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A Practical Guide to Spoliation Sanctions Under Amended Rule 37(e)

Federal Rule of Civil Procedure 37(e), addressing the availability of sanctions for failure to preserve electronically stored information (ESI), was amended effective December 1, 2015. One purpose of the amendments, as the advisory committee explained upon the new rule's promulgation, is to resolve disagreement among the federal courts of appeals regarding the circumstances under which sanctions are available. *See* Fed. R. Civ. P. 37(e) advisory committee note (2015). Noting that under the prior version of the rule (which had been adopted in 2006) litigants often felt compelled to undertake excessive preservation measures in order to avoid the possibility of losing a case because of an inadvertent preservation error, the committee sought a compromise under which the district courts would retain authority to punish extreme violations of discovery obligations without creating a mandate that would lead to excessive or disproportionate penalties. The amended rule aims to achieve this goal in part by specifying a detailed sequence of conditions to the imposition of sanctions.

- First, the preamble of the rule makes clear that it applies *only if* (i) relevant ESI "should have been preserved in the anticipation or conduct of litigation"; (ii) that ESI "is lost because a party

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INSIDE

Tax Investigations and Disputes Expert Joins London Office

Liesl Fichardt has joined the firm as a partner based in the firm's London office. Liesl was formerly a partner at Clifford Chance where she was head of the firm's Tax Investigations and Disputes practice. Liesl advises on all areas of UK domestic and international tax disputes, including complex cross-border tax investigations, tax litigation, management of raids by tax authorities, and strategic discussions with tax authorities. She is one of the leading advisors on tax treaty and bilateral investment treaty disputes. Liesl is a qualified solicitor advocate in England and Wales and is admitted as an advocate in South Africa. She is a former Chair of the British Branch of the International Fiscal Association, sits on the International Taxes Committee of the Law Society of England and Wales, and is a member of the Advisory Committee for the MSc degree in International Taxation at the University of Oxford. Q

Top Patent Trial Lawyer Joins Quinn Emanuel's New York Office

Steven Cherny has joined the firm as a partner based in the firm's New York office. Steve was formerly a partner at Kirkland & Ellis, where he practiced patent litigation in federal courts and before the United States International Trade Commission. He is an experienced trial lawyer who tries high profile patent cases involving IP in many different industries including telecommunications, electronics, medical devices, pharmaceuticals, financial and business methods, and consumer products. Steve has tried and won some of the largest and most important cases in the history of patent law. His victory for Bard against Gore currently stands at close to 2 billion dollars, the largest patent judgment ever collected. Steve recently tried the case Gore brought in response and invalidated Gore's asserted patent on three grounds and also obtained a verdict of non infringement. Steve also has won a number of landmark cases for Cisco including the Innovatio case which was the first to set out a comprehensive method to value standardized patents as well as two trials in the ITC against Arista Networks leading to exclusion and cease and desist orders. Q

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failed to take reasonable steps to preserve it"; and (iii) the lost information "cannot be restored or replaced through additional discovery."

- Second, paragraph (e)(1) provides that *if* a loss of ESI satisfies the preamble paragraph's prerequisites *and* caused prejudice to another party, the court "may order measures no greater than necessary to cure the prejudice." This provision allows the court to grant curative sanctions even if the loss of information was *unintentional*, and thus encompasses both negligent and reckless behavior. But as the advisory committee's note makes clear, an innocent loss of information is not sanctionable so long as the party in question has taken reasonable steps to attempt to preserve the ESI at issue—perfection is not required.
- Third, paragraph (e)(2) provides that *if* a loss of ESI satisfies the preamble prerequisites *and* was the result of a party's action "with the intent to deprive another party of the information's use in the litigation," the court may impose more serious sanctions including (A) presuming that the lost information was unfavorable to the party; (B) instructing the jury that it may or must presume the information was unfavorable to the party; or (C) terminating the case by dismissing the action or entering a default judgment. The advisory committee explained that such sanctions may be ordered without an express finding of prejudice, on the theory that when a party intentionally destroys information for the purpose of depriving an adversary of that information, it may fairly be presumed that access to the information in question would benefit the adversary (and, conversely, that loss of access causes prejudice). However, the advisory committee also made clear that imposition of such harsh sanctions is not required even upon a finding of intentional spoliation—rather, "the remedy should fit the wrong," and lesser sanctions should be used when adequate.

A survey of decisions issued since the amendment went into effect, which cover a wide variety of factual scenarios and substantive subject matter, shows that courts are closely parsing the rule's new language, giving effect to each of its stated prerequisites and limiting the circumstances in which they award the harsh and potentially case-terminating sanctions authorized by paragraph (e)(2). The new provisions are thus generally having their desired effect: Issuance of ESI-spoliation sanctions has become relatively predictable and standardized, even while the discretion afforded to district court judges and the inevitable differences among fact patterns has led to variation in the particular sanctions awarded.

Enforcing the Amended Rule's Prerequisites to Sanctions

First, with respect to the duty to preserve, the advisory committee notes make clear that the rule itself "does not attempt to create a new duty to preserve," but merely provides a mechanism for enforcing rules that exist at common law or which may be imposed by some other authority (such as a court order). This leaves the courts with flexibility to determine whether and when a duty attaches on the facts of each case—though in general, once litigation is anticipated (or commenced) the common law will impose a duty to preserve information that may be relevant to the case. For instance in *Keim v. ADF Midatlantic, LLC*, No. 12-CV-80577, 2016 WL 7048835 (S.D. Fla. Dec. 5, 2016), the plaintiff brought a putative class action under the Telephone Consumer Protection Act, alleging that the defendants had unlawfully sent him unsolicited text messages. The defendants sought Rule 37(e) sanctions on grounds that the plaintiff had deleted many of his text messages, including messages over which he was suing and which had been exchanged in February or March of 2011. The plaintiff did not anticipate bringing the action until October of that year, and the defendants were unable to produce evidence that the messages were deleted after that date—in fact it appeared that the plaintiff had deleted the messages close in time to when he received them. The court thus declined to impose sanctions even though the evidence in question was potentially central to the case.

The Southern District of New York explored the meaning of the rule's next requirement—that ESI be "lost"—in *CAT3, LLC v. Black Lineage, Inc.*, 164 F. Supp. 3d 488 (S.D.N.Y. 2016). *CAT3* was a trademark case in which the parties disputed the date on which the defendant had notice of the plaintiff's mark. In seeking to establish an early notice date, the plaintiff pointed to emails purporting to show that the defendant's employee was aware of the mark—but in fact the evidence showed (and Magistrate Judge Francis found) that the plaintiff had digitally altered the emails. Undoctored copies of the emails were available (and arguably defeated any notion that ESI was "lost" in a manner that it could not be recovered), but the court concluded that Rule 37(e)

nevertheless could apply because "the fact that there are near-duplicate emails showing different addresses casts doubt on the authenticity of both." (The court also ruled in the alternative that even if Rule 37(e) did not apply, it still would have inherent authority to impose sanctions as a remedy for the plaintiff's bad-faith evidence manipulation.)

Even where ESI has been lost, Rule 37(e) sanctions will not attach if the party in possession of the information undertook "reasonable steps" to preserve it. The advisory committee explained that the amended rule "does not call for perfection," and that data loss as a result of "routine, good-faith operation of an electronic information system" likely is not sanctionable. In assessing reasonableness, courts should be "sensitive to the party's sophistication with regard to litigation," as well as to the party's financial resources. For instance, in *Best Payphones, Inc. v. City of New York*, No. 1-CV-3924, 2016 WL 792396 (E.D.N.Y. Feb. 26, 2016), the plaintiff's principal had lost a number of relevant emails with third parties, which he had a duty to preserve because of pending litigation. But the court declined to order sanctions for his breach of this duty, in part because he believed, mistakenly but reasonably in light of his level of sophistication, that he could sufficiently preserve the emails by marking them as "new." *Best Payphones* contrasts with *Feist v. Paxfire, Inc.*, No. 11-CV-5436, 2016 WL 4540830 (S.D.N.Y. Aug. 29, 2016), where the court imposed sanctions on the plaintiff, who had lost relevant ESI when her computer crashed. The court observed that the plaintiff was "not a novice at computer functioning" and should therefore have known that she would need to back up data relevant to the case. *Id.* at *4.

Consistent with the final requirement of the preamble, courts will not order Rule 37(e) sanctions where the party seeking relief is not prejudiced because the purportedly lost ESI can be "restored or replaced." For example, in *Eshelman v. Puma Biotechnology, Inc.*, No. 7:16-CV-18, 2017 WL 2483800, (E.D.N.C. June 7, 2017), a libel suit based on the contents of an investor presentation, the plaintiff sent a notice instructing to the defendant to preserve ESI including the web browser histories of individuals involved in preparing the presentation. The defendant lost that data, despite awareness of the need to preserve it, when individual users' browser software automatically deleted their histories. But the court declined to impose sanctions, explaining that "other avenues of discovery," such as deposition testimony, were "likely to reveal information about the searches performed in advance of the investor presentation."

Even where all the preamble's prerequisites are satisfied, courts have declined to impose sanctions where the record does not establish either prejudice or intentional destruction of ESI. In *Living Color Enterprises, Inc. v. New Era Aquaculture, Ltd.*, No. 14-CV-62216, 2016 WL 1105297 (S.D. Fla. Mar. 22, 2016), for instance, the court expressly found that each of the preamble's prerequisites was met, but nevertheless denied relief: Although the defendant had deleted a number of text messages, the loss of the ESI was not prejudicial to the plaintiff (ruling out paragraph (e)(1) remedial sanctions) because the plaintiff had not established that the missing messages were relevant to its claims. The court also concluded that paragraph (e)(2) was inapplicable because in deleting the messages the defendant had not intended to deprive the plaintiff of access to evidence, but had instead engaged in a routine maintenance of his phone's data and had not acted in bad faith.

Judicial Discretion to Tailor Sanctions

In cases where ESI loss has been caused by merely negligent conduct, courts have heeded the Rule 37(e) amendment's purpose by avoiding imposition of severe sanctions. For instance, in *McQueen v. Aramark Corp.*, No. 2:15-CV-49, 2016 WL 6988820 (D. Utah Nov. 29, 2016), the defendant admitted that it had lost potentially relevant data because it had failed to put in place reasonable preservation measures. But the district court concluded that there was no evidence that the defendant had *intended* to deprive the plaintiff of the ESI or otherwise acted in bad faith. Thus, rather than impose a presumption or instruct the jury about what to infer from the missing evidence, the court directed that it would allow each party "to present evidence to the jury regarding the spoliation of the … ESI and to argue any inferences they want the jury to draw" from the spoliation—an intermediate sanction expressly identified in the advisory committee notes as appropriate under paragraph (e)(1), and which other courts have imposed in similar circumstances. *See, e.g.*, *BMG Rights Mgmt. (US) LLC v. Cox Commc'ns, Inc.*, 199 F. Supp. 3d 958, 986 (E.D. Va. 2016); *Nuvasive, Inc. v. Madsen Med., Inc.*, No. 13-CV-2077, 2016 WL 305096 (S.D. Cal. Jan. 26, 2016).

The decisions also make clear that the severest sanctions under Rule 37(e)(2) are not mandatory even where the perpetrator acts in bad faith. Instead,

the amended rule leaves the courts with discretion to determine what sanction is most appropriate on the particular facts of the case. For instance, in *CAT3* (discussed above) the S.D.N.Y. declined to invoke Rule 37(e)(2) even though it found that the plaintiff had intentionally manipulated emails in a bid to strengthen its case. Instead, the court precluded the plaintiffs from using the doctored emails at trial—protecting the defendants from legal prejudice without unnecessarily preventing the plaintiffs from pursing claims that might in fact have been legitimate. The court also ordered the plaintiffs to pay the costs and attorneys' fees that the defendants had incurred in investigating and litigating the sanctions motion, explaining that this would "ameliorate[] the economic prejudice imposed on the defendants and also serve[] as a deterrent to future spoliation." Similarly in *Ericksen v. Kaplan Higher Educ., LLC*, No. 14-CV-3106, 2016 WL 695789 (D. Md. Feb. 22, 2016), the court declined to dismiss the plaintiff's case even in the face of willful violation of her preservation obligations, opting instead to preclude her from introducing into evidence certain documents whose authenticity could not be determined without the missing ESI.

Of course, serious misconduct may still lead to serious sanctions. In *GN Netcom, Inc. v. Plantronics, Inc.*, No. CV 12-1318-LPS, 2016 WL 3792833 (D. Del. July 12, 2016), one of the defendant's high-ranking executives intentionally deleted thousands of potentially relevant emails, and admitted that he had instructed other employees to delete relevant emails from their inboxes as well. When confronted with allegations of this wrongdoing, the defendant did not take steps to ameliorate the problem, but dissembled and tried to convince the plaintiff that the emails had largely been recovered. The plaintiff ultimately was forced to hire its own forensic expert, whose analysis revealed a much higher volume of deleted emails than the defendant had acknowledged. The court imposed Rule 37(e)(2) sanctions on the defendant, even though it had taken a series of facially reasonable ESI-preservation steps—including issuing and updating litigation hold notices and conducting training sessions. The defendant remained responsible for the executive's intentional deletions, and the court found that its obfuscations in response to the plaintiff's investigation demonstrated bad faith. Yet despite the defendant's bad faith, the court did not enter default judgment or order a mandatory inference against it; instead, it imposed a $3 million monetary sanction and ordered that it would instruct the jury that it would be *allowed* (but not required) to infer that the missing ESI was unfavorable to the defendant. Other cases have similarly opted for permissive rather than mandatory instructions to remedy intentional spoliation, in accord with the amendment's general goal of dialing back the severity of discovery sanctions. *See, e.g.*, *Edelson v. Cheung*, No. 13-CV-5870, 2017 WL 150241 (D.N.J. Jan. 12, 2017); *First Fin. Sec., Inc. v. Freedom Equity Grp., LLC*, No. 15-CV-1893-HRL, 2016 WL 5870218, (N.D. Cal. Oct. 7, 2016); *Lexpath Techs. Holdings, Inc. v. Welch*, No. 13-CV-5379, 2016 WL 4544344 (D.N.J. Aug. 30, 2016); *accord Sec. Alarm Fin. Enters., L.P. v. Alarm Prot. Tech., LLC*, No. 13-CV-00102, 2016 WL 7115911 (D. Alaska Dec. 6, 2016) (both granting permissive inference instruction and precluding introduction of certain evidence).

A final case illustrates the severity of wrongdoing that courts may require before imposing case-terminating sanctions under paragraph (e)(2). In *Omnigen Research v. Yongqiang Wang*, No. 6:16-CV-00268-MC, 2017 WL 2260071 (D. Or. May 23, 2017), the court granted default judgment in favor of the plaintiff, but did so only after finding numerous instances in which the defendant had intentionally deleted and blocked production of thousands of emails and documents that were obviously relevant to the dispute (including by "donating" a desktop computer containing relevant documents to Goodwill)—even *after* the court had issued *multiple* orders requiring their production. The intentional destruction was egregious, and its extent was such as to "severely undermine[] the Court's ability to render a judgment based on the evidence." *Id.* at *1. The decision confirms that Rule 37(e)'s amendments have not foreclosed the possibility of case-ending sanctions, but it simultaneously illustrates that truly extraordinary conduct will likely be necessary to persuade a court to grant a default judgment or similar case-dispositive relief based on discovery violations.

Impact of *Eli Lilly v. Teva* Parenteral Medicines Inc. on Divided Infringement

The Federal Circuit in *Eli Lilly v. Teva Parenteral Medicines Inc.*, 845 F.3d 1357 (Fed. Cir. 2017), recently addressed the issue of "divided infringement" in the context of pharmaceutical patents for the first time since its 2015 decision in *Akamai Technologies Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015) ("*Akamai V*"). Divided infringement occurs when multiple actors are involved in carrying out the claimed infringement of a method patent and no single accused infringer has performed all of the steps of the method. In cases of divided infringement, courts will generally hold a defendant infringer liable for the infringing actions of another where the defendant directs or controls the other's actions or forms a joint enterprise or acts with a common purpose together with the other. *See Akamai V*, 797 F.3d at 1022.

In *Eli Lilly*, the Federal Circuit reviewed the question of what constitutes directing another's actions in cases where pharmaceutical drug labeling information provides firm directions to physicians to instruct the patient to self-perform certain steps of a patented treatment method. The Court held that where the drug labeling information provides the required steps that physicians must direct patients to take prior to administering the drug, and provides firm instructions to the physicians relative to the drug's administration, the drug manufacturer can be held liable for inducing infringement of a method-of-use patent.

Case Background

Pharmaceutical company Eli Lilly, the plaintiff in this case, holds a patent relating to the treatment of cancer, and specifically relating to methods for administering the drug pemetrexed disodium ("pemetrexed"). Pemetrexed is a chemotherapy drug that kills cancer cells that Eli Lilly sells under the brand name ALIMTA®. Treatment with permetrexed requires physicians first to treat the patient with folic acid and vitamin B12 before administering the drug, which reduces the drug's toxicity and increases safety. The pemetrexed patent states that the process of drug treatment requires "administering an effective amount of folic acid" to the patient, specifically "between about 350 μg and about 1000 μg."

The defendants were a collection of generic drug companies that sought to sell generic versions of ALIMTA® prior to the expiration of Eli Lilly's patent. The defendants planned to sell pemetrexed for the same purpose as the patented method—to use pemetrexed to treat cancer cells after first reducing the toxicity using folic acid and vitamin B12. They nevertheless argued that they did not infringe Eli Lilly's patent because the steps that defendants proposed would be taken would be divided between physicians and patients, where the patient self-administers folic acid with guidance from the physician, while the physician administers vitamin B12 and pemetrexed.

To show that these two actions amounted to divided infringement, Eli Lilly had to show that the defendants induced direct infringement of the patent from multiple parties by establishing that "the acts of one are attributable to the other such that a single entity is responsible for the infringement." This occurs in two types of circumstances: when the entity "directs or controls" another's performance, or when the actors "form a joint enterprise." *See Akamai V*, 797 F.3d at 1022. The question in *Eli Lilly* was whether the defendants infringed Eli Lilly's patent because it called for the physician to "direct or control" the patient's performance. Following a bench trial, the district court determined that it did, and the Federal Circuit affirmed that decision.

Directing or Controlling Performance

Relying upon prior Federal Circuit precedent, in particular *Akamai V*, the court noted that "directing or controlling others' performance includes circumstances in which an actor: (1) '*conditions* participation in an activity or receipt of a benefit' upon others' performance of one or more steps of a patented method, and (2) '*establishes the manner or timing* of that performance.'" *Eli Lilly*, 845 F.3d at 1365. Given that the permetrexed labeling information, including the physician prescribing information and the patient instructions, established clear directions and methods of compliance that physicians were required to give to patients prior to administering the drug, the court concluded that defendants were liable for divided infringement by "directing and controlling" the other infringers' actions. With respect to the first prong, the district court "identified pemetrexed treatment as the benefit to be conditioned." The product labeling repeatedly tells physicians to instruct patients on taking folic acid, along with folic acid dosage ranges and schedules. Likewise, the patient information informs patients that the physician may withhold pemetrexed treatment, with both sides' experts acknowledging that if the physician knew that the patient did not first take the required amount of folic acid, any reputable physician would withhold treatment of pemetrexed. Thus, the Federal Circuit agreed that physicians do not

merely "guide or instruct" the patients to take folic acid, but rather condition participation in administering pemetrexed upon the patient first taking folic acid.

With respect to the second prong, Defendants argued that because the product labeling gives patients wide latitude to select the dose, the form of dose, and the timing of taking the folic acid, it cannot be said that the physician "establishes the manner or timing of [] performance." In rejecting these arguments, the Federal Circuit again focused on the product labeling, noting that the physician prescribing information instructs physicians to tell patients to take folic acid orally and to take between 400 μg and 1000 μg of folic acid daily for one week before the start of pemetrexed. These instructions overlap with the dosage ranges and schedules in Eli Lilly's patent, and thus the Federal Circuit determined that Eli Lilly satisfied the second prong.

Intent to Induce Infringement

Having found the two-prong *Akamai V* test met, the court next turned to the question of whether Eli Lilly proved that defendants had "specific intent and action to induce infringement." The district court found that defendants had acted with such specific intent, because the administration of folic acid was a critical step for the administration of pemetrexed—not just a suggestion or recommendation—and because the defendants' proposed labeling induced the physicians to act in accordance with that labeling. In upholding that decision, the Federal Circuit noted that the intent must be directed to the actions of the underlying direct infringer, here the physicians, but it is not necessary for the plaintiff to provide evidence regarding whether the induced activity is actually prevalent. Rather, when proving intent based upon product labeling, the "label must encourage, recommend, or promote infringement" in order for the court to be able to infer an affirmative intent to infringe the patent. If the instructions clearly instruct users to follow the instructions in an infringing manner, then the court will find intent to induce infringement, even if some users might not follow the instructions. On the other hand, if the instructions are vague and require the actor to look outside the label to understand and undertake the implied infringing action, then an intent to induce infringement cannot necessarily be inferred. In this case, the product labeling made clear what was required of the physician, including the instructions to convey to the patient. Although defendants argued that physicians often take additional steps not considered by the patent, such as asking patients to keep pill diaries or confirming compliance with folic acid administration, the court determined that these additional guidelines are irrelevant to the question of inducement whenever the product labeling would inevitably lead some physicians to infringe the patent.

Divided Infringement Going Forward

In light of the Federal Circuit decision in *Eli Lilly*, in order for a patent holder to succeed on a claim of divided infringement against a company seeking to market a generic drug by incorporating steps to be taken by different actors, the patent holder must show that the generic drug company intentionally induced a party, such as a physician, to infringe the patent by either directing or controlling the other party to engage in actions that—together with the actions of the controlling party—would infringe the patent, or by joining into an enterprise with the other party and jointly infringing the patent. Where *Eli Lilly* is additive to the existing body of case law on this question is that it identifies the drug labeling information used by the generic company as particularly important evidence both in establishing direction or control and in establishing an intent to induce infringement. If the generic company includes in its labeling to the United State Food and Drug Administration that certain tests or steps must be performed by the physician or under the physician's direction, then according to *Eli Lilly*, infringement will likely be found. If, on the other hand, the generic company is able to avoid definite requirements in the product labeling, instead leaving it to the physician to independently determine the method of administration, *Eli Lilly* suggests that it may be more difficult for the patent holder to establish the requirements to hold the generic company liable for divided infringement. *Eli Lilly* expressly did not reach the question whether more than just a patient-physician relationship is required to show that the patient is acting under the physician's "direction or control," while also leaving open the possibility that other scenarios not involving directions to physicians in FDA-approved labels could serve to satisfy the "direction or control" requirement. Q

Appellate Practice Update

Obtaining Quick Appellate Relief from Federal Courts. You've just lost in federal district court, but there's good news: the court's decision rested on what seems to be clear legal error, and you like your chances on appeal. In this case, however, winning eventually won't be enough. The median federal civil appeal takes more than eleven months, a figure that pushes past two years in busy courts of appeals like the Ninth Circuit. Moreover, those are just averages; more complex matters may take substantially longer to resolve on appeal. If you can't afford to comply with the district court's judgment while the usual appellate process unfolds, what are your options?

While expediting your appeal or obtaining a stay pending appeal is always a challenge, any strategy will hinge on making an effective showing that the appeal will likely succeed on the merits. The first steps are before the district court. Under Federal Rule of Civil Procedure 62, a money judgment is automatically stayed for 14 days, a period you can move to extend while you pursue either a further motion before the district court, like a Rule 50 motion for judgment as a matter of law or a Rule 59 motion for new trial or to amend the judgment, or an appeal. If you are appealing an order involving a request for injunctive relief, Rule 62(c) permits the district court to suspend, modify, or grant an injunction while you take the case to the court of appeals. In deciding such a motion, the district court will address the same factors applicable to motions for preliminary injunction, including whether your appeal is likely to succeed on the merits. Because the district court judge whose opinion you are seeking to overturn is making the decision, it is unlikely he or she will be inclined to find that the appeal is likely to succeed on the merits—though that judge could be influenced to grant a stay upon a strong showing of likely irreparable harm absent a stay. You need to make this motion if at all practicable, as failure to do so may preclude other means of relief.

While you seek a stay from the district court, you should simultaneously prepare to seek further relief from the court of appeals. As with any other appeal, you will first file a notice of appeal with the district court clerk, who will promptly send a copy of that notice and the docket to the appellate court.

With the appeal docketed, you can seek from the court of appeals either a stay or injunction pending appeal, an expedited briefing schedule, or both. Under Federal Rule of Appellate Procedure 8, you can seek a stay pending appeal from the court of appeals if the district court denied or failed to act on your motion for the same relief below; seeking a stay from the court of appeals in the first instance is allowed only if moving in the district court would be impracticable. In seeking relief from the court of appeals, you should be sure to include a request for an interim stay or injunction, which a single judge may grant as an administrative matter in order to give a full three-judge motions panel an opportunity to rule on a full stay or injunction pending appeal.

Seeking a Rule 8 stay or injunction is not a step you should take lightly. In addition to the challenge of quickly pulling together a full brief setting out your entitlement to relief, your Rule 8 motion will also be considered under the demanding standard that district courts apply to motions for preliminary injunction—with most circuits undertaking an independent, *de novo* assessment of your entitlement to a stay or injunction. Although the courts of appeals have largely held that decisions by motions panels denying preliminary relief do not bind merits panels, to the extent such a decision assesses your appeal's likelihood of success, it is persuasive authority and likely to color a subsequent full decision on the merits. You will thus have to consider the strength of your Rule 8 motion on each of the preliminary injunction factors to decide whether you want an appellate panel to consider the merits of your claim at this stage and under this standard.

Either alongside or in place of a motion for relief pending appeal, you can also seek to have the full merits of the appeal decided more quickly than normal by filing a motion to expedite. Federal Rule of Appellate Procedure 27, which governs federal appellate motion practice, provides that the court may act on motions at any time, even without awaiting a response, and that a single circuit judge can act alone to decide a non-dispositive motion. Most of the courts of appeals supplement Rule 27 with a specific Local Rule containing further circuit-specific rules for the service, formatting, and contents of emergency motions, including motions for expedited briefing schedules.

To strengthen your chances of getting a particularly swift appellate decision, you should submit your notice of appeal and opening merits brief earlier than the applicable deadlines. Indeed, if you file your opening brief at the same time you file a motion to expedite, your motion can simply request that the court issue a scheduling order for the opposition and reply briefs on dates you propose. Combining a full and forceful explanation of your entitlement to appellate relief can also strengthen your request that that relief not be delayed by the normal briefing and decision schedule. In fact, in one recent case, a Quinn Emanuel team that filed its merits brief alongside its motion to expedite

not only earned our client an expedited schedule and quick ultimate decision, but in fact prompted the court to invite a Rule 8 motion for a stay during the course of that accelerated appeal.

A final option, rarely invoked and rarely granted, is to seek a summary disposition. Although not explicitly contemplated by the Federal Rules of Appellate Procedure, circuit courts' broad authority to issue such rulings "as may be just under the circumstances" includes the power to summarily reverse a mistaken decision, particularly where an intervening and binding legal decision or enacted legislation resolves the issue being appealed.

At every stage of an expedited appeal, then, demonstrating that your appeal will ultimately succeed on the merits is key to convincing the courts to grant relief pending appeal and reach those merits quickly. By making the focus of every brief the fact that the district court erred, and acting with the urgency the situation requires, you can minimize the effects of a mistaken decision below and put yourself on the fast track to a favorable appellate outcome.

White Collar Litigation Update

***Three Tips for Preparing an FCA Case for Trial, One Year After* Universal Health.** The stakes in False Claims Act cases have never been higher. Potential statutory penalties per claim doubled last year, and ten cases settled in the last twelve months for over $100 million each. Over the same period of time, courts began applying new materiality, falsity, and scienter standards following the Supreme Court's seminal June 2016 false claims decision, *Universal Health Services, Inc. v. United States ex rel. Escobar*. Historically, with qui tam complaints remaining under seal while the government investigates and conducts one-sided discovery, defendants have been motivated to quickly settle false claims cases. Now, that settlement-favoring paradigm is beginning to shift. In the face of high settlement expectations from the government, with recent case law warranting potentially favorable jury instructions on each of three key elements (materiality, scienter, and falsity), the playing field can be tilted by those willing to litigate.

Collect Evidence of Government Payment Decision-Making to Prove Materiality Early. It has always been the case that a false submission to the government in connection with a request for payment is not a false claim under the False Claims Act unless the subject matter of the falsity can be proven to be something that was material to the government's decision to pay the claim. *Universal Health*, while permitting false claims in certain circumstances to be based on violations of statutes, regulations, or contractual requirements, simultaneously emphasized how "rigorous" the Act's materiality requirement is, and held that no claim rooted in statutory, regulatory, or contractual noncompliance should proceed unless the noncompliance at issue *would actually have* affected the government's decision to pay the claim. Before *Universal Health*, cases were rarely dismissed before trial on materiality grounds, and courts applied a more liberal "could have affected" standard to the question of whether the alleged conduct was material to the payment decision. Several Circuits in the last year focused on evidence of what the government actually did when they learned of the contractual or statutory violation at issue and found false claims cases to be materiality deficient pre-trial where there is evidence that the government had notice of the fraud but paid the claims anyway. As a result, where it's available, evidence demonstrating that the government paid claims in full with knowledge of the alleged noncompliance likely establishes a defendant's ability to negate the materiality element, and may dissuade government prosecutors and private whistleblowers. Wise litigants will collect evidence of government payment decision making at the first sign of a potential false claims case.

Document Lack of Contractual Clarity to Disprove Scienter in False Claims Cases. Courts following *Universal Health* in the last year have extrapolated from the premise that a false claim cannot be "knowingly" submitted if the claim is based on an alleged violation of an ambiguous regulatory, statutory, or contractual provision, to hold that a defendant's objectively reasonable interpretation of such a requirement precludes a finding that the defendant "knowingly" submitted false claims in violation of that provision and may warrant early dismissal. Plaintiffs bear the burden of demonstrating that the defendant should have adopted a different interpretation of an ambiguous regulation. If courts will require plaintiffs to establish by a preponderance of evidence that the defendant was knowingly violating a non-ambiguous contractual provision before they can prevail on a false claim based on violation of a contract provision, it behooves defendants to maintain records of every contrary interpretation of a contractual term by the government in the course of fulfilling their contracts, and to document every admission by government inspectors that contract terms lack clarity.

Consider Bifurcating Falsity as a Trial Strategy. In a sophisticated False Claims Act case involving complex issues, a court may be willing to bifurcate and first address the issue of whether or not the claim itself is false. The last year also saw the first bifurcation of trial proceedings in a false claims case, implemented so that the jury avoids the confusion and conflation of hearing evidence on whether the invoice was legally false simultaneously with hearing evidence on whether the ostensibly false invoice was knowingly submitted and other issues. In

the year since *Universal Health* first recognized that a claim can be impliedly false, courts have struggled to apply its requirements on the element of falsity. On its face, *Universal Health* mandates that a claim based on an alleged material statutory, regulatory, or contractual violation is impliedly false if the claim contains a specific representation about goods or services provided and the defendant's failure to disclose its noncompliance makes those representations misleading half-truths. But courts in the last year have not applied that rule to require the same degree of specificity, nor agreed as to what is and isn't the "mere demand for payment" that *Universal Health* deemed insufficient to establish falsity. In false claims cases based on material statutory, regulatory, or contractual violations in particular, litigants should consider a trial strategy bifurcating the falsity issue.

Conclusion. In sum, in the last year, while settlement demands have remained stratospheric, in each of three key elements (materiality, scienter, and falsity) False Claims Act case law has developed to create potential advantages for defendants willing to litigate.

Class Action Litigation Update

Tyson Foods *One Year Later—Representative Evidence in Class Actions.* Last year in *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036 (2016), the Supreme Court endorsed use of representative evidence to establish liability in a Fair Labor Standards Act collective and class action. Noting that "[e]vidence of this type is used in various substantive realms of the law," the Supreme Court held that "[w]hether and when statistical evidence can be used to establish classwide liability will depend on the purpose for which the evidence is being introduced and on 'the elements of the underlying cause of action.'" As the Court said,"[i]n many cases, a representative sample is 'the only practicable means to collect and present relevant data,'" and "[i]n a case where representative evidence is relevant in proving a plaintiff's individual claim, that evidence cannot be deemed improper merely because the claim is brought on behalf of a class." The Court also noted that "[o]nce a district court finds evidence to be admissible, its persuasiveness is, in general, a matter for the jury."

In the short period since *Tyson Foods* was decided, lower courts have begun applying its holdings in a number of disputes:

- In *Bernstein v. Virgin America, Inc.*, No. 15-CV-02277-JST, 2016 WL 6576621 (N.D. Cal. Nov. 7, 2016), the court, citing *Tyson Foods*, approved survey evidence in a wage and hour case to establish the average time spent performing unpaid tasks for which the employer did not keep adequate records, such as time class members spent taking mandatory drug tests. Similarly, in *Ridgeway v. Wal-Mart Stores, Inc.*, No. 08-CV-05221-SI, 2016 WL 4529430 (N.D. Cal. Aug. 30, 2016), another wage and hour case where the employer failed to record time spent performing unpaid tasks, the court also accepted representative liability evidence and noted that, where an employer fails to keep adequate records, a representative sample may be the only practical means for employees to establish liability.
- By contrast, in two other wage and hour actions, lower courts determined that variations in the defendants' procedures across different company offices made use of representative evidence inappropriate: In *Davenport v. Charter Communications, LLC*, No. 4:12CV00007 AGF, 2017 WL 878029 (E.D. Mo. Mar. 6, 2017), the court denied the plaintiffs' attempt to establish liability through a study that determined average unpaid time spent turning computers on and off and loading required programs. The court reasoned that, because of variations in the defendant's procedures across its offices, no plaintiff could rely on another plaintiff's experience to establish how he or she clocked in or out. And in *Arnold v. DirecTV, LLC*, No. 4:10-CV-352-JAR, 2017 WL 1251033 (E.D. Mo. Mar. 31, 2017), the court denied the plaintiffs' attempt to establish liability through representative evidence, because the defendant's allegedly illegal pay practices varied across subclasses and from plaintiff to plaintiff. The court found these variations precluded the reliability of representative evidence to determine if any particular class member had been injured by the challenged practices.
- Another court assessing a wage and hour claim found the propriety of representative evidence turned largely on the extent of the defendant company's obligation to maintain records. In *Atis v. Freedom Mortgage Corp.*, No. CV 15-3424 (RBK/JS), 2016 WL 7440465 (D.N.J. Dec. 27, 2016), the court reasoned that *Tyson Foods* found representative evidence appropriate because the employer violated its duty to record employee hours. Finding that the defendant in *Atis* owed no similar obligation to track hours worked, the court concluded *Tyson Foods* was inapposite and rejected the use of representative evidence.
- In *In re: Syngenta AG MIR 162 Corn Litigation*, No. 14-MD-2591-JWL, 2016 WL 5371856 (D. Kan. Sept. 26, 2016), the court, citing *Tyson Foods*, allowed the plaintiffs to show classwide liability and damages through representative evidence a class action under the Lanham Act and various state laws. The holding was guided by the court's determination that the plaintiffs could have relied on the representative evidence to show liability and damages in an individual suit.

VICTORIES

A Duo of Appellate Victories for Pfizer in Zoloft Birth Defect Litigation

As long-time national and lead counsel for Pfizer Inc. in various product liability matters, the firm led a defense team that secured two important appellate rulings in a mass tort litigation in which it was alleged that the use of Zoloft, an antidepressant sold by Pfizer, caused children to be born with birth defects.

One appellate decision stems from the federal multidistrict litigation *In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, which involved lawsuits filed by several hundred plaintiffs. The plaintiffs proffered Professor Nicholas Jewell, a biostatistician from the University of California, Berkeley, as their expert on general causation (*i.e.*, that Zoloft is capable of causing particular types of birth defects in the general population).

The firm helped to expose the many methodological flaws in Professor Jewell's causation opinion and secure the exclusion of his opinion under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny. Pfizer pointed out that by applying divergent methods in an unscientific manner to conform to his pre-ordained litigation opinions, Professor Jewell was engaging in "situational science" – a term coined by the firm, adopted by the MDL court in its decision, and now part of the *Daubert* lexicon. The MDL court agreed and excluded Professor Jewell's opinion, leaving the plaintiffs without admissible and sufficient evidence of causation, an essential element of their claims. Accordingly, the MDL court entered summary judgment in favor of Pfizer.

The plaintiffs appealed to the United States Court of Appeals for the Third Circuit, arguing that the MDL court committed legal error by requiring statistically significant findings for a causation opinion and abused its discretion in excluding Professor Jewell. The Third Circuit disagreed and unanimously affirmed summary judgment for Pfizer in a precedential opinion.

Among many other important rulings, the Third Circuit rejected Professor Jewell's efforts to diminish the importance of statistical significance, holding that statistical significance "remains an important metric to distinguish between results supporting a true association and those resulting from mere chance." The Third Circuit also rejected the plaintiffs' attempt to water down *Daubert* by recognizing that it is not enough to mechanically parrot in rote fashion the steps contained within the correct methodology–an expert must reliably apply the methodology.

Pfizer's victory in the Third Circuit came on the heels of another appellate victory in the Pennsylvania Superior Court. In *Porter v. SmithKline Beecham Corp.*, as in the federal litigation, the firm led the effort in getting the plaintiffs' general and specific causation experts excluded under the Pennsylvania Rules of Evidence (which adopts the standard for expert evidence set forth in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923)), and in obtaining a summary judgment on the eve of trial. Notably, in excluding the plaintiffs' experts, the court recognized the importance of statistical significance when analyzing causation: "Generally accepted methodology considers statistically significant replication of study results in different populations because apparent associations may reflect flaws in methodology." The Pennsylvania Superior Court, in rejecting the plaintiffs' appeal, affirmed the decision and held that the plaintiffs failed to prove that their experts' methodologies were generally accepted as reliable in the relevant scientific community.

These decisions are notable developments in the law on the admissibility of expert evidence under the *Daubert* and *Frye* tests. They correctly hold plaintiffs to their burden of proffering reliable or generally accepted scientific evidence of causation and will help to keep unfounded scientific testimony out of the courtroom. The firm remains a leader in successfully litigating the admissibility of expert testimony at the trial and appellate court levels in state and federal courts across the country. For example, in its continuing representation of Pfizer in other mass tort litigations, the firm also led the effort in convincing another MDL court to exclude the plaintiffs' expert causation evidence and enter summary judgment in all of the several thousand cases in that MDL and is currently defending those decisions in an appeal brought by the plaintiffs before the United States Court of Appeals for the Fourth Circuit.

Eve-of-Trial Settlement Victory in Hatch-Waxman Suit

The firm recently secured a key settlement for an innovator pharmaceutical company, Gilead Sciences, Inc., in a Hatch-Waxman patent litigation against two generic competitors in the District of New Jersey. The settlement preserves patent protection on Gilead's life-extending, $800 million/year cardiovascular drug, Letairis®.

Ambrisentan, the active ingredient in Letairis®, was originally discovered and researched as an herbicide. Further research showed that it has properties that could treat a disease of the heart and lungs known as "PAH" (pulmonary arterial hypertension), a rare disease that was previously considered a death

sentence. Letairis® changed that—it provides not only life extension, but also a significant quality-of-life upgrade.

The case began in April 2015, when Watson Laboratories, Inc. sent a notice to Gilead that it had filed an application with the Food and Drug Administration to market a generic version of Letairis® prior to the expiration of the patent that covers the product. Another generic company, Sigmapharm Laboratories LLC, quickly followed Watson's lead. Gilead's patent claims various groups of compounds, including the active ingredient in Letairis®, ambrisentan. The generics stipulated to infringement of the patent, but argued that the patent was invalid for obviousness-type double patenting in view of an earlier patent that claimed much broader groups of compounds in the field of herbicides.

Quinn Emanuel quickly identified that the generics' obviousness theory was based entirely on hindsight—starting with Gilead's patent and working backwards to piece together the claimed inventions. Throughout discovery, the firm sought to expose the flaws in the generics' misplaced theory, including that persons skilled in the art at the time would not have been able to narrow the vast genuses of compounds claimed in the herbicide patent to arrive at the narrow subset of compounds that would be useful for treating PAH. The firm obtained key admissions from the generics' experts that persons skilled in the art at the time of invention would not have had reason to focus on the later-claimed compounds of Gilead's patent, and that even if they did, they would not have reasonably expected that those compounds could effectively treat PAH.

With fact and expert discovery complete and the final Pretrial Order filed, trial was about to be scheduled. Before that could happen, however, our adversaries accepted Gilead's long-standing settlement offer rather than facing us at trial. While the terms of the settlement are confidential, Gilead is thrilled with the result.

Complete Victory for Odebrecht in Fraud Dispute

The firm recently won a complete dismissal of all claims against Brazilian contractor Odebrecht S.A. in a civil suit in Washington, D.C. seeking over $200 million in damages stemming from Odebrecht's participation in the massive Petrobras bribery scheme that has sent shockwaves through Brazil.

A group of investment funds managed by EIG Management Co., LLC and certain affiliated funds had invested over $200 million in a Brazilian company, Sete, that Petrobras had created to extract oil in waters off the coast of Brazil. EIG contended that, as part of the massive Petrobras bribery scheme, Odebrecht and certain other Brazilian shipyards paid bribes to Sete to secure lucrative contracts to build drillships for the oil extraction. When this fact came to light, Sete went bankrupt, and EIG started looking for who it could sue.

In 2016, EIG filed suit in federal court in D.C. against Petrobras, Odebrecht, and other Brazilian shipyard owners, alleging they had all conspired to defraud EIG by inducing it to invest in Sete without disclosing the ongoing bribery scheme that would render the venture worthless. Also in 2016, the Firm negotiated a $2.6 billion criminal settlement with U.S., Brazilian, and Swiss authorities on behalf of Odebrecht in connection with the massive Petrobras bribery scheme. Odebrcht's criminal guilty plea made defending this case immensely difficult, as the Firm could not deny that Odebrecht had bribed officials at Sete.

Nevertheless, the firm was able to persuade Judge Mehta of the U.S. District Court for the District of Columbia to dismiss the claims against Odebrecht, both because EIG failed to establish that an objective of the bribery scheme was to defraud EIG and because EIG had not established a sufficient connection between Odebrecht and Washington, D.C. to enable the court to exercise personal jurisdiction over Odebrecht.

This case was an important bellwether in determining the extent to which U.S. litigants could use Odebrecht's criminal guilty plea for participating in the massive Petrobras bribery scheme to extort damages from Odebrecht in civil suits. The victory goes a long way to insulating Odebrecht from such lawsuits by establishing that Odebrecht is not subject to jurisdiction in the United States.

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