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What Do California, Vermont, And Alabama Have In Common?

*Innovator Liability for Brand-Name
Prescription Drug Manufacturers*

Plaintiffs' Attorneys Keep Trying Novel Theories

But Innovator Liability is still an Elusive Target

Square Pegs And Round Holes

*Discovery from the Perspective
of Closing Argument*



DEAR CLIENT:

Is a brand-name drug manufacturer liable for injury caused by a generic manufacturer of the product? The article *What Do California, Vermont, and Alabama Have in Common? Innovator Liability for Brand-Name Prescription Drug Manufacturers* observes that, in a decidedly minority view, some courts are willing to find a way to hold a manufacturer liable for alleged injuries caused by a product they did not manufacture — despite numerous other rulings to the contrary.

Two years after the preemption decision in *PLIVA, Inc. v. Mensing*, attorneys representing plaintiffs who ingested generic drugs are still trying to hold someone — anyone — liable for alleged injuries to their clients. They have met with little success. *Plaintiffs' Attorneys Keep Trying Novel Theories, but Innovator Liability is Still an Elusive Target* discusses the plaintiffs' attorneys' unsuccessful attempts to either hold the innovator drug manufacturer liable for the generic manufacturer's product or to hold the generic manufacturer liable under some new legal theory. It also reviews the latest holding by the United States Supreme Court in *Bartlett v. Mut. Pharm. Co.*, regarding this issue critical to pharmaceutical companies.

Long before any decision is handed down from the bench, however, counsel must spend time assembling information and building a case. Predictive coding, computer-assisted review — no matter what you call it, everyone is talking about it as more and more data is compiled by companies. *Plaintiffs and Courts are Increasingly Adopting Predictive Coding Because of its Reliability: Should Your Company Consider it for Your Litigation?* will equip you to evaluate the usefulness of predictive coding.

How does your legal counsel conduct discovery in lawsuits in which your company is involved? Do they have trial themes in mind when they send out those first interrogatories, or when they depose that first witness? Trial-guided discovery is the topic of *Square Pegs and Round Holes: Discovery from the Perspective of Closing Argument*. It gives some practical tips on how you can make sure that you will have the facts you need for trial.



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PRO TE: *Solutio*

Vol. 6 No. 3 September 2013

SHARING SOLUTIONS

It's human nature to share problems. But how often is someone willing to share solutions? Butler Snow wants to do just that — provide scenarios and the solutions that turned a client's anxiety into relief and even triumph. That's why we created this magazine, *Pro Te: Solutio*, which explores how real-life legal problems have been successfully solved.

That's also why we at Butler Snow redesigned and expanded our unique health-oriented industry group, now comprised of two major sections that handle business and litigation. The Pharmaceutical, Medical Device, and Healthcare Industry Group has more than 50 multi-disciplinary attorneys who provide creative solutions for the complex issues of the healthcare industry. This group includes product liability and commercial litigators; corporate, commercial, and transaction attorneys; labor and employment attorneys; intellectual property attorneys; and those experienced in government investigations.

Pro Te: Solutio is a quarterly magazine available only to the clients of Butler Snow. If you have questions or comments about its articles, you're invited to contact Christy Jones and Charles Johnson, as well as any of the attorneys listed on the last page of this publication.

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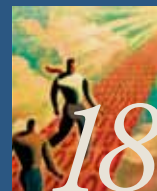
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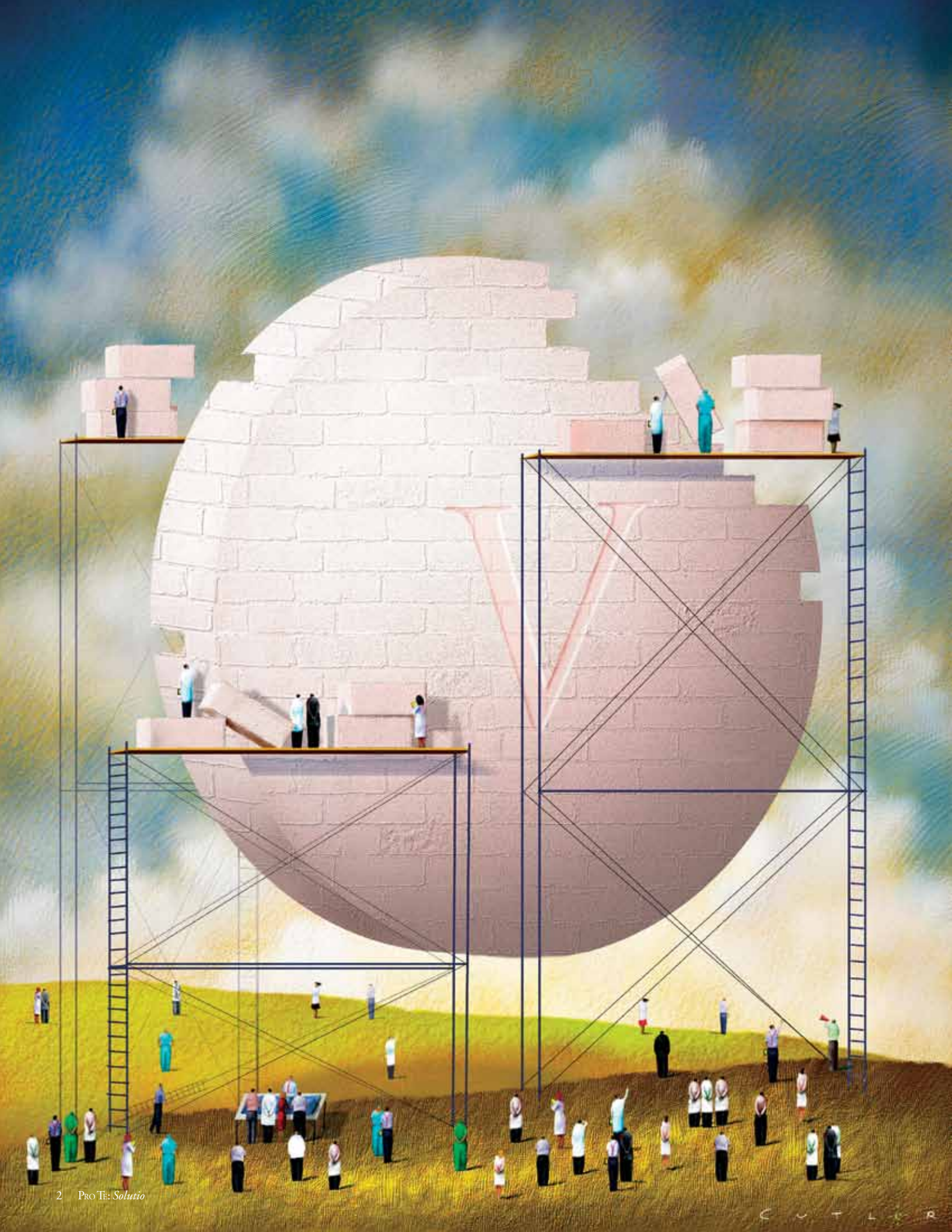
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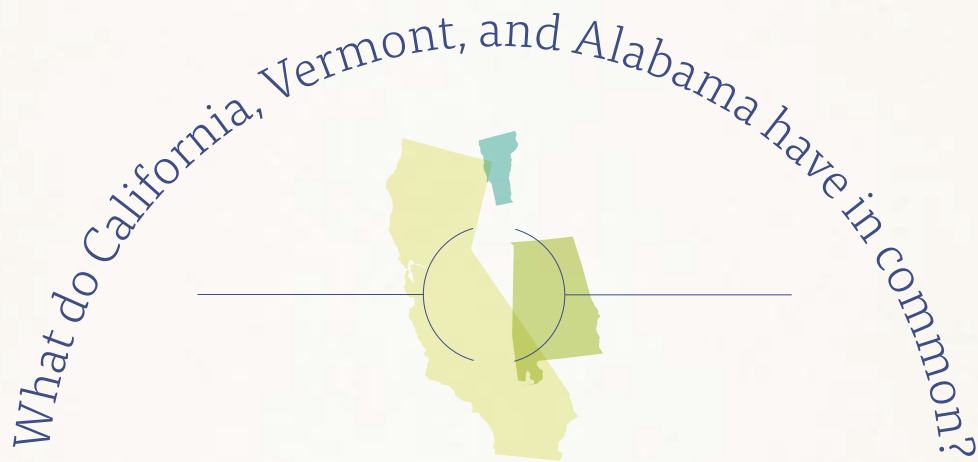


ADOPTING PREDICTIVE CODING BECAUSE OF ITS RELIABILITY



DISCOVERY FROM THE PERSPECTIVE OF CLOSING ARGUMENT





INNOVATOR LIABILITY FOR BRAND-NAME PRESCRIPTION DRUG MANUFACTURERS

Introduction

Following a decidedly minority view, the Alabama Supreme Court joined California and Vermont in adopting the so-called “innovator liability doctrine.”¹ In so doing, the Alabama Supreme Court became the first state supreme court in the country to recognize brand-name manufacturer liability for a generic drug sold by another manufacturer, departing from “the overwhelming majority of courts” that have rejected the innovator liability theory.²

Under Alabama law, brand-name manufacturers may be held liable for fraud or misrepresentation in a case involving ingestion of a generic drug.

In a case of first impression, the Alabama Supreme Court recently answered the following certified question:

May a brand-name drug manufacturer be held liable for fraud or misrepresentations in a case involving ingestion of a generic drug?

In *Wyeth, Inc. v. Weeks*,³ the Alabama Supreme Court answered “yes,” holding a plaintiff claiming personal injury from a generic product may maintain a misrepresentation claim against the brand manufacturer.⁴

Prior to certification by the Supreme Court, the Middle District of Alabama denied the brand-name manufacturer’s motion to dismiss, holding that plaintiffs had properly pleaded their claim that the brand-name defendants perpetuated a fraud on plaintiffs’ physician.⁵ The Middle District’s holding created an intrastate split in Alabama, thus warranting certification by the Alabama Supreme Court regarding the liability of a brand manufacturer for warnings provided to a physician by a generic manufacturer.⁶

Under Alabama’s learned intermediary doctrine, “[a] prescription drug manufacturer fulfills its duty to warn the ultimate users of the risks of its products by providing adequate warnings to the learned intermediaries who prescribe the drug.”⁷ Specifically, a plaintiff-patient must show that “the prescribing physician would not have prescribed the medication to his patient.”⁸ Plaintiffs Mr. and Mrs. Weeks brought suit against five brand and generic manufacturers of the pharmaceutical drug product Reglan alleging failure to adequately warn Mr. Weeks’ prescribing physician of Reglan’s risks which resulted in physical injury to Mr. Weeks.⁹

The court relied heavily on the United States Supreme Court’s holding in *PLIVA, Inc. v. Mensing*¹⁰ that “because the FDA prevented the generic-drug manufacturers from independently changing the safety label on their generic drugs, ‘it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same.’”¹¹ The Alabama Supreme Court noted that the *PLIVA* Court’s holding that state law failure-to-warn claims against a generic manufacturer are preempted by federal law was subsequent to the Alabama federal courts’ holdings in *Mosley, Overton, and*

Simpson.¹² Accordingly, the Alabama Supreme Court rationalized that these prior Alabama federal court holdings were now “questionable.”¹³

In further justification of its holding, the Alabama Supreme Court rationalized that “FDA regulations provide that a generic-drug manufacturer’s labeling for a prescription drug must be exactly the same as the brand-name-drug manufacturer’s labeling.”¹⁴ Although the court limited its holding to manufacturers and not distributors of prescription drugs, according to the *Weeks* court,

Under Alabama law, a brand-name drug company may be held liable for fraud or misrepresentation [...] based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company.¹⁵

Furthermore, the court rationalized its holding as follows:

[I]t is not fundamentally unfair to hold the brand-name manufacturer liable for warnings in a product it did not produce because the manufacturing process is irrelevant to misrepresentation theories [...] when those misrepresentations were drafted by the brand-name manufacturer and merely repeated by the generic manufacturer.¹⁶

On February 4, 2013, Justice Murdock issued his dissent in *Weeks*. Justice Murdock strongly disagreed with the court’s broad interpretation of the United States Supreme Court’s rationale in *PLIVA*, stressing:

[T]he Supreme Court’s holding in *PLIVA* — that state-law claims against generic-drug manufacturers are preempted by the federal regulatory scheme — did nothing to undermine the essential rationale in the plethora of

pre- and post-*PLIVA* decisions holding that brand-name manufacturers are not liable for injuries caused by deficient labeling of generic drugs they neither manufactured nor sold.¹⁷

The dissent further noted that the United States Supreme Court anticipated the arguably unfair scenario where a plaintiff who ingested a generic drug cannot seek compensation from the party who in fact manufactured the drug.¹⁸ Specifically, the Supreme Court acknowledged “the unfortunate hand that federal drug regulation has dealt *Mensing*, *Demahy*, and others similarly situated.”¹⁹ Justice Murdock agreed, holding that “[i]f it is unfair, however, it is an unfairness created by Congress and the Food and Drug Administration (“the FDA”) (in return for the perceived social benefit of less expensive prescription drugs), and by the follow-on application of the federal preemption doctrine by the Supreme Court in *PLIVA*.”²⁰

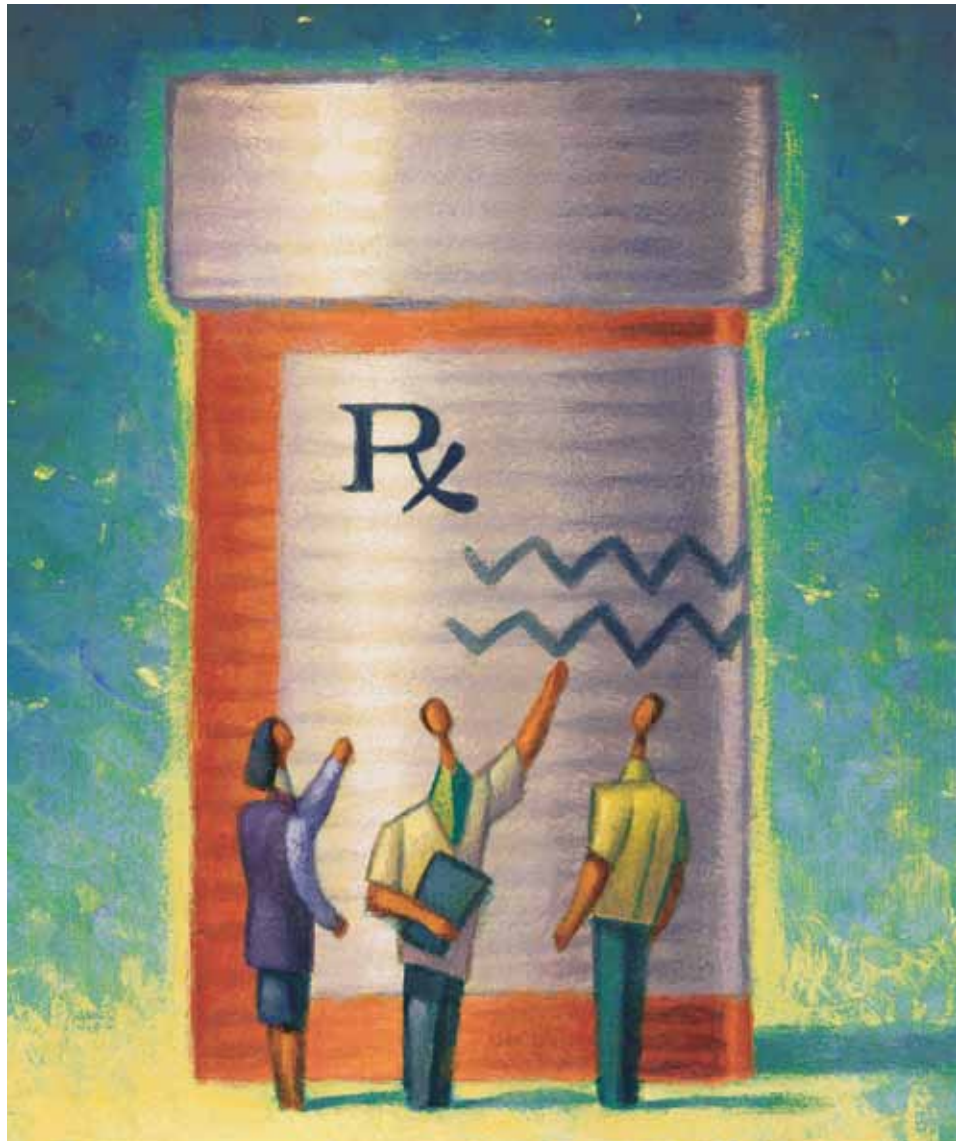
Interestingly, since *PLIVA* was decided, eleven opinions applying the law of ten states have been issued.²¹ Each of these decisions reiterated the holding that brand-name manufacturers owe no duty to consumers who ingest generic drugs the manufacturers neither manufactured nor sold.²²

According to Justice Murdock, “The answer, if there is to be one, lies at the federal level where the problem has been created.”²³ The dissent stressed, however, that broadening the *PLIVA* holding to include the liability contemplated by the majority in *Weeks* “disrupt[s] the critical dynamic” of America’s free-market system.²⁴

Conclusion

Based on the *Weeks* holding, brand-name drug manufacturers may now be held liable under Alabama law for misrepresentations in cases where plaintiff never ingested the brand-name drug product. While a certain victory for the plaintiffs’ bar, whether other states will follow and whether the “new” Alabama Supreme Court²⁵ will reconsider its decision remain open questions. ■

“FDA regulations provide that a generic-drug manufacturer’s labeling for a prescription drug must be exactly the same as the brand-name-drug manufacturer’s labeling.”




¹ *Wyeth, Inc. v. Weeks*, 2013 Ala. LEXIS 2, *59 (Ala. January 17, 2013) (recognizing that only two other courts have adopted innovator liability); *Kellogg v. Wyeth*, 762 F.Supp.2d 694 (D.Vt. 2010); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 95 (Cal. Ct. App. 2008).
² See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).
³ *Wyeth, Inc. v. Weeks*, 2013 Ala. LEXIS 2, *59 (Ala. Jan. 17, 2013).
⁴ *Id.* at 57.
⁵ *Weeks v. Wyeth, Inc.*, 2011 U.S. Dist. LEXIS 35137 (M.D. Ala. March 31, 2011).
⁶ See *Mosley v. Wyeth, Inc.*, 719 F.Supp.2d 1340 (S.D. Ala. 2010); see also *Overton v. Wyeth, Inc.*, 2011 U.S. Dist. LEXIS 38290 (S.D. Ala. March 15, 2011); *Simpson v. Wyeth, Inc.*, 2010 U.S. Dist. LEXIS 139246 (N.D. Ala. December 9, 2010) (all holding that plaintiffs who had only ingested the generic form of Reglan could not recover for alleged misrepresentations to plaintiffs’ physicians by the brand manufacturers).
⁷ *Weeks*, 2013 Ala. LEXIS, *56-57.
⁸ *Weeks*, 2013 Ala. LEXIS 2, *57.
⁹ *Weeks*, 2013 Ala. LEXIS 2, *1-2.
¹⁰ *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2578 (2011).
¹¹ *Weeks*, 2013 Ala. LEXIS 2, at *24-25 (citing *PLIVA*, 131 S. Ct. at 2578).

¹² *Weeks*, 2013 Ala. LEXIS 2, *34.
¹³ *Weeks*, 2013 Ala. LEXIS 2, *34.
¹⁴ *Weeks*, 2013 Ala. LEXIS 2, *58.
¹⁵ *Weeks*, 2013 Ala. LEXIS 2, *57.
¹⁶ *Weeks*, 2013 Ala. LEXIS 2, *59.
¹⁷ *Weeks*, 2013 Ala. LEXIS 2, *63.
¹⁸ *Id.* at 63, 96.
¹⁹ *Weeks*, 2013 Ala. LEXIS 2, *96 (citing *PLIVA*, 180 L. Ed 2d at 596-597).
²⁰ *Id.* 63-64.
²¹ *Weeks*, 2013 Ala. LEXIS 2, *97.
²² *Id.* See *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177 (5th Cir. 2012); *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011); *Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011); *Baymiller v. Ranbaxy Pharm., Inc.*, [No. 3:11-cv-858-RCJ-VPC, Sept. 6, 2012] 894 F.Supp.2d 1302, 2012 U.S. Dist. LEXIS 127285 (D. Nev. 2012); *Strayhorn v. Wyeth Pharm., Inc.*, [No. 11-2058-STAGC, Aug. 8, 2012] 887 F.Supp.2d 799, 2012 U.S. Dist. LEXIS 110806 (W.D. Tenn. 2012); *Phelps v. Wyeth, Inc.*, 857 F.Supp.2d 1114 (D. Or. 2012); *Metz v. Wyeth LLC*, 830 F.Supp.2d 1291 (M.D. Fla. 2011); *Lasbley v. Pfizer, Inc.*, 877 F.Supp.2d 466 (S.D. Miss. 2012); *Guarino v. Wyeth LLC*, [No. 8:10-cv-2885-T-30GTW, Apr. 3, 2012] F.Supp.2d, 2012 U.S. Dist. LEXIS 55665 (M.D. Fla.

2012); *Gross v. Pfizer, Inc.*, No. 10-CV-00110-AW, 2011 U.S. Dist. LEXIS 100346 (D. Md. Sept. 7, 2011) (not reported in F.Supp.2d); and *Fullington v. PLIVA, Inc.*, [No. 4:10CV00236JLH, Dec. 12, 2011] F.Supp.2d, 2011 U.S. Dist. LEXIS 142931 (E.D. Ark. 2011). Some of these [*99] are cases in which a court that addressed the issue before *PLIVA* had an opportunity after *PLIVA* to revisit its previous ruling, only to reaffirm that previous ruling and implicitly or explicitly conclude that the Supreme Court’s holding in *PLIVA* did not alter the court’s pre-*PLIVA* analysis.
²³ *Id.* at 64.
²⁴ *Id.* at 117.
²⁵ Following the 2012 elections, two of the eight justices who signed the majority opinion in *Weeks* — Justice Tom Woodall and Chief Justice Charles Malone — are no longer on the court.

WRITTEN BY
 CHRIS BERDY
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A painterly illustration of a target with a person holding a bow and arrows, symbolizing a difficult goal. The target is composed of concentric circles in red, white, and blue. A person in a dark suit stands on the white ring, holding a bow and arrows. The background is a mix of blue, green, and yellow, with faint white lines suggesting a grid or target pattern. The overall style is textured and artistic.

PLAINTIFFS' ATTORNEYS KEEP
TRYING NOVEL THEORIES, BUT
INNOVATOR LIABILITY IS STILL AN
ELUSIVE TARGET

BACKGROUND

Over the past few years, three courts have overturned the fundamentals of tort law, holding that a manufacturer of a brand-name prescription drug can be subject to liability even when a plaintiff alleges that he or she was harmed by a generic drug made by the brand manufacturer's competitor. Most courts, including four federal courts of appeal and dozens of federal district and state trial courts, have rejected this expansion of tort law. This tension intensified after two U.S. Supreme Court rulings on the viability of state failure-to-warn claims against manufacturers of prescription drugs created different liability rules for generic manufacturers than for makers of brand-name drugs.

In the first case, the U.S. Supreme Court held that federal drug law does not preempt state failure-to-warn claims with respect to brand-name drugs;¹ in the second case, it ruled that federal law does preempt failure-to-warn claims stemming from the use of generic products.² As a result, the U.S. Supreme Court allowed users of brand-name drugs to potentially have an avenue for recovery not available to users of generic drugs.

The brand-name ruling came from the 2009 case *Wyeth, Inc. v. Levine*. The Court considered whether a plaintiff who had been administered brand-name Phenergan, an antihistamine used to treat nausea, could claim that its manufacturer, Wyeth, inadequately warned of the risk of developing gangrene when the drug is injected into a patient's vein rather than administered through an IV drip.³ At the time of the suit, the drug had long been available in generic form.⁴ In allowing the claim against Wyeth to go forward, the majority

of the Court reasoned it was not impossible for Wyeth to comply with both federal labeling law and any state law warning requirements that would be derived if the litigation deemed its warnings inadequate.⁵ The majority opinion explained that Wyeth could have used the "changes being effected" (CBE) process to add the safety information required by the jury's determination and then seek FDA approval for that change.⁶ In order to demonstrate that FDA labeling law preempts a state failure-to-warn claim against a brand-name manufacturer, the manufacturer



must show "clear evidence that the FDA would not have approved a change to [the drug's] label."⁷ While Wyeth showed that the FDA had approved Phenergan's label and worked with the company to update the label several times, the Court said it did not show that the FDA would have prohibited the change required if the warning was deemed inadequate under a state's tort law.⁸ As a result, plaintiffs who take brand-name drugs can generally move forward with state failure-to-warn claims against

the drug's manufacturer.

Two years later, in *PLIVA, Inc. v. Mensing*, the Supreme Court faced the preemption issue, but this time with respect to generic drugs. In *Mensing*, two individuals who developed tardive dyskinesia claimed that the drug's manufacturer failed to adequately warn of this risk.⁹ Here, plaintiffs' doctors wrote the prescription for the brand-name version of the drug, Reglan.¹⁰ Pursuant to state substitution laws, the pharmacists filled the prescriptions with generic metoclopramide, manufactured by PLIVA.¹¹ As in *Levine*, the Court applied the forward-looking "impossibility preemption" test. Here, though, the majority found that it would be impossible for PLIVA to adhere to both its federal labeling requirements to use the "same" warning approved for the brand-name drug and to change those warnings to cure any defect a jury in a state failure-to-warn suit determines to exist.¹² Unlike the manufacturer of the branded drug, a generic drug maker cannot use the CBE process to change its labels; it can only request the FDA to make such a change.¹³

Thus, the primary distinction between the *Levine* and *Mensing* preemption rulings seems to hinge on the old adage about asking for forgiveness or permission. Brand manufacturers can change the label first and ask for permission second, while generics must ask for permission first and can only make a change once the FDA has agreed with the request. The sole issue related to the preemption analysis is whether the manufacturer had the ability to implement new labeling requirements. The Court held that brand manufacturers could do so, while generic manufacturers could not.¹⁴



NO POST-MENSING “INNOVATOR LIABILITY” FOR BRAND MANUFACTURERS

After the Court decided *Mensing* in 2011, generic drug users were left searching for possible avenues of legal recovery after incurring injury. This controversial decision made the ability to bring a successful lawsuit against generic drug manufacturers near impossible. The theory of innovator liability, which holds the brand manufacturer responsible for injury resulting from the generic drug, has been tested as a work-around to the *Mensing* decision. Innovator liability has repeatedly been defeated in courts on many occasions, with the argument made that one company does not owe a duty to those taking a drug manufactured by an entirely different company. Since *Mensing* was decided, courts have declared that traditional product liability law remains unchanged under the laws of Arizona, Arkansas, Connecticut, Florida, Georgia, Indiana, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Mississippi, Nevada, New Jersey, New York, North Carolina, Ohio, Oklahoma,

Pennsylvania, South Carolina, Tennessee, Texas, Washington, and West Virginia.¹⁵

In a recent innovator liability ruling, the Eleventh Circuit in *Guarino v. Wyeth* rejected the theory of liability where the plaintiff admitted she was harmed by generic metoprolol manufactured and distributed by a company other than the brand defendants.¹⁶ The brand defendants moved for summary judgment arguing that, as a matter of Florida law, they were not liable for plaintiff’s injuries because plaintiff did not ingest a product manufactured by them. Specifically, the brand defendants contended that Florida law prevents consumers from suing brand-name manufacturers for injuries arising from use of a generic equivalent. The district court granted summary judgment on behalf of the brand defendants.¹⁷ On appeal, the panel of judges affirmed the district court’s grant of summary judgment.¹⁸ The court relied heavily on well-settled state law that recognized that no cause of action existed against the brand manufacturer of a

drug when a plaintiff admits to having only taken the generic equivalent.¹⁹ Specifically, the court noted:

Every court in Florida to consider the question has concluded that the brand manufacturer of a prescription drug cannot be held liable for injuries suffered by consumers who ingested only the generic form of a drug[...]. As one court explained, “[i]t is well-settled under Florida law that a plaintiff may only recover from the defendant who manufactured or sold the product that caused the injuries in question.” We see no reason to doubt this interpretation of the law.²⁰

In further justification of its holding, the Eleventh Circuit noted that a “mountain of authority” from across the country “steels us in our determination” that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of a generic form of a product.²¹



THE COURT RELIED HEAVILY ON WELL-SETTLED STATE LAW THAT RECOGNIZED THAT NO CAUSE OF ACTION EXISTED AGAINST THE BRAND MANUFACTURER OF A DRUG WHEN A PLAINTIFF ADMITS TO HAVING ONLY TAKEN THE GENERIC EQUIVALENT.

INDIVIDUALS INJURED BY GENERIC DRUGS AND THEIR ATTORNEYS MAY BE FORCED TO TURN TO LEGISLATIVE AND REGULATORY AVENUES TO ADDRESS THE BROAD REACH OF FEDERAL PREEMPTION OF WARNING AND DESIGN DEFECT CLAIMS.

ATTEMPTS TO CIRCUMVENT MENSING AND HOLD GENERIC MANUFACTURERS LIABLE HAVE FAILED

Despite the clear and unmistakable holding in *Mensing*, plaintiffs have continued to challenge the adequacy of generic labels. Some have done so by making the same claims and arguments squarely rejected in *Mensing*. Others have tried to challenge the label by arguing that their claims, such as strict liability, design defect, negligence, breach of express and implied warranties, fraud, misrepresentation, unfair trade practices, etc., are not failure-to-warn claims; rather, they are distinct causes of action not addressed in *Mensing*. The generics manufacturers have maintained that *Mensing* preempts any claim that relates to the generic drug label regardless of the name given the claim. Courts across the country have routinely ruled that claims related to the generic drug label are preempted under *Mensing*.²² As one judge has explained in dismissing such claims, “*Mensing* means what it says: all failure-to-warn claims against generic drug manufacturers are preempted if generic manufacturers cannot independently alter their warning labels.”²³

The First Circuit, however, created a stir when it allowed a case to proceed against a generic manufacturer on a design defect theory for simply selling the drug. The First Circuit stated that “while the generic maker has no choice as to label[,] the deci-

sion to make the drug and market it [...] is wholly its own.”²⁴ The court suggested that a jury should be able to “second-guess the FDA”²⁵ and determine that the drug’s “risks outweighed its benefits making it unreasonably dangerous to consumers, despite [the FDA] having never withdrawn its statutory ‘safe and effective’ designation.”²⁶ The court stated it was willing to redefine the relationship between state liability law and federal drug laws because it did not believe a plaintiff should lose the right to recover “by the mere chance of her drugstore’s selection of a generic.”²⁷ The First Circuit then urged the Supreme Court to take the case and review its novel design defect theory, noting that “the Supreme Court has yet to decide” it, but that it “needs a decisive answer from the only court that can supply it.”²⁸

On June 24, 2013, the U.S. Supreme Court rejected the First Circuit’s ruling that design defect claims against generic drug companies are not preempted by *Mensing* on the grounds that the defendant could simultaneously comply with both state and federal law by choosing not to sell the medication altogether. As Justice Alito explained for the majority, the Court’s “pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in

order to avoid liability,” for “if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be ‘all but meaningless.’”²⁹

It was this understanding that the *Bartlett* decision was predicated on, with five of the nine justices finding that the same preemption standard under *Mensing* held for design defects as well. The Supreme Court held that the plaintiff’s “stop selling” theory is “incompatible” with its preemption jurisprudence, which “presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether” in order to avoid liability.³⁰

The Court’s opinion in *Bartlett* marks a decisive victory for generic pharmaceutical manufacturers who, despite *Mensing*, have continued to face personal injury lawsuits on the grounds that they could have stopped selling the medications at issue. Following this ruling, it would appear that attorneys representing individuals who claim to be injured by generic drugs may be forced to turn to legislative and regulatory avenues to address the broad reach of federal preemption of warning and design defect claims. At the close of the majority opinion, the Court stated that it “would welcome Congress’ ‘explicit’ resolution of the difficult pre-emption questions that arise in the prescription drug context.”³¹



WITH COURTS FAITHFULLY APPLYING *MENSING*
AND DISMISSING CLAIMS AGAINST GENERIC
MANUFACTURERS, BRAND MANUFACTURERS
MUST BE PREPARED TO DEFEND AGAINST
CLAIMED INNOVATOR LIABILITY.

DEFENDING AGAINST INNOVATOR LIABILITY

Despite the “mountain of authority” from across the country rejecting innovator liability, the issue still persists. With courts faithfully applying *Mensing* and dismissing claims against generic manufacturers, brand manufacturers must be prepared to defend against claimed innovator liability.



In defending such claims, the procedural history of *Mensing* could be useful to counsel in showing that the Supreme Court’s decision does not justify a departure from the overwhelming majority of authority rejecting innovator liability. Additionally, the recent Supreme Court opinion in *Bartlett* is another arrow in the quiver of pharmaceutical companies defending suits on pre-emption grounds. ■

¹ See *Wyeth, Inc. v. Levine*, 555 U.S. 555, 558-59 (2009).

² See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011).

³ *Levine*, 555 U.S. at 558.

⁴ *Id.* at 561.

⁵ *Id.* at 573.

⁶ *Id.*

⁷ *Id.* at 571.

⁸ *Id.* at 568-73.

⁹ *Mensing*, 131 S. Ct. at 2572-73.

¹⁰ *Id.* at 2573.

¹¹ *Id.*

¹² *Mensing*, 131 S. Ct. at 2579.

¹³ *Id.*

¹⁴ *Id.* at 2581.

¹⁵ See *Demaby v. Schwarz Pharm., Inc.*, 702 F.3d 177 (5th Cir. 2012) (applying Louisiana law); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423-24 (6th Cir. 2011) (applying Kentucky law); *Hogue v. Pfizer, Inc.*, 893 F.Supp.2d 914 (S.D. Ohio 2012); *Baymiller v. Ranbaxy Pharmaceuticals, Inc.*, 894 F.Supp.2d 1302 (D. Nev. 2012); *Phares v. Actavis-Elizabeth, LLC*, 892 F.Supp.2d 835 (S.D. Tex. 2012); *Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 882 F.Supp.2d 1020 (W.D. Tenn. 2012); *Lashley v. Pfizer, Inc.*, 877 F.Supp.2d 466, 471-73 (S.D. Miss. 2012); *Guarino v. Wyeth, LLC*, 2012 U.S. Dist. LEXIS 55665 at *1-2 (M.D. Fla. April 3, 2012); *In re Darvocet, Darvon and Propoxyphene Products Liability Litigation*, 856 F.Supp.2d 904, 910-13 (E.D. Ky. 2012) (applying Georgia, Indiana, Louisiana, Minnesota, Mississippi, New Jersey, New York, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, and Texas law); *Moore v. Mylan, Inc.*, 840 F.Supp.2d 1337, 1344 (N.D. Ga. Jan. 5, 2012); *In re Darvocet, Darvon and Propoxyphene Products Liability Litigation*, 2012 WL 4831632, at *2-3 (E.D. Ky. Oct. 10, 2012) (applying Arizona, Florida, Kentucky, Louisiana, Massachusetts, Michigan, Mississippi, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, and West Virginia law); *Del Valle v. PLIVA, Inc.*, 2012 WL 4747259, at *5-8 (S.D. Tex. Sept. 12, 2012); *Metz v. Wyeth, Inc.*, 830 F.Supp.2d 1291, 1294 (M.D. Fla. Nov. 18, 2011); *Madden v. Teva Pharmaceuticals, USA, Inc.*, 2012 Phila. Ct. Com. Pl. LEXIS 293 (Pa. C.P. 2012) (applying Washington law);

Condouris v. Wyeth, 2012 WL 2401776 (N.J. Super. Law Div. June 26, 2012).

¹⁶ *Guarino v. Wyeth, LLC*, 2013 U.S. App. LEXIS 12966, at *2-*3 (11th Cir. June 25, 2013).

¹⁷ *Id.*

¹⁸ *Id.* at *18.

¹⁹ *Id.* at *14-*15.

²⁰ *Id.* at *14-*15 (citations omitted).

²¹ *Id.* at *21.

²² *Demaby v. Schwarz Pharma, Inc.*, No. 11-31073, 2012 WL 5261492, at *6 (5th Cir. Oct. 25, 2012); *Gaeta ex rel. A.G. v. Perrigo Pharm. Co.*, 469 Fed.Appx. 556, 557 (9th Cir. 2012); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011), cert. denied, 132 S.Ct. 2103 (2012); *Bell v. PLIVA, Inc.*, 845 F.Supp.2d 967, 970-71 (E.D. Ark. 2012); *Moretti v. Mutual Pharm. Co.*, 852 F.Supp.2d 1114, 1118 (D. Minn. 2012); *In re Pamidronate Prod. Liab. Litig.*, 842 F.Supp.2d 479, 484 (E.D.N.Y. 2012).

²³ *Strayhorn*, 11-2058-STA-cgc, 2012 WL 3261377, at *10 (W.D. Tenn. Aug. 8, 2012) (Order Granting Generic Defendants’ Motion to Dismiss).

²⁴ *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 38 (1st Cir. 2012), cert. granted, 133 S. Ct. 694 (2012).

²⁵ *Id.* at 38. The trial would presumably consider whether all versions of sulindac, including the innovator drug, are defective in design, even though the FDA approved the branded-drug-specific design and warning.

²⁶ *Id.* at 34.

²⁷ *Id.* at 38.

²⁸ *Id.* at 36, 38.

²⁹ *Mutual Pharm. Co. v. Bartlett*, 2013 U.S. LEXIS 4702, at *27 (U.S. June 24, 2013) (quoting *Mensing*, 131 S. Ct. 2567 (slip op., at 14)).

³⁰ *Id.* at *28.

³¹ *Id.* at *36.

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Plaintiffs and Courts are Increasingly Adopting Predictive Coding Because of its Reliability:

Should your Company Consider it for your Litigation?

We've been hearing a lot about predictive coding from the Sedona Conference, the *Da Silva Moore* case, and various articles from predictive coding vendors discussing the benefits of predictive coding and how it works. So is predictive coding a win-win for everyone? The Plaintiffs' Bar certainly wants to utilize predictive coding in order to increase the number of responsive documents that keyword and Boolean searches oftentimes do not reveal; corporate counsel is attracted to cost-saving measures of predictive coding that result from decreasing the number of non-responsive documents that have to be manually reviewed; and litigation support companies undoubtedly have a financial interest in having both sides utilize their variety of predictive coding technologies and services. One can see why plaintiffs and investigators would favor the use of predictive coding's purported increased accuracy of responsive documents for complex litigation or white-collar investigations.



Predictive coding is more relevant now than ever before due to the incredible amount of electronically stored information that is generated on a daily basis. As the technological capabilities of companies increase exponentially, so too does the amount of data that those companies create and have to store and maintain. In an attempt to help you grasp the amount of data generated by a large business, in 2012, Walmart collected more than 2.5 petabytes of data every hour, which is equivalent to about 20-million filing cabinets' worth of text.¹ In fact, 90% of the data in the world today has been created in the last two years alone.² Although no clear guidelines have been set regarding the volume of documents necessary for implementation of predictive coding, some experts suggest that predictive coding becomes effective and cost-efficient in matters when there are approximately 75,000³ to 100,000 documents or more.⁴

One reason for the slow predictive coding adoption rate is that the parties involved are often fearful of the unknown and unwilling to experiment with new "black box" technology in a litigation of the caliber that requires and justifies using predictive coding. The various companies with predictive coding software have been

trying hard to dispel fears that predictive coding eliminates human-attorney review. Rest assured, manual review is still required to check for privilege and confidentiality before the responsive documents are handed over to the other side. Even with this manual safety net in place, it is critical to have a robust clawback agreement going into any litigation.

Predictive coding claims to increase the accuracy of relevant documents through the use of sophisticated algorithms. Essentially, a human reviewer, generally an attorney who is intimately familiar with the case, "trains" the computer to find relevant documents by assigning each document in the sample set a score that will allow the computer to weight the responsiveness of documents more accurately. As new keywords are revealed throughout the discovery process, users will need to ensure that their predictive coding software is capable of adapting and integrating changes to keywords on an ongoing basis.⁵ Some predictive coding experts, and even a Virginia court,⁶ have determined that predictive coding will find 75% of relevant and responsive documents, whereas keyword searches yield only 20%, and linear human review around 60%.⁷

Acceptance of predictive coding has been

slow. Until 2012, no court had validated the use of predictive coding to coordinate e-discovery. In the unprecedented case of *Da Silva Moore v. Publicis Groupe*, predictive coding, or computer-assisted review, was judicially approved by e-discovery pioneer Judge Andrew Peck for use in appropriate cases to search for relevant electronically stored information (ESI).⁸ In his opinion, Judge Peck promoted the use of predictive coding in matters "where it will help secure the just, speedy, and inexpensive determination of cases in our e-discovery world."⁹ From *Da Silva Moore* we can extract the criteria used to determine whether a case is appropriate for predictive coding, including: "(1) the parties' agreement, (2) the vast amount of ESI to be reviewed (over three million documents), (3) the superiority of computer-assisted review to the available alternatives (i.e., linear manual review or keyword searches), (4) the need for cost-effectiveness and proportionality under Rule 26(b)(2)(C), and (5) the transparent process proposed by [the parties]."¹⁰

Judge Peck explained that keyword searches "are not overly useful," but that "[keywords] along with predictive coding and other methodology, can be very instructive."¹¹ One issue that remains unclear is the level of transparency that will

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apply to the seed sets, or “training sets,” of documents that are marked as responsive or non-responsive. Although the documents would not be binding, Judge Peck suggested that defendants would have to disclose their seed set, “including the seed documents marked as nonresponsive to the plaintiff’s counsel” so that plaintiffs can say, “Well, of course you are not getting any [relevant] documents — you’re not appropriately training the computer.”¹²

Some data suggests that keyword searches by themselves are often ineffective and over-inclusive as they find large numbers of responsive, yet irrelevant documents (false positives), which then become very expensive to review manually.¹³ However, keyword searches still have a place in the discovery process as parties use keyword searches with connectors “to find documents for the expanded seed set to train the predictive coding software.”¹⁴ Likewise, keyword searches are being used to cull the initial universe of documents so that predictive coding can be applied to a more manageable pool of documents.

Judge Peck, endorsing predictive coding in appropriate cases, further opined that “what the Bar should take away from this Opinion is that computer-assisted review is an available tool and should be seriously

considered for use in large-data-volume cases where it may save the producing party (or both parties) significant amounts of legal fees in document review.”¹⁵

So what is the predictive coding buzz all about? While both parties are encouraged

to work together throughout the discovery process, the courts have not yet decided whether both parties are required to disclose the sample set documents or the responsiveness scoring of the documents in the sample set that the key reviewers ap-
plied. The issue of whether parties need to disclose the seed set documents used to train the predictive coding programs was not addressed in *Da Silva Moore* because the defendants volunteered this information.¹⁶ For many years, parties have come



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Predictive coding is not going away any time soon, particularly because plaintiffs are following the charge with early adopter Judge Andrew Peck leading the way.

Recently, in the case of *Gordon v. Kaleida Health*, plaintiffs relied on *Da Silva Moore* in order to obtain defendants' seed set of documents used to "train the computer."¹⁷ Defendants opposed the request, arguing that "ESI production is within the sound discretion of the producing party."¹⁸ We are still left in a holding pattern regarding the "seed set" issue as the courts have not had to intervene due to the parties' working out the issues (defendants in *Da Silva Moore* volunteered to provide the seed set, and defendants in *Gordon* agreed to meet with and confer with plaintiff's experts).

Plaintiffs are recognizing the enhanced reliability of predictive coding technology in complex litigation. In the recent multidistrict litigation of *In re Biomet M2a Magnum Hip Implant Prods. Liab. Litig.*,¹⁹ the court considered whether defendants could filter ESI through keyword searches and then apply predictive coding to the re-

sidual data.²⁰ Biomet disregarded plaintiffs' request not to begin the discovery process and used keyword searches to cull the universe of documents and attachments from 19.5-million down to 2.5-million documents and attachments before then applying predictive coding to the reduced document pool.²¹ Plaintiffs argued that keyword searches "tainted" the discovery process and therefore required examination of all formerly discarded material.²² In essence, plaintiffs asserted that the most reliable method for full and accurate disclosure turned on the "find more like this" predictive coding measures used to train the program.²³ The court held, without fully endorsing predictive coding as in the *Da Silva Moore* case, that Biomet fully complied with Federal Rules of Civil Procedure 26(b) and 34(b)(2), and that reexamining all collected documents would be overly burdensome, and therefore, plaintiffs would bear any costs associated with retesting the documents using only predictive

coding on the entire pool of documents.²⁴ Further, the court stated that cooperation between parties does not require "counsel from both sides to sit in adjoining seats while rummaging through millions of files that haven't been reviewed for confidentiality or privilege."²⁵ Similarly, in *Kleen Prods., LLC v. Packaging Corp. of Am.*,²⁶ plaintiffs initially demanded utilization of predictive coding technology, but after extensive negotiations between the parties, plaintiffs consented to standard Boolean searches.²⁷

While the use of predictive coding is growing more popular in the courts since the *Da Silva Moore* decision, courts are also willing to consider the cost-benefit analysis pertaining to the volume of documents to be reviewed. Previously in *EORHB, Inc. v. HOA Holdings, LLC*, the Delaware court required parties to show cause as to why they should not use a single vendor to conduct document review with predictive coding.²⁸ However, the court recently retracted



its position and entered an order that no longer required plaintiffs to utilize predictive coding due to the “low volume of relevant documents.”²⁹

Predictive coding is not going away any time soon, particularly because plaintiffs are following the charge with early adopter Judge Andrew Peck leading the way. It will be interesting to see how the courts handle various issues including transparency issues regarding seed sets. Companies facing similar circumstances in discovery should consider using predictive coding in matters involving voluminous amounts of documents (think millions). Doing so will help reduce the cost of manual document review by increasing the accuracy of relevant documents that need to be reviewed by an attorney. A cost-benefit analysis is further recommended since predictive coding vendors often charge a premium for their services. ■

¹ McAfee, Andrew, and Erik Brynjolfsson, “Big Data: The Management Revolution,” *Harvard Business Review*, October 2012. Available at <<http://hbr.org/2012/10/big-data-the-management-revolution>>. Last accessed July 7, 2013.

² IBM, “Big Data at the Speed of Business.” Available at <<http://www-01.ibm.com/software/data/bigdata/>>. Last accessed July 7, 2013.

³ Sohn, Edward, “Predictive Coding Today: Before You Jump In, What Should You Consider?” *The Metropolitan Corporate Counsel*, May 24, 2013. Available at <<http://www.metrocorp-counsel.com/articles/23960/predictive-coding-today-you-jump-what-should-you-consider>>. Last accessed July 7, 2013.

⁴ Looby, Joe, “E-Discovery Steps Outside Of The Black Box,” *The Metropolitan Corporate Counsel*, Nov. 20, 2012. Available at <<http://www.metrocorp-counsel.com/articles/21330/e-discovery-steps-outside-black-box>>. Last accessed July 7, 2013.

⁵ Sohn, Edward, “Predictive Coding Today: Before You Jump In, What Should You Consider?” *The Metropolitan Corporate Counsel*, May 24, 2013. Available at <<http://www.metrocorp-counsel.com/articles/23960/predictive-coding-today-you-jump-what-should-you-consider>>. Last accessed July 7, 2013.

⁶ *Global Aerospace v. Lindow Aviation*, No. CL 61040 (Va. Cir. Ct., Loudon County, Apr. 23, 2012).

⁷ Looby, Joseph H., “E-Discovery – Taking Predictive Coding Out of the Black Box,” *FTI Journal*, Nov. 2012. Available at <<http://www.fticonsulting.com/global2/critical-thinking/fti-journal/predictive-coding.aspx>>. Last accessed July 7, 2013.

⁸ *Da Silva Moore v. Publicis Groupe*, 287 F.R.D. 182 (S.D.N.Y. 2012).

⁹ *Id.* at 183.

¹⁰ *Id.* at 192.

¹¹ *Id.* at 185.

¹² *Id.*

¹³ *Id.* at 190.

¹⁴ *Id.*

¹⁵ *Id.* at 193.

¹⁶ *Id.*

¹⁷ No. 08-CV-378S(F), 2013 WL 2250579 (W.D.N.Y. May 21, 2013).

¹⁸ *Id.* at 2.

¹⁹ No. 3:12-MD-2391, 2013 WL 1729682 (N.D. Ind. Apr. 18, 2013) at 1.

²⁰ *Id.* at 1.

²¹ *Id.* at 2.

²² *Id.*

²³ *Id.*

²⁴ *Id.* at 3.

²⁵ *Id.* at 5.

²⁶ No. 10-C-5711, 2012 U.S. Dist. LEXIS 139632 (N.D. Ill. Sept. 28, 2012) at 6.

²⁷ *Id.* at 19-20.

²⁸ No. 7409-VCL, 2013 WL 1960621 (Del. Ch. May 6, 2013).

²⁹ *Id.*

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Square Pegs and Round Holes:

Discovery from the Perspective of Closing Argument

In one scene from the 1995 Ron Howard film *Apollo 13*, NASA Mission Control learns that the damaged spacecraft and landing module are not adequately filtering carbon dioxide; unchecked, the onboard air will become toxic to the astronauts. A frantic team of engineers assembles in a workroom and empties a box of spare parts onto a table as their spokesman explains the problem: “We gotta’ find a way to make *this* [holds up a square filter] fit into the hole for *this* [holds up a round filter], using nothing but *that*” [surveys the material strewn on the table]. The engineers begin to sort through their options, while one engineer prepares for the inevitable all-nighter: “Better get some coffee going.”

A similar scene is all too familiar to defense lawyers huddling in a cramped war room at a trial site in the late stages of the proceedings. The sensational closing argument has been scrapped, and the only way to land the client’s case safely is to clear the air by rigging the parts available: the discovery brought along from the beginning of the case, often years earlier. The problem? Despite a number of legitimate rationales and drivers, discovery is rarely pursued — particularly in complex matters or mass torts — anticipating the trial presentation.



Why do we conduct discovery the way we do?

The mechanics of discovery are often influenced by the philosophical approach behind it. Further, the more sophisticated the client or law firm (or litigation), the more an approach to discovery may be governed by such “discovery philosophies.” Examples of competing approaches include:

- **Supporting purely legal defenses or settlement.** For some clients and lawyers, trial itself — even apart from verdict — is an unacceptable outcome. The relatively high costs of defense, risks of exposure, and inherent unpredictability of a trial dictate that discovery be had with one of two goals in mind: (1) to efficiently establish only those facts necessary to satisfy the elements of discrete legal defenses; or (2) to put the case in the most favorable posture for settlement.
- **Punitive discovery.** Other clients and their attorneys view the available tools of discovery as a means to harry and deter their opponents. The mindset towards the adversary is often to “make them pay” for engaging in the suit through discovery geared to draw off an opponent’s resources or to distract from the key issues.
- **No fact too small.** In still other scenarios, lawyers view discovery as just that and try to get as much information as they can in the hopes of unearthing support for as yet undeveloped factual or legal theories. These lawyers occasionally run afoul of judicial prohibitions against “fishing expeditions,” or client complaints of churning a file.
- **Malpractice “insurance.”** Here, while the discovery may look similarly broad to other approaches, the underlying rationale is very different. That is, sometimes expansive discovery is conducted not to support theories or to find new facts, but to hedge against a client critique by eliminating any foreseeable gap. This unfortunate approach puts more stock in preserving the lawyer’s book of business than in advancing the case.

Given these discovery rationales, it should come as no surprise that defense trial counsel often find themselves cobbling together mismatched facts and sifting through mountains of irrelevant data to craft a trial presentation. This also explains why plaintiffs tend to do a better job at theming and storytelling at trial. To be sure, there are inherent advantages in the plaintiffs’ “you are here to right a wrong” posture to a jury; however, much of this success can also be attributed to a direct, uncluttered approach to discovery.

With some statistics reflecting that as few as five percent of filed cases are ultimately tried, there may be a tendency to discount a trial approach to discovery. However, the corollary benefits of the approach may serve other goals, in addition to better equipping the (rare) trial presentation.

Begin with the Endgame

The notion of working backwards from a desired result is nothing new in management and development circles but may be overlooked in the discovery context. Three practical avenues to consider are:

- **Jury instructions.** How the judge instructs the jury on the law should inform how attorneys gather the facts. Writing proposed jury instructions when a suit is initiated helps to shape the ultimate issues and meaningful arguments throughout the life of the case. Instructions also help the attorney identify the elements to satisfy or reinforce through multiple sources of evidence.
- **The “case law” paradox.** Another familiar practice after the close of discovery is the scramble to distinguish the facts from the cases cited in opponents’ summary judgment papers. Rather than responding to “bad cases” after discovery has closed, consider finding “good cases” that support the client’s position, and use discovery to establish facts aligning the case with those holdings to reinforce the strength of the client’s case.
- **Jury research.** Often in high-stakes cases, clients will commission jury research exercises in which trial counsel may test themes or arguments with mock juries in advance of trial. The predictive value in these exercises need not be limited to established evidence; jury exercises before or during discovery can help attorneys identify what facts will likely be important or meaningful to the jury at trial, at a point when the attorneys may still be able to develop those facts.

Discovery conducted when employing one or more of these tactics may look very different from more conventional approaches.

Written Discovery

Traditional law practice often delegates the preparation of discovery requests to young associates instructed not to “reinvent the wheel.” These young lawyers typically reformat existing sets of discovery from similar matters or prior sets prepared for the same client. Yet the early efficiencies gained from block-and-copy word processing can be costly at trial when discovery is incomplete or off-target. Further, with proposed changes to the Federal Rules of Civil Procedure affecting the proportional scope of discovery and the number and type of discovery requests, attorneys will be forced to conduct discovery more strategically,

which dovetails perfectly with trial-guided discovery.

For interrogatories, it is important to consider a balance between broad inquiries and narrowly focused requests. An effective set of interrogatories should include both. Additionally, do not neglect the effect interrogatories have in signaling to your opponent your strategic thinking about the case. There may be instances, for example, when it is advisable to withhold some interrogatories until *after* certain depositions have been conducted, both to preserve the ability to follow up on newly discovered facts and to prevent opposing counsel from using the interrogatories as a “playbook” from which to prepare the deponent.

Requests for admission are also under-utilized as a discovery device. Too often, “RFAs” are considered requests for *admissibility*, not requests for *admission*. A well-crafted RFA can lead not only to a highlight in front of a jury (both atmospherically and substantively), but can often impact or limit your opponent’s litigation choices relatively early in the proceedings.

Finally, when it comes to discovery in general, we have all heard lawyers instructing the jury at the outset of a trial: “Don’t check your common sense at the door.” That is also sage advice for lawyers in discovery. Well-crafted written discovery should include good questions that will prevent “loophole” deflections or responses without bogging down in indecipherable legalese.

E-Discovery

For clients and lawyers alike, the term “e-discovery” may evoke apprehension and fear. The generational divide between older clients and attorneys and the technological changes to both the corporate business model and the practice of law is rarely more evident than with the question of navigating e-discovery. However, there are two practical solutions for lawyers and clients facing e-discovery issues.

- **Find an expert.** E-discovery is now so much a part of litigation that companies have protocols and law firms have developed specialized practices to field e-discovery issues. The implications of mishandled e-discovery are too great to “wing it.” Where clients and lawyers lack the specialized skill set to deal with e-discovery, it is critical to partner with someone who does.
- **Be an expert.** Forward-thinking firms are also building internal systems to tackle e-discovery issues head-on. Task forces and working groups of lawyers are pursuing training and certification in e-discovery issues, while corporate clients have developed document retention and collection systems to avoid discovery problems.



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Depositions

While written discovery and e-discovery can make or break a case, depositions are the backbone of trial-guided discovery. Tactical approaches to depositions require analysis from two perspectives.

■ **The witness perspective.** Witness testimony at deposition has a lasting, binding effect on the case and sets the bounds for the approach to the trial. One quote can make the difference in whether the witness is called or not while — particularly in lengthy, complex litigation — the deposition may outlive the witness (both literally and figuratively). Lawyers must approach the deposition with clearly articulable goals to *elicit* testimony (*What testimony do I need from this witness?*) and to *fix* that testimony (*What can I do to prevent my opponent from distinguishing or distancing the witness from the testimony I need?*). Further, given the tension between a “perpetually available” deposition transcript or video and the dynamics of trial schedules and witness availability, lawyers should take a hard look at the conventional wisdom of deferring questions for friendly witnesses. That is, given the risk the witness may not appear at trial, lawyers may not want the only voice or questions a jury hears with a witness to be the opponents’.

■ **The lawyer perspective.** As important as the “what” of a witness’ testimony is the “how” and “when” of the lawyer’s questions. The way a lawyer crafts and orders a deposition outline can directly influence the answers the witness gives. Situational awareness is critical to determine the appropriate instances to ask open-ended, narrow, or leading questions. Further, while the goal should be fixed testimony where it is helpful, “bad answers” need not be set in stone; lawyers should consider options to rehabilitate testimony at the deposition or even to leverage that testimony for some other purpose (like an alternate legal claim or defense). Finally, plaintiffs’ counsel often approach depositions with the goal of collecting sound bite testimony to be natural highlights of a trial presentation. Too often, defense counsel view such efforts as unseemly or misleading. For trial-guided discovery, however, “sound bite”

is not a dirty word. Short, direct, memorable testimony is a powerful tool in a trial presentation; defense counsel would be wise to adopt it as one weapon in the arsenal for trial.

Experts

When it comes to experts (particularly opposing experts), trial-guided discovery may not differ too significantly from other-purposed discovery. For example, it is a universal goal to establish limits to the scope of an opposing expert’s expertise and opinions. Some trial-guided tactics, however, may seem otherwise counterintuitive.

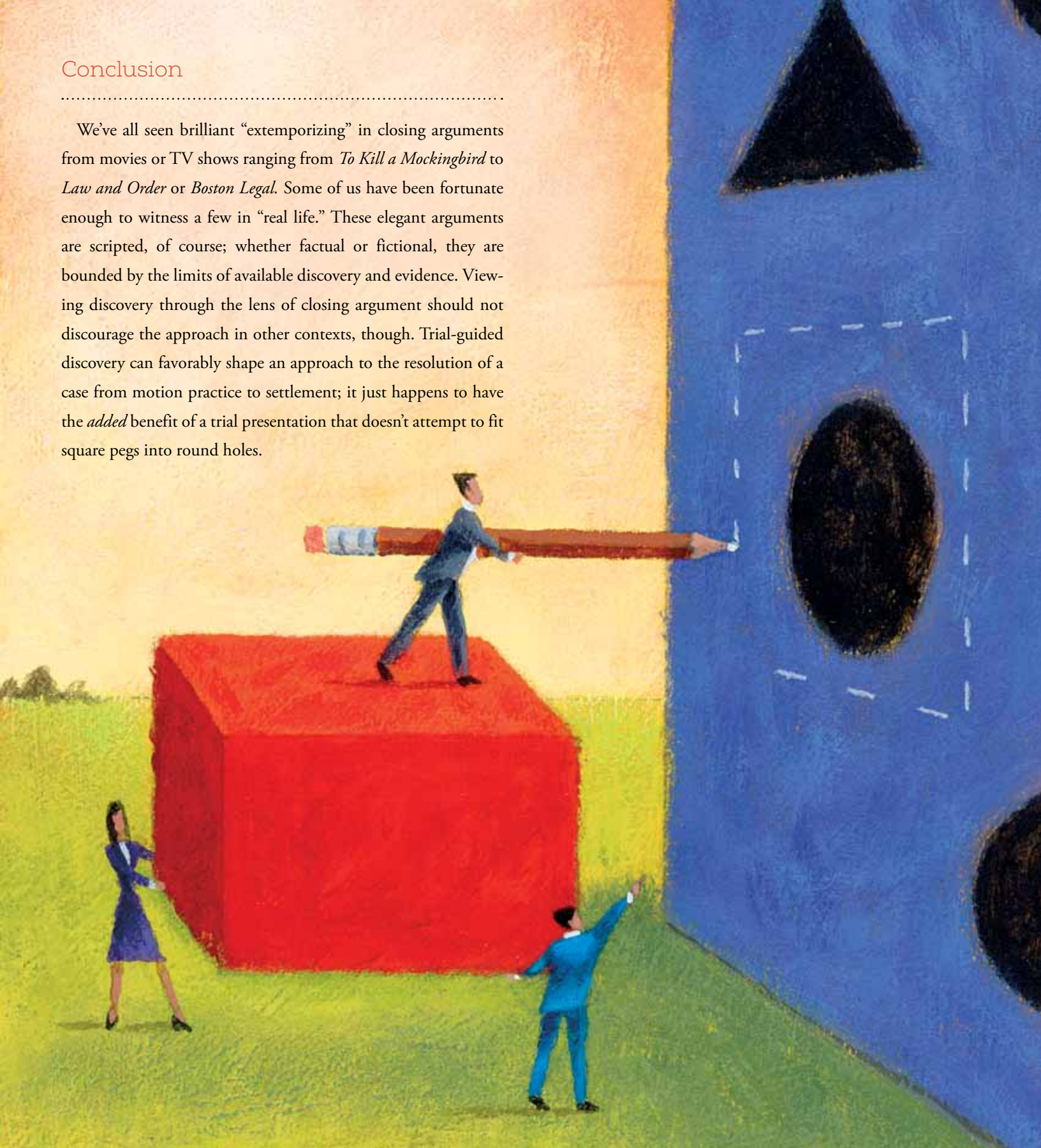
■ **Establish points of agreement.** Any valid opposing expert will offer opinions diametrically opposed to the client’s view of the case. But short of these “ultimate” opinions, there should be available common ground. Memorializing these agreements — as to objective standards or benchmarks in the field of expertise, *e.g.* — can provide a launching point for a trial cross-examination, with a simple jury assumption that trial counsel is “winning” the exchange.

■ **Don’t avoid “bad testimony.”** One mistake lawyers often make is to conflate their approach to depositions between party witnesses and experts. One goal in party witness depositions is to avoid, limit, and rehabilitate bad testimony; however, with experts, bad testimony is expected. The goal of an expert deposition should not be to avoid bad testimony but to exhaust it, in order to fix the limits of that testimony at trial.

■ **Go right at ’em.** Similarly, many lawyers attempt to contest opposing expert admissibility and testimony by attacking discrepancies in the expert’s peripheral opinions or methodology. However, “nibbling at the edges” of an opposing expert’s opinions has little effect at trial; the jury wants to focus on the big, determinative issues. Particularly when dealing with professional or well-seasoned expert witnesses, it is important to understand and establish specifics of the expert’s opinions; otherwise, lawyers risk general and dynamic critiques at trial that are difficult to rebut.

Conclusion

We've all seen brilliant "extemporizing" in closing arguments from movies or TV shows ranging from *To Kill a Mockingbird* to *Law and Order* or *Boston Legal*. Some of us have been fortunate enough to witness a few in "real life." These elegant arguments are scripted, of course; whether factual or fictional, they are bounded by the limits of available discovery and evidence. Viewing discovery through the lens of closing argument should not discourage the approach in other contexts, though. Trial-guided discovery can favorably shape an approach to the resolution of a case from motion practice to settlement; it just happens to have the *added* benefit of a trial presentation that doesn't attempt to fit square pegs into round holes.



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