Goldsmith v. Mentor Corp. CV-94-651-JD 12/04/95 P

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW HAMPSHIRE

R. Gardner Goldsmith

v. Civil No. 94-651-JD

Mentor Corporation

O R D E R

The plaintiff, Gardner Goldsmith, filed this products liability action against the defendant, Mentor Corporation, to recover for injuries resulting from the implantation and subsequent removal of a testicular prosthesis. Before the court is the defendant's motion for summary judgment (document no. 5).

Background[1]

In April 1990, the plaintiff underwent surgery to correct a testicular abnormality he had since birth. The surgery included the implantation of a silicone testicular prosthesis designed, manufactured, and marketed by the defendant as the Mentor Large Testicular Prosthesis.

During late 1991 and early 1992 the plaintiff, who was otherwise healthy, began to suffer a variety of pain, swelling,

[1]The court's recitation of the facts relevant to the instant motion are either not in dispute or have been alleged by the plaintiff.

and other symptoms in many areas of his body. The plaintiff's physicians concluded that the prosthesis was causing or exacerbating many of his ailments. The prosthesis was removed on June 14, 1994, and many of the plaintiff's symptoms have subsided since then. However, the plaintiff continues to suffer from other impairments related to the prosthesis.

The instant action was filed on December 19, 1994. The complaint alleges eleven separate causes of action: strict liability (count one); negligent design, manufacture, sale, and distribution (count two); failure to warn (count three); breach of express and implied warranties of merchantability and fitness for a particular purpose (count four); statutory breach of warranty under the Uniform Commercial Code (count five); misrepresentation (count seven); unfair business practices (count eight); false advertising (count nine); violation of the Magnuson-Moss Act, 15 U.S.C. § 2301 (count ten); and punitive, enhanced and exemplary damages (count twelve). See Complaint; Plaintiff's Motion in Objection to Summary Judgment at 3. The plaintiff has withdraw count six, see Motion for Voluntary Nonsuit, and has never identified a cause of action as count eleven.

The court incorporates other facts, infra, as necessary for its analysis of the legal issues presented by the instant motion.

Discussion

The role of summary judgment is "to pierce the boilerplate of the pleadings and assay the parties' proof in order to determine whether trial is actually required." Snow v. Harnischfeger Corp., 12 F.3d 1154, 1157 (1st Cir. 1993) (quoting Wynne v. Tufts Univ. Sch. of Medicine, 976 F.2d 791, 794 (1st Cir. 1992), cert. denied, 113 S. Ct. 1845 (1993)), cert. denied, 115 S. Ct. 56 (1994). The court may only grant a motion for summary judgment where the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

The party seeking summary judgment bears the initial burden of establishing the lack of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986); Quintero de Quintero v. Aponte-Roque, 974 F.2d 226, 227-28 (1st Cir. 1992). The court must view the entire record in the light most favorable to the non-moving party, "`indulging all reasonable inferences in that party's favor.'" Mesnick v. General Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991) (quoting Griggs-Ryan v. Smith, 904 F.2d 112, 115 (1st Cir. 1990)), cert. denied, 112 S. Ct. 2965 (1992). However, once the moving party has submitted a properly supported

motion for summary judgment, the non-moving party "may not rest upon mere allegation or denials of [its] pleading, but must set forth specific facts showing that there is a genuine issue for trial." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986) (citing Fed. R. Civ. P. 56(e)).

I. PREEMPTION

Congress' intent, as "explicitly stated in the statute's language or implicitly contained in its structure and purpose," Cipollone v. Liggett Group, 112 S. Ct. 2608, 2617 (1992), is the "touchstone of preemption analysis," Mendes v. Medtronic, Inc., 18 F.3d 13, 16 (1st Cir. 1994). The First Circuit has made clear that where Congress has included an express preemption clause in a statute, the court "ought to limit [its inquiry] to the preemptive reach of that provision without essaying any further analysis under the various theories of implied preemption." Id. (quoting Greenwood Trust Co. v. Massachusetts, 971 F.2d 818, 823 (1st Cir. 1992), cert. denied, 113 S. Ct. 974 (1993)). Express preemption may extend to state common law claims along with state statutes, regulations, and ordinances. E.g., id. (citing cases). Finally, the court's construction of preemption clauses must reflect the traditional presumption against preemption. See id. at 16.

Mentor argues that the plaintiff's claims are preempted by the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a). The MDA contains the following express preemption provision:

> [N]o State or political subdivision 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 [the Federal Food, Drug, and Cosmetic Act] to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the Federal Food, Drug, and Cosmetic Act].

21 U.S.C. § 360k(a). The First Circuit has ruled on at least three occasions that § 360k(a) expressly preempts any claim the resolution of which would establish a state "requirement" different from or in addition to that established under the MDA. E.g., Talbott v. C.R. Bard, Inc., 63 F.3d 25, 27 (1st Cir. 1995); Mendes, 18 F.3d at 16; King v. Collagen Corp., 983 F.2d 1130, 1135-36 (1st Cir.), cert. denied, 114 S. Ct. 84 (1993). The scope of such preemption necessarily extends to common law claims because

> [t]he common law, no less than agency regulations and statutes, can impose 'requirements' on a manufacturer. The tort and implied warranty theories of products liability are regulatory in that the "obligation to pay compensation can be . . . a potent method of governing conduct and controlling policy." Cipollone, 112 S. Ct. at 2620. . . . Products liability "regulation" under the common law imposes requirements by case law precedent.

Mendes, 18 F.3d at 18 (citations and internal quotation marks omitted); see Wilson v. Bradlees, 93-47-JD, slip op. at 5 (D.N.H. Nov. 8, 1995).

The controlling question, then, is whether the plaintiff's statutory and common law claims fall in the "broad, but limited" path of the § 360k(a) express preemption provision. See King, 983 F.2d at 1134. This inquiry requires the resolution of two related issues. The court first must determine if and to what extent the prosthesis at issue was regulated under the MDA for preemption purposes. If the court determines that the prosthesis was regulated, it then must examine each of the plaintiff's claims to determine whether their litigation would yield a state law standard or requirement different from or in addition to that prescribed by the federal government. See 21 U.S.C. § 360k(a)(1); Mendes, 18 F.3d at 16.

I. The Mentor Prosthesis is Regulated Under the MDA

A. The Prosthesis is a Class III Device

Under the MDA, the Food and Drug Administration ("FDA") classifies all medical devices intended for human use into three categories according to the degree of regulation necessary to assure safety and effectiveness. See 21 U.S.C. § 360c. The FDA lists "testicular prosthesis" as a "Class III" medical device,

21 C.F.R. § 876.3750 (1995), the designation given to those devices subject to the most stringent MDA controls, see Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392, 396 (4th Cir. 1995); 21 U.S.C. § 360c(a)(1)(C).

In support of its motion the defendant has submitted two brief affidavits from its regulatory affairs manager, Lynn Breckenridge, to establish that the prosthesis is regulated under the MDA. Breckenridge testified that, based on her personal knowledge of the federal regulations applicable to her company's products, "[p]ursuant to the [MDA] . . . the testicular ("prosthesis") is a Class III medical device." Breckenridge Affidavit at ¶¶ 1-3. In her supplemental affidavit Breckenridge testified that the "Mentor Testicular Prosthesis is an implanted device that contains reinforced, molded silicone elastomer and is implanted surgically to resemble a testicle." Breckenridge Supplemental Affidavit at ¶ 4.

The plaintiff responds that the testimony "fails to assert that the prosthesis at issue, i.e., the defendant's product, is a Class III medical device and fails to attach, cite to or otherwise reference FDA approval or certification." Plaintiff's Memorandum in Opposition to Summary Judgment at 6. The argument is unavailing. Although the affidavits are brief, the court finds that, fairly read, they establish that the prosthesis at

issue is a Class III device. Significantly, Breckenridge's description of her company's product tracks the language used by the FDA to describe Class III testicular prostheses in the regulations. See 21 C.F.R. § 876.3750 ("a testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rubber prosthesis that is implanted surgically to resemble a testicle."). The plaintiff has not presented evidence under Rule 56(c) to challenge this conclusion. Finally, as discussed infra, the fact that this particular prosthesis may not have received "FDA approval or certification" is irrelevant to the court's preemption analysis. The court concludes that the prosthesis is a Class III medical device within the meaning of the MDA.

B. Class III Devices are Subject to Preemption Regardless of the Route to Market or Actual Compliance with Federal Law

Generally, manufacturers must receive premarket approval ("PMA") from the FDA before they can market a Class III device. E.g., Mendes, 18 F.3d at 17; 21 U.S.C. § 360c(a)(1)(C). This process involves, inter alia, the submission of various clinical and manufacturing data and proposed labeling, see 21 U.S.C. § 360e(c), "in order 'to provide reasonable assurance of [the] safety and effectiveness' of the device." Duvall, 65 F.3d at 396 (quoting 21 U.S.C. § 360c(a)(1)(C)). However, certain Class III devices do not require PMA and a manufacturer may market such a

device by demonstrating that it is "substantially equivalent" to a device that was on the market prior to 1976. See English v. Mentor Corp., 1995 WL 573387 * 1-2 (3d Cir. 1995) (citing 21 U.S.C. § 360c(f)(3)). This alternative method requires the manufacturer to provide the FDA with various information through a premarket notification process known as 510(k) notification in order to ensure that "the device is safe, effective and performs as well as or better than the [predicate] device." Id. (quoting 21 C.F.R. § 807.95 and citing 21 U.S.C. § 360c(i)(3)(A); 21 C.F.R. § 807.92).

The plaintiff asserts that his claims are not preempted because the prosthesis "was never subjected to the extensive premarket approval [PMA] process" and, instead, was in all likelihood marketed pursuant to the less exacting 510(k) prenotification process. Plaintiff's Supplemental Memorandum in Opposition to Summary Judgment at 1-2. Consistent with Rule 56, the court takes as true the assertion by plaintiff's counsel that, according to FDA officials, "Mentor simply filed a barebones 510k notification . . . [and] there was never any comprehensive analysis or review by the FDA." Affidavit of Joseph Keefe at ¶ 3.

The plaintiff correctly notes that products cleared for market under the 510(k) process encounter less scrutiny from the

FDA than those requiring PMA. Nonetheless, most courts that have addressed the issue, including the First Circuit, have ruled that the 510(k) prenotification process does impose federal requirements on the product such as to trigger preemption by the MDA. See English, 1995 WL 573387 at * 4-5 (listing cases) ("We are satisfied that [the 510(k)] process is sufficiently rigorous to constitute a 'requirement . . . relating to the safety or effectiveness' of Class III medical devices"); Duvall, 65 F.3d at 399; Feldt v. Mentor Corp., 61 F.3d 431, 435-36 (5t Cir. 1995) ("Preemption does not depend on the route the product takes to the market, but on whether there are any specific federal requirements applicable to the device."); Mendes, 18 F.3d at 18-19 (finding preemption where pacemaker was marketed under 510(k) prenotification process). Contra Larsen v. Pacesetter Sys., Inc., 74 Haw. 1, 16-17, 837 P.2d 1273, 1282 (1992) (510(k) process does not preempt state claims because prenotification does not constitute FDA approval of device). Accordingly, the court finds that the MDA's express preemption provision, 21 U.S.C. § 360k(a), applies regardless of whether the prosthesis was subject to PMA.

The plaintiff next asserts that summary judgment is foreclosed by a factual dispute of whether the particular prosthesis at issue did, in fact, satisfy the applicable federal

standards. Plaintiff's Memorandum in Opposition to Summary Judgment at 9 ("nowhere in its motion or affidavit does the defendant even allege that it has received, or even applied for, FDA approval"), 11, 15-16. The plaintiff argues that state law claims are preempted only where the device at issue "had been cleared for marketing by the FDA" under the 510(k) process. Id. at 19-20 (quoting Mendes, 18 F.3d at 17).

The argument is contrary to the recently clarified law of this circuit. In Mendes, the First Circuit did state that "[w]e express no opinion on whether products liability claims are preempted only if the manufacturer complied with applicable regulations." 18 F.3d at 19-20. However, in its August 14, 1995, decision in Talbott, the First Circuit squarely addressed the issue and ruled that "Congress did not intend to provide for an exception to the MDA's preemption clause where a manufacturer fails to comply with the provisions of the MDA by fraudulently obtaining approval of its device from the FDA." 63 F.3d at 28, 25 (citing cases). The court explained:

> The terms of the statute make no distinction based upon whether or not a manufacturer has in fact complied with the federal standard. We find nothing to indicate that preemption is conditional upon satisfactory compliance with the federal standard. Section 360k(a) does not mention compliance at all. . . . [T]he relevant inquiry is simply whether, in the abstract, the state tort law requirement is "different from, or in addition to" the federal requirement. If a device manufacturer fails to

> meet the federal requirements, it will be subject to federal penalties as set forth in the MDA.

Id. at 29; see English, 1995 WL 573387 * 5 ("[MDA's] preemption provision is triggered not by FDA approval of a device's safety and effectiveness, but by federal requirements relating to a device's safety and effectiveness."). Accordingly, the court's preemption inquiry focuses on the regulations and requirements to which the prosthesis is subject under federal law without regard to whether or to what extent the device actually complied with such regulations and requirements.[2]

II. The Plaintiff's Claims are Preempted

The court next "scrutinize[s] the plaintiff's claims to determine whether the successful litigation of any of them would "establish or continue in effect" a standard or regulation other than that established by the federal government. Mendes, 18 F.3d at 16; see 21 C.F.R. § 808.1(d) (requirements imposed by state law preempted where there are "specific requirements applicable to a particular device under the act") see Levesque v. Miles, Inc., 816 F. Supp. 61, 64 (D.N.H. 1993) (when faced with express preemption, "the only remaining question is whether a particular

[2]The First Circuit also has ruled that the MDA preempts state law claims even where the claims are based on a violation or breach of the applicable federal standards or requirements. Talbott, 63 F.3d at 29 (listing cases).

state statute [or cause of action] intrudes into the federal pale")). This inquiry requires an examination of both the scope and extent of the federal regulations and of the specific claims asserted by the plaintiff.

The federal requirements fall into two general categories, either of which can trigger preemption under the MDA. First, the 510(k) process itself imposes requirements on the device:

> The FDA mandates that a 510(k) Notification include, inter alia, "proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use"; a statement indicating the similarity of the device to currently marketed devices (including data to support the statement, such as information on similarity in materials and design); and additional information as requested by the FDA. 21 C.F.R. § 807.87. And, if [the manufacturer] wishes to substantially change the design, components, or manufacturing processes used in making the device, it must submit a new 510(k) Notification. 21 C.F.R. § 807.81(a)(3). . . . We therefore conclude that the 510(k) Notification is a requirement applicable to the device under the MDA.

Duvall, 65 F.3d at 399-401 (citing Reeves v. AcroMed Corp., 44 F.3d 300, 305 (5th Cir.), cert. denied, 115 S. Ct. 2251 (1995)).

Second, all medical products, regardless of classification or the premarket process to which they are subject, are regulated by the federal good manufacturing practices ("GMP"), 21 C.F.R. § 820 et seq., and the federal labeling requirements, 21 C.F.R. § 801 et seq. The GMP regulations require, inter alia, "manufacturers to develop and implement `appropriate,'

`adequate,' or `sufficient' quality control, quality assurance personnel training, environmental controls, equipment maintenance, testing, inspection, and storage and distribution procedures, to assure that devices are safe and effective." Mendes, 18 F.3d at 19 (citing 21 C.F.R. §§ 820.1, 820.5, 820.20, 820.25); see Duvall, 65 F.3d at 399 (citing 21 C.F.R. pt. 820) (GMP include "standards for production facilities, quality assurance, monitoring of package labels, and device failure reporting" obligations). For example, the quality assurance requirements compel manufacturers to design and implement a protocol "to ensure, among other things, that all components, labels, packaging, and finished devices are inspected, and either approved or rejected." Mendes, 18 F.3d at 19 (citing 21 C.F.R. § 820.20(a)). The labeling requirements, which are independent of those imposed by the GMP regulations, specify the content and prominence of the required language. Duvall, 65 F.3d at 399 (citing C.F.R. pt. 801).

The court will consider the plaintiff's claims seriatim.

The common law claims asserted in counts one and two are, by definition, performance-based claims in that they concern the safety of the prosthesis. Under New Hampshire law, the viability of each claim, whether sounding in strict liability or negligence, hinges on the plaintiff's ability to prove that the

prosthesis was defective or otherwise did not satisfy applicable performance standards. See generally Wilson v. Bradlees, 93-47-JD, slip op. at 8. As discussed supra, both the 510(k) notification process and the GMP regulations address the design, manufacture, marketing, sale, and distribution of the Mentor prothesis. Litigation of the negligence and strict liability claims necessarily would be based on a state standard or requirement "different from or in addition to" these federal requirements. See 21 U.S.C. § 360k(a)(1). Thus, counts one and two are preempted by the MDA.

Count three asserts liability for the defendant's failure to "furnish adequate warnings and instructions of the risks associated with the use of the testicular impact." Complaint at ¶ 14. The 510(k) notification process, the GMP requirements, and the labeling regulations address and relate to the nature and form of the prosthesis' labeling and instructions. Thus, litigation of a failure to warn claim would be based on warning or labeling requirements "different from or in addition to" these federal requirements. See 21 U.S.C. § 360k(a)(1). Count three is preempted.

Counts seven, eight, and nine are variations of the plaintiff's failure to warn claim and are preempted for the same reasons. Count seven asserts that the defendant "made

misrepresentations to the plaintiff regarding its product that induced him to act to his detriment and is liable for fraud and misrepresentation." Complaint at ¶ 18. Count eight asserts that "the defendant misled the plaintiff as to the safety and quality of the testicular implant" in violation of N.H. Rev. Stat. Ann. ("RSA") § 358-A. Id. at ¶ 19. Count nine asserts that the "defendant falsely advertised the safety and quality of the testicular implant." Id. at ¶ 20. Each of these claims, although advanced under different legal theories, essentially alleges that the defendant mislabeled, misadvertised, or otherwise failed to warn or provide necessary information about its product. The litigation of such a claim would saddle the defendant with labeling, packaging, disclosure, or other warning-related duties "different from or in addition to" those imposed by both the 510(k) process and the GMP and labeling regulations. See 21 U.S.C. § 360k(a)(1). Thus, the court finds that counts seven, eight, and nine are preempted for the reasons discussed in connection with count three. See also Talbott, 865 F. Supp. 37, 52 (D. Mass. 1994) (claim under state consumer protection statute preempted where its resolution "has the potential to impose state requirements in addition to, or different from, the FDA's requirements"), aff'd 63 F.3d 25 (1st Cir. 1995).

Count four asserts that the "defendant breached express and implied warranties of merchantability and fitness for a particular purpose." Complaint at ¶ 15. The plaintiff argues that breach of warranty claims cannot be preempted because they "arise[] from the manufacturer -- not from state law or regulation." Plaintiff's Memorandum in Opposition to Summary Judgment at 23 (citing Cipollone, 112 S. Ct. at 2622).

The warranty claims are analogous to the strict liability and negligence claims to the extent that each focuses squarely on the safety or "fitness" of the prosthesis. As discussed supra, such performance-based claims are preempted because their litigation necessarily would rest on requirements different from or in addition to those imposed by under the 510(k) process or the GMP regulations. The plaintiff cannot skirt the preemptive reach of § 360k(a) by re-casting these performance-based product liability claims as claims based on a breach of an express or implied warranty. Specifically, "[a]s an implied warranty is a requirement upon a product that arises exclusively from the operation of state contract law, this claim is preempted expressly by the MDA. Otherwise, it would impose a requirement additional to those imposed under the MDA." Talbott, 865 F. Supp. at 51; see Mendes, 18 F.3d at 18 (successful implied warranty claim would supplant federal GMP). Likewise, the

plaintiff's "suggestion that Cipollone indicates that [his] express warranty claims are not preempted has been rejected by the Court of Appeals for the First Circuit." Talbott, 865 F. Supp. at 51. The First Circuit has observed that

> [t]he FDA retains rigid control over the labeling and packaging of Class III products, largely displacing the ability of manufacturers to make additional claims. This high level of control contrasts with the low level of control in Cipollone, and ensures that manufacturers will not be held liable for packaging and labeling imposed by the FDA.

Id. at 51-52 (quoting King, 938 F.2d at 1135). In any event, the plaintiff, like those in Talbott, has not even alleged that the defendant provided express warranties or claims beyond whatever information was communicated through the federally regulated packaging, labels, and advertising. See id. at 52; Complaint. For the foregoing reasons, as well as those discussed in connection with counts one and two, the court finds that the claims stated in count four are preempted.

Count five asserts that "[a]s a result of its breach of the Uniform Commercial Code and N.H. R.S.A. 382-A, the defendant is liable to the plaintiff." Complaint ¶ 16. The court's analysis of this claim is constrained by the plaintiff's failure to specify which articles and sections of the Uniform Commercial Code ("UCC") he believes the defendant violated. See id. However, based on its review of the pleadings and its familiarity

with the UCC as codified in New Hampshire, the court understands the plaintiff to allege a violation of the various warranty provisions of Article 2 (Sales), RSA § 382-A:2-312 to 2-317.

The court finds that for purposes of preemption an implied or express warranty action under the UCC is indistinguishable from an implied or express warranty action arising under common law. Both species are creatures of state law and, if litigated, would yield requirements "different from or in addition to" those established by either the 510(k) notification process or the GMP and labeling requirements. See 21 U.S.C. § 360k(c)(1). Accordingly, the court finds that the UCC claims alleged in count five are preempted for the reasons announced in its consideration of the common law warranty claims alleged in count four.

Finally, count twelve requests punitive, enhanced, and exemplary damages as these remedies are available under New Hampshire law. The preemption of each of the plaintiff's state law claims, supra, dispenses with any related claims for additional damages. The court finds that count twelve fails as a matter of law.

II. MAGNUSON-MOSS ACT

Count ten asserts that defendant violated the Magnuson-Moss Act ("MMA"), 15 U.S.C. § 2301 et seq.. Complaint ¶ 21. The

defendant argues that it is entitled to summary judgment because the prosthesis is not considered a "consumer product" within the meaning of the MMA. The plaintiff has not addressed the argument.

The MMA only applies to "consumer products," a term defined as "any tangible personal property which is normally used for personal, family, or household purposes." 15 U.S.C. § 2301(1); see Kemp v. Pfizer, Inc., 835 F. Supp. 1015, 1024 (E.D. Mich. 1993). Beyond this definition, the MMA does not catalogue the products which fall within its protection. However, the Consumer Product Safety Act ("CSPA") explicitly states that "devices" regulated under the Federal Food, Drug, and Cosmetic Act, of which the MDA is part, are not "consumer products." 15 U.S.C. § 2052(a)(1)(H). The Eastern District of Michigan has adopted the CSPA definition and ruled that a prosthetic heart valve is not a consumer product under the MMA because it is regulated by the MDA. Kemp, 835 F. Supp. at 1024-25. The court is persuaded that the Kemp court properly construed the applicable statutes and, for the same reasons, finds that the plaintiff's injuries are not actionable under the MMA because the prosthesis, a medical device regulated under the MDA, is not a consumer product. In the alternative, the court finds that a testicular prosthesis is not a consumer product under the MMA because it is

not "tangible personal property . . . normally used for personal, family, or household purposes." See 15 U.S.C. § 2301(1). Accordingly, the defendant is entitled to summary judgment on count ten.

Conclusion

The defendant's motion for summary judgment (document no. 5) is granted. The clerk is ordered to close the case.

SO ORDERED.

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Joseph A. DiClerico, Jr.
Chief Judge

December 4, 1995

cc: Joseph F. Keefe, Esquire
Michael A. Pignatelli, Esquire