5-3-1994

Gile v. Optical Radiation Corporation, et al.

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 93-5555

HELEN GILE,
Appellant

v.

OPTICAL RADIATION CORPORATION;
XYZ COMPANIES, #1 through #5;
JOHN DOES, #1 through #5

Appeal from the United States District Court
for the District of New Jersey
D.C. No. 92-cv-02957

Argued March 24, 1994
Before: HUTCHINSON, ROTH, and ROSENN, Circuit Judges
Opinion Filed May 3, 1994

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OPINION OF THE COURT

ROSENN, Circuit Judge.

This case raises an interesting question of liability which has its origin in the coordinated efforts of the Government

and manufacturers of optical medical devices to advance the cause of medical treatment through research, experimentation, and optimum freedom for scientific investigation in the pursuit of that purpose.

In 1981, the Food and Drug Administration (FDA) approved for clinical investigation an intraocular lens manufactured by defendant Optical Radiation Corporation (ORC). An intraocular lens (IOL) is a lens intended to replace surgically the natural lens of the human eye. In December 1985, Dr. Henry Scimeca, an investigator approved by the FDA, implanted in the eye of plaintiff Helen Gile, who suffered from cataracts, an ORC model UV11H intraocular lens. Prior to the surgery, Gile signed an informed consent form, which she claims that she did not read before signing. Gile subsequently had the ORC lens surgically removed from her left eye, and is now legally blind in that eye.

In May of 1992, Gile commenced this products liability and negligence action against ORC in the Superior Court of New Jersey. ORC removed the case to the United States District Court for the District of New Jersey.[1] Thereafter, ORC moved for summary judgment on the ground that Gile's claims were expressly preempted under the Federal Food, Drug and Cosmetic Act (FDCA or the Act), 21 U.S.C. § 301 et seq. The district court entered summary judgment in favor of ORC and dismissed the complaint with prejudice. Gile timely appealed to this court. We affirm.

[1]The district court exercised diversity jurisdiction over this case pursuant to 28 U.S.C. § 1332. This court has jurisdiction over this appeal from a final order pursuant to 28 U.S.C. § 1291.

I.

This court exercises plenary review over a grant of summary judgment, and we apply the same test the district court should have utilized initially. Oritani Sav. and Loan Ass'n v. Fidelity and Deposit Co., 989 F.2d 635, 637 (3d Cir. 1993). Summary judgment is appropriate only when it is demonstrated that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-32 (1986); Fed.R.Civ.P. 56(c). An issue of material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In deciding a motion for summary judgment, all reasonable inferences must be drawn in favor of the non-movant. Oritani, 989 F.2d at 638.

At the heart of this action are the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c et seq., to the FDCA. Pursuant to the FDCA, and amendments thereto, including the MDA, the FDA strictly regulates the development, marketing, and monitoring of medical devices. The MDA sets forth various requirements concerning the safety and effectiveness of medical devices and the approvals to be obtained from the FDA before bringing a device to the market. The MDA also limits entities other than the FDA from imposing requirements on the makers of medical devices and the process by which those devices are discovered, investigated, and manufactured. Section 360k(a), the focus of this appeal, provides:

> [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).

In enacting the MDA, Congress recognized the need for special treatment of investigational devices which, by their very nature, could not meet the requirements applicable to marketed devices:

> It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. § 360j(g)(1). Persons seeking an exemption from pre-market approval for a particular medical device (an "investigational device exemption" or "IDE") must apply to the FDA for permission to undertake clinical investigations. Id. at § 360j(g)(2)(A).

The FDA issued specific regulations governing the development of IOLs. 21 C.F.R. § 813 et seq. (the "IOL Regulations"). The regulations require a detailed application, describing the device under investigation and setting forth a plan for studying its use in human subjects, which is reviewed by

both the FDA and an institutional review committee. 21 C.F.R. §§813.20, 813.30. The device must be described in sufficient detail to permit "a knowledgeable judgment about the anticipated safety and effectiveness of the lens." Id. at § 813.20(b)(2). After approval, the committee has a duty to monitor the clinical investigation. Id. at § 813.65. The regulations detail the monitoring of the studies and set forth reporting and recordkeeping requirements, including evaluation of complaints about devices. Id. at §§ 813.46, 813.180 et seq. Under the IOL Regulations, the FDA can refuse an exemption if it finds, inter alia, that the lens may be unsafe or ineffective, that the investigational plan is not a reasonable one, or that manufacturing, storage, and implantation methods do not assure adequate safety and effectiveness. 21 C.F.R. § 813.30(c). In sum, the IOL regulations broadly govern nearly all facets of the investigational program. See Covey v. Surgidev Corp., 815 F. Supp. 1089, 1095 (N.D.Ohio 1993) ("[t]o say that the regulations covering intraocular lenses are expansive would be an understatement").

II.

Gile first argues that Congress never intended to preempt state common law when it passed the MDA. She contends that the word "requirement" in 21 U.S.C. § 360k(a) refers only to positive legislative enactments and not to state tort common law claims. This argument must be rejected, however, in light of Cipollone v. Liggett Group, Inc., 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). The Cipollone Court addressed the Public Health

Cigarette Smoking Act of 1969, which preempted certain "requirement[s] or prohibition[s] . . . imposed under state law." The Court rejected the contention that the act did not extend to state tort claims:

> The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."
>
> Although portions of the legislative history of the 1969 Act suggest that Congress was primarily concerned with positive enactments by States and localities, the language of the Act plainly reaches beyond such enactments.

112 S.Ct. at 2620; 120 L.Ed.2d at 426 (citations and footnote omitted). Thus, the Supreme Court has clearly stated that the word "requirement," in the context of an express preemption provision, includes state law claims. See also Stamps v. Collagen Corp., 984 F.2d 1416, 1421 (5th Cir. 1993), cert. denied, 114 S.Ct. 86 (1993); King v. Collagen Corp., 983 F.2d 1130, 1133 (1st Cir. 1993), cert. denied, 114 S. Ct. 84 (1993).

Gile contends that there cannot be express preemption unless Congress uses "the words 'common law' or something analogous" to indicate its intent to preempt such claims. However, the MDA, providing "no State or political subdivision of a State may establish . . . any requirement . . . different from, or in addition to, any requirement applicable under this

chapter," is indistinguishable from the act at issue in Cipollone, which provided, "[n]o requirement or prohibition . . . shall be imposed under State law with respect to the advertising . . . of any cigarettes." Thus, Gile's argument that Congress needs to explicitly provide that common law claims are preempted in order to find express preemption is unpersuasive.

Gile further argues that even if her tort claims in general are preempted under § 360k, her specific claims based on lack of informed consent and adulterated products are exempt from preemption. First, she relies on 21 C.F.R. §§ 50.20 and 50.25(c) as support for her contention that her claim for failure to obtain informed consent is not preempted. Section 50.20, which addresses general requirements for informed consent, provides in part: "No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence." Section 50.25(c), which addresses elements of informed consent, provides: "[t]he informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective." Gile further notes that the court in Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir. 1992), cert. denied, 113 S.Ct. 327 (1992), held that not all claims are

preempted under § 360k, including claims for informed consent. Id. at 1334.

The Slater court, however, stated that 21 C.F.R. §50.20 "preserves the patient's common law rights outside of the limited scope of the preemption provision. It does not . . . repeal the preemption provision itself." Id. Similarly, the court in Hunsaker v. Surgidev Corp., 818 F. Supp. 744 (M.D.Pa. 1992) concluded that "the consent regulation should be read to prevent patients from waiving legal rights which are not preempted under federal law. That is, those common law rights which are retained by a patient and not preempted by the federal scheme may not be waived by the patient." Id. at 750 (emphasis in original). Gile, however, ignores that the predicate of a claim for informed consent addresses the duty of the physician, not the manufacturer, to the patient. See e.g., Largey v. Rothman, 540 A.2d 504 (N.J. 1988); Kershaw v. Reichert, 445 N.W.2d 16 (N.D. 1989). She is unable to provide any support for her contention that she is entitled to bring such a claim against the manufacturer of an experimental product. Moreover, despite the completion of discovery in this action, Gile has not offered any proof to support her vague allegation that ORC failed to provide her physician with the proper forms and information necessary to obtain informed consent.

Gile next quotes the first sentence of section 808.1(d)(6)(ii) of the FDA Regulations, which states: "[g]enerally, [§ 360k(a)] does not preempt a State or local requirement prohibiting the manufacture of adulterated or

misbranded devices." 21 C.F.R. § 808.1(d)(6)(ii).[2] But the next sentence, not quoted by Gile, provides:

> Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act.

Id. This action by Gile challenging the design of the Stableflex lens and the warnings and instructions that accompanied it, if successful, would impermissibly result in new common law standards for lens design and warnings. See e.g., Stamps, 984 F.2d at 1421-22; King, 983 F.2d at 1135-36; Slater, 961 F.2d at 1333. Thus, it is preempted. Moreover, read in its entirety, section 808.1 prohibits, not supports, challenges such as Gile's to FDA requirements affecting the safety and effectiveness of investigational devices under the guise of product liability actions by reflecting the FDA's determination that the word "requirement," as used in § 360k, includes "court decisions."[3]

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[2] 21 C.F.R. § 808.1(d) sets forth examples of state or local requirements that are not preempted by § 360k. Significantly, the list of requirements exempted from § 360k does not include state tort or common law claims.

[3] Section 808.1(b) states:

> [Section 360k provides that] no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or

Similarly, Gile's argument that her claims are not preempted because the IOL was "adulterated" within the meaning of 21 U.S.C. § 351(i) must fail.[4] The FDA can determine an investigational device to be adulterated if requirements under the IDE are not complied with. Here, the FDA made no findings of adulteration and the record does not contain any facts to support such a claim. Moreover, violations of the FDCA do not create private rights of action. See e.g., Pacific Trading Co. v. Wilson & Co., Inc., 547 F.2d 367, 370 (7th Cir. 1976); Kemp v. Pfizer, Inc., 835 F. Supp. 1015, 1022 (E.D.Mich. 1993); Brinkman v. Shiley, Inc., 732 F. Supp. 33, 35 (M.D.Pa.), aff'd, 902 F.2d 1558 (3d Cir. 1989). Thus, only the government has a right to take action with respect to adulterated products. Additionally, as noted by the district court, to the extent Gile's adulteration claim is derivative of her other claims for inadequate design, manufacture, and warnings, she cannot overcome a finding of preemption merely by claiming that the product was adulterated.

III.

Every court that has considered the issue of the preemptive effect of § 360k in the context of ORC's product, has

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> effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

21 C.F.R. § 808.1(b) (emphasis added). See Stamps, 984 F.2d at 1421 n.1.; King, 983 F.2d at 1134; Slater, 961 F.2d at 1331.

[4] 21 U.S.C. § 351(i) provides that a device shall be deemed to be adulterated "[i]f it is a device for which an exemption has been granted under section 360j(g) of this title for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section."

ruled in favor of ORC. See Slater, 961 F.2d 1330; Hinners v. Optical Radiation Corp., 15 F.3d 1096 (11th Cir. 1994) (per curiam); Rogers v. Optical Radiation Corp., 12 F.3d 194 (11th Cir. 1994). In Slater, as here, the plaintiff alleged that following implantation of a Stableflex lens, his vision deteriorated and the implant had to be removed, leaving him with permanent damage. 961 F.2d at 1332. The plaintiff in Slater advanced causes of actions for strict liability, breach of warranty, failure to provide adequate warnings, negligent design, and failure to conduct proper clinical testing. Slater v. Optical Radiation Corp., 756 F. Supp. 370, 371-72 (N.D. Ill. 1991), aff'd, 961 F.2d 1330 (7th Cir. 1992). The lens in Slater, like the one in this case, was governed by the IOL Regulations. 961 F.2d at 1331.

The district court in Slater found that all of the plaintiff's claims were expressly preempted by § 360k, and granted the defendant's motion to dismiss the entire complaint. The Seventh Circuit affirmed, emphasizing that § 360k(a) forbids states to subject a medical device to requirements "different from, or in addition to" requirements that relate to the safety and effectiveness of the device. The Slater court noted that although the regulations imposed no requirement concerning the specific design of intraocular lenses,

> [t]he FDA can hardly be expected to specify the safe and effective design of a device when it is still experimental. If there were a known safe and effective design, the device would no longer be experimental. The point of the experiment is to find out whether it is safe and effective.

961 F.2d at 1333 (citation omitted). The court concluded:

> The theory underlying the complaint is that the design of the Stableflex was not sufficiently safe and effective to allow it to be used on human beings. This theory sets up a direct collision with federal policy. The FDA decided, whether rightly or wrongly, but pursuant to regulations the validity of which the plaintiff does not question, that the Stableflex could be sold, subject only to requirements, procedural in character and, so far as appears, fully complied with, designed to assure that this experimental distribution was in fact a worthwhile experiment. The plaintiff wishes in the name of state tort law to impose additional requirements--namely that the Stableflex have had design characteristics that it lacked--and this engrafting of additional requirements relating to safety or effectiveness is forbidden by the preemption provision in the Medical Devices Amendments.

Id.

Gile argues that Slater is not persuasive because the court noted that preemption "is limited to efforts by states to impose sanctions for compliance with federal regulations relating to the safety or efficacy of the experimental lenses." 961 F.2d at 1334. Gile submits that she is not seeking to impose sanctions for compliance with regulations, but rather is seeking damages for injury received and for the failure to warn of the danger of the experiment. The quoted dicta from Slater, however, preceded the court's observation that preemption under § 360k would not affect claims based on negligence in the implantation of a lens, negligence in the removal of a lens, contamination of the lens by bacteria or fungi, or medical battery resulting from

failure to obtain the patient's informed consent to the procedure. Id.

Notably, all of these claims might be brought against a physician, not against the lens manufacturer. The dicta does not detract from Slater's holding that the plaintiff's claims for negligence, strict liability, and breach of warranty against the manufacturer were preempted under § 360k as impermissible attempts to impose additional safety and effectiveness requirements on the manufacturer. See also Rogers, 12 F.3d 194 (11th Cir. 1994) (affirming entry of summary judgment in favor of ORC on plaintiff's causes of action for design defect, inadequate warning, breach of warranty, and inadequate testing on express preemption grounds); Hinners, 15 F.3d 1096 (11th Cir. 1994) (affirming dismissal of plaintiff's claims regarding safety and effectiveness of intraocular lenses on preemption grounds).

In the only IOL case within this circuit, Hunsaker v. Surgidev Corp., 818 F. Supp. 744 (M.D.Pa. 1992), the court agreed with Slater that "the standards implicit in the state tort actions would be 'different from or in addition to' those requirements of both the FDCA and the IDE regulations." Id. at 752 (citation omitted). The court reasoned that the difference between experimental devices and those approved for marketing supports a finding of express preemption under § 360k. Id. at 749. The court concluded:

> A jury determination that the device is not sufficiently safe and effective would not only be contrary to the experimental purposes of the exemption, but, more important, would directly conflict with the FDA's contrasting

> judgment. Therefore, state tort law invoked to challenge the safety or effectiveness of a IOL which is part of an FDA investigation is federally preempted.

Id. at 752-53. Thus, the district court's finding of preemption under § 360k is in conformance with the holdings of the vast majority of cases which have addressed this issue.[5]

IV.

Next, Gile argues that public policy favors remedies for victims of medical experimentation. Gile erroneously contends that if preemption is permitted, medical device manufacturers will be granted immunity for all manner of improper acts. As explained by ORC, violations of the FDCA and FDA regulations are punishable by significant fines, civil penalties, and imprisonment. Similarly, Gile's assertion that preemption will encourage shoddy clinical investigations and development of defective medical devices lack merit. As shown by the detailed regulations discussed above, it is unlikely that a non-efficacious or unsafe investigational device would survive FDA review.

Moreover, Gile ignores the countervailing public policy of the discovery and development of new products. See 21 U.S.C. § 360j(g) (one purpose of investigational device exemptions is "to maintain optimum freedom for scientific investigators"). As explained by the Slater court:

[5]In light of our statutory interpretation and the extensive authority discussed above, we reject Gile's sole reliance on two lower court cases from Louisiana, Lewis v. Intermedics Intraocular, No. 93-0007 (E.D.La. Dec. 9, 1993) and Mitchell v. IOLAB Corp., 700 F. Supp. 877 (E.D. La. 1988).

> [I]f experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer.

961 F.2d at 1334. Thus, state tort claims run counter to the important public policy, recognized by Congress, of promoting scientific inventions.

Finally, Gile argues that the district court's grant of summary judgment based on federal preemption encompassed both forum and claim preemption, leaving her without a remedy. She contends that public policy disfavors preemption of common law where no remedies are available to consumers injured by the unreasonable conduct of a manufacturer. However, Congress has the power to displace state tort law remedies, and clearly did so by enacting the MDA. See e.g., Stamps, 984 F.2d at 1421 (citing Chicago & N.W. Transp. Co. v. Kalo Brick & Tile, Co., 450 U.S. 311, 331 (1981)). Moreover, Gile is not precluded from asserting a right of redress in the state forum because her claims against her physician are not preempted under the MDA. See Slater, 961 F.2d at 1334; Hunsaker, 818 F. Supp. at 751. Thus, despite her arguments to the contrary, Gile is not left without a remedy because she may still pursue her claims, if any, against her physician in state court.

V.

There being no genuine issues as to any material facts in this case, the district court committed no error in rendering summary judgment in favor of ORC as a matter of law. Accordingly,

the judgment of the district court in favor of Optical Radiation Corporation will be affirmed.