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Recent Trends in Class Action and Aggregate Litigation in the Life Sciences Industry

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Introduction

For the last several years, the life sciences industry has been fertile ground for class action and aggregate litigation. Developments in this area have driven several trends, including state consumer fraud claims, securities class actions, antitrust class actions, and aggregate litigation brought by private healthcare insurers and state attorneys general. These recent trends have been driven, in part, by legislative and doctrinal developments. For example, in 2005—based on legislative findings of abuse in class action practice in state courts—Congress enacted the Class Action Fairness Act (CAFA), permitting defendants to remove to federal court putative class actions that previously may have been subject to less stringent standards in state court. In *Standard Fire Insurance Co. v. Knowles*,[1] the U.S. Supreme Court held that a plaintiff's stipulation that he would not accept more than $5 million in damages could not be used to avoid CAFA's amount in controversy requirement. In other words, a class representative may not agree to seek less money to try to keep a case in state court.

Recent U.S. Supreme Court decisions have also significantly shaped class action practice. The Supreme Court's decision in *Wal-Mart Stores, Inc. v. Dukes*[2] established that claims for individual money damages may be certified under Federal Rule of Civil Procedure (FRCP) 23(b)(2) in only limited circumstances, and the Court's decision also announced a more restrictive view of the meaning of a ''common question'' under FRCP 23(a). Most recently, in *Comcast Corp. v. Behrend*,[3] the Court held that plaintiffs seeking class certification in antitrust cases must tie their theory of harm and damages to their liability theory, and, in appropriate circumstances, individual questions of damages can predominate over liability issues common to the class.

These developments have likely played a role in shaping the kinds of class actions that companies in the life sciences industry are seeing today. For example, personal injury class actions and other kinds of mass torts are now largely viewed as inappropriate for class treatment and often must confront motions to strike the class claims from the complaint at the outset of the case. Claims requiring plaintiffs to prove reliance on alleged conduct also face significant obstacles to class certification. After the *Dukes* decision, in particular, these obstacles seem to have resulted in an increase in consumer fraud actions brought by individuals, healthcare insurers, and state attorneys general. The recent developments also may explain the increase in proposed class actions in the securities and antitrust arenas. These trends as well as some considerations for minimizing risk in such litigation are discussed in further detail below.

Class Action Litigation Trends

Products Liability Claims

Individualized questions of causation and damages have driven the vast majority of courts to refuse class action treatment in products liability actions in the pharmaceutical and medical device arenas.[4] In re-

[1] 133 S. Ct. 1345 (2013).

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[2] 131 S. Ct. 2541 (2011).

[3] 133 S. Ct. 1426 (2013).

[4] *See, e.g., In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1084–85 (6th Cir. 1996) (vacating certification of national class in im-

sponse to these developments, plaintiffs bringing personal injury claims have attempted to create multidistrict litigation proceedings and serial litigation to ''aggregate'' claims of individual plaintiffs in lieu of a class action. In short, plaintiffs are bringing mass actions instead of class actions.[5] Still, many consumers and third-party payors pursue class actions seeking solely economic losses.

Third-Party Payor Claims

A recent wave of third-party payor litigants sued the pharmaceutical and medical device industries, seeking to recover alleged economic losses arising from their payments for pharmaceutical medicines or medical devices and, in some cases, payments to treat personal injuries. The third-party payors included private insurers and states as Medicaid payors. These third-party payors advanced claims for breach of warranty, violation of consumer protection statutes, violation of the Racketeer Influenced and Corrupt Organizations (RICO) Act,[6] common law fraud, and unjust enrichment. The claims have proven vulnerable to attack for lack of injury and lack of a direct causal link between the supposed injury and the challenged conduct. For example, in *Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals, LP*,[7] the U.S. Court of Appeals for the Eleventh Circuit affirmed the dismissal of claims by a consumer and third-party payors suing under RICO and various state laws to recover payments for off-label prescriptions of a medicine where an allegedly cheaper substitute medicine was available. The court stated the following:

> In light of physicians' exercise of professional judgment, a patient suffers no economic injury merely by being prescribed and paying for a more expensive drug; instead, the prescription additionally must have been unnecessary or inappropriate according to sound medical practice—i.e., the drug was either ineffective or unsafe for the prescribed use. This is true even when the physician's decision to prescribe the more expensive drug in lieu of a cheaper alternative is the product of fraud. To allow recovery based purely on the fact that the prescription was comparatively more expensive than an alternative drug—but otherwise safe and effective—would mean that physicians owe their patients a professional duty to consider a drug's price when making a prescription decision. No such duty exists.[8]

Similarly, in *Pennsylvania Employees Benefit Trust Fund v. AstraZeneca Pharmaceuticals LP*,[9] a third-party payor sued for breach of express warranty and unjust enrichment, claiming that ''it was duped into expending millions of dollars in reimbursements for . . . prescriptions issued for medically unnecessary uses'' and forced to pay for treatment of personal injuries allegedly caused by those prescriptions.[10] The claims were dismissed for failure to establish causation between the alleged damages and the challenged conduct. The plaintiff's request for recovery of treatment costs required ''onerous individualized inquiries into the specifics of each patient's medical history and the circumstances of each patient's alleged injury.''[11] And, because the alleged warranties reached the third-party payor ''only by way of a treating physician's prescription pad, if at all,'' they could not have formed the basis of a bargain between the payor and AstraZeneca, as is required under state law.[12] A payor ''cannot simply rely on the prescription pads of physicians or claims for reimbursement from pharmacies as a means by which express warranties [a]re conveyed.''[13] This is, in essence, the learned intermediary doctrine: Where a claim requires '' 'proof of justifiable reliance and causation, . . . such requirements cannot be present when the defendant is a pharmaceutical company that did not sell its product directly to the patient.' The same reasoning extends to manufacturers of prescription medical devices.''[14] Other recent opinions provide a solid foundation for defending similar claims.[15]

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plant products liability litigation due to predominance of individual issues); *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555, 567 (E.D. Ark. 2005) (''As in many cases before them, Plaintiffs have attempted to frame the 'predominant' issues broadly to compensate for variations in the class members' claims. But they suffer the same fate. '[I]ndividual issues abound and are magnified by the necessity of applying diverse state laws,' making certification under 23(b)(3) inappropriate.''); *Zehel-Miller v. AstraZeneca Pharm., LP*, 223 F.R.D. 659, 663 (M.D. Fla. 2004) (observing that certification of personal injury class arising from prescription medicine ''would be indisputably inappropriate, since individual issues would overwhelm any common questions''); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 208 F.R.D. 625, 632 (W.D. Wash. 2002) (''An assessment of specific causation—in this case, whether PPA caused, may cause, or caused a fear of injury to these individuals—thus, necessarily dissolves into a myriad of individualized causation inquiries.''); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 65–66 (S.D.N.Y. 2002) (''It . . . is not surprising that all relevant Court of Appeals and the bulk of relevant district court decisions have rejected class certification in products liability cases.'').

[5] Even if not styled as a ''class action,'' a plaintiff's case may nonetheless be removable to federal court under CAFA's ''mass action'' provision. 28 U.S.C. § 1332(d)(11).

[6] 18 U.S.C. § 1964(c).

[7] 634 F.3d 1352 (11th Cir. 2011).

[8] *Id.* at 1363 (internal citations omitted).

[9] No. 6:09-cv-5003-Orl-22DAB, 2009 WL 2231686 (M.D. Fla. July 20, 2009).

[10] . *Id.* at *1.

[11] *Id.* at *6.

[12] *Id.* at *3.

[13] *Id.* at *4.

[14] *Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405, 411 (E.D. Pa. 2012) (quoting *Kester v. Zimmer Holdings, Inc.*, No. 2:10-cv-00523, 2010 WL 2696467, at *14 (W.D. Pa. June 16, 2010)).

[15] *See, e.g., In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 238 (3d Cir. 2012) (affirming dismissal of RICO and state law claims for lack of standing under Article III of the U.S. Constitution because plaintiffs ''did not allege a plausible nexus between the assailed marketing campaign and the physicians' decisions to prescribe certain drugs for off-label use''); *Commonwealth v. Ortho-McNeil-Janssen Pharm.*, 52 A.3d 498, 511 (Pa. Commw. Ct. 2012) (affirming dismissal of the Commonwealth's claims of common law fraud and unjust enrichment in view of the absence of proof of reliance or causation); *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401, 408 (11th Cir. 2011) (rejecting third-party payor's economic loss claims for failure to establish a causal nexus between alleged fraud and payments for prescription medicine); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 133 (2d Cir. 2010) (rejecting class certification where plaintiffs claimed economic losses caused by third-party physicians' alleged reliance on the manufacturer's representations); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 484 F. Supp. 2d 973, 984 (D. Minn. 2007) (''In essence, the TPP Plaintiffs allege that Guidant committed a tort on their insureds, causing injury and

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Consumer Protection Act Claims

Plaintiffs bringing Consumer Protection Act (CPA) causes of action aim to focus the courts' attention on an alleged common course of action by the defendant. As a result, the heightened requirements for class certification established by *Dukes* may, in some cases, be more easily avoided by class claims under states' CPAs. For example, the plaintiff in *Delarosa v. Boiron, Inc.* made CPA claims in an apparent effort to avoid the *Dukes* requirements.[16] In that case, the plaintiff alleged that the defendant falsely marketed a homeopathic cold remedy that allegedly had no beneficial effect on cold sufferers. The plaintiff brought CPA claims and common law fraud claims. The U.S. District Court for the Central District of California found that common issues predominated and that class certification was justified because, in its view, the claims turned primarily on one defendant-focused issue—whether the defendant's advertising included false statements. In *Delarosa*, the plaintiff's choice of law and venue was key to avoiding a reliance requirement that could have interfered with certification. In California, a plaintiff is presumed to have relied on a defendant's misrepresentation if the misrepresentation was material.[17]

Another emerging strategy among plaintiffs is to characterize the class CPA claims as involving concealment of or a failure to disclose material information to the class members to avoid the element of reliance. In *White v. Wyeth*, the plaintiffs structured their claims in this fashion.[18] The plaintiffs alleged that a pharmaceutical manufacturer had withheld material information regarding a hormone replacement drug. They brought class action claims under the West Virginia Consumer Credit and Protection Act. Normally, reliance is a required element of this type of action, and the defendant attempted to defeat class certification on this basis. The court concluded, however, that ''[w]here concealment, suppression or omission is alleged, and proving reliance is an impossibility,'' the putative class was not required to prove reliance.[19]

The foregoing cases illustrate plaintiffs' focus on framing claims as CPA causes of action. Put simply, some plaintiffs have concluded that ''[a]lleging a common course of conduct or business practice that applies uniformly to class members . . . is the key to certifying a CPA class post-[*Dukes*].''[20] Plaintiffs can be expected to continue to actively seek class certification through state consumer protection statutes.[21]

Securities Fraud Claims

In recent years, despite a significant decrease in securities fraud class actions overall, these actions have been more prevalent against pharmaceutical and medical device companies. Securities class actions '' 'pose a special risk of vexatious litigation' '' because of the cost of defending them coupled with substantial potential liability exposure.[22]

Shareholders have recently filed claims under section 10(b) of the Securities Exchange Act of 1934[23] and its implementing regulation, Rule 10b-5.[24] Shareholders have a right of action to enforce these laws, but such laws exist ''not to provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations actually cause.''[25] To prevail on a claim under section 10(b) and Rule 10b–5, a plaintiff must plead and prove ''(1) a material misrepresentation (or omission); (2) scienter, i.e., a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance . . . ; (5) economic loss; and (6) loss causation[.]''[26] A plaintiff's complaint must also satisfy the heightened pleading requirements of FRCP 9(b) and the Private Securities Litigation Reform Act of 1995.[27]

In *Amgen Inc. v. Connecticut Retirement Plans & Trust Funds*,[28] a retirement fund sued a biotechnology company for violations of section 10(b) and Rule 10b-5. The complaint alleged that Amgen and several of its officers allegedly concealed safety information about an anemia medicine arising from clinical trials, exaggerated the safety of its medicine, and failed to inform investors that it had allegedly promoted the medicine for off-label indications. According to the complaint, those alleged misrepresentations and omissions artificially inflated the price of Amgen's stock. The U.S. Supreme Court granted certiorari in the case to resolve a circuit court split over whether a plaintiff in a securities fraud class action must **prove** (as opposed to plausibly allege) the materiality of the supposedly false statements in order to invoke the fraud-on-the-market presumption of

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resulting in the injureds seeking medical treatment, which in turn caused economic harm to the TPPs because they were contractually obligated to pay for the injureds' medical care. Without a more direct connection, these claims are too speculative to establish a causal link between the alleged injury and the alleged misconduct.''); *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 320 (5th Cir. 2002) (''The plaintiffs claim that Wyeth violated the implied warranty of merchantability by selling a defective drug, but then aver that the drug was not defective as to them. Similarly, the plaintiffs claim Wyeth violated the [Texas Deceptive Trade Practices Act] by failing to issue warnings sufficient to advise injured users, but then concede they were not among the injured. Such wrongs cannot constitute an injury in fact.'').

[16] 275 F.R.D. 582 (C.D. Cal. 2011).

[17] *Id.* at 586.

[18] 705 S.E.2d 828 (W. Va. 2010).

[19] *Id.* at 837.

[20] Beth E. Terrell & Kimberlee L. Gunning, *Recent Developments in UDAP Class Actions from the Plaintiff's Perspective*, *in* 17th Annual Consumer Financial Services Institute Course Handbook Series 503, 518 (Practising Law Institute ed., 2012).

[21] A number of CPA-style state common law causes of action also share the characteristics of CPA statutory actions that some plaintiffs believe make class certification easier post-*Dukes*. Common law causes of action that focus primarily on the conduct of the defendant—such as unjust enrichment, breach of the implied covenant of good faith, and even fraud (when reliance is not required)—can similarly be used by plaintiffs' counsel to characterize claims in a manner that avoids the heightened standard for predominance created by *Dukes*. *Seeid.* at 503 (''[I]n some circumstances, less utilized common-law claims, such as a claim for breach of the implied covenant of good faith and fair dealing, can be certified on a classwide basis even when a CPA claim is dismissed precertification.'').

[22] In re Boston Scientific Corp. Sec. Litig., 686 F.3d 21, 30 (1st Cir. 2012) (quoting Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit, 547 U.S. 71, 86 (2006)).

[23] 15 U.S.C. § 78j(b).

[24] 17 C.F.R. § 240.10b-5.

[25] *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 345 (2005).

[26] *Id.* at 341–42 (internal citations omitted).

[27] Pub. L. No. 104-67, 109 Stat. 737 (codified as amended in scattered sections of 15 U.S.C.).

[28] 133 S. Ct. 1184 (2013).

reliance at the class certification stage of the case. In a 6–3 decision, the Court held that proof of materiality ''is not a prerequisite to class certification'' in securities fraud cases.[29] The Court found that ''the pivotal inquiry is whether proof of materiality is needed to ensure that **questions** of law or fact common to the class will 'predominate over any questions affecting only individual members' as the litigation progresses.''[30] The Court noted further that ''materiality can be proved through evidence common to the class'' and that a failure to prove of materiality would not result in individual questions predominating.[31] The decision is important because it allows plaintiffs to establish elements of FRCP 23 without proving an essential element of a fraud-on-the-market theory, thus potentially increasing defendants' exposure to substantial discovery costs and threats of large judgments.

A recent U.S. Supreme Court opinion addressing disclosure of adverse events is *Matrixx Initiatives, Inc. v. Siracusano*.[32] There, the plaintiffs filed a putative class action claiming violations of section 10(b) and Rule 10b-5. The plaintiffs alleged that a pharmaceutical company failed to disclose reports of adverse events associated with an over-the-counter cold-remedy product and that those alleged omissions were ''material,'' even if the reports did not represent a statistically significant number of adverse events. The Court agreed, reasoning that ''[a] lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events.''[33] The Court made clear that pharmaceutical manufacturers need not disclose all reports of adverse events, which ''are daily events in the pharmaceutical industry,''[34] and stated:

> [T]he mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events—will not satisfy th[e materiality] standard. Something more is needed, but that something more is not limited to statistical significance and can come from the source, content, and context of the reports.[35]

The Court concluded that the plaintiffs in *Siracusano* adequately pleaded materiality.

In *In re Boston Scientific Corp. Securities Litigation*, another putative class of shareholders filed suit alleging violations of section 10(b) and Rule 10b-5.[36] There, the U.S. Court of Appeals for the First Circuit underscored the Supreme Court's holding in *Siracusano* that section 10(b) '' 'do[es] not create an affirmative duty to disclose any and all material information.' ''[37] In *Boston Scientific*, the company conducted an audit of a segment of its sales force regarding expenses incurred to provide food and entertainment to physician customers. The company also received a subpoena from the U.S. Department of Health and Human Services (HHS), requesting information about contributions it made to charities with ties to physicians or their families. The company did not immediately disclose the audit or the subpoena to the public. More than a month later, the company issued a press release and held a conference with investors and analysts discussing its sales prospects for a particular product line. Two weeks later, the company publicly disclosed the HHS subpoena, and, two weeks after that, it began to fire some of its previously audited employees. Many of the fired employees were hired by the company's direct competitor, a fact that the company later disclosed and that was followed by a drop in the company's stock price. From the First Circuit's perspective, all of these alleged omissions from the company's public statements in question were either immaterial or unaccompanied by allegations or evidence from which scienter could be inferred. The claims, therefore, were dismissed.

Other recent cases illustrate that a variety of public statements have given rise to securities fraud claims and that evaluation of such claims at the motion to dismiss stage are highly fact specific.[38]

Antitrust Claims

The conventional wisdom has long been that antitrust claims, especially claims alleging horizontal price-fixing, were uniquely well suited for classwide resolution because of the view that ''common issues regarding the existence and scope of the conspiracy predominate over questions affecting only individual members.''[39] However, recent case law arising in the antitrust context has called that conventional wisdom into question. The trend toward more intense scrutiny of putative antitrust class actions began in earnest with the U.S. Court of Appeals for the Third Circuit's decision in *In re Hydrogen Peroxide Antitrust Litigation*,[40] in which the court held that there is no presumption of classwide im-

[29] *Id.* at 1191.
[30] *Id.* at 1195 (quoting Fed. Rule Civ. Proc. 23(b)(3)).
[31] *Id.* at 1195–96.
[32] 131 S. Ct. 1309 (2011).
[33] *Id.* at 1319.
[34] *Id.* at 1321.
[35] *Id.* (internal quotation omitted).
[36] 686 F.3d at 24.
[37] *Id.* at 27 (quoting *Siracusano*, 131 S. Ct. at 1321).

[38] *See, e.g., Kleinman v. Elan Corp.*, 706 F.3d 145 (2d Cir. 2013) (affirming the dismissal of securities fraud claims alleging omission of preliminary clinical trial data from a press release); *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972, 981 (8th Cir. 2012) (rejecting company's argument that ''the receipt of Form 483s can never render a company's statements about compliance with [Food and Drug Administration (FDA)] regulations or cGMP false or misleading''); *Plumbers & Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc.*, 679 F.3d 952, 956 (7th Cir. 2012) (affirming the dismissal of securities fraud claims alleging omissions from statements by the company's CEO during a conference call with analysts and observing that the CEO's statement was true and at worst ''evasive, which is short of fraudulent,'' and that he ''did not know what question was coming, had to answer off the cuff, and did not have an opportunity to review the question and edit his answer before the next question was posed''); *Hill v. Gozani*, 638 F.3d 40, 59 (1st Cir. 2011) (affirming the dismissal of securities fraud claims against devicemaker NeuroMetrix, Inc. and noting that ''[a]lthough the company took an aggressive, and in the view of some, an unrealistically aggressive view of the appropriate resolution in the promotion of its product, its press release does state explicitly that the ultimate resolution of the issue is unknown and, by reasonable implication, out of its hands''), *reh'g denied*, 651 F.3d 151 (1st Cir. 2011); *Detroit Gen. Ret. Sys. v. Medtronic, Inc.*, 621 F.3d 800, 806 (8th Cir. 2010) (affirming the dismissal of securities fraud claims alleging omissions from a Dear Doctor letter and noting that ''[i]t is difficult to see how a letter disclosing a possible problem and an investigation into that problem was materially misleading'').
[39] *In re Foundry Resins Antitrust Litig.*, 242 F.R.D. 393, 408 (S.D. Ohio 2007).
[40] 552 F.3d 305 (3d Cir. 2008).

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pact in antitrust cases and that a trial court cannot permissibly certify a class without resolving disputes between experts who have posited conflicting economic theories on issues relevant to the essential elements of FRCP 23.[41] The U.S. Supreme Court recently built upon those principles in its *Comcast* decision, where it held that plaintiffs seeking class certification in antitrust cases must tie their theory of harm and damages to their liability theory and that, in appropriate circumstances, individual questions of damages can predominate over liability issues common to the class.[42] This decision represents a departure from lower court decisions holding that, in antitrust cases in particular, the failure by a plaintiff to come forward with a viable theory of classwide damages will not foreclose certification.

Despite the recent obstacles to class certification that have been created by these and other decisions, governmental antitrust enforcement is on the rise. As a result, it is reasonable to expect class action filings that allege violations of the antitrust laws and seek substantial damages amounts on behalf of large classes of direct and indirect purchasers. One of the areas that appears particularly ripe for antitrust class action activity in the immediate future is the life sciences industry and, in particular, pharmaceuticals.

As discussed in more detail below, the class action antitrust cases brought against pharmaceutical companies vary in terms of the exclusionary conduct theories that form the underpinnings for the claims, but the essential theme is the same, i.e., that a pioneer drug manufacturer (also referred to as a ''branded'' firm) has taken steps—either unilaterally or in concert with a rival—to wrongfully insulate itself from generic competition. By doing so, that firm enables itself to charge monopoly prices to those who buy the drug. The variations on this theme continue to evolve but presently focus on (1) so-called ''reverse payment settlements''; (2) supposedly false Orange Book listings and manipulation of the Citizen Petition process; (3) so-called ''product hopping''; and (4) alleged abuses of Risk Evaluation and Mitigation Strategies (REMS).

Reverse Payment Settlements

Among the high-profile targets of the class action bar are reverse payment settlements—or ''pay for delay'' settlements—in pharmaceutical patent lawsuits. In reverse payment settlements, which arise in the context of Hatch-Waxman Act[43] patent litigation brought by a pioneer drug company against its generic rival, the pioneer firm pays money or other consideration to the allegedly infringing generic firm, which then agrees not to enter the market with a competing generic drug for a period of years. The Federal Trade Commission (FTC) and the class action plaintiffs' bar repeatedly have challenged such arrangements on the grounds that they are, in essence, agreements between horizontal rivals not to compete, which they say invariably raise prices to consumers and are thus unlawful under the Sherman Antitrust Act.[44]

After a split between the Third Circuit and three other circuit courts as to the appropriate standard to be applied to reverse payment settlements,[45] the prism through which such arrangements should be viewed recently was addressed by the Supreme Court in *FTC v. Actavis, Inc.*[46] On one end of the spectrum, the FTC and the class action plaintiffs' bar consistently have advocated for the application of the ''quick look'' standard for reverse payment settlements, under which such settlements are presumed unlawful without extensive analysis into the actual effect of the settlement on competition, thus placing the burden on the settling parties to demonstrate an absence of anticompetitive effects. That view had been adopted by the Third Circuit.[47] In contrast, the U.S. Courts of Appeals for the Second Circuit, the Federal Circuit, and the Eleventh Circuit espoused the application of the ''scope of the patent'' rule, which deems reverse payment agreements lawful so long as they do not go beyond the temporal or substantive limitations of the patent grant and the patent infringement suit is not a sham.[48] Although the ''scope of the patent'' test, which had been adopted by a majority of the circuits, was in line with longstanding precedent outside the pharmaceutical context,[49] critics of that approach argued that, in practice, the ''scope of the patent'' test resulted in a rule of per se legality for reverse payment settlements in pharmaceutical patent litigation that would be detrimental to consumers.

The Supreme Court's *Actavis* decision put to rest the debate as to the appropriate standard of scrutiny that should be applied to reverse payments, but the decision will likely give rise to more questions than it answers. Ultimately, the Court took a middle-ground approach, declining to adopt the ''scope of the patent'' rule espoused by the Eleventh Circuit and also rejecting the ''quick look'' presumption that was advocated by the FTC and the plaintiffs' bar and adopted by the Third Circuit in *K-Dur*. Instead, the Court opted for a flexible rule of reason analysis that requires courts to balance the pro-competitive benefits of an agreement against its anticompetitive effects. Although rule of reason analy-

[41] *Id.* at 323, 326.

[42] *Comcast*, 133 S. Ct. at 1435.

[43] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (1994)).

[44] *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).

[45] See, e.g., id.; Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799 (D.C. Cir. 2001); Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006), abrogated by FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), abrogated by Actavis, 133 S. Ct. 2223.

[46] 133 S. Ct. 2223 (2013).

[47] In re K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012), cert. granted, vacated sub nom. Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013), and cert. granted, vacated sub nom. Merck & Co., Inc. v. Louisiana Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013), reinstatement granted, Nos. 10-2077, 10-2078, 10-4571, 2013 WL 5180857 (3d Cir. Sept. 9, 2013).

[48] FTC v. Watson Pharm. Inc. (Actavis I), 677 F.3d 1298 (11th Cir. 2012), rev'd and remanded sub nom. Actavis, 133 S. Ct. 2223.

[49] *See, e.g., Standard Oil Co. (Ind.) v. United States*, 283 U.S. 163 (1931) (upholding, under the antitrust laws, cross-licensing agreements among patentees that settled actual and impending patent litigation).

sis is well-trodden ground in antitrust doctrine, the Court in *Actavis* provided little guidance as to the structure or scope of the analysis in the context of a reverse payment settlement case, except to say that a large payment to the Abbreviated New Drug Application (ANDA) filer by the pioneer manufacturer could be evidence weighing in favor of a finding that a particular settlement violates the Sherman Antitrust Act. But, as Justice Stephen Breyer acknowledged in his opinion for the majority, the analysis of the consideration paid in the settlement is hardly a straightforward exercise, especially when a settlement payment, even if substantial, in part ''reflect[s] compensation for other services that the generic has promised to perform—such as distributing the patented item . . . .''[50]

Actavis has raised and will continue to raise many questions for firms—both pioneer and generic—that are seeking to resolve Hatch-Waxman Act patent litigation. However, one thing is virtually certain—as a consequence of the Supreme Court's ruling, and its elimination of the ''scope of the patent'' safe harbor, most reverse payment settlement cases will not be susceptible to early dismissal by way of an FRCP 12 motion and, instead, will need to be resolved on summary judgment or at trial. The fact that most reverse payment settlement cases now are likely to proceed beyond a motion to dismiss and into discovery makes them attractive cases to bring for class action lawyers and virtually guarantees that class action activity in this area will be on the rise for the foreseeable future.

Orange Book Filings and Citizen Petitions

Another area that has been ripe for class action antitrust activity is the alleged manipulation of so-called ''Orange Book filings'' by pioneer drug companies in an effort to allegedly preclude generic entry. The Approved Drug Products with Therapeutic Equivalence Evaluations, or ''the Orange Book,'' is the FDA's official listing of drugs and the patents that would be infringed by an ANDA applicant seeking to market a generic equivalent drug pursuant to the protocols set forth in the Hatch-Waxman Act. Generic firms have asserted that certain manufacturers of pioneer drugs have improperly listed patents in the Orange Book that do not actually cover the drugs they are alleged to cover. Once a drug is listed—either properly or improperly—in the Orange Book, the patentee has 45 days to sue an ANDA filer for infringement and automatically obtain a 30-month stay of FDA approval of the generic drug if the ANDA contained a paragraph IV patent certification seeking to challenge the patent.

In a typical case, the generic drug manufacturer defending against an infringement action asserts that the pioneer wrongfully listed a patent in the Orange Book that does not, in fact, cover the branded drug, thus impeding the market entry of the generic equivalent. Class action litigation by direct and indirect purchasers of the branded drug invariably follows. In a paradigmatic case, Bristol Myers Squibb Co. (BMS) faced massive antitrust litigation arising out of its alleged improper listing in the Orange Book of a patent covering the oral administration of a metabolite of buspirone hydrochloride, a widely used antidepressant. Four patent disputes and 22 antitrust cases filed by generic competitors, purchasers, and attorneys general were consolidated by the Judicial Panel on Multidistrict Litigation and transferred to the U.S. District Court for the Southern District of New York, and a purchaser class was later certified.[51] Ultimately, BMS reached a global settlement, under which it agreed to pay $535 million to the various plaintiffs' groups. There have been several other cases predicated on similar theories in which significant settlements have been achieved by the plaintiffs' bar.

Class action activity also has arisen in the antitrust context with regard to the filing by pioneer drug companies of Citizen Petitions at or near the time of generic entry, which generic competitors—and, in putative class actions, direct and indirect purchasers—contend is a gambit designed to preserve the monopoly position of a branded drug.[52] FDA regulations permit anyone to file a Citizen Petition urging the FDA to refrain from taking a particular administrative action. It generally is the FDA's practice to respond to an outstanding Citizen Petition before approving an ANDA, thus paving the way for generic entry. FDA regulations historically provided a 180-day period for resolving such Citizen Petitions—a deadline that was recently shortened by Congress to 150 days[53]—but plaintiffs in these cases typically claim that, in reality, the FDA takes much longer to respond. Plaintiffs assert that pioneer drug companies facing threats from generic competition knowingly manipulate this process and the FDA's timeline by filing scientifically unsupported Citizen Petitions for the specific purpose of delaying generic entry and preserving their monopoly power. Such claims frequently are asserted by both the generic drug manufacturer allegedly excluded from the market and the proposed classes of direct and indirect purchasers who claim they were overcharged.

The success of both theories, i.e., improper Orange Book listing and the predatory filing of a Citizen Petition, frequently turns upon the application of the *Noerr-Pennington* doctrine, which immunizes legitimate government petitioning from antitrust liability.[54] *Noerr-Pennington* immunity does not attach, however, to petitioning that is a ''sham'' or, in other words, petitioning that is objectively and subjectively baseless,[55] nor does the immunity typically apply to petitioning where the government action sought by the defendant is merely perfunctory.[56] Plaintiffs in Orange Book and Citizen Petition cases have invoked these exceptions to

[50] *Actavis*, 133 S. Ct. at 2236.

[51] *See In re Buspirone Patent Litig.*, 210 F.R.D. 43 (S.D.N.Y. 2002).

[52] *See La. Wholesale Drug Co. v Sanofi-Aventis*, No. 07 Civ. 7343(HB), 2009 WL 2708110 (S.D.N.Y. Aug. 28, 2009); *In re Wellbutrin XL Antitrust Litig.*, 268 F.R.D. 539 (E.D. Pa. 2010); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677 (2d Cir. 2009); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300 (E.D. Pa. 2011).

[53] *See* Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. No. 112-144, § 1135, 126 State. 993 (2012), *amending* 21 U.S.C. § 505(q).

[54] See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965).

[55] Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49 (1993).

[56] *See, e.g., Ticor Title Ins. Co. v. FTC*, 998 F.2d 1129, 1138 (3d Cir. 1993) (holding that a collective rate filing is not a petition to the government); *City of Kirkwood v. Union Elec. Co.*, 671 F.2d 1173, 1181 (8th Cir. 1982) (holding that utility rate filings are not protected petitions and that tariff filings ''may not

  PLIR ISSN 1542-9547

the *Noerr-Pennington* doctrine with somewhat mixed results.[57] The law in this area is still developing and likely will dictate the extent to which Orange Book and Citizen Petition manipulation theories continue to provide viable claims for the class action antitrust bar.

''Product Hopping''

''Product hopping'' is the practice by which a pioneer drug manufacturer changes the formulation of an Orange Book reference–listed drug without any true clinical benefit in order to forestall generic competition. Although unilateral product design changes by a manufacturer only rarely give rise to Sherman Antitrust Act liability,[58] the unique regulatory environment in the pharmaceutical industry created by the Hatch-Waxman Act has given the plaintiffs' bar a new theory to challenge such conduct on behalf of classes of purchasers of branded drugs that may have been insulated from generic competition as a result of allegedly predatory design changes.

''Product hopping'' occurs when the manufacturer of the branded product makes a nontherapeutic change to the drug formula, such as an alteration in dosage or form, immediately before generic entry. Then, the pioneer manufacturer removes the predecessor drug from the market directly or raises the price of the predecessor drug so it is significantly higher than the reformulation. According to plaintiffs, this strategy shifts market demand by prescribing physicians and patients to the reformulated drug. Because a generic prescription must contain, among other things, the same dosage and form as the branded version for it to be substituted, plaintiffs bringing these cases contend that this practice eliminates substitution at the pharmacy counter and thus retards meaningful generic competition.

Life cycle management practices began to attract increased attention in 2010 as a result of a speech by then-FTC Commissioner J. Thomas Rosch, in which he voiced concerns about the legality of nontherapeutic product modifications that are ''a sham'' and that allow the pioneer drug manufacturer to eliminate a competitive threat from a generic rival.[59] Before Commissioner Rosch's speech, only a handful of challenges to the practice of ''product hopping'' had been mounted by the government or by private litigants, and, in the few cases that were filed, the results were mixed.[60] Commissioner Rosch's remarks, however, have emboldened the plaintiffs' bar and prompted the filing of several recent ''product hopping'' class action cases. One of the most prominent and carefully watched ''product hopping'' case to have been filed since Commissioner Rosch's remarks is *Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited Co.*, which is pending in the U.S. District Court for the Eastern District of Pennsylvania.[61] In that case, Mylan principally claims that Warner Chilcott violated Sherman Antitrust Act sections 1 and 2 of the Sherman Antitrust Act by engaging in ''product hopping'' in connection with its Doryx product, which is prescribed for the treatment of severe acne and other bacterial infections. Specifically, Mylan alleges in its complaint that, when generic competitors were on the verge of securing FDA approval for the capsule equivalent of Doryx, Warner Chilcott converted the marketplace from capsules to tablets, thus eradicating the threat from generic competitors. Class action lawsuits filed by direct and indirect purchasers followed close on the heels of Mylan's complaint.

In October 2012, Warner Chilcott filed a comprehensive motion to dismiss Mylan's complaint and the complaints of the class action plaintiffs. The reasoning for the motion was that there had been no actionable exclusionary conduct alleged because ''[a]ntitrust law does not impose a duty on anyone to slow down innovation, roll out new products at a certain pace, keep older versions on the market, or do anything else to help competitors compete.''[62] Citing the two prior life cycle management cases in which dismissal was granted, Warner Chilcott also argued that ''competitive loss from alleged 'product switching' is not antitrust injury.''[63] In short, in its papers, Warner Chilcott advocated for the adoption of a rule of per se legality for ''product hopping.''

On November 21, 2012, the FTC filed a motion for leave to file an amicus brief in the *Mylan* case. In its brief, the FTC urged the court to reject a rule of per se

be used as a pretext to achieve otherwise unlawful results''); *In re New England Motor Rate Bureau, Inc.*, 112 F.T.C. 200, 284 (1989) (holding that joint applications to regulators for tariff changes are not protected petitions), *modified on other grounds*, *New England Motor Rate Bureau v. FTC*, 908 F.2d 1064 (1st Cir. 1990); *In re Wheat Rail Freight Rate Antitrust Litig.*, 579 F. Supp. 517, 537 (N.D. Ill. 1984) (finding that a tariff filing is not protected under *Noerr* because ''[t]hough the [Interstate Commerce Commission] may reject a tariff on its own initiative or at the request of a third party, the filing of a tariff itself cannot be considered a 'petition' to the government'').

[57] *See In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 372 (S.D.N.Y. 2002) (holding that an Orange Book filing sought only administrative action from the government and thus was not a government petitioning within the meaning of the *Noerr-Pennington* doctrine); *In re Prograf Antitrust Litig.*, No. 1:11-md-2242-RWZ, 2012 WL 293850 at *7 (D. Mass. Feb. 1, 2012) (denying motion to dismiss in a Citizen Petition case because the plaintiff had adequately alleged that the petition was a sham designed to prevent generic entry); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 312–16 (E.D. Pa. 2011) (denying summary judgment because there was a genuine issue of fact as to whether the challenged Citizen Petition was baseless and thus exempt from *Noerr-Pennington* immunity); *but see In re Wellbutrin XL Antitrust Litig.*, Nos. 08-2431, 08-2433, 2012 WL 1657734, at *40 (E.D. Pa. May 11, 2012) (granting summary judgment because there was insufficient evidence that the Citizen Petition was a sham).

[58] *United States v. Microsoft*, 253 F.3d 34, 65 (D.C. Cir. 2001) (en banc) (''As a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes.'').

[59] J. Thomas Rosch, Comm'r, FTC, The Antitrust/Intellectual Property Interface: Thoughts on How to Best Wade Through the Thicket in the Pharmaceutical Context, Remarks before the World Generic Medicine Congress (Nov. 17, 2010), *available at* http://www.ftc.gov/speeches/rosch/101117roschworldspeech.pdf.

[60] *Compare Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) (denying motion to dismiss on product hopping claims with respect to TriCor), *with Walgreen Co. v. AstraZeneca Pharm., LP*, 534 F. Supp. 2d 146 (D.D.C. 2008) (granting motion to dismiss where reformulation was not accompanied by removal of predecessor product from the market).

[61] Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824 (E.D. Pa. filed July 6, 2012).

[62] Memorandum in Support of Defendant Warner Chilcott's Motion to Dismiss at 12, *Mylan*, No. 12-3824.

[63] *Id.* at 12–16.

legality for ''product hopping,'' noting that, in certain circumstances, ''pharmaceutical product redesigns can constitute exclusionary conduct.''[64] The FTC further asserted that '' '[p]roduct-hopping seems clearly to be an effort to game the rather intricate FDA rules. . . .The patentee is making a product change with no technological benefit solely in order to delay competition.' ''[65] On December 3, 2012, the district court formally accepted the FTC's amicus filing, and, in June 2013, the court declined to grant Warner Chilcott's motion to dismiss, despite expressing some reservations about the plaintiffs' theory. The only other ''product hopping'' class action case to date to survive a motion to dismiss—*TriCor*[66]—settled after one day of trial for $250 million, and, thus, the court's ruling in the *Mylan* case is being monitored closely by the plaintiffs' bar. If the plaintiffs in *Mylan* can muster sufficient facts to survive summary judgment, class action cases alleging ''product hopping'' are likely to increase in the Third Circuit and elsewhere.

Distribution Restrictions and REMS Abuses

Although there are no current class action cases asserting REMS abuses by pioneer drug manufacturers, such claims would fit nicely in the class action antitrust lawyer's toolkit. The extent to which such a theory will be a viable basis for class action lawsuits going forward depends in large measure on the outcome of *Actelion Pharmaceuticals Ltd. v. Apotex, Inc.*,[67] which currently is being litigated in the U.S. District Court for the District of New Jersey.

Under the FDA Amendments Act of 2007, the FDA may require the manufacturer of a potentially dangerous drug or biologic medicine to adopt REMS for that drug or biologic if it concludes that such protocols are necessary to ensure that the benefits of the drug or biologic outweigh its risks. REMS for a drug or biologic proposed by a pioneer manufacturer often include restrictions on distribution and disbursement to ensure safe use. These distribution restrictions seemingly conflict with the notion that generic manufacturers need access to a minimal amount of the branded drug in order to develop generic versions of a particular drug or biologic. Generic manufacturers thus have asserted that pretextual use of REMS restrictions by a pioneer manufacturer insulates the manufacturer from meaningful competition because it impedes the ability of generic firms to perform the bioequivalence testing needed before an ANDA can be filed under the Hatch-Waxman Act.

The first case to test this proposition was filed in the U.S. District Court for the Eastern District of Pennsylvania against Celgene Corporation, in which Lannett Company alleged that Celgene misused REMS requirements to deny access to samples of the branded myeloma drug Thalomid to its generic rivals.[68] The court summarily denied Celgene's FRCP 12 motion and the lawsuit subsequently was settled before trial.

More recently, in the *Actelion* case, Apotex and Roxane claimed that Actelion imposed pretextual distribution restrictions on Tracleer—a pulmonary arterial hypertension drug that obtained FDA approval subject to a REMS program. Both generic manufacturers sent letters to Actelion seeking a Tracleer sample for use in bioequivalence testing and threatening antitrust litigation if a sample was not forthcoming. Actelion, however, refused to provide drug samples to the companies, ''maintaining its right to choose with whom it does business'' and citing certain REMS compliance issues. Instead of waiting to defend itself against antitrust claims, Actelion also preemptively sought a declaratory judgment asserting that ''Apotex and Roxane are seeking to force Actelion to supply them with product, turning well-settled law, not to mention basic free-market principles, on their head,'' and that ''Apotex's and Roxane's demands would also require Actelion to violate its regulatory obligations.''[69] Apotex and Roxane brought antitrust counterclaims alleging violations of Sherman Antitrust Actsections 1 and 2 of the Sherman Antitrust Act, and Actavis filed a motion to intervene as a counterclaim plaintiff, asserting that it too was victimized by Actelion's refusal to supply Tracleer samples for bioequivalence testing.

Actelion filed a motion for judgment on the pleadings, arguing that, as a matter of law, a pioneer drug manufacturer has no duty to sell its patented product to a competitor, especially when doing so would violate FDA regulations. The FTC, however, asked the district court's permission to file an amicus brief, which ostensibly adopts the position of the generic manufacturers and claims that refusing to sell to rivals in the pharmaceutical space may constitute actionable exclusionary conduct.[70] On October 21, 2013, the court granted the FTC's motion and denied Actelion's motion for judgment on the pleadings without issuing a written opinion.[71] The court's ruling in *Actelion*, which is a case being closely watched by the class action plaintiffs' bar, potentially opens up a viable new avenue for claims of generic exclusion and another potential basis for class action litigation on the part of direct and indirect purchasers of pioneer drugs.

Similarly, the plaintiffs' bar and the FDA have raised antitrust concerns with respect to a pioneer company's actions in allegedly refusing to cooperate with generic competitors in the development of a statutorily required classwide REMS protocol. Along with the REMS requirement imposed on innovator drugs, their generic counterparts likewise are subject to the REMS protocols. In these situations, Congress has stated that the innovator and generic drugs ''shall use a single, shared system'' (SSS), intended to ensure consistent product protections across the healthcare system regardless of

[64] FTC's Brief as *Amicus Curiae* at 10, *Mylan*, No. 12-3824.

[65] *Id.* at 9 (quoting Herbert Hovenkamp et al., *IP and Antitrust* § 15.3 at 15–75 (2d ed. 2010)).

[66] *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006).

[67] *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743-NLH-AMD (D. N.J. filed Sept. 14, 2012).

[68] *Lannett Co. v. Celgene Corp.*, No. 2:08-cv-3920 (E.D. Pa. Dec. 7, 2011).

[69] Complaint for Declaratory Judgment at 2, *Actelion*, No. 1:12-cv-05743-NLH-AMD.

[70] *See* FTC's Brief as *Amicus Curiae*, *Actelion*, No. 1:12-cv-05743-NLH-AMD.

[71] The Generic Pharmaceutical Association (GPhA) has also filed an amicus brief in the case. *See* Brief *Amicus* Curiae of Generic Pharm. Ass'n in Support of Defendants/Counterclaim Plaintiffs, *Actelion*, No. 1:12-cv-05743-NLH-AMD. The GPhA's brief does not weigh in on the antitrust issues raised in the case but, rather, focuses on the intent of the Hatch-Waxman Act Amendments.

  PLIR ISSN 1542-9547

the manufacturer.[72] When the parties fail to agree on an SSS, the FDA can waive the SSS requirement. The FDA did so in the case of Suboxone (buprenorphine hydrochloride and naloxone hydrochloride) sublingual tablets, referencing the waiver decision in its February 22, 2013 denial of a Citizen Petition filed by Reckitt Benckiser Pharmaceuticals Inc., in which the FDA also referred the matter to the FTC for a possible investigation of Reckitt's actions as anticompetitive business practices.[73] Civil antitrust class actions were then filed against Reckitt, which are pending in the U.S. District Court for the Eastern District of Pennsylvania and elsewhere. In the future, as other innovator companies question the value of negotiating with competitors over REMS that have an SSS, the plaintiffs' bar is likely to respond with antitrust allegations.[74]

Civil Penalties Actions by State Attorneys General

CPA Claims

State attorneys general have sought to recover civil penalties under CPAs without proving actual damages, causation, or reliance. The Mississippi attorney general sued a pharmaceutical company seeking to recover a statutory penalty of up to $10,000 for each and every Zyprexa prescription ever written in Mississippi, amounting to approximately one million prescriptions.[75] The Mississippi CPA provides for ''a civil penalty in a sum not to exceed Ten Thousand Dollars ($10,000.00)'' for each knowing and willful violation.[76] The statute vests judges with discretion to determine the appropriate amount of the penalty with respect to each violation, whether $10,000 or a smaller amount. In the *Zyprexa* case, the judge noted his desire to consider whether the prescription was for an on-label or off-label use; whether the prescription was medically necessary; whether the patient received any benefit from Zyprexa; whether and the extent to which the patient experienced any of Zyprexa's potential metabolic side effects; the information about Zyprexa available to the medical community at the time the prescription was written; and the times of the various alleged instances of misconduct by the manufacturer and whether and to what extent each instance may have impacted the prescription in question. The Mississippi attorney general, however, did not offer evidence relating to any particular prescription that the court needed to impose penalties for. The judge, therefore, entered summary judgment against the state on its CPA claim, noting that ''imposition of civil penalties on a per-violation basis would entail separate examination of each of hundreds of thousands of claimed violations for purposes of determining the appropriate fine. Such an inquiry is impractical and beyond the resources of any court. Summary judgment is appropriate with respect to Mississippi's claim for statutory penalties under the CPA.''[77]

A case involving a virtually identical legal theory resulted in a different outcome in South Carolina. That state brought a penalties-only action against another pharmaceutical company.[78] There, the court noted that the state did not seek damages in any form. Rather, it sued under South Carolina Code section 39-5-110, which authorizes the attorney general to bring an action for the assessment of civil penalties for the willful violation of the state CPA. The state sought a penalty for an allegedly misleading Dear Doctor letter and an additional penalty for every prescription written in South Carolina, based upon its assertion that the prescriptions' FDA-approved labels were false and misleading. The judge awarded the state $327 million in civil penalties, based upon his analysis of the good or bad faith of the defendant, the injury to the public, the desire to eliminate the benefits derived from a violation of the CPA, the necessity of vindicating the authority of the agency involved, and the defendant's ability to pay.[79] Similar civil penalties actions have been brought under other state's CPAs as well.[80]

Notably, future civil penalty actions brought by attorneys general—when accompanied by claims for individual relief, such as restitution—will be significantly impacted by the Supreme Court's recent decision in *Mississippi ex rel. Hood v. AU Optronics Corp.*[81] The Court addressed whether a state's *parens patriae* action is removable as a ''mass action'' under CAFA. In order for a case to be removable as a ''mass action,'' among other requirements, the suit must involve claims of 100 or more persons. The Court interpreted the definition of ''mass action'' as requiring 100 or more parties to be actually named as plaintiffs.[82] In so doing, the Court rejected arguments that the State's citizens should have been counted as the real unnamed parties in interest for purposes of the 100-person threshold.[83] Instead the Court found that Mississippi's *parens patriae* lawsuit included only one plaintiff, the State. The importance of this decision is that it creates a significant limitation for

[72] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355-1(i)(1)(B).

[73] *See* No. FDA-2012-P-1028-0011 (Food & Drug Admin. Feb. 22, 2013).

[74] *See, e.g.*, No. FDA-2013-P-0572 (Food & Drug Admin. Oct. 7, 2013) (denying Prometheus Laboratories, Inc.'s Citizen Petition).

[75] *In re Zyprexa Products Liab. Litig.*, 671 F. Supp. 2d 397, 453–54 (E.D.N.Y. 2009).

[76] Miss. Code § 75-24-19(1)(b).

[77] *Zyprexa*, 671 F. Supp. 2d at 459.

[78] *State v. Ortho-NcNeil-Janssen Pharm., Inc.*, No. 2007-CP-42-1438, 2011 WL 3794016 (S.C. Com. Pl. Feb. 25, 2011), *appeal argued and pending decision*, No. 2012-206987 (S.C. Mar. 21, 2013).

[79] Penalty Order, *State v. Ortho-NcNeil-Janssen Pharm., Inc.*, No. 2007-CP-42-1438, 2011 WL 2185861 (S.C. Ct. Com. Pl. June 3, 2011).

[80] *See, e.g.*, *Commonwealth v. TAP Pharm. Prods., Inc.*, 36 A.3d 1112, 1180 (Pa. Commw. Ct. 2011) (''Section 8(b) of the [Consumer Protection Law (CPL)] . . . applies to an action brought under Section 4 of the CPL, dealing with suits brought in the public interest. Where the court finds that a firm or corporation has willfully used a practice declared unlawful, the Commonwealth may recover civil penalties.''); *State v. Guidant Corp.*, No. 170-487, 2007 WL 4692890 (Dist. Ct. Wyo. Aug. 30, 2007) (action brought under Wyoming statute, arising from sale of medical devices); *Milgram v. Pfizer Inc*, No. MER-C-134-08, 2008 WL 4718557(N.J. Super. Ct. Ch. Div. Oct. 22, 2008). Attorney general actions under CPAs are often accompanied by requests for injunctive relief limiting future marketing and promotion. *See, e.g., State v. Purdue Pharma L.P.*, No. 07C1319, 2007 WL 2905352 (Tenn. Cir. Ct. May 8, 2007).

[81] *Mississippi ex rel. Hood v. AU Optronics Corp.*, 134 S.Ct. 736 (2014).

[82] *Id.* at 742.

[83] *Id.*

parties seeking to remove certain actions under CAFA's mass action provision generally, and for attorney general actions specifically because it requires ''100 or more persons'' be actually named as plaintiffs. Implicitly, the ruling also requires that each plaintiff must have a claim in excess of $75,000 for the claim to remain in federal court. As a practical matter, the Court's ruling enhances the incentive for private contingency-fee counsel to pair with state attorneys general and bring *parens patriae* actions in state court in tandem with or immediately following private class actions. Likewise, it also increases the risk that multiple cases for essentially the same conduct can proceed in different courts and raises concerns of potential double recovery for the same harm. In sum, the Supreme Court's decision opens the door to attorneys general functionally serving as class representatives for individual citizens' rights while avoiding removal to federal court. Thus, the full impact of the Court's ruling will only be revealed as new claims are pursued by or in the name of state attorneys general.

Statutory Safe Harbors

Many state consumer protection statutes contain a general exemption, or ''safe harbor,'' for activities that are already regulated, and courts have analyzed these exemptions separate from a federal preemption defense.[84] A typical safe harbor provision reads:

> Nothing in this chapter shall apply to actions or transactions otherwise permitted, prohibited or regulated under laws administered by the insurance commissioner of this state, the state utilities and transportation commission, the federal power commission or any other regulatory body or officer acting under statutory authority of this state or the United States.[85]

Other states, however, provide a narrower exemption for only those activities ''permitted'' by a regulatory body.[86] Additionally, the application of such exemptions varies by state. Some courts apply the safe harbor if the general **transaction** is authorized by law, while other courts require the **allegedly deceptive activity** to be specifically authorized by law or the relevant regulatory authority.

The broadest application of these safe harbors is the ''general activities'' test. Courts applying this test find that the statute exempts all activities where the '' 'general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited.' ''[87] For example, in *Peter v. Stryker Orthopaedics*, the plaintiff brought a claim under Michigan's CPA, alleging that the defendant failed to provide the promised benefits in connection with the sale of a prosthetic knee because it fractured after implantation. The court noted that ''[p]rosthetic knees are medical devices, which are heavily regulated by the FDA'' and ''the FDA specifically authorized Defendant to market the prosthetic knee at issue.'' Thus, the safe harbor applied, despite the alleged defect, because the sale of prosthetic knees was authorized by law.[88]

Other courts abandoned the ''general activities'' test, instead applying safe harbor provisions more narrowly.[89] Under this narrower interpretation, alleged deceptive activity is exempt only if that activity is specifically permitted or authorized by a regulatory scheme.[90] For example, in pharmaceutical and medical device cases, marketing and promotional statements may be protected by a safe harbor if the statements are consistent with the FDA-approved label.[91]

In *DePriest*, the plaintiffs alleged that AstraZeneca's ''actions in marketing Nexium as a superior product to Prilosec were fraudulent and violated the Arkansas Deceptive Trade Practices Act [(ADTPA).]'' [92] The trial court examined the FDA-approved labeling for Nexium, which included clinical studies showing that Nexium performed better than Prilosec for healing erosive esophagitis. The court concluded that AstraZeneca's ''activity fell within the safe harbor provision of the ADTPA because the challenged promotional and advertising activity was supported by Nexium's FDA-approved labeling.''[93] The Arkansas Supreme Court upheld the trial court's decision and agreed that the FDA-approved labeling indicated Nexium was superior to Prilosec. Additionally, the court noted that ''information in the labeling of a new drug reflects a determination by the FDA that the information is not false or mislead-

[84] See Prohias v. Pfizer, Inc., 490 F. Supp. 2d 1228, 1232 (S.D. Fla. 2007); DePriest v. AstraZeneca Pharm., L.P., 351 S.W.3d 168, 171 (Ark. 2009); Prohias v. AstraZeneca Pharm., L.P., 958 So. 2d 1054, 1056 (Fla. Dist. Ct. App. 2007).

[85] Mary Dee Pridgen, *Consumer Protection and the Law* § 4:32 (Thomson/West ed., 2013) (citing the consumer protection statutes of Alabama, Alaska, Delaware, the District of Columbia, Florida, Indiana, Louisiana, Missouri, Nebraska, Utah, Virginia, and Washington).

[86] *Id.* (citing the consumer protection statutes of Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New Mexico, New York, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Utah, Virginia, and Wyoming).

[87] *Peter v. Stryker Orthopaedics, Inc.*, 581 F. Supp. 2d 813, 815 (E.D. Mich. 2008) (quoting *Smith v. Global Life Ins. Co.*, 597 N.W.2d 28, 28 (1999)); *see also Arnett v. Mylan, Inc.,* No. 2:10-cv-00114, 2010 WL 2035132, at *3 (S.D. W. Va. May 20, 2010) (the statutory language of the exemption ''focuses solely on whether there is regulation, not whether there is compliance''); *Duronio v. Merck & Co.*, No. 267003, 2006 WL 1628516, at *7 (Mich. Ct. App. June 13, 2006) (''Because the general marketing and advertising activities underlying plaintiff's [CPA] claim are authorized and regulated under laws administered by the FDA, the [statutory] exemption . . . applies to plaintiff's [CPA] claim.'').

[88] *Peter*, 581 F. Supp. 2d at 816.

[89] *See State v. Ortho-McNeil-Janssen Pharm., Inc.*, No. 2007-CP-42-1438, 2011 WL 3794016 (S.C. Com. Pl. Feb. 25, 2011).

[90] *See Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 941 (7th Cir. 2001).

[91] *See id.* at 941 (''If the parties are doing something **specifically authorized** by federal law, section 10b(1) will protect them from liability under the CFA. On the other hand, the [Illinois Consumer Fraud and Deceptive Business Practices Act (CFA)] exemption is not available for statements that manage to be in technical compliance with federal regulations, but which are so misleading or deceptive in context that federal law itself might not regard them as adequate.''); *DePriest*, 351 S.W.3d at 174 (''[F]ederal law specifically permits drug manufacturers to promote their drugs to consumers and physicians in a manner that is consistent with and supported by the labeling approved by the Food and Drug Administration.'').

[92] *DePriest*, 351 S.W.3d at 170.

[93] *Id.* at 175.

  PLIR ISSN 1542-9547

ing.''[94] Thus, ''if the FDA labeling supports the statements made in the advertising for an FDA-approved drug, the statements are not actionable under the ADTPA.''[95]

However, the statutory safe harbor will not protect a company's marketing activities where its statements are allegedly **inconsistent** with the FDA-approved label.[96] In *Prohias*, the plaintiffs alleged that Pfizer marketed its drug Lipitor inconsistently with the FDA-approved label. Specifically, at the time of its pre-2004 advertisements, Lipitor was not approved to reduce the risk of coronary heart disease in any group of people, and, according to the FDA approval, its effect on coronary heart disease was unknown. The court noted that Florida's and Massachusetts's consumer fraud statutes ''only bar lawsuits challenging conduct which is specifically permitted by a federal or state regulatory scheme.''[97] In this case, the plaintiffs alleged that Pfizer engaged in advertising that was not approved or even viewed by the FDA; therefore, the court held that the conduct was not protected by the relevant safe harbor provisions.[98] On the other hand, the court found that plaintiffs' post-July 2004 claims were barred by the safe harbor provision because the FDA approved Lipitor to reduce the risk of heart attacks in patients in 2004. Thus, the court held that Pfizer's advertisements fell within the relevant safe harbor provisions because the ''advertisements that stated or implied that Lipitor reduced the risk of heart disease or heart attacks simply marketed an approved use for the drug.''[99] This was true even though the defendant's advertisements may not have comported precisely with the approved label.[100]

An additional issue arises when deceptive marketing claims are based on a party's continuing duty to warn or update its label. In *Ortho-McNeil-Janssen Pharmaceuticals*, the plaintiff alleged that the defendant's FDA-approved package inserts were deceptive because they failed to warn of some adverse effects associated with the drug.[101] The court found that the defendant was not protected by the statutory safe harbor because drug manufacturers have a continuing duty to update their labels and emphasized that the FDA does not **allow or permit** deceptive activities in the marketing and labeling of drugs.[102]

In the end, safe harbor provisions found in state consumer protection acts can provide a powerful defense against deceptive marketing claims when the challenged marketing is consistent with the FDA-approved label.

State Medicaid Fraud Act Claims

Another enforcement tool utilized by attorneys general is a state Medicaid Fraud Act, sometimes referred to as a state false claims act, which, unlike some CPAs, typically does not contain a statutory safe harbor for FDA approval. Under the federal-state Medicaid scheme, states are financially incentivized to enact false claims acts that are modeled after the federal False Claims Act. Enacting such a state false claims act entitles a state to a 10% increase in its share vis-à-vis the federal government of any amounts recovered under the law. Most states have enacted some version of the federal False Claims Act. The federal act, however, has been amended by the Fraud Enforcement and Recovery Act of 2009 (FERA), the Patient Protection and Affordable Care Act (ACA), and the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act). States were given until March 31, 2013 to conform their state false claims acts to the amended federal act to qualify for the financial incentive, and many states have done so.

State attorneys general have sought to recover damages and civil penalties where a person or company was alleged to make or cause to be made a false claim for Medicaid benefits. Companies have secured dismissals of Medicaid fraud claims on the grounds that the regulatory ambit of the statute extends only to healthcare ''providers,'' which does not include pharmaceutical or medical device companies.[103] Another company won summary judgment on a Medicaid fraud claim after the court characterized the claim as a ''product liability claim'' within the meaning of a state statute that expressly exempted such claims from liability under the state's Medicaid fraud statute.[104]

In *Zyprexa*, Mississippi sued to recover penalties and damages under the state false claims act based on the state's payments for a prescription medicine.[105] The state sought to recover amounts paid and civil penalties for each off-label or ''non-medically necessary'' prescription that resulted from the alleged misconduct. The court ruled that the medical necessity of each prescription was a highly individualized determination. The state, however, offered only aggregated evidence of alleged nonmedical necessity of all of the prescriptions. Concluding that the aggregate evidence was insufficient, the court granted summary judgment for the defendant.[106]

Similarly, the Supreme Court of Louisiana held that the Attorney General failed to establish sufficient facts to prove a cause of action under Louisiana's Medical

[94] *Id.* at 177 (internal quotation omitted).

[95] *Id.* at 177–78 (citing *Bober*, 490 F. Supp. 2d at 941 (''Where statements concerning Zantac 75 and Zantac 150 did not falsely claim that one could not be substituted for another and comported with the FDA-approved label, the Illinois Consumer Fraud Act [(CFA)] would not impose higher disclosure requirements than those that are sufficient to satisfy federal regulations; therefore if drug manufacturer was doing something **specifically authorized** by federal law, safe harbor provision of Illinois CFA would protect it from liability, and plaintiffs failed to state a cause of action.'').

[96] *See Prohias*, 490 F. Supp. 2d at 1232–33.

[97] *Id.* at 1233.

[98] *Id.* at 1234–35; *see also South Carolina v. Eli Lilly & Co.*, No. 2007-CP-42-1855, 2009 WL 6058384 (S.C. Com. Pl. Sept. 22, 2009) (holding that the safe harbor was not applicable where plaintiff alleged that defendant engaged in misleading marketing and promotion of a drug in several populations where the efficacy and safety of the drug were not yet established because ''[t]he FDA does not allow or authorize the illegal or deceptive activities that the Plaintiff alleges occurred in this case'').

[99] *Prohias*, 490 F. Supp. 2d at 1234.

[100] *See id.* at 1235.

[101] *See Ortho-McNeil-Janssen Pharm., Inc.*, No. 2007-CP-42-1438, 2011 WL 3794016.

[102] *Id.*

[103] See, e.g., Commonwealth v. AstraZeneca Pharm., LP, No. 2178 (Pa. Com. Pl. Dec. 10, 2008).

[104] *Att'y Gen. v. Merck Sharp & Dohme Corp.*, 807 N.W.2d 343, 347 (Mich. Ct. App. 2011).

[105] *Zyprexa*, 671 F. Supp. 2d at 401–02.

[106] *Id.* at 453.

Assistance Programs Integrity Law (''MAPIL'') against defendant, a pharmaceutical company.[107] In *Caldwell ex rel. State v. Janssen Pharmaceutical, Inc.*, the Louisiana Attorney General sued under the Louisiana MAPIL to recover civil penalties from a pharmaceutical company.[108] The state alleged that the company caused fraudulent claims to be presented to the Louisiana medical assistance agency and further alleged that the company made misrepresentations about its prescription medicine in order to attempt to obtain payment from Louisiana's medical assistance program funds. A jury concluded that the company's marketing violated MAPIL, resulting in a civil penalty of $257 million. The pharmaceutical company was also assessed $70 million in attorney fees and $3 million in costs. Louisiana's intermediate appellate court affirmed these awards.[109] The Louisiana Supreme Court, however, conducted an in-depth statutory analysis and held that ''there must be causal link between the misleading marketing statement and a false or fraudulent claim for payment to a health care provider or other person to establish liability under MAPIL.''[110] Finding there was insufficient evidence in the record for the Attorney General to prove the necessary causal link, the court reversed the district court's judgment in favor of the Attorney General.[111] Nevertheless, this case and others illustrate the risks posed to companies by similar penalties-only Medicaid fraud suits.[112]

[107] *Caldwell ex rel. State v, Janssen Pharmaceutical, Inc.*, —So. 3d—, 2014 WL 341038, at *1 (La. Jan. 28, 2014)

[108] *Id.*

[109] *Id.*

[110] *Id.* at 11.

[111] *Id.*

[112] *See State ex rel. McGraw v. Johnson & Johnson*, No. 04-C-156 (W. Va. Cir. Ct. 2008) (''[F]or the purposes of determining an appropriate civil penalty, [that] Court conclude[d] as a matter of law that whenever false or misleading promotional materials that concern health [are] delivered to the public, or its healthcare providers, that such promotional materials in and of [themselves] cause harm and injury.''), *rev'd and remanded*, 704 S.E.2d 677 (W. Va. 2010); *State v. Ortho-McNeil-Janssen Pharm., Inc.*, No. CV 2007-15345, 2012 WL 1669841 (Ark. Cir. Ct. May 9, 2012) (''On the plaintiff's claim for violation of the Arkansas Medicaid Fraud False Claims Act the court ruled that based upon the verdict of the jury the defendants had committed 238,874 violations of such Act for the period of time from November 20, 2002 through June 30, 2006, and assessed the minimum statutory penalty allowed by law of $5,000.00 per violation, resulting in an aggregate penalty of $1,194,370,000.00.''), *appeal docketed*, No. 12-1058 (Ark. Dec. 7, 2012).

Conclusion

In view of the recent trends, the risks to companies posed by class action cases have waned in some areas of litigation but remain vigorous or have increased in others due to adaptations by the plaintiffs' bar. Although products liability class actions have dramatically decreased and the recent wave of third-party payor class actions has subsided, securities fraud, antitrust actions, and ''mass actions'' against the pharmaceutical and medical device industries have been prevalent, and the CPA-based class action is becoming a more attractive vehicle for plaintiffs. As noted at a recent class action summit, the plaintiffs' bar is encouraging its members to explore CPA strategies in response to *Dukes*:

> Once certification is granted, settlement prospects (usually) increase, given the resources defendants must expend trying a case on a class-wide basis. Following the Supreme Court's 2011 decision in [*Dukes*], the defense bar has largely concluded that the glory days of CPA class actions are over. We disagree. . . . [F]ar from sounding the death knell for class actions, as many early post-[*Dukes*] commentators opined, CPA class actions are still being certified.[113]

Recent cases show that, when the plaintiff invoking the CPA is a state attorney general rather than a private plaintiff, the CPA may allow recovery of substantial civil penalties, plus costs and attorney fees, without a need for the state to prove actual damages or injury to anyone. There have been successful strategies employed to defeat these claims and, in other instances, to substantially reduce potential exposures. Knowing the specific requirements for CPA claims in the states where claims may be advanced is critical to managing risk and limiting exposure. A robust compliance program that takes into account the potential triggers for aggregate litigation is essential. If a litigation defense becomes necessary, early development of a cohesive strategy is key. The rise in class actions and aggregate litigation has made threshold disputes over CAFA jurisdiction, multidistrict litigation proceedings, pleading challenges under *Twombly*[114]/*Iqbal*,[115] standing challenges, and class certification challenges especially important battlegrounds in these cases.

[113] Terrell & Gunning, *supra* note 20, at 507–08.

[114] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).

[115] *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

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