PATRICIA ADELMANN-CHESTER, ET AL.	*	**NO. 2008-CA-0770**
	*	**COURT OF APPEAL**
VERSUS		
	*	**FOURTH CIRCUIT**
JOHN N. KENT, D.D.S., LOUISIANA STATE UNIVERSITY SCHOOL OF DENTISTRY AND FACULTY DENTAL PRACTICE, ET AL.	*	**STATE OF LOUISIANA**
	* * * * * * *	

APPEAL FROM
CIVIL DISTRICT COURT, ORLEANS PARISH
NO. 98-18330, DIVISION "G"
Honorable Marvin Gahagan, Judge Ad Hoc

* * * * * *

Charles R. Jones
Judge

* * * * * *

(Court composed of Judge Charles R. Jones, Judge Michael E. Kirby, and Judge Roland L. Belsome)

BELSOME, J., DISSENTS WITH REASONS

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AFFIRMED

Patricia Adelmann-Chester, *et al.*, (the appellants), seek review of the district court's grant of Dr. John Kent's, Louisiana State University School of Dentistry and Faculty Practice through the Department of Health and Human Resources', and the State of Louisiana through the Board of Supervisors, through the Louisiana Attorney General's Office (the named appellees), motion for summary judgment, thereby dismissing the appellants' claims for damages. We affirm.

The appellants filed suit against Vitek in district court alleging that they sustained damages from dental implant devices manufactured and distributed by Vitek, Inc., a company based in Houston, Texas. Dr. Charles and Mrs. Ann Homsy,[1] also named as original defendants, were officers, directors, and principal shareholders of Vitek. Dr. John Kent and the LSU School of Dentistry, *et. al.*, were also named as defendants.

Dr. Kent, one of the named appellees, graduated from the University of

[1] Per the record, Dr. Homsy has left the United States.

Nebraska School of Dentistry and was an oral and maxilliofacial surgery resident at the University of Texas in Houston from 1966 through 1969. He came to the LSU School of Dentistry as the Department Head in Oral and Maxillofacial Surgery in 1973, and became a professor in 1979, a position he currently holds.

In the mid 1970s, Dr. Kent began a professional relationship with Dr. Homsy and Vitek. When Dr. Homsy discovered Dr. Kent's experience with Proplast,[2] he was approached to be a scientific advisor. In conjunction with his role as a scientific advisor, Dr. Kent performed multiple tasks such as drafting package inserts which accompanied some Vitek medical devices. He also offered advice on the products manufactured by Vitek.

In particular, Dr. Kent, Dr. Homsy, and a Vitek employee, John Tellkamp, designed the shape of the "glenoid fossa"[3] that was used in the VK-I and VK-II implants, and obtained several design patents concerning the same. Dr. Kent received a royalty payment of 2-4% of the price for certain products sold. He also provided services to Vitek as one of their scientific consultants. While acting as a consultant for Vitek, Dr. Kent acquired Vitek stock, but it is alleged that he never owned more 1% of Vitek stock. He is also alleged to have never participated in any stockholder meetings. Dr. Kent never participated in or had control over the fabrication, construction, and marketing of the Interpositional Implants (IPI's), VK-I and VK-II's.

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[2] Per *Online-Medical-Dictionary.org*, *Proplast* is a polymer of polytetrafluoroethylene and carbon filaments; porous biocompatible material used in orofacial and middle ear reconstruction and as coating for metal implants. *See, http://www.online-medical-dictionary.org/I,+Proplast.asp?q=I%2C+Proplast.*

[3] Per *encyclopedia.com*, the *glenoid fossa* is the smooth depression on the ventral side of the skull into which the condyle (a knob of bone, round or ellipsoid in shape, that fits into a socket of an adjacent bone to form a joint) of the jaw bone fits. See, *http://www.encyclopedia.com/doc/1O8-glenoidfossa.html.*

The dental implant devices were intended as a remedy for degeneration of the temporal mandibular joint ("TMJ"), and were widely used from 1970 until 1991, and were marketed between 1974 and 1990 for persons specifically suffering from TMJ disorders.

However, because of alleged defects in some implant models, the implants were recalled in 1991 by the United States Food and Drug Administration. As a result of the alleged defects, numerous lawsuits were filed nationwide. Each suit alleged the implants were defective or that Vitek failed to give adequate warning that the use of the implants caused suffering, injury or both. Dr. and Mrs. Homsy were also named as defendants in those lawsuits.

By 1990, 426 lawsuits were pending against Vitek; however, within that same year, Vitek filed for bankruptcy. As a result of Vitek's bankruptcy and Dr. Homsy's subsequent flight from the country, plaintiffs from around the country relied upon other theories of recovery to obtain relief against the remaining defendants[4] in these suits.

The original lawsuit filed in the instant case involved 675 plaintiffs. However, 443 of the original 675 plaintiffs eventually accepted settlements and executed releases dismissing their cases. The executed settlement agreements established a TMJ research fund at the LSU Dental School and provided for the payment of the plaintiffs' court costs.[5]

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[4] For example, in Forest v. Vitek, Inc, et al, 884 F.Supp. 378 (D. Nev. 1993), several TMJ implaint patients sued for damages related to the jaw implants they received which contained polytetrafluoroethylene, a product that was manufactured by DuPont and was later sold to Vitek. The court granted DuPont's motion for summary judgment based on the "bulk supplier doctrine," which is an absolute defense to warning claims. The court held that the third party bulk supplier was not liable based upon a derivative claim of breach of implied warranty stating, "because Vitek can have no warranty claim against [the third party], there can be none from which the plaintiffs can derive such a claim." Id. at 380.

[5] Since an additional 69 of the original plaintiffs' claims were dismissed on the basis of prescription, only 163 plaintiffs remain.

Nevertheless, Dr. Kent and LSU filed a motion for summary judgment seeking to dismiss the claims of the remaining 163 plaintiffs. The motion was heard by the district court on October 27, 2006. The district court subsequently granted Dr. Kent's and LSU's motion for summary judgment, thereby dismissing the appellants' claims, on February 1, 2008. This timely appeal followed.

The appellants list six (6) assignments of error as follows:

1. The district court erred as a matter of law in granting a final summary judgment without addressing the plaintiffs negligence claims because the appellants [allege that they] have proven that their damages were caused by Dr. Kent's and LSU's negligence, both before and after the effective date of the Louisiana Products Liability Act (LPLA).

2. Alternatively, the district court erred as a matter of law in granting a final summary judgment without addressing the appellants' strict products liability (Halphen) claims, because the appellants have proven their damages were caused by Dr. Kent's and LSU's defective product manufactured before the enactment of the LPLA.

3. Alternatively, the district court erred as a matter of law in dismissing the appellants' claims under LPLA, because the appellants have proven that Dr. Kent and LSU were manufacturers of an unreasonably dangerous product in violation of the LPLA.

4. The district court erred, as a matter of law, in dismissing the appellants' claims for exemplary damages, because the appellants have proven the necessary elements for recovery under La. C.C. art. 2315.3.

5. The district court erred, as a matter of law, in dismissing the appellants' claims under the Louisiana Unfair Trade Practices and Consumer Protection Law, because the appellants filed suit within the one-year preemptive period imposed by La. R.S. 51:1401, et seq.

6. The district court erred, as a matter of law, in dismissing the appellants' strict liability claims, under Louisiana C.C. art. 2317 and/or 2317.1 because the appellants have proven that the appellee had custody and control of the defective TMJ implants, and their components, which caused appellant's damages.

DISCUSSION

In Danos v. Avondale Industries, Inc., 2007-1094 (La.App. 4 Cir. 7/2/08), 989 So.2d 160, we reiterated the standard of review for summary judgment as follows:

> Appellate courts review summary judgments *de novo* under the same criteria that govern the district court's consideration of whether summary judgment is appropriate. Independent Fire Ins. Co. v. Sunbeam Corp., 99-2181, 99-2257, p. 7 (La.2/29/00), 755 So.2d 226, 230; Grant v. American Sugar Refining, Inc., 06-1180, p. 3 (La.App. 4 Cir. 1/31/07), 952 So.2d 746, 748. Summary judgments shall be rendered if the pleadings, depositions, answers to interrogatories, and admissions on file together with affidavits, if any, scrutinized equally, show that there is no genuine issue as to material fact, and that the mover is entitled to judgment as a matter of law. La.Code Civ. Proc. art. 966(B). However, as noted by the Supreme Court in Sunbeam, supra, the trial court cannot make credibility determinations on a motion for summary judgment. Sunbeam, 99-2181, 99-2257, p. 16, 755 So.2d at 236.
>
> A fact is material if it is essential to plaintiff's cause of action under the applicable theory of recovery and, without the establishment of the fact by a preponderance of the evidence, plaintiff could not prevail. Grant, 06-1180, p. 4, 952 So.2d at 748-49. Generally, material facts are those that potentially insure or preclude recovery, affect the litigant's ultimate success, or determine the outcome of a legal dispute. Grant, 06-1180, p. 4, 952 So.2d at 749. Thus, to determine if the trial court erred in granting…[a] motion for summary judgment, we must determine whether any genuine issues of material fact exist.

Id., pp. 2-3, 989 So.2d at 162.

In their first assignment of error, the appellants argue that the district court erred as a matter of law in granting a final summary judgment without addressing their negligence claims because the appellants assert that they have proven that

their damages were caused by the appellees' negligence, both before and after the effective date of the Louisiana Products Liability Act (LPLA), discussed *infra*.[6]

This Court, in McCloud v. Housing Authority of New Orleans, 2008-0094 (La.App. 4 Cir. 6/11/08), 987 So.2d 360, held that:

> There are two theories of liability available to a plaintiff who claims she was injured as a result of the condition of a thing; negligence, under Louisiana Civil Code Articles 2315 and 2316, and strict liability, under Louisiana Code Article 2317. Under both theories of liability, a plaintiff must prove that the condition of the thing presented an unreasonable risk of harm, or was defective, and that this condition of the thing was a cause-in-fact of her injuries. Seal v. State Farm Fire & Cas. Co., 00-2375, p. 10 (La.App. 4 Cir. 3/20/02), 816 So.2d 868, *writ denied* 02-1083 (La.6/14/02), 817 So.2d 1160. Both theories are analyzed under the duty/risk analysis. Schreiber v. Jewish Federation of Greater New Orleans, 02-0992, p. 8 (La.App. 4 Cir. 1/29/02), 839 So.2d 51, 55. The duty-risk analysis is employed on a case by case basis. Daye v. General Motors Corp., 97-1653, p. 7 (La.9/9/98), 720 So.2d 654, 659. Under this analysis, the plaintiff must prove that the conduct in question was a cause-in-fact of the resulting harm, the defendant owed a duty of care to the plaintiff, the requisite duty was breached by the defendant, and the risk of the harm was within the scope of the protection afforded by the duty breached. See Schreiber, *supra*, 02-0992, p. 8, 839 So.2d at 55.

Id., p. 3, 987 So.2d at 362-363. The appellants argue that the district court failed to address any of their negligence claims, despite their assertion that they presented "overwhelming evidence that Kent's and LSU's negligence" caused their damages. They also argue that the court should have applied a duty risk analysis in considering whether the defendants' negligence caused their damages. In particular, they assert that the court should have determined: (1) whether the defendants' conduct was the cause in fact of their injuries; (2) what, if any duties

[6] The part of this first assignment of error concerning the LPLA will be discussed in the appellants' second assignment of error.

were owed to the "respective parties;" (3) whether any duties were breached; and (4) was the risk and harm caused within the scope of protection afforded by the duty breached.

The appellants assert that Dr. Kent was an agent for the LSU School of Dentistry, and that he engaged in a "continuous effort" to design, test, manufacture, and market the defective Proplast implants dating back to 1978. Specifically, the appellants point to the evidence produced by Dr. Kent and LSU which support the appellants' argument that Dr. Kent was the designer of the defective implants. The appellants also point to a TMJ IPI brochure that notes, in particular, that the devices were designed by Dr. Kent.

The appellants also contend that since Vitek considered Dr. Kent the pioneer of the VK devices, Vitek agreed that he (Dr. Kent) provided significant and ongoing input into the design of the VK prostheses, and that he drafted package inserts for these products. The plaintiffs also argue that Dr. Kent gave specific instructions concerning the design of various devices, once problems began to occur with Vitek implants. They maintain that Dr. Kent provided assistance in drafting the guidelines and instructions for the use of various Proplast products, and also provided suggestions regarding specific tools to be provided with the implants. The appellants contend that Dr. Kent also assisted in drafting Vitek's correspondence with other professionals in the field recommending the use of various Vitek products, and also gave seminars to professionals throughout the United States and Europe concerning the surgical procedures for implanting the Vitek-Kent prostheses. They assert that Dr. Kent kept Vitek informed about opinions in the oral and maxillofacial community concerning the use of the prostheses and the Proplast product.

The appellants also argue that Dr. Kent and LSU knew that the implants were not safe as early as 1982, and that there was no significant effort put forth to have the implants tested prior to making them available to the public. The appellants, in fact, point to a written communication whereby Dr. Kent allegedly admitted that he was aware of the potential dangers posed by the Proplast implants in a 1984 letter to Vitek, in which he wrote:

> Remember—we are making these recommendations on the suspected strength and wear of each laminate—we still do not know what the proper thickness should be—Someday Vitek may wish that animal studies were funded as I have screamed about for many years. Jack

The appellants also maintain that Dr. Kent and LSU may have had knowledge about the problems associated with the implants as early as 1984. They assert that Dr. Kent possessed first-hand knowledge from seeing his own patients suffer from ill-effects of the implants. They also alleged that he received feedback from peers concerning other patients who suffered from similar, if not the same, ill effects he had seen in his patients. Additionally, the appellants assert that Dr. Kent recommended that a "soft" warning be issued to surgeons about the wear of the Teflon surface of the prostheses.

However, despite all of the concerns allegedly expressed by Dr. Kent, the appellants assert that he continued to use the implants on his own patients and that he also recommended the implants to other professionals in the field to purchase the implants for use in their patients.

In sum, the appellants assert that the district court erred because they submitted overwhelming evidence that Dr. Kent and LSU breached their duties because: (1) they knew of the dangers posed by the Proplast implants; (2) they

misrepresented the known dangers of the implants to the public, the Food and Drug Administration, and to the medical professionals who surgically implanted the devices; (3) that despite their knowledge of the dangers, they actively promoted the use, sale and implementation of the defective implants; and (4) they failed to warn the users of the dangers the implants posed.

Dr. Kent and LSU argue that the appellants' opposition to the motion for summary judgment filed in the district court relied upon 225 improper, unverified, and unauthenticated documents.[7] They assert that in the instant appeal, the appellants are relying on the same documents in an attempt to persuade this Court to reverse the district court's judgment. Dr. Kent and LSU also maintain that the documents were never verified in the district court and that these attempts to verify the documents were "insufficient."

The appellees assert that since the appellants did not submit properly verified affidavits or depositions in support of their opposition to the motion for summary judgment, that the record is devoid of any admissible factual support that the appellants may rely upon to satisfy their burden of proof under La. C.C.P. art 966. The appellees argue that a motion for summary judgment must be supported by the pleadings, depositions, answers to interrogatories, admissions on file and affidavits pursuant to La. C.C.P. art 966.

In addition, Dr. Kent and LSU maintain that the appellants are attempting to "artificially create a material issue of fact" via "numerous unverified, unsworn memoranda, letters, and various other documents which were improperly attached

[7] The appellees refer to the entire 225 numbered exhibits attached to the appellants' opposition to the motion for summary judgment.

to the [appellants'] opposition to the motion for summary judgment to satisfy the necessary factual support." In particular, they note:

> …[o]ne hundred and eighty-one (181) of these exhibits consist of unverified matters, dating from 1974 through 1990. Forty-four (44) of these exhibits consist of unverified drawings, designs, inter-office memoranda, and various other documents. Nineteen (19) memoranda the plaintiffs attached and relied upon are typed and handwritten letters from one person to another relaying previous conversations the writer of the memorandum had with various individuals. The documents are various pamphlets and articles that contain various personal handwritten notes, yet neither the documents or the handwriting in many of these documents has been verified. Exhibit 226, the only deposition appearing among the [appellants'] inadmissible documents, only contains a small and confusing excerpt taken out of context from another proceeding. Moreover, exhibits 226-330 were not even attached to the opposition in the court below. It is difficult to discern exactly how and when these documents made their appearance in this appellate record. These documents were not properly before the district court.

Dr. Kent and LSU note that in the district court the appellants attached the unverified documents to their opposition to the motion for summary judgement on September 8, 2006. On October 17, 2006, Dr. Kent and LSU filed an objection to the admissibility of these documents in their reply memorandum to the appellants' opposition to the motion for summary judgment. Three days later, the appellants filed one additional affidavit in an attempt to verify all two-hundred twenty-five (225) unverified and unsworn documents. Specifically, the one affidavit from Ms. Jimmie W. Murvin sets forth that she was present when the appellants received the exhibits, presumably all 225 exhibits.

Dr. Kent and LSU challenge the "Murvin affidavit" on four particular bases: (1) the affiant, Jimmie W. Murvin, did not create any of these documents, nor did she witness the creation of any of the documents; (2) that because the affiant is an

employee of the appellants' attorney, John W. deGravelles, she is a biased party; (3) that she had no familiarity with any handwriting that would give her a basis to verify the handwritten documents and notes; and (4) the affidavit did not appear in the record until October 20, 2006.

Dr. Kent and LSU point out that while the appellants have attached a notice of designation of the record on appeal in an effort to legitimize the 225 exhibits, these same exhibits were deemed inadmissible by the district court. They assert that only the record considered by the district court should be a part of this Court's *de novo* review. In support of this contention, the appellees cite Boland v. West Feliciana Parish Police Jury, 2003-1297 (La.App. 1 Cir. 6/25/04), 878 So.2d 808.

In this First Circuit Case, the plaintiff sought review of the district court's grant of the defendants' motion for summary judgment. On appeal, the plaintiff attached additional unverified documents. However, the First Circuit refused to consider the plaintiff's unverified documents. Additionally, the court noted that a document is not verified simply because "it is stapled or paper clipped to a motion or memorandum, is referred to in one of those documents, and is filed in the record." Id. p. 7, 878 So.2d at 814.[8] Dr. Kent and LSU also note that "merely stapling them (the documents) to a motion for summary judgment does not magically transform such documents into competent summary judgment evidence." Williams v. Memorial Medical Center, 03-1806, pp. 14-15 (La. App. 4 Cir. 3/17/04), 870 So.2d 1044, 1053.

[8] Boland states specifically, "[w]e do not consider those cases as suggesting that "anything goes," as long as it is stapled or paper-clipped to a motion or memorandum, is referred to in one of those documents, and is filed in the record." Id.

Dr. Kent and LSU also maintain that the district court did not err in dismissing the appellants' claims in negligence under La. C.C. 2315 because the plaintiffs have simply failed to produce any admissible evidence that will support their contentions. They assert that under the duty-risk analysis, the plaintiffs can only recover if they can prove (1) that a duty exists, (2) the defendant breached the duty, (3) it was a cause-in-fact of the injuries to the plaintiff, and (4) the risk is within the scope of the duty, *citing* Peterson v. Gibraltar Savings and Loan, 98-1609, pp. 6-7 (La. 5/18/99), 733 So.2d 1198, 1204. They also assert that "where there is no duty on the part of the defendant to protect the plaintiff from the risks involved, there can be no liability under a duty-risk analysis." *citing* Crovetto v. New Orleans City Park Improvement Ass'n, 94-1735, p. 1 (La. App. 4 Cir. 3/29/95), 653 So.2d 752, 753.

Dr. Kent and LSU conclude their argument by asserting that the instant appeal is a last ditch effort by the appellants to assert claims against the LSU School of Dentistry. They argue that the same claims were brought by the appellants against Vitek, Dupont, and Dow, but the appellants were unsuccessful.

Our review of the record does not establish a relationship between the appellants and Dr. Kent and LSU. Considering the fact that the only actual evidence relied upon by the appellants are unverified affidavits that were deemed inadmissible by the district court, we can only consider the evidence accepted by the district court below.

Our review of the record reveals that although the appellants have vigorously argued that Dr. Kent and LSU owed them a duty, they have not demonstrated that Dr. Kent or LSU owed a duty to them, so their negligence claim under a duty-risk analysis must fail because this Court cannot go beyond the first

prong of a duty-risk analysis. "A duty is not owed or breached in all situations that involve injury." Crovetto v. New Orleans City Park Improvement Ass'n, 94-1735, p. 1 (La. App. 4 Cir. 3/29/95), 653 So.2d 752, 753.

Pursuant to La. C.C.P. art 966(B), the [summary] judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to material fact, and that mover is entitled to judgment as a matter of law.

> An adverse party to a supported motion for summary judgment may not rest on the mere allegations or denials of his pleading, but his response, by affidavits or as otherwise provided by law, must set forth specific facts showing that there is a genuine issue of material fact for trial. La.C.C.P. art. 967; Danna v. Barq's, Inc., 612 So.2d 253, 255 (La.App. 4 Cir.1992). Mere conclusory allegations, improbable inferences and unsupported speculation will not support a finding of a genuine issue of material fact. King v. Phelps Dunbar, LLP, 01-1735, p. 16 (La.App. 4 Cir. 4/2/03), 844 So.2d 1012, 1022. Such allegations, inferences and speculation are insufficient to satisfy the opponent's burden of proof, even if contained in a deposition. King, *supra* at pp. 16-17, 844 So.2d at 1023.

Sears v. Home Depot, U.S.A., Inc., 2006-0201, pp. 11-12 (La.App. 4 Cir. 10/18/06), 943 So.2d 1219, 1228.

Hence, considering the record before us as a whole, and further considering that the appellants have not shown that there are genuine issues of material fact, we find that the district court did not err in granting Dr. Kent's and LSU's motion for summary judgment.

In their second and third assignments or error, the appellants argue that the district court erred as a matter of law in granting a final summary judgment without addressing their strict products liability (Halphen) claims allegedly caused

by Dr. Kent's and LSU's defective product which was manufactured before the enactment of the LPLA. Alternatively, they argue that district court erred as a matter of law in dismissing their claims under LPLA, because they have proven that Dr. Kent and LSU were manufacturers of an unreasonably dangerous product in violation of the LPLA.

Our Court in Asbestos v. Bordelon, Inc., 1996-0525 (La.App. 4 Cir. 10/21/98), 726 So.2d 926, discussed Halphen and the LPLA as follows:

> …[T]he Halphen case is a Supreme Court decision which answered a certified question posed by the United States Court of Appeals for the Fifth Circuit, 755 F.2d 393, regarding Louisiana's products liability law prior to the enactment of the Louisiana Products Liability Act (LPLA) in 1988. The LPLA placed a higher burden of proof on the injured consumer by abolishing the "unreasonably dangerous per se" category in Halphen. The LPLA also required the consumer to prove by a preponderance of the evidence that the defective nature of the product at issue, and the manufacturer's knowledge of such defect existed before the product entered into commerce. See LSA-R.S. 9:2800.51 et seq., Acts 1988, No. 64, § 1, eff. Sept. 1, 1988.

Id., p. 8, 726 So.2d at 938. The Court went on to note that:

> We must first determine whether Halphen, a 1986 decision, or Weber, a 1971 decision, can be used in the trial of a lawsuit filed in 1991, after the enactment of the LPLA.
>
> The Supreme Court in Cole[9] noted that the reviewing court must implement a two-fold inquiry under LSA-C.C. art. 6, to resolve this question.
>
> LSA-C.C. art. 6, requires that we engage in a two-fold inquiry. First, we must ascertain whether in the enactment the legislature expressed its intent regarding retrospective or prospective application. If the legislature did so, our inquiry is at an end. If the legislature did not,

[9] Cole v. Celotex Corp., 599 So.2d 1058 (La.1992).

we must classify the enactment as substantive, procedural or interpretive. Cole, *supra*, p. 1063.

Substantive laws, in the absence of contrary legislative expression, apply prospectively only because they establish new rules, rights, and duties or change existing ones. McCann v. Normand, 97-103 (La.App. 3 Cir. 6/4/97), 696 So.2d 203, 206; *citing* Segura v. Frank, 93-1271, 93-1401 (La.1/14/94); 630 So.2d 714, *cert. denied*, 511 U.S. 1142, 114 S.Ct. 2165, 128 L.Ed.2d 887 (1994). Although the LPLA is not specifically classified as substantive, procedural or interpretive law, the Supreme Court and this Court have declared the LPLA to be substantive law.

> Since the [LPLA] alters substantive rights, it is not retroactive and does not apply to this lawsuit. A statute that changes settled law relating to substantive rights only has prospective effect.

Gilboy v. American Tobacco Co., 582 So.2d 1263 (La.1991)[10]

Therefore, in light of Gilboy, the LPLA has prospective effect only because it overruled Halphen. Nevertheless, our inquiry is not complete until we ascertain when the plaintiffs' cause of action accrued.

Generally, the determinative point in time separating prospective from retroactive application of an enactment is the date the cause of action accrues. Cole, 599 So.2d at 1062. Accrual of a cause of action is when a suit may legally be instituted on the cause of action, that is, when it becomes immediately enforceable. DeGeorge v. Allstate Insurance Co., 93-612 (La.App. 5 Cir. 1/25/94), 631 So.2d 1257, 1261. Once a party's cause of action accrues, it becomes a vested property right that may not constitutionally be divested. Cole, *supra*, p. 1063; *citing* Crier v. Whitecloud, 496 So.2d 305, 308 (La.1986).

The primary elements for asserting a cause of action in Louisiana are: (1) defining a wrongful act by the

[10] In Gilboy, a cigarette smoker brought a products liability action against the cigarette manufacturer for lung and brain cancer allegedly developed as consequence of having smoked for approximately 46 years. The district court granted summary judgment to defendants on the theory that the smoker voluntarily encountered risks associated with cigarette smoking. The First Circuit, 572 So.2d 289, affirmed. Granting writs of certiorari, the Supreme Court, held that multiple questions of material fact precluded summary judgment. Id., at 582 So. 2d at 1276.

> defendant; and (2) declaring damages resulting from this act. See LSA-C.C. art. 2315, *et seq*.

Id., pp. 9-10, 726 So.2d at 939.

The appellants acknowledge that the LPLA did not become effective until September 1988; that it is not retroactive; and that it does not apply to acts which occurred prior to its effective date, referring to Gilboy v. American Tobacco, Co., 582 So.2d 1263 (La. 1991), and Page v. Gilbert, (La. App. 4 Cir. 1992), 598 So.2d 1110 as controlling. The appellants note that since injury to the plaintiffs in the Page case occurred prior to the adoption of the LPLA in 1988, the specific burden of proof in Halphen applies, and hence, the same burden of proof applies to their claims in the case *sub judice*. Specifically, the appellants assert that because Dr. Kent's and LSU's acts occurred before the September 1988 effective date of the LPLA, its exclusivity provision is not applicable to the claims in the instant matter.

The appellants also assert that the LPLA is also inapplicable because the IPIs were "designed, manufactured, and pulled off the market between 1983 and 1988," specifically noting that the implants were removed from the market before 1988. They also note that the VK-1 and VK-2 models were manufactured between 1984 and 1997.

Furthermore, the appellants argue that the LPLA is inapplicable, as related to acts of negligence which occurred after September 1, 1988, because Dr. Kent and LSU were not manufacturers nor professional vendors under the LPLA because, as indicated by the district court: (1) they did not act as professional vendors and, (2) they were not manufacturers who placed the items into the stream of commerce. Particularly, they point out that the rationale expressed by the district court was

that Dr. Kent and LSU were not liable because they did not fall within the definition of a manufacturer.

As to the Halphen claims, the appellants argue that the district court erred as a matter of law in granting a final summary judgment without addressing their strict liability claims. They assert that Halphen and not the LPLA is applicable to their claims for products manufactured before September 1, 1988. Alternatively, they argue that if this Court finds no evidence that Dr. Kent was not negligent in his pre-1988 actions and omissions, the district court erred as a matter of law in finding that there was no evidence that Dr. Kent or LSU acted as manufacturers. They maintain that while Halphen does not define a manufacturer, there is no doubt that Dr. Kent and LSU qualify as manufacturers under Halphen.

Furthermore, the appellants argue that although knowledge is not necessary, when Dr. Kent and LSU became aware that the implants were causing bone deterioration in patients implanted with the devices, they did nothing to warn patients of the potential risks. The appellants contend Dr. Kent and LSU "designed [the] devices with the intent and knowledge that they would be placed on the market to be used by innocent patients." They assert that Dr. Kent assisted Vitek in promoting the use of the Proplast devices by supporting and participating in numerous presentations, instructional seminars, and in the drafting of medical articles and correspondence which put the IPIs in a positive light.

Dr. Kent and LSU argue that the district court did not err in dismissing the appellants' product liability claims under the LPLA and strict products liability claims under Halphen. They assert that the LPLA and the Louisiana Products liability law predating the LPLA only imposes liability on those persons found to be a manufacturer, or in some circumstances, a vendor, *citing* Stahl v. Noartis

Pharmaceuticals Corp., 283 F.3d 254, 261-262 (5 Cir. 2002). Additionally they assert that Louisiana law predating the LPLA determines liability for defective products on the principles of strict liability, and this law is found in "former"[11] Louisiana Civil Code article 2317[12] and in article 2322.[13]

Dr. Kent and LSU assert that the district court was correct in finding that the appellants' LPLA claims were not convincing because there was no clear showing that Dr. Kent acted as a professional vendor, or that he manufactured or placed any relevant item into the stream of commerce. They further assert that the district court correctly concluded that the appellants failed to produce any convincing evidence that Dr. Kent or LSU had custody and control over the devices.

In support of their argument, Dr. Kent and LSU cite Reeves v. Acromed Corp., 103 F.3d 442, 449 (5 Cir. 1997). In Reeves, the recipient of a metal bone implant brought a products liability action against the implant's manufacturer, alleging that the implant had aggravated and compounded her back injuries. After a judgment on the jury verdict was entered for the implant recipient, the Court of Appeals, 44 F.3d 300, vacated and remanded the matter for a new trial. Following

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[11] Although La. C.C. art 2317 was amended by the Louisiana Legislature in 1996 and by such act appended 2317.1, the requirement of garde (care or custody) persists as a proof threshold. Essentially, "[a] plaintiff must prove…the defendant either owned or had care, custody, or control of the thing in question…." Graubarth v. French Market Corp., 2007-0416, p.5 (La.App. 4 Cir. 10/24/07), 970 So.2d 660,664.

[12] La. C.C. art. 2317, titled *Acts of others and of things in custody*, provides:

> We are responsible, not only for the damage occasioned by our own act, but for that which is caused by the act of persons for whom we are answerable, or of the things which we have in our custody. This, however, is to be understood with the following modifications.

[13] La. C.C. art. 2322, titled *Damage caused by ruin of building*, provides:

> The owner of a building is answerable for the damage occasioned by its ruin, when this is caused by neglect to repair it, or when it is the result of a vice or defect in its original construction. However, he is answerable for damages only upon a showing that he knew or, in the exercise of reasonable care, should have known of the vice or defect which caused the damage, that the damage could have been prevented by the exercise of reasonable care, and that he failed to exercise such reasonable care. Nothing in this Article shall preclude the court from the application of the doctrine of res ipsa loquitur in an appropriate case.

remand, and after the implant recipient also asserted claims against the inventor of the implant device, who also acted as chairman of the board of the manufacturing corporation, the United States District Court for the Eastern District of Louisiana, entered judgment on the jury verdict which awarded the implant recipient $318,000 and determined that the inventor was personally liable. The defendants appealed, and the Fifth Circuit Court of Appeal held, *inter alia*, that the inventor was not the manufacturer or supplier and could not be held personally liable under a products liability theory of recovery. Id., 103 F.3d at 449.

The Proplast jaw implants include the IPIs,[14] VK-I and VK-II. The IPIs were used as a meniscal replacement and consisted of shaped Proplast sheeting and were manufactured and placed on the market in 1983. They were removed from the market in 1988. The estimated damages caused by the IPIs applied to 80% of the plaintiffs remaining in the lawsuit. The VK-I and VK-II implants were total joint replacements manufactured and placed on the market between 1984 and 1990.

In September 1991, the Food and Drug Administration issued a public health notice on the Proplast TMJ devices, IPIs, VK-I, and VK-II, informing patients that some of these implants were breaking down, and were sometimes doing so without symptoms, and needed to be removed. Additionally, the public health notice indicated "[t]he VK-II implants contain some of the same material found in implants manufactured by Vitek and was sold without the permission of the FDA." The public health notice also established a registry for all Vitek TMJ implant patients to join.

[14] "IPI" the acronym used for Interpositional Implant devices.

Specifically, the problem with the Proplast devices was that the Teflon coating on the devices would sometimes fragment causing the implant itself to break down. As a result of the breakdown, Teflon particles would then travel throughout the patients' bodies from the implant sites. The patients would then suffer "massive bone deterioration, bone spur development, proliferation of giant cell granulation tissue, and severe TMJ pain."

The record reflects that the dental implant devices were: intended as a remedy for degeneration of the temporal mandibular joint ("TMJ"); were widely used from 1970 until 1991; and were marketed between 1974 and 1990 for persons specifically suffering from TMJ disorders.

In the instant matter, the plaintiffs filed their petition for damages in November 1998, approximately ten years after the LPLA became effective in 1988. Although the district court did find that negligent acts did occur related to the implants, there was no clear showing made by the appellants that Dr. Kent's or LSU's acts were negligent. This Court would be hard pressed to go beyond this finding, considering that the record fails to support the appellants' argument that Dr. Kent's and LSU's peripheral involvement with the IPIs remained continuous and ongoing. The record, in this Court's view, establishes that despite Dr. Kent's communications to Vitek relating his concerns about the implants, Vitek and Dr. Homsy marketed the implant devices. To arrive at the conclusion that Dr. Kent and LSU are negligent under the LPLA, or as Halphen claims, requires more than allegations that they may have had involvement as advisors. Dr. Kent and LSU would have to have acted as manufacturers and/or professional vendors.

Our review the record indicates that Dr. Kent began a professional relationship with Dr. Homsy sometime in 1970. Sometime thereafter, Dr. Kent

was asked to be a scientific advisor because of his experience with Proplast, and he performed multiple tasks such as drafting package inserts which accompanied some Vitek medical devices as well as offered advice on the products manufactured by Vitek.

Dr. Kent, Dr. Homsy, and a Vitek employee, John Tellkamp, designed the shape of the glenoid fossa that was used in the VK-I and VK-II implants, and obtained several design patents related to the same. Dr. Kent received royalty payments between 2-4% for certain products sold. He also provided services to Vitek as one of their scientific consultants. While working as a consultant for Vitek, Dr. Kent acquired 1% of Vitek stock, but allegedly did not participate in any stockholder meetings.

Pursuant to La. R.S. 9:2800.53(1), entitled *Definitions*, a "manufacturer":

> …[M]eans a person or entity who is in the business of manufacturing a product for placement into trade or commerce. "Manufacturing a product" means producing, making, fabricating, constructing, designing, remanufacturing, reconditioning or refurbishing a product. "Manufacturer" also means:
>
> a. A person or entity who labels a product as his own or who otherwise holds himself out to be the manufacturer of the product.
>
> b. A seller of a product who exercises control over or influences a characteristic of the design, construction or quality of the product that causes damage.
>
> c. A manufacturer of a product who incorporates into the product a component or part manufactured by another manufacturer.
>
> d. A seller of a product of an alien manufacturer if the seller is in the business of importing or distributing the product for resale and the seller is the alter ego of the alien manufacturer. The court shall take into consideration the following in

> determining whether the seller is the alien manufacturer's alter ego: whether the seller is affiliated with the alien manufacturer by way of common ownership or control; whether the seller assumes or administers product warranty obligations of the alien manufacturer; whether the seller prepares or modifies the product for distribution; or any other relevant evidence. A "product of an alien manufacturer" is a product that is manufactured outside the United States by a manufacturer who is a citizen of another country or who is organized under the laws of another country.

Even when considering La. R.S. 9:2800.53(7)(b),

> The failure of a person or entity, other than the manufacturer of a product, reasonably to provide to the product user or handler an adequate warning that the manufacturer provided about the product, when the manufacturer has satisfied his obligation to use reasonable care to provide the adequate warning by providing it to such person or entity rather than to the product user or handler.

The appellants have not established that any such warning was placed onto the IPI packaging. Hence, Dr. Kent and LSU had no obligation to provide adequate warnings to the appellants because no such warning was issued by the manufacturers, Vitek or Dr. Homsy. Furthermore, there is no evidence in the record that either Vitek or Dr. Homsy—as the IPI manufacturers—took any of Dr. Kent's advice related to the devices. Additionally, neither Vitek nor Dr. Homsy took the initiative to bring possible concerns related to the devices to the public's attention. The manufacturers made the decisions on how the product would be advertised and marketed; therefore, the duty of placing the warning on an item placed into the stream of commerce lies with the manufacturer.

The record before us supports the district court's finding that Vitek and Dr. Homsy manufactured and sold the IPIs. Additionally, the record also supports the

district court's findings that based on the facts and evidence presented at trial, the appellants failed to establish that Dr. Kent and/or LSU acted as professional vendors or manufacturers who placed items into the stream of commerce. Our review of the record indicates that neither Dr. Kent nor LSU ever participated in or had control over the fabrication, construction, and marketing of the Interpositional Implants (IPI's), VK-I and VK-II.

As stated earlier in this discussion, the LPLA represents a substantive change in the law and has prospective effect only because it overruled Halphen.[15]

> In the absence of contrary legislative expression, substantive laws apply prospectively only. Procedural and interpretative laws apply both prospectively and retroactively, unless there is a legislative expression to the contrary." La. C.C. art. 6. "Substantive laws," for purposes of determining whether a law should be applied retroactively, are those which establish new rules, rights, and duties, or change existing ones.

Brown v. Schwegmann, 2007-0210 p. 6 (La.App. 4 Cir. 7/30/08), 990 So.2d 1282, 1286, *citing* Anderson v. Avondale Industries, Inc., 2000-2799, p. 3 (La.10/16/01), 798 So.2d 93, 97.

Considering that the claims raised by the appellants in the district court concern allegations that Dr. Kent and LSU were negligent for the design of the subject IPIs, it becomes crucial to the appellants claims to prove that a correlation exists between Dr. Kent, LSU, and their alleged damages. This Court, per Asbestos v. Bordelon, must inquire whether the appellants' have properly asserted a cause of action under the LPLA, particularly, (1) whether the appellants have asserted a cause of action against Dr. Kent and LSU, and (2) whether they have declared damages resulting from Dr. Kent and LSU. In the matter *sub judice*, the

[15] See discussion of Asbestos v. Bordelon, 1996-0525 (La.App. 4 Cir. 10/21/98), 726 So.2d 926, *infra* at page 14.

district court determined that there was no clear showing of negligence and dismissed the appellants' pre-LPLA strict liability claims. Our review of the record establishes that the district court's findings are consistent with the evidence with which it was presented at trial, and reflects that the appellants failed to meet their evidentiary burden of showing that genuine issues of material fact exist to defeat Dr. Kent's and LSU's motion for summary judgment. As a result, we find that this assignment of error has no merit.

In their fourth assignment of error, the appellants argue that the district court erred, as a matter of law, in dismissing their claims for exemplary damages, because they have proven the necessary elements for recovery under La. C.C. art. 2315.3. However, we pretermit discussion of this assignment of error as the issue has been resolved in the appellants' first assignment of error.

In their fifth assignment of error, the appellants argue that the district court erred, as a matter of law, in dismissing the appellants' claims under the Louisiana Unfair Trade Practices and Consumer Protection Law, because the appellants filed suit within the one-year preemptive period imposed by La. R.S. 51:1401, *et seq*.

In Harris v. Poche, 2005-0664 (La.App. 4 Cir. 4/12/06), 930 So.2d 165, this Court discussed the Louisiana Unfair Trade Practices and Consumer Protection Law, as follows:

> The Louisiana Unfair Trade Practices and Consumer Protection Law is set forth in La. R.S. 51:1401, *et seq*. It declares unfair methods of competition, as well as unfair or deceptive acts or practices in the conduct of any trade or commerce, to be unlawful. An act is not required to be both unfair and deceptive. What constitutes unfair and/or deceptive practices is not specifically defined, but is determined on a case-by-case basis. Core v. Martin, 20,528 (La.App. 2 Cir. 5/10/89) 543 So.2d 619, 621. The Unfair Trade Practices Law does not prohibit sound business practices, the exercise of permissible business

> judgment or appropriate free enterprise transactions. A practice is unfair when it offends public policy and when the practice is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers. Ahmed v. Bogalusa Kidney Care Center, 89-0313 (La.App. 1 Cir. 4/10/90) 560 So.2d 485, 489. Conduct is considered unlawful when it involves fraud, misrepresentation, deception, breach of fiduciary duty or other unethical conduct. United Group of Nat. Paper Distributors, Inc. v. Vinson, 27,739 (La.App.2 Cir. 1/25/96), 666 So.2d 1338. A defendant's motivation is a critical factor; the actions must have been taken with the specific purpose of harming the competition. Id.; Monroe Medical Clinic, Inc. v. Hospital Corp. of America, 24,426 (La.App. 2 Cir. 7/21/93) 622 So.2d 760. On the issue of damages, the Louisiana Unfair Trade Practices Act, La. R.S. 51:1409(A), provides as follows:
>
> > A. Any person who suffers **any** ascertainable loss of money or movable property, corporeal or incorporeal, as a result of the use or employment by another person of an unfair or deceptive method, act or practice declared unlawful by R.S. 51:1409 may bring an action individually but not in a representative capacity **to recover actual damages**. If the court finds the unfair or deceptive method, act or practice was knowingly used, after being put on notice by the director or attorney general, the court shall award three times the actual damages sustained. **In the event that damages are awarded under this Section, the court shall award to the person bringing such action reasonable attorney's fees and costs**. Upon a finding by the court that an action under this section was groundless and brought in bad faith or for purposes of harassment, the court may award to the defendant reasonable attorney's fees and costs. (Emphasis added)

Id., 2005-0664 p. 7-8, 930 So.2d at 171.

Given that we have already concluded that the appellants have failed to satisfy their evidentiary burden to defeat a motion for summary judgment as to Dr. Kent's or LSU's liability under the previously discussed theories of recovery, we pretermit discussion related to this assignment of error as moot.

In their final assignment of error, the appellants argue that the district court erred, as a matter of law, in dismissing their strict liability claims, under La. C.C. art. 2317 and/or La. C.C. art. 2317.1, because the appellants argue that they have proven that the appellees had custody and control of the defective TMJ implants, and their components, which caused the appellants' damages. However, we pretermit discussion of this assignment of error, since we have already discussed strict liability in our discussion of negligence and have determined no error by the district court.

DECREE

The judgment of the district court is affirmed.

AFFIRMED