SUPREME COURT, APPELLATE DIVISION, FIRST DEPARTMENT,

David B. Saxe, J.P.
John W. Sweeny, Jr.
James M. McGuire
Dianne T. Renwick
Helen E. Freedman, JJ.

4147-4147A-4147B
Index 109838/06
109845/06
109847/06

Michael Devore, et al.,
Plaintiffs-Appellants,

-against-

Pfizer Inc.,
Defendant-Respondent.

Plaintiffs appeal from orders of the Supreme Court, New York County (Martin Shulman, J.), entered March 22, 2007, which granted defendant's motions to dismiss the respective complaints.

Law Offices of Mark Jay Krum, New York (Mark Jay Krum of counsel), for appellants.

Skadden, Arps, Slate, Meagher & Flom LLP, New York (Mark S. Cheffo, Barbara Wrubel and Mara Cusker Gonzalez of counsel), for respondent.

SAXE, J.P.

This consolidated appeal presents a choice of law question relating to three actions brought by Michigan residents, all alleging that they were physically injured in Michigan as a result of taking Lipitor, a drug manufactured by defendant Pfizer Inc., a pharmaceutical company headquartered in New York. Pfizer contends that Michigan law must be applied, while plaintiffs argue that New York law ought to be applied because the alleged tortious conduct took place in New York. If Michigan law applies, we must further consider whether a cause of action can be sustained based upon the application of an exception contained in the Michigan statute.

Plaintiffs' claim is that they suffered debilitating side effects and conditions from taking Lipitor, including myopathy, peripheral neuropathy, memory loss, and depression, which were not identified on Lipitor's label. Plaintiffs assert six causes of action against Pfizer: (1) fraud; (2) negligent representation; (3) products liability (failure to warn); products liability (design defect); (5) breach of the implied warranty of merchantability; and (6) fraudulent concealment.

Pfizer moved to dismiss the complaints, asserting that Michigan law governed plaintiffs' claims under New York choice of law rules because plaintiffs were Michigan residents claiming personal injury in their home state resulting from their use of

Lipitor in Michigan. The application of Michigan's drug products liability statute, Mich Comp Laws § 600.2946(5), Pfizer argued, requires that the actions be dismissed as a matter of law, because the statute shields pharmaceutical companies from liability in products liability actions if the suit involves an FDA-approved drug such as Lipitor.

The Michigan statute creates an immunity against a claim that an FDA-approved drug is defective, unless the plaintiff can establish that: (1) the FDA revoked its approval of the drug; or (2) the manufacturer secured FDA approval through either (a) fraud or (b) bribery. The statute provides:

> "In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. *This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following*:
>
> "(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . . and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

> "(b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug" (Mich Comp Laws § 600.2946[5] [emphasis added]).

New York's choice of law analysis, commonly referred to as an "interest analysis," involves several steps and focuses on determining which jurisdiction, "because of its relationship or contact with the occurrence or the parties, has the greatest concern with the specific issue raised in the litigation" (*Cooney v Osgood Mach.*, 81 NY2d 66, 72 [1993], quoting *Babcock v Jackson*, 12 NY2d 473, 481 [1963]). This analysis addresses two inquiries: "(1) what are the significant contacts and in which jurisdiction are they located; and (2) whether the purpose of the law is to regulate conduct or allocate loss" (*Padula v Lilarn Props. Corp.*, 84 NY2d 519, 521 [1994], citing *Schultz v Boy Scouts of Am.*, 65 NY2d 189, 197 [1985]).

Loss-allocating rules apply once there is admittedly tortious conduct, while conduct-regulating rules are those which people use as a guide to governing their primary conduct (*see Schultz*, 65 NY2d at 198; *K.T. v Dash*, 37 AD3d 107, 112-113 [2006]). The Michigan statute in question, since it in effect dictates the standard of care required for a product liability claim against a pharmaceutical company (*see Taylor v Smithkline Beecham Corp.*, 468 Mich 1, 19, 658 NW2d 127, 137 [2003]), falls within the category of conduct-regulating rather than loss-

allocating. When the purpose of the statute is to regulate conduct, "the law of the jurisdiction where the tort occurred will generally apply because that jurisdiction has the greatest interest in regulating behavior within its borders" (*see Cooney v Osgood Mach.*, 81 NY2d at 72). The locus of a tort is generally defined as the place of the injury (*see Schultz v Boy Scouts of Am.*, 65 NY2d at 195).

Michigan has far greater significant contacts with the litigation. Not only do plaintiffs live and work there, but in addition, it is the jurisdiction where the alleged injuries occurred.

Moreover, we must recognize that the Michigan Legislature made a policy judgment intending to shield drug manufacturers from liability, and its "interests in protecting the reasonable expectations of the parties who relied on it to govern their primary conduct and in the admonitory effect that applying its law will have on similar conduct in the future assume critical importance and outweigh any interests of [New York State]" (*Schultz*, 65 NY2d at 198; *see also Garcia v Wyeth-Ayerst Labs.*, 385 F3d 961, 967 [6th Cir 2004]; *Rowe v Hoffman-La Roche, Inc.*, 189 NJ 615, 629, 917 A2d 767, 776 [2007]).

To the extent plaintiffs rely on *Carlenstolpe v Merck & Co., Inc.* (638 F Supp 901 [SD NY 1986], *appeal dismissed*, 819 F2d 33 [2d Cir 1987]), for the proposition that the locus of the tort is

the place where the tortious conduct occurred, their reliance is misplaced. The district court in *Carlenstolpe*, while acknowledging controlling New York law that "in a situation where the place of the allegedly wrongful behavior and the place of the injury are different, the place of the wrong is defined as the place of the injury," nevertheless applied a different rule, treating the place of the wrong as that where the defendant is present and where its allegedly wrongful behavior occurred (at 910). Not only is this reasoning unsupported in other cases, but in addition, the case the *Carlenstolpe* court cited in support, *Long v Pan Am. World Airways* (16 NY2d 337 [1965]), involved circumstances that rendered the usual "place of the injury" rule incongruous. The case arose out of an airplane crash, and the court declined to treat the location of the crash as the locus of the tort because it perceived that spot as "purely adventitious"; the court reasoned that the place of manufacture of the planes should be treated as the locus of the tort (at 342-343). Here, however, the place of injury was *not* "adventitious," and application of the general rule that the locus of the tort is the place of plaintiffs' injury is fully warranted.

Moreover, as the motion court observed, the district court's reasoning in dicta in the later case of *Doe v Hyland Therapeutics Div.* (807 F Supp 1117 [SD NY 1992]) is far more persuasive. There, in granting a forum non conveniens motion, the court

remarked:

> "Where rules of product liability are involved, we think the forum where the products are sold and consumed has the predominant interest in implementing the rules that form the basis for the "reasonable expectation of the parties" involved . . . [F]rom the perspective of influencing primary conduct, the forum where the product is sold is uniquely qualified to determine the controlling standards that reflect an equilibrium between its need for the product, and its desire to deter the sale of potentially harmful products to its citizens. Therefore . . . under a true application of the "interest analysis" approach, the law of the forum in which the products are sold should govern" (at 1130 n 16; *see also Ledingham v Parke-Davis Div.*, 628 F Supp 1447, 1452 [ED NY 1986]).

Indeed, the conclusion that Michigan law governs plaintiffs' claims is consistent with this Court's holding that where an out-of-state plaintiff was exposed to DES in states other than New York, "the substantive laws of the respective Foreign States are applicable" (*Kush v Abbot Labs.*, 238 AD2d 172, 173 [1997], quoting *Matter of New York County DES Litig.*, 223 AD2d 427, 428 [1996], *lv denied* 88 NY2d 801 [1996] ["the place of the wrong is considered to be the place where the last event necessary to make the actor liable occurred"]).

Having concluded that Michigan law applies in this action, we decline plaintiffs' request that this Court defer a ruling while the Michigan Legislature considers proposed legislation that would repeal the Michigan products liability statute (*see Rowe v Hoffman-La Roche*, 189 NJ at 630 n 1, 917 A2d at 776 n 1).

We therefore turn to plaintiffs' contention that even if

Michigan law governs their claims, Pfizer's motions to dismiss should have been denied as premature in that plaintiffs must be given the opportunity to obtain pretrial discovery in order to defeat Pfizer's immunity defense by demonstrating the applicability of a statutory exception to the liability shield.

Pfizer correctly points out that plaintiffs did not argue before the motion court that either of the exceptions applied here. Indeed, their amended complaints merely added allegations relevant to plaintiffs' contention that Pfizer's conduct and residency in New York supported their position that New York law should govern their claims. The motion court therefore had every reason to assume that no such claim was being asserted by plaintiffs. However, the failure to make such an argument is not the legal equivalent of a waiver, as Pfizer suggests, and the issue may be reviewed by this Court as a purely legal issue apparent from the face of the record (*see e.g. Bonilla v Rotter*, 36 AD3d 534, 535 [2007]).

A court considering a motion pursuant to CPLR 3211 is required to accept the allegations as true and determine whether those facts are sufficient to plead *any* cause of action (*see Leon v Martinez*, 84 NY2d 83, 88 [1994]). Therefore, the motion court had the authority to determine whether the complaint's allegations were sufficient to plead that the Michigan statute did not apply because one of its exceptions was applicable,

regardless of the legal theory pressed by plaintiffs as grounds to deny the motion.

Neither the allegations of plaintiffs' complaints nor any other submissions contained in the record before us suffice to set forth a claim that Pfizer fraudulently obtained the FDA approval on which it relies. The bare assertion that Pfizer engaged in deceptive marketing and other fraudulent and/or negligent conduct in the marketing of Lipitor without adequately disclosing health risks is insufficient to entitle plaintiffs to proceed with discovery on a claim of fraud in the agency approval process. Plaintiffs take the position that their complaints "implicitly" allege that Pfizer did not fully disclose Lipitor's dangerous side effects during the FDA approval process. These assertions and suggestions neither offer the requisite particularity for a fraud claim (*see* CPLR 3016[b]) nor establish that the necessary facts are solely within Pfizer's knowledge and possession. Plaintiffs will not be allowed to use pretrial discovery as a fishing expedition when they cannot set forth a reliable factual basis for what amounts to, at best, mere suspicions (*see Orix Credit Alliance v R.E. Hable Co.*, 256 AD2d 114, 116 [1998]).

Nor may plaintiffs rely on *Desiano v Warner-Lambert & Co.* (467 F3d 85 [2d Cir 2006], *affd sub nom Warner-Lambert Co., LLC v Kent*, __ US __, 128 S Ct 1168 [2008]) to justify their failure to

plead fraud in the FDA approval process so as to raise the applicability of the exception to the Michigan immunity statute. Even though under *Desiano* plaintiffs may not have had reason to plead fraud in the FDA approval process before defendant raised the Michigan statute's immunity defense, that defense was raised in the underlying motions, and plaintiffs failed to interpose, either by amended pleading or in opposing submissions on the motion, factual assertions that would support the application of any exception to that defense (*see Cole v Mandell Food Stores, Inc.*, 93 NY2d 34, 40 [1999]). Accordingly, we need not determine whether we agree with the Second Circuit's or the Sixth Circuit's analysis of the federal preemption issue (*compare Garcia v Wyeth-Ayerst Labs.*, 385 F3d 961 [6th Cir 2004], *with Desiano*, 467 F3d 85 [2d Cir 2006]).

We have considered plaintiffs' remaining arguments and find them unavailing.

Accordingly, the orders of the Supreme Court, New York County (Martin Shulman, J.), entered March 22, 2007, which granted defendant's motions to dismiss the respective complaints, should be affirmed, without costs.

All concur.

THIS CONSTITUTES THE DECISION AND ORDER
OF THE SUPREME COURT, APPELLATE DIVISION, FIRST DEPARTMENT.

ENTERED: NOVEMBER 20, 2008