To the contrary to find in Plaintiff's favor necessarily requires imposing a different set of requirements The warnings packaging labeling instructions and inserts are all required by the FDA through the rigorous PMA process To pursue claims that the warnings, labels packaging, instructions and inserts should have been different necessarily imposes new requirements on the product manufacturer (requirement that are drafted by attorneys in civil action complaints not through any scientific disciplined process) This is exactly what Plaintiff does in her Amended Complaint [e g Para 43(a) (j)] To suggest that this Court somehow missed the ball in its Order completely ignores the South Carolina s clear pronouncement in the recent case of *Whaley v CSX Transp Inc* 362 S C 456, 609 S E 2d 286 (SC 2005) There, writing for the Court Chief Justice Toal stated

> To uphold the jury s verdict would support a finding of liability despite CSX s compliance with all applicable statutes and regulations and would force CSX to alter its locomotives in a way that would conflict with the uniformity and consistency that the LIA is designed to provide As a result CSX would be forced to install cooling devices on all locomotives to protect itself against future lawsuits in South Carolina Therefore we hold that Whaley s claim under the LIA is preempted

Id at 481 609 S E 2d at 299 The instant case is indistinguishable from the *Whaley* case with regard to the effect of state civil causes of action on federal regulatory requirements Accordingly, as found by the Court Plaintiff's terminated causes of action and related theories are preempted under the express language of the Medical Devices Amendments of 1976 and Plaintiff's Motion should be denied

THE COURT PROPERLY LIMITED DISCOVERY, AND PLAINTIFF'S ARGUMENT THAT CIBA VISION IS AVOIDING DISCOVERY HAS NO MERIT

Consistent with their scorched earth procedural strategy in this case, Plaintiff's counsel contends that the Order improperly limits further discovery on several issues that are relevant to the remaining causes of action However rather than identifying for the Court the particular issues on which discovery was allegedly inappropriately limited and how those issues pertain to the remaining causes of action Plaintiff's counsel merely rehashes their position that CIBA Vision is seeking to avoid discovery [8] Plaintiff likewise fails to identify the particular discovery that CIBA Vision has failed to produce Thus Plaintiff's argument not only lacks substance it fails to satisfy the standard set forth under Rule 59(e)

The Court's Order clearly states that Count II (negligence) Count V (sale of a defective product), and Count VI (Unfair Trade Practices Act) are dismissed The Order also states that Plaintiff's remaining causes of action Count I (negligence per se) Count III (breach of implied warranty), and Count IV (strict liability) are dismissed to the extent that such counts are dependent on evidence of warning labeling, design, marketing, misbranding or similar claims" Pursuant to and in accordance with this ruling, the Court limits further discovery to issues unrelated to warnings labeling packaging use instructions product design marketing

[8] Plaintiff's counsel also conveniently fails to include that their initial motion to compel was denied in part because of valid discovery concerns raised by CIBA Vision

or illegal sales of contact lenses Because counts I III and IV of the Amended Complaint are dismissed to the extent that they are premised on these issues Plaintiff's contention that the Order limits discovery on issues relevant to the remaining causes of action is not only unfounded it is erroneous Plaintiff is only limited from conducting further discovery on issues that support claims that have been expressly dismissed by the Court

Further the limitation is far from a prohibition The Order expressly states that discovery on issues of warnings packaging use instructions product design marketing or illegal sales of contact lenses is only restricted without further court order Thus if Plaintiff's counsel articulates for the Court that particular discovery on one or more of these issues is relevant to a viable theory to one of the remaining causes of action they are free to seek permission for that discovery

Plaintiff's position that CIBA Vision is seeking to avoid discovery is similarly unfounded By Order dated September 25 2006 Plaintiff's counsel was expressly ordered to promptly inform counsel for CIBA Vision of any information or categories of information responsive to Plaintiff's outstanding requests for discovery that Plaintiff believed CIBA Vision was improperly withholding from production Following entry of this Order and to date Plaintiff's counsel has not identified a *single* discovery item or category of information that CIBA Vision has allegedly withheld from production[9] Despite this fact Plaintiff summarily states in her Motion for Reconsideration that CIBA Vision has still not produced all the information regarding its illegal sales of contact lenses This conclusory and argumentative

[9] Notably although Plaintiff's counsel has not identified any information improperly withheld from production following entry of the September 25 Order CIBA Vision has identified several areas in which Plaintiff's discovery responses are deficient but Plaintiff continues to fail to provide appropriate discovery responses

language mirrors the language in Plaintiff's counsels September 13 correspondence to the Court in which Plaintiff's counsel urged the Court not to limit discovery in the manner set forth in CIBA Vision s proposed order Plaintiff's argument in this regard has not changed nor has Plaintiff proffered any new or additional evidence to support the argument submitted and rejected previously by the Court Therefore, the argument should be denied under Rule 59

CONCLUSION

For the foregoing reasons Plaintiff's Motion for Reconsideration/Clarification and/or to Alter or Amend Judgment pursuant to SCRCP 59(e), is both procedurally improper and without any substantive merit Therefore, CIBA Vision respectfully requests that the Court deny Plaintiff's Motion In addition CIBA Vision requests that the Court place Plaintiff's motion under seal as it quotes from documents that Plaintiff's counsel previously filed under seal and should have been originally filed under seal by Plaintiff's counsel A proposed order reflecting the disposition sought herein is attached

December 15 2006 By

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

Keith D Munson
Sandi R Wilson
Womble Carlyle Sandridge & Rice
A Professional Limited Liability Company
P O Box 10208
Greenville, SC 29603
Phone (864) 255-5400
Fax (864) 255 5480

ATTORNEYS FOR DEFENDANT CIBA VISION

STATE OF SOUTH CAROLINA) COURT OF COMMON PLEAS
COUNTY OF RICHLAND) 05-CP-40-0655

MONICA WESTON)
)
PLAINTIFF)
VS) TRANSCRIPT OF RECORD
) (MOTIONS)
)
CIBA VISION KIM S DOLLAR)
STORE)
)
DEFENDANTS)

AUGUST 28 2006
COLUMBIA SOUTH CAROLINA

BEFORE

THE HONORABLE G THOMAS COOPER JR JUDGE

APPEARANCES

A VICTOR RAWL JR
CELESTE JONES
ANDREW G MELLING
STEVE ELLIOTT
ATTORNEYS FOR THE PLAINTIFF

KEITH D MUNSON
CURTIS OTT
JEFF PASCOE
ATTORNEYS FOR DEFENDANT CIBA VISION

DANIEL SULLIVAN
STEVEN HALL
ATTORNEYS FOR DEFENDANT KIM S DOLLAR STORE

JENNY H WILLIAMS
OFFICIAL CIRCUIT COURT REPORTER
(803) 576-1743

MONDAY, AUGUST 28, 2006

THE COURT ALL RIGHT WHO IS ON FIRST?

MR MUNSON YOUR HONOR, KEITH MUNSON FOR WILMA CARLISLE I'M HERE WITH JEFF PASCOE OF OUR OFFICE

THE COURT WHOA WHOA, WHOA JUST WAIT A MINUTE

COURT REPORTER NO, SIR I DON'T KNOW THEY ARE

THE COURT LET'S JUST START TO MY COURT REPORTER'S LEFT AND JUST COME ACROSS I JUST NEED TO KNOW WHO YOU ARE AND WHO YOU'RE REPRESENTING

MR RAWL THIS IS ANDREW MELLING, CELESTE JONES AND VIC RAWL WITH THE MCNAIR LAW FIRM, AND WE REPRESENT THE PLAINTIFF ALSO STEVE ELLIOTT WITH THE ELLIOTT LAW FIRM, AND HE ALSO REPRESENTS THE PLAINTIFF

MR PASCOE JEFF PASCOE, P-A-S-C-O-E, KEITH MUNSON WITH WOMBLE, CARLISLE, CURTIS OTT WITH TURNER, PADGETT, REPRESENTING CIBA VISION

MR SULLIVAN DAN SULLIVAN AND STEVEN HALL WITH YOUNG & SULLIVAN REPRESENTING KIM'S DOLLAR STORE

THE COURT ALL RIGHT WHOSE MOTION?

MR MUNSON THIS IS CIBA VISION'S MOTION FOR SUMMARY JUDGMENT BASED ON FEDERAL PREEMPTION, YOUR HONOR THIS IS A CASE IN WHICH THE PLAINTIFF

OBTAINED A CONTACT LENS WHICH SHE WORE, GOT AN INFECTION, EVENTUALLY GOT A NASTY SORE ON HER EYE, HAD TO HAVE A CORNEAL TRANSPLANT SOMETIME DURING THAT PERIOD OF CONCERN WITH HER EYE SHE STEPPED IN A HOLE AND BUSTED HER FOOT AND HAS BROUGHT A CLAIM AGAINST CIBA VISION FOR SIX VARIOUS CAUSES OF ACTION, BASICALLY A PRODUCTS LIABILITY CASE WITH NEGLIGENCE, STRICT LIABILITY, BREACH OF WARRANTY, SOUTH CAROLINA UNFAIR TRADE PRACTICES

ANOTHER DEFENDANT IN THE CASE IS KIM'S DOLLAR STORE WHICH WAS THE BEAUTY SUPPLY STORE AT WHICH SHE OBTAINED A CONTACT LENS WITHOUT A PRESCRIPTION

THE COURT A CONTACT LENS AT A DOLLAR STORE?

MR MUNSON CORRECT, YOUR HONOR CIBA VISION ONLY DISTRIBUTES THROUGH EYE CARE PROFESSIONALS SOMEHOW SOME OF THEIR CONTACT LENSES EITHER GOT PURCHASED WITH A PRESCRIPTION BY A CUSTOMER THAT HAD SOME LEFTOVER ONES, GAVE THEM TO A DOLLAR STORE TO SELL OR THEY GOT AHOLD OF THEM SOME OTHER WAY BUT SOME OF -- THE ALLEGATIONS OF THE COMPLAINT ARE THAT SOME OF OUR LENSES ENDED UP IN THE DOLLAR STORE, GOT SOLD TO THE PLAINTIFF WITHOUT A PRESCRIPTION

THE COURT WHO IS KEHOE?

MR MUNSON KEHOE IS THE CURRENT CEO OF CIBA VISION, THE CIBA VISION ENTITY IN THE UNITED STATES

RESPONSIBLE FOR MANUFACTURER OF THE ALLEGED LENS

THE COURT SO THEY SUED HIM IN HIS INDIVIDUAL CAPACITY?

MR MUNSON NO THE ONLY DEFENDANTS ARE KIM'S DOLLAR STORE AND CIBA VISION, YOUR HONOR

THE COURT ALL RIGHT I'M SORRY I WAS LOOKING AT THE ROSTER GO AHEAD

MR MUNSON OKAY WE BROUGHT THIS MOTION BECAUSE ALL OF THEIR CLAIMS ARE -- THE UNDERLYING CLAIM IN ALL THEIR CLAIMS IS THAT CIBA VISION FAILED TO ADEQUATELY PROVIDE LABELING AND WARNINGS ON THE PRODUCT

THIS CONTACT LENS WHICH IS AN EXTENDED WEAR CONTACT LENS WOULD BE REGULATED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION AS A CLASS 3 MEDICAL DEVICE, MEANING THAT IT WAS REQUIRED TO HAVE WHAT'S CALLED PMA APPROVAL THROUGH THE MEDICAL DEVICES AMENDMENTS OF 1976 TO THE FEDERAL FOOD, DRUG AND COSMETIC ACT

UNDER THE MEDICAL DEVICES AMENDMENT THERE IS A PREEMPTION PROVISION THAT PROHIBITS ANY STATE OR LOCAL ENTITY FROM HAVING A LABELING OR WARNING REQUIREMENT DIFFERENT FROM THE REQUIREMENT REQUIRED BY THE FDA IN SOUTH CAROLINA THAT WOULD INCLUDE JURY VERDICTS SO A TORT CASE THAT IMPOSED A DIFFERENT WARNING OR LABELING REQUIREMENT ON THIS

CONTACT LENS WOULD VIOLATE FEDERAL PREEMPTION UNDER THE SUPREMACY CLAUSE OF THE UNITED STATES CONSTITUTION

SO WE BRING OUR MOTION FOR SUMMARY JUDGMENT TO ESTABLISH THAT FEDERAL PREEMPTION APPLIES IN THIS CASE AND WOULD INVALIDATE AND PROHIBIT ANY CLAIMS THAT WOULD SUGGEST THAT THE LABELING OR WARNINGS ON THIS PRODUCT WERE INSUFFICIENT BECAUSE THEY HAD BEEN SUBMITTED AND APPROVED BY THE FDA THROUGH ITS PREMARKET APPROVAL

THE COURT I'M LISTENING

MR MUNSON AS I SAID, THIS WAS A CLASS 3 MEDICAL DEVICE UNDER THE FDA OF THE MEDICAL DEVICES ACT AND, YOUR HONOR, JUST FOR THE COURT'S BENEFIT, I PUT THREE NOTEBOOKS UP ON THE BENCH THERE ONE OF THEM CONTAINS THE MOTION AND THE DEPOSITIONS AND THE AFFIDAVITS THAT UNDERLIE THE SUMMARY JUDGMENT THE OTHER TWO CONTAIN THE VARIOUS CASES AND STATUTES AND CODE OF FEDERAL REGULATION PROVISIONS THAT ARE CITED IN THE DOCUMENTS

UNDER THE MEDICAL DEVICES ACT, MEDICAL DEVICES ARE DIVIDED INTO THREE CATEGORIES CATEGORY 3 IS THE MOST RIGOROUSLY REGULATED BY THE FDA IT REQUIRES A PREMARKET APPROVAL PROCESS SO BEFORE YOU EVEN HAVE THE IDEA THAT I'M GOING TO SELL CONTACT LENSES,

YOU'VE GOT TO SUBMIT REAMS OF DOCUMENTS TO THE FDA ON AVERAGE THEY TAKE 1200 HOURS GOING THROUGH THIS THE END RESULT IS PREMARKET APPROVAL FROM THE FDA WHICH INCLUDES APPROVAL OF YOUR FINAL LABELING AND WARNINGS

SUBSEQUENT TO THE PREMARKET APPROVAL, THE FDA MAINTAINS CONTROL OVER THE DEVICES IF YOU MAKE ANY CHANGES TO THE DEVICE, YOU'VE GOT TO GO THROUGH A PMA SUPPLEMENT PROCESS WHERE YOU GO BACK TO THE FDA AND YOU SAY WE WANT TO CHANGE THE LABELING OR WE WANT TO ADD A UV PROTECTANT TO OUR CONTACT LENSES OR WE WANT TO MAKE SOME FOR DAILY WEAR INSTEAD OF ALL FOR EXTENDED WEAR

THAT BRINGS THE ENTIRE PMA BACK INTO THE FDA'S JURISDICTION THEY CAN DO WHATEVER THEY WANT TO AT ANY TIME THEY DEAL WITH A PMA SUPPLEMENT AGAIN, THE LABELINGS AND WARNINGS AND PATIENT INFORMATION, PACKET INSERTS ALL GET SUBMITTED TO THE FDA, ALL GET APPROVED BY THE FDA

THE COURT WHAT'S THE TECHNICAL NAME OF THIS PRODUCT?

MR MUNSON THIS PRODUCT IS CALLED FRESH LOOK COLORS

THE COURT FRESH LOOK COLORS

MR MUNSON COLORS AND IT IS --

THE COURT IS IT IDENTIFIED BY SOME PRODUCT NUMBER OR SOMETHING?

MR MUNSON WELL, WE DON'T KNOW BECAUSE SHE NEVER -- SHE DIDN'T KEEP THE CONTACTS SHE DIDN'T KEEP THE PACKAGING SO WE DON'T KNOW -- WE HAVE NO WAY OF IDENTIFYING THESE PARTICULAR CONTACTS WHAT WE HAVE THAT THEY'VE SUBMITTED IN THIS CASE IS ANOTHER PHOTOCOPY OF A PACKAGE FROM A DIFFERENT CONTACT LENS WHICH PLAINTIFF CLAIMS IS SIMILAR TO THE ONE THAT SHE PURCHASED AND THAT WOULD HAVE A LOT NUMBER AND AN EXPIRATION DATE HOWEVER, IT'S NOT THE CONTACT SHE HAD SO WE DON'T KNOW THE EXPIRATION DATE OR THE LOT NUMBER FOR THE CONTACT THAT SHE HAD

THE COURT SORT OF LIKE NOT HAVING THE BODY

MR MUNSON EXACTLY, YOUR HONOR THAT IS A PROBLEM IN THIS CASE BUT FOR THE PURPOSES OF THIS SUMMARY JUDGMENT MOTION WE'RE NOT CONTESTING WHETHER OR NOT WHAT THEY REPRESENT TO BE THE TYPE OF CONTACT INVOLVED IS IN FACT --

THE COURT THAT'S A MERIT ISSUE

MR MUNSON YES, YOUR HONOR AND WE FOR THE PURPOSE OF THIS SUMMARY JUDGMENT MOTION CONCEDE THAT POINT

THE COURT ALL RIGHT

MR MUNSON AND WE WOULD BE ENTITLED TO SUMMARY

JUDGMENT ON THE BASIS OF PREEMPTION EITHER ON WHAT THEY CLAIM TO BE THE PRODUCT --

THE COURT EITHER ONE

MR MUNSON EITHER ONE

THE COURT GO AHEAD

MR MUNSON THESE FRESH LOOK COLOR LENSES COME IN A RANGE OF NEGATIVE 20 CORRECTIVE POWER TO POSITIVE 20 CORRECTIVE POWER THIS PARTICULAR LENS ACCORDING TO THE EXEMPLAR AND ACCORDING TO THE PLAINTIFF'S ALLEGATIONS WAS A ZERO POWERED LENS WHICH IS IN THE INDUSTRY ALSO CALLED A PLANO LENS I'M NOT SURE WHY, BUT IT'S A NON-CORRECTIVE ZERO POWERED PLANO LENS AND THAT'S ABOUT AS SPECIFIC AS WE CAN BE ON THE ACTUAL IDENTIFICATION OF THE LENS

BUT, REGARDLESS, EVEN AT THE ZERO POWERED LENS, CIBA VISION WOULD -- CIBA VISION SOUGHT PREMARKET APPROVAL FROM THE FDA FOR FRESH LOOK COLOR LENSES IN THE RANGE FROM NEGATIVE TO POSITIVE THAT WOULD INCLUDE ZERO

AND IF YOU THINK OF THIS AS KIND OF A TREE WITH BRANCHES, AT SOME POINT IN THE PAST THEY GOT AN ORIGINAL PREMARKET APPROVAL FOR A DURA SOFT SOFT CONTACT LENS THIS FRESH LOOK COLOR LENS IS RELATED THROUGH BRANCHES AND LIMBS BACK TO THAT ORIGINAL TRUNK IN 1983 SO THAT'S KIND OF A GENEALOGY

NOW, FOR EXAMPLE, IN 1994 THE FDA ALLOWED -- THIS IS PROBABLY MORE HISTORY THAN YOU WANT BUT PRE 1976 CONTACT LENSES WERE REGULATED AS DRUGS THE MEDICAL DEVICES ACT IN 1976 MADE ALL CONTACT LENSES CLASS 3 MEDICAL DEVICES IN 1994 THE FDA -- CONGRESS PASSED ANOTHER BILL, AND THE FDA STARTED REGULATING DAILY WEAR AS CLASS 2 DEVICES, EXTENDED WEAR AS CLASS 3 DEVICES

THE COURT ALL RIGHT

MR MUNSON AND SO YOU GET SOME PMA SUPPLEMENTS THAT GO DOWN THESE DIFFERENT BRANCHES BUT THIS ONE WAS --

THE COURT WELL, WOULDN'T THEY ALL -- IF, AS YOU SAY, THEY'RE ALL REGULATED BY THE FDA, WOULDN'T THEY ALL BE REGULATED BY THE FDA? OR IS IT --

MR MUNSON YES, YOUR HONOR THEY ALL ARE THEY ALL ARE REGULATED BY THE FDA THE KEY WITH THE PREMARKET APPROVAL IS THAT UNDER THE PREEMPTION PROVISION THE PREMARKET APPROVAL ESTABLISHES WARNINGS AND LABEL REQUIREMENTS FOR THE PRODUCT SO THEN WHEN YOU STEP BACK TO THE PREEMPTION PROVISION THAT SAYS NO STATE WILL HAVE ANY RULE OR REGULATION THAT'S CONTRARY TO WHAT'S BEEN ESTABLISHED, IT'S THE PREMARKET APPROVAL PRODUCTS THAT CLEARLY FALL WITHIN THAT PREEMPTION

NOW, THERE MAY BE SOME ARGUMENTS IN CLASS 2 AND CLASS 1, ALSO GET PREEMPTED, BUT THEY DON'T GO THROUGH THIS PREMARKET APPROVAL FOR THE CLASS 3 DEVICES, IT'S VERY EASY TO SEE, HERE IS THE LABLE ON THE PRODUCT, HERE IS THE PACKAGE INSERT, THOSE HAVE BEEN APPROVED BY THE FDA IF YOU'RE MAKING AN ARGUMENT THAT SAYS THE PACKAGE INSERT SHOULD SAY SOMETHING ELSE, THE LABEL SHOULD SAY SOMETHING ELSE, THAT'S GOING TO BE PREEMPTIVE, BECAUSE THE PREMARKET APPROVAL DOCUMENT FOR DEVICES, THEY HAVE BEEN -- THOSE LABELS AND PACKAGE INSERTS HAVE ALL BEEN SUBMITTED IN FINAL FORM AND APPROVED BY THE FDA

AND JUST SO THAT I DON'T MISSTATE IT, THE MDA EXPRESS PREEMPTION PROVISION WHICH IS FOUND AT 21 USC 360K(A) STATES -- AND I'LL LEAVE SOME OF THE STUFF OUT THAT'S NOT RELEVANT -- BUT "NO STATE OR POLITICAL SUBDIVISION OF A STATE MAY ESTABLISH OR CONTINUE IN EFFECT ANY REQUIREMENT WHICH IS DIFFERENT FROM, OR IN ADDITION TO, ANY REQUIREMENT APPLICABLE UNDER THIS ACT TO THE DEVICE "

THE COURT ALL RIGHT LET ME HEAR FROM -- MR RAWL, ARE YOU GOING TO ARGUE?

MR RAWL YES, SIR, YOUR HONOR

THE COURT TELL ME WHY WHAT HE SAYS IS NOT PREEMPTIVE WHY IS THIS CASE OR WHY SHOULD THIS CASE

BE IN STATE COURT AS A TORT ACTION?

MR RAWL SIMPLY PUT, YOUR HONOR, THIS CASE SHOULD BE IN STATE COURT BECAUSE THE CONTACT LENS AT ISSUE IS NOT A MEDICAL DEVICE AS DEFENDANT CIBA VISION CLAIMS BUT INSTEAD IS WHAT'S DESIGNATED AS A COSMETIC UNDER THE FDA FOOD AND DRUG COSMETIC ACT AND PREEMPTION PROVISIONS THAT MR MUNSON REFERRED TO AND CORRECTLY READ INTO THE RECORD SPECIFICALLY DOES NOT RELATE TO COSMETICS

THE COURT IS THAT THE ISSUE?

MR RAWL YES, SIR

THE COURT WHETHER IT'S A MEDICAL DEVICE OR A COSMETIC DEVICE?

MR RAWL THAT IS THE PRIMARY ISSUE THEN THERE ARE SECONDARY ISSUES THAT ARE BEFORE THE COURT BUT THE PRIMARY ISSUE AND WHAT WE ARE HERE TO PROVE TODAY, YOUR HONOR, IS THIS CONTACT LENS IS A DECORATIVE CONTACT LENS IT IS A COLOR --

THE COURT ALL RIGHT I DON'T MEAN TO CUT YOU SHORT BUT IF IT WERE DETERMINED OR THE COURT WERE TO DETERMINE IT'S A MEDICAL DEVICE, WOULD YOU AGREE WITH HIM THAT THAT WOULD BE PREEMPTED IF IT WERE A MEDICAL DEVICE?

MR RAWL NO, SIR, YOUR HONOR AND THE REASON IS, THERE ARE SEVERAL REASONS THE FIRST REASON IS,

CIBA VISION HAS TO MAINTAIN THIS PMA APPROVAL AND THERE ARE ALL TYPES OF CONDITIONS FOR APPROVAL IN ORDER THAT CIBA VISION HAS BEEN TOLD BY THE FDA THAT THEY HAVE TO DO AND CIBA VISION HAS NOT DONE ALL THOSE THINGS AND THE LETTER SAYS -- APPROVING THE PMA SAYS -- IF YOU FAIL TO MEET EVERY CONDITION OF APPROVAL, THEN THIS PMA IS INVALIDATED SO THEY LOSE THE PMA APPROVAL

THE SECOND POINT, YOUR HONOR, IS THE PREEMPTION PROVISION SPECIFICALLY STATES THAT ONLY LAW, ONLY SOUTH CAROLINA LAW THAT IS IN ADDITION TO OR DIFFERENT FROM SOUTH CAROLINA LAW IS PREEMPTED AND SOUTH CAROLINA LAW MIRRORS THE FDA LAW WITH REGARD TO WARNINGS THAT ARE REQUIRED ON PACKAGING

WHAT THE FDA SAYS -- AND I CITED ALL THESE PROVISIONS, I'LL BE HAPPY TO GO THROUGH THEM RIGHT NOW IF YOU'D LIKE -- IS THAT IF CIBA VISION LEARNS THAT ITS PRODUCTS, ITS COLOR DECORATIVE NON-CORRECTIVE CONTACT LENSES ARE BEING USED IN A DIFFERENT WAY THAN THEY EXPECT IT TO BE USED, THEN THEY STILL HAVE THE DUTY TO WARN CONSUMERS, YOU KNOW, MAYBE USING THEM IN A DIFFERENT WAY

WHAT CIBA VISION CLAIMS IS WE ONLY WANTED THESE LENSES TO BE USED AS MEDICAL DEVICES HOWEVER, CIBA VISION HAS ADMITTED THAT HUNDREDS OF DIFFERENT

LOCATIONS, BEAUTY SUPPLY STORES AROUND THE COUNTRY FROM 1999 -- AND THE PROCESS IS STILL GOING ON TODAY -- ARE SELLING CIBA VISION'S DECORATIVE NON-CORRECTIVE COLOR CONTACT LENSES OVER THE COUNTER WITHOUT A PRESCRIPTION, WITHOUT ANY WARNING WHATSOEVER THAT THE PRODUCT CAN MAKE THE CONSUMER GO BLIND

AND IN THIS CASE, YOUR HONOR, MY CLIENT, YOU KNOW, AFTER SEEING -- WENT TO HER LOCAL BEAUTY SUPPLY STORE ON THE DISPLAY WERE THESE COLOR CONTACT LENSES AND SHE BOUGHT A PACKET OF COLOR CONTACT LENSES IN MARCH OF 2004 THESE COLOR CONTACT LENSES WERE SOLD OVER THE COUNTER WITHOUT A PRESCRIPTION, WITHOUT ANY INSTRUCTIONS FOR USE, HANDLING OR CARE AND WITHOUT ANY WARNING WHATSOEVER THAT THE PRODUCT COULD MAKE HER GO BLIND

MY CLIENT, MS WESTON, --

THE COURT DID SHE GO BLIND?

MR RAWL SHE WENT BLIND YES, SIR, YOUR HONOR SHE WENT BLIND FOR A YEAR AND A HALF AND SUFFERED EXTREME PAIN AND ONLY WORE THE CONTACTS FOR A MATTER OF HOURS CIBA VISION IN ITS 30(B)(6) DEPOSITIONS HAS ADMITTED THAT THEY KNEW THAT THESE WERE VERY DANGEROUS PRODUCTS, THAT THEY KNEW THAT THEY WERE SOLD OVER THE COUNTER WITHOUT A

PRESCRIPTION, WITHOUT ANY DOCTOR INVOLVED IN IT WHATEVER THEY KNEW THAT THEY WERE BEING SOLD WITHOUT ANY TYPE OF WARNING WHATSOEVER, AND THEY KNEW THAT PEOPLE WERE ACTUALLY BEING INJURED WE HAVE THEIR RECORDS OF OTHER PEOPLE WHO HAVE GONE BLIND THAT CIBA VISION WAS AWARE OF AND MY CLIENT, FORTUNATELY, AFTER A YEAR AND A HALF OF EXTREME PAIN AND BEING BLIND IN HER EYE WAS A CANDIDATE FOR A CORNEAL TRANSPLANT AND SHE --

THE COURT WELL, WE DON'T NEED TO GET INTO ALL THAT IF THAT'S NOT THE ISSUE THE ISSUE AS I UNDERSTAND IT THEN IS WHETHER OR NOT THIS COURT OR THE FEDERAL COURT OUGHT TO BE HEARING THIS CASE IS THAT WHERE WE ARE?

MR MUNSON I DON'T THINK THE FEDERAL COURT SHOULD HEAR IT, YOUR HONOR I MEAN, IT'S A STATE COURT CASE THE QUESTION IS WHETHER OR NOT THEIR CAUSES OF ACTION ARE PREEMPTED BY THE SUPREMACY CLAUSE

THE COURT OKAY I SEE I THOUGHT YOU MEANT -- I'M WITH YOU

MR RAWL YOUR HONOR, I BELIEVE THAT CIBA VISION WOULD AGREE THAT IF THE COURT FINDS THAT THE PRODUCT AT ISSUE HERE IS A COSMETIC AND NOT A MEDICAL DEVICE, THEN THE PREEMPTION DOES NOT APPLY AND THEIR

MOTION FOR SUMMARY JUDGMENT SHOULD BE DENIED THAT IS OUR PRIMARY FOCUS TODAY, YOUR HONOR I HAVE ADMISSIONS FROM THE COMPANY IN THEIR OWN 30(B)(6) DEPOSITION THAT THE PRODUCT AT ISSUE IN THIS CASE IS A COSMETIC

THE COURT WHERE IS THAT? HAS THAT BEEN SUBMITTED?

MR RAWL I HAVE THE EXCERPTS OF THE DEPOSITION, OF THEIR 30(B)(6)

THE COURT WELL, I CAN'T READ THEM IF --

MR RAWL MAY I BRING IT UP, YOUR HONOR?

THE COURT SURE

(DOCUMENT HANDED TO THE COURT)

MR RAWL AND ALL OF THESE DEPOSITIONS HAVE BEEN FILED THESE ARE JUST THE EXCERPTS THAT WE NEED TO GO THROUGH FOR THE PURPOSES OF DEFEATING THE MOTION AT ISSUE, YOUR HONOR AND IF I CAN JUST WALK YOU THROUGH VERY BRIEFLY, I CAN DEMONSTRATE WHY THIS IS A COSMETIC --

THE COURT THESE ARE 30(B)6?

MR RAWL THESE ARE EXCERPTS FROM CIBA VISION'S 30(B)6 DEPOSITIONS AND CIBA VISION'S OWN INTERNAL DOCUMENTS AND EXHIBIT 1, YOUR HONOR, IS THE DEPOSITION FIRST OF PAUL ORIS WHO IS CIBA VISION'S HEAD OF GLOBAL REGULATORY AFFAIRS AND WAS DESIGNATED

FOR REGULATORY AND THE ISSUE SPECIFIC TO THIS PREEMPTION AND, YOUR HONOR, ON PAGE 38 WHICH IS BEHIND TAB 1 WE ASKED CIBA VISION THE FIRST QUESTION, WHICH IS, "HAS CIBA VISION EVER SOUGHT EITHER 510K CLEARANCE OR PMA CLEARANCE FOR PLANO COLOR CONTACT LENSES?" "NO "

SO THE WHOLE PMA APPLICATION THAT CIBA VISION IS CLAIMING THEY WENT THROUGH WAS NEVER SOUGHT FOR THE NON-CORRECTIVE CONTACT LENSES THAT WE HAVE HERE TODAY

MR MUNSON YOUR HONOR, I WOULD OBJECT TO HIS READING OF THE TRANSCRIPT IT SAYS SPECIFICALLY FOR PLANO CONTACT LENSES THE AFFIDAVIT OF PAUL ORIS CLEARLY STATES THAT THEY OBTAINED PMA APPROVAL WITH A RANGE THAT INCLUDED PLANO LENSES BUT THE ANSWER TO THIS QUESTION IS SPECIFICALLY PLANO LENSES

MR RAWL AND THE FDA REQUIRES YOU TO SEEK APPROVAL FOR EACH USE, EACH INDICATION THAT THE PARTY WANTS TO USE THEIR PRODUCT FOR AND THEY WOULD HAVE HAD TO HAVE MOVED SPECIFICALLY TO GET APPROVAL FOR A PLANO LENS

IF YOU GO TO EXHIBIT -- EXCUSE ME, TAB 2 -- I ASKED MR PHILLIP PHILLIPS WHO IS CIBA VISION'S FDA EXPERT, WHO IS ONE OF THEIR -- THEY -- HE DID AN AFFIDAVIT IN THEIR SUPPORT AND ON PAGE 45 OF

MR PHILLIPS' EXCERPT THE QUESTION IS "WITHOUT A PMA APPROVAL FOR A 510K APPROVAL, WHAT IS YOUR UNDERSTANDING OF PREEMPTIVE EFFECT OF FDA LAW OVER THAT PRODUCT?" AND HE ANSWERS "WITHOUT THE PMA 510K, WELL, I DON'T BELIEVE THERE IS ANY PREEMPTION "

AND SO THEIR 30(B)6 SAID THAT THEY DID NOT SEEK PMA APPROVAL OR 510K APPROVAL THEIR OWN EXPERT SAYS WITHOUT SEEKING THAT THERE IS NO PREEMPTION

IF YOU GO TO TAB 3, YOUR HONOR, THIS IS AN INTERNAL EMAIL WITHIN CIBA VISION AND RICK WISEBARTH IS A VERY UPWARD LEVEL VICE-PRESIDENT OF CIBA VISION, AND THIS IS BEING REPORTED TO HIM, THAT IN APRIL OF 2003 CIBA VISION RECEIVED THE FEDERAL REGISTERED NOTICE AND GUIDANCE ABOUT DECORATIVE CONTACT LENSES

AND WHAT IS HIGHLIGHTED THERE SAYS "THE FEDERAL REGISTER NOTICE STATES THAT BY REGULATION DECORATIVE CONTACT LENSES ARE COSMETICS, NOT A MEDICAL DEVICE BECAUSE THEY ARE NOT FOR PROSTHETIC OR VISUAL CORRECTION "

AND THEN BEHIND THAT EMAIL IS THE ACTUAL RELEASE THAT THE FDA DID IN APRIL OF 2003 EXPLAINING TO ALL OF THE INDUSTRY IN THE BACKGROUND SECTION THAT COSMETIC OR DECORATIVE NON-CORRECTIVE CONTACT LENSES ARE COSMETICS, NOT MEDICAL DEVICESAND THE FDA CANNOT

REGULATE THEM AS MEDICAL DEVICES AND I'VE HIGHLIGHTED THE APPLICABLE SECTIONS OF THE FDA STATEMENT IN THE FEDERAL REGISTER

AND WHAT THE FDA SAYS IS THAT EYE CARE PROFESSIONAL INVOLVEMENT IS LEGALLY REQUIRED FOR CONTACT LENSES INTENDED FOR A MEDICAL PURPOSE, I E , PROSTHETIC USE OR VISUAL CORRECTION "THESE PRODUCTS ARE REGULATED BY THE FDA AS MEDICAL DEVICES UNDER THE FEDERAL DRUG AND COSMETIC ACT SUCH CONTROL IS NOT AVAILABLE FOR DECORATIVE CONTACT LENSES BECAUSE THESE PRODUCTS ARE COSMETICS UNDER THE SECTION "

SECTION 201(I) OF THE ACT DEFINES COSMETIC TO INCLUDE "ARTICLES 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, LENDING TO ATTRACTIVENESS OR ALTERING APPEARANCE DECORATIVE CONTACT LENSES ARE ARTICLES INTENDED TO BE INTRODUCED INTO THE EYE WHICH IS PART OF THE BODY TO BEAUTIFY THE WEARER, PROMOTE THE ATTRACTIVENESS OF THE WEARER OR ALTER THE WEARER'S APPEARANCE "

AND THEN BELOW IT, THE FDA INDICATES THAT DECORATIVE CONTACT LENSES ARE PROPERLY REGULATED AS COSMETICS UNDER THE ACT YOUR HONOR, WITH THAT DEFINITION OF COSMETICS --

THE COURT I'LL READ IT GO AHEAD

MR RAWL -- I ASKED THAT SAME 30(B)(6) WITNESS, PAUL ORIS, WHETHER OR NOT THE LENSES AT ISSUE IN THIS CASE MEET THAT DEFINITION AND IF YOU LOOK BEHIND TAB 7 ON THE LAST PAGE OF THE DEPOSITION EXCERPT WHICH IS PAGE 83, THE SECOND PORTION THAT IS HIGHLIGHTED, I ASKED "AND WOULD YOU AGREE THAT THE PLANO COLOR CONTACT LENS AT ISSUE IN THIS CASE IS INTENDED TO BE INTRODUCED INTO THE EYE FOR THE PURPOSE OF EITHER BEAUTIFYING, PROMOTING ATTRACTIVENESS OR ALTERING THE APPEARANCE?" AND THE WITNESS ANSWERED YES THAT WAS THE EXACT QUOTE OUT OF THE FDA REGULATION STATING WHAT IS A COSMETIC AND WHAT IS NOT A COSMETIC

YOUR HONOR, IF YOU LOOK TO PAGE OR TAB 4, TAB 4 IS A WARNING LETTER THAT WAS SENT OUT SHORTLY AFTER THE FDA ISSUED ITS NOTICE IN APRIL OF 2003 TO A COMPANY THAT WAS SELLING COSMETIC NON-CORRECTIVE COLOR CONTACT LENSES AND THE FDA IN THIS LETTER STATED ON THE SECOND PARAGRAPH, "BECAUSE YOUR FIRM'S CONTACT LENSES ARE INTENDED SOLELY TO CHANGE THE APPEARANCE OF THE NORMAL EYE IN A DECORATIVE FASHION, THEY ARE COSMETICS WITHIN THE MEANING OF THE STATUTE "

YOUR HONOR, I ASKED THE SAME 30(B)(6) WITNESS,

MR ORIS, ON BEHALF OF CIBA VISION BACK BEHIND TAB 7, THE SAME PAGE, 83, THE FIRST THING IS HIGHLIGHTED, I SAID, "AND I BELIEVE WE SAID EARLIER THAT THE CONTACT LENS AT ISSUE IN THIS CASE IS A PLANO COLOR CONTACT LENS INTENDED SOLELY TO CHANGE THE APPEARANCE OF THE NORMAL EYE IN A DECORATIVE FASHION?" AND THE WITNESS ANSWERED YES SO THAT IS THE EXACT DEFINITION THAT IN THE LETTER, THE WARNING LETTER SENT OUT BY THE FDA, THE FDA SAID WAS A COSMETIC

YOU KNOW, WANTING TO MAKE SURE THAT THERE WAS NO ISSUE IN THIS DEFINITION, I ALSO ASKED CIBA VISION'S FDA EXPERT, MR PHILLIPS, IF HE AGREED WITH THAT STATEMENT AND IF YOU LOOK AT TAB 5, YOUR HONOR, BEHIND TAB 5, THE FIRST PAGE, AND IT'S HIGHLIGHTED THERE, I ASKED CIBA VISION'S FDA EXPERT ABOUT THE EXACT SAME QUESTION I ASKED THE 30(B)(6) WITNESS

THE QUESTION IS "YOU AGREE THAT A CONTACT LENS INTENDED SOLELY TO CHANGE THE APPEARANCE OF THE NORMAL EYE IN A DECORATIVE FASHION WOULD BE CONSIDERED TO BE A COSMETIC UNDER THE ACT?" AND THE ANSWER WAS YES

ON THE FOLLOWING PAGE I MADE SURE THAT APPLIED TO CIBA VISION AND THE QUESTION WAS "YOU WOULD AGREE THAT CIBA VISION'S COLOR PLANO CONTACT LENSES IF THEY WERE INTENDED SOLELY TO CHANGE THE APPEARANCE

OF THE NORMAL EYE IN A DECORATIVE FASHION WOULD BE CONSIDERED COSMETICS UNDER THE MEANING OF THE ACT?" AGAIN THE ANSWER IS YES

AND KEEP IN MIND THAT THE FACT WITNESS, THE 30(B)(6) WITNESS OF CIBA VISION, ADMITTED THAT'S EXACTLY WHAT THEY DID AND SO CIBA VISION HAS ADMITTED THAT THIS CONTACT LENS AT ISSUE IN THIS CASE IS A COSMETIC UNDER THE ACT

BUT IT GOES FURTHER THAN THAT, YOUR HONOR BEHIND TAB 6 --

THE COURT I'VE READ IT

MR RAWL TAB 6 IS SIMPLY -- I'LL JUST SAY WHAT IT IS OKAY THAT IS AN ADMISSION BY CIBA VISION IN A LETTER TO THE FDA THAT THEY NOTED THEIR OWN CONTACT LENSES ARE COSMETICS

THE COURT RIGHT

MR RAWL AND BEHIND TAB 7, YOUR HONOR, I ASKED ABOUT THE LETTER BEHIND TAB 6 AND THE STATEMENT TO THE FDA, THAT THE CONTACT LENS AT ISSUE WAS A COSMETIC AND THE HIGHLIGHTED PORTION SAYS THAT, YES, THE 30(B)(6) WITNESS ON BEHALF OF CIBA VISION SAID, "CURRENTLY PLANO COLOR CONTACT LENSES HAVE RECEIVED A COSMETIC DESIGNATION " I ASKED IF HE AGREED WITH THAT STATEMENT, AND HE SAID, "THAT'S WHAT IT SAYS, YES "

AND THE QUESTION IS, "SO AS OF DECEMBER THE 9TH, 2003, PLANO COLOR CONTACT LENSES WERE DESIGNATED AS COSMETIC BY THE FDA, CORRECT?" THE WITNESS SAYS YES "AND IT'S YOUR UNDERSTANDING THAT IF A CONTACT LENS IS DESIGNATED AS A COSMETIC IT'S NOT DESIGNATED AS A MEDICAL DEVICE?" THE WITNESS AT THAT POINT EXPLAINED "IT'S ALWAYS BEEN A MEDICAL DEVICE IN OUR COMPANY " AND I SAID, "MEANING THAT CIBA VISION HAS ALWAYS TREATED ALL CONTACT LENSES AS IF THEY WERE MEDICAL DEVICES?"

"A THAT'S CORRECT

"Q BUT CIBA VISION ACKNOWLEDGES IN THIS DOCUMENT THAT PLANO COLOR CONTACT LENSES RECEIVED A COSMETIC DESIGNATION AS OPPOSED TO A MEDICAL DEVICE, CORRECT?"

THE WITNESS SAYS YES

IF YOU LOOK BEHIND TAB 8, YOUR HONOR, THAT IS ANOTHER 30(B)(6) DESIGNEE ON BEHALF --

THE COURT LET ME HEAR FROM MR MUNSON I THINK YOU'VE AT LEAST CREATED AN ISSUE OF FACT

MR MUNSON WELL, YOUR HONOR, IT'S ACTUALLY NOT AN ISSUE OF FACT IT'S A ISSUE OF LAW BUT IT IS CLEARLY AN ISSUE IS IT A COSMETIC? IS IT A MEDICAL DEVICE? ONE OF THE BIG PROBLEMS, YOU HAVE SHIPS SAILING THROUGH THE NIGHT, IS THAT IT CAN BE BOTH A

COSMETIC AND A MEDICAL DEVICE AND IF IT IS BOTH, IT'S REGULATED AS A MEDICAL DEVICE AND THAT'S THE SITUATION THAT WE HAVE HERE THE --

THE COURT HOW CAN IT BE BOTH?

MR MUNSON IT CAN BE -- HERE'S HOW IT CAN BE BOTH IN THIS CASE, AND THIS IS ADMITTED TO BY THEIR EXPERT IN HER DEPOSITION --

THE COURT IT'S NOT YOUR EXPERT

MR MUNSON I MEAN THEIR EXPERT, SUZANNE PARISIAN, WILL ACKNOWLEDGE THIS

THE COURT AND YOUR EXPERT SAYS THAT --

MR MUNSON MY EXPERT SAYS IT CAN BE BOTH HE GAVE YOU ONE PAGE OUT OF A DEPOSITION AND SAID --

THE COURT HE GAVE ME A LOT OF THEM

MR MUNSON ASSUMING THAT --

THE COURT WHERE DOES IT SAY IT CAN BE BOTH?

MR MUNSON PHILLIPS SAYS IT THROUGHOUT THE DEPOSITION AND HE SAYS IT IN HIS AFFIDAVIT THAT IT CAN BE BOTH AND HERE IS HOW IT CAN BE BOTH, YOUR HONOR IF YOU LOOK AT THAT IMPORT DOCUMENT, THIS ONE, PRIOR TO 2003 THE FDA TREATED ALL CONTACT LENSES AS CLASS 3 MEDICAL DEVICES THAT WERE INTENDED FOR EXTENDED WEAR WHEN THIS THING CAME OUT, THIS IMPORT ALERT --

THE COURT IS THERE A DATE QUESTION HERE AS TO

WHEN?

MR MUNSON NOT REALLY, OTHER THAN SHE PURCHASED HER LENS IN 2004 WHICH WAS AFTER THIS IMPORT ALERT CAME OUT IN 2003 SO IN 2003 THIS IMPORT ALERT COMES OUT AND THE FDA SAYS IT'S POSSIBLE FOR SOME NON-CORRECTIVE DECORATIVE LENSES TO BE JUST COSMETICS, AND IF THEY ARE SOLELY DECORATIVE LENSES, THEY ARE COSMETICS, NOT MEDICAL DEVICES

THE COURT WELL, CAN YOU PURCHASE A MEDICAL DEVICE WITHOUT A PRESCRIPTION?

MR MUNSON CERTAINLY YOU CAN PURCHASE A CLASS 1 MEDICAL DEVICE WITHOUT A PRESCRIPTION A WHEELCHAIR WOULD BE A CLASS 1 MEDICAL DEVICE I DON'T BELIEVE YOU CAN PURCHASE ANY CLASS -- WELL, YOU CAN PURCHASE CLASS 2 MEDICAL DEVICES --

THE COURT 3 WE'RE TALKING ABOUT 3

MR MUNSON YOU CAN AT LEAST LET'S SAY PRIOR TO 1994 WHEN THEY HAD THIS DAILY EXTENDED WEAR SPLIT, YOUR CONTACT LENS SOLUTION IS A CLASS 3 MEDICAL DEVICE

THE COURT WELL, LET'S TALK ABOUT I MEAN THIS DEVICE CAN YOU WALK INTO A CVS AND BUY THIS DEVICE THAT YOU CALL A MEDICAL DEVICE WITHOUT A PRESCRIPTION?

MR MUNSON FDA WOULD NEVER ALLOW A PLANO LENS

TO BE PURCHASED WITHOUT A PRESCRIPTION EVEN WHEN THEY CALL THEM COSMETICS, THEY STILL REQUIRE THAT THAT YOU --

THE COURT HOW DID THIS LADY PURCHASE ONE?

MR MUNSON SHE -- KIM'S DOLLAR STORE GOT AHOLD OF SOME IN A GRAY OR BLACK MARKET OR FROM A CONSUMER WHO HAD ALREADY PURCHASED THEM USING A PRESCRIPTION, TOOK THEM INTO THEIR STORE AND SOLD THEM LIKE ANY DRUG THAT GETS SOLD, OXYCONTIN GETS SOLD ON THE CORNER, ANYTHING THAT REQUIRES A PRESCRIPTION GETS YOU THIS KIND OF ON-THE-STREET CORNER MARKET AND THAT'S WHAT THIS CASE IS, YOUR HONOR

BUT BACK TO THE FDA'S PRONOUNCEMENT ABOUT THE POSSIBILITY OF NON-CORRECTIVE DECORATIVE LENSES FALLING UNDER A COSMETIC AND NOT A MEDICAL DEVICE, THAT IMPORT IS LIMITED SOLELY TO THE SITUATION WHERE A CONTACT LENS IS SUBMITTED TO BE SOLELY FOR DECORATIVE PURPOSES THAT IS NOT THE CONTACT LENS AT ISSUE IN THIS CASE

AND ATTACHED TO OUR SUPPLEMENTAL PRODUCTION WHICH IS IN THIS NOTEBOOK IS THE PACKAGE INSERT APPROVED IN JULY OF 2003 WHICH WOULD HAVE BEEN MONTHS BEFORE SHE PURCHASED THIS THERE WOULD HAVE BEEN A PACKAGE INSERT RELATED TO THESE FRESH LOOK LENSES IT INCLUDES INDICATIONS OF USE FOR CORRECTING VISION,

FOR ENHANCING EYE COLOR AND FOR THE PROTECTION OF UV HARMFUL RAYS FOR AN EXTENDED WEAR SO YOU CAN WEAR THEM FOR UP TO SEVEN DAYS

THE TWO THINGS THAT MAKE THIS LENS NOT ELIGIBLE FOR COSMETIC DESIGNATION, OR, TO BE MORE PRECISE, EVEN THOUGH IT CAN BE A COSMETIC, IT IS ALSO A MEDICAL DEVICE, ARE AT LEAST THE FACTS THAT IT PROVIDES UV PROTECTION AND IT'S AVAILABLE FOR EXTENDED WEAR

WHAT THE FDA SAID, THAT ITS IMPACT -- THAT IMPORT ALERT WAS THAT IF IT'S GOT A MEDICAL USE OR A PHYSIOLOGICAL ASPECT TO IT, IT IS NOT SOLELY FOR DECORATIVE PURPOSES THEY USE AS AN EXAMPLE IN THAT IMPORT ALERT SUNTAN LOTION THAT INCLUDES SUN SCREEN BECOMES A DRUG BECAUSE OF ITS UV RADIATION PROTECTING CLAIMS AND USES

THIS CONTACT LENS, AND YOU CAN SEE IT FROM THE COVER OF THE BLISTER PACK, THERE'S A UV CIRCLE AROUND IT THEIR EXPERT ACKNOWLEDGES THAT MEANS THERE'S A UVA CLAIM THE PACKAGE INSERT ASSOCIATED WITH THIS LENS SAYS THAT THIS PROTECTION FROM UVA RADIATION, AND IT HAS SOME OTHER STUFF, BUT IT'S INCLUDED AS AN INDICATION OF USE FOR UVA PROTECTION

THAT THE FDA WOULD SAY MAKES THIS A COSMETIC AND A MEDICAL DEVICE WHEN IT'S BOTH, IT HAS TO BE

REGULATED AS A MEDICAL DEVICE AND PHIL PHILLIPS SAYS THAT PHIL PHILLIPS WAS WITH THE FDA IN THEIR DEVICE EVALUATION OFFICE UNTIL 2005, THROUGHOUT THIS WHOLE PERIOD, INTIMATE KNOWLEDGE OF THIS EXACT FACT

THEIR EXPERT WITNESS WHO WAS THERE AT THE BEGINNING OF 1990 NEVER HAD ANYTHING TO WITH EYE DEVICES NEVERTHELESS, SHE ACKNOWLEDGES THAT UV PROTECTION WOULD BE A MEDICAL USE, AND THAT WOULD TAKE THIS BEYOND SOLELY DECORATIVE LENSES WHICH WOULD CONTINUE IT AS A MEDICAL DEVICE

THE FACT THAT A 30(B)(6) WITNESS SAID THAT -- ACKNOWLEDGED THAT IT WAS -- THE FDA CLASSIFIED DECORATIVE LENSES AS COSMETIC IS IRRELEVANT BECAUSE THEY'RE ALSO MEDICAL DEVICES AND THEN THEY'RE BOTH REGULATED AS A MEDICAL DEVICE, THESE ARE EXTENDED WEAR CONTACTS, THEY REQUIRE PREMARKET APPROVAL PREMARKET APPROVAL INCLUDES VERIFICATION OF THE FINAL LABELING AND WARNINGS THAT MAKES IT PREEMPTED UNDER THE STATUTE BUT THAT IS A HUGE ISSUE THAT HAS TO BE RESOLVED IN THIS CASE AND IT'S A MATTER OF LAW UNFORTUNATELY, WE THINK THE COURT HAS TO RESOLVE IT

THE COURT WHAT ABOUT, WHAT IS THIS 60 FED REG 41453, SUBSECTION 9, TALKING ABOUT NON-CORRECTIVE, TINTED CONTACT LENSES? IT'S IN THE TOBACCO REGULATIONS

MR MUNSON ONE OF THE ISSUES THAT CAME UP WITH THEIR EXPERTS' DEPOSITIONS, SUZANNE PARISIAN, WAS WHETHER OR NOT FDA CONSIDERED DECORATIVE LENSES TO BE MEDICAL DEVICES PRIOR TO 2003 WHEN IT ISSUED ITS IMPORT ALERT

THE COURT WELL, THIS CITES NEW YORK, USC INTERNATIONAL HYDRON

MR MUNSON YES, YOUR HONOR WHAT THAT SHOWS IS THAT THAT'S A NOTICE SUBMITTED TO THE FEDERAL REGISTER BY THE FDA IT HAPPENED TO BE SUBSTANTIVELY ON SMOKING CIGARETTES BUT THEY DO A DETAILED ANALYSIS OF THEIR --

THE COURT WELL, THIS CITES, IT SAYS "THE AGENCY IS TAKING THE POSITION TINTED CONTACT LENSES THAT DO NOT CORRECT OR IMPROVE VISION AND ARE PROMOTED TO ENHANCE EYE COLOR ARE MEDICAL DEVICES "

MR MUNSON CORRECT

THE COURT AND CITES A FEDERAL -- I GUESS IT'S --

MR MUNSON THAT IS THE CASE IN WHICH THEY WENT INTO FEDERAL COURT AND SIGNED AN INJUNCTION AGAINST THE COMPANY TRYING TO SELL THEM NOT AS MEDICAL DEVICES AND I CAN'T -- I DON'T --

THE COURT IS THIS PRECEDENTIAL?

MR MUNSON NO

THE COURT PRECEDENTIAL?

MR MUNSON ALL IT STANDS FOR IS ACKNOWLEDGEMENT THAT THE FDA'S POSITION AS NOTED IN THERE PRIOR TO 2003 WAS THAT PLANO COLOR LENSES SOLELY FOR DECORATIVE PURPOSES WERE MEDICAL DEVICES AND THAT THEIR EXPERT IS WRONG TO SAY THEY HAD NO POSITION ON IT AND IN 2003 WAS THE FIRST TIME THEY TOOK A POSITION THEY HAD A POSITION 2003 THEY CARVED OUT AN EXCEPTION FOR SOLELY DECORATIVE CONTACT LENSES THAT WOULD NOT INCLUDE THINGS THAT HAVE MEDICAL USES, SUCH AS UVA PROTECTION OR EXTENDED WEAR OUR CONTACT BOTH HAS UVA PROTECTION AND EXTENDED WEAR THE FDA WOULD NEVER CONSIDER OUR CONTACT LENS TO BE PURELY A COSMETIC

THE COURT WHAT MAKES IT MEDICAL? UV PROTECTION?

MR MUNSON AND ITS EXTENDED -- ITS ELIGIBILITY FOR EXTENDED WEAR, BECAUSE THAT CREATES A PHYSIOLOGICAL CHANGE ON THE EYE

THE COURT YOU THINK THOSE TWO FEATURES OF LENS MOVE IT OVER INTO THE MEDICAL DEVICE CATEGORY?

MR MUNSON CORRECT AND, YOUR HONOR, I THINK THE FDA DID NOT INTEND BY THE IMPORT ALERT TO GO BACK AND RE-CLASSIFY LENSES IT HAD ALREADY CLASSIFIED AS PMA-APPROVED CLASS 3 MEDICAL DEVICES SO I ALSO

DON'T THINK IT APPLIES IN THAT RESPECT

BUT ON THE SUBSTANTIVE ANALYSIS THAT'S KIND OF SET FORTH IN THAT IMPORT ALERT, BOTH THE UVA AND THE EXTENDED WEAR WERE TAKEN OUTSIDE OF BEING SOLELY FOR DECORATIVE PURPOSES

THE COURT WHERE IS THE INSERT? DO YOU HAVE IT?

MR MUNSON YES IT'S IN THAT NOTEBOOK

THE COURT WHICH ONE?

MR MUNSON THE ONE THAT DOESN'T SAY "CITE" IT SHOULD BE THE -- IT'S THE ONE UNDER THAT

THE COURT YOU GOT A TAB?

MR MUNSON IT SHOULD BE AT TAB -- THE SUPPLEMENTAL MEMO I BELIEVE WAS ATTACHED

THE COURT IT'S NOT I DON'T SEE IT WITH THE SUPPLEMENTAL MEMO, JUST THAT TOBACCO NOTICE AND DRAFT LETTERS TO A BUNCH OF --

MR MUNSON IS THERE AN INDEX ON THE FRONT PAGE OF THAT?

THE COURT YEAH OH NO

MR MUNSON OKAY SO, IS THE FIRST THING OUR MOTION FOR SUMMARY JUDGMENT? OUR COVER SHEET?

THE COURT YES, IT IS

MR MUNSON OKAY THE FIRST TAB THERE, DOES IT SAY "SUPPLEMENTAL MEMO"?

THE COURT YES, IT DOES

MR MUNSON OKAY IT IS ATTACHED AS EXHIBIT C TO THAT MEMO TOWARDS THE BACK AND IT'S --

THE COURT IS THIS CIBA VISION PRESCRIPTION ONLY VERY, VERY, VERY SMALL PRINT?

MR MUNSON THAT'S THE PACKAGE INSERT THAT GOES WITH THIS PRODUCT, YOUR HONOR

THE COURT YOU EXPECT CONSUMERS TO READ THAT?

MR MUNSON WELL, ACTUALLY IT GOES DOCTORS, NOT CONSUMERS, BECAUSE THIS IS A PRESCRIPTION DEVICE THEN THE DOCTOR ACCESSES IT AS AN ALERTED INTERMEDIARY TO INTERACT WITH THE PATIENT, MAY OR MAY NOT GIVE THAT PACKAGE INSERT TO THE PATIENT HE MAY HAVE HIS OWN

THE COURT THIS WAS WITH THESE BLACK MARKETED LENSES?

MR MUNSON NO, YOUR HONOR THEY BROKE OPEN THE BOX AND SOLD THE LITTLE BLISTER PACK BY ITSELF THAT WOULD GO TO THE -- THAT IS THE FDA-APPROVED PACKAGE INSERT THAT GOES TO THE EYE CARE PROFESSIONAL WHO IS THE AUTHORIZED DISTRIBUTOR OF THE CONTACT LENSES WITH A PRESCRIPTION YOU'LL FIND A BETTER COPY UNDER TAB 6 OF PAUL ORIS' DEPOSITION

THE COURT WELL, --

MR MUNSON THAT'S THE SAME DOCUMENT THAT

HASN'T BEEN FAXED AND SO IT'S MORE LEGIBLE

THE COURT PAUL ORIS IS --

MR MUNSON IT SHOULD BE IN THAT SAME MEMO, YOUR HONOR

THE COURT WHO IS HE?

MR MUNSON PAUL ORIS IS THE --

THE COURT HE'S YOUR MAN?

MR MUNSON HE IS OUR REGULATORY EMPLOYEE

THE COURT AND PHILLIPS IS YOUR EXPERT?

MR MUNSON AND PHIL PHILLIPS IS OUR EXPERT AND UNDER "INDICATIONS OF USE" WHICH IS IN THE MIDDLE COLUMN DOWN TOWARDS THE BOTTOM, IT TALKS ABOUT -- IT'S AT THE VERY LAST THING IN THAT FIRST PARAGRAPH -- "FRESH LOOK SOFT CONTACT LENSES WITH UV ABSORBING PROTECTION HELP PROTECT AGAINST TRANSMISSION OF HARMFUL UVA RADIATION TO THE CORNEA AND IN THE EYE "

UNDER THE PRODUCT DESCRIPTION ON THE VERY FIRST COLUMN THERE IS ADDITIONAL DISCUSSION ABOUT THE HARMFUL NATURE OF UV RADIATION AND IN FACT A GRAPH DOWN AT THE BOTTOM TALKS ABOUT DIFFERENT LEVELS OF UV PROTECTION

THE COURT WELL, WHAT IS THE RESULT OF GRANTING YOUR MOTION?

MR MUNSON THE RESULT OF GRANTING MY MOTION, WE MAY HAVE TO TALK ABOUT THAT, BECAUSE WE THINK IT

ELIMINATES ALL THE CAUSES OF ACTION BECAUSE THEIR THEORY HAS BEEN BASED ON FAILURE TO WARN, INADEQUATE LABELING TECHNICALLY, THEY BRING -- FOR EXAMPLE, TECHNICALLY --

THE COURT NOT JUST KIM'S DOLLAR STORE?

MR MUNSON CORRECT, YOUR HONOR

THE COURT GO AHEAD

MR MUNSON TECHNICALLY, THEY BRING A CAUSE OF ACTION FOR A MANUFACTURING DEFECT, DESIGN DEFECT AND WARNING DEFECT BUT THEY DON'T HAVE THE CONTACT THEY'VE NOT IDENTIFIED ANY WARNING OR DESIGN PROBLEMS THEY DON'T HAVE AN EXPERT ON THOSE THINGS SO IT MAY BE THAT WE HAVE TO CLEAN SOME THINGS UP IF YOU WERE TO FIND THE FEDERAL PREEMPTIONS WERE APPLICABLE IN THIS CASE, YOUR HONOR

THE COURT BY THE OFF CHANCE JUST HOLD UP MR RAWL IS JUMPING OUT OF HIS SEAT YOU THROUGH?

MR MUNSON I AM YES, YOUR HONOR

THE COURT ALL RIGHT, MR RAWL

MR RAWL THANK YOU, YOUR HONOR FIRST OF ALL, --

THE COURT WHAT ABOUT THIS ISSUE OF IT'S BOTH?

MR RAWL FIRST OF ALL, ON THE ISSUE OF IT'S BOTH, THEIR OWN EXPERT SAID THAT IT'S NOT BOTH AT THE VERY END OF MR PHILLIPS' DEPOSITION AFTER

FRANKLY I HAD DETERMINED IT WAS A COSMETIC --

THE COURT YOU HAD?

MR RAWL AFTER -- WELL, AFTER WE'D GONE THROUGH THE DISCUSSION WHEREIN HE AGREED THAT IF THE CONTACT LENS AT ISSUE WAS SOLELY FOR DECORATIVE PURPOSES IT WOULD BE A COSMETIC, WHICH IS WHAT THEIR 30(B)(6) SAID HOW IT WAS, AND I ASKED MR PHILLIPS, YOU KNOW, IT'S AT LINE 13 "SO IF CIBA VISION WERE TO TAKE THE POSITION THAT ITS PLANO COLOR CONTACT LENSES WERE INTENDED ONLY AS A DECORATIVE FUNCTION AND DID NOT CLAIM INTENDED USE TO CHANGE THE STRUCTURE OR THE FORM, THEN IT WOULD ONLY BE A COSMETIC AND NOT A MEDICAL DEVICE, CORRECT?" HE STARTED TO GIVE ANOTHER ANSWER I SAID, "PLEASE ANSWER MY QUESTION FIRST DO YOU NEED ME TO READ IT BACK?"

"A YOU DON'T NEED TO READ IT BACK MY ANSWER IS YES"

NOW, RESPECTFULLY, YOUR HONOR, MR MUNSON'S STATEMENTS TO THE COURT ARE NOT EVIDENCE THAT'S JUST ARGUMENT BY COUNSEL WHAT I AM, YOU KNOW, OFFERING TO THE COURT ARE CIBA VISION'S SWORN STATEMENTS UNDER OATH OF HOW THEY INTENDED THEIR PRODUCT TO BE USED AND, YOU KNOW, WHAT THE FDA APRIL 2003 NOTICE SAID WAS, IF A DECORATIVE COLOR

CONTACT LENS, ITS ONLY PURPOSE IS TO CHANGE THE COLOR OF THE EYE, THEN IT IS A COSMETIC AND CANNOT BE REGULATED UNDER THE ACT BECAUSE IT'S NOT --

THE COURT WELL, I UNDERSTAND THAT WHAT ABOUT THIS UV PROTECTION AND EXTENDED WEAR FEATURE OF THIS LENS?

MR RAWL THOSE ARE COMPLETE RED HERRINGS, YOUR HONOR AND THE PURPOSE, IF YOU LOOK AT THE DEFINITION OF A COSMETIC VERSUS A MEDICAL DEVICE, AND I CITE THAT IN MY -- IT TALKS ABOUT ITS INTENDED USE, THAT A COSMETIC IS INTENDED TO BE DECORATIVE AND A MEDICAL DEVICE IS INTENDED FOR MEDICAL USE

THE COURT WELL, --

MR RAWL AND, YOUR HONOR, --

THE COURT -- WAIT ARE YOU SAYING THAT UV PROTECTION IS INTENDED TO BE COSMETIC?

MR RAWL YOUR HONOR, I'M SAYING THAT THE COMPANY NEVER MADE ANY CLAIMS -- AND "CLAIM" IS A TECHNICAL TERM -- OR INTENDED OR MARKETED THE PRODUCT AS A UV PROTECTANT OKAY

FOR EXAMPLE, YOUR HONOR, ON THE SUNTAN LOTION EXAMPLE, SUNTAN LOTION THAT IS MARKETED WITH WHAT'S CALLED UV PROTECTION WHERE IT SAYS, YOU KNOW, SPF 10 OR 15, --

THE COURT YEAH I KNOW ALL THAT

MR RAWL -- IT HAS A SKIN SOFTENER IN IT, IF THE COMPANY MARKETS IT AS SUN SCREEN, THEN IT IS A DRUG HOWEVER, IF IT IS MARKETED AS A CONDITIONING CREME THAT HAPPENS TO HAVE SPF IN IT AND THEY'RE NOT MARKETING THE SPF, THEN IT IS A COSMETIC THE WHOLE LAW IN THIS AREA DEPENDS UPON THE INTENDED USE

THE COURT LET ME ASK YOU THIS WHAT'S THIS LITTLE -- IN THIS EXHIBIT C WHICH IS THE PRODUCT INSERT, WHAT'S THIS LITTLE LOGO AT THE TOP? IT SAYS "RX ONLY"? WHAT DOES THAT MEAN?

MR RAWL YOUR HONOR, THAT IS HONORED BY THE FDA, THAT THEY ALLOWED THAT LITTLE THING FOR PRESCRIPTION DEVICES TO HAVE "RX ONLY" AS OPPOSED TO "CAUTION FEDERAL LAW PROHIBITS THE DISTRIBUTION OF THIS DEVICE WITHOUT A PRESCRIPTION"

THE COURT SO IF YOU BUY THIS DEVICE, IT'S SUPPOSED TO BE DISTRIBUTED BY A PRESCRIPTION ONLY?

MR RAWL YOUR HONOR, IF IT ACTUALLY WAS A DEVICE, MEANING IF IT ACTUALLY WAS A MEDICAL DEVICE, THEN IT WOULD HAVE TO BE DISTRIBUTED BY PRESCRIPTION ONLY

THE COURT HOW DOES THE CONSUMER KNOW THAT?

MR RAWL THE CONSUMER DOESN'T KNOW THAT AND WHAT MR MUNSON EXPLAINED TO YOU IS THAT PACKAGE INSERT IS KIND OF A MISNOMER THERE IS NO PACKAGE

INSERT IN A BOX OF COLOR CONTACT LENSES THAT PAGE IS SENT ONLY TO DOCTORS

THE COURT NAKED?

MR RAWL NAKED, JUST LIKE THAT THEY GET A STACK OF THEM DOCTORS GET A STACK OF THOSE

THE COURT A STACK OF PAPERS

MR RAWL A STACK OF PAPERS

THE COURT WITHOUT THE LENSES?

MR RAWL WITHOUT THE LENSES YOU KNOW, YOUR HONOR, THAT IS NOT GIVEN --

THE COURT YOU MEAN DOCTORS JUST SIT AROUND AND READ THESE THINGS?

MR RAWL I HAVE NO IDEA WHAT DOCTORS DO, YOUR HONOR ALL I KNOW IS THEIR 30(B)(6) WITNESS TESTIFIED THERE IS NO PACKAGE INSERT THAT PAGE IS NOT FOLDED UP INTO A LITTLE SQUARE AND PUT INTO A BOX OF CONTACT LENSES

THE COURT WELL, IS IT PUT INTO A CASE THOUGH?

MR RAWL IT IS NOT PUT INTO ANY PACKAGING OF CONTACT LENSES THERE IS ABSOLUTELY NO WARNING WHATSOEVER EITHER ON THE BLISTER PACK OR ON THE BOX OF SIX CONTACT LENSES

AND, YOUR HONOR, YOU KNOW, THIS IS BEYOND THE SCOPE OF THIS MOTION I HAVE EVIDENCE THAT THEY PRODUCED THAT WE DISCUSSED IN 30(B)(6) MOTIONS THAT

THEY'RE SELLING MILLIONS, JUST ONE COMPANY, 3 7 MILLION DOLLARS WORTH OF DECORATIVE CONTACT LENSES TO A COMPANY THAT THEY HAVE NO IDEA WHAT THEY'RE DOING WITH THEM SO THIS IS NOT AN ISOLATED EVENT

BUT FOR PURPOSES OF THIS MOTION, IF YOU LOOK ON THAT PAGE, THE KEY WORD IS "INTENDED TO" AND THE ONLY INDICATION ON THAT PAGE IS UNDER "INDICATIONS" WHERE IT SAYS "THIS PRODUCT IS INTENDED" --

THE COURT WHERE IS THIS?

MR RAWL THAT IS UNDER "INDICATIONS" ON THE MIDDLE OF THE -- I DON'T HAVE IT IN FRONT OF ME, YOUR HONOR

THE COURT WELL,

MR RAWL ON THE MIDDLE OF THE PAGE WHERE IT SAYS "INDICATIONS"

THE COURT HOLD ON I SEE "ACTIONS"

MR RAWL IT'S BELOW "ACTIONS"

THE COURT "INDICATIONS" ALL RIGHT

MR RAWL YOU KNOW, THE KEY WORD THAT HAS TO BE USED FOR THE FDA IS "INTENDED" AND SO, WHAT IT SAYS IS THE INTENDED USE IS TO CORRECT VISUAL ACUITY, WHICH IS THE ONLY THING --

THE COURT WHOA, WHOA WHERE? WHERE DOES IT SAY THAT?

MR RAWL I APOLOGIZE

MR MUNSON I'D LOOK AT 6, TOO, PAUL ORIS', BECAUSE IT'S EASIER TO READ IF THE JUDGE CAN READ IT AS EXHIBIT C FAXED, I'M IMPRESSED I CANNOT

THE COURT I NEED SOME CORRECTIVE LENSES I MEAN, THIS IS CIBA VISION'S DOCUMENT

MR RAWL RIGHT AND WHAT IT SAYS IS THE FRESH LOOK COLORS SOFT CONTACT LENSES --

THE COURT HEY, MR --

MR RAWL I APOLOGIZE

THE COURT -- RAWL, THIS THING IS EXTREMELY DIFFICULT TO READ ALL I NEED IS YOU TO POINT ME TO WHERE YOU'RE READING, THE FIRST COLUMN, THE SECOND COLUMN, THE THIRD

MR RAWL MAY I APPROACH?

THE COURT SURE

MR RAWL I'M NOT SURE EXACTLY WHAT YOU'RE LOOKING AT RIGHT HERE WHERE IT'S HIGHLIGHTED AND IT SAYS "VISUAL CORRECTION"

THE COURT YEAH

MR RAWL AND IT SAYS "SPHERICAL"

THE COURT "SPHERICAL" ALL RIGHT I'VE GOT IT I HIGHLIGHTED THAT I FOUND IT

MR RAWL YES, SIR

THE COURT BUT I DIDN'T -- GO AHEAD FRESH LOOK'S SPHERICAL --

MR RAWL WHAT IT SAYS, WHAT CIBA VISION HAS TO DO IS TELL SPECIFICALLY THE FDA WHAT IT WANTS TO MARKET THIS PRODUCT AS AND THAT'S WHAT'S CALLED AN INTENDED USE AND WHERE IT SAYS "VISUAL CORRECTION", THAT IS THE ONLY THING THAT --

THE COURT "CORRECTION OF VISUAL ACUITY" --

MR RAWL RIGHT

THE COURT -- "IN PERSONS WITH NON-DISEASED EYES OR MYOPIC OR HYPEROPIC AND MAY EXHIBIT REFRACTIVE ASTIGMATISM " RIGHT?

MR RAWL AND WHERE IT SAYS "INTENDED TO", THAT IS THE ONLY THING THAT CIBA VISION REQUESTED THE FDA PERMISSION TO DO THEY DID NOT REQUEST PERMISSION TO SELL IT IN ANOTHER MANNER AND I CONFIRMED THAT IT GOES ON TO SAY OTHER THINGS THAT THE LENSES ACT TO DO, BUT THE ONLY THING THAT CIBA VISION CAN SELL IT FOR IS WHAT IS IT INTENDED TO DO AND I CONFIRMED THAT --

THE COURT IS IT NOT INTENDED FOR THE CORRECTION OF VISUAL ACUITY?

MR RAWL EXACTLY AND I CONFIRMED THAT WITH THE 30(B)(6) WITNESS

THE COURT WELL, THAT DOESN'T SOUND LIKE A COSMETIC TO US

MR RAWL CORRECT THAT IS NOT THE DEVICE THAT

WAS SOLD TO MY CLIENT THAT IS A PMA -- THAT IS A PAPER FOR A MEDICAL DEVICE THAT ONLY COVERS CORRECTIVE LENSES WHAT THEY SOLD THOUGH --

THE COURT THIS IS NOT EVEN PART OF THIS CASE?

MR RAWL RIGHT, YOUR HONOR IT'S NOT THEY NEVER RECEIVED A PMA APPROVAL FOR A PLANO NON-CORRECTIVE LENSE THAT IS ONLY FOR A CORRECTIVE LENSE THAT ALSO CHANGES THE COLOR OF THE EYE AND, YOUR HONOR, DON'T TAKE MY WORD FOR IT I ASKED SPECIFICALLY THIS QUESTION TO THEIR OWN WITNESS AND IT'S IN THE TAB THAT I HANDED YOU

THE COURT DO YOU AGREE WITH THAT?

MR MUNSON NO, YOUR HONOR THAT'S JUST WRONG INTENDED USE IS -- IT'S CLEAR FROM THIS PACKAGE INSERT THAT ONE OF THE USES IS -- THERE'S THREE USES TO THIS LENS VISUAL CORRECTION --

THE COURT HE SAYS THIS DOESN'T EVEN APPLY TO THE LENS IN QUESTION

MR MUNSON THAT IS WRONG AS WELL, YOUR HONOR THE FDA APPROVED A PMA FOR A RANGE OF POWERS FROM A NEGATIVE TO A POSITIVE ZERO IS IN THE MIDDLE OUR EXPERT WHO WAS AT THE FDA UNTIL 2005 SAYS THAT THAT WOULD INCLUDE PLANO LENSES IF YOU LOOK AT FOOTNOTE 1 TO THE IMPORT ALERT THAT THE FDA ISSUED --

THE COURT WHERE IS THAT?

MR MUNSON -- FOOTNOTE 1 SAYS "MANUFACTURE" --

THE COURT WHERE IS THE FOOTNOTE? YOU KNOW, I'M --

MR MUNSON IT IS -- I WANT TO SAY IT'S -- IT'S TAB 3 OF THIS DOCUMENT, YOUR HONOR, TAB 3 OF THIS THE SECOND PAGE IS THAT IMPORT ALERT

THE COURT IMPORT ALERT

MR MUNSON AND ON THE SECOND PAGE OF THAT IMPORT ALERT THERE IS A FOOTNOTE ON IT

THE COURT I'VE GOT IT WAIT A MINUTE TAB 3 OF THIS?

MR MUNSON OF THAT AND THEN TURN -- THE FIRST PAGE OF TAB 3 IS --

THE COURT AUDREY

MR MUNSON -- AUDREY TURN TO THE NEXT PAGE THAT IS THE FEDERAL REGISTER IMPORT ALERT

THE COURT WHAT'S THAT YOU CALL IT?

MR MUNSON YES IMPORT ALERT 8610 ON THE SECOND PAGE OF THAT DOCUMENT IS A FOOTNOTE 1

THE COURT THERE ARE SOME LENSES?

MR MUNSON YES, YOUR HONOR THAT FOOTNOTE CONFIRMS THAT THE FDA ROUTINELY APPROVES PLANO LENSES ON SUBMISSION FOR APPROVAL WHEN THERE IS A RANGE REQUESTED SO THE THREE INTENDED USES OF THESE

CONTACT LENSES ARE VISUAL ACUITY, TO ENHANCE THE BEAUTY OF THE EYE, AND UV PROTECTION

NOW, THIS PARTICULAR CONTACT LENS DIDN'T HAVE ANY VISUAL ACUITY CORRECTION, AND SO THIS PACKAGE INSERT IS INCLUDED WITH THOSE LENSES BECAUSE OF THE OTHER USES LAID FORTH IN THE DESCRIPTION HERE, THAT IS, TO ENHANCE THE BEAUTY OF THE EYE AND TO PROVIDE ULTRAVIOLET PROTECTION

IN ADDITION, THIS ONE MAKES CLEAR THAT THESE ARE EXTENDED WEAR LENSES WHICH CAUSE PHYSIOLOGICAL CHANGES ON THE EYE, BOTH OF WHICH WOULD MAKE THIS NOT BE MERELY A COSMETIC BUT A COSMETIC AND A DEVICE, AS SUCH REGULATED AS A DEVICE NOW, --

THE COURT DO THEY SELL DEVICES THAT ARE STRICTLY TO ENHANCE THE BEAUTY OF THE EYE?

MR MUNSON CIBA VISION DOES NOT, YOUR HONOR I DON'T KNOW HOW CLOSE WE'RE COMING TO THE END OF WHAT YOU WANT TO HEAR FROM US, BUT --

THE COURT VERY CLOSE

MR MUNSON -- IN OUR SUPPLEMENTAL RESPONSE WHICH IS THE SECOND -- IT'S THE FIRST TAB OF THIS NOTEBOOK, THE LAST PORTION OF THAT TALKS ABOUT THE FDA ACTUALLY HAS A PROCEDURE TO HELP TRY AND RESOLVE THESE PROBLEMS UNDER THE CODE OF FEDERAL REGULATIONS, IF A STATE OR A LOCALITY OR EVEN AN

INTERESTED PERSON HAS A CONCERN ABOUT HOW THE FDA WOULD TREAT SOMETHING GENERALLY, THEY CAN WRITE TO THE FDA AND ASK THEM FOR WHAT'S AN ADVISORY OPINION

THE COURT HAS THAT BEEN DONE?

MR MUNSON WE HAVE AS CIBA VISION HAD CONTACT WITH THE GENERAL COUNSEL'S OFFICE FOR THE FDA AND ASKED THEM TO ANSWER SOME OF THESE QUESTIONS WHICH THEY HAVE PREVIOUSLY IN CASES WHERE SUZANNE PARISIAN, THEIR EXPERT, HAS BEEN INVOLVED INTERVENED BECAUSE THEY DISAGREED WITH WHAT HER POSITION WAS AND FILED STATEMENTS OF INTEREST

WE'VE ASKED THEM TO DO THAT IN THIS CASE WE'VE HAD SOME PRELIMINARY DISCUSSIONS WITH THEM THEY HAVE NOT FORMALLY AGREED TO DO THAT IF THE COURT WERE TO SEND A LETTER, AND WE'VE INCLUDED A DRAFT OF WHAT THAT LETTER MIGHT BE, TO THE FDA, WE'VE SET FORTH THESE ISSUES IS IT A COSMETIC, IS IT NOT? WAS IT RATED A MEDICAL DEVICE? WERE THE PLANO LENS OF CIBA VISION'S WITHIN THIS RANGE PREMARKET APPROVED? IF THE COURT WOULD SEND THAT TO THE FDA, THAT MIGHT -- IT WOULD CERTAINLY ADD WEIGHT TO OUR REQUEST FOR THEM TO GET INVOLVED AND HELP ANSWER THESE LEGAL REGULATORY QUESTIONS

THE COURT WHAT DO YOU THINK ABOUT THAT, MR RAWL?

MR RAWL YOUR HONOR, I BELIEVE THAT IS A DELAYING TACTIC THEY HAVE ALREADY SOUGHT THE FDA APPROVAL WE'VE ACTUALLY FILED A FRIVOLOUS MOTION LETTER WE'VE PUT THEM ON NOTICE THIS IS THE FRIVOLOUS MOTION THEIR OWN --

THE COURT WELL, HE HASN'T MADE ANY MOTION

MR RAWL NO, NO, NO YOUR HONOR, YOU KNOW, I SENT THEM A LETTER WITH THE TESTIMONY OF THEIR OWN 30(B)(6) WITNESS ADMITTING THAT THIS IS A COSMETIC, ADMITTING THAT THEY INTENDED --

THE COURT WELL, CAN IT BE BOTH?

MR RAWL PARDON?

THE COURT CAN IT BE BOTH?

MR RAWL IT CANNOT BE BOTH AND THEIR OWN EXPERT --

THE COURT SO YOU SAY THEY SELL LENSES FOR ENHANCEMENT OF THE BEAUTY OF THE EYE SOLELY?

MR RAWL YOUR HONOR, I --

THE COURT IS THAT WHAT YOU'RE SAYING?

MR RAWL YOUR HONOR, THEIR OWN WITNESS SAYS IT

THE COURT SOLELY

MR RAWL SOLELY AND I'LL READ IT RIGHT BACK TO YOUR HONOR THEIR OWN WITNESS SAYS ABOUT THESE CONTACT LENSES UNDER TAB 8 -- I'M SORRY TAB --

MR MUNSON 6 ISN'T IT 6?

MR RAWL IT'S TAB 7, PAGE 83 AND THE QUESTION WAS "I BELIEVE YOU SAID EARLIER THAT THE CONTACT LENS AT ISSUE IN THIS CASE IS A PLANO COLORED CONTACT LENS INTENDED SOLELY TO CHANGE THE APPEARANCE OF THE NORMAL EYE IN A DECORATIVE FASHION?" AND I INCLUDED THE TESTIMONY I SHOWED YOU EARLIER OF THEIR EXPERT THAT SAYS, IF THAT IS THE CASE, THEN IT IS AUTOMATICALLY A COSMETIC, SOLELY A COSMETIC AND NOT A MEDICAL DEVICE THAT IS THE PAGE I HANDED UP TO YOU JUST A SECOND AGO IT USES THE EXACT SAME LANGUAGE

THE COURT YOU USED THE WORD SPECIFICALLY IN THE OTHER ONE I BELIEVE

MR MUNSON AND I WOULD ALSO NOTE, YOUR HONOR, THIS QUESTION MERELY CONFIRMS PRIOR TESTIMONY IN THE DEPOSITION AND I NOTE THAT THEY DIDN'T INCLUDE THE PRIOR TESTIMONY WHICH OBVIOUSLY IS NOT THE SAME AS THIS QUESTION AND THIS IS KIND OF A MISLEADING QUESTION HE BEGINS BY TELLING THE WITNESS "I'M JUST CONFIRMING WHAT'S BEEN SAID EARLIER " AND THIS WITNESS BY THE END OF THE DAY APPARENTLY MAY NOT HAVE BEEN PAYING CLOSE ENOUGH ATTENTION TO SEE THAT IN FACT THE QUESTION IS DIFFERENT IF IT WERE THE SAME, WE'D HAVE THOSE OTHER PAGES HERE

THE COURT WELL, WHAT ABOUT THE NEXT QUESTION?

MR MUNSON WELL, THAT IS IT'S JUST NOT SOLELY IT HAS TO BE SOLELY IN ORDER FOR IT TO BE ONLY A COSMETIC AND IT TAKES HIS ENTIRE DEPOSITION OUT OF CONTEXT IT TAKES HIS AFFIDAVIT OUT OF CONTEXT WHICH CLEARLY SHOWS THAT THESE ARE MEDICAL DEVICES I THINK IF YOU READ THE WHOLE CONTEXT, YOU WOULDN'T RESOLVE THIS SUMMARY JUDGMENT MOTION BASED ON THAT QUESTION AND ANSWER

MR RAWL YOUR HONOR, AND WHAT THE DEFENDANT IS NOT DOING IS SHOWING YOU ANY OTHER TESTIMONY THAT CONTRADICTS THIS TESTIMONY BECAUSE THERE'S NOT ANY HE IS MAKING ARGUMENT IF I COULD FINISH MY ARGUMENT FOR A FEW MORE MINUTES, I'VE STILL NOT FINISHED THE OTHER EXHIBITS THAT I HAVE THAT CLEARLY DEMONSTRATE THAT THIS WAS A CONTACT --

THE COURT WELL, I'M GOING TO GO THROUGH YOUR SUBMISSION YOU UNDERSTAND THAT

MR RAWL YES, SIR, YOUR HONOR IF I COULD JUST POINT OUT ONE OTHER THING, YOUR HONOR?

THE COURT ONE

MR RAWL YES, SIR JUST ONE BEHIND TAB 9 --

THE COURT YES, SIR

MR RAWL -- THIS IS AN E-MAIL TO JOE MALLOCK WHO IS THE CEO OF CIBA VISION AND THIS WAS AN EMAIL IN MAY OF 2003 DURING THIS TIME PERIOD AND WHAT JOE

IS BEING UPDATED ON, THE CEO IS BEING UPDATED ON IS, "I FEEL THAT I SHOULD GIVE YOU A BRIEF UPDATE ON OUR" -- O-U-R -- "PLANO COLORED CONTACT LENS ISSUES AS YOU KNOW, THE FDA TOOK THE POSITION THAT PLANO LENSES ARE NOT REGULATED AS MEDICAL DEVICES UNDER THE FDA "

THEY SENT AN EMAIL TO THEIR PRESIDENT ACKNOWLEDGING THAT THEN THEY STATE, AND THIS IS WHAT THEY DID, IS THEY HIRED A BUNCH OF LOBBYISTS TO GO TO CONGRESS TO CHANGE THE LAW THEY SAY, "WE HAVE BEEN WORKING WITH DAVID DRAKE AT OUR WASHINGTON OFFICE TO CHANGE THE LAW TO ENSURE THAT PLANO LENSES ARE REGULATED EXACTLY LIKE CORRECTIVE LENSES "

AND THAT'S WHAT THEY DID IN NOVEMBER OF 2005 THE LAW CHANGED AND THE LAW SAYS NOW EVEN PLANO NON-CORRECTIVE LENSES CAN BE DEEMED MEDICAL DEVICES AND REGULATED AS MEDICAL DEVICES BUT NOT PRIOR TO NOVEMBER OF 2005

AND WHAT IS CLEARLY AT ISSUE IN THIS MOTION RIGHT HERE IS THE SECOND PARAGRAPH TO THE LETTER TO JOE MALLOCK YOU KNOW, HE SAYS, "THE NEW LAW WILL HELP" -- IF YOU LOOK AT THE LAST LINE, HE LISTS THREE THINGS -- "PROVIDE BETTER INSULATION FROM PRODUCT LIABILITY LITIGATION FOR US ON A RELATED NOTE, WE HAVE BEEN SUED BY A TEEN FOR VISION LOSS ASSOCIATED

WITH THE PLANO COLORED CONTACT LENSES NOT PURCHASED FROM A DOCTOR "

YOU KNOW, THIS IS CIBA VISION'S ATTEMPT TO NOT BE HELD LIABLE FOR SOMETHING THAT IS HAPPENING ALL OVER THE COUNTRY, THAT THEY KNOW IS HAPPENING ALL OVER THE COUNTRY AND THEY'VE ADMITTED THAT THEY'RE SELLING LENSES SOLELY FOR THE INTENDED DECORATIVE PURPOSE

YOU KNOW, FRANKLY, ANOTHER CIBA VISION WITNESS STATED THEY SPEND 20 MILLION DOLLARS A YEAR PROMOTING COSMETIC CONTACT LENSES AND IF I CAN, YOU KNOW, I KNOW I SAID ONE LAST THING, CAN I POINT OUT ONE OTHER THING TO YOU? YOU KNOW, BEHIND TAB 8, THEIR 30(B)(6) WITNESS, I ASKED HIM, "ISN'T IT TRUE THAT THE 20-MILLION-DOLLAR NORTH AMERICAN CONSUMER MARKETING COMPAIGN WAS CIBA VISION'S LARGEST EFFORT TO PROMOTE COSMETIC CONTACT LENSES WITHIN THE PAST 20 YEARS?"

"A YES

AND I ASKED THE QUESTION -- THIS IS BEHIND TAB 8 -- "ISN'T IT TRUE THAT IN JANUARY OF 2002 THE 20-MILLION-DOLLAR FRESH LOOK CONSUMER MARKETING CAMPAIGN WAS A DEPARTURE FROM EARLIER MARKETING CAMPAIGNS FOR THE FRESH LOOK BRAND? THE NEW CAMPAIGN EMPHASIZED THE LENSE'S APPEAL AS A COSMETIC ACCESSORY LIKE NAIL POLISH, LIPSTICK OR EYE SHADOW?" AND THE

ANSWER WAS YES

THE COURT OKAY PROPOSED ORDERS, HOW MUCH TIME DO YOU NEED? UNLESS THEY'RE ALREADY DRAFTED

MR RAWL I CAN HAVE YOU ONE BY THE END OF NEXT WEEK

MR MUNSON AS WELL, YOUR HONOR

THE COURT LET'S PUT A DATE ON IT

MR RAWL I CAN ACTUALLY -- WE CAN ACTUALLY DO IT BY THIS FRIDAY IF YOU'D LIKE, YOUR HONOR

THE COURT ALL RIGHT

MR MUNSON YOUR HONOR, OBVIOUSLY I HAVE TO SUBSTANTIATE SUMMARY JUDGMENT ON MY PROPOSED ORDER SO IT'S GOING TO TAKE ME A LITTLE BIT LONGER BUT NEXT FRIDAY WOULD BE FINE

THE COURT WELL, I'M NOT PUSHING YOU THIS CASE HAS NOT REACHED THE TRIAL ROSTER, HAS IT?

MR MUNSON CORRECT, YOUR HONOR IT'S GOT A TWO, TWO AND A HALF WEEK TERM OF COURT

THE COURT IS THERE A SCHEDULING ORDER?

MR MUNSON YES THERE IS A -- THERE IS -- WELL, --

MS JONES IT'S SUBJECT TO BE SET CURRENTLY, YOUR HONOR

MR MUNSON YES BUT WE UNDERSTAND THERE AREN'T ANY TERMS THAT LARGE AVAILABLE FOR THE REST OF

THE YEAR

THE COURT HOW ABOUT -- BY THE END OF THE MONTH SUITS ME

MR RAWL WE CAN HAVE IT BY NEXT FRIDAY

MR MUNSON THAT'S NEXT THURSDAY?

MR RAWL THAT'S FINE

THE COURT NO I MEAN THE END OF SEPTEMBER GIVE YOURSELF PLENTY OF TIME

MR MUNSON HOW ABOUT WE SAY TWO WEEKS?

MR RAWL YOUR HONOR, I WOULD NOT LIKE TO DELAY ANY MORE THAN NECESSARY IF WE CAN DO IT BY NEXT FRIDAY, I'D LIKE TO GO AHEAD AND GET THIS DONE BECAUSE WE HAVE A LOT OF DISCOVERY LEFT TO DO

THE COURT THAT WILL BE THE 8TH

MR MUNSON THE 8TH OF SEPTEMBER?

THE COURT YEAH NOW, BEFORE WE DO THIS, MR OTT, DO YOU HAVE A DOG IN THIS FIGHT?

MR OTT I DO I REPRESENT CIBA VISION

THE COURT I'M SORRY WHO REPRESENTS --

MR SULLIVAN WE REPRESENT KIM'S DOLLAR WE BELIEVE IT'S A COSMETIC DEVICE ALSO, YOUR HONOR YOU NEED TO UNDERSTAND IT'S A NON-CORRECTIVE LENS YOU CAN CALL A BIRD AN ELEPHANT, BUT IT'S STILL A BIRD AND WE BELIEVE IT IS A COSMETIC DEVICE THAT'S THEIR POSITION THAT'S WHY THEY WERE ALLEGEDLY SELLING

THESE CONTACTS

THE COURT IT'S NON-CORRECTIVE?

MR SULLIVAN IT'S NON-CORRECTIVE AND, THEREFORE, WE BELIEVE IT'S SOLELY FOR --

THE COURT BUT WOULD NOT UV PROTECTION OR EXTENDED WEAR MOVE IT OVER INTO THE MEDICAL DEVICE?

MR SULLIVAN WELL, THE ISSUE -- WE DON'T KNOW BECAUSE WE DON'T KNOW WHAT SHE PURCHASED BECAUSE THE PACKAGE WAS NOT -- SHE DID NOT KEEP THE PACKAGE, THE INSERT SO WE DON'T KNOW WHAT SHE PURCHASED THE UV, I DON'T THINK -- I DON'T REALLY HAVE A POSITION ON THAT, YOUR HONOR, TO BE QUITE FRANK WITH YOU I'LL DEFER TO THE RESEARCH THEY HAVE DONE ON THAT ISSUE I DON'T TAKE A POSITION ON UV BUT WE DO THINK IT'S A COSMETIC DEVICE BECAUSE ITS SOLELY FOR THE APPEARANCE OF THE EYE

AT ONE POINT THE LAW DID CHANGE IN SOUTH CAROLINA, IN JULY OF '05, WHICH HAPPENED SUBSEQUENT TO THIS, THEY ACTUALLY ENACTED STRINGENT LAW FOR PRESCRIBING THIS IT'S A STATE LAW PRIOR TO THAT THERE WAS NO -- WE KIND OF TAKE ISSUE TO THESE PEOPLE SAYING YOU HAVE TO HAVE A PRESCRIPTION, THEY CAN'T DISPENSE IT WITHOUT A PRESCRIPTION WHEN THIS HAPPENED, BECAUSE THE LAW WAS A LITTLE BIT MURKY ON THAT ISSUE BUT THAT'S NOT REALLY --

THE COURT DO YOU WANT TO GIVE ME A CITATION?

MR SULLIVAN I DON'T HAVE THE CITATION, YOUR HONOR BUT I DON'T THINK THAT'S DISPOSITIVE OF THIS ISSUE BUT THE STATE -- IT DID CHANGE IN JULY OF '05 I BELIEVE BOTH COUNSEL HAS THAT STATUTE I DO NOT HAVE THAT

THE COURT ALL RIGHT AND THIS WAS PURCHASED WHEN?

MR SULLIVAN 2004

THE COURT SOMETIME IN '04?

MR SULLIVAN CORRECT, YOUR HONOR

MR MUNSON YOUR HONOR, ON THAT POINT, YOU JUST MIGHT WANT TO MAKE A NOTE THAT EXHIBIT 4 TO PAUL ORIS' DEPOSITION IS THE BLISTER PACK AND IT DOES HAVE THE "RX ONLY" ON THE INDIVIDUAL BLISTER PACK AND THE UV --

THE COURT WELL, WHERE IS THAT?

MR MUNSON IT'S EXHIBIT 4 IT'S A LOT OF PLACES BUT EXHIBIT 4 OF PAUL ORIS'S DEPOSITION IS IN THAT BIG NOTEBOOK

THE COURT IN WHICH?

MR MUNSON THE --

THE COURT JUST HOLD ON A MINUTE EXHIBIT 4

MR MUNSON EXHIBIT 4

THE COURT FRESH LOOK COLORS

MR MUNSON YES

THE COURT "RX ONLY"

MR MUNSON IT'S NOT THE ACTUAL ONE, BUT THIS IS THE ONE THAT'S BEEN PRESENTED TO US AS WHAT THE PLAINTIFF SAYS IS THE TYPE OF LENS SO, FOR THE PURPOSES OF THIS MOTION, THAT'S WHAT IT IS

THE COURT YOU AGREE WITH THAT?

MR RAWL YES, SIR, YOUR HONOR

THE COURT ALL RIGHT SEPTEMBER THE 8TH

MR MUNSON THANK YOU, YOUR HONOR

THE COURT THANK YOU

(WHEREUPON, THE PROCEEDINGS ARE CONCLUDED)

COPY OF TRANSCRIPT

IN THE COURT OF COMMON PLEAS
STATE OF SOUTH CAROLINA
COUNTY OF RICHLAND

MONICA WESTON,

Plaintiff,

vs CASE NO 05-CP-40-0655

KIMS DOLLAR STORE and CIBA VISION, a division of Novartis Company,

Defendants

30(b)(6) DEPOSITION OF

SEO HA

August 9, 2005
10 05 a m

Young & Sullivan
907 Calhoun Street
Columbia, South Carolina

Ashley James, Court Reporter

Alexander Gallo & Associates, Inc.
COURT REPORTING VIDEO SERVICES
TRIAL PRESENTATIONS
ATLANTA'S TECHNOLOGICAL LEADERS IN LITIGATION SUPPORT & MULTIMEDIA PRESENTATIONS

RECEIVED
SEP 12 2005
McNair Law Firm, PA

ATLANTA GEORGIA WASHINGTON DC CHICAGO ILLINOIS NEW YORK NEW JERSEY

Telephone (404) 495 0777
Facsimile (404) 495 0766
Toll Free (877) 495 0777

Complimentary Conference Rooms
Throughout Georgia And
Major Cities Nationwide

500 The Candler Building
127 Peachtree Street
Atlanta Georgia 30303

business name

Q Okay Is the business located here in Columbia?

[Question translated]

A Yeah

MR FORKER Yes

Q Does he know where?

[Question translated]

MR FORKER At the Decker -- [inaudible]

Q Why did you begin purchasing contact lenses from SK Enterprises?

[Question translated]

MR FORKER When the SK Enterprises sales person came to his store and introduced his contact lenses, he asked the sales person, which is operating in Atlanta, Georgia, he asked the question to the sales person, he won't have any problem selling the contact lens and the sales person told him that everybody's doing -- everybody's selling the contact lens, there is no problem selling the contact lens That's why he started have a -- [inaudible]

Q To the best of your knowledge,

when did that person come to your store?

[Question translated]

MR FORKER He cannot remember exact month or date, but the weather was kind of cold --

[Discussion between translator and deponent]

MR FORKER Yeah, 2003 So he assumes it sometime in beginning of the 2003

Q Did you purchase any items from SK Enterprises prior to that time?

[Question translated]

A No

MR FORKER No

Q Other than contact lenses, did you ever purchase anything else from SK Enterprises?

[Question translated]

A No

MR FORKER No

Q What was the name of the sales person?

[Question translated]

MR FORKER All he remembers, the last name is Mr Lee, L-e-e He cannot

Q Do you recall seeing the letters Rx on any of the information that you received regarding the contact lenses, the boxes or the instructions?

[Question translated]

A No

MR FORKER No

Q To your knowledge, has Kims Dollar Plus or Kims Beauty had any business dealings with a company called CIBA Vision?

[Question translated]

MR FORKER What was the company name?

MS WILSON CIBA Vision

[Question translated]

A No

MR FORKER No

Q Do you have any knowledge with regard to how the contact lenses that were sold at Kims Dollar Plus or Kims Beauty were designed?

[Question translated]

THE WITNESS Designed?

MR FORKER Yes

[Discussion between translator and

deponent]

MR FORKER He does not know the designs, but all he's aware is the contact lens doesn't have any -- the power except the colors

Q What do you mean by power?

MR FORKER Like optometrist prescribe the 1 5 or 1 7, whatever the power, but the contact lens does not have that prescription It's just plain contacts with colors --

Q Was it your understanding that anybody could wear these contacts?

MR WHANG There was no focus for the lens --

MS WILSON Um-huh [yes]

MR FORKER And your question was?

Q For example, you wear glasses Is it your understanding that both he and I could wear the same contact lenses?

[Question translated]

A Yeah

MR FORKER Yes

Q To your knowledge, have you ever

had any communications with any employees or representatives of a company called CIBA Vision?

[Question translated]

A No

MR FORKER No

Q To your knowledge, has Kims Dollar Plus or Kims Beauty had any business dealings or communications with a company called Novartis?

[Question translated]

MR FORKER Novaris?

Q Novartis, N-o-v-a-r-t-i-s?

MR FORKER N-o-v-a-r-t-i-s

A No

MR FORKER No

Q Did you have any trouble returning your excess contact lenses to SK Enterprises?

[Question translated]

MR FORKER No

Q Did you tell them why you were returning the contact lenses?

[Question translated]

MR FORKER Yes He told them that he's returning because DHEC, not to --

not allowed to sell the contact lenses

Q And what was the owner's response, if any?

[Question translated]

MR FORKER The SK Enterprise says everybody's selling, don't understand why it's only Columbia accept the return of contact lenses

Q Do you know where SK Enterprises acquired the contacts that it sold to you?

[Question translated]

[Discussion between deponent and translator]

MR FORKER No

MS WILSON That's all the questions I have right now I might have a couple of follow-up questions when he gets done

[Translated]

[OFF THE RECORD]

EXAMINATION

BY-MR MELLING

Q Mr Ha, my name is Andrew Melling with the McNair Law Firm, and I represent the plaintiff in this lawsuit

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING & REGULATION
BEFORE THE BOARD OF EXAMINERS IN OPTICIANRY

110 Centerview Drive P O Box 11329
Columbia, SC 29211-1329
(803) 896-4681

00552

In the Matter of

KIM'S DOLLAR PLUS
4119 W BELTLINE BLVD
COLUMBIA, SC 29204

Respondent

ORDER TO CEASE AND DESIST THE PRACTICE OF OPTICIANRY



WHEREAS it appears that you have engaged in the practice of opticianry without being duly licensed as required by law by dispensing contact lenses, to include non-corrective, colored or patterned cosmetic lenses without a prescription, and

WHEREAS you are not currently licensed or authorized by the South Carolina Board of Examiners in Opticianry to engage in the practice of opticianry and

WHEREAS this Order is authorized by Sections 40-38-30 and 40-1-100(A) of the Code of Laws of the State of South Carolina (1976 as amended)

THEREFORE, YOU ARE HEREBY NOTIFIED AND EXPRESSLY ORDERED to immediately cease and desist from engaging in the practice of opticianry as defined by S C Code Ann § 40-38-5 *et seq* (2001) until such time, if ever, as you may be properly authorized by the Board in accordance with law Upon application, you must personally appear before the Board or its designee to review your qualifications for licensure

VIOLATIONS MAY BE PUNISHED BY THE IMPOSITION OF CIVIL PENALTIES IN AMOUNTS OF UP TO $10,000 00 FOR EACH VIOLATION, AND CRIMINAL PENALTIES WHICH MAY INCLUDE FINES OR IMPRISONMENT, AS PROVIDED BY LAW

AND IT IS SO ORDERED

SOUTH CAROLINA BOARD OF EXAMINERS IN OPTICIANRY

July 12, 2004
Date

BY Angela M. Combs
Angela M Combs Administrator

Accepted by X SEE SIK HA SEE SIK HA

Served by Meyer Johnson

Original (White) to Office Canary copy to recipient Pink copy to file

IN THE COURT OF COMMON PLEAS
STATE OF SOUTH CAROLINA
COUNTY OF RICHLAND

COPY

MONICA WESTON,
Plaintiff,

vs

CIVIL ACTION FILE NO
05-CP-40-0655

KIMS DOLLAR STORE and CIBA VISION, a division of Novartis Company,
Defendants

~~~~~~~~~~~~~~~~~~~~~~~~~~~~

30(b)(6) DEPOSITION OF CIBA VISION

BY JULIE ANN COLLINS

RECEIVED
JUL 13 20
McNair Law Firm P.A.

June 28, 2006
10 25 a m

One Atlantic Center, Suite 3500
1201 West Peachtree Street
Atlanta, Georgia

Anthony D Lorenz, RMR-RDR, CRR, CCR-B-2022
~~~~~~~~~~~~~~~~~~~~~~~~~~~~

that " There's dialogue, as we develop, based on what our numbers are actually looking at -- looking like, and what can we actually spend for each of the businesses

Q Would this be an accurate scenario?

You have a discussion with somebody who's above you on the food chain in the company They give you a suggestion of how much you should be able to spend on, for example, an advertising campaign for FreshLook contact lenses You go and develop an advertising plan, figure out how much it's actually going to cost, trying to stay within the parameters that that person gave you, and then go back to get approval for the number you think it's going to cost?

A That is correct

Q With that understanding, can you tell me what the marketing budget was -- and it can be approximate I know that you won't know to the actual dollar -- but within, you know, a million dollars, for color contact lenses, for the years -- for example, the first year you got there, 2001, what was that marketing budget?

A I don't have visibility into the complete marketing budget What I can tell you is the advertising budget

Q Okay Thank you for that clarification Then I'll clarify my question

What was the advertising budget for color contact lenses in 2001?

A 2001 was about 5 million

Q And 2002?

A 5 5 million

Q 2003?

A It was about 8 million

Q 2004?

A 2004 was about 4 million

Q And 2005?

A 2005 was $750,000

Q Now, for example, in 2002, you said it was approximately $5 5 million What did that buy you? Where did that money go? How was it used?

A We purchased print advertising in magazines

Q And so was all of that money spent on print ads?

A Correct

Q And how about the TV ads, or were there none in 2002?

A The television ads did not run in 2002

Q When did they start?

A 2003

Q Okay And did the television ad air time come out of that $8 million?

A Correct

Q Okay And the print ads

A Correct

Q Does that include the cost of the production? -- meaning the making of the TV ad?

A No

Q So these budgets are just for the actual buying the space in the magazines, and buying the air time on TV

A Yes

Q Does your budget include, for example, you know, the concert series that was put on -- was it MTV?

One of the press releases talks about, you know, that the FreshLook line sponsored a concert series Not under you

that under your budget?

A The development of the websites, yes, is under my group and under our budget

Q Now, what did you do to prepare for this deposition?

A I had conversations with our attorney, and our --

Q I don't want to know the -- I can't know the substance of the conversations

A I understand that

And then reviewed documents

Q What documents did you review?

A I reviewed our print advertising -- yeah, that was it

Q Did you review any of the press releases?

A And the television spots I looked at the television spots

Q Okay

A And I looked at one press release where I was quoted

Q Okay Did you -- I want to ask your attorney a question

MR RAWL I have the CDs with me that you gave me, that have the media --

advertising media, and I have the actual originals that you gave me I want to mark those as an exhibit

Q (By Mr Rawl) Have you looked at -- now, back to the witness Have you looked at these?

A Let me see them

MR RAWL And I have no problem if y'all want to talk about this

MS GUEST Yes I think you looked at the jewel case, so she wouldn't know

Q (By Mr Rawl) Well, I mean, there's no way you looked at those, unless you looked at them before they were given to me, but

MS WILSON Do you have names of -- you didn't bring your computer, and you have those on them

THE WITNESS Can we look at what's on them?

MR RAWL Sure I'm happy to I'm just saying those are the actual ones that are produced I have a laptop, you're welcome to look at them

MS WILSON Okay

MR RAWL I was having a hard time trying to figure out how I was going to make those an exhibit I definitely want them

MS WILSON I mean, you can mark this --

MS GUEST You can mark them

MS WILSON -- but I don't want her talking about what's on this disc unless she sees what's on the disc so we can confirm what it is, which I'm sure you're probably going to do anyway

MR RAWL You know, frankly, I just want to make sure that I have those authenticated, okay? And made an exhibit You know, there are two ways I can do that One is to do, you know, a request for admission, or two, to ask her You know, clearly I prefer just to ask her and make it easier

I'm happy to pull out a laptop and show you what's on them, but I'm telling you, those are exactly what was given to me And what I was going to suggest is make those -- exactly what you've given

Page 28

A I haven't memorized all of our press releases, so I'm not sure

Q I'm not asking you if you've read this press release I'm asking you whether you were aware that there was a $20 million marketing campaign in 2002, for FreshLook contact lenses

A No

Q You were not aware of that

A No

Q What you were aware of is that you had a $5 5 million budget

A Yes

Q And so you don't know how the alleged other $14 5 million was spent

A No

Q Okay In developing the FreshLook advertising, what were your goals? I mean, generally, I mean, what were your goals, in developing the FreshLook advertising?

A Well, our goals in developing our advertising is to grow our business, with vision-corrected women, and continue our brand awareness growth, as part of that effort

Q So the only goal that CIBA Vision

has with regard to advertising, that you're aware of, is to advertise to women that need vision correction

A That is correct

Q Y'all don't ever advertise to people who don't need vision correction

A Say more

Q Pardon?

A Could you extend the question? What do you mean?

Q Yes I'm asking you, do you ever advertise to people with, say, perfect vision, or people with, say, 20/20 eyes?

A Not as a specific group, no Do we include that copy in some of our content? Yes

Q So you're marketing to everybody, regardless if they need vision correction, or not, correct?

A We develop all of our plans for vision-corrective women, but we include content to include those with perfect vision, yes

Q So you market to both

MS WILSON Objection

Page 34

A Yes

MS WILSON Objection

Q (By Mr Rawl) You're familiar with the content that was placed in different magazines from the time you arrived through March of 2004, right?

A Yes

Q And you were aware that much of that content also includes people with 20/20 eyes, and it states also with people with 20/20 eyes, correct?

A Yes

MS WILSON Objection

Q (By Mr Rawl) And it also states also with people with perfect vision, correct?

MS WILSON Objection

THE WITNESS No It doesn't say that

Q (By Mr Rawl) What does it say?

A In 2003? Is that what you're asking?

Q Between the time you arrived at the company in April of 2001, through March of 2004, there was print media that is also focused towards people with, quote, "Perfect

vision," end quote, correct?

MS WILSON Objection

THE WITNESS My recollection is that's not the specific language

Q (By Mr Rawl) What do you think the specific language is?

A The specific language is, "For light eyes, for dark eyes, even for 20/20 eyes "

Q Okay And you're not aware of any of the print content that refers to people with perfect vision

A In what time period?

Q And I may be messing up the time periods Are you aware of that in any time period?

A I believe in some of the earlier work prior to my being at the company, that language may have been used

Q Oh, okay So it may be something that was in '99, 2000 or 2001, before you got there?

A Yes

Q Okay But while you were there, the language, "Even with 20/20 eyes," was used

A Yes

MS WILSON Objection

THE WITNESS I don't understand the question

Q (By Mr Rawl) For reasons other than to correct their vision

A Yes

Q Which would be a cosmetic reason, correct?

MS WILSON Objection

THE WITNESS I wouldn't agree with that definition

Q (By Mr Rawl) What do you believe "cosmetic" means?

A I view the business as, they use the lenses to change the color of their eye

Q Okay For beautification reasons?

A For enhancement

Q Beauty enhancement?

MS WILSON Objection

THE WITNESS Yes

Q (By Mr Rawl) So you were aware, at the time that you approved the language, "Also 20/20 eyes," that CIBA Vision made plano color contact lenses, correct?

A Yes

Q Can you explain to me what "plano" means?

A Plano means that there's not a power to the lens

Q Meaning there's no vision correction

A Correct

MS WILSON I'm going to object to that characterization

Q (By Mr Rawl) And it's your understanding that by including the "also 20/20 eyes" language, that you were advertising those plano color contact lenses, correct?

A Yes

Q And it would also be correct that from the year 1999 through the present, CIBA Vision continues to advertise plano color contact lenses, correct?

MS WILSON Objection

THE WITNESS Not specifically, no It is blended in with our overall business, which is vision corrected, which is the bulk of the business And we direct the consumer to the eye care

professional

Q (By Mr Rawl) So the answer to my question is "yes "

MS WILSON Objection

Q (By Mr Rawl) Right?

A With the explanation in context that goes with it But yes

Q You're not aware of any ad that only advertises plano color contact lenses, are you?

A Repeat the question?

Q Are you aware of any advertising that is done, or has ever been done by CIBA Vision, that advertises only plano color contact lenses?

A To my knowledge, there are no ads that advertise only plano lenses, for any of our FreshLook lenses

Q So your clarification earlier simply meant that while CIBA Vision markets plano color contact lenses, they do it in context with all of the rest of their color contact lenses

A That is correct

Q Which makes my earlier statement a

Page 40

true statement, which is that from the year 1999 through the present, CIBA Vision has advertised, in some context, plano color contact lenses

A Yes

Q Do you know what percentage of color contacts produced by CIBA Vision are plano?

A Produced?

Q Manufactured

A No I --

Q Has anybody ever shared that information with you?

A I know what percentage of our sales are plano, but as -- I don't have insight into the manufacturing capabilities, so I don't -- I don't know how many we make I know how many we sell

Q Okay Even though --

A I don't mean to be literal, but I'm trying to answer your questions as best as I can

Q I really do appreciate that I want you to be as exact as possible

How many plano color contact lenses does CIBA Vision sell?

A Nineteen percent of our sales are plano

Q And what year was that?

A That's current year

Q That's current, okay How about for 2004?

A It's consistent It's a stable business It doesn't change

Q Has it been that way since -- it's been consistent since you got there?

A Yes

Q Okay And is that consistent within the FreshLook -- would that be a tradename?

A FreshLook color contact lenses is our brand, yes

Q It's a brand And is that consistent within that brand also?

A That is the number for that brand, yes

Q Okay And are you aware of the total sales of FreshLook?

A Yes

Q Like, for example, in 2004, how many FreshLook lenses total were sold?

A I don't have any insight into the

lawsuit's about?

A Yes

Q Do you personally -- excuse me Strike that

Does your department have anything to do with what the box of color contacts looks like?

A No

Q What -- prior to March of 2004, what magazines have color contacts produced by CIBA Vision been run in? -- the advertising?

A Could you repeat your question?

Q Prior to March of 2004, what magazines have FreshLook ads been run in?

A Okay Magazines like "Glamour," "Cosmo," "Vibe " Those are the ones I can recall

Q You can't think of any other ones?

A We were in "Honey "

Those are the ones I can remember

Q And you chose which magazines they would go in

A Yes

Q And how do you make that decision? What criteria goes into making that decision?

Page 56

A We look at the distribution of each of the books how many people read those books And the cost factor, of how much does it cost

Q You look at the type of person that's buying that magazine, and the amount of the distribution

MS WILSON Objection

THE WITNESS Will you repeat your question?

Q (By Mr Rawl) Basically, when looking at each magazine in deciding whether or not to run an ad in that magazine, you want to know the type of person that's buying that magazine, right?

A That's reading that magazine, yes

Q Yes And the number of distribution How many people are reading --

A How many they put out there

Q -- it, and the type of people that are reading it

A Yes

Q Okay And do you research that information about these magazines, prior to buying space --

A Yes
Q -- for your advertising in them? Okay
And do you do that research yourself?
A No Our media agency provides that information to me
Q And does somebody from, you know -- above, in CIBA Vision, instruct you the type of person that you are to focus your advertising on?
A No I do that
Q You do that What -- for example, for the FreshLook advertising, what were your instructions?
A We purchase a reader who is a woman 18 to 24, who likes to read magazines that have content in it about lifestyle, issues that she would be interested in
Q And fashion issues
A Some of it, yes But other things, too "Cosmo," of course, they care about relationships, and other components of their -- you know, their life So it's subject matter that's intriguing to them

Also celebrities

Q Do you work out the focus on whether you're going to focus on white, Hispanic, or African-American females?

A Could you repeat the question? I'm not quite sure I understand

Q When deciding which magazine, and how to do your advertising, do you focus, or have, you know, in your decision-making process, whether you're going to focus on white, Hispanic, or African-American females?

A We include all ethnicities in our outreach, yes

Q Okay Are you focused on one group more than another group?

A No

Q But, for example, clearly for "Vibe" and "Honey," you know that a majority of those readers are African-American

A Yes

Q Okay Isn't there a Hispanic --

A There is

Q -- magazine that you advertise to also? -- I mean, advertise in?

A Yes "Latino "

Q And you know that the majority of women that are purchasing "Latino," are Hispanic

A Yes

Q Do you consider the -- when considering the readers of these magazines, the level of education that these people would have, that are buying these magazines?

A Education isn't a factor in our decision-making process, no

Q And when you get the information on these magazines, that information gives you, you know, the average education of the person that's buying it, you know, the numbers, the breakdown of ethnicity -- all that kind of stuff You get all that information, don't you?

A I do not look specifically at education levels We look at age, we look at lifestyle preferences But education level isn't a -- isn't a factor

Q I'm asking you, you receive that information, though, don't you?

A I assume it's there I will tell you, I don't review that

Page 60

Q Okay And, for example, for "Cosmo," the information that you would research would indicate everything from average age --

A Uh-huh

Q -- you know, to the age breakdowns of -- you know, you have roughly this many people who are in their 18 to 20, this many people that are 20 to 26, and you get those types of breakdowns, correct?

MS WILSON Objection

THE WITNESS It's not as granular as what you just described, because the media breakdowns don't -- don't break out with age limits that small

Q (By Mr Rawl) Who do you get the information from?

A The information comes from industry standards, Simmons Data, that our media agency pulls for us

Q And you also get the information from the magazine themselves, about their readership

MS WILSON Objection

Q (By Mr Rawl) Correct?

Page 88

A Yes

Q Okay And the target of the "Just for Tonight" theme was the 18- to 34-year-old female market? Is that your understanding?

MS WILSON Objection

THE WITNESS To the best of my knowledge, yes

Q (By Mr Rawl) And in 2001, you reviewed a proprietary consumer research report conducted by CIBA Vision in 2000, which said that 80 percent of the 18- to 34-year-old female market reported being interested in eye color change, is that correct?

MS WILSON Objection

THE WITNESS I don't remember specifically reviewing a report to that effect, no

Q (By Mr Rawl) Okay Are you aware of any CIBA Vision proprietary consumer research that's been done with regard to women who were interested in changing their eye color?

A Yes

Q And when was that done? -- that research performed?

change?

A Yes

Q Okay So as you sit here today, you have no reason to believe that -- that the direct consumer marketing department at CIBA Vision, did not know that 80 percent of the 18- to 34-year-old female market was interested in eye color change

A That's right

Q Are you aware that -- strike that

Isn't it true that in January of 2002, CIBA Vision announced the launch of a 20 million North American consumer marketing campaign to promote FreshLook cosmetic contact lenses?

A Could you repeat the question?

Q Yes Isn't it true that in January of 2002, CIBA Vision announced the launch of a $20 million North American consumer marketing campaign, to promote FreshLook cosmetic contact lenses?

A Yes

Q Isn't it true that that $20 million North American consumer marketing campaign, was CIBA Vision's largest effort to promote

Page 94

cosmetic contact lenses within the past 20 years?

A Yes

Q And that was as of 2002

A (Witness nods head)

Q Right?

A And historically, yes

Q Okay Isn't it true that the $20 million FreshLook marketing campaign, included a combination of print advertising, a remodeled website, rebates, and a free-pair consumer promotion?

A Yes

Q And isn't it true that in January of 2002, the $20 million FreshLook consumer marketing campaign was a departure in positioning from earlier marketing campaigns for the FreshLook brand? The new campaign emphasized the lens' appeal as a cosmetic accessory, like nail polish, lipstick, or eye shadow?

A Yes

Q And again, that campaign was aimed to the 18- to 34-year-old female market, correct?

A Vision-corrected market, yes
Q Under oath today, you're saying that that campaign was only directed at the vision-corrected market
A Yes Because that's the group of people who were most likely to buy the lenses, because they already know how to wear contact lenses
Q And you were instructed not --
A Not a new experience for them
Q I'm sorry
A I'm sorry
Q And you were instructed, back in 2002, to make that marketing campaign only towards the vision-corrected market
MS WILSON Objection
THE WITNESS I'm not sure I understand what you mean by "instructed "
Q (By Mr Rawl) Well, you didn't create the marketing strategy personally, did you?
A No
Q All right So somebody had to tell you who to focus the ad campaigns on, right?
A Yes

Page 96

Q And they told you specifically to only focus on people who need vision correction

MS WILSON Objection

THE WITNESS It's more that the vision-corrected person, because they already need vision correction, is more likely to purchase color, because that's already a physical need that they have

Q (By Mr Rawl) It's more likely that people who need vision correction will already be going to their doctor -- their eye doctor

A Yes

Q And in 2002, you said that approximately 19 percent of all the sales were for noncorrective color lenses

MS WILSON Objection

THE WITNESS For plano lenses, yes

Q (By Mr Rawl) Which are noncorrective

A It depends on your definition of "corrective "

Q They don't correct your vision

A Correct

Q They change the color of your eye

only

A Correct

Q And isn't it true that the $20 million consumer marketing campaign for the FreshLook cosmetic contact lenses, included placements in such national beauty, fashion and teen publications as "Glamour," "Cosmo," "Allure," "In Style," "Vibe," and "Honey"?

A Yes

Q And that also along with that marketing campaign in 2002, there was a remodeled website at www FreshLookcontacts com, which featured new attention-grabbing graphics, and sound that reflect the attitude of the new advertising campaign

A Yes

Q What are demographics?

A It is information about a group of people that is descriptive of who they are age, ethnicity

Q And prior to January of 2002, did CIBA Vision focus only on demographics, in doing their marketing?

A Typically, yes

Q And what does that mean with regard to only focusing on demographics in doing marketing?

A It means it just -- it's just that they're just looking at characteristics of humanity, based on the things that I described age, gender, ethnicity

Q Isn't it true that CIBA Vision's $20 million consumer marketing campaign for the FreshLook cosmetic contact lenses, that was announced in January of 2002, was defined by attitude, was aimed at the experimental young woman, who was sassy and stylish, and sees cosmetic lenses as a way to express her vibrant personality?

MS WILSON Objection

THE WITNESS Could you repeat the question?

MR RAWL Will you read it back, please?

(The question referred to was read back by the reporter as follows

"QUESTION Isn't it true that CIBA Vision's $20 million consumer marketing

campaign for the FreshLook cosmetic contact lenses, that was announced in January of 2002, was defined by attitude, was aimed at the experimental young woman, who was sassy and stylish, and sees cosmetic lenses as a way to express her vibrant personality?")

THE WITNESS Yes

Q (By Mr Rawl) Isn't it true that in -- or by the end of May 2002, as a result of increased marketing spending for cosmetic contact lenses by CIBA Vision, CIBA Vision estimated that demand for cosmetic lenses increased 20 to 25 percent in North America during the first quarter of 2002?

A I don't know That's inconsistent with what I know

Q So you would disagree with that statement

A I would

Q Isn't it true that based -- because of, excuse me -- the $20 million marketing campaign, CIBA Vision reported, in May of 2002, that sales of its FreshLook ColorBlends toric lenses, increased 250 percent in the

Page 100

first quarter, versus the first quarter of 2001?

MS WILSON Objection

THE WITNESS I'm not familiar with that report

Q (By Mr Rawl) Would you disagree with that statement?

MS WILSON Objection

THE WITNESS I don't know

Q (By Mr Rawl) Nobody shared that information with you, at CIBA Vision

A No I -- I collaborate The toric lens is teeny, teeny, teeny, teeny, teeny I wouldn't have any knowledge on how much it increased It's not even a product that I look at, or consider

Q Would you agree with the statement that in May of 2002, CIBA Vision was the world leader in cosmetic contact lenses?

MS WILSON Objection

THE WITNESS No

Q (By Mr Rawl) Who would you say the world leader was?

A We are the world leader in color contact lenses

Q What's the difference between a cosmetic contact lens, and a color contact lens?

A I don't make a -- I make the distinction that it's a color contact lens It changes the color of your eye

Q But you don't think that that means it's a cosmetic contact lens

A No

Q I'll ask the question in a slightly different way

Isn't it true that CIBA Vision announced, in May of 2002, that it was the world leader in cosmetic contact lenses, with its FreshLook ColorBlends, FreshLook Colors, Focus SoftColors, DuraSoft Colors, DuraSoft ColorBlends, CIBASoft SoftColors, Elegance, and Illusion brands?

MS WILSON Objection

THE WITNESS I'm not familiar with that document

Q (By Mr Rawl) So if somebody announced that CIBA Vision was the world leader in cosmetic contact lenses, you would say that that's inaccurate

Page 102

MS WILSON Objection

THE WITNESS I characterize the lenses as color contact lenses

Q (By Mr Rawl) How does CIBA Vision characterize the lenses?

A My understanding is, our language is "color contact lenses "

Q Is there a reason you're objecting to the word "cosmetic"?

A It's not the way I look at it No

Q Is it your understanding that a cosmetic contact lens would be a lens that doesn't have correction? -- meaning a plano lens?

A I refer to our lenses that do not have a power, as plano lenses

Q And you refer to your lenses that have a color as color lenses

A (Witness nods head)

Q And what would a cosmetic lens be?

A I don't use that language in reference to our brand, or to our product

Q Does anybody at CIBA Vision use that language? -- "cosmetic lens"? And if so, what is your understanding that CIBA Vision means

when it says "cosmetic lens"?

MS WILSON Objection

THE WITNESS I -- I don't know

Q (By Mr Rawl) So when in press releases, CIBA Vision announces that they are the world leader in cosmetic contacts, you have no idea what that means, do you?

MS WILSON Objection

THE WITNESS I am not responsible for that --

Q (By Mr Rawl) I'm not asking if you're responsible I'm asking if you understand what that means

A I don't know what that means

Q Is it your understanding that in 2001, CIBA Vision sales of colored contact lenses exceeded $125 million?

A In 2001 I don't recollect the exact number, but the neighborhood sounds right

Q So you think it -- are you saying you don't know?

A I'm saying that sounds like the approximate number

Q So is the answer to my question

"yes"?

A Yes

Q You wouldn't have anything to do with CIBA Vision being committed to doing what is in the best interest of the public health, and taking extra steps to publicly express its concern over sales of color contact lenses by unauthorized vendors such as beauty supply stores That's not you, is it?

A No

Q And those efforts wouldn't have anything to do with CIBA Vision's marketing, would they?

A It's --

MS WILSON Objection

THE WITNESS It's outside my area of responsibility

Q (By Mr Rawl) And your area of responsibility is only marketing

A Correct Advertising and marketing

Q And marketing

And none of your marketing materials communicated to consumers that if they buy contact lenses, with or without vision correction, from unlicensed vendors, without

receiving proper fitting instruction and followup care, that they were putting themselves at unnecessary risk, did it?

A No

Q In November of 2002, did CIBA Vision select Grey Worldwide as its global consumer advertising agency?

A Yes

Q Was the purpose for that, to further strengthen CIBA Vision's consumer marketing and advertising messaging?

A Yes

Q And at that time, was CIBA Vision looking forward to accelerating new sales growth through several new consumer advertising campaigns for CIBA Vision's leading brands, including FreshLook?

A Yes

Q And in June of 2003, isn't it true that CIBA Vision's FreshLook color contact lenses, were spotlighted on UPN's, quote, "America's Next Top Model," end quote, television show?

A Yes

Q And that show chronicled the

transformation of everyday young women into potential supermodels, featured the models filming a mock television commercial for FreshLook lenses?

A Yes

Q And your understanding that that show was hosted by supermodel Tyra Banks?

A Yes

Q And was that promotion also only focused towards women needing vision correction?

MS WILSON Objection

THE WITNESS No They were shown being fit by a doctor, as part of the content of that show

Q (By Mr Rawl) But it was focused at all consumers

MS WILSON Objection

THE WITNESS It was focused at women between 18 to 24, yes

MS WILSON Is it a good time to go ahead and take a lunch break?

MR RAWL Let me go through one or two more

MS WILSON Okay

Q (By Mr Rawl) And isn't it true that in June of 2003, CIBA Vision launched the Most Beautiful Eyes campaign for FreshLook color contacts?

A Yes

Q And that the Most Beautiful Eyes campaign for the FreshLook color contacts, was CIBA Vision's effort to strengthen brand preference among consumers for the FreshLook color contact lenses brand

A Yes

Q And that the Most Beautiful Eyes campaign was CIBA Vision's strongest marketing campaign ever, for color contact lenses in the United States, targeted at women ages 18 to 24, and included television and consumer magazine advertisements, a redesigned website, a summer concert tour, a new logo, and new packaging for FreshLook lenses

A Yes

Q And with that Most Beautiful Eyes campaign, CIBA Vision was trying to reach even more consumers who might not otherwise know about the possibilities that color contact lenses can offer

A Yes

Q And with the launch of the Most Beautiful Eyes campaign, it was CIBA Vision's intention that the new FreshLook Colors -- strike that I'm sorry

That along with the Most Beautiful Eyes campaign, CIBA Vision launched the new FreshLook color lens colors, and that along with the aggressive consumer marketing efforts, CIBA Vision was trying to go into the consumer's world, to get them excited by FreshLook lenses

A Yes

Q That the Most Beautiful Eyes campaign was launched via television during the week of June 30th, 2003, on stations such as MTV, WB, UPN, E', and Comedy Central

A Yes

Q And that with that campaign, there were two TV spots -- one named "Zoom," which included both a 30-second spot showcasing the entire FreshLook brand, as well as a 15-second spot featuring the new FreshLook Dimensions line

A Yes

Q That the most -- isn't it true that the Most Beautiful Eyes print campaign included advertisement in magazines such as "Cosmopolitan," "Glamour," "Allure," "Honey," "Vibe," "Estylo," and "Latina "

A Yes

Q And that -- isn't it true that towards the end of 2003, the FreshLook brand sponsored programming on MTV, and teamed up with BNG Music, to host a summer concert tour for emerging BMG recording artist called, quote, "FreshLook, fresh faces," end quote?

And I'm sorry -- that tour was in August of 2003

A Yes

Q And that tour hit 11 U S cities?

A Yes In malls

Q In malls?

A In malls

Q And in -- or actually, after June 2003, the FreshLook brands featured updated packaging, featuring eye-catching graphics, to appeal to consumers

A Yes

Q And that updated packaging on the

FreshLook brands went along with the most aggressive consumer marketing CIBA Vision had ever done for the FreshLook brand

MS WILSON Objection

THE WITNESS The timing was consistent, yes

Q (By Mr Rawl) Isn't it true that in February of 2004, CIBA Vision announced that it will strengthen its substantial investment in consumer advertising more than 60 percent during 2004?

A Could you be more specific? Is that overall, or one brand specifically?

Q I'd love to be, if I could, but I can't be I'm sorry

A My understanding is that was overall, across all brands And yes

Q And that included the FreshLook brand, right?

A There was no additional money that was going to be invested in FreshLook, at that point The additional investments were going to new products that we were planning to launch in that same time period

Q Isn't it true that the Most

been marked as Exhibit No 19

A Uh-huh

Q Can you identify that, please?

A Yes It is a consumer ad for FreshLook color contacts

Q And when was this created?

A It was likely created in 2000

And I'm making a distinction between created and run

Q I understand

A Okay "Created" means when we made it

Q Were they copyrighted the year it was made, or the year it was run?

A No, typically it's copyrighted the year it runs

Q Okay So this would have run in 2001

A Correct

Q And can you tell me what magazines this ad ran in?

A Yes

Q Please do

A This would have run in "Glamour," "Cosmo," and "Essence "

Page 132

Q And is this an exact duplicate of the ad that was run?
A Yes
MR RAWL Move to admit Exhibit No 19
(Exhibit-20 was marked for identification)
Q (By Mr Rawl) I'll show you what's been marked as Exhibit No 20
A Uh-huh
Q Same question Can you identify Exhibit No 20?
A Yes It is a consumer ad for FreshLook color contacts
Q And can you tell me when this ad was created by CIBA Vision?
A It would have been created in 2000
Q And it would have been run in 2001?
A Correct
Q Would it be run in 2002 also, or just 2001?
A No, it did not run in 2002
Q Okay
A Because I was there then, so
Q Okay

A These never ran when I was at the company

Q Gotcha And what magazines would this have run in?

A "Glamour," "Cosmo," "In Style "

Q And is this an exact -- is Exhibit No 20, an exact duplicate of the ad that was run in those magazines?

A To the best of my knowledge, yes

Q Okay

MR RAWL Move to admit No 20

(Exhibit-21 was marked for identification)

Q (By Mr Rawl) I'll hand you what's been marked as Exhibit 21

A Uh-huh It is a consumer ad for FreshLook color contact lenses

Q Can you tell me what magazines it ran in, please?

A I can give you best guess

Q Please

A Because it's translated, it would have only run in "Latina "

Q And to the best of your knowledge, is this an exact duplicate of the ad that was

Page 134

run in "Latina" in 2001?

A Yes

MR RAWL Move to admit Exhibit 21

(Exhibit-22 was marked for identification)

Q (By Mr Rawl) I'll show you what's been marked as Exhibit 22

A Uh-huh

Q Can you identify that document for me, please?

A Yes It is a consumer ad for FreshLook color contact lenses

Q And what magazines was this run in?

A To the best of my knowledge, it would have been in "Glamour," and "Essence "

Q And this would have been created by CIBA Vision in 2000, and it looks like it would have run in 2001?

A To the best of my knowledge, yes

MR RAWL Move to admit Exhibit No 22

Q (By Mr Rawl) Looking at Exhibit 22 again, this is one of the ads that says for -- excuse me -- "For dark eyes, light eyes, even if your vision is perfect," correct?

A It does

Q And there's no warning on this ad that you could be injured if you put the contact in your eye without being fitted by a doctor first, right?

MS WILSON Objection

THE WITNESS No

Q (By Mr Rawl) Is that -- you're agreeing with my statement that no, there is no warning?

A There is no language that says what you just said

Q Okay

(Exhibit-23 was marked for identification)

Q (By Mr Rawl) I'll show you what's been marked as Exhibit No 23

A Uh-huh

Q Can you identify 23 for me, please?

A Yes It is a consumer ad for FreshLook color contact lenses

Q And when did CIBA Vision create this ad?

A To the best of my knowledge, it would have been created in 2000

Page 136

Q Okay And to the best of your knowledge, when was this ad run?
A In 2001
Q In "Latina"?
A My guess would be yes, given the translation
Q Okay
MR RAWL I'll move to admit Exhibit No 23
Q (By Mr Rawl) Number 23 was an exact duplicate of the ad that you understand was run, correct?
A Yes To the best of my knowledge, yes
(Exhibit-24 was marked for identification)
Q (By Mr Rawl) I'll show you what's been marked as Exhibit 24 Can you identify that for me, please?
A Yes It is a consumer ad for FreshLook color contact lenses
Q And can you tell me to the best of your knowledge when this ad would have been created?
A To the best of my knowledge,

sometime in 1999

Q Okay And to the best of your knowledge, when, and in what magazine would this ad have run?

A That far back, I don't have a -- I can guess

Q Your best guess is fine

A Best guess Best guess is going to be a "Glamour," and a "Cosmo "

Q Okay Was it your understanding that if you had this ad, it was run in some magazine?

A Yes

Q And to the best of your knowledge, this is an exact duplicate of the ad that was run in whatever magazine it was run in?

A Yes

MR RAWL Move to admit Exhibit 24

(Exhibit-25 was marked for identification)

Q (By Mr Rawl) I'll show you what's been marked as Exhibit 25 The same question Can you identify Exhibit No 25, please?

A Yes It is a consumer ad for FreshLook color contact lenses

Page 138

Q And when did CIBA Vision create this ad?

A In 1999

Q And do you have an understanding of what magazines this ad was run in?

A Similar to the answer previously likely to be "Cosmo," "Glamour "

Q Okay But it was definitely run in some magazine

A Yes

Q And it would have been run in the year 2000?

A Yes

Q Okay To the best of your knowledge, is this an exact duplicate of the ad that was run?

A Yes

MR RAWL Move to admit Exhibit 25

(Exhibit-26 was marked for identification)

Q (By Mr Rawl) I'm handing you Exhibit 26 Can you identify Exhibit 26, please?

A Uh-huh It is a consumer ad for FreshLook color contact lenses

Q And when was this created by CIBA Vision?
A It would have been created in 2000
Q And to the best of your knowledge, what magazines was this ad run in?
A To the best of my knowledge, "Cosmo," "Glamour," "In Style "
Q And that would have been in 2001?
A Yes
Q And to the best of your knowledge, is this an exact duplicate of the ad that was run in whatever magazine it was run in?
A Yes
MR RAWL Move to admit Exhibit 26
(Exhibit-27 was marked for identification)
Q (By Mr Rawl) I'm handing you Exhibit 27 Can you identify that, please?
A Yes
Q Please do
A It is a FreshLook -- consumer ad for FreshLook color contact lenses
Q And your best estimate as to when this ad was created, and when it was run?
A In 19- -- created in 1998, run in

Page 140

1999

Q And your best estimate of what magazines this would have been run in?

A "Glamour," "Cosmo," "Latina "

Q And this would be an exact duplicate of whatever ad was run, correct?

A Yes

MR RAWL Move to admit Exhibit No 27

(Exhibit-28 was marked for identification)

Q (By Mr Rawl) And Exhibit 28, can you identify 28 for me, please?

A Yes It is a consumer ad for FreshLook color contact lenses

Q And when would it have been created by CIBA, and when would it have been run?

A It would have been created -- I don't know I'm going to guess 1999, and then runs in 2000

Q It was either created in '99 or 2000, right?

A Yes

Q And it would have been run in 2000, correct?

A Yes

Q And what magazines do you believe this might have been run in?

A Guess would be the same likely "Glamour," "Cosmo "

Q "Glamour" or "Cosmo"? And this would be an exact duplicate of the ad that would have run, correct?

A Yes

MR RAWL Move to admit Exhibit 28

Q (By Mr Rawl) I'm just going to mark them all and hand them to you, and we'll go through them one by one

(Exhibit-29 was marked for identification)

Q (By Mr Rawl) Please grab Exhibit No 29

A Uh-huh

Q Can you identify that for me, please?

A Yes It is a FreshLook color contact lens consumer ad

Q And when was this created by CIBA Vision?

A This was created in 2003

Page 142

Q And this was run in what magazines?
A This ran in "Honey," in "Glamour," in "Cosmo," in -- I believe "In Style," and "Essence "
Q Just in 2003, or 2003 and 2004?
A That was in 2003
Q And is this an exact duplicate -- at least the back two pages, is that an exact duplicate of the ad that was run in those magazines?
A Yes
MR RAWL Move to admit Exhibit 29
(Exhibit-30 was marked for identification)
Q (By Mr Rawl) Please grab Exhibit 30 Can you identify that for me, please?
A Uh-huh
Q Please do
A It is a consumer ad for FreshLook color contact lenses
Q And you're referring to Page 2 and 3 of this exhibit, right?
A Correct
Q And when was that ad created, and

when did it run in magazines?

A This ad was created in 2002, and it ran in 2003

Q Okay And what magazines did it run in, please?

A This ran in "Cosmo," and "Glamour "

Q And is this an exact duplicate of the ad that was run?

A And "Essence "

Q Is this an exact duplicate of the ad that was run, Page 2 and 3?

A Yes

MR RAWL I move to admit Exhibit 30

(Exhibit-31 was marked for identification)

Q (By Mr Rawl) Number 31, please Can you identify Exhibit No 31, please?

A Yes It is a consumer ad for FreshLook Radiance contact lenses

Q And are FreshLook Radiance contact lenses, also color contact lenses?

A They are, yes

Q And do they make a plano, in FreshLook Radiance?

Page 144

A Yes
Q And the ad you're referring to is Pages 2 and 3 of this exhibit?
A Yes
Q And what magazines did this run in?
A This ran in "Glamour," "Cosmo," "In Style "
Q Okay And in what year?
A In 2003
Q And is Page 2 and 3 of Exhibit 31, an exact duplicate of the ad that was run?
A Yes Yes
MR RAWL Move to admit exhibit --
THE WITNESS I was making sure I had my timing correct
(Exhibit-32 was marked for identification)
Q (By Mr Rawl) Please look at Exhibit 32, please
A Yes I'm sorry
Q Can you identify Exhibit 32, please?
A Yes It is a consumer ad for FreshLook color contact lenses
Q And when was this ad created by CIBA Vision?

A This would have been made in 2000- -- 2004

Q It would have been made in 2003, or 2004?

A 2004 Pretty sure

Q You might want to check the -- I may be wrong --

A I can't read the date, but -- it had to be, because I remember when this was done And this was after we had launched the other -- this work (indicating) It was -- the photography was shot, but this particular ad was created after we created this ad It's the same girl

Q Will you tell me which exhibit you're looking at right now?

A I'm sorry I'm looking at 32, and 29

Q So Exhibit 29 was created first?

A Correct

Q Okay And I'm asking you to look at the bottom corner of the second page of Exhibit No 32

A Uh-huh

Q Do you see where it has the

copyright, 2003?

A I do

Q Okay But you still think that this was not run until 2004?

A I'm reasonably sure it couldn't have been

Q Okay

A I'm sorry I'm confused Forgive me We make a lot of ads I'm so sorry

This was done in 2003 I apologize

Q Oh, it's no problem

A We use the same models to do different things Yes This one was made in 2003

Q And that's Exhibit 32

A Correct

Q Okay And it was run in 2003 also?

A Yes Forgive me I'm sorry I'm getting it confused with a later version that had the same girl, but a different headline

Q Okay

MR RAWL Off the record for a second

(Discussion ensued off the record)

MR RAWL Back on the record,

please
Q (By Mr Rawl) What magazines was Exhibit 32 run in?
A This ran in "Honey," and in "Vibe "
Q And that would have been in 2003, and 2004, or just 2003?
Definitely 2003, right?
A Definitely 2003
Q Maybe 2004
A Possibly
Q Okay And the second page --
A Actually -- actually, I can answer the question No, not 2004
Q Okay Only in 2003
A Correct
Q And Page 2 of Exhibit 32 is an exact duplicate of the ad that was run?
A Yes
MR RAWL Move to admit Exhibit 32
(Exhibit-33 was marked for identification)
Q (By Mr Rawl) Please look at Exhibit 33 Can you identify that exhibit, please?
A Yes It is a consumer ad for

Page 148

FreshLook Radiance contact lenses

Q And when was this ad created by CIBA Vision?

A This ad was created in 2000- -- late 2002, and it ran in 2003

Q And what magazines did this ad run in?

A This ran in "Honey," and "Essence" and "Glamour "

Q And are Pages 2 and 3 an exact duplicate of the ad that was run in those magazines?

A Yes

MR RAWL I move to admit Exhibit 33

(Exhibit-34 was marked for identification)

Q (By Mr Rawl) This is Exhibit 34

A Uh-huh

Q I have the same question Can you identify this?

A Yes It is a consumer add for FreshLook Radiance

Q And what magazines was this run in?

A This ran in "Glamour" and in

"Cosmo "

Q And when was this created by CIBA Vision?

A This was created in late 2002, and ran in 2003

Q And is this Pages 2 and 3 an exact duplicate of the ad that was run?

A Yes To the best of my knowledge, yes

MR RAWL Move to admit Exhibit 34

(Exhibit-35 was marked for identification)

Q (By Mr Rawl) Would you look at 35, please? Can you identify Exhibit 35?

A Yes It is a consumer ad for FreshLook cosmetic contact lenses

Q Okay And when was this ad created?

A It was created in 2002

Q And when was it run?

A In late 2002

Q And in what magazines was this run in?

A It ran in "Glamour," and in "Cosmo "

Q And does this -- at least Pages 2 and 3, an exact duplicate of the ad that was

Page 150

run in those magazines?
A To my knowledge, yes
MR RAWL Move to admit Exhibit 35
(Exhibit-36 was marked for identification)
Q (By Mr Rawl) Will you look at Exhibit 36, please?
A Uh-huh
Q Can you identify Exhibit 36, please?
A Yes It is a consumer ad for FreshLook color contact lenses
Q And you're looking at Pages 2 and 3 of that exhibit?
A Yes
Q And when was that ad created by CIBA Vision?
A It was produced in 2001, and ran in 2002
Q And in what magazines?
A In "Marie Claire," "Cosmo," "Glamour," "In Style "
Q And to the best of your knowledge, is Page 2 and 3 of Exhibit 36 an exact duplicate of the ad that was run in those magazines?

A Yes

MR RAWL Move to admit Exhibit 36

(Exhibit-37 was marked for identification)

Q (By Mr Rawl) Will you look at Exhibit 37, please? Can you identify that, please?

A Yes It is a consumer ad for FreshLook color contact lenses

Q And can you tell me when that was created by CIBA Vision?

A Yes It was created in 2002, and ran in 2003, and into 2004

Q And in what magazines was this run?

A This ran in "Cosmo," "Glamour," "Essence," and "Vibe "

Q Okay And is Exhibit 2 an exact duplicate of the ad that was run?

A Yes

Q Excuse me -- Page 2 of Exhibit 37

A I understood, yes

Q I was getting it right on the record

(Exhibit-38 was marked for

Page 152

identification)

Q (By Mr Rawl) Exhibit No 38, please?

A Yes

Q Can you identify that, please?

A Yes It is a consumer ad for FreshLook color contact lenses

Q And can you tell me when this ad was created by CIBA Vision, and when it was run?

A Yes It was created in 2003, and it ran in 2004

Q Can you tell me when in 2004 this ran?

A I can definitely tell you it ran in February It likely ran from February to April of that year

Q Okay And in what magazines?

A "Glamour," "Cosmo," "In Style" -- I'm just cycling through It wouldn't have been in "Latina", it wouldn't have been in any others

Did I say "In Style"?

Q You did

A Okay Yes

Q And is Page 2 an exact duplicate of

the ad that was run in those magazines?

A Yes

MR RAWL Move to admit Exhibit 38

Q (By Mr Rawl) I'm going to mark a stack of what I believe to be ads, as Exhibit 39

(Exhibit-39 was marked for identification)

Q (By Mr Rawl) And I'm going to ask you to look at Exhibit 39, and let me know if any of these ads were run prior to March of 2004

A Okay

No They were not

Q Is Exhibit 39 a compilation of ads for FreshLook, or other color contact lenses, that was made by CIBA Vision?

A Yes

Q And all of those ads were run after March of 2004?

A Yes

Q Are those all exact duplicates of ads that were run?

A Yes

MR RAWL Move to admit Exhibit

Page 154

No 39

(Exhibit-40 was marked for identification)

Q (By Mr Rawl) I'll hand you what's been marked as Exhibit 40 Can you identify that for me, please?

A Yes It is a consumer ad for FreshLook color contact lenses

Q And when was it created by CIBA Vision?

A It was created in 2003, and ran in 2004

Q And it ran --

A This would have run in "Glamour," "Cosmo," "Essence" and "Vibe "

Q In March of 2004?

A It may not have been in all of those issues during 2004

Or excuse me During the month of March, but it would have run in those books

Q Okay

A On or about the time of March

Q So that ad would have run in one of those magazines at the -- in March

A Yes

Q And would it have run before March, in any of those magazines?
A Yes
Q Okay But it possibly could have run after March also
A Yes
Q And is the second page of Exhibit No 30 -- excuse me, 40 --
A 40
Q -- an exact duplicate of the ad that was run?
A Yes
MR RAWL Move to admit Exhibit 40
(Exhibit-41 was marked for identification)
Q (By Mr Rawl) This is Exhibit 41 Same question Can you identify 41 for me, please?
A Yes It is a consumer ad for FreshLook color contact lens
Q And when was that created by CIBA Vision?
A This was created in 2003, and ran in 2003 and 2004
Q Okay And what magazines was that

Page 156

run in?

A This would run in "Cosmo," "Glamour," "In Style "

Q And is Page 2 of Exhibit 41, an exact duplicate of the ad that was run?

A Yes

MR RAWL Move to admit Exhibit 41

Q (By Mr Rawl) I'm going to ask you about exhibits -- all of the ads, other than 39, which are going to be -- I believe it's seven, eight and nine, and then 18 through 41, skipping 39

Do any of those ads include a warning that states that if someone puts this contact lens in their eye without first being fitted by an eye care professional, it could cause serious eye injury?

MS WILSON Objection

THE WITNESS No

Q (By Mr Rawl) When you were hired in 2001, were you told that you would be responsible for developing consumer advertising and promotional campaigns for CIBA Vision's FreshLook cosmetic tinted lenses?

A Not in that specific language, no

Q Was part of your job responsibilities, the development of consumer advertising and promotional campaigns for CIBA Vision's FreshLook cosmetic tinted lenses?

A Yes

Q We were talking about some of the marketing campaigns, and specifically, the marketing campaign that was introduced in June of 2003 Do you remember talking about that? That's the Most Beautiful Eyes campaign?

A Yes

Q Okay And you're familiar with that campaign?

A I am

Q And one of the things that campaign included was that FreshLook products will come in updated packaging featuring eye-catching graphics to appeal to consumers, right?

A I'm sorry? I don't understand the question

Q Part of that Most Beautiful Eyes campaign for FreshLook contact lenses, that was started in June of 2003, was updated packaging for the FreshLook contact lenses, featuring eye-catching graphics to appeal to

Page 158

consumers --

A Yes

Q -- correct? And do you know when that packaging -- that's referring to the box that the lenses come in, right?

A I assume so, yes Packaging is not in my area of responsibility

Q Do you know why the packaging was updated to feature eye-catching graphics to appeal to consumers?

A No

Q And back in the -- when we were talking about the $20 million consumer marketing campaign for FreshLook contact lenses, back in 2002 -- do you remember discussing that with me?

A I do

Q And part of that campaign included emphasizing the FreshLook Colors contact lenses' appeal as a cosmetic accessory, like nail polish, lipstick or eye shadow --

A Yes

Q -- correct? If that is the way the FreshLook Colors contact lenses are being marketed, would it be reasonable to expect a

News Release

CIBA Vision
A Novartis Company

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth GA 30097 1556

FOR IMMEDIATE RELEASE

FOR MORE INFORMATION
Kristie Madara or Amanda Cancel (678) 415 3646

FRESHLOOK® COLORBLENDS® LENSES ARE EXCLUSIVE SPONSOR OF ALLOY COM CONTEST FEATURING CHRISTINA AGUILERA

ATLANTA, Dec 1, 2000 – To increase awareness of its cosmetic contact lenses among teenage women CIBA Vision has become the exclusive sponsor of the Chill With Christina Aguilera Contest on Alloy com

Alloy Online is a leading Internet based direct marketer to teens reaching more than 10 million each month through its unique Web site It presents information on entertainment sports fashion and personal advice

The contest s grand prize is a trip to a New York recording session with pop star Christina Aguilera as well as a year s supply of FreshLook® ColorBlends® lenses The contest will be featured in Alloy com electronic newsletters which are expected to reach 4 2 million teens Contest enrollment ends December 31 2000

The Alloy com contest is a cost effective high visibility way for us to reach the teen audience who are among our primary prospects for cosmetic lenses said Tom Arens CIBA Vision director of consumer marketing We are planning many more Internet based promotions in 2001 to reach teens and young adults

CIBA Vision s FreshLook ColorBlends tinted lenses feature a patented three in one color burst pattern that combines three colors into one to create the subtle and natural depth of beautiful eyes

more

Plaintiff's Exhibit
16
Alexander Gallo & Associates, Inc.

Christina Aquilera Contest and CIBA Vision / 2 of 2

With worldwide headquarters in Atlanta Georgia USA CIBA Vision is a global leader in research development and manufacturing of optical and ophthalmic products and services including contact lenses lens care products ophthalmic surgical products and ophthalmic pharmaceuticals CIBA Vision products are available in more than 70 countries For more information you are invited to visit the CIBA Vision Web site at www cibavision com or the FreshLook ColorBlends site at http //135 145 17 89/WESLEY

CIBA Vision is the eye care unit of Novartis AG (NYSE NVS) a world leader in healthcare with core businesses in pharmaceuticals consumer health generics eye care and animal health In 1999 the Group achieved sales of CHF 25 4 billion (USD 16 9 billion) and invested more than CHF 3 6 billion (USD 2 4 billion) in R&D Headquartered in Basel Switzerland Novartis employs about 66 000 people and operates in over 140 countries around the world For further information please consult www novartis com

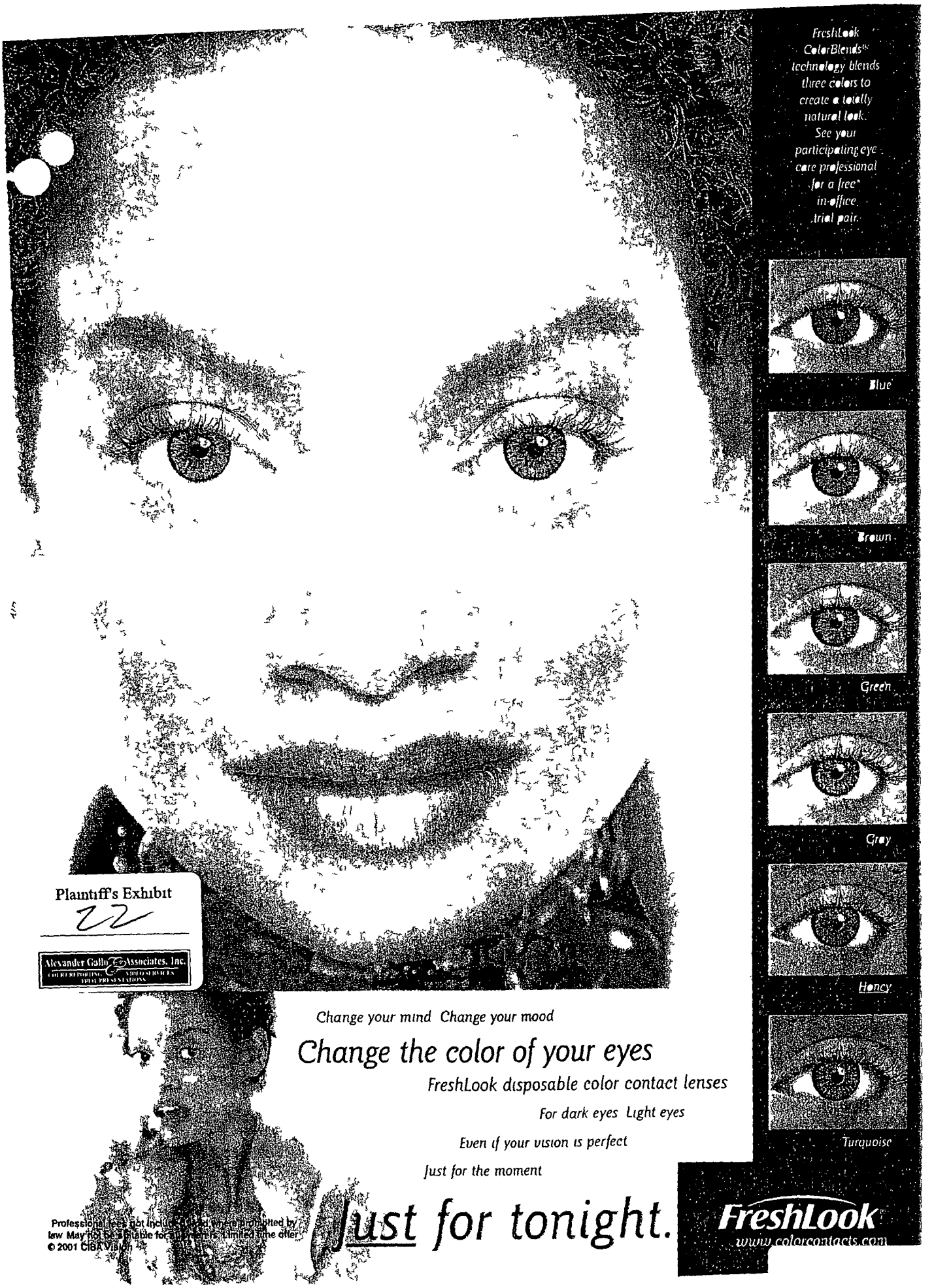
# # #


FreshLook ColorBlends® technology blends three colors to create a totally natural look. See your participating eye care professional for a free* in-office trial pair.
Blue
Brown
Green
Grey
Honey
Turquoise
Plaintiff's Exhibit
19
Alexander Gallo & Associates, Inc.
Change your mind Change your mood
Change the color of your eyes
FreshLook disposable color contact lenses
For dark eyes Light eyes
Even if your vision is perfect
Just for the moment
Just for tonight.
FreshLook®
www.colorcontacts.com
fessional fees may be charged. Void where prohibited by law. May not suitable for all wearers. Limited time offer. ©2001 CIBA Vision

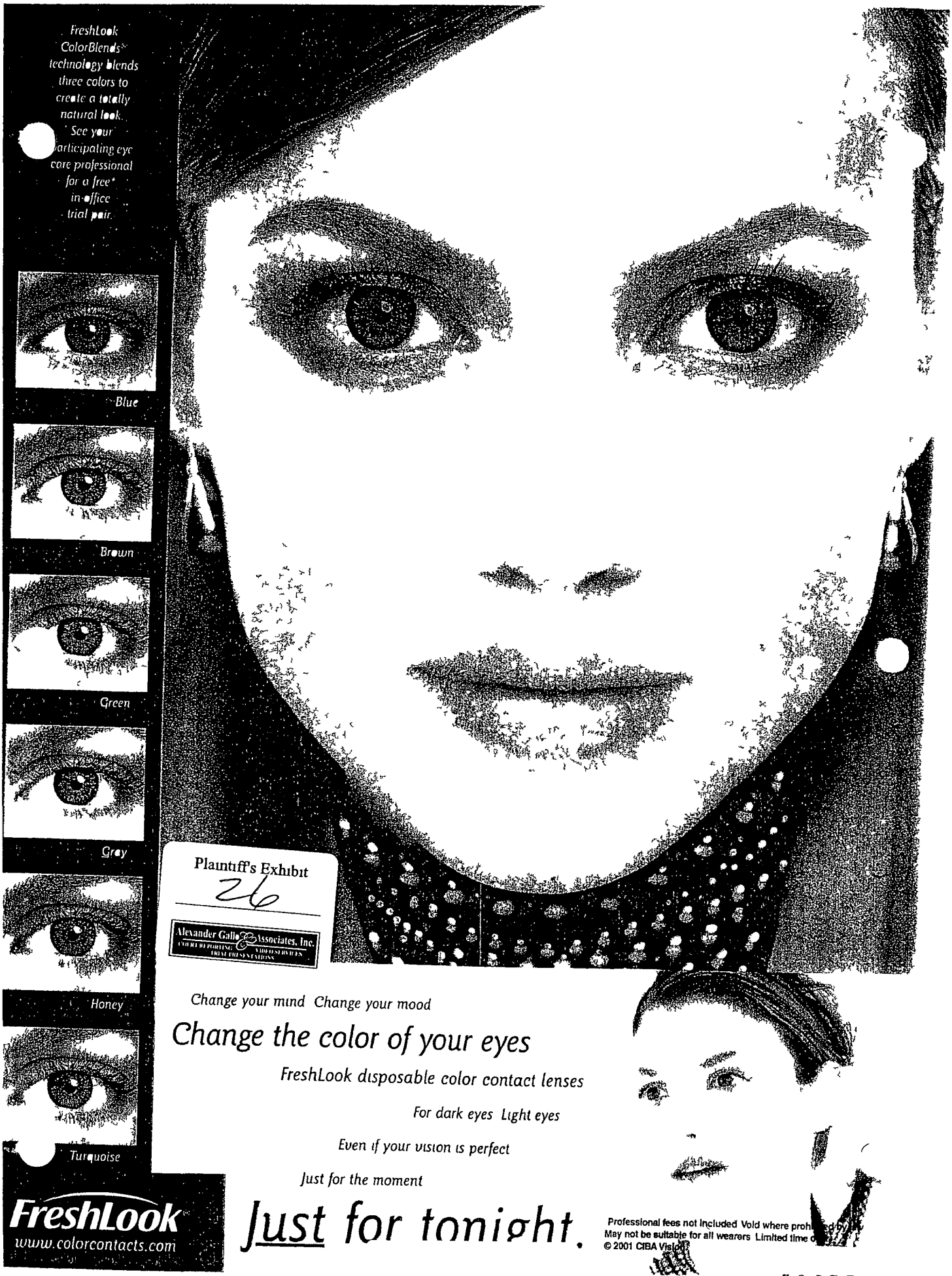

FreshLook ColorBlends® technology blends three colors to create a totally natural look.
See your participating eye care professional for a free* in office trial pair.
Blue
Brown
Green
Grey
Honey
Turquoise
Plaintiff's Exhibit
70
Alexander Gallo & Associates, Inc.
Change your mind Change your mood
Change the color of your eyes
FreshLook disposable color contact lenses
For dark eyes Light eyes
Even if your vision is perfect
Just for the moment
Just for tonight.
FreshLook
www.colorcontacts.com



708-WCSR 0061


FreshLook ColorBlends™ technology blends three colors to create a totally natural look. See your participating eye care professional for a free* in-office trial pair.
Blue
Brown
Green
Gray
Honey
Turquoise
Plaintiff's Exhibit
22
Alexander Gallo & Associates, Inc.
Change your mind Change your mood
Change the color of your eyes
FreshLook disposable color contact lenses
For dark eyes Light eyes
Even if your vision is perfect
Just for the moment
Just for tonight.
FreshLook
www.colorcontacts.com
Professional fees not included. Void where prohibited by law. May not be available for a limited time offer.
© 2001 CIBA Vision


La tecnología FreshLook ColorBlends® combina tres colores para crear un aspecto totalmente natural. Consulte a su proveedor de asistencia ocular participante para un par de prueba gratuito* en la consulta.
Azul
Marrón
Verde
Gris
Miel
Turqueso
Plaintiff's Exhibit
23
Alexander Gallo & Associates, Inc.
Cambie de opinion Cambie de animo
Cambie el color de sus ojos
lentes de contacto de color FreshLook de usar y tirar
Para ojos oscuros Para ojos claros
Incluso aunque su vista sea perfecta Por ahora
Por esta noche.
FreshLook
www.colorcontacts.com
Tarifas profesionales no incluidas. Nulo donde esté prohibido por la ley. Puede no ser indicado para todas las personas. Oferta de tiempo limitado © 2001 CIBA Vision


FreshLook ColorBlends technology blends three colors to create a totally natural look. See your participating eye care professional for a free* in-office trial pair.
Blue
Brown
Green
Gray
Honey
Turquoise
FreshLook
www.colorcontacts.com
Plaintiff's Exhibit
26
Alexander Galie & Associates, Inc.
Change your mind Change your mood
Change the color of your eyes
FreshLook disposable color contact lenses
For dark eyes Light eyes
Even if your vision is perfect
Just for the moment
Just for tonight.
Professional fees not included Void where prohi
May not be suitable for all wearers Limited time o
© 2001 CIBA Visio

ADVERTISEMENT



you in color contacts? see for yourself, whether you have perfect vision or not.



The unique 3 in 1 technology of ColorBlends™ lenses blend three colors into one to create the subtle natural depth of beautiful eyes.

Ready to create a totally new and natural look? Try 3 in 1 FreshLook ColorBlends® contact lenses. You can also choose FreshLook Color Enhancers® for light eyes. FreshLook® Colors for dark eyes or FreshLook clear disposables. The health of your eyes is important. That's why even if your vision is perfect, you must visit your eye care professional for an eye exam. Ask for a free in-office trial of any FreshLook lenses.

great tips for great looks

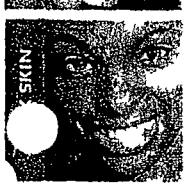




- Stick with warm eye shadows like taupe and brown. Try earth tone lipstick in light shades of brown
- Soft lavender shadow with clear mascara
- Try lipstick that are soft pink or plum
- Downplay eye makeup to brighten eye color
- Red lipstick and rose blush
- Sheer shades of brown and green shadow. Try earthy shades of blush and lipstick



- Try earthy brown shadow or sheer burgundy
- Lips can go from light reds to deep brown
- Gray shadow with a hint of green close to the brow
- Gray eyeliner and rose lipstick to finish the look
- Brown or lavender eye shadow
- For drama add black eyeliner
- Keep lips soft with pink lip gloss
- Add amber and green eye shadow. Lips should remain natural with just a hint of lip gloss



- Rich brown eyeshadow with a touch of brown liner
- Keep lip color in the deep plum family
- Amber shadows with just a touch of rose lip stick
- Rose blush
- Black eyeliner
- Soft blue eyeshadow with brown or black eyeliner
- Rose or deep plum lip stick
- Lips in rich shades of red, brown. Add black or gray eyeliner



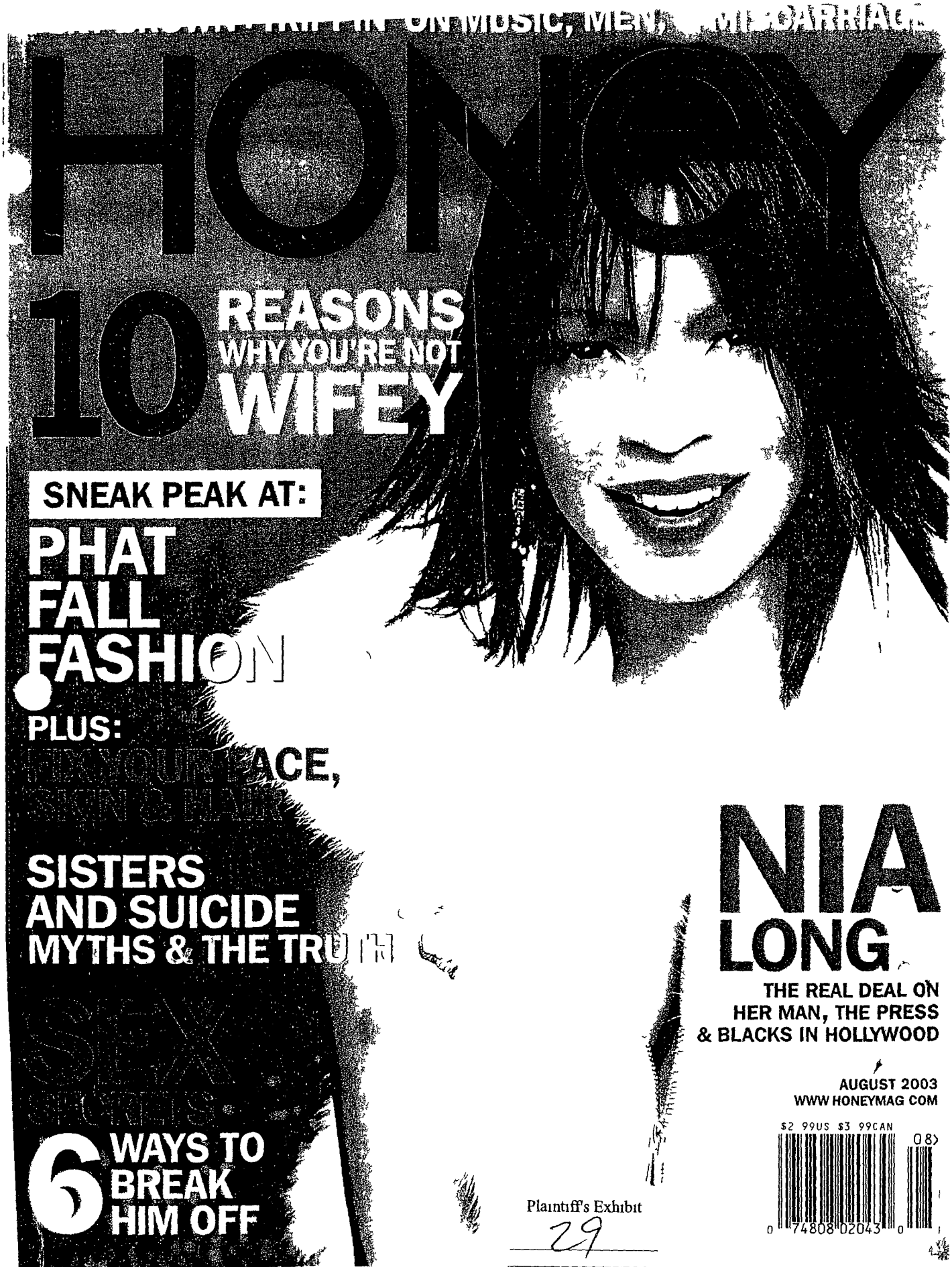
Professional fees not included. May not be suitable for all wearers. Limited time offer. Professional fees may be covered under some insurance plans. ©2000 Wesley Jessen Corporation

www.colorcontacts.com

Plaintiff's Exhibit
28

Alexander Gallo & Associates, Inc.
COURT REPORTING · VIDEO SERVICES · TRIAL PRESENTATIONS

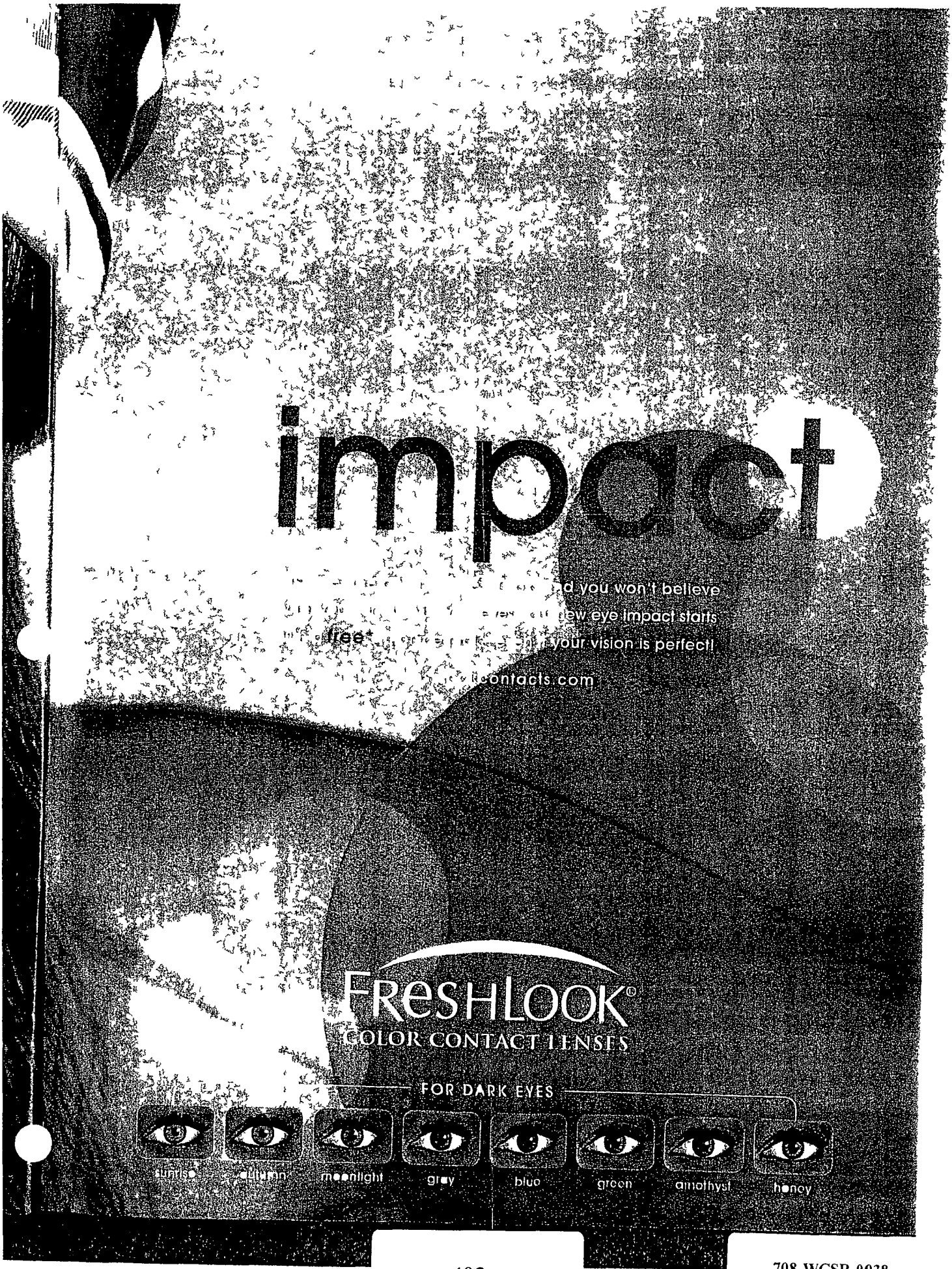
708 WCSP 0053



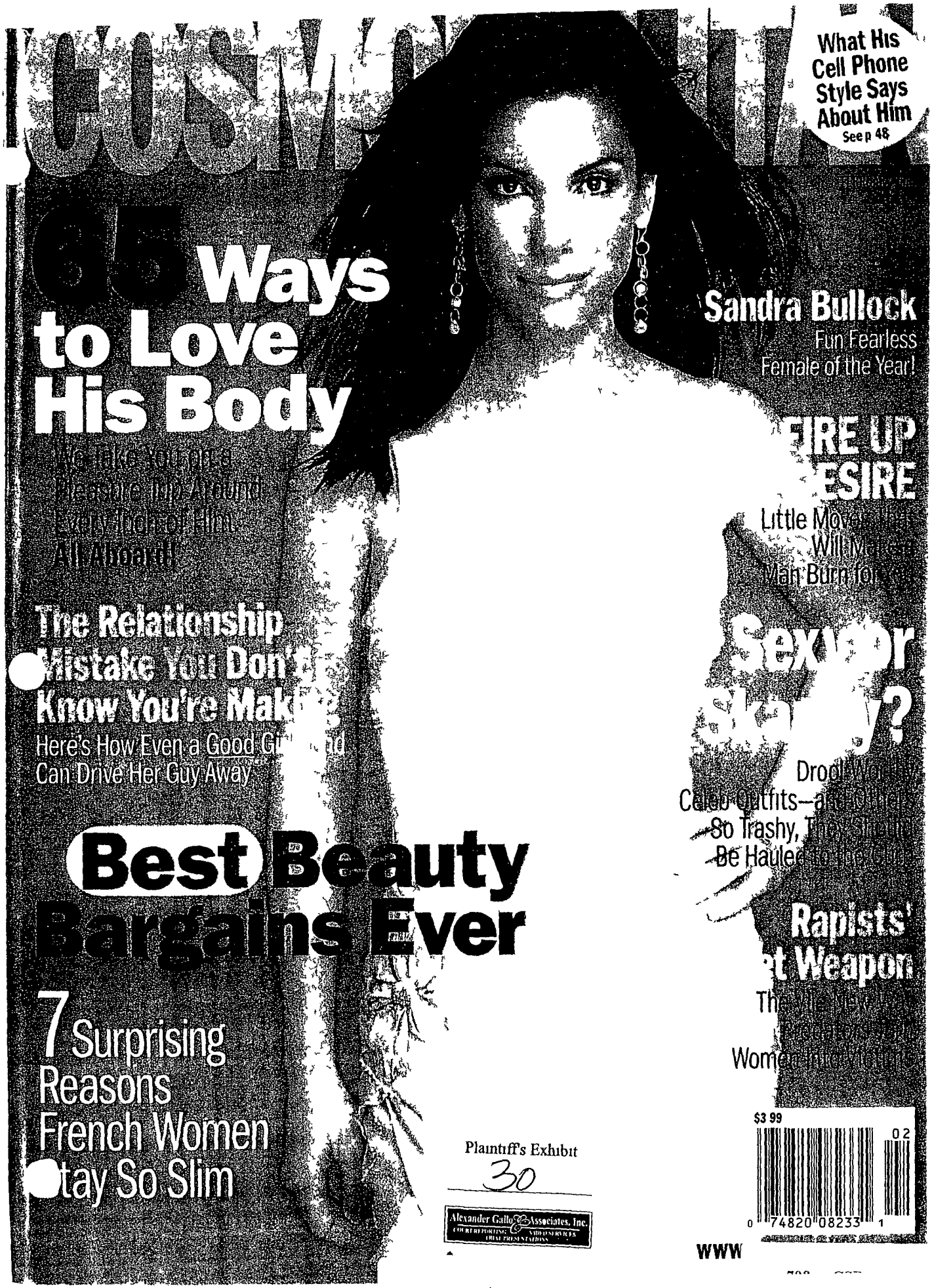
Plaintiff's Exhibit
29

Alexander Gallo & Associates, Inc.


changed her brown eyes with FreshLook ColorBlends® Gray
* Contact lenses, even if worn for cosmetic reasons, are medical devices that require a valid prescription and should only be worn under the supervision of an eye care professional. Rx only Eye exam may be required. Professional fees not included. Void where prohibited by law. ©2003 CIBA Vision

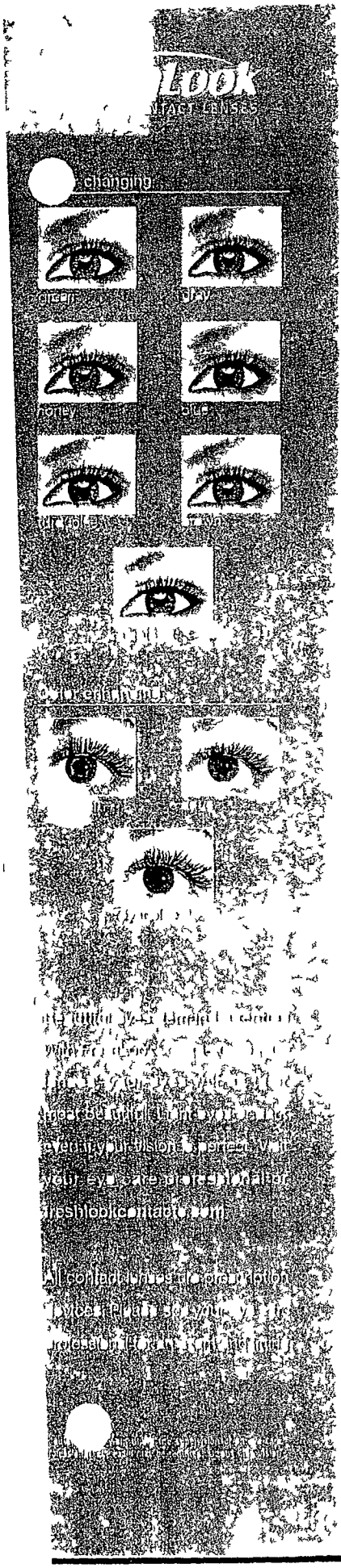


708 WCSR 0038



Plaintiff's Exhibit
30

Alexander Gallo & Associates, Inc.



might not be able to stop his head from spinning when he hits the pillow

If having too many other things on his mind isn't the issue it could be his body that's bottoming out An overtired unfit body isn't going to have the energy to get off the couch much less have sex says Castleman Studies show that the more physically fit you are the more sexually active you're likely to be A recent illness excess poundage lack of exercise eating big meals or boozing could be to blame And if he's not feeling good about the way his bod looks—yeah guys have body image bummers too—it can dampen his desire even more

Medication could also be bringing him down "There are several medications that have a negative effect on sex drive including some common cold medications and antidepressants says Dr Paola If you suspect his Rxs could be the culprit suggest that he check with his doc to see if switching meds could solve the problem There's also a small portion of the male population who simply have decreased libidos because their testosterone levels are naturally lower "The incidence of abnormally low testosterone levels in men in their 20s and 30s is very rare says Dr Paola That said if he's completely turned off to sex, he should ask his doctor for a blood test to find out if the trouble is hormonal

MOJO GOAL 3

Levitate his libido

Before you try to rev your man's stalled engine realize that not every dude's libido is the same size—just like his appetite—and that's perfectly fine Some guys have very high libidos and some have intrinsically lower ones says Castleman Nobody knows precisely what accounts for these differences but there is nothing abnormal about having a relatively lower sex drive than the next guy What is important is that your sexual desire levels are compatible So when you talk to your guy about his lagging lust don't make him feel like an inadequate freak by randomly blurting out "Why don't you want to have sex more often?" He'll probably just get self conscious about the fact that he's not satisfying you or become defensive and start a fight

Instead take a subtler tack If you suspect that stress is the problem give him a chance to vent at the end of the day then offer to give him a massage "When my boyfriend is wound up rubbing his shoulders and neck works like a charm says Kara 28 It gives him time to switch gears and remember that he has a life outside work To raise his low energy levels make a date to walk in the *129*

A Surprising Lust Buster

Women may be reputed to use headaches as an excuse to get out of sex, but it turns out some guys actually get headaches from doing the deed. According to a new study from the University of Münster in Germany, dudes are three times more likely than women to suffer from a sexual headache, technically called orgasmic cephalalgia, which happens when the blood vessels constrict and cause a sharp pain right before he orgasms. The good news: The headaches are not that common and can be prevented when he paces himself in the sack and doesn't rush toward the big O.

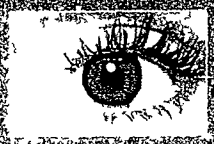

Open your eyes and


Your Body-Love Issue! Warning: May Cause Extreme Confidence
Sexy! Sweet!
Men Talk About Women's Bodies
Uncensored
Sexiest Summer Hair & Makeup
We tried on 1000 Swimsuits!
50 flattery winners inside
Plaintiff's Exhibit
31
Alexander Gallo & Associates, Inc.
X-Men 2 stars
Halle, Rebecca, Famke:
Different womanly shapes,
same amazing body confidence
Exposed
Successful Women Are Hooked On

illuminate your eyes



ORIGINAL BROWN EYE



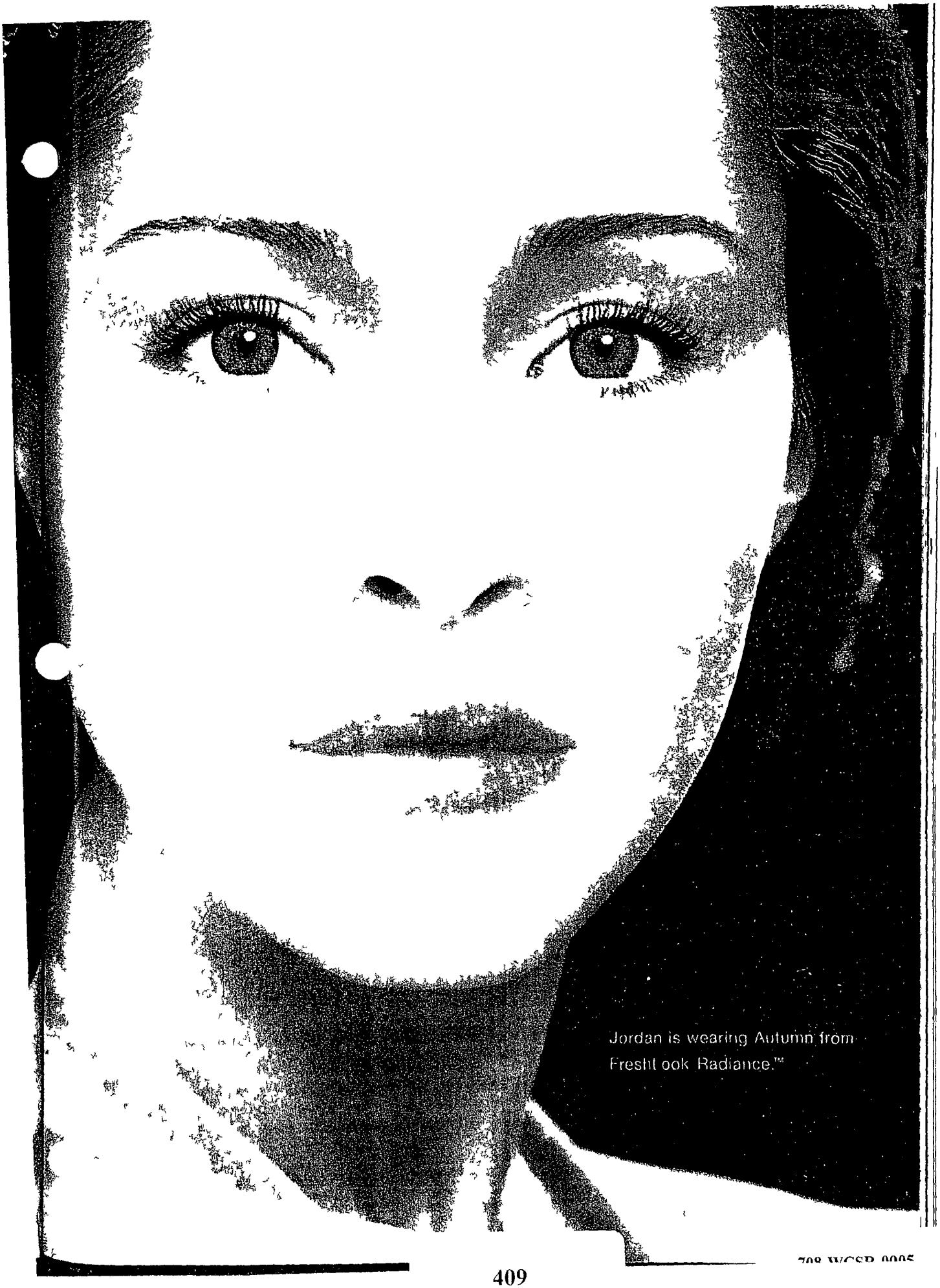


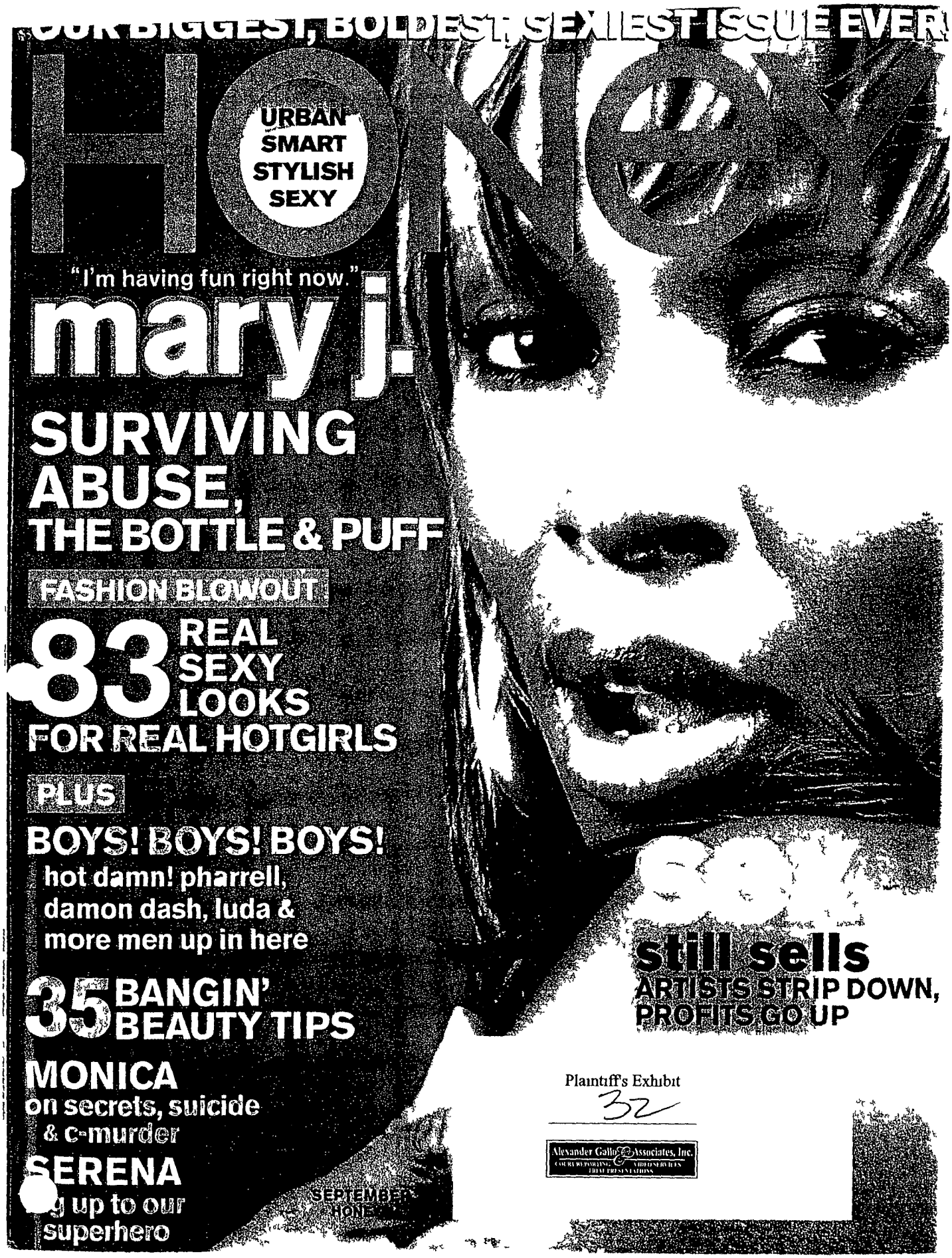






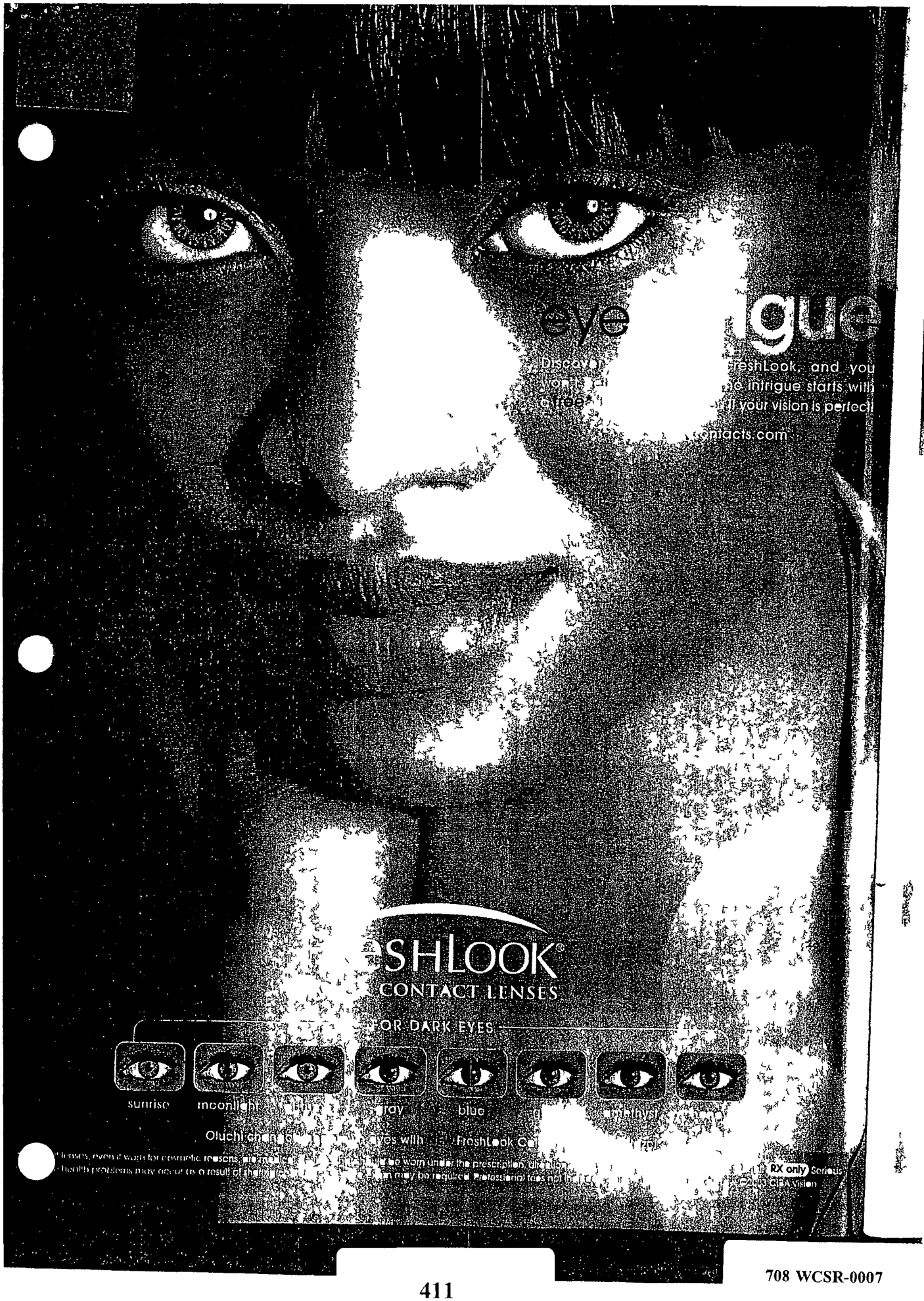



Jordan is wearing Autumn from
Fresh Look Radiance.™



Plaintiff's Exhibit
32

Alexander Gallo & Associates, Inc.
COURT REPORTING · VIDEO SERVICES
TRIAL PRESENTATIONS


eye
gue
reshLook, and you
e intrigue starts with
r if your vision is perfect
ontacts.com
SHLOOK
CONTACT LENSES
FOR DARK EYES
sunrise
moonlight
gray
blue
amethyst
Ouch! ch
eyes with
FreshLook
RX only

EXCLUSIVE! MARY J'S WEDDING, K-CI'S REACTION



THE DRAMA ISSUE

TAKE CONTROL
HANDLE YOUR MAN AND YOUR MONEY

GABRIELLE UNION PUTS LL COOL J IN CHECK

KIM & FOXY take on Eve
BOBBY BROWN gets help
GIRL GROUPS fight dirty

GET HOT HAIR NOW

Does He Have *Jungle Fever?* (don't sleep)

QUESTIONS THAT CAN SAVE YOUR LIFE

MARCH 2003
WWW.HONEYMAG.COM

$2.99US $3.99CAN

03>

0 74808 02043 0

Plaintiff's Exhibit
33

Alexander Gallo & Associates, Inc.

illuminate your eyes



ORIGINAL BROWN EYE





AUTUMN



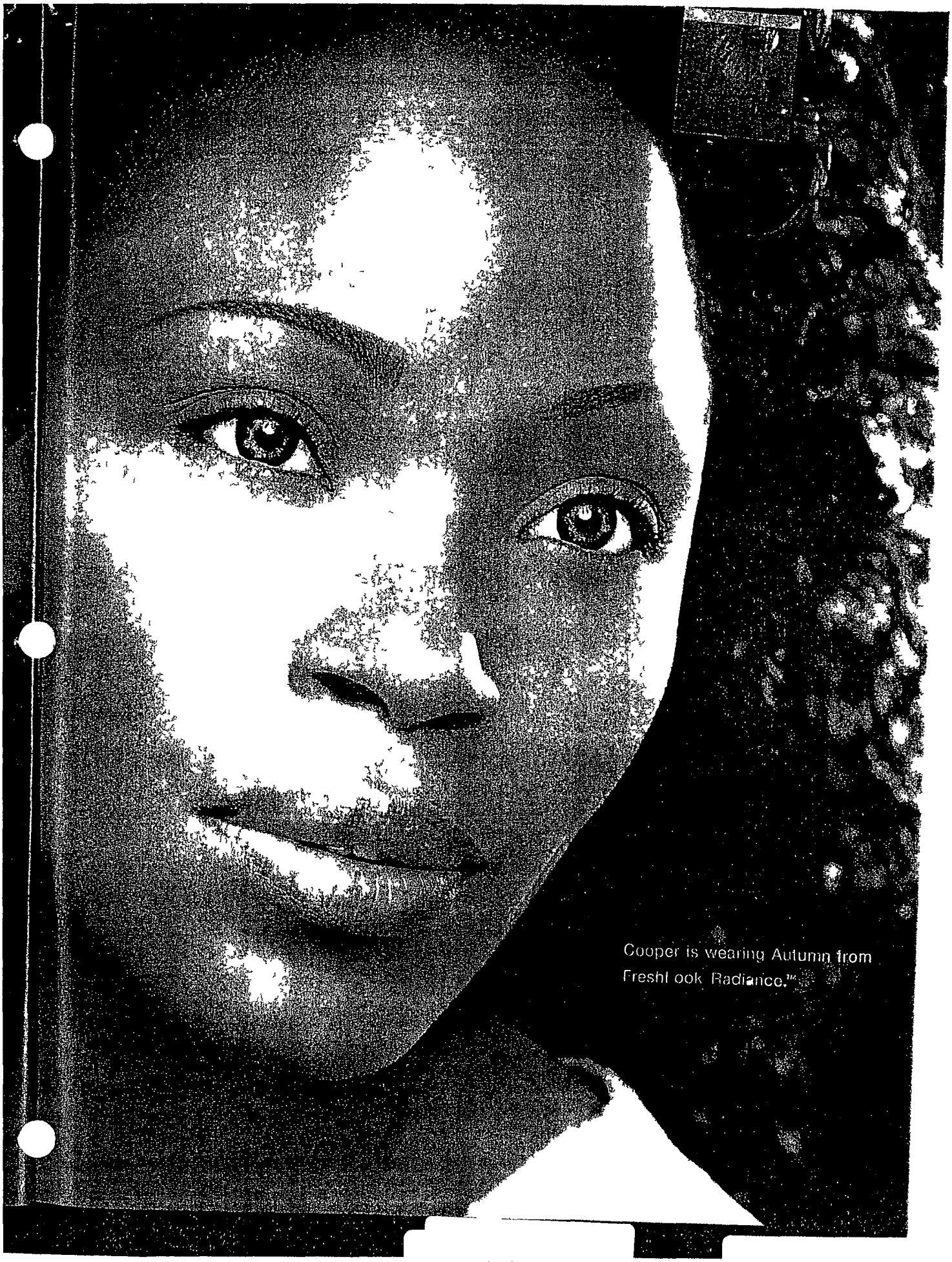
MOONLIGHT

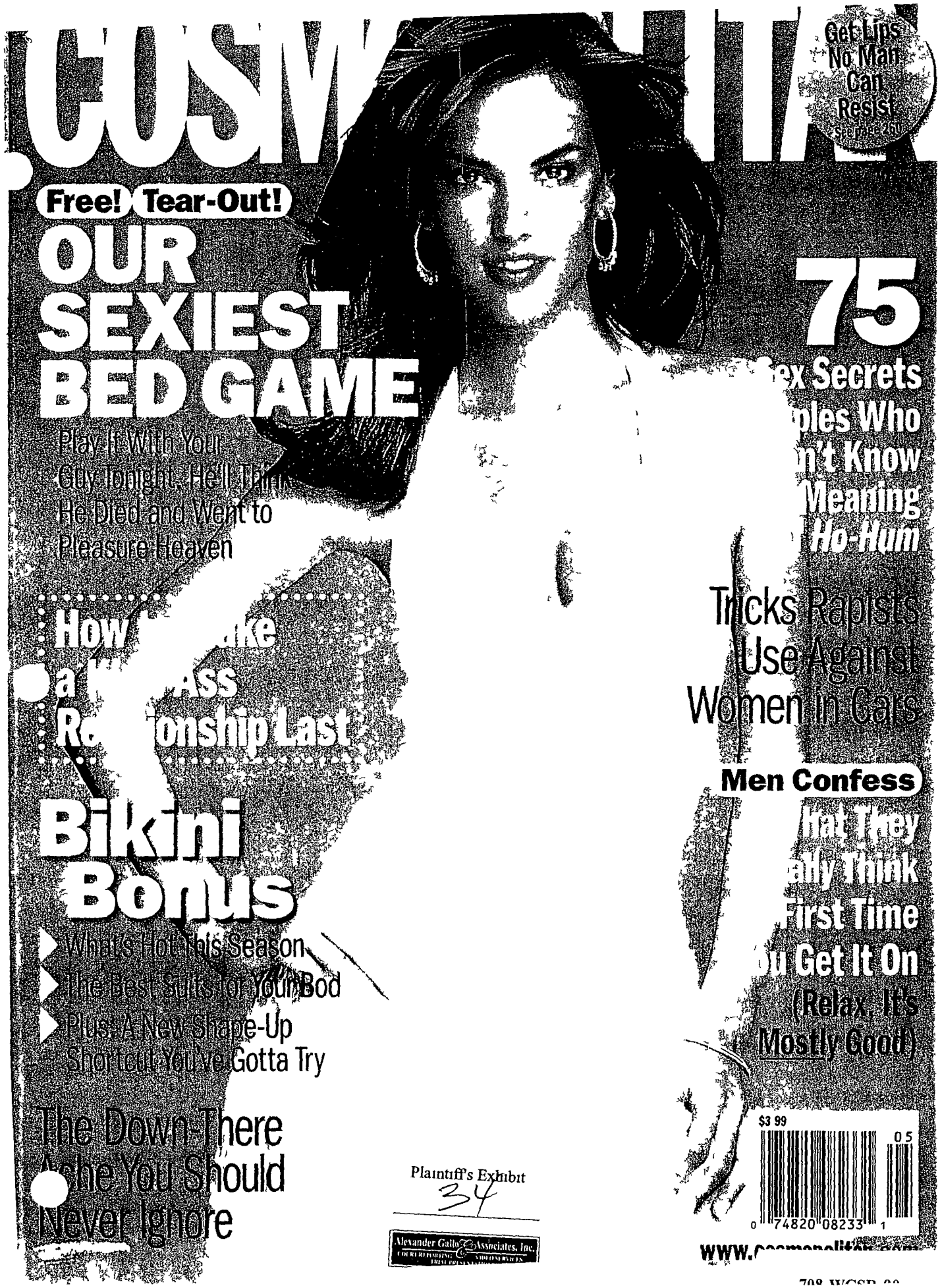


EDEN

Capture the beauty of light

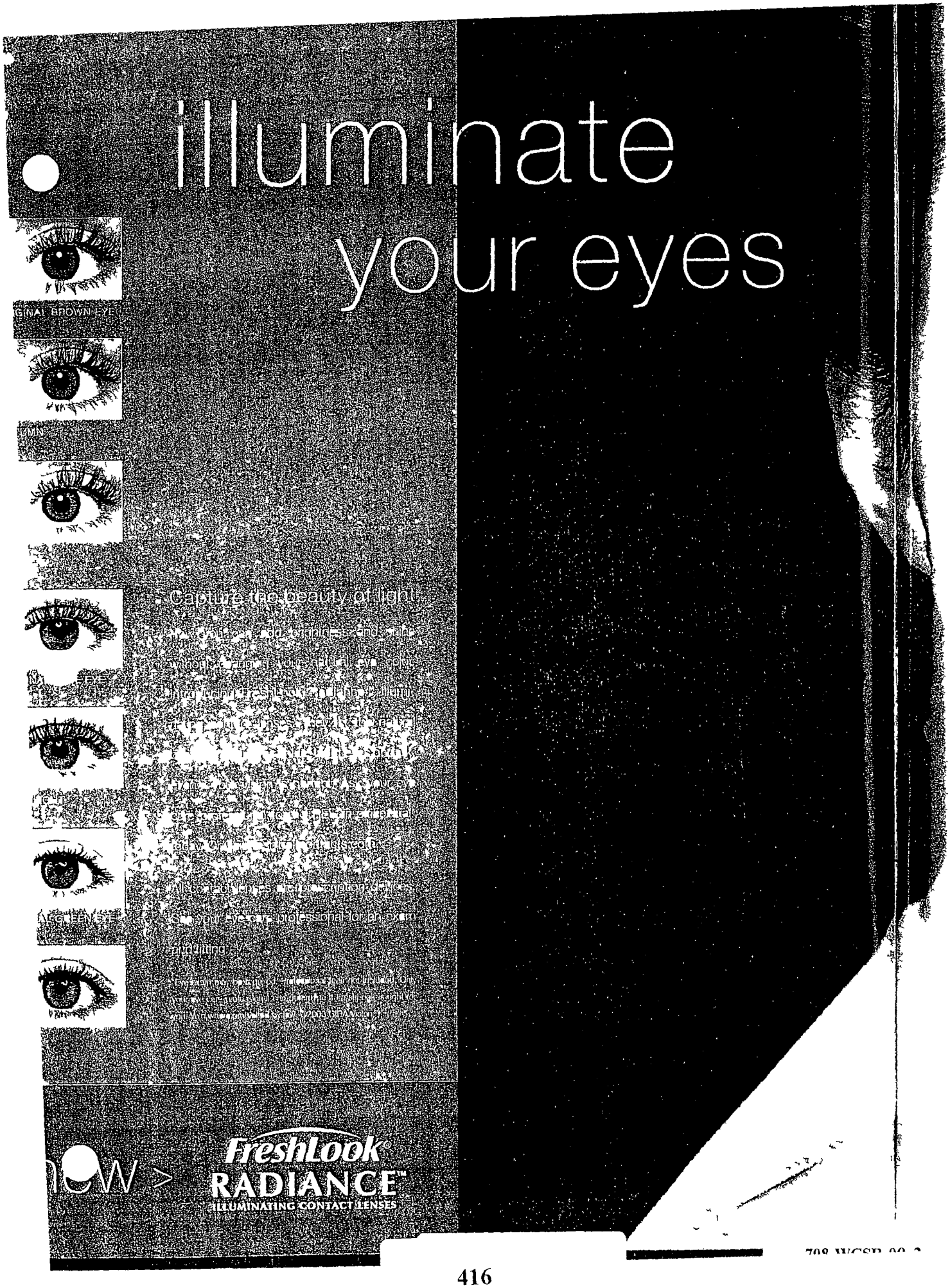


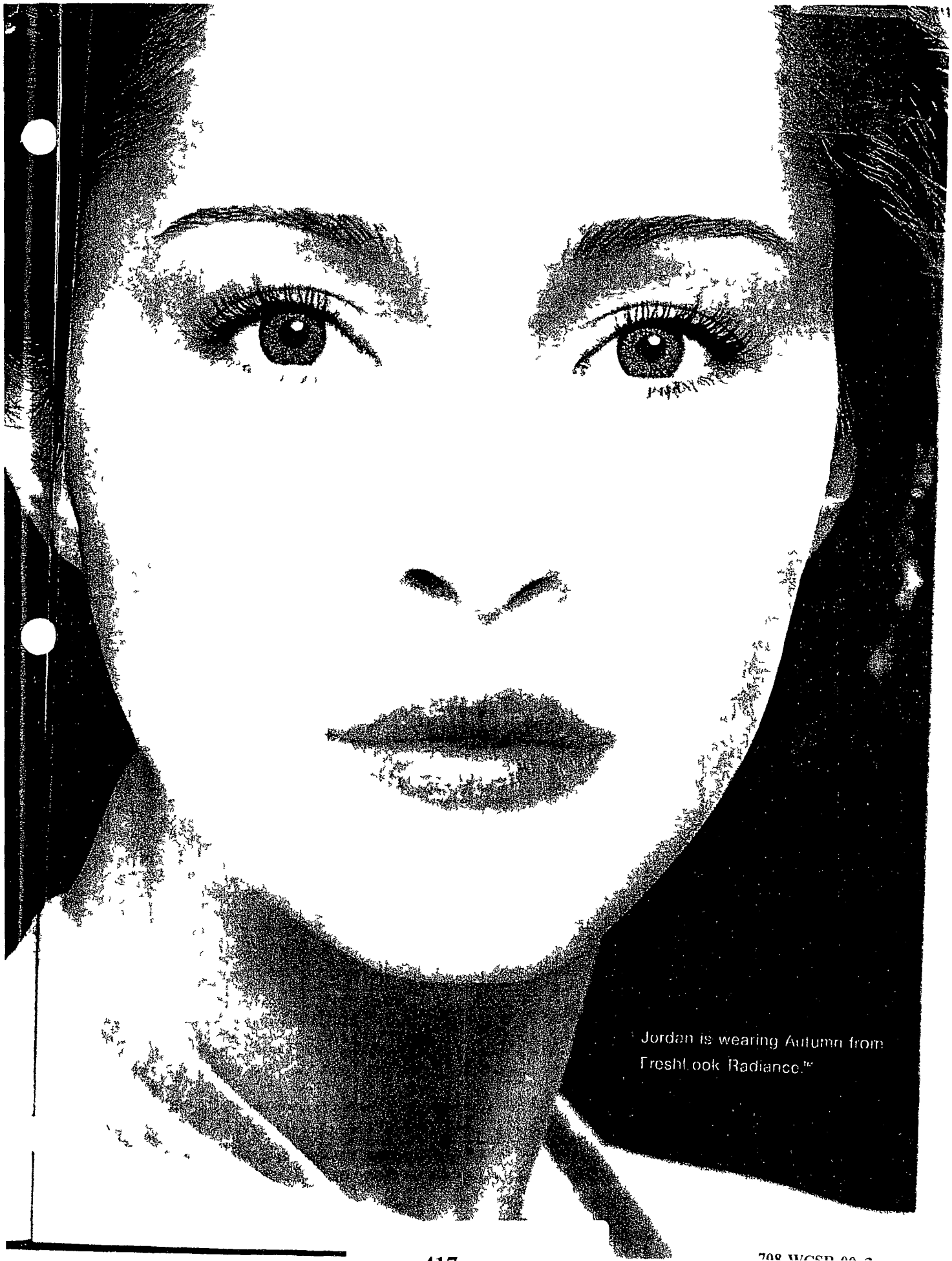

Cooper is wearing Autumn from
Fresh! ook Radiance.™



Plaintiff's Exhibit
34

Alexander Gallo & Associates, Inc.


illuminate
your eyes
Capture the beauty of light
FreshLook®
RADIANCE™
ILLUMINATING CONTACT LENSES


Jordan is wearing Autumn from
FreshLook Radiance.™

GLAMOUR

OCTOBER 200



He likes WHAT?!

MEN'S TOP 10 SEX WANTS

Stuff they'd never say—but wish you knew, p.272

Hair Help!

- Easy glam fixes
- Don'ts (whoa!) & Dos
- Jennifer Lopez's sexy beauty news

Female force
Ashley Judd

Couple Bloopers

Love life "Oops!" stories

How do they look that good, anyway?

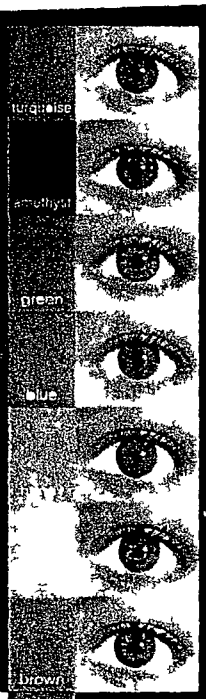
Take Charge of

Special rip-out section to help every woman stay safe
+ Free daily-tips hotline

9437
10>
0 754994 0
www.glamour.com
U.S.A. $3.50
CANADA $4.50
FOREIGN $4.50

Plaintiff's Exhibit
35
Alexander Gallo & Associates

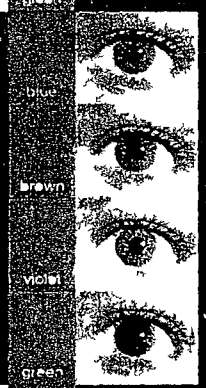
Get 2 free boxes when you buy six.





With this many colors who can pick just one? Bold, beautiful, subtle or mysterious. We have the colors for both light and dark eyes.

Even if your vision is perfect. Visit your eye care professional to get your 2 free boxes when you buy six for this year's new looks.





FreshLook
COSMETIC CONTACT LENSES
freshlookcontacts.com

...reshLook Cosmetic brand products, ...FreshLook ColorBlends Tonic Focus ...nthly Softcolors Offer valid 7/1/02 thru 12-31/02. ...imum 6 box purchase required Offer valid at ...ticipating eye care professionals. Eye exam may ...required Professional fees not included. Only your ...e care professional can determine if FreshLook is ...t for you. Void where prohibited by law. Limited ...e offer. © 2002 CIBA Vision

perfect in one more area,'" says Domar Such perfectionism often backfires "For example, a 200-pound woman probably needs to lose weight. But she may think that if she can t be supermodel thin, why try? It s best to keep a more balanced perspective

HOW TO BEAT STRESS AT

Spend time with friends Postcollege stress hits from all directions career decisions, relationship turmoil, financial pressures The best way to beat it is to lean on friends or family who can significantly reduce stress levels

Take control Women at this age are often stressed because they're juggling too much The best way to cope according to a new study is by prioritizing (Not sure how? See How to Have More You Time on page 123)

Give yourself some TLC Caring for children *and* aging parents? You may be ignoring your own needs And a new survey shows that 50 percent of women deal with stress by turning to comfort foods or exercising less Remember to take care of yourself at least once a week. —*D H*

A healthy-you *cheat* sheet

The only one-sentence answer to good health is It s a lifestyle it s learning it s baby steps says Carolyn Clancy M D Start now Go ahead—we dare you

- **WATCH YOUR WEIGHT** It s key to prevent ing type II diabetes and heart disease To find out if you re at a healthy weight go to nhlbisupport com/bmi
- **EAT WISELY** Sure good nutrition helps you stay slim but a diet rich in fruits and vegetables also protects against heart disease and several types of cancer
- **PRACTICE SAFE SEX** One of the most common questions I hear is How can I protect my fertility? says Alice Domar Ph D But women often don t make a connection between infertility and STDs like chlamydia Safe sex matters
- **LIFT WEIGHTS** Combined with regular cardio strength training helps burn fat faster and stave off osteoporosis
- **STOP SMOKING** Kick the habit—your body deserves it For quitting tips log on to quitnet org

6 STOP LOOKING FOR A MAGIC BULLET

Popping a pill can t replace a healthy lifestyle —JOANN E MANSON M D PROFESSOR OF MEDICINE AT HARVARD MEDICAL SCHOOL AND CHIEF OF PREVENTIVE MEDICINE AT BRIGHAM AND WOMEN S HOSPITAL IN BOSTON

When doctors recommend prescription drugs women expect to get extensive information about the risks and benefits "But you walk into a health food store the salesman says 'Take this it s good for you,' and you blow $49 95 says Freya Schnabel M D chief of the division of breast surgery at Columbia Presbyterian Medical Center in New York City Women need to ask as many questions about natural remedies as they would about prescription drugs

If you still can't resist overnight miracles there *is* one relatively quick fix for many health ills We ll say it again exercise It s one of the best investments of time you can make says Dr DiNubile It helps you live longer and feel happier and it makes you more efficient and alert so you actually get more accomplished

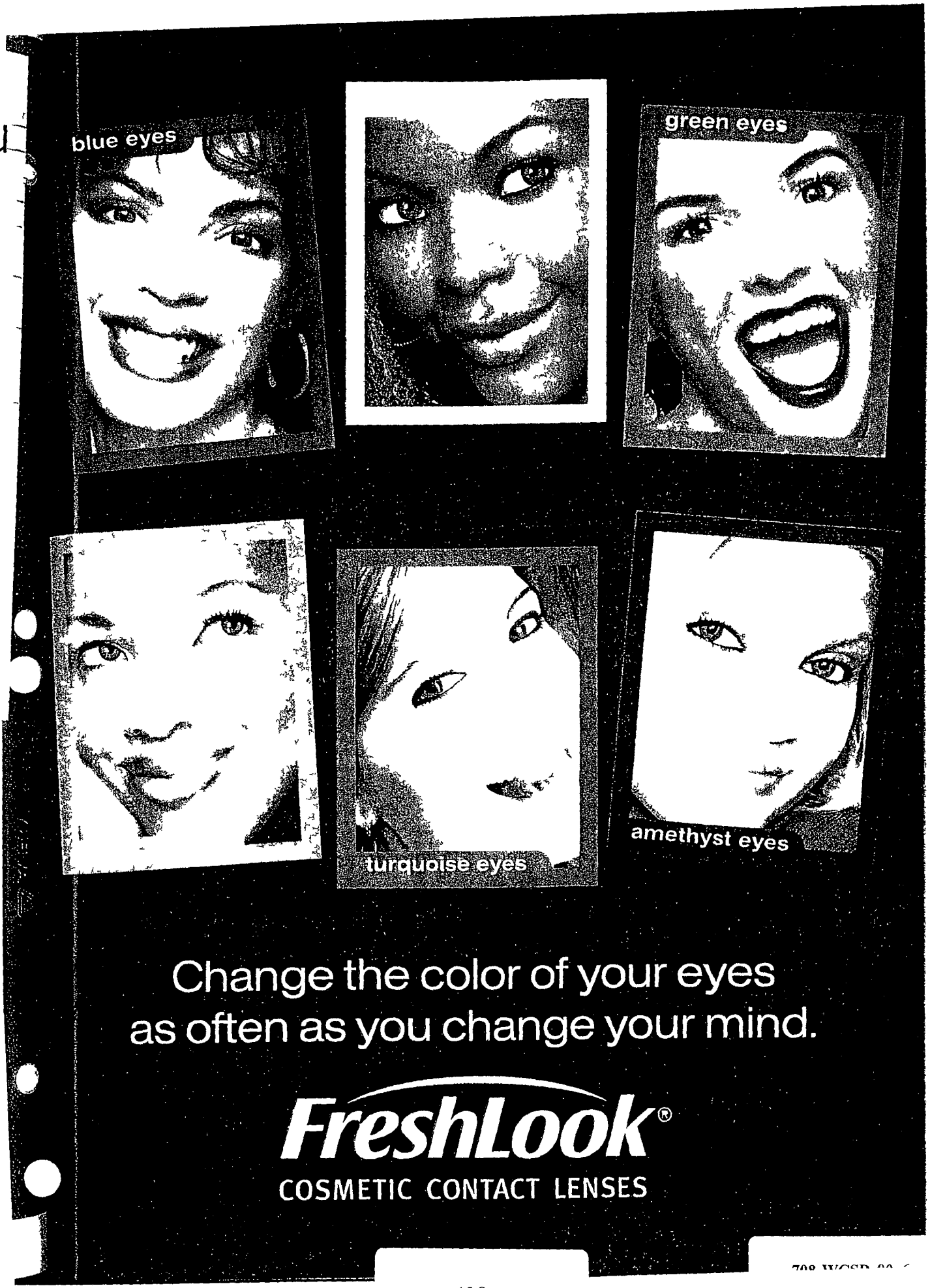
THE BEST EXERCISE AT

Butt kicking cardio Burn major calories with interval training Go all out for 30 seconds then work at a moderate pace for 60 seconds Do this for 30 minutes three times a week, plus weightlifting

Targeted toning In addition to your regular cardio fight a slowing metabolism by toning the large muscle groups (chest back hamstrings quads glutes) three times a week to burn the most fat

Weights weights weights Strength now is crucial for keeping up your metabolism and bone health so lift at least two to three days a week. —*D H* ©

Mary Duenwald writes regularly about health for The New York Times

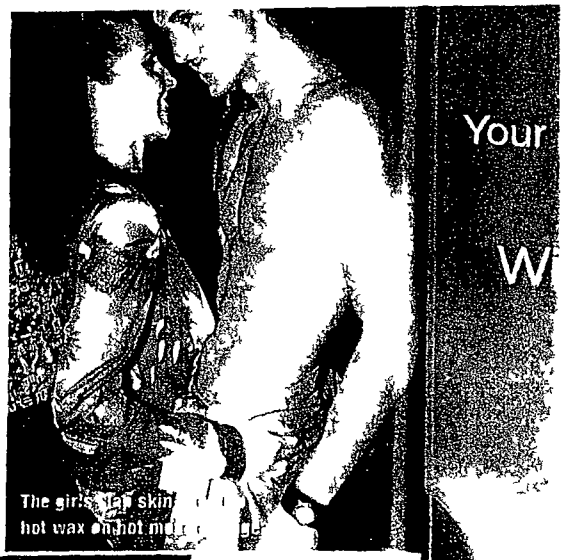

blue eyes
green eyes
turquoise eyes
amethyst eyes
Change the color of your eyes
as often as you change your mind.
FreshLook®
COSMETIC CONTACT LENSES


MARCH 2002
GET YOUR
REBECCA
ROMIJN-
STAMOS
MEN CONFESS
HOT
sexy looks
$2.95
0 74820 08530 1
Plaintiff's Exhibit
36
Alexander Gallo & Associates, Inc.

just for tonight
turquoise
new
amethyst
green
blue
brown
get a free pair!
Visit your eye care professional.
purchase FreshLook® color contact
lenses and receive a free pair
of the new amethyst lenses.
freshlookcontacts.com
FreshLook®
COLOR CONTACT LENSES

Maybe their mistake is that they re not wearing ridiculously revealing knockoffs Min, Heather, and Alexandra step out of the car and are quickly ushered through the ropes

Within minutes three shirtless boy toys are sandwiching Min, in a paean to Britney Spears salacious 'I m A Slave 4 U' video Alexandra starts dancing on a table 10 feet away, and the man sitting there—*not* amused—responds by tossing his drink all over her back A curiously ecstatic club kid in a wool cap begs Heather to pour hot wax from a lit candle onto his bare chest Naturally, she obliges







"I could be anybody, but in this dress, I'm somebody."
—Alexandra

Then, suddenly—and somewhat spetacularly—Alexandra s dress bursts into flames Actually, it s just the dress s train but it sure makes a lot of smoke One of the club kids had apparently decided that her flammable garment would make a pretty ashtray A male model graciously stomps out the fire leaving a cantaloupe size burn hole in the fabric

After 20 more minutes of madness Heather finally succumbs Exhausted she slumps onto a velvet cushion I ve had my ass grabbed three times, a tongue shoved in my ear a woman s forced herself on me, and I can t get anybody to look me in the face Apparently, my eyes have relocated to my chest," she says, examining the smudged remains of her Toni Braxton I guess that s just the price of wearing this dress It s like ordering a four course meal then saying I m not hungry

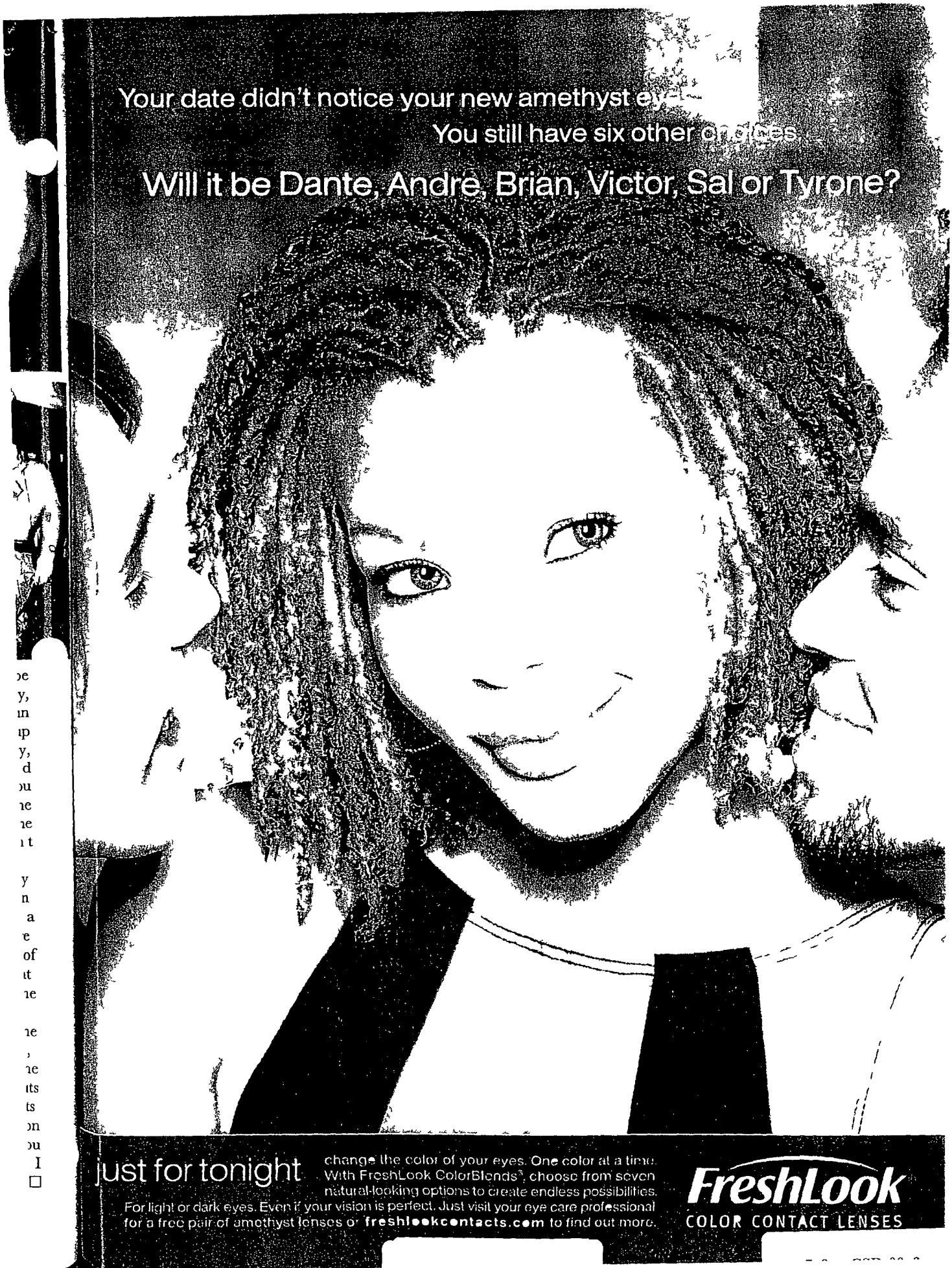
Five minutes later, Min emerges from the swarm of boy toys and retreats to a corner Her low riders have ridden so far south that they've nearly reached Paraguay Clearly she s given up caring Yee haw! she yelps catching her breath This is chaos! I mean, I always thought I wanted to be a celebrity but this has changed my mind People see you and the cameras and the lights and it's like you become public property I could never live like this

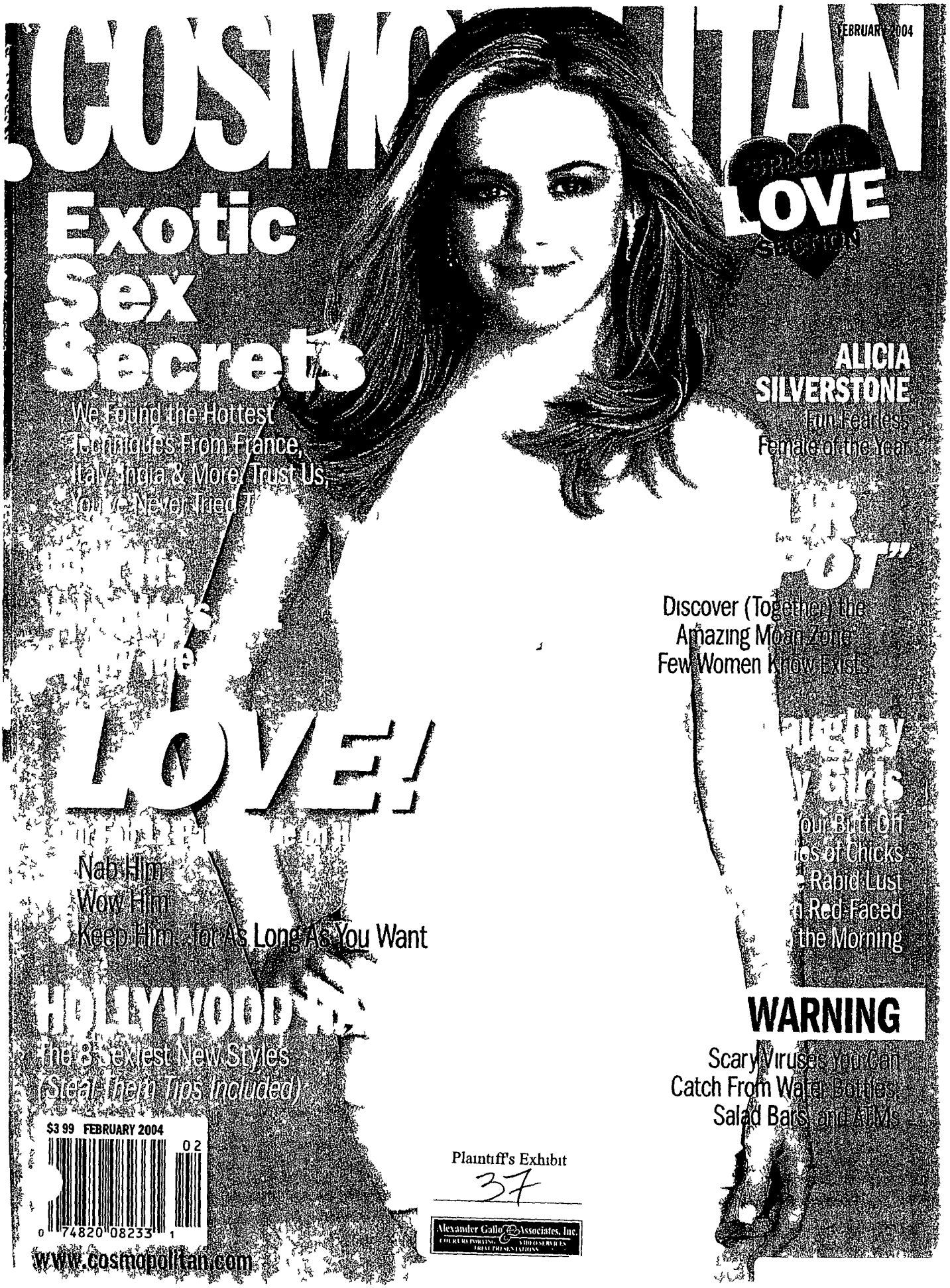
Side by side, Heather and Min head for the door—but Alexandra is nowhere to be found Suddenly she s spotted in the back of the room chatting up Billy Crystal's daughter, Lindsay while casually deflecting a rugged Austrian boy I just vant to grab you all zee time Can you blame me?" he says Alexandra doesn t seem to blame him a bit Indeed, Alexandra doesn t seem to mind any of this at all

It s just hilarious It could be any body in this dress But if there s a camera and a flash, people think I'm a somebody, she says The dress creates allure, that electric charge of having all those eyes on you The attention makes you feel sexy and the sexier you feel the sexier you are

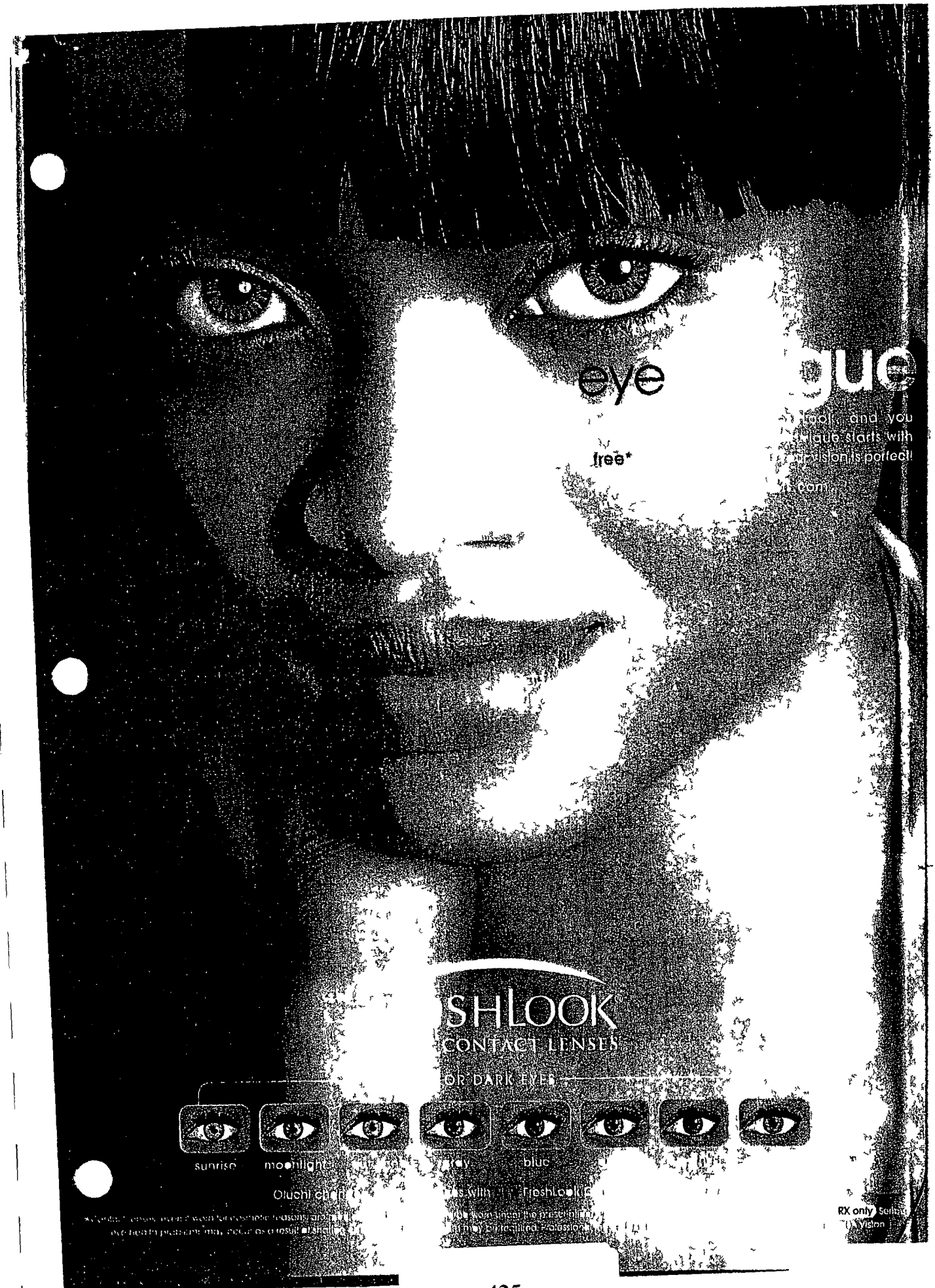
As she turns to walk toward the door, she examines her Versace soaked in the back, burned at the heels, but somehow still retaining its dignity—and containing her breasts And so, the answer to our question seems to be If you can wear it, you can, indeed, be it Alexandra sighs I just wish I could keep it □

708 WCSR-0018


Your date didn't notice your new amethyst eyes.
You still have six other choices.
Will it be Dante, André, Brian, Victor, Sal or Tyrone?
just for tonight
change the color of your eyes. One color at a time.
With FreshLook ColorBlends®, choose from seven natural-looking options to create endless possibilities.
For light or dark eyes. Even if your vision is perfect. Just visit your eye care professional for a free pair of amethyst lenses or freshlookcontacts.com to find out more.
FreshLook
COLOR CONTACT LENSES

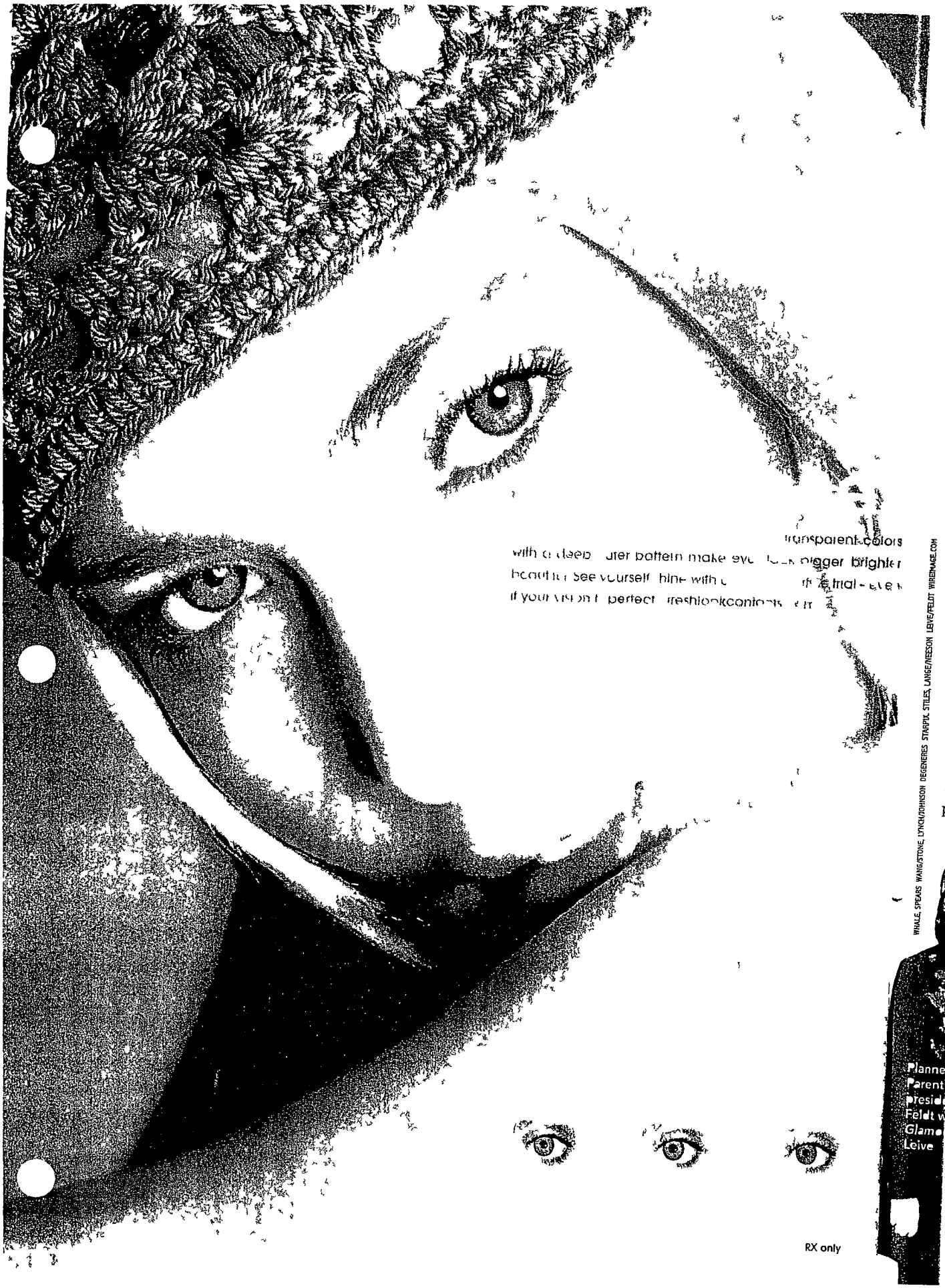


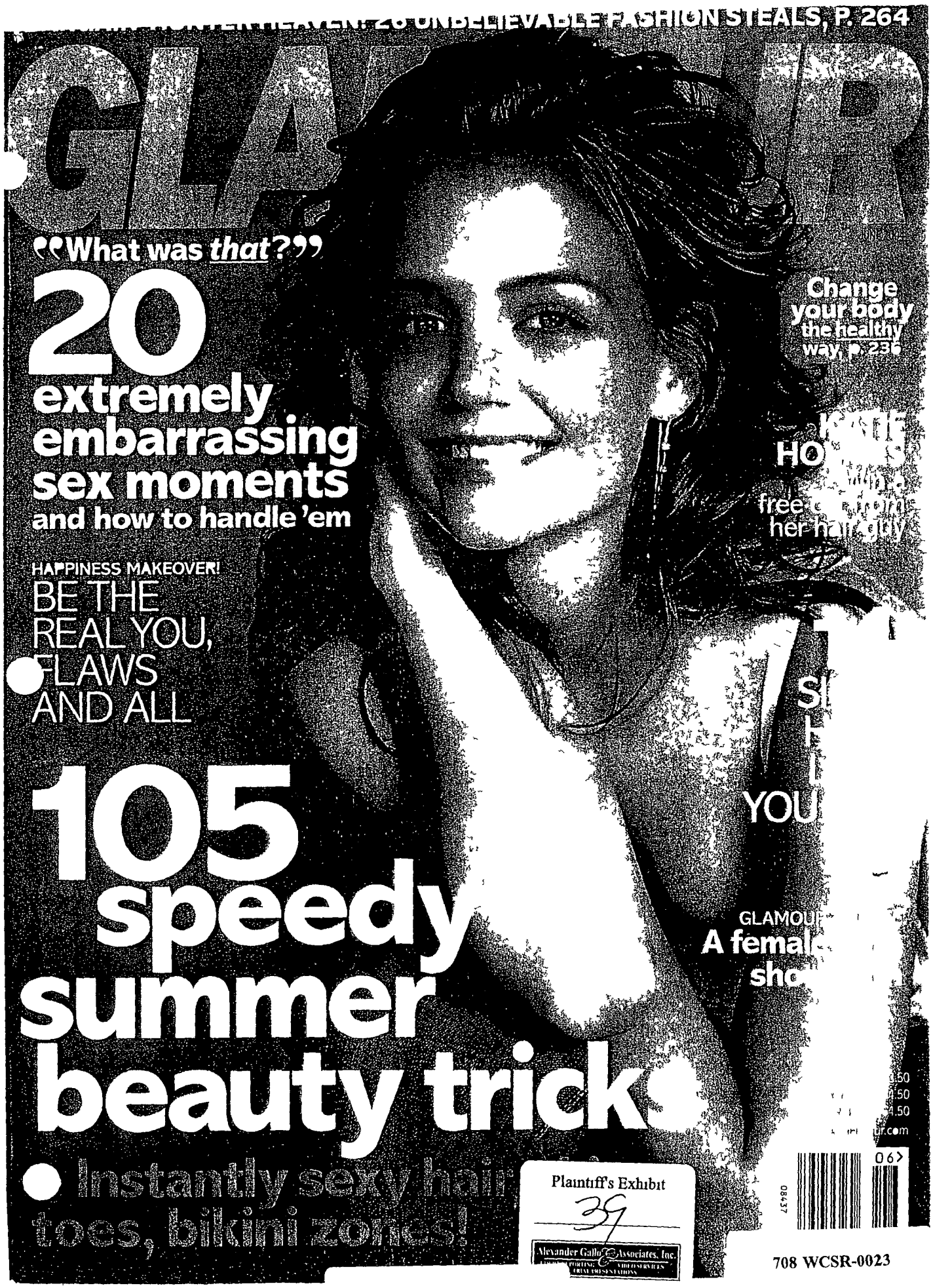
Plaintiff's Exhibit
37
Alexander Gallo & Associates, Inc.

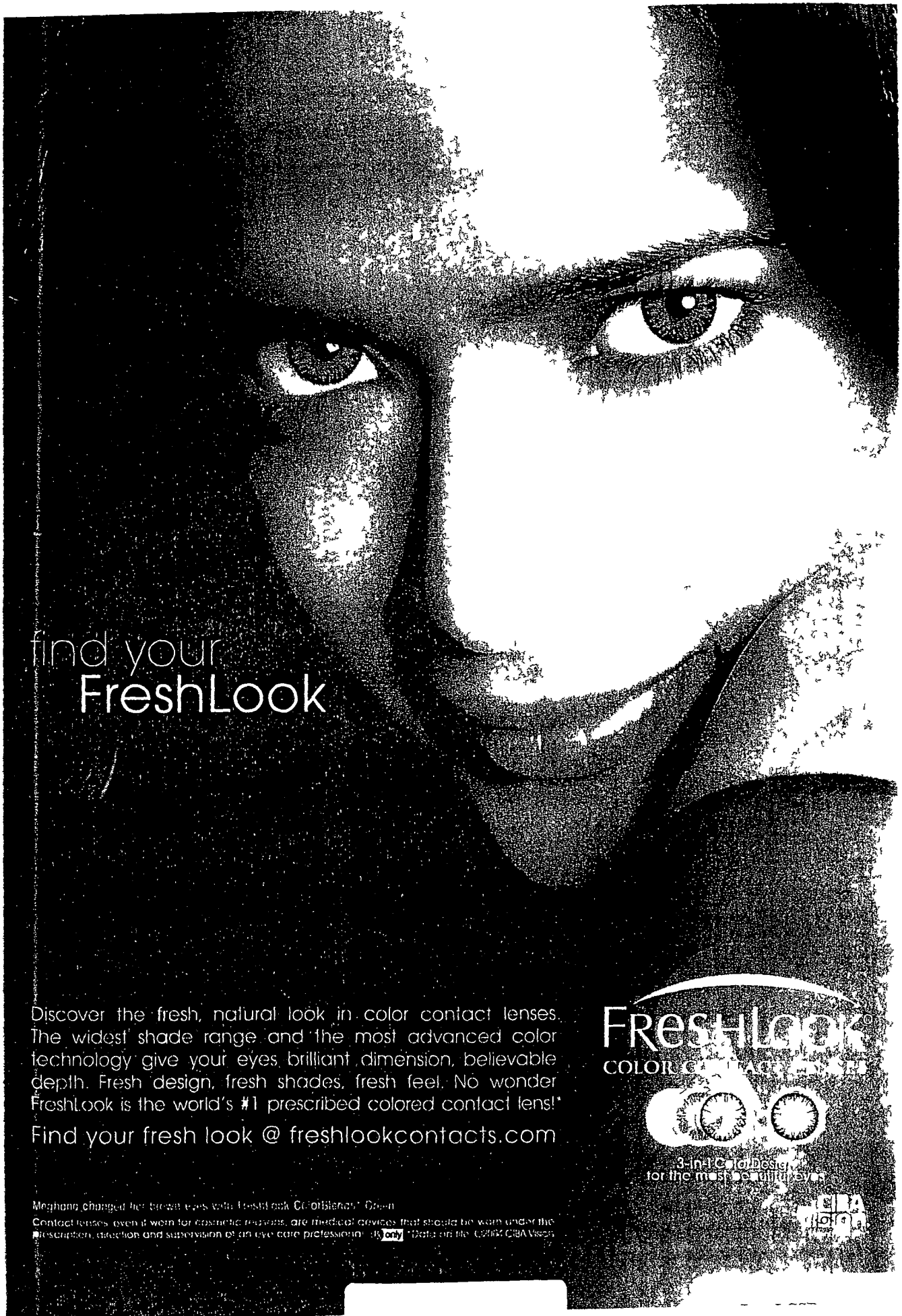


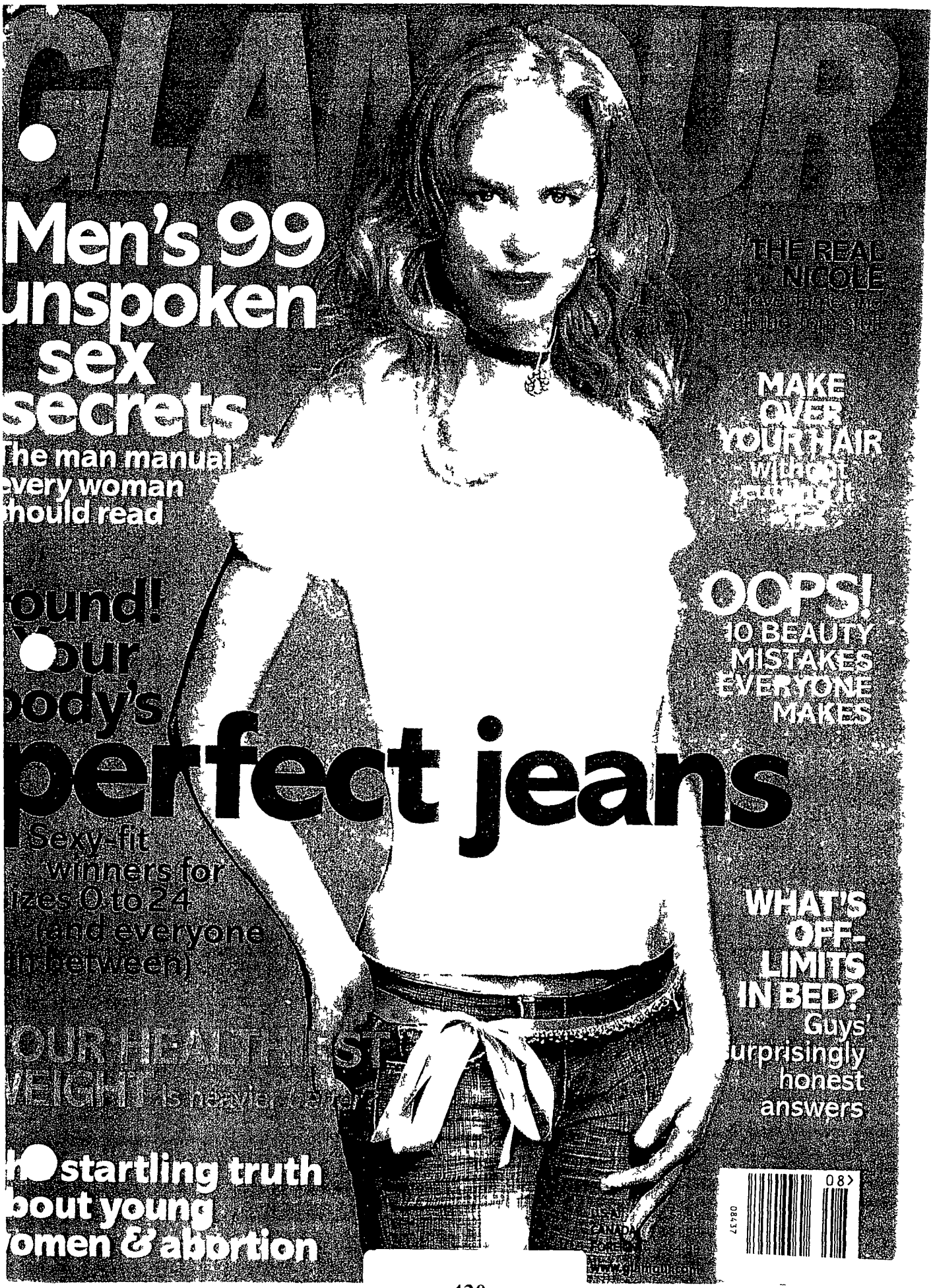
(Th rman) Charles Sykes/Rex Features (perfum) SVEND LINDBAEK. (yesh d w) ROGER CABELLO (illustrati ns) CHICO NATASAKI/www cwc-l m


VALENTINE'S DAY FREEBIES! JEANS,
HAIR STUFF, DREAM TRIPS
GLAMOUR
psst! men reveal:
FEBRUARY 2004
beauty FOR dummies
Gorgeous, goof-proof tricks
DO YOU TAKE THE PILL?
See p. 200 now
STRESS AND YOUR HEALTH AT 20, 30, 40
ways to your sexiest look
Hair, makeup, hair, clothes, hair, lingerie—did we mention hair?
Plaintiff's Exhibit
38
Alexander Gallo & Associates, Inc.
02
08437

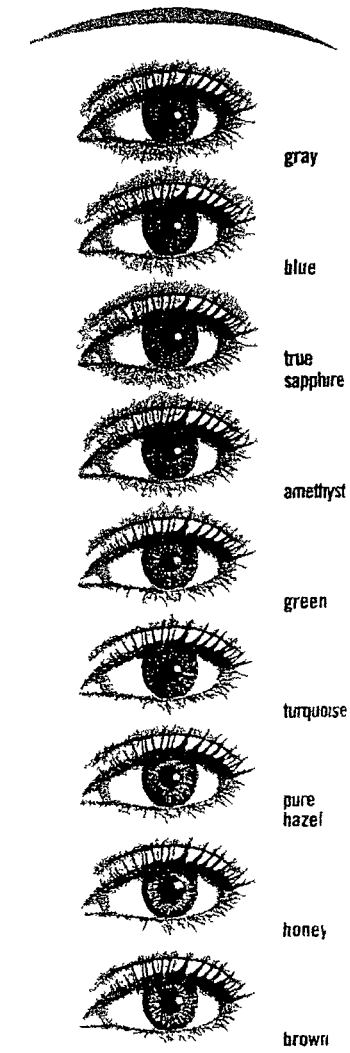

transparent colors
with a deep ...ster pattern make eye... ...k bigger brighter
beautiful See yourself shine with ... ...th a trial-size
if your vision ... perfect ...reshlook contacts ...
RX only
WHALE, SPEARS WANG/STONE, LYNCH/JOHNSON DEGENERES STRAPPX STILES, LANGE/NEESON LEIVS/FELDT WIREIMAGE.COM
Planne
Parent
Presid
Feldt w
Glame
Leive

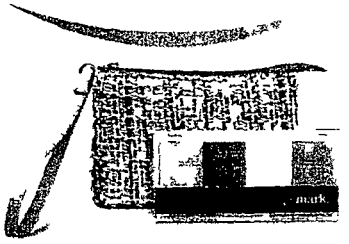

...INTERVIEW! 26 UNBELIEVABLE FASHION STEALS, P. 264
GLAMOUR
"What was that?"
20 extremely embarrassing sex moments and how to handle 'em
Change your body the healthy way, P. 236
HAPPINESS MAKEOVER!
BE THE REAL YOU, FLAWS AND ALL
105 speedy summer beauty tricks
Instantly sexy hair, toes, bikini zones!
Plaintiff's Exhibit
39
Alexander Gallo & Associates, Inc.
708 WCSR-0023


find your
FreshLook
Discover the fresh, natural look in color contact lenses. The widest shade range and the most advanced color technology give your eyes brilliant dimension, believable depth. Fresh design, fresh shades, fresh feel. No wonder FreshLook is the world's #1 prescribed colored contact lens!*
Find your fresh look @ freshlookcontacts.com
FRESHLOOK®
COLOR
3-in-1 Color Design
for the most beautiful eyes
Contact lenses, even if worn for cosmetic reasons, are medical devices that should be worn under the prescription, direction and supervision of an eye care professional only. *Data on file. ©2005 CIBA Vision


GLAMOUR
Men's 99 unspoken sex secrets
The man manual every woman should read
THE REAL NICOLE
MAKE OVER YOUR HAIR
OOPS! 10 BEAUTY MISTAKES EVERYONE MAKES
perfect jeans
Sexy-fit winners for sizes 0 to 24 (and everyone in between)
WHAT'S OFF-LIMITS IN BED? Guys' surprisingly honest answers
startling truth about young women & abortion

pick an irresistible new color





accessorize your eyes free*

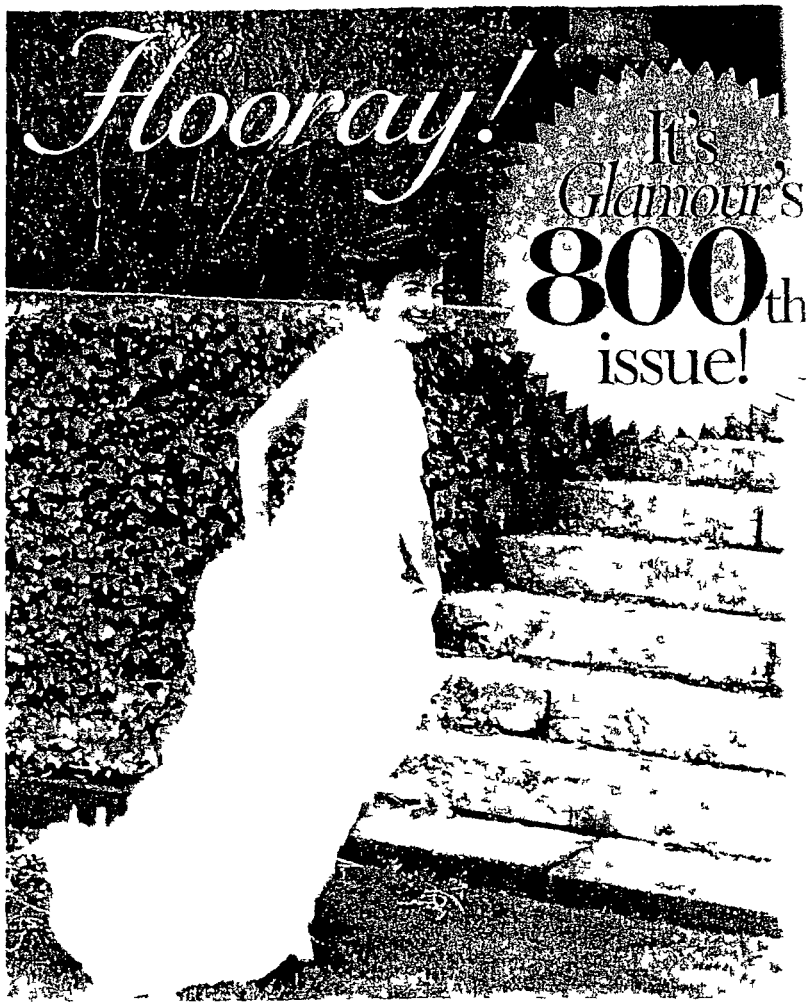
buy any two boxes of FreshLook color contacts and receive the mark custom eye palette collection—four alluring colors to create your most beautiful eyes $30 retail value visit freshlookcontacts.com for full details. for mark, call your mark Representative or go to meetmark.com

FRESHLOOK®
COLOR CONTACT LENSES

Eye exam may be required. Professional fees may apply. Contact lenses, even if worn for cosmetic reasons, are medical devices that should be worn under the prescription, direction and supervision of an eye care professional. As with all contact lenses, vision problems may occur as a result of wearing contact lenses. Void where prohibited by law. Offer valid while supplies last. ©2005 CIBA Vision. mark is a registered trademark of Alcon Products, Inc.

Coming next month in September *Glamour*...

(ON SALE AUGUST 9)



800 best-ever beauty and fashion tips, tricks, inside secrets and Dos & Don'ts

2,767 women define success—and it's not what you think it is

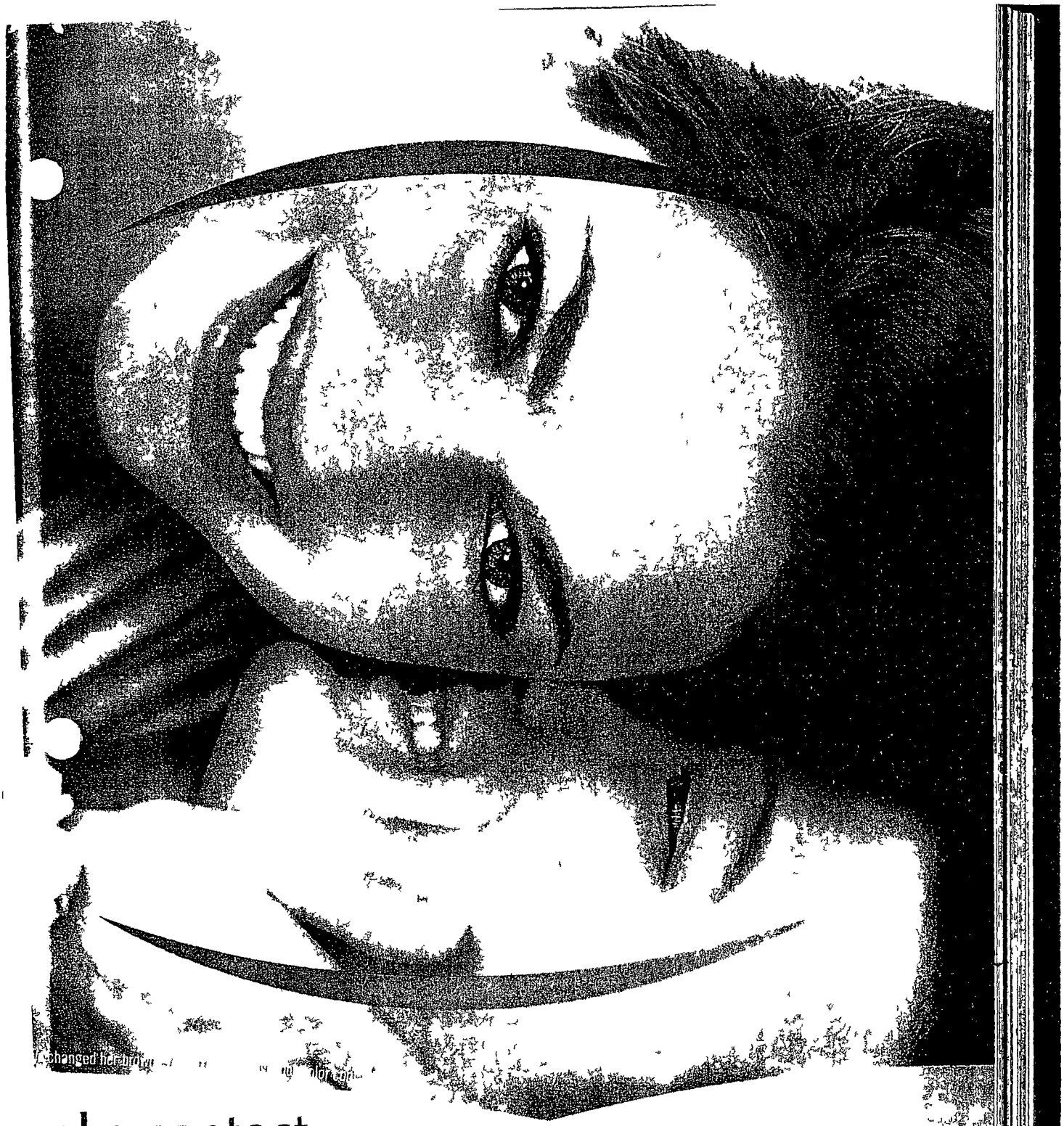
30 things every woman should have and know: an '05 update of the list millions of women have loved

The sex you want/The sex he wants at 20, 30, 40

Glamour's freebie hotline. Dial in daily—we're giving away diamonds!

Plus SPECIAL STAR APPEARANCES BY JULIA ROBERTS, LIV TYLER, ALICIA KEYS, TERI HATCHER AND MORE, MORE, MORE!

ARTHUR ELGORT. ROCHAS DRESS, RENEE LEWIS EARRINGS

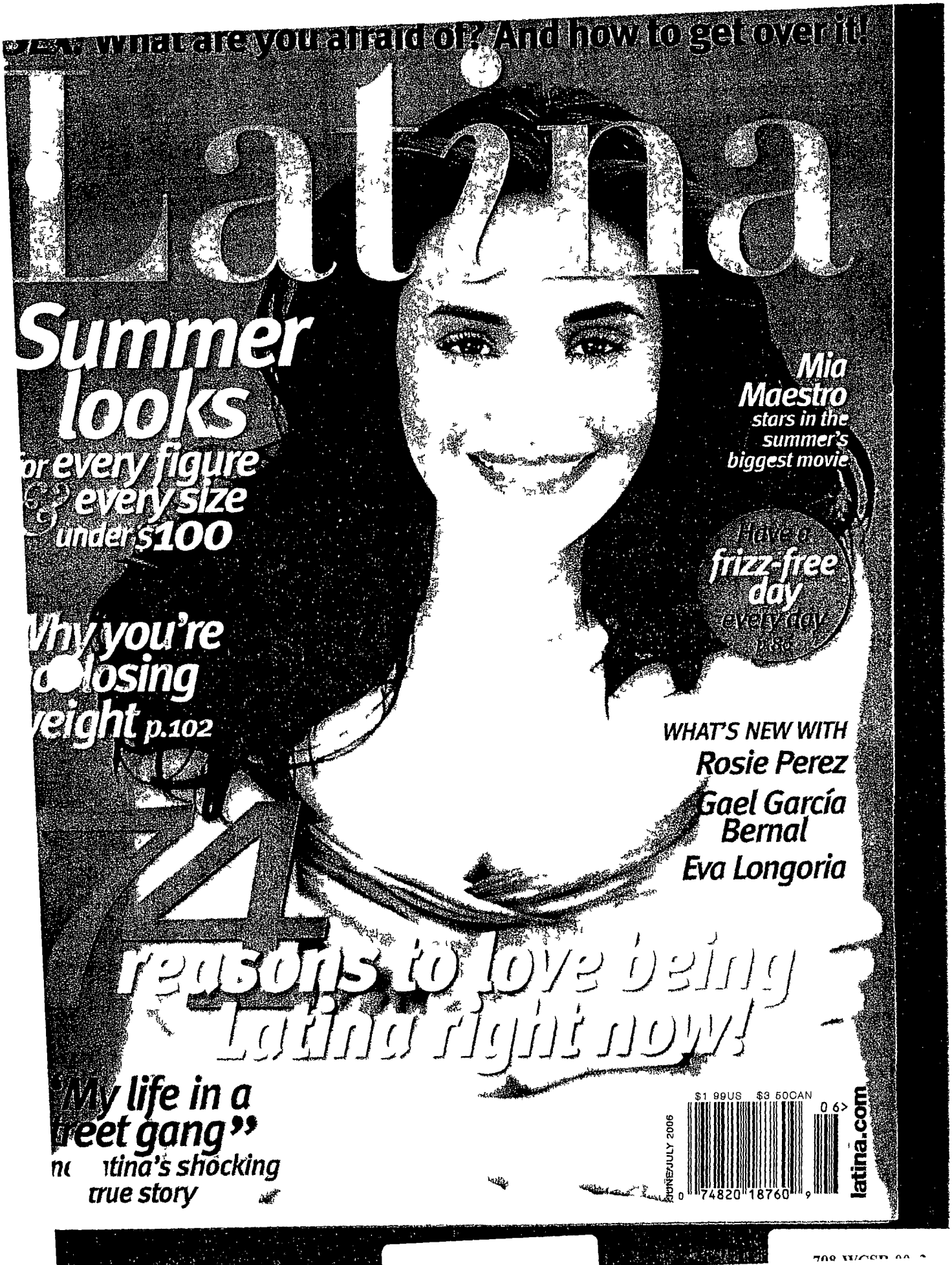


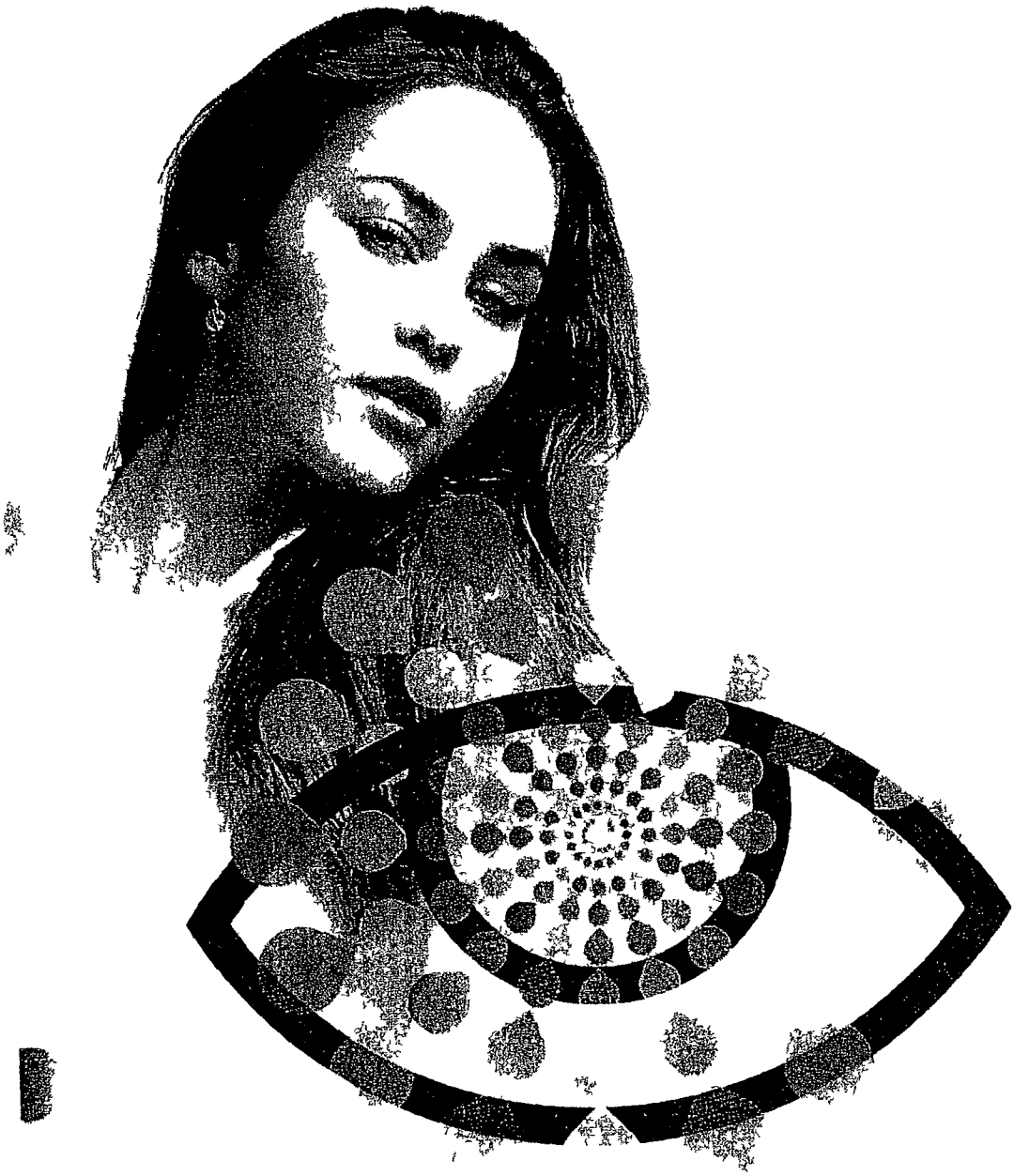
ake contact. beautiful eyes make it happen

e hot new look and capture his full attention with FreshLook color contacts choose an **exciting new color that** ches your style from playful to flirty to sassy in a color that s both natural and beautiful discover **what FreshLook** o for your eyes with a free in office trial – even if your vision is perfect!

FRESHLOOK
COLOR CONTACT LENSES

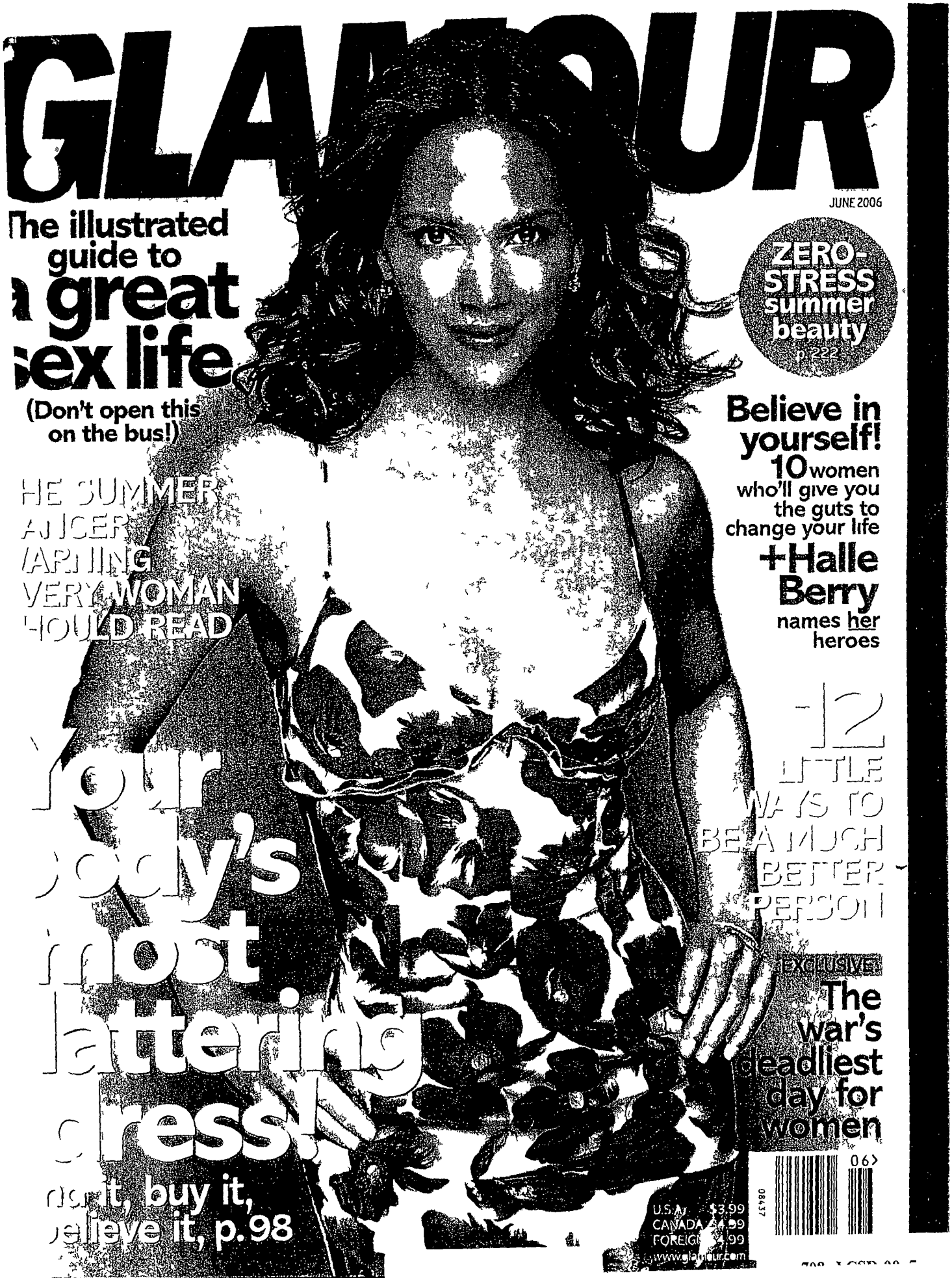
freshlookcontacts com


SEX: What are you afraid of? And how to get over it!
Latina
Summer looks
for every figure & every size under $100
Mia Maestro
stars in the summer's biggest movie
Have a frizz-free day every day p.88
Why you're losing weight p.102
WHAT'S NEW WITH
Rosie Perez
Gael García Bernal
Eva Longoria
21 reasons to love being Latina right now!
"My life in a street gang"
Latina's shocking true story
$1.99US $3.50CAN
JUNE/JULY 2006
latina.com

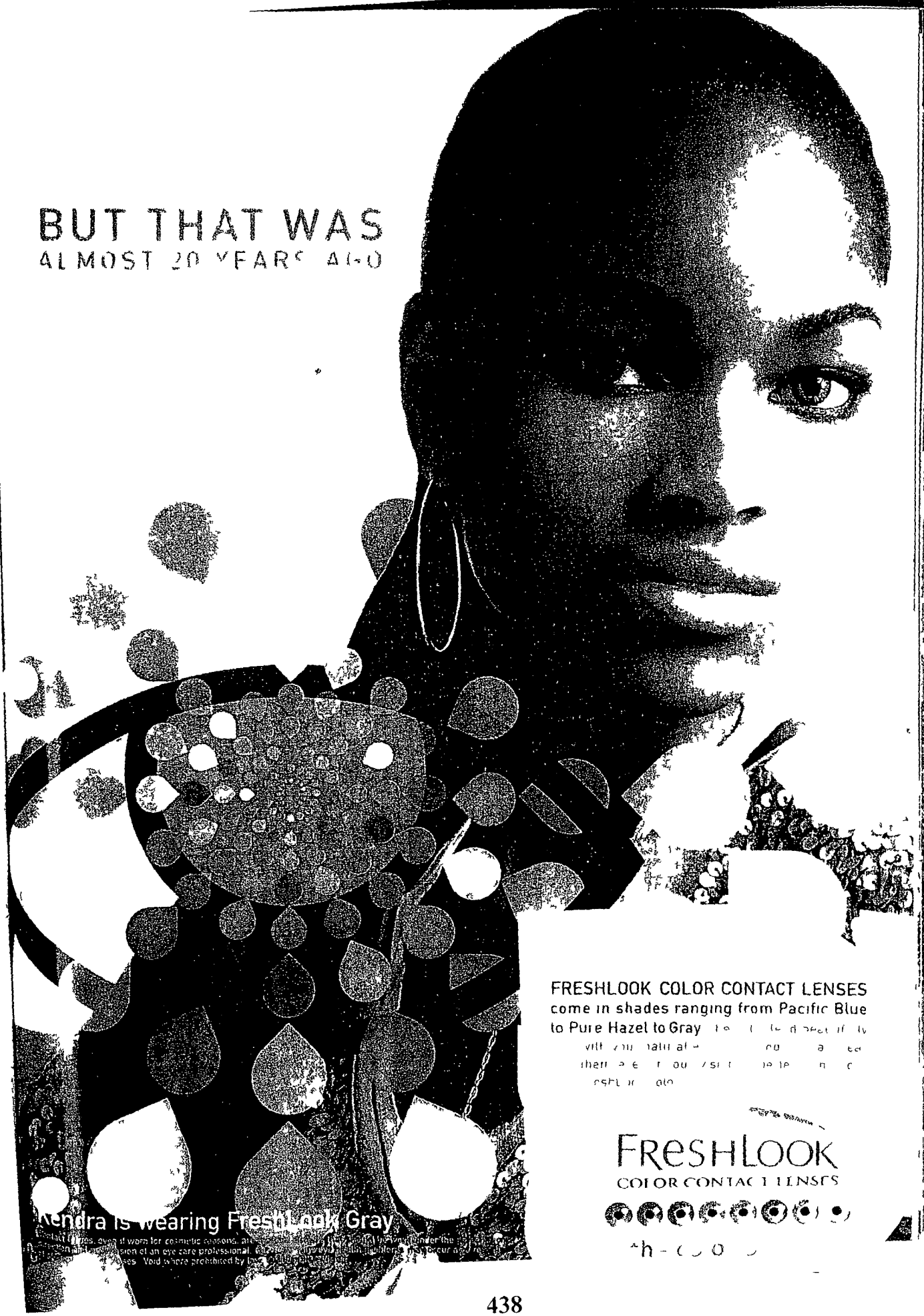



Sofia is wearing FreshLo


FRESHLOOK COLOR CONTACT LENSES
come in shades ranging from Pacific Blue
to Pure Hazel to Gray They all blend beautifully
with your natural eye color And you can wear
them even if your vision is perfect Find your
FreshLook color at
FRESHLOOK
COLOR CONTACT LENSES


GLAMOUR
JUNE 2006
The illustrated guide to a great sex life
(Don't open this on the bus!)
ZERO-STRESS summer beauty
p. 222
Believe in yourself!
10 women who'll give you the guts to change your life
+Halle Berry
names her heroes
HE SUMMER
ANCER
ARMING
VERY WOMAN
HOULD READ
-12
LITTLE
WAYS TO
BE A MUCH
BETTER
PERSON
Your body's most flattering dress
EXCLUSIVE:
The war's deadliest day for women
it, buy it,
elieve it, p.98
U.S.A. $3.99
CANADA
FOREIGN
www.glamour.com
06


MY PARENTS GAVE ME
BEAUTIFUL
BROWN EYES


BUT THAT WAS
ALMOST 20 YEARS AGO
FRESHLOOK COLOR CONTACT LENSES
come in shades ranging from Pacific Blue
to Pure Hazel to Gray
FRESHLOOK
COLOR CONTACT LENSES
Kendra is wearing FreshLook Gray

The Journal of the Association of Schools and Colleges of Optometry

OPTOMETRIC EDUCATION

Volume 31, Number 3 Spring 2006



Intercultural Sensitivity

I thank my parents

for my brown eyes.

But today, I thank my eye doctor

for my blue ones.



For the first time offer patients the natural appearance of FreshLook ColorBlends In a daily disposable lens

FreshLook ONE DAY color contact lenses are made with the Focus DAILIES material (nelfilcon A) for outstanding comfort Featuring today s most popular colors you now have an easy new way to satisfy patients who want to wear occasional color



FRESHLOOK

DAILIES

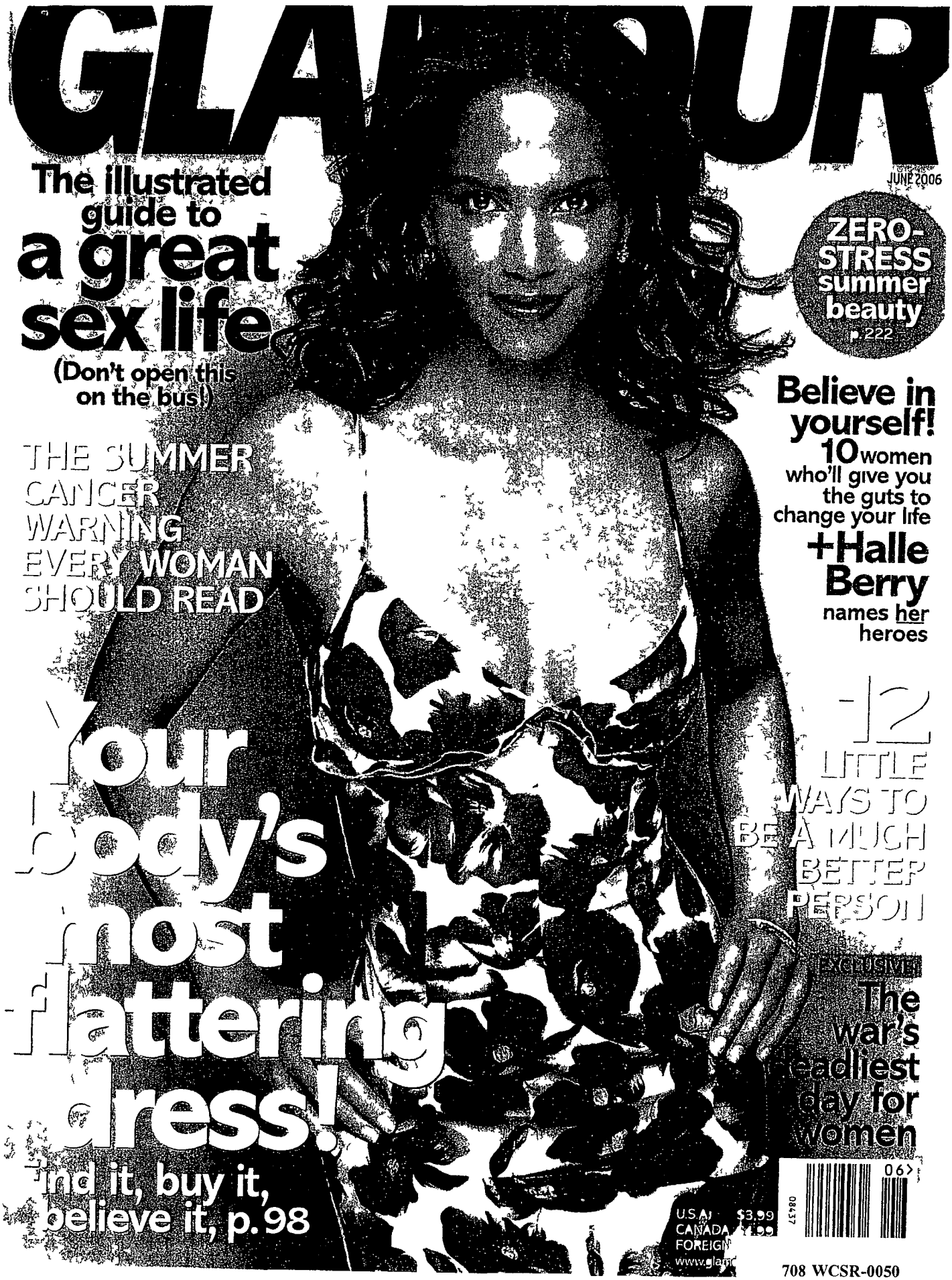
Order your FreshLook ONE DAY trial lenses at mycibavision com or call 1 800 241 5999

Contact lenses even if worn for cosmetic reasons, ar medical devices th t should be worn under the prescription direction and supervision of an eye care professional Serious eye health problems may occur as suit of sh ring cont ct lense

© 2006 CIBA Vision Corporation 2006 01 0042

1 800 241 5999 cibavision com

CIBA Vision

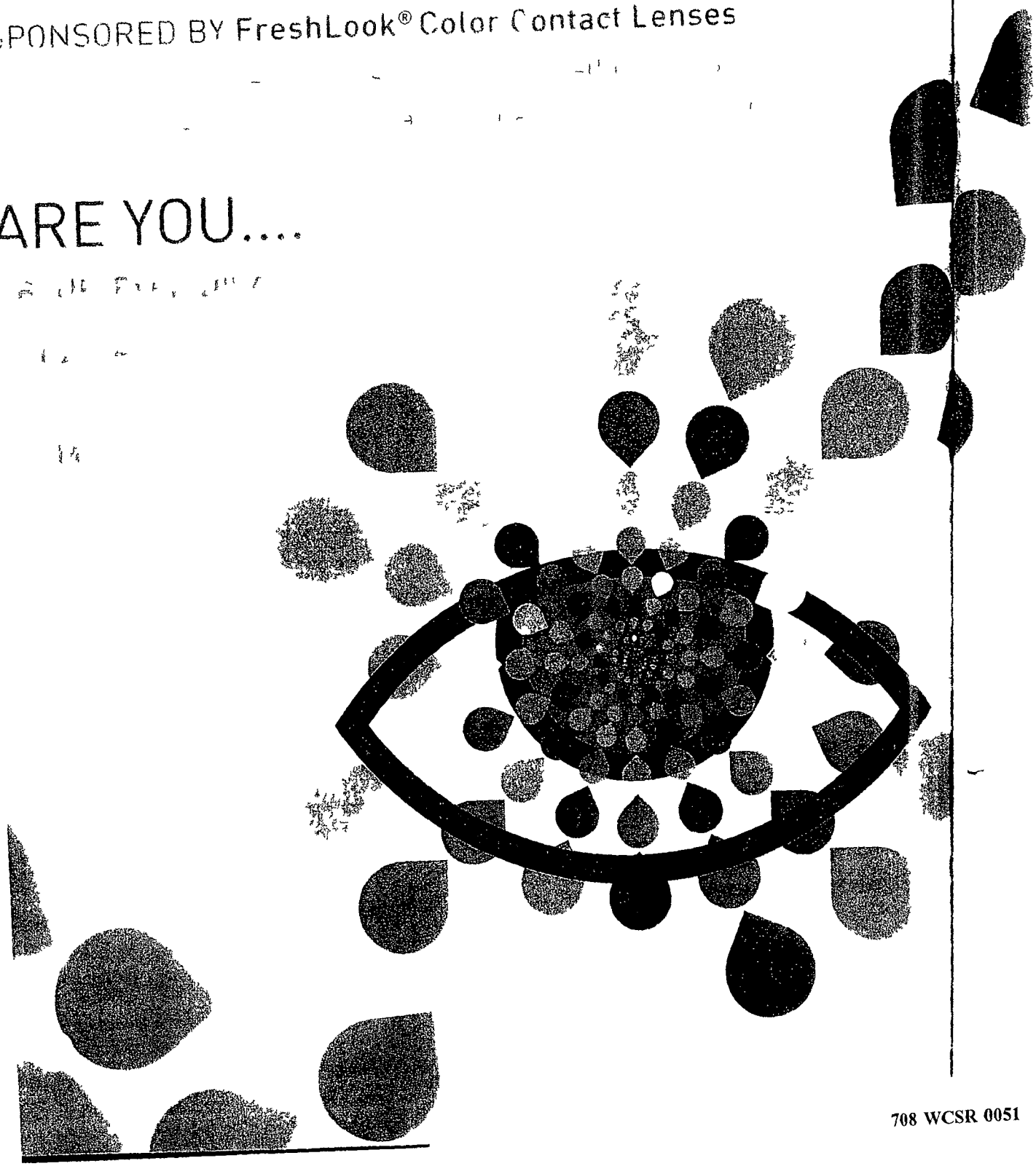


708 WCSR-0050

YOUR COLOR, YOUR STORY.

SPONSORED BY FreshLook® Color Contact Lenses

ARE YOU....



708 WCSR 0051



GOT A **STORY**?

ENTER

Visit GLAMALERT COM/FreshLook and enter now

FRESHLOOK

COLOR CONTACT LENSES

708 WCSR-0052

www PCONSuperSIte com

V l m 11 N mb r 4
APRIL 2006

PRIMARY CARE OPTOMETRY NEWS®

INSIDE

WHAT'S YOUR DIAGNOSIS?
This patient was diagnosed with glaucoma and placed on treatment, but she returned 1 month later with redness, photophobia and decreased vision.
Page 46

NCL SURVEY
A survey conducted by the National Consumers League and paid for by the American Academy of Ophthalmology concluded that consumers prefer to get advanced eye care from MDs.
Page 7

LIFE INSURANCE
Columnist Ken Rudzinski's "Wealth Building" column offers advice on how to avoid the most common life insurance planning mistakes.
Page 10

GLAUCOMA GUIDE
Our annual "Guide to Topical Glaucoma Medications" lists today's treatment choices.
Page 20

BERKELEY RESEARCH
This month's "Research on Campus" highlights the University of California Berkeley School of Optometry's involvement in more than 25 clinical studies.
Page 28

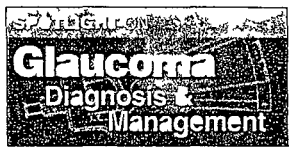
Mi h I D D P oil OD Edt

OD panel looks to study results, new drugs, technology in glaucoma management

A group of clinicians at the TOA meeting outline how new developments influence their decision making

AUSTIN Texas – Here at the Texas Optometric Association annual meeting PRIMARY CARE OPTOMETRY NEWS gathered seven practitioners to share their insights on incorporating study results optic nerve imaging new therapeutics and surgical options into their glaucoma management protocols

Panelists agreed that clinical study results have all w d them to b tte ass ss pati nt risk for the disease Current developments in the area of clinical and epidemiologic research have initiated a long overdue activation of evidence-based decision making for our patients said J James Thimons OD



While participants acknowledged the value of technology in diagnosis photography also relies on advanced diagnostic technology to help them make a diagnosis and track progress Since I kept adding more technology to my office I have said John A. McCall Jr OD

The more technology I have in my office the slower I am to treat glaucoma, because it gives me a better picture

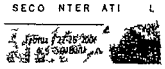
Some of the panelists agreed that when a prostaglandin is ineffective as a first line treatment choice they consider switching to another prostaglandin However others would choose another type of agent or even consider recommending surgery Bruce E Onofrey OD RPh FAAO said if a prostaglandin failed he would try another drug Either clonidine or a beta blocker would be my next drug as a single drug trial he said As I think efficacy with each individual drug I may choose a combination. I try to mix drugs that increase outflow along with drugs that decrease production

For the full discussion see page 14

SECO plans more meetings

ATLANTA – Here at 2006 SECO International, SECO board members pointed out changes to this year's conference and shared plans for the future of the organization

Outgoing President Lowell Gilbert, OD said meeting organizers introduced nine new educational tracks as well as the new SECO Scholar Program Ocular Disease Tune up which is designed to replace the Southern Diplomate Program



Incoming President Sidney Stern OD said one of his goals is to expand on SECO's meeting offerings SECO works all year long hosting other meetings and providing benefits to members he said

Dr Stern said the group is looking at holding other meetings throughout the country as well as getting involved with other optometric organizations

Meeting coverage begins on page 30

Optometry 2020: second AOA summit envisions the future

DALLAS – The end of the three American Optometric Association Optometry 2020 Summits focused on establishing a desired future for the optometric profession in years to come

Optometrists from across the country gathered here to ascertain optometry's goals for the year 2020 Attendees were divided into eight discuss on group covering topics such as patients education competency industry technology economics delivery and human resources

Objectives identified by the group included unrestricted access to optometric care an as taught approach continuing competency and credentialing process unrestricted access to technologies



Optometry 2020 Each of the eight groups presented their goals to all attendees for further discussion

elimination of discrimination in third party access and reimbursement and nationwide uniform self regulated licensure with a residency in optometric surgery

For the full story page 4

AOA president addresses SWCO

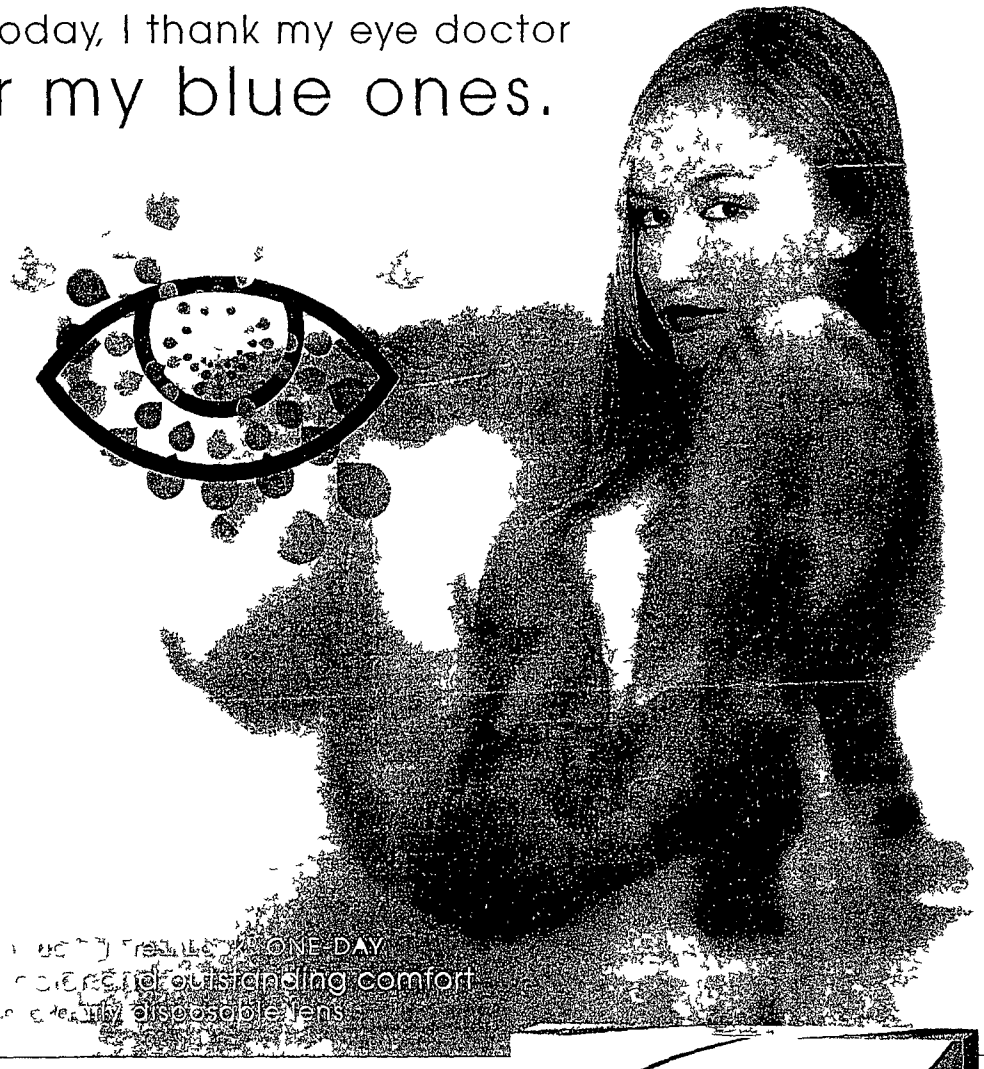
DALLAS – American Optometric Association President Richard L Wallingford OD updated Southwest Council of Optometry annual meeting attendees on the AOA's projects and priorities

He discussed recent legislation in Utah that now limits the sale of certain contact lenses cautioning attendees that similar legislation may be introduced in their state D Wallingford also encouraged optometrists to support their political action committees to help defend the profession against attacks from organized medicine

The AOA continues its efforts in children's vision by supporting the Children Vision Improvement and Learning Reading Act of 2005 and the InfantSee program

For the full report see page 12

I thank my parents
for my brown eyes.
But today, I thank my eye doctor
for my blue ones.



ONE-DAY
for outstanding comfort
and easily disposable lens

For the first time offe patients the natural appearance of FreshLook ColorB ends In a daily disposable lens

FreshLook ONE DAY color contact lenses are made with the Focus DAILIES mater al (nelfilcon A) for outstanding comfort Featuring today s most popular colors you now have an easy new way to satisfy patients who want to wear occasional color

bl g ay g p h l

FRESHLOOK
DAY COLO CONT CT LE
FOCUS
DAILIES
FE HINOLOG

Order your FreshLook ONE DAY trial lenses at mycibavision com or call 1 800 241 5999

he co or y u

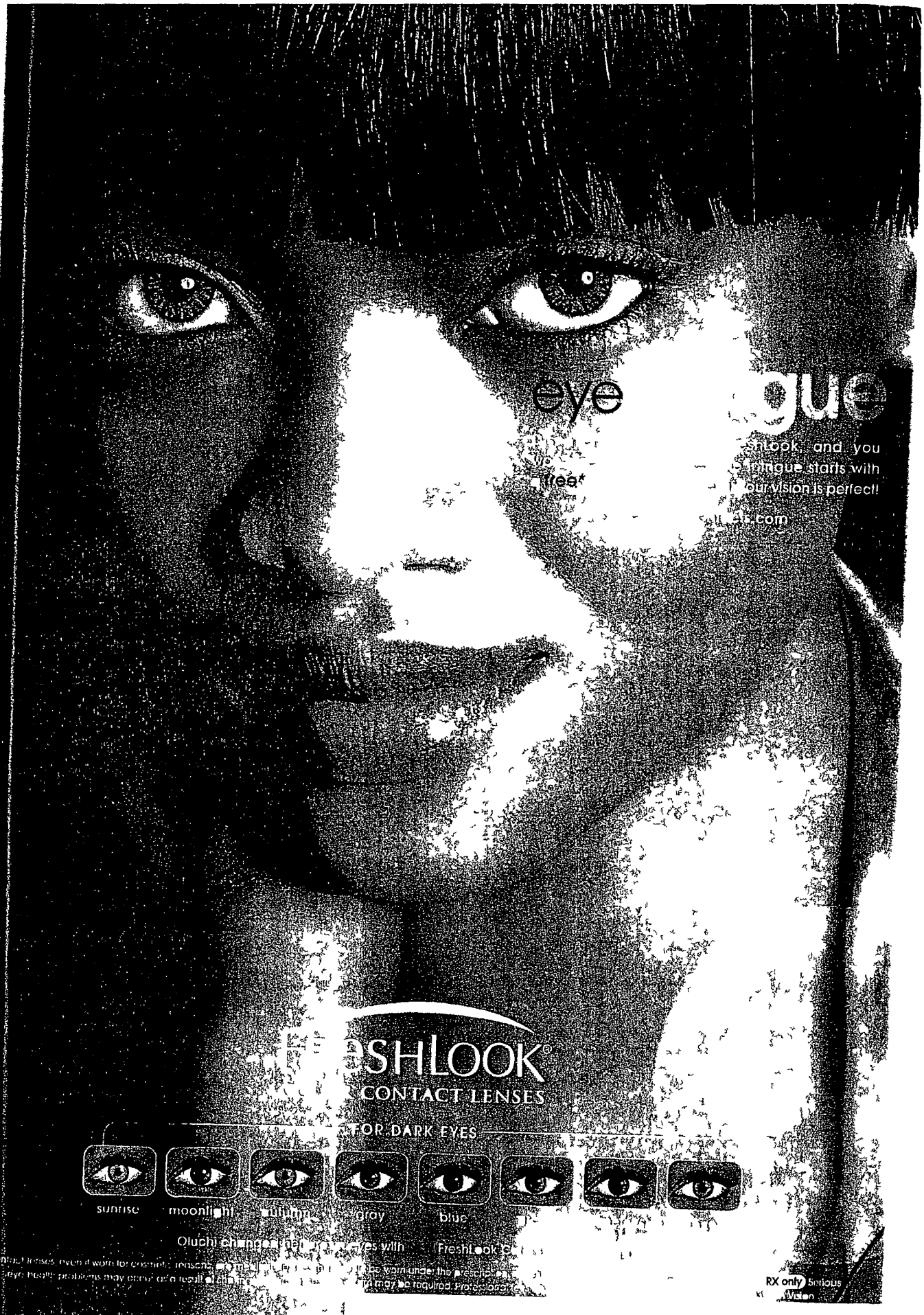
Contact lenses even if worn for cosmetic reasons are medical devices that should be worn unde the prescription direction and supervision of an eye car profess l al Serious eye health problems may occur rea lt of sharing contact lenses

© 2006 CIBA Vision Corporation 2006 01 0042

1 800 241 5999 cibavision com

CIBA Vision
No rtis Company


THIS VERY MINUTE, P232
GLAMOUR
MARCH 2004
DREW
interviewed by the friend who knows her best
free
Win an $11,000 diamond necklace, p.52
Yes, even the lusty little details
EVERY WOMAN'S SEXIEST HAIR
Va-va-voom for short, long, curly, straight
THE FAST-FOOD DIET
EAT WHAT EVERYONE SAYS NOT TO AND LOSE WEIGHT
298
Happy? Crazy-busy? What kind of mom will you be?
U.S.A. $3.50
CANADA $4.50
FOREIGN $4.50
www.glamour.com
How to dress slimmer, smarter, sexier—for less
Plaintiff's Exhibit
40
Alexander Gallo & Associates, Inc.
COURT REPORTING VIDEO SERVICES TRIAL PRESENTATIONS
03>


eye
gue
shLook, and you
ongue starts with
our vision is perfect!
.com
SHLOOK®
CONTACT LENSES
FOR DARK EYES
sunrise
moonlight
gray
blue
FreshLook®
RX only Serious Vision

MARCH 2004



LITTLE SIGNS HE'S "THE ONE"

Guys Share 75 Awesome Bedroom Tricks Used by the Best Lovers They've Ever Had

Julia Stiles Lets Us Into Her Private Life

4 Hot New Makeup Looks

These Sack Sessions Went Way Wrong Laugh Out Loud—and Pray It Never Happens to You

SKANK ALERT!

Finally, We Explain His Maddening Silences, Rude Tune-Outs, and Weird Expressions

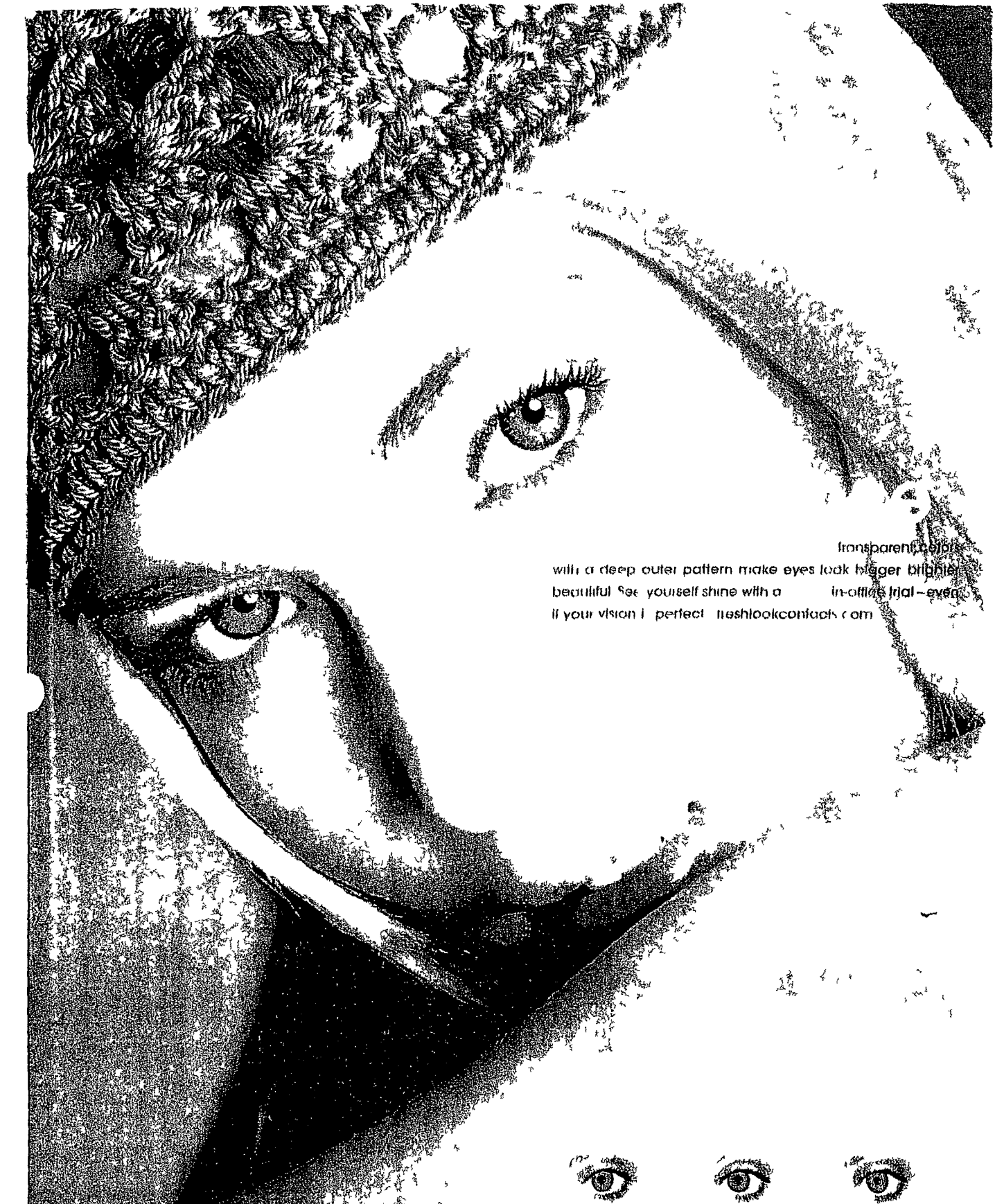
(PHOTOS INCLUDED)

$3.99 MARCH 2004

0 74820 08233 1 03

Plaintiff's Exhibit 47

Alexander Gallo Associates, Inc.


transparent colors
with a deep outer pattern make eyes look bigger brighter
beautiful See yourself shine with a in-office trial – even
if your vision i perfect freshlookcontacts com
RX only