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## Quinn Emanuel Opens First Office on European Continent

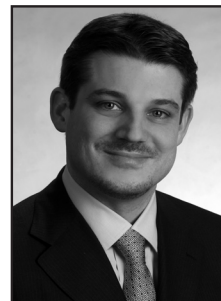
The firm has opened an office in Mannheim, Germany, its first office in continental Europe. The office will focus on patent litigation and it will be led by Dr. Marcus Grosch, one of the leading patent litigators in Germany. Grosch joins Quinn Emanuel from Allen & Overy where he led that firm's German patent litigation practice.

Opening the Mannheim office is a major step forward for the firm's IP practice. Most major patent disputes involve parallel proceedings in multiple jurisdictions. Germany has become the epicenter for patent litigation in the EU and Mannheim is one of the two most important venues in Germany. The firm intends to develop the first integrated transatlantic patent litigation practice.

Grosch, who received his PhD in law *summa cum laude* from Mannheim University, also has an LLM from Yale University. He is an internationally recognized expert in patent litigation having been recognized by publications such as

*Chambers* and *Legal 500*. The German legal publication *JUVE* has ranked him for years among the top German patent litigators and, in 2006, chose him as one of the top 40 German lawyers under age 40 (across all practice areas). Grosch has represented companies such as Assa Abloy, HID, Saint Gobain Isover, Crestron, Roche Diagnostics, Giesecke & Devrient, Freudenberg in both German and cross border litigation. Grosch teaches patent law at University of Freiburg.

The Mannheim office builds on the growing litigation practice in London, where dual qualified partner Marc Becker provides IP expertise on both U.S. and U.K. matters. Quinn Emanuel's German office will have 6 lawyers and 12 employees overall. It will open its doors March 1, 2010. 



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## Quinn Emanuel Expands Pharma, Biotech, and Medical Device Practices with Addition of Star Patent Litigator Peter Armenio

Peter Armenio, one of the country's most successful patent litigators who has won many major victories for his pharmaceutical industry clients, has joined Quinn Emanuel as a partner in the New York office. Peter joins the firm from Kirkland & Ellis where he was a leader in that firm's IP practice. At Quinn Emanuel, he will Co-Chair the firm's Global Life Sciences Practice as the firm continues to expand its patent litigation practice into the pharmaceutical, biotechnology, and

medical device fields.

Peter has a long history as one of the top lawyers for companies involved in the highest stakes patent litigation, including numerous matters where the amount in controversy exceeded \$1 billion. He has won major cases involving pharmaceuticals, biotechnology, and medical devices, including ANDA cases under the Hatch-Waxman Act. 



## Quinn Emanuel London Shortlisted for Legal Business Awards

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## THE OBAMA ADMINISTRATION'S AGGRESSIVE PUSH TO REGULATE OFF-LABEL DRUG PROMOTION

Whatever the fate of health care legislation in Congress, the Obama Administration's health care initiatives are alive and well down the street at the Department of Justice. The interagency Health Care Fraud Prevention and Enforcement Team (HEAT) has been actively filing charges since May 2009, and the first ever National Health Care Fraud Summit convened in Maryland last month. Delivering a welcome address to the packed hall of delegates, Attorney General Eric Holder described health care fraud as "one of our most urgent, destructive, and widespread national challenges." Pharma Beware.

One major aspect of the government's enhanced aggressiveness is a marked increase in enforcement activity relating to so-called off-label promotion. Off-label promotion refers to the marketing of a drug or medical device for a purpose other than the one reflected in the drug's FDA-approved labeling. In the thirteen months since President Obama took the oath of office, the Department of Justice has secured guilty pleas to off-label charges from two of the world's largest pharmaceutical corporations—Pfizer and Eli Lilly—as well as several smaller companies and individuals. The penalties paid in these cases can be staggering—in Pfizer's case, \$2.3 billion in penalties, disgorgement, and interest.

### *Widespread Off-Label Use*

In the face of such massive settlements—and the attendant press coverage demonizing the companies involved—it is easy to forget that the use of off-label drugs is a widespread, well-accepted, and perfectly legal phenomenon. Recent studies estimate that more than 20% of all prescriptions are written for off-label uses, with much higher percentages in certain medical specialties. For example, several commonly prescribed treatments for bipolar disorder have been cleared by the FDA only as antidepressants, while certain antidepressants are commonly prescribed to treat pain. The vast majority of pediatric prescriptions are off-label, as are a large percentage of drugs prescribed to cancer patients and victims of HIV/AIDS.

Indeed, in the first month of the Obama Administration, the Food & Drug Administration issued a report that recognized that off-label drugs are a critical component of medical practice and "may even constitute a medically recognized standard of care." FDA, *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical*

*or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices*, at 3 (Jan. 2009). Courts across the country have echoed that sentiment; according to one recent district court opinion, "'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature." *United States ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582, at \*6 (W.D.N.Y. May 22, 2009).

Given the critical role of off-label drugs in providing cutting-edge medical care, the government has an affirmative interest in encouraging the dissemination of information about beneficial off-label uses. Indeed, the FDA has acknowledged that "the public health may be advanced by healthcare professionals' receipt of medical journal articles and medical or scientific reference publications on unapproved new uses of approved or cleared medical products that are truthful and not misleading." *Good Reprint Practices*, *supra* at 3.

### *Off-Label Enforcement*

Where the government purports to draw the line is at *promotion* by drug companies directed at off-label uses. However significant the benefits associated with an off-label use, and however great the interest in disseminating medical information about beneficial uses, the FDA insists that a drug not be *promoted* for that use unless and until the use is reflected in the drug's approved labeling. Otherwise, they claim, drug companies would have no incentive to undertake the costly and time-consuming clinical trials necessary to secure FDA approval for new uses.

Off-label regulation is thus a very tricky piece of business; in the words of the Supreme Court, "the FDA is with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals." *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 350 (2001). On the one hand, the government has an interest in fostering the spread of information about off-label usage; on the other, the government tightly circumscribes the role that drug companies can play in the educational process.

For example, if a company underwrites a promotional speech, the speaker must stay on-label—unless she is asked a question about an off-label use, in

which case she is permitted to respond—and provide off-label information. Company sales representatives generally cannot discuss off-label uses, but the company’s scientific representatives are permitted to do so under certain circumstances, and their medical-affairs departments can send literature relating to off-label uses to physicians upon request. The reasoning behind the maze of regulations is clear enough, but the maze itself is notoriously difficult to navigate.

In the main, the government relies on two enforcement mechanisms to police off-label promotion: civil claims under the False Claims Act, and criminal charges for the sale of misbranded drugs. The False Claims Act (FCA) prohibits submitting or causing to be submitted a false claim to the government for payment. 31 U.S.C. § 3729(a)(1). Liability under the Act turns not on whether a claim is literally true or false, but on whether the claim seeks a payment to which the claimant is not entitled. Thus, a claim submitted to Medicare for reimbursement of an off-label use may accurately reflect the patient’s condition and the drugs administered to treat it, yet still give rise to False Claims Act liability if the claimant knows that the claim is ineligible for coverage. Accordingly, the government can pursue FCA actions against drug companies—or, frequently, intervene in FCA lawsuits filed by *qui tam* relators—on the theory that a company’s promotional activities caused health care providers to bill the government for uncovered off-label uses.

As courts have recognized, an essential predicate of this theory is that the off-label use is ineligible for reimbursement. See, e.g., *United States ex rel. Franklin v. Parke Davis*, 2003 WL 22048255, at \*2 (D. Mass. 2003) (noting that if a state exercised its discretion to cover off-label prescriptions, “then an off-label [] prescription would not be a false claim”). In fact, however, Medicare—like several other government-run health care programs—routinely reimburses many off-label treatments. Thus, liability under the FCA for off-label promotion may turn on a fact-intensive inquiry into the extent of coverage afforded to the off-label use. Further complicating matters, the national Medicare organization outsources most coverage determinations to regional Medicare contractors. Although each contractor applies the same standard to determine whether an off-label use is eligible for coverage, different contractors reach different results.

In the criminal context, prosecutions for off-label promotion are generally brought under 21 U.S.C. § 331. This statute prohibits the introduction into interstate commerce of any “misbranded” drug or device. A drug is misbranded if its label lacks “adequate directions for use,” meaning that the label does not

reflect all of the drug’s “intended uses.” 21 U.S.C. §§ 352(f)(1); 21 C.F.R. § 201.5. In turn, the “intended uses” of a drug are determined by reference to “the objective intent of the persons legally responsible for the labeling of drugs.” 21 C.F.R. § 201.128. Under the terms of the regulation, there is virtually no limit on the considerations that may be relevant to the assessment of a company’s intent, including “labeling claims,” “advertising matter,” “oral or written statements,” and even knowledge on the company’s part that the drug is being used off-label. *Id.*

Violations of the misbranding statute can be either felonies or misdemeanors. 21 U.S.C. § 333. To prove the felony offense, the government must establish that the defendant had the specific intent to mislead or defraud. 21 U.S.C. § 333(a)(2); *United States v. Mitcheltree*, 940 F.2d 1329, 1349 (10th Cir. 1991). In practice, this requires a showing that the company knew that the drug was misbranded, *i.e.*, that the label did not reflect all of the drug’s intended uses.

The consequences of a felony conviction are severe. In addition to massive financial penalties as high as twice the revenues generated by off-label sales—not to mention the inevitable public relations fallout—a felony triggers automatic exclusion from public health care programs. 18 U.S.C. § 3571(d); 42 U.S.C. § 1320a-7. Exclusion can be a virtual death sentence for a pharmaceutical company.

### *Legal Defenses to Off-Label Enforcement Actions*

Of course, the primary defense to a charge of off-label promotion is that the drug was not promoted off-label. This could mean: either the allegedly off-label use was in fact on-label, or the concededly off-label use was not the result of promotion. In some cases, the scope of the label is sufficiently broad that uses flagged by the government as potentially off-label are, on closer inspection, within the boundaries of the labeled indication. But many cases do not fit into this pattern. Certain uses are, however common, unquestionably off-label. The issue then turns on the nebulous definition of “promotion”—the maze which this Administration seems to interpret to include a wide range of activities that might also be seen as informational. Serious First Amendment questions are triggered by government efforts to regulate truthful speech about off-label uses.

In 1998, a federal district court in Washington, D.C. struck down as unconstitutional regulations purporting to prohibit the dissemination of scholarly materials containing truthful information about off-label uses. *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998). In subsequent

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# PRACTICE AREA NOTES

## Japan Legal Update

- **Downloaders of Copyrighted Material Now Face Civil Liability:** New amendments to the Copyright Act took effect on January 1, 2010. A user can now incur civil (but not criminal) liability for downloading music or video files knowing that those files were improperly uploaded. This represents a major change from the previously governing interpretation of the Copyright law, which allowed copying for private use.


- **Changes to Antitrust Law Broaden Potential Liability:** Amendments to the Antitrust Law have also taken effect as of January 1. Acts subject to a surcharge penalty under the Antitrust law have been expanded to now also include private monopolization generally, dumping, price discrimination, and abuse of dominant bargaining position. The surcharge penalty was previously limited to unreasonable restraint of trade and private monopolization as it related to controlling other entrepreneurs. Notification requirements were also broadened for potential acquisitions.

- **Court Dismisses Criminal Prosecution For File Sharing Software:** On October 8, 2009, the Osaka High Court acquitted Mr. Isamu Kaneko, developer of a file sharing software called Winny, of criminal charges for solicitation of copyright infringement. Prosecutors sought criminal liability for developing and making available the software, which allows uploading and downloading of copyrighted material. Prosecutors have appealed this decision to the Supreme Court.

- **The Tokyo High Court Affirms Japan Fair Trade Committee Ruling Against Sony Music:** On January 29, 2010, the Tokyo High Court denied an attempt by Sony Music Entertainment and three other record companies to overturn an earlier finding by the Japan Fair Trade Commission that they had engaged in unfair restraint of trade. The Japan Fair Trade Commission issued a decision in July 2008 finding that Sony Music and the other record companies conducted their business to impede free entry into the Chaku-uta (music ring alerts for mobile phones) market. The decision required the companies to terminate the offending conduct.

- **Court Rules for Plaintiff Mizuho Securities Against Tokyo Stock Exchange Group, But Limits Recovery:** On December 4, 2009, the Tokyo District Court

ordered the Tokyo Stock Exchange to pay Mizuho Securities ¥10.7 billion. The case arose from Mizuho's erroneous online order to sell certain stocks at an extremely low price. Mizuho, realizing its mistake, attempted to cancel its order within minutes, but the Tokyo Stock Exchange system did not recognize the cancellation. Mizuho claims it suffered damages exceeding ¥40 billion, but the Tokyo District Court reduced the damages based on the comparative liability of Mizuho. Both companies have appealed.

- **District Courts Continue to Dismiss Tobacco Litigations:** On January 20, 2010, the Yokohama District Court denied the plaintiffs' claims in the Takahashi tobacco litigation. Plaintiffs were asking Japan Tobacco to pay ¥10,000,000 for each plaintiff based on Japan Tobacco's failure to warn of health hazards and liability for those health hazards. The Supreme Court of Japan denied similar claims in 2006. 

## Patent Litigation Update

- **Damages:** On September 11, 2009, the Federal Circuit vacated a \$358 million jury award in favor of Lucent Technologies, finding that the damages award against Microsoft was not supported by substantial evidence. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301 (Fed. Cir. 2009). The Court rejected Lucent's reliance upon several licenses to determine a reasonable royalty because they were "radically different" from the hypothetical license the parties would have negotiated, and cited numerous other problems with the evidence presented for damages, including no evidence of the expected or estimated usage of the patented method and insufficient evidence of the value that should be apportioned to the patented feature. Nevertheless, the Federal Circuit in its order of remand rejected Microsoft's argument that it is improper to base royalty on the entire market value of the product containing an infringing component.

Some commentators suggest that the entire market value rule should have little role in reasonable royalty law. But such general propositions ignore the realities of patent licensing and the flexibility needed in transferring intellectual property rights. The evidence of record in the present dispute illustrates the importance the entire market value may have in reasonable royalty cases.

On December 22, 2009, the Federal Circuit made it clear that unless a party files a pre-verdict motion for judgment as a matter of law ("JMOL") on damages, it cannot apply the *Lucent* standard of review to decide

whether there was substantial evidence to support the jury's damages award. *i4i Limited Partnership v. Microsoft Corp.*, 589 F.3d 1246, 1272 (Fed. Cir. 2009). Although the Court affirmed the \$200 million award, it noted that "the outcome might have been different" if Microsoft had filed a pre-verdict JMOL on damages. However, the Federal Circuit declined to order a new trial on damages and held that the District Court, under *Daubert*, properly admitted plaintiff's expert opinion on damages which relied on "the 25-percent rule, which assumes the inventor will keep 25% of the profits from any infringing sales."

Most recently, on February 5, 2010, the Federal Circuit relied heavily on *Lucent* to vacate a damages award of \$506,305 and reaffirmed the central importance of basing damages on evidence of truly comparable licenses. *ResQNet.com, Inc. v. Lansa, Inc.*, WL 396157 (Fed. Cir. 2010). The Court held that the error to the district court's consideration of licenses for bundled software products, source code and services "which had no relation to the claimed invention."

- **Marking:** On December 28, 2009, the Federal Circuit paved the way for a new breed of opportunistic litigant—the "marking troll." In *The Forest Group, Inc. v. Bon Tool Co.*, 590 F.3d 1295 (Fed. Cir. 2009), the Federal Circuit—rejecting a nearly 100 year-old First Circuit rule that imposed a single fine for "continuous" false marking—held that the federal false marking statute authorizes fines up to \$500 for *each* falsely marked article. By holding that the penalty applies on a per article basis, the Federal Circuit greatly increased the risk of incurring large liabilities for acts of false marking, particularly for mass produced items. Because § 292(b) allows "[a]ny person" to sue for the penalty in a *qui tam* suit, even the Federal Circuit acknowledged that "marking trolls"—plaintiffs who have suffered no direct harm from the false marking—might contribute to a proliferation of litigation. *Id.* at 1303-04. Patent owners beware and proceed cautiously when marking your patented products.

The flip-side of patent marking is that failure to mark a patented product may cut off the ability to collect pre-suit damages. 35 U.S.C. § 287(a). This statutory duty to mark extends to licensees, and following the Federal Circuit's ruling in *TransCore, L.P. v. Elec. Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009), that duty now apparently extends to parties to a litigation settlement agreement memorialized as a covenant not to sue. Non-practicing entities may be particularly susceptible to running afoul of these requirements since they enter

into many license and settlement agreements but do not make or mark their own products.

- **Venue Transfers:** In late 2008, the Federal Circuit made it much tougher for patent plaintiffs to maintain a suit in the Eastern District of Texas against defendants with no significant ties to East Texas. *In re TS Tech USA Corp.*, 551 F.3d 1315 (Fed. Cir. 2008). *TS Tech* left open the question whether "decentralized" cases would stay in Texas under the theory that no single venue would be more convenient than Texas. A team of Quinn Emanuel lawyers put that theory to rest, convincing the Federal Circuit to order the transfer, on behalf of client Genentech, to the Northern District of California. *In re Genentech, Inc.*, 566 F.3d 1338 (Fed. Cir. 2009).


One strategy plaintiffs in multi-defendant cases may employ to defeat transfer is to join defendants that would not be amenable to personal jurisdiction in the same venues as the other defendants. In *Chirife v. St. Jude Medical, Inc.*, Case No. 6:08-cv-480-LED (E.D. Tex. June 16, 2009), the district court denied transfer for this very reason, holding that the case could not have been brought in the Central District of California because one of the defendants would not have been amenable to personal jurisdiction there.

Plaintiffs have also employed the strategy of incorporating in their preferred venue and/or joining local defendants with varying success. In *Balthasar Online, Inc. v. Network Solutions, LLC, et al.*, Case No. 2:08-cv-430-DF (E.D. Tex. Sept. 15, 2009), Judge David Folsom saw through the plaintiff's joinder of four small local defendants. Rather than keep the whole case in Texas, he opted to sever the four small defendants and transfer the rest to the Northern District of California.

- **Term Adjustments:** Many recently issued patents may be getting extended under the Federal Circuit's January 7th decision in *Wyeth v. Kappos*,—F.3d—, 2010 WL 27184 (Fed. Cir. 2010), which considered the provision of the e patent term adjustment statute that provides for extensions based on certain delays. Under 35 U.S.C. § 154(b), "[t]o the extent that periods of delay . . . overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." One type of delay involves specifically identified PTO delays; another involves pendencies beyond three years. The PTO interpreted the overlap provision to mean that the term should only be adjusted by the greater of the two types of delays. But the Federal Circuit, agreeing with *Wyeth*,

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held that the two types of delays only overlap when the PTO-delays occur after the application has been pending for three years.

Shortly after *Wyeth* was decided, the PTO issued a notice stating that “Applicants and Patent Owners dissatisfied with a patent term adjustment determination by the agency are reminded of the requirement to seek review of that determination within 180 days of patent issuance and the time periods set in the implementing regulations.” The PTO stated that it would follow *Wyeth* when calculating future patent term adjustments. Given the increasing backlog of patent applications at the PTO, *Wyeth* is welcome news to patent owners. 

## Securities Litigation Update

- Ratings Agencies Win Dismissal of Securities Act Claims:** On February 1, 2010, Judge Kaplan of the Southern District of New York dismissed putative 1933 Act class-action claims brought by investors against Moody’s and S&P. The decision strikes a blow to plaintiffs seeking to hold credit rating agencies liable under the federal securities laws. The lawsuit involved nearly \$100 billion in mortgage-backed securities issued by Lehman Brothers. Investors alleged that the rating agencies had a conflict of interest in rating the securities, because the rating agencies also helped to create and structure them. The court found that the agencies could not properly be considered underwriters, sellers, or control persons under the Securities Act of 1933, and dismissed the complaint.
- Pharmaceutical Securities Class Actions Often Linked to Clinical Trials, Involve Larger Market Cap Losses (February 2010):** Securities class actions filed against pharmaceutical companies often relate to clinical trial results, and typically involve larger market capitalization losses than other types of securities class actions, a recent Cornerstone Research study found. Of the ninety-two pharmaceutical securities class actions filed between 2002 and the first half of 2009, thirty-four involved allegations related to clinical trial results, and eighteen involved allegations related to FDA approval. Further, because it is common for pharmaceutical companies to experience large stock price movements when negative clinical trial results are announced, the median market capitalization loss on the disclosure date for pharmaceutical companies involved in securities class actions (\$864 million for 2008, \$426 million for 2009) substantially exceeds corresponding numbers for non-pharmaceutical companies (\$228 million for 2008, \$142 million for 2009).
- Vivendi Found Liable for Securities Fraud in Rare Jury Trial:** January 29, 2010, a New York federal jury found French media conglomerate Vivendi liable under the securities laws for misleading investors about its financial condition. This is only the ninth securities class action to be tried to a verdict since the 1995 passage of the defendant-friendly Private Securities Litigation Reform Act. The class action plaintiffs’ lawyers say the judgment could exceed \$9 billion. Vivendi has announced that it plans to appeal.
- Costs of Special Litigation Committees Potentially Covered by D&O Insurance Policies:** In a decision that may help companies decide to convene Special Litigation Committees to evaluate derivative claims, the U.S. District Court for the Southern District of New York held in *MBIA Inc. v. Federal Ins. Co.*, Civ. No. 08cv4313 (S.D.N.Y. Dec. 30, 2009), that, in certain instances, legal costs incurred by a special litigation committee may be covered under a D&O insurance policy. The case involved a claim by MBIA under policies sold by Federal Insurance Co. and ACE American Insurance Co. for costs MBIA had incurred in responding to New York Attorney General and SEC inquiries and subpoenas; MBIA also claimed its Special Litigation Committee’s costs of investigating a shareholder derivative action. Although the insurers argued that, because a Special Litigation Committee must be independent, MBIA’s defense costs did not encompass Special Litigation Committee costs, the court disagreed. The court reasoned that the committee was to determine whether the derivative action was in the best interest of MBIA, and thus the costs of its investigation constituted costs of defending MBIA within the meaning of the insurance policies.
- Claims Against CDO Seller and Collateral Manager Dismissed Despite Plaintiff’s Allegations of “Special Relationship” (December 30, 2009):** The New York Appellate Division recently reversed a lower court decision and dismissed a negligent misrepresentation claim and other claims brought by M&T Bank against Deutsche Bank and HBK. The Appellate Division held that an essential element of the misrepresentation claim, a “special relationship” between the parties, could not be established where the parties had no relationship prior to the arms-length transaction at issue and where the offering circulars contained limitations and disclaimers. The court added that allegations of defendants’ “unique or special expertise” are insufficient to survive a motion to dismiss a negligent-misrepresentation claim.


- **Delaware Court of Chancery Reaffirms Enforcement of Deal Protection Devices and Jurisdiction over Common Law Claims Based on Federal Securities Filings:** In *NACCO Industries, Inc. v. Applica Inc.*, C.A. No. 2541-VCL (Del. Ch. Dec. 22, 2009), the Delaware Court of Chancery considered motions to dismiss a jilted bidder's claims against the target corporation and the successful bidder. In denying motions to dismiss, the Court reaffirmed Delaware's commitment to enforcing deal protection devices such as no-shop and prompt notice clauses. The Court also held that it had jurisdiction over common law fraud claims even where such claims were based on allegedly misleading federal securities filings. The Court stressed Delaware's interest in adjudicating fraud allegations made against the entities it charters, and Delaware's commitment to honoring and enforcing deal partners' contractual commitments.

- **Fraud Claims Against CDO Arranger, Underwriter, and Manager Upheld Despite Contractual Disclaimers (October 2009):** Justice Lowe of the New York Supreme Court denied a motion to dismiss HSH Nordbank's fraud claim against UBS. HSH, represented by Quinn Emanuel, alleged that UBS sold it a \$500 million investment in CDO notes without disclosing embedded losses in the notes at the deal's inception. On UBS's motion to dismiss, the court held that selling debt securities as par-value-rated paper qualifies as fraud when the arranging bank knows the value and credit quality to be materially below par. The court also found that HSH's fraud claim is not duplicative of its breach of contract claim under New York law because HSH alleged that defendants intended to breach the contract prior to its inception. However, the court rejected HSH's negligence claim because it was unconvinced that HSH was a naïve investor and therefore UBS did not owe it a special duty.

- **Post-Stoneridge, Congress Revisits Securities Fraud (September 2009):** A Senate subcommittee is currently considering a contentious and growing issue in securities law: whether to allow civil lawsuits against companies that might have aided or abetted fraud. Third parties have enjoyed virtual immunity in civil securities fraud cases since 2008, when the Supreme Court reaffirmed in *Stoneridge Investment Partners v. Scientific-Atlanta* that there is no private right of action against "aiders and abettors," even those who knowingly enter into fraudulent transactions with the primary violator that facilitate material misrepresentations made to public investors. Senator Arlen Specter (D-Pa.) is currently sponsoring legislation that would override

the Court's decision in *Stoneridge* and allow civil suits against anyone who "knowingly or recklessly provides substantial assistance" to a primary violator. In a hearing last fall, Specter lashed out at the 5-3 decision in *Stoneridge*, stating that it ran counter to decades of precedent, and that "I was shocked. . . . It's hard to understand how aiders and abettors are not liable." The proposed legislation continues a recent pattern of congressional Democrats seeking to overturn Supreme Court rulings involving statutory interpretation.

- **Rating Agencies' First Amendment Defense Rejected, Common Law Fraud Claims Upheld (September 2009):** In a much-watched case regarding credit rating agencies' liability, Judge Shira Scheindlin of the Southern District of New York denied motions to dismiss brought by Morgan Stanley and the rating agencies. The case involved common-law fraud claims arising from subprime mortgage-backed investments that Morgan Stanley had arranged and marketed as highly rated and backed by safe collateral. The judge found that the rating agencies could be liable based on allegations of providing knowingly or recklessly inaccurate ratings. The court rejected the rating agencies' First Amendment defense that credit ratings are merely "opinions" because the ratings were marketed to a select group of investors, rather than the public at large, and because the rating agencies allegedly knew that the ratings were false.

- **Superior Knowledge Doctrine Supports Fraud Claims by Sophisticated Buyer Against CDO Arranger (September 2009):** Judge Crotty of the Southern District of New York upheld common-law fraud claims brought by Bank of America against Bear Stearns arising from Bank of America's investment in CDOs backed by Bear Stearns hedge funds. The court held that Bear Stearns had a duty to disclose liquidity problems with the funds arising from its superior knowledge of the funds' financial condition, regardless of plaintiff's sophistication. The court found that defendants' disclosure that there might be problems with the funds was insufficient to put plaintiffs of notice of liquidity problems because the disclosure was incomplete, ambiguous, and may not have reached the relevant parties. The court also found that disclaimers in the parties' contracts did not protect Bear Stearns because it had a duty to disclose that was independent of the contracts. 

## Entertainment Litigation Update

- **Campaign Songs:** For years politicians have used popular songs in campaign rallies and commercials without compensating rights holders. But that is changing.

Musician Joe Walsh, a guitarist for the Eagles, recently sent a cease and desist letter to an Illinois congressional candidate, also named Joe Walsh, for using his song, "Walk Away," in an online commercial. Walsh (the politician) has refused to take down the video. He argues his video, in which the lyrics to the song have been changed, is a parody that is sufficiently transformative as to be protected by the fair use doctrine.

In August 2008, Jackson Browne sued John McCain for copyright infringement based on the use of Browne's song, "Running On Empty," in a commercial. The issue was whether the use of the song was protected "political activity." McCain initially responded by filing a motion to dismiss as well as an anti-SLAPP lawsuit, both of which were denied. The parties then settled for an undisclosed amount.

Another of the Eagles, Don Henley, filed suit for copyright infringement, violation of the Lanham Act and unfair competition against Charles DeVore, who is running for the U.S. Senate in California, over online campaign videos using the songs "All She Wants to Do Is Dance" and "Boys of Summer." DeVore has raised both the fair use and the "political activity" defenses. The suit is pending.

- **Shazam:** Shazam Entertainment, a start-up company in the United Kingdom, created an iPhone application which utilizes music recognition technology to allow users to determine what song is playing on their car radios or even in bars and then to purchase an mp3 of the song. The application grew quickly, with users buying nearly 300,000 songs daily. Another software company, Digimarc, recently sued Shazam for patent infringement based on patents which date back to 1995, long before the iPhone was created, relating to a technology that enables devices to identify audio and visual content.

This litigation, which is still in its early stages, highlights the need for companies developing innovative technologies to conduct due diligence on prior art that may anticipate their products. The Shazam case also demonstrates that even products in novel entertainment media, such as cell phone applications, may be vulnerable to attack from holders of broad patents developed for use in entirely different contexts.

- **Redbox:** A key battle in the multi-billion dollar DVD rental industry is taking shape as Redbox, a kiosk operator that rents newly released DVDs for as little as \$1.00, litigates against several of the major studios. The litigation relates to efforts by studios to improve DVD sales at the expense of rentals by, among other things, delaying the date on which consumers can rent new releases. In response, Redbox had employees purchase newly released DVDs for use in its kiosks. The studios countered by allegedly convincing large retailers, such as WalMart, to limit the number of DVDs an individual can purchase.

Redbox filed suit against Universal alleging antitrust and other claims. Universal moved to dismiss the complaint, but Delaware District Court held that Redbox "sufficiently plead that Universal has induced...others to boycott Redbox in distribution of Universal DVDs..." Redbox then filed suit against Warner Brothers and Twentieth Century Fox asserting similar antitrust claims and also alleging that WalMart's limitation on DVD purchases constitutes tortious interference with prospective business opportunities and unfair competition. Redbox and Warner Brothers reportedly settled their dispute with Redbox agreeing to a 28 day gap between the start date for the sale of a DVD and the rental of the movie.

- **Australian Court Finds ISPs Not Liable for Online Piracy:** In what the Court referred to as "the first trial of its kind in the world to proceed to hearing and judgment," an Australian judge held that iiNet, Australia's third-largest Internet Service Provider, was not liable for acts of copyright infringement committed by its users.

In a lawsuit brought by the Australian Federation Against Copyright Theft (AFACT), an organization which includes all of the major United States and Australian studios, iiNet was accused of authorizing copyright infringement by failing to take steps to stop the infringing conduct. The key issue was whether iiNet, being aware that its service was being used for copyright infringement, had a duty to stop the infringement by cutting off Internet service to accused infringers. The court held that there is "no positive obligation on any person to protect the copyright of another" and, for that reason, iiNet had no affirmative duty to the motion picture studios to police its users for copyright infringement. AFACT may appeal. [Q](#)

# ATTORNEYS FEES REFORM IN ENGLISH LITIGATION

In January 2010, Lord Justice Jackson's final report of his Review of Civil Litigation Costs in England and Wales was released. Although the report, and likely the majority of its recommendations, will become into law.

It is a feature of civil litigation in England that, as a general rule, the unsuccessful party is ordered to contribute to the legal costs incurred by the successful party—the 'loser pays' or adverse costs rule. As a practical matter the unsuccessful party is usually ordered to pay around 60-70% of the legal fees and other costs incurred by the successful party. Thus, a party's decision whether to commence litigation must take into account this potential costs liability.

Lord Justice Jackson's proposed reforms do not change this fundamental rule, but, they do include a wide-ranging series of changes to the way in which the regime is operated. Lord Justice Jackson acknowledges that litigating large commercial disputes in London is an expensive exercise, but that businesses are generally satisfied with the existing costs regime and are prepared to spend the substantial sums involved for the benefit of a high quality process. The majority of proposals in the report focus, therefore, on non-business litigation in areas such as personal injury, defamation, and housing disputes.

At present, contingency fee arrangements are not allowed in English proceedings. In 2000, a regime was introduced whereby 'conditional fees' were permitted. A conditional fee agreement, or CFA, involves a discount (sometimes 100%) on fees if the claim does not succeed, with a substantial uplift, or 'success fee' payable if the client wins—the success fee can be up to 100% of the undiscounted fees that would have been charged by the lawyer. The success fee is recoverable from the losing party under the loser pays rule, together with the rest of the claimant's legal fees. The effect of this is that a defendant facing a claimant with a CFA faces a substantially higher costs liability than would be the case without a CFA. Importantly, the existing regime does not permit the success fee to be calculated as a proportion of the amount of the judgment won by the client.


Lord Justice Jackson's proposal to reform this area is twofold. First, he proposes the introduction of contingency fees (with a requirement that an independent solicitor advise the client on the contingency fee agreement at the outset in order for it to be enforceable). Second, he proposes that the adverse costs rule be modified to protect defendants from the effects of CFA's or contingency fees. For CFA's, he proposes that the success fee payable by a successful client to their solicitor no longer be recoverable from the losing party. In cases where the successful party is paying a contingency fee,

the losing party's costs contribution will be calculated by reference to the hypothetical level of fees that would have been payable if the successful party had been paying on a traditional time/cost basis.

The most visible impact of these reforms is likely to be in the areas of personal injury and defamation, where claimant solicitors have achieved substantial profits through success fees paid by defendants (or defendants' insurers), often at a level exceeding the actual damages paid in the case. Experience from the introduction of CFA's suggests that the largest impact will be in straightforward low-value claims. In more complex, high value cases where there are a range of potential outcomes (and thus challenges in defining 'success') and where the sums claimed are substantially in excess of the level of legal costs, the impact is likely to be less.

Nonetheless, the ability to use contingent fee arrangements will make it possible to bring cases that would otherwise be uneconomic for clients. The proposed reform is also likely to increase the appetite of professional litigation funders to participate in high value litigation. For defendants, the proposed protection against liability for opponent's success fees will be welcomed.

Lord Justice Jackson's report also proposes a number of mostly minor changes to the conduct of litigation generally that are intended to decrease the total costs of civil proceedings. Two procedural changes of particular note for business litigants relate to document disclosure and the use of costs budgeting and estimates. Lord Justice Jackson concludes that the current 'one size fits all' approach to disclosure in business litigation is inefficient and that a 'menu' approach should be introduced, whereby the scope of parties' disclosure obligations are defined by the nature of the case. Litigants can expect to see Judges taking a more active role in requiring and scrutinizing legal budgets for cases and subsequently monitoring compliance with those budgets—although judges in business cases will have discretion whether to use these tools, which are likely to be compulsory in non-business cases

The Report is now being considered by the Ministry of Justice. The process of putting the recommendations into effect may not be straightforward, particularly because of the likely resistance from participants in the litigation process who have built their business models around the structure of the existing rules. However, the changes proposed for business litigation are likely to find the support of the business litigation community and it is hoped that they will come into force without undue delay. 

# VICTORIES

## Defense Victory for Google in Its First Patent Trial – in Marshall, Texas No Less

The firm won a complete defense victory for Google in the Eastern District of Texas, in Google's first patent trial. The plaintiff, Function Media LLC, alleged that Google's highly successful AdSense for Content and AdSense for Mobile online products infringed three patents involving a system and method for creating and publishing customized electronic advertisements. Function Media, represented by the law firm of Susman Godfrey L.L.P., is a husband and wife co-owner and co-inventor team living in East Texas; they sought over \$600 million in reasonable royalty damages. After a one-week trial, the jury found that Google did not infringe any of the asserted patent claims and that each and every asserted claim is invalid in light of the prior art.

Quinn Emanuel took over the case from another firm only five months before trial, less than one month before the claim construction hearing, and long after most of the fact witnesses had been deposed. In the short time before the claim construction hearing, the firm narrowed the important claim construction issues and negotiated several stipulated constructions. After the hearing, the Court found that one of Function Media's three asserted patents was indefinite and therefore invalid.

At trial, Quinn Emanuel argued that Google's accused advertising systems did not infringe either of the remaining two asserted patents, and called several Google employees to testify about the inner workings of Google's online advertising systems. Using demonstratives and documentation, Google's witnesses explained to the jury how Google's highly complex AdSense systems operate in a manner that is distinct from the manner claimed by the asserted patents. The jury rejected Function Media's attempts to discredit Google's witnesses by arguing that they were biased employees.

To support its argument that Function Media's patents are invalid, Quinn Emanuel presented expert testimony and called various witnesses to testify about two key prior art advertising systems—AdForce and DoubleClick. The witnesses testified that these systems, which were publicly available before the critical date of Function Media's patents, disclosed the same functionality claimed in the two asserted patents. To further support its argument, Google presented documentary evidence showing that these advertising systems practiced Function Media's claims before the critical date. The jury rejected the testimony of Function Media's expert, who opined that the asserted


patents were novel.

Function Media attempted to support its demand for over \$600 million in damages by presenting expert testimony that relied on the value of various agreements that Google had entered into. Quinn Emanuel attacked Function Media's position by showing that the consideration Google received as part of those agreements was fundamentally different from and far exceeded the value of Function Media's patents. During the cross-examination of the inventors of Function Media's patents, Quinn Emanuel also showed that the inventors' own advertising product was a failure in the marketplace. United States Magistrate Judge Charles Everingham presided over the trial in Marshall, Texas.

## Class Action Victory

A recent order denying class certification dealt the final major blow to a class action filed against the firm's client, Barnes & Noble Booksellers, Inc. Barnes & Noble was accused of various violations of the Labor Code, including failure to provide meal breaks and rest breaks and failure to pay overtime.

Plaintiffs claimed that Barnes & Noble had a widespread practice of doctoring employees' time entries to make it appear as if a break was taken when it was not. Despite these allegations, Quinn Emanuel elicited damaging testimony from plaintiff's proposed class representative, a former Barnes & Noble employee, that Barnes & Noble's written meal break, rest break and overtime policies complied with California law, and that plaintiff himself had never worked off the clock. The firm marshaled dozens of declarations from proposed class members and their supervisors that destroyed plaintiff's premise that Barnes & Noble systematically denied its employees meal breaks, rest breaks or overtime pay. Further, the firm demonstrated that plaintiff's allegations of doctored time entries were demonstrably false given the constraints of Barnes & Noble's timekeeping system.

Plaintiff's desperation tactics did not end there. At the hearing on plaintiff's motion, plaintiff unveiled a new class definition never briefed by the parties. Plaintiff also implored the Court to grant plaintiff leave to submit statistical evidence regarding its claims or, in the alternative, to stay the Court's ruling pending the California Supreme Court's decision in a related case. The Court rejected each of plaintiff's offers. The Court denied certification in its entirety, ruling that plaintiff failed to satisfy his burden of demonstrating that common issues predominated over individual issues, and that a class action was a superior method of adjudicating plaintiff's claims. The Court also denied plaintiff's request to stay its ruling. 

(continued from cover)

## Quinn Emanuel London Shortlisted for Legal Business Awards

After only one year in operation, Quinn Emanuel London was nominated in two categories in this year's Legal Business Awards, London's equivalent of the American Lawyer awards (won by Quinn Emanuel this year as IP firm of the year).

The London team was nominated in the "Dispute Resolution Team of the Year" category, with the judges pointing out that the London team made headlines in 2009 in two major credit-crunch related disputes: *Re Sigma* and *UBS v Nordbank*. The judges recognized that Quinn Emanuel London has already built a reputation as a top firm for complex financial

disputes.

QE London has also been shortlisted in the "US Law Firm of the Year" category. The judges cited the firm's unique specialization in business litigation, noting that the firm has been able to fully exploit the counter-cyclical market conditions and has acted in some of the most significant disputes of the year.

Quinn Emanuel London partners Sue Prevezer QC, who sits as a deputy High Court judge, and Richard East were also recognized in the 2009 UK edition of *Chambers and Partners*. **Q**

## NEW CASE

### TCW v. GUNDLACH

Quinn Emanuel is representing Trust Company of the West ("TCW") in highly publicized litigation against four former officers of TCW and their new company, DoubleLine Capital LP. The suit, pending in Los Angeles Superior Court, asserts claims for breach of fiduciary duty, unfair competition, misappropriation of trade secrets, intentional interference with contractual relations, among others.

The former officers are led by Jeffrey Gundlach, TCW's former Chief Investment Officer and Group Managing Director, who managed or oversaw approximately \$70 billion of TCW's \$110 billion in assets under management. Gundlach's career at TCW made him widely recognized in the investment community and earned him *Morningstar's* 2006 "Fixed-Income Manager of the Year" award.

The complaint alleges that as Gundlach became increasingly disgruntled at TCW, he developed a plan with his co-conspirators to steal TCW's proprietary information and systems for use at the new company they formed while still employed by TCW. The complaint alleges that between September and December 2009, the co-conspirators downloaded TCW's confidential and proprietary data to external hard drives on 37 separate days. This information included over 24,000 client contacts, over 150 TCW contracts with its clients, every holding of every TCW client in Gundlach's group, and Excel spreadsheets with macros showing how TCW analyzes trade data. At the same time that the co-conspirators were downloading data, they were also acquiring office space for their new company, organizing the company in Delaware, and reserving the "DoubleLine" name.

(lead story from page 3)

years, the government abided by the position it took on appeal in that case, *viz.*, that the distribution of truthful materials about off-label uses could not, in and of itself, give rise to a prosecution for off-label promotion. This "safe harbor" for truthful scholarly reprints was affirmed once again in the FDA's most recent guidance to industry in January 2009.

At the same time, however, the FDA persists in the view that even entirely lawful promotional activity can constitute evidence of intended off-label use. Paradoxically, then, the more a company takes advantage of safe harbors, the more it may seem to FDA that the company's intended uses are off-label—and hence the more likely it may be that the government initiates enforcement action. In the *Washington Legal Foundation* litigation, while the government acknowledged that dissemination of truthful materials

could not itself be grounds for prosecution, it left open the possibility of prosecution under an intended-use theory, whereby the distribution of truthful materials could be construed as evidence of an intended off-label use.

### Conclusion

Pharmaceutical companies should continue to expect aggressive enforcement actions against off-label promotion in both the civil and criminal contexts. Quinn Emanuel is actively engaged in representing companies in this area, and we expect that more companies will face potential civil and criminal complaints arising out of prescription and use of approved drugs for off-label treatments. Great care must be practiced to avoid such actions, and to defeat them when they are brought. **Q**

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## business litigation report

Published by Quinn Emanuel Urquhart Oliver & Hedges, LLP as a service to clients and friends of the firm. It is written by the firm's attorneys. The Noted with Interest section is a digest of articles and other published material. If you would like a copy of anything summarized here, please contact David Henri at 213-443-3000.

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