Between a Regulatory Rock and a Hard Place

By Richard Dean and Corena Larimer

Does Preemption Provide an Escape?

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Companies today inevitably operate in a complex regulatory environment. As federal agencies have grown and regulations proliferated, so too have the requirements they place on companies. Add to that a secondary regulatory framework imposed by state or local environments, or duties private litigants enforce through litigation, and it is no surprise that companies frequently feel caught between a rock and a hard place as they work to satisfy the demands of their business while navigating this challenging environment.

Fortunately, a centuries-old provision of the U.S. Constitution is turning into a powerful tool for the modern era. The defense of federal preemption is rooted in the Supremacy Clause, and any company operating within a regulatory framework can—and should—consider invoking it when state and federal obligations collide. That doctrine, and specifically a sub-type known as "impossibility preemption," has seen a resurgence in recent years, with new decisions from the U.S. Supreme Court allowing companies to assert it where they would need federal permission to undertake state-required action. In plain terms, if a company must ask for the federal government's permission or assistance before it can meet state-imposed obligations (including tort duties), those obligations are preempted.

While these recent decisions arise from pharmaceutical litigation, the test they create is far broader. This article discusses these new developments in impossibility preemption and suggests how companies might be able to utilize this increasingly potent defense.

Preemption: A Basic Framework

Types of Preemption

The preemption defense itself is rooted in the Supremacy Clause of the U.S. Constitution:

> This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every State shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.

U.S. Const. art. VI, cl. 2.

Courts have identified three different ways in which federal law may preempt state law, though the boundaries are not always distinct. First, express preemption occurs when Congress enacts a statute that explicitly preempts state law. Congress has done so, for example, to protect vaccine manufacturers from design defect claims, *see Brueswitz v. Wyeth, LLC*, 131 S. Ct. 1068 (2011), and to offer certain protections on labeling to pesticide manufacturers. *See Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005).

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Second, field preemption exists when a federal regulatory scheme is so pervasive that courts may reasonably infer that Congress left no room for state action, or when federal law touches a field in which the federal interest is so dominant that enforcement of state laws on the same subject is precluded. *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218 (1947) (federal laws governing grain elevator regulation are so extensive as not to permit state regulation). Field preemption has been found in only a handful of areas, and is not frequently invoked outside of them.

Finally, implied "conflict" preemption—the focus of this article—is triggered when state and federal law conflict. Conflict preemption exists either where a particular state law presents an obstacle to the accomplishment of congressional purposes and objectives, or where it is impossible for a private party to comply with both state and federal requirements. *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990). The latter doctrine, called "impossibility preemption," has been the subject of an intense flurry of activity in the last five years in prescription drug litigation. As a result of that litigation, the test for impossibility preemption has been reshaped in ways that could have far-reaching effects across a variety of industries.

Identifying a Conflict for Preemption Purposes

The threshold question to consider for impossibility preemption is this: is a company's activity subject to competing standards or regulation? If so, and if those competing standards arise from state and federal law, respectively, the company may have a preemption defense to the state-imposed duties.

State law can run afoul of federal requirements in a number of ways. One of the starkest—though also infrequent—is a direct conflict between federal and state statutes. A recent illustration of such a conflict is found in off-track gambling restrictions for horseracing. *See Horseman's Benevolent & Protective Assoc.-Ohio Div., Inc. v. DeWine*, 666 F.3d 997 (6th Cir. 2012). The federal Interstate Horseracing Act permits off-track betting only if racetrack owners consent, but that consent is valid only if the racetrack owners have an underlying written agreement with the state association representing both owners and trainers. *Id.* at 1000–01. Ohio's statute, in contrast, allows such betting upon authorization of the owners alone. Holding that "horsemen's veto is an integral part of the [federal] Act" and that "the Ohio statute would negate the veto in certain circumstances," the court found a direct conflict with federal law and thus preemption. *Id.*

Even where statutes do not conflict on their face, judicial interpretation of an act's requirements can also provide the basis for a conflict. The Supreme Court recognized such a conflict in *Wos v. E.M.A.,* 133 S. Ct.

1391 (2013). The issue in *Wos* was how much money states could recover from tort judgments received by Medicaid beneficiaries where the state had advanced monies for medical treatment. In a previous case, the Supreme Court had decided that the federal Medicaid statute set both a floor and a ceiling on the state's potential share of a beneficiary's tort recovery, holding that the state could recover the exact amount of medical payments and no more. *Arkansas Dept. of Health and Human Servs. v. Ahlborn*, 547 U.S. 268, 282, 284 (2006). In *Wos*, the Court confronted a North Carolina statute that instead employed a simple formula for the sake of administrative convenience, allowing the state to collect up to one-third of settlement proceeds as reimbursement for the Medicaid beneficiary's related medical care. Relying on its earlier interpretation of the Medicaid statute, the Supreme Court found the North Carolina statute to be in conflict with federal law. *Wos*, 133 S. Ct. at 1398.

Some of the most fertile fields giving rise to conflicts are the multiplicity of federal regulations that have the force of law, such as within the automobile industry. *See, e.g., Geier v. Amer. Honda Motor Co.*, 529 U.S. 861 (2000) (Department of Transportation's automobile safety standards preempted tort claims). To the extent that a set of federal regulations or even a specific regulation conflicts with claims advanced under state law, such claims are subject to a preemption defense. *See City of New York v. F.C.C.*, 486 U.S. 57, 63 (1988) (The Supremacy Clause's "phrase 'Laws of the United States' encompasses both federal statutes themselves and federal regulations that are properly adopted.").

Similarly, the state law requirements subject to preemption can take multiple forms. Not only can a state impose requirements by statute or regulation, but common law duties cognizable in a state's courts are likewise subject to preemption. *See Purcell v. Bank of America*, 659 F.3d 622, 624 (7th Cir. 2011) ("a federal statute preempts state common law to the same extent as it preempts state statutory law"). *See also PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2573 (2011) ("Pre-emption analysis requires us to compare federal and state law. We therefore begin by identifying the state tort duties and federal labeling requirements applicable.").

Conflict Preemption Becomes a Robust Defense

Mensing Creates a New Test for Impossibility Preemption

The test for finding a conflict between state and federal law came into sharper focus in 2011 with the Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). There, the Supreme Court held:

> The question for "impossibility" is whether the private party could independently do under federal law what state law requires of it.…To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.

PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2579, 2580-81 (2011).

Courts have identified three different ways in which federal law may preempt state law, though the boundaries are not always distinct.

In *Mensing*, consumers sued a number of brand and generic drug manufacturers, asserting traditional failure-to-warn claims about the side effects of a particular drug. The manufacturers of the generic drug raised federal preemption as a defense, arguing that they could not be liable for alleged inadequacies of their warnings because the federal statute and regulations required them to mimic the brand-name drug's label. The Supreme Court agreed:

> We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law.
>
> If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking Mensing and Demahy's allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. *See, e.g.,* 21 CFR §314.150(b)(10). Thus, 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.

Id. at 2577.

Attempting to avoid preemption, the plaintiffs argued that the manufacturers could not demonstrate a conflict between state and federal law because the companies "did not even *try* to start the process that might ultimately have allowed them to use a safer label"—*i.e.,* they did not ask the FDA to allow a label change. *Id.* at 2579 (emphasis in original). The Supreme Court rejected that argument categorically, finding that it "would render conflict pre-emption largely meaningless because… [w]e can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it." *Id.* (emphasis in original).

Two years later, the Supreme Court fortified its *Mensing* preemption test. In *Mutual Pharmaceutical Co. v. Bartlett,* 133 S. Ct. 2466 (2013), the Court clarified that, when state and federal requirements are in conflict, a regulated actor's "option" of withdrawing from the market—in other words, avoiding the conflict by ceasing to act entirely—did not defeat an impossibility preemption defense. Instead, the Court explained that "[o]ur 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. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" *Id.* at 2477-78 (quoting *Mensing*, 131 S. Ct. at 2579).

Mensing Is Not Limited to Pharmaceuticals

Mensing leaves the lower courts with an easily applied framework for determining when a state's requirements are preempted as being "impossible." First, courts should identify what action a state requires a party to take—whether that requirement takes the form of a tort duty, statutory mandate, regulation, or other obligation. Second, courts should determine whether federal law prevents that party from *independently* complying with the state's requirements—*i.e.,* without a federal agency's "special permission and assistance." *Mensing*, 131 S. Ct. at 2580-81. If federal law prevents the defendant from taking that action unilaterally, then the state duty is preempted.

Mensing's impossibility test has been raised and applied most often in the context of generic drug litigation, but nothing in the Supreme Court's opinion suggested it should be limited to that context. It is grounded not in a statute-specific express preemption provision, but instead in fundamental implied preemption principles. And the Court articulated its preemption test in expansive terms, referring generally to "parties" rather than "drug manufacturers," "federal agencies" rather than the FDA specifically, and "independent action" rather than "independently issuing new drug warnings."

Indeed, the Supreme Court itself has cited *Mensing* in subsequent preemption decisions having nothing to do with drug regulations. *See Wos*, 133 S. Ct. 1391. A number of other courts have recognized *Mensing* far beyond the borders of pharmaceutical litigation. The Sixth Circuit, for example, cited *Mensing* in its off-track betting decision. *Horseman's Benevolent & Protective Assoc.-Ohio Div., Inc.*, 666 F.3d 997. Other courts have done the same in a variety of contexts. *See, e.g., Tarrant Regional Water Dist. v. Herrmann,* 656 F. 3d 1222 (10th Cir. 2011) (comparing state and federal water law); *Remund v. State Farm Fire and Cas. Co.,* 483 Fed. Appx. 403 (10th Cir. 2012) (flood insurance coverage dispute); *Grocers Supply, Inc. v. Cabello*, 390 S.W.3d 707, 718 (Tex. App. 2012) (involving lost wages for undocumented workers); *Suarez v. Castrillo*, No. 11-cv-01762, 2011 WL 2729074, at *1 (D. Colo. July 13, 2011) (international child custody dispute); *Chicago Title Land Trust Co. v. DeRaedt*, 2013 IL App (2d) 121193-U, 2014 WL 493909 (Ill. Jan. 29, 2014) (trespass action implicating federal Clean Water Act and Army Corps' administrative actions). These cases, coupled with *Mensing*'s general language, suggest its broad applicability.

With *Mensing's* fundamental holding that preemption applies whenever a company would have to ask the federal government for permission or affirmative relief in order to comply with state law, it is not surprising that strong preemption arguments may exist based upon a particular set of government regulations.

Practical Applications of the *Mensing* Test

Given *Mensing*'s broad terms, as well as state and federal law's frequently competing demands, any company that operates in a regulated industry should consider impossibility preemption defenses when litigation looms. With *Mensing*'s fundamental holding that preemption applies whenever a company would have to ask the federal government for permission or affirmative relief in order to comply with state law, it is not surprising that strong preemption arguments may exist based upon a particular set of government regulations.

Product Design Approved or Cleared by a Federal Agency

The need to ask for agency permission may be particularly useful where a product's design is challenged. Certain regulations in the drug arena, for example, require that not only must the FDA approve the original design of the drug, but it likewise must approve subsequent changes. The Supreme Court already found certain design defect claims preempted under *Mensing*, reasoning that those federal regulations prevent manufacturers from making major changes to the design of any drug—"whether generic or brand-name"—absent FDA approval. *Bartlett*, 133 S. Ct. at 2471.

Several courts have since applied *Mensing* and *Bartlett* to product design allegations outside of the generic drug context (though still within the pharmaceutical industry). *Amos v. Biogen Idec Inc.*, for example, echoed *Bartlett* by finding in favor of preemption because federal law required prior FDA approval for changes to a brand name drug. 2014 WL 2882104 (W.D.N.Y 2014). *Thompson v. Allergan USA, Inc.* likewise applied *Mensing* and *Bartlett* to a challenge over the fixed amount of medicated eye drops contained in each container. 993 F. Supp. 2d 1007, 2014 WL 308794 (E.D. Mo. 2014). The plaintiffs alleged that the drug manufacturer was overcharging consumers by including a larger quantity than necessary in each single-use container. The court dismissed those claims as preempted based on federal regulations requiring prior FDA approval for any change in the product specifications, including fill volume. *Id.* at 1013-14.

With these pharmaceutical cases as a foundation, manufacturers in other fields should consider whether the federal government's oversight of their products reaches the same level of control. Where it does, tort suits alleging the product is unsafe or otherwise inadequate as designed may have a strong preemption defense.

Challenges to Product Warnings or Labeling

Federal agencies also frequently regulate product labeling and the representations a manufacturer can make about its product. As with design, if those regulations require agency consent before a company can modify its warnings or labeling, the company likely has a preemption defense.

For example, in the pharmaceutical context, some changes to drug labeling do not require prior FDA approval, but others do.

Changes in the latter category include the addition of a "black box" warning, revisions to the plain-language "Medication Guide" component of some labels, and changes to sections of the label describing a drug's contraindications or clinical pharmacology information. *See, e.g., Dopson-Troutt v. Novartis Pharmaceuticals Corp.,* 975 F. Supp. 2d 1209 (M.D. Fla. 2013), citing 44 Fed. Reg. 37434, 37448 (June 26, 1979) (black box warnings); 21 C.F.R. §314.70(b)(2)(v)(B) (Medication Guide). Any claim challenging those aspects of the label, therefore, should be preempted based upon the fact that a manufacturer would need federal agency permission to correct any alleged shortcomings.

Other Circumstances

Mensing can also be invoked in other circumstances in which a particular actor cannot independently satisfy state law. In the product context, certain companies have successfully argued that impossibility preemption applies where a different entity controls the label—for example, a distributor or a former manufacturer that long ago sold its rights to the drug lacks control over the warnings. *See, e.g, Stevens v. Cmty. Health Care, Inc.*, No. ESCV200702080, 2011 WL 6379298 (Mass. Super. Oct. 5, 2011) (finding claims against drug distributor preempted because the distributor "had no ability to change labeling or warnings and thus, like a generic manufacturer, … cannot be subject to liability in connection with a state law claim premised on a 'failure to warn'"); *In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014).

While the defense has been developed only in the context of pharmaceuticals and medical devices, federal regulation is pervasive in other industries, including transportation, land and environmental areas, and workplace safety and standards. Any company that is heavily regulated should consider opportunities to raise a preemption defense by identifying hot-button industry issues that are likely to present competing requirements.

Different Stages of Litigation

Just as impossibility preemption can arise in different factual contexts, it likewise can be utilized at various stages of litigation. The most common use is seeking to dismiss a claim as preempted on either a motion to dismiss or a motion for summary judgment. *Mensing* itself reached the Supreme Court at the motion-to-dismiss stage, and since that time a large number of generic drug cases have been dismissed on the pleadings.

But dismissal of claims is not the only time a company should consider raising preemption arguments. For one, companies can *initiate* a lawsuit based on preemption if a state attempts to impose requirements in conflict with federal law. In a recent example, BP America sued for injunctive relief as part of its Deepwater Horizon clean-up efforts when the state of Louisiana demanded specific remediation steps previously rejected by the federal agency overseeing BP's efforts. *BP America Inc. v. Chustz*, ___ F. Supp. 2d ___, 2014 WL 3586493 (M.D. La. July 21, 2014) (impossibility and obstacle preemption barred state cease and desist order). And elsewhere, a drug manufacturer sued the state of Massachusetts after the state first banned and later heavily restricted sales of its FDA-approved drug. *Zogenix, Inc. v. Patrick,* No. 14-11689, 2014 WL 1454696 (D. Mass. 2014). That company similarly asked the courts to enjoin the state's actions because they conflicted with federal law approving the drug for the national market. *Id.* at *1.

Mensing has recently been invoked by pharmaceutical and medical companies in support of removal, arguing that the co-defendants who defeat federal diversity jurisdiction—generally distributors or sales representatives—are fraudulently joined because they cannot independently alter the FDA-permitted warnings. *See, e.g., Yearwood v. Johnson & Johnson, Inc.*, No. 12-1374, 2012 WL 2520865 (D. Md. June 27, 2012) (noting, without deciding, preemption argument for medical device distributor).

Finally, as a case progresses, a party may be able to narrow the arguments or evidence at trial through pretrial motions to exclude arguments or expert opinions that are in conflict with federal law. One pharmaceutical company has filed a series of pretrial motions to bar specific labeling arguments at trial because they would require prior FDA approval, citing *Mensing*. *See Hill v. Novartis Pharm. Corp.*, 944 F. Supp. 2d 943, 957 (E.D. Cal. 2013) (barring arguments over label formatting because "[w]hile the case law is clear that manufacturers may modify the contents of a brand-name drug label *without FDA approval* by adding to or strengthening the warnings, Hill has provided no authority—and the Court's research reveals no authority—to suggest manufacturers may do the same with the label's formatting") (emphasis added); *see also Guenther v. Novartis Pharm. Corp.,* 6:08-CV-456-ORL-31, 2013 WL 4648449 (M.D. Fla. Aug. 29, 2013) (barring arguments over black box warnings because "the Plaintiffs never directly dispute Novartis's contention that the FDA regulations preclude a manufacturer from adding a black box warning *without preapproval*") (emphasis added); *Dopson-Troutt v. Novartis Pharm. Corp.*, 975 F. Supp. 2d 1209, 1219 (M.D. Fla. 2013) (same).

A Note of Caution

While *Mensing* presents promising defenses for a variety of situations, it is important to understand that courts have been reluctant to accept novel applications of the impossibility test. In spite of the breadth of *Mensing's* language and the fact that even the Supreme Court has applied *Mensing* outside pharmaceutical cases, some courts have limited *Mensing* to its factual context—failure-to-warn claims involving generic drugs. *See In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 6:11-md-2299, 2014 WL 60298, *8 (W.D. La. Jan. 7, 2014); *Harmon v. DePuy Orthopaedics, Inc.,* 2012 WL 4107710 (C.D. Cal. 2012); *Ray v. Allergan, Inc.,* 2012 U.S. Dist. Lexis 76563 (E.D. Va. 2012). Others have been reluctant to address the merits of the preemption defense, instead relying on a case's procedural posture to reject the preemption argument. *See, e.g., Smith v. Amylin Pharms., LLC*, No. 13cv1236, 2013 WL 3467442, at *4 (S.D. Cal. July 10, 2013) ("recognize[ing] the logic" of finding claims against a drug's distributor preempted under *Mensing,* but refusing to remand to state court because other courts had not addressed the question). Still others, clearly uncomfortable with preventing a plaintiff from pursuing tort claims, have looked for ways to distinguish or avoid the Supreme Court's test. *See Hunt v. McNeil Consumer Healthcare*, CIV.A. 11-457, 2014 WL 1116358 (E.D. La. Mar. 11, 2014) ("There are equally compelling pol-

icy justifications for reading *Bartlett* and *Mensing* narrowly so as to preserve the viability of products liability actions."); *In re: Depuy Orthopedics, Inc. Pinnacle Hip Implant Products Liability Litigation,* 2014 WL 3557392 (N.D. Texas 2014) (foregoing implied preemption analysis altogether and finding no express preemption instead, despite binding precedent recognizing that express preemption and *Mensing* preemption were two different non-overlapping tests in *Lashely v. Pfizer, Inc.* 750 F.3d 740, 746 (5th 2014).).

When considering an impossibility preemption defense based on *Mensing*, it is important to weigh it in light of overall case strategy. This area of the law is still developing; novel applications of *Mensing*'s new preemption test may not be successful in many trial courts. Perhaps these new arguments may have to withstand a series of rejections before finally being accepted by an appellate court. The *Mensing* litigation itself is an illustration: a number of generic manufacturers lost the same preemption arguments in trial and appellate courts, but the tide turned when they were able to successfully argue the defense before the Supreme Court.

Conclusion

Mensing presents an opportunity for new defenses and may develop into a recognized and powerful tool down the road. Its straightforward preemption framework—barring claims that a party cannot satisfy without government permission or assistance—has broad application extending far beyond the pharmaceutical industry. Any industry subject to federal regulation should be alert to possible preemption arguments, especially where state requirements or claims appear to collide with a company's federal duties.