IN THE UNITED STATES COURT OF APPEALS

FOR THE FIFTH CIRCUIT

Nos. 93-4414 and 93-4626

BARBARA M. KLEM and CALVIN R. KLEM,

Plaintiffs-Appellants,

versus

E.I. DUPONT DE NEMOURS CO.,

Defendant-Appellee.

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MARCIA Y. COPELAND, ET AL.,

Plaintiffs-Appellants,

versus

E.I. DUPONT DE NEMOURS & CO., ET AL.,

Defendants,

E.I. DUPONT DE NEMOURS & CO.,

Defendant-Appellee.

Appeals from the United States District Court
for the Western District of Louisiana

(April 18, 1994)

Before HIGGINBOTHAM, and DUHÉ, Circuit Judges, and LITTLE,[*] District Judge.

HIGGINBOTHAM, Circuit Judge:

E.I. DuPont De Nemours & Co. produces a substance called Teflon. Another company, Vitek, purchased and altered DuPont's

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[*] District Judge of the Western District of Louisiana, sitting by designation.

Teflon to create a new, patented material, Proplast, which Vitek used to make medical implants. DuPont warned Vitek of failed experiments in the past using Teflon in implants and required Vitek to take full responsibility for the results of its efforts. Vitek accepted this responsibility. DuPont had no financial interest in Vitek.

Plaintiffs sued DuPont, complaining that they received Vitek implants and suffered injuries from failures of Proplast.

These suits were filed in the state court of Louisiana. DuPont removed them to the Western District of Louisiana. Federal jurisdiction rests on diversity of citizenship and Louisiana law controls. The district court granted summary judgment for DuPont. Plaintiffs appeal. Applying Louisiana law as it developed prior to the Louisiana Products Liability Act, we hold that DuPont did not manufacture an unreasonably dangerous product and that DuPont fulfilled any duty it may have had to warn of its dangers. DuPont is not liable for any injuries plaintiffs suffered from Vitek's implants.

I.

DuPont produces various plastic materials under the trademark name Teflon, among them polytetrafluoroethylene.[1] Teflon is used in hundreds of products, including nonstick frying pans and support pads on which buildings and bridges sit. Teflon also serves as an

[1] Plaintiffs appeal from a grant of summary judgment, so we summarize the facts in the light most favorable to them. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

ingredient, sometimes the primary ingredient, in various medical implant devices.

The success of such implant devices has been mixed. Reports have long indicated that Teflon may not be a suitable component for medical implants. Sir John Charnley, an English surgeon who employed Teflon to replace worn cartilage in the hip joints of dogs, found that the substance abraded or disintegrated causing serious harm. He published his conclusions in December 1963. Dr. John Leidholt, an orthopedic surgeon in Denver, Colorado, undertook similar experiments with similar results. A representative of DuPont corresponded with Dr. Leidholt about the doctor's findings as early as 1966.

An employee of DuPont, Dr. Charles Homsy, wished to develop implant technology using Teflon as an ingredient. Dr. Homsy asked, but DuPont declined to participate. Dr. Homsy left DuPont in 1966 to teach at Baylor College of Medicine and Methodist Hospital in conjunction with its Prosthesis Research Laboratory.

The following year Dr. Homsy sought to purchase Teflon from DuPont, but DuPont responded that it did not prepare Teflon for medical purposes. DuPont also insisted that Dr. Homsy exercise independent judgment regarding any medical uses he might make of Teflon insisting that Homsy assume full responsibility for the consequences of such uses. Dr. Homsy responded by explaining his familiarity with the relevant body of scientific knowledge about the use of Teflon in implants and signed a letter accepting

DuPont's policy. Only then did DuPont sell Teflon to Methodist Hospital and Dr. Homsy.

By the following year, 1968, Dr. Homsy had developed Proplast, a material employing Teflon but altering its physical composition. Dr. Homsy designed his process for making Proplast attempting to avoid problems of past implants made of Teflon. He obtained a patent on Proplast and in 1969 founded Vitek for its manufacture. Vitek undertook extensive testing to evaluate Proplast as a material for making medical implant devices. These efforts and the work of another scientist[2] indicated that Proplast, and substances derived from Teflon in general, might prove useful in replacing the meniscus in the temporomandibular joint (TMJ), a joint in the jaw in front of the ear. Proplast TMJ implants made by Vitek became available in 1974.

After passage of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1938, DuPont contacted Vitek in 1977 iterating that Vitek must render independent judgment as to the suitability of Teflon as an ingredient in medical devices. DuPont required assent to this policy and compliance with FDA statutes and regulations as a condition of its sales of Teflon to Vitek. Vitek and Dr. Homsy assented and obtained FDA classification of Proplast. Vitek then obtained FDA permission to sell its TMJ implant devices.

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[2] British researcher Dr. H. P. Cook reached this conclusion in 1972.

In the late 1970s, oral surgeons began using Proplast in TMJ replacements. Responding to this trend, Vitek began to market a pre-formed TMJ implant in 1983. Persons receiving TMJ implants made of Vitek's Proplast that contained DuPont's Teflon are now suing alleging that Proplast abraded in use, causing serious injury.

II. Strict Liability

We must apply Louisiana law governing products liability as set out in Halphen v. Johns-Manville Sales Corp.[3] The Louisiana legislature overruled an aspect of Halphen in the Louisiana Products Liability Act.[4] The Act did not take effect, however, until September 1, 1988, and the Louisiana Supreme Court has held that the Act does not apply retroactively.[5] The events relevant to this dispute occurred before 1988. We look to the case law that developed before the Act became effective.

A manufacturer is liable to a consumer under Louisiana law if (1) a condition of its product caused a harm to the consumer; (2) the condition made the product unreasonably dangerous to normal use; and (3) the condition existed at the time the product left the manufacturer's control.[6] There are several categories of unreasonably dangerous products. A product is unreasonably

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[3] 484 So.2d 110 (La. 1986).

[4] Gilboy v. American Tobacco Co., 582 So.2d 1263, 1264 (La. 1991).

[5] Id.

[6] Antley v. Yamaha Motor Corp., 539 So.2d 696, 699-700 (La. App. 3d Cir. 1989) (citing Halphen v. Johns-Manville Sales Corp., 484 So.2d 110 (La. 1986)).

dangerous: (1) if the danger involved in its use outweighs its utility, it is said to be per se unreasonably dangerous; (2) in construction or composition, if it contains an unintended abnormality or condition that renders it more dangerous than it was designed to be; (3) for lack of warning, if the manufacturer failed adequately to warn of the dangers that attend its use; or (4) by design, if safer alternative products were available or the product could have been designed in a less dangerous manner.[7] Plaintiffs must place Teflon within one of these categories.

A. Unreasonably Dangerous Per se

A product is unreasonably dangerous per se if it does more harm than good in society. Plaintiffs argue that, in making this evaluation, we should strike the balance of the harms and benefits only through their eyes. We have read Louisiana law as rejecting this approach.[8] Louisiana law requires the weighing of costs and benefits to all consumers of a product, not just to the plaintiffs.

Plaintiffs argue in the alternative that although their suit is against DuPont, we should gauge the net utility of TMJ implants, not of the ingredient of the implants that DuPont produced. The

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[7] Halphen, 484 So.2d at 114-15. These categories overlap. A product, for example, that is unreasonably dangerous per se--that is, its danger outweighs its utility--also qualifies as unreasonably dangerous by design. Id. The four approaches listed, although they are at times referred to by different labels under Louisiana law, exhaust the various definitions of unreasonable dangerousness under Halphen.

[8] See Valenti v. Surgiteck-Flash Medical Eng'g Corp., 875 F.2d 466, 467 (5th Cir. 1989) (rejecting analysis of whether dangers to plaintiff posed by product outweighed utility to plaintiff).

ambit of inquiry into whether a product is dangerous per se includes all and not a subclass of users.[9] Louisiana law not only refuses to disaggregate different users of a product, it also declines to disaggregate different uses of an ingredient in a product.[10] We are constrained by Louisiana law not to limit analysis to costs and benefits of Proplast in TMJ implants. We ask instead whether Teflon does more harm than good in society.

Plaintiffs understandably do not contend that harm suffered by users of TMJ implants renders Teflon on the whole a harmful substance. Given the many productive uses of Teflon, the conclusion that it is not unreasonably dangerous per se is inevitable.[11]

B. Unreasonably Dangerous
In Construction or Composition

A product is unreasonably dangerous in construction or composition if it contains an unintended abnormality or condition that renders it more dangerous than it was designed to be. Plaintiffs do not here allege that DuPont manufactured and sold Teflon for Vitek's implants that varied from the substance DuPont intended to produce.

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[9] See Sharkey v. Sterling Drug, Inc., 600 So.2d 701, 707 (La. App. 1 Cir.), writ denied, 605 So.2d 1100 (La. 1992) (refusing to limit analysis of utility of aspirin to children users).

[10] See Longo v. E.I. DuPont De Nemours & Co., No. 93-CA-0756, 1994 La. App. LEXIS 300 at *10 (La. App. 4th Cir. Feb. 18, 1994) (applying law prior to Louisiana Products Liability Act).

[11] See id. This method of analysis supports the same result if one addresses the harms and benefits of a particular form of Teflon, polytetrafluoroethylene.

C. Failure to Warn

Louisiana law requires a manufacturer not only to keep abreast of scientific developments but also to perform its own tests to determine that its products are safe.[12] The Louisiana Supreme Court in Halphen cited our opinion in Borel v. Fibreboard Paper Products Corp.[13] In Borel we held:

> The manufacturer's status as an expert means that at a minimum he must keep abreast of scientific knowledge, discoveries, and advances and is presumed to know what is imparted thereby. But even more importantly, a manufacturer has a duty to test and inspect his product. The extent of research and experiment must be commensurate with the dangers involved. A product must not be made available to the public without disclosure of those dangers that the application of reasonable foresight would reveal. Nor may a manufacturer rely unquestioningly on others to sound the hue and cry concerning danger in its product. Rather, each manufacturer must bear the burden of showing that its own conduct was proportionate to the scope of its duty.[14]

As lofty as this language is, the Louisiana courts have never held that the manufacturer of a component part of a finished product has a duty to the ultimate consumer to test the suitability of the component for its use in the finished product.

We reach now the most difficult question in this case:

Where does the responsibility lie to assess and warn a consumer of the appropriateness of use of a component or ingredient in a product? DuPont made an effort to act responsibly. DuPont

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[12] Halphen, 484 So.2d at 115.

[13] 493 F.2d 1076 (5th Cir. 1973), cert. denied, 419 U.S. 869 (1974).

[14] Id. at 1090 (footnotes and citations omitted).

informed Vitek, as DuPont does other potential customers, that DuPont does not produce a medical grade Teflon and has not adequately tested the substance for use in medical devices. DuPont required Vitek to assume responsibility for testing Proplast, the product Vitek developed from Teflon. Vitek also sought and received both a patent and FDA approval for Proplast.

Further, DuPont was not involved in the development of Proplast. Vitek and DuPont were independent companies. DuPont made no gains from the sale of Vitek's products other than the price of the Teflon DuPont sold Vitek. This amount was a tiny percentage of the value of each implant and an even tinier percentage of DuPont's total sales of Teflon. DuPont exercised no control over the design, composition, testing, or manufacture of Proplast or the TMJ implants. Our review of Louisiana law suggests that DuPont fulfilled any obligation it had to warn of the dangers of Teflon.

A Louisiana court in Reeves v. Great Atlantic & Pacific Tea Co.[15] held: "The mere supplier of a component part of a finished product is not liable for damages in tort, absent a showing that the injury was caused by a defect contained in the component part, rather than a defect contained in the finished product."[16] Expanding on this notion, a Louisiana court in Champion v. Panel

[15] 370 So.2d 202, 209 (La. App. 3d Cir.), writ denied, 371 So.2d 835 (La. 1979).

[16] Reeves, 370 So.2d at 209.

Era Mfg. Co.[17] addressed the problem of liability that arises when a product proves to be harmful in its application as a component of another product. In Champion, insulation material used in chicken houses caused the houses to erode prematurely. A jury found the manufacturer of the chicken houses liable for the damage that resulted but, in a third party action, refused to find the manufacturers of components in the insulation material liable to the manufacturer of the chicken houses.[18] In affirming the jury verdict on appeal, the court noted that a finished product manufacturer has the obligation to ascertain whether a component is appropriate for its intended use.[19]

A Louisiana court in Longo v. DuPont recently adopted a similar approach in assessing the relationship between DuPont, Vitek, and recipients of Vitek's implants. The court reasoned:

> Teflon was a component part of Proplast and therefore DuPont owed no duty to warn [implant recipients]. Vitek became the manufacturer. While DuPont may have sold Teflon to Vitek knowing the possibility existed that products manufactured with Teflon as a component part would be used in medical and surgical applications, it had no control over the design, composition, testing, or manufacture of Vitek products.[20]

The court concluded that DuPont had no duty to warn the recipients of Vitek's implants.[21]

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[17] 410 So.2d 1230 (La. App. 3d Cir.), writ denied, 414 So.2d 389 (La. 1982).

[18] Id. at 1234, 1241.

[19] Id. at 1241-42.

[20] Longo, 1994 La. App. LEXIS 300 at *13.

[21] Id.

DuPont informed Vitek of danger in using Teflon in implants. But Vitek went its own way with its own expertise and its own testing. Vitek altered Teflon, creating a distinct potential product, Proplast, in an effort to cure the problems scientists confronted in the past when using Teflon in implants. As we earlier noted, Vitek also secured FDA approval for the use of Proplast. Under these circumstances and in light of Longo, we conclude that DuPont fulfilled any obligation it had to warn of the dangers of using Teflon in medical implants.

D. Unreasonably Dangerous by Design

A product is unreasonably dangerous by design if it could have been safer had it been designed differently or if a different product could have served the same purpose and posed less danger.[22] DuPont did not, however, design Teflon for use in medical implants. To the contrary, DuPont made clear to Dr. Homsy that such use could be dangerous. Further, DuPont insisted that if Dr. Homsy persisted in using Teflon in implant devices, he had to do so with his own research and at his own risk. Dr. Homsy chose to adapt Teflon for use in implants because he believed the substance held particular promise. If DuPont had designed Teflon otherwise, it would not have been Teflon. Similarly, if a different product would have served more safely in its stead, Dr. Homsy erred by choosing Teflon for use in TMJ implants. The design of Teflon was not, in this

[22] Halphen, 484 So.2d at 115.

context, defective. Any fault lay with Homsy's selection. Teflon therefore is not unreasonably dangerous in design.[23]

III. Negligence, Negligence Per Se, Redhibition, False Representation, and Other Causes of Action

Plaintiffs contend, in the alternative, that DuPont had a duty to warn, or not to mislead by implication, and that the breach of that duty sounded in negligence, redhibition, and other areas of the law. These arguments essentially duplicate plaintiffs' failure to warn claim under Halphen, and the result is the same. The label placed on DuPont's activities does not change DuPont's responsibilities or its fulfillment of them.[24] Nor does the fact that DuPont let it be known that its product, Teflon, was an ingredient in Vitek's medical implants.[25] We conclude that DuPont met any duty it may have had when it informed Vitek that it did not make a medical grade Teflon and that it had not tested the

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[23] See Longo, 1994 La. App. LEXIS 300 at *11-12.

[24] The court in Longo, for example, limited DuPont's duty to warn in strict liability by looking to the obligation of the manufacturer of a component in redhibition. See Longo, 1994 La. App. Lexis 300 at *12-13 (relying on Austin's of Monroe, Inc. v. Brown, 474 So.2d 1383 (La. App. 2d Cir. 1985) ("The manufacturer of a non-defective, even though substantial, component of a thing assembled and created by another should not be liable to the buyer of that thing for redhibitory vices in the assembled and created thing. In this sense, the assembler or creator of the thing from component parts effectively becomes the manufacturer of the thing.")).

[25] Chappuis v. Sears Roebuck & Co., 358 So.2d 926 (La. 1978), on which plaintiffs rely, does not hold the contrary. Chappuis addressed the liability of the manufacturer of a defective product and of a subsequent party that sold the product under its own name. Id. at 930. DuPont did not sell Vitek's product at all, much less under its own name.

substance adequately for medical use. As a matter of Louisiana law, at least as it existed prior to the Louisiana Products Liability Act, DuPont had no further obligation to warn.

AFFIRMED.