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Update on U.S. Product Liability Law

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Introduction

U.S. courts have rendered important decisions in recent years in the areas of personal jurisdiction, federal jurisdiction, and expert witnesses, with broad implications for product liability litigation. Federal preemption continues to be a key issue in product liability law in the wake of significant decisions by the U.S. Supreme Court, with lower courts deciding numerous matters, further refining when product liability claims may be brought against the makers of prescription drugs and medical devices. In addition, recent decisions have made it more difficult for plaintiffs to prevent the removal of class actions from state court to federal court, and to obtain certification of consumer fraud class actions. Recent proposed changes to the rules governing civil litigation are designed to make discovery less burdensome and to clarify the standards governing discovery sanctions.

This chapter provides updates on each of these topics:

- Personal Jurisdiction and the Alien Tort Statute.
- Clarification of Federal Removal, Jurisdiction, and Venue Provisions.
- Federal Jurisdiction under the Class Action Fairness Act.
- Preemption.
- Expert Witness Gatekeeping and Designations.
- Revisions to the Federal Rules of Civil Procedure Governing Discovery.
- Consumer Fraud Class Actions.

Personal Jurisdiction and the Alien Tort Statute

In recent years, the U.S. Supreme Court has handed down several major decisions addressing when courts may assert personal jurisdiction over foreign manufacturers. Personal jurisdiction refers to a court's authority to require defendants to defend a lawsuit. The Supreme Court has described two types of personal jurisdiction: general and specific. General jurisdiction, considered in *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846 (2011), addresses when a corporation's contacts with the forum are sufficiently "continuous and systematic" that it is subject to being sued in that jurisdiction even for matters arising elsewhere. *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 317 (1945). Specific jurisdiction, considered by the Court in *J. McIntyre Machinery, Ltd. v. Nicastro*, 131 S. Ct. 2780 (2011), and *Walden v. Fiore*, 134 S. Ct. 1115 (2014), addresses when a lawsuit may be brought "arising out of or related to the defendant's contacts with the forum". *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 n.8 (1984).

General Personal Jurisdiction

In *Goodyear*, the U.S. Supreme Court considered whether foreign subsidiaries of a U.S. parent corporation could be sued in North Carolina on claims unrelated to any activity of the subsidiaries in that state. Parents of children who died in a bus accident in France sued Goodyear USA, an Ohio corporation, and three of its foreign subsidiaries, alleging that a defective tyre made by Goodyear's Turkish subsidiary caused the accident. 131 S. Ct. at 2850. The only contact the subsidiaries had with North Carolina was the distribution of a small number of their tyres there by other Goodyear USA affiliates. *Id.* at 2852. Nonetheless, the North Carolina court held that general jurisdiction existed over the foreign subsidiaries based on a "stream-of-commerce" approach: that the "[f]low of a manufacturer's products into the forum" serves as a basis for asserting personal jurisdiction. *Id.* at 2855. The U.S. Supreme Court unanimously reversed, holding that a "connection so limited between the forum and the foreign corporation . . . is an inadequate basis for the exercise of general jurisdiction". *Id.* at 2851. A stream-of-commerce analysis may "bolster an affiliation germane to specific jurisdiction", but not general jurisdiction, over a defendant. *Id.* at 2855.

The Supreme Court reinforced *Goodyear* in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014). There, the plaintiffs, residents of Argentina, alleged that a Mercedes-Benz subsidiary in Argentina collaborated with state security forces in the 1976-1983 "Dirty War" to harm Argentine workers. The plaintiffs sued DaimlerChrysler in California federal court based on the contacts of the company's U.S. subsidiary with California. On appeal, the Ninth Circuit allowed the suit to proceed, contending that the U.S. subsidiary acted as the parent's agent, and thus the subsidiary's California contacts (including multiple facilities and a regional office) could be properly imputed to the parent. *Id.* at 753.

The Supreme Court reversed, reiterating that a defendant's in-state activities must be "so 'continuous and systematic' as to render [it] essentially at home in the forum state". *Id.* at 761 (alteration in original) (quoting *Goodyear*, 131 S. Ct. at 2851). The Court rejected the Ninth Circuit's broader theory of jurisdiction because it would "subject foreign corporations to general jurisdiction whenever they have an in-state subsidiary or affiliate, an outcome that would sweep beyond even the 'sprawling new view of general jurisdiction' we rejected in *Goodyear*". *Id.* at 760. Next, the Court held that even assuming the U.S. subsidiary were considered "at home" in California, and even if its contacts were imputable to the parent, there would "still be no basis to subject Daimler to general jurisdiction in California, for Daimler's slim contacts with the State hardly render it at home there". *Id.* Although "*Goodyear* did not

hold that a corporation may be subject to general jurisdiction only in a forum where it is incorporated or has its principal place of business", the Court nevertheless concluded that general jurisdiction did not exist because "neither Daimler nor [its California subsidiary] is incorporated in California, nor does either entity have its principal place of business there". *Id.* at 760-61.

In a separate opinion concurring in the judgment, Justice Sotomayor posited that the Court went too far in concluding that there would be no general jurisdiction even if a U.S. subsidiary were considered "at home" in California and its contacts were imputed to the parent. She noted that this reasoning was based not on the fact that Daimler's contacts with California were too few, but that "its contacts with other forums [were] too many". *Id.* at 764. Her opinion faulted the Court for concluding, in essence, that a company can be "too big for general jurisdiction". *Id.* at 764-73.

In the wake of these decisions, lower courts have concluded that "general jurisdiction extends beyond an entity's state of incorporation and principal place of business only in . . . exceptional case[s]", if at all. *Sonera Holding B.V. v. Cukurova Holding A.S.*, 750 F.3d 221, 226 (2d Cir. 2014) (*per curiam*) (a company organised and based in Turkey was not subject to general jurisdiction in New York based on its affiliates' business activities there); see also *Lightfoot v. Cendant Mortgage Corp.*, 769 F.3d 681, 689 (9th Cir. 2014) ("The two places where a corporation is 'essentially at home' and therefore subject to general jurisdiction are its place of incorporation and its principal place of business."). Courts also have concluded, however, that *Goodyear* does not bar consideration of corporate agency relationships to establish specific personal jurisdiction. *See, e.g., Taishan Gypsum Co. v. Gross*, 753 F.3d 521, 531 (5th Cir. 2014).

Specific Personal Jurisdiction

In *Nicastro*, the plaintiff brought suit in a New Jersey State court after injuring his hand on a machine in New Jersey. The machine was made by the defendant in England, where the defendant was incorporated and had its operations. Although the New Jersey Supreme Court concluded that the defendant did not have minimum contacts in New Jersey, it nonetheless held that jurisdiction was proper because: (1) the plaintiff was injured in New Jersey; (2) the defendant knew or reasonably should have known that its products might be sold nationwide, including in New Jersey, by its U.S. distributor; and (3) the defendant failed to take reasonable steps to prevent the distribution of its products in New Jersey. 131 S. Ct. at 2786, 2790.

The Supreme Court reversed. All nine Justices agreed that specific jurisdiction requires a defendant to "purposefully avail[] itself of the privilege of conducting activities within the forum State", *Hanson v. Denckla*, 357 U.S. 235, 253 (1958), but they divided on what circumstances meet that standard. A plurality emphasised that "it is the defendant's actions, not his expectations, that empower a State's courts to subject him to judgment". 131 S. Ct. at 2789-91. The plurality concluded that the defendant's actions – including its distributor's agreement to sell machines in the U.S., its officials' attendance at trade shows in several states (excluding New Jersey), and that four machines ended up in New Jersey – "may reveal an intent to serve the U.S. market", but "do not show that [the defendant] purposefully availed itself of the New Jersey market". *Id.* at 2790. Two other Justices reached the same conclusion, but for a different reason, stating that the plurality's rationale improperly "refashion[ed] basic jurisdictional rules" by stating "strict rules that limit jurisdiction where a defendant does not 'inten[d] to submit to the power of a sovereign' and cannot 'be said to have targeted the forum'". *Id.* at 2793. Three Justices dissented, concluding that the defendant "availed itself of the market of all States in which its products were sold by its exclusive distributor". *Id.* at 2797, 2801.

Following *Nicastro*, the Supreme Court decided *Walden*, another matter involving specific personal jurisdiction. The Court held unanimously that a Nevada court lacked personal jurisdiction over a Georgia police officer who seized cash from Nevada travellers at an airport in Georgia. The Court reasoned that "the defendant's suit-related conduct must create a substantial connection with the forum State" itself, and not merely with people from there. *Id.* at 1121. Thus, "mere injury to a forum resident" is not enough, even if the injury is foreseeable and has effects in the forum. *Id.* at 1125.

In the wake of these decisions, foreign manufacturers, including subsidiaries of U.S. companies, have given increased consideration to how they structure U.S. operations in light of potential litigation exposure in different jurisdictions. Nevertheless, the limits of specific jurisdiction for foreign companies remain unsettled. Indeed, the courts of appeal have viewed *Nicastro* as doing little to resolve a longstanding debate about the contours of specific personal jurisdiction following the Supreme Court's decision in *Asahi Metal Industry Co. v. Superior Court of Cal.*, 480 U.S. 102 (1987). In *Asahi*, Justice Brennan, writing for a plurality, concluded that "jurisdiction premised on the placement of a product into the stream of commerce is consistent with the Due Process Clause . . . [a]s long as a participant in this process is aware that the final product is being marketed in the forum State, the possibility of a lawsuit there cannot come as a surprise". *Asahi*, 480 U.S. at 117. Justice O'Connor, writing for three other Justices, disagreed, concluding that "[t]he placement of a product into the stream of commerce, without more, is not an act of the defendant purposefully directed toward the forum State". *Id.* at 112. Some lower courts have followed one approach and some have adopted the other. Most have concluded this unsettled situation "remains the same" after *Nicastro*. *See Ainsworth v. Moffett Eng'g, Ltd.*, 716 F.3d 174, 179 (5th Cir. 2013); *AFTG-TG, LLC v. Nuvoton Tech. Corp.*, 689 F.3d 1358, 1363 (Fed. Cir. 2012).

Without picking a side in the *Asahi* debate, the D.C. Circuit recently held that the mere circulation in commerce of a foreign manufacturer's firearms did not give rise to specific jurisdiction in the District of Columbia, even though the manufacturer sold the weapons through a U.S. distributor. *Williams v. Romarm*, SA, 756 F.3d 777, 785 (D.C. Cir. 2014). *Williams* concluded that *Nicastro* at least "makes clear that a manufacturer's broad desire to target the United States through a distributor will not suffice." *Id.* The court also relied on the *Nicastro* concurrence's observation that "a 'single isolated sale' from a distributor to a customer in the forum state has never been sufficient to establish minimum contacts between the manufacturer and the forum, under any stream-of-commerce interpretation." *Id.*

Another question that remains open is how specific jurisdiction should work in cases involving a defendant's activity on the Internet. *See Walden*, 134 S. Ct. at 1125 n. 9; *Nicastro*, 131 S. Ct. at 2793 (Breyer, J. & Alito, J. concurring in the judgment). The Fourth Circuit recently considered this issue in *Unspam Techs., Inc. v. Chernuk*, 716 F.3d 322, 328 (4th Cir. 2013), a suit brought by Virginia residents against foreign banks, internet payment service providers, and Russian-based pharmacists. The court concluded that personal jurisdiction over persons doing business online should be determined by evaluating: (1) the extent to which the defendant purposely availed itself of the privilege of conducting activities in the State; (2) whether the plaintiffs' claims arise out of those activities directed at the State; and (3) whether the exercise of personal jurisdiction would be constitutionally reasonable. Based on these factors, the court held that there was no indication that any of the foreign defendants "acted in such a way as to subject itself to the sovereign power of a court in Virginia". *Id.* The fact that

the plaintiffs' purchases were processed by one of the foreign banks through the international Visa network was too remote to justify jurisdiction in Virginia. *Id.*; *see also Advanced Tactical Ordnance Sys., LLC v. Real Action Paintball, Inc.*, 751 F.3d 796, 801-03 (7th Cir. 2014) (company's online sales, website, and sending of emails to customers in Indiana did not establish personal jurisdiction there in a trademark infringement suit by a competitor).

Alien Tort Statute

Foreign corporations also should be aware of several recent decisions addressing the scope of the Alien Tort Statute ("ATS"). The ATS, which dates back to 1789, gives federal courts "original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States". 28 U.S.C. § 1350. For almost two centuries, the ATS was essentially ignored by federal courts. But recently, plaintiffs have increasingly pressed the ATS to sue corporations in U.S. courts for alleged torts occurring outside the United States.

The U.S. Supreme Court has clarified the scope of the ATS twice in recent years, but has left unanswered the question of whether the statute can be used to sue a corporation. In *Sosa v. Alvarez-Machain*, 542 U.S. 692 (2004), the Court determined that ATS claims must be based on alleged violations of customary international law, "rest[ing] on a norm of international character accepted by the civili[s]ed world and defined with a specificity comparable to" offences that prompted the passage of the ATS in the first place: "violation of safe conducts, infringement of the rights of ambassadors, and piracy". *Id.* at 724-25. In *Kiobel v. Royal Dutch Petroleum Co.*, 133 S. Ct. 1659 (2013), the Court determined that the ATS cannot be used to redress alleged torts that occurred wholly outside of the United States. *Id.* at 1664, 1669. The Court did not squarely address the broader question of ATS liability for corporations, but did note that "[c]orporations are often present in many countries, and it would reach too far to say that mere corporate presence [in the U.S.] suffices" to create ATS jurisdiction. *Id.*

Following *Kiobel*, courts have diverged on whether the ATS applies to corporations. The Ninth Circuit recently reaffirmed its pre-*Kiobel* conclusion that corporations may be liable under the ATS. *Doe I v. Nestle USA, Inc.*, 766 F.3d 1013, 1021 (9th Cir. 2014). The Second Circuit, in contrast, has adhered to its prior view to the contrary. *See Chowdhury v. Worldtel Bangladesh Holding, Ltd.*, 746 F.3d 42, 49 n.6 (2d Cir. 2014). The other circuits that previously allowed corporate ATS liability, *see Flomo v. Firestone Nat. Rubber Co., LLC*, 643 F.3d 1013, 1017 (7th Cir. 2011) (collecting cases), have not yet had a chance to revisit their pre-*Kiobel* precedent, and may, given the Supreme Court's silence, see no reason to do so.

Clarification of Federal Removal, Jurisdiction, and Venue Provisions

The Federal Courts Jurisdiction and Venue Clarification Act of 2011 ("JVCA") – which applies to cases commenced in federal court on or after January 6, 2012 – clarifies several important federal statutes addressing removal, supplemental jurisdiction, and venue. See Pub. L. No. 112-63, 125 Stat. 758 (2011). Many of these changes are likely to enhance defendants' federal jurisdiction rights in product liability litigation.

Removal and the Amount-in-Controversy Requirement

In product liability cases, it often is beneficial for the defendant to remove a state court action to federal court, particularly where a multi-district litigation ("MDL") proceeding has been established, so the defendant does not need to defend itself in multiple courts simultaneously. Removal is governed by statute and requires that the federal courts have subject matter jurisdiction over the case. A defendant generally has 30 days after formal service of the initial pleading to remove the case to federal court. 28 U.S.C. § 1446(b)(1).

The most common basis for subject matter jurisdiction in product liability cases is diversity jurisdiction, which requires that (1) the parties be "diverse" (typically, "citizens" of different states), and (2) the amount-in-controversy exceeds a certain threshold. *Id.* § 1332. For individual actions, the amount-in-controversy must exceed $75,000. *Id.* § 1332(a). For class actions, the aggregate amount-in-controversy under the Class Action Fairness Act ("CAFA") must exceed $5 million. *Id.* § 1332(d)(2) & (6). Where the plaintiffs claim a stated sum of damages in their state-court complaint, that amount is generally "deemed to be" the amount in controversy. *Id.* § 1446(c)(2). Further, although plaintiffs do not always claim a specific amount of damages, it often is obvious from the nature of the alleged conduct and injuries that the plaintiff seeks an amount that exceeds the jurisdictional minimum.

Where the amount-in-controversy is difficult to discern from the face of the complaint, however, courts had approached removability in a number of different ways. JVCA addresses this confusion, providing that the defendant's notice of removal may assert the amount in controversy if the complaint fails to do so. *Id.* § 1446(c)(2)(A). If the defendant lacks adequate information about the amount-in-controversy within the 30-day removal period, the defendant may use discovery in the state court case to determine the amount-in-controversy. See *id.* § 1446(c)(3)(A). The 30-day removal period is then triggered when a document or pleading indicating outside the initial complaint demonstrates that the amount-in-controversy is satisfied. See *id.* § 1446(b)(3). In general, a case (other than a class action) may not be removed more than one year after it is commenced unless the plaintiff acted in bad faith to prevent removal. See *id.* § 1446(c)(1).

The U.S. Supreme Court recently clarified the standard of proof governing a CAFA defendant's removal of a class action where the complaint does not state the amount-in-controversy. *See Dart Cherokee Basin Operating Co., LLC v. Owens,* 135 S. Ct. 547 (2014). *Dart* held that because the removal statute requires a notice of removal merely to contain "a short and plain statement of the grounds for removal", 28 U.S.C. § 1446(a), "a defendant's notice of removal need include only a plausible allegation that the amount in controversy exceeds the jurisdictional threshold". 135 S. Ct. at 554. Actual evidence of the amount-in-controversy is required "only when the plaintiff contests, or the court questions, the defendant's allegation." *Id.* Thus, after *Dart*, a CAFA defendant "can establish the amount in controversy by an unchallenged, plausible assertion of the amount in controversy in its notice of removal". *Ibarra v. Manheim Investments, Inc.*, 775 F.3d 1193, 1197-98 (9th Cir. 2015). Dart also rejected the conclusion of numerous lower courts that there is a "presumption against removal" in CAFA cases; the Court did not explicitly address the application of a presumption in other diversity cases. 135 S. Ct. at 554; *see, e.g., Dudley v. Eli Lilly & Co.*, -- F.3d ---, 2014 WL 7360016, at *2 (11th Cir. Dec. 29, 2014) ("we may no longer rely on any presumption in favor of remand in deciding CAFA jurisdictional questions").

Although *Dart* involved CAFA, it may signal a lower barrier for removal in all diversity cases, since the statutory language the Court construed is not specific to class actions and parallels the language used to prescribe the pleading standard for plaintiffs in all civil cases. *See, e.g., Statin v. Deutsche Bank Nat. Trust Co.*, No. 14-20200, 2014 WL 7235168, at *1 n.1 (5th Cir. Dec. 19, 2014) (suggesting *Dart* clarified the standard for all removals); *Heartland*

of Portsmouth, OH, LLC v. McHugh Fuller Law Grp., PLLC, No. 15-CV-007, 2015 WL 728311, at *1 (S.D. Ohio Feb. 19, 2015) (applying *Dart* in a non-CAFA diversity case); *Manibhadra, Inc. v. Aspen Ins. UK Ltd.*, No. 14-4112-SAC, 2014 WL 7246858, at *1 (D. Kan. Dec. 17, 2014) (same).

In addition, as discussed below, in *Standard Fire Insurance Co. v. Knowles*, the U.S. Supreme Court rejected efforts by named plaintiffs in a class action to prevent removal by signing a pre-certification stipulation that the amount in controversy is below CAFA's $5 million threshold. 133 S. Ct. 1345 (2013).

Removal in Multiple Defendant Cases

Before JVCA, courts disagreed about whether removal in a multiple-defendant case must occur within 30 days after service on the first defendant, or whether later-served defendants also had their own 30-day removal period. JVCA now provides that each defendant has 30 days from its own date of service to remove. 28 U.S.C. § 1446(b)(2)(B). Moreover, if a later-served defendant files a notice of removal, earlier-served defendants may consent to removal even if they themselves did not timely remove. *Id.* § 1446(b)(2)(C). These changes allow later-served defendants their own opportunity to remove, even if the earlier-served defendants did not do so.

Supplemental Jurisdiction

Apart from diversity jurisdiction, the federal courts also have original jurisdiction over "federal questions", i.e., claims arising under federal law. JVCA clarifies defendants' right of access to federal court when federal questions are joined in a single lawsuit with unrelated state-law claims. The removal statute previously authorised a defendant to remove an entire case whenever a "separate and independent" federal question was joined with one or more non-removable state-law claims. 28 U.S.C. § 1441(c)(1)(a)-(b). The JVCA eliminated the concept of "separate and independent" claims, which had generated much confusion and litigation. Now, Section 1441(c) allows removal of the entire action when a case involves: (a) any federal question; and (b) one or more non-removable state-law claims.

JVCA also clarifies the district court's remand authority in such cases. If a defendant removes a case under federal-question jurisdiction and there are unrelated state-law claims not within the original or supplemental jurisdiction of the court, the federal court must sever and remand the unrelated state-law claims; it may not remand the entire case to state court. *Id.* § 1441(c)(2). This sever-and-remand approach preserves the defendant's right to remove federal questions to federal court where they are joined with additional claims not subject to original or supplemental jurisdiction.

Transfer of Venue

Previously, 28 U.S.C. § 1404(a) authorised the transfer of civil actions for the convenience of parties and witnesses, but limited the transfer to those districts "where [the action] might have been brought". 28 U.S.C. § 1404(a) (2010). The U.S. Supreme Court interpreted this language to require that the transferee district be one in which both venue and personal jurisdiction are proper. *See Hoffman v. Blaski*, 363 U.S. 335 (1960). This sometimes precluded transfer to a district that might be mutually convenient and agreeable to the litigants. JVCA resolves this issue by permitting an action to be transferred to any district or division to which all parties consent. 28 U.S.C. § 1404(a).

Federal Jurisdiction Under the Class Action Fairness Act ("CAFA")

In class actions, removal and diversity jurisdiction raise special issues, many of which Congress addressed in the Class Action Fairness Act of 2005 ("CAFA"), Pub. L. No.109-2, 119 Stat. 4. In general, CAFA gives federal courts original jurisdiction over class actions – as well as "mass actions" involving over 100 plaintiffs – where: (a) any class member or plaintiff is diverse from any defendant; and (b) the aggregate amount in controversy exceeds $5 million. 28 U.S.C. § 1332(d)(2) & (5). CAFA also makes the removal of class actions easier than ordinary diversity removals by: (i) eliminating the one-year limit on the timing of removal based on events occurring after the initial pleading; (ii) allowing a defendant to remove even if all defendants do not consent; and (iii) allowing in-state defendants to remove. See *id.* § 1453. Cases construing CAFA continue to evolve, but plaintiffs have developed three principal strategies to challenge removal to federal court under CAFA, with varying success:

- ***Disclaiming recovery for amounts over the $5 million jurisdictional minimum***. *See, e.g., Morgan v. Gay*, 471 F.3d 469, 476 (3d Cir. 2006) (affirming remand of class action where plaintiff expressly disclaimed recovery of $5 million or more). In a significant decision for would-be removing defendants, the U.S. Supreme Court recently held that prior to class certification, a stipulation that the named plaintiff (and members of the putative class) would seek less than $5 million in damages will not defeat removal under CAFA. *Knowles*, 133 S. Ct. 1345. Plaintiff Knowles filed a class action lawsuit in Arkansas state court against Standard Fire on behalf of a class of insurance policyholders. To avoid CAFA's $5 million jurisdictional minimum, Knowles stated in his complaint that "Plaintiff and Class stipulate they will seek to recover total aggregate damages of less than five million dollars." *Id.* at 1347. The Supreme Court ruled that such a stipulation could not prevent removal. The Court's reasoning followed *Smith v. Bayer Corp*., 131 S. Ct. 2368, 2380 (2011), explaining that members of a proposed class cannot be bound before the class is certified. Thus, allowing the stipulation to defeat removal would "treat a nonbinding stipulation as if it were binding, exalt form over substance, and run directly counter to CAFA's primary objective: ensuring 'Federal court consideration of interstate cases of national importance.'" 133 S. Ct. at 1350.
- ***Filing a series of substantively identical lawsuits, each naming fewer than 100 plaintiffs, to avoid qualifying as a 100+ plaintiff "mass action" under CAFA***. *Compare Anderson v. Bayer Corp.*, 610 F.3d 390, 394 (7th Cir. 2010) (reading CAFA to permit this tactic), *and Tanoh v. Dow Chem. Co*., 561 F.3d 945, 956 (9th Cir. 2009) (same), *with Atwell v. Bos. Scientific Corp.*, 740 F.3d 1160, 1165 (8th Cir. 2013) (holding that three similar products liability cases, each consisting of less than 100 plaintiffs, constituted one removable "mass action", where plaintiffs had moved in state court for assignment to a single judge, because "the 'inevitable result' [of such coordination] will be that their cases are 'tried jointly'").
- ***Tailoring the complaint to invoke a "local controversy" exception to CAFA jurisdiction***. *See, e.g., Lafalier v. State Farm Fire & Cas. Co.*, 391 F. App'x 732, 734-35 (10th Cir. 2010) (class action met "local controversy" exception to federal jurisdiction under CAFA, where: (a) 2/3 or more of the plaintiffs were citizens of the state in which the action was filed; (b) at least one defendant from whom "significant relief" was sought, whose conduct formed a "significant basis" of the class claims, was a citizen of the state in which the action was filed; (c) the "principal injuries" occurred in the state in which the action was filed; and (d) no class action alleging the same or similar facts had been filed in the state in which the action was filed within the previous three years).

Preemption

Where state law conflicts with federal law, state law is preempted under the Supremacy Clause of the U.S. Constitution. U.S. Const. art. VI, cl. 2. In deciding whether a claim is preempted, courts determine whether Congress intended the federal law at issue to supplant state law. *See, e.g., Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992). Preemption may be expressed in an explicit provision of federal law or implied in the structure and scope of the federal regulatory scheme. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Over the last decade, preemption with respect to pharmaceuticals and medical devices approved by the U.S. Food and Drug Administration ("FDA") has received considerable attention from the Supreme Court. *See, e.g., Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011) (holding that the National Childhood Vaccine Injury Act of 1986 preempted state design defect claims) (discussed in 2011 edition of this Guide); *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that state warnings claims were not preempted absent clear evidence that the FDA would have rejected the plaintiff's proposed warnings) (discussed in 2009 edition of this Guide).

Pharmaceutical Preemption

In a case with far-reaching implications for pharmaceutical preemption, the Supreme Court held that certain product liability claims brought against generic drug makers are impliedly preempted. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). In *Mensing*, the plaintiffs alleged that the manufacturers of a generic drug failed to adequately warn of the risk of a severe and often irreversible neurological disorder. *Id.* at 2572. The manufacturers argued that the claims were preempted because federal law requires generic medications to carry warnings identical to their brand-name equivalents, making compliance with both federal law and the alleged duty under state law impossible (a recognised ground for preemption). *Id.* at 2573.

The plaintiffs asserted three bases on which the manufacturers could have independently modified the warnings: (1) by using the FDA's changes-being-effected ("CBE") process; (2) by sending Dear Doctor letters to physicians; or (3) by proposing stronger warnings to the FDA. *Id.* at 2574-77. The Court rejected the first two bases, noting the FDA's position that a generic drug maker could not unilaterally strengthen its labelling by using the CBE process or disseminating a Dear Doctor letter. *Id.* at 2576. As to the third basis, the FDA, writing as *amicus curiae*, urged the Supreme Court to hold that there was no true "impossibility" of complying with federal and state law because it was undisputed that the manufacturers could ask the FDA to strengthen the warnings but had never done so; absent such a request, plaintiffs and FDA contended, the manufacturers' preemption defence should fail. *Id.* at 2578-79. The Court rejected this "Mouse Trap game" argument because, even if the generic manufacturer had proposed different labelling to the FDA, it was not clear that the agency, in exercise of its public health judgment, would have agreed and permitted the new warning. *Id.* at 2578. The *Mensing* court held that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes". *Id.* at 2581. This holding may reinvigorate implied preemption arguments outside of the generic context in analogous regulatory settings where the FDA's prior approval is needed before the manufacturer can make changes, such as prior approval supplements or changes to highlights in physicians' labelling.

Plaintiffs have tested *Mensing*'s limits by advancing theories of liability beyond failure to warn. For example, some plaintiffs have contended that if the generic manufacturer could not amend the labelling, it should have withdrawn the drug from the market. The Supreme Court recently rejected this "'stop-selling'" rationale, however, as "incompatible" with its preemption jurisprudence. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 (2013). In *Bartlett*, the defendant generic drug manufacturer argued that it was impossible to comply with both its alleged state-law duty to strengthen the warnings for its drugs and its federal-law duty not to alter the approved labelling. The First Circuit held that the plaintiff's design-defect claims were not preempted because the manufacturer could simply stop manufacturing the drug entirely and thus comply with both state and federal law. *Id.* The Supreme Court disagreed, explaining that its preemption cases "presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability". *Id.* at 2477. The Court further noted that if the option of ceasing to act defeated a claim of impossibility, impossibility preemption "would be 'all but meaningless'" because any conflict could be avoided if the regulated actor simply ceased acting. *Id.*

The Pennsylvania Supreme Court recently took a different approach, recognising a cause of action for "negligent design defect" for "lack of due care resulting in an untenably dangerous product being put into the marketplace", and noting that "FDA approval of a drug permits the manufacturer to market it, but it does not require the manufacturer to do so. If the manufacturer concludes that its product is [too] unsafe [to be used by anyone], it can and must take it off the market". *Lance v. Wyeth*, 85 A.3d 434, 460 n.39 (Pa. 2014).

Additional post-*Mensing* theories also have been litigated. For example, one potential way to survive *Mensing* may be to allege that the generic labelling did not match the brand labelling as required by federal law. *See Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 WL 368675, at *5 (D. Vt. Feb. 3, 2012) (holding that such a claim was not preempted). Other courts have concluded that plaintiffs may be able to proceed with claims that the generic manufacturer should have disseminated a Dear Doctor letter consistent with the drug's approved labelling. *See Brasley-Thrash v. Teva Pharms. USA, Inc.*, No. 10-0031, 2011 WL 4025734, at *3-4 (S.D. Ala. Sept. 12, 2011); *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 805 (D.S.C. 2011).

Mensing has had collateral implications for product liability risk. Although *Mensing* may make it harder for plaintiffs to recover against a generic manufacturer, some cases have explored whether a patient injured by a generic drug, and unable to proceed against the generic maker because of preemption, may nontheless sue the maker of the brand drug on a theory of "innovator liability" even where the brand manufacturer has no relationship to the plaintiff and did not make the drug the patient took. The Alabama Supreme Court recently accepted such an approach in *Wyeth, Inc. v. Weeks*, No. 1101397, 2014 WL 055813 (Ala. Aug. 15, 2014). *Weeks* held that "a brand-name-drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company." *Id.* at *22. The court justified this result "because the manufacturing process is irrelevant to misrepresentation theories based, not on manufacturing defects in the product itself, but on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated, as allowed by the FDA, by the generic manufacturer". *Id.* at *23.

The approach in *Weeks* is disfavoured – every federal court of appeals to consider the issue has held that brand-name manufacturers are not liable to plaintiffs who are injured by a generic drug, whether

under state products liability law or under general principles of duty. *See, e.g., Schrock v. Wyeth, Inc*., 727 F.3d 1273, 1281-86 (10th Cir. 2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1250-53 (11th Cir. 2013); *Strayhorn v. Wyeth Pharm.,Inc.*, 737 F.3d 378, 401-06 (6th Cir. 2013); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092-94 (8th Cir. 2013); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 182-84 (5th Cir. 2012) (*per curiam*), *cert. denied*, 134 S. Ct. 57 (2013). Only a few cases have held that brand-name manufacturers may be subject to innovator liability. *See Strayhorn*, 737 F.3d at 406. Most recently, an Illinois federal court held that a brand-name drug manufacturer could be liable for injury caused by generic drug under a theory of negligence, but not strict product liability. *See Dolin v. Smithkline Beecham Corp*., No. 1:12-cv-06403, slip op. at 9-12 (N.D. Ill. Feb. 28, 2014).

Other branches of government besides the judiciary also have responded to *Mensing*. The FDA recently proposed a generic changes-being-effected rule. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,989 (Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314 & 601). Under the proposed rule, generic drug manufacturers would be able to unilaterally change their product labels through the CBE process, which is currently only available to brand-name drug manufacturers. *Id.* The proposed rule was initially promulgated for comment in November 2013, and the final rule is expected in September 2015. If the proposal is enacted, this provision could have significant implications for the preemption analysis in *Mensing* and *Bartlett*, and for the theory of innovator liability.

Buckman Preemption

The Ninth Circuit held that federal law did not impliedly preempt Arizona state law failure-to-warn claims predicated on a medical device manufacturer's alleged failure to "'report to the FDA any complaints about the product's performance'" allegedly linked to plaintiff's own injury, and about which the product's labelling did not otherwise warn. *Stengel v. Medtronic Inc*., 704 F.3d 1224, 1232 (9th Cir. 2013) (*en banc*). The Ninth Circuit reached this result notwithstanding the U.S. Supreme Court's holding in *Buckman* that state-law claims predicated on alleged failures in reporting duties owed to FDA are impliedly preempted. 531 U.S. at 348. Recognising that Congress provided that actions to enforce the Federal Food, Drug, and Cosmetic Act ("FDCA") "shall be by and in the name of the United States" and not private parties, 21 U.S.C. § 337(a), *Buckman* held that the FDCA was to "be enforced exclusively by the Federal Government", 531 U.S. at 352. Accordingly, state law claims that "exist solely by virtue of the FDCA disclosure requirements" are preempted. *Id.* at 353. Notwithstanding *Buckman*, the Ninth Circuit in *Stengel* held that because the manufacturer allegedly "failed to comply with its duty under federal law, it breached its 'duty to use reasonable care' under Arizona negligence law". 704 F.3d at 1232. The same court recently reached a similar result in *McClellan v. I-Flow Corp*., 776 F.3d 1035, 1040 (9th Cir. 2015), which held that the plaintiff's state-law claims against the manufacturer and distributors of a pain pump for negligent failure to warn and strict liability based on lack of adequate warnings were not preempted under *Buckman*. The court purported to distinguish *Buckman* on the ground that the plaintiff's claims were not "fraud-on-the-agency" claims under the FDCA, as in *Buckman*, but were rather "parallel" to federal law. *Id.*

The Ninth Circuit's decisions depart from the holding of other courts, including the Eighth Circuit, that allegations that a manufacturer "failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations" are "foreclosed by [the FDCA] as construed in Buckman". *Bryant v. Medtronic, Inc*. (*In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*), 623 F.3d 1200, 1205-06 (8th Cir. 2010). The Supreme Court declined to review *Stengel*, see 134 S. Ct. 2839 (2014), but may have an opportunity to consider *McClellan*.

Additional *Buckman*-related issues also are percolating in the federal courts of appeals. In *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008) (*per curiam*), an evenly divided Supreme Court left unresolved whether federal law preempts a Michigan statute that immunised pharmaceutical manufacturers from product liability suits unless the plaintiff could show that the FDA would not have approved the medication but for the manufacturer defrauding the FDA, a question that divides the lower courts. *Compare Desiano v. Warner-Lambert & Co*., 467 F.3d 85 (2d Cir. 2007) (holding that the Michigan statute was not preempted under *Buckman*), *aff'd sub nom*, 552 U.S. 440 (2008), *with Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965-67 (6th Cir. 2004) (holding that the same Michigan statute was preempted by *Buckman*), *and Lofton v. McNeil Consumer & Specialty Pharms*., 672 F.3d 372 (5th Cir. 2012) (holding that a Texas statute similar to the Michigan law was preempted under *Buckman* absent an FDA determination of fraud-on-the-agency).

More recently, the Fifth and Sixth Circuits have split over whether "failure to update" claims against generic drug manufacturers are preempted under *Buckman*. *Compare Lashley v. Pfizer, Inc*., 750 F.3d 470, 475 (5th Cir. 2014) (holding that plaintiffs' claim that a generic drug manufacturer failed to update its label to match the updated brand-name drug label was preempted under *Buckman* because a claim that the defendant "breached a federal labelling obligation sounds exclusively in federal (not state) law"), *with Fulgenzi v. PLIVA, Inc*., 711 F.3d 578, 586-88 (6th Cir. 2013) (holding that the plaintiff's failure to update the claim was not preempted by *Buckman*, where such claim was not premised on an alleged violation of federal law, but rather on an independent state duty to provide adequate warnings).

"Parallel Claims" Against Manufacturers of Certain Medical Devices

The preemption of claims against medical device manufacturers has received considerable attention in the federal courts in recent years. In 2008, the U.S. Supreme Court held that claims against manufacturers of Class III pre-market approved ("PMA") devices are preempted to the extent they would impose requirements "different from, or in addition to the requirements imposed by Federal law". *Riegel v. Medtronic, Inc*., 552 U.S. 312, 330 (2008). This ruling shields manufacturers from tort liability for most claims related to PMA devices, which are subject to the most rigorous FDA review. *Id.* at 318-20. *Riegel* left open, however, the possibility that plaintiffs in future cases could plead a "parallel claim" where a PMA-approved medical device deviated from a PMA-imposed requirement. *Id.* at 330. In determining whether a "parallel claim" is sufficiently pleaded to survive a motion to dismiss, courts have considered the heightened pleading standards addressed in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009). Under these standards, a complaint must give more than "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements". *Iqbal*, 129 S. Ct. at 1949. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 1950.

Federal courts have applied these precedents in different ways. Numerous federal courts of appeals have rejected plaintiffs' attempts to circumvent *Riegel*:

- In *Bryant*, 623 F.3d at 1206-07, the Eighth Circuit held that the plaintiff's manufacturing defect and warranty claims were preempted because they generally alleged that the manufacturer failed to comply with FDA regulations and objectives, rather than alleging a violation of PMA requirements specific to that device.
- In *Wolicki-Gables v. Arrow International, Inc*., 634 F.3d 1296, 1301 (11th Cir. 2011), the Eleventh Circuit held that the plaintiff's claims were preempted where the plaintiff alleged that the manufacturer "failed to reasonably" design and manufacture the device or to provide adequate warnings.
- In *Walker v. Medtronic*, 670 F.3d 569, 576 (4th Cir. 2012), the Fourth Circuit rejected a claim that an allegedly defective drug-infusion pump "failed to adhere to the plus or minus 15 per cent specification included in the pre-market approval materials and, that by failing to administer medicine within these parameters, it had violated the terms of its premarket approval". The court held that the plaintiff's claim did not "fit within the narrow exception for parallel claims the Supreme Court carved out in *Riegel*" because she conceded the pump was "designed, manufactured, and distributed in compliance with the terms of the FDA's premarket approval". *Id.* at 576-79.

Other courts, including the Fifth Circuit, have rejected certain attempts to plead parallel claims while allowing others:

- *Funk v. Stryker Corp*., 631 F.3d 777, 782 (5th Cir. 2011), held that the plaintiff's manufacturing defect claim was preempted where "the complaint [does not] tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process".
- *Hughes v. Boston Scientific Corp*., 631 F.3d 762, 768 (5th Cir. 2011) similarly held "all of [plaintiff's] state products liability claims that purport to impose liability on [defendant] despite [defendant]'s compliance with the applicable FDA design and manufacturing specifications, as approved by the FDA during the PMA process, seek to impose different or additional state duties and are expressly preempted". The plaintiff's failure to warn claim, on the other hand, survived, but only to the extent it was based on an alleged "failure to comply with FDA regulations". *Id.* at 769.
- Applying *Funk* and *Hughes*, the court more recently concluded there were sufficient parallel claims where the plaintiff pleaded: "(1) he received a [device] implant; (2) the FDA had previously warned [defendant] of bio-burden in excess of FDA regulations in its final rinse of the [device]; (3) after [plaintiff's] surgery, [defendant] ultimately voluntarily recalled those [devices], including the [device] specifically used in [plaintiff's] implant; (4) [plaintiff] suffered from a loose [device] due to a lack of bony ingrowth; and (5) the lack of bony ingrowth is a known effect of an excess of bio-burden and manufacturing residuals on [the device]". *Bass v. Stryker Corp*., 669 F.3d 501, 510 (5th Cir. 2012); *see also Howard v. Zimmer, Inc*., 718 F.3d 1209, 1210 (10th Cir. 2013) (permitting a "parallel" state court negligence claim premised on allegations that a knee implant failed because the manufacturer left an oily residue on the implant in violation of federal requirements from federal requirements to survive a motion to dismiss).

Expert Witness Gatekeeping and Designations

Admission of Expert Testimony

Under Federal Rule of Evidence 702, expert testimony may be admitted in federal courts "[i]f scientific, technical, or other specialised knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue". Fed. R. Evid. 702. A witness qualified as an expert by "knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case". *Id.* Reviewing courts have a critical gatekeeping responsibility to ensure that the proposed expert testimony is both relevant and reliable. See, e.g., *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999); *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Numerous decisions have highlighted the importance of the trial judge's gatekeeping obligations under *Daubert*. *See, e.g., Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463-64 (9th Cir. 2013 (*en banc*) (vacating the judgment where the district court failed to conduct a *Daubert* admissibility determination); *see also In re Neurontin Mktg. & Sales Pracs. Litig.,* 712 F.3d 21, 41-42 (1st Cir. 2013) (expert testimony must have a reasoning or methodology that is scientifically valid, and that methodology must also have a valid scientific connection to the pertinent inquiry).

Expert Reports

Expert witnesses often play a significant role in products liability litigation, and issues surrounding the discoverability of materials relating to expert witnesses have been subject to significant litigation. Federal Rule of Civil Procedure 26 was amended in December 2010, and provides certain protections for draft expert materials and attorney-expert communications.

First, the amendment clarifies which experts must provide reports. Experts "retained or specially employed to provide expert testimony in the case" and experts "whose duties as the party's employee regularly involve giving expert testimony" are required to submit reports. Fed. R. Civ. P. 26(a)(2)(B). Where these requirements apply, the report must contain all of the expert's opinions (and the basis for those opinions), the facts or data considered in forming the opinions, any exhibits used to summarise or support the opinions, the expert's qualifications, a list of all cases in the past four years that the expert has testified in, and the expert's compensation. *Id.* Experts who do not meet one of these two requirements – for instance, consulting experts or an employee with specialised expertise who does not regularly provide expert testimony – are not required to submit such reports. *See Downey v. Bob's Discount Furniture Holdings, Inc*., 633 F.3d 1, 6 (1st Cir. 2011). Instead, these experts must provide a written disclosure stating the subject matter on which they intend to testify and a summary of the facts and opinions about which they expect to testify. Fed. R. Civ. P. 26(a)(2)(C).

Second, the amendment creates work-product protections for certain attorney communications with testifying experts. Rule 26(b)(4)(B) extends work-product protection to drafts of any expert disclosure or report. Rule 26(b)(4)(C) extends the same protection to attorney communications with an expert required to submit a report, except to the extent that the communications relate to the expert's compensation or identify facts, data, or assumptions that the attorney provided to the expert and that the expert considered in forming his or her opinion. *See, e.g., In re Asbestos Prods. Liab. Litig*., MDL 875, 2011 WL 6181334, at *6-7 (E.D. Pa. Dec. 13, 2011) (holding that letters exchanged between plaintiffs and their doctors were discoverable because they included "facts or data" considered by the doctors).

Questions remain about the extent to which communications with non-reporting experts are protected from discovery, and are highly context-specific. For instance, in *Graco, Inc. v. PMC Global, Inc*.,

No. 08-1304, 2011 WL 666056 (D.N.J. Feb. 14, 2011), the plaintiff submitted affidavits from several of its employees in support of a motion for a preliminary injunction and in opposition to the defendant's motion for summary judgment. See *id.* at *1. The defendant sought discovery of, among other things, the plaintiff's counsel's communications with the plaintiff's employees. *Id.* The court held that the attorney-client privilege protected such communications from discovery. *Id.* at *14. In *In re Application of Republic of Ecuador*, 280 F.R.D. 506 (N.D. Cal. 2012), the court concluded that draft worksheets prepared by an expert's assistants for use in his expert report were protected, but draft worksheets prepared by an employee of the party for the same use were not. *Id.* at 515. The court concluded that "[c]ommunications among non-attorney [company] employees and [the expert] are not work product and simply labelling them 'work product' or 'attorney-client privilege' does not suffice". *Id.* Similarly, *United States v. Sierra Pacific Industries*, No. Civ. S-09-2445, 2011 WL 2119078 (E.D. Cal. May 26, 2011), criticised *Graco* and opined that the unique nature of "hybrid fact and expert opinion witnesses" means that "it is even more important that a witness who is testifying regarding his own personal knowledge of facts be unbiased", and therefore "discovery should be permitted into such witnesses' communications with attorneys, in order to prevent, or at any rate expose, attorney-caused bias". *Id.* at *10; *accord PacifiCorp v. Nw. Pipeline GP*, 879 F. Supp. 2d 1171, 1213 (D. Or. 2012). Given this uncertainty, care should be taken before sharing otherwise privileged information with non-reporting experts.

Revisions to the Federal Rules of Civil Procedure Governing Discovery

Critics have long observed that discovery in U.S. courts tends to be broader and costlier than discovery in many other judicial systems. In addition, because companies' records and communications have overwhelmingly come to be made and kept electronically, difficult questions have arisen in recent years regarding whether, when, and how a company must preserve information related to potential litigation. A pending proposal to amend the Federal Rules of Civil Procedure aims to address these issues by clarifying the scope of discovery and reducing uncertainty over the consequences of a failure to preserve electronically stored information ("ESI"). A central purpose of the amendments is to "improv[e] the disposition of civil cases by reducing the costs and delays in civil litigation." Rep. of the Judicial Conf. Comm. on Rules of Prac. & Proc., Sept. 2014, at 13 ("Comm. Rep."). The proposal was approved by the Judicial Conference Committee on Rules of Practice and Procedure in September 2014. The amendments are pending approval before the U.S. Supreme Court, which is expected to propose them back to Congress by May 1, 2015. It currently is expected that the amendments will go into effect on December 1, 2015.

In an effort to narrow the breadth of civil discovery, the amendments would add the italicised language to Federal Rule of Civil Procedure 26(b)(1), which governs the scope of discovery: "Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, *considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit*." Comm. Rep., Rules App. B-30 (emphasis added). Although some of these "proportionality factors" already are stated elsewhere in Rule 26, the proposal would "make them an explicit component of the scope of discovery, requiring parties and courts alike to consider them when pursuing discovery and resolving discovery disputes." *Id.*, Rules App. B-8. These changes may aid parties in arguing for a more tailored discovery plan, given the burden and expense involved in preserving, gathering, and producing all possible information about a particular product or practice.

The amendments also would revise Federal Rule of Civil Procedure 37(e), which addresses the sanctions a trial court can impose if a party fails to produce ESI in discovery. The Rules Committee determined that entities (in particular, large corporations) are spending millions of dollars to *over*-preserve ESI in the fear that they might someday be sued and then accused of failing to preserve data relevant to the lawsuit. *Id.*, Rules App. B-14. This difficulty has been exacerbated in recent years by disagreements among the federal courts about when a duty to preserve ESI is triggered, *compare In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 11-MD-2299, 2014 WL 2921653, at *14 (W.D. La. June 23, 2014), *with In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL 2327, 2014 WL 439785, at *8 (S.D. W. Va. Feb. 4, 2014), and when a failure to do so can warrant sanctions, *compare Stocker v. United States*, 705 F.3d 225, 235 (6th Cir. 2013) (noting that "negligent conduct may suffice to warrant spoliation sanctions"), *with Florida Mun. Power Agency v. FERC*, 602 F.3d 454, 461 (D.C. Cir. 2010) (requiring conscious disregard of preservation obligations). The new Rule 37(e) would provide that:

> If electronically stored information that should have been preserved in the anticipation or conduct of litigation is lost because a party failed to take reasonable steps to preserve it, and it cannot be restored or replaced through additional discovery, the court[,] upon finding prejudice to another party from loss of the information, may order measures no greater than necessary to cure the prejudice[.]

Comm. Rep., Rules App. B-56–57. The harshest sanctions – an adverse presumption by the court, an adverse inference instruction to the jury, or outright dismissal – would be permitted "only upon [a] finding that the party acted with the intent to deprive another party of the information's use in the litigation." *Id.*, Rules App. B-57. Moreover, when a court imposes lesser sanctions, "there must be a finding of prejudice, the measures must be no greater than necessary to cure the prejudice, and the court may not impose the severe measures listed in [Rule 37](e)(2)." *Id.*, Rules App. B-17. These measures may provide more predictability to the discovery process, help clarify the scope of ESI preservation obligations, and provide relief to parties who inadvertently lose ESI.

Consumer Fraud Class Actions

Consumer fraud class actions typically seek damages for economic losses based on a manufacturer's alleged misrepresentations about a product. Plaintiffs' counsel may bring such actions in part based on perceived advantages over traditional state tort, such as the potential availability of treble damages and attorneys' fees (in contrast to the usual American Rule that each party bears its own fees) – and perceived lower requirements for proof of individual reliance, which is typically a highly individualised question making class certification improper. *See, e.g., In re St. Jude Med., Inc.*, 522 F.3d 836, 840 (8th Cir. 2008) (explaining, where reliance was required, that class certification was improper given that questions of liability as to each plaintiff "will be dominated by individual issues of causation and reliance"). Recent developments in California and in the federal courts have further clarified the parameters for pleading and proving reliance and other requirements in the context of consumer fraud class actions.

California

In November 2004, California voters approved Proposition 64, which limited standing under California's Unfair Competition

Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq*., to persons who "suffered injury in fact" and "lost money or property as a result of the unfair competition". Cal. Bus. & Prof. Code § 17204. The California Supreme Court has determined that this standing requirement applies only to a class representative; absent class members need not pass this test. *In re Tobacco II Cases*, 207 P.3d 20, 31-38 (Cal. 2009). Following *Tobacco II*, California appellate courts have upheld denials of class certification where it could not be established that the defendant engaged in uniform conduct likely to mislead the entire class. For example, in *Davis-Miller v. Automobile Club of Southern California*, 201 Cal. App. 4th 106 (2011), the court explained that "[a]n inference of classwide reliance cannot be made where there is no evidence that the allegedly false representations were uniformly made to all members of the proposed class". *Id.* at 125; *see Knapp v. AT&T Wireless Servs., Inc*., 195 Cal. App. 4th 932, 945 (2011) (same).

Class Actions in Federal Courts

Constitutional and procedural requirements in federal courts may provide defendants with additional arguments against class certification. The growth of federal court defences is significant because, as noted above, under CAFA, many class actions are now filed in, or removed to, federal court.

The U.S. Supreme Court's watershed decision in *Wal-Mart v. Dukes*, 131 S. Ct. 2541 (2011), "has significant implications for all class action litigation in federal court", including consumer fraud class actions, imposing a "significantly more demanding test for commonality than had been previously articulated and required by the Court". Erwin Chemerinsky, *New Limits on Class Actions*, 47 TRIAL 54, 54-55 (2011). *Wal-Mart* reversed "certification of a class comprising about one and a half million plaintiffs, current and former female employees" alleging gender discrimination by their employer. *Wal-Mart*, 131 S. Ct. at 2547. The Court held: "Commonality requires the plaintiff to demonstrate that the class members have suffered the same injury. This does not mean merely that they have all suffered a violation of the same provision of law . . . . Their claims must depend upon a common contention . . . of such a nature that it is capable of classwide resolution – which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke". *Id.* at 2551 (internal quotation omitted). Previously, "all that [had] been required for commonality [was] some issue of law or fact that is shared among the members of the class; distinct issues [could] then be tried separately". Chemerinsky, *New Limits on Class Actions* at 54. After *Dukes*, "[p]laintiff lawyers must search for a class action small enough to meet the commonality requirement but large enough to meet the numerosity requirement". *Id.* at 56.

Based on *Dukes*, a number of circuits have held that classes of plaintiffs bringing consumer fraud actions cannot be certified where the consumer protection laws of multiple states would apply. *E.g., Mazza v. Am. Honda Motor Co*., 666 F.3d 581, 596 (9th Cir. 2012); *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 946 (6th Cir. 2011). In *Mazza*, the court analysed *Wal-Mart* and concluded that plaintiffs failed to demonstrate that "'the questions of law or fact common to class members predominate'" as required by Federal Rule 23(b)(3). 666 F.3d at 589. The court recognised material differences among the various state consumer protection laws that would apply to different plaintiffs, including different scienter and reliance requirements. *Id.* at 591. *Mazza* also observed that reliance by all consumers in the class on the defendant's allegedly misleading advertisements could not be presumed where the advertising was of "limited scope", unlike the "massive advertising campaign" at issue in *Tobacco II*. *Id.* at 596.

In *Comcast Corp. v. Behrend*, 133 S. Ct. 1426 (2013), another landmark opinion, the Supreme Court addressed Rule 23(b)(3)'s predominance requirement. The Court reversed certification of a class of subscribers to the defendant's cable-television services, determining that plaintiffs had not shown that their damages for alleged antitrust violations could be calculated on a classwide basis, because "the [damages] model [asserted by plaintiffs] failed to measure damages resulting from the particular antitrust injury on which petitioners' liability in this action is premised". *Id.* at 1433. In other words, the methodology "identifies damages that are not the result of the wrong", *id.* at 1434, and, accordingly, "[q]uestions of individual damage calculations will inevitably overwhelm questions common to the class", such that class certification was improper. *Id.* at 1433. After *Comcast*, plaintiffs bringing class actions – including those asserting product liability or consumer fraud claims – may be required to demonstrate an ability to calculate damages on a classwide basis through means tailored to the injuries alleged. The Second Circuit, however, recently canvassed the circuit decisions applying *Comcast* and concluded that *Comcast* "'simply' requires that a damages calculation reflect the associated theory of liability", and "did not foreclose the possibility of class certification . . . in cases involving individualized damages calculations". *Roach v. T.L. Cannon Corp*., No. 13-3070-CV, 2015 WL 528125, at *6 (2d Cir. Feb. 10, 2015) (collecting cases).

Federal courts also continue to reject theories of plaintiff reliance premised on a "fraud-on-the-market" approach outside the securities litigation context. For example, the Eleventh Circuit affirmed dismissal of a New Jersey Consumer Fraud Act claim, explaining that under a "fraud-on-the-market" theory, a plaintiff improperly presumes that defendant's "misleading advertising inflated the price the plaintiffs paid for their products". *See, Laborers Health & Welfare Fund v. Bayer Corp*., 444 F. App'x 401, 406 (11th Cir. 2011). "[T]o the extent that plaintiff seeks to prove only that the price charged for [the product] was higher than it should have been as a result of defendant's fraudulent marketing campaign, and seeks thereby to be relieved of the usual requirements that plaintiff prove an ascertainable loss, the theory must fail." *Id.* at 405-06; *see also CGC Holding Co., LLC v. Broad & Cassel*, 773 F.3d 1076, 1095 (10th Cir. 2014) (the "fraud-on-the-market" presumption "is uniquely applicable in the securities context" and was not appropriately applied to certify a class in a consumer fraud class action under the Racketeer Influenced and Corrupt Organizations Act ("RICO")).

Standing Arguments in Federal Court

Even if applicable law does not require that absent class members actually rely on the defendant's alleged misrepresentation, a putative class action that includes many individuals who did not rely on the alleged misrepresentation gives rise to a fundamental problem: standing. The federal courts' jurisdiction is constitutionally limited to plaintiffs who allege an "injury in fact" caused by the defendant's conduct. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). In upholding the denial of class certification in the context of consumer protection claims, the Eighth Circuit underscored that "[a] district court may not certify a class . . . 'if it contains members who lack standing.'" *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 616 (8th Cir. 2011). Similarly, the federal judge in an MDL involving the use of bisphenol-A in baby bottles and sippy cups refused to certify three classes of consumers, in part because "[i]ndividuals who knew about BPA's existence and the surrounding controversy" and purchased defendants' products anyway have no injury, nor do those consumers who "fully used Defendants' baby bottles and other products without physical harm before learning

about BPA." *In re Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig.*, No. 08-1967, 2011 WL 6740338, at *1-2 (W.D. Mo. Dec. 22, 2011). Similarly, in an MDL proceeding concerning allegations of lead in fruit juice, plaintiffs' claims were dismissed because they "fail[ed] to allege any actual injury caused by their purchase and consumption of the products". *In re Fruit Juice Prods. Mktg. & Sales Practices Litig.*, 831 F. Supp. 2d 507, 510 (D. Mass. Dec. 21, 2011). The court held that "Plaintiffs' allegations of risk of future harm to class members are insufficient to meet the 'credible or substantial threat' standard. The claim of potential future injury is simply too hypothetical or conjectural to establish Article III standing". *Id.* at 511. *See also Denney v. Deutsche Bank AG*, 443 F.3d 253, 263-64 (2d Cir. 2006) ("We do not require that each member of a class submit evidence of personal standing . . . At the same time, no class may be certified that contains members lacking Article III standing."); *but see In re Nexium Antitrust Litig.*, 777 F.3d 9, 32 (1st Cir. 2015) (citing *Denney* and questioning whether "it is necessary that each and every member of the class who secures a recovery also has standing").

Pleading Requirements in Federal Court

Federal Rule of Civil Procedure 9(b) requires that fraud claims be pled with specificity. Thus, to satisfy Rule 9(b), plaintiffs bringing consumer fraud claims must plead "'the who, what, when, where, and how of the fraud'". *Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 737 (7th Cir. 2014). Even under the general civil pleading standard for non-fraud claims, a complaint must include "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged". *Ashcroft*, 556 U.S. at 678. Federal courts applying these pleading requirements have rejected consumer fraud class actions that rely on formulaic and non-specific allegations. *In re Actimmune Mktg. Litig.*, No. C 08-02376, 2010 WL 3463491, at *10 (N.D. Cal. Sept. 1, 2010) (rejecting consumer fraud class because the complaint did not explain how doctors may have relied on the defendant's alleged misrepresentations); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2010 WL 2464746, at *7-8 (D.N.J. June 9, 2010) (rejecting consumer fraud class because the class representative failed to plead any nexus between the defendant's alleged misconduct and her doctor's prescribing decision), *aff'd*, 678 F.3d 235 (3d Cir. 2012); *Franulovic v. Coca-Cola Co.*, No. 07-539, 2007 WL 3166953, at *7 (D.N.J. Oct. 25, 2007) (dismissing a consumer fraud act claim based on the alleged purchase of the defendant's soft drink, Enviga, because the plaintiff did not allege "when she purchased Enviga or for what price, how much of the beverage she purchased and consumed, which advertising enticed her to buy Enviga, her expectations for Enviga based on the advertising, or Enviga's failure to live up to those expectations").

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