SJC-12904

PATRICIA M. DUNN vs. GENZYME CORPORATION.

Norfolk. September 11, 2020. - January 29, 2021.

Present: Lenk, Gaziano, Lowy, Budd, Cypher, & Kafker, JJ.[1]

Federal Preemption. Negligence, Defective product. Practice, Civil, Motion to dismiss, Complaint.

Civil action commenced in the Superior Court Department on June 1, 2018.

A motion to dismiss was heard by Elaine M. Buckley, J.

Leave to prosecute an interlocutory appeal was allowed in the Appeals Court by John C. Englander, J. The Supreme Judicial Court on its own initiative transferred the case from the Appeals Court.

John C. Dougherty for the defendant.
Matthew J. Dunn for the plaintiff.
The following submitted briefs for amici curiae:
Lawrence G. Cetrulo, Kyle E. Bjornlund, & Jesse G. Ainlay for Massachusetts Defense Lawyers Association.
Jaime A. Santos, Sarah K. Frederick, & Edwina B. Clarke for Chamber of Commerce of the United States of America & another.
David R. Geiger, Michael Hoven, & Stephen Stich for Washington Legal Foundation.

[1] Justice Lenk participated in the deliberation on this case prior to her retirement.

GAZIANO, J. We are asked in this case involving claims of personal injury and product liability against the manufacturer of a medical device to decide whether Federal law preempts the plaintiff's State law claims because the device is regulated under the Medical Device Amendments (MDA), 21 U.S.C. §§ 360c et seq., of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. State law claims survive preemption under the MDA so long as these claims parallel, rather than supplement, Federal requirements. See Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008). Under this standard, plaintiffs need not specify the precise defect in the medical device nor the specific Federal regulatory requirement allegedly violated in order to survive a motion to dismiss. No heightened pleading standard is required. Rather, we conclude that plaintiffs asserting parallel State law claims may do so with no greater degree of specificity than otherwise required under Iannacchino v. Ford Motor Co., 451 Mass. 623, 636 (2008).

While all of the plaintiff's State law claims here properly parallel the Federal requirements, none of them is sufficiently pleaded under Iannacchino, supra, to survive the manufacturer's motion to dismiss. Accordingly, the Superior Court judge's decision denying the manufacturer's motion to dismiss must be reversed.

1. Statutory background. Congress adopted the MDA in 1976, in response to the perceived failure of the various States to provide for the adequate regulation of new medical devices. See generally Medtronic, Inc. v. Lohr, 518 U.S. 470, 475-477 (1996) (Lohr). In an effort to establish regulatory uniformity and enhance consumer protection, the MDA thus "swept back some state obligations and imposed a regime of detailed federal oversight." Riegel, 552 U.S. at 316.

The MDA establishes three classes of medical devices, and corresponding levels of oversight, depending on the risks they present to the public. Class III devices -- those "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," as well as those that "present[] a potential unreasonable risk of illness or injury" -- are subject to the most stringent oversight. 21 U.S.C. § 360c(a)(1)(C)(ii)(I), (II). Such devices generally are subject to a "rigorous" premarket approval process by the Food and Drug Administration (FDA). See Lohr, 518 U.S. at 477. This process includes, among other precautions, a review of the device's proposed labeling to evaluate the safety and effectiveness of using the device under the conditions set forth on the label, 21 U.S.C. § 360c(a)(2)(B), and to ensure that the

proposed labeling is neither false nor misleading, 21 U.S.C. § 360e(d)(1)(A).

Once a medical device has been approved, manufacturers of Class III devices also have continuing duties to comply with regulations and reporting requirements. See generally 21 U.S.C. §§ 360 et seq. The MDA, for example, prohibits the manufacturer from making changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness without FDA permission. See 21 U.S.C. § 360e(d)(5)(A)(i). More generally, the FDA's good manufacturing practice regulations impose comprehensive requirements concerning the device-manufacturing process, including a manufacturer's personnel qualifications,[2] buildings,[3] equipment,[4] production and process controls,[5] packaging and labeling,[6] distribution,[7] and recordkeeping.[8] Additionally, manufacturers are required to inform the FDA of new clinical

[2] See 21 C.F.R. § 211.25.

[3] See, e.g., 21 C.F.R. § 211.42.

[4] See, e.g., 21 C.F.R. § 211.63.

[5] See, e.g., 21 C.F.R. § 211.110.

[6] See, e.g., 21 C.F.R. § 211.122.

[7] See 21 C.F.R. § 211.150.

[8] See, e.g., 21 C.F.R. § 211.180.

investigations or scientific studies concerning the device that the manufacturer is aware of or reasonably should be aware of, see 21 C.F.R. § 814.84(b)(2), and to report incidents in which the device may have caused or contributed to death or serious bodily injury, or malfunctioned in a manner that likely would cause or contribute to death or serious bodily injury if it recurred, see 21 C.F.R. § 803.50(a). The FDA "shall" withdraw approval if it determines that a device is unsafe or ineffective under the conditions of its labeling. 21 U.S.C. § 360h(e). To facilitate this Federal regulatory scheme, the MDA expressly preempts certain State regulation of approved medical devices. Under its preemption clause,

> "Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
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> "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> "(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). An exception in subsection 21 U.S.C. § 360k(b), not relevant here, permits the FDA to exempt some State and local requirements.

2. Factual background. In an attempt to alleviate the symptoms of osteoarthritis in her knees, according to her

complaint, the plaintiff, Patricia Dunn, received two injections of Synvisc-One on June 8, 2015, one in each knee. Synvisc-One is manufactured by Genzyme Corporation (Genzyme) and is a Class III medical device subject to premarket approval under the MDA. Synvisc-One was approved by the FDA in 2009 for the treatment of pain associated with osteoarthritis of the knee in patients who have failed to respond to other treatments.

Immediately after receiving the injections, Dunn experienced severe side effects, including "pain and swelling in her knees, difficulty walking, hip bursitis and systemic pseudoseptic acute arthritis." These side effects caused her to fall several times and ultimately resulted in serious injuries, including a tear to her meniscus and breaking her neck. As a result of these injuries, Dunn asserts that she "experienced significant physical pain and suffering, under[went] surgeries, and endured prolonged hospitalization and physical rehabilitation."

In June 2018, Dunn commenced an action against Genzyme in the Superior Court, asserting that Synvisc-One was "negligently manufactured, designed, distributed, and sold by [Genzyme], and . . . failed to contain appropriate and significant warnings related to its use." Specifically, Dunn sought monetary damages based upon four State law claims: (1) failure to warn; (2) breach of warranty; (3) negligence; and (4) products

liability. In a joint stipulation filed on June 22, 2018, and subsequently approved by the judge, both parties agreed to extend the time within which Dunn could file an amended pleading until August 17, 2018. Dunn, however, failed to meet this deadline. She filed an amended complaint on September 11, 2018, three days before the parties had stipulated that Genzyme was to file its response. In her amended complaint, Dunn added a fifth claim under the Massachusetts consumer protection act, G. L. c. 93A, asserting that Genzyme "undertook certain unfair and deceptive acts or practices."

In response to the amended complaint, Genzyme filed a motion to dismiss pursuant to Mass. R. Civ. P. 12 (b) (6), 365 Mass. 754 (1974), on the grounds that the allegations of both the original complaint and the amended complaint were preempted by Federal regulation and failed to meet the applicable State law pleading standards.

Following a nonevidentiary hearing, the judge denied Genzyme's motion to dismiss, concluding that Dunn had supplied sufficient factual allegations in her complaint to "state a plausible claim for relief" and survive preemption under the MDA. The judge noted that courts, both nationally and in the Commonwealth, have disagreed about the required level of specificity with which a plaintiff must allege a violation of FDA regulations to properly plead State law claims; neither the

United States Supreme Court nor the United States Court of Appeals for the First Circuit has addressed the issue explicitly. Pointing to the decision of the United States Court of Appeals for the Seventh Circuit in Bausch v. Stryker Corp., 630 F.3d 546, 560-561 (7th Cir. 2010), cert. denied 565 U.S. 976 (2011), the judge emphasized the informational disparities between individual plaintiffs and medical device manufacturers that often limit the information available to plaintiffs prior to discovery. The judge also noted that "there [was] nothing to indicate that Dunn had access to any publicly available information which would have permitted her to plead with greater specificity" and, accordingly, determined that the complaint was sufficient, "given the amount of information to which she had access."

Genzyme appealed, and a single justice of the Appeals Court granted Genzyme's application for interlocutory review on the question of the sufficiency of Dunn's complaint. We transferred the matter to this court on our own motion.

3. Standard of review. We review the denial of a motion to dismiss under Mass. R. Civ. P. 12 (b) (6) de novo. See Rafferty v. Merck & Co., 479 Mass. 141, 147 (2018); Curtis v. Herb Chambers I-95, Inc., 458 Mass. 674, 676 (2011). Accepting the facts asserted in the complaint as true and drawing all reasonable inferences in the plaintiff's favor, we must

determine "whether the factual allegations in the complaint are sufficient, as a matter of law, to state a recognized cause of action or claim, and whether such allegations plausibly suggest an entitlement to relief." See Dartmouth v. Greater New Bedford Regional Vocational Tech. High Sch. Dist., 461 Mass. 366, 374 (2012). See also A.L. Prime Energy Consultant, Inc. v. Massachusetts Bay Transp. Auth., 479 Mass. 419, 424 (2018); Edwards v. Commonwealth, 477 Mass. 254, 260 (2017).

4. Discussion. In assessing the sufficiency of Dunn's complaint, we turn first to the issue of Federal preemption. The relative specificity of the pleadings under State law is irrelevant if constitutional principles preclude the assertion of State law claims in light of existing Federal regulation. See, e.g., Gade v. National Solid Wastes Mgt. Ass'n, 505 U.S. 88, 108 (1992) ("under the Supremacy Clause, from which our pre-emption doctrine is derived, any [S]tate law, however clearly within a State's acknowledged power, which interferes with or is contrary to [F]ederal law, must yield" [quotations omitted]). We then evaluate whether any of Dunn's claims that survive a preemption analysis also satisfy the Massachusetts pleading requirements, as set forth in Iannacchino, 451 Mass. at 636. In order for this court to affirm the judge's denial of the motion to dismiss, Dunn's claims must satisfy both requirements.

a. Preemption. Analysis under the supremacy clause begins "with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992), quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). A congressional intent to preempt State law may be stated explicitly in statutory language, or implicitly within the structure and purpose of a statute. See Cipollone, supra, quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977). The MDA, under which Synvisc-One is regulated, includes such language, and preempts State requirements "different from, or in addition to, any requirement applicable . . . to the device" under Federal law. 21 U.S.C. § 360k(a)(1).

In Riegel, 552 U.S. at 321-325, the United States Supreme Court set forth a two-part analysis for determining whether a plaintiff's State law claims are preempted under the MDA. First, the reviewing court must determine whether the FDA has imposed requirements applicable to the medical device at issue. See id. at 321. Second, the court must decide whether the particular State law claims are preempted because they are "different from, or in addition to, any requirement applicable . . . to the device" under Federal law. 21 U.S.C. § 360k(a)(1) (2020). See Riegel, supra at 323. The court has

said that the language of the MDA "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the [S]tate duties in such cases 'parallel,' rather than add to, [F]ederal requirements." Id. at 330. Thus, plaintiffs may bring so-called "parallel" State claims, i.e., tort and other claims that are based on, or coextensive with, violations of Federal statutes and regulations. See Lohr, 518 U.S. at 495. See also Hughes v. Boston Scientific Corp., 631 F.3d 762, 770 (5th Cir. 2011) ("claims for negligent failure to warn or negligent manufacturing of a device are not preempted, provided that such claims are premised entirely on violation of the applicable federal requirements"); Bausch, 630 F.3d at 552 ("section 360k protects a medical device manufacturer from liability to the extent that it has complied with [F]ederal law, but it does not extend protection from liability where the [State tort] claim is based on a violation of [F]ederal law"). Common-law duties are among the State law claims that may survive preemption. Riegel, supra at 323-324.

Turning to Dunn's complaint, we conclude that all of her claims satisfy the preemption standard.

The first question, as to whether the FDA has imposed requirements applicable to the device at issue, undoubtedly can be answered in the affirmative. As in Riegel, 552 U.S. at 321-323, the record establishes that Synvisc-One is a stringently

regulated Class III medical device under the MDA. The premarket approval process thus imposes Federal requirements under 21 U.S.C. § 360k.

With respect to the second part of the analysis, the complaint describes each of Dunn's five claims in very limited detail, but the assertions contained therein are consistent with claims under Massachusetts law that "parallel" violations of Federal statutes and regulations. The claims -- negligent failure to warn, breach of warranty, negligent manufacture, products liability, and violations of G. L. c. 93A -- all can be interpreted as coextensive with the comprehensive Federal requirements imposed on Genzyme under the MDA, such as, for example, those regulating production and process controls, see, e.g., 21 C.F.R. § 211.110, and packaging and labeling, see, e.g., 21 C.F.R. § 211.122. In other words, enforcing these State law obligations "'parallel[s],' rather than add[s] to, [F]ederal requirements." Riegel, 552 U.S. at 330.

We will not require plaintiffs who are asserting parallel State law claims to plead specific facts, such as the precise Federal regulations purportedly violated or the precise relationship between State and Federal requirements, to meet our ordinary, notice-pleading standard. "Although the complaint would be stronger with such detail, we do not believe the absence of those details shows a failure to comply" with the

requirements. Bausch, 630 F.3d at 560. See Rosbeck v. Corin Group, PLC, 140 F. Supp. 3d 197, 210 (D. Mass. 2015). "Nothing in § 360k denies [Massachusetts] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel [F]ederal requirements." Lohr, 518 U.S. at 495. Thus, Dunn's claims fit within the "narrow gap through which a plaintiff's [S]tate-law claim must fit if it is to escape express or implied preemption" under the MDA. Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

b. Sufficiency of State law pleadings. As the judge indicated, there is a wide disparity in views among the few Federal circuit courts that have examined the level of specificity necessary to plead State law claims in order to survive preemption under the MDA. Compare Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011) ("A plaintiff must allege that the defendant violated a particular [F]ederal specification referring to the device at issue" [quotation and citation omitted]), with Bausch, 630 F.3d at 560 (declining to require that plaintiffs "specify the precise defect or specific [F]ederal regulatory requirements that were allegedly violated"). See Otis-Wisher v. Medtronic, Inc., 616 Fed. Appx. 433, 434 (2d Cir. 2015) (applying traditional pleading standard in assessing State law claims purportedly preempted under MDA). While no appellate courts in the

Commonwealth appear to have addressed this issue, a few Superior Court judges have; this disparity is evident as well among those judges. Compare Morris vs. Rotolo, Mass. Super. Ct., No. 12-04046 (Middlesex County Jan. 15, 2014) (requiring plaintiffs to plead in detail Federal requirement purportedly violated), with Phillips vs. Medtronic, Inc., Mass. Super. Ct., No. SUCV2009-05286-A (Suffolk County July 10, 2012) (concluding that "plaintiffs need not plead a parallel claim with any degree of heightened specificity").

Under Mass. R. Civ. P. 8 (a) (1), 365 Mass. 749 (1974), a complaint must include only "a short and plain statement of the claim showing that the pleader is entitled to relief." Thus, "[t]o survive a motion to dismiss, the facts alleged and the reasonable inferences drawn therefrom must plausibly suggest . . . an entitlement to relief" (quotation and citation omitted). Coghlin Elec. Contrs., Inc. v. Gilbane Bldg. Co., 472 Mass. 549, 554 (2015). While a complaint need not include "detailed factual allegations[,] a plaintiff's obligation to provide the grounds of his [or her] entitle[ment] to relief requires more than labels and conclusions." Iannacchino, 451 Mass. at 636, quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (Twombly). Such factual allegations "must be enough to raise a right to relief above the speculative level . . . [based] on the assumption that all the allegations in the

complaint are true (even if doubtful in fact)." Iannacchino, supra, quoting Twombly, supra. See Galiastro v. Mortgage Elec. Registration Sys., Inc., 467 Mass. 160, 165 (2014); Lopez v. Commonwealth, 463 Mass. 696, 700-701 (2012).

Although Genzyme asserts that it is not asking that a heightened pleading standard be applied to Dunn's complaint, its interpretation of Iannacchino effectively requires such a standard for plaintiffs asserting parallel, State-law claims regarding MDA-regulated medical devices. For example, Genzyme contends that Dunn's complaint is insufficient because it "never states which [premarket approval] requirements Genzyme purportedly violated, nor describes how Genzyme allegedly violated them." Mandating that plaintiffs provide such details at the pleading stage extends well beyond Iannacchino's notice-pleading standard, see Iannacchino, 451 Mass. at 636, and essentially mirrors the level of specificity required to plead fraud. See Mass. R. Civ. P. 9 (b), 365 Mass. 751 (1974). See, e.g., Equipment & Sys. for Indus., Inc. v. Northmeadows Constr. Co., 59 Mass. App. Ct. 931, 931-932 (2003) ("At a minimum, a plaintiff alleging fraud must particularize the identity of the person[s] making the representation, the contents of the misrepresentation, and where and when it took place. In addition, the plaintiff should specify the materiality of the misrepresentation, its reliance thereon, and resulting harm").

We decline to require that plaintiffs asserting State common-law claims regarding MDA-regulated medical devices plead these parallel claims in greater specificity than otherwise would be required under the plausibility standard set forth in Iannacchino, 451 Mass. at 636. Cf. Bass v. Stryker Corp., 669 F.3d 501, 509 (5th Cir. 2012); In re Medtronic, Inc., 623 F.3d 1200, 1212 (8th Cir. 2010) (Melloy, J., concurring). Rule 9 (b) of the Rules of Civil Procedure does not impose any special requirement that such a claim be pleaded with particularity, as it does for other types of claims, such as for fraud, see, e.g., Tetrault v. Mahoney, Hawkes & Goldings, 425 Mass. 456, 463 n.7 (1997), and we discern no reason to do so. Otherwise put, plaintiffs asserting parallel State-law claims based upon a violation of FDA regulations must articulate only "factual allegations plausibly suggesting (not merely consistent with) an entitlement to relief" (quotation and citation omitted), Iannacchino, 451 Mass. at 636, in order to satisfy the Commonwealth's pleading standard; plaintiffs need not point to conclusive or specific evidence of such violations, as would be required under a heightened pleading standard, see id.

None of Dunn's claims meets this standard. Dunn asserts that the "reasonably foreseeable use of Synvisc-One involved significant dangers not readily obvious to the ordinary user of the product"; Synvisc-One had "dangerous propensities that were

known or reasonably knowable to [Genzyme] at the time of its manufacture and distribution of Synvisc-One"; Synvisc-One posed "known or reasonably knowable dangers"; or, alternatively, that the "Synvisc-One that was ultimately injected into [Dunn] was adulterated and defectively manufactured, distributed, marketed, and sold" by Genzyme. No factual allegations are, however, provided upon which to ground these "labels and conclusions." Iannacchino, 451 Mass. at 636, quoting Twombly, 550 U.S. at 555. In contrast to the judge, we discern insufficient facts in the complaint "'plausibly [to suggest]' . . . an entitlement to relief." Iannacchino, supra, quoting Twombly, supra. The complaint, as is, "require[s] a fact finder to jump from one inference to another absent any of the necessary factual support." Edwards, 477 Mass. at 265.

Fundamentally, the complaint does not proffer sufficient factual assertions that plausibly establish causality between Genzyme's purportedly tortious activities and Dunn's injuries. Rather, the complaint seems to imply that the temporal proximity between the injections of Synvisc-One and Dunn's injuries alone is sufficient to establish the necessary element of causality.[9]

[9] At the hearing on Genzyme's motion to dismiss, and during argument before this court, both parties referenced the legal doctrine of res ipsa loquitur. This doctrine "permits a trier of fact to draw an inference of negligence in the absence of a finding of a specific cause of the occurrence when an accident is of the kind that does not ordinarily happen unless the

A comparison with complaints that courts have deemed sufficient to allege parallel State-law claims is instructive. For instance, a Superior Court judge determined that a plaintiff's factual allegations, which drew upon the defendant's own admissions, plausibly suggested "a causal connection" between the purported defect in the medical device at issue and the resultant harm. This connection was sufficient to survive the defendant's motion to dismiss. See Dwyer vs. Boston Scientific Corp., Mass. Super. Ct., No. MICV2014-04747 (Middlesex County Apr. 2, 2015). Similarly, in Bausch, 630 F.3d at 559, the United States Court of Appeals for the Seventh Circuit concluded that the plaintiff's complaint was adequate based, in part, on the inclusion of evidence that the defendant manufacturer not only had received complaints regarding the failure of its medical device but also recalled the device based on that specific defect, the same defect that allegedly caused the plaintiff's injury. The complaints in these cases contrast markedly with Dunn's complaint, which invokes no facts --

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defendant was negligent in some respect and other responsible causes including conduct of the plaintiff are sufficiently eliminated by the evidence." Enrich v. Windmere Corp., 416 Mass. 83, 88 (1993). It does not "overcome the lack of evidence of the defendant's negligence." Id. Because Dunn did not plead adequate facts to establish negligence, she may not invoke this doctrine.

regulatory, medical, or otherwise -- that connect Genzyme's actions with the purported harm.

In her assessment of the sufficiency of Dunn's complaint, the judge here emphasized the disparity between the information available to Dunn and to Genzyme. Specifically, she pointed to the limited information accessible to Dunn, for example, regarding the manufacturing of Synvisc-One, as somehow justifying the sufficiency of Dunn's assertions prior to discovery. Dunn supports her bare-bones complaint, at least in part, in similar terms, drawing attention to Genzyme's "superior, and likely exclusive, knowledge of what exactly went wrong in its production, manufacture, packaging and distribution of the Synvisc-One that was ultimately injected into [her] knees and caused such catastrophic harm to her." Genzyme, on the other hand, asserts that a "[l]ack of access to information at the pleading stage does not nullify a plaintiff's pleading obligations."

Order denying motion to dismiss reversed.