Removal Can Be the Beginning of a Powerful Defense

State Law Product Liability Claims and Federal Question Jurisdiction

By David P. Graham

Attorneys for medical device defendants should not overlook the possibility of removal based upon a significant federal question under 28 U.S.C. §1331.

Federal question jurisdiction can exist over purported state law medical device product liability claims that implicate significant federal issues. When the sole focus of a plaintiff's case is whether a product manufacturer complied with federal law and regulations such as those implemented by the U.S. Food and Drug Administration (FDA), a federal question may arise and removal of a state court action may be appropriate.

Fact Scenario

Assume that you receive a complaint alleging that a medical device caused an injury. The complaint sets out facts related to off-label promotion and use of the product, including some facts about the specific intended use language approved by the FDA, but the complaint contains no facts alleging a mechanism of injury or any other facts related to a design or manufacturing defect or failure to warn. Nor does the plaintiff cite any violations of FDA-related statutes or FDA regulations. In this case, the manufacturer interpreted the intended use in a manner with which the FDA ultimately disagreed, but only several years after its original clearance.

The plaintiff files the case in state court, alleging negligence and product liability but without design or manufacturing defect or failure to warn claims. There is no diversity among the parties. How do you get the case to federal court? One avenue, which often is not fully explored, is federal question jurisdiction. While difficult to establish, certain claims may implicate a federal question upon which a plaintiff's right to relief necessarily depends.

Federal Question Jurisdiction over State Law Claims

A defendant is entitled to remove a case to federal court if the plaintiff "could have brought it in federal district court originally, 28 U.S.C. §1441(a), as a civil action 'arising under the Constitution, laws, or treaties of the United States,' §1331." *Grable & Sons Metal Prods. v. Darue Eng' & Mfg.*, 545 U.S. 308, 311 (2005). A plaintiff need not plead a cause of action created by federal law to satisfy the requirements of federal question jurisdiction under §1331. *Id.* Rather, "in certain cases federal-question jurisdiction will lie over state law claims that implicate significant federal issues." *Id.* As explained elsewhere, "[a] case arises under federal law if a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." *Schneider v. Regions Bank*, No.

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12-0574, 2012 WL 3646270, at *2 (S.D. Ill. 2012).

The "test for jurisdiction over federal issues embedded in state-law claims between nondiverse parties" is this: "[T]he question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities."

There is no single, precise definition of when a case falls within the original federal question jurisdiction of the federal courts; "rather, 'the phrase "arising under" masks a welter of issues regarding the interrelation of federal and state authority and the proper management of the federal judicial system.'" *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 8 (1983). Justice Holmes explained long ago in *American Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257, 260 (1916), that a "suit arises under the law that creates the cause of action." But it is also true that "a case may arise under federal law 'where the vindication of a right under state law necessarily turned on some construction of federal law.'" *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 809 (1986).

A substantial federal question is presented as long as the pleadings invoking federal question jurisdiction are not "so attenuated and unsubstantial as to be absolutely devoid of merit," "wholly insubstantial," "obviously frivolous," "plainly unsubstantial," or "no longer open to discussion." *Hagans v. Lavine*, 415 U.S. 528, 536–37 (1974) (quoting *Newburyport Water Co. v. Newburyport*, 193 U.S. 561, 579 (1904); *Bailey v. Patterson*, 369 U.S. 31, 33 (1962); *Hannis Distilling Co. v. Baltimore*, 216 U.S. 285, 288 (1910); *Levering & Garrigues Co. v. Morrin*, 289 U.S. 103, 105 (1933); and *McGilvra v. Ross*, 215 U.S. 70, 80 (1909)).

Finally, under this "catchall federal question provision," §1331, "jurisdiction is sufficiently established by allegation of a claim under the Constitution or federal statutes, unless it 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction.'" *See Mt. Healthy City Sch. Dist.t Bd. of Educ. v. Doyle*, 429 U.S. 274, 279 (1977) (internal citation omitted).

Product Liability Claims May Raise Substantial Federal Law Questions

Savvy plaintiffs' attorneys try to defeat the well-pleaded complaint rule by alleging state law negligence per se. For example, in one of the leading Supreme Court cases that addresses federal question jurisdiction, *Merrell Dow*, 478 U.S. at 805–06, the plaintiffs alleged a state law negligence per se claim based upon an alleged breach by a prescription drug manufacturer of its state law duty to warn that ingestion of the drug during pregnancy could cause birth defects. The alleged statutory violation that the plaintiffs sought to invoke to prove negligence per se was a violation of a federal law, as opposed to a state law, which declared a prescription drug misbranded if "the labeling or advertising fails to reveal facts material with respect to consequences which may result from the use of the article to which the labeling or advertising relates." *Merrell Dow*, 478 U.S. at 824. Thus, *Merrell Dow* directly involved an allegation of the state law duty to warn of a known or foreseeable risk through the drug's labeling, and because Congress did not create a private right of action under the federal statute that was implicated, there was no basis for federal question jurisdiction.

In a case brought by the State of Arizona against pharmaceutical manufacturers for marketing spread between wholesale prices and reimbursement rates by inflating the average wholesale price upon which reimbursement rates were based, the U.S. District Court for the District of Massachusetts concluded that federal subject matter jurisdiction existed under the *Grable* test. *In re Pharm. Indus. Average Wholesale Price Litig.*, 457 F. Supp. 2d 77 (D. Mass. 2006). The court reasoned "that the meaning of AWP [average wholesale price] in the federal Medicare statute is a substantial federal issue that properly belongs in federal court" because it was outcome determinative, could be applied in later cases, and "impacts the viability and effectiveness of the federal Medicare program." *Id.* at 80. After concluding that the issue was also disputed, the court held that retaining jurisdiction would not disturb "any congressionally approved balance of federal and state judicial responsibilities" even though litigation concerning the average wholesale price was already in state and federal courts. *Id.* at 81. Retaining jurisdiction was proper because "a federal forum provides experience, solicitude and uniformity on this important federal issue." *Id. See also Louisiana ex rel. Foti v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 375 F. Supp. 2d 170, 172–73 (E.D.N.Y. 2005) ("[T]he substantial federal funding provisions involved and the allegations about the violation of federal law through improper off-label use present a core of substantial issues more federally oriented than those in *Merrell Dow*. Federal jurisdiction lies under *Grable*.").

A sponsor of a medical device has two possible routes to gain FDA permission to market a Class II or Class III medical device.

Regulatory History Matters

The applicable regulatory requirement of the medical device in our hypothetical is important to the removal determination. A sponsor of a medical device has two possible routes to gain FDA permission to market a Class II or Class III medical device. First, a sponsor may use the Premarket Approval (PMA) process, through which a sponsor must provide the FDA with reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. §360e(d)(1). Second, a sponsor may use the Premarket Notification, or 510(k), process, through which a sponsor must show that the medical device is substantially equivalent to a legally marketable device because it has the same intended use and either the same technological characteristics or different technological characteristics, but it is as safe and effective as the predicate device. 21 U.S.C. §§360(k), 360c(f), 360c(i); 21 C.F.R. §807.81; 21 U.S.C. §360c(i); 21 C.F.R. §807.100.

In some situations, the sponsor of a cleared medical device may need to sub-

mit a new 510(k) submission to legally market the device when something about the device has changed. For example, if a sponsor intends "a major change or modification in the intended use of the device," a new 510(k) submission is required before the device can be marketed for the new intended use. *See* 21 C.F.R. §807.81(a)(3)(ii). Federal regulations define "intended use" as "the objective intent of the persons legally responsible for the labeling of devices" as determined by "such persons' expressions" or "by the circumstances surrounding the distribution of the article," for example, "by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." 21 C.F.R. §801.4.

When a defendant was or becomes aggrieved through the process of interpreting the defendant's product indication for use statement, the defendant must go to federal district court to challenge the FDA's determinations regarding the product through the Administrative Procedure Act, or go directly to the D.C. Circuit Court of Appeals under the Federal Food, Drug, and Cosmetic Act (FDCA).

The FDA recognizes that "[c]hanges in device labeling often pose the most difficult questions to be addressed by device manufacturers when deciding whether a new 510(k) submission is necessary." FDA, *Deciding When to Submit a 510(k)*, at 9 (1997). While "[c]hanges in the indication for use section of labeling raise more agency concern than any other aspect of labeling[,] [a]ny change in the indications for use that limits use within the currently cleared indication may occur without the submission of a 510(k)." *Id* at 9–10. The FDA has also issued guidance about the related issues of (1) when a device with a new, specific indication for use will likely be found to be substantially equivalent to a device legally marketed for a general indication for use, and (2) when a specific indication for use becomes a new intended use that requires submission of a PMA to establish the safety and effectiveness of the device. FDA, *General/Specific Intended Use*, at 2–3 (1998). The FDA has not provided "a bright line rule to answer these questions" because it "believes that it could not formulate such a rule without compromising the ability of FDA reviewers to factor in the important public health and regulatory considerations that are essential to making appropriate classification determinations." *Id.* at 2 (emphasis added).

In our hypothetical case, the defendant, the manufacturer, has been working with the FDA to amend the indication for use statement to include specifically the use of the product as it was used by the doctor on the plaintiff. When a defendant was or becomes aggrieved through the process of interpreting the defendant's product indication for use statement, the defendant must go to federal district court to challenge the FDA's determinations regarding the product through the Administrative Procedure Act, or go directly to the D.C. Circuit Court of Appeals under the Federal Food, Drug, and Cosmetic Act (FDCA). *See* 5 U.S.C. §702 *et seq.* (providing judicial review of federal agency actions in the courts of the United States); 21 U.S.C. §360g(a)(8) (allowing a person adversely affected by an order finding a device not substantially equivalent to a legally marketed device to petition the D.C. Circuit Court of Appeals).

The Federal Nature of the Plaintiff's Allegations

In our hypothetical case, the plaintiff's purported causes of action against the defendant sound in product liability and negligence. But the plaintiff has not pleaded facts that plausibly allege a design or manufacturing defect, made any contention that the defendant failed to warn the plaintiff's treating physician about any known or foreseeable risks from the use of the defendant's device, or made an allegation that the defendant failed to provide adequate warnings and instructions regarding the use of its device to the plaintiff's treating physician. The plaintiff also has not identified specific federal statutes or regulations that the defendant allegedly violated, preventing the statement of a claim for negligence per se under many states' laws. *See Roberson ex rel. Roberson v. Novartis Pharmaceuticals Corp.*, No. 11-2035, 2011 WL 1740137 (N.D. Ill. May 5, 2011) (pleading a cause of action for negligence per se requires the identification of a specific statute that the defendant allegedly violated). Instead, the focus of the plaintiff's case is whether the defendant's marketing and promotion of its device complied with federal law and regulations. Significantly, however, the plaintiff has not pleaded or argued that state law imposed a duty upon defendant to enter the patient-physician relationship and communicate with plaintiff about the scope of the defendant's FDA clearance. Thus, in this case, the facts necessarily raise a federal issue because the plaintiff relies upon federal law to allege the existence of a novel, state law duty owed to the defendant.

Often state law does not require a device manufacturer to communicate warnings or other information to patients. Most states apply the "learned intermediary" doctrine, under which

> the manufacturer of a prescription medical device generally has a duty to warn prescribing health professionals of the device's known dangerous propensities, rather than the patient… The adequacy of the warning 'must be judged by whether it sufficiently apprises physicians of the risks associated with the use of the medical device.

Sosnowski v. Wright Med. Tech., Inc., No. 11-59, 2012 WL 1030485, at *7 (N.D. Ill. Mar. 27, 2012).

The FDCA cannot be used to create a novel, state law duty requiring a device manufacturer to communicate warnings

or other information directly to a patient. In appropriate circumstances, "if a statute defines what is due care in some activity, the violation of the statute... presumptively establishes that the violator failed to exercise due care." *Cuyler v. United States*, 362 F.3d 949, 952 (7th Cir. 2004). To elaborate, "the statutory definition does not come into play unless the... plaintiff establishes that the defendant owes a duty of care to the person he injured." *Id.* In many states, a plaintiff cannot use a federal statute or regulation to establish the existence of an unrecognized tort duty unless Congress provided a cause of action in the statute or regulation or unless the federal courts recognize the existence of a cause of action under the statute or regulation. *See Martin v. Ortho Pharmaceutical Corp.*, 661 N.E. 2d 352, 355 (Ill. 1996) (holding that plaintiffs could not use the FDCA to create an exception to the learned intermediary doctrine that would require a manufacturer to warn a patient). Congress did not include a provision creating a private cause of action under the FDCA. *See* 21 U.S.C. §337(a), And federal courts have not recognized one by implication. *Martin*, 661 N.E. 2d at 355–56; *Accord Vanderwerf v. SmithKlineBeecham Corp.*, 414 F. Supp. 2d 1023, 1028 (D. Kan. 2006) ("Although a state by legislation or through common law can create a private state remedy for violations of the FDCA, Kansas has not done so. As explained above, the tort of negligence per se in Kansas is limited to violations of a statute where the legislature intended to create an individual right of action for injury arising out of a statutory violation.").

While a plaintiff can state a negligence or product liability claim by alleging that a medical device is unreasonably dangerous due to the existence of a design or manufacturing defect or because the manufacturer failed to warn a treating physician about the device's dangers, the plaintiff does not attempt to do so in our hypothetical case. Moreover, the plaintiff does not explain how the learned intermediary doctrine allows imposing a duty upon the defendant to communicate to a patient the scope of the product's clearance. The plaintiff in the hypothetical cannot use the alleged breach of unidentified federal statutes to skirt the learned intermediary doctrine and create a duty that does not exist under state law.

Moreover, defendants should challenge any attempt by plaintiff to rely upon *Merrell Dow*, 478 U.S. at 805–06, and *Baker v. Johnson & Johnson*, 709 F. Supp. 2d 677, 682 (S.D. Ill. 2010), to imply that they have pleaded a state law negligence per se claim. *Merrell Dow* involved a state law negligence per se claim based upon the alleged breach by the manufacturer of the prescription drug Bendectin of its duty to warn that ingestion of the drug during pregnancy could cause birth defects. *Merrell Dow*, 478 U.S. at 805–06. The alleged statutory violation that the plaintiffs sought to invoke to prove negligence per se was a violation of an FDCA provision that declared a prescription drug misbranded if "the labeling or advertising fails to reveal facts material with respect to consequences which may result from the use of the article to which the labeling or advertising relates." *Id.* at 824. Thus, *Merrell Dow* involved the established state law duty to warn of known or foreseeable risks through the drug's labeling.

Baker was a case that involved allegations that a drug manufacturer promoted a drug off-label while providing package inserts that failed to warn physicians about known severe side effects (Stevens-Johnson Syndrome and Toxic Epidermal Necolysis) that could accompany such off-label uses. 709 F. Supp. 2d at 682. *See also* Complaint at 53–55, *Baker v. Johnson & Johnson*, No. 3:10-cv-00283 (S.D. Ill. Apr. 15, 2010). The plaintiffs alleged a cause of action for negligence per se that was based upon an alleged violation of 21 C.F.R. §201.128, which requires a drug manufacturer to provide adequate labeling about known off-label uses. *Baker*, 709 F. Supp. 2d at 682. Similar to *Merrell Dow*, *Baker* also involved the established state law duty to warn physicians of known risks accompanying the use of a product.

Thus, the plaintiffs in *Merrell Dow* and *Baker* relied upon the long-recognized state law duty to warn against known or foreseeable dangers and merely used an alleged violation of a federal statute requiring such warnings to establish negligence. Unlike the plaintiffs in *Merrell Dow* and *Baker*, the plaintiff in our hypothetical points to no established state law duty to avoid off-label promotion or to inform a patient of the language of a device's FDA-cleared indication for use statement. In this case, the hypothetical plaintiff makes no allegation that the defendant failed to warn the plaintiff's physician of any known or foreseeable risks and makes no allegation that labeling was inadequate.

Instead, the only cases that would be removable under this precedent would be cases alleging naked off-label promotion claims, which are futile due to the doctrine of implied preemption.

In addition, in our hypothetical case, the plaintiff has not alleged a parallel state law claim that would escape preemption under *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), and create a basis for remand to state court. In *Bausch*, the plaintiff alleged that the device was manufactured in violation of federal law. *Bausch*, 630 F.3d at 549. In rejecting an express preemption defense for a device approved through the PMA process, the Seventh Circuit held that federal law did not expressly preempt the plaintiff's manufacturing defect claims to the extent that those claims were based upon violations of federal law. *Id.* at 556. In rejecting an implied preemption defense, the Seventh Circuit distinguished the manufacturing defect claims at issue in *Bausch* with the fraud-on-the-FDA claims at issue in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Key to the court's decision was that "the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law." *Id.* at 557.

While, similar to the defendants in *Bausch,* our hypothetical defendant will claim that the plaintiff's claims are by implication preempted by federal law, the defendant's *implied preemption defense is not the basis for federal question jurisdiction over this case.* Instead, the hypothetical plaintiff's reliance upon federal law to impose a novel, state law duty upon the defendant creates the federal question. To the extent that the *Bausch* court's discussion regarding the effect of federal regulatory violations upon state tort claims may be relevant, it is distinguishable because the *Bausch* plaintiff only alleged that the defendant violated federal law by engaging in off-label promotion and did not allege that the defendant breached "a recognized state-law duty for their benefit" such as design, manufacturing, or warning. *Bausch,* 630 F.3d at 558. In our hypothetical case, the defendant's off-label promotion is not related to any corresponding or "parallel" state duty or claim.

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Thus, plaintiffs' attorneys generally look to federal law not to define the standard of care, but as the basis for creating defendants' legal duty to plaintiffs. This may preclude plaintiffs from relying upon an unasserted cause of action for negligence per se because negligence per se cannot be used to create a duty wherever one does not already exist.

In our hypothetical case, the defendant's clearance is not only a substantial issue of federal law with respect to liability, but it appears to be the only contested issue in the case. Federal regulations must be interpreted to determine if the hypothetical defendant was required to submit a new 510(k) or to secure a PMA before marketing the device as alleged.

Congress Intended to Divide Labor Between State and Federal Courts

Not only does an essential element of our hypothetical plaintiff's case necessarily raise disputed and substantial issues of federal law, but the exercise of federal jurisdiction will not attract a horde of original product liability actions in federal courts.

First, as we can see in 21 U.S.C. §377(a), while Congress did not authorize a private right of action for violations of the FDCA, Congress did authorize litigation in federal courts related to the scope of a medical device's clearance. *See* 12 U.S.C. §§331(a), 333(a), 333(f) (allowing the government to prosecute and/or seek civil penalties against device manufacturers in federal court for promoting a medical device outside of its clearance); 5 U.S.C. §702 *et seq.* (providing judicial review of federal agency actions in the courts of the United States); 21 U.S.C. §360g(a)(8) (allowing a person adversely affected by an order finding a device not substantially equivalent to petition the D.C. Circuit Court of Appeals for review of that order). By keeping federal question jurisdiction over the plaintiff's claims here in our hypothetical, the federal court will avoid the asymmetry of having such claims determined by a state court when a patient challenges a manufacturer's interpretation of an FDA clearance and a federal court when a manufacturer challenges the FDA's interpretation of an FDA clearance.

Second, our hypothetical case does not involve an allegation of a breach of an established state law duty for which a federal statute provides the standard of care. As discussed above, the hypothetical plaintiff has neither pleaded nor argued that state law imposed a duty upon the defendant to communicate the scope of its product's clearance to the plaintiff. This fact makes this case distinguishable from the types of product liability cases that belong in state court. *See Merrell Dow,* 478 U.S. at 805–06; *Baker,* 709 F. Supp. 2d at 682. As such, accepting jurisdiction over this hypothetical case will not disrupt the division of labor between state and federal courts because the overwhelming majority of product liability cases alleging the breach of recognized state law duties will not be removable under this precedent. Instead, the only cases that would be removable under this precedent would be cases alleging naked off-label promotion claims, which are futile due to the doctrine of implied preemption. *See Buckman,* 531 U.S. 341.

Instead of involving a recognized state law duty, this hypothetical case involves actions of a federal agency—the FDA's approval of the product and subsequent interpretation of that approval—and those actions' compatibility with federal statutes, regulations, and agency policy pronouncements. Further, the interpretations issued by the hypothetical court would provide important guidance to manufacturers, providers, payers, and the FDA with respect to general and specific indications for use for medical devices. *See Empire Healthchoice Assur., Inc. v. McVeigh,* 547 U.S. 677, 700 (2006) (declining jurisdiction because, unlike *Grable* and the instant case, the resolution of *Empire* did not involve the action of a federal agency and its compatibility with a federal statute or an issue of law that would guide future cases); *Bennett v. Southwest Airlines Co.,* 484 F.3d 907, 909 (7th Cir. 2007) (declining jurisdiction because, unlike *Grable* and the instant case, the resolution of *Bennett* did not revolve around "any particular disputed issue of federal law," "the meaning of federal statutes and regulations may play little or no role," and there is no challenge to "the validity of any federal agency's or employee's action"). It is upon this basis that federal court should exercise jurisdiction over the hypothetical case.

Conclusion

Attorneys for medical device defendants should not overlook the possibility of removal based upon a significant federal question under 28 U.S.C. §1331. A plaintiff's bare bones allegations related to the conduct within a jurisdiction and under the regulation of the FDA only, when the plaintiff has not pleaded state law claims and the case does not involve recognized state law duties, should be challenged early in the case by attempting removal. Together with a preemption challenge and other defenses, removal can be the beginning of a powerful defense to medical device cases. FD