January 2019

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quinn emanuel urquhart & sullivan, llp | business litigation report

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# Off-Label Promotion After *Caronia*: Proceed with Caution

The United States Food and Drug Administration ("FDA") has long taken the view that promoting drugs for non–FDA-approved uses—otherwise known as off-label marketing—can be proof of misbranding, a criminal offense. False or misleading advertising of a drug is by definition a form of misbranding under the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 352(q)(1). Truthful, non-misleading off-label promotion can also be proof of misbranding, the FDA has argued, if it demonstrates that a drug is being sold for an unapproved intended use – another form of statutory misbranding. 21 U.S.C. § 352(f)(1); 21 C.F.R. §§ 201.5. (Because the law concerning off-label marketing is virtually the same for drugs and devices we use those words interchangeably in this article.)

Recent legal developments have called into question the FDA's long-standing position that truthful, non-misleading off-label promotion can be proof of misbranding. In 2012, the Second Circuit construed the misbranding statute not to criminalize truthful, non-misleading off-label speech "because such a construction … would run afoul of the First Amendment." *United States v. Caronia*, 703 F.3d 149, 162 (2d Cir. 2012). The Justice Department did not petition for rehearing or a writ of certiorari, perhaps in the hope that future courts would read *Caronia* narrowly. Those hopes seemed dashed when, just three years later, a New York district court judge held that the government could not treat truthful, non-misleading off-label promotion as "the act upon which an action for misbranding is based." *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 226 (S.D.N.Y. 2015). The government did not appeal.

President Donald Trump's election appears likely to give pharmaceutical companies even more protection. Most expect his two Supreme Court appointees, Justices Neil Gorsuch and Brett Kavanaugh, to uphold the Second Circuit's reasoning in *Caronia* if the issue ever arises. What is more, the new FDA head Scott Gottlieb has, as a private citizen, written extensively in favor of permitting off-label promotion. Consequently, many have predicted that courts will no longer tolerate off-label marketing prosecutions,

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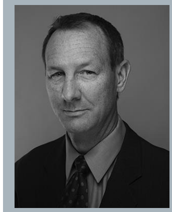
## Quinn Emanuel Mourns the Loss of Partner Steve Anderson



On December 27, 2018, Quinn Emanuel lost a friend and long-time partner Steve Anderson. Steve graduated from Harvard Law School in 1989 and joined the firm in 1994 when the firm had 30 attorneys. He was a founding member of the firm's patent practice, which he helped to grow in his 24 years at the firm. Steve was a gifted patent litigator with a background in computer sciences. Steve was smart, pragmatic, athletic, adventurous, and a fierce competitor. He loved boating, flying helicopters, and being surrounded by family and friends. For the past 15 years he displayed indomitable courage and determination fighting illness, while continuing to contribute to the firm's success and enjoying life. He leaves behind his wife Michelle and their daughter Sydney. He will be deeply missed by all who knew him.

## The Firm Welcomes Record Partner Class

The firm has elected the largest partner class in the firm's history. Half of the new partners are women, four come from offices outside the United States, and three come from diverse backgrounds. ***Page 8***

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and the federal government will not bring them.

The truth is not so simple. Prosecutors have in some cases persuaded courts to read the First Amendment protections in *Caronia* and *Amarin* narrowly. In other cases, they have argued that the challenged off-label speech is false or misleading and therefore not protected at all. Meanwhile, the FDA's guidance for companies has not undergone material change, and pharmaceutical companies have continued to pay tens of millions of dollars in fines as part of plea agreements and False Claims Act ("FCA") settlements. All in all, pharma companies still need to be as careful as ever when engaging in off-label speech.

Based on our experience, we present below some instructive background and practice pointers that we hope will be useful in managing litigation risks from off-label speech.

### ***Limits of the First Amendment***

First Amendment protections are at their height when a misbranding case rests solely on off-label speech. *Caronia* vacated the defendant's conviction because the trial record showed that the prosecution had treated the "speech itself" as "the proscribed conduct," 703 F.3d at 161, and the government had not argued that the speech was false or misleading. In *Amarin*, too, the pharma company's "conduct consist[ed] solely of truthful and non-misleading speech." 119 F. Supp. 3d at 198.

But neither case offered much guidance about the admissibility of truthful, non-misleading statements in misbranding cases that *are not* based on those statements alone. Nor did either case help explain when off-label statements qualify as truthful and non-misleading. As a result, prosecutors have continued to offer off-label speech as evidence of misbranding in post-*Caronia* enforcement actions.

Some courts have allowed prosecutors to use truthful, non-misleading speech as evidence of a drug's intended use. In *United States v. Facteau*, for example, the court instructed the jury that it could not convict for misbranding "based solely on truthful, non-misleading" off-label promotion, but such statements could "constitute evidence of an intended use." Jury Instructions at 26, 27, *United States v. Facteau*, No. 1:15-cr-10076 (D. Mass. July 15, 2016). The Second Circuit may have also endorsed this interpretation of *Caronia* in a 2016 opinion. *See U.S. ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 615 n.2 (2d Cir. 2016). The prosecution in the *Facteau* case relied on a combination of circumstantial evidence and arguably truthful, non-misleading speech to prove that the defendants misbranded a medical device by selling it for an unapproved intended use. The government in that case offered as circumstantial evidence: that the device was not actually designed or tested for its approved use; that there was no clinical data showing it actually worked for its approved used; that the company knew doctors were not willing to use it for its approved use; and that the company gave its sales force no tools to sell the device for its approved use. It also offered speech evidence in the form of: internal and external company emails acknowledging that the device did not seem to serve its on-label use; a conference call by the company's CEO to sales personnel describing the device's off-label uses; physician presentations about off-label use of the device at a company-sponsored medical conference; and marketing materials that arguably highlighted the device's off-label uses.

To be sure, not all courts may accept the limited view of First Amendment protection for off-label speech advocated by the government in *Facteau* and other cases. A federal court in Texas recently instructed the jury that it could not consider *any* truthful, non-misleading promotional speech as evidence of intended use. Final Jury Instructions at 12, *United States v. Vascular Solutions, Inc.*, No. 5:14-cr-00926 (W.D. Tex. Feb. 25, 2016) ("*VSI*"). But this case might prove the odd one out, as the government agreed to this instruction; the court never held that it was necessary. And prosecutors might prove less accommodating in future cases.

The government also has tried to avoid First Amendment limitations on off-label marketing prosecutions by seeking to expand the universe of off-label statements that qualify as "misleading." Consider three recent examples. The *Facteau* prosecutors cited statements by salespeople attesting that off-label uses of the device were safe and effective while omitting that the studies behind those statements had limited sample sizes and mixed results. Similarly, in *United States v. Aegerion Pharms. Inc.*, Case No. 17-cv-10288 (D. Mass), the defendant company was accused of training its sales staff to be purposefully vague about the drug's limited intended use without expressly lying, so that doctors would mistakenly prescribe it for off-label use. Aegerion pleaded guilty. Finally, the *VSI* indictment alleged that the defendants promoted a device's off-label use without mentioning potential safety problems.

A recent FDA guidance document provides even more insight into the government's expansive definition of "misleading" speech. It states that promotional statements are misleading if they:

- omit "material" facts about the drug or device, including risk information;

- "lack appropriate evidentiary support"; or
- overstate the results from clinical trials.

FDA, *Medical Product Communications That Are Consistent with the FDA-Required Labeling—Questions and Answers* 11–15 (June 2018). According to the FDA, marketing material might be misleading if it publicizes a study's results while neglecting to mention (1) the study's sample size; (2) its failure to test for a false positive rate; or (3) other findings that are inconsistent with the study. Even indirect misdirection—like implying a statistically rigorous conclusion where none exists by publicizing p-values for a defective study—may also be considered misleading by the government.

In short, *Caronia* and *Amarin* did not spell the end of off-label marketing prosecutions, as many commentators and practitioners thought they would. DOJ and FDA so far have successfully limited the reach of those decisions by defining "misleading" speech broadly and by arguing that even truthful, non-misleading speech can constitute *evidence* of misbranding as opposed to the *act* of misbranding itself. The upshot is that companies facing off-label marketing actions should still use every strategy available to avoid a finding that they misbranded a drug.

***Strategies for Fighting Misbranding Actions***

Defendants can make a variety of arguments at the pleading stage to dismiss or at least narrow government claims. These include:

- Attacks on the legal definition of "intended use" as unconstitutionally vague. The definition, which appears in the Code of Federal Regulations, states that "intended use" is the "objective intent of the persons legally responsible for the labeling of drugs" and lists a number of ways in which that "objective intent" may be "shown" without ever defining the somewhat enigmatic expression "objective intent." 21 C.F.R. §§ 201.128, 801.4,
- Motions to strike from the charging document – and exclude as evidence – statements about off-label uses by company personnel that were never intended for the ears of potential customers (*e.g.*, internal company emails, diary entries, boardroom conversations, etc.).
- Motions to strike from the charging document – and exclude as evidence – all statements about off-label uses that were truthful and non-misleading.

Courts have largely rejected these arguments so far, but that might change if, as many anticipate, the federal bench becomes increasingly libertarian and protective of free speech.

Defendants have even more options for fighting misbranding charges at trial. Among the most successful strategies has been turning the tables on the FDA. In *VSI*, for example, an FDA witness was forced to admit that FDA letters clearing a device for its on-label use could be interpreted as covering the alleged off-label use as well. The government tried to rebut that argument by pointing to VSI's repeated, failed attempts to obtain express FDA clearance for the off-label use, but the defendants characterized those attempts as unnecessary precautionary measures on their part. They were acquitted. In *Facteau*, the defendants argued they had no intent to defraud the FDA despite knowing their device was being used entirely off-label because they communicated frequently with FDA about their desire to clear the device for the off-label use and FDA knew doctors were using it off-label. That was enough for them to beat felony misbranding and adulteration charges, albeit not the misdemeanor versions of those crimes.

To avoid the stigma and risk of indictment, a company can seek to enjoin the FDA from prosecuting it for particular off-label statements. That was the strategy in *Amarin*. The FDA threatened Amarin with prosecution if it made several truthful statements about a study showing potential off-label uses for a drug. Amarin sued, and the court enjoined the government from prosecuting Amarin for those statements. The FDA later agreed, as part of a consent decree, to respect Amarin's right to engage in truthful, non-misleading off-label marketing for the drug at issue, and to set up a process to pre-clear Amarin's marketing statements. Pacira Pharmaceuticals also sued preemptively to protect marketing statements that, it claimed, tracked its on-label use; the FDA settled before the court could decide the case.

This approach is no panacea. A company cannot preemptively sue unless it has a concrete and imminent fear of FDA enforcement action. Amarin met this standard because the FDA had threatened prosecution ten days before it sued, and the court found that threat credible because of the government's many recent misbranding prosecutions. Pacira also predicated its suit on a contemporaneous FDA warning letter. Without similar threats, pharma and device companies might have trouble obtaining injunctions for lack of standing.

The company also might lose on the merits. The *Amarin* Court greenlighted most of the proposed off-label statements, but the FDA had already conceded that those statements were mostly true and non-misleading. The parties disputed the precise wording of just three statements. The court split the baby, siding with each party on one sentence apiece and drafting its own compromise language for the third. Yet even then, the court emphasized that Amarin had to ensure that its statements remained accurate if new data became available. As a result, companies that try to emulate Amarin's strategy may purchase, for all their legal costs, only a partial, temporary victory. And perhaps not even that if the court defers to the FDA's judgment.

***Managing Litigation Risk***

The Trump administration announced this year that it will focus healthcare fraud enforcement resources on companies that make false or misleading off-label statements, harm patients, or pay kickbacks to doctors. These types of cases seldom implicate free speech and therefore should insulate the government from First Amendment objections. The Department of Justice has recently taken aim at companies that flout their drugs' Risk Evaluation and Mitigation Strategy requirements. Both Aegerion and Novo Nordisk admitted to such infractions in 2017. The former paid $40 million in fines, the latter $58 million.

But pharma companies that do not fit this profile should not assume they are in the clear. Enforcement priorities can change before statutes of limitations run out. And as discussed above, whether an off-label statement is "misleading" is often in the eye of the beholder. Besides, the federal government is not the only potential adversary. Anyone can bring a *qui tam* action under the FCA. Insurance companies have also sued pharma companies for off-label marketing under the Racketeer Influenced Corrupt Organizations Act ("RICO"). And because RICO and the FCA offer the prospect of treble damages, lawyers have plenty reason to bring even longshot claims under both statutes. Put another way, even pharma companies that think they have done nothing wrong can face real legal risks.

Quinn Emanuel is well equipped to help its clients defend against allegations of off-label marketing, payment of illegal kickbacks, and product defects. Our government investigations and healthcare litigation teams have substantial experience in these areas, including in many of the cases cited in this article. More than 130 of our litigators, moreover, hold degrees in the hard sciences, and more than 20 are former prosecutors. And of course, no firm can match our unparalleled trial expertise.

# NOTED WITH INTEREST

## Second Circuit Applies Broadened "Fair Reading" Standard, Finds Luxury Car Service Drivers Do Not Fall Under FLSA Taxicab Exemption

The Second Circuit, in *Munoz-Gonzalez v. D.L.C. Limousine Service, Inc.*, 904 F.3d 208 (2d. Cir. 2018), became the first circuit court to publish an opinion applying a "fair" rather than "narrow" reading to exemptions to the Fair Labor Standard Act's overtime wage requirements. On that reading, the court held that "chauffeurs" employed by a "luxury car service" fell under the Act's "taxi-cab exemption," raising the question of whether other car services will also be held exempt from FLSA overtime requirement. The decision offers a glimpse of how other courts may apply a "fair-reading" analysis in in the wake of Supreme Court's opinion in *Encino Motorcars, LLC v. Navarro*, 138 S. Ct. 1134, 1140 (2018).

***Background***

The FLSA, the federal wage-and-hour statute enacted in 1938, requires that employers pay specified minimum and overtime wages, 29 U.S.C. § 206, 207. Section 13 of the Act, a point of frequent litigation, exempts thirty-eight categories of employees from the Act's overtime wage requirements. Included in section 13 is the so-called "taxicab exemption," which applies to "any driver employed by an employer engaged in the business of operating taxicabs." 29 U.S.C. § 213(b)(17). Prior to *Munoz-Gonzalez* , the Second Circuit had, like all federal courts, traditionally interpreted FLSA exemptions narrowly in light of the Act's remedial purpose, placing the burden on employers to prove that an exemption applied. *See, e.g.*, *Dejesus v. HF Mgmt. Servs.*, LLC, 726 F.3d 85, 91 n.7 (2d Cir. 2013).

*Munoz-Gonzalez* involved claims for unpaid overtime wages by twenty former driver-employees seeking to represent a class of former employees against D.L.C. Limousine Service, Inc., a self-described "luxury car service." 904 F.3d at 211. D.L.C. sought summary judgment in district court, arguing the drivers fell under the taxicab exemption and had no statutory right to overtime pay. *Munoz-Gonzalez v. D.L.C. Limousine Serv., Inc.*, No. 15-CV-9368, 2017 WL 2973980, at *3 (S.D.N.Y. July 12, 2017). The district court (Judge Oetken) granted the motion, focusing on criteria listed in the Department of Labor's Field Operations Handbook to find the drivers exempt because they did not drive along "fixed routes" and primarily served "local needs." *Id.* at *4. The drivers appealed, seeking a narrower reading from the Second Circuit.

In April 2018, while the drivers' appeal was pending, the Supreme Court issued its decision in *Encino Motorcars, LLC v. Navaro*, addressing a separate exemption for employees who sell or service automobiles. That decision "reject[ed]" the "[t]he narrow-construction principle" previously employed by all lower courts, finding that reading relied "on the flawed premise that the FLSA pursues its remedial purpose at all costs." *Encino Motorcars, LLC v. Navarro*, 138 S.Ct. 1134, 1142, (2018) (quotation marks omitted). Reasoning that exemptions under the FLSA are "as much a part of the FLSA's purpose as the overtime-pay requirement," the Supreme Court broadly stated that courts "have no license to give the exemption anything but a fair reading." *Id.* This holding marked a significant change – one that, according to Justice Sotomayor's dissent, upset "more than half a century of" Supreme Court precedent. *Id.* at 1148 n.7. Previously, the Court had held exemptions "are to be narrowly construed against the employers seeking to assert them and their application limited to those establishments plainly and unmistakably within their terms and spirit." *Arnold v. Ben Kanowsky, Inc.*, 361 U.S. 388, 392 (1960). This new change in course raises—and generally leaves open—the question of how lower courts will determine and apply "fair readings" to the Act's numerous exemptions.

### *The Second Circuit's Opinion*

Five months after *Encino Motorcars*, the Second Circuit (Judge Livingston, Judge Chin, and Judge Failla (by designation)) issued an opinion in *Munoz-Gonzalez*, affirming the district court on new grounds and imposing a three-factor test with implications for the car service industry. The panel expressly rejected the drivers' request to interpret the exemption narrowly, citing *Encino Motorcars* as requiring a "fair" interpretation of "each FLSA exemption . . . with full attention to its text." 904 F.3d at 216. The panel's "fair reading" analysis largely mirrored the Supreme Court's decision in *Encino Motorcars*, looking to contemporary dictionaries for the "ordinary meaning" of the operative term, in this case "taxicab." *Id.* at 213. The court principally drew that meaning from a 1934 edition of *Webster's Dictionary* and held that "a 'taxicab' is: (1) a chauffeured passenger vehicle; (2) available for hire by individual members of the general public; (3) that has no fixed schedule, fixed route, or fixed termini." *Id.* at 214. Finding no material dispute that drivers' vehicles met each factor and no argument that the drivers were not employees of the car service, the panel concluded the drivers were exempt under this new definition. *Id.*

The drivers' arguments before the panel primarily relied on the DOL handbook. They contended their work did not qualify as a "taxicab service" under the handbook because it involved frequent trips to the airport in unmarked and unmetered cars, "recurrent transportation" under contracts with local businesses, and occasional long distance travel. *Id.* at 216-18. The drivers also contended they did not work for a "taxicab company" because their employer controlled their work through a central dispatch, prohibited roadside pickups of "hailing" customers, mandated professional attire, and advertised itself as a "luxury car company." *Id.* at 219.

The panel roundly rejected these arguments as irrelevant or unpersuasive when weighed within to its three-factor definition of "taxicab." As an initial matter, the panel treated the handbook as lacking "the force of law" to the extent it conflicted with this definition. *Id.* at 216-17. Thus, to the extent the handbook contrasted "an airport limousine service" with taxicabs, it was unpersuasive: "DLC is not an airport limousine service for the same reasons that it *is* a taxicab company." *Id.* at 218. As for recurrent contracts, the panel acknowledged that "a company that received virtually all its business from recurrent contracts and corporate clients might not be 'available for hire by individual members of the general public' under [its] three-part definition," but found that was not the case before it, where contracts only comprised less than 5% of D.L.C.'s business. *Id.* at 217. Similarly, the panel found "occasional" long distance travel insufficient to alter the analysis. Regarding issues of control, the court deemed them "unimportant" to the taxicab exemption. Rather, the panel considered control relevant only to "whether the drivers are independent contractors or employees, not the nature of DLC's business." *Id.* at 219. Finally, the panel gave little weight to whether the vehicles were unmarked and advertised as "limousines." Those facts "go more to the marketing of the business than the core operation of the business itself." *Id.* at 219. "A taxicab is a taxicab is a taxicab; how a company *markets* its services or products does not change what it *is* for purposes of the FLSA." *Id.* at 219.

# NOTED WITH INTEREST (cont.)

***Conclusion***

*Munoz-Gonzalez* provides the first published response to *Encino Motorcars* from a circuit court. Aside from presenting possible precedent for the car-service industry, the case presents a potential template for "fair readings" of other exemptions previously provided a narrow construction. Whether and how that template may affect future rulings remains unclear, but it is an issue sure to arise as parties litigate a variety of issues in FLSA cases across the country.

# PRACTICE AREA NOTES

## Energy Litigation Update

***Arbitrational Tribunal Upholds Oilfield Forfeiture Clause.*** An arbitral tribunal seated in Paris has recently issued an award confirming the proper characterization and effect of the forfeiture provision found in many oil and gas Joint Operating Agreements, a subject which has been debated within the industry for some years but has received very little consideration by courts or arbitrators.

Oil and gas projects involve significant costs and significant risks. Uncertainties regarding the size and recoverability of reserves, the many technical difficulties that can arise in drilling wells and extracting oil or gas, and the fluctuating prices of oil and gas mean that no project can be guaranteed to be a financial success. Even if a project ultimately proves to be profitable, significant capital expenditure will be required before first oil can be achieved and any income generated, let alone before positive cash flow will be realized.

For these reasons, oil and gas companies rarely undertake projects on their own. Instead, they generally form consortia so as to spread the capital expenditure and risks associated with their projects. Although there a variety of standard forms of contract used to govern the relations between the parties to an oil and gas consortium, almost all such contracts will:

(a) require the parties to contribute (directly or indirectly) to capital and operating expenditure incurred by the Operator on behalf of the consortium in proportion to their percentage participating interest in the project;

(b) to make such contributions in full and without set-off whenever they are required to do so by way of cash calls issued by the Operator, even if they dispute the demand, with any such disputes being determined at a later date (known as the "*pay now, argue later*" principle); and

(c) provide various mechanisms to address a party's failure to pay some or all of its cash calls when required, known as a "default."

The latter mechanisms may vary from contract to contract, but will usually extend to the forfeiture of revenue and voting rights in the project and, if the default persists, the forfeiture of the defaulter's participating interest in the consortium for no consideration. In the industry's view, such mechanisms are necessary in order to provide the non-defaulting parties with means to ensure a project can continue when a party is defaulting on its obligation to contribute to its share of ongoing expenditure. In the meantime, the non-defaulting parties are required to pay their proportionate share of the defaulting party's cash calls. Such provisions have been commonly found in oil and gas Joint Operating Agreements for decades. However, they are very rarely invoked due (in part) to the uncertainty as to whether the exclusion provisions are enforceable or whether they might be found to be penal in nature, and they have therefore been considered in very few reported cases.

In October 2017, one of Quinn Emanuel's clients issued a notice to a co-venturer in a Brazilian offshore oil field development compulsorily requiring a defaulting consortium member to withdraw from the Joint Operating Agreement and to transfer its participating interest to the other consortium members in proportion to their participating interests. Under the forfeiture clause in the Joint Operating Agreement, which was in the AIPN 1995 standard form, the defaulting party which was required to transfer its interest "*at no cost.*" However, instead of doing so, it commenced an arbitration challenging the validity of the notice and the contractual provisions pursuant to which it was issued. The hearing of the challenge proceeded on the assumption that all of the (disputed) facts alleged by the defaulting party were proven, and included assumptions that it had invested nearly 100 times the amount of the cash calls of which it was in default at the time of the withdrawal notice. It was also assumed *arguendo* that the that Operator had incurred excessive costs in breach of the Joint Operating Agreement and that the other non-defaulting parties were also in breach of other provisions. Against that factual background, the defaulting party argued that the "*pay now argue later*" clause was unenforceable under Brazilian law if  gad faith is alleged. It further maintained that the forfeiture provision itself was invalid and/or that its operation was unlawful under the Brazilian constitution and various articles of its Civil Code (a civil law system). Finally, and in the alternative, it argued that the forfeiture provision was a penalty clause (or *clausula penal*) the effect of which should be moderated by requiring the non-defaulting parties to pay it compensation for the loss of its participating interest. (Although penalty clauses are generally enforceable under civil law systems, they can be moderated if the penalty is considered to be disproportionate or excessive; by contrast, penalty clauses are generally unenforceable under common law systems.)

The arbitrators heard legal argument and testimony over four days from three professors qualified in Brazilian law, as well as an expert in oil and gas industry contracts.

By the time the hearing was held, oil production had started at the field and the project in question had also been the subject of court proceedings in Brazil. The issues in dispute in the arbitration had also become common knowledge in the industry and, given the rarity of such cases, the outcome of the hearing was keenly awaited by oil and gas companies around the world.

In the event, the tribunal held that the "*pay now argue later*" clause was enforceable such that the conditions for the right to require the defaulting party to withdraw had come into existence by the time the notice was served. Second, the arbitrators confirmed the proper characterization and effect of the forfeiture provision – namely that it is not penal in nature.

Rather than to punish or deter, its commercial purpose is to enable co-venturers to continue with a project in circumstances where one of them has effectively ceased to participate by withholding cash calls. In circumstances where a party no longer wishes to participate, or is unable to do so, the Joint Operating Agreement anticipates that it will voluntarily withdraw and transfer its participating interest to the continuing co-ventures at no cost. It cannot have been intended that such a party could be better off by defaulting on its obligations, rather than voluntarily withdrawing, and then seeking compensation for the loss of its interest. So the tribunal held.

This is an important decision for the oil and gas industry, as it will help settle the long-standing debate as to whether the standard forfeiture clause is penal. It will also be welcomed by the industry, for which dealing with defaulting partners has become an increasing problem during periods of falling oil prices.

## Class Action Litigation Update

***Supreme Court Expresses Skepticism Towards* Cy Pres *Class Action Settlements.*** On October 31, 2018, the Supreme Court heard arguments in *Frank v. Gaos*, an appeal from a Ninth Circuit case involving objections to a *cy pres* class action settlement for alleged privacy violations. *Cy pres* is short for the French phrase "cy près comme possible" ("as close as possible"), referring to an equitable doctrine from trusts and estates law for effectuating a testator's intent in making a charitable gift. *In re Google Referrer Header Privacy Litig.*, 869 F.3d 737, 741 (9th Cir. 2017), *cert. granted sub nom. Frank v. Gaos*, 138 S. Ct. 1697, 200 L. Ed. 2d 948 (2018). In class actions, *cy pres* allows a court to distribute unclaimed or non-distributable portions of a class action's settlement fund to the "next best" class of beneficiaries for the *indirect* benefit of the class. *Id.* Courts have discussed potential dangers of *cy pres* in class actions, such as issues of fairness, self-interest, and the appearance of impropriety of judges and outside entities dealing in the distribution of settlement money. *See, e.g.*, *Nachshin v. AOL, LLC*, 663 F.3d 1034, 1038-39 (9th Cir. 2011) (expressing concerns and criticisms).

***Facts of the Case and Settlement.*** The plaintiffs claimed that the defendant included user's search terms in the URLs of its search results pages—meaning that if a user clicked a link on a results page, the destination website would receive the user's search terms in a "referrer header." *In re Google Referrer Header Privacy Litig.*, 87 F. Supp. 3d 1122, 1126–27 (N.D. Cal. 2015), *aff'd*, 869 F.3d 737 (9th Cir. 2017). Web analytics services could also obtain and disseminate this information. *Id.* The plaintiffs complained that the disclosure of their search information could include personal or highly sensitive information, and asserted claims for violation of the Stored Communications Act, 18 U.S.C. § 2701, and numerous state claims. 87 F. Supp. 3d at 1127.

The parties in the case ultimately agreed to settle. The defendant was to pay $8.5 million to a settlement fund, to be divided by: (1) distributions to certain *cy pres* beneficiaries, such as the World Privacy Forum, AARP, and to various universities, including alma maters of some of the plaintiffs' attorneys; (2) $2.125 million in attorneys' fees and costs; and (3) $5,000 for each named plaintiff. *Id.* at 1129-30. The defendant would also provide certain "FAQ" information on its website and provide other disclosures relating to how information from users' searches would be disclosed, but was not required to change its search, analytics, or web history practices or functionality. *Id.*

***District Court and Ninth Circuit Decisions.*** A district court approved the final settlement in March 2015, finding that the settlement met Federal Rule of Civil Procedure Rule 23(e)'s requirements for being "fair, adequate, and reasonable." *Id.* at 1138. The court also found that it would treat the plaintiffs, some 129 million individual users, as a class, and also rejected objectors' arguments for decertification of the class unless class members received direct payments from the proposed settlement. *Id.* at 1128-29. The court found that (1) a wholly *cy pres* award was appropriate because the award was non-distributable, (2) Rule 23(b)(3)'s superiority requirement was unaffected by whether the award was *cy pres*, (3) there was a substantial nexus between the *cy pres* recipients and the interests of the class members and there was no evidence that the parties' relationships with beneficiaries influenced the selection process, and (4) the attorney's fees were reasonable. *See generally id.* The Ninth Circuit also approved the settlement; however, one judge dissented in part, noting "[that] 47% of the settlement fund is being donated to alma maters of class counsel raises an issue." *In re Google Referrer Header Privacy Litig.*, 869 F.3d at 739, 748; *see id.* at 750 (suggesting vigilance for explicit collusion and for more subtle self-interest and conflicts in dissent).

***Issues on Appeal and Supreme Court Oral Arguments.*** The issues presented to the Supreme Court were whether a *cy pres* class action settlement that provided no direct relief to class members supported class action certification, and whether the settlement met requirements to be "fair, reasonable, and adequate." During oral argument, significant discussion involved standing issues of the class plaintiffs. The Court was also skeptical of *cy pres*-only settlements. The comments of the Justices ranged from noting that such settlements are very rare, to proposing not to foreclose them completely (but subjecting such settlements to greater scrutiny), to expressing severe doubts regarding the propriety of such settlements at all. *Id.*

***Supreme Court Request for Further Briefing on Standing.*** In November 2018, the Court requested supplemental briefing on whether the plaintiffs have standing. Thus far, the Court has not requested reargument, which indicates that the Court may decide the case on standing issues alone. Such a decision may leave open utilizing similar *cy pres* settlements such as the one in *Frank v. Gaos*, at least in the near term.

***Takeaways on* Cy Pres *Class Action Settlements.*** In sum, in *cy pres* class action settlements, parties should be wary of how beneficiaries are selected, who they are, and should conduct robust due diligence, particularly where class members will receive little or no compensation or direct benefit.

Further, *cy pres* settlements similar to *Frank v. Gaos* that provide no direct benefits to class members may be susceptible to greater scrutiny, skepticism, and risk of challenge, even if courts may nevertheless ultimately approve them. Q

## The Firm Welcomes Record Partner Class

The firm has elected the largest partner class in the firm's history. Half of the new partners are women, four come from offices outside the United States, and three come from diverse backgrounds.

***The newly elected partners are as follows:***

**Nicola Chesaites** – Nicola is based in the firm's London and Brussels offices. She is a barrister specializing in competition and EU litigation, with an emphasis on private damages competition disputes on behalf of claimants and defendants, and on EU banking, trade and sanctions disputes. Nicola received an LL.M in European Community Law from the College of Europe (Bruges), an LL.B from the University of Westminster, and *licence en droit* from *Université Paris X*, Nanterre.

**Jonathan Cooper** – Jon is based in the firm's Washington, D.C. office. His practice focuses on complex commercial and government-related litigation at the trial and appellate levels. He received an A.B., *cum laude*, from Harvard College, an M.Sc., *with distinction*, from the London School of Economics, and a J.D., *magna cum laude*, from Harvard Law School, where he was the Managing Editor of the *Harvard Law Review* and a member of the winning team in the Ames Moot Court Competition. Before joining the firm, Jon clerked for Chief Judge Frank H. Easterbrook of the U.S. Court of Appeals for the Seventh Circuit and worked in the Federal Programs Branch of the Civil Division of the U.S. Department of Justice.

**Jérôme Kommer** – Jérôme is based in the firm's Munich office. Jérôme's expertise as a German qualified attorney (Rechtsanwalt) covers all aspects of complex patent litigation, including the coordination of international litigation efforts. He teaches patent law at the University of Mannheim. Jérôme graduated from the University of Heidelberg and received an LL.M. from the University of California, Berkeley School of Law.

**Silpa Maruri** – Silpa is based in the firm's New York office. Silpa is a trial lawyer specializing in commercial litigation, including disputes around contracts, corporate governance, insurance, and securities. Silpa graduated Phi Beta Kappa from the University of

Chicago with a B.A. in English, and *magna cum laude* from Cornell Law School. Prior to joining the firm, Silpa worked as a law clerk to the Honorable Legrome D. Davis in the Eastern District of Pennsylvania.

**Meghan McCaffrey** – Meghan is based in the firm's Washington, D.C. office. Meghan is a trial lawyer whose practice focuses on complex commercial litigation, white collar criminal defense, government enforcement matters, internal investigations, corporate crises and other disputes. Meghan earned her J.D. with Honors from the University of Texas at Austin, and graduated *summa cum laude* as a University Scholar from the University of Pittsburgh, majoring in History and Political Science.

**Jared Newton** – Jared is based in the firm's Washington, D.C. office. He is a trial lawyer specializing in technology-based litigation, with an emphasis on patent, trade secret, and other intellectual property issues. Jared's practice includes appeals before the Federal Circuit, the U.S. International Trade Commission, and the U.S. Patent & Trademark Office. He received a B.S. in Mechanical Engineering from Virginia Tech and a J.D. with honors from the George Washington University Law School.

**Harold Noh** – Harold (Hyunshik) is based in the firm's Hong Kong office. He specializes in international arbitration as well as cross-border litigation and white-collar crime. Recently, *Chambers Asia-Pacific* Guide noted Harold's "considerable skill in Korea-related disputes" and quoted clients as saying that Harold is "a future star" and "no doubt my first choice for difficult jurisdiction issues and complex disputes outside of Korea." Harold received his LL.B. from Sogang University and graduated from the Judicial Research and Training Institute of the Supreme Court of Korea. He is qualified to practice in South Korea.

**Aidan O'Rourke** – Aidan is based in the London Office. Aidan specializes in commercial litigation, with a particular focus on contract, pension, trust and intellectual property disputes. He was named in the *Legal 500* 2019 rankings as one of 23 "Next Generation" commercial litigators in London. He graduated from Victoria University of Wellington with a B.A. in History with *First Class Honours* as well as an LLB. Aidan joined Quinn Emanuel's London Office in 2012, and prior to that was an associate at one of New Zealand's premier law firms.

**Marlo Pecora** – Marlo is based in the firm's New York office. She is a trial lawyer with extensive experience in both federal and state courts. She has represented clients—plaintiffs and defendants—in a wide range of complex commercial matters, including securities, structured financial products, trade secret, and intellectual property disputes. She received her B.A. *magna cum laude* in International Affairs and Political Science and her J.D., with honors, from the George Washington University.

**Patrick Schmidt** – Patrick is based in the firm's Los Angeles office. His practice focuses on complex business litigation and intellectual property disputes. He received a B.S. in Mechanical and Aerospace Engineering from the United States Military Academy, a M.B.A from Auburn University, and a J.D. with High Honors from the University of Texas at Austin. Before joining the firm, Patrick clerked for the Honorable James B. Loken of the U.S. Court of Appeals for the Eighth Circuit.

**Renita Sharma** – Renita is based in the firm's New York office. Her practice focuses on complex commercial litigation, with an emphasis on securities and insurance disputes. She also has extensive experience representing clients in regulatory investigations. Renita received a B.A. with high distinction in International Relations from the University of Toronto, and a J.D. from Columbia Law School.

**Sam Stake** – Sam is based in the firm's San Francisco office. He is a trial lawyer specializing in high tech litigation with an emphasis in patent, trade secret, licensing, and other intellectual property disputes. He received his B.A. with honors from Harvard University and his J.D. with honors from Georgetown University.

**Brianne Straka** – Brianne is based in the firm's Chicago office. She is a trial lawyer specializing in intellectual property litigation, with an emphasis on high tech patent disputes. She received a B.S. in Electrical Engineering *summa cum laude* from the University of Notre Dame and a J.D. *cum laude* from the Northwestern University School of Law, where she was the Executive *Colloquy* Editor for the *Northwestern University Law Review*.

**Viola Trebicka** – Viola is based in Quinn Emanuel's Los Angeles office. She maintains a diverse complex commercial litigation and trial practice, with particular emphasis on antitrust litigation, intellectual property disputes, and class actions. Since 2014, she has been consistently named a Southern California "Rising Star," and in 2017, she was selected as one of the "Top 50 Up-And-Coming Women Attorneys In Southern California" by *Super Lawyer Magazine*. Viola received her J.D. from Yale University and a B.A. (*summa cum laude*, first in graduating class) from the University of Richmond. Q

## Victory for Investors in "ISDAfix" Antitrust Class Action

After four years of painstaking work by Quinn Emanuel on behalf of a class of investors in the market for interest rate derivatives, Judge Furman of the Southern District of New York recently gave final approval to settlements in excess of $500 million in our "ISDAfix" case, *Alaska Electrical Pension Fund v. Bank of America N.A.*, No. 14-cv-7126 (S.D.N.Y).

ISDAfix is a global benchmark used to value a range of interest rate derivatives. Quinn Emanuel brought the case on behalf of investors such as insurance companies, pension funds, hedge funds, and other sophisticated actors, against 14 large investment banks and their interest rate swaps broker-dealer. We built the case from the ground up, after noticing anomalies which suggested that various interest rate derivatives were not being priced in accordance with natural market forces, and for years worked to achieve results ahead of government regulators such as the CFTC.

Achieving the settlements required Quinn Emanuel to develop a number of novel legal theories and to exercise tenacity in our pursuit of the relevant evidence. For example, as class counsel we had to find traders who worked at the various bank defendants explicitly admitting that they were interested in or had attempted to manipulate the ISDAfix benchmark. We then had to match those admission to trades conducted by the bank for whom the traders worked, at the right time of day, and consistent with the method and intended direction of the manipulation described. We then had to demonstrate that the manipulative trades had an impact on prices in the relevant derivatives markets such that class members were harmed by the wrongdoing, in some instances hours or even days later.

In approving the settlements, the experienced jurist Judge Furman described the case as "the most complicated" he had ever faced, and observed that he could "not really imagine" how much more complicated "it would have been if I didn't have counsel who had done as admirable a job in briefing it and arguing it" as Quinn Emanuel had done.

The case is significant for a number of reasons. In respect of the amount recovered for the class—over $500 million—it stands alone as one of the most significant recoveries in an antitrust class action proceeding. The fact that the proceeding survived motion to dismiss was testament to the force of Quinn Emanuel's data and statistics-centric approach to pleading and proving complex market manipulation cases. And the fact that Quinn Emanuel achieved this result by remaining—throughout—ahead of regulators seeking to punish the same type of wrongdoing, demonstrates Quinn Emanuel's preeminent position as a force among the plaintiffs' bar, capable of achieving appropriate redress for defrauded investors on an industry-wide scale.

## Pro Bono Victory

The firm received a very favorable unanimous federal jury verdict in favor of our Hispanic-immigrant clients following a trial to establish disparate impact on Hispanic immigrants in East Los Angeles. After previously representing other low income tenants and achieving successful settlements against slumlords for wrongfully trying to evict them from their east Los Angeles homes, Quinn Emanuel was contacted by LACCLA (a community service non-profit founded by two Harvard law graduates) to assist on the eve of a retrial of a case that resulted in a mistrial a few months ago. The case was brought under the FHA against a real estate investment and management firm that manages over 50 buildings in east Los Angeles and the surrounding area and the owner of the apartment complex. the defendants had planned—and attempted—to evict all the Hispanic-immigrant tenants in one building, quickly convert it into student housing, and turn a quick profit by nearly doubling the value of the property, without any regard to how its actions would force its Hispanic-immigrant tenants out of the area or possibly into homelessness.

Quinn Emanuel substituted as lead trial counsel the first day of trial and tried the case to a successful conclusion in front of Judge Otis D. Wright III. The jury awarded $50,000 to each tenant for emotional distress and $500,000 to each tenant for punitive damages for violating the FHA. This was a sweet victory—the tenant clients were in the courtroom when the jury came back after a three-hour deliberation.

The firm is very proud of this result. In short, the real estate investment firm and apartment complex owner had decided to make as much money as they could, no matter the consequences to others or the cost to our society's wellbeing. In this ruthless pursuit of profit and discrimination, the defendants terrorized the low income tenants leaving them nowhere to turn but the courts, and find lawyers willing to represent them pro bono. The court and jury held the defendants accountable, and justice was done. and, Quinn Emanuel, of course, was there to guide justice on its way.

## Victory for Tech Startup in Four-Year Dispute with Former Salesperson

On July 25, 2018, the firm achieved a victory for technology start-up C3 IoT ("C3") when a jury rejected a former salesperson's claims that the company owed him hundreds of thousands of dollars in additional compensation and had wrongfully terminated him as a result. The plaintiff—C3's former vice president of sales—sought millions of dollars in damages, including punitive damages, and attorneys' fees.

C3 is a startup founded by technology mogul Tom Siebel. In 2013, C3 hired the plaintiff pursuant to a sales compensation plan for Fiscal Year 2014, which contemplated that over half of the plaintiff's compensation would be derived from commissions. Shortly after the end of Fiscal Year 2014, and before the company issued a new compensation plan for Fiscal Year 2015, the plaintiff closed two deals resulting in substantial revenue for C3. Days after the plaintiff closed the second deal, the company issued his 2015 compensation plan, which included commission rates significantly lower than his 2014 rates. The plaintiff alleged that after he complained about the retroactive application of a plan he never agreed to for work he had already performed, the company terminated him.

In June 2018, the firm won summary adjudication disposing of the plaintiff's breach of contract claims, forcing the plaintiff to go to trial on a quantum meruit theory. After an eight-day trial in Santa Clara County Superior Court, the jury roundly rejected the plaintiff's remaining claims, finding the plaintiff did not have a reasonable expectation that he would be paid more for the two deals than what was provided for in his 2015 plan. As a result, C3 now walks away from four years of litigation without owing the plaintiff a dollar. Q

## Quinn Emanuel Involved in Two of Top Five Delaware Cases to Watch in 2019

*Law360* recently published its top five Delaware cases to watch in 2019. Quinn Emanuel is proud to be involved in two of *Law360*'s five cases: *In re: Pilgrim's Pride Corp. Derivative Litigation* and *In re: Oxbow Carbon LLC Unitholder Litigation*. Few firms are involved in *any* of *Law360*'s five cases to watch. No firm is involved in more of them than we are.

In *Pilgrim's Pride*, we represent JBS SA and other Defendants in a heavily publicized breach of fiduciary duty action. The case arises from Pilgrim's Pride Corp.'s $1.3 billion acquisition of Moy Park, a UK-based poultry firm, from JBS SA, Pilgrim's Pride's controlling shareholder. Plaintiffs allege that Defendants, including JBS SA and Pilgrim's Prides' directors, breached their fiduciary duties by allegedly permitting Pilgrim's Pride to "overpay" for Moy Park. Following the motion to dismiss argument—where our clients argued that the court lacked personal jurisdiction over them and that the complaint failed to state a claim—Vice Chancellor Laster asked the parties for supplemental briefing regarding whether actions taken by "enhanced independence directors"—i.e. independent directors that are elected solely by the minority—should be subject to the business judgment rule. We filed supplemental briefing on December 21, 2018 advocating for the business judgment rule to apply for actions taken by "enhanced independence directors." A ruling in our client's favor on this issue would provide greater clarity under Delaware law for independent committees who are assessing potential transactions.

In *Oxbow Carbon*, we represent funds associated with Crestview Partners LP in a closely watched appeal regarding Delaware's implied covenant of good faith and fair dealing. At the trial level, we secured a substantial victory on behalf of Crestview against Oxbow Carbon LLC and William Koch, Oxbow's founder and CEO. The dispute concerns Crestview's contractual right, as a minority stakeholder in Oxbow, to sell the company under the terms of Oxbow's operating agreement. In a lengthy post-trial opinion, Vice Chancellor Laster found that the implied covenant of good faith and fair dealing applied to prohibit Koch's attempts to block a sale. The Court's post-trial decision is one of only a handful of decisions in Delaware that has ever applied the implied covenant doctrine to "fill a gap" in an LLC Agreement. Q

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- We are a business litigation firm of more than 800 lawyers — the largest in the world devoted solely to business litigation and arbitration.
- As of January 2019, we have tried over 2,300 cases, winning 88% of them.
- When we represent defendants, our trial experience gets us better settlements or defense verdicts.
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- We have won five 9-figure jury verdicts.
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Prior results do not guarantee a similar outcome.

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