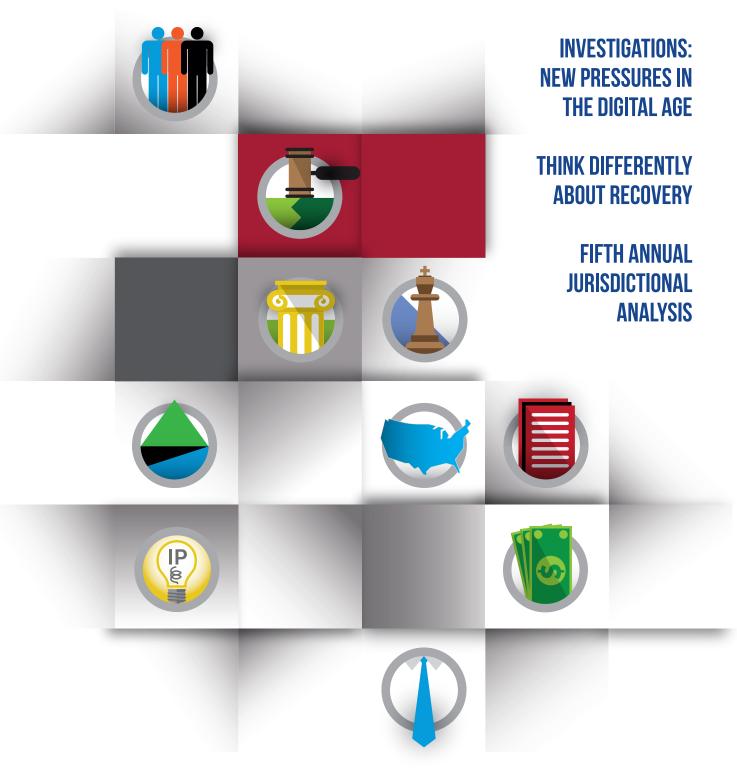
## **LITIGATION FORECAST 2017**

What corporate counsel need to know for the coming year



crowell

## LITIGATION FORECAST 2017

### The Forces of Change



Litigation is inevitable. It ebbs and flows, with its focus determined by a range of business and societal forces. Take the robust troll litigation that's dominated much of the IP landscape for the past decade. That's starting to fade away—

not because there are no trolls left, but because low settlement numbers, judicial predispositions, and the advent of the inter partes review process have beaten the profitability out of this form of litigation.

What generally drives the type and volume of litigation is change: change foments litigation; big change foments big litigation. And 2017 will clearly be dominated by big change—starting with a new administration with new priorities and continuing as rules and regulations are advanced or peeled back, as a new Congress advances—and tries to secure a new agenda, as agencies find new footing, and as new judges come on the scene.

And that makes being able to forecast likely developments in litigation more important than ever. As our clients, you've asked us to be not so much a vendor but a partner in understanding your business—and bringing that understanding to bear when considering what you need to be looking at, thinking about, and doing to move into the future.

That's the focus of this volume and of the four that preceded it: to step up to the challenge you've set before us; to see not only what's keeping you up at night, but also what critical balance sheet issues are likely to emerge in the days, weeks, and months ahead; and to help you prepare for them, contend with them, conquer them.

We hope you'll find this year's Litigation Forecast useful, informative, and even inspiring. To keep the conversation going, please visit www.crowell.com/forecasts.

> -MARK KLAPOW Partner, Crowell & Moring Editor, Litigation Forecast 2017



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### **INVESTIGATIONS:**

# UNDER PRESSURE AND OUT OF TIME

HOW GENERAL COUNSEL ARE LEADING THEIR COMPANIES THROUGH INVESTIGATIONS IN THE DIGITAL AGE

ressure. It's the one constant for all legal departments, and general counsel rarely face more of it than when they're leading an investigation that has made headlines and captured the public's attention. In the digital age, the appetite for instant answers combined with intense public scrutiny has put tremendous pressure on every aspect of investigations—from the way facts are gathered to executive accountability, government relations, and managing the impact of the crisis on the brand and the stock price.

General counsel and their legal departments must navigate investigations in less time and with more at stake than ever before. Their role extends far beyond the traditional function of chief counsel as they become crisis manager, brand guardian, defense attorney, and impartial investigator. It is difficult terrain where saying too much, or not enough, can invite consumer, regulator, and media backlash that destroys a brand or exposes executives to government enforcement actions or shareholder lawsuits.

In this article, we examine a hypothetical scenario from the near future—a company that delivers pharmaceuticals by drone—to explore insights and issues that can help legal departments create effective investigative strategies. Crowell & Moring's Investigations Practice partners created this scenario based on an amalgam of real-world experiences with actual crises. And their discussions examine sound practices in moving investigations forward—from working with the board of directors and navigating Capitol Hill to the basics of interviewing witnesses.

#### **COVER STORY**



"WHAT AT FIRST LOOKS LIKE A CONSUMER **COMPLAINT OR A ROUTINE COMPLIANCE** INQUIRY CAN QUICKLY SPIN UP INTO CRIMINAL OR REGULATORY INQUIRIES...AND CIVIL LITIGATION."

—KELLY CURRIE



"HOW YOU HANDLE THE PROBLEM **CARRIES TREMENDOUS** WEIGHT. WHETHER YOU DID THE RIGHT THING, PROACTIVELY, TRUMPS WHETHER YOU ARE EXPOSED TO A PRODUCT LIABILITY LAWSUIT."

—KENT GARDINER

#### THE SCENARIO

When Company Y, a major drugstore chain, launched a groundbreaking new home-delivery service, executives and shareholders had high hopes.

The service, AirDroneRx, used drones to take medicine to customers in selected rural areas as well as to remote Coast Guard ships and facilities. Just a month later, the company began to lose control of the airborne vehicles. Shipments were delivered to the wrong places—or not delivered at all. Then several drones crashed, damaging property and injuring people, including children.

Company Y first recognized the problem when calls began coming into its consumer hotline. Some members of Company Y's technical team suspected that malware introduced by a malicious cyber intrusion was causing the navigation system for the drones to fail. Soon, the story hit the news, and agencies including the Federal Aviation Administration and the Department of Justice were asking for more information. Parents of injured children began to file lawsuits and complain to the government, while class action lawyers started to round up patients whose prescription deliveries were at risk.

When a whistleblower emerged and filed a qui tam False Claims Act suit, claiming that the company knew about the problem but did nothing to fix it, the FAA stated it was considering grounding the full drone fleet. Some people began to wonder: How high in the organization will this go?

#### WHY IT'S DIFFERENT TODAY

Not that long ago, dealing with Company Y's scenario would have been a fairly straightforward task for the general counsel: contain the issue and pursue a step-by-step, deliberate investigation. "Most investigations were fairly predictable and linear," says Kelly Currie, chair of Crowell & Moring's **Investigations Practice** and former acting U.S. attorney for the Eastern District of New York. "But now, too often, they are neither. What at first looks like a consumer complaint or a routine compliance inquiry can quickly spin up into criminal or regulatory inquiries from multiple jurisdictions and civil litigation, all potentially hurting the company's reputation and share price, and certainly demanding the attention of senior management and the board. The general counsel's job is containment of risk and institutional harm, but in the digital age it is challenging to do."

The problem very often will involve more than legal issues. "The first job of the GC is to make the problem stop and to make sure that people are safe," says Kent Gardiner, chair of Crowell &

Moring's Litigation & Trial Department. "Instincts of protecting the company from civil and criminal liability are naturally top of mind. But today, everything is under a microscope. How you handle the problem carries tremendous weight. Whether you did the right thing, proactively, trumps whether you are exposed to a product liability lawsuit."

Gardiner recalls one investigation involving an industrial accident. The general counsel immediately set up a crisis room staffed not by lawyers, but by safety experts and others who worked with people on the ground to make sure the danger was contained and the first responders were safe. "That's a good example of the holistic approach you need today," says Gardiner. "In situations where people are injured, everything will turn on the ethics of how you dealt with the problemwhether you were fundamentally good."

A key difference between investigations today and, say, a decade ago is the rapidly expanding universe of digital information. "It used to be that you would talk to the people involved, then capture what they said to create the factual record," says Gardiner. Now, however, "the record has already been memorialized in real time, through the imperfect world of email, texting, bystander smartphone video, and voice mail."

Stakeholders in and out of the company now have easy access to that information and can use social media and other tools to create an ongoing real-time commentary around the event. "You no longer get a subpoena and respond 60 days later, with everything handled in an orderly sequence," Gardiner says. "It's all in real-time public view."

In this world, the general counsel needs to respond quickly and correctly-and the actions the legal department takes in the early stages can have significant ramifications later on.

To begin, it needs to develop an understanding of what has happened. "At first, the legal department will have an information deficit," says Currie. "Information is filtering its way up through people who may not have firsthand knowledge of events." He suggests that the general counsel rely on the old military adage: "The first reports from the battlefield are always wrong."

It takes time to gather the facts. But often management will want to hurry to make public statements about the investigation in the hopes of getting out in front of the issue. Doing so prematurely can create problems. "When you make statements to the government or the public that turn out to be only part of the story, that's a terrible place to be," says Currie.

#### THE RIGHT PEOPLE WITH THE RIGHT QUESTIONS

In gathering facts, the legal department will need to address a wide range of questions. Some will focus on determining what actually happened: What went wrong with AirDroneRx? Was it a hack —or a software problem? Has the problem been contained? The general counsel's team will need to sort out legal questions, such as:

- Is there a continued risk of injury from uncontrolled drones? Is there potential harm from missed or erroneous deliveries?
- What agencies and regulators need to be notified? A report will need to go to the FAA and the National Transportation Safety Board because there was an aircraft-related serious injury involved. But what about the Drug Enforcement Agency? Or the Coast Guard, which has a delivery contract with Company Y?
- Does the evidence suggest that the company should file a Federal Acquisition Regulation (FAR) Mandatory Disclosure because of failures to comply with federal contract requirements?
- How should the company notify the Coast Guard and others of the delivery interruptions?
- Were there breaches of private consumer data that require disclosure?
- What state laws and regulations might have been broken?

- Did lost drones potentially violate export controls? Did non-U.S. nationals gain access to controlled technology or source code?
- Did the program rely on data stored overseas? That could violate other countries' data privacy laws or make it difficult to access data for an investigation.

With so many different issues to consider, "the first thing you have to do is get just an ounce of information about what you think you've got on your hands," says Philip Inglima, a partner in Crowell & Moring's White Collar & Regulatory Enforcement Group, who also served with the U.S. Office of the Independent Counsel. "Then, bring together a team of the right people for this dialogue. You're having to move in a lot of directions at once, and you can't do that from a silo. You need a strong, horizontal team of relevant experts."

"That kind of planning early on helps manage the scope and cost of an investigation, so the general counsel can directly focus on the critical factors in evaluating the risk to the company," says Currie.

To piece together an accurate picture, Company Y will need to conduct interviews with employees, contractors, even customers. Here, it's important to think ahead to potential criminal investigations from the DOJ, as well as civil lawsuits from whistleblowers, customers, and shareholders. "You should work with the assumption that the company will be receiving a subpoena and there



"YOU'RE HAVING TO MOVE IN A LOT OF DIRECTIONS AT ONCE. AND YOU CAN'T DO THAT FROM A SILO. YOU NEED A STRONG, HORIZONTAL TEAM OF RELEVANT EXPERTS."

---PHILIP INGLIMA



"SHOWING THAT YOU ARE BEING PROACTIVE IS A GOOD WAY TO **DEMONSTRATE THAT** YOU ARE RESPONSIBLE. TELL THE REGULATORS WHAT AFFIRMATIVE STEPS YOU'RE TAKING TO CORRECT THE PROBLEM."

-GAIL ZIRKELBACH

#### KEEPING GOVERNMENT CUSTOMERS IN THE LOOP

For Company Y, keeping in touch with the Coast Guard and any other agencies it contracts with is a vital part of its investigation strategy. That means the company should tell those agencies as much as is prudently possible about the AirDroneRx problem up front. Why? "Because they don't like surprises, and they don't like to be ignored," says Gail Zirkelbach, a partner in Crowell & Moring's Government Contracts Group.

The company should not only explain the problem, but also present the solution. "The decision to suspend or disbar a government contractor is based on the determination of whether you're a responsible contractor," Zirkelbach says. "Showing that you are being proactive is a good way to demonstrate that you are responsible. Say, 'Mea culpa, this is what happened.' Tell the regulators what affirmative steps you're taking to correct the problem."

Disbarment and suspension are serious, but even lesser penalties can have long-term ramifications. "You need to work with your contracting officer to resolve the issue in such a way that he or she does not decide to terminate your contract for default. If it is terminated for default, then you will have a problem competing for future contracts; that termination for default will have an adverse effect on your evaluation," she adds.

Moving quickly to work with agencies can pay off in another way, as well. "There could be a potential False Claims Act case brewing, and a whistleblower could be racing to the courthouse to file something. If you can get a disclosure in before they make it there—and tell the government about the problem yourself—you have a much better chance of eliminating him or her as a valid whistleblower," Zirkelbach says.

#### **COVER STORY**



"IT IS IMPORTANT TO **MAKE SURE OFFICIALS UNDERSTAND THE COMPLEXITY OF... REVIEWING THE** INFORMATION THEY'RE ASKING FOR. AND HOW **LONG IT TAKES TO** MAKE IT ACCURATE."

—ANGELA STYLES



"EVERY WITNESS SHOULD BE REMINDED OF THE COMPANY'S **ZERO-TOLERANCE POLICY AGAINST RETALIATION AND TOLD** THAT THEY WON'T BE TREATED DIFFERENTLY **BECAUSE THEY'RE** PARTICIPATING IN THE INVESTIGATION."

—TRINA FAIRLEY **BARLOW** 

may be parallel criminal and civil litigation," says Inglima. "You need to make sure the investigation is conducted in a way that protects privilege." Yet companies rushing to find out what happened will rely on HR or field managers to start interviewing people, leaving that information open to later discovery in civil litigation. Instead, Inglima says, "the general counsel needs to have lawyers directing the investigation on behalf of the company."

Those lawyers should have experience in the subject matter. For example, in the AirDroneRx investigation, the interviewers should be knowledgeable about the government agencies and regulations that might be involved.

#### COPING WITH THE WHISTLEBLOWER

The emergence of Company Y's whistleblower created additional complexity for the general counsel-and considerably higher stakes for the company. The looming qui tam False Claims Act suit could result in significant claims and even treble damages. Furthermore, DOJ policy now calls for the department's criminal division to automatically review such cases to determine if it should pursue criminal charges alongside civil charges.

At this point, the government will be asking for information, and the general counsel should make delivery of that information a priority.

The general counsel may also want to help officials get up to speed on the challenges involved, says Angela Styles, chair of Crowell & Moring and former administrator for Federal Procurement Policy within the Office of Management and Budget at the White House. "The government doesn't always understand the complexity of collecting the information electronically and supplying it. The government believes corporations simply press a button and the right information pops out at no cost. So, whether it comes to navigating the DOJ or working with an agency, it is important to make sure officials understand the complexity of finding and reviewing the information they're asking for, and how long it takes to make it accurate."

"Regulators and the NTSB share the operator's goal to find the root cause of an accident and prevent recurrence. When a serious accident or incident occurs, they expect immediate notification and the full cooperation of the operator," says Marc Warren, a partner in Crowell & Moring's Aviation Group and former acting chief counsel of the FAA.

Within the company, the general counsel needs to re-emphasize the need to preserve

potential evidence. That's always important, but it becomes even more so when there's a whistleblower, which could motivate some employees to delete emails and other documentation.

Here again, the general counsel has to find the right balance between providing information quickly and being as thorough as possible, because the company does not want to find itself having to retract or amend information later on.

The general counsel should work with HR to ensure that no retaliatory actions are taken against the whistleblower. Like many corporations, Company Y has non-retaliation policies in place, but those need to be reiterated. "Every witness should be reminded of the company's zerotolerance policy against retaliation and told that they won't be treated differently because they're participating in the investigation," says Trina Fairley Barlow, a partner in Crowell & Moring's <u>Labor & Employment</u> and Government Contracts groups. "Also, remind them that if they believe they are experiencing any sort of retaliation, they should report it immediately."

Retaliation is usually not an issue with the legal team or HR, but elsewhere in the organization. Barlow suggests the company do more than offer abstract concepts. "It's important to give managers concrete examples of what may constitute retaliation. It's not just firing or demoting an employee. It can be taking work away from the individual or not inviting them to key meetings," she says.

Meanwhile, as Company Y's case unfolds, the whistleblower claims that senior managers knew about the drones' vulnerability to hacking but covered it up. Having the CEO or other executives implicated is unusual, but it's a possibility that needs to be in the back of the general counsel's mind.

An investigation that reaches the C-suite can be especially difficult to navigate for the general counsel-who, after all, reports to the CEO. That may feel like a dilemma, but, says Inglima, "the general counsel has to keep in mind who his or her client is, and remember that it's the company, not any individual member of management."

When interviewing those executives, the general counsel needs to make it clear that the company may eventually decide it is best to waive privilege and cooperate with government investigators in light of the Yates Memo's expectation that companies provide all relevant facts of individual misconduct in order to obtain credit for cooperation.

"You may need to turn over information from those interviews, and the government may use that information as evidence against the officers

of the company," says Inglima. "That can be a hard thing to explain to executives—that privilege in this case is something the company owns, not the executive, and the company can waive it. But you have the ethical imperative to basically Mirandize your executives and tell them that before you question them."

#### OPERATING AT THE CENTER OF THE STORM

Communication and coordination are essential skill sets for the general counsel and the in-house team. That can be seen in the AirDroneRx investigation, which encompasses a wide range of players, including counsel, PR experts, and the board. "The role of the general counsel has to be 'coordinator,'" says Cari Stinebower, a partner with Crowell & Moring's International Trade and White Collar & Regulatory Enforcement groups and a former counsel for the Department of the Treasury's Office of Foreign Asset Controls. "You need to look at your constituencies and have them all working seamlessly so that no one is getting out ahead of the others."

"It's important that there be a clear internal communication plan," says Stephen Byers, a partner in the firm's White Collar & Regulatory **Enforcement Group** who has handled corporate internal investigations for more than 20 years. "For example, the general counsel might hold a daily call among all the internal stakeholders. That can be a lot of people, but there is sometimes no substitute for oral discussion and realtime updating. There can be other regular calls among working groups. But there needs to be that element of overall coordination."

While the general counsel needs to be a coordinator, there are times when being more hands-on might be appropriate—for example, attending key meetings with prosecutors and regulators.

Communication with the board is especially important, and keeping members up to speed helps avoid surprises later on-something that is especially important in an age when Dodd-Frank and Sarbanes-Oxley statutes can make board members individually responsible for company crises.

Communication with the board can become even more critical when questions about upper management's involvement create "fissures" between the board and the CEO, says Gardiner. If it becomes apparent that the CEO may have some culpability in the problem, the board will be obliged to step in to protect the company. "If the board takes the lead in the investigation," he says,

"the general counsel will still need to work with the board to support its efforts—and that will be easier if he or she had been communicating with the board earlier in the crisis."

"The best general counsel have the support of their CEOs in helping the general counsel develop her own relationship with the board," Gardiner continues. "That helps the board have trust and confidence in the general counsel, which can give you some running room during an investigation." The general counsel can also help prepare for potential crises through the ongoing education of the board about the business and legal challenges.

That underscores a fundamental fact: the ability to manage an investigation has a lot to do with what is done before the crisis occurs. For example, along with building board relationships, the company should have an in-depth understanding of its suppliers. In the case of Company Y, it's possible that the drone's software vendor might have seen the problem with the hack, or at least been the key to stopping it. "It's important to know your vendors and have a robust system on the front end to understand who they are and how they operate," says Styles. "You need to understand their compliance programs, where they're based, and how they function."

In addition, the general counsel should get to know the people in government who are likely to be involved should an investigation be required. "It's better to have a solid relationship with a regulator in advance, because you want the agency to trust you if something goes wrong," says Stinebower. "The role of Congress doesn't have to be adversarial. If you become a valued subject matter expert and trusted reference for counterparts on the Hill, you're less likely to be blindsided by a congressional investigation."

Finally, the general counsel should set up a crisis investigation plan and a core crisis team in advance, and even run through practice drills to identify gaps and familiarize everyone with their roles and responsibilities.

"Pulling together everything on the fly will lead to avoidable mistakes," says Byers. Once a crisis hits, the general counsel will be dealing with multiple constituencies and the possibility of simultaneous criminal, civil, and regulatory actions. It is critical to keep all those variables in mind, and how a multitude of potential scenarios could play out in order to avoid missteps in the early stages. Overall, he says, "you'll need to be looking at the whole chessboard right from the beginning—now more than ever."



"THE ROLE OF THE GENERAL **COUNSEL HAS TO** BE 'COORDINATOR.' YOU NEED TO TAKE A LOOK AT YOUR **CONSTITUENCIES** AND HAVE THEM **ALL WORKING** SEAMLESSLY."

—CARI STINEBOWER



"PULLING TOGETHER **EVERYTHING ON THE** FLY WILL LEAD TO **AVOIDABLE MISTAKES.** ...YOU'LL NEED TO BE LOOKING AT THE WHOLE CHESSBOARD RIGHT FROM THE **BEGINNING.**"

—STEPHEN BYERS

# JURISDICTIONAL TIME TO TRIAL, FAVORABLE COURTS, AND OTHER LITIGATION TRENDS **ANALYSIS**

Some 2016 litigation trends are new, while others continue to follow familiar patterns. The Eastern District of New York became the hotbed for antitrust complaints, while the Eastern District of Texas continues its long-established reign as the most popu-

lar court for IP litigation. The Eastern District of Virginia earned its title as the "Rocket Docket," as cases proceeded

from filing to trial faster than those in any other district. False Claims Act litigation continues to be on the rise, with the Department of Justice trumpeting \$4.7 billion in 2016 FCA recoveries. Perhaps unexpectedly, more FCA cases were filed in the District of Maryland than in any other district, but Florida is the state where the most FCA cases were filed, spread among its three federal districts.

—Keith Harrison, Partner, Crowell & Moring

#### UNITED STATES **COURTS OF APPEALS**

CIRCUIT	NOTICE OF APPEAL To disposition In months	S. CT. Reversal Record
1ST	11.5	10F3
2ND	11.1	2 OF 6
3RD	7.4	2 OF 3
4TH	4.4	3 OF 6
5TH	9.2	5 OF 9
6TH	8.5	3 OF 4
7TH	6.7	0 OF 0
8TH	5.0	2 OF 6
9TH	15.4	8 OF 11
10TH	7.0	3 OF 4
11TH	6.1	3 OF 3
DC	13.3	2 OF 4
FFN	11.0	3 UE /I

USPTO PTAB TRIALS-

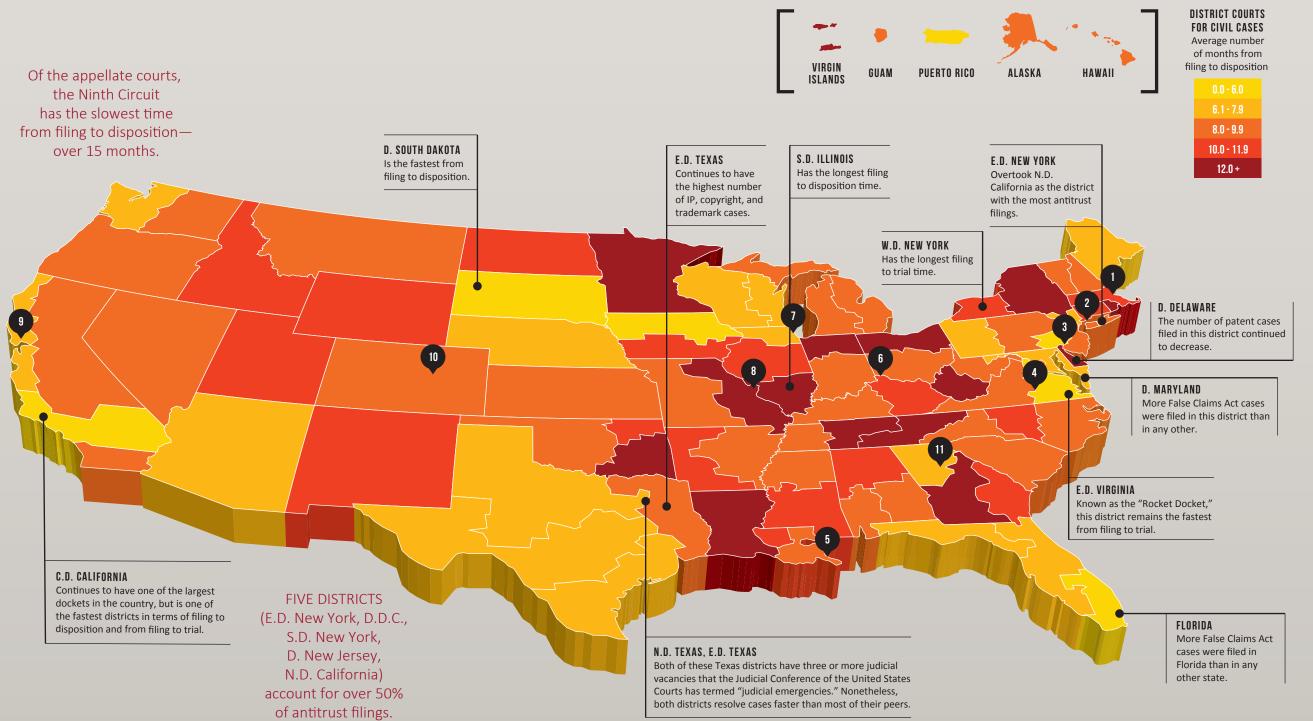


1301 CLAIMS

Patent Claims Found Unpatentable by PTAB in Final Written Decision

Patent Claims Cancelled or

Patent Claims Found Patentable by PTAB in Final Written Decision



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## **ANTITRUST**

#### THE RETURN OF "TRIAL BY FORMULA"?



A recent Supreme Court case creates new opportunities for dealing with class certification issues that often are critical to antitrust cases. In March 2016, the U.S. Supreme Court ruled in *Tyson Foods, Inc. v. Bouaphakeo*, upholding the lower

court's certification of a class suing Tyson. Although the case involved a violation of the Fair Labor Standards Act, it will have repercussions for antitrust litigation strategies, as well.

In *Tyson*, the plaintiffs relied on expert-witness evaluations that were used to calculate the average time for the conduct at issue. The Court said that this use of sampling and "representative evidence"—as opposed to evidence specific to individuals—was appropriate when certifying a class.

Many observers noted that this ruling lowered the bar for class certification, reversing a several-year trend in which the Supreme Court had generally been making certification more difficult. That trend had its roots in Wal-Mart Stores, Inc. v. Dukes, which criticized the use of statistical analyses in class certification as "trial by formula." With Tyson, however, that approach is back in play.

"As a result, antitrust defendants can now expect to see the increased use of sampling in class action suits," says <u>Chahira Solh</u>, a partner in Crowell & Moring's <u>Antitrust Group</u>.

#### **DEFENDANTS: SOME GOOD NEWS**

Certainly, that's good news for plaintiffs. However, the *Tyson* case has a silver lining for antitrust defendants as well. As Solh explains, the increased use of such sampling may provide another opening for those seeking to

prevent certification of a class. "There are opportunities for defendants to really attack those calculations and make sure that a class is not certified," says Solh. She says that defendants should focus on examining the sampling methods and underlying data being used in order to develop a deep understanding of plaintiffs' models—and then look for holes in their methods. "This is something that antitrust defendants had not focused on as much," she says. "But following the *Tyson* ruling, this is a strategy they should consider."

For example, defendants could make greater proactive use of discovery to find out which class members are going to be in the sample set, and whether the sample really demonstrates the viability of the plaintiff's claim. Defendants might find that there are problems with the way sample members are selected, or uncover administrative questions that might come up later in terms of the distribution of an award. "Serving discovery focused on the plaintiff's sampling and calculations allows a defendant to delve a little more deeply to determine if there are going to be issues that it can point to," Solh says.

#### LINES OF ATTACK

With that in mind, defendants should hone their team's ability to target discovery on the most important aspects of sampling. "Instead of going through a full analysis, they may be able to focus in on key points that quickly establish that the sample is not representative of the class," Solh explains. "They may be able to realize some efficiencies and actually decrease discovery costs, which helps reduce the pressure to settle just to keep costs down."

The time frames typically associated with antitrust cases can play into these strategies. Often, the activities alleged in cartel and conspiracy cases go on for years before a



"Serving discovery focused on the plaintiff's sampling and calculations allows a defendant to delve a little more deeply to determine if there are going to be issues that it can point to."

— Chahira Solh

#### **KEY POINTS**

#### Easier to certify

The Supreme Court has lowered the bar for class certification.

#### A silver lining for defendants

The ruling opens the door to questioning class sampling methods to prevent certification.

#### Acting early on

Consider the use of discovery and Daubert motions before actual trial proceedings begin.

lawsuit is filed. That means the information needed for the statistical analysis may well be out of date or difficult to find—which opens the door to challenges.

The heightened focus on sampling also means that defendants may want to consider the use of Daubert motions early on—in this case, challenging the expert witnessbased representative-sampling evidence. Daubert motions have traditionally been brought after certification and during the actual trial proceedings. But now, says Solh, "defendants should think about bringing these motions in the early stages to try to stop the class from being certified."

Finally, notes Solh, there is still some uncertainty about the Court's view of representative evidence that won't be settled until a new justice is named. The split Court has already prompted changes in some defendants' strategies. For example, after appealing its price-fixing case to the Supreme Court, a major corporation decided to settle the case for hundreds of millions of dollars following the death of Justice Antonin Scalia, rather than take its chances with a 4-4 Court. When a ninth member is named to the Court, companies may want to re-examine their antitrust litigation strategies.

#### MORE FOCUS ON PRODUCT **HOPPING**

With the Federal Trade Commission having clamped down on reverse payments and pay-fordelay tactics, some pharmaceutical companies have been turning to "product hopping" as an alternative—and that is likely to be a source of more litigation.

With product hopping, a drug maker takes an older drug off the market before its patent protection runs out, replacing it with a new, slightly different formulation. This allows the company to continue having patent exclusivity. "However, the FTC and some private plaintiffs have started to say that this practice is stifling competition," says Crowell & Moring's Chahira Solh.

That view, she says, sees product hopping as a way to force physicians and patients to use higher-priced drugs. The practice, some say, may also close the door on competitors that want to bring generic versions of the older drug to market.

One high-profile product-hopping case involving drug maker Actavis (now known as Allergan) and its Namenda drug has been working its way through the courts for years. In September 2016, the Southern District of New York denied a motion to dismiss the product-hopping claim against the company.

"There's not a lot of case law on product hopping yet, but it appears that it's a question that is going to be litigated more and more," says Solh. She adds that product hopping may still be a viable approach for pharmaceutical companies, "but you will have to make sure that you are doing it in the right way so that you clearly aren't pressuring or coercing doctors or patients into using your drug."

## **ENVIRONMENTAL**

## CLIMATE CHANGE: EVOLVING STRATEGIES AND REGULATORY UPHEAVAL



For years, environmental groups have been pursuing a variety of legal approaches in their fight against climate change. Now, their strategies may be changing again, as regulations are rolled back in the Trump administration.

A decade or so ago, many environ-

mental groups, and even some states, felt that the federal government was not doing enough about climate change and so began filing climate change-related nuisance law suits against power companies under federal common law. However, in *American Electric Power Company v. Connecticut*, the U.S. Supreme Court said that those common-law cases were preempted by the Clean Air Act, which gave the Environmental Protection Agency the authority to manage greenhouse gases.

That case prompted plaintiffs to explore a number of other avenues, including the filing of nuisance cases looking for monetary damages. However, these have typically failed to gain traction. In Comer v. Murphy Oil, plaintiffs sued energy companies saying their emissions contributed to property damage from Hurricane Katrina. The district court dismissed the claims as nonjusticiable political questions and for lack of standing (and the Fifth Circuit ultimately let that ruling stand). In Kivalina v. Exxon Mobil, plaintiffs sued energy companies saying their emissions contributed to arctic ice melt and seeking damages for relocation of the Kivalina village. The district court likewise dismissed on standing and political question doctrine grounds (and the Ninth Circuit affirmed dismissal on the grounds that plaintiffs' claims were displaced by the Clean Air Act). In both cases, the Supreme Court denied further appeal.

"Those two cases made it fairly clear that environmental groups would not be successful pursuing a generalized grievance in such lawsuits," says <u>Tom Lorenzen</u>, a partner in Crowell & Moring's <u>Environment & Natural Resources</u>

and Government Affairs groups, who was previously lead counsel in dozens of environmental cases at the U.S. Department of Justice.

But plaintiffs aren't giving up. Their next area of focus is likely to be corporate disclosures and climate risk, says

Lorenzen. He notes that "the New York attorney general's office has announced actions against several companies alleging that they knew climate change was a problem but failed to disclose it as required by the securities laws. I think plaintiffs will be taking a very hard look at what the various state attorneys general and the SEC are doing in this area over the next few years to determine whether they can bring claims out of it."

#### PUSHBACK ON CUTTING BACK

Following the *American Electric Power* case in 2011, the EPA stepped up its regulation of greenhouse gases. Recently, the climate change discussion has been focused on one particular aspect of EPA regulation—the Clean Power Plan. The CPP calls for a 32 percent reduction in the power sector's carbon dioxide emissions by 2030, as compared with 2005 levels. "In essence, the CPP seeks to require the power industry to shift generation from fossil-fired fuels to renewables. So it's a very significant rule—and the first major attempt by the U.S. to go after stationary-source greenhouse gas emissions," says Lorenzen.

Now, however, the U.S. presidential election result—as well as a potential lawsuit filed by some 150 plaintiffs—is putting the CPP's future in doubt. Indeed, it seems likely that the CPP will be scaled back or scrapped entirely. But that does not mean the issue will disappear from the courts, says Lorenzen, who oversaw many similar cases during the transition from the Clinton White House to the Bush administration. "Back then, the new administration wanted to scale back the Clean Air Act regulations and cut down on EPA



"As the administration tries to scale back regulations, such efforts are likely to be attacked by environmental groups and more progressive states." — **Tom Lorenzen** 

and DOJ civil enforcement efforts around environmental regulations," he says. "And as those things happened, citizen suits skyrocketed in response." With a similar situation unfolding, that history may well be repeated.

Such citizen suits could pursue a number of avenues. For example, environmental statutes give citizens the right to challenge the EPA if it fails to act to protect the environment. Citizens also have the right to sue companies, such as power generators, that are allegedly violating environmental emissions laws, providing that the EPA has been given advance notice of the suit and has declined to prosecute the case on its own.

In some ways, regulatory change may actually increase the pressure on companies. "Environmental groups may well choose to bring cases that the EPA would not ordinarily have brought," says Lorenzen. "There are situations where the EPA would probably give a company that's producing emissions the benefit of the doubt under the previous regulations." Now, he says, "environmental groups are going to be looking at those sources with a magnifying glass."

Lorenzen also points to the EPA's Next Generation Compliance initiative, which has brought increased transparency and reporting to the monitoring of emissions sources. "It also puts powerful monitoring tools that weren't previously available into the hands of the citizenry," he says. For instance, people can now use small infrared cameras attached to smartphones to capture images of emissions that aren't visible to the naked eye. "Those kinds of things can be used to support citizen suits," he says.

The anticipated rollback of rules could also be targeted in court. "As the administration tries to scale back regulations, such efforts are likely to be attacked by environmental groups and more progressive states," Lorenzen says. That means that the EPA is likely to find itself defending a more lenient regulatory regime. If so, he says, "there will be significant need for intervention in those lawsuits by the industries that are directly regulated in order to preserve the efforts to roll back the regulations."

When regulations are being cut back, "environmental groups view that as a time where they have to step up," Lorenzen continues. "They will probably keep pursuing all the avenues they can and looking for new legal theories to bring the issue to court. They are taking an all-in approach to this, pursuing both regulators and companies that are emitting greenhouse gases. That means that lots of companies can expect this to be a growing part of their litigation docket."

#### **KEY POINTS**

#### Changing focus

Environmental groups are changing strategies.

#### New avenues

Corporate disclosures about climate risk may be the next target.

#### **Expect more litigation**

As EPA activity slows, citizen suits are likely to increase.

#### PUTTING A PRICE ON CARBON

Environmental groups that seek to prevent fossil fuels from being mined or extracted—and therefore not burned—may find new avenues in litigation, thanks to new federal guidelines.

The cost of climate change has been hard to pin down, so the White House Council on Environmental Quality recently released new "social cost of carbon" guidance. This guidance attempts to monetize the cost of carbon usage, so such costs can be weighed by federal and state governments when they are making decisions about the mining of natural resources or approving other large projects. While the guidance itself will probably not be challenged, the way it is used could be.

"When the government applies the guidelines, companies might say that the government is overestimating carbon costs," says Crowell & Moring's Tom Lorenzen. "On the other hand, environmental groups might argue that the guidance is not being used appropriately, or if it's not being used at all, that it's inappropriate not to consider it. So it could be a driver of more litigation and is worth keeping an eye on."

## **GOVERNMENT CONTRACTS**

## FCA IMPLIED CERTIFICATION AND MATERIALITY: BAD NEWS, GOOD NEWS



In False Claims Act litigation—an enforcement area that has netted the federal government a whopping average \$4 billion annually since 2010—the theory of implied certification has been hotly contested for several years. Now, the Supreme Court has

shed some light on the issue while raising some additional questions—all of which will affect contractors, health care providers, and any institutions accepting federal dollars.

Traditionally, FCA liability has stemmed from claims that are factually false—for example, when a contractor or provider overbills or invoices for services that weren't delivered. The implied certification theory extends liability to claims that are not inaccurate on their face but are false in a legal sense—when, for example, a contractor fails to satisfy an underlying contractual term or regulatory provision.

"By submitting a claim for payment to the government, the theory says, the contractor is implying that it has complied with certain underlying legal, contractual, or regulatory requirements," says <a href="Brian Tully McLaughlin">Brian Tully McLaughlin</a>, a partner in Crowell & Moring's <a href="Government Contracts Group">Government Contracts Group</a>. "The contractor is liable under the FCA if the government would not have paid that claim had it known that the provider had not fulfilled the underlying obligations."

In recent years, the implied certification theory has created a significant split among circuit courts. By early 2016, two federal circuit courts of appeals had rejected the theory altogether. Eight others, however, had accepted it, though they adopted varying requirements in applying it. Some circuits said that the underlying provision in question had to expressly be a condition for payment for an implied certification theory under the FCA to hold water. Other circuits used a broader standard, saying that liability extended to cases where the contractor had simply failed to disclose any violations of underlying provisions that were material to the government's decision to pay. Under that standard, a contractor, health care provider, or other recipient of federal funds could potentially run into trouble for violating any one of countless regulations or terms of an agreement.

The Supreme Court addressed the issue in *Universal Health Services, Inc. v. U.S. ex rel. Escobar* in June 2016, saying that the implied certification theory was indeed valid. "That the Court upheld the theory makes it likely that we'll

see more litigation surrounding implied certification claims and expands the realm of liability and risk for government contractors," says McLaughlin.

However, McLaughlin continues, "this is one of those decisions that has something for everyone, and there is some potentially good news for defendants, as well." While allowing for implied certification claims, the Court also seemingly tightened the standard for determining whether a violation was material to the government's decision about whether to pay a claim. Among other things, the Court said that the government had to do more than simply assert after the fact that a defendant's failure to comply was material to its decision to pay or that the government had the right to decline payment. Instead, the burden is on the government to demonstrate that it would not have paid.

The Court also said that a requirement should be considered material if a reasonable person would attach importance to it in deciding whether to pay the claim, even if that requirement is not expressly characterized this way in the agreement or relevant regulations. For example, if a contractor were supplying watches, it would know that they should keep time, regardless of whether a provision specifically says so. On the other hand, the Court said that the government could not demonstrate materiality by simply inserting a blanket

#### **KEY POINTS**

#### Here to stay

The Supreme Court validated the theory of implied certification.

#### Something for everyone

The Court tightened up materiality standards.

#### The next battleground

Lower courts will take time to apply the ruling.



"We are going to see a lot of litigation...leaving the courts struggling to apply the Supreme Court's opinion on materiality going forward." — Brian Tully McLaughlin

requirement conditioning payment on compliance with every provision in a contract. "The decision instead leaves it to the district court to conduct a rule-of-reason type analysis," says McLaughlin.

The FCA itself defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." However, says McLaughlin, "that was widely agreed to be a very weak standard, because it didn't really require any delving into the actual facts, even at the summary judgment stage. It was basically asking, could this particular noncompliance have affected payment? Not was it likely to affect payment or even did it actually do so?" With Universal Health Services, the Court said that the materiality standard under the FCA should be considered a rigorous standard. "That opens the door to introducing actual evidence, maybe even beyond the contract at issue. What's the history here? Does the government routinely pay claims in similar contexts, even when they know that this kind of noncompliance with underlying requirements is occurring?" he says. "If so, that could undercut materiality for purposes of FCA liability."

Such questions promise to be something of a battleground in the near future. "We are going to see a lot of litigation around this as parties dispute the importance of regulatory and contractual provisions, leaving the courts struggling to apply the Supreme Court's opinion on materiality going forward," says McLaughlin. "That's starting to happen, and some recent circuit and district court decisions alike have already pointed in different directions. It may take another trip to the Supreme Court to clarify its own ruling on materiality. In the meantime, there is plenty of room for disagreement on a case-by-case basis."

All of this will only add more litigation to the steadily growing number of FCA cases. Recoveries have been growing—and so has executive risk, thanks in part to the Department of Justice's Yates Memo, issued late in 2015, which emphasizes individual accountability when looking at corporate fraud. "There's a directive under the memo that calls for corporate misconduct investigations, such as for FCA violations, to focus on both civil and criminal liability of any individuals that may have been involved," says McLaughlin. "More and more, we are seeing high-stakes, bet-the-company types of cases—but that also means more cases are going to trial, with companies fighting back, sometimes all the way to the Supreme Court."

#### THE EQUATION'S PENALTY SIDE

Under the False Claims Act, defendants face statutory penalties for submitting false claims—regardless of whether there has been any actual damage to the government. For more than a decade, those penalties have been set at \$5,500 to \$11,000 for each false claim submitted, based on the discretion of the court. In June 2016, however, the Department of Justice published adjusted civil monetary penalties for the FCA; the new amounts ranged from \$10,781 to \$21,563—nearly double what they had been.

Those penalties can add up quickly. "Many contractors submit hundreds or thousands of invoices over the life of a program. For health care providers, that number may reach into the tens of thousands," says Crowell & Moring partner Brian Tully McLaughlin. "If each invoice is determined to be a false claim, you can see how quickly statutory penalties can multiply into hundreds of millions of dollars in exposure. Now, in one fell swoop, those penalties have been doubled, and the ranges will continue to be adjusted upward annually." While the new penalty amounts are not, for the most part, retroactive, they provide strong incentives for the government and whistleblowers alike.

"Even in a case where there was little or no damage to the government, the potential for a huge recovery on penalties alone can make it worth bringing an action," says McLaughlin. "And that gives plaintiffs considerably more settlement leverage."

When the amount of penalties awarded grossly exceeds any actual damages, defendants may contest the penalties as violating the Eighth Amendment's Excessive Fines clause. Such challenges, while rarely successful, will likely become more frequent as the higher penalty ranges are applied, he says. "With the onset of penalties at nearly double the prior amounts, it is inevitable that we are going to see more cases in which the fines are vastly disproportionate to the actual damages. That means more Eighth Amendment challenges in this consequential area of the FCA, and perhaps with better results for defendants."

## **INTELLECTUAL PROPERTY**

## THE DEFEND TRADE SECRETS ACT: WHAT'S THE BIG DEAL?



In May 2016, when President Obama signed the Defend Trade Secrets Act to create a federal civil cause of action for trade secret theft, corporations gained a new tool in their effort to protect their intellectual property. But there is still much uncertainty

over how the act will be enforced, particularly in terms of its seizure provisions.

The DTSA is a response to growing trade secret theft in an era of connected systems and electronic data. Prior to the DTSA's passage, federal civil law protected patents, copyrights, and trademarks, but not trade secrets. Thus, civil actions against trade secret theft fell under a variety of state statutes and common law. While the majority of states followed the Uniform Trade Secrets Act, there were still a number of legal differences from state to state that often caused real problems in the application of a "uniform" law. Moreover, a few key states, such as New York, never adopted the Uniform Trade Secrets Act. As a federal law, the DTSA ensures that in the future the legal protections offered by trade secrets will be more consistent. Remedies under the DTSA include monetary damages, injunctive relief, and in certain circumstances, attorney fees. Courts can double damages if the trade secret misappropriation is found to be willful or malicious.

The DTSA offers a few notable changes from state laws. For example, it provides limited immunity for whistle-blowers, and companies are now required to provide notice of that immunity in any new or updated trade secret-related employee or contractor agreements. "If they haven't done that, in-house legal departments need to work with their HR departments to include that language in employment agreements," says <a href="Michael Songer">Michael Songer</a>, a partner at Crowell & Moring and co-chair of the firm's <a href="Intel-lectual Property Group">Intel-lectual Property Group</a>.

The DTSA also allows trade secret owners to make *ex parte* applications to the federal courts requesting that law enforcement seize property to prevent the theft of trade secrets. "If you believe the theft is happening quickly, you can go to the court without the defendant being present and ask that computer systems, for example, be seized in order to stop the theft," says Songer. Some observers have worried that this *ex parte* procedure will be abused by plaintiffs. However, says Songer, that concern may be ill-founded because it is still difficult to obtain a seizure order. And.

he says, "under this new law, if you get a seizure order and it turns that out you're wrong about the theft, you pay the costs—so it's not something that will be done lightly."

Overall, says Songer, those specific changes will not have a tremendous effect on litigation strategies. The real impact of the law, he says, is the fact that it gives companies the opportunity to look for trade secret protection in federal, rather than state, courts. That's important, because in general, federal courts have more experience with intellectual property cases. "Many of the judges are used to technology cases because the federal courts have exclusive jurisdiction over patent cases," he says. "Federal court judges are used to dealing with high technology, and they usually have better resources to do so."

The ability to use federal courts is also important for managing the ever-escalating costs of discovery. Federal courts apply consistent discovery procedures, set either by the federal rules or the local court rules. They are also experienced in handling discovery disputes that could otherwise cause a case to spiral out of control, particularly in complex matters. And with the federal law in place, different courts can look to the collective guidance of other federal judges, as DTSA

#### **KEY POINTS**

#### More consistent treatment

The DTSA supports a more uniform approach to trade secret cases.

### A new avenue for trade secret litigation

Companies can seek protection in federal courts, which typically have more experience in trade secret protection.

#### Improved odds for protection

Federal court involvement may make litigation a more appealing option for trade secret owners.



"Under this new law, if you get a seizure order and it turns that out you're wrong about the theft, you pay the costs—so it's not something that will be done lightly." — Michael Songer

cases result in final decisions and publicized opinions.

Having a federal law also benefits trade secret owners in cases involving trade secret theft by foreign companies and states. While these cases have usually wound up in the federal courts due to diversity jurisdiction, different legal applications in areas such as punitive damages often led to disparate results. "The new law ensures a consistent treatment for all aspects of a trade secret case that did not exist before," says Songer. In addition, he says, "Federal courts have dealt with these issues for a long time. They know how to deal with serving foreign defendants and with foreign defendants that are destroying documents or that don't show up in court."

Songer points to the fact that the DTSA can be used alongside existing federal criminal statues concerning trade secret theft. "The really significant change is that now you not only get to go into federal court with these cases, but you also have an opportunity to get the federal government involved, so you are bringing joint criminal and civil cases together," he says.

While the DTSA promises to afford companies with new solutions for trade secret theft, there are still many unknown factors regarding both the use of the law and its specific provisions. For example, a trade secret plaintiff may prefer to be in state court. Given the vagaries of jurisdiction and removal of state court actions to the federal court, a defendant may be forced to litigate in that state court if no federal counterclaims exist. In addition, it is unclear how the benefits of the DTSA—ex parte seizure actions, uniform punitive damages, and ready access to the federal court system, for example—will overcome the desire for a local system, particularly in employee disputes. "Given that the substance of the new law is similar to the old law," says Songer, "it just might be more cost-effective to stay with what you know unless the case has unusual elements."

Still, there is no doubt that there has been a shift in philosophy on how to handle trade secret cases. In the past, companies have at times been reluctant to pursue such cases. Often, they were put off by the complexity and costs of taking cases to state courts and the reality that cases involving foreign defendants were not likely to get far in those courts. Add to that the potential reputational risk of having to publicly reveal the theft. But the passage of the DTSA—and recent well-publicized thefts—has changed those views. "If you have instances where you believe foreign competitors are taking your trade secrets, you should

really consider bringing an action," says Songer. "Now you have a real chance of doing something about it, in a court system that is experienced in recovering assets and money from foreign wrongdoers."

Meanwhile, Songer continues, legal departments should increase their focus on preventing problems in the first place. "As trade secrets have grown in importance, the number of thefts has increased dramatically," he says. "So the general counsel needs to think about securing the company's trade secrets, as well as its patents, as part of their cybersecurity programs."

#### THE RETURN OF THE WILLFULNESS OPINION

In two rulings in June—Halo v. Pulse and Stryker v. Zimmer—the U.S. Supreme Court lowered the bar for willful infringement in patent cases. The Court said that the tests used for determining willfulness—which allows judges to award treble damages to patent owners—were too strict, and the decision should be left to the discretion of the court.

This change may bring back an old tactic—the "willfulness opinion." Years ago, companies would often get an opinion from outside counsel to confirm that their products were not infringing on others' patents. Thus, even if the company were found to be infringing in court, the opinion would support the view that it was not willful, and the court could take that into account in its deliberations. But in 2007, says Crowell & Moring partner Michael Songer, "the Supreme Court basically made it so hard to show willful infringement that no one bothered getting these opinions anymore."

With these more recent rulings, however, a judge can once again consider a range of evidence including the willfulness opinion. "It gives you a chance to make the point that you tried to do the right thing, that the question is an area where reasonable minds can differ, and this wasn't willful," says Songer. "So companies need to consider whether they should proactively go and get these opinions on their key products."

## **CLASS ACTIONS**

#### LIFE AFTER CLASS CERTIFICATION



In class actions, the certification of a class has always been a critical point and one often seen as the end of the road for defendants. But some are finding innovative ways to keep fighting even after a class is granted.

"Traditionally, when a class was certified, it could feel like something of a death knell for a defendant's case," says Michelle Gillette, a Crowell & Moring partner who heads the firm's Food and Beverage Industry Practice. Faced with the prospect of damages multiplied by thousands of class members, along with plaintiffs' attorneys' fees, companies tended

promised," says Gillette. This could involve, for example, pricepremium damages models. Here, plaintiffs might claim they paid a premium for a product based on a claim such as "all natural" and so are due a refund of the full purchase price of the product. But the defendant could argue that the chosen damages model does not account for evidence that the product had some actual value for many customers that must be subtracted from the full purchase price. So, the argument would be, the full-refund model is flawed and cannot be proven on a class-wide basis—and therefore, the class should be decertified.

That type of strategy was at the heart of the Ninth Circuit's Brazil v. Dole Food Company, Inc. ruling in October 2016,



"After certification, defendants often wanted to settle quickly.... Now, however, defendants are continuing the fight by filing motions for decertification—and they're winning."

- Michelle Gillette

to shy away from the uncertainty and risk posed by continuing down the road to trial on a case with a certified class. "After certification, defendants often wanted to settle quickly to get out from under that threat," she says. "Now, however, defendants are continuing the fight by filing motions for decertification—and they're winning."

At the initial class certification stage, a court does not presuppose that plaintiffs would ultimately succeed in marshaling the common proof necessary; it simply gives them the opportunity to collect evidence to prove their claims on a classwide basis, based on promises made in their certification motion. "Once discovery closes, plaintiffs no longer need to be given the benefit of the doubt—they must have actual evidence to prove their claim on a classwide basis," says Gillette. "So some defendants are now asking the court to decertify the class after discovery closes, arguing that plaintiffs cannot deliver on earlier promises to support the class claims using common proof."

One reason for doing so was created with the U.S. Supreme Court's 2013 Comcast v. Behrend decision, which requires a plaintiff's damages model to be consistent with the evidence supporting his theory of liability. "If the plaintiff's certification motion promised certain evidence to support his damages model, the defendant has the opportunity to go back and argue that plaintiff did not and cannot provide what he

which rejected the plaintiff's price-premium model. "The decision confirmed the idea that in order to certify a damages class, a plaintiff must present a damages model that provides a method of calculating damages using proof common to the class. If this is not done, defendants should consider moving for decertification," says Gillette.

#### TARGET: SLACK FILL

Today, plaintiffs are not only claiming that labeling is false, they are also claiming that the visual presentation of a product is misleading. "The issue of slack fill, where product packaging includes empty space, is starting to blow up in the class actions arena," says Crowell & Moring partner Michelle Gillette. Products ranging from lattes served with room for foam to containers of candy have come under fire.

Here, prevention is key. Among other things, says Gillette, companies should document their rationale for using slack fill in packaging to show that it is functional, consider the use of transparent packaging, and be sure that labeling of weight and volume is clear.

## LABOR AND EMPLOYMENT

### THE SPOTLIGHT SHINES ON PAY EQUITY



The issue of pay equity between women and men has been garnering a growing amount of attention from a variety of quarters, making litigation of pay-equity claims—from class actions to individual cases—an increasingly common occurrence.

The issue has been trumpeted by the White House, members of the U.S. women's soccer team, even an actress accepting her award at the Oscars. At the same time, activist investor groups are pressuring companies for more transparency around pay equity, prompting corporate boards to explore the issue before it comes up at shareholder meetings.

At the federal level, the Office of Federal Contract Compliance Programs has been stepping up enforcement of equal-pay rules. "The OFCCP's efforts have been accelerated through changes to standardized data requests at the outset of an audit, to an increasing unwillingness to share information regarding its compensation analyses during the course of an audit," says Kris Meade, chair of Crowell & Moring's Labor & Employment Group and leader of the firm's Pay Equity team.

In Congress, efforts to amend the Equal Pay Act to render pay-equity provisions more plaintiff-friendly have long been stalled. But things are changing rapidly at the state level. Some proposals that have not made it past Congress have been incorporated in state laws in California, New York, Maryland, and Massachusetts. "The groups pushing equal pay on Capitol Hill have succeeded in those four states," says Meade. California was the first to amend its labor laws, with the changes effective in January 2016. Now, he says, "we're starting to see the first litigations filed under that law."

These state laws include some provisions that differ from federal laws. For example, Meade says, "under federal law, a woman alleging discrimination has to be doing the same job as her male counterparts." That is, a lower-paid female employee would have to find a higher-paid male employee in the exact same position to file a claim. The modified state laws

have changed that standard, permitting that the work being performed need only be "substantially similar." "That's fairly vague terminology that leaves a lot of room for interpretation," says Meade. "Plaintiffs can be expected to point to different jobs and claim they are quite similar in terms of scope, responsibility, and skills required. There is likely to be battling over who is really performing substantially similar work."

Meade says that the amended state statutes will probably act as templates for other states revising their labor laws. "We're likely to see more states making their pay-equity laws more plaintiff-friendly," he says. "We think that's a trend, with more allegations of pay inequality and pay discrimination growing out of these state laws, rather than federal laws."

#### HERALDING JOINT EMPLOYMENT

More companies are relying on outside contractors for labor. As that happens, the federal government is scrutinizing "joint employer" situations, where two companies exercise control over the same employees.

In a 2015 case involving Browning-Ferris Industries (BFI), the National Labor Relations Board formulated a new standard for determining when companies were joint employers—discarding three decades of NLRB precedent. The previous standard required companies to have "direct control" over employees in terms of hiring, supervision, etc. Now, "indirect control" is sufficient. In June 2016, BFI appealed the ruling, and the case is now before the D.C. Circuit.

"The NLRB's standard makes it more likely the government will find companies that are joint employers" liable, for example, for one another's employment-law violations, says Crowell & Moring's Kris Meade. "A big question is whether the Trump administration will reverse course on this novel approach," he says.



"We're likely to see more and more states making their pay-equity laws more plaintiff-friendly." — Kris Meade

## PRODUCT LIABILITY

## UP NEXT: THE PERSONAL CARE AND COSMETICS INDUSTRY



The use of "no injury" theories and the misuse of class action procedures continue to dominate the product liability landscape. But companies need to keep an eye on other trends as well—particularly those in a handful of industries where

new product liability litigation appears to be lurking just around the corner.

"Going into 2017, we think we'll see a growing stream of product liability actions targeting certain industries," says April Ross, a partner at Crowell & Moring. For example, the medical device industry will not only continue to face its usual slate of personal injury litigation, it should expect more suits that focus on the "hackability" of Internet-connected medical devices and resulting product liability claims. Such cybersecurity and product liability issues are expected to arise in other industries where interconnectivity is at play, from autonomous vehicles to drones to 3-D printing and beyond.

Of special note, Ross continues, is the potential for a wave of product liability litigation in the personal care and cosmetics industry—a wave that is "right on the cusp of hitting." The industry is regulated by the 1938 Food, Drug, and Cosmetic Act, and under the act "cosmetics traditionally get far less scrutiny than food and drugs," she explains. Cosmetics manufacturers do not need approval for products or regularly share safety information with the Food and Drug Administration, and the FDA does not independently test the safety of ingredients or order recalls. "In general it's a passive regulatory regime, leaving much of the area largely unregulated," Ross says.

Converging events are now putting cosmetic industry product ingredients in the spotlight. A number of chemicals used in cosmetics are more heavily regulated in Europe. And some chemicals commonly used in the industry are coming under fire from consumers and environmental groups in other contexts—witness the recent lawsuits over the use of formaldehyde in lumber products. "All of this has led to an increasing media focus on the chemicals used in cosmetics and personal care products and alleged links to health concerns," says Ross. Presumably, the plaintiffs' bar is paying attention as well. The result, she says, "may be a growing litigation focus on cosmetics, including class actions from workers with prolonged exposure to such products, such as cosmetologists and salon operators."

#### **OUESTIONING THE RELEVANT SCIENCE**

For the industry, the key to the best defense lies in understanding and questioning the relevant science—or lack thereof. "There's often no strong epidemiological evidence supporting these health-related claims," says Ross. "So we can expect to see courts grappling with the scientific evidence, and specifically their gatekeeping function under *Daubert* or its state equivalents."

The issue is already starting to play out in courtrooms. In two high-profile cases in Missouri in 2016, juries awarded a total of \$127 million to plaintiffs who claimed that the use of talcum powder had caused their ovarian cancer. A few months later, a New Jersey court threw out two similar cases, citing the "narrowness and shallowness" of the scientific evidence.

"There was actually overlap between the experts in these cases, and the evidence was not markedly different," say Ross. "The judges reached different decisions about what they would deem admissible in court. We'll continue to see cases develop around these gatekeeping questions. How these play out will determine, in part, whether this litigation



"We can expect to see courts grappling with the scientific evidence, and specifically their gatekeeping function under Daubert or its state equivalents." — April Ross

trend has a long lifespan or whether it has a short one."

Changes on the legislative front are also expected to determine that future. In the seven decades since the Food, Drug, and Cosmetic Act was passed, much of the law has been updated, but the provisions related to cosmetics have remained unchanged. There now appears to be a building consensus that change is in order. "There is a lot of alignment in principle from stakeholders on all sides of the issue," says Ross. "The manufacturers, trade groups, environmental groups, consumer groups all appear to be in agreement that legislative action is needed."

That consensus has led to the introduction of two competing bills in Congress. A Senate bill would give the FDA authority to review and test ingredients, issue recalls, and require reporting of adverse events—much like the act's food- and drug-related provisions. Meanwhile, a House bill would establish procedures regulating manufacturing and distribution plants and require ingredient disclosures. It would also require the FDA to establish a safety oversight program, but would not give it the authority to issue recalls.

"The new session of Congress in 2017 may produce a compromise bill that will get more traction than these two competing bills have been getting and lead to a legislative overhaul with respect to cosmetics," says Ross. "That will then trickle down to new regulations, which will bring the kind of pressure that often drives litigation."

#### **KEY POINTS**

#### A new industry focus

Plaintiffs are looking at chemicals in cosmetics.

#### An opening for defendants

The science behind claims is still weak.

#### Legislative movement

Congress may soon update the Food, Drug, and Cosmetic Act.

## THE EPA TAKES A NEW LOOK AT CHEMICALS

In June 2016, Congress amended the 1976 Toxic Substances Control Act (TSCA) in a bipartisan effort that updated the regulation of chemicals for the first time in 40 years.

The legislation—known as The Frank R. Lautenberg Chemical Safety for the 21st Century Act—recasts the way that the Environmental Protection Agency oversees chemical safety.

The law requires the EPA to conduct safety assessments of chemicals commonly used in commerce and prioritize them in terms of risk; expands the EPA's ability to require testing of chemicals; allows industry to request risk assessments for specific chemicals; and gives the EPA the power to manage risk though labeling requirements, usage restrictions, and phasing out or outright bans on chemicals, among other actions.

While the EPA is working to implement the law and has plans to publish regulations governing the prioritization of chemicals in commerce and the evaluation of their safety by mid-2017, some observers believe that the plan is too ambitious, especially given the change in administration.

Congress essentially left it to the EPA to work through a number of questions, such as which chemicals to review and in what order to review them. However, despite the deadlines Congress imposed, observers point out that it might be some time before the final regulations come out.

Eventually, however, the risk assessments themselves will no doubt provide additional ammunition for the plaintiffs' bar. "Those assessments tend to live for a very long time," says Crowell & Moring partner April Ross. "They will be cited by experts as evidence that a given chemical can create health problems and trigger more product liability litigation."

## WHITE COLLAR

#### THE YATES MEMO: PRESUMPTION OF GUILT?



The Department of Justice's Yates Memo has gained a great deal of attention for its focus on individual accountability in white-collar investigations. But it creates other fundamental shifts that are likely to complicate internal investigations.

The Yates Memo says that corporate cooperation credit—which can significantly reduce corporate sanctions, to the point of a full declination—will be given *only* if the company identifies employees involved in wrongdoing and turns over "all relevant facts" relating to those individuals.

"Yates transformed cooperation credit into an all-ornothing proposition. You get full credit or no credit," says <u>Thomas Hanusik</u>, a Crowell & Moring partner and co-chair of the firm's <u>White Collar & Regulatory Enforcement Group</u>. "It really puts the onus on companies to investigate and identify all culpable individuals and then inform the DOI."

In essence, corporations have to give the government all the information they have on potentially guilty employees relatively quickly, which can create complications. The DOJ does not require corporations to waive privilege around interviews with their executives in order to get the credit. However, says Hanusik, "the Yates Memo does say that you have to tell the DOJ who the culpable individuals are and provide all evidence you've gathered about them. The government says it just wants the facts, but a lot of those facts are garnered during privileged interviews—so in practice, you could end up waiving privilege."

#### UNDERSTANDING THE CHALLENGES

For companies that are self-reporting, the Yates Memo may not create significant challenges. Generally, they are already aware of any misconduct and have a clear idea of what information they have and which individuals are involved. They understand what they will need to disclose to the government and the potential impact of doing so for the company.

The situation is quite different when companies are not self-reporting—that is, when an issue comes up as a result of a subpoena, a whistleblower, or some other government allegation of improper conduct. In those situations, the company essentially starts out in the dark, with

little understanding of the facts surrounding the alleged misconduct.

"The general counsel has to walk the razor's edge of trying to gather facts and evidence to be ready to defend the company, while also worrying about risking the loss of the cooperation credit because they're not handing the government everything from the outset," says Hanusik. To get credit for cooperating, companies may determine that they should disclose information about employees before they have a truly solid understanding of their potential involvement or culpability.

"That's a very difficult position for a company," he continues. "You may not know all the facts but find that you have to make a choice right away about what you're going to do with the information that you do have." And the general counsel has to think not only about whether the company should pursue the cooperation credit, but also how the decision could affect employee morale in the near term and potential civil lawsuits down the road.

In short, says Hanusik, the Yates Memo tends to replace the presumption of innocence with a presumption of culpability. In some circumstances, it can shift the burden of proof to the corporation, requiring it to perform and share

#### **KEY POINTS**

#### All or nothing

The DOJ's Yates Memo requires complete disclosure about employee conduct for cooperation credit.

#### A new burden

Companies face added pressure to do the government's investigative work.

#### Hurdles to compliance

Corporations may not have access to all the information they need for cooperation credit.



"That's a very difficult position for a company. You may not know all the facts but find that you have to make a choice right away about what you're going to do with the information that you do have." — Tom Hanusik

much of the investigative work traditionally done by the government in order to get cooperation credit.

Due to no fault of their own, corporations are not always in a position to successfully take on that work. While they often have the ability to examine internal servers and ask employees questions, they also have "significant investigative disadvantages that are very difficult, if not impossible, to overcome," says Hanusik. In particular, they don't have subpoena power to compel third parties to give them documents or to make anyone talk to them. What's more, with the Yates Memo's focus on individual accountability, some employees, former employees, and outside parties might decide not to talk to company investigators at all.

Unless there is an ongoing business relationship, companies typically have little leverage with outside parties. "Misconduct does not always occur only within the company's walls," says Hanusik. "People use external email accounts, they engage consultants and third-party vendors—and you can't compel them to talk." The Yates Memo makes some allowances for situations where international data privacy and data-blocking laws prevent companies from disclosing information, but that is not necessarily true for situations where the corporation simply cannot access relevant information.

Thus, even if a company's board and executives decide to cooperate with the DOJ in order to get cooperation credit, the company may still fall short of the DOJ's all-ornothing requirements.

#### PICK A DIRECTION—EARLY

All of this means that companies looking at potential misconduct need to map out an investigation plan as soon as possible. "In a likely self-reporting situation, you need to assure yourself that your information is sufficient enough to withstand the scrutiny of a prosecutor with 20/20 hindsight. And in a non–self-reporting situation, you need to basically get the buy-in of the enforcement agency about how you're going to proceed," says Hanusik. That buy-in might include agreed-upon search terms, identification of witnesses to interview, and prioritization of documents to review.

That said, corporations may not have to contend with these challenges indefinitely. The Yates Memo is the latest in a long line of such memos put out by various deputy attorneys general over the years. While they tend to have an impact on white-collar investigations, they also tend to be altered over time—and a future memo may recast the issue.

"With a new administration and things playing out in various cases in the courtroom," says Hanusik, "we may see drastic changes in the next couple of years." There is little likelihood that the emphasis on individual accountability will change, since being perceived as weak on crime is political suicide. But tying cooperation credit for companies to individual accountability could become a non-priority, if not tossed aside altogether.

#### WHAT'S OFFICIAL?

In June 2016, the U.S. Supreme Court overturned the conviction of former Virginia Governor Bob McDonnell, who had been convicted of bribery for receiving gifts in return for setting up meetings for a Virginia businessman. For the Court, the question in McDonnell v. United States hinged on whether setting up a meeting qualified as on "official act." The Court decided it did not—at least in this case—and determined that the jury had been given erroneous instructions on that point.

While the ruling seemed to make it harder to convict government officials for apparent corruption, it also said that such activities were not always innocent. If one official were to accept gifts in return for pressuring another official to attend a meeting, for example, that might be considered an official act. "It doesn't actually have to be an act performed by the person setting up the meeting," says Crowell & Moring's Tom Hanusik. "It could be one person putting pressure on another person to commit the official act."

"While McDonnell gives some guidance about what's not an official act, it leaves the door pretty wide open as to what sorts of things are official acts. When you consider that exerting influence on somebody else to commit an official act counts, you're talking about a pretty subjective interpretation—something like beauty is in the eye of the beholder." With that sort of uncertainty—and the stakes including jail time—McDonnell may lead to even more litigation.

## **RECOVERY**

#### LEARNING FROM EXPERIENCE



Over the past decade, many companies have increased their focus on affirmative claims and made recovery a regular part of their legal departments' activities. As these proactive approaches to recovery have evolved, legal departments are increasingly bringing

rigor to the process.

Often, recovery efforts have tended to focus on intellectual property issues—violations of licensing agreements or patent infringement, for example—or on antitrust issues, where a company might participate in a price-fixing class action. Such efforts have, at times, led to recoveries of tens of millions of dollars, or even much more. In fact, large legal departments have collected billions of dollars in recent years through these efforts.

Now, legal departments are turning their attention to areas such as financial services and, especially, health care. "Many companies today are thinking about their health care spend," says <u>Deborah Arbabi</u>, a partner in Crowell & Moring's <u>Antitrust Group</u>. "Most large corporations now have self-funded health plans—and for some employers, that has made them bigger providers of health insurance than some insurers." With health care costs rising, recovery offers an opportunity to offset that spending.

#### **DOING IT RIGHT**

As legal departments have gained experience with recovery, a number of best practices have emerged. These include:

#### **■** Establishing a central monitoring function.

Legal departments should keep tabs on class action litigation and Department of Justice and Federal Trade Commission investigations taking place across the country. "You want to have a really broad view of what's going on out there—not in just part of your core business, like IP, but also in the ancillary items of spend," says Arbabi. "Maybe there's been a price-fixing case involving office furniture you've purchased. You should track all that and funnel it to a single point of contact—one person who is in a position to see the big picture in order to identify and prioritize recovery opportunities."

Supporting and leveraging what the business is already doing. Often, business units will pursue recovery in tandem with their legal departments. In-house lawyers should keep in touch with people from various functions across the company and solicit their input about recovery. What are they doing? How can the legal department help them? How should their efforts be coordinated?

"You want to pull people from different areas into regular conversations, perhaps quarterly meetings," says Arbabi. Such communication can help ensure that recovery efforts across the company are coordinated and consistent, and pursued in a way that maximizes recovery efforts companywide. It keeps the legal department in touch with the business, and "it gets the word out and lets people in the business recognize that there is a program in which they can take part," she adds.

#### ■ Having regular conversations with procurement and buyers.

Recovery claims may involve the possibility of going to court against a key supplier. "Companies often think that kind of situation makes recovery a non-starter," says Arbabi. "But that isn't necessarily true." Legal departments should work closely with procurement and business buyers—the people who best understand the relationships with suppliers. Those groups can flag sensitivities, navigate around them, and help determine if recovery efforts are worth pursuing.

#### **KEY POINTS**

#### More systematic approaches

Legal departments are bringing rigor to recovery programs.

#### Best practices

Centralize the recovery function; support ongoing efforts of business teams.

#### Take it seriously

Assign responsibility; allocate resources.



"There is tremendous potential for creativity in how you approach the dialogue with the supplier to create a win-win situation. And a supplier in a class action suit will often welcome this kind of conversation with an important customer." — Deborah Arbabi

Those front-line business people can also help shape recovery deals that preserve the supplier relationship. "You can often avoid creating problems with the supplier while at the same time maximizing the recovery opportunities," says Arbabi. For example, rather than seek a cash payment, a recovery deal might call for a supplier to provide discounts on additional business with the company. "There is tremendous potential for creativity in how you approach the dialogue with the supplier to create a win-win situation. And a supplier in a class action suit will often welcome this kind of conversation with an important customer," she says.

#### STRUCTURING THE PROGRAM

Companies have taken a variety of approaches to building their recovery capabilities. "Some legal departments have designated one person whose sole job is recovery, and that person supports the other lawyers and business people around the company in the effort," says Arbabi. "Others share the recovery responsibility across a number of lawyers in the legal department, making it a regular part of their work." While the structure may vary, the key is to take a systematic approach, with the legal department providing a central hub for recovery activities.

By establishing that kind of approach, companies can bring greater efficiency to recovery processes and make the right trade-offs across recovery opportunities to achieve the greatest benefit for the company. They may also find it worthwhile to look at opportunities they have overlooked in the past. "There are certainly times where companies have thought some recovery opportunities were too small to be worthwhile," says Arbabi. "But if you have a recovery program in place, it can give you an efficient way to handle those together as a portfolio, without really adding a lot of work. And those smaller opportunities can really add up."

Overall, says Arbabi—whose clients have collected more than \$300 million in the past two years—the companies that have seen results from their recovery programs "recognize that this is not an extracurricular activity for the legal department, or something that the lawyers do with the last five minutes of the day. It's an important source of revenue that will drop straight to the bottom line. So putting some resources behind it can be very worthwhile."

## RECOVERY AND THE BOTTOM LINE

Many corporations are finding growing opportunities to recover for harm they have suffered due to anticompetitive activities and other forms of malfeasance in the supply chain. These recoveries have been realized both domestically and, increasingly, internationally. A nuanced approach to these opportunities can facilitate large recoveries in ways that respect important business relationships.

As experience has shown, an effective recovery program can help a company's legal department bring in significant dollars that have a direct impact on the bottom line. Over the past several years, Crowell & Moring has helped clients in various industries with efforts that have resulted in the recovery of:

- More than \$500 million for those harmed by price-fixing and cartel activity in the LCD industry.
- More than \$250 million for those harmed by pricefixing and cartel activity in the DRAM industry.
- \$60 million for those harmed by price-fixing and cartel activity in the polyurethane foam market.
- \$90 million for those harmed by attempts to monopolize a metals market.
- More than \$60 million for those harmed by pricefixing and cartel activity in the rubber chemicals industry.
- More than \$30 million for those harmed by a conspiracy by shipping companies to rig bids, fix prices, and allocate customers.



#### IN A YEAR OF CHALLENGES, A DEEP, TALENTED BENCH



This is Crowell &
Moring's fifth annual
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the fifth year in which
we've focused our sights
sharply on what are
likely to be business's

most critical litigation challenges over the course of the upcoming year. Our attorneys are working for more than a third of the Fortune 100 companies in litigation alone, and our deep bench of litigators have years of both business and government experience which provide them with an understanding of where their industries have been and where they're going. So we're uniquely positioned to identify—and dig deep—into the important issues, trends, and developments covered in this volume. And given the nature of the changes we're all facing in 2017, I'm tremendously proud of the work, and the thinking, that you'll find here. We look forward to hearing from you with comments—and suggestions for next year's Forecast.

—Angela Styles
Chair, Crowell & Moring

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