MoloLamken

Supreme Court Business Briefing

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MOLOLAMKEN
SUPREME COURT BUSINESS BRIEFING

The Supreme Court's 2012 Term produced many decisions important to corporations doing business in the United States and abroad. The Court continued its trend of strictly enforcing arbitration agreements, including those that preclude class-wide litigation of claims, and limited the ability of plaintiffs to avoid federal jurisdiction over class actions. The Court also restricted employer liability for workplace harassment. It held that federal law preempts certain state-law design-defect claims. And it limited the territorial scope of the Alien Tort Statute, precluding efforts to hold corporations liable under that statute for allegedly aiding and abetting human rights abuses overseas.

The Court also continued to read the Nation's intellectual property laws restrictively. In a case with broad implications for the biotech industry, the Court held that "isolated" human DNA is not eligible for patent protection, although modified forms of DNA may be. The Court interpreted copyright's "first sale" doctrine broadly, effectively limiting the authority of copyright holders to control the importation of their works into the United States. And it held that "reverse payment" settlements of patent-infringement suits between generic and brand-name pharmaceutical manufacturers are subject to rule-of-reason scrutiny under the antitrust laws, overturning lower court decisions that had reviewed such settlements under more lenient standards.

Even some decisions that may appear more significant for their social implications will have a substantial impact on business. The Court's rulings on gay marriage, for example, will have significant and immediate consequences for a wide range of employers.

With those and other leading decisions in mind, we are pleased to present the third annual MoloLamken Supreme Court Business Briefing. We have identified cases with the greatest potential impact on a wide range of businesses. For each one, we have distilled the facts and holdings down to a concise summary and highlighted why the decision matters to business. Our aim is to allow busy individuals to stay current on the Supreme Court's docket and understand the potential impact of its decisions with a minimum of time and effort. We hope you find it informative.

ABOUT MOLOLAMKEN

MoloLamken is a law firm focused exclusively on representing clients in complex litigation. We handle civil as well as criminal and regulatory matters across the country. We represent plaintiffs as well as defendants.

Our founding partners, Steven Molo and Jeffrey Lamken, developed national reputations based on their courtroom successes while partners at large, full-service firms, where they held leadership positions. With an abiding belief that complex litigation is most effectively handled by smaller teams comprised of smart, highly experienced lawyers focused on results rather than process, they formed the firm in the midst of the worst economic crisis since the Great Depression.

We provide experienced advocacy before juries, judges, and appellate courts, including the Supreme Court of the United States. We also represent clients in regulatory and criminal investigations and conduct internal investigations.

Our strength lies in the intellect, creativity, and tenacity of our lawyers and our experience in applying those attributes to achieve great results for clients in serious matters.

Learn more about our talented team by visiting us at www.mololamken.com.

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American Express Co. v. Italian Colors Restaurant, No. 12-133

arbitration — class-action waivers

American Express addressed the enforceability of class-action waivers in arbitration clauses.

The plaintiffs in *American Express* were small businesses who contended that American Express used monopoly power to force them to accept credit cards with significantly higher merchant fees than competing cards. Under their contracts with American Express, the merchants were required to arbitrate any claims; they also waived the right to pursue claims on a class-action basis. The plaintiffs nonetheless filed a class action against American Express, alleging federal antitrust violations. When American Express moved to compel arbitration, they opposed on the ground that a class action was the only practical mechanism for asserting their claims. They submitted a declaration from an economist who estimated that the cost of expert analysis required to prove the antitrust claims would exceed $1 million, whereas the expected recovery for any individual claimant would be less than $40,000.

The district court enforced the class-action waiver and dismissed the suit. The U.S. Court of Appeals for the Second Circuit reversed. Because requiring plaintiffs to arbitrate their claims individually would impose prohibitive costs, the court ruled the contractual waiver unenforceable and allowed the case to proceed as a class action.

The Supreme Court reversed. The Court explained that the Federal Arbitration Act reflects an overarching principle that arbitration is a matter of contract, and that courts must rigorously enforce arbitration agreements according to their terms. The class-action waiver was therefore enforceable unless it conflicted with the commands of another federal statute. The Court found nothing in the federal antitrust laws that indicated Congress's intent to alter the normal rules governing arbitration clauses. Although the Court acknowledged language in earlier cases suggesting that arbitration agreements must allow for "effective vindication" of federal statutory rights, the Court saw a difference between a contract that expressly prohibits a party from asserting a federal claim and a contract that merely renders such a claim too costly to pursue. The Second Circuit's approach, the Court added, threatened to destroy the prospect of speedy resolution that arbitration was meant to secure.

American Express continues the Court's recent trend—highlighted in decisions such as *AT&T Mobility LLC v. Concepcion*—of enforcing arbitration agreements according to their terms. The decision provides greater certainty that class-action waivers in arbitration clauses will be strictly enforced, even where enforcement allegedly impairs a party's practical ability to pursue a claim. *American Express* thus reaffirms the utility of arbitration clauses with class-action waivers as an effective means of managing exposure to class-action liability.

American Express *continues the Court's recent trend of enforcing arbitration agreements according to their terms.*

Amgen Inc. v. Connecticut Retirement Plans and Trust Funds, No. 11-1085

class actions — securities litigation

Amgen addressed whether plaintiffs bringing a securities-fraud action under the "fraud on the market" theory must prove that the alleged misrepresentations were material as a prerequisite to class certification.

Plaintiffs bringing securities-fraud claims under Section 10(b) of the Exchange Act must prove, among other things, that the defendant made a misrepresentation of material fact and that plaintiffs relied on that misrepresentation in purchasing or selling the security. Under the "fraud on the market" theory, endorsed by the Supreme Court in *Basic Inc. v. Levinson*, the price of a security traded in an efficient market reflects all public, material information about the company. Relying on that theory, the Supreme Court has established a rebuttable presumption that, in purchasing securities in an efficient market, a plaintiff relies on any public material misrepresentations concerning that security.

The plaintiffs in this case alleged that Amgen made material misrepresentations, and they invoked the fraud-on-the-market theory to support a presumption of reliance. The plaintiffs then moved to certify a class under Rule 23(b)(3), which requires that "the questions of law or fact common to class members predominate over any questions affecting only individual members." The district court certified the class, and Amgen appealed to the U.S. Court of Appeals for the Ninth Circuit. Amgen contended that the district court erred by requiring the plaintiffs merely to plead, rather than prove, materiality at the class-certification stage. If the misrepresentations were not material, Amgen argued, they would not have affected the market price of the security; the plaintiffs could not have relied on a distorted market price; and the fraud-on-the-market presumption of reliance would not apply. As a result, questions of individual plaintiffs' reliance would predominate, making class certification improper. The Ninth Circuit rejected Amgen's arguments and affirmed, deepening a circuit split over whether plaintiffs must prove materiality at the class-certification stage.

The Supreme Court affirmed. Rule 23(b)(3) requires plaintiffs to show only that common questions predominate for the class, not that the class will prevail on the merits of those questions. The materiality of a misrepresentation, the Court explained, is an objective question that can be proved through evidence common to the class. Amgen's focus on materiality as a predicate to the fraud-on-the-market theory was thus misplaced. Materiality is an independent element of the plaintiffs' securities-fraud claims; if the plaintiffs fail to prove materiality at summary judgment or trial, they lose on the merits. Thus, even if the class-wide fraud-on-the-market theory fails for lack of materiality, questions of individual class members' reliance still would not predominate, because all class members would lose on the merits for the same reason.

Amgen eliminates what in some circuits had been a significant defense to class certification. Perhaps more intriguing is what the Court did not decide. The majority noted that Amgen had not challenged the fraud-on-the-market theory itself. But Justice Alito, in a concurring opinion, and Justices Scalia, Thomas, and Kennedy, in dissent, questioned the theory's continued viability.

*While **Amgen** holds that plaintiffs relying on the fraud-on-the-market theory need not prove materiality to obtain class certification, several Justices questioned the continuing validity of the fraud-on-the-market theory itself.*

Association for Molecular Pathology v. Myriad Genetics, Inc., No. 12-398

patents — patent-eligibility of DNA

Myriad addressed whether isolated human genetic material is patent-eligible.

Section 101 of the Patent Act defines patent-eligible subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." Laws of nature, natural phenomena, and abstract ideas, however, are not patentable. While the U.S. Patent and Trademark Office ("PTO") has issued patents on isolated human DNA for three decades, the Supreme Court had never considered whether such genetic material was patent-eligible.

Overturning three decades of practice by the PTO, ***Myriad*** *holds that isolated human DNA is not eligible for patent protection, although modified DNA may be.*

Myriad Genetics discovered the location and sequence of two human genes—the BRCA1 and BRCA2 genes—that have profound significance for women's health. When certain mutations of those genes are present, the individual has a dramatically increased risk of breast and ovarian cancer. Myriad obtained a number of patents based on its discovery. Those patents cover, among other things, composition claims over BRCA1 and BRCA2 DNA sequences that have been "isolated," through chemical processes, from naturally occurring human genes. The patents also cover composition claims over complementary DNA, or "cDNA," a synthetically created DNA from which certain genetic material has been removed.

A group of physicians, patients, and advocacy groups sued to invalidate nine of Myriad's claims to sequences of both isolated DNA and cDNA. The district court ruled for the plaintiffs, concluding that Myriad's claims were not patent-eligible under § 101 because they covered products of nature. A divided panel of the U.S. Court of Appeals for the Federal Circuit reversed, with each of the three judges advancing a different view of the issue.

The Supreme Court reversed in part. The Court held that isolated DNA is a natural phenomenon and thus ineligible for patenting under § 101. The location and order of the nucleotides of the BRCA1 and BRCA2 genes existed in nature before Myriad found them. In isolating those genes, the Court reasoned, Myriad did not create or alter the genetic structure of DNA. It was undisputed that Myriad had made a major contribution in discovering the location and sequence of the BRCA1 and BRCA2 genes. But the Court concluded that "[g]roundbreaking, innovative, or even brilliant discovery does not itself satisfy the § 101 inquiry." The Court rejected the notion that the PTO's practice of awarding patents on isolated DNA was entitled to deference, noting that the United States had taken a different position in the litigation.

The Court reached a different conclusion with respect to cDNA. It found that cDNA is patent-eligible because it differs from naturally occurring DNA. By removing certain genetic material, a technician making cDNA creates something not found in nature. Accordingly, cDNA—unlike isolated human DNA—is patent-eligible.

The Court's decision may have a broad impact on biotechnology companies with significant investments in genetic research. Without the incentives of patent protection for isolated DNA, those companies must now reassess their intellectual property assets and decide how to allocate research and development efforts. The decision will be welcomed by physicians and other service providers, however, who can now make use of previously discovered portions of the human genome.

(Disclaimer: MoloLamken represented an amicus curiae *in this case)*

Federal Trade Commission v. Actavis, Inc., No. 12-416

antitrust — reverse payment settlements

Actavis addressed the standard for determining whether "reverse payment" settlements violate the antitrust laws.

Where a generic drug manufacturer seeks to bring to market a generic version of a drug already marketed by a brand-name manufacturer, the two companies often end up in litigation over the validity and scope of the brand-name manufacturer's patent for the drug. Sometimes, such suits are resolved by so-called "reverse payment" settlements in which the brand-name manufacturer pays the generic manufacturer a sum of money and the generic manufacturer agrees to stay out of the market for all or part of the remaining patent term. Such agreements allow the parties to resolve their dispute over the patent's validity and scope without the risk and expense of litigation. But because they result in a potential competitor remaining out of the market, they raise potential antitrust concerns.

Actavis involved a brand-name drug called AndroGel manufactured by Solvay Pharmaceuticals. After Actavis and other generic manufacturers challenged the validity and scope of Solvay's patent, Solvay filed an infringement action. The parties eventually settled, with the generic manufacturers agreeing to keep their drugs off the market for a number of years in return for payments from Solvay.

The Federal Trade Commission sued, claiming that the settlement violated the antitrust laws. The district court rejected the suit, reasoning that a settlement that does not exceed the scope of the patent—*i.e.,* does not exclude the generic manufacturer for longer than the patent's term or prohibit it from selling a product outside the patent's scope—cannot violate the antitrust laws. The U.S. Court of Appeals for the Eleventh Circuit affirmed on similar grounds.

The Supreme Court reversed. It rejected the notion that patent settlements are per se lawful if they do not exceed the patent's scope. Looking to past decisions, the Court noted that it had applied antitrust laws to claims of patent misuse. Although the Court recognized a general policy favoring settlement, it found that the anticompetitive effects of reverse payment settlements could outweigh that policy, particularly where the settlement payment was "large" and "unexplained." Nonetheless, the Court rejected the Federal Trade Commission's argument that reverse payment settlements are so clearly anticompetitive that they should be presumed unlawful. Instead, the Court held that such agreements should be judged under the "rule of reason" that governs most antitrust claims, under which the party challenging the agreement must prove that it unreasonably restrains trade under the particular circumstances of the case.

Actavis is a significant decision for brand-name and generic manufacturers alike. The case will make settlement of patent disputes more difficult, increasing the cost and duration of litigation. The case will also affect the manner in which such disputes are settled. Because the Court focused on "large" and "unexplained" payments, parties should document the legitimate economic justifications for a settlement and should also consider alternative settlement structures that avoid large cash payments. Although the Court refused to adopt a presumption of illegality, even "rule of reason" litigation can be time-consuming, expensive, and unpredictable, particularly because such claims may be brought by private plaintiffs as well as the Federal Trade Commission.

__Actavis__ will make settlement of certain patent disputes more difficult, increasing the cost and duration of litigation.

Gabelli v. Securities and Exchange Commission, No. 11-1274

civil penalty actions — statute of limitations

Gabelli addressed whether, in a Securities and Exchange Commission action for civil penalties, the statute of limitations in 28 U.S.C. § 2462 begins to run when the fraud is complete or when the fraud is discovered.

Section 2462 provides the limitations period that governs many government actions for civil fines, penalties, and forfeitures. It provides that such an action "shall not be entertained unless commenced within five years from the date when the claim first accrued."

In *Gabelli*, the SEC brought an enforcement action alleging that the defendants aided and abetted violations of the Investment Advisers Act. The SEC sought civil penalties, which are subject to § 2462's five-year statute of limitations. The wrongful conduct was alleged to have occurred from 1999 until 2002, but the complaint was not filed until 2008. The defendants moved to dismiss, arguing that the suit was not timely under § 2462. The district court granted the motion, but the U.S. Court of Appeals for the Second Circuit reversed. The Second Circuit held that the "discovery rule" applied. Under that rule, a claim does not accrue until the plaintiff discovers that it has a cause of action, or could have discovered it with reasonable diligence.

The Supreme Court reversed. The Court explained that the most natural reading of § 2462 is that a claim accrues when a defendant's allegedly fraudulent conduct occurs. The Court acknowledged that the discovery rule is often applied to extend limitations periods for fraud claims brought by private plaintiffs. The Court stated, however, that it had never applied the discovery rule where the plaintiff is not a defrauded victim seeking recompense but instead the Government bringing an enforcement action for civil penalties.

The Court stated that repose is particularly important where the purpose of the action is not to compensate an injured plaintiff, but to punish the defendant. The Court further noted that the government has less need for the discovery rule than a private plaintiff: While private parties often have no reason to suspect that they have been defrauded, the SEC's very purpose is to root out fraud, and it has many tools to investigate wrongdoing. Finally, the Court stated that challenges in determining when the government, with its numerous employees and agencies, knew or reasonably should have known of the fraud also counseled against applying the discovery rule here.

Gabelli is significant because § 2462's five-year limitations period applies not only to SEC actions for civil penalties, but also to a wide variety of civil enforcement actions by other government agencies. It provides a fixed date by which civil enforcement actions can be time-barred. The decision will thus pressure the SEC and other agencies to expedite investigations and decide more quickly whether to file an enforcement action or seek tolling agreements from potential targets. The scope of *Gabelli* is limited, however, in two important respects. First, § 2462's five-year statute of limitations does not apply to enforcement actions seeking equitable remedies such as injunctive relief or disgorgement. Second, the Court left unresolved whether the five-year period could be tolled where a defendant affirmatively conceals the fraudulent conduct.

Gabelli *will pressure the SEC and other agencies to expedite investigations and decide more quickly whether to file an enforcement action or seek tolling agreements from potential targets.*

Genesis Healthcare Corp. v. Symczyk, No. 11-1059

FLSA collective actions — mootness

Genesis addressed whether a putative Fair Labor Standards Act ("FLSA") collective action remains justiciable after the lone plaintiff's individual claim becomes moot.

The FLSA allows an employee to bring a "collective action" to recover damages for wage and hour violations on behalf of herself and other similarly situated employees. Other employees do not become parties to an FLSA collective action, however, unless they affirmatively "opt in" by filing written consent with the court. To facilitate that process, courts have recognized a procedure called "conditional certification," which results in the sending of court-approved notices informing employees of their right to opt in.

The plaintiff in *Genesis* brought a putative FLSA collective action seeking damages for Genesis's alleged policy of automatically deducting time for meal breaks even if an employee worked through a break. Genesis made an offer of judgment under Federal Rule of Civil Procedure 68, offering the plaintiff $7,500 to cover all of the unpaid wages she claimed for herself, as well as her court costs and attorney's fees. Genesis stipulated that if the plaintiff did not accept the offer within 10 days, it would be withdrawn. The plaintiff failed to respond and the offer expired. Because the plaintiff conceded that the offer would have given her complete relief on her individual claim, and because no other plaintiff with a live claim had opted in to the suit, the district court dismissed the entire case as moot. The U.S. Court of Appeals for the Third Circuit reversed. It held that, even though the plaintiff's individual claim was moot, her suit could proceed so that others could have the opportunity to opt in.

The Supreme Court reversed. It observed that Article III of the U.S. Constitution requires that a lawsuit always have a plaintiff with a personal stake in the litigation. The Court rejected the plaintiff's argument that she had a sufficient personal stake in the case based on her interest in representing other similarly situated plaintiffs in a collective action. Because no other employee had opted in to the lawsuit, no one with a live personal stake remained after the plaintiff's claim became moot, rendering the entire action moot. The Court rejected the plaintiff's policy argument that defendants should not be allowed to "pick off" FLSA plaintiffs with settlement offers before the collective-action process is complete, stating that such concerns cannot trump Article III's requirements.

Genesis may provide employers a means of avoiding costly FLSA litigation. By offering the sole plaintiff complete relief on her individual claim, businesses may be able to resolve FLSA suits before they escalate into larger collective actions. The Court's opinion, however, leaves several significant questions unresolved. Notably, the Court did not decide whether an unaccepted offer of complete relief would in fact moot a plaintiff's individual claim. The Court merely assumed that it would, as the plaintiff had conceded the point below. In fact, the courts of appeals remain divided on that question. It is also unclear what significance the Court's decision has for Rule 23 class actions. Although much of *Genesis*'s reasoning would seem to apply in that context as well, the Court repeatedly stressed the differences between the two kinds of suits.

(Disclaimer: MoloLamken represented an amicus curiae *in this case)*

***Genesis** may provide employers a means of resolving FLSA suits before they can escalate into costly collective actions.*

Kiobel v. Royal Dutch Petroleum Co., No. 10-1491

Alien Tort Statute — extraterritoriality

Kiobel addressed the territorial scope of the Alien Tort Statute.

The Alien Tort Statute provides that "[t]he district courts shall have 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." Although enacted over 200 years ago, the statute was little used until the 1980s. For the past generation, however, plaintiffs have invoked the statute to sue not only alleged human rights violators but also corporations, alleging that they aided and abetted such abuses. Even if ultimately unsuccessful, such suits can be both costly to defend and damaging to a corporation's reputation. Many of the cases have involved conduct that occurred entirely outside the United States. *Kiobel* addressed whether the Alien Tort Statute extends to such extraterritorial conduct.

The plaintiffs in *Kiobel* were Nigerian citizens who claim to have been abused by Nigerian military and police forces because of their opposition to oil exploration and production by a Nigerian subsidiary of companies based in the Netherlands and England. After the plaintiffs moved to the United States, they sued the companies in federal court under the Alien Tort Statute, alleging that the companies aided and abetted those human rights violations by Nigerian government forces. The district court allowed some of the claims to proceed, but the U.S. Court of Appeals for the Second Circuit reversed, holding that the Alien Tort Statute applies only to claims against individuals, not corporations.

The Supreme Court granted review and heard argument on the corporate liability issue last Term. After oral argument, however, the Court—in an unusual development—ordered supplemental briefing on whether the Alien Tort Statute applies extraterritorially. The case was then reargued, focusing on that issue.

The Court then ruled that the Alien Tort Statute does not apply to conduct that occurs within the territory of a foreign sovereign. The Court based its holding on the longstanding presumption against extraterritoriality—the principle that U.S. law is presumed not to apply to conduct occurring outside the United States unless Congress clearly manifests that intent. The Court found nothing in the text, history, or purposes of the Alien Tort Statute that overcame that presumption. Because all of the relevant conduct in this case took place outside the United States, the suit had to be dismissed. At the end of its opinion, the Court suggested that the presumption against extraterritoriality might not apply to claims that "touch and concern the territory of the United States" with "sufficient force." Although the Court did not elaborate on the meaning of that phrase, it did make clear that a defendant's mere corporate presence in the United States is not enough.

Kiobel is a significant case for corporations operating abroad. It largely eliminates Alien Tort Statute liability for corporations and individuals based on conduct that occurs overseas. Still, the decision does not completely shield such conduct from liability. It does not prevent plaintiffs from attempting to sue corporations or their officers under state or foreign law. And it does not necessarily preclude liability under other federal statutes such as the Torture Victim Protection Act, which permits suits against individual corporate officers (but not corporations) for certain actions abroad. Finally, as noted above, the decision leaves the door open for claims that "touch and concern the territory of the United States." Thus, although *Kiobel* may significantly stem the flow of litigation, some is likely to remain.

***Kiobel** largely eliminates Alien Tort Statute liability for corporations and individuals based on conduct that occurs overseas.*

Kirtsaeng v. John Wiley & Sons, Inc., No. 11-697

copyright — first sale doctrine

Kirtsaeng addressed whether the "first sale" doctrine applies to copies of a copyrighted work lawfully made abroad.

Section 106 of the Copyright Act grants copyright holders certain exclusive rights, including the right "to distribute copies . . . of the copyrighted work to the public by sale or other transfer of ownership." Section 602 of the Act also gives a copyright holder the right to restrict importation of its work into the United States. Under the "first sale" doctrine set forth in § 109 of the Act, however, a person who purchases a copy of a copyrighted work that was "lawfully made under this title" is entitled to sell or otherwise dispose of that particular copy without the permission of the copyright owner.

In this case, John Wiley & Sons, an academic textbook publisher, sued the defendant, a citizen of Thailand, for copyright infringement. The defendant had bought foreign editions of Wiley's English-language books in Thailand, where they sold at low prices, and had them mailed to the United States, where he resold them at much higher prices. The defendant argued that, under the first sale doctrine, he was not liable for copyright infringement because the books had been lawfully made and legitimately acquired in Thailand. The district court disagreed, holding that the first sale doctrine does not apply to goods manufactured outside the United States. The U.S. Court of Appeals for the Second Circuit affirmed.

The Supreme Court reversed. The central question was whether the phrase "lawfully made under this title" in § 109 requires that the copies be made in geographic territories where the Copyright Act is governing law (*i.e.,* the United States), or whether it encompasses any copies made in compliance with the Copyright Act (including copies manufactured abroad with the copyright owner's permission). The Court analyzed the statute's text and history, as well as the common-law history of the first sale doctrine, and concluded that they did not support a geographic limitation. Instead, the Court held that the first sale doctrine applies regardless of where the copies were made, so long as they were made in accordance with the Act's terms. The Court noted that introducing a geographic limitation would have significant adverse practical consequences, subjecting many U.S.-based businesses that regularly circulate, distribute, or sell copyrighted materials manufactured abroad—from libraries and booksellers to electronics retailers to car dealers—to infringement suits.

Kirtsaeng extends the protections of the first sale doctrine to businesses that purchase and resell copyrighted materials lawfully manufactured abroad. Correspondingly, it limits the rights of copyright holders. By allowing goods lawfully made and purchased abroad to be resold in the United States without the copyright holder's consent, the decision severely limits copyright holders' ability to restrict importation. That, in turn, undermines the ability of copyright holders to engage in the common practice of segmenting the global markets for their works and charging different prices in different regions.

__Kirtsaeng__ holds that copyrighted works lawfully made and purchased abroad are covered by the "first sale" doctrine, and thus may be resold in the United States without fear of copyright infringement.

Mutual Pharmaceutical Co. v. Bartlett, No. 12-142

federal preemption — Federal Food, Drug, and Cosmetic Act

Mutual Pharmaceutical addressed whether federal law preempts design-defect claims brought against generic drug manufacturers.

Federal law establishes a comprehensive regime governing the process by which a drug manufacturer may gain approval from the Food and Drug Administration to market a drug in interstate commerce. The Federal Food, Drug, and Cosmetic Act provides for streamlined approval of generic drugs, so long as the proposed generic drug is chemically equivalent to an already-approved brand-name drug and its proposed labeling is the same as the brand-name drug's labeling. Generic drug manufacturers are prohibited from making any unilateral changes to the drug's composition or labeling.

In *Mutual Pharmaceutical*, a New Hampshire plaintiff brought a design-defect claim against a generic drug manufacturer, Mutual Pharmaceutical, alleging that she developed an acute skin condition after taking a generic form of sulindac, an anti-inflammatory pain reliever. The drug's label warned of potential "severe skin reactions" but did not mention the particular affliction the plaintiff developed. New Hampshire's common law cause of action for design defects holds manufacturers strictly liable for selling products that are "unreasonably dangerous," a condition met if the magnitude of the danger outweighs the utility of the product in view of several factors, including any warnings. Applying those state-law principles, a jury awarded the plaintiff over $21 million in damages, and the U.S. Court of Appeals for the First Circuit affirmed.

The Supreme Court reversed. The Court held that the design-defect claim was preempted because it was impossible for Mutual Pharmaceutical to comply with its obligations under both state and federal law. Because Mutual Pharmaceutical could not legally change the design of sulindac, the Court reasoned, New Hampshire tort law required it to improve the labeling in order to avoid liability. But federal law also prohibited generic manufacturers from changing their labels, so it was impossible for Mutual Pharmaceutical to avoid tort liability while complying with its obligations under federal law. The Court rejected the argument that Mutual Pharmaceutical could have avoided liability by choosing to stop selling the drug in New Hampshire altogether. Where compliance with both federal and state law is otherwise impossible, the Court held, a manufacturer's theoretical option to stop selling its product altogether is not sufficient to save the state law from preemption.

The Court's decision has significant implications for generic drug manufacturers. Two years ago in *PLIVA, Inc. v. Mensing*, the Court held that the Federal Food, Drug, and Cosmetic Act preempts state-law claims for failure to warn of a generic drug's dangers. *Mutual Pharmaceutical* extends that holding to state-law claims for design defects where the warnings accompanying the drug are merely one factor the jury may consider. The Supreme Court's holding precludes a broad range of state-law tort claims against generic drug manufacturers, significantly reducing their exposure to tort liability relative to their brand-name counterparts. At the same time, the Court's holding that state law cannot avoid preemption merely because the defendant could stop selling a product altogether may provide ammunition for preemption arguments under other federal statutes.

Mutual Pharmaceutical *precludes a broad range of state-law tort claims against generic drug manufacturers, significantly reducing their exposure to tort liability relative to their brand-name counterparts.*

Standard Fire Insurance Co. v. Knowles, No. 11-1450

class actions — removal to federal court

Knowles addressed whether a purported class-action plaintiff can defeat federal jurisdiction by stipulating that he, and the class he seeks to represent, will not seek damages that exceed the $5 million threshold for federal jurisdiction and removal under the Class Action Fairness Act of 2005 ("CAFA").

Before CAFA, federal jurisdiction over class actions was governed by the general diversity statute, under which putative class members' claims were not aggregated toward the $75,000 amount-in-controversy requirement. As a result, many putative class actions brought in state court could not be removed to federal court even if the class as a whole sought millions of dollars in damages. In CAFA, Congress significantly expanded federal jurisdiction, providing federal courts with jurisdiction if the purported class has more than 100 members, the parties are minimally diverse, and "the matter in controversy exceeds the sum or value of $5,000,000." CAFA further provides that, in determining whether the $5 million threshold is met, the claims of individual class members must be aggregated.

__Knowles__ eliminates a loophole plaintiffs had used to avoid federal jurisdiction over significant class actions.

In this case, the plaintiff filed a purported class action in Arkansas state court against the Standard Fire Insurance Company, alleging that it underpaid certain homeowner claims. The plaintiff sought to certify a class of "hundreds, and possibly thousands" of Arkansas policyholders. He also purported to stipulate, on behalf of himself and the putative class, that the class would seek total aggregate damages of less than $5 million. Invoking CAFA, Standard Fire removed the case to federal court. The district court found that, absent the stipulation, the claims met CAFA's $5 million jurisdictional threshold. It ordered the case remanded to state court nonetheless because Eighth Circuit precedent held that the plaintiff's stipulation limited the amount in controversy to less than $5 million. The Eighth Circuit declined to hear Standard Fire's appeal.

The Supreme Court reversed. Its rationale was straightforward: "Stipulations must be binding." As the Court explained, a plaintiff cannot legally bind members of a class before the class is certified. Thus, while the individual plaintiff could stipulate as to his own damages, he lacked authority to concede that other class members' claims would be less than $5 million in the aggregate. The plaintiff's stipulation might bind class members if the class eventually were certified and the plaintiff were approved as a class representative. But there were a number of reasons that might not occur: For example, a court might find the plaintiff to be an inadequate representative based on his artificial capping of the class's claims. Because jurisdiction is determined at the time the complaint was filed, the Court held, the contingent stipulation could not override the district court's finding that class-wide damages could exceed CAFA's $5 million amount-in-controversy threshold.

Knowles closes a potentially significant statutory loophole. Damage-capping stipulations had become common in class actions brought in state courts within the Eighth Circuit, and district courts in that Circuit had repeatedly remanded to state courts on the basis of such stipulations. By holding that such stipulations are not determinative, *Knowles* ensures that most substantial class action battles can be fought in federal court.

(Disclaimer: MoloLamken represented an amicus curiae *in this case)*

United States v. Windsor, No. 12-307

equal protection — same-sex marriage

Windsor concerned the constitutionality of the federal Defense of Marriage Act ("DOMA").

DOMA, among other things, amended the Dictionary Act to provide standard federal definitions of the terms "marriage" and "spouse." It provided that "'marriage' means only a legal union between one man and one woman as husband and wife." And it provided that "'spouse' refers only to a person of the opposite sex who is a husband or a wife." Those definitions applied to over 1,000 federal statutes, regulations, and directives pertaining to marital status.

This case concerned two New York residents, Edith Windsor and Thea Speyer, who were lawfully married in Ontario, Canada. New York state law recognized their Canadian marriage as valid. Speyer died, leaving her estate to Windsor. Federal law exempts from taxation property that passes from a "decedent to his surviving spouse." Windsor paid over $350,000 in federal estate taxes but later sought a refund under the marital exemption. The IRS denied the refund on the ground that, under DOMA, Windsor was not recognized as Speyer's spouse. Windsor sued for a refund in federal district court, arguing that DOMA violates the Fifth Amendment. The district court held that DOMA was unconstitutional and ordered a refund. The U.S. Court of Appeals for the Second Circuit affirmed.

The Supreme Court affirmed. The Court noted that the States have traditionally defined and regulated marital relationships. Historically, marriage had been thought of as a union between only a man and a woman. More recently, 12 States and the District of Columbia granted same-sex couples the right to marry. By defining marriage as between a man and a woman, DOMA relegates same-sex marriages that have been sanctioned by those States to "second class" status under federal law. The Court held that DOMA violates the Fifth Amendment because it denies lawfully married same-sex couples the same recognition and protections as lawfully married heterosexual couples. Meanwhile, the Court steered clear of broader issues concerning state restrictions on same-sex marriage, ruling in the companion case of *Hollingsworth v. Perry* that proponents of California's Proposition 8 lacked standing to defend the measure in federal court.

Windsor impacts employers in a number of ways. The federal-law definition of marriage directly affects employee benefit programs. For example, while federal tax law allows an employer to provide tax-free healthcare benefits to an employee's spouse, DOMA made any healthcare benefits provided to same-sex spouses taxable. As a result, employers sometimes had to provide less valuable benefits to employees in same-sex marriages or implement cumbersome workarounds. *Windsor* allows employers to avoid those administrative burdens and treat all marriages valid under state law identically.

The decision affects employers in other ways as well. Under DOMA, for example, employers recruiting foreign nationals could not obtain marriage-based visas for same-sex spouses. *Windsor* removes that impediment. Thus, although *Windsor* will be remembered for its impact on the individuals in same-sex marriages themselves, its impact on the companies who employ them is important as well.

*Although **Windsor** will be remembered for its impact on the individuals in same-sex marriages themselves, its impact on the companies who employ them is important as well.*

Vance v. Ball State University, No. 11-556

discrimination law — employer liability for workplace harassment

Vance concerned the scope of employer liability for workplace harassment under federal law.

Title VII prohibits employers from discriminating on the basis of race or gender with respect to "compensation, terms, conditions, or privileges of employment." The scope of an employer's liability for harassment depends on the status of the harasser. Where that individual is a mere co-worker of the plaintiff, the employer is liable only if the plaintiff can prove that the employer was negligent. By contrast, where the harasser is a "supervisor," the employer can be held liable more readily. Under standards the Court articulated in *Burlington Industries, Inc. v. Ellerth* and *Faragher v. Boca Raton*, the employer is liable unless it proves, as an affirmative defense, that it exercised reasonable care to prevent and correct any harassing behavior and that the plaintiff unreasonably failed to take advantage of the preventive or corrective opportunities provided. The question in *Vance* was who counts as a "supervisor" for purposes of that test.

The plaintiff in *Vance* was an African-American woman who worked as a catering assistant in Ball State University's dining services division. She claimed that she had been racially harassed by another woman who worked in her division. Although the plaintiff claimed that the other woman was her "supervisor," the woman lacked any authority to fire, demote, or discipline her. The district court rejected her suit, and the U.S. Court of Appeals for the Seventh Circuit affirmed. A person with no authority to fire, demote, promote, transfer, or discipline the plaintiff, the court ruled, is not a "supervisor" for purposes of Title VII.

The Supreme Court affirmed. The Court acknowledged that the term "supervisor" has a variety of meanings and might sometimes include individuals who merely have authority to direct another person's work. But the Court held that its prior cases suggested a narrower definition that focused only on those with authority to take certain tangible employment actions, such as firing, demoting, or disciplining their subordinates. That standard, the Court explained, is clearer and easier to apply, reducing the likelihood of threshold disputes over the harasser's status.

Vance limits the scope of an employer's liability for racial or sexual harassment by employees. But the decision's reach should not be overstated. Even where the alleged harasser is a mere co-worker, the employer may still be liable if it acted negligently. Much of the evidence that would be relevant under the *Ellerth/Faragher* affirmative defense—such as the adequacy of the employer's anti-harassment policies—is also relevant to whether the employer was negligent.

Moreover, despite *Vance*'s requirement that a supervisor have power to take tangible employment actions, that standard may be broader than it first appears. For example, the Court suggested that, even if a harasser lacks authority to fire or demote the plaintiff, he may still be a supervisor if he has the ability to *recommend* such actions. *Vance* thus may help employers prevail in some discrimination cases, but it in no way reduces the importance of promulgating and enforcing strict anti-harassment policies.

Vance *may help employers prevail in some discrimination cases, but it in no way reduces the importance of promulgating and enforcing strict anti-harassment policies.*

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