



ICLG

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■ Preface by Tom Spencer, Counsel, GlaxoSmithKline Plc.

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Update on U.S. Product Liability Law

Michael W. Davis



Rebecca K. Wood



Sidley Austin LLP

Introduction

Federal preemption has continued to be a contested issue in product liability law in the wake of significant decisions by the United States Supreme Court, with federal courts of appeals deciding numerous matters further refining when product liability claims may be brought against the makers of prescription drugs and medical devices.

Courts also have rendered important decisions involving recent statutory and rules changes, most notably in the areas of personal jurisdiction, federal jurisdiction, and designation of experts in federal courts. 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 class certification of consumer fraud claims.

This chapter provides updates on each of these topics:

- Preemption.
- Personal Jurisdiction and the Alien Tort Statute.
- Clarification of Federal Removal, Jurisdiction, and Venue Provisions.
- Federal Jurisdiction under the Class Action Fairness Act.
- Update to Federal Rules: Expert Designations.
- Consumer Fraud Class Actions.

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; *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1,211 (1824). In deciding whether a claim is preempted, courts determine whether Congress intended the federal law to supplant state law. See, e.g., *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504,516 (1992) (“[The] purpose of Congress is the ultimate touchstone of pre-emption analysis”) (internal quotation omitted). 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, litigation involving preemption with respect to pharmaceuticals and medical devices approved by the United States Food and Drug Administration (“FDA”) has received considerable attention from the United States Supreme Court and other United States courts. 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 the 2011 edition of this Guide); *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that FDA approval of a prescription medication’s warnings

did not impliedly preempt certain state law tort claims) (discussed in 2009 edition of this Guide).

Pharmaceutical Preemption.

In a case with far-reaching implications for pharmaceutical preemption, the Supreme Court recently held, by a 5-4 margin, that certain product liability claims brought against generic drug makers are impliedly preempted. *Pliva, Inc. v. Mensing*, 564 U.S. ___, 131 S. Ct. 2567 (2011). In *Mensing*, the plaintiffs alleged that the manufacturers of generic metoclopramide failed to adequately warn of the risk of tardive dyskinesia, a severe and often irreversible neurological disorder. *Id.* at 2572. The manufacturers argued that plaintiffs’ claims were preempted because federal law requires generic medications to carry warnings identical to their brand-name equivalents. *Id.* at 2574. The purpose of this law was to “allow[] manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug”. *Id.*

Plaintiffs asserted three bases on which the manufacturers could have independently modified the warnings: (1) by using FDA’s changes-being-effected (“CBE”) process; (2) by sending Dear Doctor letters to physicians; or (3) by proposing stronger warnings to FDA. *Id.* at 2574-77. The Court rejected the first two bases, noting the FDA denied that a generic drug maker could unilaterally strengthen its labeling by using the CBE process or disseminating a Dear Doctor letter. *Id.* at 2576. As to the third basis, 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 were free to ask 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 ultimately rejected this “Mouse Trap game” argument because even if the generic manufacturer had proposed different labeling to the FDA, it was not clear that the agency, in exercise of its public health judgment, would have agreed and permitted the 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 generics 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’ labeling.

After *Mensing*, numerous courts have dismissed inadequate warning claims brought against generic manufacturers. See, e.g., *In re Pamidronate Prods. Liab. Litig.*, No. 09-MD-2120, 2012 WL 272889, at *3 n.6 (E.D.N.Y. Jan. 30, 2012) (collecting cases); see also *McNeil-PPC, Inc. v. Hutto*, 86 So.3d 628 (La. Ct. App.) (whether *Mensing* preempts state law failure-to-warn claims involving over-the-counter (OTC), nonprescription drugs, where drug label was consistent with OTC monograph and could not be changed by manufacturer without prior FDA approval), cert. denied (October 9, 2012) (Nos. 12-122).

Plaintiffs have tested the limits of *Mensing* by advancing theories of liability beyond failure to warn. For example, some plaintiffs have contended that if the generic manufacturer could not amend the labeling, it should have withdrawn the drug from the market. E.g., *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-2226-DCR, 2012 WL 718618 at *3 (E.D. Ky. Mar. 5, 2012). Many courts have rejected this “failure-to-withdraw theory”. *Id.* at *3 (“[T]he idea that [manufacturers] should have simply stopped selling propoxyphene is an oversimplified solution that could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether.”) (citing *Mensing*, 131 S. Ct. at 2579); accord *Gross v. Pfizer, Inc.*, No. 10-cv-00110, 2011 WL 5865267, at *3 (D. Md. Nov. 22, 2011) (noting that the Supreme Court rejected this very argument in *Mensing*); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, No. 08-008, 2011 WL 5903623, at *6 n.5 (D.N.J. November 21, 2011) (same).

More recently, however, the First Circuit took a contrary view, and the Supreme Court is poised to consider the issue in *Mutual Pharmaceutical Company, Inc. v. Karen L. Bartlett* (12-142). In *Bartlett*, the First Circuit held that state law design-defect claims against generic drugs were not preempted because any conflict could be avoided if manufacturers simply stopped manufacturing those products. *Bartlett*, 678 F.3d 30 (1st Cir. 2012). Specifically, the First Circuit concluded that “although [the generic manufacturer] cannot legally make [the drug] in another composition (nor is it apparent how it could alter a one-molecule drug anyway), it certainly can choose not to make the drug at all; and the FDCA might permit states to tell [a generic manufacturer] it ought not be doing so if risk-benefit analysis weights against the drug, despite what the Supreme Court made of similar arguments in the labelling context”. *Id.* at 37. The First Circuit acknowledged “tension” with *Mensing*, *id.* at 38, but affirmed a \$21.06 million judgment for plaintiff. Before the Supreme Court, FDA filed an *amicus curiae* brief arguing that the First Circuit’s “reasoning cannot be squared with *Mensing*, which reflects and implicit judgment that the option of withdrawing from the market is not sufficient to defeat impossibility preemption in this context”. Brief for the United States as *Amicus Curiae* Supporting Petitioner 12, *Mensing*, 564 U.S. ___. FDA further argued that plaintiff’s design defect claim is preempted because it “rests on the premise that the active ingredient of a drug that FDA approved as safe and effective for its labeled conditions of use” is actually “unreasonably dangerous” as a matter of state law. *Id.* at 14. FDA urged that conflict preemption applies when a plaintiff brings “a pure defective-drug-design claim that require[s] a jury to second-guess FDA’s safety determination, without any further need to find the existence of new and scientifically significant evidence that rendered the product misbranded under federal law”. *Id.* at 34.

Additional post-*Mensing* theories also have been litigated. For example, one potential way to survive *Mensing* is to allege that the generic labeling did not match the brand labeling 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) (claim that manufacturer failed

to update generic labeling to match its brand-name counterpart’s was not preempted). Other courts have considered whether allegations that the generic manufacturer should have disseminated a Dear Doctor letter consistent with, and not stronger than, the drug’s approved labeling, survive preemption. See *Brasley-Thrash v. Teva Pharm. 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, 802 (D.S.C. 2011). Some courts have questioned whether a letter alerting physicians to an FDA-approved label change “would arguably not be inconsistent with the drug’s approved labeling”. *Fisher*, 817 F. Supp.2d at 814.

Mensing has had additional implications for product liability risk. Where *Mensing* may make it harder plaintiffs to recover against a generic manufacturer, some cases have explored whether a patient may sue the brand manufacturer on a theory of “innovator liability”. For example, the Alabama Supreme Court recently accepted a theory of innovator liability in *Wyeth Inc. et al. v. Weeks et al.*, 2013 WL 135753 (Sup. Ct. Ala. Jan. 11, 2013). *Weeks* involved the drug Reglan and noted a split in case law about innovator liability. *Id.* at 3. *Weeks* concluded that “[i]n the context of inadequate warnings by the brand-name manufacturer placed on a prescription drug manufactured by a generic-drug manufacturer, it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce because of 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 by the generic manufacturer”. *Id.* at 52.

The dissent criticised the *Weeks* ruling as violating “bedrock principles of tort law and of economic realities underlying those principles” and being out of sync with “almost every one of the 47 reported cases decided before the United States Supreme Court’s decision in [*Mensing*], including cases decided by two United States Circuit Courts of Appeals, hold[ing] that a manufacturer of a brand-name drug has no duty to the consumer of a generic drug manufactured and sold by another company”. *Id.* at *20-21 (Murdoch, J., dissenting); *id.* at n.8 (collecting cases). See, e.g., *Foster v. American Home Prods. Corp.*, 29 F.3d 165, 167 (4th Cir. 1994) (“[A] name brand manufacturer cannot be held liable on a negligent misrepresentation theory for injuries resulting from use of another manufacturer’s product”); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612-14 (8th Cir. 2009) (defendant brand-name manufacturer has no duty or liability with respect to generic drug not manufactured or sold by it), *rev’d in part on other grounds sub nom. Mensing*, 564 U.S. ___.

Other branches of government besides the judiciary also have responded to *Mensing*. After *Mensing*, Senator Patrick Leahy introduced a bill in Congress to permit generic manufacturers to amend the warnings for their products, though the bill was not voted out of committee. For its part, FDA noted in its *amicus* brief in *Bartlett* that it is considering allowing generic-drug makers to change their labeling in certain circumstances. Br. for the United States as *Amicus Curiae* Supporting Petitioner at 15 n.2, *Bartlett*, *supra* (“If such a regulatory change is adopted [by FDA], it could eliminate preemption of failure-to-warn claims against generic-drug manufacturers”).

Buckman Preemption.

Recently, the Ninth Circuit, sitting *en banc*, held that federal law did not impliedly preempt an Arizona state law failure-to-warn claim 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. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232 (9th Cir. 2013). The Ninth Circuit did so despite the Supreme Court’s holding in *Buckman*, that plaintiffs’ 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 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 Ninth Circuit’s holding departs 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). *Stengel* already has been distinguished and limited to its facts by other federal courts. See *Simmons v. Boston Scientific Corp.*, No. 12-7962 PA (FFMx), 2013 WL 1207421 (C.D. Cal. Mar. 25, 2013) (dismissing claims as preempted).

Additional *Buckman*-related issues also are percolating in the courts of appeals. The federal courts of appeals continue to divide over a preemption question the Supreme Court left unresolved in *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008). At issue in *Kent* was a Michigan statute that immunised pharmaceutical manufacturers from product liability suits unless the plaintiff could show that FDA would not have approved the medication but for the manufacturer defrauding FDA. As the Court was equally divided, *Kent* left undecided a split in the courts of appeals. Compare *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006) (holding that the Michigan statute was not preempted under *Buckman*), with *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004) (holding that the same Michigan statute was preempted by *Buckman*). In 2012, following *Garcia*, the Fifth Circuit held that a Texas statute similar to the Michigan provision was preempted under *Buckman* absent an FDA determination of fraud-on-the-agency. *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 374-75 (5th Cir. February 22, 2012). The court reasoned that in cases “where the FDA has not found fraud, the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities”. *Id.* at 380.

“Parallel Claims” Against Manufacturers Of Certain Medical Devices.

Preemption of claims against medical device manufacturers have seen considerable attention in the federal courts in recent years. In 2008, the 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 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 light of the pleading requirements imposed by *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), lower courts have considered what plaintiffs must plead to state a sufficient “parallel claim” against a PMA device manufacturer. Generally, to state a plausible parallel claim against a PMA device manufacturer, plaintiffs must plead sufficient factual matter to “allow[] the court to draw the reasonable inference that the defendant” violated PMA requirements relating to the device. *Iqbal*, 129 S. Ct. at 1949. This requires more than “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements”. *Id.* In general, “[d]etermining 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.

Two broad categories of parallel claims have been subject to litigation after *Riegel*: breach of warranty claims and manufacturing defect claims. See *Samuel Raymond, Judicial Politics and Medical Device Preemption After Riegel*, 5 N.Y.U. J. LAW & LIBERTY 745, 766 (2010).

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.
- The Eleventh Circuit held plaintiff’s claims preempted in *Wolicki-Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011), where the plaintiff alleged that the manufacturer “failed to reasonably design the [device] in a manner which would have prevented injury”, “failed to reasonably manufacture the [device] in a reasonable manner”, and “failed to reasonably provide adequate warnings regarding the defective and unreasonably dangerous [device]”.
- The Fourth Circuit rejected a claim that an allegedly defective drug-infusion pump “failed to adhere to the plus or minus 15 percent 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”. *Walker v. Medtronic*, No. 10-2219, 2012 WL 208036, at *5 (4th Cir. January 25, 2012). The court held that 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”, and because the 15 percent specification was not a “formal performance standard” or a “requirement of the device’s premarket approval”. *Id.* at *6-8; but see *id.* at *10-14 (Wynn, J., dissenting).

The Fifth Circuit has rejected certain attempts to plead parallel claims while allowing others:

- *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011), held that 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 Boston Scientific despite Boston Scientific’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”. Plaintiff’s claim, on the other hand, survived, but only to the extent it was based on an alleged “failure to comply”. *Id.* at 769.

- Applying *Funk and Hughes*, the Fifth Circuit more recently concluded that sufficient parallel claims were plaintiff pleaded: “(1) he received a Shell implant; (2) the FDA had previously warned [defendant] of bio-burden in excess of FDA regulations in its final rinse of the Shells; (3) after [plaintiff’s] surgery, [defendant] ultimately voluntarily recalled those Shells, including the Shell specifically used in [plaintiff’s] implant; (4) [plaintiff] suffered from a loose Shell 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 Shells”. *Bass v. Stryker Corp.*, No. 11-10076, 2012 WL 266985, at *5 (5th Cir. January 31, 2012).

Personal Jurisdiction and the Alien Tort Statute

For the first time in 20 years, the United States Supreme Court recently handed down two 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 jurisdiction and specific jurisdiction. General jurisdiction, considered in *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846 (2011), refers to when a corporation’s contacts with the forum are “continuous and systematic”. *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 317 (1945). By contrast, a court may exercise specific jurisdiction, considered by the Court in *J. McIntyre Machinery, Ltd. v. Nicastro*, 131 S. Ct. 2780 (2011), “in a suit 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).

In *Goodyear*, the Supreme Court considered whether foreign subsidiaries of a United States parent corporation were amenable to suit in a North Carolina state court on claims unrelated to any activity of the subsidiaries in the forum state. Specifically, parents of children who died in a bus accident outside of Paris, France, sued Goodyear USA, an Ohio corporation, and three of its subsidiaries, organised and operating, respectively, in Turkey, France, and Luxembourg, alleging that a defective tyre manufactured in a plant of the Turkey subsidiary, caused the accident. *Goodyear Dunlop*, 131 S. Ct. at 2850. The only contacts that the subsidiaries had with North Carolina were the distribution of a small percentage of their tyres there by other Goodyear USA affiliates. *Id.* at 2852. Nonetheless, the North Carolina appellate court held that general jurisdiction existed over the foreign subsidiaries based on the stream-of-commerce approach—*i.e.*, that the “[f]low of a manufacturer’s products into the forum” serves as a basis for asserting personal jurisdiction. *Id.* at 2849, 2855. In a unanimous decision, the Supreme Court 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. In so holding, the Supreme Court recognised that the stream-of-commerce approach may “bolster an affiliation germane to specific jurisdiction”, but not general jurisdiction, over a defendant. *Id.* at 2855.

After *Goodyear Dunlop*, numerous courts have noted that “the issue under the Due Process Clauses of the Fifth and Fourteenth Amendments is whether the contacts are so ‘continuous and systematic’ as to render [defendants] essentially at home in the forum”. *Abelesz v. OTP Bank*, 692 F.3d 638, 654 (7th Cir. 2012) (no general jurisdiction where accounts owned by U.S. citizens and persons with U.S. mailing addresses account for only 0.17 percent

and 0.4 percent of defendants total worldwide accounts) (quoting *Goodyear Dunlop*, 131 S. Ct. at 2851) (emphasis added); *see, e.g., Pervasive Software Inc. v. Lexware GmbH & Co. KG*, 688 F.3d 214, 231 (5th Cir. 2012) (no general jurisdiction where foreign defendant communicated with U.S. plaintiff and made 15 Internet sales totaling \$915 to German taxpayer consumers with billing addresses in Texas); *Monge v. RG Petro-Machinery (Group) Co.*, 701 F.3d 598, 620 (10th Cir. 2012) (no general jurisdiction where a Chinese manufacturer had no physical presence in Oklahoma and made only a limited number of sales to a single Oklahoma resident).

In *Nicastro*, the Supreme Court reversed a decision to allow personal jurisdiction over a foreign corporation. Although all of the 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), they could not agree on what constitutes purposeful availment. In *Nicastro*, the plaintiff filed suit in New Jersey state court after injuring his hand while using a machine in New Jersey that was manufactured by the defendant in England, the place of defendant’s incorporation and operation. Although the New Jersey Supreme Court concluded that defendant did not have minimum contacts in New Jersey, it nonetheless held that jurisdiction was proper because: (1) plaintiff was injured in New Jersey; (2) 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) defendant failed to take reasonable steps to prevent the distribution of its products in New Jersey. 131 S. Ct. at 2786, 2790. A plurality of U.S. Supreme Court justices concluded that “it is the defendant’s actions, not his expectations, that empower a State’s courts to subject him to judgment”, thereby rejecting foreseeability, and reinforcing the purposeful availment, as the key inquiry. *See id.* at 2789-92. Accordingly, the plurality concluded that defendant’s actions (*i.e.*, that its distributor agreed to sell machines in the U.S.; that its officials attended trade shows in several states (excluding New Jersey); that up to four machines ended up in New Jersey) “may reveal an intent to serve the U.S. market”, but “do not show that [defendant] purposefully availed itself of the New Jersey market”. *Id.* at 2790. Two Justices reached the same conclusion, but disagreed with the plurality’s rationale, saying that it improperly “refashioned 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 defendant “endeavor[ed] to reach and profit from the United States market as a whole” and therefore “availed itself of the market of all States in which its products were sold by its exclusive distributor”. *Id.* at 2797, 2801.

In the wake of *Goodyear* and *Nicastro*, foreign manufacturers, including subsidiaries of U.S. companies, consider the manner in which they structure their U.S. operations to manage their exposure to litigation in different jurisdictions. Nevertheless, because the Supreme Court did not reach a consensus rationale in *Nicastro*, the limits of specific jurisdiction remain unsettled. Indeed, the courts of appeals have viewed *Nicastro* as doing little to settle the split of authority created in *Asahi Metal Indus. Co. v. Super. Ct. of Cal.*, 480 U.S. 102 (1987), where “courts reached two different interpretations of the stream of commerce approach to purposeful availment”, *Monge*, 701 F.3d at 619. In *Asahi*, one approach, penned by Justice Brennan 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”. *Id.* at 117. The second approach,

penned by Justice O'Connor, writing for three other Justices, disagreed stating, "[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. Despite the opportunity to do so, the Supreme Court, "declined to resolve the *Asahi* split" in *Nicastro*. *AFTG-TG, LLC v. Nuvoton Tech. Corp.*, 689 F.3d 1358, 1363 (Fed. Cir. 2012). Without a majority opinion, the courts of appeals follow the narrowest holding amongst the plurality opinions rendered in *Nicastro*. See *Marks v. United States*, 430 U.S. 188, 193 (1977). According to at least one court of appeals, "[t]he narrowest holding is that which can be distilled from Justice Breyer's concurrence—that the law remains the same" after *Nicastro*. *AFTG-TG, LLC*, 689 F.3d at 1363.

Nicastro leaves open numerous questions—including how personal jurisdiction will apply in an increasingly globalised, web-based economy. Indeed, two Justices in *Nicastro* openly questioned how the case would be applied to modern-day Internet marketing and distribution: "The plurality seems to state strict rules that limit jurisdiction where a defendant does not 'intend[] to submit to the power of a sovereign' and cannot 'be said to have targeted the forum.' . . . But what do those standards mean when a company targets the world by selling products from its Web site? And does it matter if, instead of shipping the products directly, a company consigns the products through an intermediary (say, Amazon.com) who then receives and fulfills the orders? And what if the company markets its products through pop-up advertisements that it knows will be viewed in a forum?" *Nicastro*, 131 S. Ct. at 2793 (Breyer, J. and Alito, J. concurring in the judgment). A future case presenting "relevant contemporary commercial circumstances" could compel the Supreme Court to further refine personal jurisdiction concepts in light of "many recent changes in commerce and communication, many of which are not anticipated by our precedents". *Id.* at 2791, 2794.

Foreign corporations also should be aware of recent developments involving the scope of the Alien Tort Statute ("ATS"), which has been used in recent years to seek a U.S. forum for certain torts occurring outside the U.S. Enacted as part of the Judiciary Act of 1789, the ATS provides federal courts with "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. In *Sosa v. Alvarez-Machain*, 542 U.S. 692 (2004), the Supreme Court determined that ATS claims must be based on alleged violations of customary international law claims, "rest[ing] on a norm of international character accepted by the civili[s]ed world and defined with a specificity comparable to the features of the 18th century paradigms". *Id.* at 725. The Court observed that Congress had focused on three offences in authorising the ATS: "violation of safe conducts, infringement of the rights of ambassadors, and piracy". *Id.* at 724. *Sosa* left unresolved whether the ATS applies where "the defendant is a private actor such as a corporation or individual". *Id.* at 732 n. 20.

In *Kiobel v. Royal Dutch Petroleum*, 569 U.S. ___, ___ (2013), the Supreme Court addressed whether and in what circumstances the ATS allows U.S. courts to recognise a cause of action for violations of the law of nations occurring within the territory of a sovereign other than the United States. The Court held that "the presumption against extraterritoriality applies to claims under the ATS". *Kiobel*, slip op., at 13. Under this presumption, "when a statute gives no clear indication of an extraterritorial application, it has none". *Id.* at 4 (internal quotation omitted). Accordingly, "the petitioners' case seeking relief for violations of the law of nations occurring outside the United States is barred". *Id.* at 14. As to future cases, "even where the claims touch and concern the territory of the United States, they must do so with sufficient force to displace the

presumption against extraterritorial application. . . . Corporations are often present in many countries, and it would reach too far to say that mere corporate presence suffices". *Id.*

Clarification of Federal Removal, Jurisdiction, and Venue Provisions

The Federal Courts Jurisdiction and Venue Clarification Act of 2011 ("FCJVCA")—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. Many of these changes are likely to enhance defendants' federal jurisdictional 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 that the defendant does not need to simultaneously defend itself in multiple courts. Removal is governed by statute and requires that the federal courts have subject matter jurisdiction over the action. A defendant generally has 30 days after formal service of the initial pleading to file a notice of removal. 28 U.S.C. § 1446(2).

The most common basis for subject matter jurisdiction over product liability cases is so-called diversity jurisdiction. The federal courts have diversity jurisdiction where (1) the parties are diverse (typically, citizens of different states), and (2) there is a minimum amount-in-controversy. 28 U.S.C. § 1332. The minimum amount-in-controversy for individual actions must exceed \$75,000. 28 U.S.C. § 1332(a). The aggregate amount-in-controversy under the Class Action Fairness Act ("CAFA") must exceed \$5 million. 28 U.S.C. § 1332(d)(2)-(10). Although not every state requires a plaintiff to plead specific damages in the complaint, it often is facially obvious from the nature of the alleged conduct and injuries that the plaintiff has put in dispute an amount that exceeds the jurisdictional minimum. Where the amount-in-controversy is difficult to discern from the face of the complaint, however, there was confusion in the courts about how the jurisdictional minimum requirement could be satisfied. See Charles Alan Wright & Arthur R. Miller, 14C Federal Practice And Procedure: Jurisdiction § 3725.1 (West 4th ed. 2011) (observing at least five different standards that courts use to assess the adequacy of the showing that the amount-in-controversy requirement is satisfied).

FCJVCA addresses this difficulty. When a pleading is silent about damages, or the amount-in-controversy is not facially apparent, the defendant may establish the amount-in-controversy through other documents. See 28 U.S.C. § 1446(c)(2)(B). If the defendant lacks information regarding the requisite amount within the 30-day removal period, FCJVCA clarifies that the defendant may utilise discovery in the state court proceeding to determine the amount-in-controversy. See 28 U.S.C. § 1446(c)(3)(A). The 30-day removal period is then triggered when a statement in response to discovery requests indicates that the damages exceed the threshold amount. See 28 U.S.C. § 1446(b)(3).

As discussed *infra*, in *Standard Fire Insurance Co. v. Knowles* (No. 11-1450), the Supreme Court recently rejected efforts by named plaintiffs in a class action to prevent a defendant from removing the case to federal court by signing a purportedly binding stipulation that the amount in controversy is below CAFA's \$5 million threshold. 568 U.S. ___, 2013 WL 1104735 (March 19, 2013).

Removal in Multiple Defendant Cases.

FCJVCA also clarifies the timing for removal in multiple-defendant cases. Before these revisions, a split of authority had arisen in the federal courts of appeals about whether each defendant received its own 30-day removal period or whether the statutory period ran only from the time the first defendant was served. *Compare, e.g., Bailey v. Janssen Pharmaceutica, Inc.*, 536 F.3d 1202, 1209 (11th Cir. 2008) (concluding that the 30-day period runs from the date of service on the last-served defendant and permitting earlier-served defendants who failed to act during their own 30-day period to join in, or consent to, the last-served defendant's timely removal); *Marano Enters. v. Z-Teca Rests., LP*, 254 F.3d 753, 757 (8th Cir. 2001) (same); and *Brierly v. Alusuisse Flexible Packaging, Inc.*, 184 F.3d 527, 532 (6th Cir. 1999) (same), with *Getty Oil Corp. v. Ins. Co. of N. Am.*, 841 F.2d 1254, 1263 (5th Cir. 1988) (holding that the first-served defendant and all then-served defendants must join in the notice of removal within 30 days after service upon the first-served defendant). FCJVCA now provides that each defendant has 30 days from his or her own date of service to remove. 28 U.S.C. § 1446(b)(2)(B). The statute further provides that 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. 28 U.S.C. § 1446(b)(2)(C). These changes allow later-served defendants their own opportunity to remove, even if the earlier-served defendants did not initially remove.

Supplemental Jurisdiction.

Apart from diversity jurisdiction, the federal courts also have original jurisdiction over so-called federal questions. FCJVCA clarifies defendants' right of access to federal court when federal questions are joined in a single lawsuit with unrelated state-law claims. The statute previously authorized 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). Although the statute previously authorized the district court either to retain the whole case or to remand all matters in which state law predominated, 28 U.S.C. § 1441(c), many courts would simply remand the entire case to state court, thereby defeating a defendant's access to federal court. *See, e.g., Morales v. Meat Cutters Local 539*, 778 F. Supp. 368, 371 (E.D. Mich. 1991). FCJVCA now provides that if a defendant removes a case under federal-question jurisdiction and there are unrelated state-law claims attached, the federal court must sever and remand the unrelated state-law claims; it may not remand the entire case to state court. This sever-and-remand approach preserves the defendant's right to remove federal questions to federal court.

Transfer of Venue.

Previously, 28 U.S.C. § 1404(a) authorized 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". The 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. FCJVCA resolves this issue and permits an action to be transferred to any district or division to which all parties consent, even if the action could not have been brought there originally.

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

The application of removal and diversity jurisdiction to class actions raises special issues, many of which Congress addressed in the Class Action Fairness Act of 2005 ("CAFA"), Public Law 109-2, 119 Stat. 4 (2005). 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. Case law construing CAFA continues to evolve, but plaintiffs have developed three principal strategies to avoid removal to federal court under CAFA:

- Filing substantively identical lawsuits, each naming less than 100 plaintiffs, to avoid qualifying as a mass action under CAFA, *see Tanoh v. Dow Chemical Co.*, 561 F.3d 945 (9th Cir.), cert. denied, 130 S. Ct. 187 (2009) (affirming remand of seven substantively identical actions, each naming 99 plaintiffs).
- Tailoring class and other allegations to invoke a "local controversy" exception to CAFA jurisdiction, *see Lafalier v. State Farm Fire & Cas. Co.*, 391 F. App'x 732 (10th Cir. 2010) (class action met the requirements for invoking the "local controversy" exception to federal jurisdiction under CAFA: (a) that 2/3 or more of the plaintiffs were citizens of the state in which the action was filed; (b) that 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) that 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).
- Disclaiming recovery for amounts at or above the \$5 million minimum amount in controversy, *see Morgan v. Gay*, 471 F.3d 469 (3d Cir. 2006) (affirming remand of a putative class action where plaintiff expressly disclaimed recovery of \$5 million or more).
- *Lowery*, 483 F.3d at 1218-20 (refusing to extrapolate damages based on unsupported extrinsic calculations to find an amount-in-controversy exceeding \$5 million, where the four original plaintiffs sought \$1.25 million and 400 additional plaintiffs were later added to the complaint).

Although some courts have given leeway to such arguments—*see, e.g., Anderson v. Bayer Corp.*, 610 F.3d 390 (7th Cir. 2010) (refusing to treat four substantially identical actions, none of which involved 100 plaintiffs, but if combined would have involved more than 100 plaintiffs, as a single action for the purposes of CAFA jurisdiction); *Johnson v. U.S. Vision, Inc.*, 415 F. App'x 841 (9th Cir. 2011) (requiring proponent of federal jurisdiction to establish with "legal certainty" that the amount in controversy will meet the jurisdictional minimum)—others have attempted to curb attempts to avoid CAFA jurisdiction, *see, e.g., Back Doctors Ltd. v. Metro. Prop. & Cas. Ins. Co.*, 637 F.3d 827, 830 (7th Cir. 2011) (where it was not "legally impossible" for the amount-in-controversy to be met, CAFA jurisdiction is proper; "When removing a suit, the defendant as proponent of federal jurisdiction is entitled to present its own estimate of the stakes; it is not bound by the plaintiff's estimate"); *Pretka v. Kolter City Plaza II, Inc.*, 608 F.3d 744, 754 (11th Cir. 2010) (where defendant supported removal with specific

facts, “combined with reasonable deductions, reasonable inferences, and other reasonable extrapolations”, CAFA jurisdiction was proper even where plaintiffs claimed to not know the extent of their damages).

In a significant decision for defendants, the United States Supreme Court recently held that prior to class certification, a stipulation that the named plaintiff and members of the purported class he claims to represent would seek less than \$5 million in damages will not defeat removal under CAFA. *Knowles*, 2013 WL 1104735. Plaintiff Knowles filed a class action lawsuit in Arkansas state court on behalf of a class of Arkansas insurance policyholders against Standard Fire with respect to its homeowner’s insurance loss payments. To avoid CAFA’s \$5 million jurisdictional minimum, Plaintiff Knowles alleged in his complaint that “Plaintiff and Class stipulate they will seek to recover total aggregate damages of less than five million dollars”. Standard Fire removed the case to federal court under CAFA, but the district court remanded, concluding that the stipulation prevented removal. *Knowles*, 2013 WL 1104735, at *2.

The Supreme Court disagreed, holding that the named plaintiff’s stipulation did not defeat CAFA jurisdiction. *Id.* at *3-6. “To hold otherwise would, for CAFA jurisdictional purposes, 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.’” *Id.* at *5. The Court’s reasoning followed *Smith v. Bayer Corp.*, 564 U.S. ___, 131 S. Ct. 2368, 2380 (2011), that members of a proposed class cannot be bound before the class is certified. *Knowles* reinforces a principal goal of CAFA: preventing plaintiffs from manipulating class action allegations to avoid federal jurisdiction. See *In re Hannaford Bros. Co. Customer Data Security Breach Litig.*, 564 F.3d 75, 80-81 (1st Cir. 2009) (one of the goals of CAFA is to eliminate “abusive practices by plaintiffs and their attorneys” such as “forum shopping to take advantage of state court biases against foreign defendants”).

Update to Federal Rules: Expert Designations

Expert witnesses often play a significant role in product 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). (“In order to give the phrase ‘retained or specially employed’ any real meaning, a court must acknowledge the difference between a percipient witness who happens to be an expert and an expert who without prior knowledge of the facts giving rise to litigation is recruited to provide expert opinion

testimony.”) 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 changes create work-product protections for certain attorney communications with testifying experts. Rule 26(b)(4)(B) now 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 the expert and that the expert considered in forming his or her opinion.

The Eastern District of Pennsylvania recently considered the work-product privilege for testifying expert physicians in the product liability context. At issue was whether “transmittal letters” exchanged between plaintiffs and physicians were subject to work product protection under Rule 26(b)(3)(A). See *In re Asbestos Prods. Liab. Litig.*, MDL 875, 2011 WL 6181334, at *6 (E.D. Pa. December 13, 2011). Defendants argued that the letters provided facts concerning individual plaintiffs’ exposure, medical, and smoking history to the doctors, and thus were discoverable “facts or data” under the federal rules. *Id.* at *6-7. Plaintiffs contended that the letters constituted “draft” expert reports and were protected. *Id.* The court held that the information regarding the individual plaintiffs fell “squarely within the definition of all ‘facts or data’ considered by the expert”, and were thus not protected under the rule. *Id.* at *7.

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. February 14, 2011), Graco submitted affidavits from several of its employees in support of a motion for a preliminary injunction and in opposition to PMC’s motion for summary judgment. See *id.* at *1. PMC sought discovery of, among other things, Graco’s counsel’s communications with the 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 found 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 labeling them ‘work product’ or ‘attorney-client privilege’ does not suffice”. 280 F.R.D. 506, 515 (N.D. Cal. 2012). 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. Given this uncertainty, care should be taken before sharing otherwise privileged information with non-reporting experts.

Consumer Fraud Class Actions

Consumer fraud class actions 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 in the context of certain consumer fraud class actions.

California.

Until 2004, “any person acting for the . . . general public” could sue under California’s Unfair Competition Law (“UCL”), Cal. Bus. & Prof. Code § 17200 *et seq.*, even without “a showing of injury or damage”. *Californians for Disability Rights v. Mervyn’s, LLC*, 138 P.3d 207, 209 (Cal. 2006). In November 2004, California voters approved Proposition 64, which limited standing to persons who “suffered injury in fact and [] lost money or property as a result of the unfair competition”. Cal. Bus. & Prof. Code § 17204. Thereafter, the California Supreme Court determined that the new standing requirement only applies to a class representative; absent class members need not meet the standing requirement. *In re Tobacco II Cases*, 207 P.3d 20, 38 (Cal. 2009); *see also, e.g., Medraza v. Honda of N. Hollywood*, 205 Cal. App. 4th 1, 12 (Cal. Ct. App. 2012). (“[T]he language in the UCL limiting standing to plaintiffs who lost money ‘as a result of the unfair competition’ imposes an actual reliance requirement on the named plaintiff (and only the named plaintiff) in a UCL action based upon the fraudulent prong or false advertising because ‘reliance is the causal mechanism of fraud’.”) (Quoting *Tobacco II*, 207 P.3d at 39.)

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 also Knapp v. AT & T Wireless Services, Inc.*, 195 Cal. App. 4th 932 (2011) (upholding denial of class certification where alleged misrepresentations were not uniformly made to proposed class members); *Schuman v. Clark Pest Control of Stockton, Inc.*, A131973, 2013 WL 372806, at *8 (Cal. Ct. App. January 31, 2013) (affirming denial of certification under California’s False Advertising Law where “[t]here is no evidence that all members of the class were exposed to a ‘uniform stimulus,’ a ‘lengthy advertising campaign,’ ‘a single material misrepresentation [made] to [all] class members,’ or to sales using a ‘common script,’ or a ‘canned presentation’”).

Class Actions in Federal Courts.

Constitutional and procedural requirements in federal courts have also provided defendants with additional arguments against class certification. The growth of federal court defences is notable because, under CAFA, many class actions are now filed in, or removed to, federal court. *See supra.*

The 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; accord, *e.g., Early v. Pinkerton Gov’t Servs., Inc.*, No. 12-1252, 2013 WL 980035, at *3 (4th Cir. March 14, 2013); *Luiken v. Domino’s Pizza, LLC*, 705 F.3d 370, 376 (8th Cir. 2013); *Bolden v. Walsh Constr. Co.*, 688 F.3d 893, 896-98 (7th Cir. 2012). 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.

The Sixth and Ninth Circuits both recently have held, consistent with the rulings in numerous other circuits, that classes of plaintiffs bringing consumer fraud actions cannot be certified where consumer protection laws of multiple states would apply. *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 946 (6th Cir. 2011); *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581 (9th Cir. 2012); *see also, e.g., In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1016-18 (7th Cir. 2002); *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 742-44 (5th Cir. 1996). In *Mazza*, the court analysed *Wal-Mart* and found that plaintiffs had satisfied their Federal Rule 23(b)(2) burden to show commonality, but had failed to demonstrate that “the questions of law or fact common to class members predominate” as required by Federal Rule 23(b)(3). *Id.* at 589. In so ruling, the court noted material differences between state consumer protection laws making certification improper. For example, although California’s consumer fraud laws “have no scienter requirement . . . many other states’ consumer protection statutes do require scienter” and California “requires named class plaintiffs to demonstrate reliance, while some other states’ consumer protection statutes do not”. *Id.* at 591, *but see, e.g., Schwartz v. Lights of America*, 2012 WL 4497398, at *5 (C.D. Cal. August 31, 2012). (“The fact that several states are involved in a class action does not itself indicate that there is a conflict of law problem. ‘A problem only arises if differences in state law are material, that is, if they make a difference in this litigation’”). The court in *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*, *supra*. *Mazza*, 666 F.3d at 596.

Federal courts also continue to reject reliance premised on a “fraud-on-the-market” theory outside the securities litigation context. In a recent Eleventh Circuit case, for example, the court affirmed dismissal of plaintiff’s 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”. *Southeast Laborers Health and Welfare Fund v. Bayer Corp.*, 444 Fed. App’x 401, 406 (11th Cir. 2011). As this is not a viable theory to recover

for consumer fraud, “to 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.

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: Federal jurisdiction is 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 reiterated 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). Accordingly, the federal judge in an MDL involving the use of bisphenol-A in baby bottles and sippy cups recently refused to certify three classes of consumers, in part because the proposed classes included individuals who had not suffered an injury in fact. *In re Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig.*, No. 08-1967, 2011 WL 6740338, at *4 (W.D. Mo. December 22, 2011). The judge held that “[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”. *Id.* at *1-2. 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 Prac. Litig.*, No. 11-MD-02231, 2011 WL 6431404, at *2 (D. Mass. December 21, 2011). The court observed that the complaint “contains no allegations that either Plaintiffs or

anyone else ever suffered any type of injury from consuming Defendants’ products” and held that “[u]nder these circumstances, 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 *3. See also *Mazza*, 666 F.3d at 594-95 (concluding that the requirement that “[n]o class may be certified that contains members lacking Article III standing” is not inconsistent with *In re Tobacco II*’s holding that “[u]nder California’s UCL, restitution is available to absent class members without individualised proof of deception, reliance, or injury”).

Pleading Requirements in Federal Court.

Federal Rule of Civil Procedure 9(b) requires that fraud claims be pleaded with specificity. In particular, to satisfy Rule 9(b), plaintiffs bringing consumer fraud claims must plead “‘the who, what, when, where, and how: the first paragraph of any newspaper story,’ or ‘otherwise inject precision or some measure of substantiation into a fraud allegation’”. *Osness v. Lasko Prods., Inc.*, 868 F. Supp. 2d 402, 409 (E.D. Pa. 2012). Indeed, as explained above, even under the pleading standards of Federal Rule of Civil Procedure 8, the Supreme Court’s decisions in *Twombly* and *Iqbal* require that allegations in a complaint plausibly state a claim for relief. 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. September 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).

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